
JMIR mHealth and uHealth

Impact Factor (2022): 5.0
Volume 4 (2016), Issue 3 ISSN 2291-5222 Editor in Chief: Laurie Buis, PhD, MSI

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Viewpoint

Taking mHealth Forward: Examining the Core Characteristics

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Abstract

The emergence of mobile health (mHealth) offers unique and varied opportunities to address some of the most difficult problems of health. Some of the most promising and active efforts of mHealth involve the engagement of mobile phone technology. As this technology has spread and as this technology is still evolving, we begin a conversation about the core characteristics of mHealth relevant to any mobile phone platform. We assert that the relevance of these characteristics to mHealth will endure as the technology advances, so an understanding of these characteristics is essential to the design, implementation, and adoption of mHealth-based solutions. The core characteristics we discuss are (1) the penetration or adoption into populations, (2) the availability and form of apps, (3) the availability and form of wireless broadband access to the Internet, and (4) the tethering of the device to individuals. These collectively act to both enable and constrain the provision of population health in general, as well as personalized and precision individual health in particular.

(*JMIR Mhealth Uhealth* 2016;4(3):e97) doi:[10.2196/mhealth.5659](https://doi.org/10.2196/mhealth.5659)

KEYWORDS

mobile health; eHealth; mHealth; health policy; health technology; text messaging; public health informatics; telehealth

Introduction

Background

The issues, problems, and opportunities in health care are composed of many interacting components such as technologies, economics, players, business models, practices, policies, and laws. These components are constantly shifting and influencing one another. A rapidly emerging, and often essential, part of health care involves the growth of information and communications technologies (ICTs) [1,2]. Electronic health, or eHealth, encompasses a remarkably wide range of interpretations related to health care [3,4] and ICTs [5,6], with one study documenting over 50 uniquely different definitions for the term “eHealth,” such as the application of e-commerce to health care and pharmaceuticals, the use of new media technologies for social policy, and the integration of the Internet

into health care [7]. Such diverse interpretations can lead to multiple operational definitions of eHealth, negatively influencing generalizability of study results [8]. This is complicated by alternative terms appearing in the literature and in practice, with those terms also evolving as the technology changes. For example, the United States federal government and other agencies use the terms “telemedicine” and “telehealth” to generally refer to applications of ICTs in the practice of medicine, but are attempting to reach consensus on the use of the terms [9]. In one bibliographic analysis, the term “telemedicine” was used more than “eHealth” in English-speaking countries, whereas “eHealth” was more popular in non-English-speaking countries; “eHealth” is trending at a higher rate overall [10,11].

Therefore, any analysis or review of telemedicine, telehealth, or eHealth programs must be cautious when comparing

outcomes, as there are interpretations supported by the definitions, the types and implementations of the technology, and how it was used in the particular health intervention context. These should not be treated as exogenous factors. Within this terminology health care, individual, clinical, and public health are often confounded, thus covering a wide range of health application contexts including financial and business sectors [12].

Regardless of the broader terms (eHealth, telemedicine, telehealth), one term has emerged and tends to refer to a specific class of technologies and the associated ways in which the class is used with respect to health—mobile smart phone telephony or mHealth. In this paper, we briefly examine the etymology of the term “mHealth,” followed by an examination of technologies used in mHealth. Then, we describe core characteristics of mHealth’s current technologies in terms of their potential relevance for the general “health of the public” which has implications for health care at large, to the localities of health practice, and to individualization of information, clinical care, and behavioral intervention. We present this paper as augmenting other discussions regarding strategies taking mHealth forward [13,14]. As mHealth evolves in methods for engaging in prevention, care, treatment, and monitoring of health, these characteristics will help guide development toward more effective and efficient health solutions. As ICTs evolve in their forms, capacity, and presence, these characteristics will help health professionals instantiate components of their health solutions to realize their health goals. In short, this paper addresses the following question: What are the core characteristics of mHealth and why are they important?

Etymology of mHealth

mHealth typically includes applications in both public health and clinical medicine, so the distinction can be blurred. In clinical medicine, mHealth includes health costs, health delivery, Health Insurance Portability and Accountability Act (HIPAA)

or health information technology, and health telematics [15,16]. Although no standard definition of mHealth exists, both the World Health Organization and National Institutes of Health have offered reasonable and overlapping definitions of mHealth consistent with the view in this paper. Table 1 includes additional agency definitions. mHealth generally involves the use of mobile phones which, depending on the particular phone, directly support audio, video, photography, geolocation, sensors (proximity infrared, touch, accelerometer, ambient light illuminance, humidity, three-axis gyroscope, temperature, magnetometer, geomagnetic, ultraviolet exposure, light spectral, gestural-infrared, barometer, pedometer, pulsometer, heart rate, radiation detection), Internet or Web access, and various forms of texting, with locally running mostly third-party applications, or “apps,” as the emerging terminology standard [17].

Ancillary devices can be connected to mobile phones, including “watches and bands,” and communicate with the apps to provide unique and often innovative capabilities, such as blood pressure monitors, pulse oximeters, blood glucose meters, environmental exposure measures (for asthmatics), microscope for remote diagnoses, single lead electrocardiogram (ECG), sleep monitor, and an ingestible biomedical sensor [18], or integration with existing devices that can communicate with apps such as Google and Novartis’s “smart” contact lens that also monitors blood sugar [19,20]. Also consider other types of nonmedical devices that are attached to or communicate with a mobile phone sold as add-ons with or without medical claims, possessing medical device capability, such as thermal imaging [21] or arrays of integrated, wearable sensors capable of streaming data in real-time to the mobile phone app [22]. New telemedicine or telehealth mHealth apps are emerging as a consequence of policy (eg, the Patient Protection and Affordable Care Act, economic returns or displacements, regulatory structures), business opportunities, and technological innovations [23-26]. This is especially prominent with devices adept at exploiting the capabilities of mobile phones [27].

Table 1. Definitions of mHealth (mobile health).

Agency example	Definition
World Health Organization	mHealth involves the use of and capitalization on a mobile phone's core utility of voice and short messaging service (SMS) as well as more complex functionalities and apps including general packet radio service (GPRS), third and fourth generation mobile telecommunications (3G and 4G systems), global positioning system (GPS), and Bluetooth technology [28].
US National Institutes of Health	At NIH, we think about this really as diverse application of wireless and mobile technologies designed to improve health research, health care services, and health outcomes, and I think this is really important because it is not just mobile phones. You can think of it as sensors, any kind of sensors you can think of [29].
US Federal Communications Commission	The use of mobile networks and devices in supporting e-care. Emphasizes leveraging health-focused applications on general-purpose tools such as mobile phones and SMS to drive active health participation by consumers and clinicians [30].
US Department of Health and Human Services	The use of wireless technologies, such as mobile phones, personal digital assistants, and netbooks, for improving health [31].
mHealth Working Group	mHealth is the use of mobile technologies in public health and health service settings [32].
European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR)	COCIR regards mHealth as a subset of eHealth and defines it as the provision of eHealth services and information that relies on mobile and wireless technologies [33].
Adopted by mHealth Regulatory Coalition	Programs (apps) that deliver health-related services using mobile phones and tablets. Some apps offer advice and tracking functionality for healthy living. Some are designed to transmit information between doctors and patients (eg, glucose readings for diabetes management) [34].

Advancements in the mHealth infrastructure are bolstered by support of the underlying operating system (OS) technology in mobile phones. In September 2014, Apple Health's HealthKit platform released with the iOS 8 systems development kit (SDK) offered a set of integrated software to collect specific types of health data, allowing developers to create iPhone apps that directly interact with the OS's health-related, built-in resources to securely acquire, retain, and transmit health data. After a rocky start [35,36,37], Apple strategically collaborated with the Mayo Clinic [38], Nike [39], and Ochsner Health System [40]. The latter was significant as it also included partnering with Epic Systems to integrate their electronic health record (EHR) with HealthKit, a leading EHR vendor handling approximately 53% Americans' EHRs [41]. Other leading health centers, such as Stanford and Duke, quickly followed by launching clinical trials using HealthKit, 14 hospitals piloting HealthKit for institutional data integration, and at least 600 HealthKit-based apps were developed [42,43]. Apple and IBM announced a partnership to build enterprise mobility apps, bringing IBM's experience in data analytics and health care to Apple's mobile iPhone and iPad platforms [44,45]. With the introduction of iOS 9, the iPhone provided wider support for women's health issues [46,47] and iOS 10 supports Health Level 7 (HL7) standard for Continuity of Care Documents, which is the EHR standard for data exchange [48].

In March 2015, Apple released ResearchKit, an open source software framework that facilitates app development in the context of medical research studies [49]. ResearchKit has an integrated informed consent module, capturing a participant's signature, and a customizable user interface, allowing data capture such as tacit data from sensors, from user-engaged active tasks, and from surveys, then uploads data to a server for retention and data analyses. By all accounts, ResearchKit's focus on clinical research and researchers has been quite successful, as it addressed several difficulties that HealthKit

encountered with this target group. For example, ResearchKit facilitates the "remote" acquisition of participants, their consent, and their data for clinical trials [50,51]. Recently, ResearchKit has been updated to now accommodate genetic data from 23andMe [52].

Finally, in March 2016, Apple has introduced CareKit, a framework for building apps that "enable people to actively manage their own medical conditions" especially patients and their caregivers, including core modules to track their health-related events (eg, taking medication, conducting physical therapy) and track their own feelings and symptoms (eg, surveys, photos, motion quantification, temperature) [53]. Unlike HealthKit, which addresses basic health tracking (eg, exercise, food intake, weight), or ResearchKit, which is more a "connection to participants and their data" type of research facilitator processes, CareKit has a patient-centered focus, offering an Insight Dashboard that maps symptoms into action items, and connectivity to physicians, care teams, and family members targeting chronic conditions, such as home monitoring of Parkinson's disease, and postsurgical care [53].

Samsung's Android S Health activity tracking app, once available only on Samsung mobile phones, is now available in the online Play Store for all Android phones, though functionality is dependent on available sensors. S Health offers its own Digital Health SDK [54], with more of a nuance toward fitness and health, like Google Fit [55]. Separately, Samsung has partnered with the University of California, San Francisco, and imec (a leading biosensing research institute) for the Samsung Digital Health Initiative, which includes a new open reference design platform for health (Samsung Architecture Multimodal Interactions) as a data broker across apps, and a wearable technology reference design, Simband, based on its Gear watch design [56]. Simband is hardware designed from the ground up as a true digital health device. However, it is not

yet a directly commercial product, but is a flexible reference device, based on the Linux-based Tizen standards-based software platform, for different types and collections of sensors, such as ECG, galvanic skin response, bio-impedance, photoplethysmogram, and other or new types generating unique data streams that can be integrated (and analyzed) across multiple devices by third party developers [57].

Finally, Google has entered the market with an initial version of the Google Fit SDK with the release of Android 5.0 Lollipop, offering developers support for sensor data acquisition (phone-based and attached wearables), cloud-synced data collection-backup, and history presentation-tracking [58], but likely to be integrated with Android Wear devices [59]. Google is also partnering with the Mayo Clinic on constructing and reviewing medical information in their Knowledge Graph system for answering health-related queries on the Web using “rich content” data [60,61]. This is consistent with Google’s mission statement, “to organize the world’s information and make it universally accessible and useful.” It also reflects the Pew Research findings that 72% of US Internet users look on the Web for health information, 77% of those start with a generic Internet search using a search engine, and 35% of US adults have attempted diagnosis from Web-based information [62]. Furthermore, the number of search queries made on mobile devices has overtaken desktop search queries [63]. In parallel, Google’s parent company, Alphabet, formed Verily Life Sciences (formerly Google Life Sciences) for biomedical research, is developing wearable technologies beyond fitness trackers that directly address data needs of medical professionals and evidences a shift to a disease-centric focus, such as their “capicola” wrist-mounted health tracker, partnering with Novartis to develop glucose monitoring contact lenses, to treat and manage diabetes [64-66].

The implications for mHealth for these types of integrated health platforms are only beginning to be realized, but Apple has taken the lead in hospital pilot programs, many of which involve close (but remotely) tracking and management of individuals’ conditions [42,52]. Two major factors motivate the growth of mHealth apps. First, the overall general movement of health prevention likely drives demand, which is fueled by a combination of individual concerns for health as well as economic incentives, such as health care reform reimbursement mechanisms for physicians and support for wellness programs. There is increased value in acquiring personal activity and health data for individual awareness, growth of wellness programs in

the workplace, and physician utility in individualization of health care advising, especially for costly chronic diseases [67]. Second, health care organizations are concerned about operational inefficiencies and outcome improvement. Data acquisition, movement, integration with EHRs, and cloud-based analytics within health care organizations are a critical part of operational and outcome-based concerns, leading to a projection that 65% of consumer transactions with health care organizations and practitioners will be mobile by 2018 [68].

As the health technology landscape is rapidly, constantly, and unpredictably changing, we suggest that successful mHealth engagements can benefit by (1) focusing on the core characteristics of mobile phone technology and (2) understanding how these characteristics are successfully engaged and integrated. Mobile phone technology is often essential for improving the effectiveness and efficiency of achieving health goals for individuals, groups, states, or nations.

Core Characteristics of mHealth

Overview

We suggest that the leading core characteristics of mHealth are the following: (1) penetration into populations, (2) availability of apps, (3) wireless broadband access to the Internet, and (4) tethered to individuals. The core characteristics are summarized in Table 2. Many capabilities are built upon these characteristics such as social network communication structures, data acquisition mechanisms, and varieties of functional apps. Furthermore, these capabilities exist in “layers” where capabilities are built on other capabilities (eg, social networking functionality built on collective use of specific apps and Internet access tethered to individuals, health apps are built on the underlying functionality of the OS and hardware) or “assemblies” where functionality is based on devices attached physically (hardware) or electronically (software). Not all characteristics are equally available to all populations at equal levels of service. State-level statistics often do not reflect the heterogeneity of technological forms and access within its borders. However, mobile telephony with Internet access is the most rapidly developing and spreading form of telecommunication-computational technology. It is a small and increasingly powerful computer with a radio attached that you can fit into your pocket. Given the correct infrastructure, it can communicate rapidly with individuals and things around the world.

Table 2. mHealth core characteristics for health care.

Representative topics	Health care implications
Penetration into populations	Unprecedented communication access to population and subgroups, possible differential access by subgroups, differential mobile phone capability or dependence by subgroups
Availability of apps	General purpose computational capabilities of increasing sophistication of functionality and data acquisition, reporting, local analysis; ease of access to apps; increasing number of health-related devices connected to mobile phones
Wireless broadband access to the Internet	Access to full Internet resources; increasing sophistication, amount, and speed of communication in general, and data communication in particular; external device connectivity; Internet of things (devices) capable of direct Internet communications
Tethered to individuals	Decreasing delays in communication with specific individuals; tailoring to, and data captured by and about, individuals; location, physiological and psychology states, behavioral, and context awareness

Core Characteristic 1—Penetration Into Populations

The first core characteristic of mobile phone technology is its *penetration into populations* in the United States and around the world, affording substantially higher basic connectivity and connectivity quality (eg, reach, continuity of service, reduced connectivity delays). Wireless penetration in the United States is estimated at 110 mobile phone subscriptions per 100 population [69] and estimates place the ownership of mobile phones by American adults approaching 80% [70,71]. In 2015, the Center for Disease Control and Prevention's National Health Interview Survey reported over 47% of American homes were wireless only (meaning they had neither cabled phone nor cabled Internet access), where 55.3% of homes with children are wireless only [72]. Note that such figures vary across reporting agencies depending on the usual factors, such as timing, sampling, operational definitions, and methodological differences.

Globally, the International Telecommunications Union (ITU) estimates that the mobile phone penetration rate is 96.8% for the world population, 120.6% for developed countries, and developing countries at 91.8%. The number of world mobile phone subscriptions (ie, the number of SIM cards used in each country) is roughly equivalent to the world population [73] and the number of subscriptions exceed the total population in several counties in Central and Eastern Europe, Western Europe, Latin American, Middle East, North American, and Asia Pacific, excluding India and China [74]. Both penetration and type of access vary widely. For example, although Africa has an average penetration rate of 69%, sub-Saharan Africa's sovereign states range from 40% to 96% in households that have at least one mobile phone and represent the second largest mobile technology market after Asia [75]. In South Africa and Nigeria, mobile phone ownership by adults is almost equivalent to ownership in the United States, but smartphone ownership in sub-Saharan Africa lags behind from a high of 34% in South Africa to a low of 8% in Tanzania and 5% in Uganda [76]. Similar situations exist in South America, where mobile phone penetration is generally high, but smartphone penetration lags, and sometimes substantially. For example, consider the 2015 estimated rate for mobile phone penetration (% of population with device) versus smartphone penetration (% of population who have mobile phones) in the following countries, respectively, is: in Chile (73.3%, 55.5%), Argentina (70.6%,

43.5%), Columbia (69.3%, 51.4%), Brazil (69.2%, 35.8%), Mexico (67.2%, 47.4%), and Peru (62.6%, 33.5%) [77,78].

Regarding health, changing preferences and expectations play a large part in adoption of mHealth services, as well as sub populations' differential access to smartphone technology and its infrastructure. Knowledge of likely access can be important. For example, an estimated 88% of American teens between the ages of 13 and 17 years have access to mobile phones and 73% own a smartphone [79], but this age group has different behavioral risk patterns than older populations regarding human immunodeficiency virus infection behavior. Such differences impact intervention design approaches and what can be supported by the target population and technology platform [80]. The number of "Millennials" (ie, ages 18 to 34 years) in the United States will increase to over 75 million and outnumber every other generational category in 2015 [81]. The *2015 State of the Connected Patient* [82], reported that 40% of Millennials did not believe their primary care physician "would recognize them if they passed each other on the street" and 60% of Millennials preferred a video chat with their physician in place of an in-office visit. Among US teens aged 13-18 years, the Internet is the primary source of health information with 84% obtaining health information from the Internet and one in three teens have changed their behavior based on that Web-based health information [83]. Such information search capability requires Internet access (Core Characteristic 3).

Mobile connectivity can be much more than a social convenience. Consider Africa, which has the lowest Network Readiness Index as defined by the World Economic Forum [84]. The growth in basic mobile-based access affords simple messaging, which reduces the need for face-to-face medical visits, thus reducing health care costs due to reduced transportation needs and reduced diagnostic or referral delays for controlling Malaria outbreaks, especially in rural areas [85,86]. In Africa, South America, and Asia, there is a disproportionate number of poor people who lack direct access to the financial infrastructure—the "unbanked." Consequently, mobile access gives access to information and services, such as sending and receiving payments, allowing them to directly participate in, and gain from, a developing economy [76,84]. Relatedly, it is estimated that "75% of the world's poor rely on agriculture for all or some of their household income," so even simple (SMS-based) text messaging allows informational

exchange with specialists to increase agricultural productivity and, consequently, income [87].

Although the costs of owning smartphone technology are decreasing, and, perhaps as a consequence, ownership of mobile phones is increasing, the penetration and adoption of this technology is not uniform. It is essential to know the adoption patterns of the target population for the technological platform itself.

Core Characteristic 2—Availability of Apps

The second characteristic of smartphone technology is the *availability of apps* installable on the device. At its heart, we noted a “smartphone” is basically a computer with radio communications capabilities. Thus, smartphones have the functions and capabilities of a general purpose computer platform, enabling third-party developers to build and run their own programs (“apps”) exploiting the functionality of the particular device. Apps must be built specifically for the device’s OS (ie, Apple iOS, Android, Windows, Blackberry, Symbian).

The software driving smartphones is the OS. Note that iOS is unique to Apple, Blackberry OS is unique to Blackberry, but several phone manufacturers use Android OS (eg, Google, Samsung, HTC, LG, Motorola, and now Nokia) and Microsoft Windows Phone OS (eg, Samsung, Nokia, HTC, Huawei). Symbian OS and its primary supporter Nokia dominated the mobile phone market from early 2000s to 2010 though it is now on a substantial downward trend [88]. Given the Android open source software availability [89] and Android “remerging” into the Linux open source project [90], other Linux-Android OS phones are emerging with uniquely branded OSs, such as the Ubuntu phone [91]. As noted, Samsung is also developing phones and devices that use the open source Linux Tizen OS [92].

Furthermore, apps can be constructed to interact (acquire data and drive functionality) with connected devices, wired or wireless. As smartphones comprise a more expensive, but more capable, subset of the general mobile phone devices, the penetration levels are comparatively lower than smartphones, but as we noted earlier they are rapidly increasing due to relative price declines. In December 2015, US estimates indicated smartphones were owned by 79.3% of mobile subscribers, with Android phones holding 53.3% of the market, Apple iOS with 42.9%, Microsoft with 2.9%, and BlackBerry with 0.9% [93]. Worldwide second quarter estimates place Android comfortably in the lead with 82.8% of smartphone OS, Apple with 13.9%, Windows with 2.6%, and BlackBerry with 0.3% [94].

There are a remarkably large and growing number of general apps available under the 2 dominant platforms—Apple (1.5 million) and Android (1.6 million)—as of July, 2015 [95]. Although the market share for the Windows phone is dominated by Android and iOS, the use of apps may be more fluid as Microsoft is targeting the development of apps for both Android and iOS devices [96] as well as providing technological support (via software development kits) to port iOS and Android apps to Windows [97].

From a health care perspective, smartphone apps reside within increasingly powerful (mobile, hand-held) hardware-software

environments, allowing sophisticated data acquisition, communication, and computation-intensive processes to be done locally, such as various types of numerical and non-numerical calculations, data analytics, display graphics, and video, along with megabytes to gigabytes of local data storage. For example, the growth of mobile phone capabilities can bring important analytics to drive treatment decisions in outbreaks in rural or underserved populations, such as the use of a microscope app that analyzes videos of whole blood samples for microfilarial parasite *L loa* motion, quantifying density for determination of treatment within 2 minutes [98]. Similar mobile phone apps are in design, development, or production for in vitro and environmental testing directly (or indirectly with attached ancillary devices) supporting onsite detection of pathogens, such as disease markers via nucleic acid isolation, gold nanoprobe Tuberculosis diagnostics, microchip ELISA detection of ovarian cancer via HE4 biomarker and other cancer cell diagnostics, fluorescent imaging cytometry, lateral flow immunochromatographic assays, loop-mediated isothermal amplification genetic testing, and acoustic wave immunoassay to name a few [99]. Thus, even in resource-poor environments, mobile phone apps in the hands of health care workers can bring critically needed point of care or point of need analytics previously unavailable to underserved populations.

The nature of this reach is enhanced by the sophistication of the apps that can be run on the mobile devices given their computational capabilities, and these computational capabilities are escalating. Estimates suggest that the Apple iPhone 6’s A8 chip is 50x faster than the chip in the original iPhone and its graphics processing unit is 84x faster [100], but the Apple iPhone 6s’s A9 SoC (System on Chip) has an estimated 50% increase in processing performance and a 90% increase in graphics performance over the A8 [101]. The ARM Mali-T760 MP8 graphics processing unit in the Samsung Galaxy S6 can generate a peak performance of 302 Gflops [102], roughly equivalent to the supercomputers in 1996 [103], whereas IBM’s Deep Blue supercomputer, which bettered the world chess champion Gary Kasparov in 1997, has an estimated performance of 11.4 Gflops and was the 259th fastest supercomputer in 1997 [104], emphasizing how the technological capability is used, the critical role of programming.

For these devices, ancillary storage and speed of types of secure digital (SD) cards, the typical detachable storage medium, is also expanding along with the transfer speed. The size of the card is contracting, with the cost per storage unit decreasing as the next wave of improvements enter the market. In 2003, SD had a capacity of 512 megabytes, but disk capacity has increased 1000-fold, where SanDisk’s 512 gigabyte SD cards are temperature tolerant (–13° to 185°F), waterproof, shockproof, and x-rayproof [105]. This capacity means the card approximates the size of a postage stamp, any given mobile phone could have direct access to over 458 million pages of text (1200 characters per page) or a complete copy (snapshot) of all Wikipedia including images, for offline access [106] with space left over for either 128,000 average size ePub formatted books (3 Mbytes) or over 4500 five-minute YouTube videos at 720p. Thus, the information “at your fingertips” can be rather large. However,

SD technology is quickly approaching one of the popular SD standards (SDHX) limit of 2 terabytes (2048 gigabytes).

The arrays of different sensors and associated computational analysis contained within the mobile hardware or attached to the phone (directly or wirelessly) complement the raw computing power and data storage capacity. The ability to gain access to mobile broadband capabilities opens the floodgates of possibilities as the connectivity and local computational capabilities allow true point-of-care enhanced capabilities; communication nor computation are tethered to landlines. Mobile phones are however tethered to individuals. The possibility of personalization of public health, real-time data acquisition, and a host of other possibilities relevant to assessing, monitoring, and reacting to individualized contexts are just beginning. Issues of data privacy, HIPAA defined risk, app functionality risk and validity, and beyond are rapidly rising to the top of development agendas [107]. Most of the legal barriers, because of technology available when they were written, are oriented toward the electronic protection and privacy of patient information held in health care databases. Yang and Silverman [108] warn that when software is voluntarily downloaded and installed (as an app), accessing data from that app about the user may not be considered “unauthorized” as it is sometimes wrongly assumed under the Computer Fraud and Abuse Act of 1986. In fact, they even conclude the Electronic Communications Privacy Act “probably does not protect against the access or acquisition of data by the developer of a private app” (p. 224).

Most users (and uses) do not demand high computational performance of mobile phones, but it is likely that this demand will escalate with the user-facing capabilities of the health-related apps. Consequently, types of health services that can be offered via these platforms are increasing in number and sophistication. Referring again to the *2015 State of the Connected Patient* report [82]: 63% of Millennials would be interested proactively providing their health data from Wi-Fi or wearable devices to their doctor or provider so they can monitor their well-being and 71% would be interested in a doctor giving them a mobile app to actively manage their well-being for preventative care. Such interests require demands going beyond simple local data capture and reporting (eg, “fitness” apps), but more sophisticated data acquisition and processing coupled with sufficient analytical and communication capabilities. Finally, it is worth noting that an IMS Institute reports that despite the 100,000+ of health apps, just 36 apps accounted for almost 50% of the downloads (ignoring use), and 40% of the apps had less than 5000 downloads [109].

Core Characteristic 3—Mobile Broadband Access

The third characteristic of mobile phone technology is the ability to *access the Internet or World Wide Web* via mobile broadband. It is not sufficient that devices are portable, powerful, and capable to run the appropriate apps, but it is often the case that they must also be able to communicate via rapid Internet pathways. The technological sophistication or maturity of a region (defining its capabilities) is determined by the particular mix of its mobile technologies [110]. Note that the term “wireless broadband” should generally not be used in place of

“mobile broadband” (or mobile cellular broadband) as wireless broadband can include fixed-wireless and satellite technologies, although some satellite broadband technologies can be mobile.

The ITU generally defines mobile broadband as download data speeds of at least 256 Kbit/s using the Internet protocol and access to the “greater Internet” (ie, World Wide Web) via the Hypertext Transfer Protocol, but solely having standard short messaging service (SMS) does not count as broadband as it is a mobile-based voice protocol and does not require Internet access [111]. Mobile broadband is also defined in terms of technological generations (G), where 2G, 2.5G, 2.75G (1990s) technologies were the first digital cellular networks with speeds in the ITU range just noted and represents an earlier 2011 definition yielding 90% world coverage [112]. As with any evolving technology, definitions must change as the categorical characteristics of the technology change [113,114], so it is important to understand the operating definition of mobile broadband being used, and whether the reported statistics refer to overall capacity (eg, gigabit levels attributed to 802.11ac) or actual expected delivery rates for individuals under operational conditions and distance. In particular, many definitions specify or assume at least 3G technologies [115], with Long Term Evolution and Long Term Evolution-Advanced being the current fastest widely deployed mobile broadband technologies in terms of overall capacities and the closest to becoming the global base standard (there are different deployment forms) for mobile broadband [116]. In addition, intermediate steps taking advantage of current standards have yielded niche standards such as WiGig (802.11ad), which is a very fast (7 gigabits per sec, low latency), but short range (1-7 m) designed for close connectivity, such as eliminating cables [117]. On the other hand, the forthcoming next-generation 802.11ax wireless specification is not only seeking increases in network capacity but also seeking to create larger “data pipes” to individual devices, thus radically increasing not only the network capacity but also the average data rates to individual devices [118].

When considering newer baseline definition of mobile broadband subscriptions (at least 3G networks), the ITU of the United Nations estimates that 47.2 per 100 inhabitants of the world’s population is to be subscribed in 2015, with 89% of the world urban population (4 billion) covered but only 29% of the rural population (3.4 billion) covered, but substantial distributional differences between the developed countries (86.7 per 100 inhabitants), developing countries (39.2 per 100 inhabitants), and the least developed countries (12.1 per 100 inhabitants), where Africa is the sole region where mobile broadband is below 20 per 100 inhabitants (though within-regional differences occur) [115]. However, comparisons are complex as there is still a great deal of variation in how “mobile broadband” is defined, how specific technologies are classified, and how measurements are conducted [119]. Regardless, Ericsson predicts that by 2021, 85% of all smartphone subscriptions will be for mobile broadband, but whether it plays a replacement role for fixed broadband or a complementary role depends on the particular segment [74].

It is important to understand how these characteristics map to target populations. For example, there are distinct issues with the lack of rural broadband (wired or wireless or mobile) in the

United States, where 53% of rural Americans (22 million people) lack such access, as do almost two-third of US territories and Tribal lands [120]. A 2015 Pew survey found that 54% of sampled African American homes had broadband, a decline from 2013, and this percent varied by household income, ranging from a low of 41% (income < \$29K) to a high of 80% (\$50K ≤ income ≤ \$75K) [121]. The same survey showed that almost 20% of African American households have smartphones, but no broadband.

There is an emerging trend of smartphone dependence among younger adults, nonwhites, lower income, and lower educational attainment, where these devices are the sole mechanism for both Web-based access (often at slow speeds) and phone calls (elimination of land lines) for communication, but also are less likely to be covered by health insurance or have a bank account [122]. The decline of landlines in the United States was further evidenced by a Centers for Disease Control and Prevention survey that estimated 47.1% of children and 39.1% of adults live in wireless-only households, with 56.2% of poor households and 53.1% of Hispanic households were wireless-only [72]. Two consequences of decline in landline use, sometimes overlooked, are (1) the loss of community revenue typically accrued by local telecommunication taxes, as federal law prohibits state and local taxation of Internet data, including communication apps such as Skype, FaceTime, WhatsApp, and Twitter [123] and (2) potential bias in “phone-based” surveys reliant on landline registers [72,124].

The penetration of mobile broadband worldwide is expected to surpass fixed-broadband by 2017 [125]. In fact, the 34 member countries of the Organization for Cooperation and Economic Development now report an average of 81.3% mobile broadband penetration (wireless subscriptions per inhabitant), with 7 members averaging above the 100% mark [126]. Collectively the Organization for Cooperation and Economic Development member countries’ population is approximately 1 billion people, and the results necessarily do not include data from other important regions, as Africa, India, Brazil, China, and Russia. For example, in the least developed countries, fixed-broadband remains less than 1% and escalation to mobile broadband is the sole option [115].

Regarding health care, mobile broadband is essential for accessing the Internet resources and supporting the sufficient bandwidth for communication capabilities of data-intensive mobile phone app, such as video, without the need for, or reliance on, geospecific landlines. For example, the Mobile MIM iOS app allowing viewing X-rays, ultrasounds, neuroimaging on iPads, or iPhones by medical professionals, but developers also provide VueMe iOS apps for secure patients to view and discuss images with their health providers without physical presence required [127].

Despite the increasing capabilities of mobile phones, attached devices offer another route to point-of-care accessibility via mobile technology, allowing local complex data acquisition (via the combined capability of the attached device and the mobile phone) by a health care professional. The MobiUS SP1 mobile phone app interacts with a hand-held ultrasound device, allowing local scanning and transfer of imaging via Wi-Fi,

cellular or USB to PC connection [128]. Dexcom’s Apple Watch app displays patterns of glucose readings. It receives data from Dexcom’s Continuous Glucose Monitoring system that captures glucose levels by a subcutaneous sensor, up to 288 readings per day, and relaying the information (and any warnings) to up to five additional “followers” [129]. The AliveECG app (with the attached device) allows individuals to take their own ECG with their Android or iOS smartphone (or tablet), which then analyzes the data to determine if atrial fibrillation (a leading cause of stroke) is detected [130]. Proteus Digital Health has both an ingestible sensor-enabled pill that works with an external patch that detects a signal that is generated from the pill when ingested (reaches the stomach) and records rest or activity patterns (steps, heart rate) that are sent via Bluetooth to the caregiver’s, patient’s, or physician’s mobile phone app, as well as to a secure database accessible by authorized health care professionals [131]. Propeller Health’s sensor attaches to most asthma and COPD inhalers, capturing time and geolocation data of use (and other data, such as user-supplied medications), linking to an app that can share that data with health care partners or anonymously (eg, capturing timing and location data across users signaling environmental situations), but the app also provides information on adherence and education [132]. Medronic’s MiniMed system connects its small insulin pump and continuous glucose monitor to a diabetics iPhone, sending pump and sensor information to the iPhone every 5 minutes, and sending history information to their CareLink health care “partners” every 24 hours, or preset text messages immediately if glucose levels exceed tolerance levels [133]. In addition, Medtronic is also partnering with Samsung to develop Android apps for that device series [134].

All of the previously noted devices are examples that have been approved, or are being reviewed for approval, by the US Food and Drug Administration at the time of this writing, which speaks to the separate topic of how smartphone technology (directly or indirectly) takes on the role of a regulated medical device [135]. But Internet connectivity is an ever-emerging architecture. Every smartphone can act as a wireless hotspot affording a gateway for other smartphones or computers or attached devices. To complicate things, Bluetooth 4.2 allows devices to securely connect to each other and to the Internet via IPv6/6LoWPAN (IPv6 over Low-Power Wireless Personal Area Networks) via direct connection to any gateway device (eg, a router) and avoid the necessity of a smartphone entirely, thus opening the communication door for the “Internet of Things”—sensors, instruments, devices, and attachments that have the capability of interacting directly with the Internet [136].

Core Characteristic 4—Tethered to Individuals

The final characteristic of mobile phone technology is that mobile phones are usually tethered to *individuals*, though the validity of this characteristic is dependent on the heterogeneity of the penetration of this technology in certain populations. With respect to penetration, consider that mobile phone technology differs critically from landlines on this metric because mobile phones are associated with individuals and not residences (requiring a permanent, physical location), so there is usually a 1:1 mapping between individuals and mobile phone use (but this mapping can also be 1:N, when individual users

have more than one mobile phone account per SIM card). In addition, a US Gallup Panel in July 2015 revealed that on the average 11% checked their mobile phone devices every few minutes (22% of those between the ages of 18 and 29 years), and an additional average of 41% reported checking a few times an hour (51% of those between the ages of 18-29) [137]. Nevertheless, the assumption of individual tethering is likely a valid default assumption sans conflicting evidence.

At a basic level, this affords an efficient technological mechanism for 2 health purposes: data monitoring-acquisition and intervention delivery. Regarding the former, individual tethering allows “immediate” acquisition of personal event data, actively or passively. For example, various types of experience sampling or ecological momentary assessment methods have emerged to capture individuals’ self-reporting episodic descriptions (event based, time based) of behaviors and experiences in “real time” (ie, to avoid delayed, retrospective autobiographic approaches that may be biased in recall or inaccurately reported) in real-world contexts, such as diaries (paper or electronic), telephone calls, generally emerging in the 1990s [138-140]. Mobile phones are now serving as a natural platform for applying such data acquisition approaches for conditions as tobacco use [141], alcohol use [142], development of virtues [143], mood and affect assessment [144], diet and physical activity [145], and obesity-specific contexts [146], with additional activity sensor capabilities that serve to augment “message-based” data for such approaches [147].

Individual tethering accordingly supports personalized medicine or public health interventions as allowing for specific messages to be sent to specific individuals. In general, individually-tailored messages in public health interventions are more likely (when properly designed) to effect behavior change than generic messages [148]. Although the particular definition of “tailoring” in public health and health care has varied widely [149,150], our interpretation simply addresses the fundamental characteristic of what the technology can deliver—connectivity tethered to an individual. How any form of tailoring will be used (and its likely impact will be) exploiting that characteristic depends on the quality of the design in the context of an intervention. For example, linking an ecological momentary assessment method with an intervention treatment to support individually-tailored SMS connectivity [151], but use of other forms of tailoring exploiting the tethered nature of mobile phones are being developed, such as with human immunodeficiency virus adherence [152], but is a growing component of many SMS intervention designs [153]. Again, the tethered technology affords various types of tailoring, but the impact of any tailoring depends on the quality of the design and its implementation. Of course, the 1:1 mapping also allows for large amounts of (and of potentially high fidelity) *patient-generated health data*, aggregated for location and time-dependent analyses at a group level, such as disease surveillance or clinical practice statistics [154,155].

A question regarding tethering involves not only the generation of individual’s data but also one of access to individual’s EHR. A survey by Accenture [156] demonstrates how both physicians’ and health consumers’ attitudes and behaviors regarding digital technology and health have changed in 2 years, for example, in

patient’s actual access their electronic records (2014: 27%, 2016: 45%), in what data they have access to in their EHR (2014: 39%, 2016: 65%), and in the use of health apps (2014: 16%, 2016: 33%). However, the same survey revealed that 92% of patients believed that they should have full access to their EHR, whereas only 18% of physicians held that same belief. This is one example of gaps that may exist between 2 of the key stakeholders with respect to use of this technology: patients and their health care providers.

Characteristic Interactions and Their Consequences

Of course, the world is often more complex and dynamic than we either describe or anticipate. Collectively, interactions and secondary impacts of these characteristics are beginning to emerge. For example, the problem of individuals’ “access to access” (ie, availability of technology that enables access to health services) is evaporating. As the penetration of smartphone into all populations continues, it affords an important vehicle for recruitment of under-represented groups in clinical trials and other health-related research [157]. But as technology forms become more effective and efficient, so do mHealth offerings, and this usually results in differential access (eg, via cost) to the “best” mHealth solutions [158].

Mobile phone-based apps allow the localization of data acquisition, processing, and presentation or response options to specific individuals, situations, and context. Access to the Internet or World Wide Web increases the amount and forms of data gathered and transmitted to and from individuals and groups, over time and across place. Consequently, mHealth for health care has generated many variations of technological use, ranging from the ability to generate tailored messages to individuals or to groups of individuals with similar needs via the Web [159] or via text messages [160], to engaging technological combinations such as those being designed in broad, social media systems [161] affording “peer-to-peer” health care [162] or to realizing new health surveillance capabilities through extant technology and relevant populations, such as “participatory epidemiology” forms of engagement and rapid communication [163-165].

The rise of inter-connectivity of local health-rated devices will not only increase the potential of mHealth but also increase the complexity of its design. The nature of “wearable” health devices are currently worn either on the wrist (55%) or the chest (27%) or the purse or pocket or shoe (17%), but are also appearing on the arm (8%), head (7%) clothing (6%) leg or ear (5%), ankle (3%), necklace (3%), or finger (1%) [109] and are highly dependent on sensors [166]. The global wearable health device market between 2015-2020 is projected to achieve revenue growth of \$41.3 billion by 2020 [167]. Pennic [168] cites a MarketsandMarkets report projecting the ingestible sensor market to grow to \$678 million by 2020. Data captured by these devices can form a personal, integrated health sensor network that could be easily collected, integrated, and analyzed by mobile phone technology.

The rapid development of mHealth technologies has resulted in market interposition wherein traditional providers of health care services have been partially displaced by preferred technological self-treatment [169]. In fact,

Price-Waterhouse-Coopers placed “Do-it-yourself healthcare” as their top health industry issue for 2015 [170] and places “care in the palm of your hand” as the third top industry issue for 2016 [171]. However, this may speak less about preference of care and more about ease of access. Given the opportunities for engaging mHealth apps for public health, it is necessary to understand the broad array of interconnection forces at play, now and likely in the future. This is a distinctly different patient-facing functionality than the failed Google Health’s medical records or health data platform [172] offering various forms of disintermediating from “traditional” health care reimbursement, face-to-face models, but it is difficult to predict how the insurance industry or federal or state regulators will respond.

What is clear is that the upcoming Stage 3 requirement of the Meaningful Use incentive program from the Centers for Medicare and Medicaid Services strongly encourages patient engagement (care management, wellness, and patient supplied data) outside of a clinic using mobile health apps, coordination of care, and patient access to health information via mobile platforms [173]. Recall that Apple’s HealthKit integrates with the Epic System’s EHR system. Consider that one of the primary reasons for HealthKit’s growing adoption in health systems is the fundamental simplicity of connecting to institutional EHR systems [174], and the top EHR vendor meeting the Meaningful Use requirement is Epic [175]. Note also that Duke Medicine recently succeeded in being the first Epic-based health system to implement the Fast Healthcare Interoperability Resources standard with Apple’s HealthKit [176], a standard that also allows Epic Systems EHR data to interoperate with IBM’s Watson Health analytics [177]. Overall, the adoption of even basic EHR by the key gatekeepers, the physicians, is occluded by the encountered difficulties of data exchange, whether it involves interoperability standards or strategic moves by vendors to gain competitive advantage [178]. Nevertheless, specific inroads work to demonstrate ways of overcoming such obstacles for specific health objectives on mobile apps [179-181].

Conclusion

mHealth is an ill-defined, but growing component of all aspects of health (prevention, diagnosis, treatment, research) around the world. We focused on 4 core characteristics of the foundational platform, the mobile smartphone, that will likely remain as important to understand to help design and implement more effective and efficient mHealth solutions. More importantly, as each characteristic has surprising depth, complexity, and relation to the other characteristics, it is essential to discern how these work together in any particular mHealth context. Each type of characteristic embodies both features and constraints.

This is the fastest spreading communication technology. The first core characteristic—penetration into populations—is possible because mobile telephony is becoming ubiquitous, and this has significant implications for reach into populations, although not homogeneously in many cases. Therefore, it is necessary to know the technological platform most adopted and how it is used by the target population or subgroup.

Apps are powerful but issues of use are complicated. The second core characteristic—the availability of app—affords potentially sophisticated function (and computation) available to the device, depending on the type of mobile phone. In addition, the growth of short-range device connectivity allows ancillary devices to be connected to the mobile phone, enlarging the set of technological options in communication, monitoring, and delivery of health solutions. In addition, both the sophistication of sensors on, or connected to, a mobile phone raises the question of whether it is (they are) a medical device (in a legal sense) and how HIPAA rules guide the storage and use of that data. Given the immense growth in apps, competition can be intense, but opportunities for innovation are practically unbounded.

Connectivity matters. The third characteristic—wireless broadband—is the most rapidly growing technological platform for Internet access, so consideration of mHealth contexts with Internet connectivity, even intermittent connectivity, affords a substantially different pathway for expected data rates to and from devices, influencing the formation and functionality of mHealth apps and their target groups. However, as lower income groups increase their (often sole) reliance on mobile broadband for Internet connectivity, data charges can escalate rapidly. Costs to the client are still a part of the use equation.

Almost everybody has a mobile phone. The fourth characteristic—that mobile phones are generally tethered to individuals—affords direct access to individuals allowing deep penetration to the individual level, with apps being tailored to individuals and having the ability to adapt to individual behaviors and physiological data, captured and communicated distally (if necessary) in real time. The primary interpretation of the 4 characteristics is that they serve as both opportunities and constraints. However, to exploit them as either, it is essential to understand what they are, and how they relate to one’s *specific* mHealth context. Regardless, they are the enduring characteristics common to all mHealth mobile phone apps.

Recently Gordon Moore (the architect of Moore’s Law) stated, *We’ve just seen the beginning of what computers are going to do for us* [182]. The ubiquity of the devices, their computational ability, and their ability to capture and rapidly transmit complex data, whether the data comes from “medical devices (Food and Drug Administration approved) or not, the rate and amount of data captured lends itself to large-scale analytics affording new, broader capabilities” [183] which, of course, can be used for “good or evil” [184]. Along with “Big Data” often comes “Big Noise,” so the merging of technology and health contexts will allow us the opportunity to move from collecting *data*, which has a cost (eg, acquisition, storage, transfer, security, integrity), to efficiently extracting *information*, which as a value by guiding decisions that lead to health improvements in individuals, groups, and societies. The key is achieving the economically-viable potential to turn acquired data into information that can be applied to the betterment of health, which necessitates not only well-designed interventions but also well-designed evaluations of those interventions [185]. Yet, there is likely another level where health care, and public health, use that information to inform policies that are enabled, and not blocked, by institutional mechanisms. Still the fundamental

mantra remains: mHealth is not about technology; it is about how technology is appropriately used in the context of achieving specific health goals [186,187]. Nevertheless, future discussions must include additional considerations of how to weave the use and usability of such technology into the foundational designs of interventions, and not simply a delivery platform afterthought, as technology is not neutral. Translating evidence-based interventions for one mode in which it was designed (eg,

workshops) cannot be adopted for another mode without determining the impact on the integrity of the original logic [188,189].

Mobile phone and communication technologies afford us characteristics with remarkable capabilities and potential. And these are rapidly, unpredictably, and even disruptively, changing and changing health care and public health. Are we ready?

Acknowledgments

This work was funded in part by a grant from Emory University's Global Health Institute and the Goizueta Business School Summer Research Fund at Emory University.

Conflicts of Interest

None declared.

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Abbreviations

- ECG:** electrocardiogram
EHR: electronic health record
HIPAA: Health Insurance Portability and Accountability Act
ICT: Information and Communications Technologies
ITU: International Telecommunications Union
OS: operating system
SD: secure digital
SDK: systems development kit
SMS: short messaging service

Edited by G Eysenbach; submitted 16.02.16; peer-reviewed by S Bull, S LeGrand, M Andrea; comments to author 16.03.16; revised version received 02.07.16; accepted 20.07.16; published 10.08.16.

Please cite as:

Davis TL, DiClemente R, Prietula M
Taking mHealth Forward: Examining the Core Characteristics
JMIR Mhealth Uhealth 2016;4(3):e97
URL: <http://mhealth.jmir.org/2016/3/e97/>
doi: [10.2196/mhealth.5659](https://doi.org/10.2196/mhealth.5659)
PMID: [27511612](https://pubmed.ncbi.nlm.nih.gov/27511612/)

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Original Paper

Deriving Requirements for Pervasive Well-Being Technology From Work Stress and Intervention Theory: Framework and Case Study

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Abstract

Background: Stress in office environments is a big concern, often leading to burn-out. New technologies are emerging, such as easily available sensors, contextual reasoning, and electronic coaching (e-coaching) apps. In the Smart Reasoning for Well-being at Home and at Work (SWELL) project, we explore the potential of using such new pervasive technologies to provide support for the self-management of well-being, with a focus on individuals' stress-coping. Ideally, these new pervasive systems should be grounded in existing work stress and intervention theory. However, there is a large diversity of theories and they hardly provide explicit directions for technology design.

Objective: The aim of this paper is to present a comprehensive and concise framework that can be used to design pervasive technologies that support knowledge workers to decrease stress.

Methods: Based on a literature study we identify concepts relevant to well-being at work and select different work stress models to find causes of work stress that can be addressed. From a technical perspective, we then describe how sensors can be used to infer stress and the context in which it appears, and use intervention theory to further specify interventions that can be provided by means of pervasive technology.

Results: The resulting general framework relates several relevant theories: we relate “engagement and burn-out” to “stress”, and describe how relevant aspects can be quantified by means of sensors. We also outline underlying causes of work stress and how these can be addressed with interventions, in particular utilizing new technologies integrating behavioral change theory. Based upon this framework we were able to derive requirements for our case study, the pervasive SWELL system, and we implemented two prototypes. Small-scale user studies proved the value of the derived technology-supported interventions.

Conclusions: The presented framework can be used to systematically develop theory-based technology-supported interventions to address work stress. In the area of pervasive systems for well-being, we identified the following six key research challenges and opportunities: (1) performing multi-disciplinary research, (2) interpreting personal sensor data, (3) relating measurable aspects to burn-out, (4) combining strengths of human and technology, (5) privacy, and (6) ethics.

(*JMIR Mhealth Uhealth* 2016;4(3):e79) doi:[10.2196/mhealth.5341](https://doi.org/10.2196/mhealth.5341)

KEYWORDS

psychological stress; professional burn-out; behavioral symptoms; self-management; health technology; early medical intervention

Introduction

Employees often report the experience of stress at work, which is related to their well-being. In this research we focus on the population of knowledge workers who are predominantly concerned with interpreting and generating information. Stress is easily caused by their typical working conditions [1]. Several tasks that need to be finished before a deadline, and their course of action is not always self-planned but also determined by external causes, like phone calls, mail, information requests, and other persons or appointments [2]. Following the definition by Selye [3], an employee complaining about stress might mean that his working conditions are very demanding (the stressor), or that he feels that demands put upon him are higher than he can take (the perception of stressors), or that he feels stress reactions in his body such as neck pain or headaches (the experience of stress). To date, the problem of work stress is often approached with questionnaires in which employees are asked to rate various aspects of their work [4,5], followed by department-wide interventions (eg, providing trainings). However, interventions trying to reduce stress have often failed: a recent study with mindfulness at the workplace found no effect on stress levels [6]. Another common approach is finding help with others via group therapy.

As knowledge workers are relatively flexible in their work (when they do what and how they work), there is great potential for them to contribute to the improvement of their own well-being. New technologies are emerging, such as sensors available in mobile phones, smart reasoning, and electronic coaching (e-coaching) apps. In the Smart Reasoning for Well-being at Home and at Work (SWELL) project [7], we see potential in using such new pervasive technologies to address well-being at work at an individual level [8]. We also see possibilities in using unobtrusive and easily available sensors to capture the knowledge workers behavior (eg, computer interactions, webcam for facial expressions), and infer stress and the context in which it appears. Based upon this information, we aim to develop a system with a suite of support apps that are context aware (ie, optimally adapted to the situation and state of the user). Knowledge workers can then directly act, gaining a more healthy work style, preventing stress building up, and curing stress-related problems like neck pain or headaches. An app could also provide a platform to come into contact with peers for support. Trends like “quantified self” already show the potential of collecting personal sensor data (eg, heart rate, activity patterns) for health improvement. In their paper on technology for well-being, IJsselstein et al [9] describe that advancements in sensing and interpretation are promising. They further state that using technology for improving well-being has many advantages including its persistence or objectiveness, the possibility to provide just-in-time notifications with relevant, actionable information or their supportive and motivating role.

To develop a theoretically and empirically grounded stress self-management system, we take a multi-disciplinary approach. By means of situated cognitive engineering [10], we combine theory on work stress with input on user needs, taking in mind

technological possibilities (Figure 1). In this way, a functional system specification with core functions and claims was generated, which is then evaluated with users. The main focus of this paper is the theoretical foundation. The general objective of the SWELL system is to improve well-being at work. An important question is: what defines well-being at work and what causes well-being? Many relevant theories are provided by several disciplines, such as work psychology, biology, or behavioral psychology. However, theories are diverse and different disciplines view the world from different angles (eg, using different levels of abstraction). Therefore, how do different concepts relate to each other? One comprehensive and practical framework that can be used as a theoretical basis for the design of the envisioned self-management support is still lacking. Moreover, psychological theories are often abstract and for implementing a solution many choices need to be made. We investigate the role of new technologies, which also provides new opportunities to study and influence behavior.

The main contribution of this paper is a general and pragmatic framework (Figure 2), which combines various stress and intervention theories, as well as possibilities for real-time measurements and interventions with technology. This framework can be used for developing technologies addressing well-being at work, as is demonstrated in our SWELL use case. Moreover, we show that, vice versa, new technologies can also be used for theory building. Our research questions and the remainder of the paper are structured around our framework, beginning with a description of an initial study on user needs as a starting point for the system design. Then, we investigate by means of a literature study, which aspects are relevant to include in the pervasive support system. We answer our *first research question*: which concepts are relevant with respect to well-being at work? The concepts “burn-out”, “engagement”, and “stress” (red/orange parts) are presented. We then use a literature study to investigate which causes of work stress our pervasive system could address. We answer our *second research question*: which person, work, and context conditions can lead to negative stress? We present different work stress models (blue parts). Following that, we integrate knowledge on technical possibilities to define how the pervasive system could quantify relevant concepts (gray parts). We answer our *third research question*: how can sensors be applied to automatically infer stress and the context in which it appears? Finally, we combine insights gained thus far with a literature study on intervention theory (green parts). We answer our *fourth research question*: which interventions can be provided by means of pervasive technology to help a knowledge worker improve his well-being at work? Based on technical possibilities, we define several technology-based interventions (black parts). All parts together form our general framework, which was used to derive requirements for our case study, the pervasive well-being support system SWELL. We present the envisioned system and first prototypes of technical support that were implemented, as well as results from evaluation studies with potential end users. We finish our paper with our conclusions, a discussion of limitations of our work, and a more general reflection, where we present six research challenges that we identified.

Figure 1. Situated Cognitive Engineering (sCE) approach.

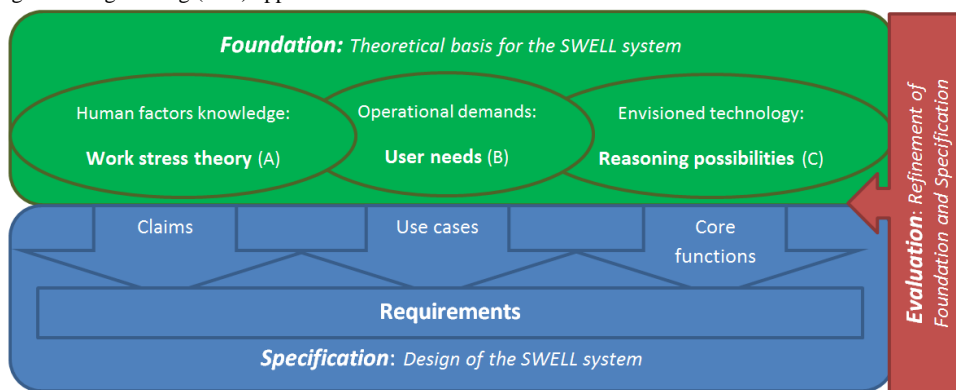
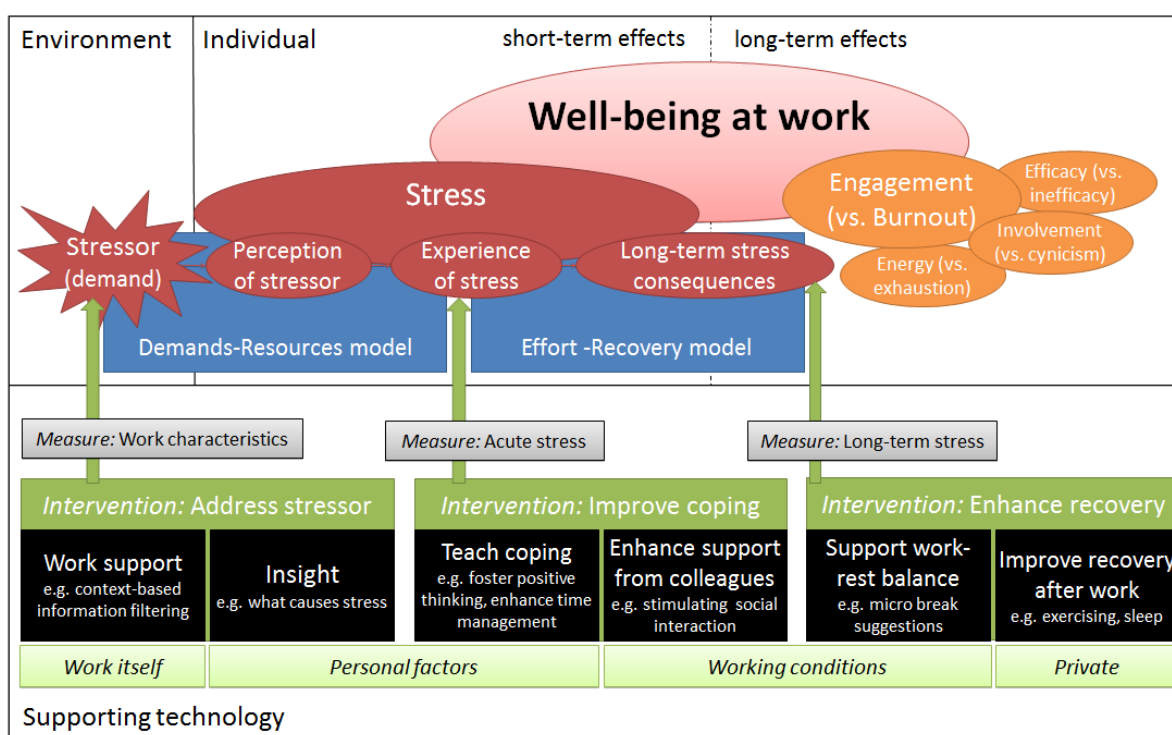


Figure 2. Our framework that combines various stress and intervention theories, as well as possibilities for real-time measurements and interventions with technology.



Methods

Initial Study on User Needs

Following the situated cognitive engineering methodology [10], we start with input from potential end users. We held interviews with five knowledge workers who had experienced burn-out and organized a workshop with seven employees to establish user needs. Knowledge workers indicated that the system should provide them an overview of performed work, preferably in combination with work behavior and the associated subjective experience. This information can then be used by the user to gain insight in work processes. For example, at the end of the day an overview could be provided on how time was spent and how stress evolved. Moreover, users indicated that they would want help in the form of tips. Ideally the tips are also well-timed, taking into account the user’s current context. Finally, users indicated that the system could actively support them during their work. The system can take an active role in supporting the

user by filtering irrelevant emails or finding information relevant to the current work topic. We also identified some important factors to address such as not irritating users and addressing privacy. This user input was used to guide the further design of the system. In the next sections we focus on important relevant domain knowledge.

Well-Being at Work Concepts

In this section we aim to answer our *first research question*: which concepts are relevant with respect to well-being at work? To answer this question, we performed a literature review [11]. The search engine “Web of Science” was used with the keywords well-being, commitment, satisfaction, stress, and engagement. Based on 23 scientific publications an overview of the different concepts was made. The literature review revealed that there are many different related concepts and many different models. Finally, the concepts “engagement” and “stress” were chosen, as they seemed most suitable to capture with sensors. In this section, we first describe the concept of

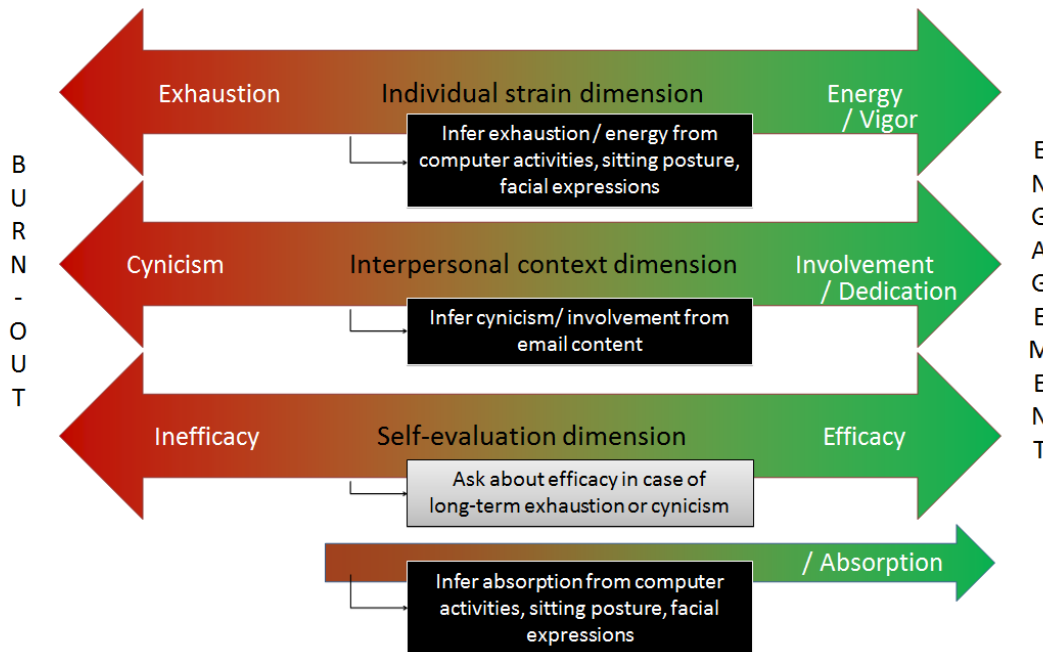
engagement in more detail (Figure 2), and then present literature regarding stress and its consequences.

Engagement and Burn-Out

The relationship people have with their jobs can be described as a continuum between engagement and burn-out (Figure 3) [12]. Maslach and Leiter distinguish the following three dimensions: (1) individual strain (exhaustion vs energy), (2) interpersonal context (cynicism vs involvement), and (3) self-evaluation (inefficacy vs efficacy). According to this terminology, an engaged employee feels energy, involvement,

and efficacy. His state can be characterized as worrisome when he feels exhaustion, cynicism and/or inefficacy, which characterizes burn-out [13]. According to Maslach and Leiter [12], “engagement represents a desired goal for any burn-out interventions.” (p 499) Schaufeli and colleagues describe engagement as the combination of vigor, dedication, and absorption [14]. The first two concepts are similar to those described by Maslach and Leiter [12]; however, the main difference lies in the third dimension, absorption, which is not the opposite of inefficacy, but a different aspect.

Figure 3. Well-being at work concepts "burn-out" and "engagement" and ideas to infer certain aspects from captured (sensor) data.



Stress

Besides engagement or burn-out, a relevant concept that can be experienced in the office is stress. In research we find that the term stress is often used to refer to different things. In our work we use the definition by Selye (Figure 2) [3]. An environmental demand, or stressor, leads to a perception of the stressor, which is dependent on the particular characteristics of the individual. The individual’s perception of the stressor results in a particular experience of stress. An employee complaining about stress might thus mean that his working conditions are very demanding (the stressor), or that he feels that demands put upon him are higher than he can take (the perception of stressors), or that he feels stress reactions in his body (the experience of stress).

Selye distinguishes good stress (eustress) and bad stress (distress) [15]. Some amount of stress is not harmful and might even be beneficial to gain concentration and focus. Eustress occurs when the person experiences the right amount of demand. Distress occurs when a person experiences too much or too little demand. This is related to the Yerkes Dodson Law [16], which describes that (empirically) performance improves with arousal, up to a certain point, after which it declines again.

Individual characteristics and appraisal play an important role in the experience of stress. The same stressor can be seen as a

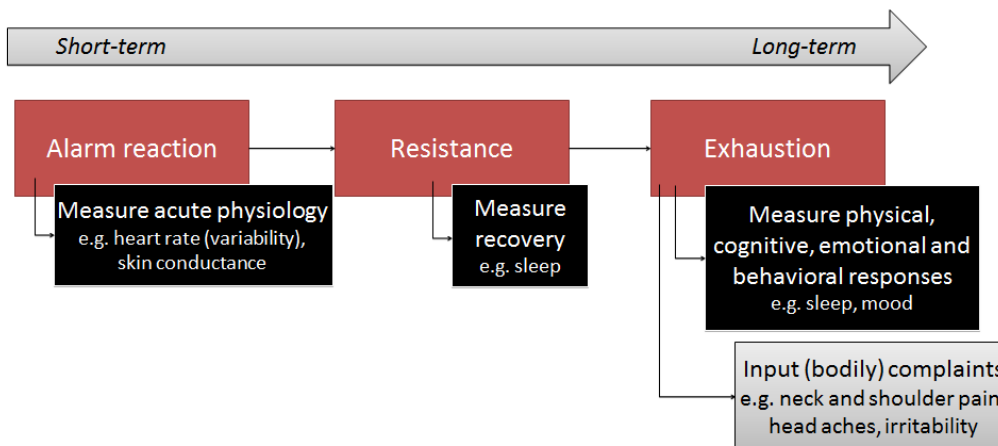
problem leading to negative emotions causing distress, or as challenge leading to positive emotions causing eustress [17]. This can depend on the amount of resources or feeling of control that the individual has. So even changing the mind-set of a knowledge worker could help him cope better with stressors. More details on the balance of demands and personal resources can be found in the section on work stress models.

The body’s short- and long-term reactions to stress can, from a biological perspective, be captured in the following three stages and in Figure 4 (General Adaptation Syndrome [18]): (1) alarm reaction - the fight or flight response, (2) resistance - the body adapts to the stressor, and (3) exhaustion - the body’s resistance decreases due to long-term stress. The alarm reaction causes adrenaline to spread through the body and a rise in blood pressure (reaction of the nervous system). Under very stressful conditions, a shift in hormone production may take place, increasing stress hormones like cortisol, which increases blood sugar, but also suppresses the immune system (reaction of the hormonal system). This stress response system works well for dealing with short-term stressors. When the stressor disappears the body gains back its natural balance. When the level of the stress hormone cortisol is high for a prolonged time, negative effects on the brain, for example, can occur. This shows the importance of recovery.

With lack of recovery, stress can accumulate and lead to health problems. Extended periods of stress can cause physical reactions (eg, increased blood pressure, muscle tension, headache, sleeping problems), cognitive reactions (eg, problems with concentrating, problems with setting priorities, decreased efficiency in work), emotions (eg, irritation, feeling restless, tense, anxious), and changes in behavior (eg, avoiding social

contact, more risk taking, not being able to relax, increased complaining) [19]. Moreover, Bakker et al [20] explain that stress can not only directly lead to illness through its physiological effects, but also indirectly through maladaptive health behavior such as smoking, poor eating habits, or lack of sleep.

Figure 4. Stress reactions of the body and measuring possibilities.



Relevant Concepts for the System

In this section we aimed to answer our *first research question*: which concepts are relevant with respect to well-being at work? We identified the concepts stress and engagement (vs burn-out), with three underlying dimensions: energy, involvement, and efficacy (or absorption) (Figure 2, orange/red parts). Moreover, we found that stress is a normal process and in the form of eustress also good for well-being and performance. It cannot be the goal to prevent stress. Rather, employees should be helped to handle distress and prevent negative long-term consequences. In a pervasive system, we could measure the stressor itself (eg, work characteristics), as well as the individual’s perception of the stressor (eg, acute stress). In addition, we could analyze long-term patterns in which stress is building up and measure recovery (eg, sleep time or the amount of physical activity).

Core Functions of the System

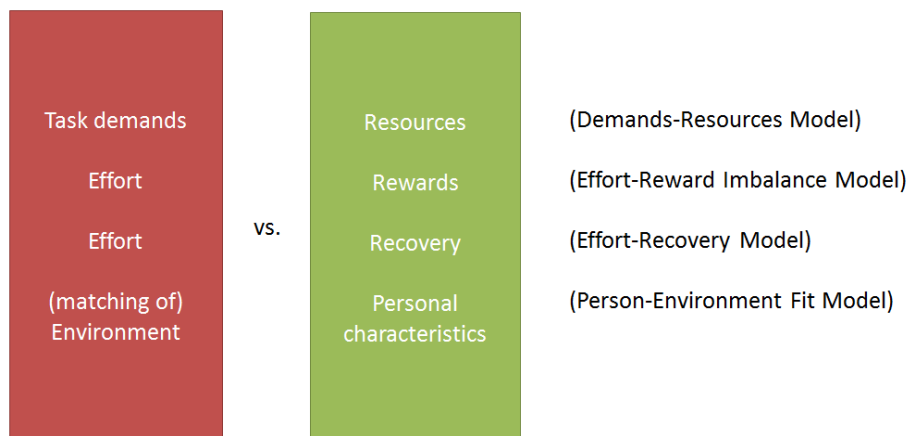
Based upon this part of the theoretical framework, we formulated the core functions (F) for the pervasive well-being

system: the SWELL system could collect information about aspects of engagement, work characteristics, acute stress, and long-term stress and recovery (F1). Its associated claim states that this information is useful for data-driven and context-aware coaching.

Causes of Work Stress

After having described the concepts related to well-being at work, we now turn to models describing underlying causes. We aim to answer our *second research question*: which person, work, and context conditions can lead to negative stress? We present the four most influential work stress models, which all describe a balance between two variables (Figure 5). The basic idea is that work becomes stressful when high demands are combined with (1) insufficient resources (such as low job control and little social support); (2) little rewards; (3) little recovery; or (4) an environment that mismatches with personal characteristics. We now outline each model in more detail. Based on each model, we identify aspects that can be addressed by means of technology.

Figure 5. Different work stress models.



Job Demands-Resources Model

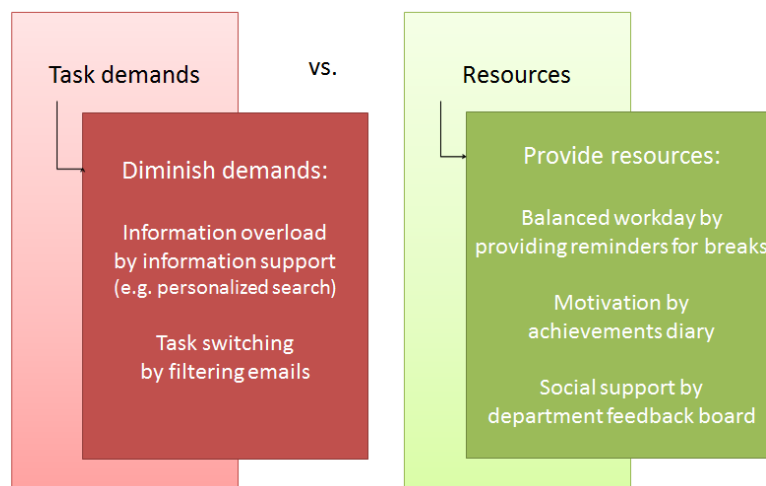
The first model can be characterized by a balance between job demands on the one hand and resources on the other hand (see Figure 6). Karasek Jr developed the initial model called the Job Demands Control (JDC) model [21]. The model was later extended to the Job Demands-Resources (JD-R) model [22]. Here, the more general interplay between job demands and job resources is described. Job demands are aspects of the job that require effort (eg, physical workload, time pressure, emotional demands, the physical environment). High job demands are not problematic; problems arise when the necessary resources lack. Job resources are aspects of the job that help in achieving work goals, reduce demands, or stimulate personal growth and development such as autonomy, job control, social support (from colleagues, supervisor, family, and peer groups), feedback, rewards, task variety, and role clarity. The WEB (Werkstressoren-Energiebronnen-Burnoutmodel) model [23] is another variant of the JD-R model, in which a direct link between demands, resources, and three aspects of burn-out is made. The aspects of burn-out are high demands cause exhaustion, whereas a lack of resources can lead to a decreased feeling of competence (inefficacy), and distancing oneself from work (cynicism).

Based on the JD-R model, we can address well-being at work from two sides. First of all, we can diminish the demands placed upon knowledge workers: a typical demand on a knowledge

worker is to deal with large amounts of information. We can make technology that can try to diminish information overload by providing information support, for example, in the form of filtering context-relevant from irrelevant emails (Technology T01) or by enabling personalized search (T02). Another demanding aspect of the work is task switching. A computer tool could diminish this demand by helping employees to remain focused on the task at hand by filtering irrelevant emails (T01 again) or with gamification, motivating employees to stay focused by giving points for less task switching (T03).

Secondly, we can provide additional resources. A resource that the knowledge worker has is his motivation and self-efficacy. The computer tool can support motivation by providing an achievements diary (T04), which is in line with work by Amabile and Kramer [24], who showed that the feeling of making progress leads to more motivation and better performance. We could also facilitate social support, facilitate support by peers by use of a department-wide feedback board (T05). Another resource is a good work-rest balance with variation in tasks. The system could help to have a balanced workday by providing insights in what gives and costs energy by providing an activity and workload overview and promoting better planning (T06). Taking enough recovery breaks could also be traced and supported with technology (T07). It is imperative to consider keeping the knowledge worker in control and not posing additional demands.

Figure 6. Job Demands-Resources model [12], and possibilities for technological support.



Effort-Reward Imbalance Model

The Effort-Reward Imbalance (ERI) model [25] can be characterized as a balance between effort on the one side and rewards on the other side. As long as the rewards are in balance with the efforts of the employee there is no problem. An imbalance might occur when the employee's efforts are higher than his rewards, which might happen due to over-commitment. Such an imbalance may result in stress and negative consequences for health.

Based upon the ERI model, we can address well-being at work by helping employees to match their efforts to the expected rewards. We might support realistic goal setting and in this way diminish pressure and disappointments. Insight regarding

planned time versus the real-time may facilitate better (re)planning and setting more realistic goals (T06 again). Moreover, looking back at ones achievements could help employees to get a better feeling of their productivity (T04 again). Also aspects of gamification might provide employees small motivating rewards, for example, collecting points for staying focused (T03 again).

Effort-Recovery Model

The Effort-Recovery (E-R) model [26] can be characterized as a balance between effort and recovery (Figure 7). Here, Meijman et al describe that job demands and resources lead to negative strain during work. After work, home demands and resources lead to strain reactions. The individual can perform activities

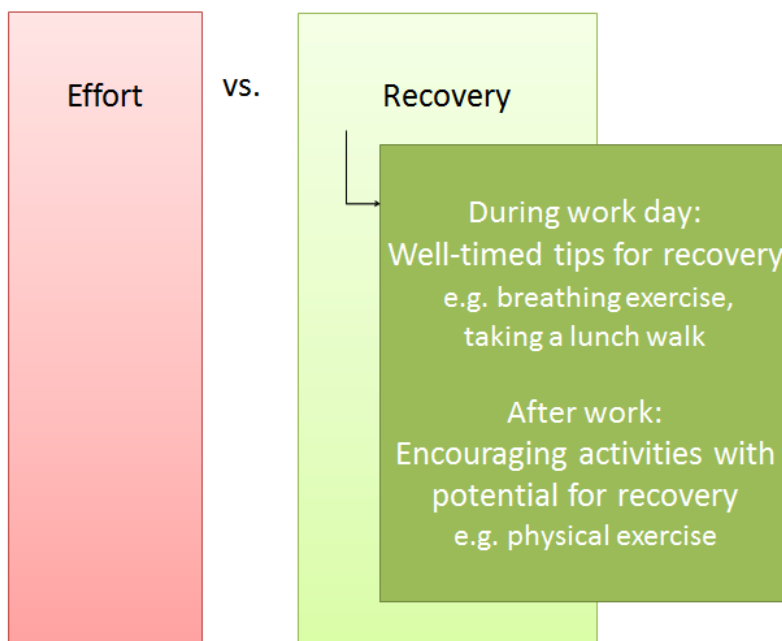
which can have a positive effect on recovery, leading to a particular psychological and energetic state at bedtime. By means of sleep, additional recovery can be gained and the individual starts the next workday with a certain psychological and energetic state. Failing to recover enough from strain can make the experience of work demands the next day higher and the experienced resources lower, leading to even more strain. This process can be a vicious circle. According to Demerouti and colleagues [27] lack of recovery can “result in an accumulative process developing into chronic load reactions or allostatic load according to McEwen’s (1998) allostatic load theory, such as chronically elevated heart rate, hypertension, chronic fatigue, and persistent sleep problems.”

Four important dimensions play a role in recovery [28]: psychological detachment, relaxation, mastery, and control. Psychological detachment from work can bring the psychophysical system back to its normal state. Relaxation causes decrease in physical activation. Controlling what activity to perform can improve esteem and efficacy. Mastery in performing challenging activities can cause improvement of skills, competence, and esteem.

In general, physical activity seems to be a good means for recovery [29]. Research showed that “in an adolescent population aerobic training does appear to provide some benefits with regard to psychological stress and well-being.” Hassmen et al [30] found that “individuals who exercised at least two to three times a week experienced significantly less depression, anger, cynical distrust, and stress than those exercising less frequently or not at all.”

Based upon the E-R model, we can address well-being at work by making employees aware that recovery during work and non-work time is very important. Interventions could be aimed at taking well-timed breaks during the work day (again T07): passive, as well as active breaks, could be suggested such as relaxation or taking a lunch walk. On the other side, an important aspect of improving well-being at work is also what someone does in his free time. We see that activities after work give potential for recovery. This model is interesting within the SWELL project, as it can combine the domains of well-being at work and at home. Interventions for more well-being could be aimed at better relaxation or detaching from work by means of a hobby (T08), for example. Addressing physical fitness could also be a good intervention (T09).

Figure 7. Effort-Recovery model [33], and possibilities for technological support.



Person-Environment Fit Model

The Person-Environment (P-E) fit model describes a fit between person and environment characteristics. A misfit between the person and his environment can lead to strain, with the danger of illness. There can be a misfit between personal abilities and environmental demands or between personal needs and environmental supplies [31,32]. Leiter and Maslach [33] developed the Areas of Worklife Scale (AWS) around this idea. They say that “the greater the perceived gap between the person and the job, the greater the likelihood of burn-out; conversely, the greater the consistency, the greater the likelihood of engagement with work.” The AWS has items on six aspects: workload, control, reward, community, fairness, and values.

Based upon the P-E fit model, we can address well-being at work by helping employees realize that performing tasks that fit their personal preference is very important for their well-being. Tasks that give energy and tasks that cost energy could be identified by providing an overview over tasks and energy levels over the day (again T06). In the future, the employee can then try to find work fitting his preferences more.

Addressing Causes of Work Stress

In this section we aimed to answer our *second research question*: which personal, work, and context conditions can lead to negative stress? We elaborated on several work stress models that describe how stress in working environments is caused. The different models all have a different focus and complement

each other. There are no specific personal, work, or context conditions that generally lead to stress. Work becomes stressful when high demands are combined with (1) insufficient resources; (2) little rewards; (3) little recovery; or (4) an environment that mismatches with personal characteristics. The most useful models for developing pervasive systems are the JD-R model and the E-R model, which we integrated into our framework (see [Figure 2](#), blue parts). The JD-R model describes

how (environmental) stressors can cause the experience of stress. The E-R model describes how the experience of stress can lead to long-term stress consequences. We presented several ideas on how technology can diminish demands, enhance resources, or help with recovery. An overview of identified technologies, the underlying models, and the associated claims are provided in [Table 1](#).

Table 1. Overview of identified technologies and associated claims.

ID	Possibility for technological support	Underlying theory	Claim
T01	Filtering emails	JD-R model	Diminishes demands by reducing information overload
T02	Personalized search	JD-R model	Diminishes demands by reducing information overload
T03	Gamification facilitating focus	JD-R and ERI models	Diminishes demands by diminishing fragmentation, enhances motivation by means of small rewards
T04	Achievements diary	JD-R and ERI models	Enhances resources or rewards by fostering motivation
T05	Department-wide feedback board for peer support	JD-R model	Enhances resources by means of social support
T06	Activity and workload overview for insight	JD-R, ERI, P-E Fit models	Provides insight in the balance between demands and resources, efforts and rewards, or person-environment fit
T07	E-coach for taking enough recovery breaks	JD-R and ERI models	Enhances resources or recovery by taking rest breaks
T08	E-coach for relaxation or detaching after work	E-R model	Enhances recovery by detaching
T09	E-coach addressing physical fitness	E-R model	Enhances recovery by releasing stress with physical activity

Note that all models describe work stress in qualitative terms. Our aim is to quantify several aspects by using sensors. For example, demands could be quantified by measuring work characteristics (eg, tasks and content worked on), personal resources could be quantified by measuring the associated acute stress (eg, physiological stress responses, mental effort), and recovery of the individual could be quantified by measuring long-term stress aspects (eg, sleep time, physical activity).

Results

Inferring Stress and its Context

After having described concepts related to well-being at work and causes of work stress, we now focus on assessing stress and its context. In current practices, most often questionnaires are being used [4,5]. However, this data collection has several shortcomings since data is self-reported, it can suffer from recall bias and subjectivity, and data is only collected once a year, for example. Using sensors overcomes these shortcomings because can be collected in an objective way, in real-time, and in an

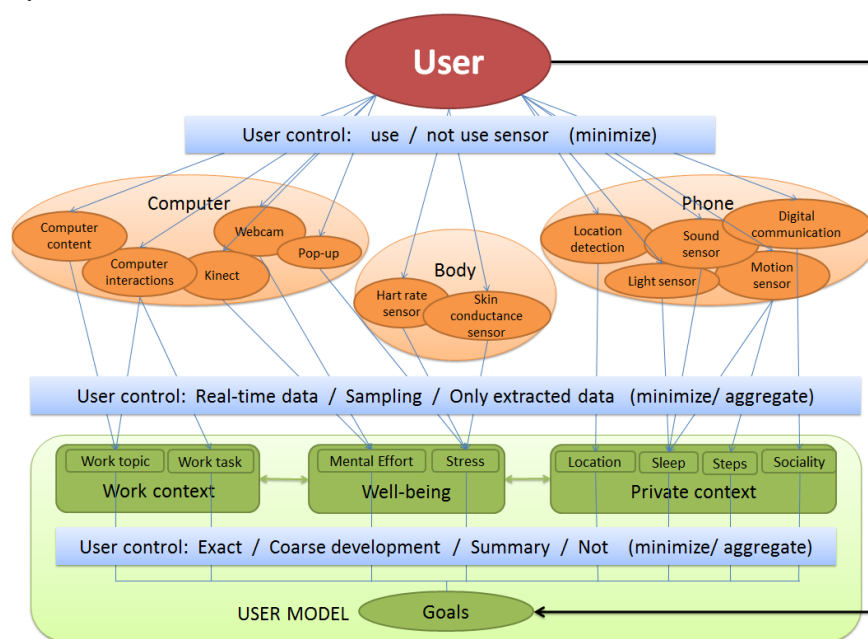
office context. Such data about stress, together with the context in which it appears can give insights that can more directly be acted upon by an employee.

Therefore, we now aim to answer our *third research question*: how can sensors be applied to automatically infer stress and the context in which it appears? We focus on (physically) unobtrusive, relatively cheap sensors that can easily be used in office environments. Following the situated cognitive engineering methodology [10], we integrate knowledge on technical possibilities. We also investigate user choices regarding data collection.

Technical Possibilities

In the previous sections, we identified several relevant concepts that the system could measure to provide data-driven coaching and context-aware support: work characteristics, acute stress, long-term stress and recovery, and aspects of engagement. An overview of the types of information and the sensors that can be used in the pervasive system to infer these aspects is presented in [Figure 8](#).

Figure 8. Overview of the system and its user's model, which holds information on the users work context and well-being.



Work Characteristics

First of all, we can measure work characteristics. The task (eg, write report, search information) someone is performing can be inferred from computer interaction data. We present algorithms for real-time task inference [34]. Moreover, which project someone is working on can be detected by analyzing the content of accessed documents and websites. We also present algorithms for topic detection [35]. The combination of tasks and topics can provide valuable information on the context in which stress appears. Based upon information on what someone was working on, we can also infer the amount of task switching, variation in tasks, and the work-rest-balance. Most informative are probably deviations from usual behavior of the specific user.

Acute Stress

With respect to inferring of stress from sensor data, Sharma and Gedeon [36] provide a compact survey. Often, body sensors are used to measure the physiological stress response directly, for example skin conductance [20] or heart rate [37]. More and more unobtrusive devices are entering the market, like measuring watches, so this might be a potentially interesting measure to use. As a critical side note, however, these devices may not be accurate enough to determine the more insightful variable of heart rate variability (HRV). Moreover, many external influences on physiology exist (eg, drinking coffee or physical activity). Asking the user himself for input on stress may be useful.

There is also potential in using outward characteristics, such as facial expressions, postures, or computer interactions as indicators for the user's mental state. Facial expressions are currently mainly used for inferring emotions, but facial expressions could also show cues to infer other mental states that might be more relevant in a working context. In earlier work, where working conditions were manipulated with stressors, we found that specific facial action units may be indicative of experienced mental effort [38]. Research by Dinges

et al [39] suggests that facial activity in mouth and eyebrow regions could be used to detect stress. Moreover, Craig and colleagues [40] looked at facial expressions while students worked with an online tutoring system. Association rule mining identified that frustration and confusion were associated with specific facial activity. Mental states are also being estimated from computer interaction data. Results by Vizer et al [41] indicate that stress can produce changes in typing patterns. Finally, Kapoor and Picard [42] describe work on recognizing interest in students by means of computer interactions and postures. Currently, we are also investigating how far we can infer stress or experienced mental effort from facial expressions, computer interactions, and postures [38]. Due to individual differences, general models will have to be adapted to the specific user for reliable estimates.

Long-Term Stress and Recovery

To measure the more long-term physical, cognitive, emotional, and behavioral responses, as well as recovery from stress (Figure 4), it may be interesting to include aspects of the private context, outside work. With mobile phone sensors, a rough estimate of sleep time can be provided by the combination of darkness, silence, and recharging of the phone battery [43]. Moreover, the amount of physical exercise, which is a good relief for stress, can be measured by means of sensors (eg, via mobile phone [43], band [44]). A very rough estimate of sociality can be made based upon the amount of phone communication. In addition, location information, such as that obtained by Global Positioning System (GPS) can be useful to enhance the timing of feedback.

Aspects of Engagement

Besides the aspects already included in Figure 8, we have some initial ideas to measure certain aspects of engagement (Figure 3) during work. Based on sensor data, energy (vs exhaustion) may be a concept that can be inferred by looking at someone's sitting posture, computer interactions, or facial expressions. This could give longitudinal information on the individual strain of an employee. Moreover, we could get a first indication of

involvement (vs cynicism) from textual analyses of email content. A state of absorption, like “flow”, might be recognizable based on computer behavior (eg, focus on one application), typical postures (eg, leaning forward, sitting still), or facial expressions. The concept of efficacy (vs inefficacy), however, might probably best be assessed with questions to the knowledge worker. For example, when the longitudinal data shows little energy, the employee might want to fill in some questions on feelings about his efficacy, to be able to give an early warning and provide help in time.

User Choices Regarding Data Collection

To estimate the identified states, various sensors are necessary (Figure 8). Applying sensor technology to monitor personal activities most probably raises concerns related to privacy. Therefore, we performed a user study to investigate what the general perception of using various types of information and sensors is.

Nine participants tested a sensing and e-coaching prototype for two weeks. In a questionnaire, they were then asked to set the configurations for data collection to be used for their own insight and for improving the e-coaching app. We found that some

sensors are, in general, perceived as more privacy sensitive (eg, webcam, sound sensor, computer content, and digital communication), others as less privacy sensitive (eg, motion sensors, heart rate, and skin conductance). However, preferences regarding data collection are diverse and depend on the goal for which they want to use the system and the trade-offs they make for themselves regarding privacy. The system should therefore be configurable, such that the user can (1) decide which sensors to use; (2) decide in which detail information is extracted from the sensors; and (3) decide to store information in exact or only aggregated form (Figure 8). Users may want to experiment with how much functionality they can gain with disclosing certain types of data.

Using Sensing and Reasoning

In this section we aimed to answer our *third research question*: how can sensors be applied to automatically infer stress and the context in which it appears? We provide an overview of all possibilities for real-time measurements in Table 2. The user study showed that user’s are only interested to collect data that is necessary for supporting their specific goal, so the system should be configurable.

Table 2. Overview of the three aspects in the stress chain (from left to right). For each aspect, several indicative factors can be measured and different technology-based interventions can be provided .

Problem	Stressors: “My environment poses high demands”	Experience of stress: “I feel I cannot handle all demands”	Stress consequences: “I experience stress symptoms”
Measure	Work characteristics	Acute stress	Long-term stress and recovery
Concept and how to infer	Tasks and content worked on: computer activity	Physiological stress responses: skin conductance and heart rate (variability) from measuring watch	Sleep time: mobile phone sensing, using the combination of silence, darkness and recharging of the phone battery
	Variation in tasks, task switching, work-rest balance: computer activity (also calendar)	Mental effort: infer from facial expressions, posture, computer activity	Physical activity: accelerometer, GPS
Intervention	Address stressors (primary prevention)	Enhance coping (secondary prevention)	Enhance recovery (tertiary prevention)
Example technology	Providing work support: filtering emails (T01) and personalized search (T02)	Helping to improve coping abilities: gamification for focus (T03) and achievements diary (T04)	Supporting work-rest balance: e-coach for recovery breaks (T07)
	Providing insight in the sources of stress: activity and workload overview (T06)	Fostering support by colleagues: department-wide feedback for peer support (T05)	Helping to improve recovery after work: e-coach for detaching after work (T08) and e-coach for physical fitness (T09)

Core Functions of the System

The identified core functions of the system, together with the associated claims are shown in Textbox 1.

Textbox 1. Core function of the system and the associated claims.

<p>Core functions and claims</p> <ul style="list-style-type: none"> • F1.1: The SWELL system shall infer relevant information from unobtrusive sensors to provide real-time objective measurements. • Claim: Sensors provide real-time information on stress and the context in which it appears, which the employee can directly act upon. • F1.2: The SWELL system shall only collect data that is necessary to support the user’s goal. • Claim: User’s are only willing to collect information relevant to their personal goal (due to privacy).
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Improving Well-Being at Work

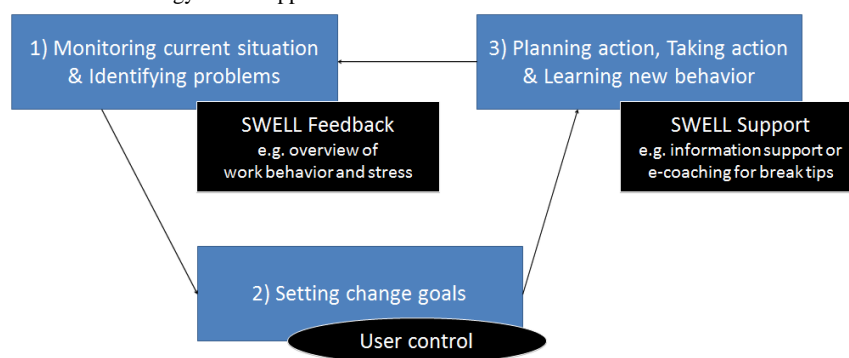
We have described concepts related to well-being at work, causes that play a role in the experience of stress, and means to assess relevant aspects with sensors. As a next step we aim to find an answer to our *fourth research question*: which interventions can be provided by means of pervasive technology to help a knowledge worker improve his well-being at work? We describe intervention and behavioral change theory.

Intervention Theory

There are different possibilities to address well-being at work and diminish stress. First of all, one can distinguish prevention approaches aimed at *different stages* in the stress chain (Figure 2; upper green parts) [45]. Primary prevention is aimed at the stressors, such as changing the work or work situation to prevent risks. Secondary prevention is aimed at the (short-term) stress reactions, including helping employees to develop good coping strategies to handle stress risks and their consequences. Tertiary prevention is aimed at addressing (long-term) stress consequences, such as promoting a balanced life style to recover.

Moreover, interventions can target different areas (Figure 2; lower green parts). Based on the literature, we identified four areas: the work itself, personal factors, the working conditions, and private circumstances [11]. To support the employee to reach more well-being, the intervention should be targeted at the problem area. First of all, one could change the work itself, improve work planning, or get a more focused work-flow. Secondly, the intervention can target personal factors. One could enhance self-knowledge (eg, what causes my stress), or improve active coping. Fourth, the intervention can target working conditions. One can address organizational aspects, social aspects (eg, support from colleagues), or the work-rest balance. Finally, the intervention can address private circumstances. One can address social aspects (eg, support from friends), or recovery.

Figure 9. Behavior change and how technology could support it.



Technology-Based Interventions

In this section we aimed to answer our *fourth research question*: which interventions can be provided by means of pervasive technology to help a knowledge worker improve his well-being at work? The system can address the stressor, improving coping, and enhancing recovery in the stress chain (Figure 2). In addition, we address the work itself, personal factors, working conditions, or private aspects.

Finally, we can distinguish *various types* of stress reducing interventions [46]. The most suitable type of intervention may depend on the employee's preference: cognitive-behavioral (eg, coping skills and being more assertive), creativity, exercise, food, journaling, relaxation, social, or time-management and organizational. Note that an intervention can be social and creative at the same time.

Behavioral Change

Until now, we explained what aspects interventions may address improvement in well-being at work. However, changing the behavior of an individual may be difficult, especially in the context of (bad) habits. Therefore, we now consider behavioral change theory [47].

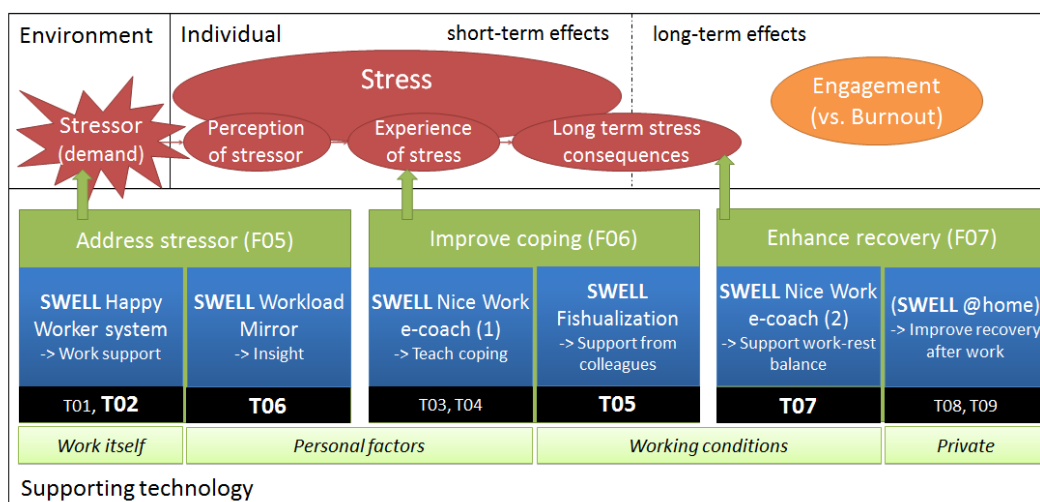
People may know that particular behavior may be good for them, but still they may sustain their old behavior. Fogg [48] identified three main hurdles preventing humans to perform the right or healthy behavior: lack of ability, lack of motivation, and lack of a well-timed trigger. The interventions should be designed in a way that they address these hurdles. More specific relevant determinants to address are risk awareness, motivation, social influences, skills, self-efficacy, supportive environment, attention, and behavioral awareness.

For someone to successfully change his behavior, the following three main aspects should be supported in the system (Figure 9): (1) monitoring current situation and identifying problems, (2) setting change goals and planning action, and (3) taking action and learning new behavior.

We identified the most appropriate behavior change techniques [49] for the pervasive system, based on the list presented by de Korte et al [50], and they include feedback, self-monitoring, contextual risk communication, and reminders or cues to action.

Finally, the pervasive system should also support the employee throughout the behavioral change chain, and specifically address barriers towards changing behavior. We show how the specific supporting technologies identified in the section on work stress models can be placed into this framework (Figure 10). Further technology-supported interventions can be designed based upon our framework, and some ideas are included in Figure 2 (black parts).

Figure 10. SWELL system functionality in our general framework.



Core Functions of the System

The identified core functions of the system based upon this part of the theoretical framework and the associated claims are shown in [Textbox 2](#).

Textbox 2. Identified core functions of the system and the associated claims.

<p>Core functions and claims</p> <ul style="list-style-type: none"> F2: The SWELL system shall address three different causes of stress: address the stressor (F2.1), coping (F2.2), and recovery (F2.3). Claim: By providing different types of interventions, different causes of stress can be addressed with the system, making it usable in more situations. F3: The SWELL system shall foster behavioral change by helping to monitor the current situation and identifying problems (F3.1), letting the user set personal goals and enable specific functionality (F3.2), and helping to learn new behavior by fostering the ability, motivation or trigger to take action (F3.3). Claim: By using behavior change theory the system will be more effective in actually bringing about behavioral change regarding well-being at work.

Envisioned System and Evaluation of Prototypes

The formulated core functions for the system are summarized here. The envisioned pervasive SWELL system supports the knowledge worker to improve well-being at work (OBJ). The SWELL system could collect information about aspects of engagement, work characteristics, acute stress, and long-term stress and recovery (F1). The SWELL system shall infer relevant information from unobtrusive sensors to provide real-time objective measurements (F1.1). The system only collects data that is necessary to support the user’s goal (F1.2). With respect to behavioral change, the user will start with getting insight in his situation and identifying problems that he wants to address (F3.1). Based on these insights the user can then set personal

goals and enable specific desired SWELL functionality (F3.2). In case the environment poses high demands, the user may decide to address some of his stressors (F2.1). In case the user feels overwhelmed by demands placed upon him, he may decide to address some of his coping abilities (F2.2). In case the employee experiences stress symptoms, he may decide to enhance recovery (F2.3). Behavior change techniques are used to foster motivation, ability and triggers to take action (F3.3).

We built the first prototypes of different SWELL functionality and show how the prototypes fall into our framework in [Figure 10](#). All of the systems are aimed at improving well-being at work and most prototypes make use of sensor information ([Textbox 3](#)).

Textbox 3. The different SWELL functionalities.

SWELL prototype systems

- The SWELL Workload Mirror is an implementation of T06 “activity and workload overview” and provides insights regarding stress and the context in which it appears. It tries to tackle stress in the beginning of the stress chain (eg, what causes stress?) with the aim of helping employees to address the stressor itself. Based on these insights, the user might want to use one of the other SWELL systems for support.
- The SWELL HappyWorker system is an implementation of T02 “personalized search” and helps employees find relevant information. It tries to tackle stress in the beginning of the stress chain (diminishing demands) with the aim of addressing the stressor itself.
- The SWELL Fishualization is an implementation of T05 “department-wide feedback for peer support” and is aimed at fostering awareness and communication about stress at work. It tries to tackle stress in the middle of the stress chain, helping employees to cope with stress.
- The SWELL NiceWork app is an implementation of T07 “e-coach for recovery breaks” and provides interventions aimed at improving coping, and enhancing recovery. It tries to tackle stress in the middle and end of the stress chain.

We now describe two of the prototypes, the SWELL Fishualization and SWELL NiceWork apps, in more detail, together with their first small-scale user studies.

Fostering Colleague Support - SWELL Fishualization

The SWELL Fishualization (for details we refer to the original work presented in [51] and [52]) is aimed at enabling employees to gain insights into their working habits and encourage social interaction about healthy working, in order to improve well-being at work (T05). It provides a feedback screen in the form of a digital fish tank (Figure 11), which is placed at a central location in the office. The primary sensor is currently a key-logging software that is installed on the user's computers. Other sensors could also be coupled to add information on, heart rate, dominant facial expression, or e-mail sentiments. Each fish in the Fishualization represents an individual employee. The speed of a fish is determined by how fast the corresponding employee is interacting with their computer (number of clicks and keystrokes) and the number of changes in direction represents the number of task or context switches. The y position of each fish currently represents the (self-reported) energy level of the corresponding employee. Plants at the bottom of the screen represent performed tasks, for example writing e-mails, editing documents, browsing, or preparing presentations. The more people worked on a tasks the larger the plant.

SWELL Fishualization tries to tackle stress in the middle of the stress chain by helping employees to cope with stress (secondary prevention). It is aimed at enhancing support from colleagues, thus addressing the working conditions. Its main basis is the JD-R model (providing additional resources). It measures work characteristics and assesses the energy dimension of engagement by means of user input. With respect to behavioral change it helps with monitoring the current situation. Moreover, it fosters the motivation to take action by means of a playful approach and social influences.

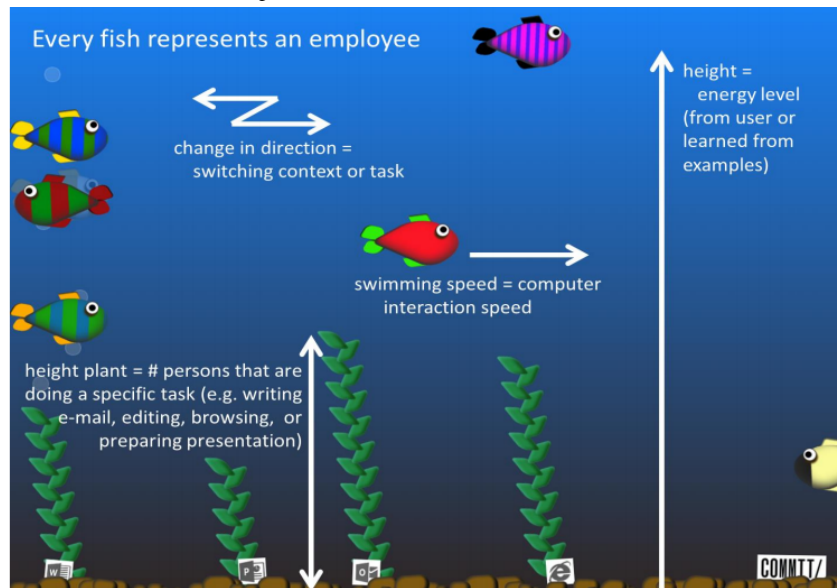
We evaluated the prototype in a real-world environment. The Fishualization trial at the Media and Network Services group at TNO (Dutch institute for applied scientific research) ran for about 2.5 months (March to May 2014). The Fishualization screen (a large computer display) was placed in the coffee corner. A subset of 10 employees volunteered to couple their computer interactions and subjective input of their energy level

to one of the fish. In order to measure the effects of the deployment of the Fishualization, all employees who use the coffee corner were asked to fill in pre- and post-questionnaires on personal awareness of working patterns and well-being at work, group awareness, and interactions with colleagues. Furthermore, camera and microphone recordings were used to measure activity at the coffee corner. To ensure privacy, only the number of detected faces, the amount of video motion, and the average sound level were deduced and stored (no video or sound was stored). This data collection started 3 weeks before the Fishualization was turned on and continued during the trial to compare activity in the coffee corner before and after deployment of the Fishualization.

In all, 30 employees filled in the pre-questionnaire and 14 employees filled in the post-questionnaire. The subset of respondents did not differ significantly in their current level of well-being or how content they were about their well-being. We used independent samples *t* tests to compare the pre- and post-test results. A significant effect on the item “I am aware of typical patterns in working behavior throughout the day or week (eg, mailbox on Monday morning, project work after lunch...)” was found ($P=0.004$). Awareness of working patterns was higher in the post-test than in the pre-test with mean (SDs) of 4.79 (1.626) and 3.27 (1.530), respectively (scale 1 “not” to 7 “very much”). Moreover, we found a significant effect on the item “I know how I can change my working behavior to gain a better level of well-being (eg, becoming more productive, reducing stress...)” ($P=0.005$). The mean (SD) score in the post-test 5.14 (1.231) was higher than in the pre-test 3.9 (1.322).

We conclude that the Fishualization caused more personal awareness on working behavior and its relation with well-being among employees. However, we did not find significant effects on items related to group awareness and interactions with colleagues. In the further development of the Fishualization we should focus on fostering social interaction among colleagues more (eg, by adding new functionality), as this may be a good buffer against stress. Moreover, most participants were enthusiastic about the Fishualization: a playful manner of feedback turned out to be engaging. Finally, we used sensor technology to quantify activity in the coffee corner, which shows the potential of new technology for experimental evaluation.

Figure 11. Screen image of the SWELL Fishualization placed in the coffee corner.



Providing Tips - SWELL NiceWork E-Coach

The SWELL NiceWork app (for details we refer to the original work presented in [53]) is designed to provide coaching for short recovery breaks (T07). The app provides simple tips, three times a day, aimed at promoting well-being at work (Figure 12). Various scientific articles, websites, and magazines on well-being at work were reviewed to collect appropriate tips which resulted in a list of 54 tips. Each tip does not take more than three minutes, and no special materials or specific locations are required. The recommended well-being tips are cognitive-behavioral, creative, physical exercises, food, journaling, relaxing, social, and time-management.

We found that different people had different preferences for tips (pilot study, in which 26 employees rated their preferences for the 54 tips). Therefore, a recommendation approach was chosen to adapt which tips are given to the specific user. After each recommendation, the user can indicate whether he performed the tip and the system learns over time to give better tips.

The SWELL NiceWork e-coach is mainly aimed at supporting the work-rest balance. The app also provides tips aimed at preventing the experience of stress (secondary prevention), as tips on recovery from coping with high demands (tertiary prevention). The tips focus on personal factors or the working context. Its main basis is the E-R model (focusing on recovery). It does not yet measure anything. The system does assess whether the user has followed-up a tip by means of user input. With respect to behavioral change it helps with taking action and learning new behavior by providing triggers and suggestions.

To evaluate the NiceWork app with users, 35 employees tested the e-coach for 2 weeks. The first hypothesis was that knowledge workers have a positive attitude towards the e-coach. This hypothesis was confirmed in the user study. The number of followed-up tips was high (2 out of 3 per day) and most participants agreed that it is pleasant to receive automatic notifications. The study also showed that three recommendations per day seemed a right amount of suggestions. Moreover, indicating whether a tip was followed-up and asking for a short motivation when a tip was rejected turned out to be a well-designed method for providing feedback. Our second hypothesis was that tailored recommendations are followed-up more often compared to randomized suggestions. We did not find strong evidence for this hypothesis. Results show that our recommendation method, which provides tailored suggestions, did not substantially increase the number of tips that were performed compared to a method that provided randomized suggestions.

Furthermore, results show that of all tips that were not followed-up, only a few were rejected because it was disliked (12.8%, 45/350). Instead, tips were mostly rejected because the moment of recommendation was somehow inappropriate including wrong timing (46.0%, 161/350), not relevant (14.8%, 52/350), or not at work (14.0%, 49/350). This finding suggests that future e-coaches may increase their effectiveness by recommending tips at appropriate times. Using sensor information to ensure that tips are suggested just-in-time was the most important personalization method that needed to be further explored [54]. Moreover, we demonstrated that technology can be used to investigate the effects of an intervention: via the app we directly investigated how many interventions were said to be followed-up and we directly asked for reasons for not following up a suggestion.

Figure 12. The SWELL NiceWork app.

The Evaluation of Prototypes

Here, we presented the general SWELL functionality and described two prototypes and their evaluation. Within the SWELL project, however, other prototypes were developed and evaluated [55].

In general we can say that we made working implementations of some pervasive technologies for improving well-being at work. Our evaluation until now was mainly aimed at user experience and testing underlying technologies. The evaluation yielded several additional requirements for our system. Moreover, we showed how technology can be used to investigate the effects of an intervention. In further research we should also

evaluate whether the prototypes have the expected positive effect on employee's well-being at work. From our small scale pilot studies we got some first insights, but ideally the systems are evaluated with in a much larger field test.

Discussion

Principal Findings

By means of situated cognitive engineering [10], we combined stress and intervention theory with knowledge of technological possibilities and input by users to design a pervasive system that helps knowledge workers to improve well-being at work. The questions answered in this paper are discussed in [Textbox 4](#).

Textbox 4. The questions addressed in this paper and their relevant discussions.

Questions

1. Which concepts are relevant with respect to well-being at work? We found that the relationship that people have with their jobs can be described as a continuum between engagement and burn-out [12]. Engagement is characterized by energy, involvement, and efficacy or absorption. Biology describes more short term effects of stress [3]. A stressor causes a particular perception of the stressor in the individual. This can lead to acute physiological stress responses and, in the long run (due to lack of recovery) long-term physical, cognitive, emotional, and behavioral stress consequences.
2. Which person, work, and context conditions can lead to negative stress? There are no specific personal, work, or context conditions that generally lead to stress. Work becomes stressful when high demands are combined with insufficient resources, little rewards, little recovery, or an environment that mismatches with personal characteristics. The most useful models for developing technology based interventions are the JD-R model [21] and the E-R model [26]. We presented several ideas to diminish demands, enhance resources, or help with recovery.
3. How can sensors be applied to automatically infer stress and the context in which it appears? We can use technology to sense work characteristics (eg, tasks and topics worked on), measure acute physiological stress responses in the body (eg, HRV), or assess cognitive, emotional and behavioral effects of stress (eg, sleep duration). The user study showed that users are only interested to collect data that is necessary for supporting their specific goal, so the system should be configurable.
4. Which interventions can be provided by means of pervasive technology to help a knowledge worker improve his well-being at work? In general, three stress prevention approaches are distinguished, aimed at different stages in the stress chain [45]. Technology can thus either address the stressor (eg, by providing work support), address short-term stress reactions (eg, by enhancing coping), or address long-term stress consequences (eg, helping to improve recovery). Suitable behavioral change techniques [49] should be used to address the motivation, ability, or trigger to take action (eg, self-monitoring and reminders to action).

We presented the resulting general framework in which we related several relevant theories. We related work on engagement and burn-out [12] to work on stress [3], and described how relevant aspects can be quantified by means of sensors. We also outlined underlying causes of work stress

[21,26], and described how interventions can address these [45], in particular by means of new technologies utilizing behavioral change theory [49]. This framework can be used by other researchers to design pervasive systems that address well-being at work.

Finally, we described the envisioned SWELL system and core functionality that was identified. We also presented two built prototypes: the SWELL Fishualization [51,52] that provides department wide feedback for peer support, designed to improve coping, and the SWELL NiceWork e-coach [53] that provides well-being tips, designed to improve coping or recovery. All in all, we demonstrated the (technological) feasibility of our ideas. First evaluations with users were positive and provided further insights to refine the systems.

Limitations

The biggest challenge in developing our comprehensive and practical framework was the vast amount of available concepts and models regarding well-being at work. We consulted experts in the field and had to make choices on what concepts and theories to include. Our selection may reflect our specific scoping, such as addressing work stress in the population of knowledge workers. We focused on providing a general and simple overview, combining different areas of research.

Another challenge in this respect was relating concepts of different fields to each other. These concepts differ in their level of abstraction: organizational psychology provides the most high-level terms, including the relation between resources versus demands or recovery [12]. Biological theories provide more low-level terms, such as physiological stress responses in the body [3]. Our aim was to make several of these aspects quantifiable. This means translating these concepts into even more low-level terms, such as a specific sensor, the data to be collected, and the interpretation of this data.

Besides the high-level versus low-level continuum, there is also a temporal continuum from short-term stress [3] to developing a burn-out [12]. In traditional approaches with questionnaires, mainly long-term aspects are assessed. Sensing, however, enables real-time measurements in real-world work settings. We aimed to translate relevant aspects identified based on theories into variables that are measurable at the workplace.

The resulting general and pragmatic framework provides a structure to develop pervasive technology for improving

well-being at work. We noticed that far more diverse technology-based interventions can be developed than initially assumed. The theoretical foundation gave many different pointers of how well-being at work can be improved from coaching during work, over fostering social support, to addressing recovery after work. Besides the ideas and prototypes presented here, many more (technological) solutions can be developed based upon this general framework (eg, teaching coping in an online course, building a social network for peer support, enhancing recovery by letting people play a computer game).

We built prototypes of some pervasive technologies for improving well-being at work [51-53]. Our evaluation until now was mainly aimed at user experience and testing underlying technologies. Further research should evaluate whether the prototypes have the expected positive effect on employee's well-being at work. From our small scale pilot studies we got some first insights, but ideally the systems are evaluated with in a much larger field test.

As a final note, we need to be cautious to put responsibility for managing work stress at the individual level. Certainly the company and management also play a role. Therefore, an intervention provided one-on-one at an individual by means of a pervasive system is ideally part of a larger intervention program. In case many employees struggle with similar problems, a department wide intervention may be more effective. Furthermore, specific problems at work may not be solvable by the employee himself. In this case, the management or organization may need to be approached.

Reflection

We think a pervasive system aimed at an individual's abilities to cope with stress and improve well-being at work poses many new opportunities. A system using real-time during work can provide much valuable information on work stress. Moreover, employees can be empowered to self-manage their well-being at work by means of tailored interventions. Throughout our work we encountered several challenges and opportunities for further research in several categories (Textbox 5).

Textbox 5. Challenges and opportunities for further research.

Opportunities and challenges

1. Multi-disciplinary, theory and data-driven research, and development. New technology brings new possibilities. The now very abstract models can be more refined to include directly measurable concepts and new types of support. New technology can also be used to directly evaluate the success of an intervention. Sensors can be used to investigate how far interventions are indeed followed-up (eg, whether users take a break or become physically active after a suggestion by an e-coach). Moreover, the effects of an intervention can be measured (eg, whether provided information support indeed decreased mental effort and stress). Technical experts and social scientists should aim to work together. It is therefore necessary that the experts understand each others' domains well, which is challenging.
2. Interpreting personal sensor data. Sensor data is relatively easy to collect, the challenge is making sense of this data. We should investigate which behavior is indicative of stress during work and how these can best be captured by means of unobtrusive sensors. People differ in their (work) behavior, so there is a need to build personalized models This brings methodological challenges, such as how to instantiate a model for a new user.
3. Relation between measurable aspects and burn-out. In future work, the relation between subjective experience based upon our own feelings and objective measures based on objective data should be investigated. Can objective measurements help us with detecting stress? Ideally, a system would be able to give a warning in case it predicts that the current behavioral pattern will cause long-term problems. Therefore, research should be done on how longitudinal patterns in sensor data relate to long-term stress consequences and burn-out.
4. Combining strengths of human and technology. Ideally, the strengths of technology (eg, being objective or persistent) and the strengths of a human (eg, being good in interpretation) should be combined. The role of the system and the user should be clear. The most suitable manner for pervasive technology to interact with an employee is a challenging question for human-computer interaction research. Issues of control are important. The system needs to interact in a way that provides support, while not irritating the user.
5. Privacy. The success of pervasive systems collecting context data depends on the acceptance by users. A system that collects personal data raises many privacy questions. Therefore, privacy should be integral part of the design process (eg, doing a Privacy Impact Assessment or implementing Privacy by Design).
6. Ethics. Measuring and trying to change the behavior of individuals poses all kinds of ethical questions. Is it acceptable to monitor and change the behavior of an employee? It is difficult to predict how such new pervasive e-coaching systems will be perceived and used (or even misused) when applied in real-world work settings.

Conclusions

In this work we developed a theoretical framework for the design of pervasive well-being technology. The framework is based on several relevant work stress and intervention theories,

as well as possibilities that new technologies as sensors and mobile phones provide. This framework can be used to systematically develop theory-based technology supported interventions to address work stress, as we demonstrated in our SWELL case study.

Acknowledgments

This publication was supported by the Dutch national program COMMIT (project P7 SWELL).

Conflicts of Interest

None declared.

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Abbreviations

AWS: Areas of Worklife Scale

e-coach: electronic coach

E-R model: Effort-Recovery model

ERI: Effort-Reward Imbalance model

GPS: Global Positioning System

JD-R model: Job Demands-Resources model

P-E fit model: Person-Environment fit model

SWELL: Smart Reasoning for Well-being at Home and at Work project

Edited by G Eysenbach; submitted 13.11.15; peer-reviewed by L Andersen, M Mulvenna; comments to author 10.12.15; revised version received 04.04.16; accepted 11.04.16; published 05.07.16.

Please cite as:

Koldijk S, Kraaij W, Neerincx MA

Deriving Requirements for Pervasive Well-Being Technology From Work Stress and Intervention Theory: Framework and Case Study
JMIR Mhealth Uhealth 2016;4(3):e79

URL: <http://mhealth.jmir.org/2016/3/e79/>

doi: [10.2196/mhealth.5341](https://doi.org/10.2196/mhealth.5341)

PMID: [27380749](https://pubmed.ncbi.nlm.nih.gov/27380749/)

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Original Paper

Physical Activity, Mind Wandering, Affect, and Sleep: An Ecological Momentary Assessment

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Abstract

Background: A considerable portion of daily thought is spent in mind wandering. This behavior has been related to positive (eg, future planning, problem solving) and negative (eg, unhappiness, impaired cognitive performance) outcomes.

Objective: Based on previous research suggesting future-oriented (ie, prospective) mind wandering may support autobiographical planning and self-regulation, this study examined associations between hourly mind wandering and moderate-to-vigorous physical activity (MVPA), and the impact of affect and daily sleep on these relations.

Methods: College-aged adults (N=33) participated in a mobile phone-delivered ecological momentary assessment study for 1 week. Sixteen hourly prompts assessing mind wandering and affect were delivered daily via participants' mobile phones. Perceived sleep quality and duration was assessed during the first prompt each day, and participants wore an ActiGraph accelerometer during waking hours throughout the study week.

Results: Study findings suggest present-moment mind wandering was positively associated with future MVPA ($P=.03$), and this relationship was moderated by affective state ($P=.04$). Moreover, excessive sleep the previous evening was related to less MVPA across the following day ($P=.007$). Further, mind wandering was positively related to activity only among those who did not oversleep ($P=.007$).

Conclusions: Together, these results have implications for multiple health behavior interventions targeting physical activity, affect, and sleep. Researchers may also build on this work by studying these relationships in the context of other important behaviors and psychosocial factors (eg, tobacco use, depression, loneliness).

(*JMIR Mhealth Uhealth* 2016;4(3):e104) doi:[10.2196/mhealth.5855](https://doi.org/10.2196/mhealth.5855)

KEYWORDS

physical activity; mHealth; attention; sleep; affect

Introduction

Approximately half of waking thought is unrelated to events occurring in the moment [1]. Despite being a predominant form of thought, researchers are only beginning to understand the role of task-independent thought (ie, mind wandering) in daily

functioning. Results from numerous studies suggest thought unrelated to the task at hand is often prospective in nature (ie, focused on the future), which may play an important role in regulating and managing future behavior [2,3]. Moreover, it has been suggested that our ability for future-oriented mind

wandering supports patience over impulsivity [4], and may be crucial for creative thought and problem solving [5,6].

Despite the apparent value of task-independent thought, some have cautioned that a number of factors related to the individual or to the tasks in which they are engaged may modulate the nature of the effect of mind wandering on daily functioning and health [6]. For instance, Baird and colleagues [2] noted that during times of low affect, high stress, or during complex tasks, task-independent thoughts tended to shift toward past experiences. Indeed, a number of studies have found this type of retrospective mind wandering is often ruminative in nature and associated with a variety of deleterious outcomes ranging from impaired cognitive performance (eg, reduced working memory function, reading comprehension) [7-10] to accelerated cellular aging [11]. Many of these negative findings have been noted in studies conducted in and out of the research laboratory. For instance, in a seminal study, Killingsworth and Gilbert [1] utilized mobile phone-based ecological momentary assessment (EMA) techniques [12] to examine the relationship between mind wandering and affect throughout the day in a sample of 2250 adults. The researchers reported individuals were less happy during periods when their minds wandered, and this occurred regardless of the activity in which the individual was currently engaged. Other investigators have drawn similar connections, reporting associations between negative affect and increased mind wandering during reading, and an increased likelihood for retrospective thought [13,14]. Moreover, mind wandering appears to be both a cause and consequence of negative affect [13-15].

Because affective valence and other state-like psychological factors appear to influence the tendency for one's wandering thoughts to be prospective or retrospective in nature, mind wandering may be of particular importance in the daily self-regulation of a number of complex health behaviors, including physical activity. Regular participation in moderate-to-vigorous physical activity (MVPA) is vital to health across the life span, and failure to engage in sufficient levels of the behavior has been related to increased risk for myriad disease states, including cardiovascular disease, type 2 diabetes, several types of cancer, and osteoporosis among others [16]. Still, only half of adults in the United States participate in levels of physical activity sufficient to achieve health benefits [17]. This may be due, in part, to its nature as a challenging and complex behavior that requires considerable self-regulatory skill to maintain, particularly in the face of modern technologies and environments that often incentivize inactivity [18,19]. Although limited research has examined factors impacting an individual's activity behavior at the daily or hourly level, it may be expected that the nature of one's mind wandering may impact one's ability to plan for, and engage in, this important behavior.

A number of lifestyle factors likely play an important role in the ongoing relationship between mind wandering and physical activity, and one's affective state and sleep habits may be expected to be particularly important. As described previously, affect has a demonstrable impact on the nature of mind wandering, and one's sleep habits are closely tied with both physical activity and affect. Indeed, poor sleep habits have been associated with a number of correlates of retrospective mind

wandering, such as impaired working memory function [20,21] and negative affect [22-24]. Moreover, several studies have demonstrated that these habits contribute to lower levels of physical activity [25-27]. If one's mind wandering is indeed associated with their participation in physical activity, sleep may be an important moderator of this relationship. More specifically, healthy sleep may predispose an individual to prospective mind wandering, in turn supporting participation in physical activity.

Researchers have not yet examined the relationship between mind wandering and MVPA, or the influence of potentially potent correlates such as affect and sleep. Thus, the purpose of this exploratory study is to extend previous research related to mind wandering by examining these relations at the hourly and daily level in a sample of college students. Because previous research suggests mind wandering is most often biased toward the future [13], we hypothesized that hourly mind wandering would indeed facilitate higher levels of accelerometer-measured MVPA in subsequent hours. Next, because affect has been demonstrated to modulate the tendency for mind wandering to focus on the future rather than past [2], we hypothesized that a positive affective state would also be associated with increased participation in subsequent MVPA. Importantly, we also hypothesized that this state would moderate the relationship between mind wandering and physical activity whereby during hours of positive affect, mind wandering would be related to increased physical activity. Conversely, during times of low affect, mind wandering would be related to less activity. Finally, given the prevalence of sleep disturbances in this population [28], and the documented associations between sleep, affect, and cognitive functioning, we hypothesized that better sleep (assessed via daily self-reported sleep quality and duration) would be related to greater MVPA.

Methods

Participants

A convenience sample of adults aged 18 to 25 years (N=36) were recruited via posted flyers and Web-based advertisement from a large Midwestern university to participate in a study investigating the relationships between mind wandering, affect regulation, and MVPA. Eligible participants were adults 18 to 25 years of age, able to communicate in English, able to walk independently, and owners of an Android or iPhone mobile phone with access to text messaging and mobile Internet.

Procedures

The Ecological Momentary Assessment System

Mobile phone-delivered EMAs have increased in popularity in recent years, and for good reason. The devices are nearly ubiquitous (85% of young adults in the United States owned a mobile phone in 2014 [29]), and are carried with the individual at all times. Accordingly, researchers are able to collect and screen self-reported information from individuals as the behavior occurs and in the context in which it occurs [12,30]. This offers a unique opportunity to behavioral researchers, allowing for the examination of important psychological constructs and their interactions with an individual's behavior at the daily or hourly

level. Additionally, because data may be collected as a behavior occurs, EMA methods have the potential to decrease recall bias [12].

Importantly, recent advances in mobile phone and mobile Internet technologies have allowed for the development of EMA apps that are cross-platform compatible (ie, able to be used regardless of mobile operating system), automated, highly individualized, and easily scalable. The app used in this study was developed by one member of the research team (JF) using Perl, hypertext markup language, cascading style sheets, and JavaScript, and was integrated with the commercial text messaging service Twilio (Twilio, San Francisco, CA, USA) to provide automated text message prompts. These prompts were delivered at 10 minutes to the hour between 6:50 am and 9:50 pm to accommodate student class schedules. Each prompt contained a link to a survey tailored to the individual and the time of day (eg, sleep questions were delivered during the individual's first answered survey of the day). Each survey took between 30 seconds and 1 minute to complete, and assessed a number of aspects of attention, including mind wandering, affect, and sleep. The Institutional Review Board of the University of Illinois approved all study procedures.

Study Progression

Interested individuals contacted the research staff via telephone and were screened for eligibility. Those who were eligible were

provided an institutional review board-approved informed consent and completed a series of online questionnaires and demographic items. Following questionnaire completion, participants attended a brief orientation session. During this time, trained research staff introduced each participant to the mobile phone EMA system, and participants were familiarized with each question presented during the daily mobile phone-based surveys. Following this orientation appointment, participants began receiving prompts via text message to complete study assessments, and each participant wore an ActiGraph accelerometer during waking hours on each day of the study period. For this early study, a 7-day study period was selected to align with common accelerometer protocols concerned with capturing adults' usual physical activity [31].

Measures

Demographics

Demographic information was collected via telephone. Items included gender, race, ethnicity, and date of birth (used to calculate age at the time of screening).

Mind Wandering

Mind wandering was assessed each hour using an item adapted from Killingsworth and Gilbert [1]. This item asked, "Were you thinking about something other than what you were currently doing?" Response options were "yes" and "no" (see Figure 1, panel 1).

Figure 1. Panel 1 demonstrates the survey item assessing mind wandering; panel 2 demonstrates the survey item assessing affect; and panel 3 demonstrates the survey item assessing sleep.



Affect

Affect was assessed each hour using the Feeling Scale [32]. This item asked the participant to "estimate how good or bad you feel right now." Answers were provided on an 11-point Likert-type format with possible response options ranging from "very bad" to "very good" (see Figure 1, panel 2).

Sleep

Two sleep-related measures were adapted from the Pittsburgh Sleep Quality Index [33] and were administered during the first assessment of each day. To assess the previous night's sleep quality, participants responded to the following statement: "For last night, how would you rate your sleep quality overall?" Response options were "very bad," "fairly bad," "fairly good," and "very good." Next, participants entered the previous night's

sleep and wake times, and these were used to calculate time spent sleeping (see [Figure 1](#), panel 3).

Physical Activity

ActiGraph accelerometers (model GT3x+; ActiGraph, Pensacola, FL, USA) were used to objectively assess physical activity. Participants wore the device on the nondominant hip during waking hours for the duration of the study period. Data were downloaded as activity counts, reflecting raw accelerations summed over a specific epoch length (eg, 60 seconds [34]). These data were processed in ActiLife version 6.13.2 (ActiGraph, Pensacola, FL, USA) using cut points for adults [35]. The cut point denoting MVPA was ≥ 1952 counts per minute. Data were summed within 1-hour periods, and time-matched with hourly survey data. These data represented activity occurring within the hour in which the survey was completed. Finally, a time-lagged activity variable was created to represent physical activity occurring 1 hour beyond the completion of a given prompt.

Data Analyses

First, the proportion of surveys completed during each hour between 6:50 am and 9:50 pm, and the proportion of all hourly surveys completed by each participant, were examined for missing data. Hours with a response rate less than 0.5 standard deviations of the mean were removed from the dataset. Due to the high number of potential prompts delivered per day, an a priori criterion of 25% completion per participant was employed. Such an approach is common to EMA protocols [36]. Next, skewness and kurtosis were examined to verify normality. Due to the nested structure of the data, such that observations were nested within persons, multilevel linear regression was used to

conduct analyses [37]. Analyses followed a forward-stepping hierarchical approach in which fixed and random effects of linear and quadratic time, as well as day of week on hourly MVPA were tested. Next, fixed effects of person-level, average daily, and hourly mind wandering were examined. Hourly affect, nightly sleep quality and duration, and demographic factors were then tested. Finally, simple slopes analyses were conducted to aid in interpretation of significant interaction effects [38]. Model fit was assessed with -2 restricted log-likelihood, Akaike information criterion (AIC), and the Schwarz Bayesian information criterion (BIC). Predictors were retained in the model at $P < .10$, and were considered significant at $P < .05$. Demographics were described using descriptive statistics, and all data analyses were conducted in SPSS version 23 (IBM Corp, Armonk, NY, USA).

Results

Participant characteristics are displayed in [Table 1](#). The mean age of participants was 20.5 (SD 1.5) years, 75% (27/36) were female, and 50% (18/36) were white. Participants reported mind wandering on 41.11% (908/2204) of answered prompts. Preliminary analyses revealed that response rates to prompts delivered at 6:50 am and 7:50 am fell outside of the 0.5 SD range, and these observations were subsequently removed from the dataset. Additionally, three of 36 participants (8%) answered fewer than 25% (24/98) of the prompts and were removed from analyses. As a result, a total of 3234 person*hour*day observations across 33 participants were included in the analyses. On average, participants responded to 64% (63/98) of their prompts (range 27%-92%).

Table 1. Participant characteristics (N=36).

Measure	Participants
Age (years), mean (SD)	20.5 (1.5)
Sex, n (%)	
Female	27 (75)
Male	9 (25)
Race, n (%)	
African American	3 (8)
Asian	11 (31)
Native American	2 (6)
White	18 (50)
Unknown/Other	2 (5)

As expected, results from the unconditional means model suggested a large amount of total variance in MVPA was within-person (intraclass correlation coefficient [ICC]=.05). Analyses revealed a significant negative linear ($P=.001$) and quadratic ($P<.001$) time effect for MVPA over the study period, and there was a significant positive relationship for day of week ($P=.01$) such that individuals tended to engage in greater MVPA as the week progressed. The degree to which an individual experienced mind wandering within an hour was not associated with MVPA during the hour ($P=.47$), but was positively

associated with their participation in MVPA in the coming hour ($P=.03$). Hourly affect was also significantly and positively related to MVPA in the coming hour ($P=.02$), and there was a significant interaction between hourly affect and hourly mind wandering ($P=.04$; see model 1). Simple slopes analyses indicated that during times of greater positive affect, mind wandering was positively related to MVPA ($\beta=3.74$, $SE=0.23$; $t_{1842.8}=15.96$, $P<.001$), whereas this relationship was negative in nature during times of negative affect ($\beta=-3.02$, $SE=0.23$,

$t_{1842.8}=-12.87$, $P<.001$; see Figure 2). The residual pseudo R^2 indicated that this model accounted for a moderate amount of within-person variance (pseudo $R^2=.06$ [39]).

Although daily sleep quality was unrelated to MVPA ($P=.17$), there was a negative association between nightly sleep duration and MVPA during the following day ($P=.001$), a finding that is in line with numerous epidemiological studies relating excessive sleep to lower physical activity participation rates [40–42]. To further investigate this finding, we examined nights with overly long sleep duration (ie, <10 hours per night=1 vs ≥ 10 hours per night=-1 [42,43]; see model 2). This “oversleep” was associated with less physical activity on the following day ($P=.007$). The interaction between long sleep duration and mind wandering was not statistically significant ($P=.07$), but further

investigation via simple slopes analyses indicated that for those who overslept, mind wandering was unrelated to physical activity ($\beta=-0.31$, $SE=0.40$; $t_{1797.8}=0.76$, $P=.45$). Among those who did not oversleep, mind wandering was significantly and positively related to physical activity ($\beta=0.50$, $SE=0.19$; $t_{1797.8}=2.69$, $P=.007$; see Figure 3). These relationships were not present when alternative sleep duration cutoffs were applied (eg, ≥ 9 hours; $P=.27$). No demographic items were associated with MVPA (all P s $\geq .11$). The final model, when compared with the unconditional means model, accounted for a small-to-moderate amount of within-person variance (pseudo $R^2=.05$ [39]). The model fit, fixed effects, and random effects for the unconditional means model and important model steps are displayed in Tables 2–4.

Table 2. Model fit statistics for mixed models associated with moderate-to-vigorous physical activity.

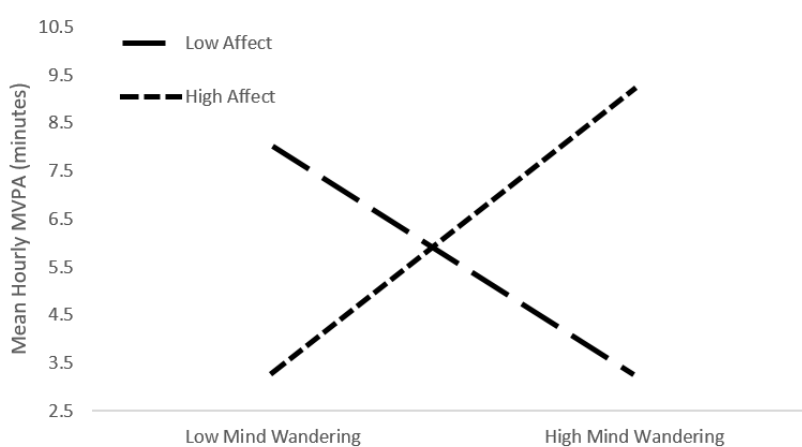
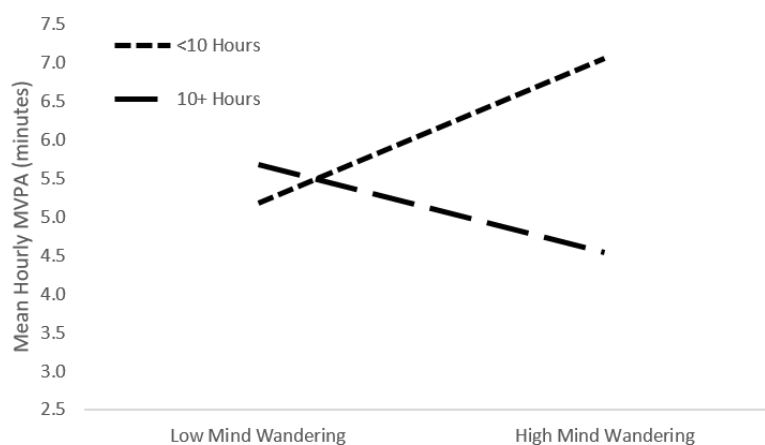
Model fit	Unconditional means model	Model 1	Model 2
-2LL	17,216.30	11,846.30	11,655.82
AIC	17,222.30	11,868.30	11,681.82
BIC	17,239.99	11,929.14	11,753.51
Pseudo R^2 within	NA	.08	.05

Table 3. Fixed effects for mixed models associated with moderate-to-vigorous physical activity.

Fixed effects	Unconditional means model			Model 1			Model 2		
	β (SE)	t (df)	P	β (SE)	t (df)	P	β (SE)	t (df)	P
Within-person									
Intercept	4.72 (0.25)	19.09 (32.85)	<.001	5.95 (0.51)	11.74 (51.95)	<.001	5.62 (0.53)	10.68 (58.07)	<.001
Linear time				-0.18 (0.05)	-3.90 (15.18)	.001	-0.17 (0.05)	-3.59 (27.96)	.001
Quadratic time				-0.04 (0.01)	-3.97 (1836.18)	<.001	-0.04 (0.01)	-4.08 (1805.99)	<.001
Day of the week				0.17 (0.07)	2.58 (1830.15)	.01	0.17 (0.07)	2.42 (1803.66)	.02
Hourly mind wandering				0.36 (0.17)	2.15 (1831.54)	.03	0.10 (0.22)	0.44 (1798.93)	.66
Hourly feelings				0.19 (0.08)	2.26 (1823.58)	.02	0.21 (0.09)	2.45 (1802.09)	.02
Feeling*mind wandering				0.21 (0.10)	2.07 (1842.83)	.04	0.23 (0.10)	2.19 (1815.89)	.03
Oversleep							0.51 (0.19)	2.72 (1412.30)	.007
Mind wandering*oversleep							0.41 (0.22)	1.82 (1797.80)	.07

Table 4. Random effects for mixed models associated with moderate-to-vigorous physical activity.

Random effects	Unconditional means model			Model 1			Model 2		
	β (SE)	Wald Z	P	β (SE)	Wald Z	P	β (SE)	Wald Z	P
Residual	34.58 (0.95)	36.45	<.001	32.55 (1.09)	29.95	<.001	32.69 (1.10)	29.68	<.001
Intercept	1.59 (0.50)	3.19	<.001	3.86 (1.61)	2.40	.02	3.94 (1.64)	2.40	.02
Linear time				0.03 (0.02)	1.45	.15	0.03 (0.02)	1.46	.14
Rho				-0.79 (0.13)	-5.91	<.001	-0.82 (0.12)	-6.96	<.001

Figure 2. Interaction between mind wandering and affect.**Figure 3.** Interaction between mind wandering and sleep duration.

Discussion

Principal Findings

This study is the first to examine the associations between mind wandering, sleep, affect regulation, and MVPA. The results offer preliminary support for our primary hypothesis. Specifically, they suggest that daily mind wandering in conjunction with positive affect is positively associated with MVPA among college students. These early and exploratory findings appear to add support to previous laboratory-based research that highlighted the often-prospective nature of mind

wandering, which supports planning of personally relevant future goals [2], by demonstrating associations between mind wandering and a complex and important self-regulated behavior in the real world. That the impact of mind wandering on physical activity is influenced by the individual's affective state and sleep is a novel finding that may have implications for health researchers.

These findings provide support for relatively recent recommendations made by Smallwood and Andrews-Hanna [6]. The authors advise researchers to take a nuanced view of mind wandering. Clearly, the ability to disengage from the

present is required for thinking about and planning for the future, which is a necessary daily behavior when carrying out challenging and complex behaviors such as physical activity [18]. Still, when an individual finds they “feel” badly, have slept poorly, or are in a cognitively demanding situation, these thoughts are likely to move away from such beneficial, future-directed thought [2,44]. By recognizing these important determinants, interventionists can begin to develop strategies to nudge individuals away from unproductive mind wandering, perhaps impacting a number of outcomes such as program adherence, long-term behavioral maintenance, or academic performance.

Better sleep quality was unrelated to physical activity, which was counter to our initial hypothesis given the relationships between sleep quality and physical activity, as well as with a number of related constructs. For instance, sleep has been associated with a number of aspects of cognition believed to be necessary for self-regulation (eg, working memory, problem solving, attention-set shifting) [20,21]. The finding related to excess sleep duration, however, was less surprising. Poor sleep hygiene is common among college students [28], and is marked by irregular wake and sleep times as well as too little or too much sleep [45]. Numerous studies have found overly long sleep to be related to a number of negative outcomes, including greater risk for heart disease [42], less physical activity [40,46], depression, and overall morbidity and mortality [41]. In this study, students tended to engage in less MVPA on days following sleep lasting 10 or more hours. Additionally, the interaction between extended sleep and mind wandering approached significance, and indicated that mind wandering was positively related to physical activity only among those that slept less than 10 hours per night.

Implications for Future Work

These findings lay the groundwork for future research examining the efficacy of a multiple health behavior change approach to improving physical activity and sleep habits concurrently. Over the last decade, a number of efficacious and scientifically sound Web-based sleep therapy tools have been developed (eg, SHUTi [47]), and it would be quite feasible to integrate such approaches with a physical activity intervention. Additionally, these findings hint at the possible reciprocal nature of the relationships between mind wandering, affect regulation, sleep, and physical activity. Although exercise is a common method for improving sleep hygiene [28,48-52], improved sleep habits may support prospective mind wandering, in turn promoting physical activity behavior and ultimately contributing to better sleep. Although sleep quality was unrelated to physical activity and mind wandering in this study, it was assessed via daily self-report. Future research utilizing objective measures of sleep and sleep quality may shed important light on these relationships.

Although it was outside of the scope of this study, working memory capacity and its relation with mind wandering and physical activity is another promising target for future research as several researchers have found this construct to be related to affect and self-regulation [53-55]. Carpenter et al [55] manipulated the affective state of 46 older adults, reporting that those in the positive-feeling condition performed better on tasks

of complex decision making and working memory capacity relative to individuals in a neutral-control condition. These working memory skills are necessary for the maintenance of goals over time, and researchers have demonstrated those with greater working memory capacity can not only limit or inhibit intrusive thought, but may also better downregulate the effects of “hot” processes such as negative affect and cravings [18,56]. These individuals are often more capable of disengaging from information that may distract them from self-regulatory efforts [57].

Mindfulness training may offer one promising strategy for influencing affect, bolstering working memory, and biasing mind wandering toward prospective thought [58-61]. Importantly, these strategies might also be readily introduced into a physical activity intervention. Although definitions vary, the mental state of mindfulness is often characterized by the devotion of full attention to the present without judgment or emotional reactivity [58]. Jha and colleagues [58] administered 8 weeks of mindfulness training to members of the military readying for deployment. The researchers reported that greater time spent practicing mindfulness meditation was related to lower levels of negative affect and with increased working memory capacity, and the association between affect and mindfulness training was mediated by working memory capacity. If successful, the application of such training methods in the context of a physical activity intervention has potential to increase the likelihood of future-oriented mind wandering, perhaps improving study outcomes. The provision of these self-regulation supporting skills may also improve long-term maintenance of the behavior, which is a recurring challenge for health behavior researchers [62].

Strengths and Limitations

We believe this study has a number of strengths. It is the first to establish relationships between mind wandering, affect regulation, sleep, and physical activity. Additionally, physical activity was measured objectively, and the use of mobile phones allowed for the examination of these relations as individuals moved throughout their daily lives over the course of 1 week. Finally, the population of college students recruited for this study was quite diverse, with approximately one-half being nonwhite.

We do acknowledge several limitations present in this exploratory study. First, although many assessments were collected for each participant, the overall sample size was rather small, potentially impacting our ability to draw conclusions related to between-persons relationships. Similarly, due to the large number of daily physical activity assessments, participants may have experienced some degree of measurement reactivity [63], in turn temporarily altering their behavior in response to the measurement. To ensure the effects of this study were not impact by reactivity, future researchers may consider the inclusion of supplementary assessment groups (eg, EMA only, activity monitor only). Additionally, the sample was college-aged and largely female (75%), potentially reducing the broader generalizability of these findings; further work would benefit by extending this assessment to nonstudent populations. The decision to use a high rate of prompting may

have contributed to rather high degree of missing data. Future researchers may consider the use of longer study periods with more contemporary prompting schemes (eg, random prompting, prompting based on individual schedules) to reduce missingness. Further, in accordance with our primary aims, we collected assessments of self-reported mind wandering, but we did not collect assessments of the content of an individual's thoughts. Thus, we are unable to draw clear ties between the specific nature of mind wandering and future behavior. Doing so may add further richness to our understanding of the nature of the relationships demonstrated in this study. Similarly, as was previously noted, accelerometers were worn during waking hours only. As a result, only daily self-reported measures of sleep were used in analyses. By utilizing more objective measures of sleep, researchers may better understand the relationships between sleep, mind wandering, and physical activity. It is also likely that working memory plays an important role in the relations between mind wandering and physical activity. With the growing popularity of mobile cognitive assessments, it is becoming increasingly feasible to collect multiple assessments of working memory over time, potentially shedding light on the temporal relations between working

memory, mind wandering, and health behaviors such as physical activity.

Finally, this exploratory work was concerned specifically with the relationships between mind wandering and physical activity behavior. However, it is important to note this important health behavior does not occur in a vacuum. Indeed, it is likely to operate synergistically with a number of other health behaviors, including sleep, dietary behaviors, substance use behaviors, and social activities [64]. One's daily activity behaviors may also be affected by myriad psychosocial factors (eg, depression, anxiety, loneliness). The interesting relationships highlighted in this analysis underscore the novelty of this area of research and lay the initial groundwork for additional research into the influences of these important factors.

Conclusions

Our findings suggest the degree to which an individual's mind wanders is associated with their participation in MVPA and this relationship is influenced by both affect and sleep duration. Future physical activity research implementing strategies to improve attention, affect regulation, and sleep hygiene is warranted, potentially offering important information for those attempting to begin or maintain a physically active lifestyle.

Conflicts of Interest

None declared.

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Abbreviations

AIC: Akaike information criterion
BIC: Bayesian information criterion
EMA: ecological momentary assessment
MVPA: moderate-to-vigorous physical activity

Edited by G Eysenbach; submitted 08.04.16; peer-reviewed by JY Kim, M Chrisman; comments to author 27.07.16; revised version received 01.08.16; accepted 21.08.16; published 31.08.16.

Please cite as:

*Fanning J, Mackenzie M, Roberts S, Crato I, Ehlers D, McAuley E
Physical Activity, Mind Wandering, Affect, and Sleep: An Ecological Momentary Assessment
JMIR Mhealth Uhealth 2016;4(3):e104
URL: <http://mhealth.jmir.org/2016/3/e104/>
doi: [10.2196/mhealth.5855](https://doi.org/10.2196/mhealth.5855)
PMID: [27580673](https://pubmed.ncbi.nlm.nih.gov/27580673/)*

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Original Paper

Measuring Users' Receptivity Toward an Integral Intervention Model Based on mHealth Solutions for Patients With Treatment-Resistant Schizophrenia (m-RESIST): A Qualitative Study

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Abstract

Background: Despite the theoretical potential of mHealth solutions in the treatment of patients with schizophrenia, there remains a lack of technological tools in clinical practice.

Objective: The aim of this study was to measure the receptivity of patients, informal carers, and clinicians to a European integral intervention model focused on patients with persistent positive symptoms: Mobile Therapeutic Attention for Patients with Treatment-Resistant Schizophrenia (m-RESIST).

Methods: Before defining the system requirements, a qualitative study of the needs of outpatients with treatment-resistant schizophrenia was carried out in Spain, Israel, and Hungary. We analyzed the opinions of patients, informal carers, and clinicians concerning the services originally intended to be part of the solution. A total of 9 focus groups (72 people) and 35 individual interviews were carried out in the 3 countries, using discourse analysis as the framework.

Results: A webpage and an online forum were perceived as suitable to get both reliable information on the disease and support. Data transmission by a smart watch (monitoring), Web-based visits, and instant messages (clinical treatment) were valued as ways to improve contact with clinicians. Alerts were appreciated as reminders of daily tasks and appointments. Avoiding stressful situations for outpatients, promoting an active role in the management of the disease, and maintaining human contact with clinicians were the main suggestions provided for improving the effectiveness of the solution.

Conclusions: Positive receptivity toward m-RESIST services is related to its usefulness in meeting user needs, its capacity to empower them, and the possibility of maintaining human contact.

(*JMIR Mhealth Uhealth* 2016;4(3):e112) doi:[10.2196/mhealth.5716](https://doi.org/10.2196/mhealth.5716)

KEYWORDS

mHealth solution; treatment-resistant schizophrenia; intervention model; qualitative research; needs assessment

Introduction

In the European Union, approximately 5 million people (0.2%-2.6%) suffer from psychotic disorders [1]. Patients with schizophrenia make up the largest subgroup, and between 30% and 50% of them can be considered resistant to treatment [2,3]. Standard intervention focused on patients with treatment-resistant schizophrenia is complex because of the presence of persistent positive symptoms, extensive periods of hospital care, and increased risk of multimorbidity. The full scope of this scenario generates a high degree of suffering for patients and their families and a great financial burden on the health care system [4-6].

Study of these patients' needs is necessary for a better understanding of their psychosocial functioning, in order to develop rehabilitation goals as well as to provide them with better care [7,8]. According to the published literature, decreasing psychological distress and psychotic symptoms, keeping company and social activity, daytime activities, and information concerning the condition and treatment are the most common needs identified by patients [9-11]. This assortment of needs is similar to what caregivers and clinicians report [12-15], with nuances across countries, given the different design and functioning of the health care systems [14,16,17]. Moreover, members of professional organizations have proposed, as an important issue in the clinical intervention in treatment-resistant schizophrenia, the development and implementation of programs to promote the use of individualized treatment, taking into account the patient's wishes and preferences whenever possible [18].

Over the last decade, different mHealth applications have been designed with the aim of meeting some of these needs. On the basis of digital technology, which offers information and therapy remotely drawing on the support of mobile devices, these solutions tend to be focused on 3 intervention areas: psychoeducation, symptom monitoring, and self-management [19-23]. Web-based psychoeducational interventions have been proven to offer patients information about the illness as well as training through systematic education programs [24]. Monitoring of the disease in mHealth interventions has usually been implemented using the Internet and mobile phone apps. It is particularly helpful in increasing medication adherence, offering medical information about patients' conditions, monitoring symptoms, and conducting cognitive behavioral therapy [25,26].

Despite the proven efficacy of these applications, we still face a lack of technological intervention models in the treatment of patients with psychotic illnesses. According to Ben-Zeev [27], Ben-Zeev et al [28], Granholm et al [19], and Rotondi et al [20], this is explained by the existence of a professional discourse on telemonitoring, with concerns about both the control that the usage of technological solutions can generate in patients and the lack of ability and willingness of patients to engage in mobile interventions. These conceptions derive from the fact that, to date, mHealth interventions for people with schizophrenia have

focused on alternative means of delivering preexisting services, such as therapy, and attempting to increase adherence to medications and symptom monitoring. Thus, their potential contribution to social networks and self-management support for people with a diagnosed, serious mental illness has been overlooked [26].

With the intention of improving the quality of care of outpatients with treatment-resistant schizophrenia, an mHealth solution termed Mobile Therapeutic Attention for Patients with Treatment-Resistant Schizophrenia (m-RESIST) is being designed in the European Union. This innovative project focuses on patients with persistent positive symptoms, with the aim of empowering them, personalizing their treatment by integrating pharmacological and psychosocial approaches, and developing knowledge of the illness using predictive models to analyze historical and real-time data based on environmental factors and treatment outcomes. In the course of the project, designed by a consortium of 12 entities from the public and private sectors (including clinical and technological institutions), a system based on computer and mobile application as well as wearable devices will be developed. The system will serve patients, caregivers, and clinicians and will include the following functions: monitoring, medical-psychological assessment, intervention, and information. Contrary to previous applications focusing only on one area (education, monitoring, or self-management), m-RESIST is an integral intervention model that covers all of these features.

The objective of this study was to identify the needs and preferences of outpatients with treatment-resistant schizophrenia, informal carers, and clinicians that could be met through mHealth interventions and particularly the m-RESIST solution.

Methods

Design

In order to involve users in the design of the system, a qualitative study of requirements of outpatients with treatment-resistant schizophrenia was performed before the implementation of the solution. The study was carried out by 3 of the member institutions of the m-RESIST consortium: Parc Sanitari Sant Joan de Déu (Spain), Semmelweis University (Hungary), and Gertner Institute (Israel), from March to June 2015. The selection of core ideas provided below satisfies 2 requirements: to appear in the 3 countries and to be the most commonly mentioned by participants in focus groups.

Study Participants

Outpatients with treatment-resistant schizophrenia, informal carers (relatives), and clinicians were included in the sample. There were a total of 9 focus groups, 3 in each pilot country. Each group was composed of one of the participant profiles. Additionally, 35 individual interviews were performed, which were unevenly distributed throughout the 3 institutions (Table 1). The aim of the interviews was to examine issues that were

not sufficiently discussed in the focus groups, so their maximum number depended on reaching the theoretical saturation point.

Selection of participants was carried out using nonrandom sampling. All participants had to be fluent speakers of the main language in each country (Spanish, Hebrew, and Hungarian) in order to ensure that the range of needs and opinions was recorded accurately. Patients and informal carers were referred to the research teams by their treating psychiatrist, according to specific inclusion criteria described below. Once patients agreed to be part of the study, their contact numbers were

provided to the research staff to arrange the date of the focus group or interview. Clinicians from the hospital and mental health center network staff were directly contacted by the research team. Before the start of the focus groups and interviews all participants were asked to provide written informed consent, after the nature of the study was fully explained to them.

Inclusion criteria, both common to all participants and specific for each profile, were established ([Textbox 1](#)).

Table 1. Number of people included in focus groups and interviews.

Category	Sex	Spain, n	Israel, n	Hungary, n
Focus groups				
Patients	Males	7	1	2
	Females	3	5	3
Informal carers	Males	0	2	6
	Females	5	7	4
Clinicians	Males	4	2	3
	Females	8	7	3
Total		27	24	21
Interviews				
Patients	Males	0	10	2
	Females	4	10	5
Informal carers	Males	4	0	0
	Females	0	0	0
Total		8	20	7

Textbox 1. Common and specific inclusion criteria.

<p>Inclusion criteria common to all participants:</p> <ul style="list-style-type: none"> • Older than 18 years • Basic knowledge and use of information and communications technology <p>Specific inclusion criteria for clinicians:</p> <ul style="list-style-type: none"> • Psychiatrists, psychologists, social workers, nurses, and case managers • A minimum of 5 years of experience in the treatment of patients with treatment-resistant schizophrenia <p>Specific inclusion criteria for informal carers:</p> <ul style="list-style-type: none"> • Family members: parents, partners, and siblings • Primary responsibility for patient's care <p>Specific inclusion criteria for outpatients:</p> <ul style="list-style-type: none"> • Younger than 45 years • Schizophrenia diagnosed according to the <i>Diagnostic and Statistical Manual of Mental Disorders</i> (Fourth Edition, Text Revision) • A maximum of 15 years of illness progression • More than 6 months since the diagnosis of treatment resistance • Positive symptoms ≥ 4 (at least moderately ill), according to Clinical Global Impressions Scale [29]
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Treatment-resistant schizophrenia is defined when adequate antipsychotic treatment is prescribed but there is no response to it (not satisfying the Andreasen remission criteria based on the Positive and Negative Syndrome Scale, PANSS) [30]:

1. Primary resistant patients defined as patients with persistent auditory hallucinations and/or delusions that have not responded to treatment with 3 adequate regimens of antipsychotic medication (including one failed trial of clozapine) for at least one year from the screening visit [31].
2. Patients with persistent psychotic symptoms ("Pseudoresistant") owing to the following causes: low adherence, drug abuse, poor insight, isolation tendency, low involvement of caregivers in the therapeutic process, or ineligibility for treatment programs [32].

Patient eligibility for treatment-resistant criteria was confirmed following clinical evaluation using PANSS interview by trained, experienced clinicians.

Two exclusion criteria were defined regarding patients: intellectual disability and being admitted in an acute care unit.

Criteria concerning patients, as well as those related to informal carers and clinicians, were confirmed through a short questionnaire administered at the beginning of the focus groups and interviews. All participants had to consent to audiotaping of the sessions and be willing to clarify portions of the transcripts if necessary.

This study complied with the provisions of the Declaration of Helsinki [33] and was approved by the ethical committees of the 3 institutions involved.

Procedures

Both focus groups and interviews were carried out in a venue (meeting rooms) outside the hospital areas where patients were usually treated. The average duration of the sessions was 90 minutes for focus groups and 1 hour for interviews. The participants were asked about a range of different issues, which were divided into 3 parts:

1. Outpatients' needs in their everyday life, identified by them, the informal carers, and the clinicians.
2. The role played by the health care system, focusing on their strengths and deficiencies, in order to meet these needs.
3. Opinions about the solutions originally intended to be part of the m-RESIST: online visits, alerts, data transmission system, instant messages, and a webpage specialized in treatment-resistant schizophrenia.

Research Team

Two professionals were required to conduct focus groups: a moderator and a coordinator. The research team designed an in-depth procedure for focus groups and interviews (internal document) where we specified the question and the topics to be covered. The moderators, who proposed the different issues to talk about and guided the conversation, were professionals with more than 5 years of experience in qualitative techniques: a psychologist in the case of Spain, a sociologist in Hungary, and an art therapist in Israel. The coordinator was a sociologist

in the focus groups carried out in Spain, a psychologist and a psychiatrist (depending on the group) in Hungary, and a transcriber in Israel. Coordinators were responsible for welcoming participants, taking notes, recording the conversation, and distributing the questionnaires among the participants. In the specific case of Israel, a third profile was additionally included, a psychologist, to clarify those questions related to the treatment and symptoms that emerged during the conversation. In addition, all of these professionals acted as interviewers.

There was no preexisting relationship between the research team and the group of patients and informal carers who participated in the study. In the specific case of clinicians, the research team members were acquainted with some of them by sight, although they were not colleagues.

Theoretical Framework

The study was based on the principle of discourse analysis. This method is predicated on the understanding that there is much more going on when people communicate than simply the transfer of information. It is not an effort to capture literal meanings; rather, it is the investigation of what language does or what individuals accomplish through language. This method concerns itself with the use of language in a running discourse, continued over a number of sentences, and involving the interaction of speaker and listener in a specific situational context: mainly interviews and focus groups. The type of linguistic material is described as "performance data" and may contain features such as hesitations, clichés, and nonstandard forms such as colloquial expressions [34]. The consideration of these forms of expressions is essential in examining opinions and attitudes of patients with schizophrenia, given that they tend to show a lack of verbal fluency in their speech regarding needs because of their awareness of the social stigma attached to the illness.

Results

Assessment of the Receptivity to the m-RESIST Services and Applications

The range of needs reported by patients with treatment-resistant schizophrenia, their carers, and the clinical staff involved in their treatment is extremely broad and includes a large variety of areas. In this study, we focused on those needs that m-RESIST aims to meet within the following intervention modules: psychoeducational, monitoring, treatment, and self-management of the disease.

Psychoeducational Services: Webpage and Online Forum

With regard to medical care attention, *additional information* on treatments, medication side effects, and symptoms is the main need of the patients, according to them and their informal carers. Despite the potential usefulness of the Web in meeting this need, the majority of patients and carers are skeptical about the information submitted. This is the main reason why the possibility of having a webpage specialized in treatment-resistant schizophrenia was very much appreciated:

Participant 1: *Information about what schizophrenia is, the medication you are taking...*

Participant 2: *Yes, I agree.*

Coordinator: *Sorry?*

Participant 1: *Yes, the most suitable medication for you.*

Moderator: *What else would you like to include?*

Participant 2: *The most important thing is...it has to be a secure page...because people are so confused and some people include wrong information...* [Spain; patients group]

With regard to those issues to be included in the webpage, available treatments, side effects of medication, and symptoms are the most mentioned.

Together with the need for additional information, patients and clinicians pointed out the lack of a social network that provided *company* and emotional support as one of the main patient needs. This explains the broad acceptance of an online forum aimed at promoting contact among patients. Regarding the potential participants in the forum, both outpatients and clinicians considered that it should be restricted to outpatients, through an authorization procedure, as a way of ensuring their privacy:

Participant 1: *Part of the forum needs to be private, just for patients.* [Hungary; clinicians' group]

The patients expressed a need to protect their privacy using online "nicknames":

Moderator: *What do you think about virtual forums for people dealing with schizophrenia...there is a certain disclosure in this.*

Participant 1: *You don't have to write your real name...*

Moderator: *Yes, you can use nicknames if you prefer.* [Israel; patients group]

For outpatients, the forum was also perceived as a chance to feel useful helping other people with the same illness, given that those with recently diagnosed schizophrenia could be supported by long-term patients like them:

Participant 1: *I would like...for instance, to talk about the paranoidias I have had...because maybe other people have had the same ones...I don't know.*

Participant 2: *Well, I think that...on the basis of the experience gained...advice is much better, when it comes from someone experienced in the same situation. You can say "Hey, keep calm, just do this or do that." Given what the other person has experienced...* [Spain; patients group]

The need for information shown by patients, as well as their readiness for greater contact with other people with treatment-resistant schizophrenia, attests to their potential to play a more proactive role in the management of the disease.

Monitoring: Data Transmission

Within the field of medical care, in addition to further information on the disease, insufficient follow-up by clinicians involved in the treatment (mainly psychiatrists) was identified as a key complaint. Longer and more frequent visits were most

often mentioned as being needed, by patients, clinicians, and, especially, those family members responsible for patients' care. Therefore, a lack of immediacy and of continuity of attention was identified as an important gap in the current intervention scenario for patients with persistent positive symptoms.

The implementation of data transmission service, aimed at storing patients' patterns using a smart watch sending clinicians the information recorded, could help meet this need.

The watch could really be suitable for my son, in the event that a destabilization of his heart rates is observed...My son spends the whole day at home, with his PC, watching video clips... [Spain; informal carers group]

The caregivers pointed out the relevance of wearable devices such as smart watches in monitoring the patient's condition and adherence to medical regimen:

There needs to be some kind of smart watch or other device that could let me know that my son visited his doctor...or when he doesn't take the meds—so the doctor knows about it... [Israel; informal carers group]

Regarding what type of data should be recorded, sleeping patterns and rhythm of activity were the most frequently mentioned, according to informal carers. For patients and clinicians, however, the recording of mental state parameters was particularly relevant in order to prevent psychotic episodes:

A worsening of symptoms can occur anywhere, anytime, even when patients are on their way somewhere. For example when they are alone...In those moments, if patients feel distressed or unstable, this device could indicate this immediately. [Hungary; clinicians group]

With the intention of increasing the effectiveness of this service, the majority of patients considered that sharing data with informal carers would be useful:

Moderator: *Who would you like to share an alarm like this with?*

Participant 1: *With my mother.*

Participant 2: *With my mother as well.*

Participant 3: *With no one.*

Participant 4: *In my case...with my mother.*

Participant 5: *With my wife.* [Spain; patients group]

Despite this broad agreement concerning the idea of sharing this information with informal carers, a written approval from patients would have to be obtained by the clinical staff before their participation.

Clinical Treatment: Online Visits and Constraint Messages

On the basis of patients' and informal carers' opinions on the need to increase the *contact between patients and clinicians*, both profiles showed a positive opinion about patients' having the chance for online visits using a webcam.

With regard to their regularity, clinicians considered that online appointments and in-person visits should take place on an alternating basis. From the patients' perspective they could be especially suitable in those specific situations in which they have difficulties attending an in-person visit, such as when they fall particularly ill:

This is a great opportunity to reach the doctor, especially in times of crisis...I would love to [have online sessions]...This is something that makes the hassle of leaving home and going all the way, unnecessary...It can really help. [Israel; interview with a patient]

In addition to online visits, instant messages were also presented as a way of improving patient follow-up, in this case through mobile phones. With regard to the procedure to be followed, after initial contact with patients through a message, clinicians would assess the suitability of sending instant messages as containment or, in case of a significant deterioration in a patient's functioning, contacting the psychiatrist. This service was perceived positively by all 3 user profiles. Apart from its usefulness in improving contact between clinicians and patients, the receptivity of these messages among participants is due to their familiarity with similar online messenger applications:

Moderator: *Can you imagine using such devices/services as chat or Skype with patients?*

Participant 1: *Yes, you can communicate by short messages and e-mails as well. [Hungary; clinicians group]*

Both outpatients and clinicians spontaneously mentioned the possibility of using instant messages in a positive way and not only to prevent a worsening of symptoms:

Participant 1: *This could assist a person to manage a kind of dialog with himself...Let's say, a personal treatment plan, goals that he needs to achieve, and if he succeeds, he gets points, but this is something that he decides for himself, maybe, with a therapist.*

Participant 2: *And positive reinforcements. The issue of positive reinforcement is the best. Research also shows this, with points and similar strategies...This is fantastic! [Israel; clinicians group]*

From the professionals' point of view, these messages could benefit the patients' self-esteem because they would feel their progress is being appreciated, which has a positive effect on the evolution of the illness.

Self-Management of Tasks: Alerts

Mobile alert is the solution originally intended to meet needs related to patients' daily tasks, in addition to those concerning the management of the disease: medication intake and medical visits.

Within the domestic sphere, patients' days begin with difficulties getting out of bed given feelings of tiredness. Daily hygiene appears as the next functioning challenge for patients.

In addition to personal care, outpatients, informal carers, and clinicians identified difficulties in dealing with medication intake. They concluded that although the patients are fully aware of the importance of medication to prevent worsening of symptoms, they are suspicious of its use, and that this apprehension toward medication is a common occurrence among patients, so this task should be monitored by informal carers.

The major and immediate concern is what will happen if he misses his meds...we know what a crisis is, one or two days of missed meds and the consequences can be very drastic. [Israel; interview with an informal carer]

Together with medication intake, most informal carers who were part of the sample reported that they were also responsible for reminding patients of the time and date of the next visit.

Patients' difficulties in dealing with daily tasks and managing the illness explain why alerts were well appreciated by the 3 groups. From the perspective of patients, the chance of sharing these alerts with their informal carers, through an additional alert, was also well received:

Participant 1: *I would like to share it with other people, in case something happens to you...*

Moderator: *Who would you like to share them with?*

Participant 1: *I don't know. With my father, my mother...even my brother.*

Participant 2: *Yes.*

Coordinator: *And you?*

Participant 3: *My mother.*

Participant 4: *Yes, my mother as well. [Spain; patients group]*

In general, alerts were seen positively and related with different perceived needs (Table 2). The ability of the system to generate automatic reminders for medications and appointments was also pointed out by the 3 profiles.

Table 2. Relation between perceived needs and the m-RESIST^a services.

Sphere	Needs	m-RESIST service
Personal care	Getting out of bed Daily hygiene	Mobile alert
Management of the disease	Medication intake Visit reminders	Mobile alert
Health care attention	Greater follow-up Additional information	Online visit, data transmission, instant message Webpage
Relational environment	Company Mutual support	Online forum

^am-RESIST: Mobile Therapeutic Attention for Patients with Treatment-Resistant Schizophrenia.

Suggestions for Improvement

Despite the usefulness ascribed to the solution, several concerns were brought to light by the participants in focus groups and interviews, which were matched by proposals on how to minimize them.

Personalized Data Transmission Service

The main risk perceived by outpatients, informal carers, and clinicians with regard to the implementation of the m-RESIST solution was the possibility that some of the services and applications could promote a passive role in patients. These opinions focused on data transmission service and mobile alerts.

With regard to the first of these, clinicians were particularly concerned about this risk:

I think the problem is the lack of autonomy. I mean, the person has to be capable of deciding... Why does everything patients decide have to be controlled? I mean, it is irrelevant for us, as clinicians, and can even be counterproductive, to have more information than patients want to report to us. [Spain; clinicians group]

Professionals suggested adapting this service to individual patient's needs, implementing it only for those who were less capable of managing the disease on their own and more reluctant to provide information about their symptoms to clinicians. Additionally, clinicians emphasized the need for periodically checking patients' acceptance of the service over time.

Flexible Number of Alerts

According to clinicians, avoiding situations stressful for users is essential in preventing a worsening of symptoms. Therefore, the need to create the right number of alerts was found to be extremely important. Both outpatients and clinicians emphasized this idea, especially the case managers, given their previous expertise in using alerts.

Participant 1: *I think...in the case of patients that argue "I usually forget to take the medication" Ok, so, I can make a note of it on your mobile phone or an alarm.*

Moderator: *Do you agree?*

Participant 2: *Yes. In the following visit patients often tell you, "I deactivated the alarm because the whole day it was buzz, buzz, buzz. It drove me crazy" So, you, as a professional, have to find another sort of strategy to help patients associate the pills with their daily habits. Because, after all, an alarm is something stressful, isn't it? [Hungary; clinicians group]*

Health care professionals and outpatients pointed out that service should be targeted to specific patient profiles, aimed at those who usually forget to take medication and miss their visits with the staff. With regard to the right number of alerts, although it would depend on individual patient needs, most clinicians set a maximum of 3 a day.

Alternation of Online and In-Person Visits

The need to keep in-person visits with clinicians was another concern mentioned by patients, family members, and health care professionals. Thus, online visits were perceived with skepticism and fear owing to the possibility that regular visits would disappear.

I have respect for technology, but I really feel that the human contact, when you come, once a week, to see your therapist face to face, sometimes it's the only human contact that these patients have... [Israel; clinicians group]

The 3 groups suggested combining online and in-person visits, as a way of maintaining the human contact between outpatients and clinicians, and promoting the mutual contact when patients were unwilling or unable to visit clinicians.

Differences Between Countries

We found differences in users' needs between the 3 studied countries (Spain, Hungary, and Israel). With regard to the current health care system, everyone asked for information about the disease (negative symptoms, side effects of medication, etc), but Israel also specified the need for information on how to deal with internalized and social stigma. In terms of resources, the 3 countries required the creation of a specific website and an online forum, but with differences (whereas in Spain it was considered that there should be a moderator in the forum, Hungary accepted the existence of a forum exclusively for patients), and Israel added the idea of a "matchmaking app" for patients. Moreover, there is a general acceptance of the

m-RESIST solution in Spain and Hungary, but in Israel there is more reluctance to it, considering it a supplementary treatment to the currently established treatment in any case. There are also different views on some sections: regarding the online visits, Hungarian clinicians did not agree with it, because it would increase their work; the alerts are mainly considered as reminders in Spain and Hungary, whereas Israel would extend them to customized messages; finally, regarding the smart watch device, the Spanish patients think that wearing it could be stigmatizing, whereas in Hungary there is great worry about the responsibility of maintenance and having to assume the costs in case of loss, and in the Israel group the opinion of the matter is unknown.

Discussion

Despite the proven usefulness of mobile technology in mental health care, to date only a limited number of mHealth solutions have been implemented [28,35]. Concerns have been raised about the cognitive limitations of people with severe mental illness in dealing with Web-based and mobile applications [23,36]. The few solutions designed tend to be focused on a specific intervention area, mainly within the psychoeducational field [20] or as a way to improve adherence to medication through telemedicine systems [25,37]. Therefore, the design of an integral intervention model involving different areas of patients' attention has been left aside.

Our study provides preliminary indications that outpatients with treatment-resistant schizophrenia and positive symptoms are willing to use the services that were originally intended to be

part of the m-RESIST solution and feel capable of doing so. These include online visits, instant messages, data transmission, and alerts. This broad acceptance of the solution is also supported by informal carers and clinicians. This is largely due to the capacity of m-RESIST to meet the most relevant needs in the outpatients' lives [9,12] and the possibility of encouraging them to assume a more active role in the management of their day-to-day lives [38,39]. Nevertheless, in order to further increase their suitability, it is important to consider the need to modify the initial approach of some services. In the case of data transmission service, users pointed out the importance of personalizing the service according to the capacity of patients to self-manage the illness. Mobile alerts should also be focused on those patients who usually forget to take medication or miss their medical appointments. The number and frequency of alerts have to be previously agreed upon with patients, in accordance with previous studies [19]. Regarding online visits, the importance given to the human contact in schizophrenia treatment explains users' proposal for combining them with in-person visits.

Further studies on the point of view of users toward mHealth solutions are needed [40]. It is important to consider the effects of gender and age on the patients' perspectives when identifying and explaining the differing use of technology among patients [11,41-43]. In addition, the suspicions of clinicians regarding the possibility of using technological solutions in patient care should be taken into account in the design of future technological solutions. In the current digital era, this implies the need to prove the advantages of technology in their everyday work to them and encouraging them to actively use it.

Acknowledgments

We would like to acknowledge the people who have collaborated in focus groups: the clinicians, informal carers, and people with schizophrenia. This study is part of the m-RESIST project, Work Package 2: User requirements and health care routes. The project is funded by the European Union under the Horizon 2020 research and innovation framework program (grant agreement No. 643552) in the domain of PHC-26-2014: Self-management of health and disease: citizen engagement and mHealth.

Conflicts of Interest

None declared.

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Abbreviations

m-RESIST: Mobile Therapeutic Attention for Patients with Treatment-Resistant Schizophrenia

PANSS: Positive and Negative Syndrome Scale

Edited by G Eysenbach; submitted 04.03.16; peer-reviewed by S Chan, P Yellowlees; comments to author 27.06.16; revised version received 29.07.16; accepted 21.08.16; published 28.09.16.

Please cite as:

Huerta-Ramos E, Escobar-Villegas MS, Rubinstein K, Unoka ZS, Grasa E, Hospedales M, Jääskeläinen E, Rubio-Abadal E, Caspi A, Bitter I, Berdun J, Seppälä J, Ochoa S, Fazekas K, M-RESIST Group, Corripio I, Usall J

Measuring Users' Receptivity Toward an Integral Intervention Model Based on mHealth Solutions for Patients With Treatment-Resistant Schizophrenia (m-RESIST): A Qualitative Study

JMIR Mhealth Uhealth 2016;4(3):e112

URL: <http://mhealth.jmir.org/2016/3/e112/>

doi: [10.2196/mhealth.5716](https://doi.org/10.2196/mhealth.5716)

PMID: [27682896](https://pubmed.ncbi.nlm.nih.gov/27682896/)

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Original Paper

Evaluating Patient Usability of an Image-Based Mobile Health Platform for Postoperative Wound Monitoring

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Abstract

Background: Surgical patients are increasingly using mobile health (mHealth) platforms to monitor recovery and communicate with their providers in the postdischarge period. Despite widespread enthusiasm for mHealth, few studies evaluate the usability or user experience of these platforms.

Objective: Our objectives were to (1) develop a novel image-based smartphone app for postdischarge surgical wound monitoring, and (2) rigorously user test it with a representative population of vascular and general surgery patients.

Methods: A total of 9 vascular and general surgery inpatients undertook usability testing of an internally developed smartphone app that allows patients to take digital images of their wound and answer a survey about their recovery. We followed the International Organization for Standardization (ISO) 9241-11 guidelines, focusing on effectiveness, efficiency, and user satisfaction. An accompanying training module was developed by applying tenets of adult learning. Sessions were audio-recorded, and the smartphone screen was mirrored onto a study computer. Digital image quality was evaluated by a physician panel to determine usefulness for clinical decision making.

Results: The mean length of time spent was 4.7 (2.1-12.8) minutes on the training session and 5.0 (1.4-16.6) minutes on app completion. 55.5% (5/9) of patients were able to complete the app independently with the most difficulty experienced in taking digital images of surgical wounds. Novice patients who were older, obese, or had groin wounds had the most difficulty. 81.8% of images were sufficient for diagnostic purposes. User satisfaction was high, with an average usability score of 83.3 out of 100.

Conclusion: Surgical patients can learn to use a smartphone app for postoperative wound monitoring with high user satisfaction. We identified design features and training approaches that can facilitate ease of use. This protocol illustrates an important, often overlooked, aspect of mHealth development to improve surgical care.

(*JMIR Mhealth Uhealth* 2016;4(3):e113) doi:[10.2196/mhealth.6023](https://doi.org/10.2196/mhealth.6023)

KEYWORDS

telemedicine; smartphone; surgical site infection; postoperative wound infection

Introduction

Telemedicine has begun to supplement, and in some cases supplant, postoperative care received in the clinic in many surgical practices. Existing platforms include Web and mobile phone-based portals for virtual follow-up after elective general surgery and telephone follow-up after laparoscopic cholecystectomy and open inguinal hernia repair [1-3]. These platforms have been met with wide acceptance and enthusiasm by patients and their surgeons in the low-risk, elective surgery cohorts studied [4]. However, patients have not been rigorously included in the design of these apps despite an extensive literature on user-centered design in the scientific literature from the disciplines of medical informatics and human-computer interaction [5-8]. Indeed, recognizing the importance of involving users in the development of new devices and protocols, the Food and Drug Administration (FDA) has mandated consideration of the user experience in their Quality System Regulation [9].

As ownership of tablets and mobile phones becomes more common [10], patients and their caregivers are increasingly willing to use technology to access care [11]. Alongside this trend, policy mandates have made improving transitions of care following hospital discharge and reducing hospital readmissions a national priority [12-15]. These trends together create an enormous opportunity for telemedicine to improve transitions of care for surgical patients. However, with increasing enthusiasm for telemedicine, new platforms must be rigorously vetted by patients, the end users, to ensure their full acceptability and accessibility. This can be achieved through the use of established user-centered design guidelines, which comprise a diverse set of concepts and methods grounded in human factors engineering and ergonomics that facilitate the usability of technology for the target user. Although clinical outcomes from the studies of existing telemedicine platforms in surgical practice are encouraging, they are limited by substantial bias—more than 80% of published telemedicine interventions include only those patients who can access or are familiar with the necessary technology (eg, tablet or mobile phone), resulting in the exclusion of between 12% and 56% of otherwise eligible participants [16]. Additionally, much of the prior research of telemedicine protocols for surgical patients have focused on routine procedures that already have a low base rate of postoperative and postdischarge complications [1,2,17]. As a result, major knowledge gaps remain regarding whether telemedicine can be used to monitor a higher-risk population that is less familiar with mobile technology and what is required of novice technology users to successfully complete such protocols.

In addition, many existing telemedicine platforms designed for the postdischarge period are primarily text or audio based but transmit no visual information [2,3,18]. A crucial component of postoperative and postdischarge recovery is appropriate healing of the surgical wound. The addition of a visual component (video and images) allows more complete evaluation of wound healing, which is vital for monitoring postoperative recovery for 3 primary reasons: wound infection is the most common nosocomial infection in surgical patients, it is a leading

cause of hospital readmission [19] as infections increasingly develop after hospital discharge [20], and patients are unable to identify wound complications with a high rate of false negatives [21,22]. Telemedicine protocols that rely on mobile devices, collectively termed mobile health (mHealth), are uniquely positioned to easily provide visual information, essential to the diagnosis of a wound infection.

Those telemedicine protocols that do have a visual component are frequently asynchronous and episodic and have not been designed for ongoing monitoring of postoperative recovery. Most commonly, these protocols involve either digital images or videoconferencing intended to replace an in-person office visit [1,17,23-25]. However, while these are useful in their ability to decrease travel time and cost, they are not sufficient in diagnosing an early wound complication for reasons stated above, namely that, a surgical site infection (SSI) often develops before many follow-up visits are scheduled. Other protocols intended for wound monitoring, such as the mobile Post-Operative Wound Evaluator (mPOWER), are intended to allow patients to submit images, but do not guarantee that a provider will review them unless notified to do so [26,27]. Unless patients alert their provider regarding a concerning finding, something patients are not reliably able to do, such protocols may inadequately detect the early signs of a wound complication.

We address these gaps by creating an image-based smartphone app aimed at increasing communication between patients and their caregivers after they leave the hospital as part of a forthcoming effort to detect wound complications at an early stage and to reduce hospital readmissions. We then evaluate its usability in a largely technology-naïve population of patients undergoing general and vascular surgery. In constructing this project, we consulted 2 international standards: International Organization for Standardization (ISO) standard 9241-12 was used to optimize the design of our application and then ISO 9241-11 was used to guide usability testing of the app. ISO 9241-11, a widely used guideline for current usability testing methods, which focuses on effectiveness (ie, task completion), efficiency (ie, time within task), and user satisfaction of new technology, was used to assess the patient-centeredness and usability of this app to monitor postoperative wounds [28]. To our knowledge, we are the first to invoke ISO 9241-11 to assess an image-based app in a clinical patient population. Our findings have the potential to provide vast amounts of clinically vital information that has been otherwise unavailable to health care providers. We also address the utility of existing usability standards for image-capturing mHealth platforms.

Methods

Subjects

Eligible participants included inpatients 18 years of age or older on the vascular or general surgery service of a large, academic tertiary care hospital. Subjects were recruited during one of two usability sessions in November and December 2015. Participants were eligible if they had a surgical incision longer than 3 cm and were close to their baseline functional status.

Table 1. User interface design dimensions from International Organization for Standardization (ISO) standard 9241-12 and corresponding WoundCheck design features.

Information display dimension	Definition	Method employed	Sample app design features
Clarity	Content conveyed quickly and accurately	Physician review; focus group	All app language validated by physician review panel (for clinical usefulness) and lay focus group (for interpretation)
Discriminability	Information is readily distinguished	Iterative redesign	Tap-only response options (no text entry or scrolls) Consistent 3D button placement below text Redesign of image capture screen to prevent errors and reduce wrong-button taps Color-coded buttons
Conciseness	No extraneous content	Focus group review of content	Yes or no questions for symptoms Draft language reviewed by focus group to reduce word count while retaining interpretation
Consistency	Information is presented in the same way consistent with expectations	Focus group review of layout; Iterative redesign	All response screens are identical Each module contains review screen prior to submission
Detectability	Attention is directed to salient information	Multidisciplinary design team; physician review	Image review screens to ensure quality image Feedback screens to track and confirm submission Buttons are 100x100 pixels (0.33 in) or larger Font fills the frame
Legibility	Easy to read content	Focus group test; iterative redesign	Readable Helvetica Neue bold font choice, size 26 or larger with high contrast display (black type on white background) Button shadowing
Comprehensibility	Meaning is unambiguous and clear	Focus group review of content; physician review	6th grade reading level Focus group read-back of app questions "in your own words" to ensure faithful interpretation Focus group feedback for image capture training

Subjects with major cognitive or neurologic deficits prohibiting their independent use of the app were included only if they had a capable caregiver who consented to complete the app on their behalf. All subjects who met inclusion criteria were approached to participate. Participants were asked regarding their prior experience with smartphones, whether they owned their own smartphone, and whether they had used a smartphone to take a digital image.

We aimed for a sample size of at least 5 participants, a number based on evidence from the usability literature indicating that 5 participants make a sufficient sample size to detect 80-85% of an interface's usability problems [29]. We continued to enroll purposively past our sample size goal to utilize the remaining time.

The University of Wisconsin Health Sciences Institutional Review Board approved the study protocol.

The App

WoundCheck is an iOS app that enables patients to capture digital images of surgical wounds and sends them to their providers from home, along with brief updates on postoperative recovery. This app was developed internally through the University of Wisconsin Department of Surgery with the assistance of software programmers in our Information Technology division. In designing the app, we consulted ISO 9241-12, an international standard for screen layout and the visual display of complex information, and established guidelines on user interface design to ensure that the user interface was easily navigated by our target population of older adults and novice users [30,31]. Table 1 summarizes the app's

features and the method of development vis-à-vis the salient dimensions of the ISO standard for user centered design including clarity of the content, discriminability of information, conciseness, consistency of presentation, detectability, legibility, and comprehensibility. The app is accompanied by a training program to be delivered prior to discharge that draws on evidence-based tenets of adult learning and memory retention (Table 2), in keeping with similar transitional care programs targeting older adults [32-34]. Among these tenets is the need for adult learners to feel actively engaged in the learning process,

to frequently receive positive reinforcement, and to set the pace of learning. We allowed ample time for questions and for participants to interject comments. We also allowed participants to use the smartphone and the app directly after a short demonstration, engaging visual, auditory, and kinetic forms of learning. Adult learners also require repeated exposure to new material and to have it presented in a variety of formats. Each participant received a training booklet that reinforced the steps of the app for reference if questions arose after discharge.

Table 2. Tenets of adult learning and memory and corresponding training design features.

Evidence-based dimension of adult learning	Sample training design features
Require more time to learn new skills [35]	Let participant set the pace of training
Need repetition and multiple formats of materials [36]	Repetition; supplementary flash cards; let participant develop own narrative around the device
Challenged by complex, unusual material [37,38]	Emphasis on purpose of training; emphasize “why” of tasks
Decline in motivation when not experiencing success [38]	Frequent positive feedback; opportunities to reflect and ask questions throughout
Repeated exposure facilitates learning [39,40]	Primary training session + refresher training prior to discharge
Cue-based recall [41]	Use of reminder alarm at the time of participant choosing as a cue to use app
Task performance (not just observation) with teach-back [41]	Provide a device to participant to use throughout training

The program is ultimately designed for use during the period between hospital discharge and the routine postoperative clinic visit. The app was designed to be linear with one pathway through the app to maintain simplicity and intuitiveness. There are 2 phases to the app: an image-taking phase where participants take digital images of their wound and have the ability to review or retake their images, and a brief survey with yes or no questions regarding their recovery. Screenshots of the app are provided in Figure 1, and survey questions are provided in Textbox 1.

To vet the content of the app and training and meet the burden of the ISO design standard, we conducted 2 focus groups to review the app with Community Advisors on Research Design and Strategies (CARDS). These are standing focus groups of community members from diverse racial, ethnic, socioeconomic, and educational backgrounds who are recruited from food pantries, senior meals, parenting programs, and other similar programs. They are trained to give constructive feedback to researchers, health educators, and outreach professionals. The CARDS members, the majority of whom are novice smartphone users, evaluated prototype screens of the app and all app

language in the first focus group. The image capture training protocol was evaluated in the second focus group.

Health Insurance Portability and Accountability Act Compliance

The app and transmission of patient data were developed to fully comply with the Health Insurance Portability and Accountability Act. A passcode is used to secure and encrypt the device. Each device is profiled, allowing us to remotely wipe the device, prevent the installation of additional apps, and limit other device features. No information is stored on the mobile phone itself; the app can only be used to submit information, not retrieve it. The app transmits data to the University of Wisconsin Department of Surgery research server using the Hypertext Transfer Protocol Secure (HTTPS; Figure 2). A unique nonmedical record number identifier is used for each participant. No identifying information is transmitted, and participants were instructed not to send pictures that included identifying marks or their face. If the participant is idle for more than 10 minutes during data collection, the app times out and the data is deleted. Only research personnel with responsibility to review images have access to the submitted images. The system automatically logs off users after 30 minutes of inactivity. Audit controls monitor access.

Figure 1. Screenshots of the final app. A. Modified camera screen. B. Image review screen where participants can choose whether to keep the image they have taken or try again. C. Review screen of all added images; up to 4 images may be added. D. A series of yes or no questions follow. E. Participants can review their survey responses and have the option to change them prior to submission. F. Submission confirmation screen.



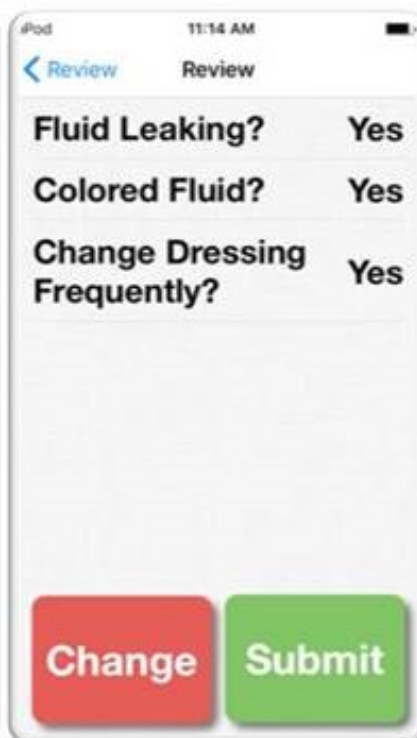
a.

b.

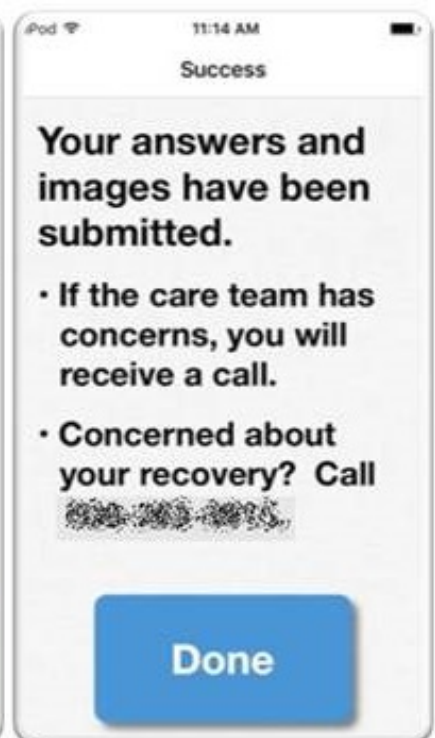
c.



d.



e.

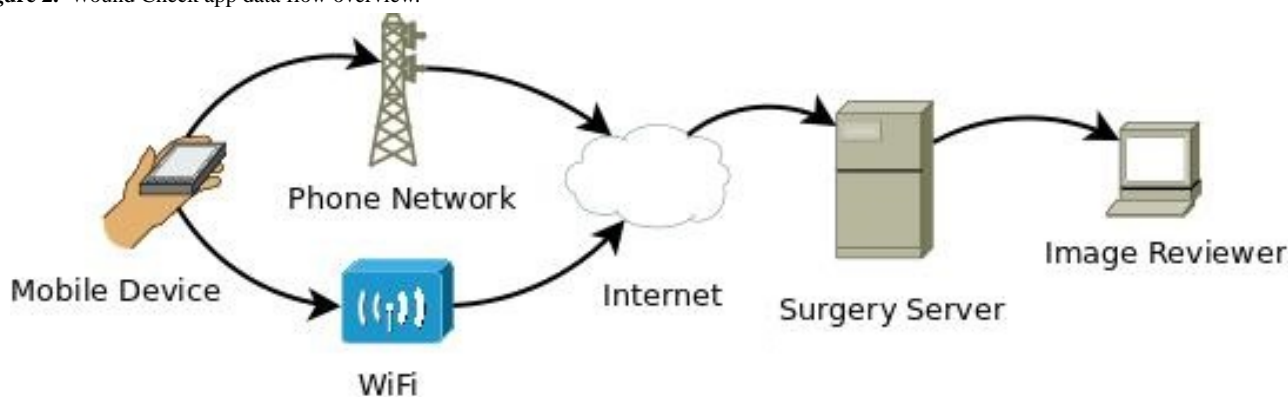


f.

Textbox 1. Questions included in the survey portion of the WoundCheck app.

1. Have you have fevers or chills in the past 24 hours?
2. Have you changed how you take your medication in the last 24 hours?
 - 2a. (If responded yes to 2) Is this change related to your pain medication?
 - 2b. (If responded yes to 2a) Did you increase your pain medicine?
3. Has the area around your wound become red in the past 24 hours?
4. Has the area around your wound become swollen in the past 24 hours?
5. Is there a bad smell coming from your wound?
6. Is fluid leaking from your wound?
 - 6a. (If responded yes to 6) Is the fluid white, yellow, or green?
 - 6b. (If responded yes to 6) Do you change the dressing more than once because fluid soaks through?

Figure 2. Wound Check app data flow overview.



User Tasks

Following preliminary design, we formally tested the usability of the app with postoperative vascular and general surgery patients at a major academic medical center. The app was loaded onto a 5th generation iPod Touch running iOS8. We assessed patients' baseline familiarity with smartphones prior to testing. A researcher introduced the device to participants with an overview of its general functions and how to operate it, if needed. User tasks included waking up the device, launching the app, image capture, review and retake or acceptance of captured images, question response, and submission. Following the first round of usability testing, an interim assessment of the app was performed and adjustments were made based upon the findings of the first round. The updated version of the app was then used for the second round of testing.

Measures and Analysis

We consulted ISO 9241-11 in designing the format for formal usability testing of the app [28]. Effectiveness (ie, the ability to

successfully complete each task independently and whether assistance was required) and efficiency (ie, the time needed to complete each task) were measured by direct observation and by mirroring of the device onto a research computer using the software AirServer (App Dynamic). The mirrored screen on the laptop was recorded using Morae (TechSmith) screen recording software. Training sessions were audio recorded for later review.

Following usability testing of the app, participants were asked to rate their performance and to provide feedback on the app itself. Participants also completed a system usability scale (SUS) to evaluate their satisfaction with the app (questions presented in Textbox 2) [42,43]. Images generated during the testing sessions were independently reviewed by 3 physicians to assess whether they could be used for diagnostic and treatment purposes. If a reviewer deemed an image as not usable, they were asked to provide a reason.

Textbox 2. System usability scale questions. Responses followed a 5-point Likert scale from “strongly agree” to “strongly disagree.”

Statement
• I think that I would like to use this app frequently
• I found the app unnecessarily complex
• I thought the app was easy to use
• I think that I would need the support of a technical person to be able to use this app
• I found the various functions of this app were well integrated
• I thought there was too much inconsistency in this app
• I would imagine that most people would learn to use this app very quickly
• I found the app very awkward to use
• I felt very confident using the app
• I needed to learn a lot of things before I could get going with this app

Results

Participant Characteristics

Of the 14 patients who were approached to participate, 5 declined due to time constraints or disinterest. Nine participants completed usability testing, 3 of whom had caregiver assistance or proxy participation. Five participants owned their own smartphone, and 7 had used a smartphone to take a digital image at least once prior to this study, leaving 2 who had no prior experience with smartphones. Demographics and basic clinical information are presented in [Table 3](#).

Four participants (44.4%) had abdominal wounds (an aortic graft explantation and an axillary-bifemoral bypass, 1; an aortobifemoral bypass, 1; an open distal gastrectomy, 1; and an open distal pancreatectomy and splenectomy, 1). Four participants (44.4%) had groin wounds (an aortobifemoral bypass, 1; bilateral groin explorations and repair of a common femoral artery aneurysm, 1; a superficial femoral artery graft resection and interposition graft placement, 1; and an endovascular aortic aneurysm repair, 1). Two participants (22.2%) had lower extremity wounds (bilateral lower extremity fasciotomies, 1; and a superficial femoral artery to posterior tibial artery bypass, 1). One participant (11.1%) had an amputation stump above the knee. Two participants had 2 wounds, bringing the total number of wounds to 11.

Table 3. Demographic and baseline characteristics.

Characteristic	n (%) or mean (SD)
Female, n (%)	5 (55.6)
Age (years), mean (range)	55.2 (19 - 80)
Race, n (%)	
White	6 (66.7)
African-American	2 (22.2)
Latino	1 (11.1)
Body mass index (kg/m ²), mean (range)	29.0 (17.4 - 43.65)
Insurance status, n (%)	
Private	4 (44.4)
Medicare	3 (33.3)
Medicaid	1 (11.1)
Uninsured	1 (11.1)
Incision site, n (%)	
Abdominal	4 (44.4)
Groin	4 (44.4)
Lower extremity	2 (22.2)
Amputation stump	1 (11.1)

Table 4. Effectiveness, efficiency, and satisfaction results of usability testing.

Participant	Training time (min)	Time to complete app independently (min)	Total time (min)	Required assistance?	Image deemed usable by majority of raters	SUS ^a score
Session 1						
P1	12.8	1.6	14.4	No	Yes (AKA ^b stump)	82.5
P2	2.7	3.1	5.8	No	Yes (Abdomen) Yes (Groin)	97.5
P3	6.4	16.6	23.0	Yes	No (Groin)	72.5
P4	2.2	2.4	4.6	No	Yes (Abdomen)	87.5
Session 1 mean (SD)	6.0 (4.9)	5.9 (7.1)	12.0 (8.6)			85 (10.4)
Session 2						
P5	2.4	1.4	3.9	No	Yes (BLE ^c fasciotomies)	82.5
P6	3.2	6.2	9.4	Yes	Yes (Groin)	87.5
P7	2.1	6.4	8.5	Yes	Yes (Lower extremity) No (Groin)	75
P8	8.0	4.7	12.7	Yes	Yes (Abdomen)	70
P9	2.9	2.2	5.1	No	Yes (Abdomen)	95
Session 2 mean (SD)	3.7 (2.4)	4.2 (2.3)	7.9 (3.5)			82 (9.9)
Overall						
mean (SD)	4.7 (3.7)	5.0 (4.7)	9.7 (6.2)			83.3 (9.6)

^aSUS: System Usability Scale (scored 0-100).

^bAKA: above the knee amputation.

^cBLE: bilateral lower extremity.

Effectiveness and Efficiency

Effectiveness and efficiency data are presented in [Table 4](#). The mean length of time spent with each participant for the full app training session, excluding study introduction and survey completion, was 9.7 minutes (range: 3.9-23.0 minutes). The mean length of time participants needed to complete the app independently was 5.0 minutes (range: 1.4-16.6 minutes). For all of these measures, the participants in the second round (ie, users of the updated version of the app) had better efficiency over the participants in the first round (ie, users of the app in its original form). Forty-four percent of participants needed prompting or assistance from a member of the research team to complete the app; 55.6% were able to complete the app in its entirety without assistance. Of the documented instances when researcher's assistance was given, 64% were related to taking images of wounds, most often related to participant positioning and navigating the device's camera functionality.

The most difficult task in the initial round of testing was to take a digital image of the wound. Participants were confused about the flow through the image-taking portion of the app, and they also faced difficulty with button placement. Specifically, the placement of the image capture button directly next to the cancel button led to image capture attempts that resulted in cancellation. In addition, the cancel button looped back to restart the app rather than sending participants forward even if they had already

captured an image. As a result of these difficulties, the image-taking portion of the app was redesigned to make it more intuitive, and the camera buttons were placed in more convenient locations on the screen to facilitate image capture ([Figure 3](#)). Following these adjustments, participants in the second round of testing had less difficulty with this section. Novice smartphone users also experienced confusion with changing the direction of the camera to face toward or away from them and required frequent reminders and assistance.

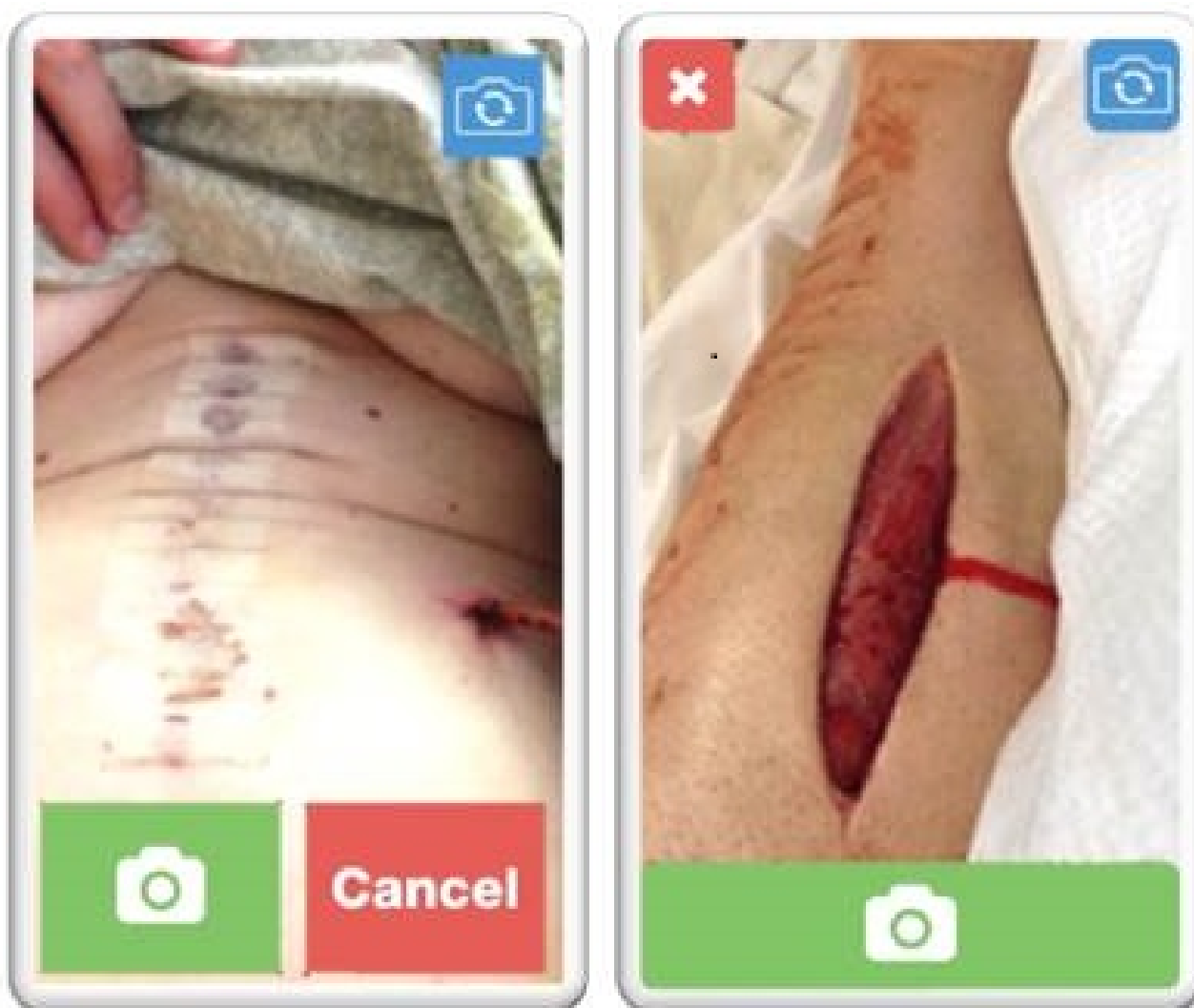
Participants with groin wounds, and particularly obese participants with groin wounds, had considerable difficulty taking images of their wound independently due to inadequate exposure of the wound. At least one other person was required to fully expose the wound, and even then, it was difficult to achieve the optimal angle for image capture. Participants who had active caregivers present were better able to perform this task without requiring researcher's assistance.

On assessment of image quality, 9 of 11 (81.8%) images were deemed sufficient for diagnostic purposes by a majority of rating physicians ([Table 4](#)). Five of 11 images had at least one physician rate it insufficient, primarily because the entirety of the wound was not visible in the image (scope). One of these was a patient who was too close to surgery to fully uncover and visualize her wounds. Another patient had the very top of his abdominal incision covered by his gown but otherwise had an

adequate image. A man with an amputation stump generated an image that had insufficient lighting for one rater to comfortably say whether there was erythema or ecchymosis, which was a function both of how wound healing appears in darker skin and the available light. The 2 wounds that the majority of raters found inadequate for clinical use were 2 of the 3 groin wounds; this was consistent with the participants' difficulty in taking the picture during usability testing, for the reasons stated above.

The survey task within the app was easy for all participants to use. On the initial round of testing, the screen for reviewing survey responses was scrollable, such that all responses appeared on a single screen, but some were not visible unless the participant scrolled to the bottom of the screen. This was confusing for some participants, as this was the only scrollable screen within the app, requiring mastery of a new functionality. The response review screen was revised in the second round of testing to be split into 2 screens to eliminate the need to scroll. After this adjustment, participants had no difficulty with this section.

Figure 3. Original and modified image-taking screen. On the left is the original camera screen with both the image-capture and cancel buttons at the bottom of the screen. On the right is the modified screen based on user feedback. The image-capture button takes up the whole bottom of the screen, but does not extend as far up into the screen, and the cancel button has been moved away from it to decrease button confusion.



Usability

The responses to the System usability scale (range: 0-100) are presented in Table 4. The overall usability score for the app was 83.3, which is considered good for usability testing [44]. Most participants found the app easy to use, though the questions that did not elicit a unanimous positive response (“I think I would need the support of a technical person to be able to use this app,” “I would imagine that most people would learn to use this app very quickly,” and “I needed to learn a lot of things before I could get going with this app”) indicate a degree of

tentativeness regarding participants' ability to independently complete the app. One participant said she would “probably have to write the steps down” to be able to complete it independently, though said she “didn't find it that complex once (she) got into it” and that she “would do it because we need to do it.” Another said she could imagine “a lot of people who would have all kinds of problems” learning to use the app.

These challenges were also observed during usability testing, particularly with novice users who, in addition to learning to use the app, needed more time to become comfortable using

the device itself. Four participants struggled with simply tapping the screen and alternating between tapping icons on the screen and pressing the home button; two came close to deleting the app by pressing the icon for too long rather than tapping it. As stated previously, novice users also struggled with using the camera, particularly with switching the direction of the camera to face them.

The most commonly cited concerns regarding the protocol were confidentiality of patient information and whether anyone in the care team would actually review the submitted images and survey responses. One participant was concerned “whether information (would be) followed through,” saying “you might have taken lots of pictures, but if no one looks at it, it’s all for nothing.” Other concerns raised were device battery life and difficulty being able to fully visualize the wound to take a digital image. Three participants stated they had no concerns. All 9 participants said they would be able to complete the app daily after discharge if they were given full instructions. One particularly enthusiastic participant said, “I wish I had it today.” All nine said they would benefit from a protocol using this app following hospital discharge. One participant said, “I think it’s really pretty neat...if you have a concern, you’ll get an answer like that.” Eight participants said they would recommend the app to a friend or family member if they had surgery, and one participant was neutral, saying “...that’s their decision.”

Discussion

Principle Findings

The current standard of care for the majority of surgical patients following hospital discharge involves little formal communication between patients and their care team until their routine clinic follow-up 2-3 weeks after discharge. This is a crucial time period during which many complications and setbacks to recovery occur, and is thus ripe for mHealth innovation [45]. Other mHealth protocols have been developed to improve patient monitoring or replace routine postoperative clinic visits [1,3,27]. However, these protocols are limited in their episodic follow-up, the lack of guaranteed provider review, or the lack of any transmitted visual information.

To address these gaps, we have developed a smartphone app that allows patients to be in daily communication with their provider with both subjective symptom data and visual information in the form of digital images. We have demonstrated that most patients and their caregivers are able to learn to use our app, can use it to transmit meaningful clinical information, and have a high level of satisfaction and enthusiasm regarding the protocol. Additionally, studying patients during the immediate postoperative period allows for the most conservative estimate of usability given that patients are still in recovery and may not be at their functional baseline. Given that our participants were mostly older adults, seen during the vulnerable postoperative period, some with very limited prior smartphone experience, the wide success we observed is encouraging for the ability of the general population to use the app without difficulty once given protocol-based training and clinical support at the outset.

Insights from the field of systems engineering provide a helpful framework for the development of mHealth protocols, as well as their attendant training programs. Work focusing on universal access and assistive technology for persons with disabilities is especially relevant for creating mHealth protocols accessible to a diverse patient population, particularly patients recovering from surgery, who are elderly or have limited prior experience with the technology, as in this study. Vanderheiden [5], a systems engineer with a focus in user experience optimization, outlines 3 approaches to assist in those efforts that are as follows: changing the individual, providing adjunct tools, and changing the environment.

For the purposes of our protocol, changing the individual involved tailored training, which we made modular so that portions could be added or skipped depending on the participant’s needs. As expected, the participants who struggled the most with the app were novice smartphone users and older participants. Most of this difficulty was in learning to navigate the smartphone itself and not necessarily related to the app. This was reflected in the responses to the system usability scale, where 11-20% of participants expressed needing to learn a lot before they could get going with the app or felt that they would need assistance of a technical person to complete it. Previous studies of mHealth apps have found similar results, with lack of familiarity with mobile devices and the need for assistance identified by participants as barriers to independent use [46-48]. As a result of this added difficulty, novice users of smartphones required dedicated training to become facile using the device before moving on to training specific to the app; those participants who were familiar with the device were able to skip this portion of training. This flexibility in training was envisioned prior to usability testing, but by doing formal usability testing, we were better able to identify components of the protocol that needed dedicated training and for which patients they were needed.

Importantly, efficiency of training should not come at the expense of effectiveness. Protocol training will need to be performed at the pace of the learner, taking care to keep them engaged. Two participants expressed training fatigue, with one saying, “I’m glad you’re getting out of here; that was time consuming” after 27 minutes of training, despite her not having fully mastered the task. Another said, “you mean we’re not done?” after 25 minutes of training. Bearing this in mind, future training efforts may need to be spread over multiple sessions both to reinforce tasks and to avoid fatigue and boredom with a single session.

The second approach for improving accessibility is to provide adjunct tools to overcome particular barriers to use. For participants who struggled with tapping the screen, a stylus may be easier and more intuitive than using their finger. One participant opted to do this on her own based on her prior experience using a stylus with her tablet device. Another barrier we encountered in our protocol was the difficulty experienced by patients with wounds in certain locations that were difficult to take an image of, particularly groin and abdominal wounds as well as amputation stumps. Potential tools to aid these patients might include training them to use selfie-sticks or mirrors to improve their ability to independently take images of wounds

in these locations. However, assistive devices or tools have the potential to add an additional layer of complexity for patients who are already uncomfortable with the device or the app, and this must be weighed against the potential benefit of their use. Because groin wounds are at increased risk of developing surgical site infection [49], these are the very patients who stand to gain the most from postdischarge wound surveillance, and every effort should be made to maximize their ability to participate, which may also include identifying a competent caregiver willing to assist.

Finally, user accessibility may be improved by changing the environment to be accessible to all users without the need for specialized devices or tailoring to the individual, an approach termed “universal design.” Following the first round of testing, we made several subtle but significant improvements to the design of the app itself to improve its usability for a wide range of users. The reconfiguration of buttons on the camera screen made capturing images easier for participants with limited fine motor ability or who had difficulty with discrete touch. We eliminated screens that required scrolling up and down to preclude novice users or those with cognitive limitations from having to learn an additional skill. In making these changes, the app becomes more accessible to all users, including those who did not have difficulty completing it prior to these modifications, by making it as simple and straightforward as possible. mHealth platforms in the future should strive for universal accessibility in their design to maximize participation and benefit.

One aspect of universal design we did not achieve was making the app compatible with an Android device. For those participants more familiar with Android technology than iOS, learning to use the app first required learning to use the device, a barrier not experienced by those participants who had used an iOS device in the past. This is particularly important given key demographic differences in smartphone ownerships, specifically that minorities, those of lower income, and those with lower educational attainment are more likely to own an Android device [50]. Future iterations of this app should be made Android-compatible to increase its usability for a wider range of patients.

However, despite our best efforts to incorporate these insights from systems engineering and develop a universal design for the app and for our training protocol, it is likely that some patients will still need the assistance of a caregiver to complete the app. Through usability testing, we identified several possible reasons why some might be unable to complete the app independently. Those patients who are novice smartphone users and are unable to learn to complete the app independently will by definition need assistance. Patients who have wounds in locations they cannot reach or cannot visualize sufficiently on their own will need a caregiver. Additionally, patients who have limited independence at baseline will need assistance, as with one of our participants who was a hemiparetic bilateral lower extremity amputee. In these cases, a competent caregiver or family member will need to be identified so that these patients may still benefit from mHealth protocols. These patients may already have a caregiver or involved family member due to their baseline functional status and reliance on others for aspects of their care.

Interestingly, participants consistently rated themselves as having successfully completed the app, even when their performance did not warrant such an assessment. When asked whether taking a digital image of their wound was easy to complete, only 2 participants were neutral, while all others agreed or strongly agreed. All 9 participants agreed or strongly agreed with the statement “I am confident I completed this task” in reference to taking a digital image of their wound, even the participants whose images were not sufficient for clinical decision making. Sonderegger et al [51] found a similar trend in their study of mobile phone usability in older adults. They posited several possible explanations for this finding. One was that this may have been a result of low expectations participants had for themselves, such that they overstated even small successes. Another was that participants may have felt that with practice they would eventually be successful, valuing their potential success over their actual success. This is an important finding, indicating that participants using new technology need to be carefully educated about what is expected of them and what constitutes meaningful success.

Despite these barriers, there was substantial enthusiasm from most participants about the protocol. One participant told the research team he wished he could take the device home upon discharge and use it to stay in contact with the care team. All participants thought they would benefit from this protocol and would be willing to complete the app daily if they were instructed to do so. This is consistent with previous studies of mHealth [11,26,52,53], which collectively indicate that patients and their caregivers are willing to participate in a variety of remote monitoring protocols, see such protocols as being potentially beneficial to them, and are satisfied when they participate.

In addition, the fact that many participants could ultimately complete the app independently or with caregiver’s assistance is encouraging. The overall usability score of 83.3 is above average for usability testing, indicating a level of comfort among first-time users of the app [54]. Following a short training session, most patients will be able to participate in a protocol using this app, though as stated above, certain populations will likely need more focused training.

This is the first study, to our knowledge, to formally investigate usability of a medical device with digital image taking capability using the ISO 9241-11 standards [28]. Our findings indicate that patients are capable of completing such an app and that there is broad enthusiasm for its use. However, increased attention will need to be paid to novice users and older adults who may need more extensive training before they will be able to complete mHealth protocols independently. Additionally, to avoid widening of existing disparities in access and health outcomes, health systems must ensure such protocols, if proven beneficial, are available to all patients and not only to those who already have access to the necessary technology. As health systems increasingly focus on improving transitions of care and maximizing outpatient management of complex patients, the ability to monitor recovery of conditions that have a physical manifestation, including fields beyond vascular and general surgery, this app and those similar to it have the potential to

revolutionize the way care is delivered in the postdischarge period.

The results of this study should be interpreted in the context of several limitations. Our study may be limited by its sample size. Considerable debate exists within the literature regarding the ideal sample size for usability testing. Historically, a sample of only 5 participants was thought to be of sufficient size, but more recent data suggests a larger sample is required to make accurate assessments [29,55-57]. However, the more recent estimates for ideal sample size were based on usability testing of more complex websites with multiple possible pathways. Given the simplicity and linearity of the app in this study and the diversity of the participants studied, we feel confident that all major areas for improvement within the app were identified and addressed in the redesign of the app. In addition, our results may be limited by the fact that data was collected only at one medical center; our findings may be specific to our patient population and need additional testing in other patient populations with different sociodemographic or cultural characteristics. Moreover, while the training was performed by a researcher for the purposes of this study, it is likely that this would need to be performed by a nurse in the clinical setting. Further work will need to be done

to examine implementation and feasibility of this protocol outside of a controlled research setting.

Conclusion

As postoperative lengths of stay decrease, health systems will need to become creative in their methods of monitoring patients in the outpatient setting. Many telemedicine protocols have emerged to address this goal, but ours is the first to add an asynchronous visual component through the use of digital images, whose power to efficiently convey vast amounts of information is unparalleled in today's standard of care. Additionally, by directly engaging with our patient population and making them active participants in their care, we participate in a growing movement toward patient-centered care and shared decision-making. We have demonstrated that the majority of patients can be taught to complete our app independently and that patients are enthusiastic about partnering with their providers in novel ways to optimize their recovery. Though the majority of participants had little difficulty completing the app, formal usability testing allowed us to identify components needing further improvement, providing invaluable information we could not have otherwise obtained. This argues strongly for the use of formal usability testing in the development of future novel protocols for patient-centered care.

Conflicts of Interest

None declared.

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Abbreviations

AKA: above the knee amputation

BLE: bilateral lower extremity

SSI: surgical site infection

SUS: system usability scale

Edited by G Eysenbach; submitted 23.05.16; peer-reviewed by K Kummerow Broman, M Georgsson; comments to author 11.07.16; revised version received 02.08.16; accepted 21.08.16; published 28.09.16.

Please cite as:

Gunter R, Fernandes-Taylor S, Mahnke A, Awoyinka L, Schroeder C, Wiseman J, Sullivan S, Bennett K, Greenberg C, Kent KC

Evaluating Patient Usability of an Image-Based Mobile Health Platform for Postoperative Wound Monitoring

JMIR Mhealth Uhealth 2016;4(3):e113

URL: <http://mhealth.jmir.org/2016/3/e113/>

doi: [10.2196/mhealth.6023](https://doi.org/10.2196/mhealth.6023)

PMID: [27683059](https://pubmed.ncbi.nlm.nih.gov/27683059/)

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Original Paper

The Effect of Smartphone Interventions on Patients With Chronic Obstructive Pulmonary Disease Exacerbations: A Systematic Review and Meta-Analysis

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Abstract

Background: The prevalence and mortality rates of chronic obstructive pulmonary disease (COPD) are increasing worldwide. Therefore, COPD remains a major public health problem. There is a growing interest in the use of smartphone technology for health promotion and disease management interventions. However, the effectiveness of smartphones in reducing the number of patients having a COPD exacerbation is poorly understood.

Objective: To summarize and quantify the association between smartphone interventions and COPD exacerbations through a comprehensive systematic review and meta-analysis.

Methods: A comprehensive search strategy was conducted across relevant databases (PubMed, Embase, Cochrane, CINHA, PsycINFO, and the Cochrane Library Medline) from inception to October 2015. We included studies that assessed the use of smartphone interventions in the reduction of COPD exacerbations compared with usual care. Full-text studies were excluded if the investigators did not use a smartphone device or did not report on COPD exacerbations. Observational studies, abstracts, and reviews were also excluded. Two reviewers extracted the data and conducted a risk of bias assessment using the US Preventive Services Task Force quality rating criteria. A random effects model was used to meta-analyze the results from included studies. Pooled odds ratios were used to measure the effectiveness of smartphone interventions on COPD exacerbations. Heterogeneity was measured using the I^2 statistic.

Results: Of the 245 unique citations screened, 6 studies were included in the qualitative synthesis. Studies were relatively small with less than 100 participants in each study (range 30 to 99) and follow-up ranged from 4-9 months. The mean age was 70.5 years (SD 5.6) and 74% (281/380) were male. The studies varied in terms of country, type of smartphone intervention, frequency of data collection from the participants, and the feedback strategy. Three studies were included in the meta-analysis. The overall assessment of potential bias of the studies that were included in the meta-analysis was "Good" for one study and "Fair" for 2 studies. The pooled random effects odds ratio of patients having an exacerbation was 0.20 in patients using a smartphone intervention (95% CI 0.07-0.62), a reduction of 80% for smartphone interventions compared with usual care. However, there was moderate heterogeneity across the included studies ($I^2=59%$).

Conclusion: Although current literature on the role of smartphones in reducing COPD exacerbations is limited, findings from our review suggest that smartphones are useful in reducing the number of patients having a COPD exacerbation. Nevertheless, using smartphones require synergistic strategies to achieve the desired outcome. These results should be interpreted with caution due to the heterogeneity among the studies. Researchers should focus on conducting rigorous studies with adequately powered sample sizes to determine the validity and clinical utility of smartphone interventions in the management of COPD.

(JMIR Mhealth Uhealth 2016;4(3):e105) doi:[10.2196/mhealth.5921](https://doi.org/10.2196/mhealth.5921)

KEYWORDS

pulmonary disease, chronic obstructive; telemedicine; smartphone; self care; disease progression; review; meta-analysis

Introduction

Chronic obstructive pulmonary disease (COPD) refers to a group of lung diseases that includes chronic bronchitis and emphysema. Often, the occurrence of COPD is associated with smoking [1]. The Global initiative for chronic Obstructive Lung Disease (GOLD) defines COPD as follows:

Chronic obstructive pulmonary disease (COPD), a common preventable and treatable disease, is characterized by persistent airflow limitation that is usually progressive and associated with an enhanced chronic inflammatory response in the airways and the lung to noxious particles or gases. Exacerbations and comorbidities contribute to the overall severity in individual patients [1]

The prevalence and mortality rates of COPD are increasing worldwide. Therefore, COPD remains a major public health problem. One of the major effects of COPD is a reduced physical activity level in the affected patients [2]. Although COPD is a preventable and treatable condition, it is the fourth leading cause of death in Canada [3].

GOLD defines a COPD exacerbation as an acute event characterized by a worsening of the patient's respiratory symptoms that is beyond normal day-to-day variations and leads to a change in medication [1]. An acute exacerbation of COPD has detrimental effects on lung function, health-related quality of life, and exercise capacity [4]. According to the Canadian Institute for Health Information, COPD now accounts for the highest rate of hospital admission and readmission among major chronic illnesses in Canada [5]. The Conference Board of Canada has stated that the combined direct and indirect costs of COPD will increase from just under \$4 billion in 2010 to roughly \$9.5 billion by 2030, an increase of 140% [6]. Dynamic modeling has shown that any intervention that can reduce the number of exacerbations in a population will have a substantial impact on morbidity and costs of COPD [6,7].

Current advances in smartphones have allowed for opportunities to provide effective health promotion and disease management interventions. Several published studies indicate that smartphones can deliver effective interventions among various age groups and diseases [8-11]. Moreover, interventions delivered via a smartphone may empower patients to play a more active role in managing their health [9].

Recent improvements in smartphones suggest a potential for integration into COPD management. Effective COPD management could delay disease progression, reduce acute exacerbations, and improve quality of life [12]. Wang et al stated that a mobile phone-based system could provide an efficient home endurance exercise training program to improve exercise capacity, strengthen limb muscles and decrease systemic inflammation in COPD patients [13]. Another study indicated that smartphone-based collection of COPD symptom diaries

allows patients to identify exacerbation symptoms at an early stage allowing for the opportunity for early intervention [14,15].

A thorough review of the literature is necessary to understand the gaps and challenges in the current use of smartphones in COPD management. It will inform the design of future smartphone apps that aim to limit COPD exacerbations. Therefore, we conducted a systematic review and meta-analysis to answer the following question:

In patients diagnosed with COPD, will using smart phone interventions, compared with not using smart phone interventions, reduce the number of patients that have at least one exacerbation?

Methods**Eligibility Criteria**

We included randomized controlled trials and quasi-randomized studies that used smartphone interventions in patients with COPD. A smartphone was defined as a mobile phone that performs many of the functions of a computer, typically having a touchscreen interface, Internet access, and an operating system capable of running downloaded applications. Some smartphone interventions can also include the use of medical devices that transfer data to the smartphone or a Web-based platform for monitoring and analysis. Studies define COPD exacerbations differently due to the lack of a universally accepted objective definition of a COPD exacerbation. Some investigators define COPD based on drug use, reported symptoms, or emergency admission. As a result, we based our definition of exacerbation according to the GOLD criteria:

COPD exacerbation is an acute event characterized by a worsening of the patient's respiratory symptoms that is beyond normal day-to-day variations and leads to a change in medication [1].

Studies that included additional medical conditions as well as COPD were retained if the outcomes specific to the COPD group were reported separately. All English and non-English language studies identified during the search were considered. Non-English language studies included an English abstract. The abstract was sufficient to apply the eligibility criteria. Observational studies, abstracts, and reviews were excluded. Studies without a control group were also excluded. Smartphones are carried everywhere, have constant Internet connections, and are used as communication devices. Therefore, studies that used only a tablet or Web-based intervention and not specifically a smartphone intervention were excluded.

Search Strategy

A comprehensive literature search was conducted in consultation with a librarian with experience in conducting systematic reviews. The literature search was run from the inception of each database until October 14, 2015 using the methods recommended by the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines [16]. Five

electronic databases: PubMed, Embase, Cochrane, CINHA, PsycINFO, and the Cochrane Library were searched for published article that studied the effect of smartphone interventions on COPD exacerbations. The references of all

included studies were examined for relevant articles. The researchers used key search terms to identify potential studies (see Table 1).

Table 1. Search terms for systematic review.

Search lines	Search terms
Line 1	(((((("obstructive lung disease"[Title/Abstract]) OR copd[Title/Abstract]) OR coad[Title/Abstract]) OR "chronic obstructive pulmonary disease"[Title/Abstract]) OR "chronic obstructive lung disease"[Title/Abstract]) OR "chronic obstructive airway* disease"[Title/Abstract])) OR (((("Lung Diseases, Obstructive"[Mesh]) OR "Pulmonary Disease, Chronic Obstructive"[Mesh]) OR "COPD, Severe Early-Onset"[Supplementary Concept]) OR "Pulmonary Emphysema"[Mesh]) OR "Bronchitis, Chronic"[Mesh]))
2. AND	((((((((((((((((((((((("mobile phone"[Title/Abstract]) OR "smart phone"[Title/Abstract]) OR smartphone[Title/Abstract]) OR "cell phone"[Title/Abstract]) OR "personal digital assistant"[Title/Abstract]) OR PDA[Title/Abstract]) OR microcomputer[Title/Abstract]) OR blackberry[Title/Abstract]) OR nokia[Title/Abstract]) OR samsung[Title/Abstract]) OR "i phone"[Title/Abstract]) OR iphone[Title/Abstract]) OR symbian[Title/Abstract]) OR windows[Title/Abstract]) OR INQ[Title/Abstract]) OR ipad[Title/Abstract]) OR "i pad"[Title/Abstract]) OR ipod[Title/Abstract]) OR "i pod"[Title/Abstract]) OR mhealth[Title/Abstract]) OR "mobile health"[Title/Abstract]) OR "m health"[Title/Abstract]) OR "m-health"[Title/Abstract]) OR app[Title/Abstract]) OR HTC[Title/Abstract]) OR samsung[Title/Abstract]) OR apps[Title/Abstract])) OR (((("Cell Phones"[Mesh]) OR "Computers, Handheld"[Mesh]) OR "Text Messaging"[Mesh]) OR "Telemedicine"[Mesh]))
3. AND	((("Disease Progression"[Mesh]) OR exacerbation[Title/Abstract])

Study Screening

Two authors (MA and WA) screened titles and abstracts for each unique citation. The screening process included removing duplicates and excluding studies that were not related to COPD or telemonitoring. The remaining full-text studies were then assessed for eligibility. Full-text studies were excluded if the investigators did not use a smartphone device or did not report on COPD exacerbations. The reviewers also included studies that reported the rate of COPD exacerbations in the intervention group but were not able to report the rate in the control group.

The remaining studies were assessed for potential bias according to the US Preventive Services Task Force (USPSTF) quality rating criteria [17]. Review of bias assessments were completed independently by 2 reviewers (MA and WA). Any disagreements arising between the reviewers were resolved by discussion until a consensus was achieved.

Data Extraction and Synthesis

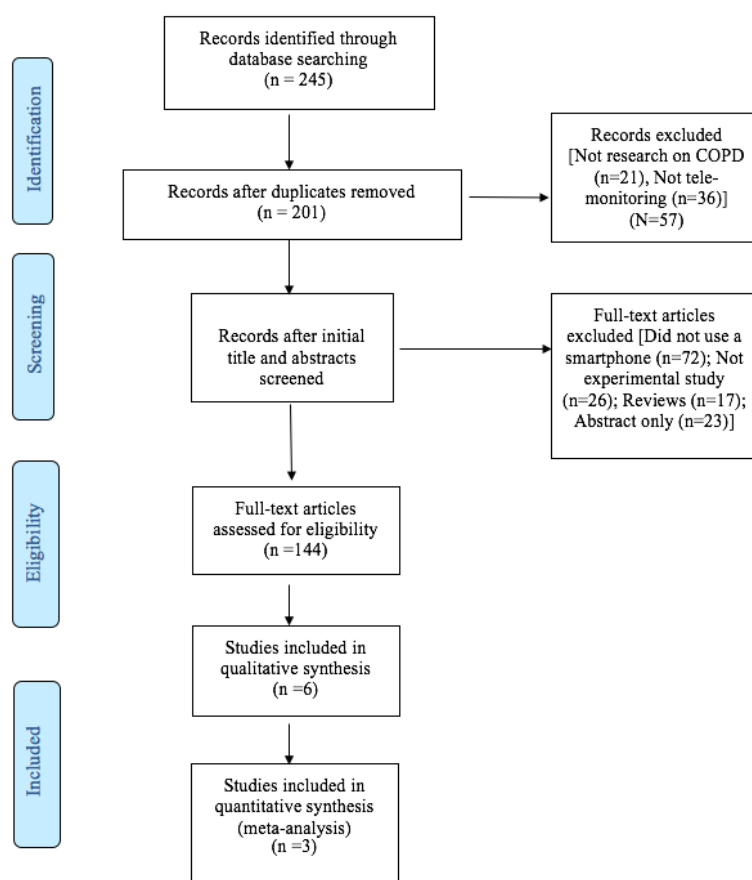
Data were extracted regarding the study design, study procedure, intervention, population demographics, and number of patients having an exacerbation. Two reviewers (MA and WA) extracted data independently. Data from 3 studies were pooled using Review Manager version 5.3 (The Nordic Cochrane Centre, The Cochrane Collaboration, Copenhagen) [18]. A random effects model was used to pool results from the included studies and calculate a summary odds ratio to measure the independent effect of smartphone interventions on COPD exacerbations. We tested for variance across studies using the chi-square test and measured the degree of heterogeneity using the I^2 statistic.

Results

Overview

The study selection process is outlined in Figure 1. The search process yielded 245 records, providing 201 citations after duplicates were removed. Of these, 6 studies met the eligibility criteria [19-24].

Figure 1. Preferred Reporting Items for Systematic Reviews and Meta-Analyses flow diagram of search results and study selection. COPD: chronic obstructive pulmonary disease.



Qualitative Analysis

Six studies were included in the qualitative analysis. Table 2 provides characteristics of the 6 included research studies [19-24]. All the articles were published after 2008. All of the studies were conducted on relatively small samples, less than 100 participants each. Some research studies specified the COPD severity stage according to the GOLD guidelines [21-23], whereas other studies included patients in all COPD stages [19,20,24]. Furthermore, patients were required to be free from COPD exacerbations for either at least 3 weeks [21] or one month [19,20,23,24] to be included in the research studies. Studies included older participants; the mean age was 70.5 years (SD 5.6). All studies had a large percentage of male participants (mean 74%).

Table 3 provides characteristics of the methodology used in the research studies [17-23]. The studies were conducted in various countries around the world. Five of the six included studies were randomized controlled trials [19-21,23,24], and one study used a quasi-experimental design [22]. Postintervention follow-up assessment for the included studies ranged between 4 months and 9 months. The smartphone in each study was primarily used to collect data about the daily symptoms of the patient. As a complement to the smartphone intervention,

education about self-management and exercise training [19,22,24] was also used in some studies. Participants used the smart phone to report physical activity level [24], daily symptoms [19-24], and heart rate and oxygen saturation [21]. One study provided a Web portal to enable patients to treat exacerbations themselves [24]. All studies compared a smartphone intervention versus usual care as the control group, except one study. Tabak et al provided both the intervention and control groups with a smartphone, but only the intervention group received automated phone calls to remind the participants about the treatment regimen and to ensure that they had sufficient medications [24]. All studies provided participants with a smartphone but did not report other incentives to participate in the study.

The frequency of collecting data from participants was different between studies. Symptoms and objective measurements such as spirometry and pulse oximetry were collected on a daily basis. Alternatively, physical activity data were collected weekly. The investigators assessed collected data on a daily basis. When an exacerbation was detected, patients were contacted to confirm the exacerbation. One study used an automated feedback mechanism that advised to start medication in case of an exacerbation [23].

Table 2. Characteristics of studies using smartphone interventions with COPD patients.

First author, (year)	COPD ^a stage	FEV ₁ ^b , mean (SD), % pre- dicted		Participant age (years), mean (SD),		Male sex, %		Sample size (analyzed)		No. of patients having an exacerbation	
		IG ^c	CG ^d	IG	CG	IG	CG	IG	CG	IG	CG
Tabak, (2014) [24]	All stages	48.7 (16.7)	56.4 (10.6)	65.2 (9.0)	67.9 (5.7)	57%	68%	15 (10)	15 (2)	33	N/R ^e
Pedone, (2013) [21]	II or III	52.5 (14.9)	55.4 (15.8)	74.1 (6.4)	75.4 (6.7)	72%	63%	50 (39)	49 (49)	9	15
Jehn, (2013) [23]	II-IV	50.2 (15)	52.6 (17.5)	64.1 (10.9)	69.1 (9.2)	81%	73%	32 (32)	30 (30)	7	22
Halpin, (2011) [20]	All stages	48 (4)	54 (3)	68.5 (1.5)	70.2 (1.6)	74%	73%	40 (39)	39 (38)	23	26
Nguyen, (2008) [19]	All stages	49.0 (16.8)	50.3 (17.6)	68.0 (8.3)	70.9 (8.6)	61%	55%	26 (20)	24 (19)	10	N/R
Liu, (2008) [22]	II or III	45.2(3.2)	46 (2.8)	71.4 (1.7)	72.8 (1.3)	100%	100%	30 (24)	30 (24)	2	10

^aCOPD: Chronic Obstructive Pulmonary Disease.

^bFEV₁: Forced Expiratory Volume in one second.

^cIG: Intervention Group.

^dCG: Control Group.

^eN/R: not reported.

Table 3. Summary of the methodology in studies using smartphone interventions with COPD patients.

First author, (year)	Design (Follow-up) Country	Intervention (Frequency)	Control
Tabak, (2014) [24]	RCT ^a (9 months) Netherlands	Short respiratory symptoms questionnaires, exercise program and self-management recommendations on the Web portal (Daily); Activity coach via an accelerometer and a smartphone (4days/week).	Usual care
Pedone, (2013) [21]	RCT (9 months) Italy	Heart rate, physical activity, near-body temperature, and galvanic skin response via wristband coupled with a smartphone (Every 3 hours); Oxygen saturation levels via a portable pulse oximeter (Every 3 hours). A physician contacted participants to provide feedback in case of abnormal readings (Daily).	Usual care
Jehn, (2013) [23]	RCT (9 months) Germany	COPD Assessment Test on the smartphone (Daily); Lung Function Tests via a portable spirometer (Daily). Six-minute walk test measured by accelerometer (Weekly). A study nurse contacted the participant to remind them about entering data (Daily).	Usual care
Halpin, (2011) [20]	RCT (4 months) United Kingdom	The Exacerbations of Chronic Pulmonary Disease Tool (EXACT) questionnaire on the smartphone (Daily); Automated phone calls to remind patients about the treatment regimen and ensure they have sufficient medication (Weekly).	EXACT questionnaire on the smartphone
Nguyen, (2008) [19]	RCT (6 months) United States	Exercise training program via smartphone (Daily); Short respiratory symptoms questionnaires on the smartphone (Daily). A study nurse contacted the participant to remind them about entering data and provide feedback (Daily).	Usual care
Liu, (2008) [22]	NRCT ^b (9 months) Taiwan	Home-based endurance exercise training program via smartphone (Daily); Short respiratory symptoms questionnaires on the smartphone (Daily).	Usual care

^aRCT: Randomized Controlled Trial.

^bNRCT: Nonrandomized Controlled Trial.

Quantitative Analysis

Three studies were included in the meta-analysis [21-23]. Two studies were excluded because they did not report the number of patients having an exacerbation in the control group [19,24], and another study provided a smartphone intervention to both the intervention and control groups [20]. The follow-up period for all 3 studies was 9 months. All 3 studies reported that participants receiving smartphone interventions experienced a reduction in COPD exacerbations [21-23]. Two studies used intention-to-treat analysis [21,23] and one study used per-protocol analysis [22]. The pooled odds ratio of patients having an exacerbation was 0.20 in the patients using a smartphone intervention (95% CI 0.07-0.62) compared with those receiving usual care. The meta-analysis of COPD

exacerbations indicates a reduction of 80% for smartphone interventions compared with usual care. There was moderate heterogeneity across the studies that were included in the meta-analysis ($\chi^2=4.9$, $P=.08$, $I^2=59\%$) [25]. The results are outlined in Figure 2.

Risk of Bias

A summary of the assessment of potential bias of studies selected for inclusion, using USPSTF Quality Rating Criteria, can be found in Table 4. The overall assessment of the studies that were included in the meta-analysis was Good [23] and Fair [21,22]. It was not possible to assess for publication bias via funnel plot asymmetry due to the low number of studies included in the meta-analysis [26].

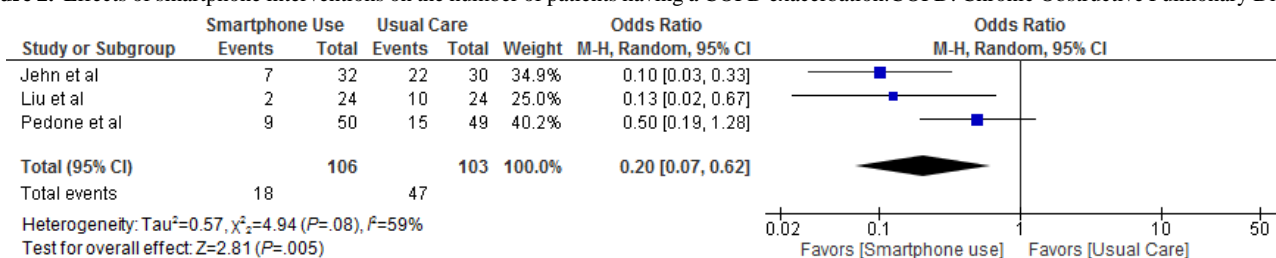
Figure 2. Effects of smartphone interventions on the number of patients having a COPD exacerbation. COPD: Chronic Obstructive Pulmonary Disease.

Table 4. Assessment of potential bias of studies selected for inclusion using USPSTF Quality Rating Criteria [16].

Study	Assembly of comparable groups	Maintenance of comparable groups	No important differential loss to follow-up or overall high loss to follow-up	Measurements: equal, reliable, valid (includes masking of outcome assessment)	Clear definition of interventions	All-important outcome considered	Analysis: adjustment for potential confounders	Overall assessed quality
Nguyen (2008) [19]	Good	Fair	Good	Fair	Good	Good	Poor	Fair
Halpin (2011) [20]	Good	Good	Fair	Fair	Poor	Fair	Fair	Fair
Pedone (2013) [21]	Fair	Good	Good	Fair	Good	Fair	Good	Fair
Liu (2008) [22]	Fair	Good	Fair	Fair	Good	Good	Fair	Fair
Jehn et al (2013) [23]	Fair	Good	Good	Fair	Good	Good	Good	Good
Tabak (2014) [24]	Poor	Fair	Poor	Fair	Good	Good	Fair	Poor

Discussion

Principal Results

The existing literature indicated that there is a potential for smartphone interventions in reducing the frequency of COPD exacerbations. Although most COPD patients were older than 65 years, they were able to use smartphones to monitor their symptoms. Rates of COPD exacerbations among participants receiving a smartphone intervention during the trials proved to be less compared with the participants not receiving a smartphone intervention. The main objective for using a smartphone is early identification of COPD exacerbations. Early identification allows the patient and health care team to intervene successfully, thus improving the management of COPD and reducing COPD exacerbations. As stated previously, Najafzadeh et al indicate that any intervention that reduces the number of exacerbations has a substantial impact on morbidity and costs of COPD [6].

Our finding that smartphones could be useful in reducing COPD exacerbations replicates the findings of 3 cohort studies. Jarad and Sund coupled a smartphone with a portable spirometer and indicated that it reduced the number of hospitalizations for COPD exacerbations [27]. Johnston et al showed that smartphone-based collection of COPD symptom diaries allows patients to identify exacerbation symptoms early on in the exacerbation allowing for early intervention [14]. Furthermore, Ding et al conducted a cohort study of a mobile phone-based home monitoring system and demonstrated the potential of smartphones in early identification of COPD exacerbations [28]. Thakkar et al conducted a systematic review and stated that

mobile phone text messaging approximately doubles the odds of medication adherence in patients with chronic diseases [29]. Smartphones can incorporate text-messaging interventions in addition to various interventions that include, but are not limited to, surveys, reminders, and the ability to be paired with medical devices.

Risk of Bias

Although the included studies reported promising results, there was moderate heterogeneity ($I^2=59\%$) across studies that were included in the meta-analysis. Liu et al [22] did not randomize patients to the intervention while the other 2 studies conducted randomized controlled trials [21,23]. The studies also varied in location, COPD severity, smartphone intervention, frequency of data collection from the participants, and the feedback strategy.

In many studies, the smartphone intervention was combined with different variations of symptoms diaries, physiological monitoring, and educational elements directed at patients. Patients used the smartphone to report daily symptoms [22,23] or deliver a home-based exercise training program [21]. In addition, investigators coupled the smartphone with various medical devices to measure physical activity levels [21,23], heart rate and oxygen saturation [21], and pulmonary function tests [22]. Each intervention, patient education or use of medical devices, could itself account for the differences between groups. Therefore, researchers should be cautious when interpreting the synergistic effect from the combination of these interventions.

The frequency of data collection from participants and feedback strategy also differed between the studies. Liu et al collected

data from participants every day [22]. The data was reviewed weekly and feedback was given to participants during their three-month follow up visits. Jehn et al collected data from participants every day and physicians reviewed the data daily; however, the feedback strategy to patients was unclear [23]. Pedone et al collected data more frequently than other studies due to the use of the wristband and portable pulse oximeter [21]. Unusual data were flagged and physicians assessed the data on a daily basis. Then, physicians contacted the participants to assess for a COPD exacerbation and suggest an intervention.

Only 2 studies reported on metrics related to user experience [19,24]. Nugyen et al conducted semistructured interviews with participants at the end of the study [19]. Participants were asked to provide feedback on what aspects of the program were most or least helpful for managing their dyspnea and how the program could have been done differently to support self-management. On the other hand, Tabak et al used the Client Satisfaction Questionnaire to measure user satisfaction [24]. Unfortunately, we were unable to combine the usability results due to the differences in the methods used to measure user experience.

The frequency of data collection from the participant was also dependent on the type of data being collected. Symptoms were collected daily while exercise progress was assessed weekly. Collecting data from participants frequently could yield more accurate data; nevertheless, it must not compromise the participant's adherence to the intervention. There are many factors that could have caused the reduction in COPD exacerbation. Early detection of symptoms and timely treatment could be possible by the use of smartphones or due to phone contact by the research team. Currently, we are uncertain whether the reduction in the number of patients having an exacerbation is caused by the smartphone intervention or merely due to bias among the studies. Additional investigations are required before large-scale implementation of smartphone interventions.

Limitations

Aside from the methodological heterogeneity among studies, there are several limitations with this systematic review. There are a limited number of studies using smartphones in the management of COPD exacerbations, each with relatively small samples, less than 100 participants each. A comprehensive search strategy was used, but studies utilizing smartphones in

the management of COPD exacerbations that are still in progress or provided only an abstract were excluded. All investigators provided a smartphone to participants. This could have caused highly motivated participants who are familiar with smartphones to contribute data. Another limitation is that studies did not clearly define exacerbations (recognized and unrecognized) and how to identify it (eg, drug use, reported symptoms, and emergency admission). Tabak used a self-management Web portal to measure exacerbations, which could have yielded many false positive results. The review favored smartphone interventions across all studies, thus overall findings do indicate that smartphone interventions may reduce the number of patients having COPD exacerbations across a wide variety of contexts.

Implications for Future Research

Implementing a mixed methods research design to investigate the validity and clinical utility of smartphone interventions could help to understand why a particular component is successful and how patients will use smartphone interventions for a long-term. There is limited research regarding smartphone interventions among COPD patients. Although the studies in this review have a small sample size and a relatively short follow-up period, current literature supports the potential of smartphones in reducing COPD exacerbations. There is a need for more studies evaluating smartphone interventions, including studies using smartphones as the main intervention. This will assist in determining whether smartphones can be effective in the management of COPD. Investigators should include participants with different stages of COPD severity and age spans to minimize the risk of bias and enhance the generalizability of the study results.

Conclusion

Although the current literature on the role of smartphones in reducing COPD exacerbations is limited, our results suggest that smartphone interventions may reduce COPD exacerbations. Nevertheless, using smartphones require synergistic strategies to achieve the desired outcome. The results should be interpreted with caution due to the heterogeneity among the studies, risk of small study bias, and limitations in study quality. Researchers should focus on conducting rigorous randomized controlled trial (RCT) studies with adequately powered sample sizes to determine the validity and clinical utility of smartphone interventions in the management of COPD.

Acknowledgments

We acknowledge the assistance and feedback we received from Dr. Marshall Godwin and Dr. Douglas Dorward. We would like to thank Mrs. Michelle Swab for her assistance in designing the search strategy. JMG holds a New Investigator Award from the Canadian Institute of Health Research and a Clinician Scientist Award from the Canadian Diabetes Association.

Conflicts of Interest

None declared.

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Abbreviations

CG: Control Group

COPD: Chronic Obstructive Pulmonary Disease

FEV1: Forced Expiratory Volume in one second

GOLD: Global initiative for chronic Obstructive Lung Disease

IG: Intervention Group

N/R: Not Reported

NRCT: Nonrandomized Controlled Trial

PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses

RCT: randomized controlled trial

USPSTF: US Preventive Services Task Force

Edited by P Morita; submitted 28.04.16; peer-reviewed by J Thakkar; G Spina; comments to author 10.06.16; revised version received 27.07.16; accepted 16.08.16; published 01.09.16.

Please cite as:

Alwashmi M, Hawboldt J, Davis E, Marra C, Gamble JM, Abu Ashour W

The Effect of Smartphone Interventions on Patients With Chronic Obstructive Pulmonary Disease Exacerbations: A Systematic Review and Meta-Analysis

JMIR Mhealth Uhealth 2016;4(3):e105

URL: <http://mhealth.jmir.org/2016/3/e105/>

doi: [10.2196/mhealth.5921](https://doi.org/10.2196/mhealth.5921)

PMID: [27589898](https://pubmed.ncbi.nlm.nih.gov/27589898/)

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Original Paper

User-Centered Design of a Tablet Waiting Room Tool for Complex Patients to Prioritize Discussion Topics for Primary Care Visits

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Abstract

Background: Complex patients with multiple chronic conditions often face significant challenges communicating and coordinating with their primary care physicians. These challenges are exacerbated by the limited time allotted to primary care visits.

Objective: Our aim was to employ a user-centered design process to create a tablet tool for use by patients for visit discussion prioritization.

Methods: We employed user-centered design methods to create a tablet-based waiting room tool that enables complex patients to identify and set discussion topic priorities for their primary care visit. In an iterative design process, we completed one-on-one interviews with 40 patients and their 17 primary care providers, followed by three design sessions with a 12-patient group. We audiorecorded and transcribed all discussions and categorized major themes. In addition, we met with 15 key health communication, education, and technology leaders within our health system to further review the design and plan for broader implementation of the tool. In this paper, we present the significant changes made to the tablet tool at each phase of this design work.

Results: Patient feedback emphasized the need to make the tablet tool accessible for patients who lacked technical proficiency and to reduce the quantity and complexity of text presentation. Both patients and their providers identified specific content choices based on their personal experiences (eg, the ability to raise private or sensitive concerns) and recommended targeting new patients. Stakeholder groups provided essential input on the need to augment text with video and to create different versions of the videos to match sex and race/ethnicity of the actors with patients.

Conclusions: User-centered design in collaboration with patients, providers, and key health stakeholders led to marked evolution in the initial content, layout, and target audience for a tablet waiting room tool intended to assist complex patients with setting visit discussion priorities.

(*JMIR Mhealth Uhealth* 2016;4(3):e108) doi:[10.2196/mhealth.6187](https://doi.org/10.2196/mhealth.6187)

KEYWORDS

primary health care; chronic disease; computers, handheld; mobile applications; medical informatics; health communication

Introduction

Complex patients with two or more concurrent health conditions represent almost a third of Americans, including 80% of those aged 65 or older, and this number is growing rapidly as we face an increasingly aging and chronically ill population [1]. Complex patients make up almost three-quarters (71%) of total health care spending in the United States, and patients with multiple conditions face a variety of poorer outcomes such as decreased quality of life and increased mortality [2-5].

A large body of evidence suggests that improving patient-provider communication during primary care visits can lead to better clinical outcomes for complex patients with chronic illness. For example, patients with diabetes who see providers with shared decision-making styles are more likely to receive appropriate screening tests [6], and those who report high provider communication ratings have better self-care behaviors [7], physical and mental functioning, and glycemic control [8]. However, the current health care setting, with short face-to-face visits and high numbers of competing demands that require discussion, presents significant challenges for both patients and providers to achieving high-quality communication during visits [9,10]. Particularly for complex patients who make multiple shared decisions with their provider during the same visit, limited time during visits presents a significant obstacle to effective communication [11].

Given these challenges, our team sought to design a technology solution to facilitate visit communication between complex patients and their primary care providers. Mobile health tools like tablets offer a well-matched strategy for improving communication in a way that minimizes impact to the clinician workflow and better utilizes patients' time in clinic [12]. Tablets in the waiting room are being increasingly used to (1) educate patients about specific health topics and (2) collect patient-reported outcome data to inform care [13]. We focused on designing a tablet app to assist patients with prioritizing their top health concerns for their next in-person visit to optimize the

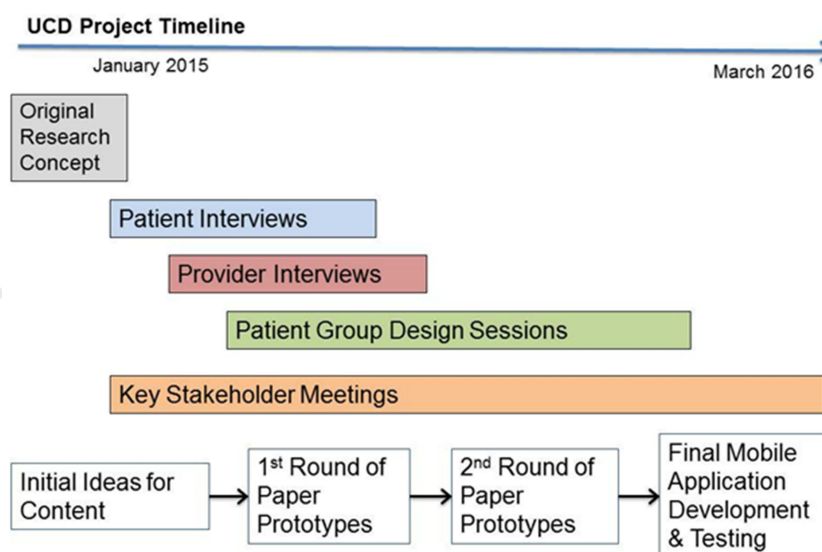
limited time patients and providers have together. To achieve this goal, we employed a user-centered design process to create a tablet tool for visit discussion prioritization that would be used in the clinic waiting room. We also assessed key stakeholder opinions to plan for broader dissemination of the tablet tool once built because we were well aware of the challenges in widespread adoption of technology within existing clinical settings [14]. We outline here the main findings from this qualitative work with a focus on the specific design changes that emerged from our user-centered design approach.

Methods

Funded by a 3-year contract from the Patient-Centered Outcomes Research Institute, we planned a clinical trial intervention to help complex patients more effectively prepare for time-limited primary care visits using a tablet-based waiting room tool. The creation of this tool in the first year of the project was informed by user-centered design methodology. Borrowing from the fields of industrial and human factors engineering, user-centered design involves understanding the needs, values, and abilities of users to improve the quality of users' interactions with and perceptions of the technology [15,16]. In practice, this involves creating a technology-delivered solution based on iterative direct user input to improve the ultimate usability of the final product before it is implemented in a real-world setting.

Our user-centered design process included close work with three distinct stakeholder groups: complex patients; their primary care providers; and key leaders in health communication, education, and health technology implementation within a large integrated delivery system. We used three types of qualitative data collection approaches: one-on-one interviews with patients and providers, patient focus groups, and key informant discussions (discussed in detail below). Figure 1 outlines the steps that take the original funder research concept to the final product—through several stages of the user-centered design process.

Figure 1. Stages of the user-centered design process.



Study Setting

The patient and providers who participated in interviews represented primary care practices in three large health care systems across the United States: Kaiser Permanente Northern California, Kaiser Permanente Colorado, and University of Michigan, Ann Arbor. We partnered across institutions to ensure diverse representation that was not limited to a single geographical area. All of these health care systems care for large populations of medically complex patients, and investigators at each site invited patients and providers from multiple primary care practices to participate in the study. The second phase of the iterative design process (ie, focus groups and key informant meetings) was held exclusively within Kaiser Permanente Northern California, which was the primary research and implementation site for this project.

In-Depth Interviews With Patients and Providers

In early 2015, we conducted in-person interviews with 40 patients and their 17 primary care providers: 12 patients and 5 providers from Kaiser Permanente Northern California, 13 patients and 8 providers from Kaiser Permanente Colorado, and 15 patients and 4 providers from the University of Michigan, Ann Arbor. All patients were diagnosed with two or more existing chronic conditions. Patients were selected as being medically complex by their primary care providers to ensure a high level of medical need among the sample, but the specific diagnoses of all patients were not recorded.

Patient interviews each lasted approximately 45 minutes and covered the following topics: (1) current planning processes for primary care visits, (2) usual experiences in setting a visit agenda with primary care providers, (3) interest in using a tablet in the waiting room, (4) how helpful it would be in setting their priorities for the visit, (5) what kind of support they would need before using the tablet for the first time, and (6) as the tablet was developed, what if anything about the content they would change. Providers of these patients were also interviewed regarding areas of commonality and differences in how visits should ideally be conducted and to provide specific feedback on the design of a tool to meet their workflow needs.

Patient Focus Groups

In the second phase of the project, we conducted three 60-minute focus group sessions. These sessions were held at Kaiser Permanente Northern California using the same recruitment criteria outlined above (N=12, with repeat attendance by most patients). The primary goal of these focus group sessions was to revise a paper-based prototype of the tablet tool in which patients were shown printed screenshots of the tablet content to elicit their direct input as the design unfolded.

Key Informant Discussions

We met with key informants throughout 2015 to similarly iterate the design of the tool, and we took detailed notes at each meeting to document the suggestions made for the tool. These meetings at Kaiser Permanente Northern California included Medicine Chiefs Steering Committee, Division of Research Information Technology team, the Permanente Medical Group technology group, Technology Multi-Media design team, the Regional Health Education team, Technology User Testing group,

Communication Consultant group, and the Senior Advisory Council. We used these key informant sessions to identify design issues related to implementation and dissemination of the tablet tool, alignment with health care system priorities, and internal design and use case standards.

The stakeholders were also critical in the prototype testing of the tablet app in its various iterations, giving feedback on first the paper-based prototypes and then helping us to conduct the final prototype testing of the app once the programming was complete. More specifically, we provided key staff in the Technology User Testing and Technology Multi-Media teams with tablets with versions of the tool loaded. These individuals (in addition to 3 key research team members) clicked through all screens and available selection choices in a thorough user testing and evaluation of the more final tablet product.

Analysis

All interview and focus group discussions were audiorecorded and professionally transcribed for analysis. For the multisite interview analyses, 3 coders (one at each site: NC, DM, and CK) collectively identified all comments relating to the design of the tablet tool and conferred with a fourth coder (CRL) to isolate patterns across sites. For the focus group analysis, all design and content modification recommendations that emerged from the group design sessions were reviewed and then categorized collaboratively by 2 members of the research team (CRL and RWG).

We organized the overall themes separately from the patient interviews, provider interviews, and patient focus groups, generating both major design theme categories and subtopics from all three sets of data. We also identified a series of exemplary quotes that reflected the topic and subtopics.

Implications for Tablet Design

We documented major changes we made to the tablet's design and content, informed by the user-centered design themes uncovered in our qualitative work. During this process, we used the meeting notes from the key informant discussion process in combination with the qualitative data to map the evolving tool content and design over time. As a part of this process, we saved the iterations of the prototypes to document changes as the design emerged.

Results

Interviews and Focus Groups

The patients in the baseline interviews across the three sites represented a mix of age, sex, and races/ethnicities. At Kaiser Permanente Northern California, the mean age was 66 (range 41-86), 67% (8/12) were female, and 67% (8/12) were white. At Kaiser Permanente Colorado, the mean age was 73 (range 57-84), 77% (10/13) were female, and 92% (12/13) were white. At the University of Michigan, the mean age was 70 (range 42-92), 40% (6/15) were female, and 87% (13/15) were white. Principal patient one-on-one interview themes are shown in [Table 1](#). Patients were concerned about the level of technology proficiency needed to use the tool and gave specific advice about making the tool easy to use, such as adding audio

instructions to walk patients through the content. They also had many specific recommendations for types of discussion topics that the tablet could trigger or prompt patients to select as they prepared for the visit, such as listing chief complaints/symptoms as well as a place to write down a sensitive issue that might be difficult to bring up. Finally, they suggested groups of complex patients for whom the tool would be most useful, stating that those who were already well organized or had productive communication with their primary care provider would not likely benefit from the tool. Despite broader comments where patients highlighted different workflows across the various clinic sites, there were not major differences in the tablet-focused themes reported here.

In parallel with the patient interviews, we asked the primary care providers of interviewed patients to answer similar questions about the agenda and priority-setting process (Table 2). Providers gave additional feedback about the content

categories for a tablet tool, echoing the patients' sentiments that this tool may be able to elicit more embarrassing or sensitive issues. These issues could otherwise be overlooked because the tool itself was viewed as a way to normalize sensitive topics as common for many patients. In addition, the providers specifically recommended the tablet as a medium to deliver brief education to patients about bringing up the top concerns to be addressed at the beginning of the visit to ensure the best use of the encounter time. Providers also suggested specific types of patients for whom the tool would be most relevant and mentioned new patients or those who recently switched their primary care providers as an important audience. Finally, providers preferred that we limit to two the number of priorities that could be highlighted by patients. To accommodate this limit, we made clear in the first brief coaching video (of two) that these two topics were simply to help start the visit and that patient could always bring up additional concerns as needed.

Table 1. Patient interview findings.

Category	Subtopic	Example quote(s)
Challenges for patients with limited technology proficiency	Patient lacks skills to use a tablet	<p>"I finally bought an iPad not too long ago and I still don't even know how to use that. I don't know much about computers."</p> <p>"Yeah, I'm not sure how many elderly people can use an iPad. I will ask you that, because I have friends who are my age or older. They don't have a computer. They're not computer-savvy. They don't want to learn."</p>
	Suggestions to make tablet easier to use	<p>"Can [the tablet tool] be like something like [what I have] on my phone: you have 'speak' and 'talk'?"</p> <p>"Well, if you eliminated the writing part [for entering information into the tool], it's okay."</p>
Patient recommendations for content of Pre-Visit Tool	Elicit simple lists of ongoing or new problems	<p>"What am I here for?" You know, "What is my major complaint?"</p> <p>"I don't mind checking when you give me a pad and it says 'Check off what's wrong with you.'"</p>
	Provide a way to bring up topics patients might overlook	<p>"Maybe [I want to see on the tablet tool] some things that I wouldn't think of that would be related to what I'm dealing with."</p> <p>"I may need, like, you know, a trigger: Oh, yeah, you know, I did want to ask about this."</p>
	Provide opportunities for personalized information/education	<p>"It depends on how the information is presented to a patient... then it could be an educational experience."</p> <p>"Yeah, after you teach them how to use it... If I knew what I was doing, you know. If somebody tells me."</p>
	Provide a safe place to bring up sensitive topics	<p>Patient would add to the list of topics on the tablet: "Are there any issues you're dealing with that maybe you're hesitant to bring up?"</p> <p>"You know there's some things that you don't, even with, even with Dr. [PCP] you know that you may not feel comfortable bringing out and maybe if you could write it down that maybe actually helpful in your treatment."</p>
Recommendations for which patients should not receive tool	Those who are very stable	"I could see how people who don't really know what is wrong could find that useful, but my conditions have been the same for 15 years now. Nothing has really changed."
	Those with clear communication with provider already	"I'm doing all that right now by the email. And if he [my doctor] reads them, he knows what I'm talking or thinking about."

Table 2. Provider interview findings.

Category	Subtopic	Example quote
Provider recommendations for content of Pre-Visit Tool	Prioritize the most important health concern(s)	“Let’s get your most important issue out first.”
	Helps with sensitive issue discussions	“If they got to write it [a sensitive topic] down, they maybe potentially feel more comfortable letting it flow.”
	Want to see the entire list of patient concerns	“I like to actually see it [the whole list] so I know, you know, how much is there that we’re going to have to get through?”
Recommended role in preparing patient for time-limited encounter	Help set expectations/priorities	“I want you to choose which is priority to you today, because I don’t think I can go through all these problems today.”
	Help patient focus on long-term health issues	“Too much time spent on ‘urgent & not important,’ not enough time spent on ‘not urgent & important.’”
	Emphasize the importance of next steps/follow-up	“Think about what your health goals might be going forward... a lot of times the patients have not thought about it.”
Recommendations for which patients should receive tool	Some patients need more time to complete it	“It would probably work better if [my patients] had it at home somehow and they could complete it and then either bring it with them or send it in advance.”
	Especially helpful for new patients	“But, I am having brand-new patients added every day and, really, honestly, sometimes, this focus [on their top priorities for the visit] is very important.”

Focus group participants were primarily women (n=9, 75%) and an average age of 71 years. For the focus group sessions, patients reviewed iterative versions of the tablet tool prototype. At this stage in the design, the groups gave very specific feedback about the length of time to complete, the simplicity of wording used, and the final layout (Table 3). As one example

of wording changes, we originally used the language of “documenting the care plan” as a goal for patients and providers to work on during the visit. However, patients thought this meant the type of insurance coverage they had rather than the treatment decisions made during the visit, and we therefore renamed this to “plan for your treatment,” which was clearer.

Table 3. Patient focus group feedback.

Category	Example quote
Shorten tool length	“I like to just zip through things, and just give me the basics. Don’t extrapolate.”
	“That’s what I’m talking about. I guess getting to the short point of it.”
Simplify/clarify wording	“I’m focusing in on what I’m hoping to get from this visit, and I wouldn’t know what ‘form filled out’ meant.”
	Most preferred terminology of “concerns” over “issues.”
	They didn’t like describing the tool as “private” (as it doesn’t mean much in this day and age), but stating that the information “will not be shared with anyone” is clearer.
Improve the layout	Other word suggestions included the use of first person: “we” or “us.”
	“I need to have something visual. I’m not a hearing learner. I’m a visual person.”
	They felt that skipping should be possible in case people didn’t want to fill something out
	They gave positive feedback about having the doctor’s picture on the first page with the patient’s name: “You gave it some thought. You know my name.”
	Instead of a progress bar, they suggested “Page 2 of 5” or “Step 1 of 5.”
	They needed more clarity about the conclusion of the tool: “Patients need to know what to do going forward”; “Say something like ‘Please share this with your doctor’ or ‘Remember to bring up this list at the beginning of your visit.’”

Key Stakeholder Meetings

During the stakeholder meetings, we identified additional design areas that could be modified. Stakeholder groups provided essential input on the need to combine text with video to reinforce patient learning and to employ first-person pronouns to help engage patients. They also suggested allowing patients to choose videos at the start of tool by offering several options that showed individuals of different sexes and races/ethnicities,

which also increased the personalization of the patient experience when using the technology.

One of the other major findings from the key informant meetings was the critical importance of both executive and clinical leadership support to enable more seamless implementation of the tool into existing clinical workflows. More specifically, the buy-in achieved in these meetings allowed us to consider other provider workflow considerations for use of the tool in

real-world practice and to jumpstart the Spanish language adaptation of the tablet app to expand the reach of the project for a larger patient population.

Finally, the stakeholder prototype testing allowed us to identify long lists of potential bugs and incorrect sequencing of information to fix on the more final version of the tablet tool. Their assistance also allowed us to verify that the information entered by patients was being populated and stored correctly on our servers. These final prototyping steps were critical to the launch of the subsequent randomized trial phase of this project.

Design Changes to the Tablet Tool

These qualitative findings were used in concert with the key informant meeting results to inform major design decisions to the tablet tool, some of which are visually represented in [Figures 2 and 3](#) displaying early versus later prototypes of the tablet tool. First, we made several changes to make the tool more accessible, especially for older adults without tablet experience. We removed all scrolling from the app, increased the size of the font and the choice buttons even more than anticipated, and worked continuously to edit text and keep it below a 7th grade reading level.

Next, to capture the full educational potential of the tool, we embedded two <30-second video recordings to give patients guidance about the importance of (1) bringing up discussion priorities at the beginning of the visit with their doctor and (2) making a plan with the doctor for the next steps after the visit. Participants could pause these videos or skip them altogether based on their individual preference. Videos featured a health provider speaking directly to the patient. To appeal to a wider range of both visual and auditory learning styles, these videos also had brief text intermittently appear on the screen to underscore the key points of the video. These audiovisual elements also reduced the overall reading burden of using the tool. Finally, based on participant feedback, we made the decision to offer headphones to all participants to make the experience private while listening to the videos in the waiting room and to have wipes accessible to clean off the tablet in between users.

Based on our iterative design process with patients, physicians, and other stakeholders, our final six discussion topic choices on the tool also improved. We used the feedback from

participants outlined above to ensure that “new problems/symptoms” were made distinct from “old problems/symptoms” and that an open-ended “personal concern” choice was prominent to allow space for patients to bring up sensitive topics as needed. In response to additional provider feedback, we added a discussion topic choice of “Need something from the doctor” in order to address the administrative requests from patients for referrals or other paperwork, and we limited the number of allowed choices to the patient’s one or two top priorities.

Importantly, we cut out significant portions of script text as we went through the design process. While we started out with a relatively short app, we continued to reduce the information presented at every step. The final version of the tablet tool contained three sections with a maximum of six screens that included sufficient space for free text entry. Most of the information on each screen that was deleted from the original version of the tool was explanations about “why” the tool could be helpful, leaving simply the “how-to” information as the core messages presented. For example, early prototypes envisioned using the tool content to walk patients through the beginning, middle, and end of their visit with their provider—that is, to help them prepare to raise their concerns at the beginning, engage with care planning during the middle portion of the visit, and then leave the visit with concrete action items for follow-up. However, we realized throughout our process that patients would be better served with straightforward prompts eliciting their discussion priorities, followed by tips for staying engaged during and after the visit—without extraneous details about when or why they might use this information when communicating with their provider. This time-agnostic approach was much more flexible for applying to all encounters, including visits with less predictable scenarios not following a typical linear timeframe.

Finally, we expanded the target audience for the tablet tool. We originally designed and tested the tool for complex patients: those identified by their providers as needing additional time or assistance with visit discussion prioritization. Our user-centered design findings identified another target audience: new patients, either to the health care system or switching to a new primary care provider. Moving forward to the next randomized trial phase of this project, we made a decision to focus patient recruitment on both of these groups who might need this tool.

Figure 2. Early prototypes of the tablet tool.

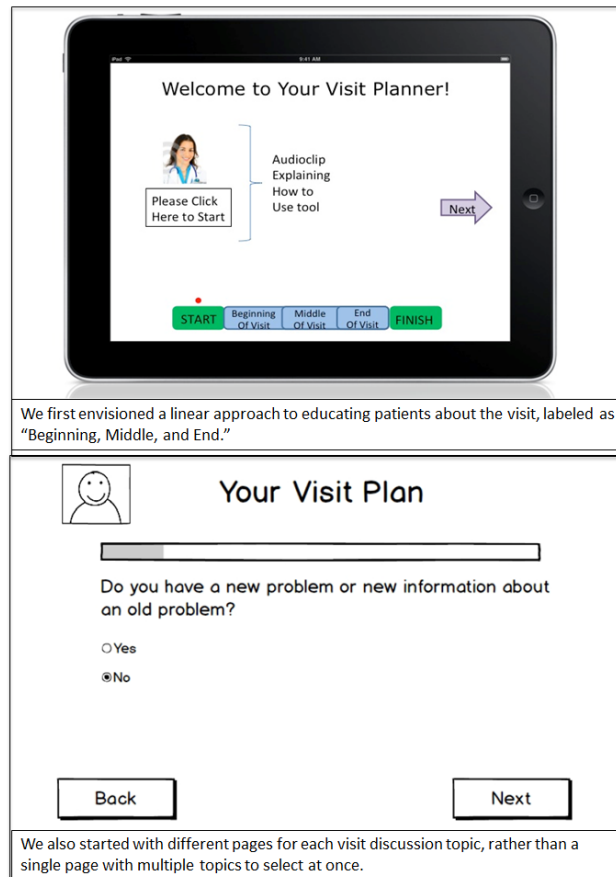
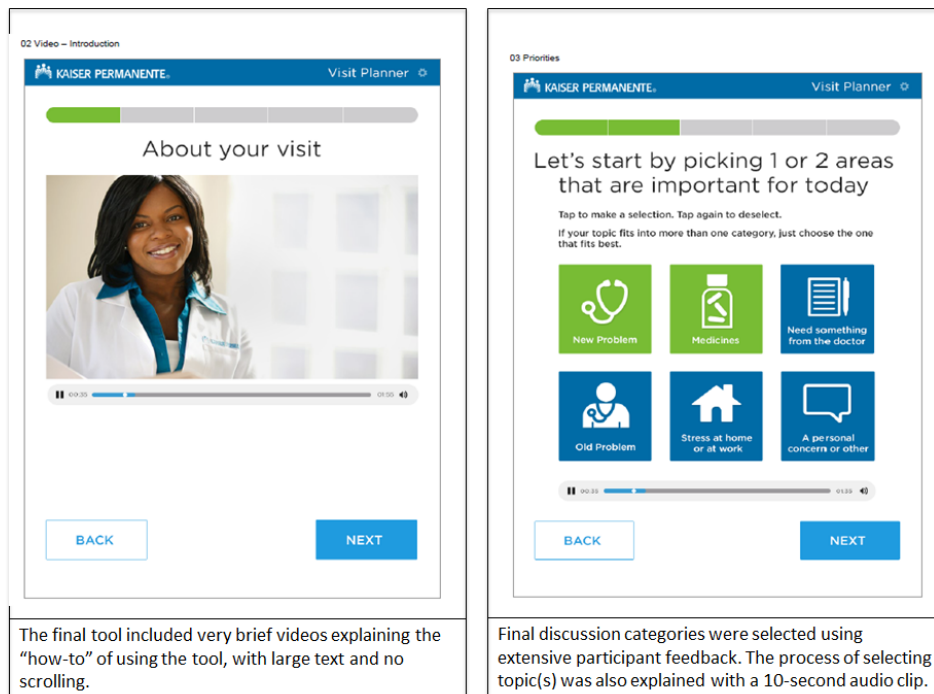


Figure 3. Later prototypes of the tablet tool.



Discussion

Principal Findings

Through the use of user-centered design methods, we substantially modified our initial design concept based on robust

input from patients, physicians, and key informant leaders within a large integrated delivery system. The final tool was simpler to use while also providing richer choices and more engaging layouts and was better suited for widespread implementation within the health care system.

Our findings are significant because user-centered design methods are largely underdeveloped within the health care literature [17,18]. The data on the efficacy of health technologies are limited in part because health technology studies often report on the overall effectiveness of the technology once tested rather than describing the scientific process of incorporating structured user feedback during the design phase [14]. This relative lack of attention to user-centered design in the published literature may help explain why there is overall very mixed evidence of the benefit of health technologies within real-world clinical practice [14,19]. That is, technology studies that report a null effect on outcomes could attribute the failure of the technology to a lack of health behavior change rather than basic design flaws that resulted in poor fit of the technology to meet the end user's needs. Furthermore, our findings highlight the need to conduct user-centered design with complex patients with multiple chronic conditions, as most interventions and technologies are targeted to single diseases or health behaviors [20].

Similar to previous studies, our design and testing process found that using a combination of methodologies (in our case several different types of qualitative inquiry) produced more robust results than a single user-centered approach alone [21,22]. For example, if we had relied on only patient one-on-one interviews, we would have missed key provider perspectives about how to focus in on their new patients for whom the tool could be particularly beneficial. Furthermore, the layout-specific prototype feedback during the patient focus groups and the key informant meetings identified key areas where changes in the design could remove extraneous information and thus reduce patient confusion.

We also included a diverse patient population with complex health care conditions in this user-centered design work that better reflected the general patient population with multiple

chronic conditions [23]. This diversity in participants ensured a wide range of feedback about the tool, as opposed to only recruiting participants who had prior experience using tablets. This was a particularly relevant aspect of our design process that helped us make concrete decisions about simplifying the text presented in the tool and incorporating several audiovisual features to enhance patient comprehension. Use of multiple modalities (text, video, audio) and including flexibility to skip sections allowed us to create a tool that could be used by patients with varying levels of comfort with technology or with absorbing new information. These changes are more likely to make the final tool accessible for a broader target audience, which has implications for wider implementation in future work.

Limitations

There are several limitations to note. First, we recruited patients from three large integrated delivery systems, which may not be representative of other health care settings. Second, we did not do more formal usability testing (such as with validated usability ratings) [18], relying instead on more general prototype iterations to improve the layout. While additional methods may have further enriched our findings, we decided from the outset that multiple user groups of patients, providers, and key informants were the most critical to the design process in our setting.

Conclusions

Our study rigorously documented findings from our tablet tool design, which is a critical step of health informatics research that can produce generalized knowledge about the user-centered design process. Future mHealth research should combine several design and usability testing methods in health technology development, as well as document this design process. This can not only improve the technology and its ultimate impact but also disseminate key lessons learned that other developers and investigators can build on.

Acknowledgments

Funding for this study came from the Patient-Centered Outcomes Research Institute, Washington, DC, USA (CDR-1403-11992) and Agency for Healthcare Research & Quality (R00HS022408).

Conflicts of Interest

None declared.

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Edited by G Eysenbach; submitted 13.06.16; peer-reviewed by L Nelson, T Hale; comments to author 27.07.16; revised version received 15.08.16; accepted 21.08.16; published 14.09.16.

Please cite as:

Lyles CR, Altschuler A, Chawla N, Kowalski C, McQuillan D, Bayliss E, Heisler M, Grant RW

User-Centered Design of a Tablet Waiting Room Tool for Complex Patients to Prioritize Discussion Topics for Primary Care Visits
JMIR Mhealth Uhealth 2016;4(3):e108

URL: <http://mhealth.jmir.org/2016/3/e108/>

doi: [10.2196/mhealth.6187](https://doi.org/10.2196/mhealth.6187)

PMID: [27627965](https://pubmed.ncbi.nlm.nih.gov/27627965/)

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Original Paper

Psychologist in a Pocket: Lexicon Development and Content Validation of a Mobile-Based App for Depression Screening

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Abstract

Background: Language reflects the state of one's mental health and personal characteristics. It also reveals preoccupations with a particular schema, thus possibly providing insights into psychological conditions. Using text or lexical analysis in exploring depression, negative schemas and self-focusing tendencies may be depicted. As mobile technology has become highly integrated in daily routine, mobile devices have the capacity for ecological momentary assessment (EMA), specifically the experience sampling method (ESM), where behavior is captured in real-time or closer in time to experience in one's natural environment. Extending mobile technology to psychological health could augment initial clinical assessment, particularly of mood disturbances, such as depression and analyze daily activities, such as language use in communication. Here, we present the process of lexicon generation and development and the initial validation of Psychologist in a Pocket (PiaP), a mobile app designed to screen signs of depression through text analysis.

Objective: The main objectives of the study are (1) to generate and develop a depressive lexicon that can be used for screening text-input in mobile apps to be used in the PiaP; and (2) to conduct content validation as initial validation.

Methods: The first phase of our research focused on lexicon development. Words related to depression and its symptoms based on the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) and in the ICD-10 Classification of Mental and Behavioural Disorders: Clinical Descriptions and Diagnostic Guidelines classification systems were gathered from focus group discussions with Filipino college students, interviews with mental health professionals, and the review of established scales for depression and other related constructs.

Results: The lexicon development phase yielded a database consisting of 13 categories based on the criteria depressive symptoms in the DSM-5 and ICD-10. For the draft of the depression lexicon for PiaP, we were able to gather 1762 main keywords and 9655 derivatives of main keywords. In addition, we compiled 823,869 spelling variations. Keywords included negatively-valenced words like "sad", "unworthy", or "tired" which are almost always accompanied by personal pronouns, such as "I", "I'm" or "my" and in Filipino, "ako" or "ko". For the content validation, only keywords with CVR equal to or more than 0.75 were included in the depression lexicon test-run version. The mean of all CVRs yielded a high overall CVI of 0.90. A total of 1498 main keywords, 8911 derivatives of main keywords, and 783,140 spelling variations, with a total of 793, 553 keywords now comprise the test-run version.

Conclusions: The generation of the depression lexicon is relatively exhaustive. The breadth of keywords used in text analysis incorporates the characteristic expressions of depression and its related constructs by a particular culture and age group. A content-validated mobile health app, PiaP may help augment a more effective and early detection of depressive symptoms.

(*JMIR Mhealth Uhealth* 2016;4(3):e88) doi:[10.2196/mhealth.5284](https://doi.org/10.2196/mhealth.5284)

KEYWORDS

depression; Psychologist in a Pocket; lexicon development; text analysis

Introduction

Depression has been identified as the most prevalent clinical disorder and main cause of illness among college students and young adults [1,2]. In this age group, depression manifests itself in poor academic performance, problems in communication, strained relations with family and peers, lesser interaction time with friends, and increased frequency in drinking and smoking behaviors [3]. It may also be signaled by loss of weight or increase in appetite and poor sleeping patterns [4]. In worse cases, severe depression is manifested in suicidal thoughts, plans and attempts, and self-harming behaviors [5].

Timely recognition of depressive symptoms is not without challenges. First, mood is transient, changing, and must be captured at the time of experience [6]. Second, primary strategies or traditional techniques used in assessment, such as face-to-face interviews and questionnaires, may overlook the presence of depression or produce negative recall bias [7]. Third, cultures influence the understanding and acceptance of mental illness. In many Asian countries, stigma, fears of misconception, and “losing one’s face” [8-10] hinder help-seeking behaviors. In the Philippines, despite having the highest depression incidence (over 4.5 million) in Southeast Asia, only few will seek help [11], while a significant number underreport self-harm and suicide cases due to religious reasons [12]. Others remain ill-informed, avoid acknowledging their condition, or treat depression as normal sadness. Filipino college students who experience depression tend to suffer in silence, although symptoms are highly observed [3].

Language, and the words that one uses, is a reflection of an individual’s mental state, exposing how one organizes and interprets his/her world and revealing thoughts and feelings. The study of language and emotions, specifically lexical or text analysis, rests on the assumption that language features can be markers of mental health and that mental states and personal characteristics are reflected in the words people use in natural language [13]. The choice of spoken or written vocabulary conveys an individual’s thoughts irrespective of the intentions during communication [14]. Moreover, mental processes that may be out of awareness influence how an individual selects the words to be used by revealing itself through lexical leakages. Regardless of the contextual meaning of words, the selection, per se, is determined by a mental preoccupation with a particular theme. In other words, an individual, possessing a certain thought pattern (eg, I am worthless), may reveal these thoughts through spoken and written language.

In studying depression and its symptoms, everyday language reveals the cognitive mechanisms activated [15]. Depression

involves negative schemas that guide attention towards and enhance recall of negative experiences [16]. Continually being reinforced, active negative schemas progress and develop into negative views of the self, the world, and the future. However, at times, latent or dormant negative schemas expose themselves only upon the experience of a stressor or cognitive load/task that interferes with a person’s attempts to reduce unwanted negative thinking [17]. Either way, schemas control one’s beliefs and automatic thoughts which are accessible and are manifested as words indicating negative emotions and negative thinking [18] or sometimes suicide and death [19,20]. According to the Self-Focus Model of Depression, depressed or depression-prone individuals tend to ruminate and interpret events in terms of themselves [21]. Depressed individuals generally engage in higher levels of self-focus resulting in a higher activation of negative self-schema. The depressive self-focusing style then maintains and exacerbates the disorder or heightens vulnerability. Modalities, such as increased social media activity, raised negative affect, high self-attentional focus, heightened relational and medicinal concerns, and greater expression of religious involvement, may characterize and signal depression onset [22].

Worldwide, mobile phone ownership has reached more than 6 billion [23]. Daily life events and digital behaviors, such as Internet usage, SMS text messaging (short message service, SMS), online chatting, blogging and social media access, are converging around mobile devices [24,25], making the technology a highly integral part of day-to-day activities, specifically in the Asia Pacific. In the Philippines, mobile phones with app capabilities are increasingly utilized for communication and entertainment [26], especially in the 18 to 24 age bracket [27].

The popularity of mobile technology is harnessed in the delivery of health care and information via mobile health (mHealth) [28]. Mobile technology’s adoption in mental health care prevents stigmatization since it attracts no undue attention to its user [29,30]. Furthermore, as it is highly integrated in daily routine, mobile devices have the capacity for Ecological Momentary Assessment (EMA), where behavior is captured in real-time or closer in time to experience, in the natural environment, and with a multitude of measurements over time [31,32]. It could also augment clinical assessment, particularly mood disturbances such as depression, and make it possible to study cognition and other processes through the analysis of daily activities, such as language use [33].

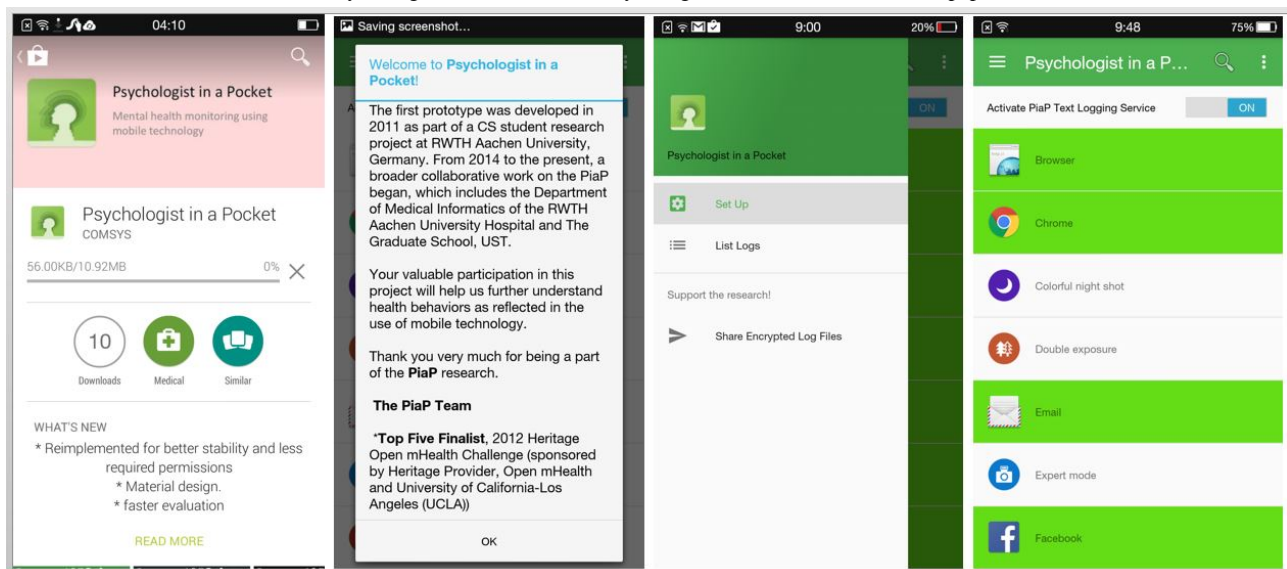
According to Rude and colleagues, language is a medium in detecting depression and depression proneness in individuals [34]. In studies involving novel avenues of communication, activities in social networking sites (SNS) could signal or reveal

symptoms of depression or expose at-risk and fatal suicidal behaviors: disclosing feelings of depression through status updates on Facebook [35,36], decreasing levels of social activity accompanied by increasing levels of negative emotions, and interest in medication [22,37], reading more tips and facts about depression [38], hinting at signs of hopelessness and meaninglessness, even somatic pains through Facebook [39], posting ruminating behaviors on Twitter [40], and expressing suicidal feelings or communicating suicide-related behavior on social media [41].

Tapping into the pervasive presence of mobile technology in daily functioning and its utilization in mental health care, this

paper presents the development and validation of a depression lexicon for the mobile mental health app Psychologist in a Pocket (PiaP), an open source Android-based app designed to detect symptoms of depression using EMA [42]. PiaP is envisioned to be a novel screening approach for depression symptoms to augment traditional clinical assessment (Figure 1). It is not intended to diagnose or to replace mental health professionals. Specifically, the objectives of the study are (1) to develop a depression lexicon using both bottom-up and top-down approaches for automated text analysis functions; and (2) to validate this lexicon in terms of its content or adequacy in representing its domain.

Figure 1. Screenshot of the version of Psychologist in a Pocket currently being tested and discussed in this paper.



Methods

Lexicon Development

The PiaP app is designed to be a measurement tool for depressive symptoms employing a novel method by performing text analysis directly on a mobile device. One of the first stages in developing a test or a measurement tool is to create items to represent the domain. In this case, the initial step in PiaP's development is to generate a lexicon of keywords to represent depressive symptoms. While the development of the lexicon is purported for the text analysis function of PiaP, the depression lexicon or database of depressive words and phrases may be used in any type of text analysis or sentiment analysis that could be computer or mobile-based.

In building a lexicon of a particular subject or domain such as depressive symptoms, the top-down and bottom-up approaches may be utilized in order to represent an entire domain [43]. The top-down approach, also called the gold-standard approach, starts with a domain and from there, fills in details that would be descriptive of that domain using expert knowledge. It establishes the principles with which the domain may be communicated, and for each principle, determines on the basis of competence or observational data, what words are employed to communicate the same or a particular meaning. The

bottom-up approach starts with individuals and their linguistic elements and then records and analyzes each word while testing if the same words or expressions always have the same meaning.

In building the depression lexicon, both the gold-standard descriptions (ie, DSM and ICD classification systems) and the accounts of the individuals themselves who experience the symptoms were utilized to ensure that the lexicon encompasses most of the domain. Furthermore, the language culture of the target population must be considered to make certain that the lexicon reflects both the traditional and slang ways of symptom expression.

Building of Categories

The depressive symptoms listed and described under Depressive Episode in the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) [44] and in the ICD-10 Classification of Mental and Behavioural Disorders: Clinical Descriptions and Diagnostic Guidelines [45] were the basis for the categories of the depression lexicon (Table 1). We created keywords under each category to represent their domain or construct. In other words, DSM-5 depressed mood/irritable mood symptom and ICD-10 depressed mood symptom correspond to the PiaP category termed Mood which has keywords encompassing and representing symptoms of depressed mood or irritable mood.

Table 1. DSM-5 and ICD-10 codes and their category representation.

Category	DSM-5	ICD-10
Mood	Depressed mood	Clearly abnormal depressive mood
Interest	Markedly diminished interest or pleasure in all or almost all activities	Marked loss of interest or ability to enjoy activities that were previously pleasurable
Appetite and weight	Significant weight loss or gain, or increase or decrease in appetite	Changes of appetite (decrease or increase), with the corresponding weight change
Sleep	Sleep problems	Sleep alterations of any kind
Psychomotor agitation	Psychomotor agitation or retardation	Changes of psychomotor activity, with agitation or inhibition
Psychomotor retardation	Psychomotor agitation or retardation	Changes of psychomotor activity, with agitation or inhibition
Fatigue	Fatigue or loss of energy	Lack of vitality or increase of fatigability
Guilt and self-esteem	Feelings of guilt, worthlessness, negative self-appraisal	Disproportionate self-reproaches and feelings of excessive guilt or inadequacy; loss of confidence and self-esteem and feelings of inferiority
Concentration	Diminished concentration or indecisiveness	Complaints about or decrease of the ability to concentrate and think, accompanied by a lack of decision and vacillation
Suicide	Recurrent thoughts of death or suicidal ideation	Recurrent thoughts of death or suicide or any suicidal behavior
Anxiety	Anxiety	Anxiety
Alcohol and substance use	Substance abuse	Excessive consumption of alcohol
Histrionic behavior	Histrionic behavior	Histrionic behavior

Symptoms, such as anxiety, substance use, and histrionic behavior, which are associated symptoms or features of depression according to these diagnostic systems, were also included in the lexicon. The keywords in each category were gathered using the approaches of focus group discussions with college students, interviews with mental health professionals, review of depression scales, and spelling variation of keywords generated.

Focus Group Discussions

Focus group discussions were conducted with 76 college students with a mean (SD) age of 17.28 (1.14) and 61% female (46/76) whose depression symptoms based on Beck's

Depression Index II (BDI-II) scores ranged from 14 (mild) to 63 (severe) (Table 2). The purpose of the focus group discussions was to gather words, expressions, and symbolic representations of depression. This bottom-up process of lexicon building creates an inclusive representation of the linguistic ways people use to express the experience of depression. Participants were randomly assigned to 1 of the 7 focus group discussion sessions (10 to 11 participants per session), each lasting for 45 to 60 minutes. Before the conduct and recording of each session, 2 of the researchers acting as moderator and note-taker, provided a quick briefing of the study. Informed consent from participants was also obtained prior to the sessions.

Table 2. Focus group discussion participants (N=76).

Variables	Categories	n (%)
Gender	Female	46 (61)
	Male	30 (39)
Age, years	16	18 (24)
	17	29 (38)
	18	17 (22)
	19	5 (7)
	20	2 (3)
	22	1 (1)
	Not specified	4 (5)
BDI-II score	Mild	32 (42)
	Moderate	29 (38)
	Severe	15 (20)

Questions centered on how the participants define and describe their depression, what words they typically use to express depression in mobile text inputs and in social media, and how they recognize the signs of depression in another person's text input or social media activity. At the end of each discussion, participants were presented with a set of emoticons and emojis depicting negative emotions. They were asked to choose the emoticons and emojis they frequently used to describe the emotions and feelings associated with the experience of depressive symptoms.

All responses were transcribed verbatim into Excel and examined by 3 of the researchers for analysis and synthesis of possible themes. Transcripts were coded according to identified patterns and relationships.

Interviews With Mental Health Professionals

As part of the top-down or gold standard method of lexicon building, 5 selected mental health professionals, 2 psychiatrists, 2 clinical psychologists, and 1 counselor facilitator of a support group for depression and substance use, were interviewed. The purpose of the interview was to determine how depressive symptoms among Filipino adolescents are linguistically expressed via mobile technology. Specifically, questions revolved around typical words and phrases of a patient or client who experiences depressive symptoms, ways to identify

depressed individuals through novel communication like social media, and feasibility of mobile apps for depression.

The selection criteria of the mental health professionals for interview included (1) more than 10 years experience in their chosen fields (mean 19 years); (2) are officially recognized by the Philippine Regulatory Commission as a licensed psychologist, psychiatrist, or counselor; and (3) have been working with adolescents and young adults suffering from depression. Letters of request for interview were sent to 12 mental health professionals. Of those, 5 agreed to participate in the interview. They were also requested to confirm the findings and the generated keywords from the focus group discussions. Each interview was tape recorded and transcribed verbatim into Excel to infer the main points.

Review of Depression Scales

Another top-down approach in lexicon building was to inspect established and psychometrically sound measurement tools for depression. Words that depict depressive symptoms and variables related to depression, such as negative affect, were extracted from 18 scales, questionnaires, and inventories (Textbox 1). Nouns, verbs, adjectives, and adverbs that relate to depressive symptoms were gathered and frequencies were computed for each keyword found in these sources.

Textbox 1. Reviewed scales for depression and related constructs.

Reviewed scales

1. Beck Depression Inventory II (BDI-II) (Beck, Steer, and Brown, 1996)
2. Center for Epidemiologic Studies-Depression (CES-D) scale (Radloff, 1977)
3. Affect Balance Scale (ABS) (Bradburn, 1969)
4. Experiences of Low Mood and Depression (ELMD) questionnaire (Peyton and Critchley, 2005)
5. Hospital Anxiety and Depression Scale (HADS) (Zigmond and Snaith, 1983)
6. Patient Health Questionnaire 9 (PHQ-9) (Kroenke and Spitzer, 2002)
7. Major Depression Inventory (MDI) (Bech, 1997; Bech and Wermuth, 1998)
8. Inventory to Diagnose Depression (IDD) (Zimmerman and Coryell, 1987)
9. Depression Anxiety Stress Scales (DASS) (Lovibond and Lovibond, 1995)
10. Crandell Cognitions Inventory (CCI) (Crandell and Chambless, 1986)
11. Dysfunctional Attitudes Scale (DAS) (Weissman and Beck, 1978)
12. Situational Self Statement and Affective State Inventory (SSSASI) (Harrell, Chambless, and Calhoun, 1981)
13. Smith Irrational Beliefs Inventory (SIBI) (Smith, 2002)
14. Automatic Thoughts Questionnaire (ATQ) (Hollon and Kendall, 1980)
15. Cognitive Triad Inventory (CTI) (Beckham, Leber, Watkins, Boyer, and Cook, 1986)
16. Cognition Checklist (CCL) (Beck, Brown, Steer, Eidelson, and Riskind, 1987)
17. Irrational Beliefs Inventory (IBI) (Koopmans, Sanderman, Timmerman, and Emmelkamp, 1994)
18. Young's Early Schemas Questionnaire (YSQ) (Young, 2003)

Spelling Variation of Keywords

Young Filipinos typically abbreviate or change the spelling of certain words and mix Filipino/Tagalog and English words whilst communicating. This even coined the terms “textolog” and “tag-lish”. Written language in communication modes such as text messages or SNS has unique characteristics, thus a detection tool must encompass the peculiarities of language expression of different cultures.

To take into consideration the unique culture of Filipinos in inputting text in mobile devices, 500 printed forms containing the list of all main keywords and their derivatives (eg, verb changes) gathered from the previously mentioned methods were distributed randomly to students in 4 universities and colleges (3 in Metro Manila and 1 in Central Luzon). Instructions were to provide at least 3 abbreviations or spelling variations of the keywords. Through convenient selection, data was only considered from 328 students who were able to complete the forms within 2 weeks.

Categorization of Keywords

In the top-down approach, all keywords are generated based on the previously defined categories and are therefore inherently categorized. For the bottom-up approach, all keywords generated by the focus group participants need to be classified into one of the existing categories. This task was initially performed by 2 of the authors (PGFC and RMR). Keywords were distributed and grouped according to the symptom they represent. This keyword categorization was then subjected to content validation by 8 experts.

Content Validation by Experts

According to Kaplan and Saccuzzo [46], the adequacy of representation of the construct or domain the test or tool is designed to measure is reflected by its content-related evidence for validity. Content validation is one the psychometric procedures that index a test's validity or its ability to measure what it purports to measure. A typical method of content validation involves multiple judges rating each item in the test in terms of its relevance to the content [47].

Content validation was conducted to ensure that each keyword belonged to the correct category. Mental health practitioners (N=22) comprised of licensed clinical psychologists, psychiatrists, guidance counselors, and psychology instructors were requested to validate the list. Of those, 36% (8/22) agreed to conduct the content validation. These experts (1) have at least 10 years experience in their chosen fields (mean 17.13 years); (2) are officially recognized by the Philippine Regulatory Commission as licensed psychologists, psychiatrists, or counselors; (3) work with adolescents and young adults with mental health problems; and (4) are currently professionally involved in at least 2 fields such as in the academe and clinical practice.

Using Lawshe's content validity ratio (CVR) in deriving the content validity index (CVI), the experts rated whether the keywords were “essential”, “useful but not essential”, or “not necessary” to the performance of the construct [48,49]. CVR per keyword is depicted by the ratio of the number of experts indicating a keyword as “essential” over the total number of experts. The greater the number of the experts indicating a keyword as “essential”, the greater is the keyword's content

validity. For the 8 validators, each item or keyword must reach a CVR equal to or more than 0.75 to be included in the lexicon [49,50]. The CVI is the mean CVR of all the retained keywords representing the commonality of judgments regarding the validity of the lexicon. The overall content validity is considered high since the value of the CVI approached 1. For the CVRs that did not reach the acceptable CVR level, further selection of keywords to be retained is still possible. For every keyword, 2 judgement points were awarded per acceptance by a validator or when a validator rates the item as “essential”. Afterwards, mean judgement points per keyword were calculated. If a keyword’s CVR is between 0.0 and 0.5 and the mean of judgment points is greater than 1.5, then the keyword is accepted [51].

Results

Lexicon Development

Building of Categories

Since the depression lexicon categories were based on the symptoms described in the DSM-5 and ICD-10, the current

lexicon is comprised of 13 symptom categories: mood, interest, appetite and weight, sleep, psychomotor agitation, psychomotor retardation, fatigue, guilt and self-esteem, concentration, suicide, anxiety, alcohol and substance use, and histrionic behavior.

Focus Group Discussions

From the focus group discussions, words typically used to express depressive symptoms were gathered. As seen in Table 3, 27% (21/78) of the responses indicate being “sad” and “lonely” as major descriptions of people with depression. Specifically, the words “sad”, “unhappy”, and “loneliness” as well as the word “loner” were used most often. In Filipino/Tagalog, some describe the experience of depression as having no focus (“tulala”, “lutang”, “malayo ang iniisip”) and as being disturbed or messed up (“wala sa sarili”).

Table 3. Descriptions of depression (N=78).

Responses	n (%)	Cumulative %
Sad; lonely; unhappy	21 (27)	27
No focus; disturbed	11 (14)	41
Isolation; lack of interest; low interaction	7 (9)	50
Sleep problems	7 (9)	59
Hopelessness; loss of meaning in life	6 (8)	67
Fatigue; stressed	5 (6)	73
Pessimism	4 (5)	78
Uneasiness; instability	4 (5)	83
Moody	3 (4)	87
Emotional	2 (3)	90
Eating problems	2 (3)	92
Low self-esteem	2 (3)	95
Suicidal	1 (1)	96
Anxiety	1 (1)	97
Have no emotional support	1 (1)	99
Pretending to be happy	1 (1)	100

As seen in Table 4, 56% (37/66) of the responses suggest that people who are depressed reveal their depression online. SNS serve as emotional outlets, thus allowing them to verbalize their feelings and release their sadness, frustrations, and problems. This capability to express emotions is somewhat foreshadowing, especially for those about to become clinically depressed.

However, 20% (13/66) of the responses indicate that depression may be disguised by expressing opposite emotions. Still, 9% (6/66) of the responses suppose that people with depression use SNS and text messages as a signal and a means to reach out for help.

Table 4. Revealing own depression in texts and social media (N=66).

Responses	n (%)	Cumulative %
Social network sites are emotional outlets	37 (56)	56
Hide depression or show the opposite of depression	13 (20)	76
Social network sites and text messages signal help	6 (9)	85
Sadness and troubles are expressed via social network sites (mildly depressed > severely depressed)	6 (9)	94
Seek attention via social network sites or text messages	3 (5)	99
Simply follow trends	1 (1)	100

As seen in Table 5, 35% (18/50) of the responses indicate that they are able to recognize people with depression from SNS posts and text messages through the use of sad words. These may include not only personal messages but also quotations or lyrics of sad songs. In addition, 24% (12/50) of the responses claim that they do notice someone experiencing depression, particularly via the changes in behavior and topics of messages as observed in the history of postings and group messages or messages sent to predefined contacts, usually consisting of close friends. However, depressed people, even though they may post

texts online, are thought to be difficult to talk with and are hesitant to open up about their depression in face-to-face interactions, as 8/50 (16%) responses point out that people with depression may be very aloof and keep quiet about their condition. They may not answer truthfully when asked directly about their feelings (despite having posted sad texts online). Depressed people have difficulty expressing themselves when confronted but would post messages, seemingly asking people for help or putting forth a message and reaching out for people.

Table 5. Recognizing others' depression in texts and social media (N=50).

Responses	n (%)	Cumulative %
Presence of "sad" words	18 (36)	36
Change in behavior or topics	12 (24)	60
Asking for help	8 (16)	76
Only recognized if the reader is in a close relationship with the depressed individual	5 (10)	86
Postings or text messages as insincere or inconsistent	4 (8)	94
Might be misinterpreted	2 (4)	98
Only mental health professionals can recognize	1 (2)	100

Interviews with Mental Health Professionals

From the interviews with 5 mental health professionals, it was confirmed that language in any form, written or verbal, is able to reveal signs of depression. The following points have emerged. First, clients or patients usually tell them when they are depressed. Some of the words, phrases, or sentences typically used by the clinically depressed are "can't eat", "can't sleep", "just going through the motions", "no purpose or meaning", "not interested", "I'm tired all the time", "I feel worthless", "guilty", "It's not going to work whatever I do", "Nothing will change", "My head/stomach/muscles ache/s", "I'm losing weight", and "I'll never get well".

Second, description of symptoms, such as that of the DSM and depression tests, may differ from the exact expressions of the individual when communicating with others. For instance, suicidal thoughts among the participants may be expressed as "Lord, please take my life". Another example is that some symptoms described in the diagnostic systems such as psychomotor retardation may be difficult to translate into words but can be represented by specific actions in sentences such as "I find it tiring to dress up" or "I have a hard time making decisions". This suggests the possibility that the symptoms, as

indicated in items of traditional paper-and-pencil tests, may be general descriptions or collective terms for the experiences of the individual. Personal descriptions of depression may differ from the words used in these tests.

Third, current and contemporary language styles play an important role in developing a lexicon. The use of emoticons and emojis in expressing feelings is a trend in SNS and text messaging. Depressed mood, for example, may be expressed using ":-(", which may mean "sad" or "lonely".

Finally, it is feasible to express depression through text messages, blogs, or SNS. A clinical psychologist with 13 years of experience handling young adults mentioned that such apps are new technologies adolescents use; however, to detect depression through these apps, developers must consider all the possible words that maybe be used. Due to the integration of mobile devices in daily activities, a mobile app for depression may be useful for individuals who need help.

Review of Depression Scales

Keywords gathered from the review of depression scales were mostly statements in the first-person point of view. The words were grouped according the depressive symptoms, as stated in

the DSM-5 and ICD-10 (Table 6). Words with the highest frequency convey either guilt or lowered self-esteem. This is followed by depressed mood and decreased interest or pleasure.

However, no items related to alcohol consumption or substance use and abuse were found in these scales.

Table 6. Keyword frequency from depression scales (N=449).

Depressive symptoms	Frequency (%)	Cumulative, %
Feelings of guilt and low self-esteem	148 (33.0%)	32.96
Depressed mood	103 (22.9)	55.90
Loss of interest or pleasure	40 (8.9)	64.81
Anxiety	35 (7.8)	72.61
Psychomotor agitation	27 (6.0)	78.62
Fatigue	23 (5.1)	83.74
Increase or decrease in appetite or weight	20 (4.5)	88.20
Diminished concentration	17 (3.8)	91.98
Sleep problems	15 (3.3)	95.32
Suicidal thoughts and behavior	12 (2.7)	98.00
Psychomotor retardation	8 (1.8)	99.78
Histrionic behavior	1 (0.2)	99.78
Consumption of alcohol	0 (0.0%)	100.00

Spelling Variation of Keywords

A total of 823,869 spelling variations of keywords were generated. The spelling variations were extended by the

researchers by determining all possible combinations of individual words within a keyword (Table 7).

Table 7. Sample spelling variations of keywords.

Category	Keyword	Variation 1	Variation 2
Depressed Mood	Can not stop crying	Cant stp crying	Cnt stop cryin
Interest	Want to detach	Wnt 2 detach	Wanna detach
Sleep	Trouble falling asleep	Trouble fallng asleep	Trble fallin aslp
Suicide	Take my life	Tke my life	Take my lyf
Guilt/self-esteem	I am worthless	I'm wrthless	Im worthlss

Categorization of Keywords

The PiaP lexicon development phase yielded a database consisting of 13 categories patterned after DSM-5 and ICD-10 symptom criteria for depressive episodes. The categorization and frequency of keywords per category is shown in Table 8. For the lexicon draft, we were able to gather 1762 main

keywords, 9655 derivatives with different tenses or arrangement of words of the main keywords, and 823,869 spelling variations. The keywords included negatively-valenced words like “sad”, “unworthy”, or “tired” which are almost always accompanied by personal pronouns such as “I”, “I’m” or “my” and in Filipino “ako” or “ko”.

Table 8. Categorization of keywords.

Categories	Main Keywords, n	Derivatives, n	Spelling variations, n	Total, n
Mood	241	1582	63,340	65,163
Interest	129	1035	107,417	108581
Appetite and weight	216	1357	19,032	20,605
Sleep	162	786	187,365	18,8313
Psychomotor agitation	174	750	12,957	13,881
Psychomotor retardation	74	431	16,160	16,665
Fatigue	112	424	14,964	15,500
Guilt and self esteem	180	1000	30,067	31,247
Concentration	165	753	239,291	240,209
Suicide	90	635	58,732	59,457
Alcohol and substance use	63	315	20,875	21,253
Anxiety	112	399	45,251	45,762
Histrionic behavior	44	188	8418	8650
Total	1762	9655	823,869	835,286

Content Validation by Experts

The CVR per keyword was computed and averaged to the CVR per PiaP category. The categories of appetite and weight (CVR=0.98), suicide (CVR=0.97), and guilt and self-esteem (CVR=0.94) obtained the highest ratios (Table 9). On the other hand, the lowest ratios were for the psychomotor retardation (CVR=0.80) and psychomotor agitation (CVR=0.78) categories.

The mean of all CVRs yielded an overall CVI of 0.90. For the 8 validators, an acceptable CVR per item or keyword should be greater than or equal to 0.75. The overall CVI was determined to be 0.90.

The content validity testing resulted to 1498 keywords, 8911 derivatives of main keywords, and 783,140 spelling variations, with a total of 793, 553 keywords which comprise the test-run version of the PiaP lexicon (Table 10).

Table 9. CVR per keyword category.

PiaP category	CVR
Mood	0.86
Interest	0.93
Appetite and weight	0.98
Sleep	0.92
Psychomotor agitation	0.78
Psychomotor retardation	0.80
Fatigue	0.89
Guilt and self-esteem	0.94
Concentration	0.93
Suicide	0.97
Alcohol and substance use	0.91
Anxiety	0.89
Histrionic behavior	0.92
CVI	0.90

Table 10. Categorization of keywords after content validation.

Categories	Main keywords, n	Derivatives, n	Spelling variations, n	Total, n
Mood	181	1375	52,130	53,686
Interest	113	1011	102,081	103,205
Appetite and weight	213	1353	19,018	20,584
Sleep	148	743	183,123	184,014
Psychomotor agitation	129	544	8993	9666
Psychomotor retardation	51	366	12,578	12,995
Fatigue	103	420	15,080	15,603
Guilt and self-esteem	173	984	29,837	30,994
Concentration	135	668	229,375	230,178
Suicide	86	612	58,355	59,053
Alcohol and substance use	53	315	20,760	21,128
Anxiety	82	359	44,065	44,506
Histrionic behavior	31	165	7745	7941
Total	1498	8915	783,140	793,553

Discussion

Principal Findings

The current study involves lexicon development and content validation for a lexicon of depressed words to be used in mobile mental health apps, such as the PiaP. In lexicon development, we found that (1) language used in contemporary avenues such as social media and mobile technology serve as channels for expressing depression-associated emotions while subtly asking for help and avoiding stigmatization; (2) depressive language consists of words with negative undertones plus pronouns pertaining to the self; and (3) gold standard depiction of depressive symptoms, such as that of tests and diagnostic systems, may be different from the exact verbal expressions of the individual experiencing it. In addition, the uniqueness of a group or of a specific culture's language expressions should be taken into account. A measurement tool, in this case a depression lexicon, with a high content validity shows its potential in detecting the domain, which are depressive symptoms.

The focus group discussions with the college students pointed to the idea that with the use of social media incorporated in their mobile phones, it becomes easier to simultaneously express one's self and to relate and reach out to others. Language use is analyzed in detecting depression and depression proneness as shown in a study using an essay writing activity with students expressing their thoughts and feelings about college [34]. With social media offering a platform where language can be studied, it is even possible to identify people with depression in their free-texts and novel ways of communication [22,37]. College students' disclosure of feelings or emotions related to depression can likewise be determined through status updates and postings on Facebook [35]. Students who may be experiencing depression spend more time on Facebook and could reveal more about themselves online rather than interpersonal communication [36]. Previous studies also support our focus group discussion findings in terms of recognizing depressive symptoms through

increasing levels of negative emotions [22], reading more tips and facts about depression [38], hinting at signs of hopelessness and meaninglessness and posting ruminating behavior, and expressing suicidal feelings or communicating suicide-related behavior on social media [39-41].

Depressive language consists of words with negative undertones plus pronouns pertaining to the self as evidenced by keywords gathered from focus group discussions, interviews with professionals, and depression tests. Our interviews and discussions with mental health professionals confirmed that depressed clients often have a negative description of themselves, of their situation and environment, and of their lives and futures that may be revealed in social media. These findings are supported by Beck's cognitive theory [16], and Pyszczynski and Greenberg's self-focus model [21], which describe individuals experiencing depression as using more words with negative connotations and often making self-references when sharing their experiences. Whenever people are posting in social media, sending emails or text and instant messages, reacting to a friend's status message, or using search browsers, the schema, negative or positive, with which their minds operate can be observed regardless of the purpose or intention of communication through the words they choose to type in their mobile devices.

Gold standard depictions of depressive symptoms, such as that of tests and diagnostic systems, may be different from the exact verbal expressions of the individual experiencing depression. This is supported by a study by Neuman and colleagues when they created the Pedesis system by gathering depressive words as experienced and expressed by individuals who have depression (eg, blogs and social media) [43]. People have vast ways of expressing depression, which may not be encompassed by a list created by experts or by diagnostic systems, such that the classification provided by the DSM or ICD. Even descriptions made by mental health professionals mainly consist of symptoms and signs rather than expressions of depression

[43]. Culture or generational differences makes it even more complicated when trying to make a representation of expressing depression in words. With novel platforms for communication such as mobile technology and social media, it is indeed challenging to encompass the variety of ways people may express themselves [52,53]. A guideline of what to look for is provided by the gold standards but it is in the examination of the lexical expressions of people experiencing depressive symptoms that depression can be adequately characterized [43,52,53]. In addition, the current study's findings show the texting behaviors of Filipinos, particularly among college students, involve abbreviating or changing the spelling of words, which, to an outsider appears almost incomprehensible. The inclusion of abbreviations or spelling variations increased the bulk of keywords, but since text analysis relies on the lexicon for detecting the symptoms, disregarding this cultural and generational peculiarity, would make it impossible to capture relevant depressive language.

The content validation procedure is a measure of validity of the lexicon in detecting words that can be related to depressive symptoms using text inputs. The data suggests that depressive language can express the majority of the symptom categories. This might indicate that symptoms more cognitive in nature are better expressed in verbal behavior. Schemas supporting such symptoms influence automatic thoughts that become observable in language use or choice of words. However, the identification of motor or physiological symptoms, such as psychomotor retardation and agitation, was less obvious. These symptoms are likely to be better observed in bodily movements and gestures and reported by others. Individuals who exhibit these symptoms may not be able to notice them themselves.

With its sound content validity, the depression lexicon adequately represents words that can be related to depressive symptoms and may be able to help in the detection of symptoms using text analysis in the mobile mental health app PiaP. An ongoing study involves a test trial of PiaP with selected college students and will investigate the individual keywords and their ability to discriminate and detect individuals who may have depressive symptoms through the psychometric process of item analysis. In addition, data will be used to calculate the internal consistency of the depression lexicon. Further trials with college students will also determine the normative structure of the population chosen.

Significance

The study has significance in the fields of mental health (eg, clinical psychology, psychiatry, counseling) and health informatics by seeking to deliver not just a psychometrically sound instrument but also a highly usable tool for the assessment of depression. Mobile phones with app capabilities have enabled ordinary individuals to do almost anything and everything with ease. The flexibility and proliferation of mobile phone software programs have allowed professionals in many fields in science and medicine to accomplish tasks related to gathering pertinent physiological data from their patients to aid diagnosis and help monitor the progress of physical or pharmacological treatment [54]. Psychologists, psychotherapists, guidance counselors, and

other mental health professionals may take advantage of this timely approach to monitor their clients, patients, or students.

The field of mHealth has much potential in developing countries [29,25], even more so mobile mental health, which in some places is still in its infancy. The mental health profession has been heavily relying on traditional and conventional assessment tools such as pen-and-paper tests, observations, and interviews to gather data. Mobile mental health solutions such as the PiaP may contribute to the diagnosis process in a proactive way as well as monitor current symptomatology. Together with other technology-based tools that allow EMA, our approach may help provide increased statistical power of datasets gathered due to the amount of observations available. With the introduction of the new technique in screening for depressive symptoms described in this paper, the mental health field may begin exploring other possibilities like providing treatment aids with the use of mHealth technology. This may be accomplished in collaboration with experts and professionals in mobile technology and computer science.

Lastly, this study is intended to support suicide prevention among students by contributing a dependable and suitable tool for guidance counselors and mental health experts in the academe. Although depressive signs and symptoms may or may not lead to suicide, it is advantageous for the early detection of signals (such as non-fatal self-harm behaviors) to facilitate prompt action.

Prior Works in Lexicon Development

The lexicon development used in the PiaP has taken into consideration the processes employed in creating earlier lexica from other researches to be able to provide a comprehensive representation of the depressive language used by college students.

First, the current depression lexicon underwent an exhaustive process using both the top-down and bottom up processes. Pedesis [43] was built using the bottom-up process only, by harvesting the Web for metaphors in which the target terms (ie, depression) embedded are used by individuals who may or may not be experiencing depressive symptoms. De Choudhury et al [22] built a lexicon of depression-related terms based on the social media platform Twitter. Emotex [52] includes unigrams, emoticons, negations, punctuations and hashtags, emotions and moods in social media language, and utilized words from regular individuals to build their lexicon. On the other hand, in the development of the current lexicon used by PiaP, descriptions from mental health professionals and established literature in the field of emotion studies as well as words depicting depression in diagnostic system such as DSM and ICD were also included.

Second, the developed lexicon is culturally sensitive, having included language and jargon used by a specific group of people, particularly college students. In addition, the app also analyzes emoticons in SNS and abbreviations or spelling variations of text inputs which are novel ways of expressing feelings and emotions. De Choudhury et al [22] utilized a dataset which classified emotions in various technological contexts and used a list of mood words from a blogging website. It also

incorporated various lexica for positive and negative emotions and for basic emotions, but novel words used in social media communication such as emoticons, emojis, or abbreviations were not included. In Xue and colleagues' study [53], although the tweets they examined were a combination of English and Chinese words, the lexicon they built only included English words pertaining to stress, negative emotion, degree, and negation. However, Chinese tweets needed to be translated to English before submitting to text analyses.

Third, the initial validation of the lexicon offers content-related evidence for its psychometric property of validity. Pedesis [43] employs inter-rater or inter-judge reliability testing; however, they did not test for domain representativeness of the words in the lexicon itself.

Current and Future Work

Currently, PiaP research in the Philippines is working with college students to establish construct validity against tests and scales for depression and related constructs such as BDI-II, CES-D scale, Satisfaction with Life Scale, and Affect Balance Scale. This approach may show the possible correlations with constructs similar or related to depressive symptoms. Also, PiaP is being administered to selected college students to gather data

for item analysis which will examine the usage of words and its ability to discriminate between individuals who are depressed or non-depressed. Furthermore, PiaP data will be used to establish normative structure for college students. In Germany, a third depression lexicon (in German) is being initialized. In addition, work is being performed on the behavioral indicators of depression using sensors and voice markers. Future research will also include the incorporation of physiological test plug-ins such as mobile electroencephalography (mEEG).

Conclusions

By utilizing the ubiquity and functionalities of mobile technology, the immediate detection of symptoms of one of the most prevailing clinical disorders worldwide may be improved using text analysis. The generation of this depression lexicon is exhaustive, utilizing both top-down and bottom-up approaches. The breadth of keywords used in text analysis also incorporates the characteristic expressions of depression and its related constructs by a particular culture and age group. A content-validated mobile health app, such as PiaP, may help augment early detection of depression signs by providing a lexicon, which effectively characterizes words related to depressive symptoms.

Acknowledgments

We would like to thank, from Germany, Mr Paul Smith and Ms Sarah Winter for developing the PiaP prototype and Mr Eugen Seljutin and Mr Marko Jovanović for the additional technical support, and, from the Philippines, Ms Myra Gurango and Mr Jovan Lorenz Torres for the initial Filipino translations, Mr Angelo Dullas for gathering additional data for the keyword spelling variations, and Dr Francine Rose de Castro-Bofill for co-moderating our focus group discussions.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Paper Presentation at the 11th Biennial Conference, Asian Association of Social Psychology (AASP) and 52nd Convention, Psychological Association of the Philippines (PAP) 2015, Cebu City, Philippines, 19 -22 August.

[[PDF File \(Adobe PDF File\), 1MB - mhealth_v4i3e88_app1.pdf](#)]

Multimedia Appendix 2

Paper presentation at the InPACT International Psychological Applications Conference and Trends 2016, Lisbon, Portugal, 30 April - 02 May.

[[PDF File \(Adobe PDF File\), 234KB - mhealth_v4i3e88_app2.pdf](#)]

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Abbreviations

BDI-II: Beck's Depression Index II

CES-D: Center for Epidemiologic Studies-Depression

CVI: content validity index

CVR: content validity ratio

DSM-5: Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition

EMA: ecological momentary assessment

ESM: experience sampling method

ICD-10: The ICD-10 Classification of Mental and Behavioural Disorders: Clinical Descriptions and Diagnostic Guidelines

mHealth: mobile health

PiaP: Psychologist in a Pocket

SNS: social networking sites

Edited by G Eysenbach; submitted 27.10.15; peer-reviewed by C Yang, B Jeong; comments to author 03.04.16; revised version received 07.05.16; accepted 24.05.16; published 20.07.16.

Please cite as:

Cheng PGF, Ramos RM, Bitsch JÁ, Jonas SM, Ix T, See PLQ, Wehrle K

Psychologist in a Pocket: Lexicon Development and Content Validation of a Mobile-Based App for Depression Screening

JMIR Mhealth Uhealth 2016;4(3):e88

URL: <http://mhealth.jmir.org/2016/3/e88/>

doi: [10.2196/mhealth.5284](https://doi.org/10.2196/mhealth.5284)

PMID: [27439444](https://pubmed.ncbi.nlm.nih.gov/27439444/)

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Original Paper

Mobile Sensing and Support for People With Depression: A Pilot Trial in the Wild

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Abstract

Background: Depression is a burdensome, recurring mental health disorder with high prevalence. Even in developed countries, patients have to wait for several months to receive treatment. In many parts of the world there is only one mental health professional for over 200 people. Smartphones are ubiquitous and have a large complement of sensors that can potentially be useful in monitoring behavioral patterns that might be indicative of depressive symptoms and providing context-sensitive intervention support.

Objective: The objective of this study is 2-fold, first to explore the detection of daily-life behavior based on sensor information to identify subjects with a clinically meaningful depression level, second to explore the potential of context sensitive intervention delivery to provide in-situ support for people with depressive symptoms.

Methods: A total of 126 adults (age 20-57) were recruited to use the smartphone app Mobile Sensing and Support (MOSS), collecting context-sensitive sensor information and providing just-in-time interventions derived from cognitive behavior therapy. Real-time learning-systems were deployed to adapt to each subject's preferences to optimize recommendations with respect to time, location, and personal preference. Biweekly, participants were asked to complete a self-reported depression survey (PHQ-9) to track symptom progression. Wilcoxon tests were conducted to compare scores before and after intervention. Correlation analysis was used to test the relationship between adherence and change in PHQ-9. One hundred twenty features were constructed based on smartphone usage and sensors including accelerometer, Wifi, and global positioning systems (GPS). Machine-learning models used these features to infer behavior and context for PHQ-9 level prediction and tailored intervention delivery.

Results: A total of 36 subjects used MOSS for ≥ 2 weeks. For subjects with clinical depression (PHQ-9 ≥ 11) at baseline and adherence ≥ 8 weeks (n=12), a significant drop in PHQ-9 was observed ($P=.01$). This group showed a negative trend between adherence and change in PHQ-9 scores ($\rho=-.498$, $P=.099$). Binary classification performance for biweekly PHQ-9 samples (n=143), with a cutoff of PHQ-9 ≥ 11 , based on Random Forest and Support Vector Machine leave-one-out cross validation resulted in 60.1% and 59.1% accuracy, respectively.

Conclusions: Proxies for social and physical behavior derived from smartphone sensor data was successfully deployed to deliver context-sensitive and personalized interventions to people with depressive symptoms. Subjects who used the app for an extended period of time showed significant reduction in self-reported symptom severity. Nonlinear classification models trained on features extracted from smartphone sensor data including Wifi, accelerometer, GPS, and phone use, demonstrated a proof of concept for the detection of depression superior to random classification. While findings of effectiveness must be reproduced in a RCT to proof causation, they pave the way for a new generation of digital health interventions leveraging smartphone sensors to provide context sensitive information for in-situ support and unobtrusive monitoring of critical mental health states.

(JMIR Mhealth Uhealth 2016;4(3):e111) doi:[10.2196/mhealth.5960](https://doi.org/10.2196/mhealth.5960)

KEYWORDS

depression; mHealth; activities of daily living; classification; context awareness; cognitive behavioral therapy

Introduction

In October 2012, the World Health Organization (WHO) estimated that 350 million people worldwide suffer from depression [1]. It is expected that depression will be the world's largest medical burden on health by 2020 [2]. Beyond its burden on society, depression is associated with worse global outcomes for the affected individual, including reduced social functioning, lower quality of life in regards to health, inability to return to work, as well as suicide [3]. Traditionally, depression is treated with medication and/or face to face psychotherapy using methods such as cognitive-behavioral therapy (CBT), which has been proven to be effective [4]. However, it must be noted that mental health personnel, usually psychologists and psychiatrists with a specialized education that goes beyond both geospatial ubiquity and skills of general practitioners, are strongly required for CBT but limited. For 50% of the world's population there is only one mental health expert responsible for 200 or more people [2]. In recent years, this led to the rise of digital versions of CBT in the form of educational interactive websites and smartphone apps [5]. Many of these solutions presented reasonable effects sizes [6], sometimes even on a par with face to face therapy [7]. However, a recent review revealed an array of shortcomings still present in most of the approaches, for example, the lack of personalization and missing in-situ support [8]. A key to the solution could lie in digital health interventions offered through modern smartphones and their sensors. The overwhelming prevalence of smartphone devices in society suggests that they are becoming an integral part of our lives. Recent estimates indicate that, for example, 64% of American adults and almost one quarter (24.4%) of the global population own a smartphone [9]. By 2016, the number of global smartphone users is estimated to reach 2.16 billion [10]. With these devices, an ensemble of techniques from the field of Artificial Intelligence, mobile computing, and human-computer interaction potentially represents the new frontier in digital health interventions. Learning systems could adapt to subject's individual needs by interpreting feedback and treatment success [11] and smartphones could provide important context information for adequate in-situ support [12,13], in the form of interactive interventions and even infer a subject's condition state. For example, physical activity, shown by numerous studies to be related to depression [14,15], can be approximated by acceleration sensors [16], duration, and time of the day of stays at different physical locations were shown to be related to a person's mental state and can be approximated by WiFi and global positioning systems (GPS) information [17,18]. Another relevant aspect is social activity. It is highly related to a subject's mental state and the risk of developing depression [19,20]. Smartphones offer numerous sources of information acting as proxies for social activities such as the frequency and average duration of calls, or the number of different persons being contacted.

While until today, there is no study presenting results of a context aware digital therapy for people with depression

providing in-situ support, recent studies by Saeb et al and Canzian et al [17,18] demonstrated promising results in objectively and passively detecting whether a subject might suffer from depression solely using information provided by the smartphone. Saeb et al [17] used the information of GPS sensors and phone use statistics to distinguish people without (Patient Health Questionnaire, PHQ-9, <5) from people with signs of depression (PHQ-9≥5) in a lab experiment over 2 weeks with high accuracy. Canzian et al [18] were able to show a tendency of correlation between a range of GPS metrics similar to the ones presented by Saeb et al [17] and a self-reported depression scores. In another recent explorative study, Asselbergs et al [21] were able to resemble a subject's day-to-day mood level solely based on passively collected data provided by the smartphones with 55% to 76% accuracy. This development shows a promising direction in objective and unobtrusive mental health screening, potentially reducing the risk of undetected and untreated disorders. It is, however, still an open question whether it is possible to distinguish people with and without clinically relevant depressive symptoms (PHQ-9≥11 [22]) in an uncontrolled real life scenario.

This would open up a range of opportunities for unobtrusive mental health screening potentially able to alert a subject if a critical mental state is reached and, as a consequence, an additional professional treatment highly recommended. This could not only reduce costs in the health care system by preventing severe cases from getting into worse and costlier states, but also by preventing subjects with symptom severity below clinical relevance to strain the system.

Therefore, the aim of the present work was to explore the potential of context-sensitive intervention delivery to provide in-situ support for people with depressive symptoms, and to explore the detection of daily life behavior based on smartphone sensor information to identify subjects with a clinically meaningful depression level.

Methods

System Architecture

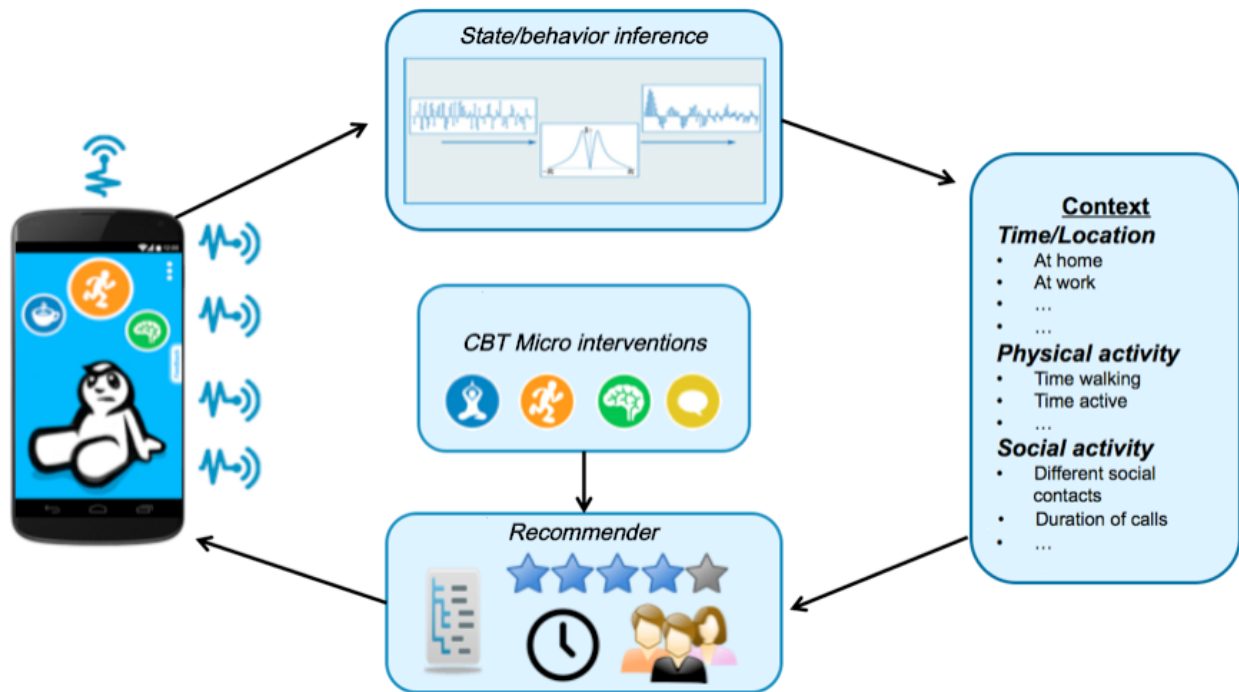
At the core of the present work, a novel digital health intervention for people with depressive symptoms was developed.

Figure 1 represents a schematic overview of the process flow within the Mobile Sensing and Support (MOSS) app. A range of smartphone sensors holds potentially valuable information about a subject's individual context. Using techniques from the field of machine learning, this sensor information can be used to infer a subject's behavior. For example, classification techniques [23] can be used on accelerometer and GPS data to detect what type of physical activity a subject carried out throughout the day or how much time the subject spent at home or outside. These analyses result in an array of context features the app uses to provide the subject with evidence-based interventions stemming from the theory of cognitive behavioral

therapy. After each intervention, the system receives passive or active feedback from the subject regarding the last recommendation. Over time, this enables the system to learn a subject's preference to change recommendations accordingly.

In the following sections, we give a detailed description of the context features, the functional principles of the recommender algorithm, as well as a description of the developed interventions.

Figure 1. Schematic overview of Mobile Sensing and-Support (MOSS) app process flow. Note: Starting left (1) MOSS app collects sensor and use data, (2) data is analyzed and transformed into (3) context information, (4) context information in combination with user preference and decision logics are used to recommend (5) evidence-based interventions presented via (1) the MOSS app.



Context Features

In order to be able to provide a subject with meaningful recommendations in everyday life, we need to analyze subjects' context solely based on their interaction with a smartphone. In a first step, the current implementation constructs a context from information about time of the day, location, smartphone usage, and physical and social behavior. While information such as time of the day or smartphone usage can directly be extracted, other information needs to be approximated with the help of behavioral proxies derived from processed sensor data. For sensor data collection, we made extensive use of the open source framework UBhave by Hargood et al [24]. Next, we provide an overview of context features that we developed for the study together with a motivation why the feature is relevant in the context of depression, followed by a detailed description how our recommendation algorithm uses these features to present meaningful interventions.

General Activity

Numerous studies showed a bidirectional relationship between depressive symptoms and physical activity [25-27]. Our approximation of physical activity is 2-fold. Using the acceleration sensor data provided by the smartphone, we analyze a subject's general activity level and a subject's walking time.

To assess the general activity levels, the standard deviation of the three-dimensional (3D) acceleration norm was computed according to Equation 1:

$$\text{STDEV}(3\text{DaccNorm}) = \text{STDEV}(\sqrt{(a_x^2 + a_y^2 + a_z^2)} - 9.81\text{m/s}^2) \quad (1)$$

Where a_x^2 , a_y^2 and a_z^2 represent the 3 acceleration axis and 9.81m/s^2 represents the gravity of Earth.

Each acceleration axis was sampled with 100 hz resulting in a total of 300 samples per second. To estimate a subject's general activity intensity over a finite time window, the standard deviation of the 3D acceleration norm was computed as described by Vähä - Ypyä et al [28]. A recent study showed that the standard deviation of the 3D acceleration norm resembles intensity of physical activity of 2 widely used commercial acceleration-based activity trackers with reasonable consensus [29]. For this trial, we used a time window of 2 minutes. As we did not aim at classifying micro movement, this window size was appropriate for our app needs and trades of phone memory usage and frequency of computation and information gain.

Walking Time

To approximate the walking time, for every time window of 2 minutes, we made use of the standard deviation of the 3D acceleration norm (1) again. Adapting the approach of Vähä - Ypyä et al [28], we used an intensity-based classification approach to determine whether a subject was walking. To derive a meaningful threshold for our app, we conducted numerous tests with different test subjects varying walking speed and smartphone carrying positions. We found, that this approach is

robust to variance in the orientation of the smartphone was confirmed by Kunze and Lukowicz [30] and different walking speeds. We chose the final threshold at 1.5.

Time at Home

To measure the time a subject stays at home, an approach by Rekimoto et al [31] for WiFi-based location logging was adapted. Every 15 minutes, the WiFi basic service set identifier of hotspots in the surrounding were scanned. Based on a rule-based approach, MOSS tried to learn a subject's home by comparing WiFi fingerprints stored during the first 3 consecutive nights. If a reasonable overlap of hotspots was detected, the MOSS app stored this information. In order to avoid tagging the wrong location, the MOSS app asked the subjects whether they are at home, if the tagged fingerprints were not detected in any 3 consecutive nights.

Phone Usage

This feature measured the total time subjects were using their mobile phone depicted by the time the smartphone was unlocked following Saeb et al [17]. The time spent with the MOSS app was excluded.

Geographic Movement

As described earlier, 2 recent studies were able to show a relationship between depressive symptoms and geographic movement. Building on these works, an array of metrics from GPS information were constructed [17,18]. Every 15 minutes, coordinates of the current location of the subject were captured. From these coordinates, the maximum and the total distance traveled were calculated using techniques for geographical distance calculation. Additionally, the location variance was calculated from the latitudes and longitudes using the Equation 2:

$$\text{locVar} = \log(\sigma_{\text{lat}}^2 + \sigma_{\text{long}}^2) \quad (2)$$

To compensate for skewness in the distribution of location variance across participants, we also used the natural logarithm of the sum of variances.

Number of Unique WiFi Fingerprints

In addition to GPS information as a proxy for geographic movement, every 15 minutes, WiFi fingerprints of the surrounding were scanned. Besides the fingerprints for home detection, a list of unique hotspots was kept to keep track of the total number of fingerprints detected.

Number of Text Messages

This feature kept track of the incoming and outgoing text messages together with a count of different unique contacts the messages were sent to and received from. This adopts a social mining approach by Eagle et al [32] and represents one dimension of social activity. Past studies showed a negative correlation between the amount of social interaction and depression levels [19] and diminished social activity in increased depression levels [20].

Number of Calls

This feature kept track of the number of incoming and outgoing calls a subject made together with a count of different individuals as also described in [32]. This feature follows the same argumentation line as the number of text messages feature.

Number of Calendar Events

This feature kept track of the number of calendar events stored. It distinguished between events taking place in the morning, afternoon, and evening time [33]. This feature tried to act as a proxy for stress caused by too many calendar events, which could have an influence on depression levels [34]. Further, calendar events in the evening could represent another dimension for social activity (eg, a cinema or restaurant visit). As we solely look at the number of events per time frame, we cannot interpret the context of the event.

To provide subjects with insights about their behavior and to further guarantee a high level of transparency about the collected data and computed features, we implemented a dedicated section into the user interface. Here, the subject was able to observe collected information over the course of different time periods. The screens of Figure 2 provide the subcategories social activity, physical activity, and used apps.

Figure 2. Social activity, physical activity, and used app screens of the Mobile Sensing and Support (MOSS) app. Note: The initial user interface was in German, the first screen shows number of calls, total time of calls, amount of SMS text messages, and number of persons contacted over the last 7 days. The second screen shows time spent at home and time spent moving during the current day.



Recommender

The recommender was responsible for presenting interventions to the subject. It tried to optimize the delivered content with respect to the context and subject preferences.

As described earlier, the context was composed of time of the day, the location, smartphone usage, as well as physical and social behavior. The recommender was designed to work in 2

phases. In the first phase it delivered interventions based on assumptions about the behavior of the general depressed population and handcrafted weights for appropriate interventions to be delivered depending on the characteristics of the context (this will later be explained in more detail). In the second phase, the delivery quality was enhanced by adjusting the assumptions according to a subject’s actual behavior. In Table 1, example assumptions about the general depressed population and the characteristics of a subset of context features are presented.

Table 1. Assumptions about people with depression.

Context feature	Weakly pronounced per day	Strongly pronounced per day
Time spent at home	Weekdays <7 hours a day	Weekdays >14 hours a day
Total number of calls	0 calls per day	>6 calls per day
Walking time	Weekdays <30 minutes	Walking time >300 minutes

Only context features where reasonable assumptions of characteristics in the overall population could be made, were included into the recommendation algorithm. Furthermore, this includes the number of texts sent/received, number of calendar events, average call duration, and time of phone use.

To reduce complexity, interventions with similar characteristics were grouped into baskets. For each basket, domain experts, in our case 2 trained psychologists, attached importance weights of features, in order to help the MOSS app to decide which baskets should be considered for recommendation depending on the subject’s context. For example, the recommendation to take a walk in the park should be related to the general activity level of a subject so that, if the subject had a low general activity, the probability that a walk in the park is recommended, increases. The score for each basket is calculated according to Equation 3:

$$\text{basketScore}_n = w_1 * \text{scaleToRange}(x_{1_max}, x_{1_min}, x_1) + w_2 * \text{scaleToRange}(x_{2_max}, x_{2_min}, x_2) + \dots + w_n * \text{scaleToRange}(x_{n_max}, x_{n_min}, x_n) \quad (3)$$

Where w_n is the weight of feature n , x_n is the value of feature n over the last 24 hours, $\text{scaleToRange}()$ is a function to calculate the fraction of x_n reached of the range between defined small and large values of x_n .

The baskets with the highest scores were presented to the subject in the form of touchable circles on MOSS’s home screen as shown in Figure 3. The size of the circles indicated the recommendation score of the basket. The higher the score, the larger the radius of the circle. Unique icons represented the type of the domain the basket belongs to. Figure 3 shows examples where baskets with physical exercises received the highest score (orange circle).

This basket score computation was repeated every 6 hours to present relevant baskets. Once the subject clicks an icon, specific

interventions of the related basket are presented to the user. See Figure 4 for an example of interventions of a chosen basket presented to the user.

For the most relevant baskets of each domain and every 6 hours, only the top 3 interventions can be carried out by the user. Once the user completes/neglects all 3 interventions, the basket and its related circle disappears from the home screen until the next context evaluation. In order to determine which 3 interventions of each basket are shown to the user, individual interventions are ranked according to a score.

The following Equation (4) was used to score interventions using a weighted combination of the subject's preference depicted by a simple star rating after the execution of an intervention (Figure 5), the completion rate of the interventions depicted by the fraction of times the subject finished an intervention and did not cancel it early and a small factor of chance:

$$\text{interventionScore} = 0.75 * \text{pastRatings}/5 - 0.25 * \text{cancelationRate} + 0.5 \text{ (if random} \leq 0.05) \text{ (4)}$$

Where *pastRatings* is the average rating over all past ratings for this intervention, *cancelationRate* is the fraction of times the subject canceled the intervention early and *random* is a uniformly distributed random number between zero and one.

The static weight parameters of the intervention score were set following an explorative approach. The values follow the assumption that past ratings of an intervention represent the preference for an intervention and therefore should have the highest impact on the scoring function. Contrary, the cancelation rate has a negative impact on the overall score. The decision to

cancel an intervention early, is not necessarily related to a subject's general liking of the intervention, therefore the impact is significantly lower than past ratings. Finally, to prevent interventions from not being recommended over a long period of time because their average past rating is too low, a factor of chance is introduced with a positive impact on the score to promote fluctuation.

In addition, 2 clinically trained psychologists predefined rules to prevent the MOSS app making unreasonable intervention recommendations. For example, an intervention asking the subject to lie down for a relaxation exercise is only recommended if the subject is at home and if the current time period is in the morning or in the evening.

Also, after each execution, an intervention was blocked for a period of time to avoid early repetition. The length of this period in hours depended on the subject's rating of the intervention according to Equation 5:

$$\text{blockTime} = 36 * (6 - \text{pastRating}) \text{ (5)}$$

Where *pastRating* is the last rating of the intervention.

In the second phase, the following changes to Equation 3 were applied. After 2 weeks, the basket scoring computation (see basket score Equation 3) was automatically adjusted, by applying information of individual subject's actual behavior: x_{n_max} and x_{n_min} are defined as $\mu \pm (2 * \sigma)$ (ie, the average feature value of the subject during the last week ± 2 times the standard deviation). This way, the MOSS app does not suffer from potentially flawed assumptions about a subject's behavior with respect to the general population and adapts to the subject's actual behavior.

Figure 3. Example recommender results with physical activity baskets showing the highest score (orange circle) compared with social activity (yellow), mindfulness (green), and relaxation (blue).



Figure 4. Sample screenshots of lists of interventions of two different baskets. Each item shows the approximate time it takes to carry out the intervention together with a short summary (in German language) Note: The left, green list presents 3 mindfulness exercises: “muse chair,” “new perspective,” and “praise yourself.” The right, yellow list presents 2 social exercises: “Movies&Popcorn” and “kaffeeklatsch.”.

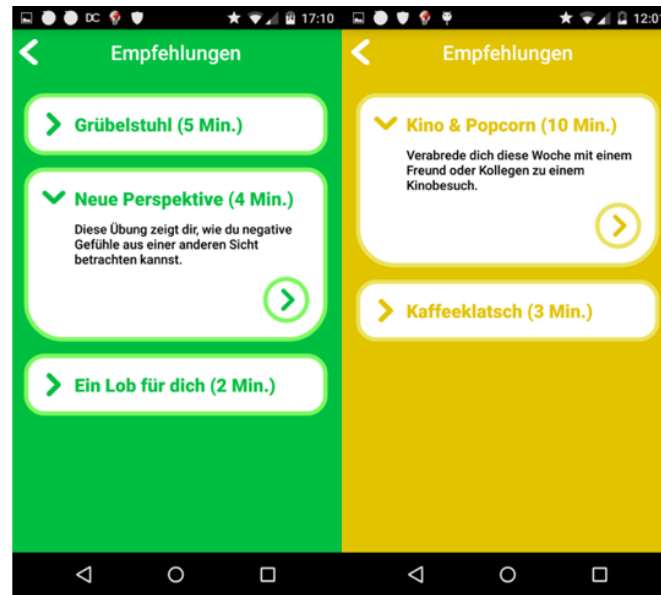
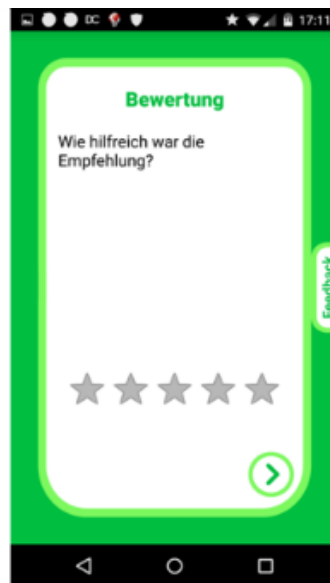


Figure 5. Sample screenshots of an intervention rating. The subject is asked for perceived usefulness of the intervention on a 5-star rating scale (in German language).



Interventions

In line with the majority of Web-based health interventions targeting people with depressive symptoms [8], MOSS uses CBT. CBT is a highly-structured psychological treatment [35]. It is based on the assumption that thoughts determine how one feels, behaves, and physically reacts. This form of intervention contains various treatments using cognitive and behavioral techniques with the assumption that changing maladaptive thinking leads to change in affect and behavior. Examples for therapeutic CBT interventions are activity scheduling, relaxation exercises, cognitive restructuring, self-instructional training, or skills training such as stress and anger management [36]. CBT

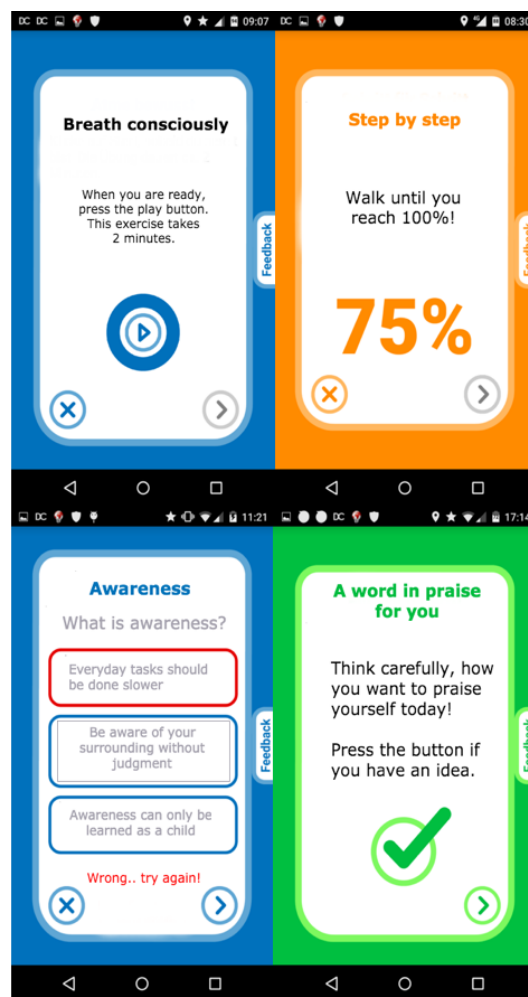
is often regarded as the mental health intervention of choice due to its large evidence on a variety of psychological disorders [4]. Moreover, and with regard to its structure, it is suitable for implementation in digital health interventions [37-40]. For MOSS, a set of 80 interventions including social, relaxation, thoughtfulness, and physical activity exercises were designed and implemented following best practice in CBT.

To promote motivation and adherence [41], 8 different types of diverse interactive interventions were used. Table 2 provides an overview of different types of interactive interventions together with a specific example. Figure 6 depicts exemplary screenshots of the MOSS app.

Table 2. Overview of interactive elements of the Mobile Sensing and Support (MOSS) app.

#	Type of intervention	Description	Example
1	Activity tracker	Based on the walking detection described above, every 2 minutes the progress is updated.	“Take a 10 minute walk outside”
2	Quiz	The subject is asked to answer questions about educational material shown before. Answers can be chosen from multiple choice answers.	“How do you define awareness?”
3	Checkbox	The subject is asked to tick a box with a checkmark on the screen.	“Think of something you did well during the last days, if you found something, check the box!”
4	Button	The subject is asked to tap a virtual button on the screen decreasing a countdown to (eg, encourage physical exercise).	“Morning exercise: sit on the edge of your bed, place the phone on your lap and tap the countdown button with your nose 5 times”
5	Mirror	The subjects see themselves on the smartphone, using the frontal camera. After a countdown the camera is switched off.	“You will see yourself on the phone. Look at yourself in the eye and smile for at least 20 seconds”
6	Audio	Audio files are played to the subject. The subject can pause/stop the audio with common controls.	“Press the play button and listen to instructions for a breathing exercise”
7	Multitext	Educational texts are presented to the subject, spanning multiple screens the subject can navigate through.	“On the following 3 pages, you will get an introduction on awareness”
8	Countdown	The subject is asked to carry out a distinct task during a given time. After the countdown ends, a signal sound rings.	“Sit straight on a chair, start the countdown, lift your feet from the ground and hold this position until you hear a signal sound”

Figure 6. Sample screenshots of intervention types (see Table 2) #6, #1, #2, and #3 (clockwise). Note: The screenshots were translated from German for demo purpose.



Trial Design

A monocentric, single-arm clinical pilot study was conducted. The study was approved by the local ethics committee of the Canton of Zurich in Switzerland and the Swiss Agency for Therapeutic Products. It was conducted in full accordance with the Declaration of Helsinki, with all subjects providing their electronic informed consent prior to participation. As the main interest lied in a proof of concept of the proposed MOSS app, emphasis was put on real life conditions. A range of different recruitment channels was used to attract subjects from the general public; they included physical flyers, Internet posts on relevant Web-based bulletin boards, and the Google Play Store. Interested people were lead to a website with information about the project and an initial screening survey. To be applicable for the study, subjects had to be at least 18-years old, not suffering from bipolar disorder, addiction, or suicidality. If subjects met no exclusion criteria they received a participation code and a download link to the MOSS app. At no point, direct contact with members of the research team was necessary. Subjects were able to enroll on a rolling basis until 2 weeks prior to the end of the trial. The clinical trial took place within 9 months, from January 2015 until September 2015.

Analysis

Symptom Severity Change

As we were interested in changes of PHQ-9 scores of subjects while using the MOSS app, we compared PHQ-9 scores after different time-period lengths. A Kolmogorov-Smirnov test [42] rejected the normality assumption, we therefore conducted Wilcoxon signed rank tests at time t_0 and t_n . In order to be able to do group-wise tests, we synchronized the starting time point t_0 among all subjects and repeated tests between t_0 and t_n . N is incremented for every 2 weeks where subjects were still participating and provided a PHQ-9 value. We included subjects who were considered clinically depressed ($\text{PHQ-9} \geq 11$) at baseline measurement and who at least used the MOSS app for consecutive 4 weeks and provided 2 PHQ-9 measures after the baseline. We considered 2 additional measurements the minimum in order to conduct reasonable analysis.

Relationship of MOSS App Usage and Severity Change

Even though causation cannot be tested with the study design, we tried to find evidence that cumulated change in symptom severity is related to MOSS usage. As a proxy, we used the number of times MOSS was used. A single app use was defined as at least one intervention execution within a session. Multiple intervention usage within one session does not count as multiple MOSS usage. To quantify the relationship between cumulated change in symptom severity and MOSS usage, we conduct a Spearman correlation analysis between the total number of MOSS Sessions and the absolute change in PHQ-9 level between t_0 and t_{end} . Spearman correlation was used because both distributions deviated from normality ($P < .001$, Kolmogorov-Smirnov test).

Passive Depression Detection

This section describes the development of MOSS's depression detection model from features that are derived from smartphone sensor information.

As described earlier, we developed an array of features acting as proxies for behavioral dimensions potentially related to depression. We proposed that a combination of these feature characteristics act as the base for a depression detection model.

For each of the features outlined above, we calculated descriptive statistics over the course of 14 days prior to each time a subject provided a new PHQ-9 measurement. This adds additional potentially valuable information with respect to our classification goal and includes the following computations: mean, sum, variance, minimum, and maximum values per day of the last 2 weeks. In total, this leads to a feature space of 120 features potentially holding information about a subject's depression level of the last 2 weeks. The goal therefore is to relate these time-dependent feature characteristics, to a subject's current depression level. In a very first step, the developed model aimed at separating subjects into 2 groups. For this, we chose a PHQ-9 cut off value of 11, in line with the PHQ-9 [22] to separate people with (≥ 11) from people without (≤ 10) a clinically relevant depression level. In order to derive a binary classification model, we make use of techniques from supervised machine learning. In particular, 2 learning algorithms were used; Support Vector Machines (SVM [43]) and Random Forest Classifier (RFC [44]), which share a predominant role in a range of research domains [45].

The SVM is a supervised learning model with associated learning algorithms that analyze data used for classification analysis. The concept of the SVM method is to project the input features onto a high dimensional space using the kernel-method. In this space, based on transformed feature values, a set of hyper planes is constructed. The goal of the SVM method is to generate optimal hyper planes that are used as decision boundaries to separate different classes. In our system, the radial basis function (RBF) kernel was used for mapping the features to a multidimensional space. SVM and kernel parameters were optimized using Nelder-Mead simplex optimization [46,47].

RFC is a classification algorithm that uses an ensemble of decision trees [48]. To build the decision trees, a bootstrap subset of the data is used. At each split the candidate set of predictors is a random subset of all predictors. Each tree is grown completely, to reduce bias; bagging and random variable selection result in low correlation of the individual trees. This leads to the desirable properties of low bias and low variance [49].

To report on classification performance of the model proposed for this study, we make use of accuracy scores. Accuracy is defined as the fraction of correctly classified samples of both, positive and negative classes. This makes it easy to interpret and ensures a neutral interpretation with respect to importance of positive and negative classes [50].

For unbiased performance estimation of both classifiers, leave-one-out cross validation was conducted [51]. This involved splitting the data into as many subsets as subjects who

provided at least one PHQ-9 value in addition to the baseline (adherence ≥ 2 weeks). All but one set is used to train the models. The left out set is used for testing. This procedure is repeated for every subject, providing a range of unbiased test scores. The average of these scores is reported as the unbiased performance estimate [52]. In order to provide further insights on the classification performance, sensitivity and specificity scores are also reported together with the accuracy score [50].

Results

Subject Statistics

A total of 126 subjects were recruited from the general public. A large portion of subjects uninstalled the MOSS app within the first 2 weeks (64/126, 50.8%). Another 20.6% subjects (26/126) uninstalled the app in the following 2 weeks. Approximately one-fifth of the subjects (28/126, 22.2%) had an adherence of 4 weeks or longer providing at least 2 PHQ-9 measures in addition to the baseline measure (male = 10, female

= 18). Because the study was primarily advertised in Switzerland and on German-speaking Internet forums, the majority of participants came from Switzerland and Germany.

Symptom Severity Change

Figure 7 shows the PHQ-9 progression of subjects who were classified as clinically depressed at the first use of the MOSS app and who had an adherence of at least 4 weeks, providing 2 PHQ-9 values in addition to the baseline measure. Twelve subjects met these criteria, where all of these had an adherence of 8 weeks or longer. For every 2 weeks of MOSS app use, the PHQ-9 distribution represented by a bar plot is shown.

Table 3 provides further insights on the development of PHQ-9 values of the 12 subjects. For every 2 weeks, we present the interquartile range together with the median of PHQ-9 scores. For every additional 2 weeks, we conducted a Wilcoxon sign-rank test with respect to t_0 . At $t=6$ and $t=8$ we observe a significant difference in means.

Table 3. Wilcoxon signed rank test results between t and t_0 .

PHQ-9 score ^a	t_n , median PHQ-9 (IQR ^b)	t_0 , median PHQ-9 (IQR)	N	z^c	P value
t_2 , median (IQR)	14.00 (11.25-20.00)	13.00 (11.00-20.00)	12	0.283	.77
t_4 , median (IQR)	13.00 (8.75-17.25)	13.00 (11.00-20.00)	12	1.216	.22
t_6 , median (IQR)	11.00 (8.25-16.00)	13.00 (11.00-20.00)	12	2.013	.04 ^d
t_8 , median (IQR)	10.00 (8.75-13.75)	13.00 (11.00-20.00)	12	2.479	.01 ^d

^aPHQ-9: Personal Health Questionnaire.

^bIQR: interquartile range.

^cWilcoxon signed rank test.

^dSignificant at the 5% level.

Subject's with a PHQ-9 < 11 at baseline and an extended time of use of at least 4 weeks ($n=8$) did not show significant difference between t_0 and t_4 . ($P=.22$)

Relationship of MOSS Usage and Symptom Reduction

Figure 8 shows a scatter plot of cumulated app starts over time and cumulated change in PHQ-9 values. At each biweekly PHQ-9 measure, we cumulated the number of MOSS app uses. For almost all subjects, we see a constant increase of MOSS app use over time, indicated by the length of arcs between dots of same color.

The scatter plots indicates a negative correlation between cumulated change in PHQ-9 and the total number of MOSS app uses between t_0 and t_{end} .

We conducted a spearman correlation analysis between total app starts and change in PHQ-9 from t_0 to t_{end} of the 12 subjects classified as clinically depressed at t_0 and with a system adherence of at least 4 weeks. We observed a negative correlation with $\rho=-.498$ and $P=.099$.

Depression Detection

Figure 9 shows the sample distribution of the 143 PHQ-9 samples of the 36 subjects with an adherence of at least 2 weeks collected during the trial. Each sample represents a PHQ-9 score provided by a subject via a questionnaire within the MOSS app triggered every 14 days. The distribution shows, that the majority of samples represents a PHQ-9 value close to the classification threshold for clinical depression of 11.

Table 4 shows the average SVM cross-validation score and the RFC out of bag performance with respect to a binary classification of samples with a PHQ-9 ≥ 11 and PHQ-9 ≤ 10 . We separately report sensitivity, specificity, and accuracy. Where sensitivity represents the fraction of samples correctly classified as PHQ-9 ≥ 11 , specificity represents the fraction of samples correctly classified as PHQ-9 ≤ 10 , and accuracy represents the fraction of correctly classified samples among both groups. The RFC showed the highest accuracy performance with 61.5 at 450 trees in the model ($n_{trees} = 450$). The SVM performed slightly worse with an average accuracy of 59.4. The SVM favored sensitivity over specificity leading to a higher sensitivity score of 72.5 compared with the RFC at 62.3, whereas the RFC has a higher specificity score of 60.8 compared with 47.3.

Figure 7. Plot of PHQ-9 progression of clinically depressed individuals over time. Note: Gray dots represent individual PHQ9 values, red lines show distribution mean for each time point, the red area shows the 95% confidence interval for the mean, the blue surface shows 1 standard deviation.

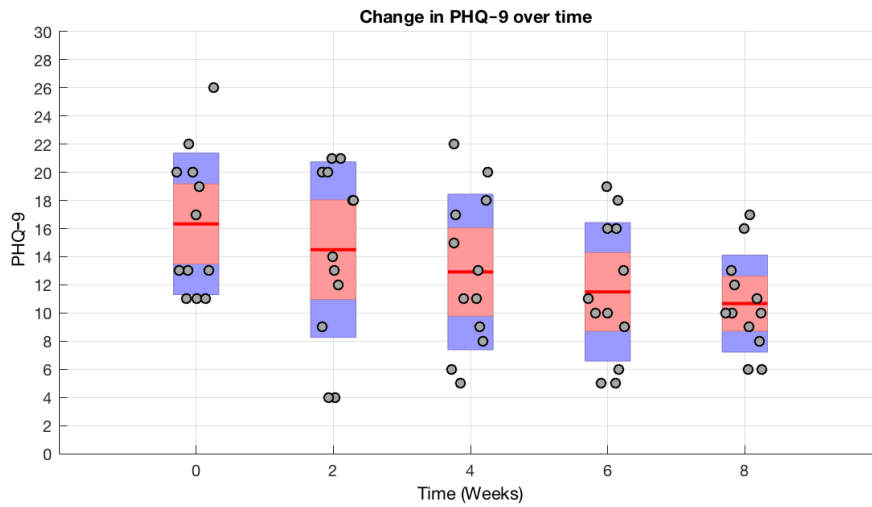


Figure 8. Scatter plot of cumulated app starts per subject over time and cumulated change in PHQ-9 values. Note: The development of PHQ-9 scores of individual subjects is indicated by connected points of the same color.

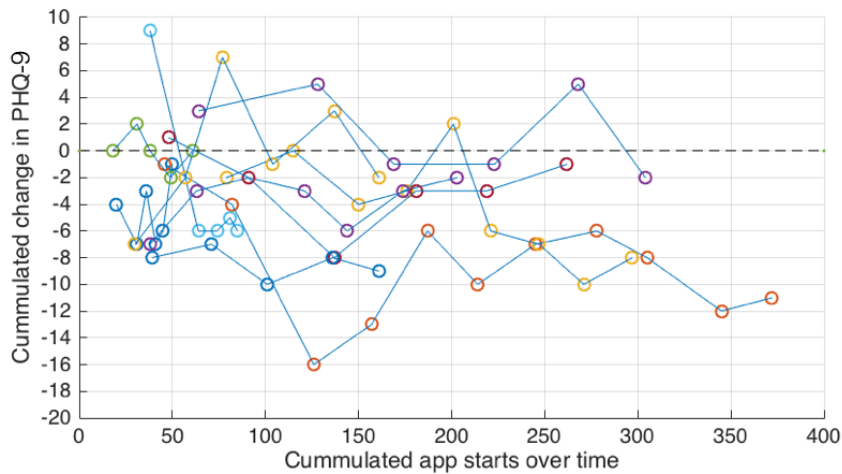
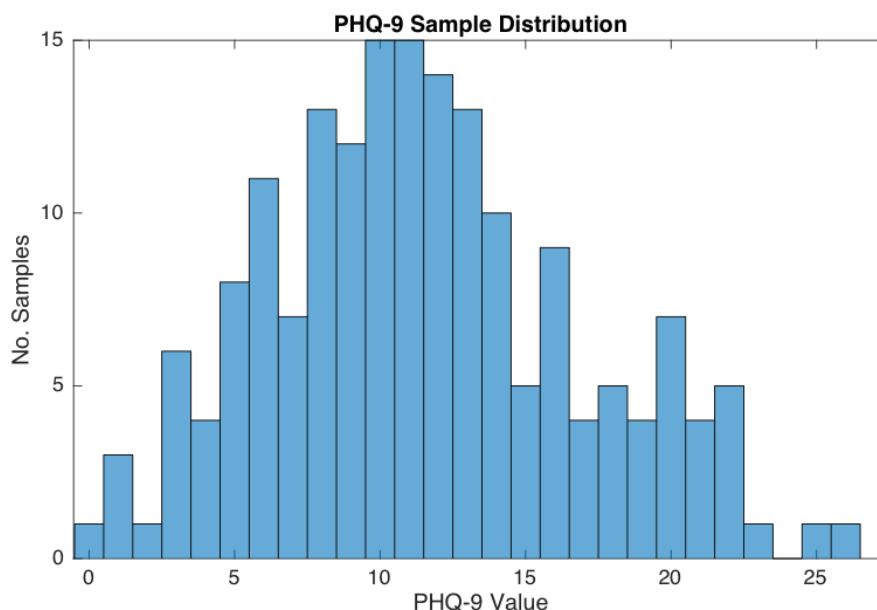


Table 4. Classification performance of support vector machines and random forest classifier.

PHQ-9 ^a ≥11 vs PHQ-9≤10 classification performance	Support vector machines, radial basis function kernel	Random forest classifier, ntrees = 450
Accuracy	59.4	61.5
Sensitivity	72.5	62.3
Specificity	47.3	60.8

^aPHQ-9: Personal Health Questionnaire (self-reported depression survey).

Figure 9. Sample distribution of the 143 Personal Health Questionnaire (PHQ-9) samples of the 36 participating subjects.

Discussion

Principal Findings

Based on commonly available smartphone sensor data an array of proxies for physical and social behavior known to be related to a person's mental health status were introduced. Magnitude of behavior proxies over time periods of 24 hours in comparison to assumptions about healthy behavior were successfully used to dynamically provide meaningful interventions to support people with depressive symptoms in their everyday life. For participants with a clinically relevant PHQ-9 score and an extended MOSS app adherence, a significant drop in PHQ-9 was observed. Among these participants, the relation between frequency of MOSS app usage and change in PHQ-9 scores showed a negative trend. Albeit the fact that we addressed a target population where low motivation toward treatment engagement can be assumed [53], retention rate was above average retention rate of android apps [54].

Two different, supervised, nonlinear machine learning models trained on multiple features calculated from collected sensor data, were able to distinguish between subjects above and below a clinically relevant PHQ-9 score with comparable accuracy exceeding the performance of a random binary classifier.

Limitations

While this work could present the first app of a context sensitive smartphone app to support people with depressive symptoms, the results are preliminary and a number of limitations need to be addressed. The clinical study carried out is based on a nonrandomized, uncontrolled single-arm study design, which rules out the possibility to prove a direct causal link between symptom improvement and MOSS app use. Additionally, to lower the inhibition threshold, subjects were not asked to provide information about relevant control variables such as other current treatments to rule out their impact on treatment outcome. Furthermore, although research has shown that the

PHQ-9 is strongly correlated with depression, not all subjects with an elevated PHQ-9 are certain to have a depression. Moreover, in this first pilot we did not quantify the efficacy of the proposed recommendation algorithm, as this would involve detailed feedback from participants in order to judge appropriateness of context-related intervention recommendations.

Conclusions

To our best knowledge, this study presents the first trial of a context sensitive smartphone app to support people with depressive symptoms under real life conditions. Although we were able to observe an improvement of subject's depression levels, evidence in the form of a large RCT needs to be collected. Nevertheless, we assume that the presented approach is a cause for thought for a new generation of digital health interventions, providing caretakers with tools to design context aware and personalized interventions potentially providing a leap forward in the field of digital therapy for people with depression and other mental disorders.

Complementary to the work of Saeb et al [17], we could successfully demonstrate a first proof of concept for the detection of clinically relevant PHQ-9 levels using nonlinear models on features extracted from smartphone sensor data. This includes WiFi, accelerometer, GPS, and phone usage statistics, acting as proxies for physical and social behavior. Albeit the moderate classification performance, the presented work shows yet another promising direction to develop passive depression detection toward clinically relevant levels. Improved models would create opportunities for unobtrusive mental health screening potentially able to alert a subject if a critical mental state is reached and professional treatment highly desirable. In conclusion, this could not only relieve the health care system by preventing severe cases from getting into worse and costlier states but also by preventing subjects with a subclinical PHQ-9 value to strain the system.

Acknowledgments

This study was part-funded by the Commission for Technology and Innovation (CTI project no. 16056) with makora AG acting as research partner and cofinancier. All rights to the app are owned by makora AG.

SW was supported by the University of Zurich – career development grant “Filling the gap.”

Conflicts of Interest

None declared.

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Abbreviations

- 3D:** three-dimensional
- CBT:** cognitive behavior therapy
- CV:** cross validation
- GPS:** global positioning systems
- IQR:** interquartile range
- MOSS:** Mobile Sensing and Support
- PHQ-9:** Personal Health Questionnaire
- RBF:** radial basis function
- RCT:** randomized controlled trial
- RFC:** random forest classifier
- SVM:** support vector machine
- WHO:** World Health Organization

Edited by G Eysenbach; submitted 09.05.16; peer-reviewed by C Mascolo, S Saeb, M Zhang; comments to author 04.06.16; revised version received 24.07.16; accepted 07.09.16; published 21.09.16.

Please cite as:

Wahle F, Kowatsch T, Fleisch E, Rufer M, Weidt S
Mobile Sensing and Support for People With Depression: A Pilot Trial in the Wild
JMIR Mhealth Uhealth 2016;4(3):e111
URL: <http://mhealth.jmir.org/2016/3/e111/>
doi: [10.2196/mhealth.5960](https://doi.org/10.2196/mhealth.5960)
PMID: [27655245](https://pubmed.ncbi.nlm.nih.gov/27655245/)

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Original Paper

Popular Mobile Phone Apps for Diet and Weight Loss: A Content Analysis

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Abstract

Background: A review of the literature has revealed that the rates of overweight and obesity have been increasing in Australia over the last two decades and that wellness mobile phone apps play a significant role in monitoring and managing individuals' weight. Although mobile phone app markets (iTunes and Google Play) list thousands of mobile phone health apps, it is not always clear whether those apps are supported by credible sources. Likewise, despite the prevailing use of mobile phone apps to aid with weight management, the usability features of these apps are not well characterized.

Objective: The research explored how usability taxonomy could inform the popularity of downloaded, socially focused wellness mobile phone apps, in particular weight loss and diet apps. The aim of the study was to investigate the Australian mobile phone app stores (iTunes and Google Play) in order to examine the usability features of the most popular (ie, most downloaded) wellness apps.

Methods: The design of this study comprises 3 main stages: stage 1, identifying apps; stage 2, development of weight loss and diet evaluation framework; and stage 3, application of the evaluation framework. Each stage includes specific data collection, analysis tools, and techniques.

Results: The study has resulted in the development of a justified evaluation framework for weight loss and diet mobile phone apps. Applying the evaluation framework to the identified apps has shown that the most downloaded iTunes and Google Play apps are not necessarily the most usable or effective. In addition, the research found that search algorithms for iTunes and Google Play are biased toward apps' titles and keywords that do not accurately define the real functionality of the app. Moreover, the study has also analyzed the apps' user reviews, which served as justification for the developed evaluation framework.

Conclusions: The analysis has shown that *ease of use*, *reminder*, *bar code scanning*, *motivation*, *usable for all*, and *synchronization* are significant attributes that should be included in weight loss and diet mobile phone apps and ultimately in potential weight loss and diet evaluation frameworks.

(JMIR Mhealth Uhealth 2016;4(3):e80) doi:[10.2196/mhealth.5406](https://doi.org/10.2196/mhealth.5406)

KEYWORDS

applications; diet; monitoring; obesity; weight loss

Introduction

The World Health Organization (WHO) defines overweight and obesity as abnormal or excessive fat accumulation, which may result in harm to the person's health [1]. The Centers for Disease

Control and Prevention refers to these terms as labels used to describe ranges of weight that are considered greater than the normal healthy weight for a given height [2].

There are many health problems that occur as a consequence of obesity, including musculoskeletal disorders, cardiovascular

disease, type 2 diabetes, and some cancers (endometrial, breast, and colon). Many of these diseases are preventable if a person follows a healthy and active lifestyle [1].

According to WHO global estimates [1], in 2014, about 13% of the world's adult population (11% of men and 15% of women) was obese, while 39% of adults aged 18 years and older (38% of men and 40% of women) were overweight. The rate of obesity has more than doubled between 1980 and 2014 [1]. The main problem is that overweight and obesity is killing more people than underweight worldwide (this includes all people in high-income and most middle-income countries) [1].

One of the most important strategies to manage this problem is behavioral intervention for weight management and lifestyle changes, which requires *self-monitoring*. This strategy not only leads to weight loss but also prevents weight gain or regaining weight and encourages physical activities [3]. Self-monitoring is observing and recording person's exercise and eating patterns, followed by feedback on those behaviors [3]. Self-monitoring increases self-awareness with regard to targeting behavior and outcomes in relation to food intake goals. In addition, it can act as an early warning system, indicating whether a risk of becoming overweight is increasing [3]. Although health care providers can monitor an individual's health, they face clear problems with providing treatment and advice to the people who are at risk of overweight and obesity [4]. Self-monitoring combined with healthy weight guidelines provides an alternative solution to weight management [4].

Wellness technologies and wellness apps can be used to monitor users' health and help them maintain a healthy lifestyle. *Mobile phone apps* play an important role in monitoring and managing individuals' weight. They provide real-time feedback and can employ persuasive technology among both chronically ill and healthy individuals [5]. Wellness monitoring apps are redefining the concept of self-monitoring by altering the isolated process of self-monitoring into a communal, supportive process whereby multiple individuals with similar health interests can check the user's progress and give encouraging feedback [5]. MyFitnessPal, Lose it!, FatSecret's Calorie Counter, and SparkPeople are some of the popular apps with features that can track diets and physical activities [6].

Although mobile app markets (iTunes and Google Play) list hundreds of thousands of health apps, it is not always clear whether those apps are supported by credible sources [7]. Despite the prevailing use of mobile phone apps to aid with weight management, the usability features of these apps are not well characterized [8]. Therefore, the aim of this study was to investigate the Australian mobile phone app stores (iTunes and Google Play) in order to examine the usability features of popular wellness apps, particularly in the area of diet and weight loss. In addition, it aimed to explore and recommend any important aspects of the most popular mobile phone apps for diet and weight loss that could assist users in the selection of diet and weight loss apps and assist developers in decisions regarding those apps.

Methods

Research Objectives

In order to achieve the research aims, the following objectives were identified:

1. Identify the most popular weight loss and diet apps according to specific criteria.
2. Build or find a framework for evaluating these apps and apply this evaluation framework to the identified apps.
3. Compare the outcomes of the developed evaluation framework with specific metrics for justification.

Design

The design of this research has included 3 main stages: stage 1, *identifying apps*; stage 2, *development of the evaluation framework*; and stage 3, *application of the framework*. At the end, a thematic analysis of apps' user reviews was conducted to serve as justification and exploration step of the results.

Stage 1: Identifying Apps

Identifying Apps included a review of the apps that were located in iTunes and Google Play stores. This review was based on predefined inclusion and exclusion criteria. The inclusion criteria for selecting the apps from the stores were as follows: (1) free, no charge, (2) high star rating (1 and 2 considered low ratings, 3 stars standard, and 4 and 5 stars considered high ratings), (3) app language is English, (4) consumer-oriented app, and (5) app should be related to weight loss and diet. The first 2 criteria were considered because they represent important factors for users in terms of selecting mobile phone wellness apps from among alternatives [7]. The third criterion was identified because the study focused on the Australian mobile phone app stores where English was found to be the most commonly spoken language among mobile phone app users [9]. The fourth and fifth criteria were created to serve this study's purpose. An app was excluded if it did not meet any of these inclusion criteria.

Apps were selected from the stores using the search terms "weight loss" and "diet." Because of time constraint, only the top 30 popular apps from each store were examined. First, iTunes apps were collected between June 24 and June 25, 2014, using the aforementioned search terms. The Google Play apps were collected using the same search terms from June 26 to June 30, 2014. The list of possible apps for iOS was obtained using iTunes version 11.2 and for Android using Google Play. Second, the 30 most popular iTunes apps were collected on June 25, 2014 and the 30 most popular apps for Google Play on July 4, 2014. As iTunes does not provide an estimate of the number of downloads per app, the displayed search queries on the computer monitor were used as an indication of the apps' popularity [10]. Therefore, the first 30 displayed apps were considered the 30 most popular iTunes apps. Unlike iTunes, Google Play store provides a worldwide total number of downloads for each app, which has been utilized as a proxy of apps' popularity. Consequently, the 30 apps that were downloaded the most were considered as the most popular Google Play apps. The 30 most popular iTunes and Google Play

apps that resulted from the search terms “diet” and “weight loss” were only included in the analysis of this study.

iTunes and Google Play descriptions were used to review the 5 inclusion criteria per app. The description page of both stores includes a list of features the app offers, user ratings, customer reviews, and 1 to 4 screenshots of what the app looks like when downloaded. The description page provides sufficient information for evaluating the inclusion criteria. Only the apps that met the 5 inclusion criteria were considered; all other apps were excluded.

Stage 2: Development of Evaluation Framework

The development of the evaluation framework was achieved using principles of qualitative content analysis to analyze previous studies related to evaluating wellness apps. Qualitative content analysis methods were utilized to draw on existing theories in order to develop the evaluation framework and its elements, which allowed for a meaningful evaluation of the weight loss and diet mobile phone apps.

Stage 3: Application of the Framework

The application of the framework started on July 14, 2014. This stage followed the method by Breton et al [11] of applying the evaluation framework to the wellness mobile phone apps. Thus, an Excel worksheet was used to apply the framework to the apps. The application of the evaluation framework required the individual downloading of the refined apps that resulted from stage 1—identifying apps. After the app was downloaded, the framework components were examined. When the app satisfied the framework component, an “X” was assigned as a code to indicate the presence of the framework component (ie, X=1). Otherwise, the cell was left empty. After investigating the 9 components of the framework, the value of the *index score* was calculated. After the framework was applied to all identified apps separately, the apps were ranked according to their index scores. This method of evaluating apps’ content is a valid technique that has been used by other similar app evaluation studies [8,10-12].

Thematic Analysis of Apps’ User Reviews

As the third objective of this study was aiming to compare the outcomes of the developed evaluation framework with a specific metric as justification, a deductive thematic analysis was conducted to search for patterns in the apps’ user reviews after applying the framework to all apps. The thematic analysis was conducted on August 4, 2014. The most recent user reviews were analyzed for both iTunes and Google Play apps (available user reviews for all months in 2014). The user reviews were analyzed manually by the authors using the deductive way of thematic analysis. Thus, using Excel worksheets, we first coded the reviews, developed themes, and then generated categories. Patterns that were searched for in the users’ reviews were

matched either in wording or meaning to the elements of the evaluation framework. In addition, new patterns discovered from the thematic analysis were also considered. There are several studies that demonstrate the usefulness of investigating apps’ user reviews as it can reflect a key part of users’ experience [13-16]. Thus, analyzing users’ reviews put the lens on the developed evaluation framework elements. In addition, it allowed for discovering new evaluation elements that should be utilized in future weight loss and diet evaluation frameworks.

Results

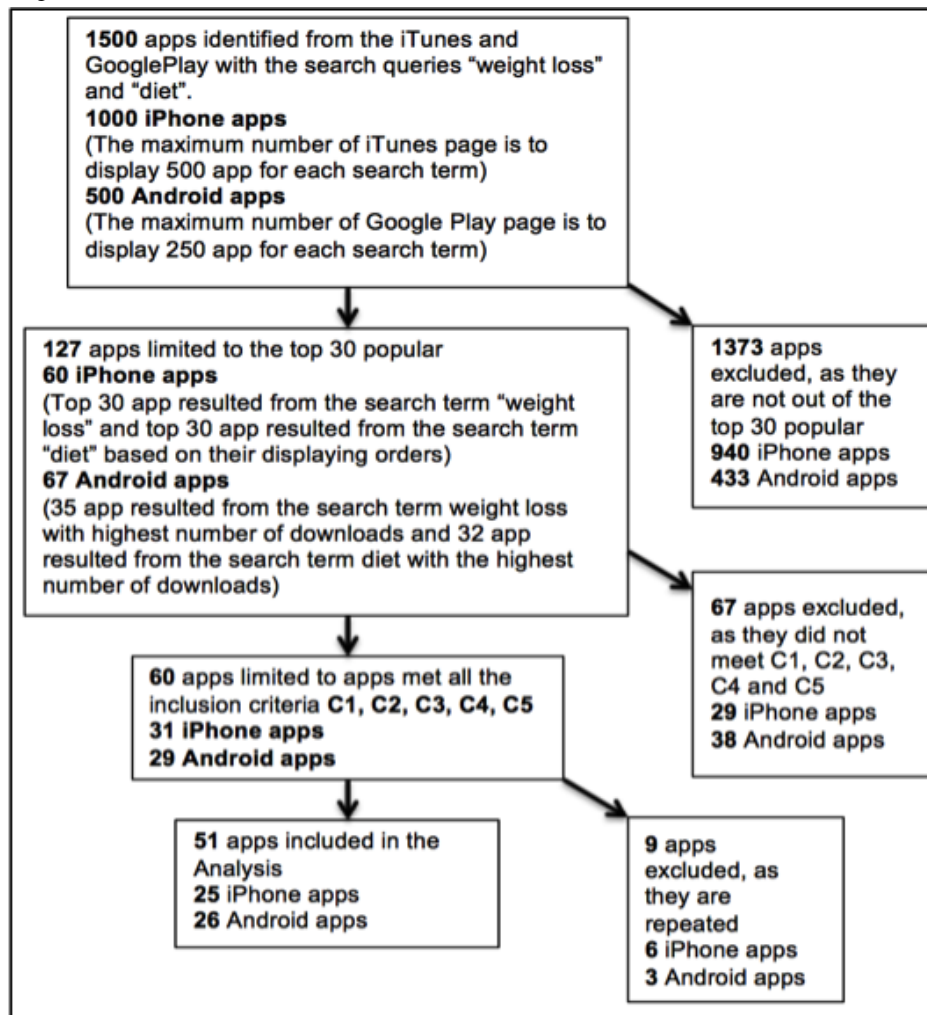
Stage 1: Identifying Apps

Figure 1 summarizes the results of stage 1: identifying apps in the Australian iTunes and Google Play stores.

Some apps in the Australian Google Play market, such as “Woman’s DIARY period.diet.cal” developed by HighLab Co Ltd, were excluded from the analysis as they were not related to weight loss or diet. The aforementioned app included a tracking weight feature. However, the content was mainly related to tracking women’s menstrual cycle information. This might suggest that the search engine primarily retrieves apps based on the key terms in the apps’ titles. Some other factors such as the main function of the app must be considered in retrieving apps. Likewise, in the Australian iTunes store, the following 2 apps (FatBooth by PiVi & Co and Fatify - Get fat by Apptly LLC) were retrieved as a result of the following search terms (“weight loss” and “diet”) even though they were not related to diet or weight loss. Apparently, the search engine has considered the term “fat,” hence it retrieved those 2 apps in the search results.

Although this study was performed using the Australian Google Play store, there were many apps retrieved in languages other than English, such as DietShin-diet *칭혈주스 레시피*. The country of the customer should be considered when retrieving apps. This is another example of search engine bias toward keywords in the apps’ titles.

In Google Play, some apps’ contents were the same; these have been developed by the same developer but appeared under different names. For example, “How To Lose Weight Quickly” and “How To Lose Weight Fast” by Venture Technology Ltd have exactly the same content. One problem with the duplicated apps that appear under different names in the store could be that users might download all of them while they only need to download one. This problem is potentially more serious when the apps are not free. All the aforementioned initial findings of stage 1 indicated that the search algorithm of the stores was biased toward the apps’ titles and keywords and not necessarily reflective of the apps’ content.

Figure 1. Summary of stage 1 results. (C1 to C5 refer to the 5 inclusion criteria).

Stage 2: Development of Weight Loss and Diet Evaluation Framework

Analyzing the literature revealed 2 main methods of evaluating mobile phone apps. The first method is the People At the Centre of Mobile Application Development (PACMAD) model by Harrison et al [17]. The PACMAD model includes the following elements: effectiveness, efficiency, satisfaction, learnability, memorability, errors, and cognitive loads. Each of these elements has utility to be evaluated. The PACMAD model considers three factors: user, task, and context [17]. The second method is the method mentioned in the following studies [8,10-12]. The method of these studies evaluated wellness mobile phone apps by first identifying specific usability elements and then evaluating the apps according to the presence or absence of these elements. Each of these studies has its own app scoring system.

The second method was used in this study to evaluate the 51 iTunes and Google Play apps that resulted from stage 1. The second method of evaluating apps was more appropriate for this study as elements of the PACMAD model tend to be general in nature [17]; hence, it might be less efficient if applied to examine the usability of weight loss and diet apps. In addition, applying the first method for large number of apps would exceed

the resources available for this study. Thus, the second method of evaluating apps was selected.

The included evaluation elements were related to usability, app design, and index score; these elements resulted from qualitative content analysis of several studies related to evaluating wellness mobile phone apps. The usability elements are concerned with the functionality of the apps. They were based on common evaluation elements gained from behavioral weight loss strategies [18], as well as from the following studies [8,11,12]. However, one of the usability elements (namely, regular physical activity) has been included as it was a common element between some of these studies, which proved the importance of regular physical activity in the context of weight loss and diet. Although it is essential to consider the hedonic design aspects besides the functional side when developing health wellness apps, none of these aforementioned evaluation studies has focused on the apps' design when evaluating wellness apps. This might be caused by a lack of wellness apps' design strategies.

Studies in the literature and thus in this field need more investigations in the foreseeable future. Therefore, the authors have decided to consider the design elements in evaluating the selected apps. The design elements were based on wellness apps' design strategies stated in the study by Alagoz et al [19].

The last element of the developed evaluation framework is the index score. The index score is a score calculated based on the existence of functionality and design elements in the identified apps. Index score values range from 0 (minimum value indicating that the app did not meet any of the developed evaluation elements) to 11 (maximum value indicating that the

app incorporated all the developed evaluation elements). The value gained by the index score allowed for an incremental ranking of the apps.

Table 1 lists the elements of the developed weight loss and diet mobile phone apps evaluation framework.

Table 1. Elements of the developed weight loss and diet evaluation framework.

Elements	Description
Usability elements	
Self-monitoring	App was scored based on whether or not it provided a means to monitor users' weight over time.
Social support	App was scored on whether it allowed users to access social support services such as message boards, chat rooms, email an expert, or a networking component like Twitter.
Knowledge resource	App was scored according to whether it provided a knowledge resource that can increase users' knowledge/information related to nutrition and awareness of weight control or reduction.
Weight loss goal	App was scored on whether it recommends certain weight loss goals for users and whether it allows users to achieve targeted weight.
Regular physical activity	The app was scored on whether it recommends a certain amount of physical activity.
Design elements	
Abstract and reflective	This strategy scores apps on the basis of whether they use a graph, chart, or other virtual means to easily reflect the users' data.
Public	This strategy aims to evaluate an app on whether or not it provided a log-in feature or similar to avoid unwanted disclosure of user's personal data.
Aesthetic	Apps were scored on whether they enable users to customize or adapt some features in the app according to their personal preferences (eg, backgrounds, user interfaces).
Controllable	This strategy is concerned with scoring an app on whether it allows a user to manually manage and control access to data. This can remove the possibility of errors that could occur when the apps only depend on sensory data.
Trending and historical	This strategy scored an app on whether or not it enables a user to access historical data to show changes and trends over time.
Comprehensive	Considers apps that allow users to manually enter data as well as collect sensory data.
Index score	
	A score determined based on the aforementioned 11 functionality and design elements of the developed evaluation framework. The sum of the scores provided a total value to the index score.

Stage 3: Application of the Evaluation Framework

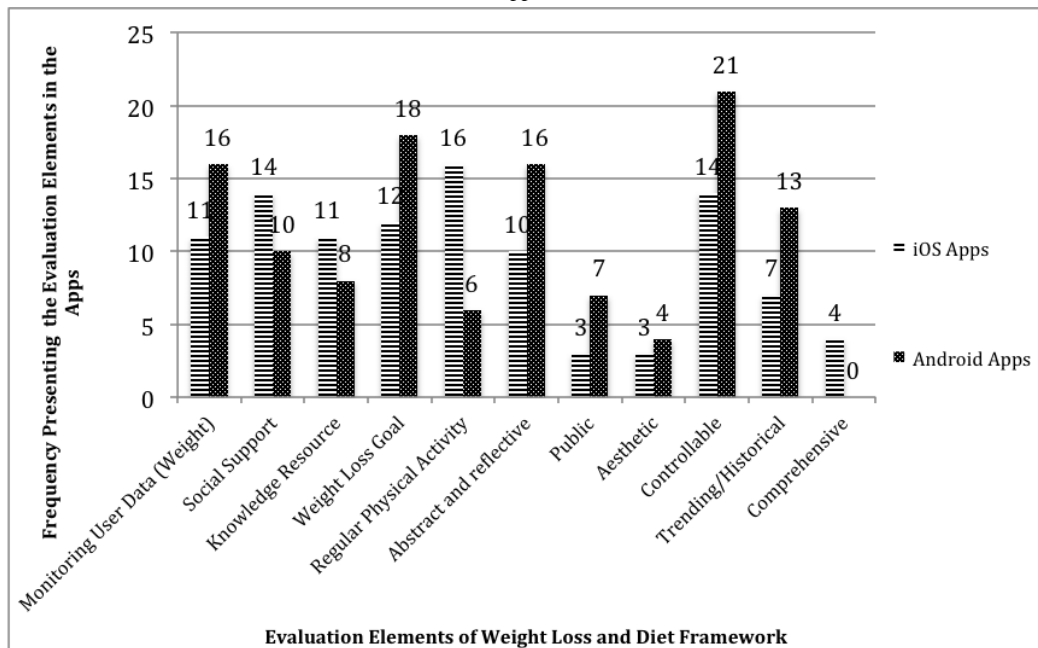
None of the iTunes and Google Play apps achieved the highest proposed index score value (ie, 11) after applying the developed evaluation framework to the identified iTunes and Google Play apps. There were 2 interpretations for this outcome:

1. iTunes and Google Play search engines only consider the keywords entered by users to retrieve apps [20-22].
2. The popularity of iTunes and Google Play apps does not necessarily indicate the usability of the apps [20].

All the developed evaluation elements were found at least once in iTunes and/or Google Play apps (see Figure 2).

Applying the evaluation framework to the iTunes and Google Play apps showed that 18% (9/51 apps) of the evaluated apps achieved index scores equal to the average index score (ie, 5). Whereas only 37% (19/51) of the evaluated apps achieved index scores that were higher than average, 45% (23/51) achieved index scores that were lower than average. The aforementioned outcome indicates that the proportion of apps that gained index scores below the average is higher than the proportion of apps with index scores above the average.

Figure 2. The presence of the evaluation elements in iOS and Android apps.



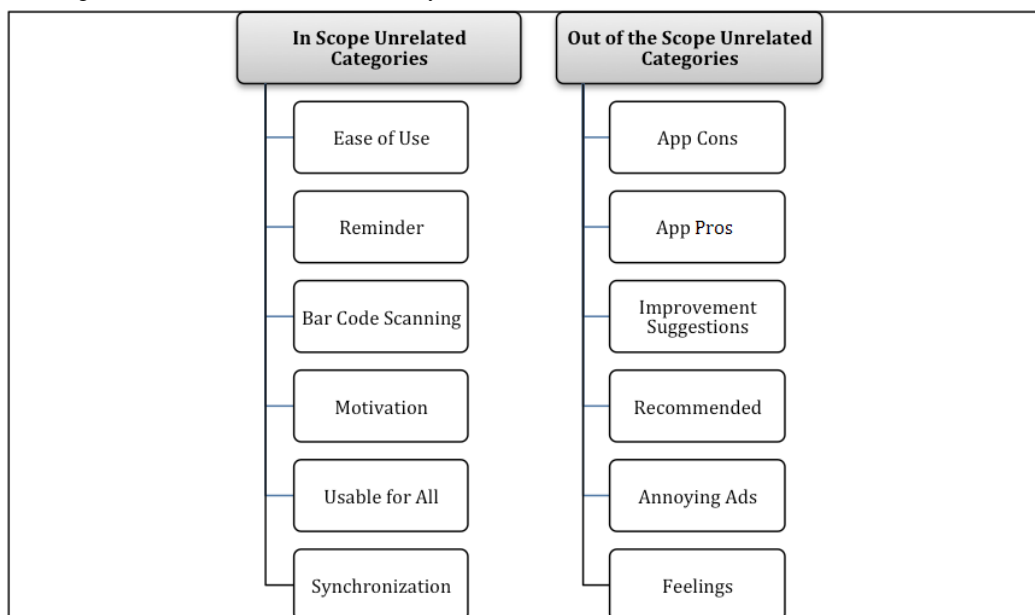
Thematic Analysis of Apps' User Reviews

Many of the 25 identified iTunes apps did not include users' reviews. However, almost all of the 26 Google Play apps had users' reviews. A total of 402 Google Play user reviews and 150 iTunes user reviews were analyzed. Analyzing the iTunes and Google Play apps' user reviews resulted in 11 categories directly related to the elements of the developed evaluation framework. *Related categories* to elements of the evaluation framework resulted from apps' user reviews that included themes related in wording or meaning to the elements of the evaluation framework (ie, monitoring user data, social support, knowledge resources, weight loss goal, regular physical activity, abstract and reflective, public, aesthetic, controllable, trending and historical, and comprehensive). As Google Play apps had more user reviews than iTunes apps, a larger number of *related categories* were found when analyzing the Google Play apps' user reviews.

Analyzing the iTunes and Google Play apps' reviews also resulted in 12 categories that were not related to the elements of the evaluation framework. *Unrelated categories* resulted from analyzing users' reviews that included themes not related in wording or meaning to elements of the evaluation framework (see Figure 3). Some of these categories emerged as a result of

analyzing iTunes and Google Play users' reviews, while some only resulted from either one of them.

As an additional justification step for the outcomes of the evaluation framework, the emerged *related categories* were compared with the gained index score values. The comparison led to two main conclusions. First, the numbers of *related categories* recognized by analyzing iTunes apps' user reviews relatively match the index score values obtained by employing the evaluation framework. Second, the numbers of *related categories* identified by analyzing the Google Play users' reviews more closely matched the index score values. As the analysis of the content used a quantitative element (ie, index score) as part of the rationale for inclusion of the ultimate framework elements, accordingly the *related categories* were viewed in the same manner. Conversely, because of the way the *unrelated categories* were formed, the interpretative nature of the study did not compare their existence with the elements of the evaluation framework (ie, index score values). Accordingly, the *unrelated categories* were not ranked or ordered through any type of quantitative measure. This distinction between the analysis of the related and unrelated categories is in line with the philosophical nature of this study, which is subjective ontology and interpretive epistemology.

Figure 3. Unrelated categories that resulted from thematic analysis.

Discussion

In stage 1 of this study, the most popular weight loss and diet apps were identified according to specific criteria. The initial findings of stage 1 demonstrated that the search algorithm of iTunes and Google Play was biased toward apps' titles and keywords. Stage 2 of this study developed a justified weight loss and diet apps' evaluation framework by utilizing a content analysis of the literature. The developed evaluation framework included elements related to the usability and design of the apps.

Even though the identified apps were the most popular ones on iTunes and Google Play, after applying the developed evaluation framework to the identified apps, none of the apps was able to achieve the maximum index score value. There were two ways to interpret this initial finding. The first interpretation claims that the search algorithm of iTunes and Google Play was biased toward apps' titles and keywords, which does not necessarily reflect the functionality of the app. Hence, when the developed evaluation framework evaluated these apps, they achieved low index scores. The second interpretation was that the most downloaded iTunes and Google Play apps are not necessarily the most usable and effective apps.

Analyzing the apps' user reviews has resulted in 11 categories that supported the identified evaluation elements of the developed evaluation framework. The presence of 11 *related categories* in the iTunes and Google Play apps' user reviews at least once provided additional assurance of the robustness of the developed framework and its outcomes. All the 11 identified thematic categories were related to the identified evaluation elements of the developed framework. This indicated that none of the identified evaluation framework elements was irrelevant or inappropriate for evaluating weight loss and diet apps.

Analyzing the apps' user reviews resulted in 12 unrelated categories. On one hand, there were six unrelated categories that considered within the scope of this study and hence analyzed in detail (i.e. the *ease of use*, *reminder*, *BCS*,

motivation, *usable for all*, and *synchronization*) as they were found in the users' reviews of apps that had high index score values. The existence of these categories in the high index score users' reviews reflected the importance of these elements in health apps, particularly in weight loss and diet apps. On the other hand, the following six unrelated categories that resulted from the thematic analysis of apps users' reviews namely *app cons*, *app pros*, *improvement suggestions*, *recommended*, *annoying ads*, *feelings* have not been analyzed in detail as some of these categories found in apps users' reviews of apps with low index score values or they were beyond the scope of this study.

The *ease of use* category was considered one of the most important *unrelated categories* as it was in the user reviews of almost all the apps that gained high index score values. The attribute of easy to use in mobile phone apps encourages people to use wellness apps [7]. One of the factors that affect individual choices of apps is ease of use [23]. Ease of use of health apps was considered one of the important aspects missing from the developed evaluation framework. Therefore, as it was considered one of the factors that encourage use of the wellness app, this element is recommended to be included in any future evaluation frameworks for weight loss and diet apps.

Reminder, *BCS*, *motivation*, *usable for all*, and *synchronization* were categories that were not included in the developed evaluation framework even though analysis of the users' reviews revealed their importance. There was agreement on the importance of the *reminder* element in the literature. However, it was not incorporated in the framework, because evaluating this element for all the identified apps would require resources that exceed the scope of this study. Mobile phone health functions such as reminders and alerts could encourage individuals to sustain positive attitudes and improve quality of life among adults [24]. Hence, the inclusion of the *reminder* attribute in future evaluation frameworks of health apps, particularly weight loss and diet apps, seems vital.

Bar code scanning can be used to scan foods to be consumed. In addition, BCS could provide other information such as data concerning exercise [25]. For example, scanning a box of biscuits via an app with BCS feature could reveal that the biscuit contains 140 calories. This calorie data can be transmitted into apps through BCS. Then, the apps could also specify the amount of exercise needed to burn those calories. Therefore, BCS can be used to assist individuals to achieve any weight control goal if added to weight loss and diet apps [26]. The inclusion of the BCS attribute in upcoming weight loss and diet apps and evaluation frameworks is essential.

Motivation is an important attribute that should be included in weight loss and diet apps and their evaluation frameworks. Wellness technologies and wellness apps should be designed to motivate users to continue using wellness technology and to achieve their goals [27]. For example, there are several attributes that can increase motivation toward physical activity, such as real-time feedback and having a virtual personal trainer. These attributes would strongly motivate users toward physical activity [27]. In addition, the design of user interface of mobile phone wellness apps can support and motivate users toward initial and long-term use [27]. These motivating attributes were not evaluated for the apps in this study. However, they should be included in future weight loss and diet apps and their evaluation frameworks.

Usable for all and *synchronization* elements were not previously mentioned in the analyzed studies that evaluate wellness apps. However, the inclusion of the perception of these categories in future evaluation frameworks for weight loss and diet apps is recommended. *Usable for all* was identified in this study as an app suitable for a wide variety of individuals. For example, wellness apps can be used in different languages; they can include different exercises, and can be suitable for women, men and a wide range of age groups. The app may include different products, diet plans and foods that are suitable for different people such as individuals with diabetes, pregnant women, vegetarian people, etc. By offering several options, the app would not be restricted to specific group of users. Instead, it would give them the freedom of choice. This can be one of the factors that attract users to use the app.

These days, *synchronization* is a very important aspect of mobile phone apps. Mobile phone apps can produce one more function if synchronized with other technology (eg, with wearable medical devices) [28]. Wearable medical devices can provide a huge advantage when it comes to monitoring and early detection of symptoms [28]. The sensors in these wearable medical devices enable monitoring of vital signs and physiological parameters such as electrocardiogram, heart rate, body activity, blood pressure, and weight, to name but a few [28]. Monitoring these features can greatly help the users of weight loss and diet apps. Early examples of independent wearable devices are Fitbit, Jawbone, and Samsung Gear Fit. Currently, Apple has developed a sensor-laden smart watch,

and that wearable device synchronizes with an iPhone over Bluetooth and other wireless technologies. Likewise, Google is working on its own smart watch. Similarly, recently Samsung introduced an improved smart watch that supports basic health measurement functionality [29]. Therefore, it can be concluded that the use of these wearable health devices, which enhance and help manage health features, will increase in the future. Hence, the ability of apps to sync with such devices would further inform the evaluation of weight loss and diet apps.

As it has been found that ease of use, reminder, bar code scanning (BCS), motivation, usable for all, and synchronization are significant attributes, it should be incorporated in weight loss and diet mobile phone apps, and thus in potential weight loss and diet evaluation frameworks.

When it comes to selecting weight loss and diet apps from iTunes and Google Play stores, users should be aware that the search engines of these stores are biased toward apps' titles and keywords, and hence one might end up with some apps that do not really serve the intended weight loss and diet functions. In addition, users should be mindful that the most popular apps are not necessarily the most usable and effective. Therefore, popularity is by no means a measure of usability and effectiveness of apps. Diet and weight loss apps' users and developers can utilize elements of the developed evaluation framework as a basis for their selection and development of apps based on robust literature.

There was a time constraint on this study (only 6 months), and the qualitative nature of the study ideally requires a longer time span. Thus, the number of apps included in the analysis was reduced. As a result of this, the number of iTunes users' reviews was very small, which led to not-so-fully saturated thematic categories. A longitudinal study or one with more time and resources can include more apps and users' reviews and thus give more accurate results. The limitation of researcher bias can be overcome by applying the evaluation framework more than once to the identified apps. This study merely focused on evaluating the most popular iTunes and Google Play apps. There is here an opportunity for future research to evaluate popular and unpopular apps so as to compare the results. Likewise, as this study has focused only on evaluating high-rated apps, future research could consider the evaluation of both high- and low-rated apps. Such research could determine if there is a relationship between high- and low-rated apps on the one hand and the index score values of evaluated apps on the other. The numbers of analyzed iTunes and Google Play users' reviews were relatively small, so that a greater number of users' reviews may result in additional thematic categories from the analyzed reviews. Future improvement to the evaluation framework can be achieved by adding the identified in-scope *unrelated categories* that resulted from the thematic analysis. This will no doubt result in a more robust and comprehensive weight loss and diet evaluation framework.

Acknowledgments

This study was completely supported by personal funds.

Authors' Contributions

SBZ was responsible for developing, designing, collecting of data, and manuscript drafting. All authors participated in editing and revising the manuscript. All authors read and approved the final manuscript.

Conflicts of Interest

None declared.

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Abbreviations

BCS: bar code scanning

WHO: World Health Organization

Edited by G Eysenbach; submitted 09.12.15; peer-reviewed by PH Lin, A Lucas, B Turner-McGrievy, P Wark; comments to author 24.01.16; revised version received 13.03.16; accepted 24.05.16; published 11.07.16.

Please cite as:

Zaidan S, Roehrer E

Popular Mobile Phone Apps for Diet and Weight Loss: A Content Analysis

JMIR Mhealth Uhealth 2016;4(3):e80

URL: <http://mhealth.jmir.org/2016/3/e80/>

doi: [10.2196/mhealth.5406](https://doi.org/10.2196/mhealth.5406)

PMID: [27400806](https://pubmed.ncbi.nlm.nih.gov/27400806/)

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Original Paper

Mobile Apps for Weight Management: A Scoping Review

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Abstract

Background: Obesity remains a major public health concern. Mobile apps for weight loss/management are found to be effective for improving health outcomes in adults and adolescents, and are pursued as a cost-effective and scalable intervention for combating overweight and obesity. In recent years, the commercial market for ‘weight loss apps’ has expanded at rapid pace, yet little is known regarding the evidence-based quality of these tools for weight control.

Objective: To characterize the inclusion of evidence-based strategies, health care expert involvement, and scientific evaluation of commercial mobile apps for weight loss/management.

Methods: An electronic search was conducted between July 2014 and July 2015 of the official app stores for four major mobile operating systems. Three raters independently identified apps with a stated goal of weight loss/management, as well as weight loss/management apps targeted to pediatric users. All discrepancies regarding selection were resolved through discussion with a fourth rater. Metadata from all included apps were abstracted into a standard assessment criteria form and the evidence-based strategies, health care expert involvement, and scientific evaluation of included apps was assessed. Evidence-based strategies included: self-monitoring, goal-setting, physical activity support, healthy eating support, weight and/or health assessment, personalized feedback, motivational strategies, and social support.

Results: A total of 393 apps were included in this review. Self-monitoring was most common (139/393, 35.3%), followed by physical activity support (108/393, 27.5%), weight assessment (100/393, 25.4%), healthy eating support (91/393, 23.2%), goal-setting (84/393, 21.4%), motivational strategies (28/393, 7.1%), social support (21/393, 5.3%), and personalized feedback (7/393, 1.8%). Of apps, 0.8% (3/393) underwent scientific evaluation and 0.3% (1/393) reported health care expert involvement. No apps were comprehensive in the assessment criteria, with the majority of apps meeting less than two criteria.

Conclusions: Commercial mobile apps for weight loss/management lack important evidence-based features, do not involve health care experts in their development process, and have not undergone rigorous scientific testing. This calls into question the validity of apps’ claims regarding their effectiveness and safety, at a time when the availability and growth in adoption of these tools is rapidly increasing. Collaborative efforts between developers, researchers, clinicians, and patients are needed to develop and test high-quality, evidence-based mobile apps for weight loss/management before they are widely disseminated in commercial markets.

KEYWORDS

weight loss; obesity; mobile apps; smartphones; mHealth

Introduction

Background

The prevalence of overweight and obesity worldwide is predicted to exceed 1.12 billion and 573 million people, respectively, by 2030 [1]. Excess weight is closely linked to a myriad of chronic diseases such as hypertension, type 2 diabetes mellitus, cardiovascular disease, and stroke [2]. The economic costs of obesity globally are estimated at 0.7% to 2.8% of total health care expenditures [3] and the burden of mortality is estimated at 2.8 million deaths annually [4]. Environmental changes promoting intake of highly caloric, inexpensive, nutrient dense foods, and larger portion sizes, coupled with decreased physical activity and increased sedentary behaviors are significant causative factors for obesity [5]. Accordingly, efforts to curb obesity have aimed to promote adherence to evidence-based recommendations for daily exercise, healthy eating, and associated behavioral determinants of weight [6].

Clinical interventions for obesity have demonstrated variable efficacy, which has been primarily attributed to fluctuations in treatment adherence over time [7,8]. Clinical interventions employ evidence-based strategies primarily based on behavior change theory to drive permanent lifestyle modifications necessary for long-term weight control [9]. These strategies include self-monitoring, goal-setting, healthy eating training, increasing physical activity, providing personalized and objective feedback, stress reduction, and problem solving [10]. Clinical interventions for obesity are rigorous and typically require face-to-face contact often for over a year [11]. These programs can be time, cost, and resource intensive, and often inconvenient for patients to attend, limiting long-term treatment adherence and weight maintenance [10,11]. Novel, low-cost, and widely accessible tools are needed to support the practice of evidence-based strategies for weight control [12], particularly when patients face significant barriers to accessing clinical treatments.

To address these concerns, efforts have shifted to emerging interactive information and communication technologies as a novel means to support chronic disease self-management with the potential for low-cost scalability [10-13]. Clinical intervention strategies can be translated to mobile devices, such as mobile apps, leveraging the multifunctional capabilities and widespread use of mobile devices [10,14]. Growing research supports the ability for mobile devices to deliver effective intervention strategies for weight loss [13,15-17]. Mobile devices purposed toward improvements in weight, diet, and physical activity have demonstrated superior effectiveness on weight outcomes and behavioral determinants of weight when compared with standard no-intervention controls as well as to controls receiving nonmobile device interventions [17]. Mobile devices can be used to enhance self-efficacy by priming behavior activation and reducing the burden of behavior change techniques, such as providing convenient ways to self-monitor,

set and update goals, communicate with supports, and access personally relevant education and resources efficiently [17].

Health researchers have started to develop and test their own mobile apps for weight management, with the objective to create new clinical and research tools that incorporate evidence-based strategies used in the treatment of obesity. A review of behavior change techniques in 12 primary trials and five secondary analyses examining mobile device interventions for weight loss found that interventions contained a minimum of five techniques, the most common of which were self-monitoring, goal-setting, tailored feedback, general health information, encouragement, prompting practice, and social support [17]. Mobile device interventions with multiple techniques that differentiated it meaningfully from the comparison treatment were associated with superior weight and health behavior outcomes [17].

However, studies that have explored commercial app markets have found that mobile apps for weight loss typically incorporate only a minority of the evidence-based strategies used in the treatment of obesity [11,18-21]. It is likely that the lack of evidence-based features limits the effectiveness of these tools, which is concerning given the abundance and availability of such tools for assisting with the general public's weight management needs.

Objective

To our knowledge, no studies have systematically and comprehensively explored the current commercial mobile app market to examine evidence-based strategies, health care expert involvement, and scientific evaluation of weight loss/management apps since these earlier investigations. The rapid growth in the number of health and fitness apps, combined with an increase in adoption of these tools in recent years underscores the need for an updated assessment of this rapidly changing market. Prior studies that have examined the inclusion of evidence-based strategies in commercial mobile apps for weight loss have mostly confined their search to a limited sample of apps (eg, <50) [11,18], to a single app store (eg, iTunes) [18-21], to a single population (eg, children) [20,21], or require updating (eg, published more than 3 years ago) [19]. The objective of the current study was to conduct an updated and comprehensive systematic review of weight management mobile apps across four major commercial app stores to describe the inclusion of evidence-based strategies for weight control, health care expert involvement, and scientific evaluation. Findings from this study will be used to identify the major overarching strategies relied upon by current weight management apps in order to provide direction for the advancement of research and app development.

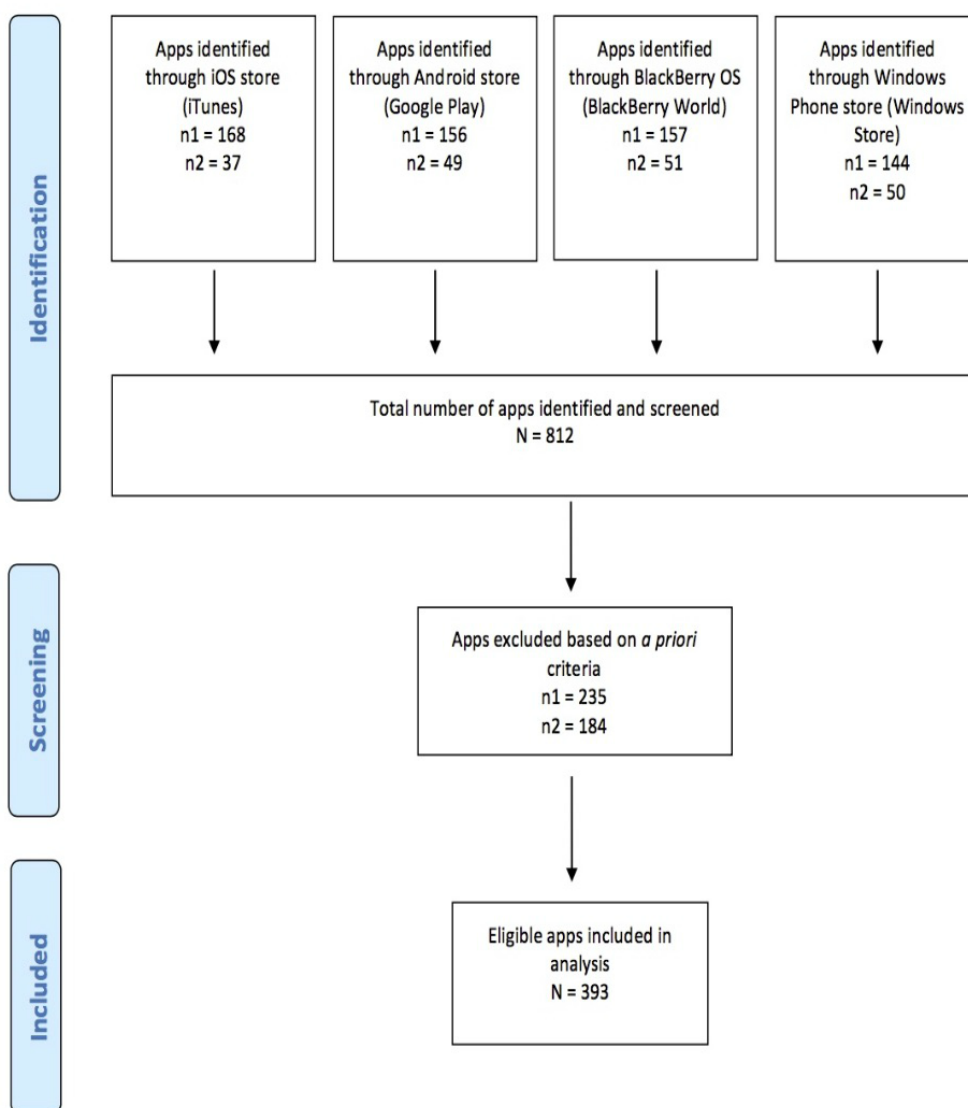
Methods

App Search

Figure 1 displays the methodology used in this study, which replicates that used in studies evaluating the functionality and content of mobile apps for health management [11,18-23]. An electronic search was conducted between July 2014 and July 2015 of the official app stores for iPhone operating systems (OS; iTunes), Android (Google Play), BlackBerry OS (BlackBerry World), and Windows Phone (Windows Store). Stores were searched separately using the search term ‘weight loss’ and no restrictions related to store subcategories were imposed. A secondary search was also performed to identify

apps intended for children and adolescents using the search term ‘weight loss kids’. Results of the searches were not limited by language and no date of app publication was used to restrict search results. Because the indexing of apps varied greatly across app stores, prior to app selection we performed a calibration exercise in order to validate our ability to detect weight management apps. This comprised testing our search term for the ability to produce app results that were known to meet the inclusion criteria and be currently available in the app store for download (ie, if a search of ‘weight loss’ produced results that included a popular, widely known weight loss app such as Lose It!). In all cases, our search term identified the apps we expected to find.

Figure 1. Flow diagram of study methods.



Selection of Apps

Apps met study inclusion criteria if the purpose of the app involved weight loss or weight management and the primary intended app user was a person seeking to reduce or manage their weight. Apps appearing in more than 1 app store were rated independently in order to account for differences in features supported by different mobile OS. For our secondary

search, the app also needed to state its intended user to be a child, adolescent, teenager, young person, or youth. Apps were excluded if they were classified as “e-books” by the respective app store or were judged by the reviewers as such. Three investigators performed app selection independently and all discrepancies regarding selection were resolved through discussion with a fourth party. There was greater than 95%

agreement between authors across all app stores prior to fourth author resolution.

Data Abstraction

Metadata from all included apps were abstracted into a standard Microsoft Excel

spreadsheet. Metadata were collected from the respective app store where the app was identified. Abstracted metadata included: app name, developer (individual or organization), and price. A systematic approach to data abstraction was used. Specifically, two investigators independently collected data from each app store and each dataset was then cross-verified against the other.

Evidence-Based Strategies

Apps' evidence-based strategies were characterized based on inclusion/exclusion of app features or informational content selected through consensus by our team of obesity experts. The set of features/content used to characterize apps' evidence-based strategies are supported by public health recommendations [19-21], widely disseminated clinical interventions [11,24], research in behavior change theory [9,17,18,25], as well as systematic reviews and meta-analyses of mobile device intervention studies [12,13,15-17,26-32]. While this particular list of features does not address every evidence-based strategy used in the management of obesity, our goal was to create broad categories representing the major aspects of evidence-based treatment in order to describe the overarching evidence-based quality of the current market for weight loss/management apps.

The following eight evidence-based strategies were examined: presence of (1) self-monitoring capabilities [11,12,15,17-19,25,26,28] for weight, meals, nutrition (including protein, fats, carbohydrates, fiber, and water), physical activity, cardiometabolic indicators, sleep, mental health indicators, including mood, thought patterns, cognitions, and stress, environmental influences, and custom metrics, (2) goal-setting [11,15,17,18,25] with/without customization, (3) healthy eating support [11,15,17-19,25,29], including information, education, and skills development, (4) physical activity support [11,15,17-19,25,29], including information, education, and skills development, (5) social support [12,15,17-19,26,30], (6) weight and/or health assessment [11,17,19], with/without personalization, (7) motivational strategies [15,17,18], including prompts, rewards, or gamified design, and (8) personalized feedback [12,15,17,26,30].

Health Care Expert Involvement and Scientific Evaluation

Health care expert involvement in app development and stated involvement in formal scientific evaluation were also examined. An app was required to reference the involvement of a health care professional listed in the Ontario Regulated Health Professions Act [33] and app descriptions as well as publicly accessible scientific literature databases (ie, National Center for Biotechnology Information PubMed and Google Scholar) were searched by app name for any published research related to the app. For each category, we assessed inclusion as either 'present'

or 'absent'. Descriptive statistics were used to summarize the results of the assessment.

Results

Summary of Search Results

Our first search across all app stores identified a total of 625 apps. Of these apps, 37.6% (235/625) were excluded from further review based on the a priori inclusion and exclusion criteria. The primary reason for app exclusion was the inability to provide any weight management support (ie, the app was used exclusively as a game). A total of 390 apps were included in the primary analysis. Our secondary search identified a total of 187 apps. Of these apps, 184 were excluded based on the a priori inclusion and exclusion criteria, which also required the app's intended user to be a child, adolescent, teenager, young person, or youth. A total of three apps were included in the secondary analysis. In total, 393 apps were included in the final analysis.

Summary of General App Characteristics

Overall, identified apps were most often classified as 'medical', 'lifestyle', or 'health and fitness'. The cost of apps also varied, with approximately 87.3% (343/393) being free to download. The cost of paid apps ranged from \$0.99 to \$7.99 CDN.

Assessment of Evidence-Based Strategies

Table 1 shows the frequency of evidence-based strategies across included apps. The most common strategy was self-monitoring (139/393, 35.3%), which allowed the user to track targeted weight-related metrics over time, the majority of which consisted of weight, energy balance, water intake, and quantity of physical activity. Few apps included more comprehensive tracking options such as nutrition, sleep, and cardiometabolic indicators. No apps allowed for tracking of mental health indicators, environmental influences, or allowed for the creation of customized metrics. Within these apps, 10.2% (40/393) could automatically monitor the user's physical activity without the requirement for manual logging. The second most common strategy was physical activity support (108/393, 27.5%), which mostly included fitness plans, exercise guides, and tracking of daily physical activity. Of apps, 25.4% (100/393) included weight and/or health assessment, which was limited to assessment of body mass index (BMI). No other types of health assessment capabilities were found. Of apps, 23.2% (91/393) provided healthy eating support, most commonly healthy eating guidelines, meal plans, calorie balance goals, and nutritional information for specific foods. No apps included skills development needed for healthy eating such as stress reduction, emotion regulation, stimulus control, time management, and problem solving. Of apps, 21.4% (84/393) included goal-setting, which mainly consisted of weight loss goals, calorie balance goals, water intake goals, and physical activity goals. No apps allowed for the creation of customized goals. Of apps, 7.1% (28/393) possessed motivational strategies including prompts, gamification, or use of rewards (ie, points for meeting weight goals). Of apps, 5.3% (21/393) featured a social support component such as online communication with other users. Lastly, 1.8% (7/393) of apps provided personalized feedback

to the user, such as through virtual meetings with a health coach or through notifications.

Health Care Expert Involvement and Scientific Evaluation

As shown in Table 1, only 0.3% of apps (1/393), *Kurbo Health*, stated the involvement of a regulated health care professional in the app's development. This app reported involving a medical advisory board consisting of pediatricians, psychologists, and psychiatrists. Furthermore, only 0.8% of apps (3/393) were found to have been part of formal scientific research or have undergone scientific testing.

Pediatric Focused Weight Management Apps

Our search identified only three pediatric focused apps. Two of the apps lacked the majority of evidence-based strategies for weight management. *Ideal Weight BMI Adult and Child* only provided assessment of BMI and *Choose My Food* used only a gamified design. The third app, *Kurbo Health*, possessed 8 strategies including self-monitoring, goal-setting, physical activity support, healthy eating support, social support, gamification, and personalized feedback delivered via a health coach (offered as a premium paid-for feature).

Table 1. Evidence-based strategies, health care expert involvement, and scientific testing in apps for weight management.

Criteria	iTunes (n=95)	Google Play (n=98)	Windows Store (n=100)	Blackberry World (n=100)	Total (N=393)
	n (%)	n (%)	n (%)	n (%)	N (%)
Self-monitoring	47 (49.5%)	40 (40.8%)	28 (28.0%)	24 (24.0%)	139 (35.4%)
Automatic self-monitoring	9 (9.5%)	2 (2.0%)	13 (13.0%)	16 (16.0%)	40 (10.2%)
Goal-setting	29 (30.5%)	30 (30.6%)	14 (14.0%)	11 (11.0%)	84 (21.4%)
Physical activity support	26 (27.4%)	30 (30.6%)	25 (25.0%)	27 (27.0%)	108 (27.5%)
Healthy eating support	16 (16.8%)	47 (48.0%)	7 (7.0%)	21 (21.0%)	91 (23.2%)
Weight /health assessment	21 (22.1%)	24 (24.5%)	24 (24.0%)	31 (31.0%)	100 (25.4%)
Personalized feedback	1 (1.1%)	2 (2.0%)	4 (4.0%)	0 (0.0%)	7 (1.9%)
Motivational strategies (rewards, prompts, or gamification)	9 (9.5%)	7 (7.1%)	11 (11.0%)	1 (1.0%)	28 (7.1%)
Social support	4 (4.0%)	7 (7.1%)	10 (10.0%)	0 (0.0%)	21 (5.3%)
Health care expert involvement	1 (1.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
Scientific testing	0 (0.0%)	1 (1.0%)	2 (2.0%)	0 (0.0%)	3 (0.8%)

Comprehensiveness of Weight Management Apps for Assessment Criteria

As shown in Table 2, the relative representation of assessment criteria including evidence-based strategies, health care expert involvement, and scientific evaluation per app varied. Roughly one-third of apps (130/393, 33.1%) did not meet any of the assessment criteria. Just over one-quarter of apps (103/393,

26.2%) met one criterion. The remaining apps are described as follows: 16.8% (66/393) met 2 criteria, 14.8% (58/393) met 3 criteria, 5.1% (20/393) met 4 criteria, 2.3% (9/393) met 5 criteria, 0.8% (3/393) met 6 criteria, 0.5% (2/393) met 7 criteria, and 0.5% (2/393) met 8 criteria. No app met more than 8 of our assessment criteria. The average number of criteria present in an app was between 1 and 2. In general, most apps functioned as either a fitness app or a dieting app.

Table 2. Comprehensiveness of apps for assessment criteria.

# of criteria met	iTunes (n=95) n (%)	Google Play (n=98) n (%)	Blackberry World (n=100) n (%)	Windows Store (n=100) n (%)	Total (N=393) N (%)
0	39 (41.1%)	9 (9.2%)	38 (38.0%)	44 (44.0%)	130 (33.1%)
1	13 (13.7%)	41 (41.8%)	25 (25.0%)	24 (24.0%)	103 (26.2%)
2	9 (9.5%)	23 (23.5%)	22 (22.0%)	12 (12.0%)	66 (16.8%)
3	23 (24.2%)	11 (11.2%)	14 (14.0%)	10 (10.0%)	58 (14.8%)
4	6 (6.3%)	6 (6.1%)	1 (1.0%)	7 (7.0%)	20 (5.1%)
5	2 (2.1%)	6 (6.1%)	0 (0.0%)	1 (1.0%)	9 (2.3%)
6	2 (2.1%)	0 (0.0%)	0 (0.0%)	1 (1.0%)	3 (0.8%)
7	0 (0.0%)	2 (2.0%)	0 (0.0%)	0 (0.0%)	2 (0.5%)
8	1 (1.1%)	0 (0.0%)	0 (0.0%)	1 (1.0%)	2 (0.5%)
9	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
10	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

Discussion

Principal Findings

This review demonstrates that despite the abundance of mobile apps for weight management, the evidence-based quality of these apps remains generally poor. The rapid growth in the commercial market for weight management apps has outpaced progress to improve the content and functionality of these tools, creating an overabundance of weight management apps with no evidence base being made readily available to the public.

We can summarize the major limitations of current user-focused apps for weight management, characterized by: (1) simplistic capabilities that lack high-level personalization to complex user needs and preferences, (2) a lack of health care expert involvement during app development, (3) minimal use of evidence-based strategies for the management of obesity, and (4) the absence of scientific evaluation of these tools.

Current capabilities for promoting behavior change for weight management through mobile apps have low fidelity and do not reflect the individually tailored practices employed in clinical obesity interventions. Apps tend to possess a singular focus on either the physical activity or dieting practices for weight loss. Moreover, apps do not comprehensively address the full range of cognitive, behavioral, and environmental factors that can impact a person's ability to manage their weight over the long term. These findings are reflected in similar work by numerous authors [11,18-21] who also report a low level of adherence to evidence-based practices in mobile apps for weight loss and the lack of cognitive and behavioral targets related to weight control. This suggests that limited improvements have been made in the commercial app market since these studies, despite the growth in the number of apps available. The lack of evidence-based strategies employed by the apps we reviewed drastically narrows the therapeutic scope of these tool for addressing the multifactorial causes of overweight and obesity. Hence, most apps may not be suitable for supporting individuals with severe or complex obesity who have complex medical and

self-management needs. This may be in part due to the general lack of health care expert involvement during app development or that the majority of commercial apps are not developed with the intention for use by clinical populations. Only three apps, *My Fitness Pal*, *Lost It!*, and *Fitbit* were found to be involved in formal scientific research. The lack of rigorous scientific evaluation by most apps calls into question the validity of apps' claims regarding their therapeutic benefit and safety, as well as encourages the rapid development and sale of medical apps with no demonstrated clinical efficacy.

Evidence-based strategies are critical to most clinical weight loss programs but were largely absent from the mobile apps we reviewed. Approximately one-third of the apps included self-monitoring and physical activity support, less than one-quarter facilitated goal-setting or provided healthy eating support, less than one-tenth contained motivating components or provided appropriate social support, and only 1.8% (7/393) provided personalized feedback to the user. While research has yet to be conducted into the appropriate and optimal number of strategies employed by a single app, effective long-term weight management requires a range of behavioral and lifestyle changes in order to address the multifactorial etiology of obesity.

Goal-setting and self-monitoring are key strategies derived from self-regulation theory to enhance self-efficacy and significantly predict weight loss and behavior change success [17,18]. Apps with goal setting focused mainly on weight, calorie, or exercise goals and generally could not be customized to personal objectives or personalized to user preferences. Most apps with self-monitoring features focused on tracking activity, meals, and calories, but important metrics related to nutrition, cardiovascular health, sleep, mental health, and environmental influences, as well as custom metrics, were mostly neglected. Moreover, the self-monitoring capabilities of current mobile apps are limited by the manual input demands on the user, requiring that users remember and be consistently motivated to input multiple types of data frequently in order to be successful. Providing personalized feedback to the individual on their

progress as well as facilitating social support from peers are strategies routinely performed in intensive behavioral interventions to improve long-term success in goal-setting and self-monitoring [17]. These important features are mostly absent from current mobile apps, which do not possess the functional capabilities to deliver this complex level of interaction and communication. Furthermore, the limited amount of content and features dedicated to healthy eating is concerning given the pivotal role nutritional factors play in obesity management.

Limitations

The search methods used in this review were modeled after those previously conducted in this area [11,18-21] and in the management of other chronic diseases [22]. Our search protocol was intended to mimic the search experience of a general user who would most likely follow a similar strategy when choosing apps for their own weight management. Although we attempted a comprehensive abstraction of data related to app content and functionality, reviewers did not download apps onto a smartphone device for thorough review. Rather, information was gathered from the app store and from associated websites. Hence, the data presented should not be interpreted to reflect the accuracy of any particular feature (ie, accuracy of energy expenditure measurement), as this was not the aim of the present study. These findings reflect the general knowledge of app developers regarding practices for effective weight management, as well as the evidence-based quality of current commercial weight loss apps. These findings provide an overview of the current state of the mobile weight loss app market in order to guide the future direction of research and development of these tools. Moreover, the findings reported are very broad characterizations of current app features meant for weight management, yet the specific strategies relied upon, such as specific nutritional content offered by the app, is not described. Future research will be required to determine the accuracy of particular app features and to characterize the specific types of strategies employed within each of the reported criteria categories.

Future Directions

Our findings contribute to the growing work into the development and evaluation of mobile- and Internet-based tools for overweight and obesity management. The challenges to sustaining clinic-based interventions in the long-term, in addition to the near-ubiquity and multifunctional capabilities of today's smartphone devices position mobile apps as a potential translational platform for the widespread delivery of weight management interventions. Numerous studies now support the ability for mobile phones to facilitate weight loss and promote associated healthy behaviors [12,13,15-17,26-31], as well as

reduce obesity-related comorbidities [32]. While these benefits have been observed in clinical trials involving researcher-developed apps, limited data exist evaluating the quality of commercial mobile apps and their inclusion of evidence-based strategies for weight loss/management. Our findings demonstrate that while significant progress has been made in the development and accessibility of mobile apps for weight loss, considerable improvements are needed before these tools can truly be considered evidence-based.

Future efforts by both researchers and commercial developers should aim to address the limitations discussed. More stringent standards for the provision of medical apps should be established and incorporated into the process of submission to an app store. More comprehensive use of evidence-based strategies used in routine behavioral counselling for weight loss should be integrated into apps' functionality and content. This is not a straightforward objective because many of these strategies would require complex, intelligent interaction with the device (eg, such as providing tailored feedback) and would also need to be adapted to the usability constraints of a mobile device interface (eg, screen size). However, the potential outcome of these efforts would be that mHealth interventions would become personalized to the user's needs for managing their health (eg, tailored to the patient's lifestyle), rather than providing generic and homogenous support to every user. In addition, health care experts need to become more integral to the development and distribution of medical apps. The concerns of any medical treatment, such as safety and efficacy, must be equally considered to those more typically focused on by app developers, namely the user interface and keeping the user engaged. Lastly, there is a need for rigorous evaluation and refinement of these apps using high-quality feasibility testing and multicenter randomized controlled trials.

Conclusions

The overall conclusions advanced in this review are that despite the high accessibility of mobile apps for weight management, the quality of their content and functionality remains poor. Efforts to address these problems must involve health care experts during the app development process, a more comprehensive grounding in evidence-based practice, improved personalization and tailored feedback, and evaluation and refinement through scientific trials. The potential for mobile apps to improve health outcomes in the management of chronic diseases presents a real opportunity for widespread, cost-effective delivery of health care. Future research is urgently needed to develop comprehensive, evidence-based, and clinically-informed weight management mobile tools toward these aims.

Acknowledgments

This research project is supported by Dr. Jennifer Stinson's Peter Lougheed Canadian Institutes of Health Research New Investigator Award.

Conflicts of Interest

None declared.

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Abbreviations

BMI: body mass index
OS: operating systems

Edited by G Eysenbach; submitted 09.09.15; peer-reviewed by M Allman-Farinelli, F Saigí-Rubió, HA Park, E Knight; comments to author 06.10.15; revised version received 26.04.16; accepted 19.05.16; published 26.07.16.

Please cite as:

Rivera J, McPherson A, Hamilton J, Birken C, Coons M, Iyer S, Agarwal A, Lalloo C, Stinson J
Mobile Apps for Weight Management: A Scoping Review
JMIR Mhealth Uhealth 2016;4(3):e87
URL: <http://mhealth.jmir.org/2016/3/e87/>
doi: [10.2196/mhealth.5115](https://doi.org/10.2196/mhealth.5115)
PMID: [27460502](https://pubmed.ncbi.nlm.nih.gov/27460502/)

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Original Paper

Usage and Dose Response of a Mobile Acceptance and Commitment Therapy App: Secondary Analysis of the Intervention Arm of a Randomized Controlled Trial

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Abstract

Background: Mobile phone apps offer a promising medium to deliver psychological interventions. A mobile app based on Acceptance and Commitment Therapy (ACT) was developed and studied in a randomized controlled trial (RCT).

Objective: To study usage metrics of a mobile ACT intervention and dose-response relationship between usage and improvement in psychological flexibility.

Methods: An RCT was conducted to investigate the effectiveness of different lifestyle interventions for overweight people with psychological stress. This paper presents a secondary analysis of the group that received an 8-week mobile ACT intervention. Most of the analyzed 74 participants were female (n=64, 86%). Their median age was 49.6 (interquartile range, IQR 45.4-55.3) years and their mean level of psychological flexibility, measured with the Acceptance and Action Questionnaire II, was 20.4 (95% confidence interval 18.3-22.5). Several usage metrics describing the intensity of use, usage of content, and ways of use were calculated. Linear regression analyses were performed to study the dose-response relationship between usage and the change in psychological flexibility and to identify the usage metrics with strongest association with improvement. Binary logistic regression analyses were further used to assess the role of usage metrics between those who showed improvement in psychological flexibility and those who did not. In addition, associations between usage and baseline participant characteristics were studied.

Results: The median number of usage sessions was 21 (IQR 11.8-35), the number of usage days was 15 (IQR 9.0-24), and the number of usage weeks was 7.0 (IQR 4.0-8.0). The participants used the mobile app for a median duration of 4.7 (IQR 3.2-7.2) hours and performed a median of 63 (IQR 46-98) exercises. There was a dose-response relationship between usage and the change in psychological flexibility. The strongest associations with psychological flexibility (results adjusted with gender, age, and baseline psychological variables) were found for lower usage of *Self as context* related exercises (B=0.22, P=.001) and higher intensity of use, described by the number of usage sessions (B=-0.10, P=.01), usage days (B=-0.17, P=.008), and usage weeks (B=-0.73, P=.02), the number of exercises performed (B=-0.02, P=.03), and the total duration of use (B=-0.30, P=.04). Also, higher usage of *Acceptance* related exercises (B=-0.18, P=.04) was associated with improvement. Active usage was associated with female gender, older age, and not owning a smart mobile phone before the study.

Conclusions: The results indicated that active usage of a mobile ACT intervention was associated with improved psychological flexibility. Usage metrics describing intensity of use as well as two metrics related to the usage of content were found to be most strongly associated with improvement.

Trial Registration: ClinicalTrials.gov NCT01738256; <https://clinicaltrials.gov/ct2/show/NCT01738256> (Archived by WebCite at <http://www.webcitation.org/6iTePjPLL>)

(*JMIR Mhealth Uhealth* 2016;4(3):e90) doi:[10.2196/mhealth.5241](https://doi.org/10.2196/mhealth.5241)

KEYWORDS

mobile apps; Acceptance and Commitment Therapy; retrospective study; adherence

Introduction

Digital health interventions hold a promise of providing help and support more continuously and cost-effectively than traditional face-to-face therapies. Mobile technologies, especially, enable seamless integration of interventions into the daily lives of users by partitioning the intervention content into smaller doses. Despite growing evidence of effectiveness of digital interventions, it is still unclear how the usage of interventions should be measured, how usage is associated with benefits, and how much interventions should be used in order to gain health benefits.

Several studies have found that active usage mediates the effects of interventions, in both face-to-face [1] and digital interventions [2-6]. Active digital intervention usage has been associated with outcomes in several areas of well-being and health, including weight loss [2,3], physical activity [4], mental well-being [5], and depression and anxiety [6].

The definitions and metrics used for describing usage vary between studies. Many studies describe usage in terms of adherence, which has been adopted from health care and means the extent to which a person's behavior follows instructions or recommendations from a health care provider [7]. Christensen et al [8] defined adherence as "the extent to which individuals experience the content of the Internet intervention." In many studies, adherence is defined in terms of expected intensity of usage, predefined by intervention designers. As found by Kelders et al [9], the most typical intended usage frequency in Internet interventions is once a week. However, when dealing with digital interventions, it may be difficult to predefine the measure of adherence as the required intensity may not be known. Therefore, it is important to collect and analyze in-depth data on usage in order to understand which metrics of usage are most strongly associated with effectiveness. The best metrics may also be different for different types of interventions. In their review, Donkin et al [10] found that the number of log-ins and the number of modules completed were the most commonly reported measures of usage. They also found that in interventions targeting aspects of physical health, the number of log-ins was most consistently associated with outcomes, whereas in psychological health interventions, module completion was the strongest predictor of success [10]. In their own study, Donkin et al [11] investigated the associations of several usage metrics and outcomes in a Web-based intervention for depression. They found that the total number of activities completed, the total number of minutes spent in the program, the average number of activities completed per log-in, and the

average number of minutes online per log-in were associated with improvements [11]. They hypothesized that sometimes the inability to find dose-response relationships may be due to the metrics used [11].

Usage and outcomes of interventions are influenced by several factors that need to be taken into account when designing and studying interventions. For example, study design, interaction with a counselor, more frequent intended usage, and use of persuasive features have an impact on usage [9,12]. Most research indicates that the treatment outcomes in Internet-based treatments are associated with the amount of support—eg, [13,14]. In addition, adherence and retention can be improved by offering personal support (face-to-face, telephone, or email) before and during Internet interventions [15,16]. The background characteristics of users, such as sociodemographic factors, psychological traits, and prior experiences with technologies, may also influence usage. For example, in the review by Christensen et al [8], a lower level of baseline depression, younger age, and poorer knowledge of psychological treatments were associated with a higher adherence to depression interventions. Also, for generalized anxiety disorder, lower levels of symptoms were associated with higher usage. A trial on posttraumatic stress disorder found that women, older persons, those who lived with a partner, and those less experienced with a computer used the intervention more actively [8]. In a Web and mobile technology-assisted employee health promotion program, older age and poorer aerobic fitness were found to be associated with sustained usage of the technologies [17]. In the field of Internet interventions, there are some indications that treatments work best for slightly older people and those who are able to take responsibility for their treatment [18]. Having fewer comorbid depressive symptoms, a stable economic situation and an employment, and being in a relationship have also been found to predict positive outcomes [18].

Acceptance and Commitment Therapy (ACT) is a third-generation cognitive and behavioral therapy that aims to increase psychological flexibility. Psychological flexibility is the ability to fully contact the present moment, and to change or persist in behavior when doing so serves valued ends [19]. In other words, psychological flexibility consists of skills for handling one's emotional reactions and thoughts in a constructive way as well as skills for promoting well-being through effective actions. Psychological flexibility has been found to be associated with better mental health and to predict future mental health [19]. It has also been associated with behavioral effectiveness, for example, job performance [20].

Psychological flexibility is established through 6 core processes, namely, *Being present*, *Self as context*, *Acceptance*, *Cognitive defusion*, *Values*, and *Committed action*, which are addressed in ACT interventions [19]. The processes are interrelated and overlapping, and therefore investigating their individual effects on well-being is challenging. However, preliminary evidence supporting the impact of *Acceptance* and *Cognitive defusion* processes exists [19].

There is already evidence on the effectiveness of ACT-based digital interventions. Several Internet interventions, especially, have shown promising results [21-27]. Bricker et al [23] evaluated a 3-month ACT-based smoking cessation intervention and found that the intervention achieved a quit rate of 23% (13/57) compared with 10% (6/58) in the control condition and that the participants logged in to the service, on average, 9 times and spent, on average, 19 minutes online per log-in. Carlbring et al [24] found that their 8-week ACT-based depression intervention resulted in large effects on depression, and the average number of modules completed was 5.1 out of 7 and the median log-in time was about 3.5 hours. Levin et al [26] evaluated a 3-week program for preventing mental health problems among college students and found improvements in depressive symptoms, and they reported that the majority of participants 70/76 (92%) completed both lessons and spent an average of 82 minutes in the program.

Mobile apps based on ACT and related techniques such as mindfulness are also emerging [28-32]. Bricker et al [28] converted their Web-based smoking cessation intervention into a self-paced mobile intervention. In an 8-week study, a quit rate of 13% (10/80) was achieved for the ACT intervention compared with 8% (7/84) for the control app, and the participants self-reported opening the app, on average, 37 times [28]. Heffner et al [33] further investigated the usage of the smoking cessation app and the associations between feature usage and quitting. They were able to identify several features that significantly predicted smoking abstinence and found that only 2 of the 10 most actively used features predicted smoking abstinence, that is, the users used less effective features more actively. Ly et al [29] developed an ACT-based self-help program combining a mobile phone app and Web-based psychoeducation and found an effect size of 0.50 for psychological flexibility. The participants self-reported using the app a couple of times a week during the 4-week intervention [29]. In another study, Ly et al [32] evaluated an ACT-based mobile app for stress management and found a within-group effect size of 0.62 for perceived stress. They defined adherence as the minimum of 2 registered activities per week, and by this criterion, 16/36 (44%) participants adhered to the program for all of the 6 weeks of the intervention [32].

The aims of this study were (1) to investigate the dose-response relationship between usage and the change in psychological flexibility, (2) to identify the usage metrics that were most strongly associated with improvement in psychological flexibility, and (3) to study the associations between usage and baseline participant characteristics.

Methods

Overview

A randomized controlled trial (RCT; trial registration: ClinicalTrials.gov NCT01738256) was organized to study the effectiveness of 3 low-intensity lifestyle interventions against a no-intervention control. The interventions were (1) a face-to-face, group-based ACT intervention, (2) an ACT-based mobile intervention, and (3) a Web-based educational intervention with cognitive behavioral therapy components. The RCT consisted of a 10-week period during which the interventions were delivered, followed by a 26-week follow-up period. The recruitment began in August 2012 and ended in February 2013. The last follow-up measurement was performed in December 2013. The RCT was performed in 3 study centers in Finland—Jyväskylä, Kuopio, and Helsinki. The purpose of the lifestyle interventions was to improve the participants' well-being and activate them to make beneficial changes in their everyday life. The design of the RCT was described in detail by Lappalainen et al [34]. See [Multimedia Appendix 1](#) for the CONSORT-EHEALTH checklist [35].

The primary outcome of the RCT was psychological flexibility (measured with the Acceptance and Action Questionnaire II, AAQ-II [36]). The main analysis of the RCT found that although AAQ-II did not change significantly, psychological flexibility related to weight issues (Acceptance and Action Questionnaire for Weight-Related Difficulties, AAQW) improved significantly in both ACT intervention groups (in manuscript in preparation by Marjukka Kolehmainen and colleagues). This paper presents a secondary analysis, which focused solely on the mobile intervention group and investigated the usage of the mobile intervention and the dose-response relationship between usage and the change in psychological flexibility (AAQ-II).

Participants

Participants were recruited through newspaper advertisements seeking overweight individuals suffering from psychological stress. The inclusion criteria were (1) age between 25 and 60 years, (2) body mass index (BMI) of 27-34.9 kg/m², (3) psychological stress (at least 3/12 points in the General Health Questionnaire (GHQ-12 [37])), and (4) the possibility to use a computer and Internet connection. Out of the 645 individuals who responded to the advertisements, 339 fulfilled the inclusion criteria and consented to participate. After baseline examinations, further 41 participants declined to participate or were excluded because of findings in baseline measurements. Thus, 298 participants started the actual study. The participants consisted of 48 males and 250 females. Their mean age was 49.0 (SD 7.6) years and BMI was 31.1 (SD 3.0) kg/m².

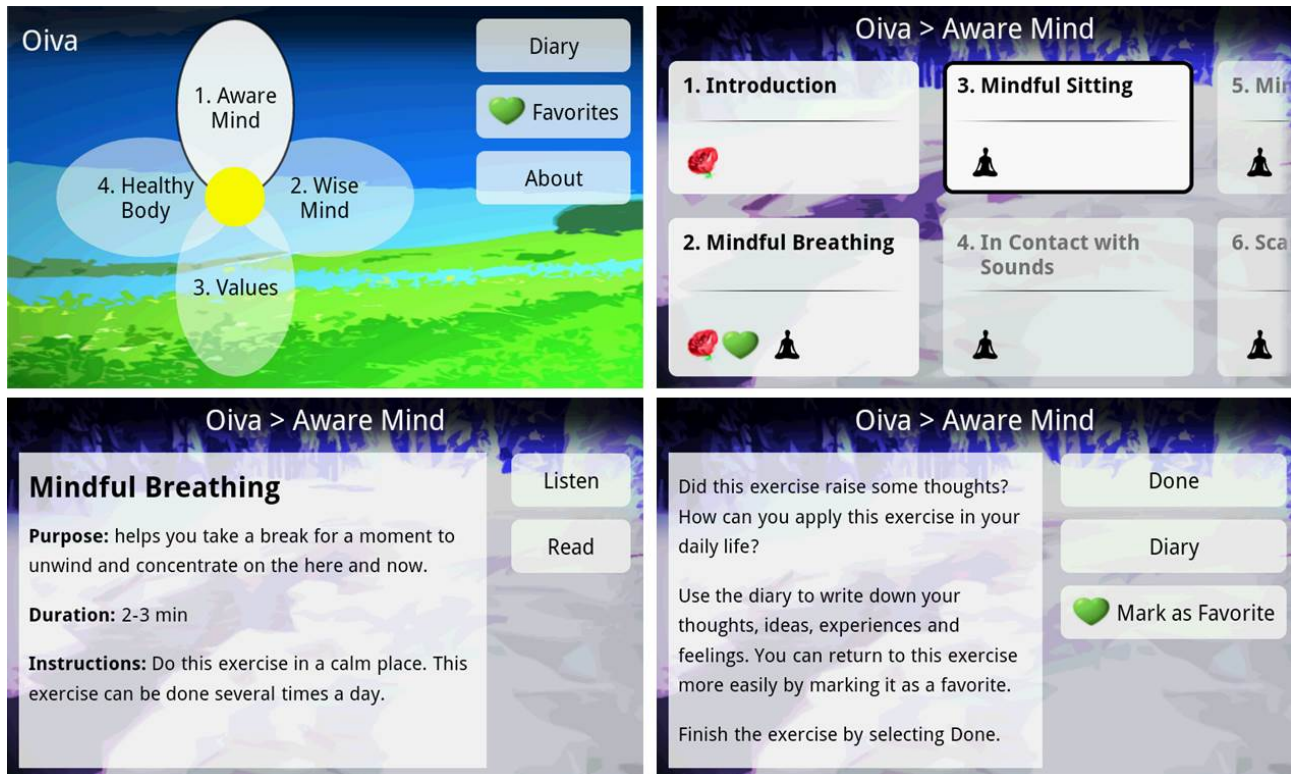
In this study, only the mobile intervention participants were analyzed. Altogether, 85 of 339 (25.1%) participants were randomized to the mobile intervention group. Of these, 78 (92%) received the intervention, and 75 (88%) participated in postintervention measurements. One participant did not provide postintervention results on psychological flexibility and thus was excluded, leaving 74 (87%) participants for the analyses.

Mobile Intervention

The mobile intervention group received their ACT intervention through a mobile application, called Oiva [Figure 1](#), which has been previously described by Ahtinen et al. [37]. The aim of the app was to improve psychological flexibility by teaching the users the 6 core processes of ACT. The processes are (1) *Being present*, that is, having a nonjudgmental contact with psychological and environmental events; (2) *Self as context*, that is, being aware of one's flow of experiences without

attachment to or investment in them; (3) *Acceptance*, that is, actively embracing feelings and inner events without trying to change them; (4) *Cognitive defusion*, that is, changing the undesirable functions of thoughts and feelings, for example, by observing them without attachment to them; (5) *Values*, that is, identifying things that are truly important to an individual and that help determine life directions; and (6) *Committed action*, that is, committing to concrete goals and actions based on personal values [19].

Figure 1. Screenshots of Oiva app: main view (top left), exercise browser (top right), instructions for an exercise (bottom left), and reflection screen (bottom right).



The content was provided as 45 exercises, divided into 4 main modules. Each exercise was coded according to the ACT process or processes it addressed. There were 14 exercises related to the *Being present* process including, for example, a mindful sitting exercise and a mindful eating exercise [39]. The *Self as context* process had 5 exercises, for example, the “Floating leaves on a moving stream” metaphor [39]. The *Cognitive defusion* process had 9 exercises, for example, the “Passengers on a bus” metaphor [40]. The *Acceptance* process had 8 exercises, for example, the “Tug of war with a monster” metaphor [40]. The *Values* process had 8 exercises, for example, the “Attending your own funeral” exercise [39]. The *Committed action* process had 10 exercises, for example, a goal-setting exercise [39]. Of the exercises, 9 were associated with 2 processes.

Most exercises were short, taking about 1-3 minutes to complete, and were provided both in text and in audio format in Finnish. The participants were free to use the exercises in any order while the app provided subtle guidance by highlighting the next recommended exercise and module. The aim was to guide the users to proceed from easier exercises and basic skills to more challenging ones. A feasibility study was conducted to ensure

the app's readiness for the RCT, reported by Ahtinen et al [38]. Currently, mobile and Web versions of the app are available in Finnish [41-43].

In the beginning of the study, the participants were invited to a 1.5-hour group meeting where a trained psychologist gave a 30-minute presentation about the principles of ACT. The features of the mobile app were introduced by a researcher. The participants were given Android mobile phones (ZTE Blade or ZTE Skate; ZTE Corporation, Shenzhen, China) with the app preinstalled along with printed user instructions. The participants were allowed to use the phones as their personal phones, but as the intervention period was only 8 weeks, it was not expected of them. The phones and the app were briefly tested in the group to make sure everyone knew how to use them. The participants were encouraged to use the app independently and actively, a few times a week, for the following 8 weeks. The participants did not get any feedback or support during the course of the intervention. The suggested number of exercises to be performed per session was 1-3, but the participants were encouraged to find personally appropriate ways of use. At the end of the intervention period, the participants attended postintervention measurements and returned their phones. Researchers had no

access to the app during the intervention, and the app and its contents remained constant during the intervention.

Measurements

This study analyzed the data collected during the baseline measurements and postintervention measurements of the RCT as well as the usage log data collected by the mobile app. The psychological measurements and prior experience in using technologies were collected through Web-based questionnaires.

The main outcome measure of the study was psychological flexibility—or, more precisely, psychological inflexibility—measured with the AAQ-II [36]. The AAQ-II is a 7-item questionnaire that assesses experiential avoidance and psychological inflexibility. The statements of the questionnaire (eg, “I’m afraid of my feelings” or “Worries get in the way of my success”) are rated on a scale from 1 (=never true) to 7 (=always true). Higher scores on the AAQ-II reflect lower levels of psychological flexibility. Thus, improvement in psychological flexibility is defined as a decreased score on the AAQ-II.

Weight-specific psychological flexibility was measured using the AAQW [44], which is a 22-item questionnaire measuring acceptance of weight-related thoughts and feelings and their interference with valued actions. The statements include, for example, “I try hard to avoid feeling bad about my weight and how I look” and “If I’m overweight, I can’t live the life I want” and are rated on a scale from 1 (=never true) to 7 (=always true) [44]. Higher scores on the AAQW reflect lower psychological flexibility regarding weight.

Participants’ prior experience in using smart mobile phones, mobile wellness apps, and wellness devices was assessed in the

beginning of the study as part of the baseline questionnaire. Each participant was assigned 3 binary attributes based on his or her prior experience in using technologies: (1) Smart mobile phone owner (if the participant owned a smart mobile phone before joining the study), (2) mobile wellness user (if the participant had used wellness-specific apps on the mobile phone), and (3) wellness device user (if the participant had used wellness devices, such as pedometers or heart rate monitors).

Usage Metrics

The mobile app recorded usage log files locally in the mobile phone. The log files were obtained from the phones at the end of the intervention period. The log files were analyzed to extract altogether 15 usage metrics, detailed in Table 1. The usage metrics can be divided into 3 categories: metrics describing the intensity of use (metrics 1-7 in Table 1), metrics describing the usage of content (metrics 8-13), and metrics describing the ways of use (metrics 14 and 15).

First, individual usage sessions were identified and their durations were calculated. Then, individual exercises performed, and whether they were performed by reading or listening, were identified. The usage of exercises related to the 6 processes of ACT was studied based on the coding of exercises. First, the number of exercises performed was calculated for each process and normalized by the number of exercises belonging to the process, to account for there being a different number of exercises related to the processes (varying between 5 and 14). Then, a percentage of use compared with the total number of exercises performed by the participant was calculated for each process, indicating what the participants focused on the most.

Table 1. Usage metrics.

Usage metric	Description
Number of usage sessions	Total number of usage sessions performed by a participant.
Number of usage days	The number of days containing the start of a usage session.
Number of usage weeks	The number of weeks containing a usage session.
Number of exercises	The number of exercises performed by a participant, containing also repeated exercises.
Total duration of use	The sum of all sessions’ durations in hours.
Session duration	The mean duration of individual sessions in minutes.
Completion %	Percentage of all exercises performed, that is, program completion percentage.
Being present %	Percentage of exercises performed related to the “Being present” process.
Self as context %	Percentage of exercises performed related to the “Self as context” process.
Cognitive defusion %	Percentage of exercises performed related to the “Cognitive defusion” process.
Acceptance %	Percentage of exercises performed related to the “Acceptance” process.
Values %	Percentage of exercises performed related to the “Values” process.
Committed action %	Percentage of exercises performed related to the “Committed action” process.
Usage pattern	The ratio of sessions during the first half of the intervention period versus the second half.
Listen %	Percentage of exercises performed by listening.

Analysis

The dose-response relationship between the usage metrics and the change in psychological flexibility was analyzed using linear

regression analyses on continuous variables. First, univariate linear regression models were used, and then potential confounders (age, gender, baseline GHQ-12 score, and baseline

AAQ-II and AAQW scores) were added to the models. Regression coefficients (B's) with their 95% confidence intervals and significance levels were reported for both unadjusted and adjusted models. In addition, the R^2 values were reported for the unadjusted models to assess the magnitude of the effect.

To assess the effects of usage between those whose psychological flexibility improved and those whose flexibility did not improve, binary logistic regression analyses were conducted. The participants were divided into 2 groups based on the change in psychological flexibility during the intervention. Those whose psychological flexibility increased (ie, the change in the AAQ-II score was negative) were labeled "improvers" and those whose psychological flexibility remained unchanged or decreased (ie, the change in the AAQ-II score was zero or positive) were labeled "nonimprovers." The cutoff of zero was used because AAQ-II does not have reference values for clinically significant change. First, univariate logistic regression models were used to test the independent effect of each usage metric and then, multiple regressions were employed to adjust for the potential confounders. The odds ratios (ORs) with their 95% confidence intervals and significance values were reported both for the unadjusted and for adjusted models. In addition, medians and interquartile ranges (IQRs) of usage metrics were reported for both groups.

The usage metrics found to be significant in the regression analyses were further investigated for associations with baseline variables. As the distributions of the usage metrics were skewed, Spearman correlation was used for continuous variables and Mann-Whitney U test for cases where 1 variable was categorical.

The statistical analyses were performed using the IBM SPSS Statistics version 22 (IBM Corp, Armonk, NY, USA). Statistical significance was set at $P < .05$.

Ethical Approval

The RCT was approved by the ethics committee of the Central Finland Health Care District, and written informed consent was obtained from all participants. The approval and consent also covered the secondary analyses performed. The trial was registered at ClinicalTrials.gov with the identifier NCT01738256.

Results

Mobile Intervention Participants

The mean level of psychological flexibility in the mobile ACT intervention group was 20.4 (95% CI 18.3-22.5) at baseline and 18.5 (95% CI 16.4-20.7) at postintervention. The mean change was -1.9 (95% CI -3.2 to -0.5) and the within-group effect size (Cohen's d) was 0.2, indicating a small improvement in psychological flexibility.

Table 2 presents the participants' baseline characteristics. The baseline score of psychological flexibility (AAQ-II) was significantly correlated with the change in psychological flexibility during the intervention ($\rho = -.33$, $P = .004$). Also, the correlation between weight-related psychological flexibility (AAQW) and the change in psychological flexibility indicated slight association ($\rho = -.20$, $P = .09$).

Table 2. Participants' baseline characteristics: age, gender, body mass index, education, prior technology experiences, and psychological characteristics.

Characteristic	Participants, n=74
Age ^a in years, median (IQR ^b)	49.6 (45.4-55.3)
Gender, female, n (%)	64 (86)
BMI ^c (kg/m ²), mean (SD)	31.5 (2.8)
Education (college or higher), n (%)	59 (80)
Smart mobile phone owner, n (%)	25 (34)
Mobile wellness user, n (%)	9 (12)
Wellness device user, n (%)	60 (81)
AAQ-II ^d , mean (SD)	20.4 (9.1)
AAQW ^e , mean (SD)	88.8 (21.0)
GHQ-12 ^{a,f} , median (IQR)	6.0 (5.0-9.0)

^a Skewed distribution.

^b IQR: interquartile range.

^c BMI: body mass index.

^d AAQ-II: Acceptance and Action Questionnaire II.

^e AAQW: Acceptance and Action Questionnaire for Weight-Related Difficulties.

^f GHQ-12: 12-item General Health Questionnaire.

When the participants were divided into 2 groups (improvers, $n=38$; and nonimprovers, $n=36$), the mean change from baseline to postintervention in psychological flexibility was -6.3 (95%

CI -7.6 to -5.0) for improvers and 2.8 (95% CI 1.6-3.9) for nonimprovers ($P < .001$). The within-group effect size was 0.8 for improvers and -0.3 for nonimprovers.

Usage Metrics

The mobile app was available to the mobile intervention participants for a median of 58 days (IQR 55-60). During this period, they used the app as follows. The median number of usage sessions was 21 (IQR 12-35), the number of usage days was 15 (IQR 9.0-24), and the number of usage weeks was 7.0 (IQR 4.0-8.0). Less than half of the participants, 31/74 (42%), used the app for 8 weeks or more.

The median total duration of use was 4.7 (IQR 3.2-7.2) hours and the number of exercises performed was 63 (IQR 46-98). The median session duration was 13.5 (IQR 9.8-17) minutes. The median completion percentage was 91% (IQR 64%-96%), that is, the participants completed most exercises. The most used exercise types were *Being present* (26%, IQR 20%-33%) and *Self as context* (24%, IQR 17%-30%).

The usage was mostly focused on the first half of the intervention period, as the median usage pattern was 2.4, IQR

1.7-4.1. Most exercises (81%, IQR 63%-92%) were performed by listening instead of reading.

Impact of App Use on Psychological Flexibility

Dose Response

Table 3 presents the results of the linear regression analyses. The strongest association with psychological flexibility in the unadjusted analyses was seen with the use of *Self as context* related exercises ($B=0.19$, $P=.002$, $R^2=.12$), indicating that active usage of these exercises was associated with decreased psychological flexibility. The adjusted analyses revealed a dose-response relationship with the majority of metrics describing the intensity of use, indicating that a higher number of usage sessions ($B=-0.10$, $P=.01$), usage days ($B=-0.17$, $P=.008$), usage weeks ($B=-0.73$, $P=.02$), and exercises ($B=-0.02$, $P=.03$); the total duration of use ($B=-0.30$, $P=.04$); and the use of *Acceptance* related exercises ($B=-0.18$, $P=.04$) predicted increased psychological flexibility. These parameters were also borderline significant in the unadjusted models.

Table 3. Linear regression analyses between usage metrics and change in Acceptance and Action Questionnaire II score.

Usage metric	B (95% CI) ^a	R ²	P ^a	B (95% CI) ^b	P ^b
Number of usage sessions	-0.07 (-0.15 to 0.01)	.05	.07	-0.10 (-0.18 to -0.02)	.01
Number of usage days	-0.12 (-0.24 to 0.01)	.05	.06	-0.17 (-0.30 to -0.05)	.008
Number of usage weeks	-0.61 (-1.22 to -0.01)	.05	.047	-0.73 (-1.34 to -0.11)	.02
Number of exercises	-0.02 (-0.04 to 0.003)	.04	.09	-0.02 (-0.05 to -0.002)	.03
Total duration of use, hours	-0.24 (-0.51 to 0.03)	.04	.08	-0.30 (-0.59 to -0.02)	.04
Session duration, minutes	0.01 (-0.19 to 0.22)	0	.91	0.05 (-0.15 to 0.26)	.60
Completion %	-0.004 (-0.06 to -0.05)	0	.87	-0.03 (-0.08 to 0.03)	.33
Being present %	-0.03 (-0.10 to 0.45)	.01	.43	-0.004 (-0.08 to 0.07)	.92
Self as context %	0.19 (0.07-0.31)	.12	.002	0.22 (0.10-0.34)	.001
Acceptance %	-0.13 (-0.31 to 0.04)	.03	.14	-0.18 (-0.36 to -0.01)	.04
Cognitive defusion %	-0.14 (-0.35 to 0.09)	.02	.23	-0.19 (-0.42 to 0.04)	.10
Values %	0.06 (-0.18 to 0.31)	0	.61	-0.04 (-0.31 to 0.22)	.75
Committed action %	-0.05 (-0.33 to 0.23)	0	.72	-0.16 (-0.46 to 0.13)	.28
Usage pattern	0.45 (-0.01 to 0.91)	.05	.06	0.35 (-0.12 to 0.82)	.14
Listen %	0.06 (-0.005 to 0.12)	.05	.07	0.05 (-0.01 to 0.11)	.12

^a Unadjusted.

^b Adjusted for baseline values of age, gender, 12-item General Health Questionnaire, Acceptance and Action Questionnaire II, and Acceptance and Action Questionnaire for Weight-Related Difficulties.

When all usage metrics found to be significant in the adjusted analyses were entered together into a linear regression model without adjustments, the adjusted R^2 was .05

Binary Effect

Table 4 presents the results of the binary logistic regression analyses assessing the effects of usage between improvers and nonimprovers. Median (IQR) values of usage metrics in the improvers' and nonimprovers' groups were presented. The adjusted models identify similar parameters as found with linear regression models. The odds of improved psychological

flexibility increased significantly along with the number of usage sessions (OR=1.08, $P=.002$), usage days (OR=1.13, $P=.001$), usage weeks (OR=1.48, $P=.005$), and exercises (OR=1.02, $P=.003$), and the total duration of use (OR=1.42, $P=.002$). Regarding the type of exercises used, the odds of improved psychological flexibility increased with active use of *Acceptance* exercises (OR=1.15, $P=.005$) and *Cognitive defusion* exercises (OR=1.15, $P=.01$) and decreased with active use of *Self as context* exercises (OR=0.90, $P=.005$). The results were similar also in the unadjusted models.

Table 4. Logistic regression analysis; associations between usage parameters and improvement in psychological flexibility.

Usage parameter	Improvers (n=38) median (IQR ^a)	Nonimprovers (n=36) median (IQR)	OR ^{b,c} (95% CI)	P ^c	OR ^d (95% CI)	P ^d
Number of usage sessions	27.5 (16.3-41.0)	18.0 (10.0-23.8)	1.05 (1.02-1.10)	.005	1.08 (1.03-1.13)	.002
Number of usage days	19.0 (13.0-28.3)	11.5 (8.0-16.0)	1.09 (1.03-1.15)	.004	1.13 (1.05-1.21)	.001
Number of usage weeks	8.0 (5.8-8.0)	5.5 (4.0-7.0)	1.38 (1.09-1.74)	.007	1.48 (1.13-1.95)	.005
Number of exercises	82.5 (51.8-148)	51.5 (39.5-79.0)	1.02 (1.00-1.03)	.009	1.02 (1.01-1.04)	.003
Total duration of use, hours	6.0 (3.7-11.1)	4.0 (2.6-6.0)	1.27 (1.08-1.51)	.005	1.42 (1.14-1.76)	.002
Session duration, minutes	13.5 (9.9-17.5)	13.7 (9.6-17.7)	0.99 (0.93-1.06)	.84	0.97 (0.90-1.05)	.48
Completion %	93 (86-98)	83 (56-93)	1.01 (0.99-1.03)	.17	1.02 (1.00-1.05)	.06
Being present %	21 (16-28)	28 (21-38)	0.99 (0.97-1.02)	.61	0.99 (0.96-1.01)	.33
Self as context %	21 (14-28)	26 (21-36)	0.93 (0.88-0.98)	.006	0.90 (0.84-0.97)	.005
Acceptance %	13 (11-20)	11 (5-14)	1.10 (1.03-1.19)	.009	1.15 (1.04-1.27)	.005
Cognitive defusion %	15 (11-19)	11 (8-15)	1.11 (1.02-1.20)	.02	1.15 (1.03-1.27)	.01
Values %	11 (9-14)	11 (8-14)	0.99 (0.91-1.07)	.74	1.01 (0.92-1.11)	.86
Committed action %	11 (7-13)	9 (6-11)	1.06 (0.97-1.17)	.20	1.11 (0.98-1.25)	.09
Usage pattern	2.1 (1.5-2.9)	3.1 (1.9-5.7)	0.88 (0.75-1.04)	.15	0.92 (0.78-1.10)	.37
Listen %	81 (55-91)	81 (70-92)	0.98 (0.96-1.01)	.19	0.99 (0.96-1.01)	.26

^a IQR: interquartile range.

^b OR: odds ratio.

^c Unadjusted.

^d Adjusted for baseline values of age, gender, 12-item General Health Questionnaire, Acceptance and Action Questionnaire II, and Acceptance and Action Questionnaire for Weight-Related Difficulties.

Associations Between Usage Parameters and Baseline Variables

The usage metrics that were found to be significant predictors of changes in psychological flexibility (Tables 3 and 4) were analyzed for associations with the participants' baseline characteristics (Table 2).

Older participants used the app more actively, as indicated by the number of exercises ($\rho=.25$, $P=.03$) and the total duration of use ($\rho=.25$, $P=.04$). Older participants used the *Self as context* exercises ($\rho=-.33$, $P=.005$) less than younger participants.

Women used the app more than men in terms of the number of usage sessions (median 23, IQR 13-38 vs median 14, IQR 8.8-19; $P=.04$), usage days (median 16, IQR 10-25 vs median 11, IQR 5.8-16; $P=.03$), and usage weeks (median 7, IQR 5.0-8.0 vs median 4, IQR 3.0-8.0; $P=.04$).

Participants who owned a smart mobile phone before the study were less likely to use the app actively than those who did not own a smart mobile phone, based on the number of usage days (median 11, IQR 6-18 vs median 16, IQR 12-25; $P=.02$) and usage weeks (median 5.0, IQR 3.0-8.0 vs median 7.0, IQR 5.5-8.0; $P=.005$), the number of exercises (median 52, IQR

25-71 vs median 79, IQR 50-108; $P=.02$), and the total duration of use (median 220 minutes, IQR 131-324 vs median 319 minutes, IQR 227-461; $P=.01$). Smart mobile phone owners also used *Cognitive defusion* exercises (median 11%, IQR 7%-16% vs median 14%, IQR 11%-18%; $P=.04$) and *Acceptance* exercises (median 11%, IQR 3%-13% vs median 13%, IQR 11%-19%; $P=.003$) less.

Discussion

Principal Findings

This study focused on metrics describing the usage of a mobile ACT intervention and their associations with the change in psychological flexibility during an 8-week intervention. The purpose of the ACT intervention was to increase psychological flexibility and thereby support value-based approach in life. The aims of this study were to investigate the dose-response relationship between usage and the change in psychological flexibility and to identify the usage metrics most strongly associated with improvement. The importance of psychological flexibility has been highlighted in a review by Kashdan and Rottenberg [45] describing flexibility as a fundamental aspect of health. There is ample evidence on the value of psychological flexibility. For example, in many forms of psychopathology, the processes associated with flexibility are absent. It is also proposed that psychological flexibility may be helpful not only to people suffering from different pathologies but also to highly functioning people in finding greater efficacy and fulfillment in their daily lives [45].

On the group level, the mean change in psychological flexibility was -1.9 points, indicating a small improvement with an effect size of 0.2 . The psychological flexibility of about half of the participants (38/74, 51%) increased and the mean change in this group was -6.3 , indicating a large improvement with an effect size of 0.8 . In comparison, Ly et al [29] reported a within-group effect size of 0.5 for psychological flexibility for an ACT-based mobile self-help program.

A dose-response relationship between usage and the change in psychological flexibility was found. The usage metrics that were the most strongly associated with the change in psychological flexibility were related to the intensity of use, that is, the number of usage sessions, the number of usage days, the number of usage weeks, the number of exercises performed, and the total duration of use. Logistic regression analyses confirmed these findings. However, the R^2 values of individual usage metrics, ranging from $.04$ to $.12$, as well as the R^2 of the combined model ($.05$) consisting of all significant usage metrics showed that the predictive power of the usage metrics was relatively low. Interestingly, the session duration was not associated with improvement of psychological flexibility. This may be due to the fact that as the exercises were relatively short, the session duration was naturally rather limited.

A dose-response relationship was found also for 2 metrics describing content usage. Active usage of exercises related to the *Acceptance* process and less active usage of *Self as context* related exercises predicted increased psychological flexibility. Logistic regression analyses confirmed these findings and also

indicated that more active usage of *Cognitive defusion* related exercises was associated with increased flexibility. Hayes et al [19] found that, based on a series of small-scale dismantling studies, *Acceptance* and *Cognitive defusion* related exercises had the strongest evidence of effectiveness.

When comparing participants whose psychological flexibility increased (improvers) and whose did not increase (nonimprovers), we saw that the total duration of use was more than 6 hours for improvers compared with 4 hours for nonimprovers. This result highlights that, even when an intervention is delivered through a mobile app, the participants need to commit substantial time and effort to the intervention in order to gain benefits. In comparison, in the study by Bricker et al [23] the average total usage time of the Web-based smoking cessation intervention was about 2.9 hours, and in the study by Carlbring et al [24] a depression intervention was used, on average, for 3.5 hours.

Older age, female gender, and not owning a smart mobile phone before the study were associated with more active use. The reason why not owning a smart mobile phone before the study affected usage may be that participants who already had a smart mobile phone were more reluctant to take a secondary phone into use. Another factor may be that those who did not own a smart mobile phone before were actually motivated by receiving a new phone for a few weeks.

Comparison With Prior Work

Donkin et al [11] investigated the associations between several usage metrics and improvement in depression during a 12-week Internet intervention. Similar metrics and associations with outcome as in our study were found for the following usage metrics: (1) the total number of minutes spent in the program and (2) the total number of activities completed. There was also an interesting similarity in the total usage time in these 2 studies, despite the fact that one of the interventions was delivered through the Internet whereas the other was a mobile app. Donkin et al [11] reported an average total usage time of 5.9 hours for those whose depression improved compared with 4.9 hours for those who did not achieve improvements. In our study, the median total usage time was 6.0 hours for improvers versus 4.0 hours for nonimprovers. Ly et al [32] reported a study of an ACT-based mobile intervention for stress management. In their study, 16/36 (44%) participants adhered to the study for all of the 6 weeks of the intervention. In our study, using a similar criterion, 31/74 (42%) participants used the mobile app weekly for the entire 8-week intervention period.

Studying the usage of content in digital interventions is a relatively new area of research, made possible by automatic and detailed tracking of usage. Only a few studies have attempted to investigate the associations between the usage of content and improvement in mobile interventions. Heffner et al [33] studied the usage of a mobile ACT intervention for smoking cessation and found that only 2 of the 10 most popular features were associated with smoking abstinence and, furthermore, that there were several features among the less popular ones that were associated with smoking abstinence. Our study provided preliminary evidence that focusing on *Acceptance* and *Cognitive defusion* related exercises was associated with improvement of

psychological flexibility, whereas focusing on *Self as context* related exercises actually decreased the likelihood of improvement. These results suggest that *Acceptance* and *Cognitive defusion* related exercises are needed in addition to *Self as context* related exercises in order to gain a significant effect on flexibility. Identifying the most effective components of interventions is important because it enables better design of interventions and making sure that users are exposed to those components instead of or in addition to the less effective ones. For example, in our app, most *Self as context* related exercises were presented earlier than *Acceptance* and *Cognitive defusion* related exercises. As many participants proceeded in the app in the suggested order, those who used the app less may not have been exposed to the more advanced exercises appearing later in the app as extensively.

Many studies have tried to identify demographic predictors of usage and depending on the type of intervention, different and often conflicting predictors have been found. Female gender has often predicted better adherence [8,46]. This was the case also in our study, but as there were very few men involved in the study, strong conclusions cannot be drawn from this result. Sometimes older [8,17,47] and sometimes younger age [8] have been found to predict better adherence. In our study, older participants were more active users. Owning a smart mobile phone before the study was associated with less active usage, which is in line with the finding by Christensen et al [8] who found that participants who were less experienced with using computers adhered better. Also, lower symptom levels have been found to predict adherence, especially in psychological disorders [8]. In our study, no such associations were found.

Other important predictors of adherence to interventions reported in the literature include, for example, outcome expectancy, social support, and autonomous motivation [3,48,49]. The importance of these factors probably increases in the case of self-help and digital interventions where users need to find the time and initiative to use the intervention on their own. Although we did not measure motivation, we found that the baseline level of psychological flexibility correlated with the changes in flexibility, that is, those with a lower baseline level of psychological flexibility improved more. This may mean that those who gained more benefits may have had more room for improvement and may have felt a greater need—and motivation—to use the intervention. Also, RCT as the study setup and having counselor contact have been found to predict usage [9,15,16]. Although in our study the study procedures included only 1 face-to-face meeting and only a short presentation by a trained psychologist, it may have contributed to active usage along with all the study procedures related to the RCT setup.

Limitations

The study population consisted of participants who volunteered to take part in the RCT. Although they were randomly allocated to different interventions and therefore did not know which intervention, if any, they would receive, the group is likely to be biased and the results cannot be generalized. Volunteering in a research study often requires a lot of effort from the

participants and they may therefore be highly motivated. Also, the large proportion of female participants, which is not uncommon in health trials, limits making generalizations.

The baseline level of psychological flexibility correlated significantly with the change in psychological flexibility. This means that those who had more room for improvement also experienced larger effects. It is not possible to evaluate whether this is due to higher motivation, greater perceived need, or features of the app.

We acknowledge that we performed a large number of statistical tests without correcting the statistical significance level of .05, which means that some of the low *P* values may have occurred by chance. However, this study was exploratory by nature and any results should be confirmed in future studies.

Regarding the design of the RCT, the duration of the mobile intervention (8 weeks) was arbitrary and does not correspond to real-life use of mobile apps. Because the participants had to return the phones at the end of the intervention period, there is no way of knowing how the usage would have evolved over time and whether additional benefits would have been gained as a result. On the other hand, the knowledge of the limited availability may also have motivated the participants for such active use. Also, the fact that the app did not run on the participants' personal mobile phones probably affected the ways they used the app.

There were also some limitations related to the mobile app logs that were recorded automatically by the mobile phone. As the app did not require logging in and out for session, it could be running constantly in the background without being used, or the app could be closed accidentally during a usage session, which made the log files challenging to analyze. Therefore, the usage metrics may not be absolutely accurate. However, the rules for determining the usage metrics were verified by manually inspecting several random log files and therefore we can be fairly confident that the metrics describe actual usage satisfactorily.

Conclusions and Future Research

The results indicated that active usage of a mobile ACT intervention was associated with improved psychological flexibility. Usage metrics related to the intensity of use and the usage of content were found to be the strongest predictors of the change in psychological flexibility. This study showed that rather intensive usage was required in order to gain benefits, and therefore the study highlights the need to measure and optimize the intensity of usage in mobile interventions. The study also implies that, to ensure effectiveness, the components known to be the most effective should be prioritized to make sure all users are exposed to them.

Future research should strive to study the usage of mobile apps in a more natural way, including using the participants' personal mobile phones and not limiting usage time. The results provided in this study about the associations between usage of different types of exercises and outcomes highlight the capabilities of digital interventions to enable detailed analyses of what the participants are actually exposed to during interventions.

Acknowledgments

We would like to thank Ms Anna-Leena Vuorinen for her help in designing the statistical analyses in this study and Professor Urho Kujala and Associate Professor Sampsa Puttonen for their valuable comments on the manuscript.

The study was supported by the SalWe Research Program for Mind and Body (Tekes – the Finnish Funding Agency for Technology and Innovation grant 1104/10). We would like to thank the following companies for their contributions to the study: Duodecim Medical Publications Ltd (Helsinki, Finland), Firstbeat Technologies Ltd (Jyväskylä, Finland), Vivago Ltd (Espoo, Finland), Finnish Red Cross Blood Service (Helsinki, Finland), and Valio Ltd (Helsinki, Finland).

Conflicts of Interest

The mobile ACT intervention app was developed in collaboration between VTT Technical Research Centre of Finland and University of Jyväskylä. The authors involved in the development of the app were EM, PV, ME, ES, PL, and RL.

Multimedia Appendix 1

CONSORT-eHealth (V 1.6.1) checklist [35].

[[PDF File \(Adobe PDF File\), 1MB - mhealth_v4i3e90_app1.pdf](#)]

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Abbreviations

- AAQ-II:** Acceptance and Action Questionnaire II
AAQW: Acceptance and Action Questionnaire for Weight-Related Difficulties
ACT: Acceptance and Commitment Therapy
BMI: body mass index
GHQ-12: 12-item General Health Questionnaire
IQR: interquartile range
OR: odds ratio
RCT: randomized controlled trial

Edited by G Eysenbach; submitted 13.10.15; peer-reviewed by I Buchan, W Pots, M Sperrin; comments to author 29.03.16; revised version received 26.05.16; accepted 10.06.16; published 28.07.16.

Please cite as:

Mattila E, Lappalainen R, Väikkynen P, Sairanen E, Lappalainen P, Karhunen L, Peuhkuri K, Korpela R, Kolehmainen M, Ermes M
Usage and Dose Response of a Mobile Acceptance and Commitment Therapy App: Secondary Analysis of the Intervention Arm of a Randomized Controlled Trial
JMIR Mhealth Uhealth 2016;4(3):e90
URL: <http://mhealth.jmir.org/2016/3/e90/>
doi: [10.2196/mhealth.5241](https://doi.org/10.2196/mhealth.5241)
PMID: [27468653](https://pubmed.ncbi.nlm.nih.gov/27468653/)

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Original Paper

Using Personal Mobile Phones to Assess Dietary Intake in Free-Living Adolescents: Comparison of Face-to-Face Versus Telephone Training

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Abstract

Background: Traditional paper-based methods to assess food intake can be cumbersome for adolescents; use of mobile phones to track and photograph what they eat may be a more convenient, reliable, and compelling way to collect data.

Objective: Our aims were to determine (1) the feasibility of using personal mobile phones to send food records with digital images (FRDIs) among free-living adolescents and (2) whether the quality of food records differed between a high-level intervention group (ie, face-to-face training plus real-time support) and a low-level intervention group (ie, telephone training plus next-day follow-up).

Methods: Adolescents (N=42, 11 males and 31 females) aged 12-18 years who had a mobile phone with camera enrolled in the study via consecutive sampling. The first group (n=21) received face-to-face training while the second group (n=21) was trained via telephone. Participants received a fiducial marker (FM) and completed a 1-day FRDI using their mobile phones. At every eating occasion, participants were to (1) take clear images of their meals/food with a correctly placed fiducial marker before eating, (2) send the image immediately to a designated email address, (3) right after completing a meal, send a text message listing the time and name of the meal, foods eaten, and amounts eaten, and (4) before sleep, send an "end" text message to indicate completion of food recording. Those who received face-to-face training received real-time support during reporting; those trained by telephone received next-day follow-up. Descriptive statistics and comparison tests were used to determine performance of the groups.

Results: All participants (N=42) who underwent training completed their 1-day FRDI. A significantly greater proportion of the low-level intervention group compared to the high-level intervention group placed their FM correctly in the image (95% vs 43%, $P<.001$), had complete information for each meal in their food record (95% vs 71%, $P=.04$), and had a higher overall score in meeting the criteria for food recording (4.3 vs 3.4 out of 5 points). Both groups had energy intake values that moderately correlated with their estimated energy requirements: low-intervention $r=.55$; high-intervention $r=.51$.

Conclusions: Using personal mobile phones to report dietary intake via texting and digital images is feasible among free-living adolescents. Real-time support or high-level intervention does not guarantee better food recording quality among adolescents.

(*JMIR Mhealth Uhealth* 2016;4(3):e91) doi:[10.2196/mhealth.5418](https://doi.org/10.2196/mhealth.5418)

KEYWORDS

adolescents; dietary assessment; dietary records; digital images; follow-up; mobile phones; real-time support; technology

Introduction

Dietary assessment is an important component in the investigation of diet-health relationships; thus, it is crucial that methods used to determine intake are reliable and valid. Several approaches are used to measure what people eat, but each has inherent biases and limitations. Specific characteristics of populations also contribute to bias in assessing dietary intake. For instance, underreporting is common among obese and overweight individuals [1-3]. Inaccuracy in dietary assessment is compounded further by an exponential increase of food products on the market, a glut that necessitates timely upkeep of existing food and nutrient databases to prevent them from getting outdated.

An accurate assessment of dietary consumption by adolescents is particularly challenging. Youth in this age group have difficulty conceptualizing or averaging food portion sizes [4], have a limited food vocabulary, and lack the patience and perseverance to engage in food recording [5,6]. Recall of routine or regularly occurring events can be relatively accurate, but adolescents tend to skip meals [7,8] and have wide and inconsistent day-to-day variation in the frequency, composition, and timing of their meals [6]; thus, their recall could be unreliable unless they record what they eat immediately after meals and snacks.

Often, social pressure or the lack of confidentiality also makes adolescents unwilling to undertake paper-based food recording; in addition, they tend to modify their intake to ease the burden associated with food recording [9]. Although conventional methods of dietary assessment can be cumbersome for adolescents, innovations that tap into their technological skills may keep them engaged in reporting their dietary intake [5]. Given that the traditional paper-and-pen food recording entails detailed descriptions of foods eaten, pictures taken during eating events can potentially reduce such burden because pictures can convey those details as well.

Mobile electronic devices have made their way into most households—approximately 78% of adolescents own mobile phones, 23% own a tablet computer [10], and a large percentage are constantly occupied with technological devices (eg, computers and mobile phones) [11]. Mobile electronics are already part of the adolescent lifestyle. Digital photography used as either the main method to record intake or in conjunction with the traditional food record can provide objective information about dietary intake, reduce participant burden, and potentially decrease the need for portion size estimation [12-15]. Since digital images can simplify food recording [16], use of the camera feature of mobile phones had been tested among adolescents in both monitored [17-19] and free-living [20] settings.

While considerable work has been done in dietary assessment methods for the purpose of reducing participant and research burden, most of the work has not been completed and is still undergoing refinement or validation. Development of software and mobile phone apps for dietary assessment purposes can be exceedingly costly, extremely challenging, and may take several years to complete [21]. However, existing mobile phone

technology (eg, camera and short message service [SMS] text messaging) may be efficiently utilized to serve practically the same purpose in collecting dietary information until apps for mobile phones are made available for researchers at a reasonable cost. Adolescents were willing to use SMS text messaging when reporting their health information needs [22]. Likewise, the use of SMS text messaging and camera features of mobile phones needs to be tried when assessing dietary intake of adolescents.

We determined the feasibility of assessing the dietary intake of free-living adolescents by using their own mobile phones to do digital image-assisted food recording. We also explored whether the quality of food records from these adolescents would differ based on the type of training and support provided during food recording. It had been suggested that automated feedback may improve intake reporting accuracy of adolescents [17,20,23]. Considering that the concept of automated feedback could be mimicked with real-time human monitoring, we used the latter as a proxy to test whether real-time feedback would indeed improve recording accuracy. We hypothesized that high-level intervention, which includes face-to-face training and real-time support, would promote higher-quality food records compared to low-level intervention, which includes training through telephone conversation and next-day follow-up.

Methods

Participant Selection and Study Design

We recruited 12- to 18-year-old adolescents from select middle and high schools to be part of a study to determine the feasibility of using personal mobile phones in keeping food records with digital images (FRDIs). Participants were recruited via consecutive sampling in April and August 2012. Eligibility requirements included ownership of a mobile phone with a camera, unlimited texting/calling, and the ability to send SMS text messages and images to an email address. All study protocols were approved by the Loma Linda University Institutional Review Board. We obtained consent of parents and their children's assent prior to starting the study.

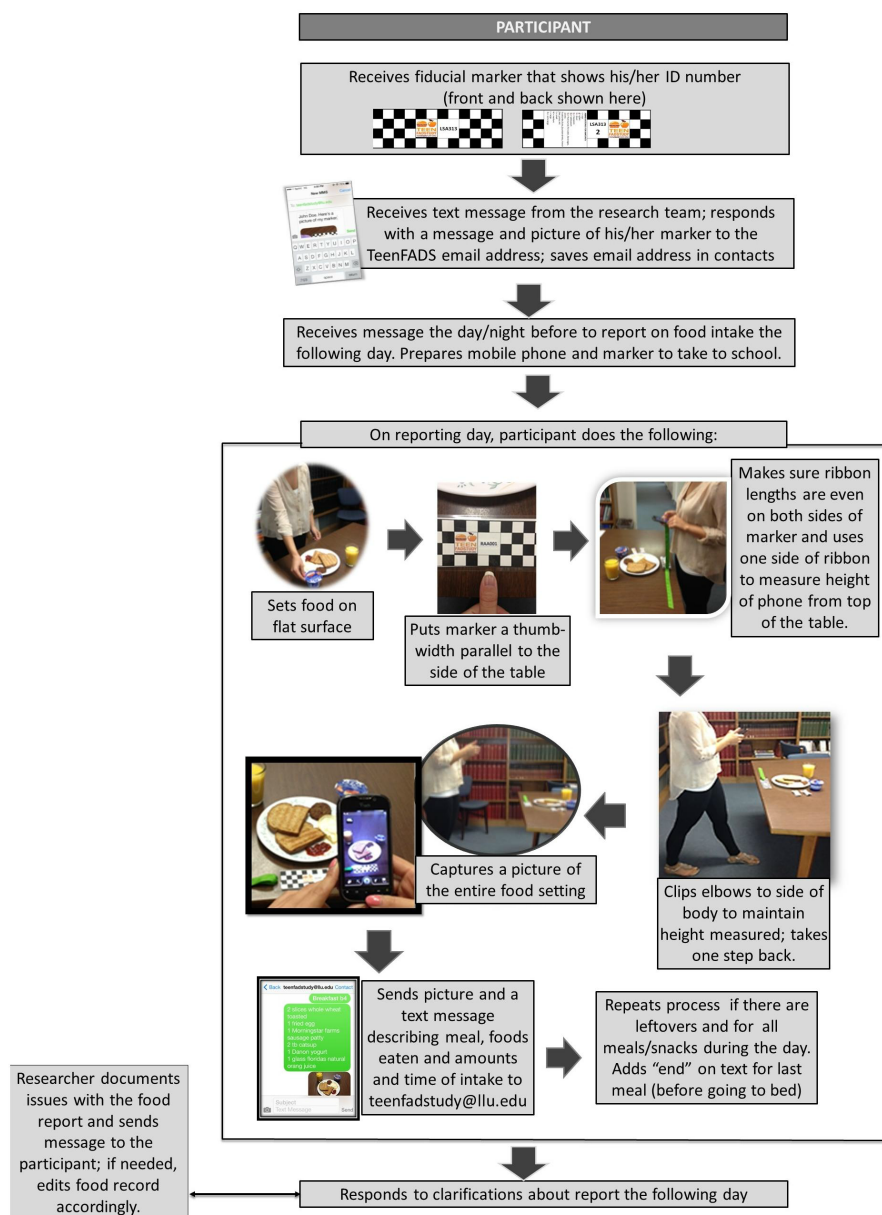
To avoid cross-contamination and for logistical reasons, this pilot study was designed such that the first group of available volunteers who met the eligibility criteria were assigned to high-level intervention while the second group who joined the study later were assigned to low-level intervention. High-level intervention was conducted in May 2012, and low-level intervention in September 2012. Participants of the high-level intervention (n=21) were instructed to watch an instructional video prior to an in-depth, one-on-one, face-to-face training session, which took place in the school. Three research assistants were assigned to do the face-to-face training. On the other hand, personal training for the participants of the low-level intervention (n=21) was delivered via a one-one-one telephone conversation by a research assistant. Each participant received illustrated instructions beforehand, which served as the training material during the telephone conversation. Instructional content was similar for both groups. After training, participants were scheduled to perform a 1-day FRDI. All the participants who joined the study (N=42) completed the training, did their 1-day FRDI, and received a US \$10 iTunes gift card as incentive.

Real-time support entailed sending reminder messages or prompts, particularly when SMS text messages and images were not coming in around expected eating times, and on-the-spot instructions when they saw reporting errors (eg, blurred or missing FM). The monitors also reminded participants to send the closure “end” messages before they retired for the night.

While actively monitoring the high-level intervention participants, texted images and corresponding messages from the email inboxes were collated into PowerPoint slides. Each slide included an image and text report of a meal or food/beverage; Figure 3 shows this process. In addition, researchers logged observations and issues encountered during monitoring.

Low-level intervention only entailed next-day follow-up. No reminders or any kind of monitoring was given during the reporting day of low-level intervention participants. The following day, research assistants checked the participants’ reports and transferred the images and corresponding SMS text messages from their email inboxes to their individual food records (ie, PowerPoint slides). Observations about the messages and images were logged. Participants were informed about items that needed clarification, and their responses were entered into their PowerPoint record (see Figure 4). For both high-level and low-level interventions, the food record was a product of the participant’s (text and image) and the research assistant’s (interpretation and assembly of sent texts and images) contributions.

Figure 3. Diagram of the food record with digital images (FRDI) using personal mobile phones by adolescents. High-level intervention (ie, real-time support) participant responds to prompts and feedback by researcher; low-level intervention participant responds to researcher feedback after reporting day (ie, next-day) follow-up. ID: identification.



Data Analysis

To determine the quality of reports, we computed the proportion of participants in each group who (1) sent images with their FM, (2) correctly placed their FM relative to the food arrangement, (3) sent an accompanying SMS text message that described the foods eaten and/or if there were any leftovers, (4) gave complete information, including the time, meal name, food list, and corresponding amounts eaten, and (5) sent good-quality images (ie, images with foods that could be clearly identified).

We also created a scoring system to determine the quality of reports for each individual based on the following criteria: (1) proper placement of the FM in all images (1 point), (2) complete meal information—with time of intake, name of meal, and the names and corresponding amounts of foods eaten—in the texted food report (1 point), (3) texting the closure “end” message (1 point), (4) each image accompanied by a text message (1 point), and (5) quality of images (0 point if all images were blurred, 0.5 point if some were blurred, or 1 point if all were of good quality). Since participants were instructed to take an *after* image only if there were leftovers, no score was assigned to *before-and-after* photos. We used the quality of reports to determine adherence to instructions. The maximum score was 5 points, which was equivalent to 100% adherence to instructions.

Descriptive statistical (ie, frequencies) and comparison (ie, paired and independent *t* tests) analyses were used to evaluate

the quality of FRDIs. All analyses were done using IBM SPSS version 22.0 for Windows (IBM Corp, Armonk, NY) [24].

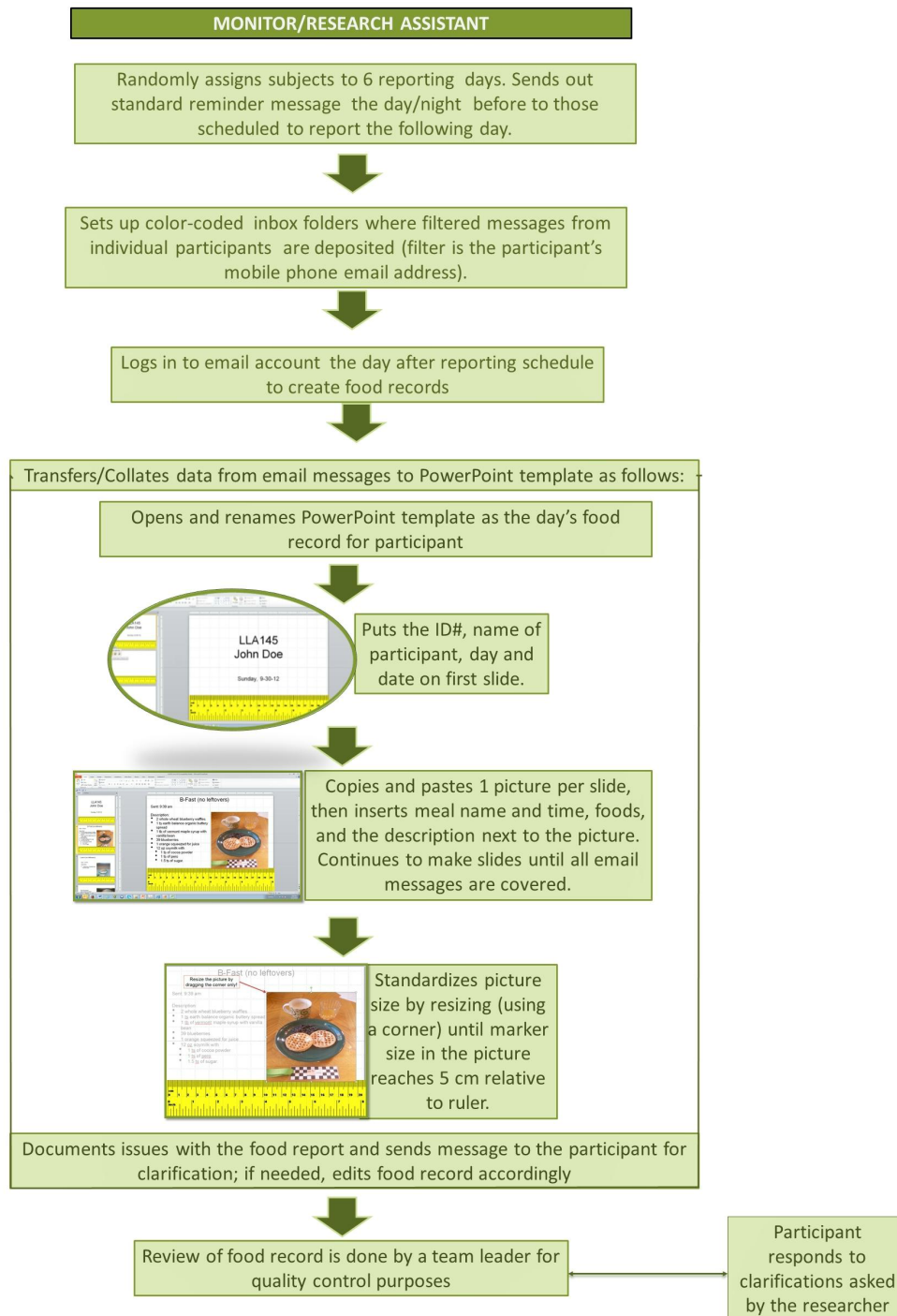
To determine if type of training would differentiate reported intake among these adolescents, we compared their energy intake from the 1-day FRDI with their estimated energy requirement (EER). Energy intake (EI) from food records was determined by using the Nutrition Data Systems for Research version 2012 software developed by the Nutrition Coordinating Center, University of Minnesota, Minneapolis, MN. EER was computed using the equations to calculate the Dietary Reference Intake for energy [25]; physical activity level (PAL) was set at low active (PAL of 1.40-1.59), which has equivalent physical activity (PA) values of 1.13 for boys and 1.16 for girls:

$$EER_{\text{boys},9-18 \text{ years old}} = 88.5 - (61.9 \times \text{age [y]}) + \text{PA} \times \{(26.7 \times \text{weight [kg]}) + (903 \times \text{height [m]})\} + 25 \quad (1)$$

$$EER_{\text{girls},9-18 \text{ years old}} = 135.3 - (30.8 \times \text{age [y]}) + \text{PA} \times \{(10.0 \times \text{weight [kg]}) + (934 \times \text{height [m]})\} + 25 \quad (2)$$

Accuracy of energy reporting was determined using the EI:EER ratio. Given that we have a small sample size, the cutoff points determined from 1-day dietary information on a more representative sample of adolescents—the National Health and Nutrition Examination Survey (NHANES) 2003-2011 data (N=14,044 children and adolescents) [26]—were applied to this study. The cutoff points to categorize under-, plausible, and overreporters were <0.61, 0.61-1.64, and >1.64, respectively.

Figure 4. Diagram of the researcher procedure in collecting food records with digital images (FRDIs) using mobile phones by adolescents. The researcher provides real-time prompts and feedback during high-level intervention, but only asks for clarifications on reports from low-level intervention participants during next-day follow-up. ID: identification.



Results

Profile of Participants

The low-level intervention group was composed of 15 females and 6 males, while the high-level intervention group had 16 females and 5 males of similar age. Table 1 describes the composition and demographic characteristics of the participants as a whole and by groups. There were no significant differences in gender, age, or ethnicity. The majority of students were 16 years of age or older, and there were more non-Hispanic whites in the low-level compared with the high-level intervention

group. Average body mass index (BMI) Z scores and BMI percentiles for both groups were within the normal category.

Assessment of 1-Day Food Reports by Group

The number of meals reported ranged from 2 to 6, with the majority of participants reporting 3 meals (9/21, 43% high-level intervention group; 11/21, 52% low-level intervention group). Participants sent images for every eating occasion and each additional serving, as well as *after-eating* images when there were leftovers. The number of images showing the FM ranged from 1 to 11 for the high-level intervention group and from 1 to 6 for the low-level intervention group. *Before-eating* images

ranged from 2 to 8, with a mean of 4.1 (SD 1.5) for the high-level intervention group and 3.8 (SD 1.5) for the low-level intervention group, but not all of these images included the FM. Since participants were instructed to only send *after-eating* images if there were leftovers, they sent very few. The majority of participants from both high-level (15/21, 71%, mean 0.5 [SD

1.2]) and low-level (17/21, 81%, mean 0.2 [SD 0.5]) intervention groups did not send *after-eating* images. Out of the 21 participants in the low-level intervention, 4 (19%) had no problems with their reports and, thus, did not need follow-up; 14 (67%) responded in a timely manner to follow-up; and 3 (14%) either did not respond or had a delayed response.

Table 1. Demographic profile of participants.

Demographic characteristics	All participants (N=42), n (%) or mean (SD)	High-level intervention ^a (n=21), n (%) or mean (SD)	Low-level intervention ^b (n=21), n (%) or mean (SD)
Gender, n (%)			
Male	11 (26)	5 (24)	6 (29)
Female	31 (74)	16 (76)	15 (71)
Ethnicity, n (%)			
Non-Hispanic white	13 (31)	4 (19)	9 (43)
Other ethnicities	29 (69)	17 (81)	12 (57)
Age in years, mean (SD)	15.8 (1.9)	15.9 (2.1)	15.6 (1.6)
Age group, n (%)			
12-13 years	7 (17)	5 (23)	2 (10)
14-15 years	9 (21)	2 (10)	7 (33)
16-18 years	26 (62)	14 (67)	12 (57)
BMI ^c Z score, mean (SD)	0.50 (0.89)	0.46 (0.80)	0.54 (0.99)
BMI percentile, mean (SD)	64.3 (25.9)	63.9 (23.6)	64.7 (28.6)

^aHigh-level intervention involved one-on-one, face-to-face training and real-time support during food recording day.

^bLow-level intervention involved one-on-one training via telephone conversation with only a follow-up after the food recording day.

^cBMI: body mass index.

Table 2 shows the assessment of the 1-day FRDIs for the two groups. The total number of *meals eaten* images with the FM were similar for the two groups. However, the low-level intervention group sent more images with correctly placed FMs compared with the high-level intervention group (mean 4.0 [SD 1.7] vs mean 2.1 [SD 2.4], respectively). Compared with their high-level intervention peers, more participants in the low-level intervention group had their FM in all the images they sent (20/21, 95% vs 15/21, 71%, respectively). These FMs were correctly placed relative to their food settings more often by the low-level versus high-level intervention group (20/21, 95% vs 9/21, 43%, respectively). SMS text messages sent with accompanying images from those in the high-level intervention

group had more missing information compared with participants in the low-level intervention group. The majority of participants from the high-level intervention group had missing information on their texted report, such as time and name of meal (12/21, 57%); 1 did not include amounts of foods eaten and another reported a food in the text that was not in the image. In the low-level intervention group, 2 out of 21 (10%) did not give the meal time and name, and 1 out of 21 (5%) did not have amounts of foods eaten. In the high-level intervention group, a total of 5 participants out of 21 (24%) did not complete their FRDI: 3 did not report dinner, 1 did not report breakfast, and 1 did not report lunch. Out of 21 low-level intervention participants, 1 (5%) did not report lunch.

Table 2. Assessment of the 1-day food record with digital images, by group.

Factor	High-Level intervention ^a (n=21)		Low-Level intervention ^b (n=21)	
	Count	Mean (SD)	Count	Mean (SD)
Total number of:				
Meals eaten	75	3.6 (1.3)	73	3.5 (1.1)
Images with FM ^c	80	3.8 (1.3)	84	4.0 (1.7)
Images with correctly placed FM	45	2.1 (2.4)	83	4.0 (1.7)
Images accompanied by text report ^d	95	4.5 (2.3)	85	4.1 (1.7)
Text reports ^e with missing information	30	1.4 (1.1)	5	0.2 (0.6)
Number of participants with:				
Completed FRDI ^f	15	N/A ^g	20	N/A
“End” message	7	N/A	8	N/A
FM in all images	15	N/A	20	N/A
Correctly placed FM in images	9	N/A	20	N/A

^aHigh-level intervention involved one-on-one, face-to-face training and real-time support during food recording day.

^bLow-level intervention involved one-on-one training via telephone with only a follow-up after the food recording day.

^cFM: fiducial marker.

^dImage—showing or not showing fiducial marker—accompanied by the food report text.

^eText information should include meal name—breakfast, snack, lunch, or dinner/supper— meal time, and foods and corresponding amounts eaten.

^fFRDI: food record with digital images. Completed FRDI refers to reporting all meals eaten and reporting not eating a main meal during food recording.

^gN/A: not applicable.

Quality of 1-Day Food Record and Energy Intake Reports

Table 3 shows the quality of the 1-day FRDIs submitted by the participants based on the criteria used to determine compliance

with the requirements for food recording. Overall, a greater percentage of participants in the low-level intervention complied with the requirements and had a higher total score for meeting the criteria compared with those in high-level intervention.

Table 3. Proportion of adolescents that met the requirements for food recording with digital images, by group.

Criteria ^a	High-Level intervention ^b (n=21)	Low-Level intervention ^c (n=21)	P ^d
1. Correctly placed FM ^e in the image, n (%)	9 (43)	20 (95)	<.001
2. Only good-quality images for whole report, n (%)	15 (71)	20 (95)	.11
3. Texted food intake accompanied by image with FM, n (%)	17 (81)	20 (95)	.15
4. Complete information for each meal in FRDI ^f , n (%)	15 (71)	20 (95)	.04
5. Sent “end” message, n (%)	9 (33)	8 (38)	.75
Total score for meeting criteria, mean (SD)	3.4 (1.1)	4.3 (0.7)	.01

^aEach criterion met was worth 1 point, except for image quality, where a score of 1 was given if all images in the food record with digital images (FRDI) were of good quality, 0.5 if at least half were of good quality, and 0 if less than half were of good quality.

^bHigh-level intervention involved one-on-one, face-to-face training and real-time support during food recording day.

^cLow-level intervention involved one-on-one training via telephone with only a follow-up after the food recording day.

^dChi-square test for each criterion and Mann-Whitney U test for the total score.

^eFM: fiducial marker.

^fFRDI: food record with digital images. Information on meal name—breakfast, snack, lunch, or dinner/supper—meal time, and foods and corresponding amounts eaten were included in text messages.

Table 4. Comparison of reported energy intake (EI)^a with estimated energy requirement (EER)^b according to type of intervention.

Intervention group	Correlation <i>P</i> (<i>r</i>) ^c	EI (kcal), median (IQR) ^d	EER (kcal), median (IQR)	Energy intake report ^e (n=21), n (%)			
				Under	Plausible	Over	
High-level group	.51	.02	1526 (1214)	1808 (336)	7 (33)	14 (67)	0 (0)
Low-level group	.55	.01	1655 (1275)	1837 (679)	7 (33)	14 (67)	0 (0)

^aEI: energy intake reported on the 1-day food record with digital images.

^bEER: estimated energy requirement based on Dietary Reference Intake equations (see Data Analysis section) to estimate energy requirement for boys and girls, 9-18 years old. Physical activity level (PAL) was set at low active (PAL of 1.40-1.59, equivalent to physical activity [PA]=1.13 for boys and PA=1.16 for girls) for lack of physical activity data.

^cSpearman rank correlation coefficient (*r*) between EI and EER.

^dIQR: interquartile range.

^eEnergy intake is underreported if EI:EER<0.61, plausibly reported if EI:EER is 0.61-1.64, and overreported if EI:EER>1.64.

Comparison between the EI and EER for both groups are shown in Table 4. Energy intake reports on the FRDI and correlations between EI and EER were similar between the two groups. The counts of energy intake reports considered *plausible* and *underreported* based on the cutoff points adopted from Mukarami and Livingstone [26] were exactly the same in both groups.

Discussion

Principal Findings

This study demonstrated that it is feasible to assess dietary intake in free-living adolescents, who were willing to use their own mobile phones, in taking digital photographs and texting their food intake according to the training they received. Our study also showed that low-level intervention (ie, training via telephone conversation plus next-day follow-up) yielded higher-quality reports compared to high-level intervention (ie, face-to-face training plus real-time support during food recording).

Instructions on how to take images, place the fiducial markers, text the details of their food intake, and send the information to the email address we set up solely for the study were followed carefully by the majority of the participants. Adherence to instructions in this study of free-living adolescents was higher compared with that in a study that determined how amenable adolescents were to recording their dietary intake using a mobile phone app [20]. An age difference might explain this disparity—our subjects were older (ie, 12-18 years old) than those in the previous study (ie, 11-14 years old). In-depth, one-on-one training and the short duration of the study also possibly contributed to better compliance. We found that this innovative approach of utilizing existing resources (ie, asking participants to use their own mobile phones) in reporting dietary intake is not only attainable, but could also potentially save financial resources (eg, cost of phone service fees and researcher-provided mobile phones for participants). Conducting the study in a free-living situation and during school days, which are relevant routines for school-age youth, also renders good external validity. This study also allowed us to examine if real-time feedback, albeit in a different delivery mode than automated feedback suggested by investigators [17,20,23], is

an appropriate method to improve intake reporting accuracy among adolescents.

Our results indicate that it does not take a high-level intervention to get better-quality 1-day FRDIs from adolescents. Compared to the high-level intervention participants, the low-level intervention group complied better with the requirements of food recording; all of them had their FM during the day of reporting as evidenced by the appearance of FMs in all images, and a higher proportion of this group also provided images with correctly placed FMs—an important consideration when estimating portion sizes—good quality images, SMS text message image with FM pairs, and food records with complete information. The low-level intervention group also met more quality criteria and had higher total scores, indicating greater adherence to instructions. A possible explanation for this difference could be the reliance of the low-level intervention group on the pictorial instructions, which many in the group brought with them to school during their reporting day. Extra emphasis was given to reviewing the pictorial instructions in the food recording reminder message sent the day before to the low-level intervention group. On the other hand, the high-level intervention group was simply reminded about food recording the following day. Both groups, however, were reminded to prepare their phones and FM; despite that, two of the high-level intervention members forgot to bring their FMs to school and, thus, the FM was missing in their images. Since we assumed that participants read their reminder messages, we did not verify if the reminders were actually read.

The reported energy intake on the FRDI and proportion of underreported and plausibly reported energy intakes were similar for both groups. The agreement between the EI and EER was moderate, which indicates that the use of mobile phones in recording dietary intake assisted by digital images provided good estimates of a day's intake. However, energy intake based on just one day would be insufficient to determine over- or underreporting given the wide day-to-day intake variation especially among adolescents [27]. Also, there is evidence that adolescents tend to underreport their intake, which becomes more pronounced as weight increases [28,29]. Since some of our participants skipped a meal during the day (6/42, 14%), this could partly explain why median intakes of energy for both groups were lower compared to the EER.

Contrary to our hypothesis, real-time support during food recording did not produce better outcomes. Logs during real-time monitoring consistently showed nonresponse among participants who were asked to take better images with properly placed FMs. Since we collected the 1-day FRDIs during school days, schoolwork and activities and short break times might have accounted for the nonresponse or tendency of the face-to-face participants to ignore text reminders from researchers. Although we asked school administrators to exempt study participants from the rule of not using their mobile phones while at school, classroom teachers may have enforced the rule in their classes without exception. In addition, although we did not find any issues when we pretested our email interface on different mobile phones and service carriers, delays in communication exchanges during the monitoring may have played a role as well. In another study, poor compliance was observed when adolescents were preoccupied with a more engaging activity (ie, a minor league baseball game) [23]. Given the results of our human-mediated prompts and reminders, further investigation on how automated prompts/reminders compare to human-mediated intervention in facilitating accuracy in reporting diet among adolescents would be needed.

Better results from low-level versus high-level intervention have implications for the design of subsequent studies. Manually administered real-time support or immediate feedback was more time-consuming than next-day follow-up. To anticipate the volume of incoming messages based on the number of scheduled participants, we needed monitors on hand from the approximate times for breakfast (ie, from 5:30 AM) until late-night snacks (ie, approximately 10:00 PM). To make immediate feedback cost-effective, a proper balance between manpower needs and peak demand was necessary. On the other hand, a next-day follow-up intervention allowed time to identify issues with full reports, ask for clarifications, and then make changes as needed. We scheduled follow-up at mutually agreed-upon times, ensuring that the participant would be available when contacted. This arrangement eliminated the need for excess manpower and was, thus, more economical. Monitor time was also well-spent in collating text messages and images into PowerPoint slides. Although this process was also time-consuming, we found such follow-up to be a crucial step in ascertaining the accuracy of collected data.

Food record apps for mobile phones lessen the burden associated with the traditional paper-and-pen food recording, since subjects are required to only take quality images and to confirm or adjust their input based on a feedback loop after the automated identification and quantification of food images [18]. The concept we used in our method is similar: take good-quality images and provide a food report—which is minimal, considering that only the meal name, time of intake, list of foods, and amounts eaten need to be texted—then confirm or adjust input as needed after review by the researcher. Although digital images usually include metadata on date and time the image was taken, we cannot assume that different mobile phone brands, models, and service carriers uniformly provide such information. Thus, we asked participants to still include the time their meals were eaten in their texted reports. Technology-assisted dietary assessment using computer algorithms to estimate food intake

[30] holds great promise. However, fully automated analysis of digital images from mobile phones to identify and quantify foods could become inaccurate or lead to underestimation without additional information about the foods eaten [12]. For example, an automated image analysis that fails to distinguish a veggie burger from a meat burger would lead to inaccurate dietary analysis. Incorporating other technologies, such as voice recorders [31] and bar code scanners, may eventually improve the identification and quantification of food images. In the interim, human intervention is still necessary to supervise data collection, management, and analysis in ways that improve accuracy [13].

The incorporation of new dietary assessment technologies in mobile phone apps remains cost-prohibitive for use in large epidemiological studies. Although mobile phone food record apps are being developed and/or utilized, it will take time for the software algorithms to optimize human input. Until the full potential of these approaches are realized, our method of direct interpretation of simple texts and images can be considered feasible. However, we need to develop approaches that can speed up the transfer of texted food messages and digital images into files that can be easily encoded or linked with nutrient composition databases.

Limitations

This study has a number of limitations. Although the method we used eased some of the burdens associated with pen-and-paper food recording, data collation, management, and quality control on the part of the researcher was time-consuming and prone to human error. However, feasibility studies on mobile phone food record apps developed to assess dietary intake of adolescents [17,20] have also demonstrated similar data management challenges. The lack of random assignment to the two intervention groups could have biased the results. The low-level intervention group had older participants, which might explain why the group had better results. However, cross-contamination between the two groups was also highly possible if the two interventions were simultaneously conducted. The two interventions were separated by 3-4 months which minimized possible cross-contamination. This arrangement also made the most logistical sense. Given that mobile phones with camera capability and unlimited phone service were necessary to conduct this study, this precluded participation of individuals who did not own mobile phones and/or high-quality phone service. Also, a 1-day food record may not provide enough information about adherence to instructions when food recording is done for more than 1 day. However, our intent in this study was to test the workability of self-reporting intake using the functions of personal mobile phones, so a 1-day food record would be considered sufficient. The email interface between participants and the researchers in the exchange of SMS text messages could be another limitation if technological glitches existed. However, we had tested this interface for different carriers and different mobile phones before the study started. Technological glitches, however, could possibly affect responsiveness of the high-level intervention group.

Conclusions

Using personal mobile phones to report dietary intake via texting and taking digital images of foods eaten is feasible among free-living adolescents. High-level intervention involving

real-time support is not a guarantee that the quality of food recording among adolescents will be more accurate. This food recording method is a prudent alternative until technology-assisted dietary assessment apps for mobile phones become widely available.

Acknowledgments

This study was supported in part by the Soy Nutrition Institute; the sponsor had no role in the development, implementation, or findings of this study. The authors acknowledge Rita Buckley for her editorial services and all the research assistants who were involved in the recruitment and training of subjects, and in the collection of data.

Authors' Contributions

Both authors (GSS, JS) designed the study. GSS supervised the recruitment and training of participants and collection of data, and performed the statistical analysis. Both authors wrote the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Sample of an actual 1-day food record with digital images from a study participant.

[[PDF File \(Adobe PDF File\), 457KB - mhealth_v4i3e91_app1.pdf](#)]

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Abbreviations

- BMI:** body mass index
- EER:** estimated energy requirement
- EI:** energy intake
- FM:** fiducial marker
- FRDI:** food record with digital images
- ID:** identification number

IQR: interquartile range
N/A: not applicable
NHANES: National Health and Nutrition Examination Survey
PA: physical activity
PAL: physical activity level
SMS: short message service

Edited by G Eysenbach; submitted 07.12.15; peer-reviewed by P Stumbo, S Casperson, D Kerr; comments to author 08.01.16; revised version received 25.04.16; accepted 25.06.16; published 29.07.16.

Please cite as:

Segovia-Siapco G, Sabaté J

Using Personal Mobile Phones to Assess Dietary Intake in Free-Living Adolescents: Comparison of Face-to-Face Versus Telephone Training

JMIR Mhealth Uhealth 2016;4(3):e91

URL: <http://mhealth.jmir.org/2016/3/e91/>

doi: [10.2196/mhealth.5418](https://doi.org/10.2196/mhealth.5418)

PMID: [27473291](https://pubmed.ncbi.nlm.nih.gov/27473291/)

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Original Paper

Overcoming Barriers: Adolescents' Experiences Using a Mobile Phone Dietary Assessment App

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Abstract

Background: The use of new technology has the potential to increase participation rates in dietary studies and improve the validity of collected dietary data. However, to evaluate the usability of developed dietary methods, qualitative studies of participants' experiences and perceptions are needed.

Objective: To explore adolescents' experiences using a newly developed mobile phone dietary assessment app, with a focus on factors that could affect their recording of dietary intake.

Methods: Focus group interviews were conducted with 75 participants who had used a newly developed mobile phone dietary assessment app in a quantitative evaluation study. The interviews were analyzed using qualitative content analysis and the theoretical framework of Self Determination Theory was applied.

Results: The adolescents' use of the mobile phone dietary assessment app was characterized by their struggle to overcome several perceived barriers. Facilitators that helped adolescents complete the method were also identified. Motivation was found to be an important facilitator, and intrinsically motivated participants completed the method because they found it fun to use. The autonomous extrinsically motivated participants completed the method for the greater good, in order to contribute to the study. The controlled extrinsically motivated participants completed the method to get a reward or avoid punishment. Amotivated participants did not complete the method. More motivated participants were assumed to be more able to overcome barriers and needed less facilitators.

Conclusions: Future studies that examine the recording of food intake should include systematic efforts that aim to minimize identified barriers and promote identified facilitators. Further research should specifically aim at studying methods for (and effects of) increasing intrinsic motivation by supporting autonomy, competence, and relatedness among adolescents asked to participate in dietary studies.

(*JMIR Mhealth Uhealth* 2016;4(3):e92) doi:[10.2196/mhealth.5700](https://doi.org/10.2196/mhealth.5700)

KEYWORDS

adolescents; content analysis; dietary assessment; Self Determination Theory; mobile phone app

Introduction

Studies that examine the associations between diet and health outcomes require methods of dietary assessment that correctly

assess food intake during the time period of interest [1]. Furthermore, there is a need for improved dietary assessment methods that are accepted by study participants. The food record (FR) is a commonly used method to assess individual dietary

intake for one or several days, which has the advantage of not being dependent on the respondent's memory [2]. However, the burden of recording all consumed foods can lead to altered dietary intake, and some foods may be omitted from the FR. Consequently, the assessed dietary intake will be either unrepresentative or underestimated, representing a widespread problem when using FR and other dietary assessment methods [3].

The assessment of dietary intake is challenging in all age groups and especially among adolescents [4]. Studies have suggested that adolescents are less accurate reporters of their dietary intake compared to young children and adults due to less structured eating habits, a relatively large proportion of meals consumed outside of the home, or lack of motivation to participate in dietary studies [4,5]. It is therefore important to improve dietary assessment methods in this age group.

Children's and adolescents' views of keeping an FR have been investigated using qualitative methodology, and it was found that those aged 12 years and older were reluctant to keep FRs [6]. One reason for this was that adolescents did not want to carry a paper FR and portion size booklet while they were with their peers. Respondents also expressed that they would consider changing their dietary intake to avoid recording, suggesting a need to make the process of keeping an FR less burdensome. One study found that adolescents preferred using technology-based FRs (ie, camera or personal digital assistant) versus a traditional pencil and paper FR [5]. The widespread use of smartphone technology has led to new possibilities in dietary assessment.

In Sweden, 89% of adolescents aged 13-16 years own an advanced-feature mobile phone [7]. Using a mobile phone to keep an FR is one way to adapt the dietary assessment method to adolescents' lifestyles, and to circumvent the need to bring a traditional pencil and paper FR to school and friends' homes. No evaluated mobile phone FR method was available in Sweden to make it more convenient for adolescents to record dietary intake, so we developed a mobile app in a previous study [8]. To evaluate the feasibility of the newly developed method, there was interest in exploring not only quantitative parameters indicating its validity, but also the users' experiences and views of using the Swedish mobile phone dietary assessment app.

The aim of the present study was to explore adolescents' experiences using a newly developed mobile phone dietary assessment app, with a focus on factors that could affect their recording of dietary intake.

Methods

Participants and Setting

This study includes adolescents who participated in an evaluation study of a newly developed mobile phone dietary assessment app during 2013. Participants were recruited by visits to schools in the city of Göteborg and neighboring municipalities in Västra Götaland, Sweden. The evaluation study has been described in a previous paper [8]. A total of 389 adolescents in 28 school-classes were given information about the study during a first visit in class; 148 of whom chose to

participate in the quantitative part of the evaluation study (47 during spring term and 101 during autumn term). In the qualitative part of the study, twelve group interviews (three during the spring term and nine during the autumn term) were performed. Teachers made it possible to assign class time for interviewing 92 of the 148 adolescents, and at the time of the interview 17 students were not in school. Thus, group interviews were conducted with a total of 75 participants.

Ethical Considerations

This study was approved by the Regional Ethical Review Board in Umeå, Sweden. The adolescents were informed about the aim of the study, and were told that participation was voluntary and all collected data would be treated with confidentiality. All participants gave written informed consent, and for adolescents younger than 15 years of age, a parent additionally gave written informed consent.

Pilot Test of Procedures and Methods

A pilot test was conducted in November 2012 to test all methods included in the evaluation study, and to practice the study procedures. The pilot test took place in a school on Orust, an island located one hour from Göteborg, with five girls and one boy from one school-class. A group interview was conducted to explore possible improvements that could be made in the procedure of data collection and the mobile phone dietary assessment app itself, as well as to practice the interview procedure. The pilot test did not lead to any fundamental changes to the app, but revealed some technical problems that needed to be solved.

Procedures and Methods in the Quantitative Part of the Evaluation Study

The mobile phone dietary assessment app has been described in detail [8], and the procedure of recording dietary intake in the app is illustrated in Figure 1. In summary, the first step was to enter the date and time of the meal (with the current date and time as default) and type of meal (breakfast, lunch, dinner, or snack). Thereafter, the user searched for the consumed food/drink/dish in a food database by using free text search, and choosing from a food group category or type of dish. The app uses the Swedish national food database, which includes over 1900 foods, drinks, and dishes. The amount consumed was thereafter entered by choosing from portion sizes (eg, in gram, deciliter, table spoon, tea spoon, or piece) that were given as alternatives for each food/drink/dish. For several items there were also pictures of foods of known weight and increasing portion size to aid the estimation of consumed amounts. After all foods in a meal had been entered, the meal was saved and automatically sent to a central server for storage and calculation of energy and nutrient contents. The saved meals could be accessed in the app through an archive of registered days, in which entered foods and amounts could be changed if necessary.

In addition to recording dietary intake, the user was asked to answer eight questions in the app every evening. The questions pertained to the use of dietary supplements, the approximate percentage of the dietary intake that was recorded, the physical activity level during the day (out of five predefined levels), the level of dietary intake and physical activity (higher or lower

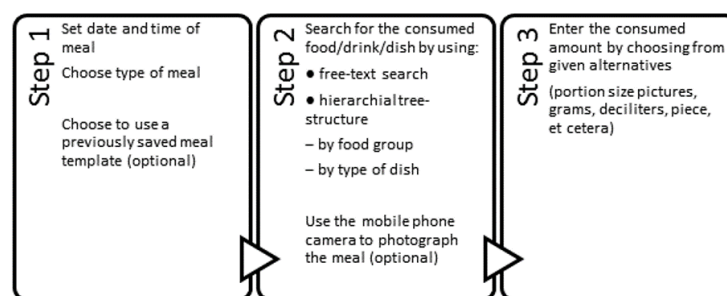
than normal), whether the user had tried to gain or lose weight during the day, and if the user had felt stressed or anxious. Users had access to feedback about the dietary intake (energy, fruits and vegetables, macronutrients, and five micronutrients) in relation to recommended daily intakes [9], as well as total energy expenditure calculated from the reported daily activity level, basal metabolic rate [10], and body mass index. The study participants were encouraged to eat as usual and not change their intakes based on the feedback. Additional functions in the mobile phone dietary assessment app were to receive reminders (status bar notifications) to register with a chosen time interval, and to save a meal as a template to be loaded the next time the same meal was consumed. The app was connected to the mobile phone camera and the user could take a picture of their meal as a memory aid if the consumed foods could not be entered until later.

Participants in the quantitative part of the study were asked to record all foods and drinks consumed for three consecutive days using the mobile phone dietary assessment app. Respondents were also asked to answer the in-app questions in the evenings, during the same days as recording their dietary intake. Those

who did not have an Android mobile phone (72/81; 89% of the participants who completed the quantitative part of the study) borrowed a phone with data traffic subscription and a charger, and were given an instruction manual on how to use the mobile phone. Those who had their own Android mobile phone were given instructions, and help to download and install the app on their own phones.

Additional measurements in the evaluation study included the SenseWear Armband (BodyMedia, Inc.; Pittsburgh, PA, USA) for registration of total energy expenditure during the same days as recording dietary intake, anthropometric measurement of weight and height, and a questionnaire aiming to measure factors that could possibly influence the accuracy of reported dietary intake. Participants in the spring term also recorded dietary intake using a web-based FR. However, due to high perceived participant burden, participants in the autumn term were not asked to complete the additional three days of dietary recording using the web-based FR. During the first part of the autumn term, participation was still low and it was decided that a cinema ticket would be used as an incentive that was given to the participants who completed all methods.

Figure 1. The steps involved in registering dietary intake in a newly developed Swedish mobile phone app. The three steps are repeated until all foods and drinks in a meal have been entered, and the meal is thereafter saved and automatically sent to a server for storage and calculation of energy and nutrient contents.



Focus Group Interviews and Data Collection

A second in-class visit was made after one to two weeks, when the adolescents had finished the quantitative part of the study. The adolescents were then asked to participate in a focus group interview that examined how they perceived the use of the mobile phone dietary assessment app. Semistructured interviews were performed with groups of 4-9 participants. Teachers provided rooms in which the interviews could take place undisturbed. The interviews were audio recorded after consent from the participants, who were ensured that the material would be treated with confidentiality and that no one except the researchers involved in the study would have access to the recordings and transcripts. The first author conducted the interviews using an interview guide that included questions related to the study aim (see [Multimedia Appendix 1](#)). The interview guide consisted of 20 questions that were grouped into introductory questions, key questions, and concluding questions. The guide was used as an aid to ensure that the interviews focused on relevant topics, and was not followed to the letter. The questions were used to initiate a discussion, and the participants were free to elaborate on the topics and introduce topics of their own interest, in relation to the study. In seven of the twelve interviews, an assistant was present to

take notes and occasionally ask questions. Participants in three of the interview groups had used the web-based FR, and participants in seven of the groups had been offered cinema tickets if they completed all methods in the quantitative part of the study.

Data Analyses

The interviews were transcribed verbatim and data were analyzed inductively using the principles for qualitative content analysis according to Graneheim and Lundman [11]. The first and second author performed the analysis separately, and thereafter discussed and agreed on the findings. Each transcribed interview was treated as a unit of analysis. The transcripts were read several times and meaning units, with content related to the research questions, were identified and condensed. Thereafter, codes were applied to the condensed meaning units. After the spring term, the first three interviews were coded, and after the autumn term the remaining nine interviews were coded. Codes were then compared and changed if necessary, so that one set of codes fit the entire collection of materials. Thereafter, the codes were sorted into categories that were exhaustive and mutually exclusive [11]. Examples of condensed meaning units, codes, and categories can be found in [Table 1](#). The original spoken language in the interviews was Swedish. After the

analysis had been completed, the results were translated into English.

Table 1. Examples of meaning units, condensed meaning units, codes, and categories.

Meaning unit	Condensed meaning unit	Code	Category
You always have the phone with you any-way, so it is only to record directly	You have the phone with you all the time and can record directly	Advantage with mobile phone	Benefits of using the mobile phone app
Sometimes I felt that there were too many differences; if you searched for butter and milk there were different types so I just wrote milk. You have no idea which one to choose	Sometimes there were too many different types of butter and milk; you have no idea which one to choose	Hard/difficult to choose between many alternatives	Recording correctly
You thought more about it; now I will eat a snack because now I will be the good type	You thought of what you ate, eating a snack to be good	Improve dietary intake	Dietary intake was affected

Theoretical Framework

Many motivational theories exist, and according to Self Determination Theory (SDT) there are three basic psychological needs for an individual to function well: autonomy (a sense of choice and freedom from external pressure), competence (the ability to master a task and understand the rationale behind it), and relatedness (the need to belong and feel connected to others) [12]. Social contexts may support these three needs and thus result in better persistence and performance on activities. Consequently, when these needs are satisfied, motivation is enhanced.

For the present study, the motivational types of SDT described by Wenemark [13] were applied. Rather than categorizing the participants according to the motivational types on an individual level, we tried to identify the different motivational types among the participants to see if examples of all types could be found. SDT categorizes motivation into six groups: intrinsic motivation, four types of extrinsic motivation, and amotivation. Intrinsic motivation is a natural inclination to explore and learn, and is characterized by spontaneous interest and enjoyment in an activity [12]. Extrinsic motivation can be integrated to different degrees, or can be self-determined, and locus of causality can be perceived as external or internal. In the two types of extrinsic motivation characterized by external locus of control, actions are controlled by others or by the self through rewards or punishments [12]. Wenemark [13] named these motivational types *controlled extrinsic motivation*. In the two categories of extrinsic motivation characterized by internal locus of control, actions are of importance for the self and possibly internalized. These motivational types were named *autonomous extrinsic motivation* by Wenemark [13]. Amotivation is a complete lack of intention to act [12].

Results

Characteristics of the Participants

The 92 participants in the school-classes in which group interviews were conducted were 14-16 years of age and spoke fluent Swedish. Most participants (71/92, 77%) were normal weight, 59% (54/92) were girls, and 49% (45/92) had at least one parent with a university/college education. This finding was comparable to the 148 adolescents who participated in the quantitative part of the evaluation study. The schools and municipalities in which recruitment took place were comparable regarding the proportion of adolescents with a foreign background (adolescents and/or both parents born outside of Sweden). Of the 92 adolescents, the proportion with at least one parent with a university/college education was smaller (45/92, 49%) than the proportion of adolescents with at least one parent with higher education in the municipalities (63%). The participants were not identified at the time of the group interviews, so characteristics of the 75 who participated are not available separately from the 92 adolescents in the school-classes in which the interviews were conducted.

The interviews lasted between 12 and 29 minutes (average time 19 minutes). More time had been earmarked for the interviews; however, the participants had said what they wanted to leave before the time had run out.

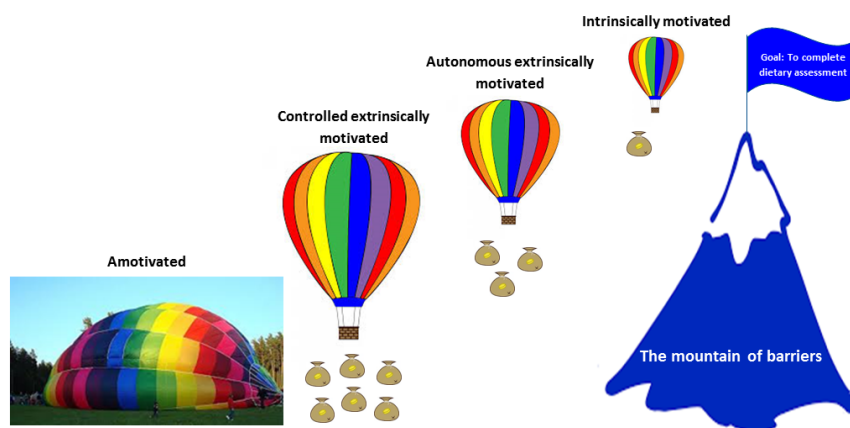
Categories

Categories illustrating participants' views of recording dietary intake with the mobile phone dietary assessment app were grouped into seven categories, consisting of 43 codes (Table 2). An underlying theme in the material was identified as *To overcome the barriers* (Table 2, Figure 2). The theme should be interpreted as a thread of meaning that runs through the entire material [11]. In the following text, the manifest content is presented for the seven categories, followed by the theme.

Table 2. Codes, categories, and theme from qualitative content analysis of 12 group interviews.

Code	Category	Theme				
<i>The design of the app matters</i>	Difficulties of using the mobile phone app	To overcome the barriers				
<i>The app was difficult</i>						
<i>There were technical problems with the app/mobile phone</i>						
<i>Unclear with feedback</i>						
<i>Unclear/frustrating with reminders</i>						
<i>Unnecessary functions</i>						
<i>Is the feedback correct?</i>						
<i>Difficult to find the feedback</i>						
<i>Difficulty with the questions in the evening</i>						
<i>Type of mobile phone matters</i>						
<i>Wants to record exercise</i>	Benefits of using the Mobile phone app					
<i>App is simple/good/fun</i>						
<i>Good and interesting with the results</i>						
<i>Good with the questions in the evening</i>						
<i>Advantage with mobile phone</i>						
<i>It is easy to forget</i>			The process of recording			
<i>Easier to record in the evening</i>						
<i>Difficult to record (in general)</i>						
<i>Combines techniques to remember</i>						
<i>You do not give up</i>						
<i>You have to think about when you eat and when to record</i>						
<i>You get tired</i>						
<i>Impractical sometimes</i>						
<i>The recording was fun/OK</i>						
<i>Good with pictures</i>	Recording correctly					
<i>Good selection of foods</i>						
<i>There is a need for more composite dishes</i>						
<i>Had to take something similar</i>						
<i>Difficult to record food with lots of ingredients</i>						
<i>Difficult to record sandwiches</i>						
<i>Difficult and unnecessary to record small meals</i>						
<i>Difficult/hard to estimate amounts</i>						
<i>Unclear what should be recorded</i>						
<i>Foods/dishes were missing</i>						
<i>Hard/difficult to record if you do not know content/type</i>	Dietary intake was affected					
<i>Hard/difficult to choose between many alternatives</i>						
<i>Improve dietary intake</i>						
<i>Avoided eating so you do not have to record</i>						
<i>Reflects over the diet</i>			Awareness of diet and physical activity habits			
<i>The days of recording were not representative</i>						
<i>Lack of interest</i>					The study is not for me	
<i>Unclear with the study/methods</i>						
<i>Worry about focus on weight and dietary habits</i>						

Figure 2. Illustration of adolescents' experiences of using a mobile phone dietary assessment app. To reach the goal of a complete dietary registration at the top of the mountain, participants must overcome several perceived barriers. Depending on their motivational type, subjects are in a smaller or larger balloon, and therefore need less or more facilitators (sandbags to let go of) to make it rise.



Difficulties of Using the Mobile Phone App

Difficulties of using the mobile phone app were, according to participants, mainly technical and related to the app or type of mobile phone used. Many of the participants had to borrow an Android mobile phone for the study. Those who were not familiar with Android phones sometimes had difficulties using the phone, and participants stated that it would have been easier for them if the app had been available for iPhone.

Other difficulties that were mentioned concerned the design of the app, unnecessary functions, unclear reminders to record, the questions in the evening, and the feedback function. Some participants also said that they would have preferred to register exercise instead of answering a question about the physical activity level during the day.

Benefits of Using the Mobile Phone App

In contrast to the above, some participants thought it was beneficial to answer the questions in the evening since it gave them a good summary of the day, and they appreciated getting feedback about their dietary intake in the mobile phone dietary assessment app.

Other *benefits of using the mobile phone app* were that it was fun and easy to use. Participants liked the idea of using the phone, which they claimed to have with them all the time.

many usually take photos of their food and things, and put these out on the Internet; so it's just to have an app and record what you eat.

The Process of Recording

Participants found the study interesting and fun, but there were also views that the recording of dietary intake was burdensome and that one could get tired of it after a while. Some participants expressed that even though the study could be experienced as burdensome, it only lasted for three days, which was not difficult to endure, and they did not want to give up. Some participants found it easier to record in the evening (eg, when they used a borrowed mobile phone), thus avoiding carrying two phones during the day. Some participants combined techniques (ie, took photographs or notes about the consumed foods using their own mobile phone and entered it in the app in the evening). Other

important factors related to *the process of recording* include that it was easy to forget to record dietary intake, that one had to be constantly aware of what was consumed, and that it was sometimes impractical to record the foods consumed.

Recording Correctly

As presented in [Figure 1](#), the process of *recording correctly* in the mobile phone dietary assessment app consisted of several steps, from knowing what type of food was consumed to making sure that the correct amount was entered in the app. For these steps, the design and user-friendliness of the mobile phone dietary assessment app (as well as other factors) were important. Participants sometimes found it difficult to know the type of food consumed or the content of a composite dish (eg, lunch in the school canteen when someone else had prepared the food). Another problem was how to correctly record a dish that consisted of several ingredients.

Tacos were very difficult to record because there was ground meat, spices and then all the other ingredients.

It was suggested that the mobile phone dietary assessment app needed more composite dishes. Some foods or dishes were not found when searched for, and participants had to choose something similar, although they were not always happy with the substitute and pointed out that it did not have the same nutritional content as the foods they had consumed. Despite this, some participants were surprised by the number of foods and dishes in the database, and that they also could find *foreign foods*. Interestingly, the opposite could also be perceived as a problem: there were too many alternatives for some foods (eg, cheese, bread, butter, and milk).

Sometimes I felt that there was too much difference; if you searched for butter and milk there were different types so I just wrote milk. You really have no idea which one to choose.

Participants found it tiresome and unnecessary to record snacks and small meals. Some stated that they did not record every snack. Sandwiches, which are a common meal in Sweden, were problematic in this study, since participants had to know and search for the correct type of bread, butter, cheese, or other spread. Defining the consumed amount was also pointed out as difficult. However, the portion size pictures were found to be

helpful. Finally, there was some uncertainty regarding what foods needed to be recorded (eg, whether snacks and drinking water should be entered).

Dietary Intake was Affected

Some participants stated that they ate as usual and recorded everything they ate. However, in spite of the fact that the participants were told to eat as usual during the study, *dietary intake was affected* emerged as a category. The major influence was on those participants abstaining from their usual snacking to avoid having to enter the foods, and participants who stated that they consciously or unconsciously *improved* their dietary intake.

I sometimes did not eat things because then I would have to record them.

Awareness of Diet and Physical Activity Habits

Participants showed *awareness of their diet and physical activity habits* by questioning whether the days of recording were representative, as they considered that they had not exercised or eaten as usual during the study. This issue was especially true for those who participated during the weekend. After being in the study, some participants expressed that they had gained new insights about their dietary intake, and some were surprised by the results (eg, that the diet during the weekend was so *bad*, or that their energy intake was not higher).

The Study Is Not for Me

One participant asked if the purpose was to test the app or to assess their diet, even though it had been stressed that the aim was to evaluate the mobile phone dietary assessment app, and that no focus would be on individual diets when recruiting the participants. The purpose of the study was not clear to everyone, and some participants found that *the study was not for them*. Within this category, worries about body weight were a potential barrier to participating in the study. In one interview, participants said that the adolescents who decided not to participate did so because they were afraid that there would be a focus on their diet, physical activity, and body weight.

There were many who were afraid to become aware: "how bad I am, and I'm so bad for eating all this" or like... "I really should lose some weight"

Some participants stated that they joined the study in order to avoid other tasks assigned by the school teacher, thereby showing a lack of interest in the study even if agreeing to participate.

Category Interpretation

Several barriers to keep a correct FR can be discerned in the categories described above. In [Figure 2](#), barriers are illustrated as a mountain, which the participant must ascend to complete the FR. The barriers include perceived difficulties with handling the mobile phone and app, and the app not working as it should. These issues were obviously problematic for the completion of the study. The problems with the mobile phone dietary assessment app not working properly arose later during the study, and the source of these technical problems was not detected. Other barriers were related to recording the correct

food and amount in the app, and were often related to the food database. Barriers also included the effort needed to keep an FR, such as keeping the app in mind when participants were unmotivated to do so, or were busy with other things. Furthermore, uncertainties about what to record (and why) made it more difficult for some participants. Barriers for an accurate reporting of the diet arose when participants changed their intakes because of the study.

In contrast to these barriers, there were also facilitators for using the mobile phone dietary assessment app and completing the FR. In [Figure 2](#), facilitators are illustrated with sand bags that the participants are able to release in order to let the air balloon rise. Facilitators included notions that the app was easy to use and that it was fun and interesting to record dietary intake, use the methods, and see the results. Participants thought it was a good idea to use a mobile phone for the task, and if they did not succeed in using it during the day, they found their own solutions by combining techniques (eg, by using the camera function on their own mobile phones) and recording in the evening. Furthermore, participants thought that the food database had enough foods to correspond to their diets, and if they did not find an exact match they could choose something similar. Entering the correct amounts was facilitated by the portion size pictures. Finally, the participants' determination to carry through facilitated their completion of the study.

Theme

When considering the participants' experiences and perceptions of using the mobile phone dietary assessment app, the theme of *overcoming barriers* became apparent ([Table 2](#), [Figure 2](#)). It was burdensome to keep an FR and wear the SenseWear Armband, but even so, many participants were able to complete the task. Some participants admitted to getting tired of using the methods, but they still did their best to finish the study.

Motivation was an important facilitator in this study, and the motives to participate differed among participants. When applying the different types of motivation in SDT to the results of the present study, amotivated participants would be the only subgroup in the study that lacked motivation to use the mobile phone dietary assessment app, and fail to complete the FR. This subgroup is illustrated in [Figure 2](#), with the participants lacking the necessary means (a balloon in flight-worthy condition) to overcome the barriers and reach the goal of a complete and correct FR on the top of the mountain. Controlled extrinsically motivated individuals would include participants who were facilitated by the motivation to get a reward or avoid punishment. In [Figure 2](#), the controlled extrinsically motivated participants are in possession of a large balloon and need several facilitating factors to make it rise. Some participants stated that they were not interested in the study, but decided to participate in order to get a cinema ticket. Other respondents said that they participated so they would not have to go for a walk, which one teacher suggested as an alternative activity for students that were not recruited to the study. During the interviews conducted in spring and beginning of autumn, participants said that they would have liked some sort of reward for being in the study, as they lacked other motives to participate. In addition to the question of being rewarded or not, participants found the design

of the app important, and some said that a more stylish app would motivate them more to use it.

Using the terminology of SDT, the autonomous extrinsically motivated participant completed the FR for *the greater good* to contribute to the study, and the intrinsically motivated participant enjoyed using the mobile phone dietary assessment app and completed the FR because it was fun. The second smallest and the smallest balloons in Figure 2 belong to the autonomous extrinsically motivated and the intrinsically motivated participants, respectively. The smaller the balloon, the less facilitators are needed to reach the top of the mountain (Figure 2). In the present study, some respondents said that they wanted to participate irrespective of rewards, as they found the procedures and results of the study fun and interesting (ie, they were more autonomous and perhaps even intrinsically motivated). One adolescent claimed that she chose to participate since not many of her classmates participated, and she felt sorry for the researchers, which could be considered autonomous extrinsic motivation. Furthermore, the participants differed in their interests in diet and health, which could explain differences among participants with autonomous extrinsic and intrinsic motivation, and their ability to overcome the barriers.

Discussion

The goal of an FR is to obtain a correct record of all consumed foods and drinks, as well as the correct amounts during the day(s) of recording [2]. Furthermore, the dietary intake should not be changed as a result of keeping an FR. Using technology such as mobile phones in dietary assessment could facilitate the collection of valid dietary data. The present study aimed to explore adolescents' experiences using a mobile phone dietary assessment app, with a focus on factors that could affect their recording of dietary intake. The results generated the theme *To overcome the barriers*. Even though the mobile phone dietary assessment app had the potential of being fun and easy to use, there were difficulties with the method, and the end result depended on whether or not the participants were able to overcome the barriers with the help of facilitating factors. The adolescents' motivation to continue recording their dietary intake when facing barriers to use the mobile phone dietary assessment app was an important facilitator.

SDT has been used in various areas of research [14]. For example, it has been used in the study of self-care in type 1 diabetes [15] and in relation to body image and unhealthy weight control behavior in adolescents [16]. However, to our knowledge, it has not been used in the study of dietary assessment methods. The results of the present study demonstrated that adolescents differed in their motivation; some participants appeared to be intrinsically motivated while others appeared to be controlled or autonomously extrinsically motivated. The most amotivated adolescents presumably chose not to participate in the study.

According to SDT, in order to enhance intrinsic motivation, the adolescents' autonomy, competence, and relatedness in relation to the task of using the mobile phone dietary assessment app need to be supported. One way to achieve this goal is to plan studies that facilitate shared influence between participants and

researchers (ie, with a participatory design). One study involving adolescents (before the current FR method was developed) found that participants preferred using mobile phones versus other methods of recording food intake [5]. Another study used participatory methods when developing text messages to improve nutrition and physical activity behaviors among teens [17]. However, the adolescents participating in these studies were not involved in formulating the research questions. It might not be feasible to involve adolescents in all steps of the research process. However, to feel that the research question is important to them, to be able to influence the way data are collected, and to be consulted in the interpretation process and the dissemination of results are all aspects that may increase the intrinsic motivation (ie, participate because the task is perceived as interesting or fun) [13]. Furthermore, in the present study, rewarding the controlled extrinsically motivated participants with a cinema ticket probably improved participation in this group, but the use of incentives likely reduced intrinsic motivation, since autonomy was thwarted [12].

One study that aimed to increase response rates in surveys showed that respondents were more satisfied with a questionnaire designed using SDT, and the response rates and data quality were higher compared with a standard questionnaire [18]. A limitation of the present study was that the mobile phone dietary assessment app was not designed using SDT. In future studies, by involving adolescents from the start, intrinsic motivation is likely to increase and there will be less need for rewards. Another advantage of involving adolescents in the design of the study and method development could be an increased potential to avoid two barriers that were identified in the present study (ie, uncertainty about what to record and what the study aim was). The number of practical barriers to use the method could also be reduced, further increasing the participants' perceived competence. According to Ryan and Deci, consideration of the autonomy, competence, and relatedness of the participants may increase their motivation to complete an otherwise uninteresting task [12].

The identified barriers and facilitators for adolescents to record their diets with the mobile phone dietary assessment app need to be considered in future development of the method and research. Many of the categories point at practical barriers, and the method should be improved so that not only the most motivated adolescents manage to complete the FR. For example, the app should be developed for other operating systems than Android, and tested thoroughly to detect any technical problems before a study begins. A limitation of the present study was that the mobile phone dietary assessment app was only developed for Android. Some of the participants had problems using a type of mobile phone that they were not accustomed to, which likely distorted the perceived user-friendliness of the app. Very few studies have evaluated experiences using dietary assessment methods via qualitative methods. Vereecken et al used focus groups with children and parents to evaluate a web-based 24-hour recall method [19]. The children were enthusiastic about the method, but similar to the present study, some changes to improve the user-friendliness were requested (eg, regarding food items and reminders).

A study examining adult US women used focus groups to qualitatively investigate possible behavioral changes when keeping FRs [20]. The results showed that the participants altered their diets to include less snacks and more simple foods, because of the burden to complete the records. The women in the study also discussed the wish to report socially desirable foods, but claimed that they did not alter their recording. Conversely, children and adolescents said that they might change their dietary intake to make the recording process easier [6]. It is challenging to make adolescents want to keep an FR, and also to record data correctly, making it important to consider the effect that individual factors (such as social desirability) have on the results.

Qualitative methods are suitable when exploring experiences and views, and focus group interviews allow for self-disclosure among participants, and are suitable to shed light on quantitative data already collected [21]. When aiming to describe and interpret patterns in data, qualitative content analysis may be an appropriate technique [22]. Both focus group interviews and data analysis can be conducted by one researcher alone. However, focus groups often involve an observer, in addition to the researcher moderating the group [23]. Coding can be conducted by one researcher, although interrater subjectivity can be viewed as an approximation of objectivity [24]. Thus, we considered two research staff to be enough for both interviews and analysis in the present study.

Focus groups were chosen as the interview method because it was assumed that the method would provide rich data, as a result of interaction between the participants. Individual interviews have the advantage of decreasing the impact of peer pressure, allowing the participant to speak more freely. Even so, we assumed that the participants would be more comfortable being in a group interview, as opposed to talking to the interviewer and assistant alone. The interviews were held in separate rooms in the schools, aiming to make the participants feel comfortable. Each room was nearby in an environment well known to the students, and they were not disturbed by other students or teachers. The group interviews were held approximately two weeks after the participants had used the mobile phone dietary assessment app. We believe that this time was short enough for the participants to remember how they perceived the method, but long enough for them to have time to reflect.

The interviews did not last as long as anticipated, with an average of 19 minutes. However, there was not much small talk, and participants started to talk about the method almost immediately when entering the room. The participants might

have found it difficult to focus on the interview since it was held in school and interrupted the usual schedule. During some interviews, the participants seemed restless and eager to get back to class. However, recruiting outside of school settings introduces other difficulties such as reaching adolescents from various backgrounds.

The present study included adolescents who had agreed to participate in an evaluation study of a mobile phone dietary assessment app. Although some participants did not finish the task, they were probably more motivated than those who choose not to participate in the study. Not all of the participants in the quantitative part of the evaluation study were interviewed. It was not possible for all teachers to assign class time on the second visit, and 17 of the 92 adolescents (who were in school-classes when initial group interviews were conducted) were not present at the time of the interview (eg, due to illness). This factor might imply that the adolescents who were interviewed were in better general health than those who were absent from school. This possible implication should be kept in mind when transferring results to other settings. It was the opinion of the researchers that data saturation was reached and that interviewing more participants would not change the results substantially.

The first and second author looked at the data separately, and after discussion agreed about the interpretation. The data were thoroughly discussed, from examples of meaning units and condensed meaning units, to labelling with codes and sorting responses into categories. The researchers further agreed about the theme, barriers and facilitators, and the application of SDT to the material. According to Graneheim and Lundman, these are important steps to achieve credibility of the research findings [11].

In conclusion, adolescents perceived several barriers, but also highlighted facilitators, when using a mobile phone dietary assessment app. Intersubject variations in the willingness to overcome the barriers could be understood by applying the different motivational types in SDT. Further research should aim at studying methods for (and effects of) increasing intrinsic motivation by supporting autonomy, competence, and relatedness among adolescents asked to participate in dietary studies. Hypothetically, such increased intrinsic motivation would decrease the negative impact of barriers, both on participation rate and quality of results. Participatory methods (ie, involving adolescents in decision making) may create potential for fewer barriers and more facilitators, further increasing the probability of obtaining valid FR.

Acknowledgments

This study was supported by grants from: The Swedish Agency for Innovation Systems; Swedish Research Council for Environment, Agricultural Sciences, and Spatial Planning; Umeå University; and Vårdal Foundation for Healthcare Sciences and Allergy Research. The funders had no role in the design, analysis, or writing of this paper.

The authors would like to thank the adolescents who participated in the evaluation study, and would also like to thank Moa Hallmyr Lewis, Agneta Mattiasson, and Christopher Holmberg for assistance with data collection.

Authors' Contributions

ÅS and CL designed the study and developed the mobile phone dietary assessment app, and ÅS and MM analyzed the data. ÅS drafted the paper, and MM and CL contributed to its content and approved the final version submitted.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Interview guide.

[[PDF File \(Adobe PDF File\), 6KB - mhealth_v4i3e92_app1.pdf](#)]

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Abbreviations

FR: food record

SDT: Self Determination Theory

Edited by G Eysenbach; submitted 01.03.16; peer-reviewed by S Bonn, S Christensen; comments to author 24.03.16; revised version received 13.05.16; accepted 04.06.16; published 29.07.16.

Please cite as:

Svensson Å, Magnusson M, Larsson C

Overcoming Barriers: Adolescents' Experiences Using a Mobile Phone Dietary Assessment App

JMIR Mhealth Uhealth 2016;4(3):e92

URL: <http://mhealth.jmir.org/2016/3/e92/>

doi: [10.2196/mhealth.5700](https://doi.org/10.2196/mhealth.5700)

PMID: [27473462](https://pubmed.ncbi.nlm.nih.gov/27473462/)

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Original Paper

The Empowering Role of Mobile Apps in Behavior Change Interventions: The Gray Matters Randomized Controlled Trial

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Abstract

Background: Health education and behavior change programs targeting specific risk factors have demonstrated their effectiveness in reducing the development of future diseases. Alzheimer disease (AD) shares many of the same risk factors, most of which can be addressed via behavior change. It is therefore theorized that a behavior change intervention targeting these risk factors would likely result in favorable rates of AD prevention.

Objective: The objective of this study was to reduce the future risk of developing AD, while in the short term promoting vascular health, through behavior change.

Methods: The study was an interventional randomized controlled trial consisting of subjects who were randomly assigned into either treatment (n=102) or control group (n=42). Outcome measures included various blood-based biomarkers, anthropometric measures, and behaviors related to AD risk. The treatment group was provided with a bespoke “Gray Matters” mobile phone app designed to encourage and facilitate behavior change. The app presented evidence-based educational material relating to AD risk and prevention strategies, facilitated self-reporting of behaviors across 6 behavioral domains, and presented feedback on the user’s performance, calculated from reported behaviors against recommended guidelines.

Results: This paper explores the rationale for a mobile phone-led intervention and details the app’s effect on behavior change and subsequent clinical outcomes. Via the app, the average participant submitted 7.3 (SD 3.2) behavioral logs/day (n=122,719). Analysis of these logs against primary outcome measures revealed that participants who improved their high-density lipoprotein cholesterol levels during the study duration answered a statistically significant higher number of questions per day (mean 8.30, SD 2.29) than those with no improvement (mean 6.52, SD 3.612), $t_{97.74} = -3.051$, $P = .003$. Participants who decreased their body mass index (BMI) performed significantly better in attaining their recommended daily goals (mean 56.21 SD 30.4%) than those who increased their BMI (mean 40.12 SD 29.1%), $t_{80} = -2.449$, $P = .017$. In total, 69.2% (n=18) of those who achieved a mean performance percentage of 60% or higher, across all domains, reduced their BMI during the study, whereas 60.7% (n=34) who did not, increased their BMI. One-way analysis of variance of systolic blood pressure category changes showed a significant correlation between reported efforts to reduce stress and category change as a whole, $P = .035$. An exit survey highlighted that respondents (n=83) reported that the app motivated them to perform physical activity (85.4%) and make healthier food choices (87.5%).

Conclusions: In this study, the ubiquitous nature of the mobile phone excelled as a delivery platform for the intervention, enabling the dissemination of educational intervention material while simultaneously monitoring and encouraging positive

behavior change, resulting in desirable clinical effects. Sustained effort to maintain the achieved behaviors is expected to mitigate future AD risk.

Trial Registration: ClinicalTrials.gov NCT02290912; <https://clinicaltrials.gov/ct2/show/NCT02290912> (Archived by WebCite at <http://www.webcitation.org/6ictUEwnm>)

(*JMIR Mhealth Uhealth* 2016;4(3):e93) doi:[10.2196/mhealth.4878](https://doi.org/10.2196/mhealth.4878)

KEYWORDS

behavior; health behavior; behavior change; motivation; Alzheimer disease; smartphone

Introduction

Health Education Programs and Alzheimer Disease

Health education programs have demonstrated their effectiveness in educating individuals with targeted knowledge relating to risk factors of various diseases [1,2]. With this knowledge, individuals are subsequently capable of making educated decisions regarding lifestyle choices, which may have a significant effect on their future health outcomes. Most health education programs target the leading causes of mortality [3], such as heart disease and stroke [4], cancer [5], diabetes [4], and respiratory diseases [3,6]. Nevertheless, only a limited number of studies have been conducted with a focus on health education for Alzheimer disease (AD) risk reduction, despite being the sixth leading cause of total mortality in the United States [7] and the first and second leading cause of mortality of females and males older than 80 years, respectively, in the United Kingdom [8].

Alzheimer's Disease Risk

Unfortunately, efforts to create a vaccine for AD have proven unsuccessful. Nevertheless, findings from clinical and epidemiological studies have suggested that behavioral, social, and environmental factors may delay or prevent the onset of AD [9,10]. At the G8 dementia summit held in December 2013, clinical AD experts called upon the governments of G8 countries to make the prevention of AD a major health aim, while highlighting the suggestion to study the risk factors associated with the disease [11]. Currently, identified risk factors include dietary factors (food choices; body mass index, BMI; endocrine disorders; and diabetes) [12], cardiovascular factors (sedentary lifestyle, hypertension, and high cholesterol) [13], and psychosocial factors (education, higher work complexity, social participation, and intellectual activities). Importantly, these factors are modifiable and therefore have the potential to be useful targets for the prevention of cognitive decline and AD through behavioral change programs.

The health education interventions that individually targeted such factors for other conditions exhibited positive results, suggesting that a similar effort targeting AD would be likely to result in the desirable adoption of healthy behaviors [14]. Given that many of the risk factors can be interdependent (eg, BMI and sedentary lifestyle), a multifactorial preventative intervention targeting several risk factors simultaneously presents the greatest likelihood of being effective [9]. A study by Lin et al simulated the potential health and economic effects of addressing AD risk factors. Their simulated scenarios found that as each of the factors were addressed, additional unintended

benefits were observed, such as lowering the risk of other chronic diseases (diabetes, heart disease, and stroke), accompanied with a 10% reduction in BMI in those who were overweight [15].

It is therefore hypothesized that a health education program that provides evidence-based information regarding AD risk factors and prevention methods may have the additional benefit of reducing risk for other health conditions, with particular improvement in cardiovascular functions.

When to Intervene?

Although the risk factors for cognitive decline and AD have been identified and are natural targets for a behavior change intervention, there is variation in the literature as to when such interventions should take place. It has become widely accepted that the neuropathological processes involved in AD begin decades before symptoms emerge [16]; however, behavior intervention programs relating to AD have focused almost exclusively on an elderly population (65-80 years) [17], rather than introducing interventions in midlife (40-64 years). Numerous midlife health markers have been linked with higher late-life AD risk, such as obesity [18], hypertension [19], serum cholesterol levels [20], and physical activity during leisure time [21], all of which can be addressed simultaneously via a behavior change intervention to prevent the onset of the disease.

It is therefore further hypothesized that an intervention targeted at those in midlife holds the greatest potential for reducing future risk of developing AD.

Technology as an Intervention Tool

To appropriately distribute an education-based behavioral intervention program, a suitable method of delivery is required. This paper will describe the numerous empowering roles, for both end users and investigators, that the mobile phone has facilitated during an evidence-based multi-domain behavior change intervention, entitled "The Gray Matters study," which aims to reduce the future risk of developing AD, while in the short term promoting cardiovascular health (ClinicalTrials.gov identifier: NCT02290912) [22].

Background

This section details related works in the areas of behavior change interventions and public education programs, covering how intervention material is typically delivered to users, how engagement is maintained, and how various behaviors are tracked. This study also investigated the current use and potential unexplored capabilities of technology in each of these areas.

Delivery of Interventions

The term *delivery* encompasses both the psychological message of the intervention material and also the mode of distribution. Educational material for the purpose of behavior change can be designed to evoke certain emotional responses. Fear appeals, that is, the use of persuasive messages to stimulate fear based on harmful outcomes that are associated with dangerous lifestyle practices, have been used extensively for more than 60 years [23,24]. Perhaps not surprisingly, they have been found to be rather ineffective and can produce a polarizing effect within the intended cohort [24]. Because most people wish to think of themselves as healthy, such threatening information can lead to a defensive response, motivating intended recipients to avoid exposure to the material in the future [24]. An example of a public health campaign aiming to use fear appeal can be observed globally in tobacco packaging via the use of clear warning messages and graphic images of smoking-related diseases.

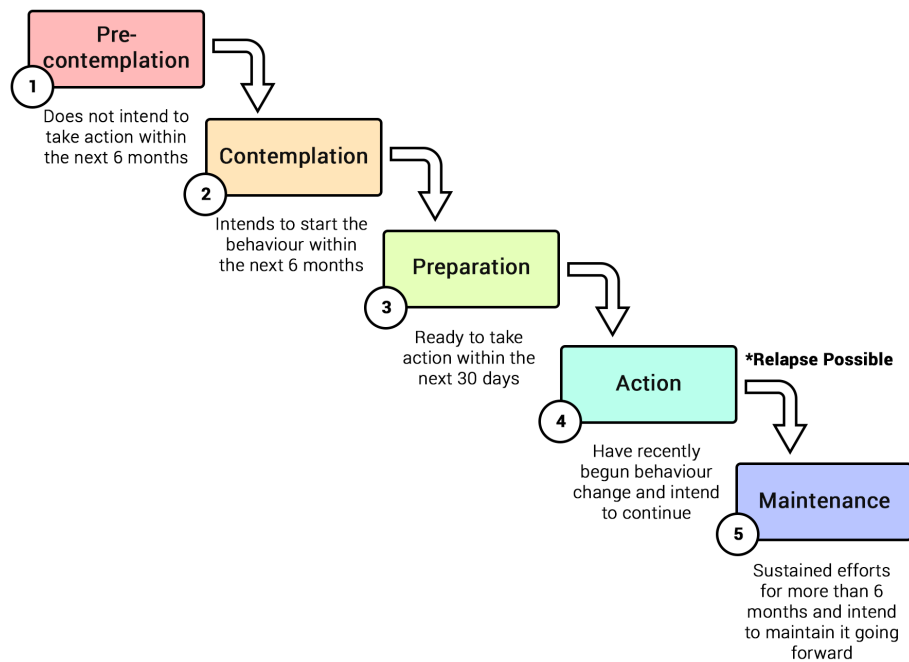
There are a number of ways in which an individual's behavior change can be theoretically modeled [25]. These include the widely cited and applied Theory of Planned Behavior (TPB) [26], the Health Belief Model (HBM) [27,28], and the Transtheoretical Model (TTM). The most apt models for planning a behavior change intervention, however, are the HBM and the TTM. The TPB is useful in predicting certain behaviors, and for retrospective analysis, but is not considered useful or effective in relation to designing and planning an intervention that should result in behavior change [29]. The aforementioned example utilizing fear appeals, including cues to action and perceived threats, belongs to the HBM. The TTM, however, is a stage theory that is often used as a guiding framework for many health-related interventions. This model posits that an individual's willingness to make behavioral changes is driven

by his or her readiness to change. Stages of readiness are described as precontemplation, contemplation, preparation, action, and maintenance, with relapse to prior unhealthy behaviors possible between the action and maintenance stages (Figure 1) [30].

This type of approach aims to empower an individual via education and introspection to create a positive feedback loop as behaviors are changed over time [31]. For AD prevention, this TTM approach would be performed by educating an individual on specific behaviors, having the individual introspectively assess his or her own behaviors, and setting attainable future goals to target change. On completion of these goals, the individuals are affirmed of their efforts and subsequently reevaluate their goals, thus creating a positive feedback loop.

Using such an approach in a health care intervention would rely heavily on the ability to personalize the education material and the ability to set attainable goals. To achieve such an intervention in the physical world, using people, buildings, and paper, would require enormous resources and planning. Fortunately, Internet-based technologies can reduce this burden, by digitally delivering intervention material.

Mobile and Internet-based technologies have been accepted as suitable and sustainable methods to deliver intervention material in various studies. Mobile phone-based delivery, such as short message service (SMS), has been used extensively and successfully in the literature to support portable and widespread interventions [32]. Internet-based services, such as email and website portals, have also been used extensively and with good success [33]. The ability to digitally disseminate material offers many advantages to health care investigators and end users alike: notably, personalization of material, increased scalability, and reduced expenses.

Figure 1. Stages of behavior change within the Transtheoretical Model.

Maintaining Engagement

Evidence from Internet-based interventions suggests that repeated visits are necessary to achieve sustainable change [33]. Nevertheless, visitor engagement with these interventions is typically lower than expected, with many users opting out before becoming fully exposed to all the intervention material, resulting in suboptimal outcomes [33]. There is therefore the need to encourage and maintain engagement with interventions, while enhancing an individual's motivations to return at a later date.

Gamification is the application of game design techniques and mechanics to nongaming domains [34]. To encourage engagement within a game, game designers utilize mechanics such as points, level systems, avatars, badges, and leaderboards. These reward systems encourage continual progression, with the ultimate aim of maintaining engagement. Recently, there has been a surge of interest in the use of gamification for behavior change studies, given that these reward systems help to promote engagement. Young adults and children are especially attracted to games, with virtually all young children having access to gaming consoles, computers, and mobile phone games [35]. As such, gamification elements have been used to educate and encourage desirable behaviors in children, such as increasing intake of fruits and vegetables through the use of fictional avatars [36], preventative education on substance abuse and risk using mobile phone and tablet apps [37], and an obesity prevention intervention via mobile and Web platforms [38]. The use of gamification in adult behavior change studies, however, is limited.

For health-conscious adults, commercially available mobile phone apps and activity tracker companies, such as Strava,

Fitbit, and Nike, use gamification elements extensively in their efforts to maintain and promote continual engagement. Although each platform has its own approach, they all record health-related data; examples include monitoring physical activity levels, tracking meals, and monitoring sleep quality. From these data, various performance metrics are calculated from which achievements are rewarded, such as badges and trophies. In addition, a user can view, typically at a high level via interactive graphs, their performances across time, allowing them to become informed of their behaviors and their resulting outcomes. Social sharing of recorded data also plays a role in enabling gamification elements, such as leaderboards, allowing users to compare their efforts with those of others. Apple and Google, whose mobile phone platforms combined account for 96.3% of the worldwide market share [39], are now shipped with iOS HealthKit and Google Fit services preinstalled. The aforementioned services are proprietary to their platforms; however, they act to consolidate the available data of various health-related apps and activity trackers into one common interface. The inclusion of such services into the base functionality of the most extensively adopted mobile phone platforms in the world shows the market's anticipation of widespread adoption of health-related apps.

It is therefore hypothesized that the combination of constantly accessible, highly interactive, and individually tailored feedback, combined with gamification elements, such as rewards and leaderboards, would have the largest opportunity to maintain and encourage engagement with adults in a behavior change study [40], given the advantages that each element brings.

Reporting Behaviors

To accurately assess the effect of a behavior change intervention, the validity of the reported behaviors must be accurate. There are numerous methods by which behaviors can be recorded within an intervention, including diaries, questionnaires, direct observation, and by proxy reports [41].

Diaries present a low-cost, easily maintained, and time-efficient method of recording behaviors; however, they are open to cognitive bias due to subjective self-assessment and rely heavily on the person's ability to accurately recall past events [42].

Direct observation offers health investigators an accurate portrayal of behaviors within the given window of observation [43]. They are believed to offer more truthful recordings and can be used as a method to increase precision and accuracy for the purposes of validating self-reported behaviors. With regard to monitoring physical behaviors, total energy expenditure can be calculated using calorimetry (ie, doubly labeled water), heart rate monitors, and motion sensors [43]. Although such approaches offer exceptional accuracy, they are intrusive, expensive, and time intensive. It is also the case that the Hawthorne effect, commonly referred to as the observer effect, may change how an individual behaves under direct observation, and observations made may not be a true reflection of their behaviors outside of the observation window [44].

Self-reported questionnaires are commonly used in large-scale longitudinal studies because of their uniformity in questioning, repeatability, and ability to extract qualitative and quantitative information [45]. Quantitative oriented questionnaires, seeking to gather quantifiable information about past events, such as the "number of glasses of water consumed today," can be at risk of cognitive bias and recall inaccuracy. Nevertheless, a comparative study seeking to validate previous day recall accuracy for active and sedentary behaviors when compared with direct observation found agreement of 85% or higher in certain conditions and suggests adults can accurately report their behaviors using previous day recall [46].

Proxy reporting is typically used when the subject in examination is somehow dependent on another adult, such as young children and the elderly. A study assessing the level of agreement between 6425 children and their parents regarding dietary, physical, and sedentary behaviors reported a mean agreement rate of 43% [47]. Similarly, studies assessing memory recall for the same events in children, young adults, and the elderly showed that the reports of the elderly were as complete as the children's but were the least accurate overall [48]. This highlights both the potential inaccuracies of self-reporting within certain cohorts and the need for ground-truth data due to the rate of disagreement found in reporting utilizing a proxy.

Although a variety of approaches can be employed to record behaviors, each has its own distinctive weaknesses relating to accuracy, repeatability, scalability, and cost [43]. There is a need for an objective mediator to draw agreement across the various approaches. Pervasive computing may provide such a solution.

The widespread public adoption of mobile phones, smartwatches, and wearable technology has enabled computing

to become truly pervasive. Wireless digital devices can enable the digitization of individuals' behaviors, often without the need for interaction. Wearable wrist-worn devices can be used to calculate an individual's energy expenditure and step count [49], current activity [50], sleep quality [51], and heart rate [52]. Mobile phones, via the use of onboard accelerometers and the Global Positioning System, can also track physical activity levels [53] and sleep efforts [54], while various apps encourage self-reporting of food consumption [53], enabling immediate calculation of calorie consumption. In addition, social media websites contain a plethora of social interactions that can be analyzed for behavioral trends [55]. There is an abundance of potential use cases for such technology in the self-management of one's health, yet the adoption of this technology for the purpose of public health education or behavioral change interventions is extremely limited. Eric Topol, a physician who has been heavily involved with wireless medicine since its inception, states in his book: "Our health care approach is reactive, and, as a result, we have a world of chronic diseases, most of which are poorly managed, such as congestive heart failure, high blood pressure, and diabetes, or not managed at all, as in the case of Alzheimer's." He continues, "Now comes a new wave of technology to not only improve the outlook for the chronic diseases of today but shift the capability, for the first time, to true prevention" [56].

To leverage this opportunity, the Gray Matters study has designed a clinically focused, technology-driven intervention program. An interdisciplinary team of computer scientists, biomedical engineers, mathematicians, psychologists, gerontologists, epidemiologists, and statisticians designed the Gray Matters mobile phone app: an app intended to deliver health education material, promote and monitor behavior change, and encourage the motivations of the participants via gamification elements [57].

Methods

Topics Addressed

This section details the study design and the technical development of the Gray Matters app, including study components, participant recruitment, eligibility criteria, outcome measures, and procedures.

Study Design

The study was a randomized controlled trial (RCT) consisting of 144 subjects who were randomly assigned to either treatment or control group. The treatment group was not given a strict regimen and therefore a wide range of engagement levels were anticipated. A uniform random number generator (0,1) within SPSS v21 was used to randomize participants to treatment and control groups, with the aim of allocating 1/3 to control and 2/3 to treatment. The rationale for a 2:1 ratio for treatment and control was in consideration of the full autonomy given to each participant in the study. On recruitment, each participant was asked which behavioral domain or domains were of greatest interest to him or her to improve upon. In order to have a reasonably good power to study both the change in individual behavioral domains and its effects on those who wished to improve on particular domains, the ratio was adjusted to

accommodate this. The intervention was delivered over a 6-month period, commencing in April 2014, with posttest collection performed at the close of the trial.

Recruitment

Recruitment of participants was achieved by emailing announcements to faculty, alumni, and staff of Utah State University and distributing flyers at health fairs and other venues, assisted by the local health department and their community liaisons. For those interested a prescreening eligibility survey was completed. Eligibility criteria included (1) age between 40 and 64 years, (2) BMI no higher than 41, (3) possession of a mobile phone or tablet (iOS or Android), (4) fluency in the English language, (5) residence in Cache County, and (6) not having any of the following medical conditions: pregnancy, dementia, unmanaged diabetes, or untreated major depression.

Statistical Power

To achieve 80% statistical power to detect a medium effect size (Cohen's $d=0.50$) when comparing the difference between 2 independent means at a 2:1 (treatment to control) ratio, 96 treatment and 48 control (144 total) participants were needed, calculated using G*Power [58]. Upon randomization, 104 participants were assigned to treatment and 42 to control. To avoid intracouple contamination of intervention material, married couples were assigned to the same randomized group ($n=12$).

Outcome Measurements

Primary outcome measures of the trial registration included a set of anthropometric measures, blood-based biomarkers, objective cognitive testing, and behavior in targeted domains. Secondary outcome measures included metacognition, motivation, readiness for change, sleep quality, social engagement, depression, and couple satisfaction (among married persons). Tables containing full summaries of all recorded values at the beginning of the study, for all 146 Gray Matters study participants, can be found in the study by Norton et al [22]. In addition to the outcome measures recorded as part of the trial registration, app usage metrics and behavioral data collected through self-reporting within the app are also analyzed [57].

App Design, Development, and Deployment

This subsection details the design of the Gray Matters mobile phone app and accompanying educational material, the development of the systems to support the collection of behavior data, and the method of deployment to the cohort within the Gray Matters study.

Educational Material

To enable the dissemination of evidence-based educational material relating to AD risk and prevention strategies, more than 130 peer-reviewed journals and papers relating to AD risk were analyzed. From the analysis, it was identified that risk factors and their prevention methods could be categorized into 6 domains: food, physical, cognitive, social, sleep, and stress. For these 6 domains, fact and suggestion pairs were produced (hereafter referred to as daily facts). An example daily fact from the food domain is as follows: "Consuming high amounts of processed foods is related to cognitive decline"; "Try a fresh salad for dinner instead of something from a box". In total 164 succinct daily facts were produced across the 6 domains: physical (23), food (66), social (27), sleep (14), cognitive (24), and stress (10).

In addition to the daily facts, questions were designed for each domain to capture behaviors relevant to AD risk. All questions were quantitative in nature; however, they contained a mixture of subjective and objective questions. For example, a user may be asked to report the number of fruits and vegetables they consumed in a day (objective) and also rate their quality of sleep on a scale of 0-10 (subjective). In addition to the questions for the original 6 behavioral domains, a question was added to collect the activity data observed via a wearable device. In total 12 questions were designed for the domains: physical (2), food (3), social (1), sleep (1), cognitive (2), stress (2), and wearable activity monitor (1). For each question, a recommended value was extracted from external sources, such as the World Health Organization, the American Heart Association, the National Institutes of Health, and the Centers for Disease Control and Prevention's (CDC) recommended daily targets (see Table 1). The recommended value served two purposes: to act as an observable goal for the participant and as a means by which a participant's performance could be calculated, relative to other participants.

Table 1. The questions presented to the user, showing their minimum, maximum, and recommended values.

Domain	ID ^a	Question	Min ^b	Max ^c	Recommended (source)	Type
Cognitive	1	How many minutes did you spend today doing “novel mental exercises”?	0	120	30 minutes (NIH ^d)	Objective
Cognitive	2	How many minutes did you spend today doing “cognitively stimulating activities”?	0	120	30 minutes (NIH)	Objective
Food	3	How many cups of fruits and vegetables did you eat today?	0	10	5 cups (CDC ^e)	Objective
Food	4	How many ounces of whole grains did you eat today?	0	10	3 ounces (CDC)	Objective
Food	5	How many servings of nuts, seeds, or legumes did you eat today?	0	5	1 serving (CDC)	Objective
Physical	6	How many minutes of “moderate” physical activity did you do today?	0	60	30 minutes (AHA ^f)	Objective
Physical	7	How many minutes of “vigorous” physical activity did you do today?	0	60	20 minutes (AHA)	Objective
Sleep	8	How would you rate your sleep promotion efforts over the past 24 hours?	0	5	5	Subjective
Social	9	How would you rate your social engagement in the last 24 hours?	0	7	7	Subjective
Stress	10	How much effort have you put into decreasing your stress over the past 24 hours?	0	10	10	Subjective
Stress	11	On a scale of 1-10 how would you rate your stress level over the past 24 hours?	1	10	1	Subjective
Wearable	12	How many Nike Fuelpoints did you earn today?	0	5000	2000 (Nike)	Objective

^a ID: identification.

^b Min: minimum.

^c Max: maximum.

^d NIH: National Institutes of Health.

^e CDC: Centers for Disease Control and Prevention.

^f AHA: American Heart Association.

App Development

The mobile phone app was developed natively for both Apple iOS and Google Android mobile phones. The decision to develop for both platforms was made based on rudimentary market analysis of mobile phone sales within the intended cohort's location (Cache County, Utah, USA). Initially the app was developed for iOS 7.x devices, including iPhone and iPad, as the analysis showed a favoring for these devices in the area. As technology screening during the recruitment phase progressed, additional demand appeared for an Android version, which was subsequently developed. The functionality and visual layout of both versions are virtually indistinguishable, yet allowing enough flexibility to adhere to each platform's user interface design guidelines [59,60].

As the primary method to deliver health education material and track behavior change in the study, the app was designed to fulfill the following core functions:

1. Presentation of educational material relating to AD risk and prevention strategies.
2. Facilitation and recording of behavior self-reporting.
3. Calculation and presentation of personalized feedback based on reported behaviors.

User Interface Structure

Each function was presented in the user interface as a tab in the aforementioned order, allowing for easy and logical navigation. For the end user, the functions are displayed as the Tips tab, Log tab, and Performance tab.

Tips

This tab displays the evidence-based daily facts regarding risk factors and preventative strategies. The tab also contains a sports coach avatar, designed to aid visual delivery and personification of the recommendations offered in the daily fact (refer to [Figure 2](#)). The text is also tappable, which presents a pop-up box displaying the reference source and a URL, which can be navigated to if further information is desired. Although it may be argued that for the layman the use of clinical references may be deemed superfluous, its inclusion considers the broad spectrum of potential users' needs and also acts to instill confidence in the recommendations provided.

Log

This tab facilitates the collection of behavioral data via self-reporting. As seen in [Table 1](#), a total of 12 questions were designed to collect all relevant behavioral data for the study. During the requirements elicitation, it was specified that data entry for all questions should take no more than 2 minutes to complete, to reduce time burden for the study participants. As such, a time-efficient approach was developed. The questions

are presented in a list, ordered by their domain (refer to Figure 3). Data entry is achieved by moving a fixed-width slider across the screen until the desired value is presented. As the questions were designed to be quantitative, the use of a slider allows data from the questions to be represented in a scale, using increments of 1. In most instances, for objective data types, the upper limit of the slider is twice the recommended value, facilitating those who wish to overachieve. The use of a recommended value is an observable target for the user, which when achieved acts to reward and reinforce the desired behaviors, as outlined in the action stage of the TTM [30].

In order to reduce subjectivity in the questions, a user who is unsure about the exact meaning of the question may tap on it to present an expanded and elaborated phrasing of the question, including examples. For example, the question “How many

minutes of moderate physical activity did you do today?” may be considered subjective if the term “moderate” is not understood. To counter this, tapping on the question presents the description “The CDC recommends 2 hours 30 minutes of ‘moderate’ activity per week. Examples of moderate activity are walking, skiing, raking leaves, washing the car.”

By answering each question, the users can longitudinally track their behaviors across all 6 domains, including their wearable device metrics. Answering all 12 questions is not compulsory; however, it is advantageous for both the participants and the study investigators as it increases the granularity of the data for each user and the study cohort as a whole. Answers are uploaded to a remote server via http protocols, using the open-standard JSON format to package the data.

Figure 2. Tips tab main screen showing daily fact (fact and suggestion pair; left). Evidence-based literature reference and link are displayed when the fact section of the daily fact is tapped (right).

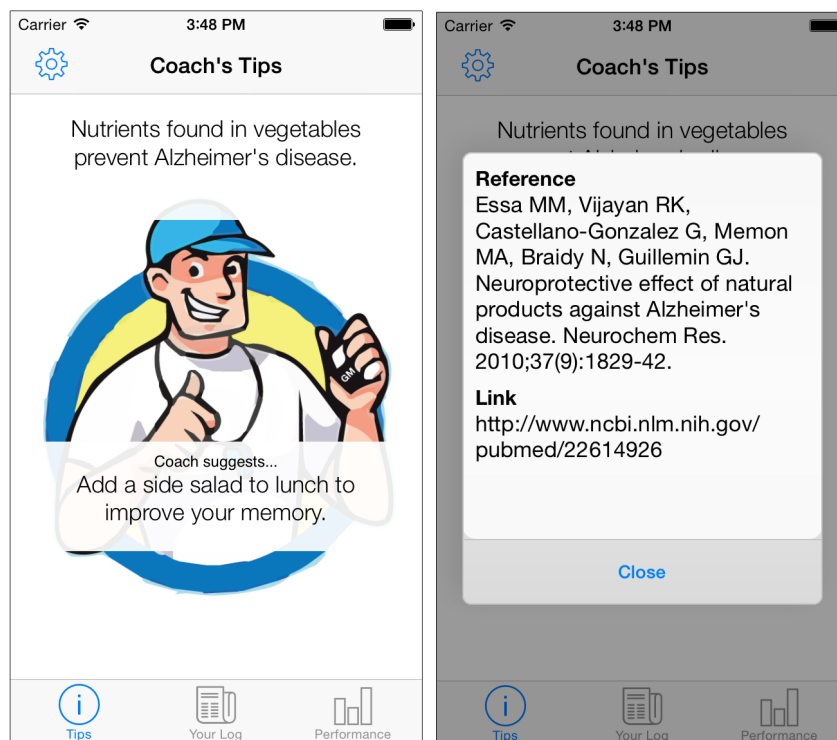
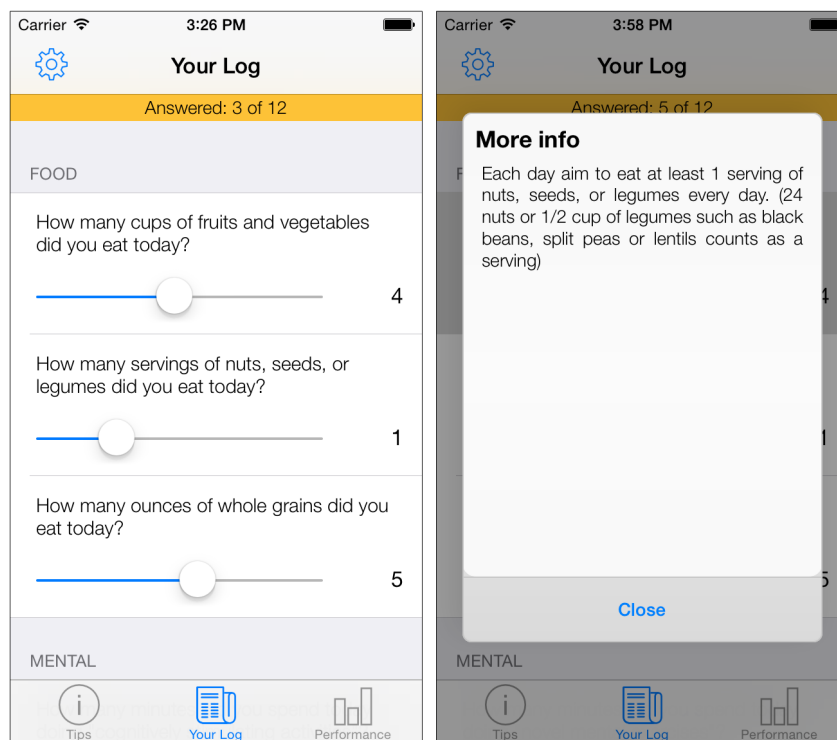


Figure 3. Log tab main screen showing list of questions ordered by domain (left). The sliders can be dragged to adjust logged amount. Dialog box containing additional information displayed for a question regarding servings of nuts, seeds, and legumes (right).



Performance

The performance tab is designed to present various summaries of the data collected from the log tab, while encouraging continual participation via rewards. The main mode of presentation is via star ratings (refer to [Figure 4](#)). These stars can be considered a variant of points-earning system, a system commonly used to encourage continual progression within behavior change programs [61,62]. Utilizing the concepts explored in gamification, a user can achieve a maximum of 5 stars for each behavioral domain each day. This is achieved by reaching the recommended value, for each question, in each topic. As such, all recorded values in the logs must be normalized to within a range of 0-5 in relation to the recommended value. To perform this necessary step, the authors developed the equation presented in [Figure 5](#).

In the equation, x is the user's answer value to a particular question, Q_G is the goal value for the question, Q_L is the lowest possible value for that question, R_U is the upper boundary of the normalized result, and R_L is the lowest boundary.

The stars are designed to encourage and reinforce a participant's effort to change his or her behavior. Because all domains can be viewed on screen at the same time, it provides a fast method to deliver visual feedback on the domains that require more effort and those that are under control. Users may also tap on each domain to receive additional pertinent information and an additional graphical representation of their efforts. The users may also view their performance aggregated across the previous 7 days in the form of a spider diagram or a bar chart. Again, this serves to visually assist the participants in understanding their behaviors for the purpose of self-affirmation.

Figure 4. Performance tab showing star ratings for each domain, calculated by assessing a user’s reported values against recommended values (left). Expanded view of performance with a domain, containing additional information and helpful tips (center). A bar chart showing aggregated performance, as a percentage, from the previous week’s data (right).

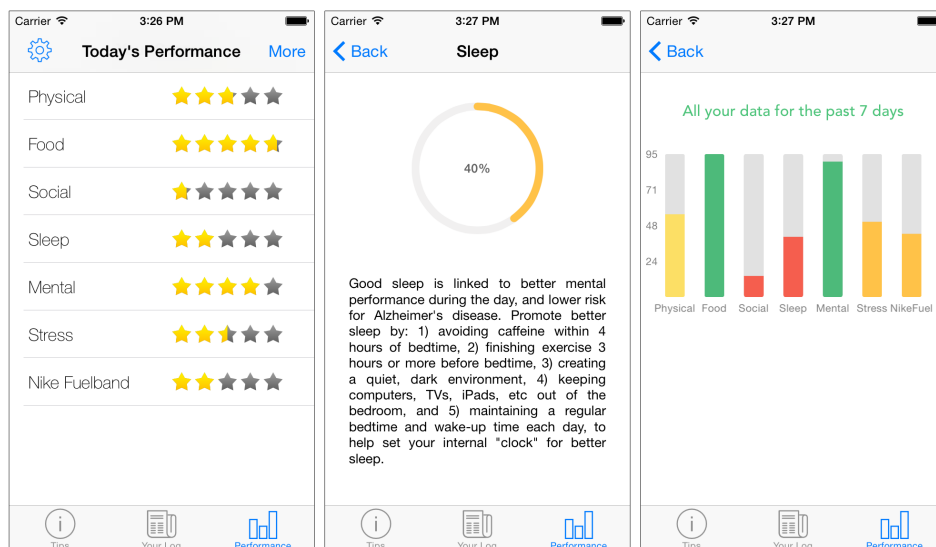


Figure 5. Equation developed by the author to normalize users performance metrics to a 5 star rating for visual representation.

$$f(x) = \begin{cases} R_U & \text{if } x \geq Q_G \\ \frac{(x-Q_L) \times (R_U-R_L)}{Q_G-Q_L} + R_L & \text{if } Q_L \leq x < Q_G \end{cases}$$

Remote Monitoring

Participant data from the app are uploaded to a remote MySQL server located at Ulster University. This occurs in real time if a user has a valid Internet connection, via Wi-Fi or mobile network. This instant transmission of behavioral data offers health investigators in the study an opportunity to perform immediate analysis, at any given point during the intervention. Because the data are in a structured digital format, very little human processing or interaction is required to run queries or statistical analysis. This presents a huge advantage over studies that control their data collection and processing via paper-based postal services and questionnaires [63].

App Analytics

To exploit the opportunity and increase the granularity of available data, the app also monitors all in-app actions using proprietary and open-source analytical tools. These analytical data enable the investigators to examine the profile of the average user and provide insight into how the app is actually being used. Examination of the analytical tracking data also highlights features that fulfill their purpose, while also identifying problematic areas of the app, flagging them to be addressed in future updates. Components of the app that contain analytical tracking code include app launching, tab navigation, updating log values, changing notification times, question detail expansion, and performance analysis.

Additional Intervention Components

In addition to the aforementioned mobile phone app, participants in the treatment group had access to a number of components to encourage behavior change. These included a wrist-worn

activity monitor, booster events, a personal coach, and a study website.

Wrist-Worn Activity Monitor

Each participant was given a Nike FuelBand SE activity monitor. This device is worn on the wrist and serves to collect information such as steps taken, stairs climbed, and minutes of activity. This information is then consolidated into Nike’s proprietary metric of “NikeFuel points.” This device not only serves to collect data, but also acts as a physical reminder and motivator to increase levels of activity. Participants were asked to manually enter their total number of NikeFuel points earned at the end of each day via the mobile phone’s log tab.

Booster Events

All participants had the option of attending organized booster events. Each booster event was designed to emphasize the link between a specific domain and the risk it posed to developing AD, accompanied by preventative measures that the participants could apply in their daily lives. For example, a booster event that focused on the food domain hosted cooking classes that promoted sustainable healthy eating choices, while educating attendees about the link between the ingredients and AD risk. In total 46 booster events were organized and delivered across the 6-month intervention period.

Personal Coach

Participants also had access to a personal coach whom they could contact if they required assistance with any aspect of the behavioral domains. A team of 28 student interns with majors in the 6 behavioral domains volunteered to be personal coaches. Student coaches were trained in motivational interviewing and the TTM and provided a weekly email or text message exchange

with their assigned participants to provide emotional support and encouragement for lifestyle change goals.

Study Website

Participants also had access to a password-protected website [64,65] that provided content for the 6 domains, support material for the use of the study technology, including instructional YouTube videos showing users how to install and use the app for iOS and Android. In addition, an email address was provided should additional issues arise.

Exit Survey

An exit survey was designed to capture opinions of participants in the treatment group. The survey asked questions about app usage, motivations, their perceived behavior change, and social network usage. At the end of the study, 102 of the 104 participants completed this survey.

Results

A Brief Overview of This Section

This section presents the results from the RCT, including analysis of the treatments group's adoption, typical usage, and perceptions of the app. This section also examines the app's observed effects within the clinical and behavioral domains.

App Adoption and Usage

In week 1 (April 10, 2014), the first iOS version of the app was released to the treatment group. This was performed through a launch event, in which attending participants were instructed how to sign up and download the app through the TestFlight platform. TestFlight is a platform by which developers can distribute apps to internal or external testers. This platform allowed the investigators to control visibility in the app marketplace, ensuring that only enrolled participants could see and install the app. By the end of week 1, a total of 31.7% (33/104) participants had installed the app on their iPhone and/or iPad. In week 3 (May 13, 2014), the first Android version of the app was released to the treatment group because of demand from Android users. Two weeks after this release, 19.2% (20/104) participants had installed the first version of the

Android app. By week 10, a total of 86.5% (90/104) of participants from the treatment group had installed an iOS or Android version of the app on their mobile phone and/or tablet, with the remainder shortly afterward. Many users opted to install the Gray Matters app on both their mobile phone and tablet. Of the 104 users using the app, at the end of the study, 75.97% of all Gray Matters app sessions were on iOS devices (iPhone: 54.7%; iPad: 21.27%) and the remainder on Android devices (24.03%). Regarding self-reporting of behaviors, the average user answered 7.3 (standard deviation, SD 3.16) questions per day during their participation in the study. The average duration of each session with the app, across all devices, was 1 minute 55 seconds. This time is less than the originally specified goal of 2 minutes for a user's session duration. For further information on app usage statistics during the initial 10 weeks of the study please refer to the study by Hartin et al [57]. Additional analytical tracking code was added to the app in week 18 to analyze the specific behaviors when answering questions in the log screen. The tracking code recorded the number of times the users altered their behavioral values (Figure 6). Across all users in the study, question 12 was altered a statistically significant amount more than the rest ($z=3.054$, $P=.0023$). Question 12 belongs to the wearable domain and relates to the number of NikeFuel points earned. It is assumed that users frequently updated this amount, more than the others, because of the variability in the data generated from the wearable device each day when they were active.

The app was distributed with two default notification times. The first notification was issued in the morning at 8 am by default, which reminded the users to check their daily fact every day. The second notification was issued at 6 pm by default, which reminded the user to complete the questions in the app's log tab. Analysis of app usage times (Figure 7) shows that the users do have a period in the morning around 7-9 am that they use the app. In the evening, however, app usage rapidly increases around 8 pm and declines sharply after 11 pm. It is believed that the users wait until the end of the day before entering their log data, so that it is the most valid representation of their day. This behavior may also be encouraged by the fact that users cannot alter their previous day's log once the day has passed.

Figure 6. Bar graph showing the mean number of times each domain’s questions were edited using the sliders in the log screen, using updated analytical code, from week 18 to study end. The wearable domain is updated almost twice as often as the other domains.

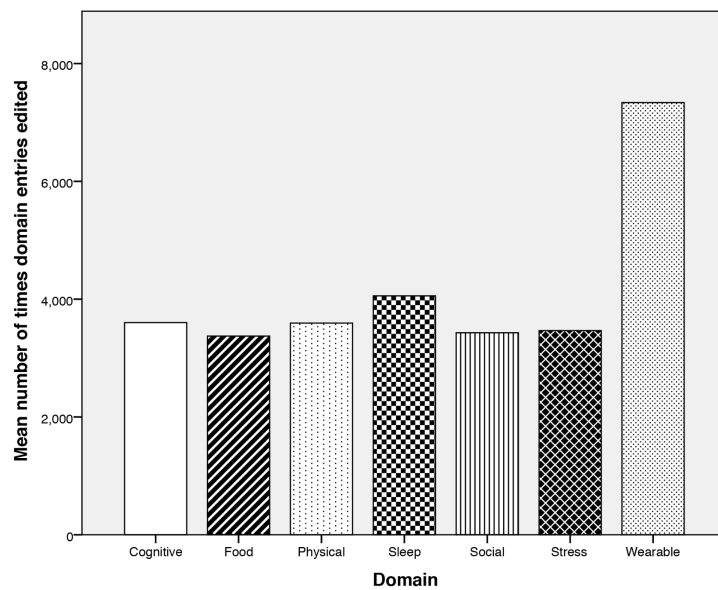
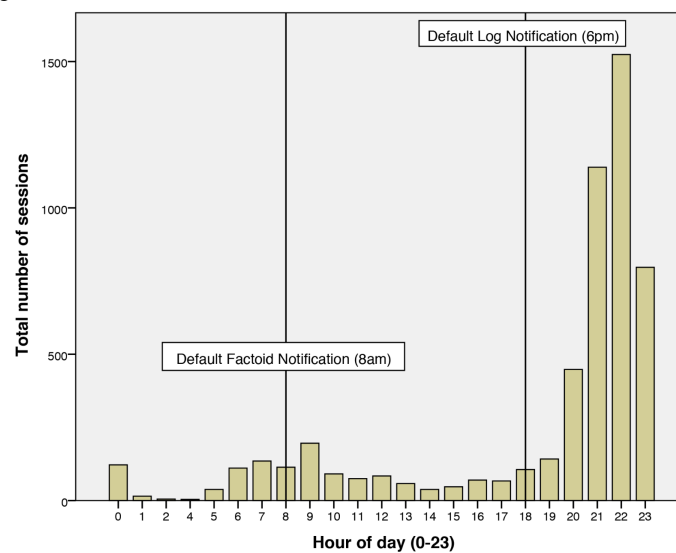


Figure 7. Bar graph showing the typical hours of use, with morning activity around the default daily fact notification time at 8 AM and activity peaking at 10 PM, 4 hours after the default log notification time.



User Survey

Upon the close of the study, an exit survey was issued to those in the treatment group. A total of 41 participants completed the survey. The survey acted to gather users’ motivations for

behavior change and thoughts on the various components of the study, how they used them, and where they felt improvements could be made. First, users were asked how often they used the app (Table 2).

Table 2. Respondents’ answers to survey question: “Over the six month Gray Matters intervention period (April 2014 – October 2014), how often did you use the App?”

Usage	N	Mean	Standard deviation
Months used	39	5.54	1.315
Days per week	38	6.21	1.695
Times per day	38	1.66	3.122

Motivations

In addition, the survey acted to glean how the app altered motivations toward various parts of the intervention. The survey

also revealed that the app motivated users to perform physical activity (never: 14.6%, rarely: 12.2%, sometimes: 24.4%, often: 31.7%, and all of the time: 17.1%) and make healthier food choices (never: 12.5%, rarely: 2.5%, sometimes: 17.1%, often:

48.8%, and all of the time: 17.1%). When queried about their past, current, and future behaviors, 46.3% said they definitely would continue with their physical activity changes and 31.7% wanted to continue and increase their activity; 46.3% wished to continue their improved eating habits, with 29.3% wanting to continue and improve. When asked if they would continue using the app, 46.3% said they would not, 29.3% said they likely would not, and 24.4% said they would continue.

Future App Feature Elicitation

In addition, users were asked about features that they wished were included in the app. A total of 68.3% of users wished that guidelines were based on their “current” health status, 34.1% wished they could set their own target goals, 53.7% wished they could focus the daily facts on specific behavior goals of interest, and 51.2% wished to receive text feedback if they had made good progress or no progress. A total of 53.7% wished they could compare their behaviors with others relative to their age, gender, and initial fitness status. Regarding the wearable device and app interaction, 70.7% of poststudy survey respondents wished that their wearable device automatically synched to the app. Such a feature would greatly reduce user burden of data entry.

App Usage and Clinical Outcomes

During the duration of the study, 122,719 behavioral logs were uploaded to the central database. These logs have been analyzed for trends and correlations with clinical and biological markers recorded at the beginning and end of the intervention.

Number of Times App Used per Week

Logically, it is hypothesized that increased exposure to the app and its material would result in favorable outcomes, both in behavior change and in clinical markers. First, the number of times that the app was launched per week was calculated and categorized into groups (<1, 1-3, 3-5, 5-7, 7+ per week). These groups were then evaluated with various clinical and biometric measurements taken from the participants at the start and end of the study, along with the control group.

From a high level, it is evident that increased app exposure had an observable effect on various clinical measurements, in particular for BMI (Figure 8) and systolic blood pressure (SBP; Figure 9).

It can be seen that the control group had undesirable increases over the intervention period, whereas the treatment group had sustained or reduced the measurements. Notably, those who looked at the app *more than 7 times* per week appear to have the largest reduction in BMI and blood pressure, whereas those who looked *less than 7 times* and *more than 1* vary in their results. It is also interesting to note that those who looked at the app *once or less* per week also maintained favorable rates of decline. It is proposed that these users are self-sufficient in their efforts to effect behavior change and do not require the app to aid them. To further investigate the app’s apparent effect, we analyzed various functions of the app in relation to clinical outcomes.

Figure 8. Boxplot showing no app (control) and grouped app launches per week (treatment) against observed changes in body mass index (BMI). Outliers are plotted as individual points.

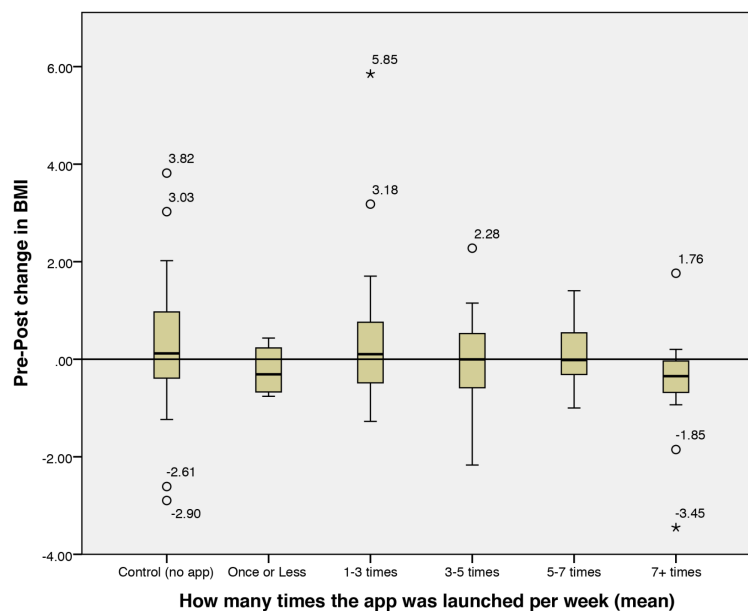
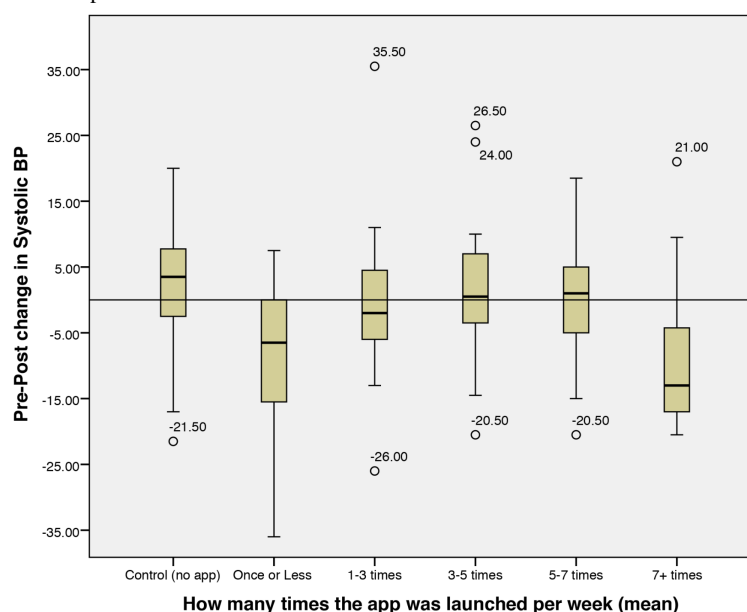


Figure 9. Boxplot showing no app (control) and grouped app launches per week (treatment) against observed changes in systolic blood pressure (BP; mm Hg). Outliers are plotted as individual points.



Compliance to Log Entry and Clinical Observations

The average number of logs completed per day was analyzed for correlations to the clinical changes observed in the study, suggesting the following hypothesis:

H_0 : There is no supported relationship between daily log and clinical or biological markers.

H_1 : The number of logs completed each day will correspond to greater change in clinical and biological markers.

Continuous Variables

Analysis shows that daily log completion rates show no relationship between pre-post BMI scores ($r=.016$, $P=.872$) and diastolic blood pressure ($r=.064$, $P=.523$). There is a weak positive correlation found in SBP ($r=.28$, $P=.784$) and weak negative relationships in resting heart rate ($r=-.121$, $P=.23$) and blood carotenoids ($r=-.105$, $P=.294$). Further correlation analysis was completed on the biological markers, which also showed positive, but weak, correlation between the number of logs completed and pre-post total cholesterol ($r=.145$, $P=.91$) and triglycerides ($r=.145$, $P=.15$), and negative weak correlation in serum glucose ($r=-.88$, $P=.382$) and blood insulin levels ($r=-.105$, $P=.296$). Nevertheless, calculating partial correlation, controlling for the number of days the participant had the app installed, highlighted toward a significant correlation between total cholesterol and average questions per day ($r=.193$, $P=.055$). Adding an extra control for the participant's initial recorded total cholesterol levels resulted in a significant correlation ($r=.228$, $P=.024$). We therefore reject the null hypothesis for this particular case.

Dichotomous Variables

Using domain knowledge, it was possible to group the clinical and biological markers into dichotomous groups (improvement or no improvement), which allowed for further analysis to be carried out. Independent samples t tests showed that participants

who improved their high-density lipoprotein (HDL) cholesterol levels during the study duration answered a statistically significant higher number of questions per day (mean 8.30, SD 2.29) than those with no improvement (mean 6.52, SD 3.612), $t_{97.74}=-3.051$, $P=.003$.

Achieving Recommended Daily Targets and Clinical Observations

Participants' self-reported behaviors were analyzed to find the frequency and percentage of times that they achieved the recommended daily goal value for each question. The following hypothesis is tested:

H_0 : There is no supported relationship between achieving recommended values and clinical or biological markers.

H_1 : The higher the number of recommended goals achieved, the greater the degree of change in clinical and biological markers.

Continuous Variables

Correlation analysis between a participant's mean percentage of recommended goals achieved, across the study duration, and observed clinical measurement changes showed the following: no relationship for systolic ($r=-.013$, $P=.896$) and diastolic ($r=-.35$, $P=.732$) blood pressures and no relationship in carotenoids ($r=-.013$, $P=.895$). Negative and Positive, but weak, correlation was found in resting heart rate ($r=-.107$, $P=.285$) and also BMI change ($r=.157$, $P=.116$) respectively. Biomarker changes were also correlated against percentage of recommended values achieved showing no correlation in serum glucose ($r=-.075$, $P=.455$) and blood insulin levels ($r=-.049$, $P=.624$). Positive, but weak, correlation was found for pre-post triglyceride values ($r=.155$, $P=.124$). Significant correlation, at the 95% confidence interval, was found in pre-post total cholesterol ($r=.217$, $P=.03$). The null hypothesis is accepted for all cases except this case.

Dichotomous Variables

Once again, each pre-post clinical and biological reading was categorized as either improvement or no improvement. For each individual, a baseline performance level was calculated from his or her self-reported behaviors in the first week of enrollment. Because there were a number of individuals within the treatment group who were highly active and maintained a healthy lifestyle, to reduce the ceiling effect on the data the first quintile (n=20) of participants were removed from the analysis. Using the dichotomous groupings of improvement and no improvement, significant correlations were found between daily goal percentage achieved and BMI reduction ($r=.264$, $P=.017$). An

independent samples t test showed participants who decreased their BMI performed significantly better in attaining their recommended daily goals (mean 56.21%, SD 30.4%) than those who increased their BMI (mean 40.12%, SD 29.1%), $t_{80} = -2.449$, $P=.017$. Further analysis showed that 69.2% (n=18) of those who achieved a mean performance percentage of 60% or higher, across all domains, reduced their BMI during the study, whereas 60.7% (n=34) of those who did not, increased their BMI. Analysis of cross tabulation shows that those who achieved more than 60% of their recommended daily goals were 1.762 times more likely to decrease their BMI during the study, or 0.507 times less likely to increase their BMI, than those who did not achieve 60% (Table 3).

Table 3. Odds ratio and relative risk analysis for participants who achieved more than 60% of their recommended daily targets (mean) and body mass index change outcome.

	Value	95% confidence interval	
Lower	Upper		
Odds ratio for recommended targets achieved >60% (achieved/did not achieve)	0.288	0.107	0.774
For cohort BMI ^a change = increased	0.507	0.274	0.936
For cohort BMI change = decreased	1.762	1.164	2.667
N of valid cases	82		

^a BMI: body mass index.

Physical Activity and Clinical Observations

Participants' reported their levels of physical activity via 3 self-reporting questions:

1. Number of minutes performing moderate physical activity
2. Number of minutes performing vigorous physical activity
3. NikeFuel points earned via wearable device.

Each participant's results were analyzed for correlations between these values and clinical observations. The following hypothesis is tested:

H₁: The higher the number of minutes performing physical activity/higher the NikeFuel points, the greater the degree of change in clinical and biological markers.

H₀: There is no supported relationship between achieving physical activity levels and clinical or biological markers.

Using the dichotomous variables (improvement or no improvement), each physical activity feature was analyzed. Again, using the baseline performance metric calculated in the first week of observation, participants in the last decile (bottom 10%) were excluded from the analysis to reduce ceiling effects. An independent samples t test found that the remaining participants (n=92) who decreased their BMI (n=45) reported statistically significantly more vigorous physical activity (mean 23.94, SD 10.76 minutes) than those who increased their BMI (mean 19.09, SD 12.36 minutes), $t_{90} = 2.002$, $P=.048$. Interestingly, no correlation was found with moderate physical activity levels or NikeFuel points and BMI reduction status. Conversely, upon removing the first quintile, it was uncovered that those who improved their levels of HDL cholesterol during

the intervention achieved significantly higher NikeFuel points on a daily basis (mean 2569.39, SD 641.17) than those who observed no improvement (mean 2233.9, SD 800.34), $F(82)=-2.052$, $P=.043$. Literature in the area of endocrinology and metabolism supports this observation as physical exercise is associated with increases in HDL [66].

Stress Reduction Effort and Clinical Observations

Participants' self-reported stress reduction efforts were analyzed for their effect on clinical measures. Participants' SBP were recorded before and after intervention and categorized into low (<90), ideal (90-120), prehypertension (120-140), and hypertension (>140). Those with nonideal SBP at their preintervention recording (n=50) were analyzed to observe if a change of category occurred during the intervention. Changes observed in these participants were categorized into 3 groups: improvement (n=13), no improvement (n=14), and deterioration (n=23). One-way analysis of variance of their category changes showed a significant correlation between efforts to reduce stress (effort rated 1-10, where 10 is high effort) and SBP category change as a whole, $P=.035$ (excluding first quintile of baseline performers). Multiple comparisons of the 3 groups showed significance between those who had no improvement (mean 3.11, SD 2.32 effort rating) and those who had deteriorated (mean 5.28, SD 2.105 effort rating), $P=.028$. No significant difference was found between improvement (mean 4.18, SD 1.89 effort rating) and the remaining groups.

Demographic Data Versus Percentage of Recommended Values Achieved

The percentage of recommended values achieved for the entire treatment cohort was categorized into quintiles (1=highest, 5=lowest). These performance quintiles were then compared

with a number of demographic variables collected at the start of the study. Analysis of these data showed relationships between a participant's achieved percentages and whether that participant knew of a family member having dementia. This relationship is apparent between the second and fifth quintiles (Figure 10). Partial correlation within these quintiles, controlling for number of days enrolled in the study, shows significant correlation ($r=.232$, $P=.036$).

Percentages achieved (0%-100%) and gender (male or female) were also analyzed (Figure 11). Independent samples t test shows that females achieved a statistically significant higher percentage of recommended targets (mean 52.44, SD 29.24)

compared with their male counterparts (mean 38.69, SD 28.50), $t_{102} = -2.302$, $P=.023$.

It would appear that users who have family members with dementia are motivated to reach their recommended daily targets, therefore performing better, perhaps because of first-hand experience with the condition. In addition, analysis shows a visible correlation between gender and the ability to reach the recommended daily target values. The reasons behind this observation are currently unclear and require additional analysis; however, they could relate to motivations, occupation, and education level.

Figure 10. Bar chart showing the log performance quintiles against the number of users who report to have known of a family member having/had dementia.

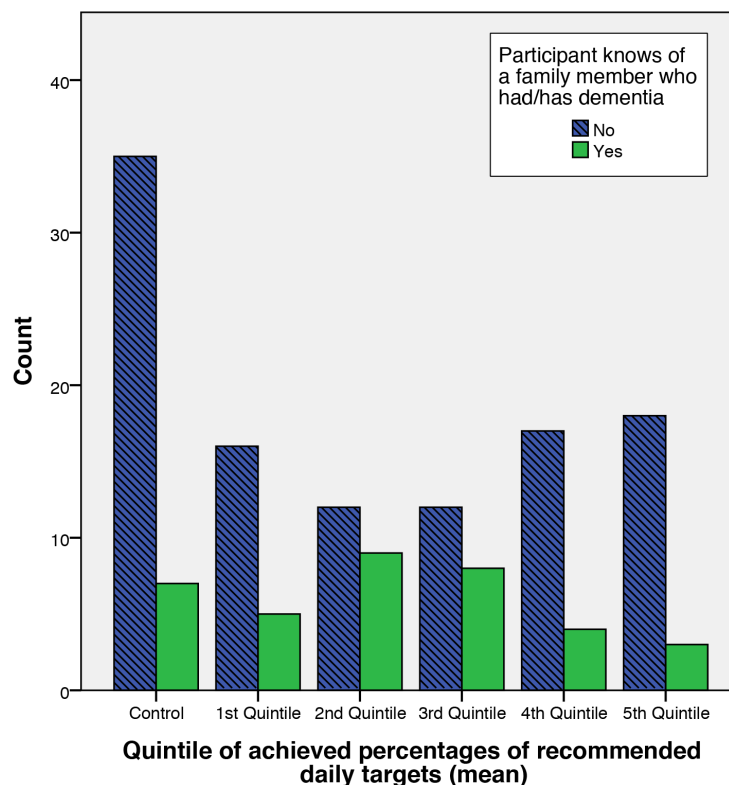
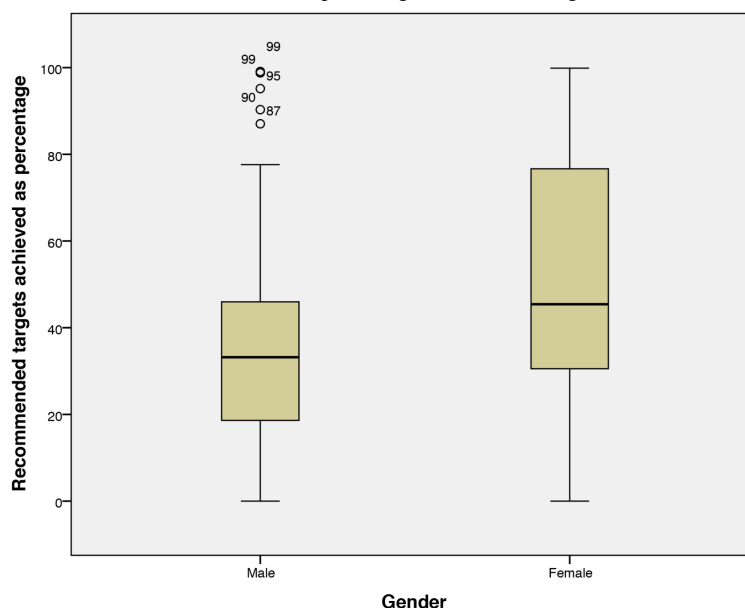


Figure 11. Boxplot showing distributions of male and female mean percentages of achieved targets across all domains.

Discussion

Principal Findings

The mobile phone app provided a novel method to remotely monitor participants in a behavior change intervention, while also facilitating the delivery of intervention material. In addition, analysis of exit survey shows that the app facilitated stages 3-5 of the TTM, preparing participants for change, allowing them to accurately monitor and assess their actions, and encouraging continued maintenance and improvement of their desired behaviors. Results from the exit survey showed that most users wished to continue their behavior change efforts, which if maintained, are expected to yield superior outcomes in AD prevention.

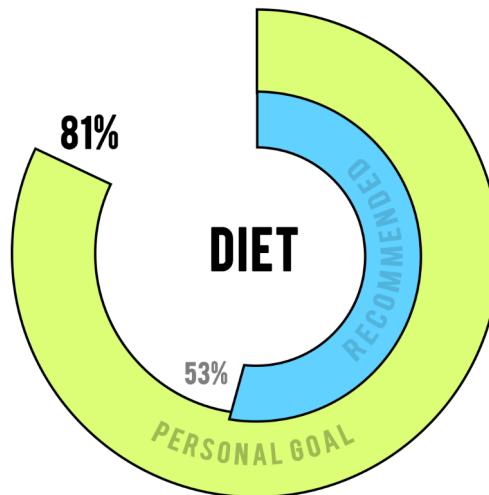
In this trial, the recommended values for each behavior played a key role in the uniform assessment of participants' performance. Analysis of pre-post measurements from the treatment group showed clear physiological changes in those who achieved the highest in their attempts to meet recommended values. This was especially apparent in those who were

previously underachievers in certain behavioral domains, before the study (based on the first week of observed behavior logs). Effects observed included a desirable lowering of BMI, improvements in HDL and low-density lipoprotein cholesterol levels, improvements in SBP, lowering of resting heart rate, and improvements in perceived stress levels.

Regarding user experience, most app users stated that they wished to alter their recommended values to be based on their "current" health status, whereas others wished to manually set their own target goals. Such a feature could improve engagement with the app, at the detriment of a true representation of progress. A compromise would be to present the user with their efforts against both personal and global targets (Figure 12).

Half of the users wished that their educational material was focused on a specific domain of interest, rather than evenly spread throughout all behavioral domains. Such a focus may be beneficial if the user requires extensive change in one particular domain, but for the purpose of a multidomain intervention the investigators decided it was of great importance to educate across all domains.

Figure 12. A prospective graphical representation of a user's efforts against globally recommended values and his or her personal goals.



Limitations

The findings of the study may be biased toward the study cohort's locale and ethnic group. The study cohort was predominantly white (96.6%) and the participants resided in a county that is classified as 96.23% rural [67]. Although desirable changes in behavior were observed within this cohort, additional research is required to examine the efficacy of the approach within other countries, in various settings, spanning numerous ethnic groups.

Within this larger study, additional work would be required to accommodate and account for the cultural, regional, and religious differences across groups; for example, adjusting dietary recommendations based on religious practice.

Future Improvements

Through direct communications with participants and survey analysis, various aspects of the app and supplementing technology have been identified for improvements for a future version of the study.

Wearable Device Integration

The Nike FuelBand's proprietary and nondisclosed metric of NikeFuel points is rather ambiguous for the purpose of a scientific study. Many users reported that the device did not accurately award them with points during activity and, conversely, awarded them with points when they were performing sedentary tasks, such as when they were driving their car. These false positives removed the opportunity to use the data to validate reported physical activity with the FuelBand's NikeFuel metric. In agreement with the participants' comments, a recent study assessing the validity of commercially available activity monitors found the FuelBand to be one of the weakest performers overall, undercounting daily step count, on average, by 2529 steps [68]. There are now numerous commercially available alternatives that allow for greater granularity in their data, such as step counts, distance travelled, sleep quality, and resting heart rate. Many of these wearables allow for direct integration with apps via simple application program interface calls. Because of this feature, self-reported sleep and physical activity may be correlated against the data

collected directly from the wearable device to examine validity. The future iteration plans to seek alternatives.

As discussed earlier, the users also had the burden of repeatedly entering their NikeFuel points via the log screen. This user burden of data entry can be greatly reduced by enabling the transfer of data from relevant wearable devices directly to the app, greatly increasing the convenience of the solution.

Social Network Integration

Participants had informed us that they wished that the app were more socially engaging. For future development we have identified that a social element is required, allowing users to add friends with whom they can publicly compare their efforts. Integrating the app with existing social networks, such as Facebook and Twitter, can facilitate this feature. Social network integration will allow the users to find friends already in their network, who are also using the app. From here they may compare their own accomplishments with those in their friend group, thus offering an opportunity to heighten motivations for change. In addition, integration with these networks will also allow users to post their accomplishments to their public pages, allowing those outside the study to view their efforts and provide an opportunity for additional peer support, while boosting the public profile of the study.

Personalization

There is a huge opportunity for personalization in all aspects of the app. Users of the Gray Matters app have suggested that they would like to set their own targets and behavior change goals. This includes adding or removing domains based on a user's motivations. Daily fact delivery could also be revised to prioritize daily facts from a domain of interest to the user.

Higher Granularity Reporting

Within the study, participants were asked to report behaviors that were reasoned as favorable by the investigators because of their role in AD prevention. However, the participants were not asked to report behaviors that should be avoided. For example, although participants were encouraged to consume fruits and nuts, they were not asked to report how many refined sugars or processed foods they consumed. Using solely the measure of

desirable food intake, without observing the undesirable food intake, results in a skewed representation of diet macronutrients and overall calories consumed.

Additional Behavioral Domains (Smoking Cessation)

Smoking cessation was not included in the original study, as there is an extremely low rate of smokers in the Cache County area [69]. Nevertheless, if the Gray Matters study were to target a larger geographical area, state or nationwide, facts and suggestions related to smoking cessation would be included.

Improvement of Daily Fact and Question Database

On an ongoing basis, we will strengthen and expand the daily fact database, adding new facts and suggestions, with each vetted using a modification of the rating system developed by the Grading of Recommendations Assessment, Development and Evaluation working group [70]. Analysis of in-app behaviors showed that users had tapped on questions numerous times to help them understand the exact semantics of a question. In addition, some external feedback outside of the study cohort suggested that some of the daily facts could have been clarified. As such, in future versions resources should be allocated to analyze the average user's interpretation of daily facts and questions, to ensure that confusion is limited.

Distribution

A number of suggestions were provided by users of the app informally via email during the duration of the study. A familiar

complaint included improving the distribution method of the app. The TestFlight platform, although useful for maintaining control of distribution, was developed for tech-savvy users, not for clinical interventions. As such, many users had problems registering with the platform and subsequently approving certificates and downloading the app. In the next iteration, all distribution will take place via the platform's official app repositories, iOS App Store and Google Play Store.

Conclusions

The prevailing theme of this paper has been to express the benefit of using a mobile phone app as a core component of a behavior change intervention—to yield the advantages offered by the pervasive nature of the mobile phone within an individual's daily life and routines. In this study, the mobile phone offered the opportunity for clinical effect to occur through behavior change. The app excelled as a delivery platform for the intervention, enabling the dissemination of educational intervention material, while simultaneously monitoring and encouraging positive behavior change. Although the effect of behavior change in midlife, observed during the 6-month RCT, on future AD risk is still relatively unclear, it is evident that participants in the treatment group had favorable improvements across numerous physiological domains, suggesting that a sustained effort would yield superior outcomes in the future.

Acknowledgments

This work has been supported by the Vice President for Research seed grant, Utah State University, and the Department for Employment and Learning, Northern Ireland.

Authors' Contributions

PH, doctor of computer science, designed and developed the Gray Matters apps and supporting server architecture; facilitated distribution of the software; provided one-to-one user support; created instructional videos for users; collected app and user behavioral data; performed statistical analysis of app, clinical, behavioral, and booster data; and authored the manuscript.

CN, professor of biomedical engineering, supervised PH; directed the technical development of the Gray Matters apps; and provided critical feedback on the manuscript.

SM, professor of mathematics, supervised PH; oversaw data processing and statistical analysis of behavioral data from the Gray Matters app; and provided critical feedback on the manuscript.

IC, research associate in pervasive computing, assisted with data preprocessing and analysis; provided technical recommendations on app development and data processing; prepared and carried out statistical analysis of self-report data from the app; and contributed to the writing of and feedback on the manuscript.

JT, neuropsychologist, directed the selection, collection, and interpretation of cognitive tests; organized and delivered several booster events in the domain of cognitive stimulation; and provided critical feedback on the manuscript.

CC, doctoral student in gerontology, assisted the principal investigator in all aspects of the study including recruitment, eligibility prescreening of participants; setting up and maintaining laboratory, cognitive testing, and survey data collection procedures; supervising undergraduate research interns; Web design; technical support for activity monitors assigned to participants; coordination of participant and intern appointment calendar; and provided critical feedback on the manuscript.

MN, gerontologist, was principal investigator, directing all aspects of the study; supervised the collection of the AD prevention "fact and suggestion" database; designed the functionality of the Gray Matters mobile phone app, trained study participants in the installation and use of the app; contributed text to the manuscript and provided critical feedback on the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

CONSORT-EHEALTH Checklist (v1.6.1).

[\[PDF File \(Adobe PDF File\), 751KB - mhealth_v4i3e93_app1.pdf\]](#)**References**

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Abbreviations

AD: Alzheimer disease
BMI: body mass index
CDC: Centers for Disease Control and Prevention
HBM: Health Belief Model
HDL: high-density lipoprotein
RCT: randomized controlled trial
SBP: systolic blood pressure
SMS: short message service
TPB: Theory of Planned Behavior
TTM: Transtheoretical Model

Edited by G Eysenbach; submitted 30.06.15; peer-reviewed by J Walsh, J Diezma; comments to author 30.09.15; revised version received 02.12.15; accepted 07.01.16; published 02.08.16.

Please cite as:

Hartin PJ, Nugent CD, McClean SI, Cleland I, Tschanz JT, Clark CJ, Norton MC

The Empowering Role of Mobile Apps in Behavior Change Interventions: The Gray Matters Randomized Controlled Trial

JMIR Mhealth Uhealth 2016;4(3):e93

URL: <http://mhealth.jmir.org/2016/3/e93/>

doi: [10.2196/mhealth.4878](https://doi.org/10.2196/mhealth.4878)

PMID: [27485822](https://pubmed.ncbi.nlm.nih.gov/27485822/)

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Original Paper

Evaluating an Adaptive and Interactive mHealth Smoking Cessation and Medication Adherence Program: A Randomized Pilot Feasibility Study

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Abstract

Background: Mobile health (mHealth) interventions hold great promise for helping smokers quit since these programs can have wide reach and facilitate access to comprehensive, interactive, and adaptive treatment content. However, the feasibility, acceptability, and effectiveness of these programs remain largely untested.

Objective: To assess feasibility and acceptability of the My Mobile Advice Program (MyMAP) smoking cessation program and estimate its effects on smoking cessation and medication adherence to inform future research planning.

Methods: Sixty-six smokers ready to quit were recruited from a large regional health care system and randomized to one of two mHealth programs: (1) standard self-help including psychoeducational materials and guidance how to quit smoking or (2) an adaptive and interactive program consisting of the same standard mHealth self-help content as controls received plus a) real-time, adaptively tailored advice for managing nicotine withdrawal symptoms and medication side-effects and b) asynchronous secure messaging with a cessation counselor. Participants in both arms were also prescribed a 12-week course of varenicline. Follow-up assessments were conducted at 2 weeks post-target quit date (TQD), 3 months post-TQD, and 5 months post-TQD. Indices of program feasibility and acceptability included acceptability ratings, utilization metrics including use of each MyMAP program component (self-help content, secure messaging, and adaptively tailored advice), and open-ended feedback from participants. Smoking abstinence and medication adherence were also assessed to estimate effects on these treatment outcomes.

Results: Utilization data indicated the MyMAP program was actively used, with higher mean program log-ins by experimental than control participants (10.6 vs 2.7, $P < .001$). The majority of experimental respondents thought the MyMAP program could help other people quit smoking (22/24, 92%) and consistently take their stop-smoking medication (17/22, 97%) and would recommend the program to others (20/23, 87%). They also rated the program as convenient, responsive to their needs, and easy to use. Abstinence rates at 5-month follow-up were 36% in the experimental arm versus 24% among controls (odds ratio 1.79 [0.61-5.19], $P = .42$). Experimental participants used their varenicline an average of 46 days versus 39 among controls ($P = .49$). More than two-thirds (22/33, 67%) of experimental participants and three-quarters (25/33, 76%) of controls prematurely discontinued their varenicline use ($P = .29$).

Conclusions: The MyMAP intervention was found to be feasible and acceptable. Since the study was not powered for statistical significance, no conclusions can be drawn about the program's effects on smoking abstinence or medication adherence, but the overall study results suggest further evaluation in a larger randomized trial is warranted.

Clinical Trial: ClinicalTrials.gov NCT02136498; <https://clinicaltrials.gov/ct2/show/NCT02136498> (Archived by WebCite at <http://www.webcitation.org/6jT3UMFLj>)

KEYWORDS

tobacco use cessation; smoking; mobile health; mHealth; eHealth; secure messaging; varenicline

Introduction

Smoking is a global health concern [1] and the leading preventable cause of death and illness in the United States [2]. This is particularly striking since most tobacco users in the United States want to quit (69%) and have tried to quit in the past year (52%) [3]. Despite this, smoking rates have remained fairly flat in the last decade—decreasing by only about 3% [4]. New intervention strategies are needed to more effectively reduce smoking rates.

Smartphones offer a promising platform for delivering mobile health (mHealth) interventions to smokers [5,6]. The advantages of mHealth interventions include their wide reach—most Americans now own a smartphone [7]—their convenience, the ability to adaptively update content to match smokers' changing needs and interests, and the ability to connect smokers with peer or expert clinical support. The latter characteristics were recently identified as important intervention components by both cessation treatment providers and smokers [6] but neither is commonly included in commercially available cessation apps, and no studies we are aware of have tested mHealth programs that incorporate adaptively tailored feedback and access to clinical experts. As such, the feasibility, acceptability, and effectiveness of these features are unknown. Research is needed to address these gaps in the literature.

It is well established that the effectiveness of any cessation intervention is, in part, dependent on treatment adherence. This is particularly true for stop-smoking medications, which require consistent use to be most effective. However, nonadherence is a common problem with each of the three US Food and Drug Administration (FDA)–approved stop-smoking medications (nicotine replacement therapy, varenicline, and bupropion SR) [8-18]. In a recent trial comparing the effectiveness of each medication, about one-quarter of participants were nonadherent 1 week post–target quit date (TQD), one-third were nonadherent after 4 weeks, and more than half were nonadherent after 8 weeks [18]. These findings held true across all three medications; however, varenicline was associated with more frequent reports of adverse side-effects (eg, nausea). Similarly, we found nonadherence to be an issue with varenicline in a prior clinical trial evaluating its use with three different behavioral interventions [19]. Adherence was also strongly associated with treatment outcome; good adherence (medication taken on 80% or more of days prescribed) [20] was associated with a 2-fold increase in long-term quit rates (52% vs 25% at 6 months) [12]. The most frequent reason people reported stopping their medication before the end of the treatment course was due to side-effects commonly associated with medication use and/or nicotine withdrawal. This finding is consistent with reports from a recent meta-analysis which found that varenicline adverse effects were associated with higher discontinuation of treatment and lower abstinence rates compared to alternate treatment across studies [21]. We hypothesized that helping people better

manage their nicotine withdrawal symptoms and medication side-effects could support better medication adherence and, in turn, improve cessation rates. Smartphones may provide an ideal platform for delivering this type of just-in-time intervention to smokers since most people already use one, but to our knowledge this has not been tested empirically.

The goal of this study was to assess the feasibility and acceptability of an mHealth smoking cessation program designed to provide real time, adaptively tailored advice to smokers and facilitate timely communication with clinical experts (cessation counselors and a study physician). A secondary goal was to estimate the program's effects on smoking cessation and medication adherence to inform future research planning. Interactive program content was specifically designed to improve smoker management of medication side-effects and nicotine withdrawal symptoms, promote better treatment adherence, and ultimately, enhance abstinence rates. The system also allowed us to monitor adverse events in real time so they could be addressed quickly and appropriately. This issue is particularly relevant for varenicline, which currently carries a black box warning in the United States and warrants close clinical monitoring but may be equally important to other stop-smoking medications. Findings from this novel pilot study can inform the design of future mHealth cessation programs for smokers.

Methods

Setting and Review

All research activities were conducted at the Group Health Research Institute and approved by the Group Health Institutional Review Board. The project was also approved by the University of Michigan Institutional Review Board and registered with ClinicalTrials.gov [NCT02136498]. Study recruitment began in 2014 and was completed in 2015.

Intervention Design and Development

The My Mobile Advice Program (MyMAP) intervention was developed using a multiphased, iterative process which included initial semistructured interviews with smokers (n=21) to confirm interest in the program concept; a semistructured interview with a panel of clinical experts (n=9; physicians, psychologists, and a pharmacist, all trained in nicotine dependence treatment) to confirm the feasibility of the design concept and solicit reactions to early treatment content; and iterative design sessions with smokers (n=14) to gauge reactions and develop a low fidelity mock-up of the initial prototype. Final content for the adaptively tailored advice was then developed with a team of clinical experts (physician, pharmacist, two psychologists, and several health education counselors) to ensure each message was accurate and medically appropriate. Following development of the MyMAP program, additional user testing was performed to refine the final content and design prior to study launch. Specific

program content and design features are presented in the Intervention section.

Based on feedback from smokers and developers, the final MyMAP program was designed as a mobile optimized website. The program is accessed on one's smartphone like an app, but the design allowed viewing across different mobile platforms and operating systems and provided additional privacy since participant data were stored behind a secure firewall instead of on participant phones.

Participants

Participants (n=66) were members of Group Health's integrated group practice. Group Health is a large regional health care system in Washington state. Each participant had an electronic medical record and a Group Health primary care physician and was eligible to receive medication through Group Health's mail-order pharmacy. People were eligible if they were aged 18 to 65 years, had no plans to disenroll from Group Health over the next 6 months, smoked at least 10 cigarettes a day, could read and speak English, were willing to use varenicline, were ready to quit smoking in the next month, had a smartphone which they used at least once a week, were willing to receive emails or text messages, and were eligible to receive varenicline as a covered insurance benefit. Persons were excluded if they had hearing, comprehension, or visual limitations that precluded study participation; currently used noncigarette forms of tobacco or nicotine; were actively using other stop-smoking treatments; were unwilling to use contraceptives while taking varenicline (if female); or had another medical or psychiatric exclusion for varenicline use based on self-report and physician review of their medical history.

Screening, Randomization, and Enrollment

The recruitment flow is depicted in [Figure 1](#). Likely smokers who met age and medical requirements were identified via automated health plan records and mailed a study invitation. Those who did not opt out of contact were proactively called to be screened for eligibility and complete a baseline survey (n=1280). The primary reasons for ineligibility were use of multiple forms of tobacco or e-cigarettes (n=446), not interested in varenicline (n=234), not owning a smartphone or not using it at least weekly (n=139), nonsmoker (n=118), not interested in quitting smoking (n=117), already receiving treatment to quit smoking (n=66), or did not receive care through an eligible Group Health facility (n=63). Thirty people were deemed medically inappropriate for varenicline and ineligible. Exclusions were not mutually exclusive.

If eligible based on self-report and physician review, individuals were instructed to visit the study website and log in with a

unique ID code. Those interested provided consent and set a TQD and were randomized to one of two treatment groups. Randomization was stratified by gender and prior varenicline use (yes/no). Following randomization, participants were granted access to their assigned version of MyMAP and instructed on how to use the program and download the MyMAP icon to their smartphone. Directions for logging in to the study website and downloading the MyMAP icon to one's phone were provided by phone, email, and written letter.

Intervention

Medication

All participants were provided an initial 1-month course of varenicline from the health care system's mail-order pharmacy and could order an additional 60-day supply using standard refill procedures. Standard dosing was ordered unless adjustments were recommended by the prescribing physician.

MyMAP Control Intervention

Control participants received an mHealth-delivered self-help Quit Guide which included psychoeducational content for quitting smoking. To protect confidentiality, content was accessed after securely logging in to the program. No information was stored on participant devices.

The control program content was standardized across participants and not adaptively tailored. Content was grounded in cognitive behavioral therapy and the key principles of best-practice tobacco cessation treatment as defined by the US Public Health Service Clinical Practice Guideline for nicotine dependence treatment [22]. Content was designed to lead smokers through a 5-step guide for how to quit smoking ([Figure 2](#)):

- Step 1: Make a quit plan
- Step 2: Use your medicine
- Step 3: Prepare yourself
- Step 4: Learn to be a nonsmoker again
- Step 5: What to do if you slip and smoke

Each step included detailed self-help instructions. Step 1 included how to use the MyMAP program, the importance of having a quit plan, and how to create a quit plan. Step 2 included information about how to take varenicline, common medication side-effects, and how to manage these. Step 3 included an overview of common nicotine withdrawal symptoms and strategies for managing these. Step 4 focused on strategies for managing cravings and craving triggers, and Step 5 provided tips for getting back on track if one slipped and smoked.

Figure 1. Enrollment flow.

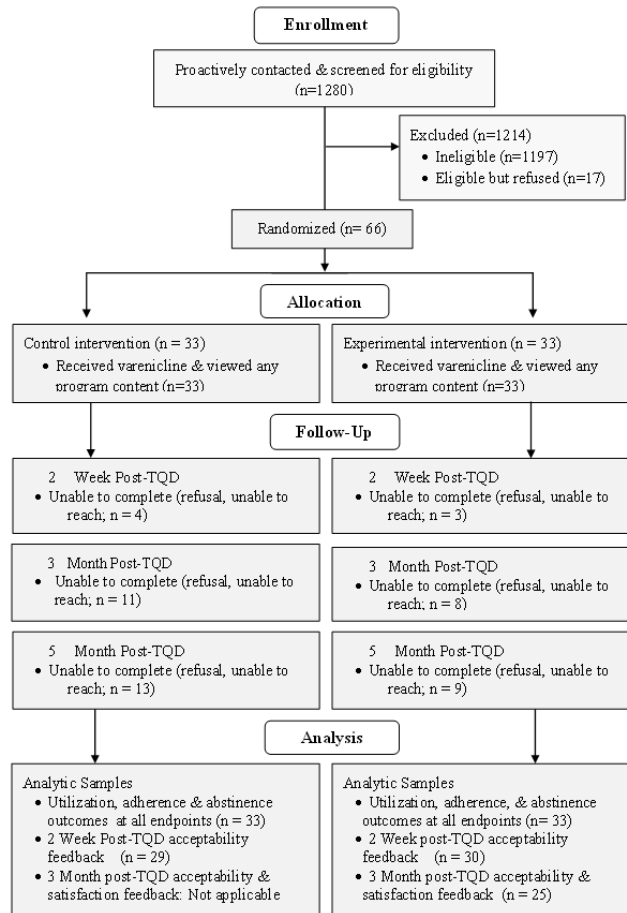


Figure 2. Self-help quit guide.



MyMAP Experimental Intervention

Participants in the experimental arm received the same self-help Quit Guide as in the control group with some minor additional content addressing how to manage withdrawal symptoms and tips for improving medication adherence, the focuses of the intervention. In addition, the experimental program contained two unique, interactive features: (1) on-demand, adaptively tailored advice for managing common nicotine withdrawal symptoms (eg, cravings, cough, insomnia) and medication side-effects (eg, nausea, rash) and (2) a secure messaging system.

Experimental participants could access the adaptive advice at any time by completing a brief check-in survey to report current symptoms and side-effects. Participants then received a personalized report with their advice (Figure 3). Reports also included motivational encouragement tailored to each person’s current level of motivation for quitting and confidence in quitting or staying quit. In addition to initiating a check-in survey in response to current symptoms, participants were periodically proactively prompted by text or email (based on user preference) to complete a check-in survey. Proactive check-in prompts initially occurred weekly but tapered down to every two weeks over the course of the 5-month study period.

Advice was tailored based on the duration, intensity, and whether the intensity was judged to be improving or not for each symptom or side-effect. Multiple scripted messages were developed for each possible combination of symptoms and side-effects, intensity, and duration to ensure novel responses each time. Each message also contained links to where to find additional advice within the MyMAP self-help Quit Guide.

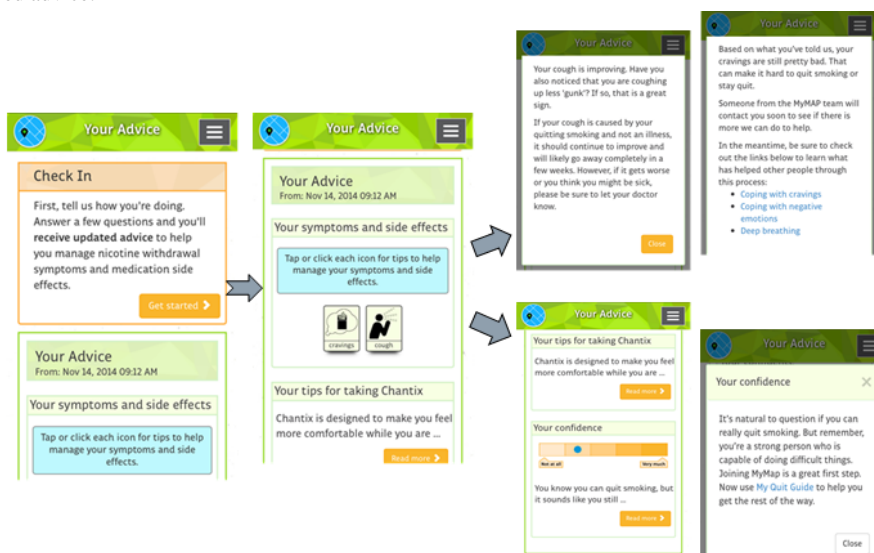
If participants reported symptoms or side-effects which were nonserious but ongoing and bothersome, study clinicians were

alerted to follow up with the participant for additional assessment and intervention. This follow-up was conducted via a secure text-messaging system built into the MyMAP program. The secure message functionality was patterned after what is commonly used to allow patient-provider communication via electronic health record portals, in which email alerts notify users to log in to a secure website to view and respond to messages. In the MyMAP system, clinicians could log in to a back-end administrative dashboard to view and send messages to participants. Participants would then receive an email alert that a message was available. After logging in to the MyMAP program, they could retrieve and respond to the message, which would send an email alert to the study clinicians to log in and retrieve the response. In this way, all communication was protected behind a firewall. No personal health information was saved on participant phones or included in email.

If potentially serious health events were reported during a check-in survey (eg, significant changes in mood, suicidal ideation, chest pain), the automated advice would instruct participants to discontinue their medication and seek immediate medical attention from their physician or the health care system’s consulting nurse. Alerts would also go to study clinicians in real time with advice to follow up with the individual within 24 hours. Study clinicians in this pilot trial included a master’s trained cessation counselor, clinical psychologist, and physician. Issues were triaged by the counselor to the psychologist or physician as appropriate based on the reported adverse events.

In addition to responding to secure messages from the study clinicians, participants could initiate a secure message when they had a question or concern. Participants were encouraged to use this messaging when they needed additional support.

Figure 3. MyMAP tailored advice.



Assessment and Outcome Measures

Participants completed a baseline survey and three phone-based follow-up surveys: 2 weeks after their TQD, which correlated with 3 weeks following their planned varenicline start date; 3 months post-TQD; and 5 months post-TQD. Participants

received \$20 for completing each survey. Baseline assessment included demographics, smoking history, nicotine dependence assessed via the Fagerstrom Test of Nicotine Dependence (FTND) [23], and prior use of varenicline (yes/no). Follow-up surveys assessed smoking status, recent adverse events (nicotine

withdrawal symptoms and medication side-effects), and varenicline use.

Study outcomes included MyMAP program utilization and satisfaction, 7-day point prevalence smoking abstinence (PPA), and varenicline use. Time-stamped, automated event data were analyzed to assess use of the MyMAP program including number of log-in visits, duration of time spent viewing content, Quit Guide content viewed, number of secure messages sent, and use of the check-in surveys and adaptively tailored advice.

At 2 weeks post-TQD follow-up, all participants rated the helpfulness of their assigned MyMAP program on a 5-point Likert scale from not at all to extremely helpful. Participants also provided open-ended feedback about what they liked or disliked about their assigned MyMAP program. At 3-month follow-up, experimental participants but not controls provided additional ratings for the helpfulness of MyMAP and their satisfaction with specific aspects of it.

PPA was defined as a self-report of no smoking, even a puff, in the past 7 days. Varenicline use was assessed using automated pharmacy fill data and self-reported days of use. Final duration of use was defined as the total days of varenicline dispensed during the study period; however, if a participant self-reported taking the medication for fewer days than were dispensed, total duration of use was limited to their self-report.

Analysis

Descriptive statistics were used to summarize participant characteristics, MyMAP program utilization, and satisfaction ratings. Wilcoxon rank-sum tests were used to assess group differences for continuous measures of program utilization and adherence, including the total number of visits to the

intervention website, cumulative duration of site use, and mean days of medication use. Fisher's exact tests were used to compare intervention groups on the proportion who discontinued varenicline early for any reason (fewer than 84 days of use) and abstinence rates at each follow-up. Logistic regression models were used to estimate both unadjusted and adjusted odds ratios (ORs) of each binary outcome in the experimental group relative to the control group. Adjusted models included age and baseline nicotine dependence. Smoking abstinence was assessed using the intent-to-treat principle, with participants analyzed based on assigned randomization group regardless of use of any intervention materials or medication. For the primary analysis, to be consistent with the Russell Standard [24] and the a priori defined outcomes, nonresponders were classified as smokers and included in the analysis. Exploratory analyses also examined abstinence rates among responders only. Analyses were conducted using Stata/MP 13.1 statistical software (StataCorp LP).

Results

Participants

Participant characteristics are presented in Table 1. Most participants were middle-aged, white (61/66, 92%), female (37/66, 56%), and employed (58/66, 88%). Less than one-third had a college degree (18/66, 27%) and the majority had a household income under \$80,000 per year (38/66, 58%). Participants smoked an average of 18 (standard deviation [SD] 7.2) cigarettes per day. Half (33/66) were characterized as having medium to very high levels of nicotine dependence on the FTND. By design, an equal number of participants in each arm had used varenicline previously.

Table 1. Baseline characteristics.

	Control n=33	Experimental n=33	Overall n=66
Age, years, mean (SD)	50.6 (8.9)	48.4 (8.4)	49.5 (8.7)
Cigarettes smoked per day, mean (SD)	16.9 (4.5)	18.5 (9.1)	17.7 (7.2)
Female, n (%)	18 (55)	19 (58)	37 (56)
White, n (%)	31 (94)	30 (91)	61 (92)
Married/living with partner, n (%)	18 (55)	23 (70)	41 (62)
College degree or higher, n (%)	8 (24)	10 (30)	18 (27)
Employed, n (%)	30 (91)	28 (85)	58 (88)
Household income, n (%)			
<\$40,000	9 (27)	5 (16)	14 (22)
\$40,000-\$60,000	7 (21)	8 (25)	15 (23)
\$60,000-\$80,000	6 (18)	3 (9)	9 (14)
>\$80,000	11 (33)	16 (50)	27 (42)
Nicotine dependence (FTND) score, n (%)			
Very low	6 (18)	7 (21)	13 (20)
Low	10 (30)	10 (30)	20 (30)
Medium	11 (33)	4 (12)	15 (23)
High	4 (12)	11 (33)	15 (23)
Very high	2 (6)	1 (3)	3 (5)
Prior use of varenicline (yes), n (%)	14 (42)	14 (42)	28 (42)

MyMap Program Utilization

Overall Use

Experimental participants logged in to their assigned mHealth program on more occasions than did control participants (mean 10.6 [SD 7.0] log-ins vs 2.7 [SD 2.0] log-ins, $P<.001$) and spent more cumulative time viewing program content (mean

cumulative minutes = 52.9 [SD 35.1] vs 20.3 [SD 20.6], $P<.001$.) (see [Table 2](#)).

Self-Help Quit Guide

An equal number of participants in both arms viewed the self-help Quit Guide during the 5-month study period. See [Table 2](#) for additional details on the proportion of people in each arm who viewed each of the five content sections.

Table 2. Program utilization by randomization arm.

	Control n=33	Experimental n=33	<i>P</i> value
Overall program use			
Number of log-ins, mean (SD)	2.7 (2.0)	10.6 (7.0)	<.001
Cumulative minutes viewing content, mean (SD)	20.3 (20.6)	52.9 (35.1)	<.001
Quit Guide			
Viewed any self-help Quit Guide, n (%)	27 (87)	27 (87)	>.99
Viewed Step 1, n (%)	21 (64)	25 (76)	.42
Viewed Step 2, n (%)	14 (42)	14 (42)	>.99
Viewed Step 3, n (%)	11 (33)	9 (27)	.79
Viewed Step 4, n (%)	13 (39)	16 (48)	.62
Viewed Step 5, n (%)	15 (45)	13 (39)	.80

Adaptively Tailored Advice

Overall, 88% (29/33) of experimental participants completed at least one check-in survey (median 4) during the 5-month study period. In total, 168 check-in surveys were completed, resulting in adaptively tailored advice for managing 258 current medication side-effects or nicotine withdrawal symptoms. Of the 168 check-in surveys completed, 11 were self-initiated and the remainder were in response to a reminder prompt. More than one-quarter of the check-ins (43/168) reported no adverse withdrawal symptoms or side-effects, 53 (32%) reported 1, 38 (23%) reported 2, and 34 (20%) reported 3 or more. The mean number of symptoms and/or side-effects endorsed per check-in was 1.5 (SD 1.5). The most commonly reported symptoms and side-effects were craving to smoke (78 reports), unusual dreams (30 reports), gas (22 reports), headaches (22 reports), changes in appetite (21 reports), and nausea (16 reports). In total, 131 symptoms and side-effects were rated as mild, 122 were rated as moderate, and 5 were rated as severe. Ratings are based on participant subjective experience and do not necessarily reflect the medical seriousness of events. For example, the 5 events characterized as severe were cravings to smoke (3 reports), constipation (1 report), and irritability/anger (1 report).

Secure Messaging

Among the 33 experimental participants, 15 used the secure messaging feature and exchanged a total of 130 messages with study clinicians during the 5-month study period. Participants initiated 22 messages with questions or concerns; clinicians initiated 44 messages in response to secure message alerts generated by check-in surveys. Participants responded to clinicians 40 times after queries and comments and 22 times after advice. Two messages were generated by study clinicians to follow-up on medical issues or changes to medication doses. Common themes for message threads were nicotine withdrawal symptoms and medication side-effects, updates on changed TQDs, and questions on how to take and refill stop-smoking medications.

Acceptability Feedback and Satisfaction Ratings

At 2-week follow-up, 63% (17/27) of respondents in the experimental group and 35% (8/23) of control respondents

indicated they had received advice on managing their medication use or quitting smoking from the MyMAP program. Participants in both arms rated the MyMAP program as helpful (mean 3 [SD 1], both arms), although control participants were more critical of their program content than experimental participants and wanted more interactivity.

I think it's good, but is there anything more to [the program] than helpful tips and ideas?

It needs to be more interactive.

The program is not very interactive . . . It's just a digital pamphlet..

Conversely, experimental participants generally liked the interactive features of their program version.

I liked the check-in where you complete the minisurvey and the program comes back with things like if you are having nausea then do this. This was helpful and I didn't have to look things up.

I explored the icons regarding my side-effects and followed the advice. It was helpful.

The routine check-in kept me on track.

Other experimental participants liked the convenience and support received.

I like the accessibility from my phone

The advice actually does work

It was nicer than having to talk with someone

I like that you get a response from the study staff or doctor when something arises.

Some comments were more critical ("I dislike that it is all computer generated") or offered constructive feedback such as adding a journal, calendar, or ability to track one's symptoms across days. Experimental participant acceptability ratings at 3-month follow-up were also positive (see [Table 3](#)). Most of these participants thought the program could help people quit smoking (22/24, 92%) and consistently take their stop-smoking medication (17/22, 97%), and most would recommend the program to others (20/23, 87%).

Table 3. Experimental participant program (n=25) acceptability ratings based on a 5-point Likert scale (1 for “not at all” and 5 for “extremely”) at 3-month follow-up.

	mean (SD)
How helpful was . . .	
Your varenicline (Chantix) prescription?	4.4 (1.1)
Feedback you received from the MyMAP staff?	4.1 (1.4)
Advice you received for how to manage your nicotine withdrawal symptoms and medication side-effects?	3.8 (1.3)
MyMAP Quit Guide and materials?	3.7 (1.3)
Motivational encouragement you received to help you quit smoking or stay quit?	3.1 (1.5)
How satisfied were you with . . .	
Confidentiality of the MyMAP program?	4.6 (1.0)
Ease of using the MyMAP program?	4.6 (0.7)
Convenience of the MyMAP program?	4.5 (0.9)
Information and support you received about taking varenicline (Chantix)?	4.4 (1.1)
Responsiveness of the MyMAP team to your needs?	4.4 (1.2)
Reminders you received to log in to the MyMAP program?	4.3 (1.2)
Content of the MyMAP program ?	3.8 (1.1)
Personalized advice you received for managing your symptoms and side-effects?	3.6 (1.4)

Medication Adherence

All control participants reported taking varenicline compared with 94% (31/33) of experimental participants. In contrast, 67% (22/33) of experimental participants reported discontinuing their varenicline before the end of their treatment course compared to 76% (25/33) of controls ($P=.29$). Of these, 10 of 33 experimental participants (30%) and 10 of 33 controls (30%) reported they stopped their medication due to side-effects. Overall, experimental participants took varenicline an average of 46 (SD 31.9) days compared to 39 (SD 28.9, $P=.49$) days among controls.

Smoking Cessation

Abstinence rates and odds ratios are presented in [Table 4](#). Long-term abstinence rates were 36% (12/33) among experimental participants versus 24% (8/33) among controls ($P=.42$). Adjustment for age and baseline nicotine dependence did not meaningfully alter these results (OR 1.87 [0.62-5.66], $P=.27$). When data were analyzed without imputing missing cases as smokers, abstinence rates were 50% (12/24) among experimental participants abstinent versus 40% (8/20) among controls, unadjusted OR 1.50 [0.45-4.98], $P=.51$.

Table 4. Self-reported 7-day point prevalence abstinence rates by follow-up with missing values imputed as smokers (n=33).

	Total n (%)	Control n (%)	Experimental n (%)	OR (95% CI)
2-week post-TQD 7-day PPA (yes)	26 (39)	16 (49)	10 (30)	0.46 (0.17-1.27)
3-month post-TQD 7-day PPA (yes)	23 (34)	11 (33)	12 (36)	1.14 (0.41-3.15)
5-month post-TQD 7 day PPA (yes)	20 (30)	8 (24)	12 (36)	1.79 (0.61-5.19)

Discussion

Principal Findings

The results of this study confirm that an mHealth smoking intervention which combines standard self-help content, adaptively tailored advice for managing medication side-effects and nicotine withdrawal symptoms, and supplemental support from qualified clinicians using a secure messaging system is feasible and acceptable to smokers. Smokers in both arms had similar overall use of the self-help Quit Guide, but experimental participants actively used the additional support provided via the tailored support and secure messaging features. As a result, experimental participants logged in and accessed treatment more

often than control participants (10.6 vs 2.7 times). To put this level of use in context, in an examination of tobacco quitline services across the United States, most callers completed an average of 2 to 2.5 counseling calls and those using an online cessation program through their quitline logged in an average of 1 to 2 times [25]. Thus, program use in the control arm was comparable to the level of treatment use observed with other public health smoking cessation interventions, and treatment use in the experimental arm exceeded this by 4-fold.

The MyMAP system also appears to be a feasible way to monitor adverse events and provide timely advice using both immediate automated messaging and follow-up by a clinician. No medically serious adverse events were reported via MyMAP,

but several subjectively severe events were reported (eg, severe cravings) which could have jeopardized participant ability to quit or remain abstinent and warranted timely intervention. Many mild to moderate events were noted which could also undermine quit attempts if not adequately addressed.

MyMAP was optimized for use with varenicline. Although varenicline carries a black box warning from the FDA, emerging evidence suggests it is safer than originally thought [26-33]. However, serious medical events are possible, and a system like MyMAP could prove particularly useful with patients taking this medication. Similar monitoring could be useful with bupropion (which also carries a black box warning) or nicotine replacement therapy. Furthermore, since suboptimal adherence is a common problem with all three FDA-approved cessation medications [8], the MyMAP system could be used to better support adherence and enable medication switches as appropriate based on smoker medication tolerance.

It is important to note that the study was not powered to detect statistically significant differences in behavioral outcomes of interest (smoking abstinence or medication adherence) and, as a result, no conclusions can be drawn about the effectiveness of the intervention. However, the observed behavioral outcomes further support the need for a larger effectiveness trial of the MyMAP program.

Strengths

Study strengths include a rigorous trial design which only varied the two experimental features of interest (adaptively tailored advice and secure messaging with a cessation counselor), allowing group differences to be attributed to these features. Other strengths include evaluation of the program in a real-world setting and use of automated data to monitor use of the MyMAP program.

Limitations

The chief limitation of this pilot study is the small sample size, which prevents any definitive conclusions about the efficacy of the MyMAP intervention.

Another study limitation is our reliance on automated pharmacy data, adjusted based on self-report, to assess total days of medication use. This strategy is less inherently biased than relying on self-report or pharmacy fill data alone, but it could still over- or underestimate use in any given case. However, there is no reason to expect a systematic bias affecting either arm. Similarly, our reliance on self-reported smoking status is less preferable than if we had biochemically confirmed abstinence at each follow-up, but participants were geographically dispersed across Washington state making in-person confirmation impossible. However, it has been suggested that such biochemical confirmation may be unnecessary in studies which do not involve face-to-face contact

and have low demand characteristics for misreporting outcomes [34].

Finally, the requirement that participants had to log in to a secure mobile website to access content can be viewed as both a strength and a limitation of the intervention design. The design ensured the security of participant information, but logging in also creates a potential barrier to care and could deter program use and limit its ultimate effectiveness. We believe the benefits of this design outweigh its downside, but it is important to acknowledge this potential design limitation and evaluate it further in a larger trial.

Comparison With Prior Work

Relatively little is known about the effectiveness of mHealth interventions for smoking cessation. While preliminary pilot studies of cessation apps using small samples or short follow-up periods [35-39] and protocols of trials in progress [40-44] have been published, no large scale randomized effectiveness trials have, although several are in progress. Despite this, hundreds of cessation smartphone apps are commercially available. A recent review concluded that most of these programs are not particularly “smart” [45]. That is, their designs are largely simplistic and do not take advantage of the technological capacities of smartphones to do things like adaptively tailor content or allow 2-way interactions between users or between users and clinicians. In fact, most existing commercial cessation apps do not even include best practice treatment recommendations; only a handful recommend use of approved stop-smoking medications [22]. To our knowledge, MyMAP is the first mHealth program to explicitly target cessation medication adherence as an intervention goal. Kreb et al [46] recently conducted formative research to inform the design of a text messaging intervention to promote varenicline adherence, but to date no published studies have used an mHealth intervention to improve varenicline adherence. In short, the approach used in MyMAP is unique.

Conclusions

The MyMAP intervention was found to be feasible, acceptable, and potentially effective as a means for supporting varenicline use and smoking cessation. This model could easily be expanded to support adherence to other stop-smoking medications like nicotine replacement therapy and bupropion. In addition, the intervention framework used in this trial—which combines standard self-help content, adaptively tailored just-in-time advice, and secure message access to clinicians when needed—is a significant advance over the functionality of current commercially available cessation apps and may well represent the next generation of mHealth cessation programs. Future research is warranted to evaluate the efficacy of this intervention.

Acknowledgments

Funding for this project was provided by the Group Health Research Institute and the National Institute for Drug Abuse (R34DA034612; J. McClure, principal investigator). The authors are grateful to the volunteer research participants; Ella Thompson, Barb Carste, and Jackie Saint-Johnson for their assistance coordinating the study; Mary Shea for her help recruiting participants,

managing incentives, and other miscellaneous tasks; June BlueSpruce for her role as a study clinician; the Group Health Survey Research Program for collecting follow-up data; Malia Oliver for setting up study databases and assisting with the analyses; the Group Health Pharmacy for providing medication to study participants; and Annie Shaffer for assistance preparing the final publication. Thanks also to Mike Nowak, Emma Steppe, Jocelyn Gotlib, Kate Barr, and Katrina Lanahan at the University of Michigan's Center for Health Communications Research for their assistance designing and implementing the MyMAP program.

Conflicts of Interest

None declared.

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Abbreviations

FTND: Fagerstrom Test of Nicotine Dependence

MyMAP: My Mobile Advice Program

OR: odds ratio

PPA: point prevalence abstinence

SD: standard deviation

TQD: target quit date

Edited by G Eysenbach; submitted 25.05.16; peer-reviewed by R Vilardaga, J Ferron, G Wadley; comments to author 13.06.16; revised version received 27.06.16; accepted 20.07.16; published 03.08.16.

Please cite as:

McClure JB, Anderson ML, Bradley K, An LC, Catz SL

Evaluating an Adaptive and Interactive mHealth Smoking Cessation and Medication Adherence Program: A Randomized Pilot Feasibility Study

JMIR Mhealth Uhealth 2016;4(3):e94

URL: <http://mhealth.jmir.org/2016/3/e94/>

doi: [10.2196/mhealth.6002](https://doi.org/10.2196/mhealth.6002)

PMID: [27489247](https://pubmed.ncbi.nlm.nih.gov/27489247/)

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Original Paper

Prioritizing the mHealth Design Space: A Mixed-Methods Analysis of Smokers' Perspectives

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Abstract

Background: Smoking remains the leading cause of preventable disease and death in the United States. Therefore, researchers are constantly exploring new ways to promote smoking cessation. Mobile health (mHealth) technologies could be effective cessation tools. Despite the availability of commercial quit-smoking apps, little research to date has examined smokers' preferred treatment intervention components (ie, design features). Honoring these preferences is important for designing programs that are appealing to smokers and may be more likely to be adopted and used.

Objective: The aim of this study was to understand smokers' preferred design features of mHealth quit-smoking tools.

Methods: We used a mixed-methods approach consisting of focus groups and written surveys to understand the design preferences of adult smokers who were interested in quitting smoking (N=40). Focus groups were stratified by age to allow differing perspectives to emerge between older (>40 years) and younger (<40 years) participants. Focus group discussion included a "blue-sky" brainstorming exercise followed by participant reactions to contrasting design options for communicating with smokers, providing social support, and incentivizing program use. Participants rated the importance of preselected design features on an exit survey. Qualitative analyses examined emergent discussion themes and quantitative analyses compared feature ratings to determine which were perceived as most important.

Results: Participants preferred a highly personalized and adaptive mHealth experience. Their ideal mHealth quit-smoking tool would allow personalized tracking of their progress, adaptively tailored feedback, and real-time peer support to help manage smoking cravings. Based on qualitative analysis of focus group discussion, participants preferred pull messages (ie, delivered upon request) over push messages (ie, sent automatically) and preferred interaction with other smokers through closed social networks. Preferences for entertaining games or other rewarding incentives to encourage program use differed by age group. Based on quantitative analysis of surveys, participants rated the importance of select design features significantly differently ($P<.001$). Design features rated as most important included personalized content, the ability to track one's progress, and features designed to help manage nicotine withdrawal and medication side effects. Design features rated least important were quit-smoking videos and posting on social media. Communicating with stop-smoking experts was rated more important than communicating with family and friends about quitting ($P=.03$). Perceived importance of various design features varied by age, experience with technology, and frequency of smoking.

Conclusions: Future mHealth cessation aids should be designed with an understanding of smokers' needs and preferences for these tools. Doing so does not guarantee treatment effectiveness, but balancing user preferences with best-practice treatment considerations could enhance program adoption and improve treatment outcomes. Grounded in the perspectives of smokers, we identify several design considerations, which should be prioritized when designing future mHealth cessation tools and which warrant additional empirical validation.

(JMIR Mhealth Uhealth 2016;4(3):e95) doi:[10.2196/mhealth.5742](https://doi.org/10.2196/mhealth.5742)

KEYWORDS

mobile health; human-centered design; human-computer interaction; smartphone; smoking cessation; telemedicine; software design

Introduction

Smoking is the leading preventable cause of disease and death in the United States [1] and kills 6 million people worldwide each year [2]. Despite this, an estimated 40 million people in the United States continue to smoke [3]. Most make a quit attempt each year [4], but do not use recommended behavioral or pharmacological treatments [5], preferring instead to quit on their own [6]. However, unaided cessation attempts are generally not effective [7]. Thus, there is an important need to create new nicotine dependence treatment programs and behavior change aids that are grounded in best-practice treatment recommendations, but are also acceptable and engaging to smokers. Well-designed tools that offer attractive intervention components (ie, design features) could enhance program utilization and improve treatment efficacy.

Advances in mobile computing offer the potential to deliver smoking cessation interventions that are both effective and engaging, in part because treatment can be delivered when and where it is needed. Research shows that technology-based interventions can effectively promote cessation [8-12], and can include a wide array of mobile health (mHealth) options ranging from wearable devices to sensors and mobile phone apps. Yet, beyond traditional text messaging, we know little about which mHealth intervention strategies are most promising. For example, apps are attractive to many smokers [13-15], but to date no large-scale randomized effectiveness trials of cessation apps have been published, only preliminary pilot studies with small samples or short follow-up periods [16-20] and protocols of trials in progress [21-24]. Among commercially available cessation apps, most fail to adhere to treatment guidelines [13-14], are not evidence based [15], and do not include design features that could most effectively support sustained behavior change [25], such as a personally tailored experience preferred by many smokers [26] and recommended by treatment experts [27].

It is too early to determine if mHealth smoking cessation apps or other tools will meet their potential. But it is clear that they will not if these programs are not designed with features that attract and engage smokers. In prior work, we showed that smokers and treatment experts do not always agree on design features that are most important [27]. In this paper, we advance the field with an in-depth characterization of smokers' preferences and delineate key considerations that should be prioritized when designing mHealth cessation tools. Before describing our mixed-methods study, we summarize related work that motivates our focus on designing mHealth from the perspective of smokers.

Approaching Design of mHealth Quit-Smoking Tools From the Perspective of Smokers

In the absence of empirical evidence to inform optimal mHealth program design, it is critical that clinical investigators and software developers consider the needs and preferences of

smokers. This alone will not ensure treatment effectiveness, but it is an important consideration for treatment engagement, and engagement is necessary for efficacy. Surprisingly little published work has engaged smokers in the design process [28-30], yet important lessons can be learned from those who have. For example, Bock and colleagues [28] engaged smokers in the design of a text-based cessation program and learned smokers wanted a broader program that included social networking and control over the timing and delivery of text messages. Similarly, Ploderer and colleagues [30] field-tested a mobile app and discovered unanticipated strategies smokers use to cope with cravings and leverage peer support. Similarly, Paay and colleagues [29] engaged smokers in focus groups and design workshops and gained insight for tailoring smoking cessation apps to accommodate individual differences among smokers.

Other studies have not engaged smokers in the design process, but gained important information about smokers' needs and preferences from observing their adoption and use of mHealth tools [31]. For instance, Heffner and colleagues [32] observed smokers' use of a mobile quit-smoking app over 8 weeks and discovered that the most popular features were not necessarily associated with quitting. This underscores an important lesson—user preference does not guarantee treatment outcome. This is why it is important to ground design considerations in solid treatment theory and empirical evidence, but user preferences can offer important insights about how best to do this.

Knowledge Gaps in Design of mHealth Quit-Smoking Tools

Solicitation of user preferences may be most effective when guided by existing knowledge gaps in the literature on messaging, social support, and incentivizing use. For example, it is known that text message reminders may be effective cessation aids [9,10] and may be useful for delivering tailored motivational messages [33,34], quit advice based on expert recommendations [10,35], and support on demand. However, text reminders about quitting smoking may also prompt people to smoke [29], so some smokers may not be receptive to this messaging. Some smokers prefer to control the timing of automated messages [28], whereas others prefer messages sent at unexpected times [35]. Smokers' relative preferences for push messages received automatically versus pull messages delivered upon request has been largely unexplored [31], but is an important issue that warrants further exploration.

Similarly, social support is an important feature in smoking cessation programs [7,36]. Several technology-based strategies can be found in the literature, including mobile quit buddies [9], role model videos delivered via text message links [37], or public pledges posted on social media [15,38]. Research highlights unresolved tensions between the diffusion of quit-smoking information and experiences through online social networks [39-42] versus smokers' desire to maintain anonymity

[29,43]. These gaps also warrant further investigation to better understand how smokers wish to use mHealth technologies for social support during the quit process.

Finally, insight into smokers' preferences for strategies that can make mHealth cessation aids rewarding and engaging can fill gaps in knowledge about how to best incentivize program use. Gamification is the use of game design elements in nongame contexts [44], such as health [45]. Some mHealth interventions pair game features with desired behaviors [46], such as encouraging physical activity by growing a digital garden as fitness goals are attained [47] or scoring points on familiar games (eg, hangman, Sudoku) for accurately estimating nutritional value of foods [48]. Gamification is well suited for motivational aspects of behavior change [49-51]. As a smoking cessation aid, game mechanics (eg, points, badges, leaderboards) have been used to encourage the use of educational "quit guides" [38]. Such game-based incentives can be integrated and viewable to others via social media [24,38]. However, others have advocated offering smokers more personally meaningful rewards, such as money [29]. Although prior work has elicited opinions of experts [52], smokers' relative preferences for the use gamification features have been largely unexplored to date despite enthusiasm for their use by developers.

In summary, user-centered studies that engage smokers have proven valuable to uncovering important design considerations from the user's perspective [28-30]. Given gaps in our understanding of smokers' preferences for the range of possible mHealth support, further research is warranted to characterize their design priorities. In this study, we employed user-centered mixed methods to characterize the design preferences of smokers. Given the considerable opportunities to advance quit-smoking tools with mHealth innovations, such engagement of smokers in the design process is critical for identifying the most promising design features for future mHealth cessation tools.

Methods

To characterize smokers' design feature preferences for mHealth quit-smoking tools, we engaged smokers in a series of six focus groups using mixed methods, including group discussion and individual surveys. Our goals were to (1) qualitatively explore smokers' "blue-sky" thinking (ie, brainstorming) about ideal mHealth design features; (2) elicit qualitative preferences among specific messaging, social support, and gamification features; and (3) quantitatively assess the importance of a selected list of features identified by treatment experts. Because preferences could differ by age, we completed three focus groups with younger adults aged 18 to 39 years and three focus groups with older adults aged 40 years and older. All data were collected in June of 2015 at Group Health Research Institute (GHRI). Study procedures were approved by the GHRI Institutional Review Board.

Recruitment

We recruited smokers in the Seattle area via online ads (eg, Craigslist), posted flyers, and invitation letters mailed to likely smokers who were members of Group Health Cooperative (a

nonprofit health care system in Washington State). Interested smokers were invited to contact study staff to learn more and be screened for eligibility. Individuals were eligible if they were at least 18 years old, a current smoker interested in quitting, could read and write in English, and owned a mobile phone or tablet computer which they used to access the Internet. We purposively recruited by age for three groups younger than 40 years of age and three groups 40 years of age and older.

Procedures

Each focus group lasted approximately 2 hours and was moderated by the lead author (AH) with support and note taking by a coauthor (JB). We began each group with a paper survey to collect participant characteristics, including demographics (ie, race, ethnicity, education, employment status, income), smoking status (ie, cigarettes smoked in past 30 days, smoking frequency, plans to quit), and experience with technology (ie, some experience, intermediate, very experienced, expert). Then, participants engaged in a two-part group discussion. The first part focused on blue-sky brainstorming about the ideal design of future mHealth quit-smoking tools (part I). In the second part (part II), participants were asked to react to contrasting design options for mHealth messaging, social support, and incentivizing program use. At the end of the session, after participants had considered a range of design options for quit-smoking tools, they completed an exit survey rating their perceived importance of various mHealth features. Group discussion was audio recorded and transcribed for analysis, and field notes were written after each group meeting. Attendees received US \$50 for their participation.

Part I: Blue-Sky Brainstorming

Inspired by the future workshop method [53], our goal was to generate visions for the ideal design of mHealth tools with desirable features for quitting smoking. Participants were asked: "If you were to design a mobile health tool to help you stop smoking, how would you want it to work? In a perfect world with no technical barriers, what features would you want such a tool to have?" We encouraged participants to consider a range of mobile devices (eg, mobile phones, tablets, wearables, sensors) and to share design ideas about content, interaction, and communication features in an open and nonjudgmental manner. We also encouraged participants to draw upon challenges in their prior experience with mHealth tools or attempts to quit smoking as they envisioned future designs that can address those barriers.

Part II: Preferences for Specific mHealth Features

We presented participants with two contrasting options for each of three design features: messaging, social support, and gamification. We selected these design features because they represent gaps in the literature. Messaging options for communicating with smokers were push messages that show up automatically on your device (eg, notifications, alerts, reminders) versus pull messages delivered only upon your request. Social support options were prerecorded peer testimonials delivered in the form of stories (eg, blogs or vlogs to passively view) about what helped others to quit smoking versus interactive social networking to actively interact with

others and share information about yourself. Gamification options to promote use were entertaining games that are fun and distracting versus incentives that provide rewards, such as earning badges. We asked participants to discuss which option they preferred for each feature.

Exit Survey

At the close of the session, each participant completed an exit survey to rate the importance of 21 hypothetical app design features. Features were categorized into four domains: cost and reputation, privacy and security, content and user experience, and communication with others. Individual features were chosen to (1) reflect technology-based strategies for implementing best-practice treatment recommendations (eg, addressing use of pharmacotherapy, providing social support, and offering cognitive behavioral-based content), (2) reflect ways to leverage other mobile phone capacities to make these programs more engaging (eg, gaming), (3) assess perceived limitations of mHealth tools (eg, security and privacy), or (4) understand other user preferences which may inform future program development (eg, cost, reputation). Each feature was rated using a 4-point Likert scale (1=not at all important, 2=somewhat important, 3=very important, and 4=extremely important). Participants were asked to rate the importance of each feature if they were considering downloading or using a smoking cessation app.

Analysis

We conducted a mixed-methods analysis of qualitative focus group transcripts and quantitative surveys. Following each focus group session, the two facilitators (AH, JB) met to summarize key themes that emerged. After completion of all six groups, the facilitators (who are both trained in qualitative interviewing and coding methods) reviewed field notes and applied thematic analysis [54] to transcripts to identify qualitative themes regarding participants' blue-sky design ideas and preferences for messaging, social support, and gamification features of mHealth quit-smoking tools. Each facilitator summarized themes in transcripts, which were then reviewed by the second facilitator for accuracy. Any discrepancies were resolved during meetings

between the coders. An initial synthesis of themes depicting the data were reviewed with study team members. This coding scheme was applied to individual transcripts by AH capturing representative quotes for the themes. Themes were compared across the six focus groups and between age groups.

We summarized participant surveys with descriptive statistics. We compared importance ratings among all design features with Friedman chi-square tests (χ^2) and paired comparisons within domains with Wilcoxon signed rank tests (W). We compared ratings between younger and older participants and between participants grouped by experience with technology and smoking frequency with Mann-Whitney *U* tests (*U*). We adjusted *P* values for post hoc comparisons using a Bonferroni correction. We computed statistics in R (version 2.15.1) [55].

Results

Participants

Of the 119 respondents in total, 25 screened ineligible, one refused, and 38 could not be recontacted for eligibility screening. In all, 56 respondents were eligible and scheduled to attend a focus group stratified by age (<40 vs \geq 40 years old); 16 failed to attend, leaving a final sample of 40 participants (Table 1). The younger focus groups included a total of 22 participants (P1-P22) and the older focus groups included a total of 18 participants (P23-P40). Participants were primarily white (63%, 25/40), non-Hispanic/Latino (90%, 36/40), and had less than a college degree (65%, 26/40). On average, participants smoked 12 cigarettes per day. Compared with younger participants, a higher proportion of older participants were heavy smokers. More than half of participants reported being "very experienced" with computers or better (58%, 23/40) and approximately half had health apps on their mobile phones (48%, 19/40). Examples of apps that emerged during group discussion focused largely on diet and fitness (eg, MyFitnessPal). Only five participants (13%) had downloaded a quit-smoking app before. Of the remaining 35 participants, the majority (83%, 29/35) reported they would consider downloading one.

Table 1. Participant characteristics by age group.

Characteristic	All (N=40)	Younger (<40 years) (n=22)	Older (≥40 years) (n=18)
Age (years)			
Mean (SD)	38 (12)	29 (5)	50 (5)
Range	20-58	20-39	40-58
Gender (female), n(%)	20 (50)	13 (59)	7 (39)
Ethnicity, n (%)			
Hispanic/Latino	2 (5)	1 (5)	1 (5)
Non-Hispanic/Latino	36 (90)	20 (90)	16 (90)
Decline to state	2 (5)	1 (5)	1 (5)
Race, n (%)			
White	25 (63)	15 (68)	10 (56)
Black/African American	10 (25)	2 (9)	8 (44)
Other/Multiple races	4 (10)	4 (18)	—
Decline to state	1 (3)	1 (5)	—
Education, n(%)			
Less than high school	3 (8)	3 (14)	—
High school graduate	12 (30)	7 (31)	5 (28)
Some college	11 (28)	3 (14)	8 (44)
College graduate (BA, BS)	9 (23)	6 (27)	3 (17)
Postgraduate (MA, MS, PhD, MD)	5 (13)	3 (14)	2 (11)
Cigarettes smoked per day in last 30 days, mean (SD)	12 (7)	9 (6)	14 (8)
Smoking frequency, n (%)			
Light smokers (<10 cigarettes per day)	17 (43)	12 (55)	5 (28)
Heavy smokers (≥10 cigarettes per day)	23 (58)	10 (45)	13 (72)
Plans to quit smoking, n (%)			
I am not thinking about quitting smoking	1 (3)	1 (4)	—
I am thinking about quitting smoking in the next 6 months	19 (48)	11 (50)	8 (44)
I am thinking about quitting smoking in the next 30 days	7 (18)	5 (23)	2 (11)
I am actively trying to quit smoking	12 (30)	5 (23)	7 (39)
Decline to state	1 (3)	—	1 (6)
Experience with technology, n (%)			
Some experience	3 (8)	1 (5)	2 (11)
Intermediate	14 (35)	7 (32)	7 (39)
Very experienced	20 (50)	11 (50)	9 (50)
Expert	3 (8)	3 (14)	—
Have health apps on mobile phone, n (%)	19 (48)	12 (55)	7 (39)
Ever downloaded a quit-smoking app, n (%)	5 (13)	4 (18)	1 (6)

Blue-Sky Design Ideas for Ideal mHealth Quit-Smoking Tools

Blue-sky brainstorming led to a range of design features smokers envisioned for future mHealth quit-smoking tools. Most

participants expressed a strong overarching expectation for a highly individualized and responsive experience: “What if you had a profile where you could personalize it and make it your own?” (P1). Rather than follow a prescribed and impersonal quit process that several participants experienced with current

apps, P12 wanted the ability to “...personalize your notification or whatever you want your phone to tell you. Write it yourself; set your own goals.” More specifically, the most universal design preferences that emerged across groups were personalized tracking with adaptive feedback and real-time peer support. Both of these themes reflect the critical importance participants placed on support to combat smoking cravings.

Personalized Tracking With Adaptive Feedback

When asked how they envisioned an ideal tool working in a perfect world, the first response from all groups was for immediate physical feedback on smoking behavior: “Maybe on a wearable it would be something that was like a little electric shock therapy thing. That’s pretty extreme, but...” (P10). Other examples included having the mobile phone or a bracelet “vibrate me” (P33). Another participant reflected: “I’m getting ready to smoke, okay, well I’m sending a shock to you, be prepared. Something a little more than talking is going to—yeah, they’re going to have to do some interference” (P22). Participants expressed a desire for immediate feedback to navigate smoking triggers and combat adaptation. For example, P33 expressed the concern: “After a while I’m going to see if I can get immune to that shock, something to build my tolerance to it just like we build our tolerance to nicotine now” (P33).

In addition to tracking smoking behavior, participants described concurrently tracking the context (eg, location) in which smoking occurs to intervene on triggers: “I could see one being kind of a diary...you would enter when you smoked and the environment you were in. And then it would kind of create like a profile for you, what your triggers are, and help you...just like my front page on my phone in the morning time gives me the news, this, that, and the other. ‘Hey [P33], let’s go to the gym instead of smoking that cigarette’” (P33). P35 added: “It would have to connect to your GPS” to make it easier to track your location and learn such patterns.

As discussion progressed, more sophisticated and nuanced design features emerged. These highlighted participants’ interest in personalized tracking that helps them navigate smoking triggers by giving behavioral feedback that adapts as a user cuts back and quits smoking. For instance, P8 described passively tracking smoking rhythms to predict and intervene before future triggers: “I have a pretty bad track record with manually keeping and tracking data...ideally with an app like that you would be able to give it a few parameters toward the beginning of it, things very generalized, like how much you smoke in a day, what cigarettes cost in your region, et cetera, and it would be able to sort of intelligently track metrics for you and reinforce that to you throughout time and that’s the encouragement to keep going.”

Younger participants were less willing than older participants to track triggers manually and tended to favor automatic capture of contextual information about triggers, such as through GPS location. However, some participants were uncomfortable with passive sensing: “I don’t like...knowing a computer is tracking where I’m going, so I usually leave those off if I can, the notifications of where you are at, because it’s kind of creepy” (P18). Some participants found value in manual tracking because it can raise behavioral awareness: “Half of the time we do it

[smoking] when we’re not even thinking about it. But if we’re literally tracking consciously every time we did it...I think that would be—like you’re able to do it for a couple weeks, be like, ‘Wow!’” (P37). P36 agreed: “To get so when you’re having a cigarette it’s not an automatic mindless thing; that you’re really aware of what you’re doing and it’s a conscious decision that you’re making at that point.”

Coupled with personalized tracking, participants expressed the desire for adaptive feedback that matches their changing needs in two major ways. First, participants desired tailored feedback matched to their personal needs and interests. Some participants preferred receiving discouraging “scare tactics” (P36), such as pictures of black lungs, rather than encouragement. Other participants preferred feedback from a real person to automated messages. Most participants agreed that mHealth tools should enable users to select preferred styles of feedback from a menu of choices.

Second, the majority of participants desired dynamic feedback that varies and evolves as their smoking habits change. Adaptive feedback could “help you come up with a plan to reduce. What scares me is, like, quitting just cold turkey. So, like, a person’s specific plan to reduce day by day” (P11). In contrast, only one participant advocated for repetition in feedback over time: “If you hear it consistently, you know, you start thinking about it” (P26).

Real-Time Peer Support

A second universal theme that emerged in all groups was the design priority of real-time peer support. In contrast to ongoing tracking and feedback on smoking behavior, participants envisioned the ability to make emergent requests for support to combat smoking cravings. Although a few participants preferred a distracting image or encouraging message, most participants expressed value in connecting on demand with other smokers or people who had quit (ie, peers). For example, “You could have a small profile that you set up and choose somebody that’s almost like online dating but you’re just finding a quit partner” (P36).

Compared with peers, participants expressed little interest in connecting with their existing social networks (eg, family, friends) about their quit-smoking experience through social media they regularly use. When asked to compare real-time peer support with holding out for professional advice, one participant shared: “In the heat of a craving for me, it [advice from a health professional tomorrow] would probably be too late. I would prefer to connect with somebody right now while I’m having that craving and I’d prefer it be somebody in my area for some reason, just make it more personal” (P32). Several models of real-time pairings for peer support emerged, from a “quit-smoking buddy” (P35) to sponsors: “It’s like when somebody goes into AA [Alcoholics Anonymous] when they have that support...they have a sponsor they go to” (P28).

Other participants envisioned design features that tap into a larger support network through video calls, voice, or text: “If there’s a big red button, ‘Oh, I’m about to smoke’ and I hit it and then like Chatroulette it randomly picked me with someone” (P9). Another participant envisioned “a ‘911’ [emergency

hotline] and then you just get on your phone, hit that app, and automatically it will dial into like a support system, like a hotline or a person. And you say, 'Oh, I'm ready to smoke, is there something I can do?' And that person will give you suggestions to steer you away" (P28). Because cravings can come on strong and last several minutes, some participants thought automated support might be more feasible than having a real person "on call" 24/7. However, many participants thought that interacting with a real person could be essential for not giving in to cravings.

Participants also envisioned tools for exchanging quit-smoking advice within a social network of peers. For example, P9 described "a blog space where you have the availability to see tips and tools that have helped other people" (P9). Another participant envisioned "a club for quitting smoking through this club on your phone, this app" (P24). In one focus group session, a participant suggested using GPS to connect "in your very own city if you need to meet up to talk about it" (P3). However, participants agreed that meeting strangers face-to-face could raise privacy and security concerns. Yet more generally, younger and older participants agreed that real-time peer support delivered safely is a key design priority for mHealth quit-smoking tools.

Design Preferences for Messaging, Social Support, and Gamification

Participants' preferred design options expanded on themes from their blue-sky ideation of mHealth quit-smoking tools. Their feedback on preferred options for messaging, social support, and gamification features provided deeper insight into their needs and priorities as target users.

Messaging

Compared with "push messages" sent automatically, most participants preferred "pull messages" they could request in real time, especially to help manage emergent cravings to smoke. Participants varied in the type of messages they wished to pull, ranging from photos of loved ones to chat with peers. Messages that were personalized and reinforcing were preferred by a majority of participants. For example, P5 suggested "a note to yourself, a kind of personalized quit plan" and P36 suggested "affirmations or telling you how much your lung capacity has improved."

Several participants described their distaste for automated alerts and push notifications that they routinely disable on their mobile phones. Participants expressed concern that poorly timed push messages would only remind them about smoking and trigger cravings. One participant worried that push messages for quitting smoking might be too easy to dismiss: "You have to combat it [a craving] with something that's going to be more foolproof [than a notification] because it is a very strong habit" (P24). A few participants expressed interest in receiving infrequent, but targeted notifications if they could control timing, frequency, and delivery. Examples included messages timed with cravings, such as alternatives to smoking ("Instead of smoking a cigarette, eat a banana" P35), encouragement ("You've gone 3 hours without smoking, congratulations" P27), or reminders ("Go to the gym instead of smoking that cigarette" P33). One participant

expressed interest in receiving messages from a quit-smoking "sponsor" (P28).

Although concern was raised about timing push messages to coincide with cravings, a few participants reflected on the opportunity if push messages were adaptively coupled with intelligent tracking features: "I think it would be extraordinarily difficult...with some sort of automated message, it would have to be dialed in pretty deep to gain the proper context [of a craving]. Push notifications on the other hand, based off of data that you actually initially give the app—and that's something maybe you would be able to give over time rather than having to keep regular track of any sort of data" (P1). P8 agreed: "Being able to set notifications based on either time or geography based off like GPS location or an address—I can see that being really, really useful" (P8).

Social Support

Compared with social support from peer testimonials in the form of stories that could be read (eg, blog), listened to (ie, audio), or watched (ie, video), most participants preferred interactive social network features, such as making friend connections with other smokers, sharing user profiles, and exchanging messages. Echoing the priority of peer support during brainstorming, the majority of participants expressed the most interest in a closed social network of similar peers: "Some sort of community of just like-minded people [who] were there for one common goal regardless of where they are from [sic]. That needs to be the only similarity really, is that trying to quit. This is what we are here for" (P19).

Although a few participants expressed interest in supportive connections with their spouse or health care provider, most preferred greater anonymity: "A lot of times you will be quitting smoking, you will tell all your friends because you want them to encourage you, and it's like your double-edged sword when you are doing well, but when you are not you have this guilt associated with it. I am not going to tell anybody because if I fail. But if you have people encouraging you, they are not going to care if you fail, but they are going to be encouraging you along the way, so it's the support without the personal attachment" (P22). A few participants expressed interest in connecting with a quit-smoking sponsor who had previously quit or health care professionals to whom they might not otherwise have access. A couple of participants were interested in connecting with counselors or quit coaches through a mHealth quit-smoking tool.

One participant saw value in "testimonials from people that have quit of like the things that they didn't realize that were hidden benefits [of quitting]" (P22). However, most participants found peer testimonials less appealing than social networking because prerecorded stories can be impersonal: "If it's just story after story, I'm this person, I smoked for...I would get bored really easy. If they were more like tell a brief story and here's an exercise routine, and they walk you through it. I would be more inclined to stay and listen" (P3). Overall, younger and older participants were interested in tips and advice from peers who had successfully quit, but sought interactive modes of communication, such as a discussion forum.

Gamification

Given the choice, participants did not have a clear preference for either entertaining games or rewarding incentives based on program use; rather, participants preferred aspects of both. Older participants found traditional incentives and rewards more appealing, whereas younger participants described more interest in and diversity of gaming features.

Younger participants described a broad number of gaming features of interest, but mostly, participants preferred games that could serve as fun distractions from cravings to smoke. Examples ranged from simple distractors, such as the popular clicker app “cow evolution” (P19), to more involved role-playing or social games. For example, P22 told us: “I see sort of like a cast of characters, the good cop and bad cop, the stop-smoking buddy, the drill sergeant, the temptress so to speak to try to vanquish—‘No, no, I shall not smoke’—some sort of little Sims-type world.” Other participants described interacting with other users through social gaming features: “[This discussion] makes me think of a ‘swarm’ on Foursquare, like when people are all in the same place...adding experience points and leveling up and achievements that you’re all basically earning extra credit for” (P8). Social games were thought to stimulate “a healthy sense of competition” (P8) and remind users “you’re not the only one struggling” (P22).

Several younger participants talked about incorporating rewards into games such as “leveling up.” Yet a broader range of rewards that could help smokers stay motivated to quit surfaced in all

groups, both extrinsic and intrinsic incentives. For example, participants in every group talked about loyalty points and monetary rewards: “A money reward...it’s not to be paid [to quit smoking]...it’s an added extra—it’s a reward” (P28). Other extrinsic rewards included personal accountability to others, such as sharing progress with a quit-smoking sponsor or buddy: “You want to input your progress too so other people can track what you’re doing and they can motivate you, say, ‘keep it up,’ you know. That will keep you going. So you don’t want to let them down” (P35).

Intrinsic rewards included a feature “that reminds me of the progress I make” (P12) or enables one to “challenge yourself” (P3). A couple of participants suggested tying the design to behavior change theory: “There’s like a bunch of different stages of change, and they could measure where you’re at and kind of work with you to see what has to be done to get you to the next level” (P5).

Importance Ratings for Select mHealth Features

Following focus group discussion that covered a wide range of design ideas and options, participants completed the exit survey to individually rate the importance of 21 specific design features (Table 2), each chosen to reflect best-practice treatment, ways to leverage mobile technology to support quitting smoking, or other important user preferences across domains of cost and reputation, privacy and security, content and user experience, and communication [27].

Table 2. Perceived importance of mHealth design features using 4-point Likert ratings.^a

Design feature	All, mean (SD) (N=40)	Younger, mean (SD) (n=22)	Older, mean (SD) (n=18)
Cost and reputation: a tool that...			
Is free or low cost	3.4 (0.8)	3.3 (0.8)	3.4 (0.7)
Is highly rated by other people	2.8 (1.0)	2.7 (1.0)	2.9 (1.0)
Is “research tested”	2.8 (0.9)	2.7 (0.9)	2.9 (0.9)
Is endorsed by clinical experts	2.7 (1.0)	2.5 (0.9)	2.9 (1.1)
Privacy and security: a tool that...			
Keeps your information private	3.3 (0.8)	3.1 (0.9)	3.6 (0.7)
Stores information on your phone	2.8 (1.0)	2.4 (1.0)	3.2 (0.9)
Stores information in a secure “cloud”	2.6 (1.2)	2.4 (1.1)	2.9 (1.2)
Content and user experience: a tool that...			
Includes games or entertainment	2.5 (1.0)	2.7 (1.0)	2.2 (0.9)
Matches content to your personal needs and interests	3.5 (0.6)	3.6 (0.6)	3.4 (0.7)
Changes content as your needs and interests change	3.2 (0.9)	3.4 (0.8)	3.0 (1.0)
Helps you manage nicotine withdrawal or medication side effects	3.5 (0.6)	3.5 (0.7)	3.5 (0.6)
Helps you track your progress (cigarettes/day)	3.5 (0.7)	3.6 (0.5)	3.3 (0.9)
Sends supportive or motivational messages (eg, text or email)	2.8 (1.0)	2.4 (1.0)	3.2 (0.9)
Includes stories from other smokers about quitting	2.6 (0.9)	2.5 (0.9)	2.7 (1.0)
Includes videos about quitting smoking	2.1 (1.0)	1.8 (0.9)	2.3 (1.1)
Includes information on stop-smoking medicines	2.6 (1.1)	2.3 (1.0)	2.9 (1.1)
Communication: a tool that...			
Lets you to communicate with other smokers about your progress	2.8 (1.0)	2.6 (1.0)	3.1 (1.1)
Lets you communicate with family and friends about your progress	2.4 (1.1)	2.1 (1.0)	2.6 (1.1)
Lets you communicate with stop-smoking experts about your progress	2.9 (0.9)	2.6 (1.0)	3.2 (0.8)
Lets you communicate with your personal doctor or health care team	2.5 (1.0)	2.3 (1.0)	2.8 (1.0)
Lets you post information on Facebook or other social media sites	1.8 (1.0)	1.7 (0.9)	2.0 (1.1)

^a 1=not at all important, 2=somewhat important, 3=very important, and 4=extremely important.

Participants rated some design features as significantly more important than others ($\chi^2=189$, $P<.001$). The highest ratings (n=40) were for tools that matched content to ones needs and interests, helped with withdrawal and side effects, and tracked progress. The lowest rated feature for all was posting to social media. This pattern was consistent across age groups, with the exception of older participants placing the greatest importance on privacy.

For readers interested in a granular examination of how perspectives on the 21 surveyed design features differed, we include a full list of paired comparisons within domains by each age group in the [Multimedia Appendix 1](#). Briefly, importance ratings differed significantly within each domain (cost and

reputation: $\chi^2_3=21.2$, $P<.001$; privacy and security: $\chi^2_2=11.6$, $P=.003$; content and user experience: $\chi^2_8=96.1$, $P<.001$; communication: $\chi^2_4=46.8$, $P<.001$). Paired comparisons suggested participants prioritized cost, maintaining privacy, and the ability to track, obtain personalized content, and support for nicotine withdrawal over other design features in mHealth tools. Participants also prioritized communicating about smoking outside of social media, perhaps with individuals whom are less familiar. For example, ratings were significantly higher for communicating with stop-smoking experts than family and friends ($W=38$, $P=.03$). Further, several participants shared the sentiment expressed by P32: “It’s a lot easier to be honest with somebody that you don’t personally know because like my

doctor I've had her for 15 years and I love her, yet there's stuff I don't want her to know. But I want to be able to be honest at the same time."

Compared with younger participants, older participants rated the following features as significantly more important: a tool that "stores information on your phone" ($U=116, P=.02$), "sends supportive or motivational messages" ($U=113, P=.02$), and "lets you communicate with stop-smoking experts about your progress" ($U=122, P=.03$). Compared with participants who had some or intermediate experience with technology ($n=17$), those who were very experienced or expert ($n=23$) rated "helps you track your progress" significantly more important ($U=113, P=.01$).

Compared with heavier smokers ($n=23$), lighter smokers ($n=17$) rated the importance of most features higher overall. Lighter smokers rated the following features significantly higher than heavier smokers: a tool that "matches content to your personal needs and interests" ($U=250, P=.03$) and "changes content as your needs and interests change" ($U=271, P=.03$). However, both of these features were among the features heavier smokers rated highest. There were no significant differences in importance of features rated by participants who were actively trying or thinking of quitting in the next 30 days ($n=19$) and participants thinking about quitting in 6 months ($n=19$).

Finally, after synthesizing the feedback from both the qualitative focus group feedback and qualitative survey results, several key design considerations emerged and are presented in [Table 3](#).

Table 3. Synthesis of preferred design considerations across assessment methods.

Design consideration	Part I: qualitative blue-sky brainstorm	Part II: qualitative design preferences	Exit survey: quantitative importance ratings
Content and user experience	Support personalized tracking of smoking behavior and context (eg, location) with tailored, dynamic feedback that adapts to evolving needs	Enable pull messages on demand with personalized content; provide distracting games, social games, and extrinsic or intrinsic rewards	Enable users to track progress on quitting; offer personalized content; provide support for nicotine withdrawal
Communication channels for support	Enable real-time peer support to combat smoking cravings and exchange quit smoking advice	Offer a closed network to connect and interact with current and ex-smokers about quitting	Protect smokers from exposing personal smoking information on social media; help smokers connect with experts
Other key considerations	Create a highly personalized and responsive support through active and passive channels	Target select features to groups based on preference (eg, gaming for younger smokers)	Offer tools for free or low cost; keep information private

Discussion

Principal Findings

Using a mixed-methods approach, we explored smokers' ideal design features for mHealth cessation tools and assessed the relative importance of specific design considerations and treatment components that are particularly relevant to this design space. Our qualitative findings illuminated a number of creative design ideas, but most importantly, highlighted smokers' desire for a highly personalized and adaptive experience, the ability to connect with peers for support, and the use of active and passive communication channels. Qualitative insights also highlighted preference for pull messages (ie, delivered upon request) over push messages (ie, sent automatically), interaction with other smokers through closed social networks, and targeted incentives based on user group. Quantitative results reinforce considerations of importance, including personalized content, the ability to track progress, support for nicotine withdrawal, connecting with peers and quit-smoking experts, and keeping information private. However, some preferences vary by age, experience with technology, or smoking frequency. For example, older smokers were more sensitized to issues of privacy and younger smokers were more interested in gaming as a means of smoking distraction. Smokers who had more experience with technology placed more importance on tracking features than those with less experience. Compared with heavy smokers, lighter smokers placed more importance on personalized content that matches and dynamically adapts to one's changing needs and interest.

Although incorporating smokers' preferences will not guarantee mHealth tools will be effective, balancing user preferences with best-practice treatment considerations could enhance program adoption and improve treatment outcomes. Thus, these findings offer guidance to addiction treatment experts and developers working in this design space.

Implications for Future Research and Development

The results of this study have implications for future research and development. For example, smokers wanted a highly personalized experience that included tracking (of smoking and smoking locations) and adaptively tailored content. In the future, tracking tools could couple self-monitoring [29] with passive sensing via wearable devices [56,57] and machine learning to predict smoking triggers and proactively intervene with real-time tailored recommendations [58]. This intelligent tracking should coincide with smokers' cravings and deliver support when and where it is needed [59]. Notably, this type of passive push intervention is in contrast to smokers' stated preference for active pull messaging to control timing on demand [28,31]. Remaining unanswered empirical questions include which type of intervention smokers would actually prefer based on real-world experience and how effective each strategy is relative to the other. These are important issues for future research.

Another design consideration worthy of further exploration is the use of gaming features in mHealth cessation programs. Relative to other design features, few studies to date have employed gamification strategies to help people quit smoking [24,38,52], but one could envision these strategies being used

to incentivize participation or reaching milestones (eg, 48 hours smoke-free) using earned badges or offering game play to distract smokers during cravings to smoke. Among our participants, older smokers were more responsive to traditional rewards and incentives [29,60,61], whereas younger smokers were more open to gaming features. The use of gaming features have also been recommended by design experts [52,62], but further research is needed to inform whether these features can truly enhance treatment participation or outcome and for whom.

Social support from peers was also highly valued by our participants, as was support from stop-smoking experts. Both of these are recognized as important best-practice treatment components [7], so understanding how to most effectively integrate this support in mHealth interventions is another important consideration for future research. Our findings suggest that smokers want support from peers “on demand” and most preferred interactive modes of support over prerecorded peer testimonials, such as automated video messaging found ineffective for cessation in prior work [37]. Participants’ lack of interest in posting to social media echoes patients’ preferences for sharing personal health information on closed online networks that are condition-specific rather than general-purpose social media they regularly use [63]. However, with experience, smokers might find value posting in quit-smoking communities [64-66], particularly if combined with interventions tailored to one’s readiness to quit [67]. Open research questions remain about protecting privacy [64,66,68] while facilitating exchanges among social ties through which smoking cessation information is known to spread [39-42].

Our results further suggest communication with treatment experts may be more highly valued than sharing one’s progress with friends, family, or even a personal doctor. Congruent with prior research [29], these findings may reflect a preference for the anonymity of weak social ties (ie, peer smokers, treatment experts) over strong social ties. If so, this preference for greater anonymity would support the notion that smokers are “ambivalent socializers” who are simultaneously keen yet reluctant to engage with others about smoking via social media [68]. Yet this preference could create a treatment challenge. Support provided by a trusted clinician through counseling is an important element of best-practice cognitive behavioral-based nicotine dependence treatment [7], in part because it holds smokers accountable. Interacting with others anonymously could reduce the risk of peer pressure or embarrassment due to failures to quit [64], but could also reduce the effectiveness of the intervention due to lack of accountability. This raises yet another important area for future research to determine the effectiveness of anonymous peer support and expert advice provided in the context of mHealth cessation interventions.

Strengths and Limitations

Strengths of this study include a diverse demographic group and our mixed-method research design. The use of blue-sky

thinking to illuminate smokers’ “perfect world” design priorities is a unique strength of this paper. To our knowledge, this approach has not been used previously in this context. It revealed many creative design ideas, some of which were further confirmed as important in participants’ quantitative survey ratings. Finally, our comparison of younger versus older smoker preferences highlighted important distinctions in these groups and is another strength of the study design.

The study also has some limitations. First, the findings may not generalize to all smokers due to the small sample size. Participants varied in age, education, experience with technology, and smoking frequency, yet their limited ethnic and racial diversity may have not captured opinions across known differences in smoking patterns [69]. It is also possible that the views represented do not generalize to smokers who do not own mobile devices, although the opinions of that group are less relevant in this context.

Finally, our results only reflect the perceived preferences of smokers’ for mHealth cessation tools. Future research is needed to determine if these stated preferences hold true in real-world practice. Such studies could lay the foundation for future work to assess the relative value and effectiveness of mHealth tools compared with other quit-smoking modalities (eg, peer support groups, professional behavioral support, pharmaceuticals, and nicotine replacement).

Conclusions

We assessed smokers’ design preferences for future mHealth smoking cessation tools and identified several features, which should be prioritized when designing future mHealth cessation tools. These include making programs that are highly personalized, adaptive, interactive, and can facilitate communication with peers and experts. Prioritizing these features in future mHealth interventions could improve their acceptability to smokers and program engagement, and improve treatment effectiveness as a result. However, the integration of popular mHealth features alone may not ensure a program’s use or effectiveness [32]. Future programs must also be grounded in relevant behavioral theory [59] and evidence-based treatment recommendations [13-15]. Aligning design preferences with evidence-based solutions is particularly important for addictive behaviors such as smoking [70] in which design priorities of treatment experts and smokers can differ [27].

Future mHealth smoking cessation tools will also require empirical validation. We highlight several important research questions worthy of investigation. It is our hope that this work will inform and inspire collaboration between addiction treatment experts, designers, and developers to create the next generation of mHealth smoking cessation tools.

Acknowledgments

We thank the study participants who took part in this study. We are grateful for the research support provided by Emily Westbrook and Mary Shea. Funding for this project was provided by Group Health Research Institute and the National Institute for Drug Abuse (R34DA034612; J McClure, Principal Investigator).

Conflicts of Interest

None declared.

Multimedia Appendix 1

[PDF File (Adobe PDF File), 84KB - [mhealth_v4i3e95_app1.pdf](#)]

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Abbreviations

GHRI: Group Health Research Institute
mHealth: mobile health

Edited by G Eysenbach; submitted 09.03.16; peer-reviewed by S Cutrona, V O'Reilly-Shah, N BinDhim, K Grindrod, C Beishuizen; comments to author 06.04.16; revised version received 07.07.16; accepted 20.07.16; published 05.08.16.

Please cite as:

Hartzler AL, BlueSpruce J, Catz SL, McClure JB
Prioritizing the mHealth Design Space: A Mixed-Methods Analysis of Smokers' Perspectives
JMIR Mhealth Uhealth 2016;4(3):e95
URL: <http://mhealth.jmir.org/2016/3/e95/>
doi: [10.2196/mhealth.5742](https://doi.org/10.2196/mhealth.5742)
PMID: [27496593](https://pubmed.ncbi.nlm.nih.gov/27496593/)

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Original Paper

Retrofit Weight-Loss Outcomes at 6, 12, and 24 Months and Characteristics of 12-Month High Performers: A Retrospective Analysis

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Abstract

Background: Obesity is the leading cause of preventable death costing the health care system billions of dollars. Combining self-monitoring technology with personalized behavior change strategies results in clinically significant weight loss. However, there is a lack of real-world outcomes in commercial weight-loss program research.

Objective: Retrofit is a personalized weight management and disease-prevention solution. This study aimed to report Retrofit's weight-loss outcomes at 6, 12, and 24 months and characterize behaviors, age, and sex of high-performing participants who achieved weight loss of 10% or greater at 12 months.

Methods: A retrospective analysis was performed from 2011 to 2014 using 2720 participants enrolled in a Retrofit weight-loss program. Participants had a starting body mass index (BMI) of >25 kg/m² and were at least 18 years of age. Weight measurements were assessed at 6, 12, and 24 months in the program to evaluate change in body weight, BMI, and percentage of participants who achieved 5% or greater weight loss. A secondary analysis characterized high-performing participants who lost ≥10% of their starting weight (n=238). Characterized behaviors were evaluated, including self-monitoring through weigh-ins, number of days wearing an activity tracker, daily step count average, and engagement through coaching conversations via Web-based messages, and number of coaching sessions attended.

Results: Average weight loss at 6 months was -5.55% for male and -4.86% for female participants. Male and female participants had an average weight loss of -6.28% and -5.37% at 12 months, respectively. Average weight loss at 24 months was -5.03% and -3.15% for males and females, respectively. Behaviors of high-performing participants were assessed at 12 months. Number of weigh-ins were greater in high-performing male (197.3 times vs 165.4 times, $P=.001$) and female participants (222 times vs 167 times, $P<.001$) compared with remaining participants. Total activity tracker days and average steps per day were greater in high-performing females (304.7 vs 266.6 days, $P<.001$; 8380.9 vs 7059.7 steps, $P<.001$, respectively) and males (297.1 vs 255.3 days, $P<.001$; 9099.3 vs 8251.4 steps, $P=.008$, respectively). High-performing female participants had significantly more coaching conversations via Web-based messages than remaining female participants (341.4 vs 301.1, $P=.03$), as well as more days with at least one such electronic message (118 vs 108 days, $P=.03$). High-performing male participants displayed similar behavior.

Conclusions: Participants on the Retrofit program lost an average of -5.21% at 6 months, -5.83% at 12 months, and -4.09% at 24 months. High-performing participants show greater adherence to self-monitoring behaviors of weighing in, number of days wearing an activity tracker, and average number of steps per day. Female high performers have higher coaching engagement through conversation days and total number of coaching conversations.

KEYWORDS

behavior; body mass index; BMI; engagement; fitness; self-monitoring; obesity; overweight; weight loss

Introduction

Obesity is the leading cause of preventable death in the world, yet it continues to remain a crisis in the United States with two-thirds of the American adult population overweight or obese [1]. The overweight population in the United States has nearly doubled, while obesity rates have nearly tripled in the past 50 years [2]. Direct and indirect health care costs for preventable chronic disease, including obesity-related diseases such as heart disease and diabetes, range from US \$147 billion to US \$215 billion per year [3,4]. On average, women report trying to lose weight 7 times in their lifetime, whereas men report an average of 3.6 times [5]. In fact, Americans spent US \$2.5 billion on weight-loss programs and products in 2014 [6].

The Affordable Care Act encourages employee wellness programs designed to increase health knowledge and skills to promote healthy behaviors, which can aid in the reduction of health care costs incurred by employers [7]. A morbidly obese employee currently costs employers, on average, an additional US \$4000 or more per year than an employee who is of a healthy weight [8]. When achieving 10% weight loss, it increases the likelihood of lowering cholesterol, blood pressure, and risk for diabetes, and even a modest 5% weight reduction can lead to clinically significant decreases in comorbidities associated with overweight and obesity [9-12]. Owing to the extreme impact overweight and obesity have on morbidity, mortality, and the financial state of health care in the United States, the development of effective weight-loss programs is imperative [13-18].

Many employers have taken experts' recommendations and implemented an employee wellness program; however, these programs are often underused with short-term benefits [19]. Lack of education, personalization, and slow weight loss in Web-based interventions are directly connected to weak adherence and high attrition leading to unsuccessful outcomes [20]. Therefore, initiating programs that are accessible, personalized, easy to use, and interesting to employees is a key factor to achieving successful outcomes that decrease employer health care costs [21].

The Look AHEAD (Action for Health in Diabetes) trial resulted in increased outcomes and greater retention in participants receiving education with an intensive behavior modification plan including nutrition and physical activity over education alone [22-24]. Remote programs are also desired and improve adherence in intensive programs [25]. In recent years, Internet accessibility and technology advancements have positively impacted weight-loss programs through the development of mobile phone apps, Web-based weight-loss methods with both personalized and nonpersonalized approaches, and point-click nutrition and fitness information [26,27]. Successful Web-based programs include a structured approach with a hypocaloric nutrition plan, cognitive behavioral strategies, self-monitoring,

and individualized feedback and support [28]. Behavioral weight control approaches that include a comprehensive lifestyle modification program using Wi-Fi scales, mobile phones, or tablets for self-monitoring are shown to be effective in achieving a 7%-10% weight reduction [12,25,29].

Combining in-person support with remote technologies has been shown to significantly increase 5% weight-loss outcomes over remote technologies alone [15]. Remote technology such as mobile phone and tablet apps, wireless activity trackers, and wireless scales allows for convenient self-monitoring of weight, food choices, and activity; however, individualization of a participant's program and personalized feedback create greater adherence, and adherence is associated with greater retention rates [20,30-33].

Efficacy of structured research projects with commercial and proprietary weight-loss programs lack real-world outcomes, meaning that current populations are being selected by the study staff [6]. This lack of evidence is visible in a systematic review regarding efficacy of commercial and proprietary weight-loss programs released by Gudzone et al [6].

Retrofit is a personalized weight management and disease-prevention solution (see [Multimedia Appendix 1](#)). The purpose of this study was to report Retrofit's weight-loss outcomes at 6, 12, and 24 months using real-world data. A secondary purpose of the study was to characterize behaviors, age, and sex of participants who achieved a weight loss of 10% or greater at 12 months, who are labeled as high performers.

Methods

Research Design

A retrospective analysis using deidentified data of the Retrofit weight-loss program was performed using a case series [34] approach that included the participants with known weight measurements at 6, 12, and 24 months. This study characterized the changes in participants' body weight and body mass index (BMI) from the first weight measurement (start date) to different time points and the percentage of participants who reached a clinically significant weight loss of 5% at the corresponding time period. A secondary analysis was conducted focusing on participants with known weight at 12 months, to characterize the differences in various behaviors, age, and sex between participants who lost $\geq 10\%$ of their starting weight and remaining participants. Western Institutional Review Board granted institutional review board exemption.

Subjects

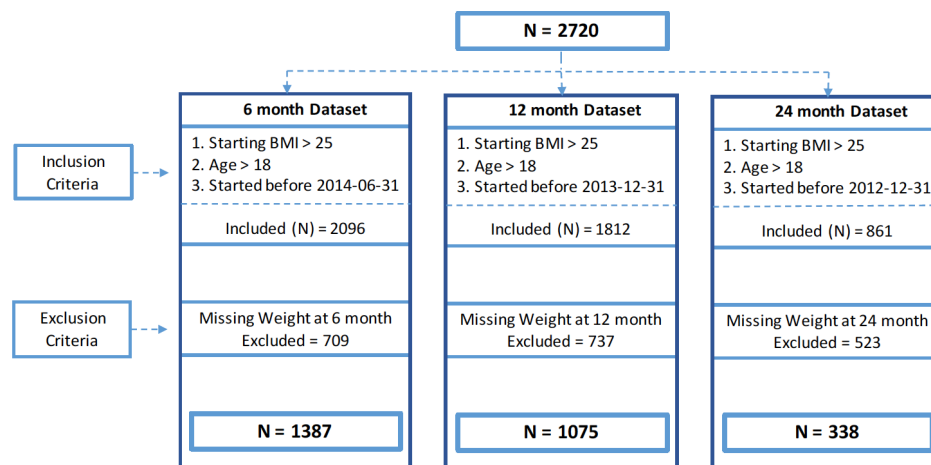
Clients in this study were paying customers of the Retrofit program who enrolled through the direct-to-consumer website (Retrofitme.com) or through an employer-sponsored program. Participants were defined as a client who provided at least one weight measurement (N=2720).

Inclusion criteria included participants who had a starting BMI of >25 kg/m², had signed up for the program between September 27, 2011, and December 31, 2014, and were at least 18 years of age. Exclusion criteria included a participant having no weight measurement available at 6, 12, or 24 months. A lack of available weight measurement was due to either a start date more recent than the reviewed data window (see Figure 1, inclusion criteria) or not providing a known weight measurement (see Figure 1, exclusion criteria). Decreasing numbers of participants at each data window was related to study design and not directly related to dropping out of the Retrofit program. The reported Retrofit programs are 12-month programs. However, participants could request to continue their program beyond 12 months. If a participant does not remain in an active program guided by an expert coach, the participant still has continued access to program devices, Wi-Fi scale and activity tracker, and private dashboard. According to previous study

observations, self-weighing adherence decreases over time [35-39]; therefore, including only those participants with weight data in this study design, the number of excluded participants increased as the data windows progressed. For the purposes of this study, excluded participants will be defined as dropouts.

Initially, 2720 clients were considered as study participants who provided at least one weight measurement. On the basis of the inclusion and exclusion criteria defined in Figure 1, the final study sample sizes were determined at different time points. At 6 months, 1387 participants met the final inclusion criteria. At 12 months, 1075 participants met the final inclusion criteria. At 24 months, 338 participants met the final inclusion criteria. The sample was treated as an independent group at each data window, as a participant could have a known weight measurement at any one or more than one of the observed milestones. See Figure 1.

Figure 1. Study population with exclusion, with restrictions at each time point. BMI: body mass index.



Program Description

Retrofit offered 3 programs during the period of analysis: Expert 10 Weight Loss Program, Expert 15 Weight Loss Program, and Advisor Weight Loss Program. The programs were designed with a 6-month weight-loss phase and an additional 6-month weight maintenance phase. Weight maintenance after the 12 months was anticipated to be observed through continued application of the learned health behaviors.

The participant was initiated into the program, meeting with a personal program advisor who explained the components of the program, and tested familiarity with the provided technology and Web-based video communication capabilities. Client information was collected during the initial setup period.

The participant was provided with a Fitbit activity tracker, Wi-Fi-enabled scale, and access to a private dashboard (see Multimedia Appendix 2). The dashboard allowed each participant to keep a personal food and exercise log, review his or her personal data, and enabled communication between the participant and his or her expert coach through a Web-based electronic messaging feature. The private dashboard was accessed via the Retrofitme.com Web application, mobile website, or mobile phone app, which was available on Apple iOS and Android platforms.

Participants were provided with sessions and check-ins to use with an expert coach during their program. The initial session was scheduled for 60 minutes with follow-up sessions scheduled for 30 minutes. Scheduled check-ins were 15 minutes. Sessions were conducted via Web-based video chat or mobile phone (see Multimedia Appendix 3). All sessions included an educational component, allowing the participant to learn the Retrofit philosophy and weight-loss guiding principles associated with nutrition, mindset, exercise, and daily activity. Sessions and check-ins were used for collaboration between the expert coach and participant to evaluate current health-related behaviors, goal setting, and create individualized plans and strategies. The sessions and check-ins also provided accountability to previously agreed upon strategies. A minimum of 24 one-on-one coaching sessions that included sessions and check-ins, or only check-ins, were allotted to each participant's program. One-on-one coaching session totals included 24 sessions for Expert 10, 36 sessions for Expert 15, and 12 sessions and 12 check-ins for Advisor.

Participants were encouraged to weigh in and wear their activity tracker daily. Wearing an activity tracker and setting a step goal has been associated with a decrease in BMI and increase in activity [40]. Step count goals were personalized to the participant's baseline step count. Expert coaches recommended

that participants increase step counts in increments of 500 to ultimately achieve their personal daily step goal at 6 months. Participants were encouraged to communicate daily with the expert coach via Web-based messages on the dashboard. Expert coaches were required to review a client's food and exercise logs, step data, weight data, and progress toward goals a minimum of 1 time per week to provide feedback via Web-based messages. If a client initiated a coaching conversation, the expert coach was required to respond within 24 hours.

All 3 programs provided the participants with the same technology, access to a weight-loss expert, accountability, feedback, and the opportunity to communicate with a weight-loss expert via Web-based messages equally. The differences among programs were defined by number and type of one-on-one coaching sessions a participant was provided, and the Advisor program provided access to 1 expert coach, whereas Expert 10 and Expert 15 programs provided a team of experts in mindset, nutrition, and exercise. Weight-loss experts were employed professionals with a master's or doctorate level college education in nutritional sciences, exercise physiology, health education, counseling, or psychology. Mindset experts had degrees in counseling, health education, social work, or psychology. Nutrition experts were registered and licensed dietitians, and exercise experts were exercise physiologists.

Experts are assigned to a participant for the duration of their program; however, a new expert may have been assigned to a participant's program related to employee turnover or as part of the quality assurance process. Expert coaches were trained on and utilized Retrofit's weight-loss protocol.

Data Collection

Weight data were collected through use of the provided Wi-Fi connected scale (97.87% of recorded weights) or self-reported entry (2.13%). Self-reported entry was permissible if participants had difficulty setting up their Wi-Fi scale. Starting weight was determined at the first collected weight from the participant. The criteria for determining if a participant had a known weight measurement at different time points in the program are outlined in Table 1. A widening window approach was used at each time point to account for decreased self-weighing behavior. A reduction in the frequency of self-weighing behavior is observed in existing research [35-39]. Therefore, a wider range of time was used to determine a participant's weight at 12 and 24 months. Similar widening window approaches have been used in previous commercial weight-loss studies [41].

When more than one measurement was collected within the identified range, the weight measurement on or closest to the specified day of measurement was used. Participants were encouraged to step on the scale daily.

Table 1. Criteria for identifying participants' weight at specific time points in the program.

Accepted days for selecting known weight	Milestone		
	6 Months	12 Months	24 Months
Target	Day 180	Day 360	Day 720
Range	Days 159-187	Days 300-367	Days 660-727

Participant self-monitoring adherence was analyzed at 12 months through the use of the activity tracker and frequency of weigh-ins. Participant behaviors and engagement were observed through the number of coaching conversations in the form of an electronic message posted on the private dashboard between participant and weight-loss expert, number of days that an electronic message was logged, along with the length of each electronic message. Coaching conversations include both coach-initiated and participant-initiated Web-based messages. In addition, number of coaching sessions attended were also analyzed for participant engagement.

Analysis

The primary outcome measurements were total weight lost in kilograms, percentage of weight lost, change in BMI, and percentage of participants who lost $\geq 5\%$ and $\geq 10\%$ of their starting weight. Program outcomes were analyzed at 6, 12, and 24 months, grouped by sex. At each milestone, data of participants with a known weight measurement were used to calculate outcomes.

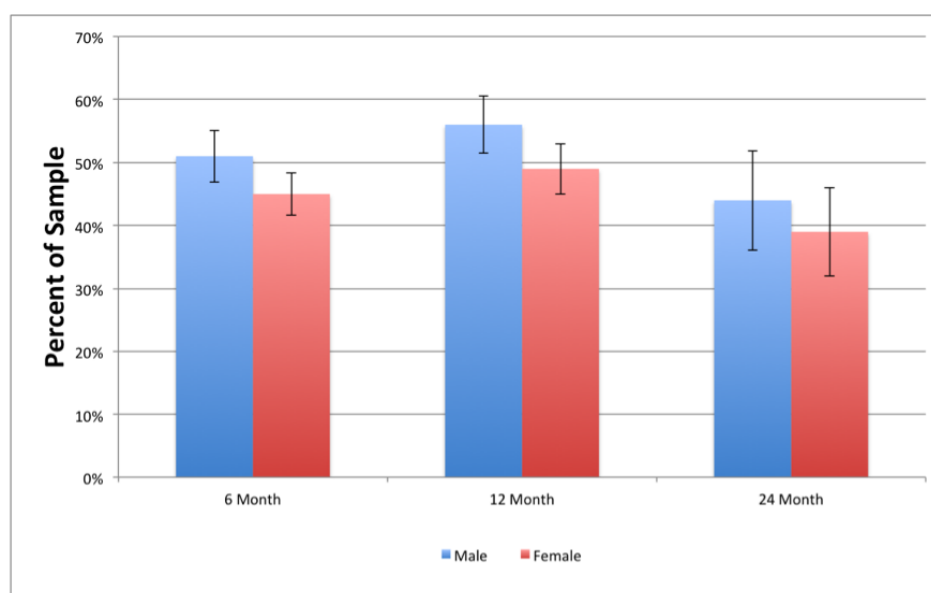
Further analysis summarized self-monitoring behaviors and coaching conversations via Web-based messages between the participant and weight-loss expert at 12 months. The analysis

grouped participants based on sex. Participants were also divided into groups that lost at least 10% of their starting weight at 12 months and those who had a weight loss of less than 10% at 12 months.

The summarized behaviors include total weigh-in measurements, total days of activity tracker use, daily step count average, total number of coaching conversations via Web-based messages, total count of days with a conversation, average conversation length, and number of coaching sessions attended.

Primary data analyses were performed using Python 2.7.11, which included NumPy 1.10.4, Pandas 0.17.1, and SciPy 0.17.0 analytic packages. For two-group comparisons, *t* tests of equal variance were conducted on continuous variables at baseline and subsequent time points. One-way analysis of variance (ANOVA) was used to determine mean differences for more than two-group comparisons. Subsequently, Tukey tests were conducted to determine mean differences. Chi-square analyses were performed to determine differences among categorical variables when appropriate. Outcome variable means are summarized with standard errors (SEs) and a 95% confidence interval is included in the populations summarized in Figure 2. Alpha was set at .05 for all statistical tests to determine statistical significance.

Figure 2. Percentage of male and female participants who lost $\geq 5\%$ of starting weight at 6, 12, and 24 months. Error bars indicate 95% confidence intervals.



Results

Baseline Characteristics

Of the participants with a known weight measurement at each time point, 41.9% (581/1387) at 6 months, 43.6% (469/1075) at 12 months, and 44.4% (150/338) at 24 months were male.

Table 2. Baseline demographics.

Demographics	6 Months, mean (SD)		P value	12 Months, mean (SD)		P value	24 Months, mean (SD)		P value
	Male (n=581)	Female (n=806)		Male (n=469)	Female (n=606)		Male (n=150)	Female (n=188)	
Age, years	47.3 (11.3)	47.2 (10.8)	.85	47.6 (11.4)	47.6 (10.8)	.99	48.3 (12.0)	48.3 (11.2)	.99
Starting weight, kilograms	109.5 (22.2)	91.3 (20.2)	<.001	108.9 (22.0)	90.9 (19.5)	<.001	105.3 (19.6)	88.47 (17.1)	<.001
Starting BMI ^a , kg/m ²	33.8 (6.4)	33.5 (7.1)	.40	33.6 (6.4)	33.4 (6.8)	.61	33.0 (6.1)	32.9 (6.0)	.87

^aBMI: body mass index.

Weight Change Status

The average weight loss at 6 months was -5.55% (SE 0.20) and -4.86% (SE 0.18) for males and females, respectively. Males at 12 months had an average weight loss of -6.28% (SE 0.28). Females at 12 months lost an average of -5.37% (SE 0.28). The average weight loss at 24 months was -5.03% (SE 0.61) and -3.15% (SE 0.62) for males and females, respectively. Weight loss was calculated by subtracting baseline weight from milestone weight. There was a significant difference in total weight lost in kilograms, percentage of weight lost, and BMI change at all of the observed milestones, when comparing males and females. A complete outline of these weight change outcomes, for all 3 observed durations is available in [Table 3](#).

There were no differences in age or starting BMI at baseline, between male and female participants, for each sample. Male participants had a higher starting weight at 6 months ($P<.001$), 12 months ($P<.001$), and 24 months ($P<.001$). Baseline summaries for age, starting weight, and starting BMI are outlined in [Table 2](#).

[Figure 2](#) shows the percentage of the male and female participants who lost $\geq 5\%$ of their starting weight. There was a significant difference between male and female participants at 6 months ($P=.045$) and 12 months ($P=.02$).

Baseline Characteristics for High-Performing and Remaining Participants

Participants who lost $\geq 10\%$ of their starting weight were identified as high performers. Those participants who did not achieve that amount of weight loss were identified as the remaining participants.

At baseline, high-performing males had a statistically significant higher average starting weight of 112.7 (SD 22.11) kg, whereas the remaining male participants had an average starting weight of 107.8 (SD 21.84) kg ($P=.045$). High-performing females

were older on average than the remaining females, where the average ages were 50.3 (SD 11.0) years and 46.9 (SD 10.7) years, respectively ($P=.001$). All other baseline characteristics

were similar between the high-performing participants and the remaining participants. Baseline characteristics are outlined in [Table 4](#).

Table 3. Weight-loss outcomes.

Outcomes	6 Months		<i>P</i> value	12 Months		<i>P</i> value	24 Months		<i>P</i> value
	Male (n=581)	Female (n=806)		Male (n=469)	Female (n=606)		Male (n=150)	Female (n=188)	
Weight change, kilograms mean (SE)	-6.17 (0.24)	-4.44 (0.17)	<.001	-7.03 (0.34)	-4.90 (0.26)	<.001	-5.68 (0.76)	-2.78 (0.58)	0.002
Weight change, % mean (SE)	-5.55 (0.20)	-4.86 (0.18)	.01	-6.28 (0.28)	-5.37 (0.28)	.02	-5.03 (0.61)	-3.15 (0.62)	.03
BMI ^a change, kg/m ² mean (SE)	-2.09 (0.08)	-1.83 (0.06)	.009	-2.37 (0.11)	-1.99 (0.10)	.009	-2.04 (0.24)	-1.28 (0.22)	.02
% With ≥5% weight loss (n/N)(SE)	50.6% (294/581) (2.07)	45.2% (364/806) (1.75)	.045	56.3% (264/469) (2.29)	48.8% (296/606) (2.03)	.02	44.0% (66/150) (4.05)	39.4% (74/188) (3.55)	.39
% With ≥10% weight loss (n/N)(SE)	17.2% (100/581) (1.23)	14.3% (115/806) (1.57)	.16	22.4% (105/469) (1.92)	21.9% (133/606) (1.68)	.92	16.7% (25/150) (3.04)	20.7% (39/188) (2.96)	.42

^aBMI: body mass index.

Table 4. Characteristics of high performers versus remaining participants at 12 months.

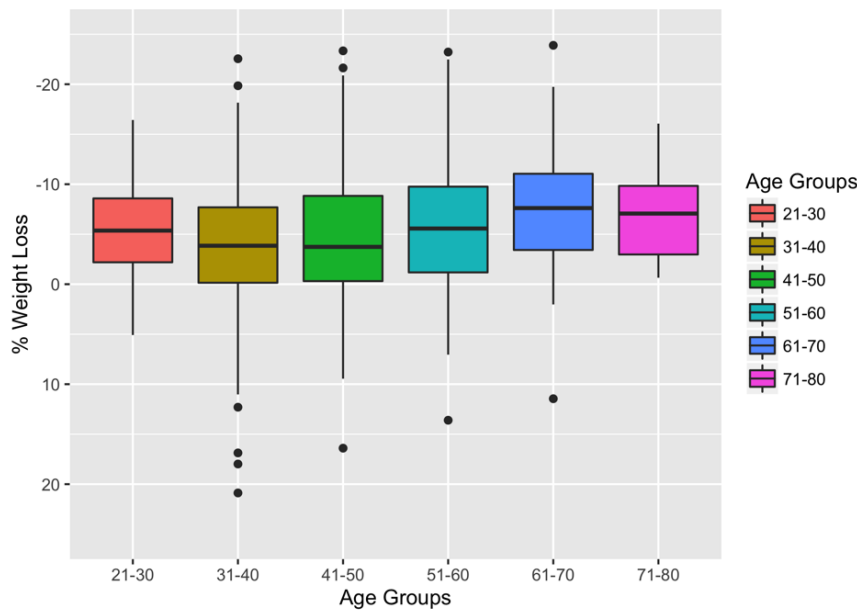
Characteristics	Male, mean (SD)		<i>P</i> value	Female, mean (SD)		<i>P</i> value
	High performers (n=105)	Remaining (n=364)		High performers (n=133)	Remaining (n=473)	
Age, years	46.9 (11.3)	47.9 (11.4)	.44	50.3 (11.0)	46.9 (10.7)	.001
Starting weight, kilograms	112.7 (22.11)	107.8 (21.84)	.045	91.1 (18.2)	90.8 (19.9)	0.87
Starting BMI ^a , kg/m ²	34.6 (6.37)	33.3 (6.37)	.06	33.3 (5.9)	33.4 (7.05)	.94

^aBMI: body mass index.

Further analysis of participants' sex, age, and average weight loss at 12 months was performed by dividing participants by sex, grouping them by 10-year age ranges, and conducting a one-way ANOVA. To address outlying age groupings, participants 20 years and younger or 80 years and older were not included in the assessment. For male participants, there was no statistically significant difference ($P=.37$) in relation to age

and weight loss. However, for female participants, there was a significant difference of mean weight loss between the different groups ($P=.002$), see [Figure 3](#). A subsequent Tukey test was performed, finding that the significant mean differences occurred between the 31- to 40-year age group and 51- to 60-year age group ($P=.026$) and between the 31- to 40-year age group and 61- to 70-year age group ($P=.004$).

Figure 3. One-way analysis of variance: female age groups and percentage of weight lost ($P=.002$). The bold horizontal line is the median, the bottom and top borders of the boxes are 25th and 75th percentiles, respectively; the vertical lines below and above the boxes extend up to 2.5th and 97.5th percentiles, respectively; the black circles are outliers.



Self-Monitoring Behaviors and Coaching Conversations at 12 Months

For all self-monitoring behaviors, the high-performing participants had significantly higher adherence at 12 months. High-performing males weighed in 197.3 (SE 9.97) times, whereas remaining males weighed in 165.4 (SE 4.39) times ($P=.001$). High-performing females weighed in 222 (SE 8.47) times compared with 167 (SE 4.12) times for remaining females ($P<.001$). The total days of activity tracker use and average

steps per day for high-performing females was 304.7 (SE 6.81) days and 8380.9 (SE 268.5) steps, respectively, whereas the remaining females had 266.6 (SE 98.1) days ($P<.001$) and 7059.7 (SE 2499.9) steps ($P<.001$). Males had 297.1 (SE 88.0) and 255.3 (SE 106.3) activity tracker days ($P<.001$) for high performers and remaining participants, respectively. On average, high-performing males had 9099.3 (SE 2954) average daily step counts, whereas the remaining males had 8251.4 (SE 2821) steps ($P=.008$). Self-monitoring measurements for males and females are outlined in [Table 5](#).

Table 5. Self-monitoring and engagement.

	Male, mean (SE)		P value	Female, mean (SE)		P value
	High performers (n=105)	Remaining (n=364)		High performers (n=133)	Remaining (n=473)	
Weigh-in days ^a	197.3 (9.97)	165.4 (4.39)	.001	222 (8.47)	167 (4.12)	<.001
Activity tracker days ^b	297.1 (8.71)	255.3 (5.60)	<.001	304.7 (6.81)	266.6 (4.52)	<.001
Daily step count	9099.3 (289.7)	8251.4 (148.7)	.008	8380.9 (268.5)	7059.7 (115.1)	<.001
Total coaching conversations ^c	260.2 (14.02)	236 (7.87)	.14	341.4 (15.7)	301.1 (8.9)	.03
Coaching conversation days ^d	100.9 (3.60)	95.9 (2.21)	.27	118 (4.10)	108 (2.17)	.03
Coaching conversation length ^e	239.1 (6.93)	262 (5.13)	.03	232.4 (5.31)	247.6 (3.61)	.04
Number of coaching sessions attended ^f	18.7 (0.62)	16.7 (0.43)	.008	19.7 (0.57)	17.7 (0.34)	.003

^aWeigh-in day: day where participant reported weigh-in via Wi-Fi scale or self-report.

^bActivity tracker day: day where participant's activity tracker recorded more than one step count.

^cCoaching conversation: online communication between expert and participant in the form of an electronic message, excludes communication between coach and participant in live one-on-one coaching sessions.

^dCoaching conversation days: a day where a participant or expert posted an electronic message.

^eCoaching conversation length: the number of characters of an electronic message.

^fNumber of coaching sessions attended: the total number of one-on-one coaching sessions a participant attended, includes both 30-minute sessions and 15-minute check-ins.

Reviewing engagement between the participant and expert coach, high-performing female participants had significantly more total coaching conversations via Web-based messages with 341.4 (SE 15.7) compared with 301.1 (SE 8.88) for the remaining participants ($P=.03$). High-performing females also had more days with at least one coaching conversation, with 118 (SE 4.10) days compared with the remaining participants who had 108 (SE 2.17) days ($P=.03$). Similar trends were found when reviewing male participant coaching conversation totals; however, these were not significant. High performers had 260.2 (SE 14.02) coaching conversations and 100.9 (SE 3.60) days, compared with the remaining males with 236 (SE 7.87) coaching conversations ($P=.14$) and 95.9 (SE 2.21) days ($P=.27$). Interestingly, the coaching conversations were not longer for high performers. This was true for females where conversation length was 232.4 (SE 5.31) characters for high performers and 247.6 (SE 3.61) characters for remaining participants ($P=.04$). This also was found with males, as high performers' conversation length was 239.9 (SE 6.93) characters compared with 262 (SE 5.13) characters ($P=.03$) for remaining participants. Coaching conversations via electronic message measurements can be found in [Table 5](#).

Further engagement was reviewed in number of coaching sessions attended. High-performing male participants attended 18.7 (SE 0.62) sessions compared with remaining male participants attending 16.7 (SE 0.43) sessions ($P=.008$). High-performing female participants attended 19.7 (SE 0.57) sessions, whereas remaining female participants attended 17.7 (SE 0.34) sessions ($P=.003$). High-performing male and female participants attended a statistically significant number of coaching sessions over remaining participants. See [Table 5](#) for number of coaching session measurements.

Discussion

Principal Findings

Participants on the Retrofit program lost an average of -5.21% (male -5.55% , female -4.86%) at 6 months, -5.83% (male -6.28% , female -5.37%) at 12 months, and -4.09% (male -5.03% , female -3.15%) at 24 months. Men consistently lost more weight than women at all the milestones. At 12 months, 56.3% (264/469) of males and 48.8% (296/606) of females had clinically significant weight loss, losing 5% of starting weight. High-performing male and female participants, who lost $\geq 10\%$ of their starting weight, had higher adherence to all self-monitoring behaviors, whereas only high-performing female participants had a higher rate of engagement through coaching conversations. However, both male and female high performers attended a statistically significant number of one-on-one coaching sessions.

Male Versus Female Outcomes

Although more females were included in the study population at each time point, no differences were observed in age or starting BMI at baseline; however, males had a higher starting weight at each time point. In addition, men were significantly more successful at 6, 12, and 24 months with more total weight lost in kg, greater percentage of weight loss, and change in BMI. Therefore, more male participants lost $\geq 5\%$ than female

participants. Enrollment, baseline data, and weight loss comparison between male and female participants are consistent with other weight-loss studies; however, a higher percentage of men were represented in the Retrofit study population than presented in the literature [6,9,15,17,19,20,22,23,30,33,40,42]. Women are shown to seek out weight-loss opportunities more than men, whereas men lose more weight regardless of age or baseline weight characteristics, likely due to biological differences between males and females [5,42,43]. However, regardless of total weight lost, losing a clinically significant amount of weight at $\geq 5\%$ is of most importance to reduce comorbidities related to overweight and obesity [9-12,25,42,43].

High Performers' Characteristics and Behaviors

Determining potential baseline indicators and behaviors of participants achieving 10% or greater weight loss was important to increase the reduction of overweight- and obesity-related health conditions [9-11,23]. A majority of the baseline characteristics for high-performing males and females were not significantly different compared with the remaining participants. However, high-performing males had a higher starting weight than remaining male participants and high-performing females were older on average than the remaining female participants. Older adults have been shown to be more successful in losing weight than younger adults owing to intervention adherence in the Look AHEAD trial [42,43]. Men, in general, and specifically older women are more motivated by health risks than cosmetic or social factors [44,45].

Of particular interest were the participant behaviors associated with high-performing participants at 12 months, which included the self-monitoring behaviors of weighing in, number of days wearing an activity tracker, and average number of steps per day, as well as engagement behaviors, including total number of coaching conversations, number of days with a coaching conversation, length of coaching conversations, and number of coaching sessions attended. Male and female high performers had a greater adherence rate to all self-monitoring behaviors and attended significantly more coaching sessions, which was consistent with the large amount of available research connecting program adherence to weight loss [20,25,33,44]. Self-monitoring behaviors, specifically when incorporated through technology, have consistently been shown to improve weight-loss outcomes [20,25,28,30,32,33].

High-performing female clients engaged more through coaching conversations than high-performing male clients on both total number of conversations and number of days with a conversation. This also was seen by Tate et al [33] in number of diary submissions being significantly associated with weight loss, although the study did not divide participants by sex. Participants, both male and female, who did not achieve 10% weight loss had longer conversations than high-performing participants. This observation identifies the hypothesis that frequency of messages, as opposed to length of messages, is a critical component of participant and coach asynchronous communication via Web-based messages. Multiple studies support the hypothesis that frequency of contact does improve weight-loss outcomes, specifically in achieving $\geq 5\%$ weight loss [15,31,32].

Strengths and Limitations

This study has several strengths, including reporting of real-world weight-loss outcomes. Participants were actual clients of Retrofit and were not recruited or provided with any incentives to participate in the study. In addition, all clients who met the starting BMI, age, and weight inclusion criteria were included as participants. No client who had a lack of success on the program was removed or eliminated from the population. As an uncommon research practice noted by Gudzone et al [6], researchers conclude that this study adds value and brings a unique set of outcomes to weight-loss research. No previous commercial program has published all of its data in such a manner, providing a true picture of efficacy of the Retrofit program. In addition, outcomes were segmented by sex to identify specific baseline characteristics and behaviors for success between men and women; and lastly, age was used as an additional component to target baseline characteristics and behaviors to achieve 10% or greater weight loss in 12 months.

In addition to the identified strengths, the researchers also noted some weaknesses. According to the study design, cross-sectional samplings were performed at 6, 12, and 24 months to select participants with known weight, which provided a separate population for each weight-loss period. The case series approach of this study does not allow any causal inferences based on the critical observations. In addition, because of the real-world population, it is unknown if participants were integrating any other weight-loss practices outside of the Retrofit program components.

Future Research

Because of a lack of real-world outcomes within the commercial weight-loss industry, Retrofit encourages all commercial weight-loss programs to publish similar data to show efficacy of programs. By reporting real-world outcomes in relation to

targeted behaviors, commercial weight-loss programs can structure protocols and client strategies to enhance long-term weight-loss success. Clearly defining the necessary behaviors for long-term weight-loss success and the efficacy of each commercial weight-loss program will solidify our ability as an industry and country to combat the obesity crisis, including obesity-related diseases such as heart disease and diabetes.

Recommended future research includes studying a population over time for a causal effect of weight loss, as well as comparing the population with a control group and targeting specific characteristics and behaviors for high-performing clients such as what engagement factors matter for male participants, why older female participants are more successful, and why men with a higher starting weight are more successful. In addition, it is recommended to compare male and female high performers as a single population with the remaining participants for further insight into baseline characteristics and behaviors for success, and observing self-monitoring and health behavior adherence beyond 12 months. Finally, evaluate the impact of Retrofit's weight-loss program on short-term and long-term employer health care spending.

Conclusions

In conclusion, participants on the Retrofit program lost an average of -5.21% at 6 months, -5.83% at 12 months, and -4.09% at 24 months. Men, on average, lost more weight than women. High-performing participants, or participants who lost $\geq 10\%$ of starting weight at 12 months, had a greater adherence to the self-monitoring behaviors of weighing in, number of days wearing an activity tracker, and average number of steps per day. Female high performers had a higher engagement in coaching conversations through conversation days and total number of conversations with their expert coaches. However, both high-performing male and female participants attended significantly more one-on-one coaching sessions.

Acknowledgments

Robert Kushner, MD, MS, and James Hill, PhD, are both active members of the Retrofit, Inc Advisory Board and were involved in reviewing the manuscript for submission.

Conflicts of Interest

SP, GD, RA, and KK are employees of Retrofit, Inc, with equity in the company. BH and JB are paid consultants of Retrofit, Inc, with equity in the company.

Multimedia Appendix 1

Retrofit logo.

[[JPG File, 64KB - mhealth_v4i3e101_app1.jpg](#)]

Multimedia Appendix 2

The technology provided included a Wi-Fi-enabled scale, activity tracker, and access to a private dashboard. The dashboard was accessible via Web and mobile apps.

[[PNG File, 135KB - mhealth_v4i3e101_app2.png](#)]

Multimedia Appendix 3

Coaching sessions were conducted via video chat, available online or with a mobile phone.

[[PNG File, 237KB - mhealth_v4i3e101_app3.png](#)]

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Abbreviations

ANOVA: analysis of variance

BMI: body mass index

Look AHEAD: Action for Health in Diabetes

SE: standard error

Edited by G Eysenbach; submitted 14.04.16; peer-reviewed by Anonymous, D Gaz; comments to author 05.05.16; revised version received 16.06.16; accepted 26.07.16; published 22.08.16.

Please cite as:

Painter S, Ditsch G, Ahmed R, Hanson NB, Kachin K, Berger J

Retrofit Weight-Loss Outcomes at 6, 12, and 24 Months and Characteristics of 12-Month High Performers: A Retrospective Analysis
JMIR Mhealth Uhealth 2016;4(3):e101

URL: <http://mhealth.jmir.org/2016/3/e101/>

doi: [10.2196/mhealth.5873](https://doi.org/10.2196/mhealth.5873)

PMID: [27549134](https://pubmed.ncbi.nlm.nih.gov/27549134/)

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Original Paper

An Evaluation of a Smartphone–Assisted Behavioral Weight Control Intervention for Adolescents: Pilot Study

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Abstract

Background: The efficacy of adolescent weight control treatments is modest, and effective treatments are costly and are not widely available. Smartphones may be an effective method for delivering critical components of behavioral weight control treatment including behavioral self-monitoring.

Objective: To examine the efficacy and acceptability of a smartphone assisted adolescent behavioral weight control intervention.

Methods: A total of 16 overweight or obese adolescents (mean age=14.29 years, standard deviation=1.12) received 12 weeks of combined treatment that consisted of weekly in-person group behavioral weight control treatment sessions plus smartphone self-monitoring and daily text messaging. Subsequently they received 12 weeks of electronic-only intervention, totaling 24 weeks of intervention.

Results: On average, participants attained modest but significant reductions in body mass index standard score (zBMI: 0.08 standard deviation units, $t(13)=2.22$, $P=.04$, $d=0.63$) over the in-person plus electronic-only intervention period but did not maintain treatment gains over the electronic-only intervention period. Participants self-monitored on approximately half of combined intervention days but less than 20% of electronic-only intervention days.

Conclusions: Smartphones likely hold promise as a component of adolescent weight control interventions but they may be less effective in helping adolescents maintain treatment gains after intensive interventions.

(*JMIR Mhealth Uhealth* 2016;4(3):e102) doi:[10.2196/mhealth.6034](https://doi.org/10.2196/mhealth.6034)

KEYWORDS

obesity; adolescence; weight control; electronic intervention; self-monitoring

Introduction

Overweight and obesity are prevalent health conditions among pediatric populations that increase risk for physical, mental, and emotional problems [1,2]. These conditions are common presenting concerns in pediatric primary, secondary, and tertiary health care systems. Furthermore, treatment of overweight and obesity incurs significant burden including taxing health care systems and increasing health care costs [3]. Numerous

treatments for obesity have been developed and evaluated for adults, and treatments for children are also becoming more prevalent [4]. However, treatments targeting adolescents are few, and the efficacy of existing treatments is modest [5]. Furthermore, few studies have demonstrated maintenance of treatment gains after in-person interventions conclude [6]. Enhancing the sustainability of treatment effects is important in demonstrating the value of adolescent weight control interventions. Several studies in the adult literature suggest that

mobile health technologies are promising methods for promoting weight-loss maintenance [7]. In addition, many treatments for adolescent weight control are only available in research or hospital settings. Mobile health interventions may extend the reach of behavioral weight-loss interventions [8], an important aim in addressing obesity incidence and morbidity.

One key component of successful weight control is consistent self-monitoring. Although numerous studies have documented the importance of self-monitoring [9], adolescents are generally poorly adherent to this practice [10,11]. Studies have demonstrated that adolescents are more likely to adhere to self-monitoring goals when using an electronic device [12]. A separate but related literature suggests that text messaging is a useful tool for enhancing weight-loss outcomes. In the adult literature, numerous studies have demonstrated the efficacy of text only [13,14] and text plus standard behavioral weight control interventions [15,16]. However, text-messaging interventions for adolescent weight control have received less attention. Text messaging is ubiquitous in the lives of adolescents, with recent estimates suggesting that the daily median number of text messages sent by adolescents exceeds 60 [17]. Text messaging technology holds the capability of delivering intervention content in the treatment of adolescent overweight/obesity. One recent study demonstrated that adolescents perceived routine, automatically generated text messages delivered as part of a weight management program to be acceptable [18].

Smartphone-based behavioral weight control interventions have been evaluated for adults and adolescent studies are beginning to appear. Specifically, Thomas and Wing [19] demonstrated that after 24 weeks of smartphone-based intervention, participants obtained an average weight loss of 10.9 kg with 91% adherence to self-monitoring during the initial 12 weeks of the intervention and 85% adherence in the subsequent 12 treatment weeks. Similarly, Martin et al [20] found that 80% of participants in a smartphone-delivered weight monitoring and feedback intervention lost at least 5% of their body weight after 12 weeks. Furthermore, Burke et al [15] showed that adults who self-monitored via an electronic device demonstrated superior weight loss (63% achieved 5% weight loss) as compared with those who self-monitored via paper and pencil method (46% achieved 5% weight loss). Pretlow et al [21] recently reported that an addiction model intervention delivered by smartphone technology with phone coaching and text

messaging produced 7% change in percent over body mass index (BMI) in adolescents.

Existing studies examining smartphone interventions for adolescent weight control are few, and these studies have generally focused on self-monitoring adherence as opposed to weight outcomes [22]. Therefore, the purpose of this study was to determine whether a smartphone-assisted intervention, including self-monitoring support, feedback, and motivational enhancement, could produce changes in weight status and facilitate self-monitoring for overweight/obese adolescents. The smartphone intervention focused specifically on enhancing self-monitoring because this behavior has been shown to be central to adolescent weight control but few adolescents adhere to this practice in weight control interventions [11]. The primary outcome measures in this study were standardized BMI (zBMI), adherence to self-monitoring (percent of days adherent), treatment session attendance, and self-reported satisfaction with the intervention. We also aimed to describe the feasibility of implementing the intervention by integrating narrative feedback from participants to assist others in implementing similar interventions with adolescent populations.

Methods

Recruitment

Adolescents were recruited through advertisements posted in schools, pediatricians' offices, and community health centers. School nurses were also provided study advertisements, which they used to refer potential participants. Interested families responded to the advertisement by phone to be screened by research assistants for eligibility and to schedule an in-person intake session with both the participating adolescent and parent.

Participants

A total of 16 adolescents aged between 13-17 years with a BMI percentile $\geq 85\%$ and their parent/guardian most responsible for meal preparation were enrolled in the study. Inclusion criteria included: (1) parent/guardian and adolescent consented to participate, (2) the adolescent was aged between 13-18 years, (3) the adolescent exceeded the 85th BMI percentile for age and sex, (4) the adolescent was living at home with their parent/guardian, (5) the adolescent did not have any serious mental illnesses or developmental delays, and (6) participants consented to video recording during the group treatment sessions. Participant demographic characteristics are displayed in [Table 1](#).

Table 1. Demographic characteristics of study participants.

	N	%
Age		
13 years	6	38
14 years	7	44
15 years	1	6
16 years	1	6
17 years	1	6
Sex		
Female	12	75
Male	4	25
Educational attainment		
Junior high school (7-9 total years)	13	81
High school (10-12 total years)	3	19
Race/ethnicity		
Non-Hispanic white	9	56
Hispanic/Latino	4	25
Other	3	19
Parent education level		
High school graduate	1	6
Attended college	2	12
Associate's degree	3	18
College graduate	7	46
Graduate degree	3	18
Parent monthly income		
Range	\$2000-\$16,666	
Average	\$6151.45	

Procedure

Study procedures were approved by the Brigham Young University Institutional Review Board for Human Subjects. Participants attended an initial in-person meeting where they provided informed consent/assent and completed an initial assessment of height and weight conducted by trained research assistants and baseline questionnaires. Study assessments occurred on 4 occasions over a 1-year period including: (1) at intake (time 1; N=16), (2) after completion of the 12-week group intervention (time 2; N=14), (3) after the 12-week electronic-only intervention (time 3; N=14), and (4) 1 year after the first treatment session (time 4, N=10) with final study assessments concluding in June 2014. Missing data resulted exclusively from participant's failure to respond to invitations to complete study assessments. At the initial treatment session, each adolescent participant was provided an electronic device for self-monitoring (iPhone 4) with a diet/physical activity app installed (Daily Burn Tracker) for the duration of the intervention period (24 weeks). Unlimited data/voice/text plans were provided to participants free of charge. One participant elected to use their own iPhone to avoid challenges with

duplicate devices. All other participants used the phone supplied by the researchers exclusively during the 24-week intervention period. After completing the 12-week combined intervention (combined treatment), electronic self-monitoring and text messaging continued for an additional 12 weeks. Self-monitoring was selected as the primary goal of the electronic-only intervention period because of its documented importance in facilitating adolescent weight control.

In-Person Intervention Description

Participants attended a 12-week group weight control program led by clinical psychology doctoral students under the supervision of licensed psychologist, with parents and adolescents attending separate group meetings in adjoining rooms. Pediatric psychologists delivered the intervention because of their expertise in weight-related health behavior change. Group meeting duration was 75 minutes. Weekly treatment supervision meetings were held to ensure adherence to the treatment protocol. Group sessions were standardized by using a 12-week modular behavioral weight control program developed by Jelalian et al [23] that included important components of weight management including self-monitoring,

portion control, problem solving, stimulus control, emotional eating, and physical activity. Each parent/adolescent dyad also received 15 minutes of individual family intervention every 4 weeks after group sessions. During individual family meetings, motivational interviewing was used to assess motivation and to problem solve how to overcome barriers to treatment.

Electronic Self-monitoring and Text Messaging Intervention Description

The smartphone-based treatment component consisted of 2 parts: electronic self-monitoring and human-generated text messaging. Consistent with previous studies conducted with adults, participants were instructed to record all meals/snacks and physical activity electronically. DailyBurn Tracker, a commercially available smartphone app, was used for self-monitoring. This method simplified self-monitoring by allowing participants to search for foods in a database that contained nutrition information or to scan barcodes on food labels to locate nutrition information. Moreover, participants could store unlimited “favorite” foods in DailyBurn. An intuitive user interface in DailyBurn allowed participants to organize foods consumed by meal, indicating quantity and summing dietary characteristics (e.g., total calories, total fat, and so forth). Physical activity was tracked using the same app. Participants received real-time feedback regarding their goal attainment using DailyBurn. Specifically, participants could view a visual analog scale demonstrating percentage of their caloric goals consumed at any time during the day. DailyBurn accounts were created for each participant by study staff, allowing researchers to view participant’s self-monitoring and diet behavior in real time.

Brief text messages were sent to each participant once per day in the evening by graduate and undergraduate research assistants. Text messages served 2 purposes. First, the messages provided feedback regarding participant self-monitoring behavior and progress toward treatment goals (eg, reducing sugar-sweetened beverages). Feedback was based on real-time self-monitoring data viewed in DailyBurn by study staff. Feedback was supportive and encouraged adherence to self-monitoring (eg, “remember to track your breakfast this morning”). Second, text messages contained content designed to reinforce principles addressed in the in-person treatment, including seeking social support, expanding diets to include healthier foods, and altering food environments. These text messages were selected from a library developed by Woolford et al [24] and the messages frequently used motivational interviewing strategies to evoke introspection and encourage autonomous motivation (eg, “What motivates you to eat breakfast every day?” “How can you add fruits or vegetables to your breakfast?”). Participants were not expected to text study staff in return.

Measures

Anthropometric Data

Weight was measured using a digital scale (Seca 869, measured to the tenth of a pound) and height was measured using a portable stadiometer (Seca 217, measured to the eighth of the

inch) with participants wearing light clothing and no shoes. The zBMI scores were calculated using the standard CDC formula [25].

Adherence to Self-Monitoring and Treatment Attendance

Adolescent’s self-monitoring data were downloaded from DailyBurn to calculate self-monitoring adherence. Consistent with Thomas and Wing [19], days on which participants tracked 2 or more meals were considered self-monitoring adherent days. Treatment attendance was calculated as a percentage of in-person treatment sessions attended.

Participant Satisfaction

Satisfaction with the treatment program was measured using the Client Satisfaction Questionnaire [26]. This eight-item scale has demonstrated adequate reliability ($\alpha=.83-.93$) and validity in previous studies.

Semistructured Treatment Exit Interview

At the conclusion of the study, each participant was interviewed about his or her participation experience. Interview questions were open-ended and covered topics including study components that were helpful, changes that could be made to the intervention, and their impressions of using a smartphone as part of the study. For example, interview questions included, “What aspects of the program were helpful to you in managing your weight?” and “What is your opinion about using the smartphone as part of the program?” All interviews were transcribed by a research assistant who did not conduct the interviews.

Statistical Analysis Plan

Data analyses were conducted using Stata 13 [27]. Descriptive statistics were calculated for baseline demographic variables and primary study variables (eg, zBMI, self-monitoring, treatment satisfaction, treatment session attendance) including means and standard deviations. Paired samples *t* tests were used to examine change in zBMI over time and estimates of effect size (Cohen’s *d*) were computed. Correlation analyses were used to test associations between self-monitoring adherence/treatment session attendance and change in zBMI. Participants with insufficient data to calculate zBMI at any given time point were excluded from analyses.

Results

Mean statistics for weight status at each measurement occasion are presented in Table 2. On average, participants were in the obese category at baseline with a BMI% of 95.78 (SD=3.51). A paired samples *t* test comparing zBMI at time 1 to time 2 indicated a significant decrease; $t(13)=2.22, P=.04, d=.63$. On average, participants attained a 0.08 standard deviation decrease in zBMI. Neither time 3 nor time 4 zBMI was significantly different from baseline. These results are consistent with modest mean weight-loss over the in-person intervention period but subsequent return to baseline levels during the 3-month electronic intervention-only period.

Table 2. Changes in participant weight status.

	Time 1, mean (SE ^a), N=16	Time 2, mean (SE), N=14	Time 3, mean (SE), N=14	Time 4, mean (SE) N=10
Body weight (lbs)	175.10 (10.29)	172.53 (11.14)	177.93 (10.27)	175.40 (5.38)
zBMI ^b	1.85 (0.11)	1.74 (0.13)	1.78 (0.13)	1.78 (0.12)

^aSE: standard error.

^bzBMI: standardized body mass index.

On average, participants attended 7.5 (62.5%) out of 12 in-person treatment sessions (SD=0.85). A correlation analysis showed no significant association between treatment session attendance and change in weight status between time 1 and time 2 for zBMI. On average, participants monitored at least 2 meals on 48.3% of days during the in-person intervention (12 weeks), with 7 participants monitoring their diet over 50% of in-person intervention days. Participants monitored at least 2 meals on 16.6% of the available days during the electronic-only intervention period. On average, participants tracked at least 30 minutes of physical activity on 14.6% of available days during the 12-week in-person intervention and 4.6% of available days during the electronic-only intervention. Paired samples *t* tests comparing diet and physical activity self-monitoring during in-person and electronic-only intervention periods indicated significant differences ($t(15)=5.68, P<.001, d=.46$; $t(15)=3.67, P=.002, d=.38$, respectively). Correlation analyses examining the association between diet/physical activity self-monitoring and zBMI were not significant.

At completion of the 6-month intervention period Client Satisfaction Questionnaire rating was 20.33 (maximum=22). Participants also completed an exit interview soliciting feedback regarding perceptions of the treatment (see Table 3). Of the 15 adolescents who completed the interview, most described the

intervention favorably (N=13; 86.7%), reporting that the intervention “worked well” or was “very helpful.” Specifically, our participants endorsed enjoying learning about nutrition and exercise (N=5; 33.3%) and being able to meet with an expert to have their questions answered (N=3; 20%). Most of our participants reported that they favored meeting in a group over the electronic-only intervention (N=11; 73.3%). Two participants (13.3%) described the intervention unfavorably, stating that they “didn’t get as much help as [they] would have liked.” Overall, half of our participants viewed the intervention’s emphasis on self-monitoring as helpful (N=8; 53%). Despite this positive view of self-monitoring, about half of our participants found the DailyBurn app to be “tedious” and “difficult to use” (N=8; 53.3%).

Most of our participants viewed the text messages that they received from study staff very positively (N=11; 73.3%). Four of our participants (26.7%) stated they wished that they had received more texts. Several participants noted that the text messages were “enthusiastic” and “uplifting” and that they “reminded (them) that (they) were doing a good job.” However, a subset of our participants found the texts to be unhelpful (N=4; 26.7%). When asked what we could do improve our text messages, the most consistent feedback that we received was to include healthy recipes in our text messages (N=8; 53.3%).

Table 3. Themes from qualitative treatment exit interviews with illustrative quotations.

Intervention themes	Impressions (N)	Quotations
Broad impressions	Positive (13)	<i>I liked the (intervention); it was helpful to know that there are other kids like me.</i>
	Negative (2)	<i>I don't know how an intervention can be an enjoyable thing! It made me feel like I was doing everything wrong and nobody else has this problem.</i>
Group	Positive (11)	<i>Sharing what we did with the group was really helpful. I wish we (could have) had more group meetings together.</i>
	Neutral or negative (4)	<i>It would have been nice to have two groups...split the older group from the younger group.</i>
iPhone	Positive (9)	<i>It was easier (to track) because you always have (your phone) with you.</i>
	Negative (6)	<i>At times the phone was distracting. I used the phone for other things besides recording calories and exercise.</i>
Self-monitoring	Positive (8)	<i>Tracking helped me become come more aware, (which) was helpful. (It helped me) focus on healthy choices and making good long-term life choices.</i>
	Neutral or negative (7)	<i>The tracking was kind of annoying and I don't think that I really got help as much as I'd like.</i>
DailyBurn	Positive or neutral (7)	<i>The only thing that helped was DailyBurn.</i>
	Negative (8)	<i>It was a challenge to do DailyBurn because it took time to type (in foods) and find (foods).</i>
Text messages	Positive (11)	<i>(The texts) made me feel really nice. It reminded me that I was doing a good job.</i>
	Neutral or negative (4)	<i>I got annoyed (by the texts) really fast. I'm sorry! But when I'm told to do something I was going to do anyway, I will do the exact opposite of what is asked.</i>

Discussion

Principal Findings

This pilot study was one of the first to use smartphone technology to enhance self-monitoring and deliver tailored behavioral weight control text messages to adolescents as part of a clinical intervention. Similar to previous studies, participants demonstrated modest but significant reductions in zBMI from baseline to the end of the in-person intervention portion of the study, although reductions in zBMI were not sustained over the electronic-only intervention period. These findings suggest that text messaging and electronic self-monitoring may be helpful when paired with behavioral intervention, but that text messaging and electronic self-monitoring may not be effective as standalone treatment. Similarly, Nguyen et al [6] recently found that although adolescents were able to achieve weight loss during the in-person portion of an intervention combining face-to-face treatment plus telephone coaching and text messaging/email contact, they failed to maintain weight loss once the in-person intervention ceased. Although both standalone and adjunctive smartphone interventions (ie, smartphone plus in-person treatment) have been shown to be effective in the adult literature, our results support an adjunctive treatment model.

One potential explanation for our finding that zBMI change did not persist in the electronic intervention-only period is that adolescents were less able to draw on the social support that they received while engaging in the in-person intervention. Most of our participants favored meeting in the group setting, and several of our participants desired increased social connectedness throughout the course of the intervention.

Furthermore, studies have shown that social support is an important motivator for individuals who want to lose weight and having social support helps individuals maintain weight loss [28]. Although adult studies have found electronic device interventions to be effective without an emphasis on social support [19], we theorize that social support would be more salient and effective for adolescents. Furthermore, research has shown that electronic health interventions that have a focus on increasing social support have an additive benefit when trying to achieve weight loss [29]. mHealth interventions for weight loss could increase social support for behavior change through social media such as Facebook groups, a method that has been used successfully in young adults [30].

On average, our participants recorded 2 or more meals roughly 1 out of every 3 days. Interestingly, self-monitoring adherence did not predict zBMI change in this study. The overall adherence to self-monitoring observed in our sample is lower than what has been found in previous studies [15]. We found that adherence to diet and physical activity self-monitoring was significantly higher during in-person (vs electronic-only) intervention. These findings suggest that, even when provided with a smartphone and self-monitoring app, adolescents demonstrate relatively low adherence to self-monitoring, particularly when compared with adult studies [19]. One potential explanation for the low self-monitoring adherence observed in our study is that some participants perceived the Daily Burn app as “tedious” and “difficulty to use” which may have deterred some individuals from self-monitoring. Developing less burdensome self-monitoring apps such as those integrating gamification may increase adolescent’s adherence to self-monitoring.

Most of our participants rated their satisfaction with the intervention highly. Adolescents reported perceiving the text messaging and self-monitoring to be helpful components of the intervention. Most participants found the iPhone to be useful for self-monitoring because it was available to them throughout the day. Our participants provided several suggestions for improvement to our weight control program. For example, most of the participants viewed the DailyBurn app as burdensome. Intervention designers might consider incorporating more user-friendly apps to record diet and exercise. Several previous studies have created study-specific smartphone apps to ensure that the app was user-friendly and age-appropriate [31,32]. Consistent with previous studies [24], participants in our study perceived text messages positively, particularly messages that encouraged behavior change (eg, providing novel meal suggestions). They expressed a preference for motivational/supportive messages whereas behavior feedback messages created for this study (eg, “remember to track your diet today”) were less preferred. This finding is consistent with previous qualitative research that has indicated that adolescents may experience ambivalence about receiving directive weight control text messages [33].

Regarding feasibility, our study model requires both in-person interventions (similar to other treatments) in addition to electronic treatment content delivery. Dissemination of our intervention approach is also limited because human-delivered

text messages are cost intensive. One way to alleviate this burden is to incorporate automated delivery of text messages [18,34]. Limitations to this study include the small, homogeneous study sample and the lack of a comparison condition. We provided an iPhone with data/voice/text plan to study participants, which limits disseminability of the intervention. However, smartphones are increasingly available to adolescents and many individuals can use their own phones to receive interventions.

Conclusion

Although participants were able to lose weight during the in-person treatment, they were unable to maintain weight loss during the electronic-only intervention period. One potential explanation for this finding is that our study did not incorporate problem solving, stimulus control, and emotional eating components into the electronic-only intervention, which may have contributed to poor maintenance of weight loss. Future research integrating these components that have been shown to be important in in-person treatments into mHealth interventions is important. Despite these limitations, this study is important because it was one of the first to examine weight status outcomes of a smartphone-assisted behavioral weight control intervention for adolescents. Furthermore, our study provides important formative feedback for development of future smart phone interventions for adolescent weight control.

Acknowledgments

The authors thank Heather Heuston for her assistance in conducting treatment groups and collecting study data.

Conflicts of Interest

None declared.

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Abbreviations

BMI: body mass index

SD: standard deviation

Edited by G Eysenbach; submitted 26.05.16; peer-reviewed by R Pretlow, J Moon, K Curtis, PH Lin; comments to author 30.06.16; revised version received 07.07.16; accepted 20.07.16; published 23.08.16.

Please cite as:

Jensen CD, Duncombe KM, Lott MA, Hunsaker SL, Duraccio KM, Woolford SJ

An Evaluation of a Smartphone-Assisted Behavioral Weight Control Intervention for Adolescents: Pilot Study

JMIR Mhealth Uhealth 2016;4(3):e102

URL: <http://mhealth.jmir.org/2016/3/e102/>

doi: [10.2196/mhealth.6034](https://doi.org/10.2196/mhealth.6034)

PMID: [27554704](https://pubmed.ncbi.nlm.nih.gov/27554704/)

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Original Paper

Acceptance and Commitment Therapy in Daily Life Training: A Feasibility Study of an mHealth Intervention

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Abstract

Background: With the development of mHealth, it is possible to treat patients in their natural environment. Mobile technology helps to bridge the gap between the therapist's office and the "real world." The ACT in Daily Life training (ACT-DL) was designed as an add-on intervention to help patients practice with acceptance and commitment therapy in their daily lives. The ACT-DL consists of two main components: daily monitoring using experience sampling and ACT training in daily life.

Objectives: To assess the acceptability and feasibility of the ACT-DL in a general outpatient population. A secondary objective was to conduct a preliminary examination of the effectiveness of the ACT-DL.

Methods: An observational comparative study was conducted. The experimental group consisted of 49 patients who volunteered for ACT-DL, and the control group consisted of 112 patients who did not volunteer. As part of an inpatient treatment program, both groups received a 6-week ACT training. Participants went home to continue their treatment on an outpatient basis, during which time the experimental group received the 4-week add-on ACT-DL. Acceptability and feasibility of the ACT-DL was assessed weekly by telephone survey. Effectiveness of the ACT-DL was evaluated with several self-report questionnaires (Flexibility Index Test (FIT-60): psychological flexibility, Brief Symptom Inventory: symptoms, Utrechtse Coping List: coping, and Quality of life visual analog scale (QoL-VAS): quality of life).

Results: More than three-quarters of the participants (76%) completed the full 4-week training. User evaluations showed that ACT-DL stimulated the use of ACT in daily life: participants practiced over an hour a week (mean 78.8 minutes, standard deviation 54.4), doing 10.4 exercises (standard deviation 6.0) on average. Both ACT exercises and metaphors were experienced as useful components of the training (rated 5 out of 7). Repeated measures ANCOVA did not show significant effects of the ACT-DL on psychological flexibility ($P=.88$), symptoms ($P=.39$), avoidant coping ($P=.28$), or quality of life ($P=.15$).

Conclusions: This is the first study that uses experience sampling to foster awareness in daily life in combination with acceptance and commitment therapy to foster skill building. Adherence to the ACT-DL was high for an intensive mHealth intervention. ACT-DL appears to be an acceptable and feasible mHealth intervention, suitable for a broad range of mental health problems.

However, short-term effectiveness could not be demonstrated. Additional clinical trials are needed to examine both short-term and long-term effects.

(*JMIR Mhealth Uhealth* 2016;4(3):e103) doi:[10.2196/mhealth.5437](https://doi.org/10.2196/mhealth.5437)

KEYWORDS

mHealth; behavior change; daily life intervention; acceptance and commitment therapy; experience sampling

Introduction

Background

Over the last decade, the field of psychological treatment has seen the emergence of third generation behavioral therapies [1]. These third wave therapies focus on how to relate in a more workable way to difficult thoughts and feelings rather than trying to change them. One of these therapies is acceptance and commitment therapy (ACT). Instead of focusing on the content, the person focuses on the function of difficult experiences and the context in which they occur [2]. Here, we examine a novel strategy designed to implement ACT interventions in the daily lives of patients, thereby enhancing the usefulness and effect of the treatment.

Acceptance and Commitment Therapy

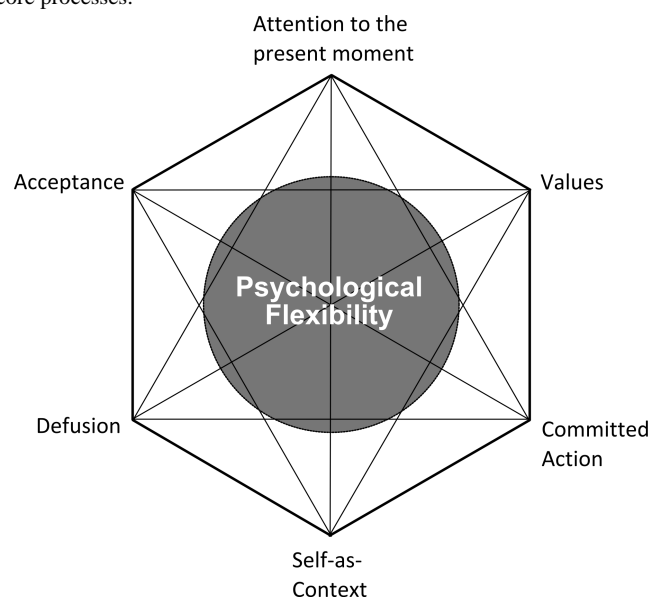
ACT is a form of psychotherapy positioned within the third wave behavioral therapies. ACT does not primarily focus on symptom reduction but teaches patients to deal with their challenging experiences in such a way that they can behave according to their values [2]. The ACT model consists of six core processes that are closely interlinked (Figure 1). *Acceptance* teaches patients to pay attention to unpleasant feelings instead of trying to get rid of them. *Defusion* helps patients to recognize thoughts for what they are: cognitions they can distance themselves from rather than truths they have to react on. The *self as context* helps patients realize they are more than their thoughts, emotions, and self-image; there is also an observer

who is having these experiences. Patients also learn to focus their *attention to the present moment*—to be aware of their internal and external environment. *Values* helps patients refocus on the things that really matter to them, and *committed action* encourages them to start investing in their personal values again. Together, these core processes form psychological flexibility, the ability to deal with challenging experiences in a flexible way while continuing to act based on one's values [3,4]. Since ACT is an experiential form of therapy, many exercises are used (learning by experiencing). The exercises also support skill-building by patients. Metaphors are also frequently applied in this form of therapy to validate the patient's experience, create awareness of the situation, and introduce new approaches to handle the situation [5].

The American Psychological Association has included ACT in its register of research-supported psychological treatments for depression, mixed anxiety, obsessive-compulsive disorder, psychoses, and chronic pain. A recent meta-analysis from A-Tjak and colleagues [6] showed that ACT is an effective intervention for treating depression, anxiety disorders, addiction, and somatic health problems. The evidence thus suggests transdiagnostic effectiveness of ACT.

Although it is most valuable to acquire ACT skills during therapy sessions, it is equally important to get ACT out of the therapist office and into the daily life of the patient. This helps the patient to generalize ACT skills to different situations and different challenges, changing behavioral patterns at home. Put shortly: learning to apply ACT in their daily lives.

Figure 1. The ACT hexaflex with the 6 core processes.



Experience Sampling Method

The experience sampling method (ESM) is an ambulatory assessment method that consists of multiple assessments per day, at random times, asking patients to complete a brief questionnaire about experiences, environments, and activities in-the-moment (ecological validity) [7]. By measuring in daily life, ESM takes into account the importance of the context in which experiences and behavior occur and also provides information regarding this context [8].

From an ACT perspective, ESM not only represents a suitable ecologically valid assessment method but also facilitates the ACT processes *attention to the present moment* and *self as context*, which together represent the core pillar “being aware.” Completing multiple assessments at random moments throughout the day promotes awareness of both internal and external experiences, as well as insight into the relationship between experiences and context [9].

mHealth

Mobile Health (mHealth) is a relatively recent technological development and can be defined as the use of mobile devices such as personal digital assistants (PDAs), mobile phones, and tablets to promote health [10,11]. In February 2016, 72% of adults in the United States and 60% to 71% of adults in Western Europe owned a mobile phone [12]. Mobile devices can assess and intervene at any time or place in the personal context of the user (online and offline). Therefore, they are an ideal medium for personal ecological assessment and intervention. ESM has already successfully found its way in mHealth [13-18], showing its potential in the treatment of depression [19] and anxiety [20]. Similarly, the first mHealth ACT interventions are showing promising results for chronic medical conditions [21], stress [22,23], and smoking cessation [24].

Objectives

The ACT in Daily Life training (ACT-DL) focuses on daily life monitoring and ACT training in context, combining ACT techniques, ESM, and mobile technology (see [Multimedia Appendix 1](#) for example). The goal of the intervention is to stimulate patients to practice ACT skills in their daily life after completing a regular ACT training. The primary objective was to assess the ACT-DL with respect to feasibility and acceptability in a heterogeneous population of patients with a mental health disorder. The secondary objective was to conduct a preliminary examination of the effectiveness of ACT-DL.

Methods

Participants

Participants were recruited in an inpatient mental health care facility in Epen, the Netherlands, between June and November 2013. The center provides treatment for common mental problems like major depression, anxiety, and substance use disorder. All patients received a flyer about the study with information about the aim and set-up of ACT-DL, duration of the training, and estimated time investment. Inclusion criteria were intentionally kept broad; all consecutive referrals in the study period could participate in the study. There were two

exclusion criteria: deviation from the length of inpatient stay (standard 7-week program) and participation in another study within the treatment facility. The control group consisted of all other patients who participated in the full treatment program (7-week inpatient and 7-week outpatient treatment) between 2013 and 2014 and completed all the required measures. Due to the clinical setting, it was impossible to randomize participants into two conditions and therefore an observational design was chosen.

The initial aim for the feasibility study was to include a minimum of 20 participants (suggested by sample size calculation, Cohen $d=1.8$, alpha error probability = .05, power = .95, allocation ratio $N2/N1=1$). Given the enthusiasm for participation, 49 participants were included in the experimental intervention (mean age 45.7 years, standard deviation [SD] 10.0 years) and 112 participants composed the control group (mean age 47.5 [SD 12.4] years).

Sample Characteristics

Both the ACT-DL and the control group were heterogeneous with regard to age, level of education, and diagnosis on *Diagnostic and Statistical Manual of Mental Disorders* (Fourth Edition) (DSM-IV-TR), Axis I and Axis 2 ([Table 1](#)). There were no significant differences in demographics between the ACT-DL and the control group with the exception of gender ($P=.02$). A total of 8 participants dropped out after the first week, 3 after the second week, and 1 after the third week. Of the 49 participants, 37 (76%) completed the full 4-week ACT-DL. The completers did not deviate significantly on demographics or baseline measures from the noncompleters. Additionally, because of the qualitative nature of the evaluation by telephone (participants did not always give a clear answer on every question), missing data points were present in the dataset (20%) and assumed to be missing at random. An intention-to-treat analysis was used.

Procedures

The Medical Ethics Committee of Maastricht University Medical Centre approved the study procedures, and all participants provided written informed consent. All participants underwent a 7-week inpatient treatment program that started with a 1-week diagnostic phase including structured interviews in which DSM-IV-TR axis I (Mini-International Neuropsychiatric Interview, or MINI [25]) and axis II disorders (Structured Interview for DSM-IV-TR Personality Disorders [26]) were assessed. Participants also completed a range of pretreatment questionnaires (T1). After the diagnostic week, participants followed an intensive 6-week treatment program (psychoeducation, cognitive-behavior therapy, ACT, mindfulness, group psychotherapy, creative therapy, relapse prevention, and vitality management). One of the main components of the program was an ACT group. This was a weekly, 90-minute group therapy session (10-12 members) guided by a structured treatment manual, during which one of the 6 ACT core components was targeted each week (handouts were provided). Throughout the 6 sessions, the metaphors and exercises that were going to be used in the ACT-DL during the outpatient phase were discussed. An experienced ACT therapist conducted the weekly sessions.

After the 6-week inpatient program, participants completed the posttreatment questionnaire battery (T2). During the last week of inpatient treatment, participants who volunteered for the ACT-DL received a 60-minute briefing on how the training would be implemented in their daily lives. At this point, the participants of the ACT-DL training received the PsyMate digital devices with the ACT-DL program. Participants were asked to keep the PsyMate with them at all times during the training days but not let this interfere with their daily lives.

Treatment was then continued for a 7-week outpatient phase to which a 4-week ACT-DL was added in the experimental group.

ACT-DL participants started with the 4-week training as soon as they arrived home. At the end of each week of training, participants were contacted by a member of the research staff for a semistructured interview (approximately 15 minutes) on their experiences of that week. The evaluation of the last training week was more elaborate and was also used for debriefing (approximately 30 minutes). The answers to the Likert-scale questions were noted, and the answers to the open-ended questions were transcribed. At the end of the outpatient treatment phase, participants completed the postoutpatient questionnaire battery (T3, [Figure 2](#)) and returned the PsyMates with the ACT-DL program.

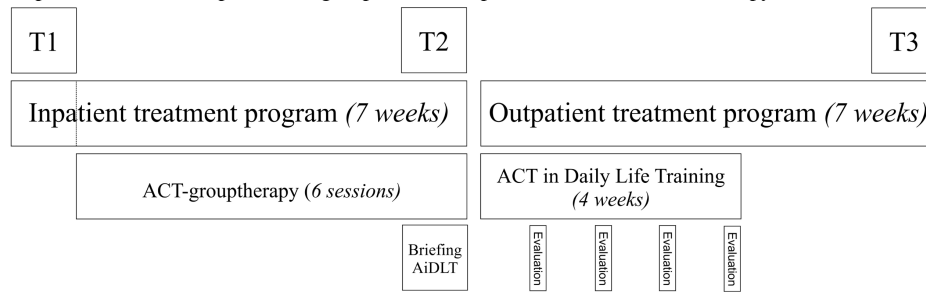
Table 1. Demographic characteristics of participants in the intervention (n=49) and control (n=112) groups.

	ACT-DL ^a	Control	P value
Age, years, mean (SD)	45.7 (10.0)	47.5 (12.4)	.38
	min 23-max 65	min 22-max 68	
Gender, n (%)			.02
Male	17 (35)	62 (55)	
Female	32 (65)	50 (45)	
Education level, n (%)			.15
Primary	—	1 (1)	
Secondary	21 (43)	51 (46)	
Undergraduate	17 (35)	21 (19)	
Graduate	11 (22)	35 (31)	
Other	—	4 (4)	
Main diagnosis on Axis I (DSM-IV-TR-TR ^b), n (%)			.63
Anxiety	6 (12)	20 (18)	
Mood	26 (53)	44 (39)	
Somatoform	4 (8)	9 (8)	
Substance	11 (22)	31 (28)	
Other	2 (4)	8 (7)	
Additional diagnosis on Axis II (DSM-IV-TR-TR), n (%)			.10
None	36 (74)	90 (80)	
Cluster A	—	—	
Cluster B	6 (12)	4 (4)	
Cluster C	5 (10)	8 (7)	
Other	2 (4)	10 (9)	

^aACT-DL: ACT in Daily Life.

^bDSM-IV-TR-TR: *Diagnostic and Statistical Manual of Mental Disorders*(Fourth Edition, Text Revision)

Figure 2. Timeline of the procedure for the experimental group. ACT: acceptance and commitment therapy.



Intervention: ACT in Daily Life Training

Design of ACT in Daily Life

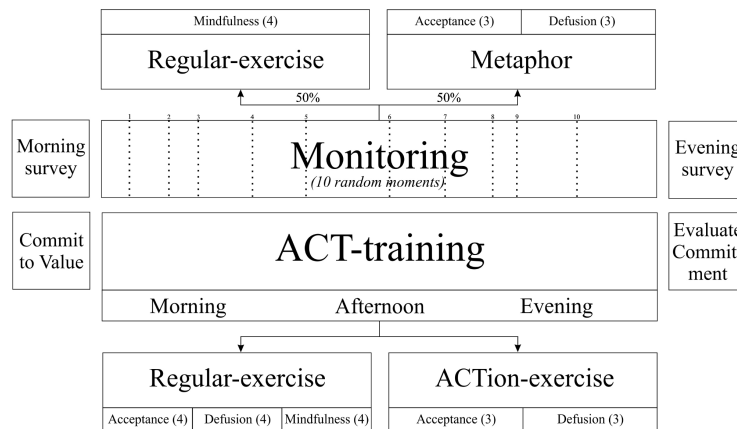
The ACT-DL is a fully automated mobile ACT intervention delivered by a PDA-like device, the PsyMate (see Myin-Germeys et al [27] for a global description). This mHealth intervention assists participants to practice with ACT skills in their daily lives. The goal of the training is to help participants integrate ACT skills in their daily life, thus improving psychological flexibility and, ultimately, quality of life. The ACT-DL has a duration of 4 weeks during which participants receive training for 3 consecutive days each week—Thursday, Friday, and Saturday—to get a cross-section of the week (approximately 1 hour per day). The ACT-DL is not a stand-alone intervention. Participants need to be familiar with ACT (prior therapy/training) to be able to benefit from this

add-on intervention. The ACT-DL consists of two main components: daily monitoring via experience sampling and ACT training in the personal environment. The ACT-DL uses persuasive techniques such as tunnelling (leading users through a predetermined sequence of actions), self-monitoring, and reminders.

PsyMate

The PsyMate is a PDA-like device that provides the ACT-DL. It facilitates both the monitoring in daily life as a pocket diary and the ACT training by providing 18 different ACT exercises and 6 ACT metaphors as described above. The mode of delivery of the exercises is text-based; metaphors are offered as an illustration. Since it is a mobile device, it allows participants to practice with ACT in their daily lives. Figure 3 provides a schematic overview of the ACT-DL.

Figure 3. Schematic overview of the ACT in Daily Life Training (ACT-DL). The ACT-DL consists of two main components: monitoring and ACT training.



Monitoring

The ACT-DL uses daily life monitoring to foster awareness of one’s mental state, as well as the impact of the context on that state. Between 7:30 AM and 10:30 PM, the PsyMate beeps randomly 10 times, prompting the participant to complete a brief self-report questionnaire about current symptoms (affect and cognition), activity, company, and whereabouts. Furthermore, participants are asked to complete a brief morning questionnaire and evening questionnaire, appraising their day and quality of sleep. Monitoring was also restricted to the three ACT-DL training days.

ACT Training

The ACT-DL focuses on four core components of ACT: acceptance, defusion, mindfulness, and committed action. Two

types of ACT exercises are available via the PsyMate during the ACT-DL: regular exercises and ACTION exercises.

The regular exercises are always applicable because they focus on general ACT skill training independent of current thought, feelings, or situations. The exercises on acceptance, defusion, and mindfulness are made available on demand (4 exercises per component). Participants are required to carry out at least 3 exercises of their choice per training day (morning, afternoon, evening). Also, mindfulness-related exercises are offered after 5 out of 10 self-assessments (signal-contingent).

The ACTION exercises are specifically designed to be applicable in distressing situations. Whenever a participant has an unpleasant thought or feeling, they can activate one of the ACTION exercises (event-contingent) to deal with those distressing experiences in an ACT-consistent manner. Both

acceptance and defusion ACTion exercises are available (3 exercises per component, see [Textbox 1](#)).

Textbox 1. Example of an ACTion exercise.

Acceptance exercise: Opening up.

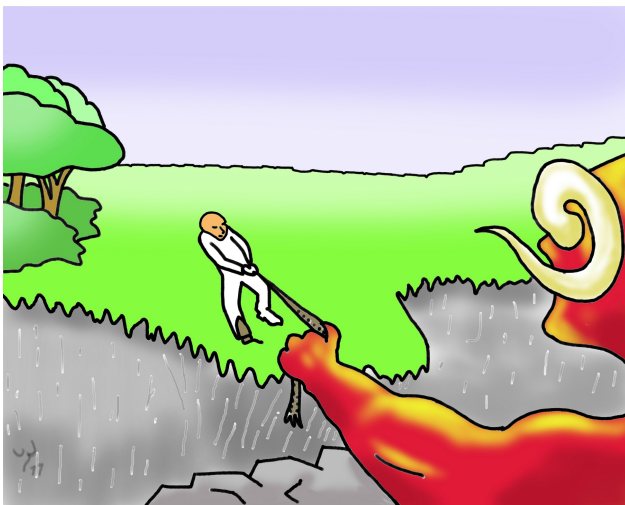
- Unpleasant feelings are showing up for you right now.
- See if you can open up to them, allowing these feelings to be there.
- Explore what there is to experience—what goes through your mind?
- Can you stay present with these difficult feelings and keep in touch with them?
- Do these feelings remain the same, or do they change?
- Are they getting heavier, lighter, do they remain the same, or do they fluctuate?
- See if you can continue giving some space to these unpleasant feelings for a while instead of trying to control them or trying to get rid of them.

In order to integrate committed action in the ACT-DL, at the end of each morning questionnaire, participants have to choose a personal value they want to invest in that day. Following the evening questionnaire, participants have to evaluate whether they had invested in their chosen value of the day (interval-contingent).

In addition to the ACT exercises, illustrated ACT metaphors are used in the training ([Figure 4](#)). These illustrated metaphors

serve as a reminder/cue to reactivate important ACT concepts learned during previous ACT training sessions (without needing to explain the concept in detail again). Both metaphors for acceptance and defusion can be accessed on demand (3 metaphors per component). The ACT metaphors are also offered after 50% of the self-assessment moments during the day, alternating with the mindfulness exercises (after 5 out of 10 self-assessments [signal-contingent]).

Figure 4. Examples of illustrated ACT metaphors. (Left, acceptance metaphor: tug of war. Try to stop your attempts of solving your pain by winning the war with it; try to let go of the rope. Right, defusion metaphor: waterfall. Instead of getting carried away by your stream of thoughts, take a step back and observe them.)



Measures

Usage and User Experiences

During the 4-week intervention period of the ACT-DL training, participants were contacted once a week by phone by a member of the research team to evaluate the previous week's training. This evaluation was conducted via a semistructured interview during which participants were asked to evaluate the usability of the PsyMate, the ACT metaphors, and the ACT exercises of that week. Open-ended questions (eg, "How did your practice go last week?") and questions using a 7-point Likert scale (eg, "The ACT exercises were useful; 1 = not at all, 7 = very much") were used. Also usage of the exercises and metaphors was evaluated (eg, "How many ACT exercises did you on average

perform per day?"). After the last week, a more elaborate evaluation was conducted.

Psychological Flexibility

The Flexibility Index Test (FIT-60) is a self-report questionnaire that measures psychological flexibility and its six underlying ACT components: acceptance, defusion, self as context, present moment, values, and committed action [26]. The FIT-60 consists of 60 items that are scored on a 7-point Likert Scale. The FIT-60 has good psychometric properties [28,29].

Coping Skills

The Utrechtse Coping List (UCL) is a 47-item self-report questionnaire that measures seven coping styles: actively addressing, palliative reacting, avoiding, seeking social support,

passive reacting, expression of emotions, and reassuring thoughts [30]. Only the subscale avoiding was used for this study. The internal consistency of the UCL is moderate to good. Construct validity and predictive validity are sufficient [31].

Psychological Symptoms

The Brief Symptom Inventory (BSI) provides an overview of symptoms and their intensity at a specific point in time [32]. The BSI consists of 53 items which are scored on a 5-point Likert scale. Besides a total symptom rating, the BSI indexes symptoms on 9 specific dimensions: somatization, obsessive-compulsive, interpersonal sensitivity, depression, anxiety, hostility, phobic anxiety, paranoid ideation, and psychoticism. The internal reliability and test-retest are sufficient. Furthermore, the inventory is sensitive to treatment effects [33,34].

Quality of Life

Quality of life was assessed with the question "How happy do you feel at this moment?" and scored on a 10-point visual analog scale (QoL-VAS). This question is used as a proxy for living a valued, committed life. The Dutch QoL-VAS has good construct validity [35].

Participants completed the self-report questionnaires before starting the inpatient treatment (T1: preinpatient), after the inpatient treatment (T2: postinpatient), and after the outpatient treatment, during which the experimental group also received the ACT-DL (T3: postoutpatient).

Statistical Analyses

Feasibility and acceptability of the ACT-DL were assessed with descriptive statistics. The open-ended answers of the user evaluation were analyzed via a conventional qualitative content analysis method (codes were derived from the verbatim transcripts and merged into a coding scheme). The effectiveness of the ACT-DL on ACT skills, coping, quality of life, and clinical symptoms were analyzed using SPSS version 22.0 statistical software (IBM Corp) with several analyses of covariance (ANCOVAs, level of significance was adjusted for the number of hypotheses with a Bonferroni correction; $P=.05/4$; $P=.01$). Interaction effects were tested with a repeated measures ANCOVA.

Results

Acceptability and Feasibility of ACT in Daily Life

The semistructured evaluation via telephone of the ACT-DL focused on user experience. These evaluations revealed that the training was rated positively, it stimulated the use of ACT, and the ACT exercises and metaphors were rated as useful (Figure

5). The ratings did not significantly change over the four assessment periods, assessed with a repeated measures analysis of variance regarding use of ACT ($F_{3,42}=0.063$, $P=.98$), usefulness of the exercises ($F_{3,39}=0.856$, $P=.47$), and usefulness of the metaphors ($F_{3,42}=0.788$, $P=.51$). The ACT exercises and ACT metaphors were rated equally useful ($t_{129}=-1.453$, $P=.15$). Participants were asked to keep track of the number of exercises they activated and how much time they spent on the training. Participants activated on average 8 to 13 exercises per week (mean 10.4, SD 6.0) in addition to the 15 exercises that were prompted that week and spent between 69 and 85 minutes (mean 78.8, SD 54.4) on the ACT training each week. The use of the ACT-DL was consistent over time, with a minor decline in use of exercises during week 3 (mean -2.5).

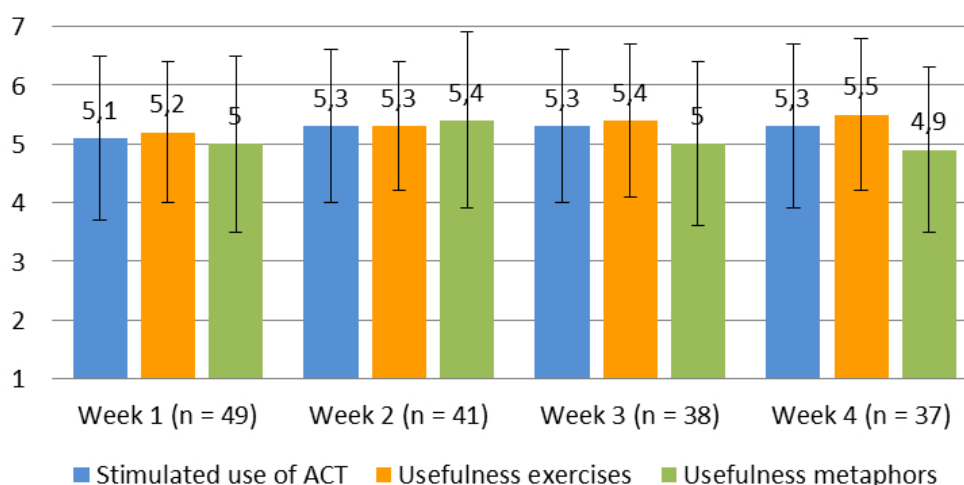
Participants responded with an average of 5.8 (SD 1.2) out of 7 on the question whether they would recommend the ACT-DL to others. Remarks from the participants during the debriefing about the training were, for example: "It helped me practice more with ACT than I would normally do," "It kept me aware of myself," and "I want to continue with this training."

When asked for suggestions for improvement of the ACT-DL, the following three considerations were proposed most commonly by the participants. The first one was the desire for more ACT exercises and more variations within these exercises (more topics, 7x). In addition, it was suggested to reduce the number of ACT metaphors that were offered each day (7x). A final suggestion was the preference for having auditory rather than visual awareness exercises (4x).

The same question was also presented to the two research assistants who conducted the close to 200 semistructured interviews by phone. An important observation both interviewers made was that some participants seemed to have had difficulty discerning between the regular ACT exercises and the ACTION exercises (which were specifically designed to help participants deal with momentary negative thoughts and feelings).

Effectiveness of ACT in Daily Life

The effectiveness of the ACT-DL was assessed with self-report questionnaires. Three assessment moments were used (Table 2): preinpatient (T1), postinpatient (T2), and postoutpatient (T3). The effectiveness of the ACT-DL was assessed by comparing results between T2 and T3. Gender was taken into account as a possible confounder. As can be seen in Table 2, generally, the direction of the effects between T1 and T2 shows improvement (decline of symptoms, increase in skills), whereas the direction of the effects between T2 and T3 shows a slight deterioration (rise of symptoms, decline in skills).

Figure 5. User experience of the ACT in Daily Life Training (ACT-DL).**Table 2.** Results of self-report questionnaires at different assessment time points for participants in the intervention (n=49) and control (n=112) groups in ACT in Daily Life Training (ACT-DL).

	ACT-DL			Control		
	Mean (SD)			Mean (SD)		
	T1 ^a	T2 ^b	T3 ^c	T1 ^a	T2 ^b	T3 ^c
FIT-60 ^d	177.4 (33.8)	206.2 (50.3)	197.7 (53.0)	181.0 (39.4)	215.4 (52.6)	208.8 (58.0)
BSI ^e	1.40 (.65)	.70 (.52)	1.00 (.72)	1.31 (.62)	.67 (.57)	.85 (.72)
UCL (avoiding) ^f	18.2 (3.5)	17.7 (3.5)	17.8 (3.3)	17.8 (3.5)	17.0 (3.0)	17.3 (3.4)
QoL-VAS ^g	2.3 (2.3)	5.8 (2.5)	4.4 (3.0)	2.8 (2.2)	5.8 (2.4)	5.3 (2.9)

^aT1: Preinpatient.^bT2: Postinpatient.^cT3: Postoutpatient.^dFIT-60: Flexibility Index Test.^eBSI: Brief Symptom Inventory.^fUCL: Utrechtse Coping List.^gQoL: Quality of Life—Visual Analog Scale.

Results show that the ACT-DL group and the control group did not differ significantly from each other at the preinpatient (T1) and the postinpatient assessment (T2). Also at the post outpatient assessment (T3), the groups did not differ significantly on psychological flexibility ($F_{1,152}=1.346$, $P=.25$), symptoms ($F_{1,153}=1.094$, $P=.30$), avoidant coping ($F_{1,148}=.153$, $P=.70$) and quality of life ($F_{1,147}=0.569$, $P=.11$). Furthermore, time (T2-T3) did not have a significant effect on these four outcomes for the ACT-DL-group ($P=.03$ to $P=1.00$). The repeated measures ANCOVA also showed no significant interactions between treatment group and time (T2-T3) on psychological flexibility ($F_{1,152}=0.023$, $P=.88$), symptoms ($F_{1,153}=0.748$, $P=.39$), avoidant coping ($F_{1,147}=1.184$, $P=.28$), or quality of life ($F_{1,146}=2.053$, $P=.15$). Treatment dose effect of the ACT-DL has been examined with Pearson correlations, showing a weak ($r=.040$ to $.210$) and nonsignificant ($P=.26$ to $.86$) association between dosage, defined as self-reported information on number of executed exercises during the ACT-DL and minutes of time spent on those exercises, and treatment effect. Finally there were no significant differences between diagnoses (determined

with the MINI) on treatment effect regarding psychological flexibility of the ACT-DL ($F_{1,44}=0.005$, $P=.95$).

Discussion

Principal Findings

The primary objective of this study was to assess the feasibility and acceptability of the ACT-DL in a heterogeneous mental health population. Due to enthusiasm for participation, the recruitment aim was more than doubled (20 to 49). Adherence to treatment was adequate given the intensity of the mHealth intervention with 76% of participants completing the full 4-week training. Other mHealth studies reported dropout rates as high as 50% [36], and even higher attrition rates were reported with Web-based interventions [37]. A systematic review from Kelders et al [38] has identified important variables that could explain why the adherence to the ACT-DL was relatively high: the intervention used persuasive techniques (tunnelling, self-monitoring, and reminders); participants had frequent contact with the researchers; and the duration of the training

was relatively short (4 weeks), which has been shown to produce higher adherence than interventions with a longer duration [39]. Taken together, the ACT-DL seems to be a feasible mHealth treatment. User evaluations showed that the program stimulated the use of ACT in daily life; participants practiced over an hour a week, doing 10 exercises on average. Both ACT exercises and metaphors were experienced as useful components of the training. Also participants would highly recommend the training to others. These results also suggest high acceptability of the ACT-DL. These findings are in line with previous studies [21-24], showing that it is feasible to deliver ACT via mHealth.

User evaluations showed that the acceptability of ACT-DL could be enhanced by extending the number of available ACT exercises. Auditory awareness exercises could also increase treatment adherence. Although ACT metaphors were generally appreciated, the frequency should be limited (once or twice a day). A further recommendation was that the tool should be simple in its design and functions (distinguishing between regular ACT exercises and ACTION exercises seemed to be unclear for some participants). These results correspond with and add to recommendations of a similar nature by Ahtinen and colleagues [40], who stressed easy-to-do daily life exercises and guiding participants gently through but not restricting choice in exercises.

A revised version of the ACT-DL, based on lessons learned from this study, will be used in future research (H, Steinhart, MSc, unpublished data, 25-2-2016). In this revised version an additional 16 ACT exercises and 8 metaphors are added, divided over all 6 instead of 3 ACT components (in line with the feedback for more exercises and variation). Also the number of beeps are lowered from 10 to 8 per day (thereby lowering the amount of metaphors offered and restricting to two different metaphors per day). Furthermore, the differences between the regular ACT exercises and ACTION exercises are more articulated. When participants activate the training menu, a question is added that helps to guide them to the exercise that is most appropriate for that particular moment. For example, when participants answer yes to the question "Do you experience unpleasant thoughts, feelings, or sensations at this moment?" they are guided to the ACTION exercises that are specifically designed to deal with negative experiences in the present moment. If answering no, participants are guided to general ACT exercises. Finally, the setup of the intervention is changed from sequential (first ACT training, than mHealth training) to synchronized (ACT training and mHealth training combined), and the training is extended from a 4-week to a 7-week training.

Finally, a preliminary examination of the effectiveness of the ACT-DL was performed. These results showed no short-term effect immediately after termination of the ambulatory ACT-DL on top of the effect of the inpatient ACT group intervention. We cannot rule out that subtle add-on effects of the ACT-DL were obscured by the impact of the transition from an intensive inpatient treatment to an ambulatory treatment. This effect was apparent in both ACT-DL and control participants. It is also possible that a ceiling effect, due to the intensive inpatient treatment, hampered measurement of additional improvement. Additionally, only short-term effects were investigated since there were no follow-up data available to assess the effectiveness of the ACT-DL in the long term. Differences may emerge at a later stage as it has been shown that effects of acceptance-based interventions can increase over time [41]. A recent RCT (randomized controlled trial) from Lappalainen [42] showed significant differences at 18-month follow-up.

Limitations

Our study had some limitations. User evaluation is sensitive to recall bias. Therefore, ESM data could be a valuable source of information on user experience, but a structured log was not available to provide this data. Hence, objectifying ACT practice was not possible. Also, there was no information available on the dropout rate in the control group making it impossible to compare rates. The proportion of females was higher in the ACT-DL group than the control group; female participants were apparently more willing to participate in the study or more willing to take ACT-DL into use. Overall, this study has a high proportion of females, and this could limit generalizability of results to males. A final limitation is the observational nature of the study. It is possible that the groups differed from each other on unmeasured confounders.

Conclusions

This is the first study that uses experience sampling, fostering awareness in daily life, in combination with acceptance and commitment therapy, fostering skill-building in daily life. The study suggests that the combination not only fits theoretically but also seems to function well in practice. Another strength of this study is the use of a heterogeneous clinical sample. Therefore, the generalizability of the results may be high, suggesting that ACT-DL is suitable for a broad range of mental health problems. Effectiveness will have to be examined further in experimental settings that also address long-term effects.

Acknowledgments

We thank our study participants, as well as the treatment facility, U-Center, for the collaboration in this research project. We also want to thank Ron Mengelers for the IT support, Truda Driesen for the PsyMate support, Rufa Diederer for the briefing, Tom Schiphof for Routine Outcome Monitoring support, and Ger Driessen for help with cleaning and restructuring the dataset. This study was supported by a European Research Council consolidator grant to IMG (ERC-2012-StG, project 309767-INTERACT) and by the Weijerhorst Foundation.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Photos of ACT in Daily Life training with the PsyMate.

[[JPG File, 2MB - mhealth_v4i3e103_app1.jpg](#)]

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Abbreviations

- ACT:** acceptance and commitment therapy
- ACT-DL:** ACT in Daily Life
- ANCOVA:** analysis of covariance
- BSI:** Brief Symptom Inventory
- ESM:** experience sampling method

FIT-60: Flexibility Index Test

MINI: Mini-International Neuropsychiatric Interview

PDA: personal digital assistant

QoL-VAS: Quality of life visual analog scale

SIDP-IV: Structured Interview for DSM Personality Disorders

DSM-IV-TR: *Diagnostic and Statistical Manual of Mental Disorders*(Fourth Edition)

UCL: Utrechtse Coping List

Edited by G Eysenbach; submitted 11.12.15; peer-reviewed by R Lappalainen, E Mattila, K Kaipainen; comments to author 14.01.16; revised version received 10.04.16; accepted 30.05.16; published 15.09.16.

Please cite as:

Batink T, Bakker J, Vaessen T, Kasanova Z, Collip D, van Os J, Wichers M, Germeys I, Peeters F

Acceptance and Commitment Therapy in Daily Life Training: A Feasibility Study of an mHealth Intervention

JMIR Mhealth Uhealth 2016;4(3):e103

URL: <http://mhealth.jmir.org/2016/3/e103/>

doi: [10.2196/mhealth.5437](https://doi.org/10.2196/mhealth.5437)

PMID: [27634747](https://pubmed.ncbi.nlm.nih.gov/27634747/)

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Original Paper

A Context-Sensing Mobile Phone App (Q Sense) for Smoking Cessation: A Mixed-Methods Study

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Abstract

Background: A major cause of lapse and relapse to smoking during a quit attempt is craving triggered by cues from a smoker's immediate environment. To help smokers address these cue-induced cravings when attempting to quit, we have developed a context-aware smoking cessation app, Q Sense, which uses a smoking episode-reporting system combined with location sensing and geofencing to tailor support content and trigger support delivery in real time.

Objective: We sought to (1) assess smokers' compliance with reporting their smoking in real time and identify reasons for noncompliance, (2) assess the app's accuracy in identifying user-specific high-risk locations for smoking, (3) explore the feasibility and user perspective of geofence-triggered support, and (4) identify any technological issues or privacy concerns.

Methods: An explanatory sequential mixed-methods design was used, where data collected by the app informed semistructured interviews. Participants were smokers who owned an Android mobile phone and were willing to set a quit date within one month (N=15). App data included smoking reports with context information and geolocation, end-of-day (EoD) surveys of smoking beliefs and behavior, support message ratings, and app interaction data. Interviews were undertaken and analyzed thematically (N=13). Quantitative and qualitative data were analyzed separately and findings presented sequentially.

Results: Out of 15 participants, 3 (20%) discontinued use of the app prematurely. Pre-quit date, the mean number of smoking reports received was 37.8 (SD 21.2) per participant, or 2.0 (SD 2.2) per day per participant. EoD surveys indicated that participants underreported smoking on at least 56.2% of days. Geolocation was collected in 97.0% of smoking reports with a mean accuracy of 31.6 (SD 16.8) meters. A total of 5 out of 9 (56%) eligible participants received geofence-triggered support. Interaction data indicated that 50.0% (137/274) of geofence-triggered message notifications were tapped within 30 minutes of being generated, resulting in delivery of a support message, and 78.2% (158/202) of delivered messages were rated by participants. Qualitative findings identified multiple reasons for noncompliance in reporting smoking, most notably due to environmental constraints and forgetting. Participants verified the app's identification of their smoking locations, were largely positive about the value of geofence-triggered support, and had no privacy concerns about the data collected by the app.

Conclusions: User-initiated self-report is feasible for training a cessation app about an individual's smoking behavior, although underreporting is likely. Geofencing was a reliable and accurate method of identifying smoking locations, and geofence-triggered support was regarded positively by participants.

KEYWORDS

mobile phone app; smoking cessation; context sensing; tailoring; geofence; just-in-time adaptive intervention; JITAI; ecological momentary intervention; craving

Introduction

Between one-third and one-half of smokers in high-income countries make a quit attempt every year [1-3]. However, over half of those attempting to quit relapse within 1 month [2]. A major reason for this high relapse rate is a failure to manage cravings brought about by smoking cues from the environment. Cue-induced cravings are implicated in almost half of all smoking lapses [4], and early lapses to smoking are highly predictive of subsequent relapse [5-7], including when experimentally induced [8]. Cues are often dichotomized into proximal cues (eg, a lighter), those directly associated with smoking behavior that may be common to multiple smoking settings, and distal cues (eg, a smoker's kitchen), which are present during smoking but not directly linked to it [9]. Both cue types have been found to trigger cravings to smoke in experiments [9]. While cue-induced cravings are not alleviated by the most commonly used cessation medications [10,11], the timely use of cognitive or behavioral coping strategies can help smokers manage or avoid these craving episodes without lapsing [10,12]. However, among smokers who use any strategies to prevent lapse, the ones most commonly used appear to be the least evidence based [13,14]. Given that tobacco smoking is the second-highest contributing factor to the global burden of disease [15], finding interventions to help smokers better address cue-induced cravings is a high priority.

Mobile phone-based ecological momentary interventions (EMIs) have potential to deliver cognitive-behavioral lapse-prevention support to help smokers address cue-induced cravings. However, user-triggered lapse-prevention support within EMIs, such as texting a *HELP* or *CRAVE* keyword to a short message service (SMS) cessation support system, is generally found to be used infrequently [16,17], as are apps relying on users to initiate access to support content, based on initial evaluations [18]. System-triggered lapse-prevention support driven by fixed schedules [19], random timing [20], or a combination of the two [16] are likely to be limited in their ability to deliver *just-in-time* lapse support, as found in a recent study showing no difference in lapse-prevention strategy use between smokers who did and did not receive an EMI [14].

A third approach, a hybrid of user- and system-triggered support, is context-triggered lapse-prevention support. Mobile phone sensors can continuously and unobtrusively interpret the context of a situation and trigger support if the individual is deemed to be in a high-risk situation for a lapse, often termed *just-in-time adaptive interventions* (JITAI). Outside of the smoking cessation field, context sensing has been used to train an app to predict mood states [21] and tailor system-triggered behavioral advice for a physical activity and eating behavior app [22]. While the concept of context-aware smoking cessation interventions has been discussed [23,24], we are not aware of any research investigating EMIs that deliver cessation support

that is context triggered in real time. Given the likely growth in use of context sensing in health apps, insights into the feasibility and user perspective of this approach are of high importance, especially in light of perceived barriers highlighted by young adults when discussing hypothetical tracking and context-sensing health behavior apps [25]. These barriers include expectations for the collection of accurate and detailed data without burdensome or boring data input; concerns about counterproductive effects if triggered support cues, rather than stops, behavior; and data privacy concerns. These remain important and largely unexplored issues.

We have developed a context-aware smoking cessation mobile phone app, *Q Sense*, that, in addition to more common features, delivers behavioral support triggered by and tailored to an individual's real-time context to prevent smoking lapses. In advance of a smoker's nominated quit date, the app employs a user-initiated real-time smoking episode and context-logging system that collects location data from the sensors in the mobile phone using open-source software libraries [26]. Once a smoker's quit date has passed, the app passively monitors their location and when they enter or dwell within a geofence [27]—a system-generated virtual perimeter—it triggers support messages, tailored to the context information it has collected for that location.

A context-aware EMI such as *Q Sense* requires both user and sensor data to train the system to infer specific contexts. Ecological momentary assessment (EMA) studies using mobile phones have found that the compliance of user-initiated reports of smoking are somewhat lower compared with when smokers are given prompts [28,29]. These studies have shown that just over half of all smoking episodes are reported when relying on users to initiate reporting [28,29]. However, a limitation with these studies in the context of real-world usage is their experimental nature; mobile phones, financial incentives, and compliance training were provided, and compliance was assessed over less than one week [28,29]. Furthermore, these studies provide little insight into why smokers underreport when recording smoking in real time.

To support its development as a smoking cessation tool, we sought to investigate the barriers and facilitators of user engagement with *Q Sense* and learn about its support delivery system under natural conditions without external reinforcement. To gain a user-centered perspective, we adopted a mixed-methods design. By integrating quantitative and qualitative components, mixed-methods designs can provide greater insight into phenomena than either method alone [30,31], and can minimize the limitations of each type of data [32].

There were four main objectives, each with explicit quantitative and qualitative elements [33]:

1. Assess smokers' engagement with self-initiated reporting of smoking (quantitative) and identify reasons for any noncompliance (qualitative).
2. Assess the app's location-sensing (quantitative) and perceived (qualitative) accuracy in identifying user-specific high-risk locations for smoking.
3. Explore the feasibility of the geofence trigger mechanism (quantitative) and smokers' views on this, and how the support it delivers could be optimized (qualitative).
4. Identify any technological limitations (quantitative), problems, or privacy concerns (qualitative) in everyday use.

Methods

Design and Participants

An explanatory, sequential, mixed-methods design was used [33]. Guided by this design, a preliminary examination of quantitative data collected by participants using the Q Sense app informed data-prompted, qualitative, one-to-one, semistructured interviews [34]. The interviews aimed to help explain the quantitative findings and generate insight into app usage behavior. The two strands were therefore connected or "mixed" during data collection. Analysis of data was undertaken separately and sequentially, and integrated during interpretation. Figure 1 provides a procedural diagram of the design.

Participants were recruited using convenience sampling. Eligibility criteria included the following: being a current tobacco smoker, aged 16-70 years, interested in quitting smoking, willing to set a quit date within a month but not less than one week, primary use of an Android mobile phone, and willing to participate in a one-to-one interview. Electronic and paper advertisements were placed on social media websites, university staff and student mailing lists, company communication pages, newspapers, and local shops and leisure centers. The research team emailed those expressing an interest on the study website with a participant information sheet before getting in touch by telephone to answer any questions and take verbal consent.

Procedure

Consenting participants were sent a link by email and SMS text message to install Q Sense. Participants were asked to use Q Sense for the duration of the pre-quit-date period and for at least 2 weeks post-quit date. When installing Q Sense, the app requests permission to collect users' locations.

Q Sense (version 1) implements a smoking cessation EMI as a three-stage process, with support informed by two theory-guided SMS text message cessation interventions [16,35], learning theory [36], and taxonomy of smoking behavior change techniques [37].

In the first stage, *Prepare and Learn*, users set a quit date after completing an 11-item demographic and smoking survey. They were then asked to log every time they smoked tobacco in the time leading up to their quit date by opening the app, tapping an *I'm smoking* button, and completing a short assessment. Each self-assessment contained five questions about their current

psychological and situational context just before they smoked: mood, stress, strength of urges to smoke (adapted from the Mood and Physical Symptoms Scale [38]), current situation (*Home, Working, Socializing, or Other*), and the presence of others (*I am alone, Friends/Family, Colleagues, or Others*) and whether the others were smoking. If the smoker reported smoking more than four times in the same proximity, the device created a geofence (ie, virtual perimeter) around that area [27]. A geofence is a circular area around a location defined by a latitude and longitude, in this case determined by the location of the smoking reports, and a radius that was set at 100 meters. Android Location Services, which uses multiple location sensors including the global positioning system (GPS), informs the app when the device enters or dwells in—defined by Q Sense as 3 hours or more—the geofence.

The combined self-assessment and location data were also sent to a server, which responded by sending a tailored support or feedback message. The support message was selected from a prepopulated database that matches the user's 11-item demographics and smoking survey, and the feedback message was based on the statistical patterns in the user's smoking reports (eg, "Did you know? Based on 12 reports, 25% of the times you smoke you are working.>").

The app's second stage, *Commit to Quit*, begins when the user's quit date has arrived and lasts for 28 days. In this stage, when the app detected that a user had entered a geofence and stayed in that location for at least 5 minutes, a support message notification was automatically triggered. Further support message notifications were then triggered after each 3-hour interval of dwelling in the same geofenced location. Tapping on the notification delivered the support message. The content of the geofence-triggered support messages were tailored to the information collected from the smoker when they reported smoking in that specific location. For example, if a user had, on average, reported moderately high stress levels when smoking at home and then entered a home geofence, the server would sometimes return a support message written for the home context and for someone experiencing moderate-to-high stress. The mean length of these messages was 198 characters (SD 50). If users reported smoking during this stage, they received postreport lapse and relapse prevention support messages (mean length 219 characters, SD 45).

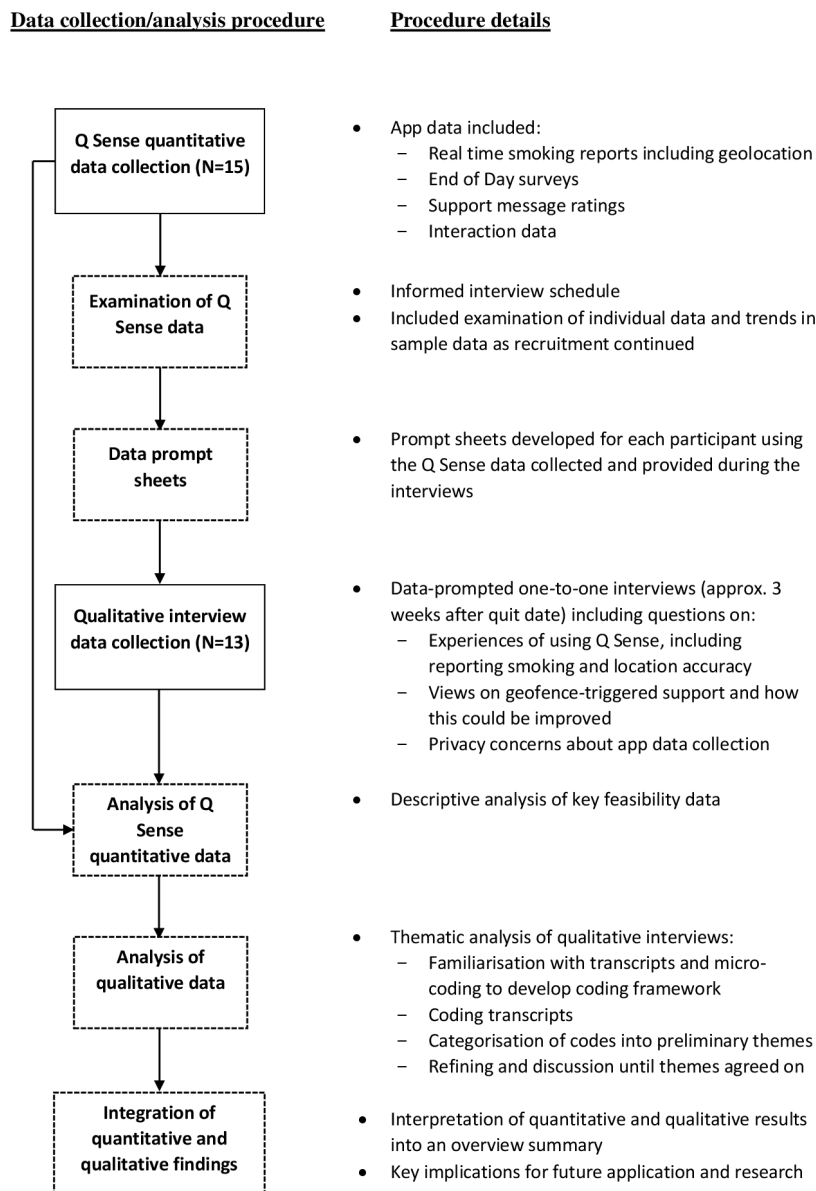
During the first two stages, users also received a morning notification linking to a tailored quitting preparation message or smoking fact, during the *Prepare and Learn* stage, and support addressing outcome expectancies of stopping smoking or general encouragement, during the *Commit to Quit* stage (mean length 181 characters, SD 63). After any support message was viewed, users were invited to rate the message using a 5-star rating scale. Users were also able to view a summary of their recorded smoking episode data split by situation as part of their app *profile*. Every day, users were also invited to complete an *end-of-day* (EoD) survey that recorded number of cigarettes smoked that day (categorical), strength and frequency of urges to smoke [38], and abstinence self-efficacy. The app also passively tracked users' location by collecting samples from their devices' location sensors in the background every 15 minutes.

In the third stage, *Maintain the Change*, the app was in a passive state and did not deliver any proactive support messages, though the profile and reporting features with postreporting lapse and relapse prevention support messages were still active. See [Multimedia Appendices 1-6](#) for app screenshots.

After participants had either used Q Sense for approximately 2 weeks post-quit date, or appeared to have disengaged (ie, no use for a week), they were invited to participate in a face-to-face or telephone interview. Interviews were audiotaped and lasted approximately 30-60 minutes. App data for each participant was examined prior to each interview and used to inform the interview schedule. To assist in generating discussion and

participant views [34], each participant was provided with a printed summary of their app data, including a map of their smoking locations (see [Multimedia Appendix 7](#)). General patterns emerging from the app data as participants completed the study informed the focus of the discussion in subsequent interviews. Interview questions focused on participants' experiences of using the app and, in particular, reporting smoking and the accuracy of smoking location identification, views on the geofence-triggered support and how this could be improved, and privacy concerns about app data collection. All interviews were transcribed verbatim. Participants who were interviewed received a £10 shopping voucher.

Figure 1. Procedural diagram of the explanatory sequential mixed-methods design used.



Feasibility Measures

Feasibility is defined as the assessment of whether processes and procedures are possible and practical to do easily or conveniently. App-based feasibility measures included the following: mean frequency and location of smoking reports,

current location (ie, background samples), proportion of EoD surveys completed, proportion of days where EoD smoking category exceeded daily smoking reports, proportion of smoking reports with geolocation data, accuracy of geolocation generated by the device (68% confidence interval of true location), number of active geofences created per participant, proportion of

participants receiving any geofence-triggered support messages, the number of geofence support messages delivered, the time to view geofence support messages, and the proportion of support messages rated.

Analysis

In line with the explanatory, sequential, mixed-methods design, the two connected but different strands of data were analyzed separately and the findings presented sequentially [33]. The findings from both strands were combined at an interpretative level to generate key conclusions.

Descriptive statistics of feasibility measures were generated using SPSS version 22 (IBM Corp) and Microsoft Excel. Thematic analysis was used to analyze the interview transcripts, informed by Braun and Clarke's phases of thematic analysis [39]. Two researchers (SH, RS) read and familiarized themselves with the transcripts and then microcoded several to identify initial concepts and categories as part of developing a preliminary coding framework. The two researchers then both coded three interview transcripts using NVivo 10 (QSR International) to check the coherence of the coding framework and refine it where discrepancies were identified. Then all remaining interviews were coded by both researchers, and the coded content was merged. Coded content was then read

through, and codes were categorized into areas of primary focus, informed by the research questions. Preliminary themes and subthemes were identified from these categories and were refined after their fit with the raw and coded data had been reviewed. After discussions between two researchers (SH, FN), agreement on the primary themes was reached.

Results

Participants

A total of 41 people expressed an interest in participation; 21 met the inclusion criteria of whom 15 participated (71%). Exclusions were due to not having access to an Android mobile phone (11/41, 27%) or wanting to quit in less than one week (9/41, 22%). Of the 15 participants, there were 8 males (53%) and 7 females (47%), and most reported smoking between 6 and 10 cigarettes per day. Of the 15 participants, 13 (87%) were interviewed either face-to-face (9/13, 69%) or by telephone (4/13, 31%). All participants set a quit date, with 5 out of 15 (33%) reporting planning to use an e-cigarette to support their attempt. See Table 1 for participant characteristics. Out of 15 participants, 3 (20%) stopped using the app during or at the end of the pre-quit-date phase due to disengagement (1/3, 33%) or technical problems (2/3, 67%).

Table 1. Participant characteristics (N=15).

Characteristic	n (%) or mean (SD)
Gender (female), n (%)	7 (47)
Age in years, n (%)	
18-24	2 (13)
25-34	9 (60)
35-44	2 (13)
45+	2 (13)
Cigarettes per day, n (%)	
1-5	2 (13)
6-10	8 (53)
11-15	5 (33)
16-20	0 (0)
21+	0 (0)
Smoked first cigarette within 30 minutes, n (%)	6 (40)
Number of days from enrollment to quit date, mean (SD)	20 (5)
Lives with other smokers, n (%)	4 (27)
Planning to use an e-cigarette to help in quit attempt, n (%)	5 (33)

Quantitative Findings

Table 2 provides a summary of app-collected feasibility outcomes. The mean pre-quit-date period was 19.8 (SD 4.8) days. During this time, the mean number of smoking reports per participant logged on Q Sense was 37.8 (SD 21.2), or 2.0 (SD 2.2) per day, reported at home (246/491, 50.1%), work (152/491, 31.0%), while socializing (30/491, 6.1%), and in *other* situations (63/491, 12.8%). Background location samples were

broadly in line with the locations where participants smoked in terms of time spent in that location: home (60.0%), work (15.0%), and *other* locations (25.0%). Out of 12 participants, 6 (50%) self-reported smoking after their quit date, with a mean of 3.7 (SD 1.9) reports, and a mean number of days until first lapse of 9.0 (SD 5.7). Of these reports, 68.2% were at work, 27.3% were at home, and 4.5% were at *other* locations. The median time taken to complete a smoking report was 12.9 seconds (interquartile range [IQR] 7.9; mean 17.5, SD 36.8).

Table 2. Feasibility outcomes for use of the Q Sense app (N=15).

Outcome	Mean (SD) or n (%)
Number of smoking reports per participant pre-quit date, mean (SD)	37.8 (21.2)
Reported situations of smoking reports (pre-quit date) (total reports N=491), n (%)	
Home	246 (50.1)
Working	152 (31.0)
Socializing	30 (6.1)
Other	63 (12.8)
Proportion of days in pre-quit-date period where the number of smoking reports was lower than end-of-day (EoD) smoking category ^a (total EoD surveys N=281), n (%)	158 (56.2)
Location capture for smoking reports ^a (total reports N=513), n (%)	498 (97.0)
Accuracy of location capture (meters) ^{a,b} , mean (SD)	31.6 (16.8)
Geofence <i>smoking locations</i> generated per participant ^a , mean (SD)	1.5 (0.7)
Participants receiving at least one geofence support message (N=9) ^c , n (%)	5 (56)
Geofence messages delivered per participant, who received any geofence messages, mean (SD)	40.4 (35.0)
Compliance with end-of-day surveys, n (%)	
Pre-quit date ^a (expected total number of surveys if 100% compliance N=250)	150 (60.0)
Post-quit date (28-day period) ^d (expected total number of surveys if 100% compliance N=336)	131 (39.0)
Total support messages delivered, n	1109
Support messages rated (N=1109), n (%)	933 (84.13)

^aN=13: excludes 2 participants who stopped using Q Sense during the pre-quit-date phase.

^b68% confidence interval of true location—generated by Android operating system.

^cN=9: excludes participants who did not report smoking a sufficient number of times to create a geofence.

^dN=12: excludes 3 participants, 2 who stopped using Q Sense during the pre-quit-date phase and 1 who only used Q Sense in the pre-quit-date phase.

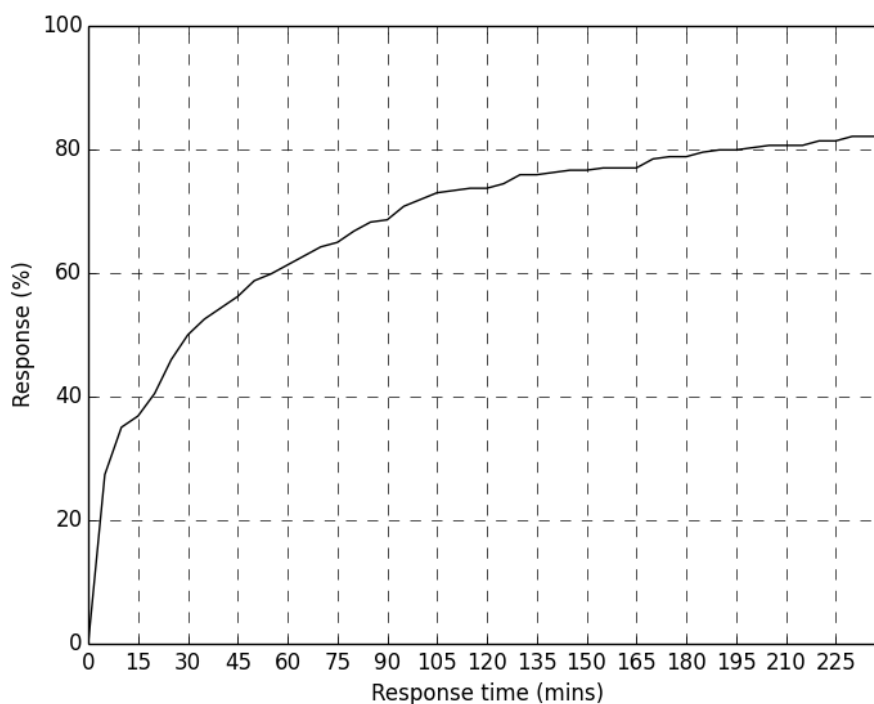
On average, the EoD surveys were completed on 60.0% of days pre-quit date and 39.0% of the 28-day post-quit-date period—52.0% when excluding 3 participants that did not complete any post-quit-date surveys. EoD survey smoking category responses indicated that participants underreported smoking in the pre-quit-date phase on at least 56.2% of days. The EoD survey data also suggested that participants reduced their smoking during the pre-quit stage relative to baseline; on 43.7% of days, participants smoked at least one smoking category less than they indicated at baseline and only smoked more than their baseline category on 7.0% of days.

Geolocation was collected in 97.0% of smoking reports with a mean accuracy of 31.6 (SD 16.8) meters. A mean of 1.5 (SD 0.7) geofences (>4 smoking reports in one location) were created per participant with 13 out of 15 participants (87%) having at least one geofence created. Of 9 participants eligible to receive geofence-triggered support—having at least one active geofence and having spent time in that area post-quit date—5 (56%) received at least one geofence-triggered support message. A total of 202 geofence-triggered messages (aggregated mean delivery rate per day of 3.0 [SD 0.8] per participant) were

delivered by the server. Of these, 60.4% (122/202) were *entry* and 39.6% (80/202) were *dwell* geofence messages.

A total of 1109 different support messages were delivered by the app (mean of 85.3 [SD 38.1] per participant) as a result of the participant tapping a message notification. Of these, 933 (84.13%) received a rating score from participants. For geofence-triggered support messages, 78.2% (158/202) of messages delivered were rated. App interaction data indicated that, of geofence-triggered support messages delivered, the median elapsed time between the generation of a notification and the user opening the app was 23.6 minutes (IQR 77.7). For all geofence-triggered support notifications, regardless of whether the notification was tapped on or not, on 50.0% (137/274) of occasions participants opened the app within 30 minutes of a notification being generated. [Figure 2](#) shows the aggregated response pattern over time.

Regarding app activity, opening the app to report smoking, complete a survey, or view a support message represented 95.94% (7129/7431) of activity occasions, accessing the profile section represented 4.01% (298/7431) of occasions, and using the settings menu represented 0.54% (4/7431) of occasions.

Figure 2. Cumulative distribution function of response times of opening app after geofence support notifications were generated.

Qualitative Findings

Compliance With Reporting

Most participants stated that they had wanted to report smoking in real time, but struggled at times to do so. The main reason given was forgetting. Other reasons included not having the phone at hand, not wanting to appear rude around others, driving, not being in the mood, and not understanding the purpose of reporting at the time of smoking. Some participants viewed the EoD survey as an opportunity to make up for reports that they had missed during the day:

I started reporting each time I had a cigarette and I think that sort of petered off, but I know there will be an end of day and I can report it then. [Participant #20]

Several participants stated that they reported less often the nearer they were to their quit date, particularly if they had set a date relatively far into the future:

Yes. It is like when you first start dieting, you do really well for the first week and then it sort of fades out doesn't it? [Participant #9]

Some participants described that the act of reporting smoking in itself led to them reduce their smoking frequency, as they became more self-aware and questioned their reasons for smoking:

When I was logging how much I am craving it was lower than what I thought it would have been without the app, which was really good. So that made me think, well, actually do I really need a cigarette now? [Participant #6]

Several participants also stated that they were unaware that they could report smoking post-quit date. Where participants had reported post-quit date, they indicated that they had been

generally happy to do so initially. However, 2 participants explained that they had stopped post-quit-date reporting after a few days of smoking, seemingly due to feelings of guilt or despondency:

The first couple of days I reported, then after that I chose not to. I don't know why, I just didn't. I probably felt like, oh God I haven't quit, so I won't use it kind of thing. [Participant #6]

A number of suggestions were made to help increase reporting compliance. These included having programmable reminders; having the option to report smoking, including location, after the event, such as tapping on a map; having the option to complete shorter smoking reports; and receiving feedback during the day about the number of cigarettes smoked.

Locations of Smoking

Apart from a few rare exceptions, participants deemed the locations of their smoking reports as recorded by Q Sense as correct and accurate, based on the data prompt sheet superimposed maps. Participants were largely happy with the way the app used location sensing (eg, GPS and Wi-Fi), though a few made reference to areas with poor GPS and Wi-Fi signals, and 1 participant described feeling frustrated with the time it took for the app to identify his location on the map. Several participants also suggested that having more options available to describe their location setting (eg, *travelling*) would be helpful.

Geofence-Triggered Messages

Those receiving geofence messages were largely positive about their value, and described them as useful in providing distractions or alternatives to smoking:

It's kind of good to have the reminder to say instead of having a cigarette take deep breaths and just take

some time out to do some breathing exercise. It's something that I know, but I wouldn't think to do it, so it's good to have that message. [Participant #20]

One participant commented on the tailoring of a message when she was at home, and that she found this to be an important aspect in making it feel personalized:

But I guess it was kind of based on the time it knew I was at home or whatever, you know...those sort of trigger times it sort of sent a message to say, yes, so I felt it was aimed directly at me as opposed to just a random blanket message. [Participant #20]

Feelings about message frequency were mixed, with one participant expressing that he received too many geofence-triggered messages and another that he would have preferred more. Three participants also explained that the geofence messages had on occasion reminded them about smoking, when they had not been thinking about it at the time:

But it just kept reminding me that I was smoking and I just wanted to forget about it, but it was kind of knowing when to get rid of the app. [Participant #8]

When I see it pop up, I think Q Sense, I think "Oh fag" and that's it, so it's like you're not even thinking about smoking and then it comes up and you're thinking, "Oh I'll have a fag now." [Participant #16]

However, these 3 participants did not specifically refer to the messages as triggering an urge to smoke and each suggested that the benefits of the messages outweighed the risks of being reminded:

Because even though the Champix tablets [meant] no cravings, I'm still thinking about smoking for some reason, but without a craving. And then when that message comes through it says like, "[Name], don't do it." I'm like, "Oh okay. Alright, I won't!" [laughter]. I won't do it [laughter]. I thought that was really helpful. [Participant #8]

But yeah, some of those things, like the tips it sends you, they're quite handy I think. It was quite useful to know really, the alternative options, because I've tried like the vapor pens and the e-liquids and stuff, they didn't work for me. [Participant #16]

In terms of message content, shorter messages, suggestions of alternatives to smoking, and messages that felt tailored to the situation were described as most helpful. Several participants also expressed a preference for more health- and risk-related geofence-triggered messages with harsher language to make risks more salient, and messages with novel information. Longer messages were seen as more time-consuming to read and, therefore, less useful.

Participants described being happy to rate messages received, and understood the rating system. Reasons for not reading or rating messages included being busy, not wanting reminders about smoking, and being unable to read them at work.

Technical Aspects and Data Privacy

Participants reported no noticeable impact of Q Sense on their phone's battery life and, when asked, participants unanimously

stated that they were unconcerned about privacy aspects of the data collected by the app. However, a few participants explained that their lack of concern was due to the study affiliation with a university and that their feelings would be different had the study been conducted by a commercial company:

I would have been happy to give more time, more personal data, things along those lines. Whilst if it was, I don't know, [name of commercial pharmacy] or someone along those lines coming up with an app, I would have given them the bare minimum because I don't trust where that data is going to go. [Participant #17]

Other App Features and Optimization

Participants also discussed several more general features of Q Sense. Setting a quit date was often described as valuable for boosting commitment. Morning support messages were also described as being a helpful motivation boost, particularly once participants' quit dates had arrived. In terms of future developments, suggestions included having the option to set a new quit date, enabling user preferences for the types of messages provided (eg, health information and motivational message), having cartoons or videos as well as text support, and including more graphics and visual displays. Several participants also suggested having a "human" element within the app, to link in with a support network or a stop-smoking advisor or service:

But it would definitely be useful to have contact, even if it was through messaging with a smoking cessation worker, because they do know more than most about smoking and how to quit. [Participant #22]

Discussion

Principal Findings

This study provides novel and in-depth insights into the feasibility of a context-sensing smoking cessation app. A study strength is the connection of two types of data to address different dimensions of key study objectives. Overall, we found that collecting self-reported smoking behavior and geolocation data in real time via the app was feasible, and participants were engaged in this process. Participants often underreported their smoking behavior. While many of the barriers to reporting that were identified are potentially addressable through in-app intervention and improved explanation of the importance of real-time reporting, promoting app-based data entry remains a challenge [28,40]. Participants receiving support triggered by entering into, or dwelling within, a geofence demonstrated good message engagement and they were positive about its value.

Participants took on average less than 20 seconds to submit smoking data and were generally positive about the process, with the main barriers of real-time data entry connected to opportunity, forgetting, social inhibition, and misunderstanding the purpose, rather than boredom or burden [25]. The smoking reporting compliance rates observed were in line with prior experimental studies, which find smokers log just over half of what they smoke when self-initiated [28,41]. Providing prompts for reporting was one approach suggested by a number of

participants to increase reporting compliance; providing the prompts themselves are unlikely to encourage or cue smoking. Another approach is to provide feedback on any mismatch between real-time reports made during the day and the total number of smoking episodes entered into the end-of-day survey. Where a mismatch occurs, this would include the provision of advice on the importance of real-time reporting and promoting techniques for increasing compliance. These approaches have been added into version 2 of Q Sense. However, low compliance may not represent a major barrier to training apps like Q Sense, providing the smoking reports logged represent an individual's usual smoking behavior, which was broadly supported by the location-sampling data recorded in this study. This could lead to some situations being underrepresented, such as those where the individual may be inhibited to report smoking due to the presence of others.

Recording geolocation data for smoking episodes was feasible, reliable, and sufficiently accurate to justify the use of geofencing to identify high-risk areas for smokers. However, not all eligible participants received geofence-triggered support. An identified error in system logic resulted in at least two participants not receiving geofence-triggered messages. A further potential issue may have been the geofence radius, set at 100 meters. If location accuracy is poor and the estimated location is not fully inside the geofence perimeter, no geofence event occurs. Increasing the geofence radius may reduce this potential issue.

On average, participants each engaged with Q Sense to either complete reports or view a support message in more than 100 separate occasions over 6 weeks or less, and provided 74 support message ratings per participant. Those receiving geofence-triggered support had higher interaction occasions. While there is little published data on interaction with smoking cessation apps, evaluations to date have generally reported much lower frequency of interaction occasions, potentially due to reliance on proactive interaction from the smoker to access support content [18,42,43]. Our evaluation also enabled us to examine novel data on the time delay from geofence-triggered message notification to the opening of the app. Half of the geofence-triggered message notifications led to the message being viewed relatively promptly, within 30 minutes. However, many messages were viewed after a much longer delay. Future attention to time delay to response is important to identify the realistic limits of just-in-time adaptive interventions and to help inform the identification of opportunities when users are most receptive to engaging with support, such as after an episode of phone activity [44].

Concerns have been raised that EMI-delivered behavioral support could inadvertently prime individuals into thinking about engaging in the behavior they are aiming to avoid [24,25]. We found that while this concern was highlighted by a few participants, they reported being mindful of smoking much of the time anyway, supporting previous findings on this issue for an SMS text message-based cessation EMI [45]. In addition, these Q Sense participants regarded the benefits of a support message to outweigh the cons of being reminded about smoking. This is reinforced by evidence of a benefit of mobile phone-based EMIs for smoking cessation [46], and evidence showing that high-intensity prompts to record EMA data related

to smoking and cravings reduce, rather than increase, cravings to smoke [47]. This recent EMA study also supports our unanticipated finding that the process of reporting smoking behavior was, for some, perceived to reduce their smoking rate, suggesting a potential self-monitoring benefit of EMA on smoking behavior [48].

Our findings highlight a number of approaches for optimizing apps like Q Sense. Suggestions from participants for overcoming reporting barriers centered around in-app reminders and feedback, as well as postevent and one-touch reporting features to combat forgetting and reporting constraints. Q Sense version 1 was designed for a relatively long pre-quit learning period to maximize the specificity of identifying locations where cue-induced cravings are likely to be experienced. However, smokers receiving specialist support have been found, on average, to select a quit date only 1 week into the future [16]. Furthermore, recent evidence indicates that the majority of smokers who download a cessation app will select the day of registration as their quit date rather than a future date (personal communication by Harveen Ubhi, March 15, 2016). To minimize the risk of damaging smokers' quitting motivation by insisting on long pre-quit-date training periods, apps relying on self-report data should be optimized to identify high-risk smoking locations in a short period. For Q Sense, this has subsequently been addressed in version 2 by lowering the frequency threshold of smoking reports to create a geofence, and enabling new geofences to be created around the locations where smokers report lapses. In addition, version 2 creates geofences for any smoking lapses reported during the quit attempt. An alternative approach as partially suggested by participants, which is relevant to smokers who might have a very short or absent pre-quit learning phase, would be to enable smokers to identify their smoking locations retrospectively, using address details or an interactive map, for geofence creation. This remains an area for exploration.

In addition to refinements described above, we have also added the following features to version 2 of Q Sense: an "inbox," where all delivered support messages are stored; a navigable "library" of support messages, including the facility for users to write their own geofence support messages; a money-saving calculator in the profile section; and the facility to reset a quit date with prompts to do so after a specified number of reported lapses.

Limitations

The technical issues preventing some participants from receiving geofence-triggered support reduced the information we were able to obtain on this intervention approach. This limits the conclusions that can be drawn about the feasibility of delivering this type of support, and the engagement that participants displayed with this support. While we discussed this type of support with all participants, future work is required to explore the user perspective and impact of context-triggered behavioral support. While we did not provide training on the use of Q Sense, in order to maximize ecological validity, inviting participants to be interviewed may have affected their app use and smoking behavior compared with having no direct contact with the study team. Future studies without the requirement for

interview feedback might reduce this potential influence on participants. As a more general limitation, only Android users were eligible to participate in this study. Evidence has emerged of differences between smokers using Android and iOS phones to access a smoking cessation app; iOS users were more likely to make a serious quit attempt and set their quit date as the day of registration (personal communication by Harveen Ubhi, March 15, 2016). Therefore, we may have missed some important perspectives. Furthermore, as a consequence of seeking out an in-depth user-centered perspective, and our largely opportunistic sampling strategy, our sample may not be representative of the population of smokers who use mobile phones. In particular, our participants had low rates of daily smoking relative to other app-based smoking studies [18]. Future research with larger and more representative samples will enable a more precise estimate of usage, acceptability, and impact of context-triggered cessation support.

Future work is also likely to include the use of additional sensors to advance the identification of smoking behavior and high-risk contexts. The use of additional sensors would expand the scope

for directly identifying proximal or other smoking cues that are present across settings, as identification would not be limited to geolocation; for example, the presence of other smokers using Bluetooth colocation traces [49,50].

Conclusions

User-initiated self-report represents a largely feasible way to train a smoking cessation app about an individual's smoking behavior. While participants often underreported their smoking, the barriers to reporting smoking in real time were primarily related to environmental constraints and forgetting, rather than low motivation to report. Geofencing was a feasible and accurate method of identifying previous smoking locations representing high-risk situations during a quit attempt. Among those who experienced geofence-triggered support, the support was valued and there was high engagement with the delivered messages, although not all were viewed rapidly in response to an alert notification. Future work is required to expand our knowledge on the impact of context-tailored support, and how JITAIs can be optimized.

Acknowledgments

This study was funded by the Medical Research Council (MRC) Public Health Intervention Development (PHIND) scheme (RG73592).

Authors' Contributions

FN conceptualized and led the study, analyzed the data, and drafted and revised the manuscript. NL, CM, SS, and AM conceptualized the study and revised the manuscript. SH and RS acquired and analyzed the data, and drafted and revised the manuscript. CB analyzed the data and revised the manuscript.

Conflicts of Interest

AM receives a personal income from Cancer Research UK via University College London. He has received travel funding, honorariums, and consultancy payments from manufacturers of smoking cessation products—Pfizer Ltd, Novartis UK, and GSK Consumer Healthcare Ltd—and hospitality from North51 who provides online and database services. He also receives payment for providing training to smoking cessation specialists, receives royalties from books on smoking cessation, and has a share in a patent for a nicotine delivery device.

Multimedia Appendix 1

Q Sense screenshot—homepage.

[[PNG File, 37KB - mhealth_v4i3e106_app1.png](#)]

Multimedia Appendix 2

Q Sense screenshot—reporting smoking.

[[PNG File, 37KB - mhealth_v4i3e106_app2.png](#)]

Multimedia Appendix 3

Q Sense screenshot—my profile.

[[PNG File, 51KB - mhealth_v4i3e106_app3.png](#)]

Multimedia Appendix 4

Q Sense screenshot—geofence-triggered support message.

[[PNG File, 87KB - mhealth_v4i3e106_app4.png](#)]

Multimedia Appendix 5

Q Sense screenshot—daily support message.

[[PNG File, 82KB - mhealth_v4i3e106_app5.png](#)]

Multimedia Appendix 6

Q Sense screenshot—lapse prevention support message.

[[PNG File, 79KB - mhealth_v4i3e106_app6.png](#)]

Multimedia Appendix 7

Example of a data prompt sheet.

[[PDF File \(Adobe PDF File\), 104KB - mhealth_v4i3e106_app7.pdf](#)]

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Abbreviations

- EMA:** ecological momentary assessment
EMI: ecological momentary intervention
EoD: end of day
GPS: global positioning system
IQR: interquartile range
JITAI: just-in-time adaptive intervention
MRC: Medical Research Council
PHIND: Public Health Intervention Development
SMS: short message service

Edited by G Eysenbach; submitted 24.03.16; peer-reviewed by H Ubhi, P Johnson, J McClure; comments to author 21.04.16; revised version received 13.05.16; accepted 20.05.16; published 16.09.16.

Please cite as:

Naughton F, Hopewell S, Lathia N, Schalbroeck R, Brown C, Mascolo C, McEwen A, Sutton S
A Context-Sensing Mobile Phone App (Q Sense) for Smoking Cessation: A Mixed-Methods Study
JMIR Mhealth Uhealth 2016;4(3):e106
URL: <http://mhealth.jmir.org/2016/3/e106/>
doi: [10.2196/mhealth.5787](https://doi.org/10.2196/mhealth.5787)
PMID: [27637405](https://pubmed.ncbi.nlm.nih.gov/27637405/)

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Original Paper

An mHealth Intervention Using a Smartphone App to Increase Walking Behavior in Young Adults: A Pilot Study

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Abstract

Background: Physical inactivity is a growing concern for society and is a risk factor for cardiovascular disease, obesity, and other chronic diseases.

Objective: This study aimed to determine the efficacy of the Accupedo-Pro Pedometer mobile phone app intervention, with the goal of increasing daily step counts in young adults.

Methods: Mobile phone users (n=58) between 17-26 years of age were randomized to one of two conditions (experimental and control). Both groups downloaded an app that recorded their daily step counts. Baseline data were recorded and followed-up at 5 weeks. Both groups were given a daily walking goal of 30 minutes, but the experimental group participants were told the equivalent goal in steps taken, via feedback from the app. The primary outcome was daily step count between baseline and follow-up.

Results: A significant time x group interaction effect was observed for daily step counts ($P=.04$). Both the experimental ($P<.001$) and control group ($P=.03$) demonstrated a significant increase in daily step counts, with the experimental group walking an additional 2000 steps per day.

Conclusions: The results of this study demonstrate that a mobile phone app can significantly increase physical activity in a young adult sample by setting specific goals, using self-monitoring, and feedback.

(*JMIR Mhealth Uhealth* 2016;4(3):e109) doi:[10.2196/mhealth.5227](https://doi.org/10.2196/mhealth.5227)

KEYWORDS

mHealth; physical activity; mobile phone app; intervention; health behavior change; feasibility study

Introduction

Physical Activity Levels in Young Adults

Physical activity (PA) is an important factor in maintaining the health and wellbeing of the population [1]. Physical inactivity is associated with over 20 chronic diseases, including coronary heart disease, diabetes, and cancer. PA patterns established in childhood tend to be maintained into adulthood [2]. Recent research suggests that over 40% of students are physically

inactive [3] and only 13-32% of this group meet the recommended PA guidelines [1,2]. The percentage of students classified as overweight or obese in the United States increased from 29% to 32.5% between 2000 and 2009, and this trend is set to continue [4]. Young people demonstrating low levels of PA are significantly more likely to be overweight after university, and may experience negative side effects, including the influence of body shape on both income or occupational attainment [4]. Overweight or obese individuals may also

experience many negative emotional and social consequences, including depression, stigmatization, and lower academic achievement [5]. The promotion of increased PA should be a priority for university students. Not only does PA play an important role in maintaining physical, psychological, and social wellbeing [2], it can also enhance cognitive performance in students [6].

Pedometers and Physical Activity

Previous research has suggested that the daily step count for healthy adults ranges from 6000 to 7000 steps per day [7], although this falls short of recommended guidelines of 10,000 steps per day [8]. Walking is often encouraged as a simple solution to physical inactivity [9]. PA interventions are more likely to cost-effective when they are easy to perform, and walking has been rated as the most favored form of PA by sedentary groups [10]. Walking is a low impact activity in which the individual can control intensity (low, moderate) or exertion to reduce the risk of injury, and can be easily incorporated into most daily routines with minimal risk [11]. Pedometers (or devices to count steps) also offer a way to monitor steps, and thus provide direct feedback on daily walking patterns. Pedometers (via mobile devices) are increasingly used, and the results of recent meta-analyses suggest that this technology is an excellent means to increase PA [12,13] with interventions delivered via mobile phones, yielding significant moderate effects ($g=.52$, 95% CI 0.11-0.94, $P=.01$) [13].

mHealth Interventions and Physical Activity

Mobile health (mHealth) involves public health initiatives that are supported by mobile devices (eg, mobile phones, tablet computers), and is increasingly being used as part of public health interventions, including PA interventions [14]. Novel mHealth technologies (eg, FitBits, Garmin watches, mobile phones), and in particular mobile phone apps, offer new possibilities that facilitate users to engage in behaviors such as planning, goal-setting, self-monitoring, and receiving continuous feedback (eg, step counts, calories burned). A recent study reported that 96% of Irish 15-35 year-olds owned a smartphone [15], thus providing significant opportunities for mHealth initiatives. Mobile phones with pedometer-enabled apps are useful, as people usually carry these devices throughout the day. Mobile apps also move beyond traditional forms of pedometer monitoring, with additional features such as automatic feedback, tracking of steps and calories, appealing graphic displays, and goal-oriented functionality [16].

Bort-Roig et al [17] highlighted the potential for PA interventions using smartphones. Glynn and colleagues [14] conducted the SMARTMOVE trial, one of the first studies to use smartphone technology to promote PA in patients with chronic disease. This study found that an app used in a primary care setting increased PA, decreased weight, and decreased blood pressure compared to controls [14]. The results from a qualitative study conducted with trial participants suggested that use of the app facilitated an interactive process of positive change in participants (and their exercise behavior) via the goal-setting and feedback dimensions of the app [18]. The authors called this the *Know-Check-Move* effect, and described how an app can affect behavior change through an increase in

awareness and knowledge, goal-setting, and the use of feedback. A recent meta-analysis that focused on increasing PA with mobile devices found that the use of mobile technology was an effective means of influencing PA behavior [13]. However, the authors suggested that interventions should focus on selecting the best possible use of these tools to measure and understand behavior. Therefore, theoretically grounded behavior change interventions that recognize and act on the potential of mobile phone technology could provide investigators with an effective tool for increasing PA [13].

Using a Theory-Based Approach in Health Behavior Change

The aforementioned findings agree with the *Behavior Change Taxonomy*, which identified key behavior change techniques (BCTs) for health behavior change interventions [19]. BCTs including education, goal-setting, and modelling, are observable and replicable components of behavior change interventions. While mHealth interventions hold significant potential, adopting a theory and evidence-based approach to intervention design is critical.

A recent review found that the use of relevant BCTs significantly increased the success of weight loss programs [20]. Students are among the most frequent users of smartphones and present a major opportunity to promote healthy lifestyles [21]. Although research evaluating mHealth interventions designed to increase PA is in its infancy, findings to date are promising.

This study sought to extend the findings of Glynn et al [14] by examining the feasibility of this approach by using the *Accupedo-Pro Pedometer* app intervention to promote PA in a healthy student sample. It was hypothesized that encouraging participants to engage with particular features of an app (eg, BCTs of goal-setting and self-monitoring) would significantly increase step counts compared to giving standard PA recommendations.

Methods

Design

This study used a *time x group* mixed design (baseline and 5-week follow-up; control and experimental groups). The dependent variable was mean daily step count. Ethical approval for the study was granted by the National University of Ireland Galway School of Psychology, Research Ethics Committee.

Sample Size and Recruitment

In order to reach a 95% confidence level in a pilot study, the estimated sample size was 59 young adults, who were randomized to receive either the intervention or usual care [22]. A final sample of 61 young adults was recruited through the university's research participation website. Students were given course credits for participating in the study. Participants were eligible for the study if they owned a smartphone (iPhone or Android). Three participants were initially excluded due to owning a non-compatible mobile phone, and two were lost before follow-up due to their phone malfunctioning. Information regarding participants' flow from recruitment to follow-up is displayed in Figure 1.

Measures

Daily step-counts were measured using *Accupedo-Pro Pedometer* app (see Figure 2); this app can give feedback on

distance, time, speed, and calories burned. *Accupedo* can also be operated to run in the background of the mobile phone without the display being visible.

Figure 1. Participant flow from recruitment to follow-up and analysis.

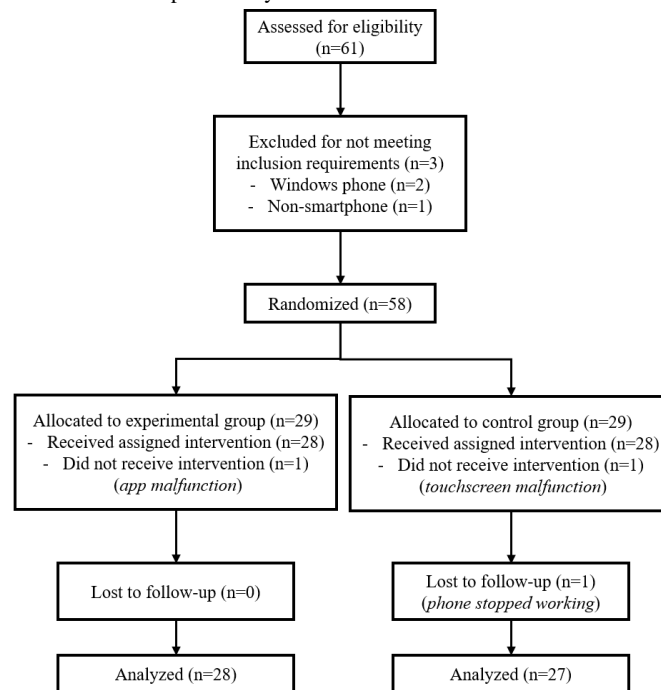
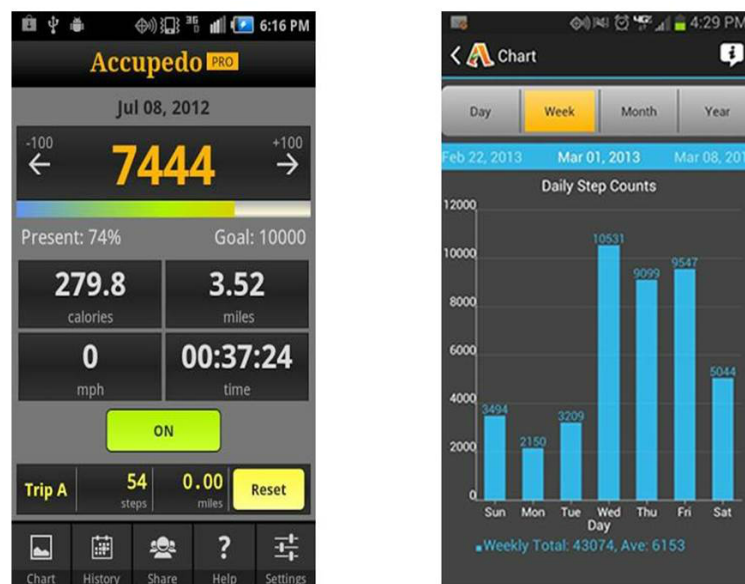


Figure 2. Accupedo Pedometer app screen shots.



Mobile Phone App and Selection Process

The *Accupedo-Pro Pedometer* app was selected for use in the current study. Notably, this app obtained the highest ratings in previous comparisons of pedometer apps [16]. This result was based on key criteria for promoting PA, including: automatic feedback and tracking of step counts and calories burnt; visually appealing graphic display of step-count history; goal-setting functionality; and goal-achievement feedback [16].

Demographics

The gender and age of participants were recorded using a demographic questionnaire that was distributed at the first meeting.

Procedure

Intervention Development

The Capability, Opportunity, Motivation, Behavior (COM-B) framework is a simple model that hypothesizes that an interaction between three components (capability, opportunity,

and motivation) influence behavior, and can provide explanations for why a recommended behavior is not undertaken [23]. The COM-B model and the Behavior Change Wheel [23] were used as guides during the intervention design process, and aided in the identification of BCTs. The Behavior Change Wheel identifies intervention functions that target relevant components of the COM-B model. In this trial, education, training, and modelling were used to address the psychological capabilities and reflective motivation of the students, in order to increase walking behavior. The complete methodology of the study can be found in [Multimedia Appendix 1](#).

Baseline Assessment

Details of the procedure are described in [Figure 1](#). Participants were self-selected via the university research website, or contacted the researcher to make an appointment. A randomization code was assigned to each participant, and relevant demographics and other data were collected. Participants were then assigned to either the control or experimental group via block randomization (which was used to guarantee similar numbers within each condition).

All participants then had the app downloaded onto their mobile phones to record their daily step counts, in order to provide a measurement of their baseline PA levels. For the week following the screening visit (*Week 1*), all participants were asked to carry their mobile phone during waking hours and to continue operating at their normal PA levels. During *Week 1*, the mobile phone app display was not visible to either group and the investigators remained blinded. At the end of this period each participant met with a researcher, who used the *share* option on the app to receive the previous week's step-count data.

Following the collection of baseline data, the randomization code was broken by the investigators. Both intervention and control groups were then given similar PA goals and information related to the benefits of exercise; however, only the intervention group was told how to use the app to help them achieve these goals.

Control Group

Participants in the control group were provided with information related to daily recommended PA levels (ie, 30 minutes daily), and information highlighting the benefits of walking regularly [8]. The control group was given a goal of 30 minutes of walking per day over the following month. The control group continued to have the pedometer app running in the background of their phone so that it continued to record their daily steps, without being visible or requiring interaction.

Intervention Group

Participants in the intervention group were provided with the same information as the control group regarding the benefits of walking and daily recommended PA levels. This group was encouraged to achieve a target goal of 10,000 steps per day, and were informed that this value was roughly equivalent to 30 minutes of walking per day (along with their normal activity). Researchers also demonstrated the usability features of the mobile phone app to the intervention group (using standardized instructions), and encouraged this group to use the app to monitor their steps and obtain feedback, in order to achieve their target goals. The follow-up meetings for both groups took place five weeks after the baseline data was taken. Data was collected in full, and participants were fully debriefed.

Statistical Analyses

A *time x group* (baseline and 5-week follow-up; control and experimental groups) mixed-analysis of variance (ANOVA) was conducted to analyze group differences in step counts over time. Post hoc *t*-tests were conducted to compute group differences. Analysis of missing data suggested that information was missing at random, and was therefore accounted for with Expectation Maximization substitution in the mixed model; the validity of this assumption was investigated by examining the missing data patterns and by modelling the probability of missing data based on the explanatory variables available. Tests of normality demonstrated that the data was normally distributed at both time points for step counts (Shapiro-Wilk $P=.07$ for both groups). Tests for equality of variance also indicated that this assumption was met (Levene's test $P=.16$).

Results

Baseline Characteristics

The final sample included a total of 55 participants (40 female, 15 male) between the ages of 17 and 26 (mean 20.55, standard deviation [SD] 2.07). Attrition was low ($n=3$), and was solely attributed to app or mobile phone malfunctions. Details regarding participant dropouts are displayed in [Figure 2](#). Descriptive statistics for each condition can be found in [Table 1](#).

Results of an independent samples *t*-test showed that there was no significant difference between daily step counts of the control and experimental groups at baseline ($t_{53}=.85$, $P=.401$), ensuring that randomization was effective.

Table 1. Descriptive statistics of demographics.

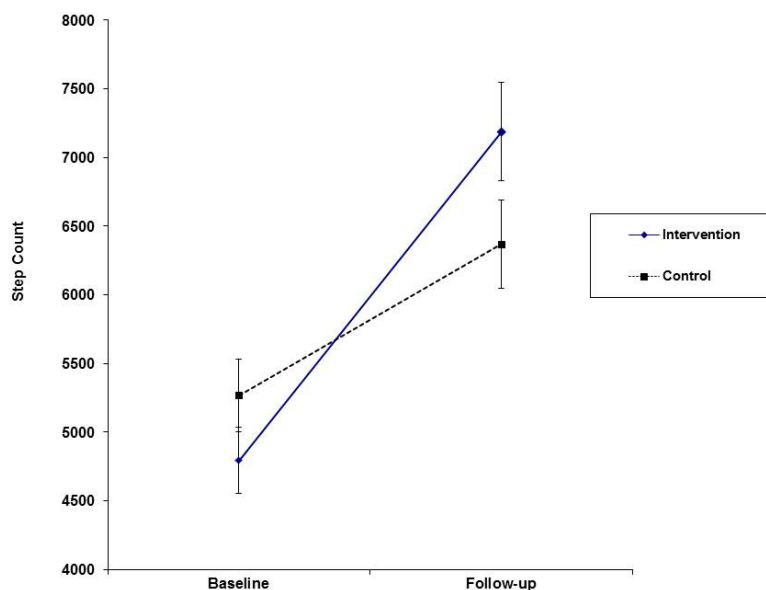
	Age	Gender	
	Years, Mean (SD)	Male, n (%)	Female, n (%)
Control group (n=27)	20.30 (1.73)	7 (25.9)	20 (74.1)
Experimental group (n=28)	20.79 (2.36)	8 (28.6)	20 (71.4)
Total (N=55)	20.50 (2.07)	15 (27.3)	40 (72.7)

Changes in Physical Activity (Step Counts)

A *time x group* mixed ANOVA was conducted to examine the impact of the experimental condition on daily step-counts from baseline to 5-week follow-up. A significant interaction effect was found between time and condition ($F_{1,53}=4.30$, $P=.043$, $\eta_p^2=.08$). A between-group *t*-test of the differences in step counts from baseline to follow-up revealed that participants in the intervention condition had a significantly higher increase in step count (2393) than those in the control condition (1101;

$t_{53}=2.07$, $P=.043$; see Figure 3). Dependent samples *t*-tests revealed a significant increase in daily step counts from baseline to follow-up for both the control ($t_{26}=-2.25$, $P=.033$) and the experimental group ($t_{27}=-6.14$, $P<.001$). A main effect was found for time ($F_{1,53}=31.43$, $P<.001$, $\eta_p^2=.37$), with both the control and experimental groups achieving a higher daily step count at follow-up (mean 6785.55, SD 2815.37) compared to baseline (mean 5026.78, SD 2071.86). No main effect was observed for in overall group differences ($F_{1,53}=.09$, $P=.77$).

Figure 3. Graph showing interaction effect between time and condition.



Discussion

Findings from this pilot study indicate that an intervention using a mobile phone pedometer app resulted in a significant increase in PA (step counts) in young adults over and above the provision of basic information on PA recommendations. The intervention group achieved a significant increase of over 2300 steps per day (an increase of approximately 45% in activity levels), equivalent to a distance greater than one mile. The medium effect size and increase in step counts were comparable to results found in a recent meta-analysis, which found that the use of pedometers had a moderate effect size (0.68, 95% CI 0.55-0.81) on the increase of PA in intervention studies [12]. This substantial change in behavior, if maintained, could result in numerous health benefits, including a reduced risk for obesity and cardiovascular disease [24]. Both the control and experimental groups displayed a significant increase in step counts during the study period. This effect was significantly greater for participants in the intervention group who had a target goal of 10,000 steps per day, and interacted with the self-monitoring aspects of the app. Findings suggest that pedometer-based interventions targeting college-aged cohorts may facilitate increases in their levels of PA over a relatively short period of time (one month).

Notably, baseline levels of activity were low in both study groups (approximately 5000 steps/day), which was less than the daily step count previously shown for healthy adults

(between 6000 and 7000 steps/day) [8]. By the end of the intervention, both groups had reached the minimum guideline targets, suggesting that pedometer apps are an effective mode of PA promotion for young adults at a life-stage when it is important to develop healthy behaviors.

Relationship with Other Research

Recent studies have highlighted the role of walking as it relates to increasing PA at a population level [10]. Heron et al [9] highlight the potential for pedometers as one technology to facilitate this activity. In particular, for students who frequently engage with apps and are generally healthy, these types of interventions may be critical in promoting activity in non-healthcare settings.

The steepest decline in PA occurs during adolescence and early adulthood [25]. World Health Organization (WHO) guidelines propose that inactive adults will have added health benefits with only minor behavioral changes, such as a shift from *no activity* to *some levels of activity*. Young adults who do not currently meet the recommendations for PA are encouraged to increase duration and frequency to achieving these goals [1]. Promotion of healthy behaviors in young adults is a priority in line with the WHO global strategy to protect health through PA, in order to substantially reduce disease burden in later years [1]. These changes may be facilitated by pedometer apps.

In this study, the control group had a significant increase in step-counts that was sustained over time. Simply using the app

or participating in the study may have been sufficient to increase step-counts or impact motivation in both groups. Brunet and Sabiston [26] suggest that PA interventions may benefit from promoting or maintaining autonomous regulations within young-adult populations. Glynn et al [14] found that the control group in their study showed an initial increase in step count, which then decreased back to baseline. A longer follow-up period may be required to examine how students' step-counts might change over time.

This study confirms that a significant increase in steps per day is achievable in a relatively inactive healthy sample [7]. This study is one of the first to consider the importance of mHealth technology tools to promote PA as a preventative measure in a healthy sample. The medium effect size and increase in step counts were equivalent to the results found in a recent meta-analysis, which found that the use of pedometers had a moderate effect size on the increase of PA in intervention studies [12].

Strengths and Limitations of the Study

One of the key strengths of this study is the use of taxonomy to describe the intervention content, and the selection of established BCTs that are associated with positive effects in the literature relating to the promotion of PA. Additional strengths of this study include the randomized design, limited exclusion criteria, and low attrition rates. Participants were only excluded due to technological issues (ie, incompatibility of mobile phone with the app or phone malfunction), therefore strengthening external validity.

This study also had a number of limitations, including (1) self-selection of the sample, (2) limited generalizability of results (given the focus on college students), (3) short follow-up timeline, and (4) use of an active control group. A longer follow-up period would have provided clearer insights into the maintenance of the behavior changes, however the 5-week follow-up in this study was comparable to that of Glynn et al [14]. The use of an active control group was deemed to be appropriate for a pilot study, as participants in the control group were provided with freely available information relating to the benefits of walking and daily recommended PA levels (eg,

government guidelines on recommended levels of PA). Ideally a passive control group would also be included in a full trial.

The 10,000 steps/day target has been criticized as a universal step-goal due to differences across different subgroups [8]. Wilde et al [27] argue that walking-based interventions should incorporate personalized step-goals. Given that the participants in this study were quite sedentary at baseline, it may have been more beneficial to provide them with easily achievable personalized goals that could be readjusted over time [28], rather than setting the same 10,000 step-goal for every participant. Recent findings also suggest that focusing on reducing sedentary behaviors may lead to a greater reduction in sedentary time, compared to interventions that focus on increasing PA [29].

Future Research

In future adaptations of this study, the target aims of the study and individual goals should be tailored to the participants' baseline level of activity, and incorporate psychosocial factors (eg, motivation or self-efficacy), in order to increase walking behavior [30]. It may be of interest to compare traditional wrist pedometers to an app, or to include objective measures of fitness, such as maximal oxygen uptake or heart rate.

Conclusions

This study has provided information on the use of a pedometer app in a community setting to promote PA, and found that students were willing to engage with the app to promote PA. This finding is encouraging for a larger research study or trial. It is important to encourage PA in inactive young adults, as PA levels [31,32] and PA motivation and enjoyment [33,34] may decrease gradually with age. The use of a pedometer app appeared to increase the number of steps taken per day by this relatively inactive group, even over a short period of time.

Mobile phone apps offer the potential to reach a large population through accessible, user-friendly, and autonomous self-monitoring means. A greater understanding of how these tools may be harnessed to promote positive behavior change is required. It is necessary to identify the most effective means of promoting PA for individuals that use their apps most frequently, before focusing on groups that are more difficult to engage.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Information on methodology.

[[PDF File \(Adobe PDF File\), 36KB - mhealth_v4i3e109_app1.pdf](#)]

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Abbreviations

ANOVA: analysis of variance
BCT: behavior change techniques
COM-B: Capability, Opportunity, Motivation, Behavior
mHealth: mobile health
PA: physical activity
SD: standard deviation
WHO: World Health Organization

Edited by G Eysenbach; submitted 12.10.15; peer-reviewed by M Bardus, J Tang; comments to author 03.12.15; revised version received 02.02.16; accepted 18.03.16; published 22.09.16.

Please cite as:

Walsh JC, Corbett T, Hogan M, Duggan J, McNamara A

An mHealth Intervention Using a Smartphone App to Increase Walking Behavior in Young Adults: A Pilot Study

JMIR Mhealth Uhealth 2016;4(3):e109

URL: <http://mhealth.jmir.org/2016/3/e109/>

doi: [10.2196/mhealth.5227](https://doi.org/10.2196/mhealth.5227)

PMID: [27658677](https://pubmed.ncbi.nlm.nih.gov/27658677/)

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Short Paper

Baseline Motivation Type as a Predictor of Dropout in a Healthy Eating Text Messaging Program

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Abstract

Background: Growing evidence suggests that text messaging programs are effective in facilitating health behavior change. However, high dropout rates limit the potential effectiveness of these programs.

Objective: This paper describes patterns of early dropout in the HealthyYou text (HYTtxt) program, with a focus on the impact of baseline motivation quality on dropout, as characterized by Self-Determination Theory (SDT).

Methods: This analysis included 193 users of HYTtxt, a diet and physical activity text messaging intervention developed by the US National Cancer Institute. Descriptive statistics were computed, and logistic regression models were run to examine the association between baseline motivation type and early program dropout.

Results: Overall, 43.0% (83/193) of users dropped out of the program; of these, 65.1% (54/83; 28.0% of all users) did so within the first 2 weeks. Users with higher autonomous motivation had significantly lower odds of dropping out within the first 2 weeks. A one unit increase in autonomous motivation was associated with lower odds (odds ratio 0.44, 95% CI 0.24–0.81) of early dropout, which persisted after adjusting for level of controlled motivation.

Conclusions: Applying SDT-based strategies to enhance autonomous motivation might reduce early dropout rates, which can improve program exposure and effectiveness.

(*JMIR Mhealth Uhealth* 2016;4(3):e114) doi:[10.2196/mhealth.5992](https://doi.org/10.2196/mhealth.5992)

KEYWORDS

mHealth; behavior change; diet; engagement; motivation; Self-Determination Theory

Introduction

The proliferation of mobile phone ownership in the United States and worldwide has provided a unique opportunity to reach broad audiences with health behavior messages and interventions [1-3]. Growing evidence suggests that text messaging programs are effective in facilitating health behavior change in multiple domains, including diet and physical activity [1,4,5]. Some of the advantages of text messaging programs over traditional health behavior change programs include their potential reach, particularly among hard-to-reach populations, and cost-effectiveness [6]. However, high user dropout rates are commonly noted in text-based programs [4]. This issue

represents a significant challenge, as the majority of disenrollment occurs early in these interventions, limiting the potential effectiveness of text messaging programs [7]. In order for programs to be maximally effective, there is a need to identify modifiable predictors of engagement that can serve as the basis for strategies to reduce dropout.

Motivation is one factor that has been associated with engagement in health behavior change programs and longer-term pursuits of health behavior change [8]. Traditional theories of motivation have typically been of limited value, in part because they have conceptualized motivation as a relatively static variable measured in terms of quantity, rather than quality [9]. Self-Determination Theory (SDT) offers an alternative approach

to characterizing motivation, and may prove to be more useful in understanding and enhancing motivation for sustained behavioral change [10-12]. SDT may also provide key insights into engagement and persistence with mobile technology-based interventions. Rather than focusing solely on motivational quantity, SDT emphasizes the importance of motivational quality in engagement with, and maintenance of, behavior [10,11]. SDT distinguishes between autonomous motivation, which arises from within the person and is congruent with other goals and values, and controlled motivation, which emerges from external and/or intrapsychic pressures (eg, incentives, approval from others, feelings of guilt or shame). Autonomous motivation has been associated with improved physical and mental health outcomes, and initiation and maintenance of health behaviors [13-15]. This study describes patterns of early dropout in the HealthyYou text (HYTtxt) messaging program and examines them through the lens of SDT.

Methods

Intervention Description

HYTtxt is a free text message-based resource that provides behavioral interventions to promote healthy diet and physical activity. HYTtxt was developed as a component of the US National Cancer Institute's Smokefree.gov Initiative (SFGI). SFGI is a large, national, multi-platform program that includes websites, text message programs, smartphone apps, and social media platforms that engage with 3-6 million users annually. HYTtxt is a 6-week intervention program that delivers 1-4 daily texts, including standardized behavioral intervention and social support messages that target specific health behavior goals each week, via unidirectional and bidirectional messages. At the time of enrollment, users answer a series of basic demographic questions and complete a brief motivational assessment. Users then select a behavior change goal related to healthy eating or physical activity. Throughout the program, users receive text messages that provide SDT-based intervention content, and assess their status in achieving health behavior goals. Users may discontinue the program at any time by texting the word *stop* to the program.

Sample

As a part of ongoing program quality assurance and improvement efforts, the sample for this project consisted of 193 consecutive individuals who enrolled in the HYTtxt healthy

eating stream of the text messaging program between June 2014 and December 2014, and met our inclusion criteria. Given our interest in the impact of motivation type on early dropout, we restricted our analysis to individuals with complete data for the motivation questions (described below). We did not collect information on the gender of our participants, but the program was promoted on the Smokefree Women Website [16] and Smokefree Women Facebook page, so the sample is presumed to be primarily women.

Measures

The dependent variable was early dropout, which was defined as actively dropping out within 2 weeks of program enrollment. Our primary independent variable was motivation quality. Table 1 includes the items used to assess motivational quality, adapted from the Self-Regulation Questionnaire [17]. Response options were *very true* (4), *a little true* (3), *a little untrue* (2), and *very untrue* (1). The *autonomous motivation* subscale was comprised of the mean of the identified and integrated questions; the *controlled motivation* subscale was comprised of the mean of the introjected and external questions. Higher values signified higher levels of motivational quality.

Users self-reported their age, educational level, and race/ethnicity during program enrollment. Users could enroll in the HYTtxt program by texting a keyword on their phone or by completing the Web enrollment form. Only individuals who enrolled using the Web enrollment were asked demographic questions; therefore, demographic data were only available for that subset of users.

Statistical Analyses

All analyses were conducted in SAS 9.3 (SAS Institute, Inc). Descriptive statistics were calculated and chi-square tests were conducted to examine associations between demographic characteristics and early dropout status. Logistic regression was used to test the association between early dropout and motivation type. Separate unadjusted logistic regression models for controlled motivation on dropout, and autonomous motivation on dropout, were computed. Subsequently, a model including both controlled motivation and autonomous motivation was run. For the subset of individuals with complete demographic data (n=126) we also examined the association between autonomous motivation and early dropout, controlling for demographic characteristics (ie, education level, race, and age).

Table 1. Question wording for each motivation type assessed at baseline.

Motivation type	Question wording: I would try to eat more fruits, vegetables, and whole grains because...
Autonomous (identified)	Eating fruits, vegetables, and whole grains helps me feel better
Autonomous (integrated)	Eating more fruits, vegetables, and whole grains is an important thing for me to do
Controlled (introjected)	I would feel bad about myself if I didn't
Controlled (external)	Others want me to eat more fruits, vegetables and whole grains

Results

Most users had at least some college education, were predominately white, and had an average age of 34.6 years

(Table 2). There were no significant demographic differences between those who dropped out within the first 2 weeks and those who did not. Overall, 28.0% (54/193) of users dropped out of the program within the first 2 weeks.

Of those who dropped out before completing the program (83/193, 43.0%), 65.1% (54/83) of users did so within the first 2 weeks.

At the beginning of the program, most users endorsed both autonomous and controlled motivations for healthy eating; however, on average users reported higher levels of autonomous motivation (mean 3.64, standard deviation 0.49) than controlled motivation (mean 2.42, standard deviation 0.88). Users with higher autonomous motivation had significantly lower odds of dropping out of the program within the first 2 weeks. A one unit increase in autonomous motivation was associated with a

significantly lower odds of early dropout (odds ratio [OR] 0.44, 95% CI 0.24–0.81; $P=.008$). This association persisted after adjusting for level of controlled motivation (OR 0.48, 95% CI 0.26–0.90; $P=.022$). Controlled motivation was not associated with early dropout (OR 0.71, 95% CI 0.49–1.02; $P=.064$). Given the association between autonomous motivation and early dropout, we further explored whether this association held true after controlling for demographic characteristics (67/193, 34.7% of cases were missing data, and were excluded), and autonomous motivation remained significantly associated with early dropout (OR 0.44, 95% CI 0.20–0.95; $P=.035$).

Table 2. Sample demographic characteristics.

Variable	% or mean (n)	Dropped out within the first 2 weeks, % (n)		<i>P</i> value
		Yes	No	
Total, % (n)	100.0 (193)	28.0 (54)	72.0 (139)	
Education, % (n)				
High school or less	18.1 (35)	22.2 (12)	16.6 (23)	0.77
Some college	32.6 (63)	33.3 (18)	32.4 (45)	
College graduate or higher	19.2 (37)	18.5 (10)	19.4 (27)	
Missing	30.1 (58)	25.9 (14)	31.7 (44)	
Race, % (n)				
White	48.7 (94)	59.3 (32)	44.6 (62)	0.19
Non-white	18.1 (35)	14.8 (8)	19.4 (27)	
Missing	33.2 (64)	25.9 (14)	36.0 (50)	
Age in years, mean (range)	34.6 (13-62)	32.6 (16-62)	35.5 (13-62)	0.22

Discussion

Principal Results

In this study, approximately two-thirds (65.1%, 54/83) of users who dropped out did so within the first 2 weeks. Users with higher levels of autonomous motivation at baseline were less likely to drop out early, even after adjusting for controlled motivation. This result is consistent with previous research that has demonstrated that autonomous motivation is predictive of initiating and maintaining health behaviors [14,18].

Limitations

Participants in this study were users of the HYTxt text messaging program, and were not recruited for a particular study. Although this sample represents a self-selected group, they are likely more reflective of individuals who would use the publicly available program in general than participants of a tightly controlled randomized trial would be. Not all users completed the motivation questions, resulting in a great deal of missing data for demographic correlates; therefore, our results may not be generalizable to all users of HYTxt. This analysis focused solely on motivation related to healthy eating, and other factors (eg, comfort with mobile technology) might influence dropout rates. Furthermore, we focused on those who actively opted out of the program, and cannot comment on those who

may have continued to receive messages but disengaged from the program.

Comparison with Prior Work

Dropout is a significant problem in behavior change text messaging interventions. This study provides insight into a modifiable factor that influences likelihood of dropping out: autonomous motivation. The extant literature on SDT-based interventions offers potential insights into techniques that could be leveraged to promote autonomous motivation early in text messaging behavior change programs to decrease early dropout. Candidate SDT techniques include: supporting users in aligning behavior change goals with broader life goals and values; providing opportunities for choice, including opportunities to disengage from the current program and either (1) return at a later time or (2) change to another health behavior that better fits the user's current interests and life situation; and providing content that normalizes the trial-and-error nature of the health behavior change processes, while offering strategies for dealing with failures and setbacks [18-20]. While these techniques have been well-validated in more traditional intervention delivery modalities (eg, in-person or telephone-based), there is a need to translate these techniques into strategies that would be applicable when using a text messaging platform. For example, more messaging can be added at early stages that encourage users to consider how this behavior change aligns with their

broader life goals and values, and ensure that users are selecting behavior change goals that are consistent with their core values. In addition, users' progress towards meeting their goals can be assessed at regular intervals, and individuals who are struggling can be provided with additional content that both normalizes setbacks and provides strategies for dealing with these setbacks.

Conclusions

Text messaging interventions have the potential to reach large numbers of individuals, especially traditionally hard-to-reach

populations. However, high early dropout rates inhibit the potential effectiveness of such programs. This study demonstrated that those who had higher levels of autonomous motivation were less likely to drop out in the first 2 weeks of the program, during which dropout rates were highest. Applying SDT-based strategies early in text messaging programs (to enhance autonomous motivation) might reduce early dropout rates, which in turn can improve program exposure and effectiveness.

Acknowledgments

The authors would like to acknowledge Dr. Erik Augustson for his comments on drafts of this manuscript. This study was funded in part by National Institutes of Health, National Cancer Institute HHSN26120140002B, HHSN26100006, HHSN26100007.

Conflicts of Interest

None declared.

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Abbreviations

HYT: HealthyYou text

OR: odds ratio

SDT: Self-Determination Theory

SFGI: Smokefree.gov Initiative

Edited by G Eysenbach; submitted 18.05.16; peer-reviewed by L Buis, R Whittaker; comments to author 23.06.16; revised version received 16.08.16; accepted 10.09.16; published 29.09.16.

Please cite as:

Coa K, Patrick H

Baseline Motivation Type as a Predictor of Dropout in a Healthy Eating Text Messaging Program

JMIR Mhealth Uhealth 2016;4(3):e114

URL: <http://mhealth.jmir.org/2016/3/e114/>

doi: [10.2196/mhealth.5992](https://doi.org/10.2196/mhealth.5992)

PMID: [27688034](https://pubmed.ncbi.nlm.nih.gov/27688034/)

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Original Paper

Increasing Nonsedentary Behaviors in University Students Using Text Messages: Randomized Controlled Trial

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Abstract

Background: Sedentary behavior (SB) has been linked to many health problems such as type 2 diabetes and heart disease. Increasing the length and frequency of breaks from sitting and increasing the time spent standing and engaged in light and moderate physical activity are ways to decrease SB. Text message-based interventions have succeeded in aiding smoking cessation and increase both physical activity and healthy eating, but they have not been shown to reduce SB.

Objective: The primary purpose of this pilot study was to determine the effectiveness of a text message-based intervention in increasing nonsedentary behaviors in university students. A secondary purpose was to (1) determine whether the intervention could enhance self-efficacy beliefs for decreasing SB and (2) whether these efficacious beliefs could predict actual SB.

Methods: Eighty-two university students were recruited via mass emails and randomized into intervention (SB-related text messages) or control (text messages unrelated to SB) groups. Participants received daily text messages scheduled by the researcher encouraging breaks from sitting, standing, light- and moderate-intensity physical activity (PA). They then reported various SBs via Web-based questionnaires at four time points (baseline, 2, 4, and 6 weeks). Self-efficacious beliefs toward taking breaks from sitting and decreasing the amount of time spent sitting were assessed at the same time points.

Results: Last observation carried forward (LOCF) method was used for incomplete data as an intent-to-treat (ITT) analysis (intervention group n=15, control group n=11). Small-to-moderate effects favoring the text intervention group were found at 6 weeks for break frequency -14.64 minutes, break length +.59 minutes, standing +24.30 min/day, light-intensity +74.34 min/day, and moderate-intensity + 9.97 min/day PA. Only light-intensity PA approached significance ($P=.07$). Self-efficacy beliefs also favored the text intervention group and reached significance ($P=.032$) for sitting less. Significant ($P<.05$) relations were found between the self-efficacy constructs and breaks, standing, and light or moderate PA.

Conclusions: Text messages have the potential to increase nonsedentary behaviors in university students. These messages can increase self-efficacy beliefs to take more breaks and reduce sitting time. Efficacious beliefs can predict actual SB and to a lesser extent light- and moderate-intensity PA.

Trial Registration: ClinicalTrials.gov NCT02562937; <https://clinicaltrials.gov/ct2/show/NCT02562937> (Archived by WebCite at <http://www.webcitation.org/6jVLwXE5M>)

(*JMIR Mhealth Uhealth* 2016;4(3):e99) doi:[10.2196/mhealth.5411](https://doi.org/10.2196/mhealth.5411)

KEYWORDS

sedentary behaviour; prolonged sitting; text messages; self-efficacy; university students; breaks from sitting; light intensity physical activity; moderate intensity physical activity

Introduction

Sedentary behaviors, such as screen viewing, reading, and riding in an automobile, can be defined as any waking activity at an energy expenditure of ≤ 1.5 METs (metabolic equivalents) while in a seated or reclined posture [1]. Many adults are physically inactive, meaning they are not meeting the current recommendations of 150 minutes of moderate to vigorous physical activity (PA) per week [2,3]. However, even those who are meeting these recommendations may still be spending too much time sitting, leading to an increase in health risks associated with sedentary behavior [4]. Researchers have found that prolonged sitting (typically in bouts of 20 minutes or more) can cause higher levels of fasting insulin and can increase an individual's chance of getting type 2 diabetes, increased waist circumference, lower levels of high-density lipoprotein (HDL) cholesterol, increased levels of C-reactive protein, higher levels of triglycerides, raised 2-hour plasma glucose level, and increased risk of all-cause mortality [5-7]. Apart from cardiometabolic risk factors and an increased risk of all-cause mortality, there is evidence that sedentary behavior is related to cancer risks. A meta-analysis found an increased risk in colon, endometrial, and lung cancer associated with extended sedentary time [8]. Healy and colleagues have examined whether breaks from sitting are associated with reductions to known health risks. In one study, they found that those who took the most breaks from sitting had a smaller waist circumference, lower body mass index, lower levels of triglycerides, and lower 2-hour plasma glucose levels, compared with those who took the least amount of breaks from sitting [9,10]. A later study by Healy and colleagues found an association between breaks from sitting and waist circumference, C-reactive protein, and fasting plasma glucose level, irrespective of total sitting time [6]. Beneficial breaks from sitting in these studies were typically 2-4 minutes in length, for every 20 minutes of sitting, which could lead to future guidelines recommending these types of breaks.

Researchers have looked into what constitutes an effective break from sitting, and have found that although standing is better than sitting, light-intensity PA is the most beneficial [6,9]. Although there are no official recommendations of how long adults should sit, early evidence suggests that sitting for 4 hours or less per day may prevent many of the aforementioned health risks. One study, for instance, found that reducing sitting to less than 3 hours per day could result in a 2-year gain in life expectancy [11]. Women who sat for less than 4 hours per day had a much lower prevalence of depressive symptoms [12] and adults who sat for less than 4 hours, regardless of gender, had a reduction in all-cause mortality [13].

The vast majority of sedentary behavior interventions have been aimed at office workers, and overweight or obese adults; however very few, if any, target university students specifically [14]. Students are an inherent sedentary population as they spend a great deal of their time in either class or studying. Studies have shown that weight gain often occurs during young adulthood [14,15], and those who led a sedentary lifestyle in college remained sedentary 5 or 10 years later [16]. Interventions aiming at this population are therefore worth implementing

when attempting to prevent high levels of sedentary behavior and reduce overweight or obesity rates in adults.

Although there have been successful interventions developed to reduce sedentary behavior, very few utilize screen-based technology. Many studies have utilized mobile phones to create interventions for other health behaviors via text messages [17-19]. Text messages allow researchers to conveniently reach a large population, either locally or globally, relatively inexpensively and without consuming a great deal of time by either the researchers or the participants. Some of the health behaviors targeted by this method include improving diet, smoking cessation, diabetes management, and increasing PA levels. A recent study used text messages to improve overall health by targeting diet, PA, smoking, and other behaviors related to blood pressure and body mass index and found significant changes in all measures [20]. These results show promise for text messages being used for lifestyle-change interventions.

We are unaware of any studies that have examined the use of text messages as an intervention to reduce sedentary behaviors or increase nonsedentary behaviors in the student or general population. With respect to the student population a large study found that 96% of American undergraduate students owned a mobile phone [21], which indicates that any text message-based intervention that is aimed at this population should be accessible by the vast majority.

Self-efficacy as a determinant of PA has been extensively studied, and results show that those with higher self-efficacy for PA will spend more time being physically active [22,23]. These findings have been replicated using university students, particularly female students [16,24]. The role self-efficacy plays in reducing sedentary behaviors or increasing nonsedentary behaviors is unknown.

The primary purpose of this pilot study was to determine whether a text message intervention would increase frequency and length of breaks from sitting, time spent standing, and time spent in light- and moderate-intensity PA in university students. A secondary purpose was to determine whether the intervention would increase self-efficacious beliefs regarding frequency and length of break from sitting and total sitting time. Another secondary purpose was to determine if self-efficacious beliefs toward length and frequency of breaks and toward sitting less would be related to actual break behavior, time spent standing, and time spent in light- and moderate-intensity PA. Pilot studies are crucial in areas of new research for obtaining preliminary findings with the use of fewer resources. Pilot studies also provide valuable insight into recruitment, randomization, treatment, and follow-up assessments so that these processes can be repeated successfully with a larger main study [25].

Methods

Recruitment

After being approved by the Research Ethics Board of Western University, the study was advertised through emails sent out to various faculties at Western University and students who were interested in the study emailed the researcher to sign up. The

study was also advertised through an article in the university newspaper due to the interest of a reporter. Eligibility requirements were as follows: participants had to be between the ages of 18 and 65, be able to read and write in English, own a mobile phone with free unlimited incoming text messages, and be a student of Western University.

Statistical Analysis

Power

No previous research exists to inform a sample size power calculation for sitting behavior following a text-based intervention.

Data Exclusion

Due to several extreme outliers, a winsorization technique was used to replace any data points over the 95th percentile with the value of the 95th percentile. A total of 196 data points out of more than 6000 data points in the sedentary and light intensity physical activity (SLIPA) questionnaire were imputed this way (60 in the control group and 136 in the intervention group). This method has been shown as a valid way to treat outliers by several authors [26,27].

Primary Outcome Measures

Frequency of Breaks

The frequency of breaks taken from sitting was measured by the following question “I currently take a break to get up and move around every _____ minutes I spend sitting.” The options the participants could choose from were as follows: every 30 minutes or less, 45 minutes, 60 minutes, 75 minutes, 90 minutes, 120 minutes, 180 minutes or 240 minutes or more.

Length of Breaks

Length of breaks taken from sitting was measured by the following question: “Currently, which number best represents the length of your breaks you usually take from sitting?” The answers included 30 seconds or less, 1 minute, 2 minutes, 3 minutes, 4 minutes, 5 minutes, 10 minutes, or 15 minutes.

Standing and Light-Intensity Physical Activity

Time spent standing and time spent doing light-intensity physical activity (LIPA) were measured using items 2, 4, 9, 10, 12, 19 and items 3, 7, 8, 11, 13, 14, respectively, of the SLIPA questionnaire. The SLIPA measures time spent doing typical daily sedentary or light-intensity physical activities. The SLIPA has been validated against ActiGraph GTX3 accelerometers, and the cut off points for sedentary behavior and light-intensity physical activity were anything under 100 counts per minute and 100-1951 counts per minute, respectively [28]. The SLIPA is typically used as a 7-day log; however, to ease participant burden, this study asked participants to fill out the items based on a typical weekday and a typical weekend day. Internal consistency Cronbach alphas for the scale constructs were acceptable (at 6 weeks: standing $\alpha=.75$; light intensity PA $\alpha=.81$). Although the SLIPA provides a measure of sedentary behavior, the goal of this text intervention was to directly target and positively change standing and light-intensity physical activity. After careful examination of the sedentary behavior

items (items 1, 5, 6, 15, 16, 17, and 18), it became evident that some items were not relevant to the text intervention (eg, driving a car) or overlapped each other (eg, sitting-studying, writing, desk work, typing vs. sitting-using a computer) causing many overestimated data points. For these reasons, this sitting measure was not calculated and used in subsequent analyses.

Moderate-Intensity Physical Activity

The short form of the Seven-Day Physical Activity Recall Questionnaire was used to measure current levels of moderate-intensity physical activity (MIPA) [22]. Participants were asked to estimate the number of minutes they spent doing MIPA during the last 7 days. Hard and very hard intensity were also measured; however, only moderate intensity was being targeted by some of the texts in the intervention (ie, “Your challenge for tomorrow is to do 30 squats for every episode of TV you watch”), whereas hard and very hard were not specifically targeted, and thus not analyzed.

Secondary Outcome Measures

Self-Efficacy

To measure self-efficacy, a purpose-built questionnaire was designed. This questionnaire was comprised of 3 questions, each with several statements. The first being “I am _____% confident I can decrease the amount of time I sit every day by 20 minutes,” with possible answers ranging from 0-100 in intervals of 5%. The question was repeated with 30, 45, 60, 75, and 90 minutes. The second question was “I am _____% confident I can take a break from sitting every 240 minutes” which was repeated for 180, 120, 90, 75, 60, 45 and 30 minutes or less. The third question was “I am _____% confident I can increase the length of my breaks from sitting by 30 seconds,” and was also repeated for 1, 2, 3, 4, 5, 10, and 15 minutes. All questions had the same possible answers. The self-efficacy scales demonstrated acceptable internal consistency.

Other Measures

Demographics

The following demographic information was obtained: name, age, phone number, sex, level of education (undergraduate, graduate, or other), number of hours in class per week, number of hours at work per week, as well as height and weight in order to calculate body mass index.

Intervention

Sedentary Behavior-Related Text Messages

The intervention group received text messages twice daily, one in the morning or early afternoon and one in the evening, depending on when they reported not being in class or meetings during the first questionnaire. They received one fact about sedentary behavior at the beginning of each week such as, “By breaking up your sitting time you will reduce your risk of developing Type II diabetes,” and included different health risks outlined by Thorpe and colleagues [28]. They then received various challenges, tips, and reminders throughout the week. The challenges started out easy and directly related to the self-efficacy questions such as, “Your challenge for the next 7 days is to get up every hour for 5 minutes,” and got increasingly

harder until they were being challenged to get up every 30 minutes for a 5-minute break. The tips and reminders were sent in between challenges and facts and included ways to decrease sitting, such as, “Get up and set a timer on your phone for 5 minutes and don’t sit down again until the timer ends,” “Get off the bus a stop or two early and walk the rest of the way,” or “Don’t forget to get up every hour today and walk around for 5 minutes.” See [Multimedia Appendix 1](#) for list of text messages.

Text Messages Unrelated to Sedentary Behavior

The control group received daily text messages in the evenings about random health or nutrition facts, such as, “Raw pumpkin seeds contain essential fatty acids and beneficial proteins” or “Between 25% to 33% of the population sneeze when they are exposed to light.”

Procedure

University students who were interested in the study emailed the researcher to sign up in January and then received a link via email that directed them to the first questionnaire, which was administered through a third party website called SoSCI. Upon completion of the baseline measurements, participants were randomized by the researcher, using computer-generated randomized stratification, into either the intervention group or the control group and were unaware of their group allocation. They were then entered into a contact list on the text-messaging website called “Oh Don’t Forget.” “Oh Don’t Forget,” is a Web-based application that works through “Recess Mobile” to send messages from a computer to mobile phone numbers that are programmed into the application.

All participants began receiving text messages within 3 days of completing the questionnaire. Every participant received the same daily texts as each other participant in their group, with times varying slightly depending on their schedule. After 2 weeks of receiving texts, participants received the link to the second questionnaire in an email and were also reminded via text to complete it. This was repeated at 4 and 6 weeks,

respectively. All questionnaires contained the same measures as described previously (except for demographics that were only asked at baseline, and physical activity recall, which was only asked at baseline and at 6 weeks in order to reduce the length of the questionnaires). Upon completion of the final questionnaire the participants were notified that they would no longer be receiving text messages and that the study was completed. Data collection was all done at Western University, beginning in January 2015 and was completed in March 2015. See [Multimedia Appendix 2](#) for the CONSORT EHEALTH checklist [29].

Statistical Analyses

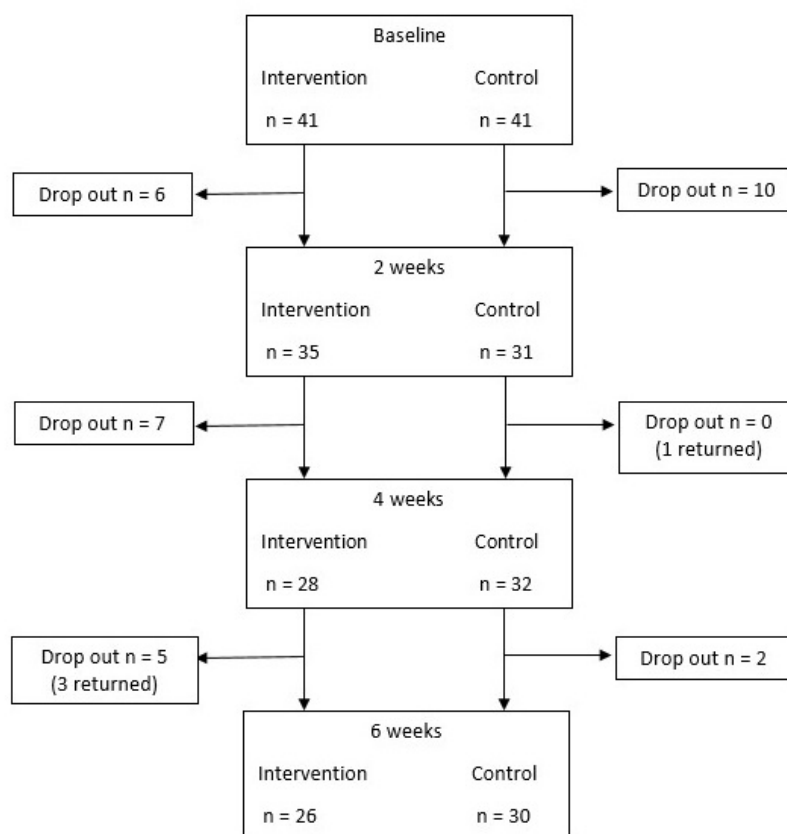
Primary and Secondary Outcome Analyses

A series of 2 (intervention vs controls) x 4 (time – baseline, 2 weeks, 4 weeks, and 6 weeks) repeated measures analysis of variance (ANOVA) were used to determine if there were any significant time or time by group interaction effects. Bivariate correlations were conducted on the self-efficacy questionnaires and their matching behaviors. Linear regression was used to determine how much of the variance in the behavior could be predicted by the matching self-efficacy questionnaire.

Results

Missing Data

Last observation carried forward (LOCF) method was used for missing data from dropouts as an intent-to-treat (ITT) analysis. Independent t-tests revealed no significant differences (all P values > .05) between those who gave complete data and those who dropped out at any time points. There were also no significant differences in the demographic variables for those that provided complete versus missing primary outcome data (all P values > .05). In addition, there was no differential loss between treatment groups for those who provided complete end point data (all P values > .05). Taken together, all missing data were considered random. [Figure 1](#) shows dropouts for each group.

Figure 1. Flow of participants through study.**Table 1.** Demographic variables of both groups at baseline.

Demographic variables	Intervention group (n=41)			Control group (n=41)		
	M	SD	%	M	SD	%
Sex (male)			24.4			26.8
Age (years)	21.37	3.60		21.02	4.76	
Body mass index	24.57	3.56		23.22	3.54	
Hours of class per week	15.63	7.42		15.67	6.73	
Hours of work per week	6.33	8.99		5.94	10.35	
Type of student						
	Undergraduate		87.8			78
	Graduate student		12.2			17
	Other		0			4.8
Physical activity						
	Moderate ^a	184.15	269.40	203.54	183.98	
	Hard ^a	94.12	120.63	83.24	121.42	
	Very Hard ^a	93.23	113.23	97.61	131.70	
Days with hard	2.80	2.34		2.93	2.40	
Days with moderate	4.25	3.61		4.34	2.66	

^aExpressed in minutes per week

User Statistics

Descriptive statistics for the demographic and physical activity variables are shown in [Table 1](#). Groups were equivalent at baseline for all measures (all P values > .05).

Evaluation Outcomes

Primary Outcomes – Break Frequency and Length, Standing, Light-Intensity Physical Activity and Moderate-Intensity Physical Activity

Descriptive data for the primary outcomes are presented in [Multimedia Appendix 3](#). These data show that the intervention group increased standing by 18.25 min/day, LIPA by 50.07 min/day, MIPA by 13.03 min/day (total increase in PA/standing of 81.35 minutes). The control group decreased standing by 6.05 min/day, decreased light by 24.27 min/day and increased moderate by 3.06 min/day (total net decrease of 27.26 minutes).

There were significant time effects for break frequency: $F(3, 78)=6.32$, $P<.001$, Wilks' $\Lambda=0.80$, $\eta_p^2=.20$; time spent in light-intensity PA: $F(3, 78)=2.75$, $P=0.048$, Wilks' $\Lambda=0.90$, $\eta_p^2=.10$; and time spent in moderate-intensity PA: $F(3, 80)=5.25$, $P=.025$, Wilks' $\Lambda=0.94$, $\eta_p^2=.06$. There were no significant time effects for break length: $F(3, 78)=0.73$, $P=.537$, Wilks' $\Lambda=0.97$, $\eta_p^2=.03$ or time spent standing: $F(3, 78)=0.45$, $P=.715$, Wilks' $\Lambda=.98$, $\eta_p^2=.02$.

There were no significant treatment group by time interaction effects for break frequency: $F(3, 78)=1.28$, $P=.287$, Wilks' $\Lambda=0.95$, $\eta_p^2=.05$; break length: $F(3, 78)=0.73$, $P=.629$, Wilks' $\Lambda=0.98$, $\eta_p^2=.02$; time spent standing: $F(3, 78)=0.72$, $P=.544$, Wilks' $\Lambda=.97$, $\eta_p^2=.03$; or time spent in moderate: $F(3, 80)=2.01$, $P=.160$, Wilks' $\Lambda=0.98$, $\eta_p^2=.03$. However, there was a trend effect for time spent in light: $F(3, 78)=2.43$, $P=.071$, Wilks' $\Lambda=0.91$, $\eta_p^2=.09$.

Secondary Outcomes - Self-Efficacy

Descriptive data for the secondary outcomes are presented in [Multimedia Appendix 3](#). Confidence to increase frequency of breaks increased by 7.74% for the intervention group and by 4.34% for controls. Confidence to increase length of break increased in the intervention group by 0.90% and decreased for the controls by 1.37%. Confidence to decrease sitting time increased by 11.44% for the intervention group and by 6.31% for the controls.

There were significant time effects for confidence to increase break frequency: $F(3, 78)=9.79$, $P<.001$, Wilks' $\Lambda=0.73$, $\eta_p^2=.27$, confidence to increase break length: $F(3, 78)=6.41$, $P=.001$, Wilks' $\Lambda=0.80$, $\eta_p^2=.20$ and confidence to sit less: $F(3, 78)=8.54$, $P<.000$, Wilks' $\Lambda=0.75$, $\eta_p^2=.25$.

There were trend interaction effects for confidence to increase break frequency $F(3, 78)=2.52$, $P=.064$, Wilks' $\Lambda=0.91$, $\eta_p^2=.09$ and for confidence to increase break length: $F(3, 78)=2.06$, $P=.112$, Wilks' $\Lambda=0.93$, $\eta_p^2=.07$. There was a significant interaction effect for confidence to sit less: $F(3, 78)=3.09$, $P=.032$, Wilks' $\Lambda=0.89$, $\eta_p^2=.11$.

Associations Between Self-Efficacy and Target Behaviors

Bivariate data for relations between the self-efficacy constructs and the targeted primary outcome variables is presented in [Table 2](#). At 6 weeks, confidence to increase break frequency was significantly related to actual break frequency, actual break length, standing time, LIPA, and MIPA. Confidence to increase break length was significantly related to actual break length, actual break frequency, standing time, LIPA, and MIPA. Confidence to sit less was significantly related to break frequency, break length, standing time, LIPA, and MIPA.

Table 2. Correlation between self-efficacy and target behaviors at baseline and 6 weeks^h

	SE-BFrequency ^c	SE-BLength ^d	SE-SL ^e	Break Frequency	Break Length	Stand	LIPA ^f	MIPA ^g
SE-BFrequency	-	.478 ^b	.585 ^b	-.408 ^b	.310 ^b	.171	.157	.172
SE-BLength	.374 ^b	-	.637 ^b	-.367 ^b	.560 ^b	.163	.260 ^a	.251 ^a
SE-SL	.347 ^b	.487 ^b	-	-.398 ^b	.347 ^b	.219 ^a	.318 ^b	.336 ^b
Break Frequency	-.576 ^b	-.091	-.093	-	-.241 ^a	-.128	-.180	-.146
Break Length	.130	.329 ^b	.147 ^b	-.114	-	-.089	.194	.323 ^b
Stand	.198	.130	.125	.079	-.073	-	.693 ^b	.305 ^b
LIPA	.174	.258	.137	.161	-.100	.665 ^b	-	.396 ^b
MIPA	.204	.032	.123	.064	-.208	.251 ^a	.195	-

^a $P < 0.05$ ^b $P < 0.01$ ^cSE-BFrequency: self-efficacy for break frequency^dSE-BLength: self-efficacy for break length^eSE-SL: self-efficacy for sitting less^fLIPA: Light-intensity physical activity^gMIPA: Moderate-intensity physical activity^hValues below the diagonal are from baseline, numbers above the diagonal are from 6 weeks.

Discussion

Summary of Results

The present pilot study aimed to use text messages to increase (1) the frequency and length of breaks from sitting, (2) the amount of time spent standing, and (3) and the amount of time engaged in light- and moderate-intensity physical activity. The study also aimed to increase self-efficacy for breaks and reduce overall sitting time. Overall small to moderate effects that did not reach significance were found that consistently favored the text intervention group for all primary outcome behaviors. Irrespective of behavior, the largest difference between treatment groups occurred at 6 weeks. Moderate to large effects that reached significance were also found consistently favoring the text intervention group for all self-efficacy constructs measured. Again, irrespective of self-efficacy measure, the largest difference between treatment conditions occurred at 6 weeks. Finally, significant relations were found when correspondence was high between the self-efficacious constructs and the primary outcome behaviors. Relations between measures were stronger at week 6 than at baseline. Beyond these general observations, the following specific issues warrant commentary.

Principal Results

Frequency and Length of Breaks

Frequency of break resulted in a net difference of 14.64 minutes between groups, favoring the intervention group. Although this difference is not statistically significant, it could still be clinically meaningful as the intervention group is getting up to move around more frequently.

Length of break from sitting resulted in a difference of 0.59 minutes between groups. This small nonsignificant increase is

not surprising because the intervention was aiming at taking 3-6 minute breaks for every 30 minutes of sitting, or 6-10 minute breaks every hour. The intervention group was above 6 minutes every hour, and thus, behaving consistently with recommendations of previous work [9,10].

Standing, Light, and Moderate Physical Activity

Time spent (1) standing resulted in net difference of 24.30 minutes per day, (2) doing LIPA resulted in a net difference of 74.34 minutes per day, and (3) doing MIPA resulted in a net difference of 69.78 minutes per week (9.97 minutes per day). Overall, the net differences were moderate in size and favored the intervention group and approached significance only for LIPA. These results are not surprising as the text messages focused more on replacing sitting with light to moderate physical activity rather than standing. Failure for the net differences highlighted above to reach statistical significance is likely due to the study being underpowered due to the small sample size and the variances of responses being widely dispersed around the means of the targeted nonsedentary behaviors.

Previous studies have shown a range of increased standing time from 57 minutes per day [30] to 127 minutes per day [31]. This study only increased standing by 18.25 minutes per day. Studies that focused on increasing LIPA were successful in increasing it by 31 minutes per day after 4 weeks [32], 21 minutes per day after 6 months [33], and 39 minutes per day after 1 year [34]. This study was able to increase LIPA by 50.07 minutes per day. One study that looked at standing and LIPA increased standing by 57 minutes per day and LIPA by 38 minutes per day for a total increase of 95 minutes after 9 months [30]. The change seen in the current intervention had a combined increase in standing and PA of 81 minutes per day. Most studies focused on standing or LIPA; however, a study by Carr et al also

measured moderate-intensity physical activity and found an increase of 8.8 minutes per day, along with a 2.2 minute increase in vigorous PA and 6.4 minute increase in LIPA per day [35,36]. The current study observed an increase of 13.03 minutes per day of moderate physical activity. Taken together, our findings provide evidence that text messaging as a way to increase standing, LIPA and MIPA is, for the most part, in line with other interventions.

Self-Efficacy

Confidence to sit resulted in a net difference of 5.13% that reached statistical significance. Confidence to take more frequent breaks resulted in a net difference of 3.4%. Confidence to increase length of breaks from sitting resulted in a net difference 2.27%. Overall, the net differences were small and favored the intervention group.

At 6 weeks, the self-efficacy measures were significantly related to their matching behaviors. These findings underscore the importance of scale correspondence between the cognition and the targeted behavior. Confidence to sit less had significant relationships with breaks, standing, LIPA, and MIPA at baseline. This suggests that those who are more confident in being able to sit less will take longer and more frequent breaks, and spend more time standing, in LIPA and MIPA. It also could mean that those WHO demonstrate these behaviors are more confident in sitting less. Future work should shed light on whether efficacious beliefs towards breaks and sitting less are antecedents or consequences of sitting less behaviors. Future work might also focus on developing scales that measure efficacious beliefs toward standing as well as using existing scales that measure efficacious beliefs towards LIPA and MIPA [22,23].

Strengths, Limitations and Future Directions

There are several strengths associated with the present pilot study. These include the randomized control design with equal contact time, the inexpensive and user-friendly text messaging system used, tailoring the text messages to each individual's schedule, and matching the text messages with the targeted nonsedentary behaviors and efficacious cognitions. Another strength is the study's scalability. This study was conducted using a sample of university students; however, it could easily be replicated using many other populations. Since mobile phones are so common, anyone who uses one daily could benefit from this type of intervention. It could be adapted to specific groups, such as office workers, by having messages scheduled during their lunch breaks, or in the evenings, to remind them to get up and move around, rather than just sit in front of their computer or television. It could also be used for retired adults, to keep them active once they no longer have the daily routines that they had during the years they spent working. Using messages similar to those from this intervention could be combined with existing technology to create other interventions that utilize fitness trackers or mobile phone apps.

The main limitation for this study was the use of a subjective self-report measure of sedentary behavior. Although the SLIPA questionnaire has been shown to be a valid and reliable measure in the past, it was not problem-free in this study. For instance, many people overestimated how much time they spend doing various activities representing sitting time (which was shown when their days would add up to many more than 24 hours) that were either not relevant to the text intervention or overlapped each other. Hence, a sitting time measure was not calculated and used in subsequent analyses. The use of an objective measurement tool such as an accelerometer with a built in inclinometer would allow for more accurate data as well as data that are more valuable. If such a device was worn throughout the study, it would give the exact amount of time that was displaced from inactivity to other behaviors. It would also allow the researchers to observe if the participants were actually utilizing the prompts from the texts by checking the data at the time the texts were received. If a text was sent that told them to get up and move around for 5 minutes, the researchers could examine the device data at that time and see if the participant did indeed move around for 5 minutes right away, if they were delayed, or if they did not move at all.

A further limitation was that there were a high number of dropouts from both groups over the 6 weeks. Fortunately, as mentioned previously, there was no real differential loss between groups and no significant differences in demographics between those who dropped out and those who remained in the study. Another limitation that was highlighted above was the small sample size that prevented many of the net differences that favored the text message intervention to reach statistical significance. The small sample size, paired with the specific population of university students, makes it hard to determine generalizability, thus more research should be done to look into other populations with larger samples. Finally, the study was advertised as a way to reduce sedentary behavior, and thus, participants in both groups self-selected into the trial because they were highly motivated to change this behavior. This may partially explain why larger net differences were not found between intervention and control group participants.

Conclusions

The present study provides preliminary evidence that facts, tips, reminders, and challenges delivered in the form of text messages have potential to increase nonsedentary behaviors, and in particular, light-intensity physical activity in university students. These text messages appear to enhance self-efficacious beliefs about taking more breaks and reducing overall sitting time. Self-efficacious beliefs are also associated with nonsedentary behavior (ie, breaks from sitting) and to a lesser extent light- and moderate-intensity physical activity. An RCT that uses a larger sample size, objective measures of sedentary and nonsedentary behavior, and assesses related efficacious cognitions over a longer period of time is warranted.

Conflicts of Interest

None declared.

Multimedia Appendix 1

List of text messages.

[[PDF File \(Adobe PDF File\), 38KB - mhealth_v4i3e99_app1.pdf](#)]

Multimedia Appendix 2

CONSORT-EHEALTH checklist V1.6.2 [29].

[[PDF File \(Adobe PDF File\), 61KB - mhealth_v4i3e99_app2.pdf](#)]

Multimedia Appendix 3

Tables (Results).

[[PDF File \(Adobe PDF File\), 54KB - mhealth_v4i3e99_app3.pdf](#)]

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Abbreviations

- ANOVA:** analysis of variance
- HDL:** high-density lipoprotein
- ITT analysis:** intent-to-treat analysis
- JMIR:** Journal of Medical Internet Research
- LIPA:** light-intensity physical activity
- LOCF:** last observation carried forward
- MIPA:** moderate-intensity physical activity
- PA:** physical activity
- RCT:** randomized controlled trial
- SLIPA:** sedentary and light-intensity physical activity
- SB:** sedentary behavior

Edited by G Eysenbach; submitted 04.12.15; peer-reviewed by J Aarts, J Aarts, B Larsen; comments to author 09.03.16; revised version received 06.05.16; accepted 29.06.16; published 19.08.16.

Please cite as:

Cotten E, Prapavessis H

Increasing Nonsedentary Behaviors in University Students Using Text Messages: Randomized Controlled Trial

JMIR Mhealth Uhealth 2016;4(3):e99

URL: <http://mhealth.jmir.org/2016/3/e99/>

doi: [10.2196/mhealth.5411](https://doi.org/10.2196/mhealth.5411)

PMID: [27543317](https://pubmed.ncbi.nlm.nih.gov/27543317/)

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Original Paper

YTH StreetConnect: Development and Usability of a Mobile App for Homeless and Unstably Housed Youth

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Abstract

Background: Homeless and unstably housed (H/UH) youth are disproportionately affected by sexual health issues, including human immunodeficiency virus/sexually transmitted diseases, teen pregnancy, and dating violence, and are at a higher risk for poor mental health and underutilization of services. Research suggests that linking health care to H/UH adolescents might help improve their continuity of care, with most preferring to access health care information via the Internet. YTH StreetConnect is a dual-purpose mobile app that helps H/UH youth access health and vital services in Santa Clara County, CA, USA. We developed YTH StreetConnect PRO in parallel with the youth app as a companion tablet app for providers who serve H/UH youth.

Objective: The objective of our study was to develop a mobile app to support H/UH youth and their providers in accessing health and vital resources, and to conduct usability and feasibility testing of the app among H/UH youth and technical consultants with local expertise in serving H/UH youth.

Methods: Formative research included a literature review on H/UH youths' mobile phone and Internet usage. In January 2015, we conducted interviews with medical and service providers of H/UH youth. Usability and feasibility testing were done with target audiences. Additionally, we conducted focus groups with youth regarding the app's youth friendliness, accessibility, and usefulness.

Results: H/UH youth and their providers noted the app's functionality, youth friendliness, and resources. Usability testing proposed improvements to the app, including visual updates to the user interface, map icons, new underrepresented resource categories, and the addition of a peer rating system. Limitations included a small sample size among H/UH youth and providers and a single site for the study (Santa Clara County, CA), making the findings ungeneralizable to the US population.

Conclusions: YTH StreetConnect is a promising way to increase service utilization, provide referral access, and share resources among H/UH youth and providers. Input from H/UH youth and providers offers insights on how to improve future models of YTH StreetConnect and similar programs that assist H/UH youth.

(*JMIR Mhealth Uhealth* 2016;4(3):e82) doi:[10.2196/mhealth.5168](https://doi.org/10.2196/mhealth.5168)

KEYWORDS

mHealth; homelessness; youth; STD; sexually transmitted diseases; mobile app

Introduction

About 733,000 to 2.8 million youth experience homelessness annually in the United States [1]. Homeless and unstably housed (H/UH) youth are disproportionately affected by sexual health issues, including human immunodeficiency virus/sexually transmitted diseases (HIV/STDs), pregnancy, and dating violence [2]. They are also at risk for poor mental health and underutilization of services [3]. Research suggests that linking care with H/UH youth services would improve continuity of care [4].

Nearly half of H/UH youth have no regular source of care [5], for reasons including fear of legal intervention, transportation problems, and disrespectful providers [6,7]. Since the Internet offers anonymity and accessible information, H/UH youth go online to circumvent these issues [8,9]. The majority of youth (62%) have cellphones and use them to access the Internet [10], with 85% of African American and 71% of white and Hispanic teens owning a smartphone [11]. Simultaneously, apps are becoming major tools for providers [12].

Apps have many capabilities, including tracking health status and collecting data. Apps also help with scheduling and patient interaction with providers [13]. Electronic case management has been proven to reach H/UH youth, leading to long-term care and improved health [14-16].

Accessing vital services (eg, shelter, food) is an important issue that H/UH youth face. Because health services are using technology and H/UH youth are using mobile phones and smartphones (see the app Sheltr as an example [17]), we have an opportunity to bridge this gap and increase service utilization.

With the goal of connecting H/UH youth to resources, this project sought to (1) develop an app for H/UH youth (mobile phone) and providers (tablet) in Santa Clara County, CA, USA,

(2) test app usability among potential users, and (3) assess the app’s feasibility among potential users.

Methods

Over 6 months (October 2014 to March 2015), YTH (Oakland, CA, USA) developed and tested the app YTH StreetConnect for Android and iOS mobile operating systems: StreetConnect for H/UH youth and StreetConnect PRO for providers. The project was funded by a US Centers for Disease Control and Prevention Small Business and Innovations Research grant. Phase 1 assessed the app landscape by viewing available apps and conducting expert interviews for insight on phone and tablet usage. After app development, phase 2 consisted of think-aloud usability testing among H/UH youth and providers, including an H/UH youth focus group. Both phases received exemption from the Quorum independent review board (Quorum Review, Inc, Seattle, WA, USA).

Phase I: Formative Research and App Development

We searched the literature on H/UH mHealth programs on the databases PsycINFO, ProQuest, and EBSCO. Research terms were “H/UH youth,” “mHealth,” “mobile,” and “SMS.” We included papers dated 2010–2016 in order to highlight current trends. We categorized each paper into type of intervention: service utilization, HIV/STDs, and resource locator. We considered these three types to be essential aspects for prototype development and used them to help garner ideas for app design, look, and functionality. We then documented apps related to health, H/UH issues, and resource locators for prototype ideas. Lastly, we conducted expert interviews with providers in Santa Clara County. Based on information gathered from formative research, university students of Santa Clara University Frugal Innovation Hub developed a prototype of YTH StreetConnect, with the features outlined in Table 1.

Table 1. YTH StreetConnect features by app type.

YTH StreetConnect mobile app (for homeless and unstably housed youth)	YTH StreetConnect PRO tablet app (for providers)
Location-based database of services	Location-based database of services
Interactive mapping	Interactive mapping
User-submitted ratings and comments	Referral function
Emergency hotlines	Emergency hotlines
Access to sexual health information	Access to best practices
Weekly text message health tips	Medical questionnaire for clients (assesses homelessness vulnerability and sexual risk)
Accessible via Wi-Fi	Accessible via Wi-Fi

Phase II: Usability Testing and App Refinement

We conducted think-aloud usability testing via the live app. Providers reviewed YTH StreetConnect PRO on a provided tablet, and H/UH youth reviewed YTH StreetConnect on a provided smartphone. We assessed the following questions and had participants use think-aloud usability methodology to openly state what they were doing, thinking, and feeling while using

YTH StreetConnect [18]. We took notes on (1) user experience, (2) feasibility, and (3) needed changes.

After usability testing, we conducted a focus group with the same H/UH youth. The focus group was audio recorded, then transcribed with pseudonyms. Transcripts were read by 2 team members and coded through an emergent coding process, in which major themes arose from the data: app usefulness,

changes needed, experience, and visuals. We considered these themes when creating the final prototype.

Participants

We recruited participants from H/UH services in the California Bay Area. We employed one H/UH youth to promote the project at shelters. Flyers were posted at shelters, at clinics, and on craigslist (San Francisco, CA, USA).

We screened potential participants via phone for eligibility. Youth eligibility criteria were age 18–25 years, reporting an H/UH situation, and being a resident of Santa Clara County. [Table 2](#) lists the youth participants' demographic characteristics. The provider eligibility criterion was providing H/UH youth services, including physicians, community center leaders, health providers, and housing directors. Youth participants received a US \$100 gift card for the Safeway food retailer (US \$50 for usability testing, US \$50 for participating in a focus group) and providers received a US \$50 gift card for participation.

Table 2. Demographic characteristics of homeless and unstably housed youth (H/UH) participants testing the YTH StreetConnect app.

Characteristics	No.
Sex	
Female	3
Male	3
Race/ethnicity^a	
African American	4
Hispanic	3
White	2
Sexual orientation	
Heterosexual	5
Not reported	1
Owned cellphone	6
Owned smartphone	5
Currently H/UH	6

^aRace/ethnicity numbers are higher than 6 because some participants selected each race/ethnicity that applied.

Results

Youth Insights

User Experience

Overall, YTH StreetConnect was well received by H/UH youth. Youth said YTH StreetConnect was intuitive, fun, and easy to use. The phone icon allowed them to easily click and call services. They considered the map to be essential. Overall, participants thought YTH StreetConnect was a good blend of current social media and app functions:

[YTH StreetConnect] is like Google and Yelp combined...I can find what I need here really easily.

Feasibility

Users thought YTH StreetConnect would be helpful for H/UH youth. It was noted for its one-stop shop functions, which made it easy to access multiple resources. In addition, youth reported a high likelihood that they and other H/UH youth would use YTH StreetConnect:

The whole app overall, it's going to be helpful. It will help a lot of young people.

Needed Changes

Participants suggested some changes, including combining the "Zip Code" and "Current Location" in one tab; adding a "home" button on all screens; and using icons to represent services. Youth said YTH StreetConnect should focus on common services (food, shelter, showers, and laundry) and that service information should be provided above map locations so that all information would be visible within a single screen.

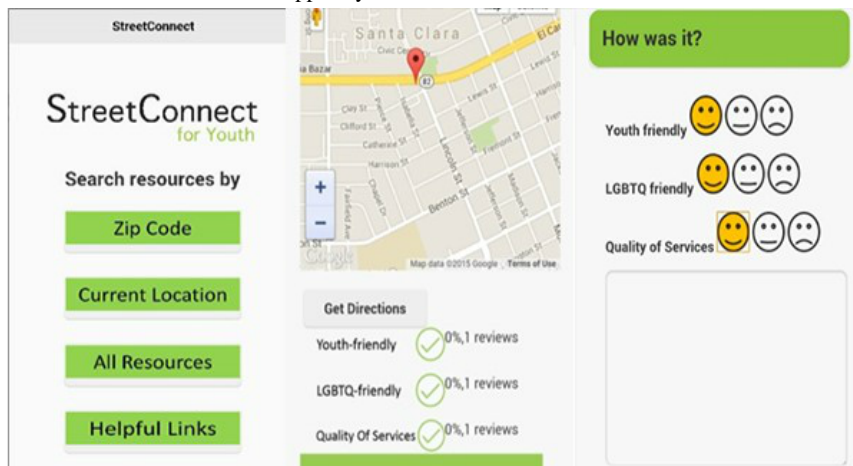
Youth wanted other services listed, including transportation, financial and legal assistance, education, substance abuse help, food banks, and family and childcare services. These services are important to H/UH youth:

Nine times out of ten, if you're homeless you're probably not gonna be driving, probably gonna be on the bus...so like, you should have public transport [on YTH StreetConnect], like what bus is gonna get me there.

Participants also wanted a forum-based platform where they could share experiences. The forum would allow H/UH youth to inform peers about best services and providers, and to build community. Youth also desired a feature that would let them see the number of beds available at local shelters. Often, participants spent their only funds to travel to a shelter, only to discover that no beds were available.

Figure 1 shows the initial YTH StreetConnect prototype.

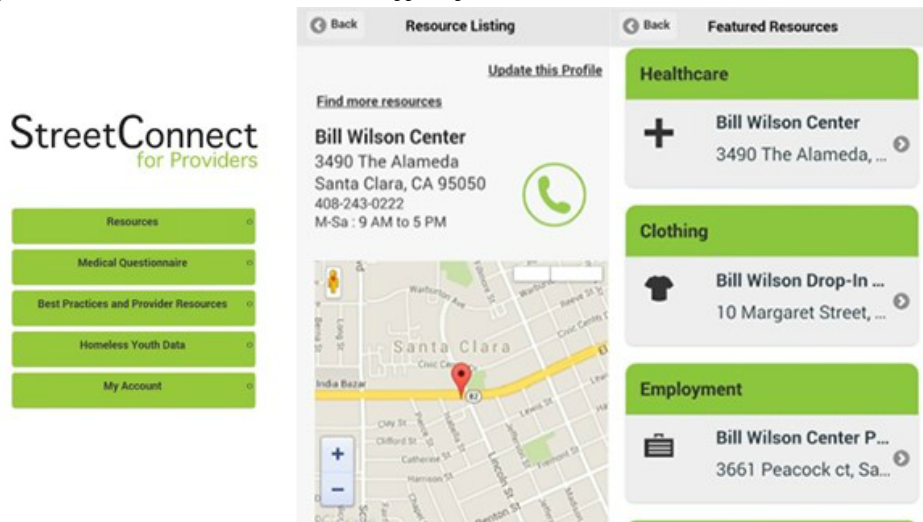
Figure 1. Initial prototype of YTH StreetConnect mobile app for youth.



Provider Insights

Figure 2 shows the initial YTH StreetConnect PRO prototype.

Figure 2. Initial prototype of the YTH StreetConnect PRO mobile app for providers.



User Experience

Providers noted the simplicity of YTH StreetConnect and appreciated the clear images and text. Providers were able to intuitively access each function of YTH StreetConnect with little difficulty:

Overall, [YTH StreetConnect] is nice, clean, and easy to read.

Feasibility

Providers stated that YTH StreetConnect would be a helpful tool when working with H/UH youth. Providers reported that the statistics and resource information functions were most useful:

Resources is pretty much what I would need and use, and they're definitely there.

Needed Changes

Providers said the medical questionnaire would provide important information and statistics on clients, but recommended to make it clear that responses would be confidential:

[The youth] will sign—but you need to tell them it's confidential. That's a must.

It was recommended that messages and referrals be sent via text. Providers said they usually give referrals to youth in person, but YTH StreetConnect simplified this exchange by bringing referrals online.

Discussion

YTH StreetConnect offers an accessible and appropriate way for H/UH youth and providers to locate services. We incorporated advice and suggested improvements from H/UH youth and providers in the final version (Figure 3).

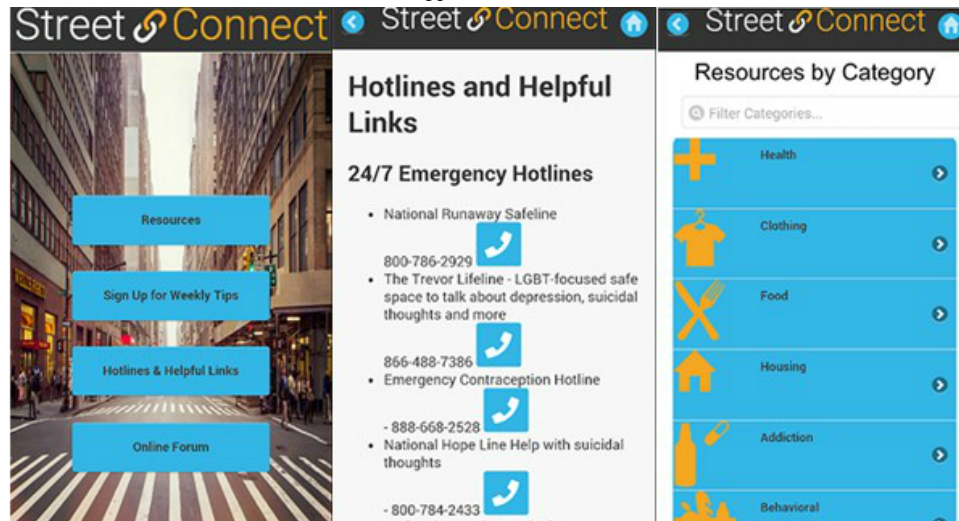
We made visual enhancements to YTH StreetConnect to make it youth friendly. Implemented changes were information and map all in one screen, a peer rating system, icons for services, and an online forum. We did not implement the ability for providers to update the number of beds, largely due to limitations in funds. In addition, this feature would require extra

labor for providers, who would need to update their bed availability on their own time.

YTH StreetConnect can give H/UH youth confidential access to resources, which is a central aspect of increasing service utilization among H/UH youth [19,20]. According to

participants, YTH StreetConnect also provides confidential access to sexual health services, a resource that H/UH youth are more likely to use if they can access it confidentially [17]. The new online referral function for providers may also help retain H/UH youth in long-term care.

Figure 3. YTH StreetConnect and YTH StreetConnect PRO final apps.



Limitations

This prototype is for a small catchment area and we cannot predict how a national database of services will function. Future work should engage with database specialists to determine the feasibility of scaling the service up to a national database. In addition, our small sample makes it difficult to capture more in-depth experiences and feedback.

Conclusions

We developed YTH StreetConnect and tested it with providers and H/UH youth. Because H/UH youth face challenges in service utilization, apps such as YTH StreetConnect may assist youth in finding and accessing services and improving continuity of care. YTH StreetConnect is a useful tool in streamlining services to H/UH youth online and can be especially useful as a supplement to in-person interactions between providers and youth. Future efforts could involve nonprofit agencies in conducting a national expansion of YTH StreetConnect and a pilot evaluation of its uptake among H/UH youth.

Acknowledgments

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

Conflicts of Interest

None declared.

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Abbreviations

HIV/STDs: human immunodeficiency virus/sexually transmitted diseases

H/UH: homeless and unstably housed

Edited by G Eysenbach; submitted 08.02.16; peer-reviewed by M Krausz, E Mangone, Y Wang; comments to author 14.04.16; revised version received 24.05.16; accepted 13.06.16; published 14.07.16.

Please cite as:

Sheoran B, Silva CL, Lykens JE, Gamedze L, Williams S, Ford JV, Habel MA

YTH StreetConnect: Development and Usability of a Mobile App for Homeless and Unstably Housed Youth

JMIR Mhealth Uhealth 2016;4(3):e82

URL: <http://mhealth.jmir.org/2016/3/e82/>

doi: [10.2196/mhealth.5168](#)

PMID: [27417882](#)

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Original Paper

“Please Don’t Send Us Spam!” A Participative, Theory-Based Methodology for Developing an mHealth Intervention

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Abstract

Background: Mobile health solutions have the potential of reducing burdens on health systems and empowering patients with important information. However, there is a lack of theory-based mHealth interventions.

Objective: The purpose of our study was to develop a participative, theory-based, mobile phone, audio messaging intervention attractive to recently circumcised men at voluntary medical male circumcision (VMMC) clinics in the Cape Town area in South Africa. We aimed to shift some of the tasks related to postoperative counselling on wound management and goal setting on safe sex. We place an emphasis on describing the full method of message generation to allow for replication.

Methods: We developed an mHealth intervention using a staggered qualitative methodology: (1) focus group discussions with 52 recently circumcised men and their partners to develop initial voice messages they felt were relevant and appropriate, (2) thematic analysis and expert consultation to select the final messages for pilot testing, and (3) cognitive interviews with 12 recent VMMC patients to judge message comprehension and rank the messages. Message content and phrasing were guided by the theory of planned behavior and the health action process approach.

Results: Patients and their partners came up with 245 messages they thought would help men during the wound-healing period. Thematic analysis revealed 42 different themes. Expert review and cognitive interviews with more patients resulted in 42 messages with a clear division in terms of needs and expectations between the initial wound-healing recovery phase (weeks 1–3) and the adjustment phase (weeks 4–6). Discussions with patients also revealed potential barriers to voice messaging, such as lack of technical knowledge of mobile phones and concerns about the invasive nature of the intervention. Patients’ own suggested messages confirmed Ajzen’s theory of planned behavior that if a health promotion intervention can build trust and be relevant to the recipient’s needs in the first contacts, then the same recipients will perceive subsequent motivational messages more favorably. The health action process approach was also a useful tool for guiding the phrasing of the messages. Participants were more positive and salutogenic than public health experts.

Conclusions: The system showed how a process of consultation can work with a set of potential recipients of an mHealth service to ensure that their needs are included. Classic behavioral theories can and should be used to design modern mHealth interventions. We also believe that patients are the best source of messaging, ensuring that messages are culturally relevant and interesting to the recipient.

(*JMIR Mhealth Uhealth* 2016;4(3):e100) doi:[10.2196/mhealth.6041](https://doi.org/10.2196/mhealth.6041)

KEYWORDS

mHealth; male circumcision; postoperative wound-healing period; health promotion; audio messaging; behaviour change

Introduction

Voluntary medical male circumcision (VMMC) has been shown to reduce the risk of male acquisition of human immunodeficiency virus (HIV) by as much as 60% [1-3]. This led the World Health Organization/Joint United Nations Programme on HIV and AIDS to endorse that male circumcision should be promoted as an additional strategy in the prevention of HIV in men [4] and subsequently to plan for scale-up of VMMC services in 13 countries in Eastern and Southern Africa with high HIV prevalence and low rates of male circumcision, including South Africa [5]. However, there have been concerns about the quality of health education provided to men who are circumcised, particularly in relation to “risk compensation,” early resumption of sex, and the potential risk to their female partners [6]. Early resumption of sex, defined as having sex before the wound has healed, usually around 6 weeks, is a particular risk of widespread rollout of VMMC. Although challenges persist, including inadequate counselling, education, and follow-up, especially for married, discordant couples [7,8], very few programs have addressed early resumption of sex. VMMC counselling to encourage men to stay sexually safe needs to be maintained throughout this wound-healing period and to take into account the real-life risk factors of the circumcised men. Many overburdened public health systems are unable to provide adequate intervention programs to assist these recently circumcised men.

Recommendations have been made for developing and evaluating optimal counselling strategies among men seeking VMMC and to assess the effectiveness of behavior change communication strategies [9]. However, lack of human resources in the VMMC scale-up countries presents a barrier to the provision of such intense services, particularly if repeated contacts and encouragement are to occur. Moving programs to the realm of self-care would alleviate this burden and provide patients with high-quality care. Evidence from Southern and Eastern Africa indicates that some men, particularly those who are married or cohabiting, initiate sexual intercourse before the wound has completely healed. Identifying culturally acceptable and effective interventions is imperative to ensure that scale-up of VMMC in Eastern and Southern Africa is not accompanied by additional sexual morbidity and mortality. Furthermore, given the human resource shortages accompanying the rollout of VMMC in Eastern and Southern Africa, innovative strategies are needed for delivering these interventions. This is particularly the case when countries turn to independent partners to carry out mass, one-off VMMC campaigns outside of the normal constellation of services [10]. Clearly, more innovative strategies for communicating with, and effectively altering behavior in, men and their partners are needed. Further, given evidence of greater risk for early resumption of sexual activity in married or cohabiting men, strategies for navigating the postoperative period through, for example, nonpenetrative sexual activity should be developed and included in such education.

Self-care programs within the public health sector have been considered as a viable stopgap measure to address the service delivery challenges within the sector. Chronic staff shortages and budgetary constraints are common features of public health systems of most developing countries [11]. Due to these challenges, mHealth—the use of mobile phone technology to deliver health care—has emerged as an important and appreciated complement to health care education delivered through traditional channels [12]. Such technology may include the use of text messaging, video messaging, voice calling, and Internet connectivity. The potential for mHealth interventions to partially compensate for physical clinics in resource-poor areas is enormous [13].

Mobile health solutions have the potential of reducing burdens on health systems and empowering patients with important information. However, theory-based mHealth interventions are lacking, despite the fact that some theories of behavior change are well validated and tested on evidence-based interventions of prevention, diagnoses, and care [14-16]. Instead, all too often, mHealth interventions rely on the novelty of their modus operandi, as opposed to behavior change theory.

South African Context

South Africa holds the dubious title of being the country with the highest number of HIV-positive individuals—over 5 million [17]. Based on the 2010 antenatal data, it was estimated that 18.5% of women in the Western Cape presenting at antenatal services were HIV-positive, with an incidence estimate of 6.2% [18]. The national prevalence based on these data was 30.2%. Transmission of HIV in South Africa is almost exclusively through heterosexual sex, thus heightening the importance of circumcision as a form of prevention. The South African Department of Health has made a commitment to rolling out medical circumcision in all provinces as one source of protection from HIV [4]. Approximately 5 million adult men could potentially be targeted. Circumcision is provided as part of a comprehensive service at district hospitals and includes HIV testing, counselling, and HIV education before the procedure.

Mobile phone use and access in South Africa is virtually universal. Mobile phone technology has been found to be acceptable and feasible for HIV- and AIDS-related prevention and services [19], and is now used in several health-related text-reminder projects in South Africa [20].

Theoretical Frameworks Considered for the Development of Our Intervention

We found a scarcity of mHealth interventions that used change theory as the basis of the content development of the intervention. In fact, Tomlinson et al [21] maintained that nearly all mHealth intervention programs that are based on information transfer only, rather than an intervention that was designed through an iterative dynamic interaction between the system and the user, are more likely to fail at their implementation phase. Throughout the development of the intervention, we

considered several theoretical frameworks for incorporation at different points in the intervention.

The Theory of Planned Behavior

The theory of planned behavior drives many behavior change interventions in existence today [22]. This theory evolved from the theory of reasoned action, which was proposed by Fishbein together with Ajzen in 1980 [23]. We used the three principle influencing factors proposed by Ajzen [14] of attitude toward the behavior, subjective norm, and perceived behavioral control to guide message selection and focus. For example, in our messaging development, the first norm, behavioral attitude, convinced the participants of the usefulness, worth, and advantages of the proposed behavior.

Within the mHealth domain, Ajzen and Fishbein's theory of reasoned action has also influenced many modern technology acceptance models, such as Davis's technology acceptance model [24,25] and Venkatesh and colleague's unified theory of acceptance and use of technology [26]. These models replaced many of the attitude measures of the theory of reasoned action with the two technology acceptance measures, which are ease of use and usefulness.

The Action Research Approach

Jacobs and Graham [15] reviewed iterative health behavior intervention development and research methodologies and concluded that the requirements and solutions of these methodologies were evolved through collaboration between the developers and their intended target audiences. They promoted adaptive planning, and evolutionary development and delivery, and encouraged rapid and flexible response to change. This strategy minimizes the overall risk and allows a project to adapt to changes quickly [15]. It further contributes to the participants having an investment in and relating to the messages and intervention that is developed.

The Health Action Process Approach

The health action process approach (HAPA) proposes a sequence of two continuous self-regulatory processes, a goal-setting phase (motivation) and a goal-pursuit phase (volition). The goal-pursuit phase might be further subdivided into a planning phase, action phase, and maintenance phase. It is claimed that perceived self-efficacy plays a crucial role at all stages, along with other cognitions. For example, risk perceptions serve predominantly to set the stage for a contemplation process early in the motivation phase but do not extend beyond it. Similarly, outcome expectancies are chiefly important in the motivation phase when individuals balance the pros and cons of certain consequences of behaviors, but these expectancies lose their predictive power after a personal decision has been made. However, if one does not believe in one's capability to perform a desired action, one will not adopt, initiate, and maintain it [16].

Aims

To our knowledge, there are some interventions for promoting safe sex within a public health context, but none in the postoperative period after VMMC apart from sending simple text messages. Here we describe a participative, theory-based,

mobile phone, audio messaging intervention attractive to recently circumcised men at VMMC clinics in the Cape Town area in South Africa. We designed the intervention to shift some of the tasks related to postoperative counselling on wound management and goal setting on safe sex. We place the emphasis on describing the full methodology to allow for replication of the method in other health care and prevention areas.

Methods

We conducted this study as part of the formative phase of a clinic-based randomized controlled trial to evaluate the effectiveness of an automated telephone message system on reducing early resumption of penetrative sex among recent recipients of VMMC. The effectiveness of the intervention will be evaluated using a 2-armed, randomized, single-blind, controlled design, where the control group will receive the standard of care and the experimental group will receive the standard of care plus the study's voice message intervention, described below, during the 6-week recuperation period [27].

Setting

The study was conducted in catchment areas of the Heideveld Public Health Clinic and Mitchells Plain Hospital in Cape Town, in the Western Cape Province of South Africa. The study sites were chosen with the help of the provincial health department. The population demographics of these two areas are almost exclusively Coloured and Afrikaans speaking. The term Coloured refers to an official South African race group used in research and census data that is predominantly mixed ancestry. The term originated in the apartheid era but remains an important descriptor and label for a distinct community. More than 48% of the people who live in the Western Cape are classified as Coloured, mostly still living in defined communities that are at least 90% Coloured. Both areas are densely populated, with a low socioeconomic base and an average population density of 9600/km². The housing is typically 1- to 2-bedroom maisonette housing. In 2011, the population of the suburb Mitchells Plain was 310,485 and the average household size was 4.57 people per household. There is a large Muslim population (10% to 15%) in the catchment area for one of the townships [28]. The Coloured community has a growing HIV prevalence rate—7.6% according to the latest antenatal data, indicating a generalized epidemic in this population [29]. The heightened HIV risk to this population group lies in a high illicit drug and alcohol use in the community, which is associated with risky sexual behavior [30].

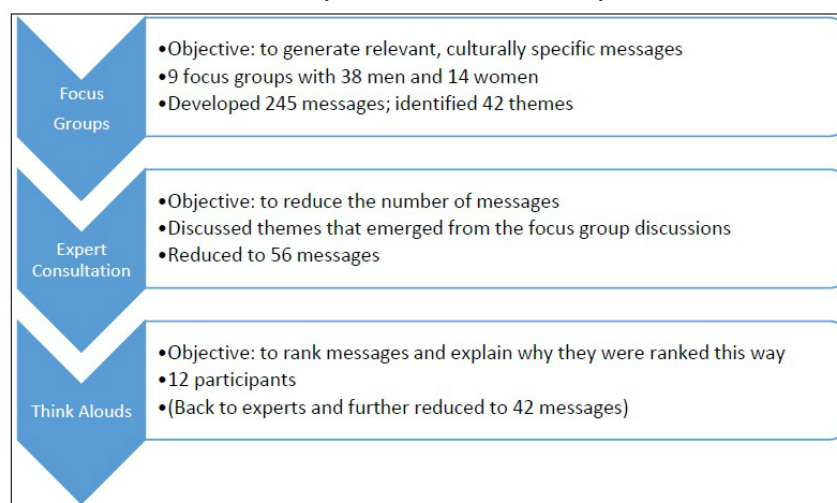
Design

We used several participative, qualitative methods to develop mHealth phone messages and their sequencing, placing the user's needs and experiences in the center. These were (1) focus group discussions with 52 recently circumcised men and their partners to develop initial messages they felt were relevant and appropriate, (2) thematic analysis and expert consultation to select final messages for pilot testing, and (3) cognitive interviews with 12 recent VMMC patients to judge message comprehension and to rank the messages (Figure 1). All

interviews were conducted in Afrikaans, tape recorded, and then transcribed and translated into English.

Message content and phrasing was guided by the theory of planned behavior and HAPA. The methods and incorporation of the theoretical frameworks are described in more detail below.

Figure 1. Steps to develop an mHealth intervention for recently circumcised men at voluntary medical male circumcision clinics in South Africa.



Focus Groups

In order to generate messages that would be considered appropriate and relevant for patients, we conducted 9 focus

groups with a total of 52 men and women (6 male and 3 female focus groups) (Table 1). The methods of recruitment, conduct, and analysis of the focus groups are explained elsewhere [31].

Table 1. The study participants of the focus groups by sex and religion.

Focus group no.	Sex	No. of participants	Age range (years)	Religion	
				Muslim	Christian
1	Male	6	19–36	4	2
2	Male	6	22–45	3	3
3	Male	6	23–63	4	2
4	Male	7	18–42	5	2
5	Male	6	20–39	4	2
6	Male	7	21–53	4	3
7	Female	4	22–41	2	2
8	Female	5	19–34	3	2
9	Female	5	25–52	3	2

In addition to providing valuable information about the perceptions and behavior patterns of couples during the wound-healing period [31], participants of these focus groups were asked to write down 5 messages they felt could have assisted them during this period. The facilitators gathered these lists before the group discussions began and the researcher captured and translated the messages. We cleaned this list and identified common themes through use of thematic analysis using Atlas.ti version 7 (Scientific Software Development GmbH). Additionally, we collected information on the general acceptability of mobile messaging, generation of appropriate and relevant messages to recipients of VMMC during their 6-week recovery period, and the acceptable frequency of mobile messages. By getting the respondents to develop the theme list, we were drawing out the relevant issues to improve motivation and reduce blocks to volition, as well as identifying key behavioral, normative, and control beliefs.

Expert Consultation

The second part of this phase was to solicit expert opinion on the internal reliability and the contextual and cultural applicability of the messages. We consulted with a health communication expert from the South African Department of Health with extensive expertise in safe sex and behavior change, and local knowledge of the population and local conditions. As a first step, we grouped the messages into themes and then deleted incorrect, duplicate, and repetitive messages. Through interrater agreement, we decided on 1 or 2 examples representing each theme. We also adjusted several messages to reflect technical correctness and missing themes such as HIV prevention messaging. This decision was guided by existing theoretical models of behavior change, including the HAPA model. The order and frequency of the messages was guided by the recommendations of the focus groups and expert opinion.

This phase is essential to ensure the accuracy of the messages and their constructive interaction with the health services.

Cognitive Interviews

The third phase of the message development was the validation phase, where we conducted cognitive interviews (“Think Alouds”) with 12 patients to rate the final selection of messages. We recruited a convenience sample of 12 recently circumcised men ages 23–39 years (mean 29.6 years) from the Heideveld and Mitchells Plain clinics to participate in this part of the study. Of these, 5 were Muslim and the rest were Christian. All were Coloured except for 2, who were foreign nationals staying in the area. We recruited men who had completed their 6-week wound-healing period during the previous month. The men were recruited from the 2 clinics’ circumcision intake registries. They were recruited via telephone, and the researcher subsequently interviewed them at convenient places in the community.

We asked the participants to evaluate and rank messages based on their appropriateness and effectiveness in the 42-day wound-healing period. The messages were put in groups of 3–6 messages for ranking purposes. Each message was read out to the participants and then tested for comprehension, such as having the participants repeat the message in their own words. We then probed for the participants’ perception of the aim of each message.

Following each section, we asked participants to reflect on the time period in the 42-day period for which we had designed this group of messages. They were then asked to rank the messages in the group for appropriateness and clarity. Following the ranking exercise, we asked participants, using a think-aloud method, to reflect on message grouping and whether there were any messages missing that could have made a difference, on whether there were any unnecessary and inappropriate messages, and on the reasons why they ranked the group in a particular way. This refined the contributions from step 1, improving the messages in terms of both the theory of reasoned action and HAPA.

Results

Step 1: Generation of Messages and Key Information on the Messaging

We had two goals for this stage: the first one was to get an unprompted set of messages from the recently circumcised men and their partners. We ended up with 245 messages the participants felt would have had an impact on their behavior and attitudes during the 42-day postoperative wound-healing period. The second aim was to solicit group responses to questions around frequency, nature, and order of the messages.

Focus group participants’ suggested messages covered 30 different themes. Some examples were wound and pain management, the roles of rest and family support, erection issues, how to stay healthy, when to resume sex, alcohol use, affirmation, sexual needs of partners, and condom use. Themes could be further grouped into phases and practical versus motivational messages. The latter aspects are described more fully below, since they have an impact on how the intervention

was later designed. The selection of messages covered the dominant areas of the HAPA theory—that is, planning and its components of self-efficacy, goal setting, and action.

The 2-Phase Approach

Participants in all focus groups repeatedly stressed that the 42-day period following the circumcision surgical procedure is roughly divided into a wound and pain management period (the first 3 weeks) followed by the adjustment period. The first phase is characterized by practical issues such as wound and pain management, while the second phase is dominated by motivational and planning issues. Examples of comments from the focus groups are

[First phase:] I think for the first period, it should be about pain management and how to take care of oneself. [Male, Muslim, 27 years]

[Second phase:] Later, anything to encourage me to stay safe would be nice. [Male, Christian, 32 years]

Examples of participants’ suggested messages in the 2 different phases are

[First phase:] Rest and don’t do anything strenuous in the first week. [Female, Muslim, 21 years]

[Second phase:] You did something great. Be proud of yourself. [Male, Muslim, 51 years]

Practical Versus Motivational Messaging

Participants also clearly distinguished between 2 different types of messages—practical and motivational—which are also associated with the 2 phases. Thus, *in the first phase*, practical messages are linked to coping themes such as inactivity and rest, wound healing, role of the clinic, and support mechanisms:

[Inactivity and rest:] Rest! This will help with the wound healing. [Male, Christian, 24 years]

[Wound healing:] Don’t mess around with the wound. No home remedies!! [Male, Muslim, 32 years]

[Role of the clinic and medication:] If there’s any problem down there, go to the clinic to fix it. [Female, Muslim, 28 years]

[Support mechanisms:] Are you having a difficult time? Talk to someone you love. They will understand. [Male, Christian, 35 years]

Motivational messages, however, which were associated with *the second phase*, were closely linked to themes of safe living, the needs of the partner, and goal setting:

[Safe living:] I think the messages should be about safe living and making sure you take responsibility for your actions. [Male, Christian, 45 years]

[Needs of partner:] Take your time when you are pleasing your partner. [Female, Muslim, 30 years]

[Goal setting:] No sex or masturbation for six weeks! [Male, Muslim, 21 years]; Want to be healthy? Look after yourself. [Male, Christian, 47 years]

Salutogenic Nature of the Messages

An interesting aspect of the focus groups was the emphasis on positive and inspirational messages as opposed to messages that emphasized disease and negative consequences:

I would like some inspirational messages. [Male, Christian, 54 years]

Start every day with a good attitude. [Female, Muslim, 24 years]

Be proud of yourself. You did it! [Male, Muslim, 30 years]

Thus, the majority of the messages that former patients and their partners suggested were positive and assertive.

Frequency of Messages

In addition to providing message content, participants were asked about their opinions on how often messages could be sent to them.

Participants were wary of unsolicited and invasive messages:

If they get too many messages, even if they are good, people won't listen. [Male, Muslim, 43 years]

This (the frequency of the messages) is very difficult to calculate. I don't think you want to turn this into spam. [Female, Muslim, 25 years]

The groups were asked of ways to counter this natural resistance to “push” messaging campaigns. The first strategy given was prior consent:

I guess if I sign up for it and expect it, then it should be okay. [Male, Muslim, 20 years]

The other strategy was a clear end-date of the program:

I don't think men would mind getting messages because they know it's only for a certain period. [Male, Christian, 31 years]

Step 2: Expert Consultation

In consultation with a health communication expert from the South African Department of Health, we reduced 245 messages to 56. This reduction was done by removing identical or similarly structured messages, and amalgamating messages of a similar theme under one exemplar. An example of this was that the messages “Have lots of rest. It will help with your recovery,” “Rest and sleep. This will help with the recovery,” “Sleep a lot. It will help with the healing,” and “Resting will help with the wound healing” were amalgamated into “Rest! This will help with the wound healing.” We made these decisions based on extensive local knowledge of the population and local conditions, and safe sex and behavior change. [Table 2](#) shows the full set of resultant themes by phase once all the messages were combined into a reduced set of thematic constructs, while remaining responsive to the community's felt needs. One message is provided for each theme as an example.

Table 2. Themes and example messages by phase after voluntary medical male circumcision resulting from expert consultation.

Phase ^a	Themes	Examples of messages
1	Inactivity and rest	<i>Rest! This will help with the wound healing.</i>
1	Role of the clinic; wound management	<i>Go back to the clinic after two and seven days so the dressing can be replaced and the wound can be checked.</i>
1	Wound management; hygiene	<i>Use lukewarm water to wash the wound every day. Keep the dressing dry.</i>
1	Wound management; erection issues	<i>Check for any skin tightness when you get an erection.</i>
1	Role of the clinic; wound management	<i>If there is pus coming out of the wound, go to the clinic.</i>
1	Pain management; medication	<i>Don't be brave! Take pain tablets to relieve the pain.</i>
1	Wound management; partner and family support	<i>Are you having a difficult time? Talk to someone you love. They will understand.</i>
2	Self-efficacy and affirmation; goal setting	<i>Want to be healthy? Look after yourself.</i>
2	Self-efficacy and affirmation	<i>You can do it!</i>
2	Partner and family support	<i>Make sure you talk to your partner.</i>
2	Self-efficacy and affirmation; motivation	<i>Did you look after your penis today?</i>
2	Goal setting; healthy living	<i>Regular exercise and healthy diet are essential.</i>
2	Wound management; erection issues	<i>Get rid of that painful erection by urinating frequently.</i>
2	Early resumption of sex	<i>Having sex too early will just set you back!</i>
2	Early resumption of sex; alcohol consumption	<i>Be aware of alcohol. It impedes your judgement.</i>
2	Safe living; condom use	<i>Remember that circumcision does not provide 100% protection.</i>
2	Motivation; goal setting	<i>No sex or masturbation for six weeks!</i>
2	Nonpenetrative sex; sexual needs of partner	<i>Find ways to please your partner without using your penis.</i>
2	Nonpenetrative sex	<i>Loving is not about sex only!</i>
2	Self-efficacy and affirmation; motivation	<i>You are the best!</i>
2	Motivation; goal setting	<i>Regular condom use, knowing your HIV^b status, and keeping to one partner is the recipe for an HIV-free future.</i>

^aPhase 1: recovery phase; phase 2: adjustment phase.

^bHIV: human immunodeficiency virus.

Step 3: Cognitive Interviews

Think-aloud participants engaged intimately with the messages and generally confirmed the set of themes proposed by the previous step. Their interaction with the messages originated from their own experiences during the wound-healing period and confirmed the elements of motivation and volition as proposed by the HAPA model. Although we previously divided the 6-week period into the initial wound-healing recovery phase during weeks 1 to 3 and the adjustment phase from weeks 4 to 6, we now separated the 6-week period into three 2-week periods for ease of discussion. Some of the comments and recommendations made on each 2-week period of the 42-day recovery period follow.

Messages for Weeks 1 and 2

This period was dominated by pain and wound management themes, as the participants ranked messages such as “Rest! This will help with the wound healing” and “Do not pull or scratch the wound while it is healing” the highest in their groupings. Toward the end of this period, the patient’s support structure was also given priority: “Are you having a difficult time? Talk to someone you love. They will understand.” The group also

recommended that the frequency of phone messages to patients should be twice a day at the beginning of the period, tapering to once a day after the first 2 days, to provide additional support for the days following the operation.

Messages that scored the lowest among the participants were those that the group found impractical, such as “Check for any skin tightness when you get an erection.” In essence, expert opinion dictates that this is an important first visual check of whether the stitching is not impeding or pulling the skin during erections, and that it should be done as early as possible so any corrective surgery can be done before the wound area heals completely. Participants found this expert-inserted message problematic because, during the preoperative wound-care talk, strong emphasis was placed on the danger of prolonged erection and the tearing of the stitches. Further, patients were instructed how to get rid of erections as soon as they could. Patients found their first erection too stressful to pay proper heed to the message’s instruction. Another message that scored very low during this period was the inspirational message “You can do it.” Participants generally liked the intent of the message but felt that it should come later, and they were more interested in practical advice on how to get through this period.

Messages for Weeks 3 and 4

The messages in this period reflect the changing priorities of the patient. The wound is practically healed and the patient is going through a period of how to adjust to this new feature, not only sexually, but also aesthetically and the way it feels. Messages with recovery themes, such as “Involve your partner in your recovery period” and “Get rid of that painful erection by urinating frequently,” still scored high, but messages such as “Regular exercise and healthy diet are essential,” reflecting adjustment themes, also received high rankings. Expert-driven messages, once again, scored low. Messages such as “If you have sex before the wound is properly healed, there is a greater chance of contracting STIs [sexually transmitted infections] or HIV” were looked at as too academic and preachy. Motivational messages that were too generic, such as “You did it!,” were scored lower than more practically orientated motivational messages such as “Think about what you are going to do before you do it.” Messages on avoiding penetrative sex were also well received during this period.

Messages for Weeks 5 and 6

The high-scoring messages in this period revolved around alternative sexual activity, such as “Loving is not about sex only!” and “Take your time when you are pleasing your partner;” validation, such as “You lost the skin! Can you feel the difference?;” and looking-ahead messages, such as “You are planning for your future.” Low-scoring messages, as in the previous period, were those expert-adjusted messages that were perceived as artificially instructive, such as “Regular condom use, knowing your HIV status, and keeping to one partner is the recipe for an HIV-free future.”

Discussion

We developed a formative research process to develop theory-driven and contextually based mHealth messages to provide additional counselling and support to recently circumcised men during their wound-healing period. We employed a process where the targeted group created the initial messages and then the targeted group, researchers, and communication and health experts collaboratively refined and optimized the message regime for the intended period.

This study’s findings suggest that phone messages should be relevant, positive, simple, few in number, and designed to be contextually appropriate for the intended audience. In order to inform and motivate these men, messages must address the reality of the experiences the men are facing throughout the 6-week period. One method is to directly engage men and their partners in iterative discussions about message design and delivery, and involve them in the development of messages so that messages are relevant and meaningful for the recipients.

A few studies have explored the construction and development of health messages delivered through a mobile device using a multiphased approach with a strong target group participation. Ybarra et al [32], in their aim to develop an mHealth HIV prevention program for adolescent gay, bisexual, and queer men, took the message development through 5 iterations with target audiences contacted in the first phase to test acceptability

of the messages and during the last phase with beta testing. They found, as in our study, that the men preferred positive and friendly content that, at the same time, did not try to sound like a peer [32]. Similarly, Woolford and colleagues [33] explored obese adolescent participants’ perspectives related to weight management messages, and they found enthusiasm for short message service text messages as a strategy to support weight loss efforts among these participants. Importantly, the findings from their study also support our study in that teen participants desired brief, positive, encouraging messages that had a “natural” tone and made specific reference to the teen demographic [33]. Another mHealth weight management program conducted by Hingle and colleagues in 2013 using a multistage youth-participatory approach found similar results [34]. The main difference between our study and the ones mentioned above is that the source of the messages in our study was the target audience and not researchers and experts.

A few studies have used behavioral change theory in the development of messages. Hingle et al [34] developed an mHealth intervention to influence the knowledge, attitudes, and behavior of adolescents on nutrition and physical activity. They used a 3-phased youth-participatory approach to develop and test messages. The first phase was content identification and initial message development, the second was message testing and refinement, and the last phase was pilot testing of a message delivery protocol [34]. Other studies by Bock et al [35] and Ybarra et al [32] also concluded that partnering with the target population in the message development is critical to ensure that a salient final product and feasible protocol are created. The pathologic versus the salutogenic nature of the messages has also been shown as a factor in the rate of acceptance of the mHealth interventions [36,37].

Our study used a participatory approach on two levels to take the needs and views of the target population into account in the development of the messages and the frequency of messages. The first level was on the generation of the messages, which was initiated by the target audience, followed by the reflection of expert opinion on these messages. The next iteration, with a cleaner and more theme-centered set of messages, was evaluated by a group of recently circumcised men for relevance and impact.

This approach recommended the development of a progression of the messages. The formative focus groups told us that the period of 42 days following the VMMC procedure is a series of progressive phases, from the purely physical pain and wound management in the early phase of healing, then to that of adjustment, to how their circumcised penis was looking and feeling, followed by an external adjustment to physical movement and sex drive. The content of the messages needed to reflect this continuous movement through the 42 days. So from more practical messages centered on pain and wound management, messages moved to more inspirational and “planning-ahead” messages.

In this study, we found that applying this theoretically informed approach carefully resulted in message content that was consistent across different recuperation phases. We identified certain key themes that we felt would be useful in the design

of mHealth messaging content, as they may facilitate men's healing rates and perceived self-efficacy to attend the clinic and other healing strategies, reduce or minimize potential fears, and provide an impetus for self-care. These included maximizing content relevancy in messaging, encouraging and validating the patient, and providing content that suggested that immediate support structures such as the man's partner, family, or the health care workers were role players in their own recuperation.

It emerged that using the content suggestions of circumcised patients as the genesis of the program's message development could help build on men's already intuitive sense of healing strategies, their knowledge of the benefits of following clear recuperation methods, and what was acceptable to them. This mix of experience and the knowledge of the benefit of adhering to the healing regimen can be leveraged to get men back to the clinic at their appointed schedule and follow the recommended healing program, with the mobile messages functioning as cues to action.

There was an interesting dichotomy in the messages that experts considered as essential messaging for circumcised men in their wound-healing period, such as countering the perception that circumcision replaces condom use; or standard HIV prevention messages, with the circumcised men's perceptions of what essential messages were. The expert messages scored consistently low in desirability or impact. It could be that the applicability aspect was low because most of the participants sought out the procedure for reasons other than HIV prevention, or it could be that there is an oversaturation of these messages and the low scores merely reflect a natural irritation caused by these "academic" messages. Related to this is the participants' strongly held consensus that salutogenic and caring messages would provide a stimulus to trigger men to take the necessary action to heal properly and refrain from penetrative sexual encounters. The salutogenic model is useful for all fields of health care, especially in the field of health promotion, as it provides a direction and focus, allowing the program to move away from disease and risk factors and to focus on the salutary and seeing the entire person in relation to the disease [36].

Implications for Research and Practice

This study demonstrates a novel way in which to engage men in conversations about health using a familiar and ubiquitous communication method. Rather than being passive recipients of top-down, expert-driven communications, participants in this study had the opportunity to actively participate in the message design process and engage with health information through informal interactions with experts and with one another, thereby increasing the likelihood that they would adopt the recommended behaviors. Based on our findings, this methodological approach to the development of theory-driven, evidence-based, and culturally appropriate health messages in mobile health interventions could be adapted to other cultural and geographic environments and various health issues. This approach can be used as a model to test and adapt health messages in a variety of mobile health intervention projects within a variety of cultural contexts. It can also be applied to health communication message development more generally.

Additional research is needed to determine whether this approach facilitates technology-based interventions to be an effective, sustainable way to promote healthy lifestyles to circumcised men and have a significant impact on behaviors that place men at increased risk. These messages are being evaluated in a randomized controlled trial among approximately 1200 men in 7 VMMC clinics in Cape Town, South Africa.

Conclusion

mHealth has the potential to provide a valuable health care service in the context of providing an expanded VMMC in resource-restricted circumstances. To provide this service, we argue that the intervention platform, the message content, and the delivery timing have to be responsive to the felt needs of the respondents, as well as providing good factual information. As with other interventions, mHealth also needs to use established behavioral theories to develop and construct interventions and messages.

Acknowledgments

We would like to extend our gratitude to the Strategy and Health Support Unit and the HIV and AIDS/STI/TB (HAST) Program of the Department of Health in the Western Cape for their support for the project.

Conflicts of Interest

None declared.

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Abbreviations

HAPA: health action process approach

HIV: human immunodeficiency virus

VMMC: voluntary medical male circumcision

Edited by G Eysenbach; submitted 30.05.16; peer-reviewed by PH Lin, J Apolinário-Hagen; comments to author 23.06.16; revised version received 17.07.16; accepted 31.07.16; published 17.08.16.

Please cite as:

Toefy Y, Skinner D, Thomsen S

"Please Don't Send Us Spam!" A Participative, Theory-Based Methodology for Developing an mHealth Intervention

JMIR Mhealth Uhealth 2016;4(3):e100

URL: <http://mhealth.jmir.org/2016/3/e100/>

doi: [10.2196/mhealth.6041](https://doi.org/10.2196/mhealth.6041)

PMID: [27535589](https://pubmed.ncbi.nlm.nih.gov/27535589/)

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Original Paper

Popular Nutrition-Related Mobile Apps: A Feature Assessment

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Abstract

Background: A key challenge in human nutrition is the assessment of usual food intake. This is of particular interest given recent proposals of eHealth personalized interventions. The adoption of mobile phones has created an opportunity for assessing and improving nutrient intake as they can be used for digitalizing dietary assessments and providing feedback. In the last few years, hundreds of nutrition-related mobile apps have been launched and installed by millions of users.

Objective: This study aims to analyze the main features of the most popular nutrition apps and to compare their strategies and technologies for dietary assessment and user feedback.

Methods: Apps were selected from the two largest online stores of the most popular mobile operating systems—the Google Play Store for Android and the iTunes App Store for iOS—based on popularity as measured by the number of installs and reviews. The keywords used in the search were as follows: calorie(s), diet, diet tracker, dietician, dietitian, eating, fit, fitness, food, food diary, food tracker, health, lose weight, nutrition, nutritionist, weight, weight loss, weight management, weight watcher, and ww calculator. The inclusion criteria were as follows: English language, minimum number of installs (1 million for Google Play Store) or reviews (7500 for iTunes App Store), relation to nutrition (ie, diet monitoring or recommendation), and independence from any device (eg, wearable) or subscription.

Results: A total of 13 apps were classified as popular for inclusion in the analysis. Nine apps offered prospective recording of food intake using a food diary feature. Food selection was available via text search or barcode scanner technologies. Portion size selection was only textual (ie, without images or icons). All nine of these apps were also capable of collecting physical activity (PA) information using self-report, the global positioning system (GPS), or wearable integrations. Their outputs focused predominantly on energy balance between dietary intake and PA. None of these nine apps offered features directly related to diet plans and motivational coaching. In contrast, the remaining four of the 13 apps focused on these opportunities, but without food diaries. One app—FatSecret—also had an innovative feature for connecting users with health professionals, and another—S Health—provided a nutrient balance score.

Conclusions: The high number of installs indicates that there is a clear interest and opportunity for diet monitoring and recommendation using mobile apps. All the apps collecting dietary intake used the same nutrition assessment method (ie, food diary record) and technologies for data input (ie, text search and barcode scanner). Emerging technologies, such as image recognition, natural language processing, and artificial intelligence, were not identified. None of the apps had a decision engine capable of providing personalized diet advice.

(*JMIR Mhealth Uhealth* 2016;4(3):e85) doi:[10.2196/mhealth.5846](https://doi.org/10.2196/mhealth.5846)

KEYWORDS

nutrition apps; diet apps; food diary; nutritional assessment; mHealth; eHealth; mobile phone; mobile technology

Introduction

Noncommunicable diseases such as diabetes and cardiovascular diseases account for almost two-thirds of deaths globally. The general recommendations for addressing this epidemic are related to lifestyle changes, mainly encouraging healthy diets, physical activity (PA), and the reduction of tobacco use and alcohol consumption [1].

Valid dietary intake recording is key for nutritional intervention. The methods used for collecting food intake data can be classified in a number of ways. Based on the time of the collection, the retrospective methods, such as the 24-hour food recall and the food frequency questionnaire (FFQ), require memory for recollection of foods eaten. In contrast, the prospective methods require diet reporting as the consumption occurs, acting as food diaries. In clinical nutrition, prospective methods are usually applied between 4 and 7 days. It is also possible to classify the methods as quantitative daily consumption or food frequencies. The first group focuses on recording the detailed food consumption as accurately as possible, typically for a couple of days. The latter assesses typical consumption patterns over longer periods [2]. These methods have been delivered traditionally using a paper-and-pen format, but there is a burden associated with this system for both the patients and health professionals. The digitalization of food diaries saves time and resources and is preferred by patients [3].

With the proliferation of mobile phones and tablets, there has been a rise in the number of software apps aimed at improving nutrition and physical fitness. The simple digitalization of input data is important and useful, but these devices have built-in capabilities that can increase the accuracy of data collection and decrease the time burden of the process and possible biases [4]. The most common example is the use of the global positioning system (GPS) for measuring PA [5]. Cameras can be used for image recognition in order to recognize foods and estimate portion sizes [6,7]. In relation to the use of technology to encourage behavior changes, there are studies and available diet apps that combine health behavior theories and persuasive technology [8]. This topic is particularly important because one of the main goals of nutrition intervention is to modify unhealthy habits.

Due to the large number of nutrition-related apps, it is difficult to understand what these apps are offering and how the apps compare with each other. This study aims to review the main features and technologies used by popular nutrition-related apps available in the online market and to analyze their use of emerging technologies in the field of online nutrition assessment and intervention. This review will be beneficial for industry, academia, and health professionals who are interested in taking advantage of the benefits of technology in nutrition assessment and intervention.

Methods

During the publication of a mobile app, a developer specifies in which stores—usually divided by countries—the app will be

available. They also specify what device requirements (eg, versions of the operating system and mobile phone or tablet) are necessary in order to install the app. Searching for apps from a specific device in a particular country can alter the apps that appear available to the user. In order to mitigate this, the initial search was conducted on a desktop personal computer (PC) not logged into any particular user account, but located in the United Kingdom. Searches were conducted in November 2015.

For the Google Play Store, the initial search was executed using the Google Chrome browser in an incognito window (ie, private mode), logged off from the Google account, using the following keywords: calorie(s), diet, diet tracker, dietician, dietitian, eating, fit, fitness, food, food diary, food tracker, health, lose weight, nutrition, nutritionist, weight, weight loss, weight management, weight watcher, and ww calculator. An initial list of popular apps, ordered by number of installs and reviews, was created. For the iTunes App Store, the initial search was performed via iTunes—software provided by Apple—logged off from any user account. The apps were ordered by number of reviews because the App Store does not list the number of installs. The user rating was used as an exclusion criterion. The rating range is between 0 and 5 and represents the user satisfaction with the app, with 5 being the most satisfied. Apps were excluded if ratings were below 3, in order to avoid considering apps that were downloaded by many users but may not be in use (eg, because they were not working properly or did not deliver what was advertised in the store). Apps which only monitored weight or PA, such as Google Fit, or that only provided recipes were also not considered. After the creation of an initial list of apps, user accounts linked with a UK address and credit card were used to install the apps and verify the apps against the inclusion criteria.

Once the apps were installed, their features were reviewed from both nutritional and technological perspectives. From the nutritional perspective, features in the following categories were considered: dietary intake, phenotype, physical activity, and others. The technological perspective analyzed what technologies were being used in order to compare with emerging technologies in the field of human nutrition assessment and intervention. The functionalities were analyzed in two main groups: input and output features. Features that required data from the user (eg, weight and height) were considered as input features, while the results shown to the user were termed output features.

Results

App Selection

In the Google Play Store, it is not possible to sort the results by number of installs. It has an internal algorithm that classifies the relevance of the apps and presents them in a list. For this reason, it was necessary to open the first 20 results by keyword to get the number of installs in order to mitigate the risk of missing an app with a high number of installs. The app list created in this process was ordered by number of installs and a total of 21 apps with greater than 500,000 installs were identified (see Table 1). To further reduce the number of apps for

inclusion—for practical reasons and readability of results—apps with less than 1 million installs were excluded.

Table 1. Popular (>500,000 installs) nutrition-related apps available in the UK Google Play Store.

App name ^a	Abbreviation	Installs (range), n	Reviews, n	Rating (0-5)
S Health-Fitness Diet Tracker	SH	100m-500m	33,619	3.7
Calorie Counter-MyFitnessPal	MFP	10m-50m	1,140,897	4.6
Calorie Counter by FatSecret	FS	10m-50m	178,438	4.3
Noom Coach: Weight Loss Plan	NC	10m-50m	161,237	4.3
My Diet Coach-Weight Loss ^b	MDC	5m-10m	102,318	4.3
Lose it! by FitNow Inc	LI	5m-10m	45,391	4.4
Weight Watchers Mobile ^c	WW	1m-5m	66,897	3.9
Lose Weight Without Dieting	LW	1m-5m	56,617	4.6
Lifesum-The Health Movement	LS	1m-5m	46,856	4.2
Diet Point-Weight Loss by Diet Point ^d	DP	1m-5m	28,906	4.2
My Diet Diary Calorie Counter	MDD	1m-5m	17,711	4.1
Effective Weight Loss Guide ^d	EWL	1m-5m	16,156	4.1
Diet Assistant-Weight Loss ^d	DA	1m-5m	10,722	3.9
Calorie Counter by Calorie Count	CC	1m-5m	7529	4.0
MyNetDiary Calorie Counter PRO ^e	N/A ^f	500,000-1m	10,405	4.4
Weight Watchers Mobile UK ^e	N/A	500,000-1m	9896	3.7
Calorie Counter & Diet Tracker ^e	N/A	500,000-1m	9306	4.3
WWDiary by Canofsleep ^e	N/A	500,000-1m	8564	4.6
Calorie, Carb & Fat Counter ^e	N/A	500,000-1m	7923	4.3
Diet Plan-Weight loss 7 days ^e	N/A	500,000-1m	5013	3.8
Calculator & Tracker for WWPP ^e	N/A	500,000-1m	1898	3.8

^aResults from November 2015.

^bMy Diet Coach provides some diet recommendations in the free version. The food diary is available only in the *Pro* version, which was not considered one of the most popular apps in this study.

^cThis app was later excluded due to subscription.

^dDiet Point, Effective Weight Loss, and Diet Assistant are not food diaries, but they provide diet recommendations via diet plans.

^eThese apps were later excluded due to minimum threshold.

^fN/A: not applicable.

All of the apps were in the “health & fitness” category of the store. No app was excluded by the rating criterion (ie, rating <3). However, although the Weight Watchers (WW) app is free to download, a subscription—£12.95 monthly for the online

plan—was required to join the online program [9] and thus it was excluded from subsequent analysis.

The same search keywords were used in the iTunes App Store (see Table 2).

Table 2. Nutrition-related apps available in the UK iTunes App Store, ordered by number of reviews.

App name ^a	Abbreviation	Reviews, n	Rating (0-5)
Calorie Counter and Diet Tracker by MyFitnessPal	MFP	108,072	4+
Calorie/KJ Counter and Food Diary by MyNetDiary	N/A ^b	6484	3.5
Calorie/KJ Counter PRO by MyNetDiary	N/A	3818	4+
Lifesum-Healthier living, better eating	N/A	2952	3.5
Tap and Track-Calorie Counter	N/A	2317	3.5
Easy Weight Loss Tips, by Michael Quach ^c	N/A	2286	2.5
Calorie Counter and Diet Tracker by Calorie Count	N/A	1716	4
Calorie Counter+ by Nutratch	N/A	1501	4+
Argus-Calorie Counter and Activity Tracker	N/A	1291	4
Calorie Counter by FatSecret	N/A	1048	3.5

^aResults from November 2015.

^bN/A: not applicable.

^cThis app was not included in the analysis due to a rating of less than 3.

One app did not meet the rating criterion—Easy Weight Loss Tips, by Michael Quach, rating 2.5—and was, therefore, excluded. The most reviewed app—Calorie Counter and Diet Tracker by MyFitnessPal (MFP), with 108,072 reviews—had around 17 times more reviews than the second-most reviewed app, which had 6484 reviews. As the latter had fewer reviews than the least popular of the apps included from the Google Play Store—Calorie Counter by Calorie Count (CC), with 7529 reviews—only MFP was considered suitable for inclusion in

the study. However, since MFP had already been included from the Google Play Store list and because an initial assessment of both the Google Play Store and iTunes App Store versions of the app did not reveal any notable differences, only the Google Play Store version was used in subsequent analysis.

Input Features

Input features were analyzed for four categories of recording: dietary intake, phenotype, PA, and others (eg, personal reminders) (see [Tables 3](#) and [4](#)).

Table 3. Nutrition-related app input features for dietary intake and phenotype.

Feature/app	SH ^a	MFP ^b	FS ^c	NC ^d	LI ^e	LW ^f	LS ^g	MDD ^h	CC ⁱ	MDC ^j	DP ^k	EWL ^{l,m}	DA ^{n,o}
Dietary intake													
Text search	✓	✓	✓	✓	✓	✓	✓	✓	✓	N/A ^p	N/A	N/A	N/A
Barcode scanner		✓	✓	✓	✓		✓	✓	✓	N/A	N/A	N/A	N/A
Serving size	✓	✓	✓	✓	✓	✓	✓	✓	✓	N/A	N/A	N/A	N/A
Food by meal	✓	✓	✓	✓	✓	✓	✓	✓	✓	N/A	N/A	N/A	N/A
Favorite foods	✓	✓	✓	✓	✓	✓	✓	✓	✓	N/A	N/A	N/A	N/A
Create meal or recipe		✓			✓		✓			N/A	N/A	N/A	N/A
Add kcal/kJ			✓		✓		✓			N/A	N/A	N/A	N/A
Water consumption	✓	✓				✓	✓	✓	✓	✓	✓	N/A	N/A
Water settings	✓						✓						
Macronutrients settings							✓			N/A	N/A	N/A	N/A
Save photo						✓			✓				
Phenotype													
Current weight	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Height	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓
Gender	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Age/date of birth	✓	✓	✓		✓	✓	✓	✓	✓		✓	✓	✓
Waist circumference		✓				✓							
Hips circumference		✓				✓							
Neck circumference		✓				✓							
Target weight		✓	✓	✓	✓	✓	✓		✓	✓			✓
Target date ^q				✓	✓		✓						
Body type									✓				

^aSH: S Health.^bMFP: MyFitnessPal.^cFS: FatSecret.^dNC: Noom Coach.^eLI: Lose it!.^fLW: Lose Weight Without Dieting.^gLS: Lifesum.^hMDD: My Diet Diary.ⁱCC: Calorie Count.^jMDC: My Diet Coach.^kDP: Diet Point.^lEWL: Effective Weight Loss.^mWeight and height for body mass index (BMI) calculation. Age and gender for calorie calculation.ⁿDA: Diet Assistant.^oWeight and height for BMI calculation. Age and gender for profile.^pN/A: not applicable. These features were assessed only in apps providing food diaries.^qTarget date in *Lose it!* is set indirectly via the plan to lose fractions of kg per week.

Table 4. Nutrition-related app features for physical activity and other input features.

Feature/app	SH ^a	MFP ^b	FS ^c	NC ^d	LI ^e	LW ^f	LS ^g	MDD ^h	CC ⁱ	MDC ^j	DP ^k	EWL ^l	DA ^m
Physical activity													
Type of PA ⁿ	✓	✓	✓	✓	✓	✓	✓	✓	✓				
Native GPS ^o	✓			✓									
Third-party GPS integration ^p		✓	✓	✓	✓		✓						
Integration with wearables ^q	✓	✓		✓	✓		✓						
Pedometer	✓			✓									
Average activity level	✓	✓	✓			✓		✓	✓				✓
Exercise goal	✓	✓		✓						✓			
Other features													
Community forums		✓	✓		✓			✓	✓	✓	✓		✓
Personal reminders	✓	✓		✓	✓	✓	✓			✓	✓		
Challenges	✓								✓	✓			
Health conditions								✓					
Daily notes	✓								✓				

^aSH: S Health.

^bMFP: MyFitnessPal.

^cFS: FatSecret.

^dNC: Noom Coach.

^eLI: Lose it!.

^fLW: Lose Weight Without Dieting.

^gLS: Lifesum.

^hMDD: My Diet Diary.

ⁱCC: Calorie Count.

^jMDC: My Diet Coach.

^kDP: Diet Point.

^lEWL: Effective Weight Loss.

^mDA: Diet Assistant.

ⁿMDD does not calculate the energy by type of activity, but asks the user to enter the amount of calories spent in the physical activity (PA).

^oGPS: global positioning system.

^pMFP integrates with other apps provided by the same company. FS integrates with Google Fit.

^qLS provides wearable integration only after upgrade to paid version.

Table 5. Nutrition-related app output features.

Feature/app	SH ^a	MFP ^b	FS ^c	NC ^d	LI ^e	LW ^f	LS ^g	MDD ^h	CC ⁱ	MDC ^j	DP ^k	EWL ^l	DA ^m
Nutrition assessment													
Calculated energy (kcal)	✓	✓	✓	✓	✓	✓	✓	✓	✓	N/A ⁿ	✓	✓	N/A
Macronutrients distribution (%)	✓	✓	✓		✓	✓	✓	✓	✓	N/A	N/A	N/A	N/A
Micronutrients intake (thresholds)	✓	✓	✓		✓				✓	N/A	N/A	N/A	N/A
Nutrition facts	✓	✓	✓	✓	✓		✓	✓	✓	N/A	N/A	N/A	N/A
Calories by meal	✓	✓	✓	✓	✓	✓	✓	✓	✓	N/A	N/A	N/A	N/A
Recommended water consumption	✓					✓	✓			✓	✓		
Maximum calories to reach a target weight		✓	✓	✓	✓	✓	✓	✓	✓		✓		
Calories of the new recipe		✓	✓		✓		✓			N/A	N/A	N/A	N/A
Diet plan						✓					✓	✓	✓
Shopping list											✓		
PA^o and phenotype													
Energy by type of PA ^p	✓	✓	✓	✓	✓	✓	✓		✓				
Weight progress	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓		✓
Circumferences monitoring		✓				✓							
Body mass index	✓					✓					✓	✓	✓
Other output features													
Forums or blogs		✓	✓		✓			✓	✓		✓		✓
Social media sharing		✓		✓		✓			✓	✓	✓		
Private social media		✓	✓		✓				✓				
Sharing with professionals			✓										
Healthy habits/rewards	✓									✓			

^aSH: S Health.^bMFP: MyFitnessPal.^cFS: FatSecret.^dNC: Noom Coach.^eLI: Lose it!.^fLW: Lose Weight Without Dieting.^gLS: Lifesum.^hMDD: My Diet Diary.ⁱCC: Calorie Count.^jMDC: My Diet Coach.^kDP: Diet Point.^lEWL: Effective Weight Loss.^mDA: Diet Assistant.ⁿN/A: not applicable. Features assessed only in apps providing food diaries.

^oPA: physical activity.

^pMDD does not calculate PA since it asks for the amount of calories instead of type of PA and duration.

My Diet Coach (MDC), Diet Point (DP), Effective Weight Loss (EWL), and Diet Assistant (DA) were not evaluated for some criteria because they are not food diaries; rather, they propose diet recommendations using different approaches. Food items could be selected by *text search* in all food diaries (n=9) or via *barcode scanner* in seven of them. *Serving sizes* could be selected using units (eg, grams) or household portion sizes (eg, teaspoon) according to the food item. Daily meals were fixed (eg, breakfast, lunch, dinner, and snacks) and the food input was divided by meal (ie, *food by meal*) in all food diaries (n=9). Only three apps—MFP, Lose it! (LI), and Lifesum (LS)—provided a feature for the users to create and save personal meals or recipes by combining existing food items in the apps. FatSecret (FS), LI, and LS also had a feature for adding calories—*quick add kcal* or *add kjoule*—without entering a food name. Lose Weight Without Dieting (LW) and CC had a feature for taking a picture of the meal, which can be used to remind the user about the food items for later entry. This feature is useful when the user does not have time to log the items during or just after the meal.

The most common phenotype inputs were current weight, height, gender, and age (see Table 3). Circumferences (ie, waist, hips, and neck) were found in two apps—MFP and LW—and entered optionally after the initial registration. In some apps, the user could also enter a target weight (n=9) and the target date (n=3) expected to reach this personal goal. When setting the target weight, Noom Coach (NC) limited the weight loss to a maximum of 1 kg per week. CC was the only app that asked the user to input their body type (ie, small, medium, or large).

For reporting PA (see Table 4), users could input the activity name and the duration in minutes (ie, feature *type of PA*). As most mobile phones have GPS hardware, they are able to perform location tracking. Accelerometers are also used for detecting the number of steps taken by the user (ie, *Pedometer*). Instead of performing movement tracking natively in the app (ie, feature *native GPS*), some apps (n=5) receive location information from other apps (ie, *third-party GPS integration*) or integrate with wearable devices (n=5) such as Fitbit, which measures distance using its internal hardware and software [10]. These wearable devices are acquired by the user separately and can be used independently of these nutrition-related apps. The *average activity level* refers to the self-report level of activity of the user (ie, low, moderate, or high).

Eight of the apps had internal forums, similar to blogs, where users post questions and recipes and can share information (see Table 4). Some apps offered the possibility of creating *personal reminders*, which could be used, for example, to remind users of snacks during the day. Some apps proposed diet challenges to users. For example, MDC users could log when they “fill half of the plate with vegetables.”

My Diet Diary (MDD) was the only software that required information about *health conditions*, including a specific mandatory input field about diabetes. Two apps offered the

possibility of saving *daily notes*. S Health (SH) had data input features for caffeine tracking, blood glucose, and blood pressure.

Output Features

Output features refer to the data and results presented by the app to the users. In terms of nutrition assessment and diet recommendation, food diaries had similar features in terms of feedback on calories and macronutrients (ie, protein, fat, and carbohydrates) (see Table 5).

Five apps provided information on micronutrient intake. MFP and SH provided tables with the daily micronutrient intake (eg, sodium, potassium, vitamin C, and iron) and the consumption *goal* and *left*. MFP provided some educational tips just after the food entry, for example, “this food is high in protein” and “this food has 1168 mg of sodium, your goal for today is to stay below 2300 mg.” Similar tips from other apps were more general and not based on the last food entry. Recommendations for water consumption (eg, “8 cups per day”) were given in five apps. After the selection of a food item, the user could examine the *nutrition facts* of the item in a way similar to the tables used in industrialized foods (n=8). LW offered a meal suggestion combining some food items that meet the suggested number of calories for the meal.

The apps that monitored dietary intake did not provide diet plans. In contrast, diet plans were the focus of DP, EWL, and DA. These apps suggested diet plans, divided by meals during the day. DP also suggested a related shopping list to the users. MDC followed a distinct approach providing generic diet recommendations via challenges and tips. Some examples of these general tips are “drink a flavored coffee (up to two cups a day),” “reduce your carbs consumption,” “restrain yourself, eat an apple instead,” and “eat a low fat yogurt.”

In terms of nutritional assessment, SH had an interesting feature named nutrient balance score. During the day, it showed this score (0-100) based on the nutritional value of the recorded daily food intake. It was not clear if this was calculated from the macronutrient distribution only or micronutrients and other possible variables. Similarly, CC had a grade (eg, A-, D+, and F) for the nutritional analysis and highlighted with colors (ie, green, yellow, and red) if the nutrients were within the recommended threshold.

The apps also had output features related to PA and phenotype (see Table 5). Weight progress, shown in graphs, was found in all the apps. Five apps presented the body mass index (BMI) calculation. *Forums and blogs* were found in seven apps and used frequently for sharing recipes and tips about weight loss and diets. Most of the possibilities for *social media sharing* (eg, Facebook) were related to weight loss achievements. MFP allowed users to connect with their Facebook friends who were also using MFP, after requesting their permission.

In addition, this review identified the existence of *private social media*, defined as having a feature for “following” other users, adding them “as a buddy” or supporting them. This feature was considered the distinction between forums/blogs and private

social media. FS provided an innovative feature for sharing the results with nutritionists and other health professionals, so that they could follow the monitoring online. NC and FS had a feature for exporting recorded data in a comma separated value (CSV) format. They did not export GPS data, but the results could be used for general data analysis or experiments.

As mentioned, MDC is not a food diary. It has a clear motivational focus using virtual rewards via the Healthy Habits (HH) points, which can be obtained by drinking more water, eating vegetables, or parking the car far away from one's destination.

Discussion

Nutrition Assessment

The most popular dietary intake apps available in November 2015 used prospective nutrition assessments. The focus of the food diaries was on the balance between the food intake and energy expenditure, with personalized recommendation of diet plans not featuring in these apps. The four generic diet plans were based on a number of inputs required from the user—weight, height, gender, and age—without subsequent dietary intake assessment. The feature for saving favorite foods and meals is an effective time-saving feature, mainly for those who consume the same food items frequently. Three apps allowed the user to set a date for reaching a target weight, but only NC limited the weight loss rate.

There is a general focus on weight loss and calorie counting, with the majority of apps containing either *calorie* or *weight* in the title. It is important to note that nutrition assessment should not be related only to weight loss to target obesity, although this might be one of the main motivations for using nutrition-related apps. Ideal weights are not suggested to the users, but are sometimes required as inputs. The target date for reaching a specific weight is also entered by the user. However, if used without professional recommendation, this may mislead the users to begin unhealthy diets or trigger an eating disorder [11,12]. Although integration of food diaries and some types of PA monitoring have been successful, personalized nutrition advice is limited. The innovative feature of sharing results with health professionals might be a possible strategy for achieving part of this goal.

A quantitative approach is the usual strategy used by apps to balance the energy content of diets with energy expenditure. Data from the diet diary is used as the estimated energy intake and the basal metabolic rate, and the energy expended through physical activities as the energy expenditure. However, this method does not take into account the quality of foods consumed. For instance, the distribution of food groups, as recommended by some public health organizations, is not considered [13]. The score feature proposed by SH to assess the nutritional quality of the dietary intake might be an alternative to address this need. The textual feedback provided by MFP related to micronutrients and food grade mentioned in the CC nutrition facts might help users to gain some knowledge related to nutrients. The portion sizes are selected based only on text. Although the serving sizes can be useful in this situation,

the apps do not present photos or icons for assisting the user to choose the most accurate portion size. Personalized advice based on health conditions or specific groups, such as vegetarians and vegans, was not available in the apps assessed.

All the apps collecting dietary intake used the same nutrition assessment method (ie, food diary record). However, there are alternative methods that are less time-consuming, such as the 24-hour recall method [14] and the FFQ [15,16], which have also been validated in Web-based formats.

Technologies

Within the apps offering food diaries, aspects of PA monitoring were available via the use of GPS or wearables. These features allow users to monitor their outdoor activities (eg, walking and running) and the use of application programming interfaces (APIs) plays an important role in these integrations because they are created to facilitate the communication with other external apps. In general, the wearable devices collect data and save them in their own systems and allow third-party apps, such as the nutrition-related apps, to import that data via APIs. In addition, indoor activities can be logged by selecting the type of activity and duration. Using the same strategy, LS and MFP provided the possibility to import weight measurements from Withings body scales (Withings Inc, Cambridge, MA), which can measure weight, BMI, and heart rate and send this information via Wi-Fi to the Internet [17].

Emerging technologies, such as image recognition and natural language processing, are not present in the most popular nutrition apps. The combination of these technologies could simplify the food and portion selection processes. Image recognition seems to be promising for recognizing food items and estimating their portion sizes [18] and natural language processing could be used to transcribe spoken dietary records [19]. In academia, some studies using apps take advantage of specific hardware, such as laser beams attached to mobile phones [18], in order to increase the accuracy of the portion size estimation.

There is room for improvement in terms of connecting users and health professionals, in that the process of making diet recommendations could include more input from trained professionals. An automated system that offers personalized nutrition advice was proposed and developed by the Food4Me study, based on a decision tree created by nutritionists and dietitians [20]. A diet information system that connects dietitians and the public was proposed by Ravana et al in order to take advantage of artificial intelligence for proposing diet planning to the public [21]. In this context, artificial intelligence is used in an attempt to solve the diet planning challenge, so that the system can learn from past experiences (ie, similar scenarios). In theory, the combination of big data analytics and artificial intelligence would create a decision engine able to propose personalized online intervention [22-24]. A similar challenge is under investigation by IBM in a project named *cognitive cooking*, using these technologies to propose recipes to users [25]. These technologies were not featured in the apps assessed. This specific analysis could be a topic for future work in both academia and industry.

Limitations

We acknowledge that the Google Play Store and the iTunes App Store have different app-ranking systems and market share. Hence, using the lowest number of reviews for the included Google Play Store apps as a threshold for including apps from the iTunes App Store may not reflect the number of downloads from the iTunes App Store. It is difficult to directly compare app popularity between the two stores, as the number of downloads from the iTunes App Store is not publically available. As the Google Play Store does not provide the exact number of installs, it is possible that some apps in the range *500,000-1m* could have approached 1 million installs. The criteria used to select the apps were based on the number of installs and reviews. Using these variables alone, it was not possible to identify the frequency and duration of use of these apps. This information would be valuable to measure the real engagement of the users and determine if they would accept the burden of text searching and barcode scanning for a prolonged period. It would also be interesting to assess the percentage of users that upgraded to the premium versions of the apps. Since it is not possible to measure the upgrades, the premium versions were not considered popular and their extra functionalities were not included in this review. A similar limitation occurred with the WW app, which requires a subscription [9]. Since the functionalities of these apps change rapidly, it is recommended that a similar assessment be conducted in the future. Although it is likely that these apps are also available and popular in other English-speaking countries, such as the United States and Canada, these results are limited to a UK perspective. A review of popular apps in

different countries and languages could reveal other important features and interesting cultural differences.

Comparison With Prior Work

Chen et al have recently published research assessing the most popular mobile phone apps for weight loss used in Australia [26]. They have developed a method for quantifying the quality of the apps and also assess the utilization of behavior change techniques (BCTs). However, given that a different methodology for defining the most popular apps was used in this study, and that the apps published in the online stores are distinct by country, only six out the 13 apps assessed in our study were alike. Some investigators have also conducted analyses of commercial nutrition-related apps in terms of content and health behavior theories [8,27,28]. This research complements and extends this prior work by providing a detailed analysis of the features offered by individual apps and also by analyzing what emerging technologies have been applied by them.

Conclusions

A total of 13 apps that had at least 1 million installs were identified. Nine of the apps collected dietary intake, all using the same assessment method (ie, food diary record). Food selection was accomplished via text search and barcode scanning. Portion size selection was conducted by selecting text, and not by images or icons. Image recognition, natural language processing, and artificial intelligence did not feature in the apps. There is significant opportunity for improvement in terms of personalized nutrition, which could include individualized feedback, diet plans, or nutrition education.

Acknowledgments

RZF was responsible for the data collection and analysis and drafting the manuscript. All authors contributed to the research design, reviewed and edited the manuscript, and approved the final version for publication. RZF is sponsored by the National Council of Technological and Scientific Development (CNPq) from the Brazilian government, via the *Science without Borders* program.

Conflicts of Interest

None declared.

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Abbreviations

- API:** application programming interface
- BCT:** behavior change technique
- BMI:** body mass index
- CC:** Calorie Count
- CNPq:** National Council of Technological and Scientific Development
- CSV:** comma separated value
- DA:** Diet Assistant
- DP:** Diet Point
- EWL:** Effective Weight Loss
- FFQ:** food frequency questionnaire
- FS:** FatSecret

GPS: global positioning system
HH: Healthy Habits
LI: Lose it!
LS: Lifesum
LW: Lose Weight Without Dieting
MDC: My Diet Coach
MDD: My Diet Diary
MFP: MyFitnessPal
N/A: not applicable
NC: Noom Coach
PA: physical activity
PC: personal computer
SH: S Health
WW: Weight Watchers

Edited by G Eysenbach; submitted 19.04.16; peer-reviewed by K DiFilippo, S Coughlin; comments to author 18.05.16; revised version received 27.05.16; accepted 27.05.16; published 01.08.16.

Please cite as:

*Franco RZ, Fallaize R, Lovegrove JA, Hwang F
Popular Nutrition-Related Mobile Apps: A Feature Assessment
JMIR Mhealth Uhealth 2016;4(3):e85
URL: <http://mhealth.jmir.org/2016/3/e85/>
doi: [10.2196/mhealth.5846](https://doi.org/10.2196/mhealth.5846)
PMID: [27480144](https://pubmed.ncbi.nlm.nih.gov/27480144/)*

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Original Paper

The Quality and Accuracy of Mobile Apps to Prevent Driving After Drinking Alcohol

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Abstract

Background: Driving after the consumption of alcohol represents a significant problem globally. Individual prevention countermeasures such as personalized mobile apps aimed at preventing such behavior are widespread, but there is little research on their accuracy and evidence base. There has been no known assessment investigating the quality of such apps.

Objective: This study aimed to determine the quality and accuracy of apps for drink driving prevention by conducting a review and evaluation of relevant mobile apps.

Methods: A systematic app search was conducted following PRISMA guidelines. App quality was assessed using the Mobile App Rating Scale (MARS). Apps providing blood alcohol calculators (hereafter "calculators") were reviewed against current alcohol advice for accuracy.

Results: A total of 58 apps (30 iOS and 28 Android) met inclusion criteria and were included in the final analysis. Drink driving prevention apps had significantly lower engagement and overall quality scores than alcohol management apps. Most calculators provided conservative blood alcohol content (BAC) time until sober calculations. None of the apps had been evaluated to determine their efficacy in changing either drinking or driving behaviors.

Conclusions: This novel study demonstrates that most drink driving prevention apps are not engaging and lack accuracy. They could be improved by increasing engagement features, such as gamification. Further research should examine the context and motivations for using apps to prevent driving after drinking in at-risk populations. Development of drink driving prevention apps should incorporate evidence-based information and guidance, lacking in current apps.

(*JMIR Mhealth Uhealth* 2016;4(3):e98) doi:[10.2196/mhealth.5961](https://doi.org/10.2196/mhealth.5961)

KEYWORDS

drink driving; alcohol; mobile apps; calculator; Mobile Application Rating Scale; blood alcohol content

Introduction

Drinking and driving remains a significant public health issue globally despite ongoing prevention efforts [1]. Alcohol intoxication is linked to slowed reaction time, difficulties in multitasking, reduced attention span, and dulled senses, which

greatly reduce the ability to drive safely [2]. Australia is considered a world leader in legislation for drink driving prevention, with national random breath testing and a set 0.05 blood alcohol content (BAC) limit for open class license holders. However, there is also a distinct drinking culture, and drink driving behavior persists. Most licensed alcohol and drug users

in the country admit to driving over the legal alcohol limit at some time, with over 40% reporting doing so at least twice in the last year [3]. One-third of crashes involve alcohol as a contributing factor [4] and as such, excessive alcohol use continues to be considered one of the main road safety concerns [5]. It is, therefore, necessary to utilize all available resources to increase drivers' education and motivation to reduce drink driving behavior. Well-targeted mobile apps may offer an innovative, user-friendly, and accessible way of reducing drinking and driving.

Mobile phones are owned by 89% of Australian adults [6] who spend an average of 29 hours per month using apps [7]. In recent years, the number of mHealth apps published on iOS and Android platforms have more than doubled. There are currently more than 165,000 mHealth apps (free and paid) publicly available [8]. However, the effectiveness of health apps remains largely untested and unknown. Commonly occurring app inaccuracy, poor information quality, lack of evidence base, and lack of efficacy trials raise concerns about app effectiveness and even risks associated with app use [9,10]. Potential hazards range from user misinformation all the way to misdiagnosis of disease [11]. In-depth, systematic review and evaluation of apps in all health areas is needed to inform end users, clinicians, and developers of best practices and common problems in existing apps [12]. Thus, apps that provide calculations of BAC level, for example, should be scrutinized to ensure their quality and accuracy in providing correct guidance on readiness to drive after consuming alcohol.

An attempt at developing a systematic heuristic for the categorization and evaluation of app quality is provided by the Mobile App Rating Scale (MARS). According to the authors, high-quality apps are generally customizable, engaging, well-targeted, easy to use and navigate, and contain high-quality graphics and information [12]. The scale contains 4 objective quality subscales (19 items): engagement, functionality, aesthetics, and information quality and one subjective quality subscale (4 items). The MARS has been recently applied to determine the quality of apps for mindfulness [13], weight loss and smoking cessation [14], and heart failure symptom monitoring [15] and was therefore deemed an appropriate measurement tool for this study.

In the drink driving context, high-accuracy apps provide specific and correct information based on customizable user content in (BAC) calculators. A recent review of apps found that calculator apps tend to overestimate BAC level and provide an extremely wide variation in scores [16]. This research suggested that such calculations were based on insufficient user data (ie, height, age, times spent drinking, and so forth) and flawed calculation methods. It is also known that apps addressing alcohol use are rarely theory or evidence based [9].

A review of apps targeting drink driving has not yet been conducted, despite the need for expert review and evaluation of their accuracy and potential application. This study aimed to (1) conduct a systematic contextual review of drink driving apps, (2) use a validated app rating scale (MARS) to measure app quality, and (3) assess BAC calculators in apps for accuracy. The secondary aim was to highlight some of the best practices

and potential issues in such apps as used for ecological momentary assessment and ongoing behavior change.

Methods

Systematic Contextual Review

Recent research into app quality highlights the necessity for systematic contextual app reviews, appropriate categorization, and expert evaluation [12]. A systematic search of apps with drink driving prevention content was conducted in June 2015 following PRISMA guidelines. The search utilized the Google "app search" filter. Searches were conducted, for the terms "drink tracker," "alcohol tracker," "alcohol driving," "drink driving," "drunk driving," "intoxicated driving," "DUI" (driving under the influence), "DWI" (driving while intoxicated), "BAC," and "blood alcohol concentration."

By default, Google returns large numbers of results. Therefore, careful scrutiny of each result page for each of the search terms was done before shortlisting and downloading all potentially-relevant apps. Initially all app titles and where necessary, app descriptions were screened. Apps were excluded if they were non-drink-driving related, duplicate, inaccessible, or not in English language. All remaining apps were downloaded and explored. Those which only measured alcohol in fluid ounces were excluded, as this measurement type is not applicable to the Australian context. Apps needed to be available in the Australian app store (though they may have been developed overseas and still applicable to the research study), as the enforced Australian BAC limit is 0.05 for open license holders. Apps related to other jurisdictions BAC limits or related detection (eg, providing information about achieving a 0.08 limit such as in the United States or how to pass sobriety tests) were excluded. Inclusion criteria were apps that either directly targeted drink driving prevention (ie, included information relating to the reading of or strategies aimed at lowering of a BAC) or apps that included information about alcohol use and its role in drink driving. Eligible apps included information about drink driving, regardless of whether drink driving prevention was the primary or secondary purpose of the app.

App Rating

The MARS contains 23 items rated on a 5-point scale (1=inadequate, 2=poor, 3=acceptable, 4=good, and 5=excellent) or not applicable. Apple iOS apps were rated and reviewed on an iPhone 6 Plus (iOS 8.4.1) and Android apps were rated on a Samsung Galaxy Edge (Android 5.0.2). All apps were rated by 2 raters to increase reliability of results. Scores were averaged for each MARS item. Both raters underwent MARS training, as suggested by Stoyanov and colleagues [12] and followed the steps presented in the YouTube training tutorial [17]. To address information-specific items, a researcher specializing in drink driving information and behavior provided a 1-hour structured information session to each rater before app evaluation. For item 19 relating to evidence base, raters conducted a literature search in Google Scholar utilizing the app name as a search term. A thorough Internet search was also conducted for each app, including the developer website, to examine any available unpublished studies.

Analyses

Measures of interrater reliability were conducted using the intraclass correlation coefficient (ICC) [18] on all MARS subscales and total score. A 2-way mixed effects, average measures model with absolute agreement was utilized [19]. Independent t tests were conducted to determine the differences between alcohol management apps and drink driving prevention apps, and effect sizes were calculated [20].

For apps containing BAC calculators, an assessment was conducted to determine the accuracy and similarity of their output. For this purpose, identical information was entered into all calculator apps, accounting for male or female users. Average Australian demographics used to test BAC calculators included: male, 25 years, 86 kg, 176 cm, 2 standard drinks over an hour; and female, 25 years, 71 kg, 162 cm, 1 standard drink over an hour (to improve accuracy across app calculations, where possible, 1 standard drink was equivalent to a mid-strength beer consisting of 375 mL, 3.5% alcohol). This calculation was used due to the widespread advice on the amount of standard drinks that can be consumed to stay under the 0.05 BAC limit, which is different for men (2/hr) and for women (1/hr), though the most recently released guidelines suggest that “for most adults, drinking no more than 2 standard drinks on an occasion will keep the BAC below 0.05” (p. 85) [21].

Key features were noted to provide a general overview of what could be expected across apps. The popularity and effectiveness of these features could highlight possible considerations for inclusion in the design of an app moving forward.

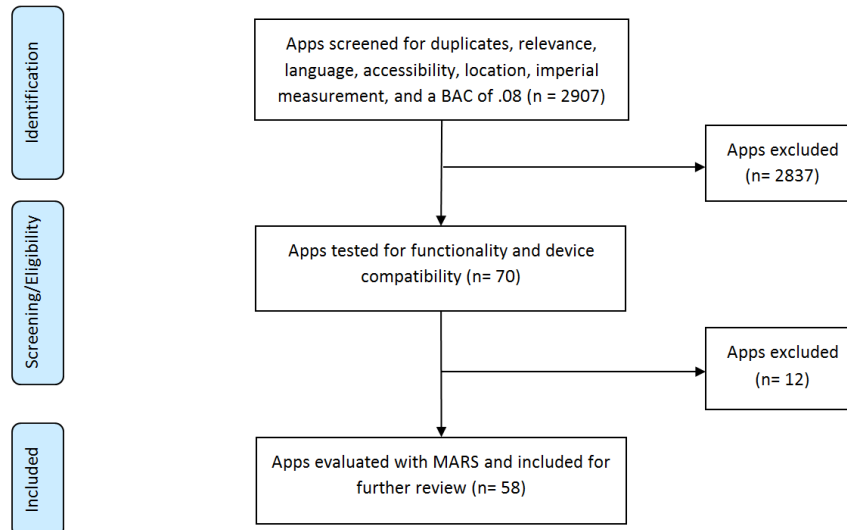
Results

Systematic Contextual Review

A total of 2907 apps were identified through keyword searches. Seventy apps were downloaded and explored. Of them, 58 were eligible for MARS evaluation at the final stage. Of these, 22 (38%) were developed by single developers and the remaining 36 (62%) were developed by institutions or businesses. The median time since last update was 16 months. The mean number of downloads for alcohol management apps was 7440 and the mean number of downloads for drink driving prevention apps was 27,266 (sourced from xyo). Figure 1 depicts the results of the systematic search.

Of these, 28 were Android and 30 were iOS apps. There were 2 core app types: alcohol management apps, containing secondary information about drink driving (n=14) and drink driving prevention apps containing Widmark-based calculators (n=44) (see Multimedia Appendix 1). These 2 app groups were separated for analysis, as they are functionally different and are aimed at different groups (alcohol management vs drink driving prevention).

Figure 1. Systematic search of drink driving prevention apps selected for MARS analysis.



MARS Reliability

The first analysis involved examination of the internal consistency and interrater reliability of the MARS and its

subscales. Independent ratings demonstrated good internal consistency (Cronbach alpha = .84) and excellent interrater reliability for the total MARS (2-way mixed ICC = 0.84, 95% CI 0.80-0.87) and for all subscales [17] (Table 1).

Table 1. Interrater reliability of the MARS subscales (95% CI).

MARS subscale	Intraclass Correlation Coefficient
Engagement	.78 (.64-.86)
Functionality	.84 (.71-.91)
Aesthetics	.86 (.78-.91)
Information	.80 (.40-.90)

App Quality of Alcohol Management and Drink Driving Prevention Apps

Quality measures as detailed in MARS subscales and total mean scores were calculated to examine individual app quality and

to present a comparison of the quality of the 2 types of apps (Table 2). For details of the mean app rating scores and subscale scores for all apps included in the analysis, see [Multimedia Appendix 1](#).

Table 2. Comparison of MARS subscale means and standard deviations in parenthesis, between alcohol management and drink driving prevention apps.

MARS subscale ^a	Alcohol management ^b	Drink driving prevention ^b
Engagement	3.14 (0.78)	2.51 (0.70)
Functionality	3.83 (0.73)	3.57 (0.82)
Aesthetics	3.23 (0.91)	2.80 (1.03)
Information ^c	3.16 (0.74)	2.78 (0.43)
MARS mean	3.34 (0.69)	2.91 (0.57)

^aMARS values range from 1 – inadequate to 5 – excellent.

^bThe rated versions ([Multimedia appendix 1](#)) of the apps may not be available in the App Store at the time of publication, as they may be replaced by newer versions.

^cThe information quality score excluded Item 19 of the MARS.

Independent t tests were used to compare the mean scores between alcohol management apps and drink driving prevention apps on the subscales of the MARS (engagement, functionality, aesthetics, information, and overall quality mean). There was a significant difference in the scores for alcohol management apps and drink driving prevention apps on the overall quality mean; $t(56) = 2.31, P = .02, 95\% \text{ CI } (0.06-0.79)$, and $d = .68$ and the engagement subscale; $t(56) = 2.88, P = .01, 95\% \text{ CI } (0.19-1.07)$, and $d = .85$. There was no significant difference in the scores for alcohol management apps and drink driving prevention apps on the functionality subscale; $t(56) = 1.09, P = .28, 95\% \text{ CI } (-0.22 \text{ to } 0.76)$, $d = .33$, the aesthetics subscale; $t(56) = 1.37, P = .18, 95\% \text{ CI } (-0.20 \text{ to } 1.04)$, $d = .44$, or the information subscale; $t(15.87) = 1.82, P = .09, 95\% \text{ CI } (-0.06, 0.82)$, $d = .63$. For the information subscale analysis, Levene's

test indicated unequal variances ($F = 5.15, P = .03$), so degrees of freedom were adjusted from 56.00 to 15.87. We could find no evidence that any app had been evaluated in either scientific literature or the Internet search, which is why item 19 “evidence base” was consistently rated as N/A.

Investigation of Information Scale Items

As there are widespread misconceptions in information sources about the safety of driving after consuming alcohol [22], provision of wrong or misleading information to app users could potentially lead to poorly-informed decisions on readiness to drive. Therefore, the information section of the MARS scale was not solely presented as a mean score, but also as individual items, so that scores of the quality and quantity of information could be reviewed separately (Table 3).

Table 3. Comparison of the MARS information subscale items overall mean scores and standard deviations in parenthesis between alcohol management apps drink driving prevention apps .

Information subscale item	Alcohol management (n=14)	Drink driving prevention (n=44)
Accuracy of app description	3.89 (0.84)	3.57 (0.70)
App goals	3.75 (0.91)	3.24 (0.73)
Information quality	2.61 (0.66)	2.59 (0.39)
Information quantity	3.14 (1.18)	2.27 (0.84)
Visual information	3.12 (0.98) ^a	3.16 (0.69) ^b
Credibility of the source	2.32 (0.61)	1.93 (0.41)
Evidence base	N/A	N/A
Information mean	3.16 (0.74)	2.78 (0.43)

^an=13 (apps rated as N/A were not included in the calculations).

^bn=32 (apps rated as N/A were not included in the calculations).

Calculator Accuracy Assessment

An analysis of the BAC calculators that were included in the apps was conducted to assess their accuracy. A random selection of apps with BAC calculators were included (n=35). Apps with the ability to only calculate the number of standard drinks (not time taken) or that resulted in extremely conservative BAC scores (outliers) were excluded from the analysis (n=2). The average male achieved a mean BAC of 0.03 (standard deviation = 0.01) ranging from 0.01 to 0.05, with an average time until sober of 1:48 hours. The average female achieved a mean BAC of 0.01 (standard deviation = 0.01) ranging from 0.00 to 0.05, with an average time until sober of 1:02 hours.

App Features and Best Practice

In terms of useful and engaging features, alcohol management apps generally provided links to additional research-based Web-based content, an in-app diary to be utilized for tracking, quizzes to test alcohol knowledge, and personalized feedback

relating to alcohol consumption norms (local or global). As drink driving prevention apps generally aimed to provide ecological momentary assessment of readiness to drive, many of the high rating apps provided a level of personalization to improve accuracy, such as creating a user profile (gender, age, height, weight) and the ability to log multiple profiles. In terms of BAC calculation, best practice for apps involved warnings that the information provided is a guideline only, being able to input specific drink data (such as grams or percentage of alcohol), and provision of information relevant to the country of origin (eg, related to BAC level). The high-quality apps generally also contained information and links to public transport or taxi options and prompts to contact friends. Many of the lower quality apps encouraged the use of alcohol by providing features such as sharing BAC level to social media or finding local venues where alcohol is available. For screenshots of the highest rated alcohol management and drink driving prevention apps in this study, please refer to [Figure 2-5](#).

Figure 2. OnTrack Screenshot 1.

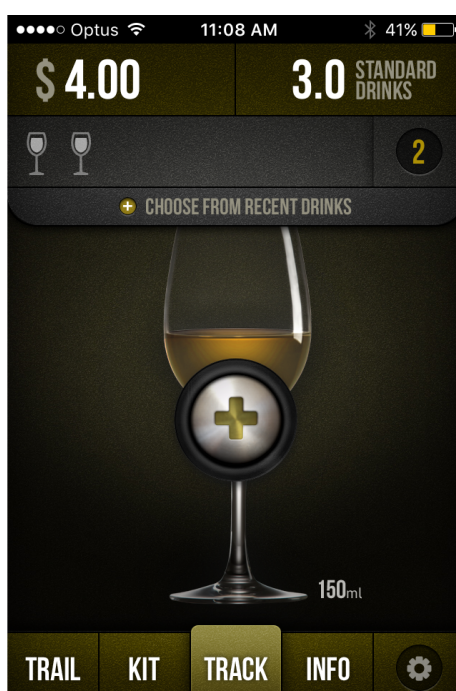


Figure 3. OnTrack Screenshot 2.

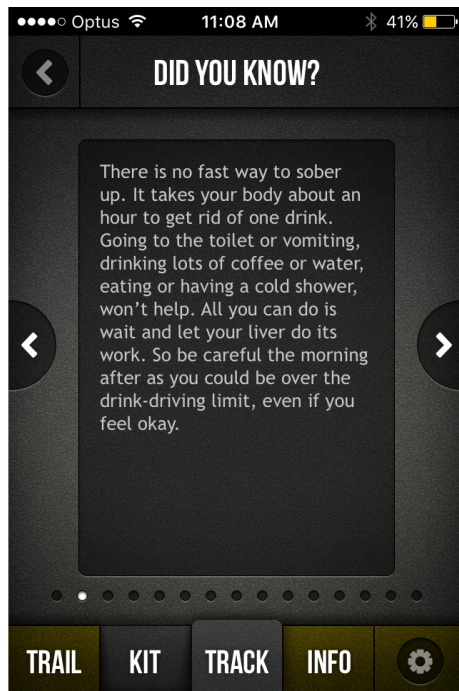


Figure 4. IntelliDrink Screenshot 1.

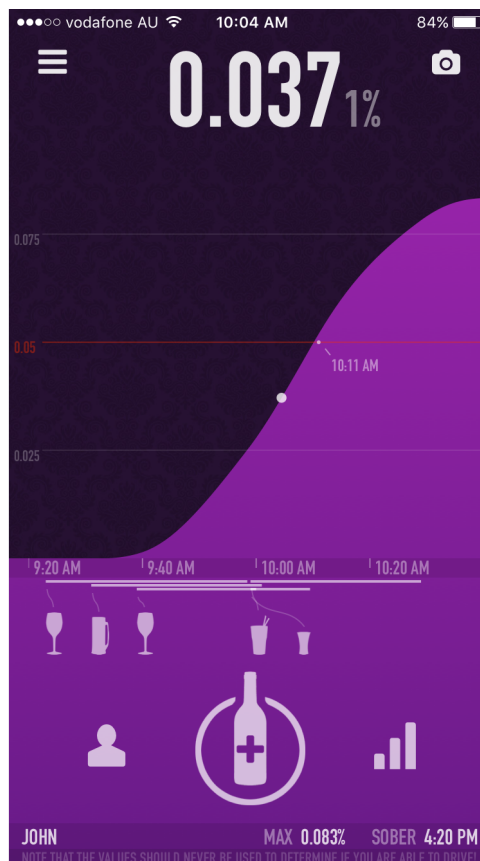
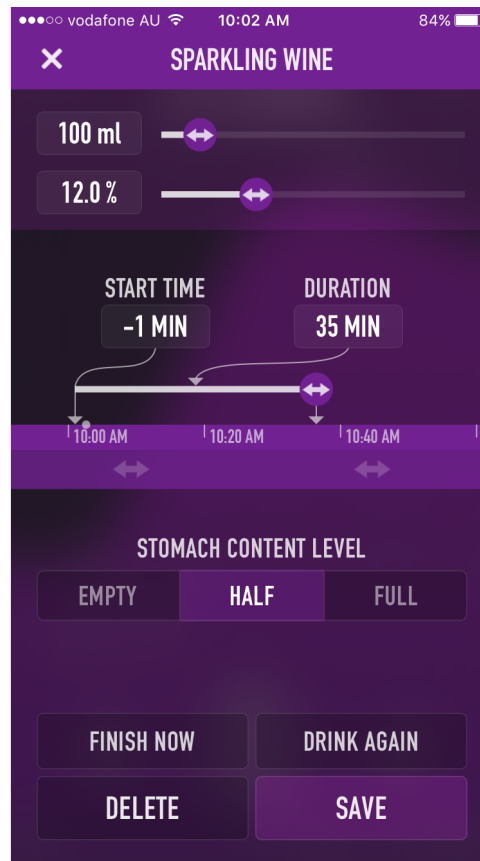


Figure 5. IntelliDrink Screenshot 2.



Discussion

Principal Findings

Driving after the consumption of alcohol presents a significant risk, and novel strategies such as mobile apps are emerging as a potential intervention strategy for prevention and behavior change. This research is the first to explore the quality of mobile apps specifically including information and strategies in the prevention of drink driving in Australia. By conducting a systematic and contextual review of relevant apps, we were able to determine that apps containing drink driving information and intervention strategies fell into 2 categories: drink driving prevention (largely utilizing calculators for a time-until-sober calculation) and alcohol management (largely utilizing harm reduction strategies to reduce alcohol use and subsequent risk taking). The overall quality between the two app types differed as a function of significantly different engagement scores. Although drink driving prevention apps had 3.5-fold more downloads on average than alcohol management apps, they were significantly less engaging. The 2 app types identified in this research are likely to be used for different purposes. Calculator apps may be utilized for ecological momentary assessment purposes while drinking alcohol to assess level of intoxication and potentially readiness to drive, whereas alcohol management apps are likely to be used in the reduction of risky and harmful drinking. Thus, the latter is used for a broader purpose.

The quality of apps was assessed and then calculators in drink driving prevention apps were analyzed for accuracy. The key

issue we found in calculator apps was their potential inaccuracy based on the formula they used. The “Widmark” formula is a predictive mathematical equation that was developed in 1932 that has largely been used forensic toxicologists to determine approximate BAC after a fatality for court proceedings [23]. There is a large and growing body of evidence that these calculations provide misleading and inaccurate information by underestimating actual BAC levels [24-26]. Replicating the findings of earlier research [16], the present study found that although calculators were largely conservative (overestimating BAC compared with national guidelines), they were inconsistent and some could lead to the provision of advice on readiness to drive when someone is still at risk of being over the legal alcohol limit, particularly for women. This is a concern particularly as the proportion of female drink drivers continues to rise [27]. Our results also confirm previous findings in the lack of evidence base and suitable evaluation for alcohol apps [9], and this should be the focus of future research to determine efficacy. In addition, while the “Widmark” formula was the most commonly noted basis for BAC calculations in the apps reviewed, a number of apps failed to indicate what formula was in use or how they arrived at their BAC value at all. This was concerning not only due to the ambiguity of app’s calculations but also in conjunction with high app downloads and positive user reviews. This suggests a user’s choice of app may be influenced by factors beyond calculation method transparency or accuracy.

On determining whether one should drive after drinking any alcohol, it should also be noted that impairment can occur at very low levels [28], supporting the argument that calculators

are ambiguous and should not be used in this context. There is evidence that skills performance starts to deteriorate at levels well below a 0.05 BAC, especially in terms of divided attention and basic driving skills [29,30]. Compared with drivers with no alcohol in their system, the risk of a drink driving crash rises for drivers with a BAC of 0.05 or greater [28]. However, balancing the evidence, it would seem that having a conservative tool in which to measure potential risk could aid in decision making to avoid drink driving. The nonambiguous message remains to separate drinking from driving completely, but while BAC limits are enforced, it is unlikely that drinkers will adopt a stance that does not enable them to calculate drinks to stay under the legal alcohol limit.

Although this study provides novel results, there are also limitations that should be considered. First, only apps applicable to the Australian context were described due to consistent legislation and detection practices and further research should be conducted to determine the quality of drink driving apps in other areas. For example, sobriety apps providing guidance on subjective assessments of impairment should be the focus of research in jurisdictions where utilizing these methods of detection. Thus, the generalizability of these results to other jurisdictions is unknown.

As calculator apps are often highly simplified, there were apps that were tested where the exact volume and percentage of alcohol could not be determined (ie, the app included only a graphic of a beer, wine or spirit with no other information). For other apps, only an amount closest to 1 standard drink could be entered, thus accuracy of calculators could be skewed due to the inability to input standard drink data. However, apps included the ability to input the time taken to consume the beverage (eg, 1 standard drink consumed over 15 minutes or over 30 minutes), which should have added to the accuracy of BAC measurement. A number of apps also included the ability to indicate the degree of food consumption (eg, empty, half full, full); however, additional accuracy of such apps was not examined in detail.

Finally, due to the ever-evolving app market, with regular additions and removal of apps and updating of search algorithms in app searches, this research provides a snapshot of apps only during the study period, and app studies should be regularly updated. It must also be noted that operating system may affect the availability of older or outdated apps. Older iOS apps were often unable to function on newer versions of the operating system and thus were automatically obsolete if not updated. However, older Android apps maintained compatibility with newer OS versions and, without manual removal by the developer, have the potential for containing outdated information and content which increases the risk of negative consequences resulting from their use.

Future Research and Development

This research has demonstrated that there are numerous apps containing information for prevention of drinking and driving.

Further research needs to be conducted to determine the contexts in which these apps are used, and the motivations for engaging with them.

Engagement is a key difference in alcohol management versus drink driving prevention apps, and thus components of more engaging apps could be transferable to less engaging ones, such as interactivity (eg, providing feedback on alcohol consumption and its progressive effect throughout the session, prompting the user to slow down or increase hydration, and utilizing notifications to keep the user informed about their current state of alcohol consumption), customization (ie, the ability to change the design to keep favorite/frequent drinks at the forefront, tailored information to provide the user with their physiological traits they feel would be most beneficial such as current BAC, time until sober, number of standard drinks consumed, tally of the cost of drinks over the period of a session, etc), entertainment (eg, awarding points for good behavior and the ability to cash in the points on unlocking aesthetics features), and interest (eg, the use of animations or eye catching design elements) [31,32].

In designing an app in this context, key elements to be considered should include: motivation for use (ie, engagement strategies), context of use (ie, as a tool to predict when is the earliest time to begin driving again), reason for continued use (ie, as a tool to track drinking/alcohol consumption) unobtrusiveness (ie, should incorporate a clear clean design showing only essential information as customized to personal preference and attempt to minimize required time spent in-app), and cost (ie, the value a user will place on the functionality to justify either paying for the app or choosing a free alternative). Technologically advanced novel features could include: location based (ie, the apps recognizes user location and customizes the number of drinks offered, cost of drinks, how best to get back home, automatically launching a session, etc), smart watch integration (ie, the ability to view alcohol consumption/BAC at a moment's notice with minimal interruption to social situations), barcode scanning of drinks (ie, more accurate information could be supplied and updated in a central database and could be much more convenient than entering specific drink information), social elements (eg, ability to track with friends, notification when a friend may require assistance or is unsafe to drive), and pre-emptive prompts (ie, information on how much alcohol may be consumed before driving may be unsafe). There is also scope to pair these apps with relevant hardware that could more accurately measure BAC such as fuel cell based breathalyzers.

Conclusions

Most apps for drink driving prevention are not engaging, and none have as yet been tested in trials to determine their effectiveness in reducing drink driving behavior. While drink driving prevention apps are a promising countermeasure addressing risky road user behavior, they require an evidence base to ensure their quality and accuracy, and this currently does not exist.

Acknowledgments

This project was funded by the Queensland University of Technology Institute of Health and Biomedical Innovation.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Mobile apps and MARS subscale and total quality scores for both app category types.

[[PDF File \(Adobe PDF File\), 131KB - mhealth_v4i3e98_app1.pdf](#)]

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Abbreviations

BAC: blood alcohol content

ICC: intraclass correlation coefficient

MARS: Mobile App Rating Scale

PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses

Edited by G Eysenbach; submitted 10.05.16; peer-reviewed by P Kvillemo, C Garnett, B Suffoletto; comments to author 09.06.16; revised version received 15.06.16; accepted 21.06.16; published 08.08.16.

Please cite as:

Wilson H, Stoyanov SR, Gandabhai S, Baldwin A

The Quality and Accuracy of Mobile Apps to Prevent Driving After Drinking Alcohol

JMIR Mhealth Uhealth 2016;4(3):e98

URL: <http://mhealth.jmir.org/2016/3/e98/>

doi: [10.2196/mhealth.5961](https://doi.org/10.2196/mhealth.5961)

PMID: [27502956](https://pubmed.ncbi.nlm.nih.gov/27502956/)

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Original Paper

Quantifying App Store Dynamics: Longitudinal Tracking of Mental Health Apps

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Abstract

Background: For many mental health conditions, mobile health apps offer the ability to deliver information, support, and intervention outside the clinical setting. However, there are difficulties with the use of a commercial app store to distribute health care resources, including turnover of apps, irrelevance of apps, and discordance with evidence-based practice.

Objective: The primary aim of this study was to quantify the longevity and rate of turnover of mental health apps within the official Android and iOS app stores. The secondary aim was to quantify the proportion of apps that were clinically relevant and assess whether the longevity of these apps differed from clinically nonrelevant apps. The tertiary aim was to establish the proportion of clinically relevant apps that included claims of clinical effectiveness. We performed additional subgroup analyses using additional data from the app stores, including search result ranking, user ratings, and number of downloads.

Methods: We searched iTunes (iOS) and the Google Play (Android) app stores each day over a 9-month period for apps related to depression, bipolar disorder, and suicide. We performed additional app-specific searches if an app no longer appeared within the main search

Results: On the Android platform, 50% of the search results changed after 130 days (depression), 195 days (bipolar disorder), and 115 days (suicide). Search results were more stable on the iOS platform, with 50% of the search results remaining at the end of the study period. Approximately 75% of Android and 90% of iOS apps were still available to download at the end of the study. We identified only 35.3% (347/982) of apps as being clinically relevant for depression, of which 9 (2.6%) claimed clinical effectiveness. Only 3 included a full citation to a published study.

Conclusions: The mental health app environment is volatile, with a clinically relevant app for depression becoming unavailable to download every 2.9 days. This poses challenges for consumers and clinicians seeking relevant and long-term apps, as well as for researchers seeking to evaluate the evidence base for publicly available apps.

(*JMIR Mhealth Uhealth* 2016;4(3):e96) doi:[10.2196/mhealth.6020](https://doi.org/10.2196/mhealth.6020)

KEYWORDS

mobile applications; mobile apps; mental health; telemedicine; depression; bipolar disorder; suicide

Introduction

For many mental health conditions, the ability to deliver information, support, and intervention outside the clinical setting is a major advantage. The growing ubiquity of smartphones is increasingly making this possible, as a recent report indicated

that 79% of smartphone users are with their phones for all but 2 of their waking hours [1]. Recent surveys suggest that 25% of adults use mobile apps for health care [2], and 71% of patients in an outpatient psychiatric setting indicated a desire to use an app to supplement their clinical care [3]. Moreover, in the United

States, a third of clinicians reported having recommended a health care app within the last year [4].

This use of mobile apps for health care is largely consumer led and commercially driven. App developers rate app stores as the preferred distribution channel of health apps, rather than through physicians or hospitals, and this distribution is likely to continue until at least 2020 [5]. However, there are difficulties with the use of a commercial marketplace to distribute health care resources.

App store descriptions offer little information about app content quality and rarely cite the source of their content or substantiate claims of effectiveness. A review of the former UK National Health Service (NHS) Health Apps Library found that, of the mental health apps accredited by the NHS, only 15% provided evidence of effectiveness [6]. Previous studies have also identified a lack of research-based evidence associated with mental health apps generally [7], and mood disorders specifically [8]. Furthermore, a growing number of studies have identified a disparity between app content and evidence-based practice [9–11]. This highlights the challenge for consumers and clinicians in selecting mobile health apps from the app stores.

A recurring limitation of these evidence reviews is that they only constitute a snapshot of a highly dynamic marketplace. The systematic review methodologies used ensure rigor; however, compared with publications in the academic literature, additions to the app stores are frequent, and removal of apps is common. There are several possible reasons for apps to be removed, including decisions made by the developer, nonrenewal of a developer account, and withdrawal by the app store operator. If apps are to be used by consumers and clinicians, app longevity is an important consideration. To date, to our knowledge, there has been no systematic investigation of the dynamics of the app stores, in particular app turnover.

Therefore, the overall purpose of this study was to provide a better understanding of the app store environment, with a specific focus on apps for mental health. To achieve this, the primary aim was to establish two metrics for the official Android and iOS app stores: the period of time after which 50% of apps identified by a specific keyword search changed and no longer appeared in the search results (the *search result half-life*); and the period of time after which 50% of apps identified in an initial search were no longer available to download (the *app half-life*). The turnover represented by the search result half-life is relevant to users broadly searching for apps using a keyword search and represents the rate of change of these search results. The app half-life metric is relevant for users searching for a specific app, for example, by following a direct link to the app's page on the app store, and provides an indication of the longevity of an app being available to download, irrespective of its inclusion in the search results (eg, due to decreasing popularity). The secondary aim of this study was to identify the proportion of clinically

relevant apps identified in the search, and to compare the longevity of these apps with that of the clinically nonrelevant apps. The tertiary aim was to identify the proportion of clinically relevant apps that substantiated claims of clinical effectiveness.

Finally, we preformed supplementary analyses to explore the factors that are publicly visible on the app stores, which may affect the search result half-life and the app half-life. These factors include app search result ranking, star rating, and number of downloads. A better understanding of this largely unregulated space will illuminate some of the challenges of mobile health (mHealth) providing valuable health care resources in an uncertain environment.

Methods

Data Collection

We identified an initial baseline group of apps by searching the Australian Google Play store for the Android platform (Google, Mountain View, CA, USA) and the Australian iTunes for the iOS platform (Apple Inc, Cupertino, CA, USA) using the keyword “depression.” Results were limited by the search engines to a maximum of 190 (Android) or 200 (iOS) apps. We also performed secondary searches for “bipolar disorder” and “suicide” to allow a comparison of the search result and app half-lives across other mental health domains as part of the primary aim; however, we did not consider them for clinical relevance in the secondary aim or for substantiation of effectiveness claims in the tertiary aim.

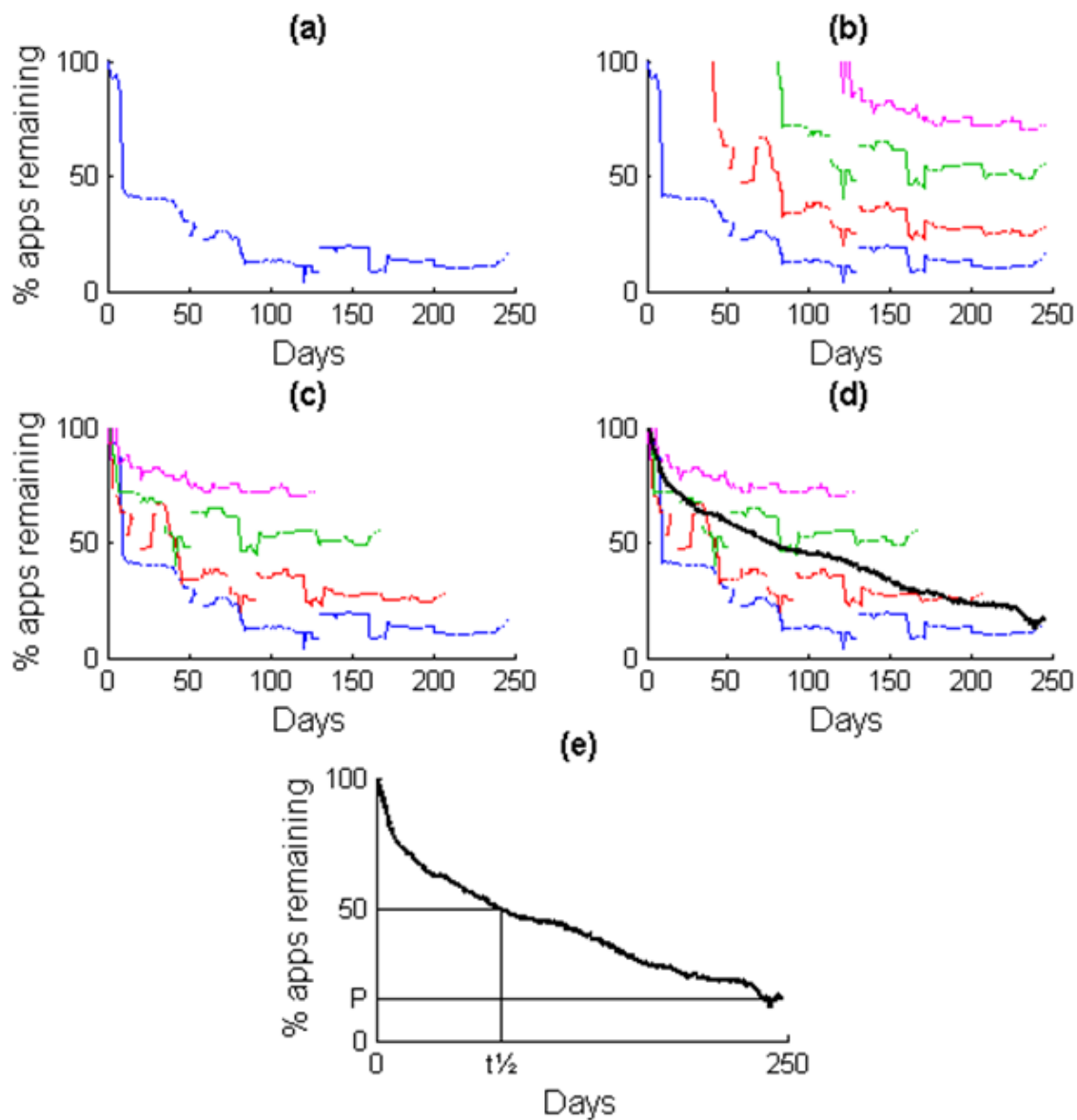
We created a custom script to automatically repeat the app store searches every day over a 9-month period. If an app identified on a previous day no longer appeared in the keyword search results, we performed an additional search for that specific app. This allowed a differentiation between an app that no longer appeared in the search results (eg, due to decreasing popularity) and an app that was no longer available (eg, having being withdrawn by the developer).

We linked longitudinal data for each app using its unique package or bundle identifier within the app store. This unique identifier allows multiple apps with the same name to be differentiated, as well as tracking of a single app if it is rebranded with a new name. [Textbox 1](#) summarizes the data items recorded each day. We recorded user-rated quality through the average app store star rating, as well as the number of reviews that contributed to the average. For consistency across the Android and iOS app stores, we recorded the rating for the entire history of the app rather than the rating for just the current version, which was only available from the iOS store. The number of downloads was only available for Android apps and was reported as a broad category (<50, 50–100, 100–500, 500–1000, 1000–5000, 5000–10,000, 10,000–50,000, 50,000–250,000, and >250,000).

Textbox 1. Mental health app characteristic data collected each day from the Android and iOS app stores.

- App available to download from app store (yes/no)
- App appears in keyword search results (yes/no)
- Search result ranking
- Version
- User rating (star rating)
- Number of user reviews
- Number of downloads (Android only)

Figure 1. The process to calculate the search result half-life ($t_{1/2}$). (a) A time series showing the proportion of apps that still appear in the search results each day, following the initial search on day 1. (b) This process is repeated for each day of the study, shown as different-colored time series (only 4 used to illustrate). (c) The time series shifted to begin at a common time point, such that the day of the search equals day 1. (d) The average of the time series was calculated (black line). (e) The $t_{1/2}$, where the average time series crosses the 50% threshold, and the proportion of apps remaining on the final day of data collection were then calculated. The same process is used to calculate the app $t_{1/2}$, where the y-axes represent the proportion of apps still available to download.



Half-Life Calculation

Figure 1 illustrates the process for calculating the search result half-life. On day 1, we performed a keyword search of the app store and recorded the results. We calculated the proportion of these apps that also appeared in the search results for each subsequent day (Figure 1, part a). We then repeated this for each new search on each day of the study period (Figure 1, part b). Then we shifted each of these time series to a common reference point, such that the day the search was performed was denoted as day 1 (Figure 1, part c), and calculated the average of these time series (Figure 1, part d). We calculated the average values only if data from at least 20 days were available. Calculating the average in this way reduced the sensitivity to changes in the half-life period based on differences in the start of the data collection period, thereby providing a more generalized measure of the dynamics in the app stores. We calculated the search result half-life ($t_{1/2}$) as the number of days after which the average number of apps still appearing in the search results dropped to 50% (Figure 1, part e). We also calculated the percentage of apps remaining on the last day of data collection. We applied a similar process to calculate the app half-life. In this case, the individual time series represented the proportion of apps that were still available to download—that is, if the app either appeared in the keyword search results, or was found by searching for its unique identifier. This contrasts with the search result half-life, which only included apps that appeared in the keyword search results.

Screening for Clinical Relevance

We screened all of the apps identified during the data collection period for clinical relevance. The title and description of each app were independently assessed by 2 reviewers to identify apps related to depression or depressive symptomology, although they did not assess clinical quality or suitability for clinical recommendation. Results of the screening were compared, and discrepancies were resolved by discussion until consensus was achieved. The proportion of clinically relevant apps was calculated. Search result and app half-lives were also calculated

separately for the subgroups of apps that were identified as clinically relevant or not clinically relevant.

Identification of Effectiveness Claims

Apps that were identified as being clinically relevant for depression were assessed for claims of evidence. The apps were initially filtered by searching the app store descriptions for any of the following keywords: effective*, clinical, study, studies, proven, proof, evaluate*, tested, guaranteed, evidence, RCT [randomized controlled trial], or trial. Apps that matched at least one of these keywords were independently screened by 2 reviewers to identify whether the app store description provided evidence of any claims of effectiveness. Results of this screening were compared, and discrepancies were resolved by discussion until consensus was achieved. The proportion of apps providing evidence was then calculated.

Supplementary Subgroup Analyses

We defined subgroups of apps based on publicly visible app store factors that may affect the search result and app half-lives. The first subgroups were defined as the top and bottom 25 apps in the search result rankings. Similar subgroups were defined based on the top and bottom apps in terms of number of reviews, star ratings, and number of downloads (Android only). The search result and app half-life measures for these subgroups were calculated and are reported in [Multimedia Appendix 1](#).

Results

We performed the initial search of the app stores on January 19, 2015 and repeated the search each day until September 21, 2015 (246 days). Data were not available for 35 days due to, for example, problems with network connectivity, resulting in a complete dataset for 211 days during this period. The maximum number of apps was returned for the “depression” keyword search on the first day, specifically 190 Android apps and 200 iOS apps (Table 1). Over the course of the study, 623 unique Android apps and 359 unique iOS apps appeared in the search results for the “depression” keyword. Table 1 also shows the results for the “bipolar disorder” and “suicide” searches.

Table 1. Number of unique apps identified on the first search day and through the data collection period.

Search term	Platform	Apps identified on first day (n)	Total apps (n)
Depression	Android	190	623
	iOS	200	359
Bipolar disorder	Android	159	535
	iOS	40	47
Suicide	Android	190	694
	iOS	144	206

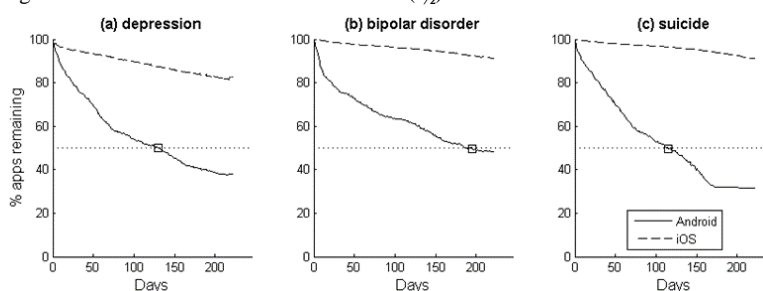
Search Result Half-Life

Figure 2 shows the average time series reflecting the proportion of apps that remained in the search results in subsequent days for the 3 search terms. The trends showed general decreases in the apps that remained in the search results. On Android, the search result half-life for depression apps was $t_{1/2}$ =130 days,

indicating that, on average, 50% of search results changed after 130 days. The search result half-lives for the Android bipolar disorder and suicide searches were 195 and 115 days, respectively. The proportion of search results remaining did not drop below 50% for any of the 3 search terms on iOS, indicating that the search result half-lives exceeded 9 months. Table 2 shows the full results.

Table 2. Search result half-life ($t_{1/2}$) and the proportion of apps remaining in the search results at the end of the study.

Search term	Platform	Search result $t_{1/2}$	Apps remaining at end of study
Depression	Android	130 days	37.8%
	iOS	>9 months	82.7%
Bipolar disorder	Android	195 days	48.4%
	iOS	>9 months	91.1%
Suicide	Android	115 days	31.6%
	iOS	>9 months	91.2%

Figure 2. Average time series trends of apps remaining in the search results for (a) depression, (b) bipolar disorder, and (c) suicide. Crossing points with the 50% threshold are highlighted to indicate the search result half-life ($t_{1/2}$).

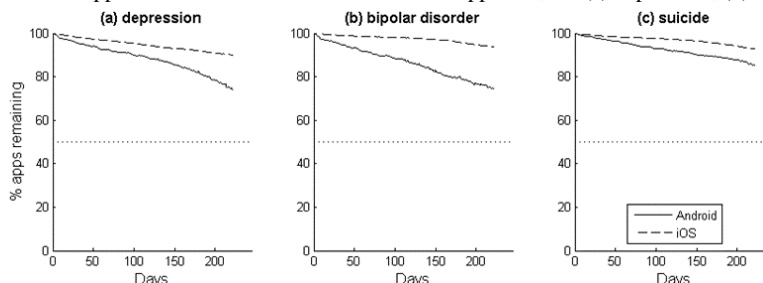
App Half-Life

Figure 3 shows the average time series of the proportion of apps still remaining in the app stores. None of the search terms on either platform crossed the 50% threshold, indicating that the

app half-lives exceeded 9 months for each of the search terms, on both platforms. This indicates that, although apps may have disappeared from the search results, many continued to be available for download. Table 3 shows the full results.

Table 3. App half-life ($t_{1/2}$) and the proportion of apps still available to download from the app stores at the end of the study.

Search term	Platform	App $t_{1/2}$	Apps remaining at end of study
Depression	Android	>9 months	74.2%
	iOS	>9 months	90.0%
Bipolar disorder	Android	>9 months	74.4%
	iOS	>9 months	93.6%
Suicide	Android	>9 months	85.2%
	iOS	>9 months	92.9%

Figure 3. Average time series trends of apps still available to download from the app store, for (a) depression, (b) bipolar disorder, and (c) suicide.

Clinical Relevance

Of the 623 Android apps identified in the depression searches, we screened 197 (31.6%) as being clinically relevant to the

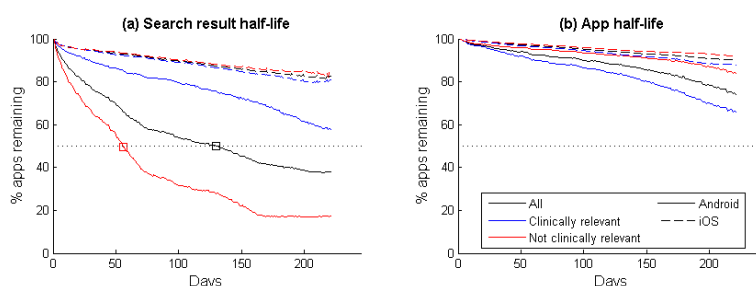
condition. On the iOS platform, we identified 150 of the 359 apps (41.8%) as relevant. Figure 4 and Table 4 summarize the search result and app half-lives for the subgroups of relevant and nonrelevant apps.

Table 4. Search result half-life ($t_{1/2}$), app half-life, and the proportion of apps still available to download from the app stores at the end of the study, grouped by whether they were clinically relevant to depression.

Platform	Clinical relevance sub-group	Search result		Available to download	
		$t_{1/2}$	Apps remaining	$t_{1/2}$	Apps remaining
Android	All	130 days	37.8%	>9 months	74.2%
	Relevant	>9 months	57.9%	>9 months	65.9%
	Not relevant	56 days	17.2%	>9 months	83.8%
iOS	All	>9 months	82.7%	>9 months	90.0%
	Relevant	>9 months	80.7%	>9 months	87.8%
	Not relevant	>9 months	84.4%	>9 months	91.9%

There was very little difference between the iOS apps identified as being clinically relevant and those that were not clinically relevant. A similar proportion remained in the search results after 9 months (80.7% vs 84.4%) and were still available to

download (87.8% vs 91.9%). The difference was greater in the Android apps, where more clinical apps remained in the search results (57.9% vs 17.2%), although fewer remained available for download (65.9% vs 83.8%).

Figure 4. Average time series trends of (a) apps remaining in the search results, and (b) apps still available to download. Plots are shown for all apps on each platform and grouped by whether they were clinically relevant to depression. Crossing points with the 50% threshold are highlighted to indicate the search result half-life ($t_{1/2}$).

Identification of Effectiveness Claims

Across both the Android and iOS platforms, we identified 347 apps as being clinically relevant for depression. We manually screened the 131 of these apps that matched at least one of the keywords related to claims of effectiveness. Of the 347 clinically relevant apps, 9 (2.6%) provided some degree of evidence to support their claims of effectiveness: only 3 apps included a full citation to a study; 3 apps included a partial citation (eg, author and year only); 2 mentioned an unspecified and unreferenced study; and 1 included a link to a website purportedly containing evidence, which we were not able to access at the time of the review.

Discussion

To our knowledge, this is the first examination of the dynamics of app marketplaces, and particularly with a focus on mental health apps. The results indicate that the mental health app environment changes daily. Volatility exists in both the visibility of apps, with half the search results changing within approximately 4 months, and in the continued availability to download apps. The number of clinically relevant apps that were no longer available to download at the end of the study period was equivalent to a depression app disappearing every 3.7 days on Android, every 13.7 days on iOS, or every 2.9 days across both platforms.

Interestingly, both the appearance in search results and continued download availability were more stable in the iOS app store than in the Android store. This is possibly partly due to a greater number of apps in the Android store; therefore, the search engine can display only a subset of the apps, increasing the likelihood of apps rising into, and falling out of, the search results. However, this does not entirely explain our observation, as the results for bipolar disorder were not truncated, but Android apps still had a shorter half-life than their iOS counterparts. The formal app review process undertaken by Apple before making an app available in their store may contribute to this finding.

Over the study period, fewer than half the apps identified using the “depression” keyword were clinically relevant to the disorder. This presents a challenge for mHealth utility and confirms the problematic indexing and searching of mental health apps highlighted previously [11,12]. Shen et al [12] reported that one-fifth of the results of a search for “depression” in the Google, Apple, Windows, Nokia, and BlackBerry app stores did not mention depression in the title or app description, and 75% of the results were not relevant to consumers with the condition. This may be partly due to ambiguity in indexing app descriptions and to developers seeking to increase the visibility of their apps [13].

This volatility presents a challenge for consumers or clinicians seeking apps for mental health conditions, as rapidly changing search results and app availability, along with irrelevant search

results, may affect confidence in this technology to facilitate and extend mental health treatment and support. With approximately one-third of clinically relevant depression Android apps no longer being available after 9 months, clinicians are in danger of recommending apps that are no longer available, and consumers may be left with defunct apps, no longer supported by the developer and without critical updates needed for continued use. Across both the Android and iOS platforms, a quarter of clinically relevant apps were no longer available after the 9-month study period. This rate of turnover is faster than that reported by Huckvale et al [9] in their updated review of asthma apps, which found that a similar proportion were no longer available after a period of 2 years.

The combination of changing search results and uncertain app availability adds to the challenge faced by consumers in identifying relevant mental health apps. To increase the relevance of the search results, searches could be performed within specific categories of apps. Developers assign their apps to predetermined app store categories, but there is no clear way for consumers to search for a keyword within these categories. Such a capability would assist in the disambiguation of terms, for example, clinical depression (a medical app) versus the great depression (a financial app).

The challenge of finding a relevant mental health app is further confounded by the absence of information about app effectiveness and a lack of substantiation of any such claim. Only 2.6% of depression apps identified in this review attempted to substantiate claims of effectiveness. This is lower than the 15% of apps that Leigh and Flatt previously identified as providing evidence for effectiveness [6]; however, this is not surprising considering the apps in their review had been endorsed for inclusion in the NHS Health Apps Library. One possible method of encouraging evaluation and reporting of clinical effectiveness would be for the app stores to allow the inclusion of a PubMed article identifier, allowing users to click through to published articles related to the app. The limited information on clinical effectiveness in app descriptions results in consumers and clinicians basing app choice on incomplete or potentially incorrect information.

There have therefore been calls for systems to assist consumers with app selection, which have primarily focused on the development of app quality indicators. However, this has proven to be difficult. Issues have plagued numerous attempts at app accreditation portals. Privacy and security flaws were uncovered in apps approved by both the Haptique and NHS Health Apps Library accreditation sites, both now offline [9,13]. A recent paper has also demonstrated obstacles with user-based app rating tools: Powell et al [14] demonstrated poor interrater reliability among practitioners rating mental health apps. Wicks and Chiauzzi [15] suggested another solution that places quality assurance at the consumer point-of-contact—specifically, the app stores. However, due to the extensive resources required to assess the health-related content of each submitted app, it is unlikely that app store operators will be able to provide this service. Nevertheless, changes in indexing, store descriptions, and search algorithms would improve search result stability and consumer experience, making relevant apps easier to find and select.

Implications for Systematic Reviews of App Content

This study also highlights a challenge for researchers evaluating and reviewing apps available for psychiatric disorders, as such volatility affects the reproducibility and the medium- to long-term validity of findings. Such app reviews provide a snapshot of the marketplace, but also can be a resource for clinicians to find information about the quality of available apps.

The range of mental health apps available in the iOS app store was relatively stable over a period of 9 months. Researchers reviewing apps can be confident that the body of apps reviewed will still be representative after 9 months, and likely over a year.

The Android app store is more dynamic: one-third of depression-related apps could not be downloaded after 9 months, which poses additional challenges. Researchers conducting reviews of apps must therefore be mindful that the results will become at least partially outdated during the duration of the review process. The rapid rate of change indicates that a rereview would be required two to three times a year to remain current. Given the impracticability of this schedule, we suggest that reviewers (1) clearly indicate the date on which searches are performed, (2) perform an updated search prior to final submission of a review manuscript, and (3) indicate in the final manuscript or supplementary material which apps are still available.

Limitations

A possible limitation of this study was the narrow scope of search terms included. The 3 terms selected (depression, bipolar disorder, and suicide) cannot capture the full spectrum of mental health apps available, nor provide a comprehensive set of apps for specific mental health conditions. The wider applicability of the results for physical health apps is also uncertain. We therefore recommend using a wider set of keywords for searches in future studies. The searches were also limited to the two most popular app stores, for Android and iOS platforms. These results may therefore not be representative of apps for Windows or BlackBerry devices, or apps downloaded through unofficial stores.

A second possible limitation is that the criteria used to screen apps were relatively simplistic, focusing on relevance for one specific condition. We did not assess app quality or the evidence quality of any claims of effectiveness; therefore, the subgroup of clinically relevant apps may not exactly reflect the range of apps that would be recommended in routine practice.

In this study, we tracked apps longitudinally using their unique package or bundle identifier. While this allows tracking of multiple apps with the same name, as well as of individual apps that change names, it does not allow identification of apps that are rereleased with a new identifier. These would appear as distinct apps within the app store and a consumer's handset. Additional in-app content analysis may allow identification of whether an app is relaunched in this manner.

The results of the subgroup analyses are provided in [Multimedia Appendix 1](#); however, these results should be interpreted with caution. This is especially true considering the small sample

sizes in the groups (25 in the top vs bottom comparisons), as spurious results from such analyses are possible [16].

Conclusions

Our study highlights challenges with the app store environments in which mobile apps operate that need to be addressed. The changing nature of the app marketplace, combined with the predominance of nonrelevant search results and lack of effectiveness indicators, may affect the ability of mHealth to fulfill expectations. Future studies may seek to further understand the reasons for app turnover, considering the factors publicly available from app store search results and further content analysis of in-app features. With 50% of search results

changing within 4 months and an app being removed every 2.9 days, the mHealth space presents a challenge for consumers, particularly in the absence of evaluative resources. As such, consumers looking to use apps for mental health should consider the following during app selection: in the absence of app effectiveness information, determine the effectiveness of the app's approach, rather than of the app itself; note the developer of the app, in particular their expertise and reputation in mental health; and examine the update history of the app to gauge whether the developer is still engaged. Ultimately, this form of consumer education about the app store and app use is needed to increase app literacy and reduce the impact of the app store environment until it is addressed.

Acknowledgments

The authors would like to thank Dr Fiona Shand for her feedback on the draft manuscript.

This study is supported by a grant from the Australian National Health and Medical Research Council (NHMRC) and forms part of research conducted by the NHMRC Centre for Research Excellence in Suicide Prevention (CRESP; 1042580). Additionally, ML is supported by a Society of Mental Health 2015 Early Career Research Award, JN is supported by an Australian Postgraduate Award, and HC is supported by an NHMRC Fellowship 1056964. The funders were not involved in the study design, data collection, data analysis, report writing, and decision to submit the manuscript for publication.

Authors' Contributions

All authors contributed to the preparation and approval of the manuscript for publication.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Subgroup analyses.

[PDF File (Adobe PDF File), 73KB - [mhealth_v4i3e96_app1.pdf](#)]

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Abbreviations

NHS: National Health Service

Edited by G Eysenbach; submitted 22.05.16; peer-reviewed by A Powell, M Losa Iglesias, SS Srinivasan; comments to author 09.06.16; revised version received 22.06.16; accepted 20.07.16; published 09.08.16.

Please cite as:

Larsen ME, Nicholas J, Christensen H

Quantifying App Store Dynamics: Longitudinal Tracking of Mental Health Apps

JMIR Mhealth Uhealth 2016;4(3):e96

URL: <http://mhealth.jmir.org/2016/3/e96/>

doi: [10.2196/mhealth.6020](https://doi.org/10.2196/mhealth.6020)

PMID: [27507641](https://pubmed.ncbi.nlm.nih.gov/27507641/)

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Original Paper

Variations in the Use of mHealth Tools: The VA Mobile Health Study

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Abstract

Background: Mobile health (mHealth) technologies exhibit promise for offering patients and their caregivers point-of-need tools for health self-management. This research study involved the dissemination of iPads containing a suite of mHealth apps to family caregivers of veterans who receive care from the Veterans Affairs (VA) Health Administration and have serious physical or mental injuries.

Objective: The goal of the study was to identify factors and characteristics of veterans and their family caregivers that predict the use of mHealth apps.

Methods: Veteran/family caregiver dyads (N=882) enrolled in VA's Comprehensive Assistance for Family Caregivers program were recruited to participate in an mHealth pilot program. Veterans and caregivers who participated and received an iPad agreed to have their use of the apps monitored and were asked to complete a survey assessing Caregiver Preparedness, Caregiver Traits, and Caregiver Zarit Burden Inventory baseline surveys.

Results: Of the 882 dyads, 94.9% (837/882) of caregivers were women and 95.7% (844/882) of veteran recipients were men. Mean caregiver age was 40 (SD 10.2) years and mean veteran age was 39 (SD 9.15) years, and 39.8% (351/882) lived in rural locations. Most (89%, 788/882) of the caregivers were spouses. Overall, the most frequently used app was Summary of Care, followed by RX Refill, then Journal, Care4Caregivers, VA Pain Coach, and last, VA PTSD Coach. App use was significantly predicted by the caregiver being a spouse, increased caregiver computer skills, a rural living location, lower levels of caregiver preparedness, veteran mental health diagnosis (other than posttraumatic stress disorder), and veteran age.

Conclusions: This mHealth Family Caregiver pilot project effectively establishes the VA's first patient-facing mHealth apps that are integrated within the VA data system. Use varied considerably, and apps that were most used were those that assisted them in their caregiving responsibilities.

(*JMIR Mhealth Uhealth* 2016;4(3):e89) doi:[10.2196/mhealth.3726](https://doi.org/10.2196/mhealth.3726)

KEYWORDS

caregivers; telemedicine; stress (psychological); veterans health

Introduction

The US health care system is under tremendous pressure to find ways to reduce costs and improve the quality of care. The responsibility for managing health is shifting from health care providers to patients and their families. This shift reflects an

overall trend in health care, moving from a provider-centered delivery system to a patient- and family-centered participatory model of care [1]. This places greater emphasis on patients and family members to assist in the provision of health care. A variety of technologies are being developed in the commercial health market to support self-management, but these technologies need to be available at the point of need to be most

useful. One specific group of technologies, the mobile health (mHealth) technologies, shows promise for offering patients and their caregivers' point-of-need tools for the self-management of health. These mHealth technologies are defined as apps that run on mobile devices for the purpose of assisting consumers or health care providers in monitoring health status or improving health outcomes [2]. mHealth also encompasses sensors, phones, or other devices worn on the body or carried that transmit and receive data wirelessly. mHealth is a subset of the larger field of electronic health (eHealth) that involves the information technologies used in health care delivery [3].

mHealth technologies that run on accessible mobile platforms may be able to accelerate the transformation of health care by empowering patients and their families with the tools and information that have historically resided with health care professionals. Studies have been published that involve the use of mHealth technologies to improve access to care, improve communication between patients and providers, assist patients in their disease management, and support disease monitoring [4-7]. However, research into the factors that influence use and acceptance of mHealth technology has not kept pace with the rapid proliferation of mHealth tools [2,7]. The factors influencing mHealth use and acceptance may be similar to the factors driving other consumer-based eHealth technologies, but evaluations of mHealth tools have been limited to small studies where key variations in use have not been assessed [6].

Technology-based interventions designed to support caregivers and their care recipients have been used with mostly positive results. mCARE, a mobile phone based secure messaging system designed for veterans, encompasses several assistive components for patient and caregiver self-management [8]. Some of these components were appointment reminders, self-report assessments, health tips, and secure messaging with their provider. More than 90% of users believed that the mCARE system was somewhat or was easy to use [9], demonstrating that this mHealth app was feasible and effective for this population. A randomized trial was conducted to assess the impact of Comprehensive Health Enhancement Support System (CHESS), a Web-based lung cancer information, communication, and coaching system for caregivers on caregiver burden, disruptiveness, and mood [10]. Caregivers randomized to CHESS reported lower burden and negative mood when compared to those in the Internet group, suggesting that eHealth and mHealth interventions similar to CHESS may improve caregivers' coping skills and, in turn, decrease their perceived burden levels. Tele-Savvy, an Internet-based version of the in-person, evidence-based psychoeducation Savvy Caregiver Program for caregivers of veterans with dementia, used synchronous (teleconferences) and asynchronous components (video modules) to provide program access to caregivers in their homes [11]. In an effectiveness trial, caregivers demonstrated moderately high initial levels of burden, anxiety, and depressive symptoms, all of which decreased significantly at follow-up. There were slightly significant increases in caregiver competence. While there is notable literature on the positive outcomes associated with already developed eHealth interventions [12], it is critical to continue to understand the needs of the caregiver users.

Numerous studies have shown that in order for technology to be accepted by consumers it must be perceived as beneficial, be easy to use, fit into the workflow of the end user, and be help desk supported [13-15]. Understanding what caregivers want from technology-based interventions is important for designing mHealth interventions as well as understanding the factors that will likely drive adoption. Focus groups conducted with community-dwelling patients with complex chronic disease and disability and their caregivers revealed that open two-way communication and dialogue between them and their providers, and better information sharing between providers in order to support continuity and coordination of care as issues that eHealth interventions could address and be of most benefit [16]. Additionally, privacy and data security, accessibility, the loss of necessary visits, increased social isolation, provider burden, shifting responsibility onto patients for care management, entry errors, training requirements, and potentially confusing interfaces were all identified as concerns of patients [16] and therefore need to be taken into consideration when developing eHealth/mHealth technologies. Despite these concerns, upwards of 95% of caregivers who use mobile systems find that interactive features of communication technologies assist in their caregiving [13].

The National Alliance for Caregiving reports that caregivers consistently convey a need for more information including information on keeping the care recipient safe at home (37%), managing their own stress (34%), identifying easy activities to do for their care recipient (34%), and finding time for themselves (32%). Only 24% of caregivers of veterans reported receiving the formal training they need to perform their caregiver responsibilities and a majority feel ill-equipped to deal with the veteran's condition, both in terms of having confidence in their own skills or knowing how to seek out additional sources of information or support [17]. In a recent survey of 1000 technology-using family caregivers by the National Alliance for Caregiving [18], caregivers were asked to rate 12 technologies on their potential helpfulness to the caregiver. Those technologies that ranked the highest were Personal Health Record Tracking, Medications Support System, and Symptom Monitoring and Transmission. Those technologies rated the lowest were Caregiving Coaching Software, Transportation Display, and Caregiver Mentor Matching Service. The top benefits expected from the technology include saving time, easing the organizational logistics of caregiving, making the care recipient feel safer, increasing the feeling of being effective, and reducing stress. The overriding barrier expected was the expense of the technology, which is echoed in other studies [13].

Using the organizing framework for caregiver interventions devised by Van Houtven et al [19] as a guide, the purpose of this study was to generate new knowledge on the relative rates of use of different mHealth tools and the characteristics of veterans and their family caregivers that would predict their use of mHealth tools. The Caregiver Intervention Organizing Framework has three main directives: (1) interventions should assess the quantity and/or quality of care provided, (2) consider a broader range of caregiver and care recipient outcomes, and (3) consider a common set of caregiver and care recipient

outcomes to facilitate comparison across studies and over time [19]. As suggested by the aforementioned framework, the quality of the intervention was assessed by using validated caregiving quality measures, as well as the quantity of care (usage rates). In considering a broader range of caregiver and care recipient outcomes, we assessed several different veteran and caregiver factors that we believed may contribute to use of the intervention. Our caregiver outcomes were measured at several points in time to allow for a longitudinal assessment. The results of this study advance our understanding of the potential for adoption of mHealth tools within the context of caregiving.

Methods

Summary

This research study involved the dissemination of iPads (N=881) containing a specific suite of mHealth apps to family caregivers of veterans who receive care in the Veterans Affairs (VA) Health Administration and have serious physical or mental injuries resulting from the post-9/11 wars. Veterans in the study had a combination of physical injuries, mental health diagnoses, and chronic medical conditions, and all were supported by a family caregiver. Thus, these patients exhibit complexities along several axes of the Vector Model of Complexity, a conceptual model that defines patient complexity along axes representing major determinants of health [20]. The suite of mHealth tools was designed by the VA to assist the caregiver in managing veteran posttraumatic stress disorder (PTSD) and pain, as well as provide support with health care-related tasks and help caregivers manage their own stress.

Study Design and Setting

This study was designed as a prospective cohort study with the objective of better understanding the factors that influence the use of a suite of mHealth tools (apps). The study participants were enrollees in the VA Comprehensive Assistance for Family Caregivers program as of May 2013, who agreed to participate in the VA Family Caregiver Mobile Health Pilot program. The VA Comprehensive Assistance for Family Caregivers program supports the care of post-9/11 veterans and service members who have sustained serious physical or mental injuries because of their service in the military. As part of this program, family caregivers provide personal care services to the eligible veteran in the veteran's home. The caregivers are eligible to receive a stipend and health insurance if they do not already qualify for it. In addition, the program provides training, counseling, and respite care to support the caregivers in their caregiving role. The Family Caregiver program is staffed by VA Caregiver Support Coordinators who are located at each VA facility and are responsible for making quarterly home visits to families enrolled in the program and provide ongoing support and assistance to these families.

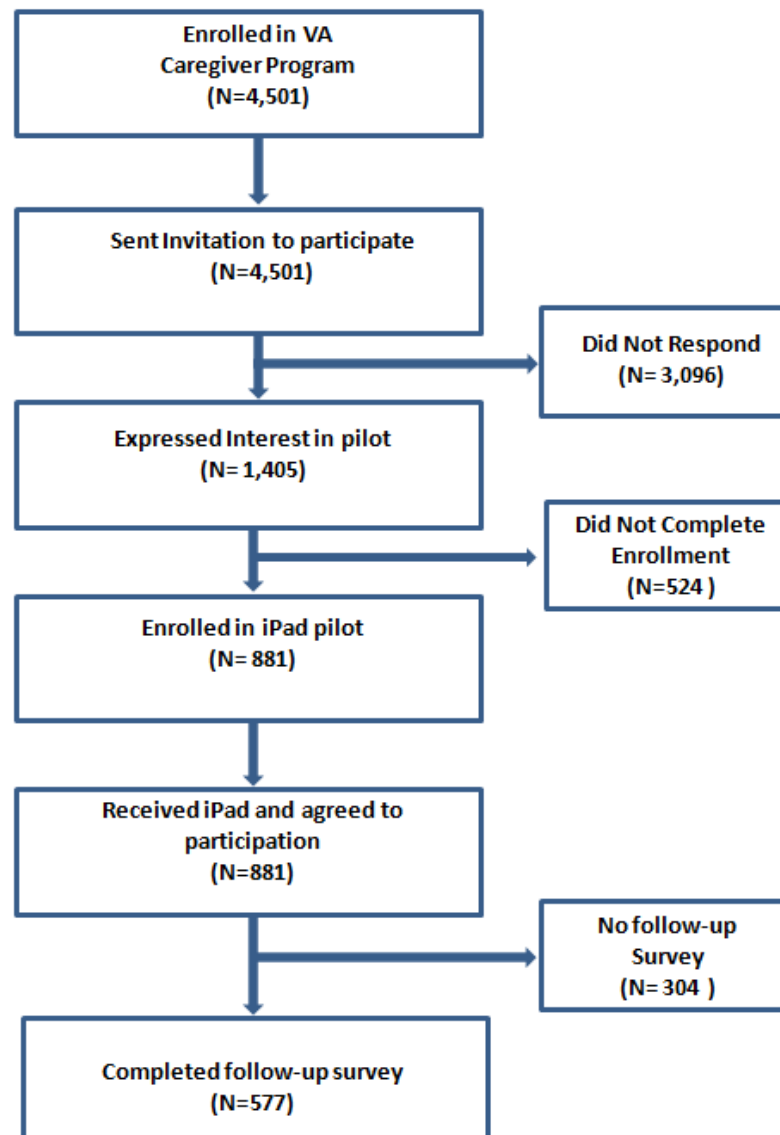
The VA Family Caregiver Mobile Health Pilot is a program that distributed government furnished iPads loaded with VA

mHealth tools to VA family caregivers and the veterans they care for. A 1-year data and service plan was provided with the iPads. The mHealth apps were developed by the VA for this mHealth pilot and were available only to pilot participants. This mHealth Family Caregiver Pilot project established the VA's first patient-facing mHealth apps that are integrated with the VA data system and allowed for the exchange of health-related data between the VA and veterans and their family caregivers.

Study Population and Recruitment

The study population comprised a cohort of 882 caregiver/veteran dyads that received the iPads, which were loaded with a suite of mHealth apps. A dyad is defined as each caregiver and the unique veteran they provide care for. There were two layers of participation within this study group. The first were caregivers who agreed to participate in the VA mHealth pilot program (N=882). VA administrative data were available for this dyad group, and consent was waived based on its use for secondary data analysis. The second was a subset of caregivers from the study group that completed three baseline surveys (n=577) and consented to participate in this research study. This group will be referred to as the survey group. The Institutional Review Boards of both George Washington University and the Veterans Administration approved the study.

The study group participants were recruited by a letter sent in August 2012 to all 4501 caregivers enrolled in the VA Family Caregiver program, inviting them to participate in the VA Family Caregiver Mobile Health Pilot program. The VA received 23.22% (1045/4501) affirmative responses. Prior to distributing the iPads, caregivers were eliminated for distribution from the original 1045 if they (1) were no longer enrolled in the Family Caregiver program or (2) could not verbally confirm their shipping address. A total of 84.31% (881/1045) of iPads were distributed in late May to June 2013 to caregivers, which represented 882 unique caregiver/veteran dyads (one caregiver had 2 veterans under care, resulting in an additional unique dyad). A second letter was sent to the 881 caregivers in the study group who had agreed to participate in the VA Family Caregiver Mobile Health Pilot program, asking them if they would like to participate in a research study that was intended to help the VA better understand the needs and challenges experienced by those using the mHealth apps. The letter indicated that by completing the initial survey the study participant was giving their consent to participate in the research study. An opt-out postcard was also provided and study participants were asked to return the card if they were not interested in participating in the study. Survey information, from three different surveys, was collected on 65.4% (577/882) of study participants (see [Figure 1](#)). The surveys completed by this survey group included the Caregiver Preparedness, Caregiver Traits, and Caregiver Zarit Burden Inventory surveys, which are provided in [Multimedia Appendix 1](#).

Figure 1. Consort diagram: how the study cohort was formed.

Intervention


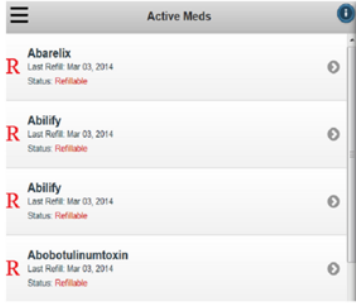

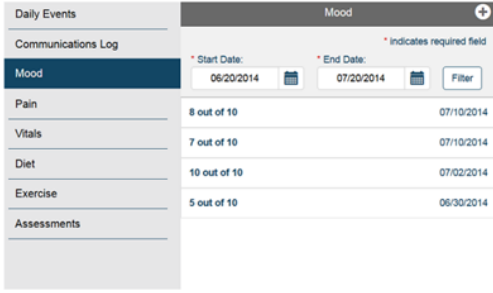


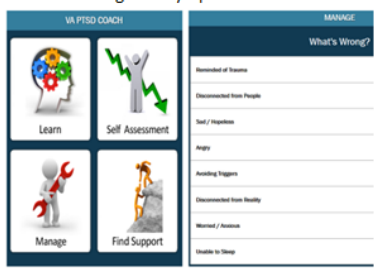

The intervention consisted of supplying an iPad loaded with a suite of mHealth apps designed to support caregivers in their caregiving role. Support was provided to users in the form of a quick start guide for setting up the iPad, a website with answers to frequently asked questions, a monthly newsletter, and a Help Desk that received call inquiries. All of the caregivers participating in the study were also called early on to facilitate obtaining a DS Logon (the Department of Veteran Affairs' self-service account) and were referred to the VA Mobile Health Help Desk for additional assistance.

Several family caregivers/veteran focus groups and usability tests were conducted to assist VA in selecting the types of apps that they would develop and in designing the apps provided in

the mHealth pilot. The apps were developed as native iOS apps for the iOS 6 operating system.

The suite of apps was bundled within the Launchpad app, which functioned as the "container" that housed all of the mHealth apps in the study. The Launchpad enabled the user to log on once rather than having to log on to each individual mHealth app. The logon credential used for the mHealth apps was the Department of Defense's "DS Logon" premium account credential. In many cases, caregivers reported using the veteran's credentials to log on to the VA mHealth apps instead of their own, thus making it difficult to distinguish whether the caregiver or the veteran was using the app. [Figure 2](#) displays the LaunchPad app and the apps as they appeared within the Launchpad.

Figure 2. Descriptions and screenshots of the mHealth apps.

<p>Launchpad: Functions as a container for all study apps. The Launchpad enables the user to log on once rather than having to log on to each individual mHealth app.</p> 	<p>RxRefill: Displays a listing of active medications with their refill status and provides the ability to submit a request for a refill. Screenshot shows active meds, clicking the right arrow will provide detailed information on the medication.</p> 
<p>Summary of Care: Displays data from VA's electronic medical record and was the most frequently used app. The data display includes demographics, diagnoses, surgeries, lab results, medications, radiology reports, consults, demographics, and future clinic appointments. Screenshot shows the graphical display of laboratory results with tabs to display medications, radiology results etc.</p> 	<p>Journal: Enables users to record daily events, communications, mood, pain, vitals, diet and exercise. Screenshot shows the selector for specifying the event to be recorded- choices include communication log, mood, pain, vitals, diet, exercise and assessments (Right) demonstrates the calendar and scale for recording information on mood.</p> 
<p>VA Pain Coach: Provides the tools needed to manage pain. Provides pain management education along with a monthly and daily pain diary and tools for setting, tracking and sharing goals. Screenshots: (Left) shows main screen; choices include learn, self-assessment, manage and goals, (Right) is the selector for inputting data on monthly and daily pain, viewing pain graph, generating pain reports, and scheduling reminders to retake pain assessments.</p> 	<p>Care4Caregiver: Provides support to Caregivers by providing educational content about the emotional consequences of caregiving and techniques for building resilience and managing stress. The Zarit Burden inventory (12 questions) was incorporated into the app for burden self-assessments and tracking. Information about caregiver support resources is also provided.</p> 
<p>VA PTSD Coach: Provides a PTSD screening tool for assessing PTSD symptoms, and enables symptom tracking, provides tools for PTSD management and information on support services. Screenshots (Left) is main screen; choices include Learn, Self-Assessment, Manage and Find Support. (Right) select the symptom being experienced for information on how to manage the symptom.</p> 	<p>Notifications: Enables users to set medication reminders into a calendar.</p> 

Data Collection

Distribution of the mHealth iPad tools began in late May 2013 and continued through June. Data were collected on the use of these tools for each study participant during their intervention

assessment period. The intervention assessment period was defined as the time between when the iPad was received by the study subject and the study end date of September 18, 2013. All the iPads distributed to caregivers were loaded with mobile device management software that allowed the VA to track the

use and location of the devices and wipe the devices if they were stolen or manipulated to remove Apple's security controls. The VA mHealth apps were developed with back-end data metrics that enabled the VA to see the utilization of each VA mHealth app by individual pilot participants and the duration of each use session. Survey data were collected by having study subjects complete three survey instruments that were rendered on the iPads, or by collecting the information verbally over the phone (see [Multimedia Appendix 1](#) for survey items). The survey data fed a back-end database that recorded the date and results of the survey by individual study participant identifier. Descriptive data about the study participants was taken from the VA's administrative databases. Nonusers of the iPad/mHealth apps intervention were contacted in the early part of the study to determine the reasons for nonuse.

Study Variables

The study outcome variable was the use of the mHealth/iPad tools. Use was measured in two ways: (1) a binary outcome representing at least one use of the apps versus no use, and (2) the frequency of app use, for those participants using the apps at least once. Frequency of app use was computed as the number of times the app was used during the intervention assessment period. App use was measured for each individual app and for the entire group of apps.

The predictor variables for the study group dyad (N=882) comprised veteran and caregiver characteristics that were obtained from VA administrative databases and which are described in [Multimedia Appendix 2](#). We received a waiver of Health Insurance Portability and Accountability Act authorization to collect this data as it was deemed infeasible to obtain consent for all caregivers enrolled in the VA Caregiver program (N=4501). The predictor variables for the survey group dyad (n=577) consisted of the same administrative predictor variables as the study group dyad and augmented with variables derived from the three self-administered survey instruments. Surveys could be completed on the iPad. If study participants had not completed the surveys on the iPad within 2 weeks of receiving the iPad and had not returned the opt-out postcard, then they were contacted by research staff and were given the opportunity to complete the survey using a telephone interview. The survey instruments are listed in [Multimedia Appendix 1](#).

The caregiver characteristic survey questions represent a subset of questions derived from the 2009 National Alliance for Caregiving survey [17]. These questions include self-reported demographics, activities of daily living, caregiver stress/strain, and computer skills. The caregiver preparedness questions were taken from the Preparedness for Caregiving Scale [21], which asks caregivers to rate themselves on their perceived readiness for the multiple domains of caregiving. The final summary question of the preparedness survey, "Overall, how well prepared do you think you are to care for your Veteran?," was used as the measure of preparedness because it correlated with the other preparedness questions and had good face validity. The 4-question Zarit Caregiver Burden screening inventory was

the survey instrument used to obtain information about caregiver burden levels [22]. The Zarit Caregiver Burden screening inventory is scored with values ranging from 0-4 for each of the four questions. The total possible score is 16. The total score was used as the measure of burden.

Statistical Analysis

Analysis began by comparing the baseline caregiver/veteran dyad characteristics of the study and survey groups using a chi-square test to determine if the groups differed from one another. Next, a parsimonious set of predictor variables was selected by examining the bivariate relationships between caregiver and veteran dyad characteristics and app use. The strength of the bivariate analysis was assessed, and those variables strongly associated with the outcome variable were reserved as potential predictor variables. Next, a correlation analysis between pairs of potential predictor variables was performed. When two variables were highly correlated, one was dropped or a composite variable was created in order to reduce model multicollinearity. Finally, multivariate modeling was undertaken using SAS version 9.3 software, to predict app use. Logistic regression modeling was performed to predict the binary use/nonuse outcome for the seven apps as a whole. The analysis was then repeated using negative binomial regression modeling. The binary use/nonuse analysis was intended to provide information on the factors associated with initial interest in using the app, while the frequency analysis was intended to provide information on the factors driving sustained use of the app once app use was established.

Multivariate models were assessed for fit. Logistic regression models were evaluated using a Hosmer and Lemeshow Goodness of Fit statistic of 0.05 or greater and a C-statistic greater than 0.65. Negative binomial fit was assessed by evaluating if the value of the Pearson chi-square statistic divided by the degrees of freedom was close to the value of 1 and by ensuring that the dispersion parameter was not equal to 0. Model results were assessed using odds ratios in the logistic regression model. Since our models were guided by a specific research purpose, we report each *P* value "as is" without further adjustment for the total number of tests conducted.

Results

Table 1 displays the characteristics of the study and survey groups. The chi-square analysis of the study group (N=882) and the survey group (n=577) showed that they were not significantly different from one another with respect to their baseline characteristics. In the study group, the majority of caregivers (94.9%, 837/882) were women and the majority of veteran recipients were men (95.7%, 844/882). The average age of the caregiver was 40 years, and the average age of the veteran was 39 years. The caregivers were primarily spouses (89.3%, 788/882) and were geographically dispersed across the United States with 60.0% (529/882) living in urban locations and 39.8% (351/882) living in rural locations.

Table 1. Baseline characteristics of caregivers and veterans dyads (N=882).

Baseline characteristics	Study group (N=882)	Survey group (n=577)
Caregiver characteristics		
Caregiver gender, n (%)		
Female	837 (95.01)	547 (96.13)
Caregiver age, mean (SD)	40.16 (10.20)	40.08 (9.92)
Relationship of caregiver to veteran, n (%)		
Spouse	788 (89.34)	521 (91.40)
Parent	69 (7.82)	37 (6.49)
Tier funding level for caregiver, n (%)		
Tier 1	145 (16.57)	98 (17.28)
Tier 2	308 (35.20)	199 (35.10)
Tier 3	422 (48.23)	270 (47.62)
Veteran characteristics		
Veteran gender, n (%)		
Female	38 (4.31)	16 (2.77)
Male	844 (95.69)	554 (97.19)
Veteran race, n (%)		
African American	153 (17.35)	88 (15.44)
Missing	41 (4.65)	25 (4.39)
Other	54 (6.12)	29 (5.09)
White	634 (71.88)	428 (75.09)
Veteran age group in years, n (%)		
≤34	317 (35.94)	208 (36.49)
≥35 and ≤44	307 (34.81)	193 (33.86)
≥45 and ≤54	199 (22.56)	134 (23.51)
≥55	59 (6.69)	35 (6.14)
Veteran service-connected category, n (%)		
<80	131 (14.94)	86 (15.14)
≥80	746 (85.06)	482 (84.86)
Veteran Aid and Attendance recipient, n (%)		
No	822 (93.30)	530 (93.15)
Yes	59 (6.70)	39 (6.86)
Time in program (days), mean (SD)	529.02 (117.03)	529.00 (117.54)
Veteran income (US \$), mean (SD)	35,038.15 (17,286.83)	35,377.63 (17,316.16)
Monthly stipend amount (US \$), mean (SD)	1534.27 (625.39)	1530.50 (629.94)
Veteran marital status, n (%)		
Married	766 (87.14)	515 (89.35)
Divorced	36 (4.10)	17 (2.95)
Other	77 (8.76)	42 (7.28)
Branch of service, n (%)		
Army	650 (77.66)	428 (79.11)
Marines	90 (10.75)	62 (11.46)
Navy/Coast Guard	57 (6.81)	28 (5.18)

Baseline characteristics	Study group (N=882)	Survey group (n=577)
Air Force	40 (4.78)	23 (4.25)
Living location, n (%)		
Urban	529 (60.11)	337 (59.23)
Rural	351 (39.87)	232 (40.77)
Veteran diagnoses, n (%)		
PTSD	600 (68.03)	390 (68.42)
Other injury (nerve, multiple fractures)	381 (43.20)	247 (42.33)
Traumatic brain injury (TBI)	268 (30.39)	180 (31.58)
Other mental health diagnosis	192 (21.77)	126 (22.11)
Other illness (diabetes, chronic obstructive pulmonary disease, stroke, cancer)	148 (16.78)	89 (15.61)
Receiving polytrauma care	144 (16.35)	104 (18.28)
Spinal cord disorder	77 (8.73)	54 (9.47)
Amputation	28 (3.17)	18 (3.16)
Vision impairment	25 (2.83)	13 (2.28)
Substance abuse	9 (1.02)	7 (1.23)
Veteran service utilization, mean (SD)		
Mental health visits	3.49 (7.57)	3.20 (6.50)
Ancillary outpatient visits	4.97 (5.66)	4.91 (5.78)
Medical outpatient visits	1.92 (2.19)	1.90 (2.16)
Specialty outpatient visits	0.40 (1.55)	0.42 (1.63)
Surgical outpatient visits	0.72 (1.50)	0.72 (1.51)
Other outpatient visits	0.02 (0.20)	0.02 (0.19)

Table 2 displays the outcome variable, App Use, as both distinct users (used at least once) and as frequency of use in the study and survey groups. Table 2 shows that 29.7% (262/882) of the study group never used one of the seven mHealth apps. In the survey group (n=577), the number of nonusers was 13.5% (78/577). An analysis of these nonusers was conducted to

understand how many of the caregiver/veterans dyads lacked the DS Logon credentials required to access the VA mHealth Apps. In the study group, 43.1% of the nonusers (113/262) did not have a DS Logon credential and 33% of the nonusers (23/78) in the survey group did not have a DS Logon credential.

Table 2. mHealth app use in study and survey groups (N=882).

App name	Study group (=882)				Survey group (n=577)			
	Distinct users	Percentage using	Frequency using	Number of uses per dyad, mean (SD)	Distinct users	Percentage using	Frequency using	Number of uses per dyad, mean (SD)
All Apps	620	0.70	8,794	14.18 (14.22)	499	0.86	7.839	15.71 (14.79)
Notifications	523	0.59	1,652	3.16 (2.71)	429	0.74	1,478	3.45 (2.84)
Summary of Care	522	0.59	2,727	5.22 (5.48)	436	0.76	2,397	5.50 (5.46)
Rx Refill	504	0.57	1,737	3.45 (3.00)	422	0.73	1,522	3.61 (3.01)
Care4Caregivers	372	0.42	756	2.03 (1.40)	327	0.57	690	2.11 (1.43)
Journal	290	0.33	1,102	3.80 (6.58)	244	0.42	988	4.05 (6.99)
VA PTSD Coach	220	0.25	392	1.78 (1.41)	200	0.35	369	1.85 (1.46)
VA Pain Coach	215	0.24	428	1.99 (2.47)	193	0.33	395	2.05 (2.58)

A subset of nonuser caregivers (n=96) were contacted by phone in the early phase of the study to understand the reasons for nonuse of the apps. Main reasons for nonuse included having DS Logon issues (55%, 53/96), having issues with the apps (22%, 21/96), or experiencing other usability issues (9%, 9/96).

The distribution of the frequency of app use displayed a negative binomial with a zero inflated dispersion. Figure 3 displays the frequency distribution of app use for the seven mHealth Apps as a whole in the survey group (n=577).

The results of the bivariate analysis that crossed each potential predictor variable in the survey group (n=577) with the outcome variable, frequency of mHealth app use, are displayed in Tables 3, 4, and 5. Tables 3 and 4 contain caregiver-specific variables and Table 5 contains veteran-specific variables. mHealth app use was categorized into four levels: high (>18 uses), medium (>7 and ≤18), low (>0 and ≤7), and no use. Use categories were constructed by selecting use ranges that produced three relatively equal groupings among the app users.

Table 3. Results of bivariate analysis of caregiver characteristics and frequency of total app use in the survey group.

	Total	High use (>18), (n=195), %	Medium use (>7 and ≤18), (n=175), %	Low use (>0 and ≤7) (n=129), %	No use (n=78), %	
Caregiver age, years						
18-34	196	30.1	32.7	26.5	10.7	
35-49	266	38.7	29.3	20.3	11.7	
≥50	115	28.7	28.7	22.6	20.0	
Caregiver education						
Less than High School / High School Grad / GED / Tech School	144	37.5	25.0	22.2	15.3	
Some college/ College grad/ Grad school/ Grad work	433	32.6	32.1	22.4	12.9	
Caregiver race						
White	393	34.1	31.8	22.7	11.5	
African American	76	29.0	27.6	26.3	17.1	
Other	108	36.1	26.9	18.5	18.5	
Caregiver gender	Female	556	33.6	30.6	22.5	13.3
Caregiver health						
Excellent	48	22.9	33.3	16.7	27.1	
Very good/ Good	437	33.4	30.0	23.6	13.0	
Fair/ Poor	92	41.3	30.4	19.6	8.7	
Urban/Rural^a						
Rural	234	33.3	33.8	22.2	10.7	
Urban	342	34.2	27.8	22.5	15.5	
Relationship ^a	Spouse	527	35.3	29.8	23.0	12.0
Tech adoption						
Early adopter	160	32.5	35.0	21.3	11.3	
Mid adopter	247	36.0	29.2	23.9	10.9	
Late adopter	170	31.8	27.7	21.2	19.4	
Computer skills^a						
1 or 2 - Limited	39	33.3	23.1	12.8	30.8	
3	131	35.1	25.2	25.2	14.5	
4	208	30.8	34.1	21.6	13.5	
5	174	39.1	32.8	23.6	4.6	

^aIncluded in the final set of predictor variables.

The influence of caregiver strain, burden, preparedness, and health was most notable in the bivariate analysis, with a high usage associated with poor health, low preparedness, high burden, and high strain. Caregiver age and education showed

an association with high use, with middle-aged and lower-educated caregivers showing higher use. Those with higher reported computer skills tended to be higher users of the apps.

Table 4. Results of bivariate analysis of caregiving behaviors and frequency of total app use in the survey group.

	Total	High use (>18) (n=195), %	Medium use (>7 and ≤18) (n=175), %	Low use (>0 and ≤7) (n=129), %	No use (n=78), %	
Choice in caregiving	Yes	371	35.6	29.7	21.6	13.2
Hours spent caregiving						
	≤20 hours	58	34.5	36.2	20.7	8.6
	21-40 hours	139	30.9	32.4	28.8	7.9
	41-80 hours	216	36.1	30.1	20.8	13.0
	≥80 hours	164	32.9	26.8	19.5	20.7
Caregiver strain						
	1 - Not a strain at all	128	33.6	29.7	19.5	17.2
	2	198	30.8	28.8	28.8	11.6
	3	184	34.8	33.2	19.7	12.5
	4 or 5 - Very much a strain	67	40.3	28.4	16.4	14.9
Caregiver stress						
	1 or 2 - Not at all stressful	186	29.0	28.5	22.6	19.9
	3	165	35.8	29.1	25.5	9.7
	4	134	36.6	32.1	18.7	12.7
	5 - Very stressful	92	35.9	33.7	21.7	8.7
Years caregiving						
	≤3 years	237	30.4	29.1	28.3	12.2
	4-7 years	217	39.6	32.3	16.1	12.0
	>7 years	122	30.3	29.5	22.1	18.0
Preparedness						
	Not at all, Not Well, Somewhat Prepared	75	44.0	30.7	16.0	9.3
	Pretty Well Prepared	255	36.9	28.6	25.1	9.4
	Very Well Prepared	228	28.1	32.0	19.7	20.2
Zarit Burden						
	High Burden	153	37.9	34.0	20.3	17.9
	Medium Burden	253	34.8	31.2	24.5	9.5
	Low Burden	126	31.0	28.6	16.7	23.8

Similar to caregivers, veterans in the middle-age range were higher users of the apps. Veterans assessed at a monthly stipend level of Tier 1 were higher users. The Tier level represents the amount of work required of the caregiver to meet the care needs of the veteran. Tier 3 represents the highest amount of work

and Tier 1 the lowest. Mental health conditions, other than PTSD, were associated with higher app use. Those veterans with a higher percentage of service connected related injuries were associated with lower app use.

Table 5. Results of bivariate analysis of veteran characteristics and frequency of app use in the survey group.

		Total	High use (>18) (n=195), %	Medium use (>7 and ≤18) (n=175), %	Low use (>0 and ≤7) (n=129), %	No use (n=78), %
Veteran age group^a, years						
	≤34	210	28.1	31.4	27.1	13.3
	≥35 and ≤54	332	38.0	30.1	19.3	12.7
	≥55	35	28.6	25.7	22.9	22.9
Monthly stipend tier						
	Tier 1	98	40.8	31.6	18.4	9.2
	Tier 2	200	30.0	25.5	11.5	
		33.0				
	Tier 3	276	31.9	30.1	21.7	16.3
Veteran race						
	Black	92	28.3	27.2	26.1	18.5
	Missing	25	32.0	20.0	28.0	20.0
	Other	29	34.5	20.7	34.5	10.3
	White	431	35.0	32.3	20.4	12.3
Branch of service						
	Air Force	24	33.3	25.0	25.0	16.7
	Army	430	35.1	31.9	20.9	12.1
	Marines	64	28.1	28.1	26.6	17.2
	Navy/ Coast Guard	30	36.7	26.7	20.0	16.7
TBI DX	1	182	28.0	35.2	19.2	17.6
PTSD DX	1	392	33.9	30.9	21.2	14.0
Other Mental Health DX ^a	1	130	40.8	23.9	27.7	7.7
Other Medical DX	1	97	35.1	29.9	21.7	13.4
Major Trauma DX	1	69	33.3	18.8	31.9	15.9
Other Nerve Injury DX	1	251	34.3	28.3	21.9	15.5
Veteran income, US \$						
	<20,000	104	33.7	25.0	26.9	14.4
	20,000-40,000	318	35.2	32.4	21.1	11.3
	>40,000	151	30.5	29.8	21.9	17.89
Time in program						
>300 and ≤400	109	37.6	28.4	19.3	14.7	
	>400 and ≤500	145	30.3	30.3	25.5	13.8
	>500 and ≤600	129	32.6	35.7	20.2	11.6
	>600 and ≤700	153	34.6	27.5	23.5	14.4
	>700 and ≤800	41	36.6	29.3	22.0	12.2
Service connection						
	<80	86	40.7	27.9	19.8	11.6
	≥80	489	32.7	30.9	13.9	
				22.5		

		Total	High use (>18) (n=195), %	Medium use (>7 and ≤18) (n=175), %	Low use (>0 and ≤7) (n=129), %	No use (n=78), %
Aid and Attendance recipient	Yes	39	25.6	35.9	20.5	18.0
Marital status						
	Divorced	17	5.9	35.3	29.4	29.4
	Married	515	34.8	30.9	22.7	11.7
	Other	42	35.7	21.4	16.7	26.2
Polytrauma care ^a	Yes	104	24.0	34.6	20.2	21.2

^aIncluded in the final set of predictor variables.

A correlation analysis was performed on the set of potential predictor variables that had a strong association with the outcome variable. Many variables were strongly correlated with one another, for example, caregiver age and veteran age, relationship and marital status, as well as caregiver stress, burden, health, and preparedness, and education with computer skills. A parsimonious set of predictor variables was selected based on the results of the bivariate and correlation analyses. The final set of variables selected for modeling included veteran age, caregiver-veteran relationship, urban-rural living location,

other mental health diagnosis, receiving polytrauma care, overall preparedness survey question, and computer skills.

Logistic regression modeling was performed to predict at least one use of the mHealth Apps. Table 6 displays the results of modeling the administrative explanatory for the study group (N=882) (Model 1a) and the administrative explanatory variables plus two additional survey variables, Caregiver Preparedness and Computer Skills, on the survey group (n=577) (Model 2b). The negative binomial analysis demonstrated similar associations (data not shown).

Table 6. Logistic regression model predicting at least one use of a clinical mHealth app.

Parameter	Level	Model 1a (N=882)			Model 2b (n=577)		
		OR	95% CI	Pr>χ ²	OR	95% CI	Pr>χ ²
Assessment period		1.036	1.023-1.050	<.001	1.010	0.975-1.047	.57
Veteran age		0.978	0.962-0.994	.007 ^c	0.983	0.953-1.014	.28
Caregiver-veteran relationship	Spouse vs Other	2.428	1.517-3.885	.001 ^c	1.591	0.637-3.975	.32
Urban / Rural living location	Rural vs Urban	1.514	1.104-2.075	0.01 ^c	1.374	0.777-2.430	.28
Other mental health diagnosis	1 vs 0	1.629	1.104-2.404	0.01 ^c	2.602	1.117-6.058	.03 ^c
Receiving polytrauma care	No vs Yes	1.260	0.847-1.874	0.25	1.844	0.981-3.468	.06
Computer skills		—	—	—	1.680	1.288-2.191	<.001 ^c
Preparedness		—	—	—	0.588	0.381-0.906	.02 ^c

^aModel 1 is based on data from all veteran and caregiver dyads that received the iPad and uses Hosmer and Lemeshow Goodness-of-Fit Test $\chi^2=12.76$ PR> $\chi^2=.121$, C-Statistic=0.65.

^bModel 2 includes all the data from Model 1 and additional survey variables and uses Hosmer and Lemeshow Goodness-of-Fit Test $\chi^2=.21$ PR> $\chi^2=.21$ C-Statistic=0.72.

^cStatistically significant at the .05% level.

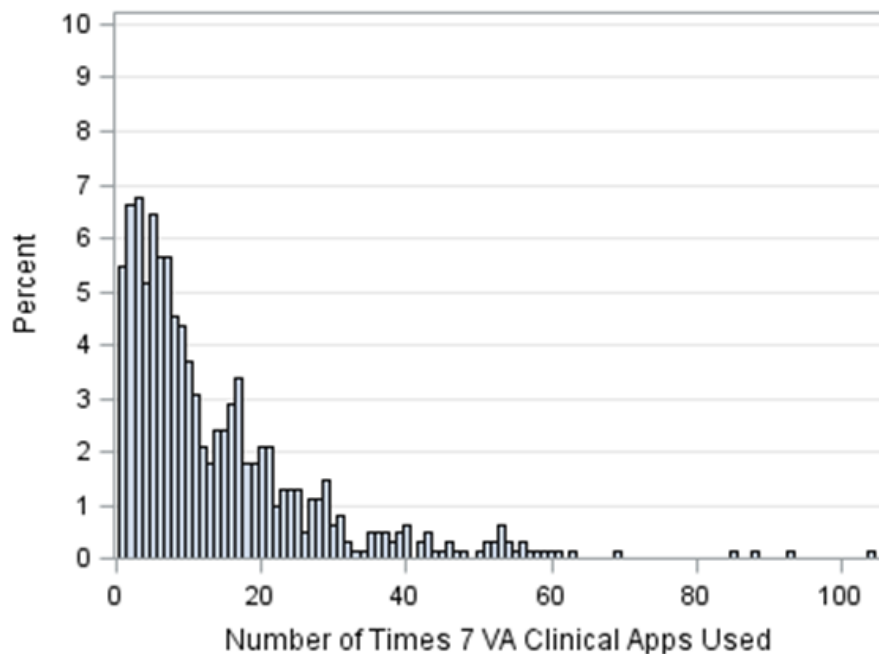
For the study group (N=882), significant predictors of using an mHealth App at least once included (1) assessment period—the longer the caregiver/veteran dyad had the mHealth/iPad intervention, the more likely it was they would use it, (2) veteran age—for every one unit increase in age, the likelihood of using a clinical app declined by 0.02%, (3) if the caregiver of the veteran is a spouse, then the odds of using at least one clinical app was 2.4 times greater, (4) those living in a rural location had a 1.5 times greater chance of using a clinical app than those living in a urban location, and (5) veterans with a mental health diagnosis, other than PTSD, were 1.6 times more likely to use a clinical app. When a dummy variable was added to the model

to reflect if the caregiver/veteran dyad had a logon credential, veteran age was no longer significant. The significance of this is that veteran age is likely a proxy for the likelihood of having a DS Logon credential. Younger veterans tend to have DS Logon credentials issued when they separated from the service, while this was not true for older veterans.

For survey group (n=577), the only administrative predictor that remained significant was the diagnosis of “Other Mental Health,” which resulted in a 12% increase in the likelihood of using a clinical app compared with those who do not have this diagnosis. Two survey variables were significant predictors.

Each one unit increase in caregiver computer skill competency increased the likelihood of using a clinical app by 28%, and each one unit increase in caregiver preparedness decreased the chances of using a clinical app by 42%.

Figure 3. The frequency distribution of total mHealth app use of the caregivers who completed the baseline surveys.



Discussion

Principal Considerations

To the author's knowledge, this is the first study that has looked at factors that predict the use of mHealth apps in the context of caregiving. The study provided a number of key insights. It was found that the mHealth apps used most frequently in this population of caregivers of seriously injured veterans were the Summary of Care, Rx Refill, and Notification apps. Apps used less frequently included the Care4Caregiver Journal, PTSD Coach, and Pain Coach apps. The implication of this finding, based on IT acceptance models, is that use is driven by the perceived usefulness of the app and ease of use [23-25].

The picture that emerged from the bivariate analysis is that there are four principal components driving mHealth app usage. The first relates to the amount of time and effort required for the caregiver to manage the veteran's medical condition. The second relates to the caregiver strain and preparedness for caregiving. The third has to do with the demographics of the caregivers and veterans. The fourth has to do with computer skills and technology adoption. Caregivers providing care for seriously injured veterans, such as those in polytrauma care or with a high percentage of service-connected conditions as reflected by a high Tier rating (ie, Tier 3) in the caregiver stipend, was associated with decreased app use. This may be related to fewer hours available by the caregiver to use the apps, or it could reflect that use of the apps was a combination of caregiver and veteran use and seriously injured veterans were not as likely to use the apps. The variable selected to represent this dimension in this study was Polytrauma Care. The second component is related to the caregiver's and veteran care recipient's physical

and mental health condition. Lower health and caregiver preparedness scores coupled with higher strain scores were associated with higher app use. The variable selected to represent the state of the caregiver is Overall Preparedness for Caregiving. The veteran's medical condition was also an important factor with a diagnosis of a mental health condition, excluding PTSD, being associated with higher usage. Consistent with other studies on factors driving eHealth, demographics were found to be important drivers associated with app use. Increased age of both the veteran and caregiver decreased app use, as did being a non-spouse caregiver. The fourth and final component was related to caregiver computer skills. Those with poor computer skills and low technology adoption rates were less likely to use the Apps; the variable Computer Skills was chosen to represent this dimension.

The results of the logistic regression modeling predicting use versus nonuse of the apps revealed that at least one use of any of the seven study apps was increased by living in a rural location, being a spouse caregiver, being younger, taking care of a veteran with a mental health condition (excluding PTSD), having better computer skills, and feeling less prepared for caregiving. These findings that older individuals and those with lower computer literacy make less use of consumer health technologies is consistent with other research [26,27]. Rural living locations have often been associated with lower eHealth use due to lower Internet access in rural areas [28]. However, in this study, rural living was associated with increased odds of using the mHealth intervention, which is likely associated with the data plans provided to study participants reducing their requirement for Internet access.

The surprising 30% nonuse rate found in the study group deserves further investigation. We know that about 50% of these nonusers did not obtain the proper logon credentials required to use the mHealth intervention. The barriers created by the requirement to obtain user credentials are an important consideration when designing future mHealth apps. Another 30% of nonuse was accounted for by issues the users had with the apps. Although the design of many of the apps was informed by collecting feedback from caregiver focus groups, this finding highlights the need to collect regular feedback from app users to understand usability issues so that these issues can be addressed in subsequent app releases. A surprising finding from this study was the low use of the PTSD app in patients with PTSD. This may be related to the fact that the VA already released a PTSD app to public app stores prior to this study. This was the only one of the study apps that has been released to the public during the course of the study.

Limitations

It should be noted that this was a pragmatic study examining a target population that is dissimilar to the general patient and caregiver populations, and therefore care must be exercised in extrapolating the results. The study population was restricted to veterans with multiple comorbidities who have sustained serious injuries due to their service in the military. The prevalence of mental health conditions in this population was high and the average age of the population was young, with the average age equal to 39 years. The caregivers in this study were also young, with the average age equal to 40 years old, and therefore do not reflect the typical family caregiver found in the general population. Due to their unique health care needs,

future research, both qualitative and quantitative in nature, should aim to evaluate the effects that programs like the Comprehensive Assistance for Family Caregivers program have on veteran/caregiver dyads.

Conclusions

This study was designed to contribute to our understanding of the factors that drive veteran and caregiver mHealth use within the caregiving context. The mHealth apps that were most used by family caregivers and their veteran recipients were those that provided information from their health care record and assisted them in their caregiving responsibilities, specifically, filling prescriptions and setting medication reminders. This is consistent with previous research indicating that patients value having health information electronically in one place so that it can be shared and used for the management of their health care. Another key finding in this study was that when tablets with data services plans are provided to health care consumers, those in rural areas were more likely to use the technology than those in urban locations. Computer skills and age continue to matter in mHealth usage as they have in other consumer health technologies, reinforcing the need to provide age-target support to avoid disenfranchising older, less computer-savvy individuals. A final key finding of this study was that those caregivers reporting that they are less prepared for caregiving were more likely to use mHealth tools to support their caregiving responsibilities. This mHealth family caregiver VA pilot project was the first to identify predictors of the use of patient-facing mHealth apps that are integrated within the VA data system and that facilitate the exchange of health-related data between the VA and veterans and their family caregivers.

Acknowledgments

The author would like to acknowledge Thomas Houston and everyone on his staff that helped, Kevin Todd who assisted in pulling data, and Brian Olinger and Jessica Bralley who both helped in the distribution of the iPads.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Survey instruments used for baseline data collection.

[[PDF File \(Adobe PDF File\), 56KB - mhealth_v4i3e89_app1.pdf](#)]

Multimedia Appendix 2

Description of variables obtained from VA administrative databases.

[[PDF File \(Adobe PDF File\), 34KB - mhealth_v4i3e89_app2.pdf](#)]

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Abbreviations

CHESS: Comprehensive Health Enhancement Support System

PTSD: post-traumatic stress disorder

TBI: traumatic brain injury

VA: Veterans Affairs Health Administration

Edited by G Eysenbach; submitted 24.07.14; peer-reviewed by W Nilsen, C Turvey, B Wakefield; comments to author 25.09.14; revised version received 13.07.15; accepted 28.03.16; published 19.07.16.

Please cite as:

Frisbee KL

Variations in the Use of mHealth Tools: The VA Mobile Health Study

JMIR Mhealth Uhealth 2016;4(3):e89

URL: <http://mhealth.jmir.org/2016/3/e89/>

doi: [10.2196/mhealth.3726](https://doi.org/10.2196/mhealth.3726)

PMID: [27436165](https://pubmed.ncbi.nlm.nih.gov/27436165/)

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Original Paper

An Evidence-Based Antimicrobial Stewardship Smartphone App for Hospital Outpatients: Survey-based Needs Assessment Among Patients

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Abstract

Background: Current advances in modern technology have enabled the development and utilization of electronic medical software apps for both mobile and desktop computing devices. A range of apps on a large variety of clinical conditions for patients and the public are available, but very few target antimicrobials or infections.

Objective: We sought to explore the use of different antimicrobial information resources with a focus on electronic platforms, including apps for portable devices, by outpatients at two large, geographically distinct National Health Service (NHS) teaching hospital trusts in England. We wanted to determine whether there is demand for an evidence-based app for patients, to garner their perceptions around infections/antimicrobial prescribing, and to describe patients' experiences of their interactions with health care professionals in relation to this topic.

Methods: A cross-sectional survey design was used to investigate aspects of antimicrobial prescribing and electronic devices experienced by patients at four hospitals in London and a teaching hospital in the East of England.

Results: A total of 99 surveys were completed and analyzed. A total of 82% (80/98) of respondents had recently been prescribed antimicrobials; 87% (85/98) of respondents were prescribed an antimicrobial by a hospital doctor or through their general practitioner (GP) in primary care. Respondents wanted information on the etiology (42/65, 65%) and prevention and/or management (32/65, 49%) of their infections, with the infections reported being upper and lower respiratory tract, urinary tract, oral, and skin and soft tissue infections. All patients (92/92, 100%) desired specific information on the antimicrobial prescribed. Approximately half (52/95, 55%) stated it was "fine" for doctors to use a mobile phone/tablet computer during the consultation while 13% (12/95) did not support the idea of doctors accessing health care information in this way. Although only 30% (27/89) of respondents reported on the use of health care apps, 95% (81/85) offered information regarding aspects of antimicrobials or infections that

could be provided through a tailored app for patients. Analysis of the comments revealed the following main global themes: knowledge, technology, and patient experience.

Conclusions: The majority of respondents in our study wanted to have specific etiological and/or infection management advice. All required antimicrobial-related information. Also, most supported the use of electronic resources of information, including apps, by their doctors. While a minority of people currently use health apps, many feel that apps could be used to provide additional support/information related to infections and appropriate use of antimicrobials. In addition, we found that there is a need for health care professionals to engage with patients and help address common misconceptions around the generation of antimicrobial resistance.

(*JMIR Mhealth Uhealth* 2016;4(3):e83) doi:[10.2196/mhealth.5243](https://doi.org/10.2196/mhealth.5243)

KEYWORDS

mobile electronic devices; mHealth; mobile health; antimicrobial resistance; patient involvement

Introduction

The increasing burden of antimicrobial resistance is a well-known global phenomenon which requires national [1] and international collaboration [2] for effective prevention, control, and management. Indeed, it is estimated that antimicrobial resistance (AMR) currently claims 50,000 lives per year across Europe and the United States [3]. The current forecast suggests that if the situation remains unchecked, AMR will be the leading cause of death in humans by 2050, surpassing cancer and diabetes-related diseases, claiming 10 million deaths annually and leading to economic losses of US \$100.2 trillion [3].

Medical health technology apps offer a practical way to increase accessibility and navigability of medical information during routine provision of patient care by health care professionals. The benefits of medical apps to facilitate optimal patient care and self-management has recently been reported in sexual health [4], HIV/AIDS management [5], increasing fitness levels [6], and cancer prevention [7] in rural communities.

A number of studies have also explored and evaluated the use of apps targeted at people living with a range of clinical conditions, including diabetes [8], asthma [9], and stroke [10]. Apps have also been used to aid in self-care in women's health [11] and mental health [12,13], and to support patients undergoing bariatric [14] and colorectal surgery [15]. These and other studies [16] delineate a consistent lack of governance around medical apps, thereby presenting significant implications for patient safety. Furthermore, many lack appropriate health care professional input and it is unclear how the needs of the target users were incorporated into the functionality and content of such apps.

A range of infection prevention and control and antimicrobial-related apps are available for medical and other clinical staff [17-20], however, to our knowledge there is as yet no study exploring the usability of apps for patients specifically targeting infections and/or antimicrobial use. In addition, a UK Wellcome Trust report [21] has provided important insights into the perception of antimicrobial resistance by the general public in the United Kingdom; the report concluded that there is a problem with communicating issues around antimicrobial resistance and an urgent need to educate the public in this field. Moreover, a recent systematic review [22] on the public's

knowledge and beliefs about antibiotic resistance confirmed the lack of understanding about the development of AMR and misperceptions about its causes. Providing patients and the public with appropriate information around infections and antimicrobial therapy using electronic resources, such as mobile phones, tablets, and personal computers, may help address this need.

We sought to explore the use of different antimicrobial therapy information resources with a focus on electronic platforms, including apps for portable devices by health care users at two large, geographically distinct teaching hospitals in England. We wanted to determine whether there is currently a need for an evidence-based app for patients, to garner public perceptions around infections/antimicrobial prescribing, and to describe patients' experiences of their interactions with health care professionals in relation to this topic.

Methods

Overview

A cross-sectional study was designed using a 12-item survey investigating aspects of antimicrobial prescribing and electronic devices experienced by patients or their carers. The following participants were involved in the design of the questions and survey format: an infectious diseases physician; three hospital pharmacists, all with infection expertise; an academic lead nurse; a public health specialist; and a patient representative. A single open question invited respondents to annotate any comments they wished to make about the survey itself and/or any aspect on antimicrobial prescribing, resistance, and infections. Feedback from a patient hospital coordinator was used to check the survey compliance with National Health Service (NHS) readability requirements for materials provided to patients and the general public [23]. The survey was then piloted with potential respondents for face validity.

Data Exclusion

Inclusion criteria for participation included being ≥ 18 years of age and participants or their dependants having taken a course of antimicrobials in the previous 6 months. Any respondents who did not meet the above criteria were automatically excluded. Although requested, this study did not require ethics committee approval, as confirmed by the NHS Research Ethics

Committee, as this work was considered to be a service evaluation.

Recruitment

The survey was distributed by pharmacy outpatient staff to people attending four different hospitals across two acute NHS institutions, from September 15-30, 2014, in London and from November 18, 2014, to February 23, 2015, in Cambridge, until a convenience sample of 100 consecutive respondents had been reached. A master copy of the survey is provided in [Multimedia Appendix 1](#). A raffle incentive—£30 shopping vouchers, one for each geographical location—was offered to respondents who completed the survey.

Data Analysis

Data were anonymized and reported using descriptive statistics. Additionally, analysis of the free-text comments portion of the survey and the feedback provided by the respondents was

conducted [24]. This was done by a single researcher (CM) who grouped the comments received into main and global themes. The themes were then reviewed and corroborated by the study team.

Results

Demographics and Ownership of Electronic Devices

A total of 100 surveys were returned, but only 99 (99.0%) surveys were eligible to be included in the analysis—one survey was excluded as the respondent was under 18 years of age. Not all respondents completed each question in the survey and this was taken into account in the analysis. For each question the number of respondents is given.

The median age of respondents (n=85) was 40 years (range 19-99), and 8% were over 70 years of age. [Table 1](#) provides details on respondent demographics.

Table 1. Demographics of the patient sample .

Patient characteristics	n (%)
Gender (female) (n=96)	46 (48)
Level of education (n=88)	
Degree	46 (52)
Other qualifications	29 (33)
No qualifications	13 (15)
Personal electronic device owned (n=89)	
Desktop/laptop	62 (70)
Android mobile phone	36 (40)
Android tablet	15 (17)
Apple mobile phone	40 (45)
Apple tablet	27 (30)
Windows-based mobile phone	6 (7)
Windows-based tablet	3 (3)
Blackberry mobile phone	1 (1)
Other device	4 (4)
No device	8 (9)

Antimicrobial Prescribing and Obtaining Information on Antimicrobials/Infections

In all, 82% (80/98) of respondents had recently been prescribed antimicrobials for themselves and 19% (19/98) stated that their dependants/children were prescribed antimicrobials. A total of 87% (85/98) of respondents were prescribed an antimicrobial by a doctor, either in hospital or in the community. The remaining 13 individuals out of 98 (13%) stated that they acquired their prescription from the one of the following: dentist (4/98, 4%), nurse (5/98, 5%), hospital pharmacist (1/98, 1%), walk-in clinic while on holiday (1/98, 1%), and by self-prescription (2/98, 2%). When asked how they obtained information about the antimicrobials prescribed or the infection treated, 80% (74/93) said they had asked a health care professional (HCP) such as a doctor, pharmacist, or nurse. A

total of 7% (6/93) had asked family and friends and 17% (16/93) had also searched the Internet. However, only 60% (51/85) of respondents were completely satisfied with the information they had been given by their HCPs.

In terms of the information that respondents wanted to know about their particular infection, 65% (42/65) wanted information on the etiology of the infection. Most common infections mentioned were as follows: upper and lower respiratory tract infections; urinary tract infections; and oral, skin, and soft tissue infections. In addition, 49% (32/65) wanted information on the prevention and/or management of their infection. When asked whether they wanted any specific information relating to the antibiotics prescribed, all the respondents who answered this question (92/92, 100%) desired at least one particular piece of information among the following: best time of day to take

antibiotics, whether the antibiotics should be taken with food, whether alcohol could be consumed, whether the antibiotics could be taken at the same time as other medicines, what to do about a missed dose, and side effects. Some patients also added their own comments, for example, the patient information leaflet used, the ability of antibiotics to induce thrush, age group of people who could take the antibiotic, safety in pregnancy, and safety in blood disorders (eg, thalassemia).

[Table 1](#) also provides information on the electronic devices owned by patients. While 30% (27/89) of patients used health care apps, 95% (81/85) completed a preference list of statements on aspects of antimicrobials and/or infections that could potentially be provided through a dedicated app for patients (see [Table 2](#)).

Table 2. Preferences for an antimicrobial app and patients' perceptions on the utilization of electronic platforms by health care professionals.

Parameter	n (%)
Characteristics of a dedicated antimicrobial app for patients/public (n=85)	
Treatment of symptoms	64 (75)
Side-effects of antimicrobials	60 (71)
Duration of common infections	53 (62)
Tips on how to reduce risk of getting common infections	49 (58)
Are antimicrobials indicated for my infection?	48 (56)
When do I need to see my doctor?	47 (55)
Signs of bacterial versus viral chest infections	43 (51)
Recording of antimicrobial treatment information	30 (35)
Other information (free text)	5 (6)
Patients' perceptions on use of mobile electronic devices during a consultation with a doctor (n=95)	
Fine to use	52 (55)
Not fine, they should not be using it	12 (13)
Depends on the situation	22 (23)
Other: specific scenario given	9 (9)

Analysis of Respondents' Feedback

Additional insights on their experience with antimicrobials, infections, and apps were provided by 15% (15/99) of respondents, and are presented in detail in [Table 3](#).

The main themes were patient information leaflets, information on infections/antimicrobials, technology awareness, and personal experience on infections/antimicrobial prescribing.

Table 3. Themes emerging from respondents' feedback^a.

Global theme	Main theme	Verbatim comment	Respondent characteristics	
Knowledge	Patient information leaflets	<i>"Leaflets included with medicines are a pain. Too clumsy and contain information overload."</i>	Male, no age supplied	
		<i>"Leaflet is fine for most people to read but needs to be concise and to the point, for example, if you miss a tablet don't take it. Tips: major things in BOLD writing."</i>	Female, 60 years old	
	Information on infections and/or antimicrobials	<i>"Would be useful to know why certain antibiotics are prescribed over others. In my case was prescribed antibiotics that didn't work."</i>	Female, 27 years old	
		<i>"Length of time till symptoms don't ease—implications of this."</i>	Male, 29 years old	
		<i>"Information needed on gaps one should leave between antibiotic courses, in order to reduce problems with resistance."</i>	Male, 60 years old	
		<i>"Gap one should leave between antibiotic courses in order to decrease resistance."</i>	Male, 66 years old	
		<i>"This survey is very interesting. It is making you actually think about the issues around taking medications."</i>	Female, 48 years old	
		<i>"Information is good but does not beat real medical assessment."</i>	Male, 39 years old	
	Technology	Technology awareness	<i>"Prefer than app, comprehensive website optimized for phones and tablets."</i>	Male, 33 years old
			<i>"This survey could be an APP!"</i>	Female, 43 years old
<i>"Doctors need to keep up to date with technology."</i>			Male, 40 years old	
Patient experience	Personal experience with infections/antimicrobial prescribing	<i>"I had severe allergic reaction to several antibiotics following brain operation and now being seen by [a specialist]."</i>	Female, 57 years old	
		<i>"Antibiotics given too often to patients and GPs [general practitioners] see it as a quick fix to get rid of the patients. There should be limitations in place to decrease antibiotic prescribing."</i>	Female, 24 years old	
		<i>"Child became ill again but GP would not issue another dose, suggested other methods and asked to return if became worse."</i>	Female, 57 years old	
		<i>"Antibiotics are good but immune system becomes so depleted after a while. When younger, had tonsillitis and always on antibiotics and effects being experienced in adulthood."</i>	Female, 32 years old	

^aOnly superfluous comments were excluded (eg, "great" or "I have a carer"); the rest are all included in the table.

Discussion

Principal Findings

In this study, we present findings indicating that the majority of patients are prescribed antimicrobials by a doctor. Two-thirds of the patients wanted information on the etiology of the infection and half of them requested information on optimal management of the infection. All wanted antimicrobial-specific information. Also, about half of the respondents supported

doctors using electronic platforms to access medical information during a consultation. In addition, ownership of electronic devices was relatively high within our sample population of people attending NHS outpatient pharmacies. Three-quarters of those who were recently prescribed an antimicrobial stated that they owned a computer and nearly half of respondents owned an Android or Apple mobile phone. Although only 30% of respondents used apps, 95% suggested useful features to include in a bespoke app targeting antimicrobials/infections.

We also identified that a significant number of those attending outpatient clinics in a hospital setting, which might also include members of the general public or even NHS staff, besides patients, were not always satisfied with the quality of information received. Overall, our findings suggest that there is a gap and demand by some patients and possibly members of the public for an app that provides antimicrobial- and infection-specific information. Collectively, the global themes that emerged from the respondents' feedback were knowledge, technology, and patient experience.

Patient Information Leaflets

Patient information leaflets failed to provide patients with easily understandable and useful information (eg, "*Leaflets included with medicines are a pain,*" "*Too clumsy and contain information overload*"). Some respondents suggested that a dedicated app with practical information might address this gap.

A recent Patient Safety Alert [25] has emphasized the need for health care institutions to engage with patients in order to optimize the use of antimicrobial agents and help prevent the spread of resistant microorganisms. This alert also references the National Institute for Health and Care Excellence (NICE) guidance on antimicrobial stewardship [26], which focuses on patient-centered care and involving patients in their treatment plans, also noting their perceptions about antimicrobial prescribing, whether or not an antimicrobial is indicated.

Information on Infections/Antimicrobials

Some respondents had scientifically incorrect views and opinions about the misuse of antimicrobials, which clearly indicates the need for targeted, patient-centered antimicrobial stewardship educational interventions. For instance, one patient stated, "*Information needed on gaps one should leave between antibiotic courses, in order to reduce problems with resistance.*" Another patient stated, "*Antibiotics are good, but immune system becomes so depleted after a while. When younger, had tonsillitis and always on antibiotics and effects being experienced in adulthood.*" Echoing the findings highlighted in the Wellcome report [21], our respondents constructed an understanding of antimicrobial resistance around the idea of their bodies "*getting used to*" antibiotics rather than as an adaptive response from microorganisms. As mentioned in the report [21], there is an urgency to address these misconceptions from a public health perspective.

Technology Awareness

While some respondents strongly supported technological innovations in health care—for instance, one respondent stated, "*Doctors need to keep up to date with technology*"—there may be concerns about privacy and medical data protection, as a small proportion of people in our study (13%) were not happy with doctors accessing electronic resources using a mobile phone/tablet during a consult. These feelings may be explained by wider societal concerns about the misuse of confidential information and data breaches, as well as perceptions of the robustness of security mechanisms and tools.

Personal Experience on Infections/Antimicrobial Prescribing

Some individuals felt strongly about their own personal/family experiences with infections, which highlights the individual angst and emotive issues experienced by people affected by an infectious disease. Examples include the following: "*Antibiotics given too often to patients and GPs [general practitioners] see it as a quick fix to get rid of the patients. There should be limitations in place to decrease antibiotic prescribing*" and "*I had severe allergic reaction to several antibiotics following brain operation and now being seen by [a specialist].*" This could also possibly be linked to the suboptimal level of satisfaction experienced by some of our respondents when they asked their HCPs about their infections/antimicrobials.

Limitations

Since only 100 respondents completed the survey and we analyzed 99 (99.0%), our results cannot be widely generalized. However, people from multiple NHS sites participated, which included two distinct geographical locations.

Some individuals also chose not to reply to certain questions and this potentially might have affected our final analysis, but we could only analyze the responses that we obtained. We used closed-ended questions which limited the responses, but we tried to balance this by including an *Other, please specify* category for respondents to provide any additional comments, in addition to an open-ended question. Since part of the recruitment coincided with European Antibiotic Awareness Day (EAAD), it cannot be ignored that this public health awareness campaign, and possibly other related media coverage, might have influenced respondents' feedback.

Comparison With Prior Work

A US study surveyed adult patients attending an emergency department (ED) [27] and found that from 300 respondents, a total of 71% owned a smartphone—from these, 33% were males—with 95% overall stating that they had apps and 44% stating that they had health-related apps. The median age was 29 years. In our study, only 30% of respondents stated that they had health-related apps and the median age of our respondents was 40 years, so it is possible that age may play a role in determining whether patients regularly access health-related apps. Also, since the patients in the US ED study were younger than the ones in this study, and specifically attended the ED, their disease conditions may have been acute, while in our study the respondents may have had more chronic conditions. Another study [28] targeted patients attending an outpatient psychiatric clinic in Boston, MA, USA. A total of 100 patients were given an uncompensated survey (ie, not offered any incentive e.g. payment, vouchers, etc) to complete and 72% stated that they owned a smartphone. Overall, more than 50% indicated that they would use an app daily for monitoring their mental health condition if this was made available. In this study, patients in the 30-45-year-old age range were more likely to show interest in downloading a mobile phone app to monitor their mental health conditions.

With the increasing availability of health care apps for medical and allied health care professionals, and also as highlighted in

a systematic review on health care apps for mobile phones [29], we were interested in exploring patients' opinions on the use of mobile phones/tablets by medical professionals during a consult. Over half of the respondents stated that they were happy for the doctors to use them, but 13% categorically declared that they were not happy; the majority of these respondents were female, but the numbers were small. Nearly one-third of the respondents selected *depends on the situation*, some adding that if the resource was NHS-approved or if their particular clinical condition was exceptional, they would not object. This finding may indicate a lack of trust in the use of highly sensitive confidential information, with the fear that this might be shared with third parties and/or an expectation that their doctor should know it all.

We also wanted to find out what personal electronic devices were being used by respondents, as this information would enable us to assess how patients obtained information and what electronic devices they used. The majority (62/89, 70%) used a desktop or laptop computer. Almost half of the respondents used an Android or Apple mobile phone. Tablet usage was less, with 17% (15/89) using an Android tablet versus 30% (27/89) using an Apple tablet. Interestingly, very few had Windows-based devices; only 1% (1/89) had a Blackberry mobile phone, but 9% (8/89) stated that they did not use any electronic devices. Market research data shows that mobile device usage has overtaken desktop computer usage since 2014; in the United States, mobile digital media time is higher at 51% for mobile devices versus 42% for desktop or laptop computers [30]. UK data [31] demonstrates that the number of adults who own a mobile phone has risen from 61% (Quarter 1, 2014) to 66% (Quarter 1, 2015); the number of people using their mobile handsets to access the Internet has also increased, from 57% (Quarter 1, 2014) to 61% (Quarter 1, 2015). In addition, 4G mobile subscriptions have dramatically increased from 2.7 million (end of 2013) to 23.6 million (end of 2014).

We explored processes around infection and antimicrobial prescriptions and can report that the majority of patients in our study were prescribed antimicrobials for personal use by a medical practitioner. More than half of our respondents obtained information regarding their infection or antimicrobials directly from their doctor, nurse, or pharmacist. However, when asked about their level of satisfaction, it was interesting to note that only 60% felt completely satisfied by the information they received. This finding may pose the question, "Do patients really understand the information being given to them by health care professionals?" as this could lead to suboptimal medication compliance. A Japanese study [32] addressed the issue of medication adherence by developing a smartphone medication self-management system based on interviews with 116 patients with chronic illnesses. Separately, a meta-analysis investigating 13 randomized controlled trials (RCTs) [33] found that electronic medication counseling improved adherence with antiretroviral therapy, as well as virologic response, when compared to control groups not receiving the counseling. However, this was only significant when it was one of multiple components in the intervention, not when it was the sole intervention. Our study does not highlight why patients were not satisfied, so there could be many other reasons, possibly

related to HCPs not providing sufficient information, HCPs providing an inappropriate format for the intended patient, and a lack of time to establish understanding/address patients' questions and concerns.

The three most common features that patients desired in an app included the following: treatment of their symptoms (75%), side-effect profile (71%), and duration of common infections (62%). This finding is very useful and could inform the design of a bespoke app targeted at facilitating the appropriate use of antibiotics by patients. It also identifies a potential gap in current public awareness campaigns around infections/antimicrobials, which needs to be addressed. From our results, it could be inferred that patients, and possibly some members of the general public, would like to have targeted information on self-care and management of infections that includes duration of these infections, as well as important considerations relating to antimicrobials.

The IMS Health report [34] issued by the IMS Institute for Healthcare Informatics, USA, identified 165,000 mHealth apps currently available to the general public, with >90% of these being free of charge. Some of these apps may well be infection/antimicrobial related, however, the report states that most have limited functionalities. Separately, a European Union (June 2015) project on eHealth and well-being [35] published a comprehensive list of eHealth apps receiving funding that failed to include any projects on antimicrobials or infections, indicating a significant missed opportunity.

In addition, both the Wellcome Trust report (2015) [21] and a systematic review [22] on the public's knowledge and beliefs on AMR suggest that more needs to be done to understand how people perceive the problem of antimicrobial resistance. Also, a careful assessment of the processes and methodologies that are needed to employ and better equip both patients and the public needs to be conducted, so they may grasp the basic concepts of this phenomenon and help curb antimicrobial resistance. Although our survey was conducted in hospital outpatient pharmacies where it is expected that most of the customers would be chronic patients receiving hospital treatment, the pharmacies are easily accessed by visitors and even NHS staff, so these too could have contributed to the survey responses—this data was unavailable as we did not capture it; as well, responses were anonymized. Hence, we postulate that the responses given in our survey could also very likely include members of the public.

Conclusions

Our findings suggest that the patients and possibly the general public would like easily accessible information about the etiology and management of infections. All of our respondents wanted information relating to the antimicrobials prescribed. We found that ownership of mobile electronic devices was high among respondents to our survey and patients are aware of the availability of health care information using modern electronic resources. We found that a significant proportion of respondents also supported the use of electronic platforms by health care professionals to access medical information.

Furthermore, our results show that there is a potential for developing an evidence-based app for patients and possibly the general public targeting infections and antimicrobials. This app would also help support HCPs to provide the necessary information on antimicrobials/infections, as required by national UK guidance.

However, prior to designing and developing an app, further work should be conducted, ideally by designing a new survey

seeking more in-depth information about how the creation of a bespoke app would be used by patients. In addition, focus group interviews with patients and the public should be employed to address some of the misconceptions identified in our study around the generation of antimicrobial resistance, as well as the global themes concerning knowledge, technology, and patient experience around infections and antimicrobial therapy.

Acknowledgments

This research was partially funded by the National Institute for Health Research (NIHR) Health Protection Research Unit (HPRU) in Healthcare Associated Infection and Antimicrobial Resistance at Imperial College London, in partnership with Public Health England (PHE), the NIHR Imperial Biomedical Research Centre, and the NIHR Imperial Patient Safety Translational Research Centre. The views expressed are those of the authors and not necessarily those of the NHS, the NIHR, the Department of Health, or Public Health England. This work was supported by Imperial College Healthcare Charity (grant no. 7006/P36U).

The authors would like to thank Professor Cliodna McNulty, Head of Primary Care Unit, Public Health England, for her support and contribution to the early phases of the research, including the design of the survey. We are grateful to the outpatient pharmacy NHS and Lloyds staff; Mrs Aleksandra Scibor-Stiepen, Specialist Antimicrobials Pharmacy Technician, Addenbrooke's Hospital; patients, visitors, and NHS staff at Imperial College Healthcare NHS Trust; and Addenbrooke's Hospital, Cambridge University Hospitals, NHS Foundation Trust, who helped distribute the surveys and/or participated.

Conflicts of Interest

CM has received travel grants to attend scientific conferences from Astellas, Gilead, Pfizer and Novartis and educational grants from Pfizer and Novartis. CM has attended a Pfizer Advisory Board Meeting and consulted for Astellas. ECS has received funding from the Florence Nightingale Foundation to study the participation of nurses in antimicrobial stewardship decisions. MG (Mark Gilchrist) reports attending advisory boards for The Medicines Company, Clinigen, Astellas Pharmaceuticals, and Cubist/ Merck, and receiving educational travel and speaker grants from Eumedica Pharmaceuticals and Astellas Pharmaceuticals, Sanofi, respectively. AHH and LSPM have consulted for bioMérieux.

Part of this work was presented as a poster at the 25th European Congress for Clinical Microbiology and Infectious Diseases (ECCMID) held in Copenhagen, Denmark, April 25-28, 2015.

Multimedia Appendix 1

[[PDF File \(Adobe PDF File\), 87KB - mhealth_v4i3e83_app1.pdf](#)]

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Abbreviations

AMR: antimicrobial resistance

EAAD: European Antibiotic Awareness Day

ECCMID: European Congress for Clinical Microbiology and Infectious Diseases

GP: general practitioner

HCP: health care professional

HPRU: Health Protection Research Unit

NHS: National Health Service

NICE: National Institute for Health and Care Excellence

NIHR: National Institute for Health Research

PHE: Public Health England

RCT: randomized controlled trial

Edited by G Eysenbach; submitted 13.10.15; peer-reviewed by D Ashiru-Oredope, S Iribarren, J Eickholt; comments to author 14.02.16; revised version received 12.03.16; accepted 29.03.16; published 06.07.16.

Please cite as:

Micallef C, McLeod M, Castro-Sánchez E, Gharbi M, Charani E, Moore LSP, Gilchrist M, Husson F, Costelloe C, Holmes AH An Evidence-Based Antimicrobial Stewardship Smartphone App for Hospital Outpatients: Survey-based Needs Assessment Among Patients

JMIR Mhealth Uhealth 2016;4(3):e83

URL: <http://mhealth.jmir.org/2016/3/e83/>

doi: [10.2196/mhealth.5243](https://doi.org/10.2196/mhealth.5243)

PMID: [27383743](https://pubmed.ncbi.nlm.nih.gov/27383743/)

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Original Paper

Expert Involvement Predicts mHealth App Downloads: Multivariate Regression Analysis of Urology Apps

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Abstract

Background: Urological mobile medical (mHealth) apps are gaining popularity with both clinicians and patients. mHealth is a rapidly evolving and heterogeneous field, with some urology apps being downloaded over 10,000 times and others not at all. The factors that contribute to medical app downloads have yet to be identified, including the hypothetical influence of expert involvement in app development.

Objective: The objective of our study was to identify predictors of the number of urology app downloads.

Methods: We reviewed urology apps available in the Google Play Store and collected publicly available data. Multivariate ordinal logistic regression evaluated the effect of publicly available app variables on the number of apps being downloaded.

Results: Of 129 urology apps eligible for study, only 2 (1.6%) had >10,000 downloads, with half having ≤100 downloads and 4 (3.1%) having none at all. Apps developed with expert urologist involvement ($P=.003$), optional in-app purchases ($P=.01$), higher user rating ($P<.001$), and more user reviews ($P<.001$) were more likely to be installed. App cost was inversely related to the number of downloads ($P<.001$). Only data from the Google Play Store and the developers' websites, but not other platforms, were publicly available for analysis, and the level and nature of expert involvement was not documented.

Conclusions: The explicit participation of urologists in app development is likely to enhance its chances to have a higher number of downloads. This finding should help in the design of better apps and further promote urologist involvement in mHealth. Official certification processes are required to ensure app quality and user safety.

(*JMIR Mhealth Uhealth* 2016;4(3):e86) doi:[10.2196/mhealth.5738](https://doi.org/10.2196/mhealth.5738)

KEYWORDS

eHealth; mHealth; urology; mobile apps; new technologies

Introduction

Medicine is constantly evolving, and medical research and development are greatly influenced by available and new technology. Mobile health (mHealth), defined as “the delivery

of healthcare services via mobile communication devices” [1], is a new element of eHealth based on mobile phone and tablet apps. Apple and Google provide the leading mHealth platforms (iOS and Android, respectively), with over 160,000 medical apps between them [2]. The number of mHealth apps is expected

to grow, not least because both companies have announced mHealth to be a top priority [3,4].

mHealth has had an impact in several medical specialties, including anesthesia [5], cardiology [6], and psychiatry [7]. Moreover, it has been applied to a diverse set of problems facing both health care professionals (HCPs) and patients, including apps that use augmented reality in the operating room [8], risk calculators for clinical practice [9], and digital diaries that aid in patient monitoring [10]. The apps available for urological practice were summarized in a recent review [11], which highlighted that not all urology apps share the same popularity; while some apps are downloaded very infrequently, other apps have been downloaded over 10,000 times. To date, the factors that contribute to the number of downloads of a medical app have not been characterized.

The economic literature indicates several factors that affect app downloads, with price being one of the significant predictors [12,13]. Even though some users are willing to pay for more sophisticated features in better-quality apps and see the price as a marker of quality, others only download free apps, sometimes with limited features. In fact, some users download a paid version only after trying the free version or use in-app purchases to get access to additional features. It has been shown that the option of in-app purchases can affect a user's decision to download the app [12].

The exchange of opinions and experiences online, that is, online word-of-mouth, influences ecommerce sales [14]. Word-of-mouth has two main characteristics: volume (the total amount of word-of-mouth) and valence (whether the attitude is positive or negative). Word-of-mouth volume generates the cognitive consequence of awareness, while word-of-mouth valence produces the cognitive consequence of attitude [15]. In the mobile apps market, to predict the number of downloads, authors use the number of user reviews as the volume and the user rating as the valence [12].

Previous studies have shown that app demand decreases with the app file size. As apps become more complex they increase in size, meaning that they take longer to download and for users to try them. Moreover, they occupy additional space in the device memory [12,13]. App availability on both platforms (Apple App Store and Google Play Store) may raise awareness about the app, influencing the number of downloads [12].

The developer's textual and visual description of an app can undoubtedly contribute to the willingness of users to download an app. Prior studies have shown that textual information and visual images affect consumer purchase decisions [16,17]. For mobile apps, the app description's length and the number of screenshots significantly affect app demand [12].

Other factors that may positively influence the number of downloads are the app's age (ie, how long the app has been available) and availability of updates (ie, whether the app has been updated since launch) because these are surrogates of the app's evolution [12]. Availability of an update also raises

awareness for the app because updates allow the app to be featured in the "New & Updated Apps" category of the Google Play Store. In contrast, age-restricted content in an app will have a negative impact on the number of downloads because it limits the number of potential users [12].

The delivery of mHealth in urology will, as in all medical fields, largely depend on app availability, benefits, and user friendliness. Although economic studies have identified some of the factors that influence app downloads [12-18], given the specificity of medical apps, we hypothesized that the involvement of a health care expert could be a significant determinant in the ultimate number of downloads of a urology app. Therefore, we aimed to determine the predictors of the number of urology app downloads, including the contribution made by HCP involvement.

Methods

Search Strategy

We conducted a commercial review of all urology apps for the Android mobile operating system in the Google Play Store (Google Inc, Mountain View, CA, USA) up to August 31, 2015: we examined all apps containing the term "urology" in their metadata (ie, the title, description, keywords, or version history). We included only urology-specific apps in this study; hence, we excluded apps containing content related to other medical specialties (ie, generic apps targeting multiple subjects; eg, an anatomy atlas), product advertisements (ie, apps only promoting pharmaceuticals or clinical equipment), and apps solely allowing the user to schedule private appointments.

We selected only Android apps for study because, in contrast to Google, Apple does not report the number of individual app downloads. Furthermore, Apple only lists the top 200 medical apps ranked by a nondisclosed proprietary algorithm. However, no urology apps were present in the top 200 medical apps listed in either app store.

Predictor Variables for the Number of Downloads

For each app, 2 reviewers (NP-A and MR) recorded all available information according to 12 predetermined variables: (1) number of downloads, the dependent variable, (2) number of written user reviews, (3) price in euros, (4) average user rating (number of stars from 1 to 5), (5) app size (in megabytes), (6) number of screenshots (ie, an actual app image that showcased its features and functionality), (7) length of app description (number of characters in the app description, not including spaces), (8) app availability in the Apple App Store (ie, whether the app was available for iOS mobile phones or tablets), (9) new versions available (ie, whether the app had been updated since launch), (10) app age (number of days available in the Google Play Store), (11) absence of age restriction (ie, defined by the developer as having content appropriate for all ages), and (12) availability of in-app purchases (ie, the opportunity to buy extra content). [Table 1](#) lists these variables and their descriptions. We did not download the apps.

Table 1. Variables included in the model to predict the number of downloads of urology apps.

Variables	Description
Level of downloads ^a	Level 0: no downloads Level 1: 1–5 downloads Level 2: 6–10 downloads Level 3: 11–50 downloads Level 4: 51–100 downloads Level 5: 101–500 downloads Level 6: 501–1000 downloads Level 7: 1001–5000 downloads Level 8: 5001–10,000 downloads Level 9: 10,001–50,000 downloads
No HCP ^b participation	0: Other 1: No HCPs mentioned
Other HCP participation	0: Other 1: Other HCPs, pharmacists, and nurses
Urologist participation	0: Other 1: Urologist or urological association participation
Number of reviews	Number of reviews in the Google Play Store
Actual price	Actual price of the app in euros
Average user rating	User evaluation on a scale from 1 to 5 stars
App size	App file size in megabytes
No age restriction	0: Age restriction 1: No age restriction (ie, appropriate for all ages)
Number of screenshots	Number of screenshots in the Google Play Store
Length of description	Number of characters (without spaces) in the textual app description in the Google Play Store
Availability in the Apple App Store ^c	0: Not available 1: Available
Version	0: One version 1: New version exists
App age	Number of days available on the market
In-app purchases	0: No in-app purchase 1: In-app purchase available

^aThe exact number of downloads is not available from the Google Play Store. We categorized it according to the system used by Google in the Play Store.

^bHCP: health care professional.

^cAvailable for iOS mobile phones or tablets.

To test the hypothesis that urologist involvement influences app downloads, we added a further variable to our model: HCP participation. We identified HCP participation by examining the app's description and considered it to be present only when explicitly mentioned. We classified the participating HCP as urologist (ie, urologist or urological association), other HCPs (ie, other medical doctors, pharmacists, or nurses), or no HCP (ie, no explicit mention of an HCP). The 2 reviewers gathered download data based on the classification system of level of

downloads used by Google in the Play Store (Table 1). At the time of final review (August 31, 2015), no urology apps had been downloaded over 50,000 times.

Statistical Analyses

Analyses were performed using IBM SPSS Statistics v20 (IBM Corp). We considered $P < .05$ to be statistically significant in all analyses. Descriptive analyses and multivariate ordinal logistic regression identified the factors predicting app downloads.

Results

A total of 250 Google Play apps contained the term urology in their metadata. We excluded 121 apps: 109 were generic apps (ie, not designed specifically for urology, eg, ArchieMD 3D Health: PREVIEW), 11 were for making appointments (eg, Dr Fateh Singh Appointments), and 1 app was designed solely for product advertisement (Actient Pharmaceuticals).

Of the 129 included apps ([Multimedia Appendix 1](#), [Multimedia Appendix 2](#)), 90 (69.8%) were free. Of the paid apps, the prices ranged from €0.68 (Urology Glossary) to €83.15 (The 5 Minute Urology Consult 3), with an average price of €8.45. The average app rating was <3 stars (mean 2.65), and 92 (71.3%) had no written review. There were 5 screenshots per app on average, and the length of the description varied from 3 to 3348 characters (without spaces). The number of days since publishing varied from 1 to 1733 (average 721 days) ([Table 2](#)).

Table 2. Summary descriptive statistics for continuous variables for apps containing the term urology.

	Mean	SD	Range	Median
Number of reviews	0.84	2.08	0–12	0
Actual price (€)				
All apps	2.55	9.89	0–83.15	0
Paid apps	8.45	16.68	0.68–83.15	2.69
Average user rating (no. of stars)	2.65	2.13	0–5	3.5
App size (MB)	7.37	10.36	0.01–48	3.2
Number of screenshots	5.4	3.86	1–25	4
Length of description (nonspace characters)	896.08	872.24	3–3348	531
App age (days)	721.18	425.76	1–1733	699

[Figure 1](#) shows the number of apps in each level of downloads and HCP participation. The proportion of apps with HCP participation was greater in the higher levels of downloads. Moreover, in the 2 highest levels (>5000 downloads), only apps designed with the participation of urological experts were present.

Even though 2 (1.6%) apps had >10,000 downloads (level 9), half of all urology apps had ≤100 downloads (level 4 or less). At the time of this review, 4 apps (3.1%) had not been downloaded ([Table 3](#)).

Table 3. Frequencies for the categorical and binary variables.

	Frequency	Percentage	Cumulative percentage
Level of downloads			
0: no downloads	4	3.1	3.1
1: 1–5 downloads	6	4.7	7.8
2: 6–10 downloads	3	2.3	10.1
3: 11–50 downloads	35	27.1	37.2
4: 51–100 downloads	16	12.4	49.6
5: 101–500 downloads	33	25.6	75.2
6: 501–1000 downloads	10	7.8	82.9
7: 1001–5000 downloads	18	14.0	96.9
8: 5001–10,000 downloads	2	1.6	98.4
9: 10,001–50,000 downloads	2	1.6	100
No HCP^a participation			
Other	104	80.6	80.6
No HCPs mentioned	25	19.4	100
Other HCP participation			
Other	111	86.0	86.0
Other HCPs, pharmacists, and nurses	18	14.0	100
Urologist participation			
Other	43	33.3	33.3
Urologist or urological association participation	86	66.7	100
No age restriction			
Age restriction	72	55.8	55.8
No age restriction	57	44.2	100
Availability in Apple App Store			
Not available	36	27.9	27.9
Available	93	72.1	100
Version			
One version	66	51.2	51.2
New version exists	63	48.8	100
In-app purchases			
No in-app purchase	118	91.5	91.5
In-app purchase available	11	8.5	100

^aHCP: health care professional.

Although most apps, that is, 86 of 129 (66.7%), were developed with specialist urological input and other HCPs were involved in a further 18 apps (14.0%), 25 apps (19.4%) had no documented HCP involvement. A total of 57 apps (44.2%) had no age restriction. Only 11 apps (8.5%) had in-app purchases available.

Multivariate logistic regression revealed the factors contributing to urology app downloads (Table 4). Apps developed with urologist involvement were more likely to be installed than those without expert involvement ($P=.003$). Availability of

in-app purchases ($P=.01$), a higher user rating ($P<.001$), and a higher number of written reviews ($P<.001$) were also significantly associated with app downloads. The app price was inversely related to the number of downloads ($P<.001$). The other evaluated factors (app age, app size, absence of age restriction, number of screenshots, length of description, availability in the Apple App Store, and new published versions) were not significantly associated with app downloads. The Nagelkerke R^2 statistic, which measures the strength of the association between the dependent variable and the predictor variables, was satisfactory.

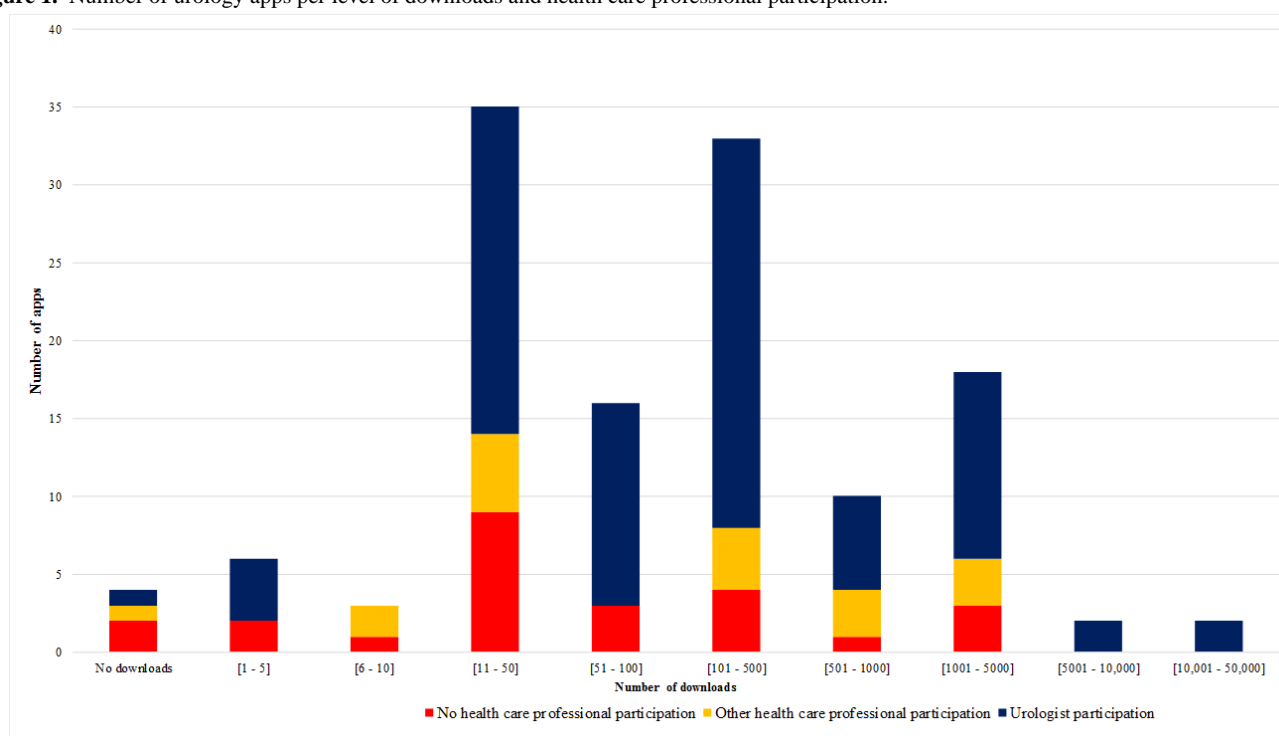
Table 4. Multivariate ordinal logistic regression of factors contributing to number of urology app downloads.^{a,b}

Variables	Estimates ^c	SE	P value	95% CI
App age	0.001	.0004	.24	-0.0003 to 0.001
Other HCP participation	0.469	.602	.44	-0.71 to 1.65
Urologist participation	1.43	.479	.003	0.49 to 2.37
Number of reviews	0.440	.102	<.001	0.24 to 0.64
Actual price in euros	-0.071	.020	<.001	-0.11 to -0.03
Average user rating	0.337	.089	<.001	0.16 to 0.51
App size	0.018	.017	.30	-0.02 to 0.05
No age restriction	0.498	.346	.15	-0.18 to 1.18
Number of screenshots	0.047	.048	.33	-0.05 to 0.14
Length of description	-0.0004	.0002	.09	-0.001 to 0.00006349
Availability in the Apple App Store	-0.641	.441	.15	-1.5 to 0.22
Version	-0.372	.340	.27	-1.04 to 0.29
In-app purchases	1.67	.682	.01	0.33 to 3.0
Nagelkerke R ²			.48	

^aThe dependent variable is the level of downloads.

^bThe reference level for health care professional (HCP) participation is “No HCP participation.”

^cEstimates are the ordered log-odds regression coefficients and they show the relative magnitude (ie, relative impact of the factor) and direction (ie, positive or negative) of the impact of the listed variables on the level of downloads.

Figure 1. Number of urology apps per level of downloads and health care professional participation.

Discussion

Principal Findings

The lack of studies on the predictors of the number of downloads for medical apps in the PubMed database suggests that this is the first study of its kind in mHealth. However, economic studies

determined the predictors of downloads for generic apps, which we tested in this study. We showed that inexpensive apps developed with expert urological input and with optional in-app purchases were more likely to be installed. Furthermore, apps with higher user ratings and with a larger number of written user reviews were more likely to have a greater level of downloads. These results confirmed, for the first time, that

urologist participation in app development positively influences urology app downloads.

Although the availability of various medical apps has been thoroughly documented, the factors that predict their downloads have, until now, not been studied. Given that mHealth is a rapidly evolving and novel field, these data are useful for practitioners and app developers interested in developing urology apps. Furthermore, the data are important for mHealth policy makers and regulators because no best practice guidelines exist with respect to medical app development.

mHealth is still a relatively new concept, and its full potential has yet to be fully explored. The number of downloads of mHealth apps will depend not only on available technologies, but also on the apps and their safety, effectiveness, and usability. However, concerns have been raised about medical apps, namely their scientific accuracy and user security [5,7], which are exacerbated by the lack of regulation. The level of regulation should be proportional to the degree of clinical implication derived from the app, ranging from low (eg, apps that give access to online medical journals, which only show content that has already been peer reviewed) to high (eg, apps that dispense clinical advice).

Apps have the potential to be hazardous to uninformed users, either by error, such as miscalculation when using an opioid dose calculator [19], or by making false claims, such as dermatology apps that claim to diagnose skin cancer in spite of evidence that they misclassify 80% of textbook melanomas [20] and apps that guarantee to cure breast cancer [21]. Although these concerns have attracted the attention of public entities such as the European Union, which has published a green paper on mHealth [22], and the US Food and Drug Administration, which has issued some nonbinding suggestions [23], there is still no mandatory certification for mHealth apps. To address the lack of official guidelines, urological societies could participate in the regulatory process by publishing mHealth recommendations similar to those issued for social media [24-26]. In this way, app safety and accuracy can be improved by the involvement of medical experts at the early stages of app development and by promoting peer review.

Our results confirm our initial hypothesis that the explicit participation of an expert in urology in the app development process increases its chances to be downloaded. Given the lack of external certification of mHealth apps, one possible explanation for this result is that users are reassured to know that a health care specialist collaborated in the app design. Expert involvement could be equivalent to a “quality mark,” guaranteeing that the app is safe and scientifically valid. However, users must be aware that, because there is no official way to authenticate the veracity or the extent of the expert participation, unscrupulous developers could potentially misuse this approach via deceptive advertising or false endorsement. Interestingly, however, our findings also indicated that there is still a deficit of HCP participation in urology app development, with only two-thirds of apps having expert participation. This is consistent with previous reports on expert involvement in app development in other disciplines, perhaps signifying a wider trend across mHealth that needs to be addressed [27,28].

Cheaper apps with optional in-app purchases were associated with a greater level of downloads. As with mobile game users, mHealth users seem to prefer to pay less initially but to have the opportunity to buy additional benefits, features, or functionalities via in-app purchases, rather than paying a higher upfront price [12]. An app’s chance of having a higher number of downloads also increased with a higher number of reviews or average user rating, which is consistent with other fields in which published reviews have been shown to affect the choices of new users [12,16]. Although customer reviews were a significant determinant of downloads, they were lacking in most apps, making it harder for potential users to learn about the app without purchasing it themselves. To ameliorate this issue, developers should provide comprehensive details about the app in their description.

A systematic review has shown that eHealth adoption by HCPs is dependent on multiple factors, namely the involvement of users in the development and implementation phases, ease of use, demonstrated advantages of the system, and adequate training and support [29]. The security of the eHealth system was the most important factor in the acceptance of eHealth by patients [30].

Even though, in the generic mobile market, factors such as app size, number of screenshots, length of description, app age, availability in other mobile stores, availability of new versions, and absence of age restriction have a significant impact on the number of downloads, we found that it was not the case in urology apps. Further studies are needed to determine whether this trend is specific to urology apps or also happens in other medical fields.

Future research may consider the number of positive or negative reviews as a potential factor to predict app downloads. It should also focus on what types of urological apps and what segments of this specific market (ie, patients, HCPs, or both) have higher downloads. Furthermore, subsequent investigations should compare the number of downloads of urological apps with those in other medical fields in order to gain insights into the state of mHealth.

Limitations

This study has some limitations. We limited our commercial review of urology apps to the search term “urology.” We included only urology-related apps and collected app data solely from information available in the Google Play Store and developers’ websites. Nevertheless, the Google Play Store and developers’ websites are the main sources of information available to potential new users before downloading the app; therefore, our study mimics the real-life information available to the user before purchase.

Android leads the mobile phone market with over 80% of market share, and there are more apps available in the Google Play Store. This is in part explained by the 2 platforms’ different approval processes: iOS apps have to undergo a thorough review process developed by Apple, but Android apps are immediately published online [3]. This distinct method may also influence the quality of the apps, which could be the subject of further research. We were unable to perform a similar analysis for the

Apple App Store because Apple does not disclose the number of app downloads, instead only listing the top 200 medical apps calculated using their proprietary algorithm. However, we noted no urology apps in the top 200 medical apps listed in either the Apple App Store or the Google Play Store at the time of data collection. Other mobile app platforms make up <5% of the overall market share [31] and, at the time of our research, no urology apps were available in the Blackberry Mobile Market and only 3 urology apps were available in the Microsoft Store Marketplace; the numbers of downloads of these apps were not publicly available.

Displayed information about the level of downloads in the Google Play Store can in itself influence downloads: if a user has to choose between 2 similar apps, most of the time they will download the most popular app first. For the sake of clarity, we studied only explicit expert participation, and it is possible that some app developers consulted medical experts during app design but did not mention it; there is, therefore, a risk of misclassification for this variable. However, when medical involvement was reported, there was no objective way to determine the extent of participation. The lack of a standardized format for the disclosure of expert participation and the absence

of readily available tools to quantify it requires further study and future recommendations.

Conclusions

To our knowledge, this is the first study to determine predictors of urology app downloads. The explicit participation of urologists in app development is likely to enhance its chances of having a greater number of downloads. Furthermore, in-app purchases, cheaper apps, and those with higher user ratings and number of written reviews are more likely to have more downloads. Until a regulated approval process is implemented by government health authorities, analogous to the one that exists for medical devices, two pragmatic changes to urology mHealth app publishing could promote user safety and assure content quality: first, medical apps should include a full disclosure, similar to that provided in scientific papers; and second, urological societies could be involved with certifying the scientific integrity of mHealth apps by issuing a professional, peer reviewed app quality mark or standard. The efforts of the Health on the Net Foundation to guide users toward trustworthy health information online were justified by the results of 10th HON survey [32].

Conflicts of Interest

None declared.

Multimedia Appendix 1

List of included apps.

[[PDF File \(Adobe PDF File\), 414KB - mhealth_v4i3e86_app1.pdf](#)]

Multimedia Appendix 2

Included apps ordered by the number of installs.

[[PDF File \(Adobe PDF File\), 337KB - mhealth_v4i3e86_app2.pdf](#)]

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Abbreviations

HCP: health care professional

Edited by G Eysenbach; submitted 10.03.16; peer-reviewed by M Johnston, N Shen, M Leveridge; comments to author 31.03.16; revised version received 26.04.16; accepted 19.05.16; published 15.07.16.

Please cite as:

Pereira-Azevedo N, Osório L, Cavadas V, Fraga A, Carrasquinho E, Cardoso de Oliveira E, Castelo-Branco M, Roobol MJ

Expert Involvement Predicts mHealth App Downloads: Multivariate Regression Analysis of Urology Apps

JMIR Mhealth Uhealth 2016;4(3):e86

URL: <http://mhealth.jmir.org/2016/3/e86/>

doi: [10.2196/mhealth.5738](https://doi.org/10.2196/mhealth.5738)

PMID: [27421338](https://pubmed.ncbi.nlm.nih.gov/27421338/)

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Original Paper

Beyond the Randomized Controlled Trial: A Review of Alternatives in mHealth Clinical Trial Methods

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Abstract

Background: Randomized controlled trials (RCTs) have long been considered the primary research study design capable of eliciting causal relationships between health interventions and consequent outcomes. However, with a prolonged duration from recruitment to publication, high-cost trial implementation, and a rigid trial protocol, RCTs are perceived as an impractical evaluation methodology for most mHealth apps.

Objective: Given the recent development of alternative evaluation methodologies and tools to automate mHealth research, we sought to determine the breadth of these methods and the extent that they were being used in clinical trials.

Methods: We conducted a review of the ClinicalTrials.gov registry to identify and examine current clinical trials involving mHealth apps and retrieved relevant trials registered between November 2014 and November 2015.

Results: Of the 137 trials identified, 71 were found to meet inclusion criteria. The majority used a randomized controlled trial design (80%, 57/71). Study designs included 36 two-group pretest-posttest control group comparisons (51%, 36/71), 16 posttest-only control group comparisons (23%, 16/71), 7 one-group pretest-posttest designs (10%, 7/71), 2 one-shot case study designs (3%, 2/71), and 2 static-group comparisons (3%, 2/71). A total of 17 trials included a qualitative component to their methodology (24%, 17/71). Complete trial data collection required 20 months on average to complete (mean 21, SD 12). For trials with a total duration of 2 years or more (31%, 22/71), the average time from recruitment to complete data collection (mean 35 months, SD 10) was 2 years longer than the average time required to collect primary data (mean 11, SD 8). Trials had a moderate sample size of 112 participants. Two trials were conducted online (3%, 2/71) and 7 trials collected data continuously (10%, 7/68). Onsite study implementation was heavily favored (97%, 69/71). Trials with four data collection points had a longer study duration than trials with two data collection points: $F_{4,56}=3.2, P=.021, \eta^2=0.18$. Single-blinded trials had a longer data collection period compared to open trials: $F_{2,58}=3.8, P=.028, \eta^2=0.12$. Academic sponsorship was the most common form of trial funding (73%, 52/71). Trials with academic sponsorship had a longer study duration compared to industry sponsorship: $F_{2,61}=3.7, P=.030, \eta^2=0.11$. Combined, data collection frequency, study masking, sample size, and study sponsorship accounted for 32.6% of the variance in study duration: $F_{4,55}=6.6, P<.01, \text{adjusted } r^2=.33$. Only 7 trials had been completed at the time this retrospective review was conducted (10%, 7/71).

Conclusions: mHealth evaluation methodology has not deviated from common methods, despite the need for more relevant and timely evaluations. There is a need for clinical evaluation to keep pace with the level of innovation of mHealth if it is to have meaningful impact in informing payers, providers, policy makers, and patients.

(*JMIR Mhealth Uhealth* 2016;4(3):e107) doi:[10.2196/mhealth.5720](https://doi.org/10.2196/mhealth.5720)

KEYWORDS

mobile health; mobile applications; smartphones; medical informatics; research design; clinical trials

Introduction

With over 165,000 mobile health (mHealth) apps on the Apple App Store and Google Play Store catalogues and 3 billion downloads in 2015 alone [1], mHealth apps represent a mature, robust marketplace for a new generation of patients who seek patient-empowered care and mHealth publishers who aim to facilitate this practice. mHealth apps are currently being developed for many different clinical conditions including diabetes [2], heart failure [3], and cancer [4], and have the potential to disrupt existing health care delivery pathways.

In recent years, numerous calls have been made to address the challenges inherent in mHealth app evaluation [5-7]. Key barriers were identified by researchers at the National Institutes of Health mHealth Evidence Workshop, notably the difficulty of matching the rapid pace of mHealth innovation with existing research designs [8]. Explicit attention was drawn to the randomized controlled trial (RCT), which has long been considered the primary research study design capable of eliciting causal relationships between health interventions and consequent outcomes [9]. However, RCTs are notoriously long—the average duration of 5.5 years from enrollment to publication clearly risks app obsolescence occurring before study completion [10]. With high-cost trial implementation and a rigid protocol that precludes mid-trial changes to the intervention in order to maintain internal validity, RCTs are perceived as an incompatible, impractical evaluation methodology for most mHealth apps [11-15]. There is also an inherent quality of software that does not lend itself to the rigidity of the RCT—software is meant to change, evolve, progress, and learn over time, all at a rapid pace. Rigid trial protocols undermine this principle attribute, since controlled trials were designed for interventions that take years, even decades to develop, that is, medical devices and drugs. In concluding the mHealth Evidence Workshop, researchers identified the need to develop novel research designs that can keep up with the lean, iterative, and rapid-paced mHealth apps they seek to evaluate.

The Chicago-based Center for Behavioral Intervention Technologies has endeavored to design methodological frameworks that can appropriately support mHealth evaluation. Mohr and colleagues proposed the Continuous Evaluation of Evolving Behavioral Intervention Technologies (CEEBIT) framework as an alternative to the gold-standard RCT [16]. The CEEBIT methodology is statistically powered to continuously evaluate app efficacy throughout trial duration and accounts for changing app versions through a sophisticated elimination process. The CEEBIT also thoughtfully addresses many other RCT-specific considerations, from randomization to inclusion/exclusion criteria to statistical analysis.

Additional alternatives to the RCT have also been presented, including interrupted time-series, stepped-wedge, regression discontinuity, and N-of-1 trial designs that may limit interval validity but are more responsive and relevant for evaluating mHealth interventions [8]. Novel factorial trial designs have been proposed for mHealth research and are increasingly being used to test multiple app features and determine the optimal combinations and adaptations to build an effective app. These include the multiphase optimization strategy (MOST) [17], the sequential multiple assignment randomized trial (SMART) [18], and the microrandomized trial [19]. Suggestions have also been made on how to increase the efficiency of traditional RCTs themselves, including using within-group designs, fully automating study enrollment, random assignment, intervention delivery and outcomes assessment, and shortening follow-up through modeling long-term outcomes [13]. Further, best practice evaluation methods in the field of human-computer interaction, notably usability testing and heuristic evaluation, have been widely adopted in mHealth research and are well suited to assess the efficacy of user-driven, digitally operationalized behavioral mechanisms required to elicit stable changes in health outcomes [20-22]. These alternatives allow us to reconsider the RCT for a more flexible and iterative evaluation approach that will mimic the attributes of software-based behavioral interventions and their agile app development process, where it is acceptable and preferable to learn from a poor trial outcome sooner in order to redesign the intervention more quickly and subsequently show success sooner.

In parallel to the development of novel research designs like the CEEBIT, new industry initiatives have also introduced novel platforms to deploy mHealth evaluations. In 2015, Apple announced the release of ResearchKit, a software framework designed for health research to allow iPhone users to participate in research studies more easily [23]. ResearchKit allows for the digital collection of informed consent, a process that has historically hindered the accrual of patients into trials and the scalability of clinical research. It also enables access to real-time data collected from the iPhone's accelerometer, gyroscope, microphone, and global positioning system (GPS), along with health data from external wearables (eg, FitBit, Apple Watch) to gain real-time insight into a participant's health behaviors [24]. Evidence of ResearchKit's impact can already be seen in several Apple-promoted research trials deployed for a range of conditions [25-27]. It is not difficult to imagine ResearchKit being adapted for use as a tool to evaluate mHealth app efficacy—an app claiming to help patients self-manage their diabetes could be launched using the ResearchKit framework and evidenced for efficacy through sensor data and in-app surveys.

Given the development of alternative evaluation methodologies and the launch of novel technologies to automate mHealth research, we sought to determine if these initiatives were being implemented in current clinical trials. Through this review, research designs and methods for current mHealth clinical trials were identified and characterized in an effort to understand the views of the field toward novel frameworks for evaluating mHealth apps.

Methods

A review of the ClinicalTrials.gov registry was conducted in November 2015 to identify and examine current clinical trials involving mHealth apps. The following search terms were trialed in a scoping search to optimize the search strategy: mobile application, mobile health app, mobile health application, mobile app, smartphone application, and smartphone app. A Boolean search was then conducted with all these search terms combined (“mobile application” OR “mobile health app” OR “mobile health application” OR “mobile app” OR “smartphone application” OR “smartphone app”). However, upon comparing the search results generated from all scoping searches, the search term “mobile application” independently yielded a higher number of results compared to the Boolean search. A precautionary decision was made to use “mobile application” as the sole search term to retrieve relevant trials registered between November 19, 2014, and November 19, 2015—a 1-year period before this review was initiated. The titles and abstracts of retrieved trials were assessed for inclusion, followed by a complete review of the entire trial registration. Following the final identification of trials to include in our review, we conducted a reverse search of each trial to determine whether it would have been found through our initial Boolean search and concluded that a small number of relevant studies would have been omitted. We therefore recommend the use of “mobile application” as the preferred comprehensive search term for those looking to duplicate our search strategy.

All trials were included if they (1) evaluated mHealth apps, (2) measured clinical outcomes, and (3) were deployed exclusively on a mobile phone as a native app and not a Web-based app.

Trials were excluded if (1) they evaluated mHealth apps that solely received text messages (short message service [SMS] or multimedia messaging; this was done due to a large amount of existing trials for SMS-based interventions in the literature) or phone calls as their primary behavior change modification, (2) the mHealth app was a secondary intervention or the study mixed mobile and non-mobile interventions, (3) the mHealth app was solely an appointment reminder service, and (4) the mHealth app did not require user input through active or passive (sensor) data entry.

Following the identification of studies that met inclusion criteria, trial data were extracted from the ClinicalTrials.gov website and coded according to relevant outcome variables. All data were collected directly from the registry, where trial information was originally reported and categorized by the investigators conducting the trials. Extracted data measures included trial identification, app name, study purpose, trial sponsor, targeted condition, data collection duration, data collection points, study duration, sample size, study type, control and masking methods, random allocation, group assignment, study site, qualitative components, app availability, and study design. [Table 1](#) lists all measures that were manually coded into categories from extracted data alongside their codes. A differentiation was made in coding “data collection duration,” defined as the amount of time allotted for primary data collection as specified in the outcome measures section of each ClinicalTrials.gov record detail, and “study duration,” defined as the amount of time between initial recruitment and complete data collection as specified by the “estimated study completion date” in the trial record detail. Studies were coded as being onsite if participants had any direct face-to-face contact with a member of the research team, and online if recruitment and follow-up data collection were done remotely—if a participant was recruited in a hospital setting but follow-up data were collected through the study app, this was coded as onsite implementation. Targeted conditions were further coded into parent condition categories for analysis. All identified app titles were also searched on public app stores (ie, Apple App Store, Google Play Store) to confirm whether they were available for public download.

Table 1. Manually coded study variables from extracted ClinicalTrials.gov registry data.

Variable	Coded values
Study purpose	efficacy, safety/efficacy, observational
Trial sponsor	academic, industry, collaboration
Targeted condition	mental health, cardiovascular, diabetes, cancer, asthma, obesity, other
Data collection points	1-3, 4+, continuous
Sample size	0-49, 50-99, 100-499, 500+
Study type	interventional, observational
Control	standard care, active, waitlist
Masking	open, single-blind, double-blind
Group assignment	single, parallel, three groups
Study site	onsite, online
Study design	1 group pretest-posttest, 1 group posttest, 1-3 group posttest control, 2-3 group pretest-posttest control, 2-3 group posttest non-randomized control, observational

Data Analysis

Descriptive statistics were first conducted on all variables to identify methodological data trends and parameters. In reference to Campbell and Stanley's experimental and quasi-experimental designs for research [28], measures of whether trials collected pretest or baseline data, and also the number of data collection points throughout the trial, were recorded. This was done to identify specific study designs and assess the range of study designs deemed suitable for mHealth app evaluation.

While the focus of this review was to provide an overview of the study designs and methodologies currently being employed for mHealth research, we were also interested in exploring the relationships between methodological variables, specifically identifying potential predictor variables for study duration. We first conducted independent *t* tests and one-way independent analyses of variance (ANOVA) to determine whether there were differences in study duration for the following categorical methodological variables: study sponsorship, clinical condition, pretest data collection, data collection frequency, presence of a control group, study purpose, presence of randomization, study group assignment, qualitative data collection, and app availability. We then performed a Pearson correlation analysis to test for a correlational relationship between sample size and study duration. These preliminary analyses were conducted to determine which variables were appropriate for inclusion in a multiple linear regression analysis. The assumptions of linearity, normality, independence of errors, and homoscedasticity were met, and diagnostic tests to check for outliers, homogeneity of variance, and multicollinearity were passed. The regression was then performed with study duration as the dependent variable and all significant predictor variables from our preliminary analyses as independent variables. Extreme outlier data were excised prior to analysis, leaving a dataset that included 64 trials (90%, 64/71), each with a sample size of 500 participants or less. Statistical significance was considered at $P < .05$ unless otherwise specified. All statistical analyses were conducted using SPSS Statistics version 22 (IBM Corporation).

Results

General Characteristics

Of the 137 trials identified, 71 were found to meet inclusion criteria. Table 2 details each included trial and outlines their general characteristics. Key highlights include the ClinicalTrials.gov study identification, app name, target condition, sample size, and study duration.

Methodological Characteristics

The great majority of reviewed trials were classified as interventional (96%, 68/71) with only 3 of the 71 trials (4%, 3/71) classified as observational. Most trials used an RCT design (80%, 57/71). Sixty-three of the 71 trials were classifiable under the Campbell and Stanley experimental design framework (89%, 63/71). Subdesign classifications included 36 two-group pretest-posttest control group comparisons (51%, 36/71), 16 posttest only control group comparisons (23%, 16/71), 7 one-group pretest-posttest designs (10%, 7/71), 2 one-shot case study designs (3%, 2/71), and 2 static-group comparisons (3%, 2/71). The remaining 8 trials included 2 three-group pretest-posttest control group comparisons (3%, 2/71), 1 two-group posttest non-randomized control group comparison (1%, 1/71), 1 three-group posttest non-randomized control group comparison (1%, 1/71), 1 three-group posttest control group comparison (1%, 1/71), and 3 observational studies (4%, 3/71). In total, 17 trials included a qualitative component to their methodology (24%, 17/71).

Control group assignment was divided into standard care (51%, 30/59), active treatment (44%, 26/59), and waitlist (5%, 3/59). Open masking was favored (69%, 47/68) over blinded masking (31%, 21/68). Randomization of groups was common practice among reviewed trials (84%, 57/68). There was a broad distribution of clinical conditions across the 71 trials, with mental health (17%, 12/71), cardiovascular conditions (11%, 8/71), diabetes (11%, 8/71), and cancer (10%, 7/71) leading the clinical focus. The full range of clinical conditions is shown in Table 3.

Table 2. General characteristics of reviewed trials registered on ClinicalTrials.gov.

ClinicalTrials.gov study ID	App name	Target condition	n	Study duration ^a
NCT02531074	Swipe Out Stroke	obesity	100	29
NCT02426814	Mobile phone app, inhaler sensor	asthma	50	6
NCT02615171	RELAX app	obesity	60	12
NCT02515500	Quitbit, digital lighter	smoking	200	21
NCT02421536	Vibrent	cancer	40	21
NCT02308176	Mobile phone app	obesity	118	12
NCT02370719	BantII	type 2 diabetes	150	25
NCT02618265	Mobile phone app	stroke	400	35
NCT02432469	Mission-2	coronary artery bypass	1000	18
NCT02429024	OneTouch Reveal, blood glucose meter	type 2 diabetes	142	12
NCT02399982	Noom Monitor	bulimia	80	27
NCT02486705	PTSD Family Coach	stress, depression, anxiety	242	8
NCT02322307	HealthPROMISE	irritable bowel syndrome	300	29
NCT02346591	Jauntly	depression, stress	298	9
NCT02503098	Recovery Record	eating disorders	12000	18
NCT02417623	OBSBIT	obesity	76	24
NCT02392000	CBT-I Coach, sleep monitor	insomnia	40	6
NCT02400710	PTSD Coach	posttraumatic stress disorder	30	32
NCT02445196	PTSD Coach	posttraumatic stress disorder	120	15
NCT02421965	FOCUS	schizophrenia	174	30
NCT02375776	CORA	cancer	104	10
NCT02451631	Health-on G, physician web monitoring	type 2 diabetes	184	11
NCT02313363	Mobile phone app	type 2 diabetes	30	3
NCT02521324	RESPERATE, breathing sensor	traumatic brain injury	40	16
NCT02501642	TBI Coach	sleeplessness	486	48
NCT02457923	M-SAKHI	malnutrition	2728	38
NCT02589730	Welltang	type 1 and 2 diabetes	234	12
NCT02431546	VIDA	coronary artery disease	40	15
NCT02359981	MyBehavior	obesity	17	1
NCT02405117	LiveWell, wrist-worn device	bipolar disorder	48	27
NCT02610894	PoCAH	surgery	40	24
NCT02472561	iHealth, Withings	peripheral artery disease	45	13
NCT02439619	TechCare	psychosis	16	35
NCT02601794	Mobile phone app	breast cancer	180	7
NCT02448888	Mobile phone app	back pain	24	11
NCT02497755	Ginger.io	anxiety, depression	25	4
NCT02555553	Noom Monitor	bulimia	200	18
NCT02554578	Mobile phone app, web platform	heart transplant	158	14
NCT02418910	KIOS-Bipolar, eMoods	bipolar disorder	50	18
NCT02510924	Airtraq	nasal obstruction, arthrosis	100	12
NCT02580396	CanADVISE+	metastatic breast cancer	25	24
NCT02350257	Mobile phone app	anxiety disorders	130	33

ClinicalTrials.gov study ID	App name	Target condition	n	Study duration ^a
NCT02551640	FeatForward	type 2 diabetes	300	9
NCT02333630	AsthmaCare	asthma	200	13
NCT02588729	Pregnant+	gestational diabetes	264	38
NCT02599857	CONCOR	congenital heart disease	500	24
NCT02496728	NUYou	cardiovascular disease	800	38
NCT02565225	RheumaLive	rheumatoid arthritis	60	32
NCT02484794	Recovery Record	eating disorders	40	12
NCT02494245	STARFISH	stroke	128	24
NCT02308878	Mobile phone app	substance use dependence	65	20
NCT02592291	Mobile phone app	spinal cord and brain injuries	160	59
NCT02341235	Mobile phone app	breast cancer	120	58
NCT02470143	Mobile phone app	coronary heart disease	20	11
NCT02480062	mWELLCARE	cardiovascular disease	3600	20
NCT02477137	Mobile phone app	prostate cancer	150	40
NCT02420015	Stay Quit Coach	schizophrenia	36	20
NCT02479607	Mobile phone app	breast cancer	150	24
NCT02591459	Mobile phone app	autism	10	2
NCT02499094	Mobile phone app	depression	1004	7
NCT02382458	Mobile phone app	chronic inflammation	120	25
NCT02517047	Mobile phone app, CareTRx device	asthma	26	22
NCT02521558	Mobile phone app	Alzheimer's disease	100	11
NCT02385643	Mobile phone app, Bluetooth sensor	alcohol dependence	100	46
NCT02317614	SteadyRx	human immunodeficiency virus	50	28
NCT02556073	MyAsthma, inhaler	asthma	112	28
NCT02302040	Team Speak	asthma	50	20
NCT02492191	Recovery Assessment by Phone Points	postoperative complications	1000	14
NCT02580409	Wellpepper	mobility limitations	76	24
NCT02341950	SCI Hard	spinal cord injury	200	12
NCT02403427	VoiceDiab, insulin pump	type 1 diabetes	42	9

^aStudy duration is measured in months.

Table 3. Targeted clinical conditions.

Conditions	n (%)
Mental health	12 (16.9)
Anxiety	2
Bipolar disorder	2
Depression	1
Psychosis	1
PTSD	2
Schizophrenia	2
Stress	2
Cardiovascular	8 (11.3)
Cardiovascular disease	2
Congenital heart disease	1
Coronary artery bypass	1
Coronary artery disease	1
Coronary heart disease	1
Heart transplant	1
Peripheral artery disease	1
Diabetes	8 (11.3)
Gestational diabetes	1
Type 1 diabetes	1
Type 2 diabetes	5
Type 1 and 2 diabetes	1
Cancer	7 (9.9)
Breast cancer	4
Prostate cancer	1
General	2
Asthma	5 (7.0)
Obesity	5 (7.0)
Eating disorder	4 (5.6)
Surgery	3 (4.2)
Insomnia	2 (2.8)
Spinal cord injury	2 (2.8)
Stroke	2 (2.8)
Substance abuse	2 (2.8)
Other	11 (15.5)
Alzheimer's disease	1
Arthritis	1
Autism	1
Back pain	1
Chronic inflammation	1
Human immunodeficiency virus	1
Inflammatory bowel disease	1
Malnutrition	1

Conditions	n (%)
Mobility	1
Smoking	1
Traumatic brain injury	1

By condition in order of prevalence, 9 mental health trials were RCTs (75%, 9/12), with 4 trials designed as classic two-group pretest-posttest control group comparisons (33%, 4/12). Seven of 8 cardiovascular trials were RCTs (88%, 7/8), with all 7 designed as two-group pretest-posttest control group comparisons. Seven of 8 diabetes trials were also RCTs (87.5%; 7/8), with 5 two-group pretest-posttest control group comparisons (63%, 5/8). Most of the asthma trials were RCTs (80%, 4/5), with all 4 adhering to a two-group pretest-posttest

control group comparison design. Finally, all 5 obesity trials were RCTs (100%, 5/5), but none adhered to a two-group pretest-posttest control group comparison design.

Most trials did collect pretest data prior to study implementation (68%, 46/68). Trials had on average three data collection points (mean 2.7, SD 1.2) with 7 trials collecting data continuously (10%, 7/68). Table 4 summarizes the distribution of apps across methodological variables.

Table 4. Distribution of apps across methodological variables.

Variable	n (%)
Study type	
Interventional	68 (95.8)
Observational	3 (4.2)
Pretest data collected	
Yes	46 (67.6)
No	22 (32.4)
Control treatment	
Standard care	30 (50.8)
Active	26 (44.1)
Waitlist	3 (5.1)
Masking	
Open	47 (69.1)
Single-blind	17 (25.0)
Double-blind	4 (5.9)
Randomization	
Yes	57 (83.8)
No	11 (16.2)
Qualitative component	
Yes	17 (23.9)
No	54 (76.1)
Study location	
Onsite	69 (97.2)
Online	2 (2.8)
Data collection points	
One	12 (17.6)
Two	20 (29.4)
Three	17 (25.0)
Four or more	12 (17.6)
Continuous	7 (10.3)

Descriptive Characteristics

Data collection duration was relatively short on average (median 6 months, IQR 8) with the majority of trials having a data collection period of 6 months or less (72%, 51/71). However, the range of duration was broad, with the shortest data collection period lasting 10 days and the longest period lasting 4 years.

Study duration was 20 months on average (mean 21, SD 12); researchers continued to collect secondary data for nearly a year after they had completed their primary data collection (median 12, IQR 13). This discrepancy between study duration and data collection duration was more pronounced in studies with a total duration of 2 years or more (31%, 22/71) where the average time from recruitment to complete data collection (mean 35, SD 10) was 2 years longer than the average time required to collect primary data (mean 11, SD 8). Of the 71 trials, only 7 had been completed at the time this retrospective review was conducted (10%, 7/71).

Enrollment varied across trials (median 112, IQR 158): 20 trials had a sample size of 0-49 (28%, 20/71), 10 had a sample size of 50-99 (14%, 10/71), 33 had a sample size of 101-499 (47%, 33/71), and 8 had sample sizes of over 500 participants (11%, 8/71)—the largest being 12,000 participants.

Studies with at least one component of onsite implementation were heavily favored, with 69 trials (97%, 69/71) opting for onsite recruitment and implementation. It should be noted that

the trial with the largest sample size ($N = 12,000$) had online study implementation.

Nearly three-quarters of the trials (72%, 51/71) had official app names, which suggested that they were positioned for commercialization or were already available on the market. However, only 17 apps (24%, 17/71) were publicly available for download as of December 2015. Academic sponsorship was the most common form of trial funding (73%, 52/71), followed by an academic-industry collaboration (18%, 13/71) and industry sponsorship (9%, 6/71).

Methodological Analysis

Our preliminary t tests and ANOVAs to determine whether differences existed in study duration across methodological variables revealed three significant variables: data collection frequency, $F_{4,56}=3.2$, $P=.021$, $\eta^2=0.18$; masking, $F_{2,58}=3.8$, $P=.028$, $\eta^2=0.12$; and study sponsorship, $F_{2,61}=3.7$, $P=.030$, $\eta^2=0.11$. Follow-up Bonferroni and Fisher's least significant difference tests were conducted to evaluate pairwise differences among study duration means. We identified a significant difference in the means between two and four or more data collection points (mean_{diff}=-15, SE=5, $P=.025$), open and single-blinded masking (mean_{diff}=-10, SE=4, $P=.026$), and industry and academic study sponsorship (mean_{diff}=12, SE=6, $P=.033$). Descriptive statistics for studies included in this analysis are presented in [Table 5](#).

Table 5. Study duration means of trials included for analysis grouped by data collection frequency, masking, and study sponsorship.

Variable	n (%)	Mean duration (months)	SD	95% CI	
				Low	High
Data collection points	61 (100)				
One	12 (19.7)	25	11	18.0	32.2
Two	18 (29.5)	16	11	10.2	21.2
Three	13 (21.3)	18	8	12.9	22.0
Four or more	11 (18.0)	30	17	18.5	41.9
Continuous	7 (11.5)	20	12	8.3	30.9
Masking	61 (100)				
Open	46 (75.4)	19	11	15.2	21.8
Single-blind	13 (21.3)	29	16	19.1	38.8
Double-blind	2 (3.3)	16	7	-47.5	79.5
Study sponsorship	64 (100)				
Academic	49 (76.6)	23	13	19.0	26.7
Industry	5 (7.8)	10	2	7.5	13.3
Academic-industry collaboration	10 (15.6)	15	6	10.4	19.4

A correlation analysis of the relationship between sample size and study duration revealed a positive but weak correlation between both variables: $r=.25$, $P=.044$. Based on this finding, we included sample size as a predictor variable in our multiple linear regression model for predicting study duration alongside data collection frequency (two versus four or more data collection points), masking (open versus single-blinded), and

study sponsorship (academic versus industry). The focus of this analysis was prediction, so we used a stepwise method of variable entry. The results of our regression analysis indicated that all four of our predictors combined accounted for 32.6% of the variance in study duration: $F_{4,55}=6.6$, $P<.01$, adjusted $r^2=.33$. Data collection frequency alone, specifically the difference between two and four or more data collection points,

was able to explain 11.5% of the variance in study duration. Together with the difference between single versus open masking, these variables explained 19.7% of the variance in study duration. Sample size added 6.7% to the explanation of variance in study duration, and the difference between academic and industry sponsorship added another 6.2%. Each step in the model added significantly to its predictive capabilities. Based

on this model, the prediction equation is as follows: $13.79 + 10.71*(\text{two versus four or more data collection points}) + 6.88*(\text{single versus open masking}) + 0.04*(\text{sample size}) - 12.00*(\text{industry versus academic sponsorship})$. Table 6 presents the regression coefficients and standard errors for each of the four significant predictors.

Table 6. Multiple linear regression model of predictors for study duration.

Variable	R ^{2a}	B ^b	SE _B ^c	β ^d	P value
Constant		13.79	2.31		<.001
Data collection frequency (2 vs 4+ data collection points)	.12	10.71	3.68	.33	.005
Masking (single vs open-blinded)	.20	6.88	3.50	.23	.055
Sample size	.26	0.04	0.01	.31	.009
Study sponsorship (academic vs industry)	.33	-12.00	5.33	-.26	.028

^aR²: amount of accounted study duration variability.

^bB: unstandardized regression coefficient.

^cSE_B: standard error of the coefficient.

^dβ: standardized coefficient.

Discussion

Principal Findings

Our review has shown that the overwhelming majority of mHealth researchers are continuing to use the RCT as the trial design of choice for evaluating mHealth apps. The consistent use of RCTs to demonstrate efficacy across disparate clinical conditions suggests that researchers view this design to be condition-agnostic and truly the gold standard for any clinical trial evaluating app efficacy. While trials of apps for managing obesity did not adhere to a two-group pretest-posttest control group comparison design as defined by the Campbell and Stanley framework, and only a third of mental health apps used this classic RCT design, the majority of trials for other prevalent conditions did favor this specific study design to evaluate health outcomes and elicit proof of app efficacy. This homogeneity of study designs within the framework suggests that researchers are not adapting designs to align with the unique qualities inherent in the mHealth apps they are evaluating.

Some unexpected findings emerged from our review, one being the near-complete lack of variation in study implementation sites—97% of trials were conducted onsite in academic centers and hospitals, with only two trials employing online recruitment and data collection. Regarding trial duration, mHealth trials had a total data collection period of 20 months on average. We were able to identify four predictor variables that accounted for 32.6% of the variance in trial duration: data collection frequency, masking, sample size, and study sponsorship.

Our analysis of the relationship between the number of data collection points in an mHealth trial and the duration of the trial revealed that trials with four or more data collection points would have a significantly longer data collection period compared to trials with two data collection points. While this finding suggests that mHealth trials might benefit from a study implementation process that includes automated data collection

through the intervention app to allow for frequent data collection without prolonging study duration, our review results are inconclusive in supporting this recommendation given the lack of a clear relationship between study length and data collection frequency. In analyzing the raw review data, there is no significant difference in study duration between one, three, and four or more data collection points, and trials with one data collection point are similarly long in duration compared to trials with four or more data collection points. With this in mind, we are cautiously optimistic in our advocacy of automated study implementation, from recruitment to data collection, for all mHealth trials.

While many trials had open masking, nearly a third chose to blind their participants or outcomes assessor, and four trials even went as far as to double-blind both participant and investigator. This level of rigor was unanticipated for a field that has been criticized for a lack of evidence demonstrating efficacy and impact [29]. We were surprised to find that single-blinded trials were significantly longer in duration compared to open trials. However, given the dearth of empirical evidence to support the role of double blinding in bias reduction [30] and the inconclusive nature of our raw data, which did not show an increase in study duration between open and double-blinded trials, more data are required to investigate this relationship prior to discounting the value of masking in favor of shorter trials.

Despite the fact that the majority of reviewed trials were funded by academic research grants, industry-academic partnerships were not uncommon and suggest that industry publishers have realized the potential of engaging with academic institutions to bolster the credibility of their apps. However, these partnerships warrant particular attention given past lessons learned from duplicitous investigative behavior exhibited by industry-funded research teams [31]. Our review results revealed that industry-funded mHealth trials were significantly shorter in

duration than their academic counterparts. A potential explanation for this difference in study duration is the use of study outcomes in industry trials that are more sensitive to short-term changes (eg, quality of life, frequency of desired health behaviors, engagement with mHealth app) over outcomes with a longer trajectory towards measurable change (eg, frequency of emergency department visits, quality-adjusted life years, mortality). These trials may also be bound by competitive industry-led timelines, which dictate how long an app can spend in research and development before it must be released to generate profit—a concern that is shared but not equally prioritized in academic mHealth app development. It is apparent that industry-funded mHealth trials differ from purely academic pursuits in both research objectives and anticipated outcomes, making efforts to maintain methodological rigor and increase the transparency of industry-academic collaborations a critical endeavor as these relationships grow in popularity.

It is very clear that only a fraction of publicly available apps are evaluated [32], and our identification of 71 mHealth trials initiated over a 1-year period is in stark comparison to the tens of thousands of unevaluated apps publicly deployed during the same time period. While the mHealth trials we reviewed were methodologically rigorous, it was obvious that the methods themselves have not changed: not once in the registration of any mHealth clinical trial was the CEEBIT methodology mentioned, nor alternate methodologies that have been identified as more suitable for mHealth evaluation. The mobile phone platform on which mHealth apps are hosted is not being leveraged through initiatives like ResearchKit to improve recruitment for large sample sizes or to passively collect data with built-in sensors. This is unfortunate given the opportunity to explore and build upon mobile phone capabilities for research purposes. It was also unclear how trials with data collection periods of 2 years or more would maintain the relevance of their findings.

From our preliminary results, it appears that investigators conducting mHealth evaluations are applying positivistic experimental designs to elicit causal health outcomes. This insight is a cause for concern because it neglects to consider that (1) mHealth apps are complex interventions [33] and as such, (2) mHealth apps might therefore be fundamentally incompatible for evaluations founded on purely positivistic assumptions [34].

In addressing the first point, mHealth apps may simply be software programs on a mobile phone, but they have personal and social components that prove unstable when they are forced to be defined and controlled [35]. mHealth researchers should acknowledge that app users may intend to use technology for improved health but also exhibit unpredictable behaviors of poor compliance, deviant use, and in rare cases even negligence. This will affect both internal and external validity of traditional trials looking to prove direct causation.

To illustrate our second point, various positivistic assumptions regarding mHealth apps should be considered. A positivistic researcher might state that mHealth apps affect a single reality that is knowable, probabilistic, and capable of being objectively measured. They might think it is reasonable to make

generalizable statements about the relationship between the app and consequent health outcomes. They might then assume a methodological hierarchy of research designs to validate this reality, with quantitative experimental studies being seen as the most robust, for which the RCT is the gold standard. While this viewpoint is evidently endorsed by the majority of mHealth researchers whose work was identified in this review, it has not been justified in practice due to the challenge of isolating the relationship between the user and the specific mHealth app being evaluated [14]. The hallmark of the RCT is its ability to control for contextual variables in order to only measure causal impact between independent and dependent variables. However, mHealth evaluations that implement an RCT methodology are often forced to engage in trade-offs that breach RCT protocol but increase the usage and adherence rates critical to study implementation [36]. mHealth researchers have recognized a host of research implementation barriers, from the deployment environment, to app bugs and glitches, to user characteristics and eHealth literacy [37]. It is arguably easier to prevent patients from taking a drug that might interfere with their health outcomes in a pharmaceutical trial than it is to prevent patients from using an alternative diabetes management app or reading about diabetes management strategies on a website during an mHealth trial. Finally, of the trials we reviewed, the apps we evaluated were not simple and static; they were sociotechnical systems [38] that were robust in functionality and provided timely, continuous, and adaptable care personalized to the needs of their users. If we ignore these natural attributes in evaluating apps and remain wedded to traditional research designs that view these strengths as confounders, we will fail to capture the complex technological nuances and mechanisms of change facilitated by apps [39] that can impact positive health outcomes.

Limitations

In addressing the limitations of our review, we must acknowledge the rapid pace at which mHealth trials are being registered to ClinicalTrials.gov. In the 5 months following our initial search, 31 new trials had been added to the registry that met our inclusion criteria. On initial assessment, these trials are in line with our review findings. The majority adhere to a classic two-arm RCT trial design, target a range of complex chronic conditions, and are on average 2 years in duration. We aim to update our review in 6-month intervals to capture the high volume of incoming mHealth clinical trials.

Our study duration calculation was based on the “study start date” and “study completion date” fields reported by researchers on ClinicalTrials.gov. We recognize that in using study duration as the primary dependent variable for analysis, we are subjecting our results to the inherent variability of prospectively estimated study durations, which may differ greatly from actual study durations reported post trial. To address this limitation in the reliability of our data, we will monitor the status of all reviewed trials as they move toward completion and update our results to reflect any significant divergences between estimated and actual study duration.

Due to time and resource constraints, we did not perform an exhaustive search of all mHealth trials that had published either manuscripts or protocols in the literature during our 1-year

search period. Our decision to have a sampling method solely focused on a single trials registry may have resulted in a biased identification of trials with more traditional positivist methods—this is also suggested by how the trials we reviewed were largely academically sponsored. We acknowledge that the trials registered on ClinicalTrials.gov do not make up the sum total of mHealth research. There is a large body of mHealth evaluative work that is not registered on ClinicalTrials.gov, notably apps that have engaged in usability testing and feasibility pilot studies but have not undergone formalized clinical research [22,40-44], as well as direct-to-consumer apps that publish evaluative reports of their in-house testing online but do not submit their work for review through formal research channels [45-47]. As such, our findings on the homogeneity of mHealth clinical trial methods are limited to trials registered on ClinicalTrials.gov. We aim to conduct a more systematic search of the mHealth literature and also search additional mobile app store catalogues (ie, Windows, Samsung, Blackberry) for

publicly available trial apps in a future review to improve the representativeness of our findings.

Conclusion

It is clear that mHealth evaluation methodology has not deviated from common methods, despite the issues raised. There is a need for clinical evaluation to keep pace with the rate and scope of change of mHealth interventions if it is to have relevant and timely impact in informing payers, providers, policy makers, and patients. To fully answer the question of an app's clinical impact, mHealth researchers should maintain a reflexive position [35] and establish feasible criteria for rigor that may not ultimately result in a positivist truth but will drive an interpretive understanding of contextualized truth. As the mHealth field matures, it presents the challenge of establishing robust and practical evaluation methodologies that further foundational theory and contribute to meaningful implementation and actionable knowledge translation—all for optimized patient health and well-being.

Conflicts of Interest

None declared.

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Abbreviations

ANOVA: analysis of variance

CEEBIT: Continuous Evaluation of Evolving Behavioral Intervention Technologies

GPS: global positioning system

MOST: Multiphase Optimization Strategy

RCT: randomized controlled trial

SMART: Sequential Multiple Assignment Randomized Trial

SMS: short message service

Edited by D Spruijt-Metz; submitted 09.05.16; peer-reviewed by H Potts, N Azevedo, M Larsen; comments to author 08.06.16; revised version received 20.07.16; accepted 12.08.16; published 09.09.16.

Please cite as:

Pham Q, Wiljer D, Cafazzo JA

Beyond the Randomized Controlled Trial: A Review of Alternatives in mHealth Clinical Trial Methods

JMIR Mhealth Uhealth 2016;4(3):e107

URL: <http://mhealth.jmir.org/2016/3/e107/>

doi: [10.2196/mhealth.5720](https://doi.org/10.2196/mhealth.5720)

PMID: [27613084](https://pubmed.ncbi.nlm.nih.gov/27613084/)

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Original Paper

Reciprocal Reinforcement Between Wearable Activity Trackers and Social Network Services in Influencing Physical Activity Behaviors

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Abstract

Background: Wearable activity trackers (WATs) are emerging consumer electronic devices designed to support physical activities (PAs), which are based on successful behavior change techniques focusing on goal-setting and frequent behavioral feedbacks. Despite their utility, data from both recent academic and market research have indicated high attrition rates of WAT users. Concurrently, evidence shows that social support (SS), delivered/obtained via social network services or sites (SNS), could increase adherence and engagement of PA intervention programs. To date, relatively few studies have looked at how WATs and SS may interact and affect PAs.

Objective: The purpose of this study was to explore how these two Internet and mobile technologies, WATs and SNS, could work together to foster sustainable PA behavior changes and habits among middle-aged adults (40-60 years old) in Taiwan.

Methods: We used purposive sampling of Executive MBA Students from National Taiwan University of Science and Technology to participate in our qualitative research. In-depth interviews and focus groups were conducted with a total of 15 participants, including 9 WAT users and 6 nonusers. Analysis of the collected materials was done inductively using the thematic approach with no preset categories. Two authors from different professional backgrounds independently annotated and coded the transcripts, and then discussed and debated until consensus was reached on the final themes.

Results: The thematic analysis revealed six themes: (1) WATs provided more awareness than motivation in PA with goal-setting and progress monitoring, (2) SS, delivered/obtained via SNS, increased users' adherence and engagement with WATs and vice versa, (3) a broad spectrum of configurations would be needed to deliver WATs with appropriately integrated SS functions, (4) WAT design, style, and appearance mattered even more than those of smartphones, as they are body-worn devices, (5) the user interfaces of WATs left a great deal to be desired, and (6) privacy concerns must be addressed before more mainstream consumers would consider adopting WATs.

Conclusions: Participants perceived WATs as an awareness tool to understand one's PA level. It is evident from our study that SS, derived from SNS and other pertinent vehicles such as the LINE social messaging application (similar to WhatsApp and WeChat), will increase the engagement and adherence of WAT usage. Combining WATs and SNS enables cost-effective, scalable PA intervention programs with end-to-end services and data analytics capabilities, to elevate WATs from one-size-fits-all consumer electronics to personalized PA assistants.

KEYWORDS

Wearable activity trackers; wearables; physical activity; social support; social network services; behavior change techniques

Introduction

Active Aging (AA) is the public policy framework stipulated by the World Health Organization (WHO) to embrace global aging challenges [1]. A systematic literature review of Social Sciences Citation Index Journal Articles on AA referred to physical activity (PA) as the second most researched determinant in AA, next only to gender [2]. However, the WHO pointed out that physical inactivity levels are still rising in many countries [3]. Wearable activity trackers (WATs) are emerging consumer electronics to assist PA, yet some empirical studies have revealed high attrition rates of WAT users with few solid explanations [4,5]. This study aimed to identify if social support (SS), delivered and obtained via social network services or sites (SNS), can increase WAT users' engagement and reduce their attrition rate to foster more sustainable PA habits.

The Importance of Midlife Physical Activity

Research results have demonstrated that there is a direct connection between midlife fitness levels and the onset and frequency of chronic diseases later in life [6]. To promote and maintain health, it is recommended that adults do moderately intensive exercise for at least 30 minutes five days each week, or vigorously intensive activity for at least 20 minutes three days each week [7]. Previous studies in Australia and other countries have revealed that middle-aged adults (45-59 years), particularly men, are least likely to achieve these recommendations [8-10].

Wearable Activity Trackers' Gaining Popularity and Looming Problem

WATs are body-worn sensors combined with smart phone apps to allow tracking and recording of one's PAs [11]. International Data Corporation predicted that the worldwide WAT market will reach a total of 111.1 million units shipped in 2016, and will grow to 214.6 million units in 2019 [12]. PricewaterhouseCoopers' (PwC) Health Wearables Report pointed out that in 2014, 21% of American consumers already owned wearable devices [13]. Analyses of PA interventions using WATs have shown that goal-setting and frequent behavioral feedback are strongly associated with successful behavior change techniques (BCT) [14-20], by offering objective monitoring rather than relying on self-reports. A systematic review has examined the validity and reliability of WATs by summarizing 22 studies regarding the ability to estimate steps, distance, PA, energy expenditure, and sleep [21]. Available studies have proven the effectiveness of WATs in increasing PA among patients with various health problems [22]. To date, there are few studies probing how WATs may be used in preventive ways (ie, helping people who are still healthy to maintain or increase their PA level). In this study, we intended to focus on middle-aged adults to explore how WATs may help them establish PA behaviors and habits. Although the use of the technology is often considered to be driven by younger age

groups, a previous study has indicated that the uptake of wearable devices is bi-modally distributed; younger (25-34 years old) groups use them for fitness enhancement, while older (55-64 years old) groups use them to improve overall health [23].

Despite the boom in the WAT market, there seems to be a looming problem. A recent study indicated that 75% of WAT users stopped using the device in just four weeks [4]. Endeavour Partners' research in late 2013 revealed that more than half of the US consumers who have owned a modern activity tracker no longer used it after 18 months, and a third stopped within six months [5]. It appears that the adoption of WATs is short-lived, and self-efficacy may have played a role in PA adherence [24]. One must believe in his or her capabilities in successfully executing one's necessary course of action to satisfy situational demands. Therefore, how to enhance self-efficacy becomes a crucial issue.

Social Support

SS has great impacts on health, and both the types and sources of SS influence the effects [25]. SS includes four domains of positive and negative social exchange factors. Positive domains are emotional, instrumental, informational, and companionship. Emotional support is defined as others' expressions of warmth, sympathy, and caring; instrumental support is defined as others' provision of services and material aid; informational support is others' provision of advice and information; and companionship is being available or accessible when needed. Negative exchanges correspond to the lack of the four positive domains described above [26,27].

Prior research indicated that WATs have been adopted by individuals seeking to enhance their personal fitness through increased self-monitoring *as well as* social connections with others using the devices [22]. The researchers wondered whether WATs designed with integrated SS functions would be more effective in changing PA behaviors and habits. Alternatively, WATs might reinforce SS, and then change PA behaviors and habits more effectively.

Social Network Services

SNSs could facilitate the online provision of social relationships to affect health outcomes. While overcoming barriers of physical distance or geographic isolation, SNS could supplement or replace in-person social networks [28]. Previous research has demonstrated the effectiveness of online health intervention programs by providing SS through participants' sharing, reading, and responding to each other's messages. Such programs resulted in decreased participant attrition, and increased adherence, completion rate, and engagement. [29-33]. A systematic SS review was undertaken, including a total of 2040 studies identified from eight databases (eg, Scopus, Medline, ProQuest, EMBASE). Of the 2040 studies, 10 met inclusion criteria with interventions using health social network websites,

which involved a total of 113,988 participants. Nine of the 10 included studies reported significant improvements in some aspect of health behavior change or outcomes related to behavior change [34]. Facebook was the most utilized SNS, followed by health-specific SNSs and Twitter.

In Asia, variations of SNS have been well-received. The social messaging application LINE surpassed 400 million users worldwide in 2014. Originally in Japan, it is now being used by 75% of the population in Taiwan [35]. Currently, there is little research published in English periodicals on how LINE could be employed as a SS delivery mechanism to influence PA. A small number of studies examined a prototype that facilitated social interactions among users, such as sending messages, greetings, comments, and setting up challenges, rather than allowing data sharing [36]. LINE can provide the aforementioned functions as well as group chat, in which members of the group can set up shared note pages and albums, and manage member lists easily [37].

We believe that SS from interpersonal interactions can achieve constructive reinforcement for using WATs and add a new dimension for designing the products, services, and eco-system. This qualitative study was designed to identify possible correlates between SS and WATs to pave the way for more evidence-based research in the future.

Methods

This research is a qualitative study using the triangulated approach of both in-depth interviews and focus groups. Triangulation is the application and combination of several research methods in a study of the same phenomenon, and is often used to facilitate validation of data through cross verification from two or more sources. Triangulation also helps ensure the credibility of qualitative analyses [38]. Group dynamics of focus groups allowed us to get richer interactions in areas in which participants had shared experiences or views. In-depth interviews allowed deeper probing of individual attitudes and emotions without interference or peer pressure from other participants. We aimed to probe participants' PA, WAT usage, and how WATs influenced their PA habits or behaviors. The study period was from August to September of 2015. All in-depth interviews were conducted in Mandarin at cafés or restaurants of the participants' choice. The three focus groups were undertaken in school lounges. Although discussion guides were developed (see [Multimedia Appendix 1](#)), they were not adhered to rigidly, to allow conversations to flow, and participants or interviewers could leave the room for probing when necessary. All discussions were audiotaped and transcribed, and all participants signed a written consent form.

We conducted the first round of three in-depth interviews (two users versus one nonuser), then used the first round's findings (from initial coding and analysis) to revise our focus group discussion guides. Two focus groups of WAT users (4 and 2 participants each) and one focus group of nonusers (4 participants) were held (see details in [Table 1](#)). We were conscious of the gender imbalance (2 female vs 11 male students), so we conducted two additional in-depth interviews

with female students (one user vs one nonuser). During these interviews, similar themes were reiterated, and considering time and budget constraints, we deemed that the data had reached satisfactory saturation for the purpose of this study.

Sampling and Recruitment

We followed the definition of the United Nations on middle-aged adults comprising the group ranging from 40-59 years old [39]. We used purposive sampling to recruit Executive MBA students from National Taiwan University of Science and Technology through the school's student directory. These executives were middle-aged and tended to lead very busy lifestyles, and found regular PA difficult to attain or maintain. We recruited a total of 15 participants, including 9 WAT users (2 females, 7 males) and 6 nonusers (2 females, 4 males) with a median age of 45. We chose to include both the users and nonusers in our study because we wanted to compare and contrast the PA behaviors and habits between the two groups. Nonusers were potentially former WAT users, and we hoped to gain insights on why they quit using WATs. In this study, nonusers were defined as those who were not currently using WATs.

Data Collection

All focus groups and in-depth interviews were conducted by the lead author and digitally recorded. The duration of each meeting was approximately 60 to 90 minutes. At the start of each session, the moderator introduced the purpose of the research and the definition of PA based on WHO guidelines [3]. The discussion guide for users was devised to explore four key questions: (1) *what types of WATs are you currently using?*, (2) *for what PA do you use WATs?*, (3) *how does your WAT affect your PA behaviors or habits?*, and (4) *what do you see as the benefits and drawbacks of WATs?*

We started out with open-ended questions with no presumptions. By the end of the first few sessions, a recurring theme of SS emerged throughout the conversation, so we decided to more deeply probe the aspect of SS in ensuing discussions.

Data Analysis

Trained research assistants transcribed verbatim from the digital audio recordings of each focus group and interview. We applied an iterative and thematic approach to the data by using constant comparative methods and manual coding with no preset categories. Two study authors independently annotated and coded the transcripts, with both identifying emerging topics for discussion as data collection proceeded, and each researcher modified and added codes in light of fresh transcripts. Observations, interpretations, and coded results were periodically compared and debated. Early common themes emerged across the WAT user and nonuser groups, such as the motivations and barriers in carrying out their PA routinely, the importance of SS sources and types of SS, and the SNS that participants had been using to re-enforce their PA behaviors or habits. After the first few sessions' data were collected and analyzed, SS was used as an overarching analytical framework. The SS lens gave us insights that went much deeper than WATs simply being used as self-monitoring devices.

Table 1. Data pertaining to focus groups and in-depth interviews.

Focus groups						
	Code	Code Denotation	Age	Occupation	Function	WAT brand, if using
<i>Focus group 1 - Aug. 26, 2015</i>						
Nonuser	NFW1	Nonuser, Focus group, Woman, #	48 years old	Telecommunications	Self-Employed Consultant	NA
Nonuser	NFM1	Nonuser, Focus group, Man, #	40 years old	Information Technology	Management Information Systems	NA
Nonuser	NFM2	Nonuser, Focus group, Man, #	44 years old	Health care & Pharmaceutical	Marketing	NA
Nonuser	NFM3	Nonuser, Focus group, Man, #	45 years old	Display Technology	Sales & Business Development	NA
<i>Focus group 2 - Sept. 6, 2015</i>						
User	UFW1	User, Focus group, Woman, #	43 years old	E-Commerce	Entrepreneur	Xiao-Mi
User	UFM1	User, Focus group, Man, #	55 years old	Building & Construction	Business Development	Xiao-Mi
<i>Focus group 3 - Sept. 12, 2015</i>						
User	UFM2	User, Focus group, Man, #	40 years old	Information Technology	Management Information Systems	CU (a local brand)
User	UFM3	User, Focus group, Man, #	42 years old	Information Technology	Marketing	Garmin
User	UFM4	User, Focus group, Man, #	54 years old	Information Technology	Technical Support	Xiao-Mi
User	UFM5	User, Focus group, Man, #	45 years old	Media	Administration	Apple Watch, Xiao-Mi
In-depth interviews						
	Code	Code Denotation	Age	Occupation	Function	WAT brand, if using
Aug. 19, 2015 User	UIM1	User, In-depth interview, Man, #	51 years old	Education	Administration	Apple Watch
Aug. 20, 2015 User	UIM2	User, In-depth interview, Man, #	50 years old	Telecommunications	Sales & Business Development	Xiao-Mi
Aug. 25, 2015 Nonuser	NIM1	User, In-depth interview, Man, #	45 years old	Financial Services	Sales & Business Development	NA
Sept. 6, 2015 Nonuser	NIW1	User, In-depth interview, Woman, #	50 years old	Semiconductor	Administration	NA
Sept. 19, 2015 User	UIW1	User, In-depth interview, Woman, #	43 years old	Information Technology	Product & Service Development	Apple Watch

Results

All participants who were WAT users adopted the device to measure their PA in order to improve their health. Underlying the broad umbrella of *health*, there were different individual motivations, including health check-up alarms (UFM4's diabetes), fear of hereditary fatal diseases (UIM1's parents both died of cancer), losing weight (UIW1, NIW1), relieving stress (NFM3, UIM1), monitoring sleep quality (UIM2), and desire for looking good (UFW1).

Our study revealed that all participants except for one expressed the need to employ other BCTs and tools such as SS and SNS alongside with WATs to keep themselves motivated. The only user (UIM1) who was satisfied with using WAT alone to assist his PA positioned WAT as a self-monitoring and goal-setting tool. He had been keeping regular exercise and healthy diet for years, which demonstrated a very high level of self-efficacy.

Thematic analysis of this study discovered six themes: (1) WATs provided more *awareness* than *motivation* in PA with goal-setting and progress monitoring, (2) SS, delivered/obtained via SNS, increased users' adherence and engagement with

WATs and vice versa, (3) a broad spectrum of configurations would be needed to deliver WATs with appropriately integrated SS functions, (4) WAT design, style, and appearance mattered even more than those of smartphones, as they are body-worn devices, (5) the user interfaces of WATs left a great deal to be desired, and (6) privacy concerns must be addressed before more mainstream consumers would consider adopting WATs.

The application of the analytical lens of SS helped us focus on what was valued by our participants in their interactions and relationships with their friends, families, peers, and health care and fitness professionals while they were striving to achieve their PA goals.

Wearable Activity Trackers Provided More Awareness than Motivation in Physical Activity with Goal-Setting and Progress Monitoring

All participants who were WAT users mentioned some triggers for starting to take PA seriously. Responding to the triggers, participants adopted WATs as assistive devices (the means) to help them track their PA progress to achieve their health goals (the end). It was not the WATs *per se* that motivated them to do PA [40].

Both of my parents died of cancer. I am afraid that I have the genes too. My kids are still small and I need to be there for them. So I have been taking PA seriously. I started using pedometers long time ago and have already changed 4-5 trackers since then. Now I am using an Apple Watch. I set the goal to take 10,000 steps a day. After I am done with my work each day, no matter how late it is, I would check to see how far behind I am and make it up by walking or running around the campus. [UIM1]

I was diagnosed with diabetes at the age of 52. It scared me to death so I started mountain climbing the very next week. I determined to climb Seven-Star Mountain during weekends as often as possible, rain or shine. Now I have accumulated over 50 climbs in two years (climbed every other week). I used Xiao-Mi to track my steps and distance. Looking back, if I had not got diabetes, I would not have been so diligent. [UFM4]

I bought an Apple Watch because I wanted to lose weight. I am a connoisseur and I am not going to let my weight concerns impede with the biggest hobby of my life. [UIW1]

Even with these seemingly strong motivations, most participants still found it difficult to adhere to regular PA. Respondents cited reasons such as being too busy to exercise, finding exercise boring, poor self-management, fear of injury, lack of skills, and lack of encouragement, support, or companionship from family and friends. Simply relying on the device itself was not sufficient.

I started using Xiao-Mi a few months ago. Originally, I set the goal to walk 10,000 steps a day. But, I could hardly adhere to my plan. Speaking of averages, I could only take 3000 to 4000 steps a day. So I gave up. [UIM2]

Once I formed the habit of mountain-climbing, I stopped using my Xiao-Mi as it served no purpose any more. Since I climbed by myself, what I really want from my WAT is to have a quick “handshake” function to exchange contact with those familiar faces I bumped into a lot on trails. This would allow us to get to know each other and can help out when necessary, such as in a case of emergency. [UFM4]

I bought a Garmin a few years ago, which cost me around 200USD. But I packed it the second day. I realized I could only see the step-counts and my heart-beats. For the rest of the things, such as taking phone calls, checking emails, text messages, etc., I still need to look at my mobile phone. The display screen on the Garmin was too small. It’s redundant to have two mobile devices with me. Moreover, just measuring and recording were not enough for me. I simply do not have time to exercise and the device could only tell me my problems, not solutions. [NIM2]

Social Support, Delivered/Obtained Via Social Network Services or Sites, Increased Users’ Adherence and Engagement with Wearable Activity Trackers and Vice Versa

Based on previous research, sharing daily activity information within a small group of friends was more satisfying and motivating compared to a control group who did not share their information [41]. A small number of existing WAT products do provide such functions to share one’s PA results on Facebook or Twitter, but these systems act as a one-way broadcasting, rather than sharing in a small private group.

Our participants used different social media for different SS. For example, respondents used Facebook to derive emotional and informational SS, and when they achieved PA results on their WATs, they would broadcast about it on Facebook. On bad days when participants fell behind their PA targets, they would keep silent to block possible negative SS. YouTube was also used to get informational SS, such as PA related tips and how-to information.

Although most WATs lack features to support sharing among smaller and more controlled groups, we observed that our participants have devised creative ways to give and receive SS by employing various tools to serve their purposes. For example, LINE social messaging application, which allows conversations within private groups only, has been used by our participants for all four kinds of SS: emotional, informational, instrumental, and even companionship (virtual and physical).

My Executive MBA classmates are all mid to high level managers and supposedly they should be very busy. I joined a jogging club, and we set a common goal to run 5 km per day. I was surprised to find that every evening, I got LINE messages from the club members reporting their progress. If I missed out on a day, they would urge me, “Hey, you owe me one. You’ve got to make it up for me tomorrow!” It’s like in the Army, it’s much easier to run distance together

with such peer pressure and team spirit. We also shared tips for warm-up and stretches before and after jogging to prevent from injury. (Emotional, informational and instrumental) [UFM3]

I used to exercise regularly when I was young. But over time, I slacked off as my work got busier. What got me back on track was the power of teams. When I started at the Executive MBA program, I joined the biking club and became a team lead. We did island-wide biking trips, which I could not have done by myself. We bought the same brand and model of WATs (Garmin devices) together to track our progress and for the Global Positioning System (GPS) function. We hired a “baby-sitting van” for those trips, which provided drinks, snacks, first-aids, and a coach. It’s a safety net any team member could fall back on if he or she did not feel well. We even put on the uniforms to show our team spirit. (Emotional, instrumental, and companionship SS) [UFM1]

For me, I have not used a WAT yet because I didn’t think it would be useful for me. My main problem about not doing PA regularly is because my working hours are long and I simply couldn’t find the time to do it. But after hearing what was being said here in this group, I can relate to the importance of receiving care and reminders from friends and families. Because knowing that someone else cares about my health may give me the strength in overcoming my inertia. [NFM2]

UIW1 invited her busy friend to jog with her virtually via LINE.

Since it took too much time to fight the traffic across the town, we decided to jog on the two sides of the same river (we live at the opposite sides) at the same time and to “keep each other posted” along the way through exchanging pictures of our WAT results and beautiful scenery via the LINE messenger app to keep us motivated. We had so much fun “together”! (Emotional and virtual companionship SS). [UIW1]

It is not only that SS increased the engagement of WAT usage, but WATs in turn could reinforce SS as well by offering objective progress towards common goals of PA among friends, family, and social groups.

I like my Apple Watch. One day I reached 200% of my goal from jogging. I shared the result on FB and got way more “likes” than usual. I felt good. (Emotional SS) [UIW1]

UFM2’s children did not like walking before and got tired easily, so he ended up carrying them home. After UFM2 started using a WAT, it became a virtual “umbilical cord” that bonded them when they exercised together.

My kids never asked me to carry them again as they got excited by looking at their step counts on my WAT and persisted on achieving the daily goal. (Emotional and companionship SS) [UFM2]

This finding echoes prior research that indicates wearable devices could be important ways to extend the social networks

of physically active people [22]. SS and WATs may be reciprocal, as they reinforce each other while influencing people’s PA behaviors and habits.

A Broad Spectrum of Configurations Would Be Needed to Deliver Wearable Activity Trackers with Appropriately Integrated Social Support Functions

When considering SS, each person’s needs and sources are different. Our participants cited their SS sources from their family, friends, co-workers, and service providers, such as fitness center coaches and health care professionals.

Inter-Generational Social Support is a Major Motivation for Adopting Wearable Activity Trackers

Many participants in this study had children and aging parents, and needed to care for both generations. Inter-generational SS turned out to be a major motivation for adopting WATs. Some participants (UFM2, UFM4, UFW1, and UIW1) intended to buy WATs for their parents to help monitor PA and chronic diseases. Both UFW1’s and UFM3’s fathers had Alzheimer’s disease and the respondents wanted to give them WATs with GPS to track if their fathers had wandered off.

I have told my dad not to ride a motorcycle again. But sometimes, he still “sneaked off” and we would be frantically looking for him. That’s why I want to have him wear a WAT with GPS so that I can track him and find him. (Instrumental SS) [UFW1]

UFM4’s and UIW1’s fathers both had diabetes, and they wished to give their fathers WATs to detect falling or to monitor glucose levels.

My dad has been diagnosed with diabetes for many years. We need to monitor his conditions carefully. When the glucose level rose too high, he might faint or fall. It could be dangerous. So I want to give him a WAT to help. It could also help me monitor if he has done PA regularly. If not, I could call to care about him and gently remind him. Or if I have time, I could just go there to accompany him in taking a walk. Otherwise every time I called, he would just tell me that everything was fine. (Emotional, instrumental, and companionship SS) [UFM4]

Common barriers mentioned by the participants included statements that their parents were not willing to utilize WATs because they did not like to be “watched” (UFW1) or found WATs cumbersome or hard to use.

Both of my parents live in rural Taiwan. We took it for granted that WAT was already very easy to use. But they didn’t even know how to download an app! (Lacking instrumental support) [UFM3]

Some participants intended for their children to wear WATs to help them build endurance through PA (UFM1, UFW1). These participants believed that this tactic would prevent their children from becoming obese (NFM1), or even monitor their sleep quality and sufficiency (UFW1).

I would consider buying WATs for my kids to help them form PA habits, which could build tenacity and

endurance to face difficulties in their lives, careers, and future. [UFW1]

Organizational Social Support from Team Challenges Could Be Transformational in Changing People's Physical Activity Behaviors and Habits, but Most of the Current Wearable Activity Tracker Designs Lack Team Support Features

Many of the Executive MBA students alluded to their team PA experiences as transformational or even life-changing. Team-building programs offered at schools or companies, such as Charity Marathons (42km or 21km), Mount Jade Climbing (the highest mountain in Taiwan), and Swim Across Sun Moon Lake (the largest freshwater lake in Taiwan) were just a few examples. Such team challenges aroused team spirit, reframed stressful events into developmental opportunities, and inspired members to undertake group missions in order to develop their professional and personal skills [42]. Previous research also suggested that working in a team increased participants' overall compliance and engagement with electronic health (eHealth) app-based intervention than those assigned to the *solo* condition [32].

WATs have been used as essential tools in team exercises, and the use of WATs could contribute to solidarity and accountability among team members. In order to accomplish the group's mission, each team member had to sign up for regular practice. Hence, participants needed objective monitoring tools to share their practice results with the team. Nevertheless, many team support features were still lacking in WATs, such as built-in real time communication (eg, walkie-talkie features), GPS locations of each team members (not just one's own), and emergency alert buttons.

The current WATs lack team support features. Our bike team members had to juggle multiple devices (mobile phone, WAT, GPS, and walkie-talkie, etc.). [UIM1]

Once I went on a biking trip with a team, though each one of us had a GPS device, I could only see my own position. I was leading yet I had no idea how far behind my team members were. Even with walkie-talkies, sometimes they fell out of range and we lost contact! It's quite nerve-wracking! I wish my Garmin could have shown all team members' locations, as well as the baby-sitting van, real time. I hope my WAT could have a feature of summarizing daily statistics/results of each team member too so that we could adjust our pace and paths for the next day. [UFM1]

When we went mountain-climbing in a team, we wish our WATs could tell us if a team member's oxygen level fell below the safety threshold and immediately triggered an alarm. [UFM4]

I am the head of HR and administration and have been in charge of promoting health at my workplace. This year, I convinced my boss to invest in giving each employee a Xiao-Mi bracelet. They used it to form teams to set group goals, to monitor progress,

and to join the grand contest hosted by the company. My boss regarded it as a worthwhile investment. [UFM5]

Social Support from Professional Services Complement Wearable Activity Trackers in Sustaining Physical Activity Behaviors and Habits to Maintain One's Health

Outside of relying on SS from one's family, friends, communities, or companies, it is evident that professional service providers such as health care professionals and fitness center coaches play critical roles in providing emotional, informational, instrumental, and companionship SS. Accenture's 2014 State of the Internet of Things Study found that more than half of consumers were willing to share their wearable data with physicians [38]. WAT producers could design their offers to include such complimentary services to help their customers' PA results to be more fruitful.

I joined a weight loss program at a municipal hospital, whose health care professionals assessed my health condition, made personal PA advice and kept monitoring my progress toward my goal. I made it! (Informational SS) [UIW1]

I loved jogging but started to feel knee pain and stopped. After I consulted a doctor and learned that my knees were fine but the problem lied on my weak muscle due to lack of toning. The doctor suggested that I practice kicking 100 times a day for a few months. Then I resumed jogging and the pain was gone. (Informational SS) [UFM2]

I joined a community gym and learned that my moderate walking in parks were not enough. I started working out at the gym. I felt cared for when I got reminder LINE messages to practice from my coach. And I was so touched by them when my fitness center waived my monthly fee for the time I was gone on business trips without my asking for it. (Emotional, informational, and instrumental SS) [NIM1]

Wearable Activity Tracker Design, Style, and Appearance Mattered Even More than Those of Smartphones, as They Are Body-Worn Devices

One female focus group participant, who was not a user, noted that all the models of WAT in the market looked too *macho and sporty* and would not go well with her outfits at work (NFW1). One user expressed his frustration when he wore his US \$300 Garmin to work the first time, it was mistaken by a coworker as a toy watch. He was quite vehement about it (UFM3). Two others (one WAT user, one nonuser) said that they definitely would not substitute their brand name watches with WAT bracelets.

There's no way I am going to trade my IWC (a high-end mechanical Swiss watch) with Apple Watch, not even the Platinum Edition. To me, IWC is part of my identity and personality. When people saw my watch and asked about it, I could proudly tell them its brand story from World War II. Apple Watch has no legacy. [UIM2]

I think a WAT bracelet would interfere with my style. I want a Rolex on my wrist. It's a status symbol. But this? Uh uh. [NFM1]

The User Interfaces of Wearable Activity Trackers Left a Great Deal to be Desired

WAT reminders and prompts aroused reactions ranging from welcoming to annoying. This issue may bear many implications for human computer interface (HCI) design. Persuasive computing could help in this regard, for WAT producers to contemplate further. The concept of persuasive computing was raised by B.J. Fogg in his seminal book, *Persuasive Technology: Using Computers to Change What We Think and Do* [43]. A persuasive system aims to encourage its users to perform specific actions or tasks, and is based on multidisciplinary fields involving human-computer interaction and psychology [44,45]. Certain WATs allowed users to set a reminder to stretch periodically. Some participants found it useful, while others felt, “annoyed”, “bothered”, or said, “I would simply ignore it”.

Well, I would not feel “embarrassed” or “ashamed” towards a machine when I am not keeping up with my work-out schedule, but I would with a real human being. So a machine will only work for me if someday, somehow, I would feel “ashamed” toward a machine as well. Ha ha! [NIM1]

I don't like getting “prompts” from a machine to tell me what to do all the time. It's like my wife's nagging me, “Hey, you are getting fat! Go out and get some exercise!” [UIM2]

Privacy Concerns Must be Addressed Before More Mainstream Consumers Would Consider Adopting Wearable Activity Trackers

A number of factors were cited by nonusers as causes for their hesitation in adopting WATs. These deterrents included unappealing design (NFW1), uncertainty about their accuracy (NFW1, NFM2, NIM1), lack of user-friendly interfaces (NFM3, UFW1), small and hard-to-read displays (NIM1, NIW1), juggling with multiple mobile devices (NFM2, NIM1), redundancy with existing smartphone fitness apps (NFM2), and high price points (NIM1). However, privacy appeared to be a major concern for nonusers and users alike. This finding is consistent with previous research and market reports. Accenture's survey indicated that 80% of consumers expressed privacy concerns about personal data-sharing [46]. PwC showed that just one in four respondents said that they wanted to share wearable-device-generated exercise information, or health information in general, with friends and family through social media [13]. This issue could explain why some of our participants expressed hesitation when they thought of sharing their PA progress on SNS such as Facebook. These concerns include minor ones such as losing face, to major ones like fearing to reveal one's whereabouts unknowingly.

What if I could not reach my weight-loss goal? I would feel embarrassed. [NIW1]

Sometimes, I saw on Facebook my friends' posts such as “check-in at this-and-that airport” or “I ran for 4km at certain park today”. I always wonder why

people would want to do that. We are not celebrities. They could have uploaded data to the public accidentally as it's easy to forget to change the setting from “public” to “friends” only. [NFM3]

My Xiao-Mi has built-in buttons to share PA results with my friends via WeChat, Twitter, and even Facebook... Maybe others would. But I won't. I think LINE is a great invention since it allows us to share things within our private groups instead of broadcasting them on Facebook. [UIM2]

Discussion

Principal Findings

Current literature reveals that WATs and SNS could be effective in increasing patients' PA [22]. However, the combined approach of reviewing how SNS and WAT could influence PA behaviors in middle-aged adults together could shed new light in this area of study. Our research demonstrated that these two forces not only work together, but are reciprocal in influencing PA.

Academic and marketing reports regarding WATs have both alerted that the merits of self-monitoring and goal-setting may not be sufficient for most users to form sustainable behavior changes [4,5]. This problem warranted more research to explore how to make the effects of WATs on PA more sustainable.

We began with the working hypothesis that there were gaps in the current designs of WATs. Our study confirmed that SS, delivered/obtained via SNS, increased users' adherence and engagement with WATs, which in turn reinforced SS in shaping PA behaviors and habits. While most existing research focused on WATs as devices, our study showed that WAT integration with SS services could be indispensable.

Our participants cared much more about WAT design, style, and appearance than about their smartphones', since WATs are body-worn devices. WATs were perceived as part of their personal identities. This finding holds potential for future research to further explore WATs from design and aesthetic perspectives.

More thoughtful HCI designs could be key considerations for adoption as well. Persuasive computing has not been widely applied in WAT designs, which could enrich interactions not just between human and machines, but also among the users' community, both online and offline [43].

In light of the recent security breaches in all major mobile phone operating systems, and the recent battle between the Federal Bureau of Investigation and Apple regarding encryption, privacy is poised to be a major issue that must be addressed with technological advancements in mobile and wearable devices, and the Internet of things. Consumers' grave concerns regarding privacy echoed previous research and market reports, so we chose to further elaborate on this theme in the following section regarding implications for practitioners.

Implications for Practitioners

At the *device* level, we recommend that WAT designs should incorporate built-in group chat functions that allow users to

receive and give SS within private, controlled groups. Integrated mutual team support features are highly desirable as well, such as opt-in team members' GPS locations and emergency alerts.

At the *service* level, participants expressed the need to not just have the measurements or *diagnosis*, but the *personalized prescription* for their PA at the same time. Services should be part of the holistic design from the very beginning, rather than an afterthought. WAT producers may join forces with health care services or fitness centers to position WAT as part of a comprehensive offering to cater to users' individual health needs.

Finally, at the *policy* level, comprehensive privacy policies need to be in place in order to render WATs as effective public health tools. With GPS and mobile technology becoming so pervasive, while still lacking end-to-end security protection, users may reveal their location unintentionally. It is important for cross-sectorial collaboration to alleviate these concerns, and not simply give these technologies an on-and-off button. Privacy settings need to be designed at a much more granular level (ie, allowing users to select settings in terms of the level, the amount, and the type of data they intend to share, and with whom), and make users aware of who has the right to access and view their personal data. Service providers need to work with authorities and related players in the service eco-system to enhance privacy protection. Government agencies need to work with telecommunication companies and WAT makers to define and regulate the classification of data being transmitted, exchanged, and utilized over public and private networks. Mechanisms must be in place to protect users from being exploited or discriminated against by parties that could potentially threaten or hurt them.

Limitations

We designed our current research by focusing on the Executive MBA students at National Taiwan University of Science and Technology with participants' median age at 45, which fit into the United Nation's *middle-age* category. A digital divide, defined as the economic and social inequality to access and use information technologies, has been a limiting factor in adopting eHealth technologies in older adult cohorts [47]. However, since most of our participants were executives, they did not seem to have such digital divide problems due to their high socio-economic status. Inevitably, such sampling criteria may be biased, and observations derived from this research may not be generalizable to other market demographics. Further studies to probe similarities and differences among various

demographics, even psychographic characteristics, would be desirable, such as income levels, professions, genders, personalities, and lifestyles.

Female representation in this study was lower than that of the general population in Taiwan (4 of 15 participants). 2014 marked the first year in history in which there were more women in Taiwan than men, with the ratio being 100 to 99.99 [48]. However, at the management level in Taiwan, females only account for 20% of the workforce [49]. Transferability of findings from this study is therefore limited.

Suggestions for Future Research

This qualitative research could not explain the trajectory of WAT attrition for a larger user base. However, the discovery that the influences between WAT and SNS are reciprocal is worth further investigation. In addition, research, guidelines, and theories about the adoption of WATs need to keep pace with technological developments. The adoption of WATs integrated with fitness or health care services could enable continuous streams of real users' data (eg, PA information and bio-signs), which may benefit preventive health research and many medical fields in the future. A pressing need exists for a better understanding of the complexities emerging in the evolution of WATs in the context of real people's everyday lives and their intertwining social networks, both online and offline. Above all, more research is needed to elevate the standards for privacy protection.

Conclusion

Our study aimed to identify possible reasons behind the high attrition rate of an emerging category of WATs and to explore possible solutions to make their effects in changing PA behaviors more sustainable. SS, delivered/obtained via SNS or other forms of online community, has been proven to increase the adherence and engagement of PA intervention programs by overcoming barriers and increasing motivations in achieving one's PA goals.

Our study confirmed that combining WATs and SNS in PA intervention programs with end-to-end services and data analytics could elevate WATs from one-size-fits-all consumer electronic devices to personalized PA assistants to cater to one's particular health needs. This study also lays the groundwork for more evidence-based research in the future, to realize new possibilities in preventive health enabled by technological advancements.

Acknowledgments

The authors thank all interview and focus group participants for taking time out of their busy schedules to accept our invitation, and to share their experiences and viewpoints.

We also thank Professor Tom M. Y. Lin and Dean Cheng-Kang Chen of the Management School at the National Taiwan University of Science and Technology, for encouraging us to pursue this research topic at the onset of this study.

Conflicts of Interest

None declared.

Multimedia Appendix 1

[PDF File (Adobe PDF File), 37KB - [mhealth_v4i3e84_app1.pdf](#)]

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Abbreviations

- AA:** Active Aging
- BCT:** behavior change techniques
- eHealth:** electronic health
- GPS:** Global Positioning System
- HCI:** human computer interface
- PA:** physical activity
- PwC:** PricewaterhouseCoopers
- SNS:** social network services or sites
- SS:** social support
- WAT:** wearable activity trackers
- WHO:** World Health Organization

Edited by G Eysenbach; submitted 11.02.16; peer-reviewed by A Benetoli, L Laranjo; comments to author 03.03.16; revised version received 15.04.16; accepted 24.05.16; published 05.07.16.

Please cite as:

Chang RCS, Lu HP, Yang P, Luarn P

Reciprocal Reinforcement Between Wearable Activity Trackers and Social Network Services in Influencing Physical Activity Behaviors

JMIR Mhealth Uhealth 2016;4(3):e84

URL: <http://mhealth.jmir.org/2016/3/e84/>

doi: [10.2196/mhealth.5637](https://doi.org/10.2196/mhealth.5637)

PMID: [27380798](https://pubmed.ncbi.nlm.nih.gov/27380798/)

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Original Paper

Physical Activity Assessment Between Consumer- and Research-Grade Accelerometers: A Comparative Study in Free-Living Conditions

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Abstract

Background: Wearable activity monitors such as Fitbit enable users to track various attributes of their physical activity (PA) over time and have the potential to be used in research to promote and measure PA behavior. However, the measurement accuracy of Fitbit in absolute free-living conditions is largely unknown.

Objective: To examine the measurement congruence between Fitbit Flex and ActiGraph GT3X for quantifying steps, metabolic equivalent tasks (METs), and proportion of time in sedentary activity and light-, moderate-, and vigorous-intensity PA in healthy adults in free-living conditions.

Methods: A convenience sample of 19 participants (4 men and 15 women), aged 18-37 years, concurrently wore the Fitbit Flex (wrist) and ActiGraph GT3X (waist) for 1- or 2-week observation periods (n=3 and n=16, respectively) that included self-reported bouts of daily exercise. Data were examined for daily activity, averaged over 14 days and for minutes of reported exercise. Average day-level data included steps, METs, and proportion of time in different intensity levels. Minute-level data included steps, METs, and mean intensity score (0 = sedentary, 3 = vigorous) for overall reported exercise bouts (N=120) and by exercise type (walking, n=16; run or sports, n=44; cardio machine, n=20).

Results: Measures of steps were similar between devices for average day- and minute-level observations (all *P* values > .05). Fitbit significantly overestimated METs for average daily activity, for overall minutes of reported exercise bouts, and for walking and run or sports exercises (mean difference 0.70, 1.80, 3.16, and 2.00 METs, respectively; all *P* values < .001). For average daily activity, Fitbit significantly underestimated the proportion of time in sedentary and light intensity by 20% and 34%, respectively, and overestimated time by 3% in both moderate and vigorous intensity (all *P* values < .001). Mean intensity scores were not different for overall minutes of exercise or for run or sports and cardio-machine exercises (all *P* values > .05).

Conclusions: Fitbit Flex provides accurate measures of steps for daily activity and minutes of reported exercise, regardless of exercise type. Although the proportion of time in different intensity levels varied between devices, examining the mean intensity score for minute-level bouts across different exercise types enabled interdevice comparisons that revealed similar measures of

exercise intensity. Fitbit Flex is shown to have measurement limitations that may affect its potential utility and validity for measuring PA attributes in free-living conditions.

(*JMIR Mhealth Uhealth* 2016;4(3):e110) doi:[10.2196/mhealth.6281](https://doi.org/10.2196/mhealth.6281)

KEYWORDS

Fitbit; activity tracker; actigraphy; physical activity; aerobic exercise; validity

Introduction

Accelerometers have been extensively used in research to objectively measure and quantify changes in physical activity (PA) and sedentary behavior [1,2]. However, research-grade accelerometers are prohibitively expensive [3] and require extensive training for data collection and analysis [4]. Low-cost wearable activity monitors, such as Fitbit, have become widely available to consumers, enabling users to self-monitor and track their daily PA levels, steps, energy expenditure (EE), and distance as well as diet and sleep patterns over time [5,6]. Many of these devices include user interface features through a mobile phone app that also provide behavior change strategies such as self-monitoring, goal setting, feedback provision, and social support communicated via push notifications, email, and social media platforms (eg, Facebook) [7]. Given that 21% of US adults report using technology to track personal health data [6], there is considerable potential for using these commercial devices in research settings as they appeal to consumers and researchers alike owing to their relatively low-cost, user-friendly apps, and potential to improve health [8-10].

Fitbit is one of the most popular brands of consumer-grade, wearable, activity tracking monitors, accounting for more than 50% of over 3 million devices sold worldwide between 2013 and 2014 [11]. Several Fitbit models can be worn at the hip (Fitbit Ultra, Zip, One) and, more recently, the wrist (Fitbit Flex, Charge, and Surge). A recent systematic review summarized the findings of 22 studies published between 2012 and 2015 that examined the validity and reliability of different wearable activity monitors for measuring steps, EE, and, to a lesser degree, moderate-to-vigorous physical activity (MVPA) [12]. Overall, 20 studies reported on at least one type of Fitbit device (Ultra, Zip, One, Flex) and findings generally indicate that Fitbit may be a valid instrument for measuring steps compared with direct observation and objective accelerometer assessment (eg, ActiGraph GT3X); however, greater measurement error has been reported during slower walking speeds [12-14]. Researchers have also examined the extent to which Fitbit provides accurate EE estimates against criterion measures such as indirect calorimetry [15-18] and accelerometry [4]. In general, these studies indicate that Fitbit underestimates EE across different modes of activity [4,16,18] and overestimates EE when activities are combined [15]. It has been suggested that the variability in EE estimates observed for individual types of activity (eg, sedentary, aerobic, and resistance exercises) offsets the overall EE estimates calculated by Fitbit [15]. To date, most Fitbit validation studies are limited to the measurement of steps and EE using waist-worn Fitbit devices with the majority of this research being conducted in controlled laboratory settings with short observation periods [12]. Extending this research to

examine the variation of activity as it occurs over time in free-living conditions can improve current knowledge about the measurement properties of the wrist-worn Fitbit Flex device.

Few studies have examined the accuracy of Fitbit compared with ActiGraph for measuring MVPA in free-living conditions [4,19,20]. One study reported that step counts and minutes of MVPA measured over 7 days were strongly correlated between the Fitbit Zip and ActiGraph GT3X; however, interdevice differences for quantifying MVPA were not reported [19]. Ferguson and colleagues [4] found that the Fitbit One and Fitbit Zip were each correlated with ActiGraph GT3X+ for minutes of MVPA ($r=.91$ and $.88$, respectively) measured over a 48-hour period; however, both Fitbit devices overestimated time in MVPA by as much as 137 minutes and 157 minutes, respectively. In addition, the study relied on a consensus approach to approximate MVPA cut points, and a short observation period limits the generalizability of these findings [4]. Considering this limited evidence, additional research is needed to examine the relative agreement between Fitbit and ActiGraph for measuring steps and time in different intensity levels over longer periods of time in free-living conditions.

By using the Fitbit application programming interface provided through a third-party service provider (eg, Fitabase, Small Steps Labs LLC), it is now possible to obtain data for steps, PA intensity, EE, as well as metabolic equivalent task (MET) estimates, stratified by specific time intervals (eg, hour- and minute-level data), that were previously unavailable to researchers. Because METs reflect oxygen consumption rates in relation to intensity, these values can be used to confirm proprietary intensity thresholds used by Fitbit to indicate a person's activity level [21]. Yet it is unclear how METs derived from Fitbit compare with METs determined by ActiGraph. Furthermore, by accessing Fitbit data across different intervals of time it is possible to examine how measurement differences vary in free-living conditions.

The purpose of this study was to examine the concordance between the Fitbit Flex and ActiGraph GT3X accelerometer for measuring steps, METs, and proportion of time spent in sedentary behavior and in light, moderate, and vigorous PA in a sample of young adults in free-living conditions. A second study aim was to compare steps, METs, and intensity between ActiGraph and Fitbit across minutes of reported exercise and by exercise type.

Methods

Participants

A convenience sample of 19 young adult men ($n=4$) and women ($n=15$) who owned a Fitbit Flex device volunteered to participate in this study. Participants were considered apparently healthy

and were recruited from within the University of Delaware. Approval from the university's institutional review board was obtained before the study. Data were collected between October and November 2014.

Instruments and Measures

Fitbit Flex

The Fitbit Flex (Fitbit Inc, San Francisco, CA) is a small, wireless device that fits within a wristband and uses a triaxial accelerometer to convert raw acceleration signals into counts. These counts are then applied to proprietary algorithms that provide estimates of steps/minute, PA level (sedentary, light, moderate, vigorous), and EE [22-24]. Because raw acceleration data are not stored on the Fitbit device, researchers must rely on the converted activity counts determined by Fitbit. A Fitabase account was created for this study in order to obtain daily and minute-level Fitbit data that included estimated METs.

ActiGraph GT3X

The ActiGraph GT3X (ActiGraph, Pensacola, FL) is a research-grade triaxial accelerometer that is approximately the size of a standard pedometer and is typically worn at the waist to provide objective measures of sedentary and PA behavior in free-living conditions [3]. The proprietary ActiLife software allows researchers to choose from several validated algorithms to quantify PA depending on the participant pool (eg, toddlers or preschoolers, adults, and older adults). The extent to which the ActiGraph GT3X quantifies data is contingent on the specific cut point and scoring algorithms that a researcher selects. Generally, PA level (sedentary, light, moderate, vigorous, and very vigorous), step count, EE, and METs are computed from the accelerometer counts detected within a specified time period (ie, epoch). Data can be calculated for different time intervals (week, day, hour, and minute-level).

Procedures

Data collection procedures were staggered over a 2-month period. Consenting participants provided their Fitbit Flex username and password that linked their device to the Fitabase platform for continuous data collection throughout the study period. At baseline, participants completed a standard demographics questionnaire that included age, sex, and race or ethnicity (African American, Asian or Pacific Islander, Caucasian, Hispanic or Latino, other). Next, anthropometric data were obtained by a trained technician using standard procedures. Standing height and weight were obtained with participants in bare feet and light clothes via stadiometer (Seca, Chino, CA) and digital scale (Seca, Chino, CA), measured to the nearest 0.1 cm and 0.1 kg, respectively. Body mass index (BMI) score was calculated as the weight in kilograms divided by height in meters squared ($\text{kg}\cdot\text{m}^{-2}$). Percent body fat was determined from bioelectrical impedance (Bodystat Ltd, Isle of Man, UK). After completing the baseline measures, participant data (birth date, sex, height, weight) were used to initialize Fitbit Flex and ActiGraph GT3X devices. Participants were then instructed to simultaneously wear the Fitbit Flex and ActiGraph GT3X on their dominant side (wrist and hip, respectively) during all waking hours for 7 consecutive days. An exercise journal was provided in which participants were instructed to list up to

4 daily bouts of "purposeful exercise" including the type of exercise and start and end times of each bout performed. Participants were also asked to report if they did no purposeful exercise on any of the 7 days.

After 7 days, participants returned to the laboratory to confirm wear time compliance, and their completed exercise journals were collected. All participants were asked to complete a second 7-day wear period that for most ($n=16$) occurred approximately 3 weeks after the first wear period. Data collection procedures for the second wear period remained the same, except that demographic and anthropometric data were not assessed a second time. Participants received a US \$15 gift card for each 7-day measurement period they completed.

Data Processing

ActiGraph GT3X data were processed using the ActiLife software version 6.11.9. Wear times were validated using the Troiano (2007) algorithm [25]. Nonwear periods were defined if no epoch counts were detected over a period of ≥ 60 continuous minutes. All participants wore both devices for a minimum of 8 waking hours over 7 consecutive days. Estimated METs and PA cut points were determined using the validated Freedson adult vector magnitude algorithm (2011) [26]. ActiGraph data were aggregated to 60-second epochs and the vigorous and very vigorous PA categories were combined to be consistent with Fitbit Flex PA data.

Minute-level Fitbit Flex data were downloaded from the Fitabase server. Data were registered based on time so that minute-level measures from Fitbit and ActiGraph were consistent. We considered Fitbit nonwear periods if a 0 was recorded for ≥ 60 continuous minutes. Data were excluded if either ActiGraph or Fitbit indicated periods of nonwear. Self-reported exercise bouts were considered valid if the days and minutes of reported exercise matched to within 5 minutes of the activity counts that were concurrently measured with ActiGraph. Because Fitbit provides overall estimates of EE (eg, total calories) and ActiGraph provides EE estimates from PA only, a decision was made to exclude EE in this study.

Measurement

Outcome measures included steps, METs, and proportion of time in sedentary activity and light, moderate, and vigorous PA determined by ActiGraph and Fitbit. Data were examined at two levels: (1) daily average of 14 days and (2) minutes of all reported exercise and by exercise type. Similar to previous studies [27,28], we defined sedentary behavior using a cut point threshold of < 200 counts/minute with an additional criterion that no steps were recorded. To compare intensity levels between devices for minutes of reported exercise and exercise type, an average intensity score was created by applying the numerical code used by Fitbit to define intensity levels for each minute of reported exercise (0 = sedentary, 1 = light, 2 = moderate, and 3 = vigorous) to the same minute-level vector magnitude counts from ActiGraph: sedentary (0 = 0-199 counts), light (1 = 200-2690 counts), moderate (2 = 2691-6166 counts), and vigorous (3 = counts ≥ 6167).

Reported exercise bouts ($N=120$) were noted and exercise types were grouped into 6 categories: walk, run or sports, bike, cardio

dance, cardio machine, and weights. Because of the wide variation in reported types of exercises, a decision was made to provide results for the 3 most homogeneous of those categories: (1) run or sports included dynamic aerobic activities such as running, jogging, basketball, football, soccer, and ultimate Frisbee; (2) cardio machine included stationary, machine-based aerobic exercises such as walking, jogging, or running on a treadmill and using the elliptical trainer, stair-climber, and stationary bike; and (3) walking exclusively outdoors.

Statistical Analyses

Participants' characteristics are reported using means and standard deviations for continuous variables and frequencies and percentages for categorical variables. All PA metrics were treated as continuous variables and are reported with means and standard deviations. Analyses were conducted using two different models: first, using simple paired samples *t* tests and second, using generalized linear mixed modeling (GLMM). The GLMM accomplishes the same comparisons as the paired samples *t* test but allows observations to be nested within individuals. Given that the intraclass correlations for the GLMM were small ($< .25$) and results for both models were equivalent, the simpler method's findings are presented. Furthermore, as recommended by the American Statistical Association [29], we wanted to draw particular attention to the effect sizes, rather than just relying on *P* values to demonstrate the magnitude of measurement differences between the devices; currently, GLMM does not provide a way to garner effect sizes. Relative agreement between devices is presented using correlations. Alpha for the

study was set at the nominal level, $\alpha = .05$; statistical significance was determined using *P* value $< .05$. Given the relatively small size of the study sample, effect sizes (Cohen's *d*) are also reported. Data were analyzed using SPSS version 23 (IBM Corp, Armonk, NY, USA).

Results

Participants

Participant characteristics (N=19) and PA levels, averaged over 14 measurement days, are reported in Table 1. Overall, most participants were female (15/19, 79%). Participants' ages ranged between 19 and 37 years. Ranges for BMI and percent body fat values for male and female participants were 18.5-28.0 kg·m⁻² and 11.4%-37.1%, respectively. Overall, 74% (14/19) of the participants were white (male, n=2; female, n=12); approximately 11% (2/19) of the participants were Latino (male, n=1; female, n=1). Remaining racial or ethnic groups included Asian or Pacific Islander, black, and other; n=1 in each group (data not shown). On average, participants spent the most time in sedentary activity followed by light-intensity PA (67.8%, SD 6.6%, and 25.2%, SD 5.8%, respectively) and less than 10% of the time in MVPA. Average time in MVPA per day ranged between 25 and 137 minutes. Overall, participants reported 153 hours of exercise (6588 total minutes) reflecting 94 person-days, of which 120 unique bouts of exercise were identified. Participants reported an average of 6.34 exercise bouts over 14 days (median = 5.5 bouts, range = 1-22 bouts; data not shown).

Table 1. Participant characteristics (N=19) and physical activity levels (determined from ActiGraph GT3X) averaged over 14 days.

Variables	Male (n=4)		Female (n=15)	
	Mean (SD)	Range	Mean (SD)	Range
Age, years	20.0 (0.8)	19.0-21.0	21.3 (4.4)	19.0-37.0
Height, cm	174.4 (6.6)	165.7-181.6	162.2 (7.9)	145.8-173.1
Weight, kg	77.2 (5.1)	72.0-83.9	57.4 (10.9)	39.3-80.2
Body mass index, kg·m ²	24.6 (1.0)	23.2-25.5	21.9 (2.7)	18.5-28.0
Body fat, %	13.5 (1.5)	11.4-14.7	25.9 (5.7)	15.4-37.1
Sedentary, %	62.1 (4.7)	57.0-70.0	69.5 (6.2)	58.0-82.0
Light intensity, %	28.5 (2.4)	25.0-33.0	24.2 (6.1)	15.0-36.0
Moderate intensity, %	8.5 (3.1)	5.0-13.4	5.1 (1.7)	2.59-8.27
Vigorous intensity, %	0.9 (0.9)	0.0-2.55	1.1 (1.8)	0.0-6.77
MVPA ^a , %	9.4 (2.9)	4.9-13.9	6.2 (2.9)	2.7-14.5
Average MVPA, minutes/day	83.4 (25.2)	40.7-120.3	55.4 (28.3)	25.0-137.7

^aMVPA: moderate-to-vigorous physical activity.

Measurement Differences for Average Day-Level Activity

Average daily MET rate, proportion of time in sedentary activity and light, moderate, and vigorous PA, and total steps/day are reported in Table 2. interdevice correlations indicated good agreement for total steps/day ($r=.91$); moderate agreement for time in vigorous PA ($r=.80$); low agreement for daily MET rate ($r=.70$), time in sedentary activity ($r=.67$), and time in light PA

($r=.68$); and very low agreement for time in moderate PA ($r=.43$). The devices did not significantly differ for estimates of total steps/day ($P=.10$, $d=0.40$). Compared with ActiGraph, the Fitbit Flex significantly overestimated daily MET rate (mean difference 0.7, SD 0.09, METs/day, $P<.001$, $d=3.76$), proportion of time in sedentary activity (mean difference 26.0% per day, $P<.001$, $d=4.33$), proportion of time in moderate PA (mean difference 3.0%, SD 11.0%, per day, $P<.001$, $d=0.86$), and

proportion of time in vigorous PA (mean difference 3.0%, SD 1.0%, per day, $P<.001$, $d=2.21$). Fitbit significantly underestimated the proportion of time in light PA compared with ActiGraph (mean difference -34.0% , SD -3.0% , per day, $P<.001$, $d=6.90$).

Table 2. Average day-level differences for activity variables between devices (N=19).

Variable	Device	Mean (SD)	r^a	Cohen's d^b	P value
MET ^c rate/day	ActiGraph	1.3 (0.17)	.70	3.76	< .001
	Fitbit	2.0 (0.26)			
Sedentary activity (daily %)	ActiGraph	43.0 (7.0)	.67	4.33	< .001
	Fitbit	69.0 (7.0)			
Light intensity (daily %)	ActiGraph	49.0 (7.0)	.68	6.90	< .001
	Fitbit	15.0 (4.0)			
Moderate intensity (daily %)	ActiGraph	7.0 (3.0)	.43	0.86	< .001
	Fitbit	10.0 (14.0)			
Vigorous intensity (daily %)	ActiGraph	2.0 (2.0)	.80	2.21	< .001
	Fitbit	5.0 (3.0)			
Total step count/day	ActiGraph	9639.41 (3456.47)	.91	0.40	.10
	Fitbit	10,286.08 (3760.31)			

^aPearson correlation.

^bCohen effect size.

^cMET: metabolic equivalent task.

Minute-Level Measurement Differences for Reported Exercise (N=120)

Table 3 reports the average minute-level step count, MET rate, and intensity score for 120 bouts of reported exercise (6588 minutes). Correlations indicate the devices had moderate agreement for steps/minute ($r=.85$) and low agreement for MET

rate/minute ($r=.70$) and intensity score/minute ($r=.65$). The devices did not significantly differ for estimates of total steps/minute ($P=.559$, $d=0.04$) or intensity score/minute ($P=.057$, $d=0.04$). The Fitbit Flex significantly overestimated MET rate/minute compared with ActiGraph (mean difference 1.8, SD 0.42, METs/minute, $P<.001$, $d=0.18$).

Table 3. Measurement differences for overall minutes of reported exercise bouts by device (N=120).

Variable	Device	Mean (SD)	<i>r</i>	Cohen's <i>d</i>	<i>P</i>
MET rate/minute	ActiGraph	4.12 (2.93)	.70	0.18	< .001
	Fitbit	5.92 (3.35)			
Intensity score/minute	ActiGraph	1.83 (0.77)	.65	0.04	.057
	Fitbit	1.96 (0.92)			
Step count/minute	ActiGraph	77.60 (51.64)	.85	0.04	.559
	Fitbit	76.10 (51.17)			

^aPearson correlation.

^bEffect size.

^cMET: metabolic equivalent task.

^dMean intensity score (range: sedentary = 0, light = 1, moderate = 2, vigorous = 3).

Minute-Level Measurement Differences by Exercise Type

Results were similar when minute-level measures between Fitbit and ActiGraph were examined by exercise type (Table 4). There were 16 bouts of walking ranging from 20 to 136 minutes (mean 68.0, SD 37.0, minutes), 44 bouts of run or sports ranging from 15 to 130 minutes (mean 52.0, SD 30.0, minutes), and 20 bouts of cardio-machine exercise ranging from 31 to 66 minutes (mean 47.0, SD 10.0, minutes).

For minutes of walking-based exercise, Fitbit significantly overestimated MET rate (mean difference 3.16, SD 1.54,

METs/minute, $P < .001$, $d = 1.34$) and mean intensity score (mean difference 0.51, SD 0.25, $P = .007$, $d = 0.78$) compared with ActiGraph. No significant measurement differences were found for walking steps/minute ($P > .05$). For minutes of run or sports exercise, no interdevice differences were found for mean intensity score or for steps/minute ($P > .05$ for both). However, Fitbit significantly overestimated MET rate compared with ActiGraph (mean difference 2.0, SD 0.72, METs/minute, $P < .001$, $d = 0.78$). There were no significant differences between ActiGraph and Fitbit for estimated MET rate, mean intensity score, or step count for minutes of cardio-machine exercise (all P values $> .05$).

Table 4. Minute-level measurement differences for activity variables by exercise type and device.

Exercise type	Variable	ActiGraph mean (SD)	Fitbit mean (SD)	<i>r</i> ^a	Cohen <i>d</i> ^b	<i>P</i> value
Walking (n=16)						
	MET ^c rate/minute	2.37 (1.38)	5.53 (2.92)	.60	1.34	< .001
	Intensity/minute ^d	1.47 (0.60)	1.98 (0.85)	.64	0.78	.007
	Step count/minute	62.93 (48.25)	70.29 (45.89)	.80	0.23	.346
run or sports (n=44)						
	MET rate/minute	5.61 (2.83)	7.61 (3.55)	.70	0.78	< .001
	Intensity/minute	2.22 (0.66)	2.31 (0.83)	.66	0.16	.308
	Step count/minute	106.37 (49.00)	103.48 (51.77)	.73	0.08	.377
Cardio machine (n=20)						
	MET rate/minute	3.37 (0.76)	3.04 (0.68)	.54	0.38	.108
	Intensity/minute	2.19 (0.92)	2.30 (0.98)	.57	0.12	.588
	Step count/minute	99.86 (50.67)	94.37 (47.43)	.52	0.04	.619

^aPearson correlation.

^bCohen effect size.

^cMET: metabolic equivalent task.

^dMean intensity score range: sedentary = 0, light = 1, moderate = 2, vigorous = 3.

Discussion

Principal Findings

Fitbit Flex and ActiGraph GT3X provided consistently similar step counts for average daily activity, overall minutes of reported exercise (N=120), and minutes of reported walking, run or sports, and cardio machine types of exercises. Mean intensity scores were generally comparable for overall minutes of reported exercise and for run or sports and cardio-machine exercise types. However, significant measurement differences were found for the average daily proportion of time in sedentary activity and light-, moderate-, and vigorous-intensity PA. Significant differences for MET rate estimates were found between Fitbit and ActiGraph for average daily activity, overall minutes of reported exercise, and also differed between devices for average day activity, overall minutes of reported exercise, and minutes of reported walking and run or sports exercises.

Average Daily and Minute-Level Step Counts

This study found that Fitbit Flex was strongly correlated with ActiGraph GT3X for steps measured per day and for overall minutes of reported exercise ($r=.91$ and $.85$, respectively), which is consistent with previous research using hip-worn versions of Fitbit (eg, Zip and One) [4,19] and, more recently, Fitbit Flex [13,20,30]. Although step counts were not significantly different between ActiGraph and Fitbit for day- and minute-level observations, interdevice agreement varied when steps/minute were examined by exercise type (walking, $r=.80$; run or sports, $r=.73$; cardio machine, $r=.52$). This finding is similar to Bai and colleagues [15] who reported that EE error estimates for ActiGraph and Fitbit Flex were approximately 17% when measured bouts of sedentary activity as well as aerobic and resistance exercises were combined. However, when examined separately, error estimates for all monitors increased and varied by activity type. The authors suggested that the lower error estimates observed for the combined protocol was likely due to an overall cancelation of inaccurate measurement estimates, which became evident once the activities were examined individually [15]. Although EE was not examined in our study, the relationship between step counts, MET rate, intensity, and EE is strongly supported by the literature [31,32]. Given that Fitbit uses step-count data to partially inform the algorithms used to estimate minute-level METs, intensity, and EE [22,23], it is likely that METs and time in different intensity levels will also vary depending on the unit of analyses (eg, overall daily activity vs minutes of exercise) and by exercise type. It is also possible that the variation in steps observed between Fitbit Flex and ActiGraph are due to differences in device placement (wrist vs hip). Previous studies have shown that the placement of activity monitors may be more or less sensitive to different body positions, movement patterns, and speeds [30,33]. Compared with researcher-counted steps, wrist- and hip-worn Fitbit devices are shown to underestimate step estimates during stationary cycling, whereas the Fitbit Flex may be more likely to underestimate steps during walking activities [30]. Our findings extend this earlier work by quantifying steps over a longer observation period in absolute free-living conditions that included analyses for day-level activities and minutes of self-reported exercise.

Daily and Minute-Level Metabolic Equivalent Tasks

Significant measurement differences were found between Fitbit and ActiGraph for estimating METs for average daily activity as well as overall minutes of reported exercise bouts. Although the mean difference in average daily METs was relatively small (0.7, SD 0.09), differences became larger for minute-level analyses (1.8, SD 0.42, METs), despite having moderately strong correlations across observation periods ($r=.70$ for both). It is probable that the small distribution in MET values contributed to this finding.

When minute-level exercise categories were examined, MET values were not significantly different between devices for cardio-machine exercise only. The finding that Fitbit overestimated METs for walking (+3.16 METs) and run or sports (+2.0 METs) exercises suggests that the algorithm Fitbit uses to estimate METs differs from the selected algorithm that was applied to ActiGraph data. For example, the mean MET estimates for walking were 5.53 (SD 2.92) and 2.37 (SD 1.38) for Fitbit and ActiGraph, respectively. From these results, walking METs derived from Fitbit approach vigorous intensity (ie, ≥ 6.0 METs), whereas walking METs estimated by ActiGraph indicate less than moderate intensity (ie, 3.0 METs) [21]. Differences in device placement may have also contributed to these findings. Although no studies are known to have measured differences in MET estimates between Fitbit and ActiGraph, previous research has reported that Fitbit Flex overestimates EE compared with ActiGraph during aerobic exercise [15]. Alternatively, a participant could have misreported his or her exercise information, for example, listing a single bout of exercise in which both walking and jogging activities were performed but were specifically recorded as “walking” or “jogging” could cause the data to be misclassified in the analyses. This explanation may also provide insight into why MET values were not different for cardio-machine exercises, as these “stationary” exercises (eg, elliptical) may be more easily recalled by participants and less likely to result in misclassification; however, further research is needed to verify this assertion. It is also possible that both devices are not sensitive enough to detect stationary-based activity, although MET estimates from Fitbit Flex and ActiGraph appear to be appropriate for moderate-intensity exercise. Future studies are needed to examine whether alternative placement of Fitbit devices improves measurement accuracy during stationary exercise, as step count and EE estimates are shown to be more accurate when research-grade accelerometers are placed on the ankle or thigh [34,35].

Average Daily Proportion of Time in Different Intensity Levels

The average proportion of time spent in sedentary activity and light, moderate, and vigorous PA per day was calculated at the day-level only. Results indicate that Fitbit and ActiGraph provided significantly different measures in all intensity levels. It is challenging to make interdevice comparisons of intensity level because interpretation of results is constrained by differences in how accelerometer counts from Fitbit and ActiGraph are used to measure intensity. A major barrier to studies examining the measurement validity and reliability of

Fitbit is the proprietary laws that prevent researchers from understanding how Fitbit determines the cut points used to classify different intensity levels, although it is reasonable to believe that the cut points used by Fitbit are not consistent with those used in research with ActiGraph. It is well documented that using different accelerometer cut points produces different MVPA outcomes [36]. This “cut-point nonequivalence” prevents comparisons across studies that use different cut points [37]. It appears that this issue now extends to commercial activity tracking devices. Efforts to incorporate signal features and patterns from raw acceleration data may help develop more sophisticated models to improve activity intensity estimates [1,38].

Mean Intensity Scores for Overall Minutes of Exercise and Exercise Category

Mean intensity scores were calculated for every minute of all reported exercise bouts (N=120) and by specific exercise category (walking, run or sports, and cardio machine). When reported minutes of exercise bouts were examined, overall mean intensity scores were marginally similar between Fitbit (1.96, SD 0.92) and ActiGraph (1.83, SD 0.77), $P=.057$. However, scores became notably more equivalent when exercises were grouped by category, except for walking (Fitbit = 1.98, SD 0.85; ActiGraph = 1.47, SD 0.60; $P=.007$). Although the small sample size of the walking category (n=16) likely influenced this finding, it is reasonable that combining the wide distribution of different walking-based activities and variation in walking speeds may have also led to these differences given that Fitbit is shown to overestimate intensity at slower walking speeds and underestimate intensity at faster walking speeds compared with direct measures of EE [13]. Future research is needed to examine the precise cut points used by Fitbit to define light, moderate, and vigorous intensity, particularly with walking-based exercise.

To our knowledge, this is the first study to examine the congruence of PA intensity estimates between Fitbit and ActiGraph using a mean intensity score. Given that the proportion of time in various intensity levels was different when device-specific cut points were examined, this approach enabled comparisons to be made between ActiGraph and Fitbit Flex that revealed that overall intensity was not significantly different for exercises performed at presumably higher intensity levels (eg, run or sports and cardio machine). Other approaches to compare intensity level between Fitbit Flex and ActiGraph have also been reported. Alharbi and colleagues [20] used METs obtained from Fitbit to approximate minutes of MVPA in a sample of cardiac rehabilitation patients (N=48) who wore the Fitbit Flex and ActiGraph GT3X over 4 days. Although the Fitbit Flex was found to overestimate MVPA by 10 minutes/day compared with ActiGraph GT3X, the device was found to be highly accurate for identifying patients who met the minimum PA guidelines of 150 minutes of MVPA per week [20]. However, results from our study suggest that Fitbit overestimates METs and therefore may not accurately reflect time in MVPA. Clearly, additional work is needed to identify methods that reduce the cut-point nonequivalence between Fitbit and ActiGraph accelerometers.

Methodological Considerations

The results of this study add to the existing literature and advance current knowledge related to PA metrics as measured by Fitbit and ActiGraph in truly free-living conditions. Assessments included observational wear periods of up to 14 days—longer than any published study to date [12]. Analyses examined measurement differences for daily average and minute-level observation periods that included 120 individual exercise bouts that were also categorized by type: walking, running/sports, and cardio machine. We also provide a detailed account as to how the devices were initialized and data were collected as recommended [12]. Moreover, we examined differences in METs and the proportion of time in various intensity levels, which is also limited in the literature [12,20]. Despite these strengths, the use of a small, convenience sample that included healthy, nonoverweight, and highly active young adults limits the generalizability of these results. Although the addition of 94 person-days of reported exercise enhanced the robustness of data collected, future research should include a larger and more diverse population. Whereas data collected from both devices were time synchronized, differences in device placement (wrist vs waist) were likely susceptible to differences in upper and lower body movement [34,35]. Although others have used similar device placements [4,20], future studies are needed to substantiate these findings using wrist-worn, research-grade accelerometers. This study also relied on self-reported exercise that is inherently subject to recall and response bias [39]. However, self-report data provide context that can complement accelerometer-based data collected in free-living conditions [1].

At the time this study was implemented (2014), the Fitbit Flex was the most recent device available and the existing literature was primarily limited to a small number of laboratory-based studies that examined the validity of earlier, waist-worn Fitbit devices (eg, Zip and One) [12]. Since then, Fitbit has released 6 different models (Charge, Charge HR, Surge, Alta, and Blaze) that offer new and more advanced features including heart rate monitoring and geographic information systems. On the basis of current literature, it is clear that the rate at which this technology is currently developed and marketed to consumers greatly outpaces the rigor of scientific investigation, and proprietary laws prevent transparency regarding the potential utility of these devices in research. Additionally, because software changes can be made at any time, this can greatly influence the measurement properties of the device and can negate findings that have been previously reported [12]. In 2015, Fitbit changed its algorithm for defining MVPA to align more closely with the Centers for Disease Control and Prevention’s recommendations [40], in which Fitbit reports active minutes only when activity levels of ≥ 3 METs are recorded for 10 or more continuous minutes [23]. Because we examined minute-level intensity scores (obtained through Fitabase) and matched these to minutes of reported exercise, it is unlikely that these changes affected the outcomes of this study. However, researchers should use caution when relying on data directly obtained from a user’s Fitbit dashboard.

Conclusions

The results of this study indicate that the Fitbit Flex provides reasonably accurate estimates for steps and overall mean intensity scores for which exercise bouts are reported, particularly for activities other than walking. However, the algorithm that Fitbit uses to estimate MET rate is not equivalent to ActiGraph in the generalized case. This study also highlights the measurement disparity between day-level and minute-level observations, as well as measurement differences for specific types of exercises. However, the lack of transparency regarding

the measurement properties used by Fitbit and routine changes that are made to the Fitbit software and firmware can affect the way Fitbit measures different PA attributes. This perpetually calls into question the validity and reliability of Fitbit data and has implications regarding the applicability of Fitbit in research settings. Future research by our investigative team will include modeling the intensity levels determined by research-grade accelerometers to those used by Fitbit in order to create a more standardized method of measurement and improve the feasibility of using Fitbit in applied PA research.

Acknowledgments

The authors thank the participants who volunteered for this study and Gabrielle Guider for assisting with data collection. This research was supported by internal funds provided by the Department of Behavioral Health and Nutrition at the University of Delaware.

Conflicts of Interest

None declared.

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Abbreviations

BMI: body mass index
EE: energy expenditure
GLMM: general linear mixed modeling
METS: metabolic equivalent tasks
MVPA: moderate-to-vigorous physical activity
PA: physical activity

Edited by G Eysenbach; submitted 28.06.16; peer-reviewed by S Hartman, R Furberg; comments to author 21.07.16; revised version received 15.08.16; accepted 24.08.16; published 19.09.16.

Please cite as:

Dominick GM, Winfree KN, Pohlig RT, Papas MA

Physical Activity Assessment Between Consumer- and Research-Grade Accelerometers: A Comparative Study in Free-Living Conditions
JMIR Mhealth Uhealth 2016;4(3):e110

URL: <http://mhealth.jmir.org/2016/3/e110/>

doi: [10.2196/mhealth.6281](https://doi.org/10.2196/mhealth.6281)

PMID: [27644334](https://pubmed.ncbi.nlm.nih.gov/27644334/)

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Letter to the Editor

The Era of Smartphones: Back to Our Biological Makeup?

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(*JMIR Mhealth Uhealth* 2016;4(3):e63) doi:[10.2196/mhealth.5193](https://doi.org/10.2196/mhealth.5193)

Physical inactivity is a major modifiable cardiovascular risk factor that has become a growing health problem in the 21st century: 83% of adolescents aged 13-15 years and approximately 1/3 of adults worldwide are inactive, that is, not meeting the minimum international physical activity (PA) recommendations (≥ 150 minutes/week of moderate to vigorous PA) [1,2]. Thus, the PA levels of the general population, especially of individuals at cardiovascular risk, should be routinely assessed by health care professionals, as it has been recently recommended by the American Heart Association [3]. To this end, accelerometers (usually attached to an elastic belt around the waist) allow objective quantification of PA by providing continuous recordings. At least 3 to 5 days of accelerometer monitoring (including weekend days) are required to determine habitual PA, and it is generally accepted that the device should be worn for ≥ 10 hours/day [4]. For this reason, the simple and inexpensive method of PA questionnaires is more widely used and generally better accepted. Unfortunately, the validity of self-reported PA is questionable.

As recently discussed by Direito and collaborators [1], a reliable and simple strategy for assessing individual PA levels, without interfering with people's daily life, is the use of smartphone

apps. Smartphones are used by millions of people and many versions include a triaxial accelerometer and a positioning system among other types of sensors, thereby allowing the development of new apps with biomedical applicability. Other devices like the “Nike+ Move” app, which converts the smartphone into an “intelligent band,” or the Apple Watch and the HealthKit, might represent the beginning of the wearable's revolution in health sciences, providing a great chance to monitor PA in an effective and inexpensive manner.

We have evolved to perform high levels of PA (>2-3 hours) on a daily basis as persistent hunter-gatherers. However, technological improvements over few generations (industrial and, most recently, digital revolution) have led to dramatic reductions in our PA levels leading to chronic maladaptation and disease, with prolonged television viewing exemplifying a behavior that is at odds with our biological makeup and is associated with an increased risk of mortality [5]. Let us hope that the technological improvements that have made us become so inactive might pay off one day by helping increase our PA levels, that is, through the use of smartphones and wearable devices.

Conflicts of Interest

None declared.

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Abbreviations

PA: physical activity

Edited by P Morita; submitted 01.10.15; peer-reviewed by A Gonzalez de Agüero; accepted 28.10.15; published 27.07.16.

Please cite as:

Santos-Lozano A, Garatachea N, Pareja-Galeano H, Fiuza-Luces C, Sanchis-Gomar F, Lucia A

The Era of Smartphones: Back to Our Biological Makeup?

JMIR Mhealth Uhealth 2016;4(3):e63

URL: <http://mhealth.jmir.org/2016/3/e63/>

doi: [10.2196/mhealth.5193](https://doi.org/10.2196/mhealth.5193)

PMID: [27465861](https://pubmed.ncbi.nlm.nih.gov/27465861/)

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