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Review

# Lifelog Retrieval From Daily Digital Data: Narrative Review

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## Abstract

**Background:** Over the past decade, the wide availability and small size of different types of sensors, together with the decrease in pricing, have allowed the acquisition of a substantial amount of data about a person's life in real time. These sensors can be incorporated into personal electronic devices available at a reasonable cost, such as smartphones and small wearable devices. They allow the acquisition of images, audio, location, physical activity, and physiological signals among other data. With these data, usually denoted as lifelog data, we can then analyze and understand personal experiences and behaviors. This process is called lifelogging.

**Objective:** The objective of this paper was to present a narrative review of the existing literature about lifelogging over the past decade. To achieve this goal, we analyzed lifelogging applications used to retrieve relevant information from daily digital data, some of them with the purpose of monitoring and assisting people with memory issues and others designed for memory augmentation. We aimed for this review to be used by researchers to obtain a broad idea of the type of data used, methodologies, and applications available in this research field.

**Methods:** We followed a narrative review methodology to conduct a comprehensive search for relevant publications in Google Scholar and Scopus databases using lifelog topic–related keywords. A total of 411 publications were retrieved and screened. Of these 411 publications, 114 (27.7%) publications were fully reviewed. In addition, 30 publications were manually included based on our bibliographical knowledge of this research field.

**Results:** From the 144 reviewed publications, a total of 113 (78.5%) were selected and included in this narrative review based on content analysis. The findings of this narrative review suggest that lifelogs are prone to become powerful tools to retrieve memories or increase knowledge about an individual's experiences or behaviors. Several computational tools are already available for a considerable range of applications. These tools use multimodal data of different natures, with visual lifelogs being one of the most used and rich sources of information. Different approaches and algorithms to process these data are currently in use, as this review will unravel. Moreover, we identified several open questions and possible lines of investigation in lifelogging.

**Conclusions:** The use of personal lifelogs can be beneficial to improve the quality of our life, as they can serve as tools for memory augmentation or for providing support to people with memory issues. Through the acquisition and analysis of lifelog data, lifelogging systems can create digital memories that can be potentially used as surrogate memory. Through this narrative review, we understand that contextual information can be extracted from lifelogs, which provides an understanding of the daily life of a person based on events, experiences, and behaviors.

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**KEYWORDS**

lifelog; lifelogging; information retrieval; image retrieval; computer vision; signal processing; event segmentation; mobile phone



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## Introduction

### Background

With the expansive use of technology by humans, such as smartphones and wearable devices accessible worldwide, the acquisition of data about a person's activity is changing dramatically, allowing the acquisition of a huge amount of different types of data every day in the form of images, locations, and physiological signals. With the rapid development of Internet of Things solutions, these personal data can be applied in a wide range of applications. One such application is lifelogging.

Lifelogging is defined as a form of pervasive computing, consisting of a unified digital record of the totality of an individual's experiences, which is usually called a lifelogger, captured multimodally through digital sensors and stored permanently as a personal multimedia archive. In a simple way, lifelogging is the process of tracking and recording personal data created through our activities and behavior [1,2].

The idea of storing knowledge and information to provide an auxiliary memory to support people was envisioned by Vannevar Bush [3]. At the end of the Second World War in 1945, Vannevar Bush presented the Memex concept to the world. Memex represented a device in which an individual stores knowledge and information, such as his books, records, and communications, based on association, similar to the brain, and exposes it as a memory aid. Bush also envisioned 2 other devices that have come to life: the minicamera worn on the forehead that would allow users to take photographs from their point of view and a device that would record voice in text format. Remarkably, the use of these 3 devices together would enable what could be considered as the starting point of lifelogging.

With the evolution of digital technologies over the years, solutions to record, store, and organize a lifetime of information and knowledge have become possible, as envisioned by Vannevar Bush. Bush's vision remains an inspiration for many information retrieval and lifelogging systems. However, the amount of information available to be stored and processed today is difficult to analyze and retrieve. To overcome this problem, a wide range of research fields can be explored, such as image and information retrieval, knowledge extraction, image understanding, sentiment analysis, and data mining just to name a few, which provide solutions to organize, process, and retrieve personal data. These personal data are also named as lifelogs and can be used as surrogate memory within a lifelogging system capable of organizing and managing these lifelogs [2]. Therefore, the extraction of relevant information from personal lifelogs can be used to improve the quality of everyday life for people with memory problems or even used as a digital diary.

The practice of lifelogging has become an important resource of contextual data. Projects such as Digital Eye Glass [4-11], MyLifeBits [12-16], and SenseCam [17,18] were the most relevant in the past. The amount of lifelog data (volume), the different types of data obtained from several sources (variety), and the agility to process the lifelogs and generate the necessary information (velocity) make lifelogging an interesting and challenging big data application [2,19]. For example, Gurrin et al [20] started to analyze the large visual lifelogs that were captured during a period of more than a year. Therefore, it is not surprising that the complexity and interdisciplinary challenges are increasing the attention on the lifelogging subject from the research community.

### Objectives

Memory is often compared with a computer as it constitutes an information processing system. Both systems have basic functions such as encoding (input and processing of information), storage (retention of information), and retrieval (obtaining information from the storage) [21]. The loss of information from memory, also known as forgetting, occurs when a failure in encoding occurs owing to interference or other memory errors. Encoding failures can be circumvented through lifelogging. Lifelogs, particularly visual lifelogs, provide context cues that can help recall and recognition [21]. As a result, lifelogging has the potential for supporting memory augmentation, which can be applied to aid memory retrieval not only for people with dementia but also for healthy people.

The world's population above the age of 60 years has been increasing since 1950, and it is estimated to reach approximately 2.1 billion by 2050 [22]. Consequently, the World Health Organization recognized dementia as a public health priority and proposed a global action plan with several action areas, which includes the development, implementation, and improvement of surveillance and monitoring systems, to improve the functional trajectories of people with dementia, their careers, and families [23]. Considering everything mentioned above, patients with dementia could benefit from a lifelogging application that would work as a digital everyday life journal or as a personal historical record [24].

Lifelogging technologies give us the opportunity to create human digital memories, allowing us to represent and understand every moment of our lives and store this information for further use. However, each memory has specific cues, which can be captured from multiple sources based on our surroundings, such as visual cues, verbal and environmental sounds, locations, and actions, thus providing a large amount of contextual information that requires an interactive software tool to retrieve and explore the memory space. In this narrative review, we have discussed about the several types of personal lifelogs and lifelogging applications used to retrieve these lifelogs.

## Methods

### Search Strategy

This narrative review [25,26] explored a broad perspective of lifelogging approaches and technologies with the aim of synthesizing and understanding the literature on this research topic. Google Scholar and Scopus databases were used to conduct an iterative search based on a combination of search terms or keywords and appropriated Boolean operators to identify relevant publications.

The following search terms were explored: *(lifelog OR lifelogging) AND (visual OR audio OR location OR physical activity OR physiological signal OR dementia)*. A search period



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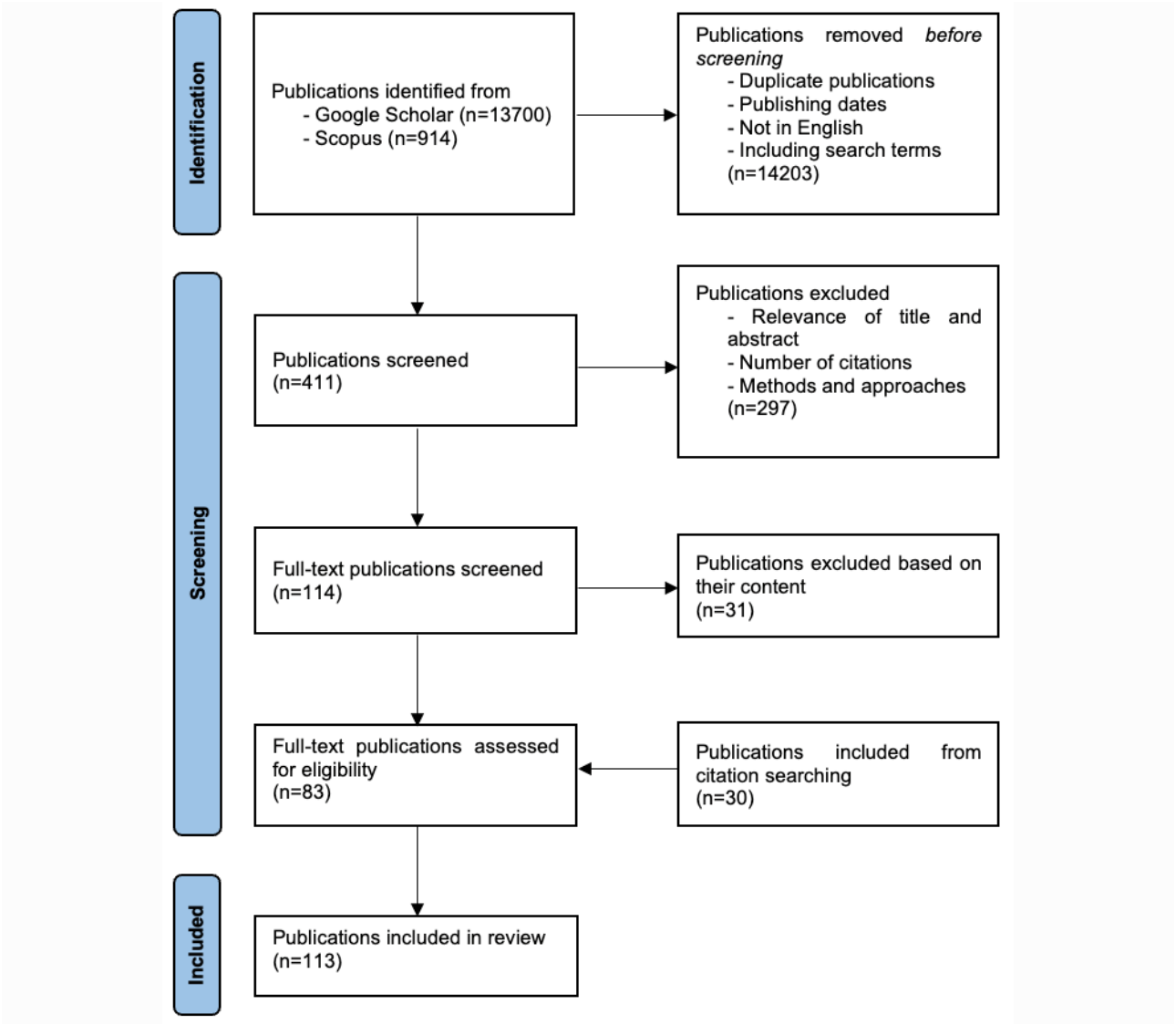
was included for searching the publications within the period of 2008 to 2020. However, to explore a historical view of the research topic, relevant publications before 2008 were manually identified and included. This additional inclusion of potential manuscripts of interest was based on our knowledge of this research topic and the association of authors and references of the publications included previously. Only publications in English were considered.

## Inclusion and Exclusion Criteria

A total of 411 search results were screened based on the relevance of their title and abstract. Of these 411 publications, 114 (27.7%) publications were selected for full-text analysis. Of the 114 publications, 31 (27.2%) publications were excluded based on their content, and finally, 113 publications were included in our narrative review after including several other publications through citation searching.

Figure 1 shows a flow diagram with the search strategy that led to the included citations, following the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) 2020 guidelines [27]. Initially, our search resulted in a total of 14,614 articles by searching the keywords *lifelog* and *lifelogging*. However, as the number of resulting publications was high, we chose to combine keywords, such as *visual*, *audio*, *location*, *physical activity*, *physiological signs*, and *dementia*. Several duplicate articles were excluded, and we selected 2.81% (411/14,614) of the publications. To further restrict our article selection, several articles were excluded based on the relevance of their title and abstract, number of citations, relevance, and approaches or methods. As a result of this search, 27.7% (114/411) of the publications were selected and fully reviewed. Moreover, 27.2% (31/114) of these publications were excluded based on their content. Finally, based on our knowledge of this research topic and by exploring the publication records of the authors of the selected papers, we included 30 more articles to conclude our manuscript collection process with 113 publications.

**Figure 1.** Flow diagram of the literature selection process for this narrative review.






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# Results

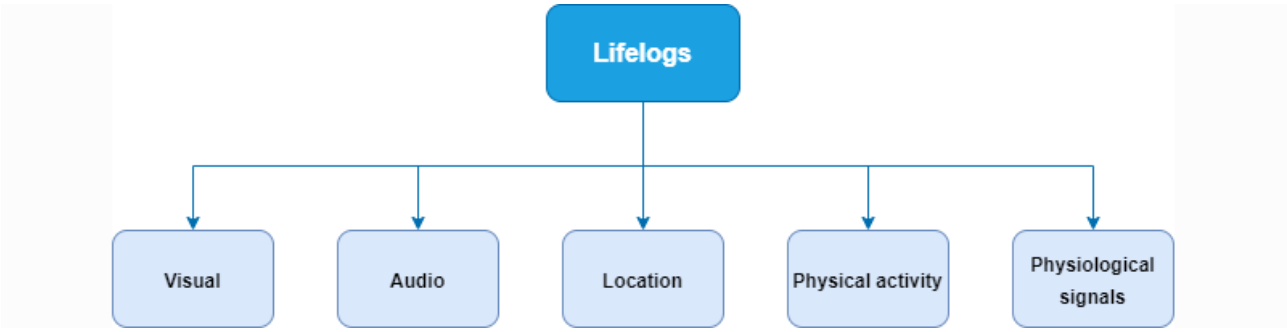
## Types of Lifelog Data

### *Overview*

Recent technological advances have introduced new types of sensors and devices that allow the compilation of vast archives of personal data. According to our research, the review of the literature proposes that the most prominent data explored in the lifelogging research are images, videos, locations, physical activities, and physiological signals, as presented graphically in Figure 2. In visual lifelogs, data are captured by cameras in the form of images or videos. Although audio is not widely used, the voice of the users or sounds in the environment can be useful data that can be integrated into lifelogging systems. The locations can be understood in 2 different ways, such as GPS locations (longitude and latitude) or physical locations (University of Aveiro, home, work, etc). Currently, devices such as smartwatches, which are wearable devices that incorporate sensors such as accelerometers, gyroscopes, force sensors, and pressure sensors, are frequently used by many people. They enable the extraction of information to monitor physical activities. However, these types of wearable devices also incorporate other sensors capable of recording physiological signals such as heart rate and body temperature.

Table 1 summarizes the types of data used in the selected studies on lifelogging. Description of the several approaches is presented in the following subsections. As seen in Table 1, visual data are the most used owing to its richness and the advances in image processing algorithms that allow the extraction of relevant information from images or video. However, several studies have already been reported on the use of other types of data and multimodal solutions.

**Figure 2.** Main types of lifelog data used in lifelogging identified from our review of the literature.






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**Table 1.** Studies and types of data used.

| Study | Visual | Audio | Location | Physical activity | Physiological signals |
|---|---|---|---|---|---|
| Piasek et al [24] | ✓ (SenseCam) | —[a] | — | — | — |
| Hodges et al [17] | ✓ (SenseCam) | — | — | — | — |
| Doherty et al [28,29] | ✓ (SenseCam) | — | — | — | — |
| Gurrin et al [30] | ✓ (smartphone) | — | — | — | — |
| Pauly-Takacs et al [31] | ✓ (SenseCam) | — | — | — | — |
| Wang et al [32,33] | ✓ (SenseCam) | — | — | — | — |
| Song et al [34] | ✓ (Google Glass) | — | — | — | — |
| Li et al [35] | ✓ (SenseCam) | — | — | — | — |
| Bolanos et al [36] | ✓ (Narrative Clip) | — | — | — | — |
| Talavera et al [37] | ✓ (Narrative Clip and SenseCam) | — | — | — | — |
| Dimiccoli et al [38] | ✓ (data sets) | — | — | — | — |
| Gupta and Gurrin [39] | ✓ (OMG Autographer) | — | — | — | — |
| Fan et al [40] | ✓ (Narrative Clip) | — | — | — | — |
| Garcia del Molino et al [41] | ✓ (data sets) | — | — | — | — |
| Furnari et al [42] | ✓ (Looxcie LX2) | — | ✓ (semantic) | — | — |
| Oliveira-Barra et al [43] | ✓ (data sets) | — | — | — | — |
| Ellis and Lee [44] | — | ✓ | — | — | — |
| Shaikh et al [45] | — | ✓ | — | — | — |
| Shah et al [46] | — | ✓ | ✓ (GPS) | — | — |
| Yamano and Itou [47] | — | ✓ | ✓ (GPS) | — | — |
| Ziaei et al [48] | — | ✓ | | — | — |
| Li et al [49] | — | — | ✓ (GPS) | — | — |
| Tanaka et al [50] | — | — | ✓ (GPS) | — | — |
| Aizawa et al [51], Hori et al [52], and Datchakorn et al [53] | ✓ | ✓ | ✓ (GPS and semantic) | ✓ (multiple sensors) | — |
| Doherty et al [54] | ✓ (SenseCam) | — | — | ✓ (smartphone) | — |
| Hurvitz et al [55] | — | — | ✓ (GPS and semantic) | ✓ (multiple sensors) | — |
| Yang et al [56,57] | — | — | — | ✓ (multiple sensors) | — |
| Dobbins et al [58] | — | — | — | ✓ (data sets) | ✓ (data sets) |
| Ni et al [59] | — | — | ✓ (GPS) | ✓ (smartphone) | — |
| Kim et al [60] | — | — | — | — | ✓ (smartwatch) |
| Choi et al [61] | — | — | — | — | ✓ (multiple sensors) |
| Dobbins and Fairclough [62] | — | — | — | — | ✓ (multiple sensors) |

[a]The study does not use this type of data.

### *Visual*

We can observe from Table 1 that several studies on lifelogs have explored the use of visual data. Visual lifelogs are generally collected in the form of photographic or videographic records to trigger memories. Photographs are the preferable representation of autobiographical memories [63,64]. In recent years, wearable devices capable of capturing images or videos continuously from a personal perspective are increasingly used. Examples of these wearable devices are SenseCam, OMG



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Autographer, Narrative Clip, Google Glass, and GoPro. In addition to these wearable devices, smartphones with high-quality cameras and other sensors are also an important tool for lifelogging. Gurrin et al [30] explored the use of smartphones as an alternative solution to wearable devices such as SenseCam and described several advantages of using smartphones as behavior monitoring devices.

The ability of devices, such as SenseCam, to improve autobiographical memory was studied on a patient with amnesia [17]. This case study indicated that short-term recall improved owing to the use of SenseCam. Furthermore, the use of SenseCam also enhanced long-term memory of autobiographical events. In contrast to the SenseCam application, the written diary helped to recall events in the short term, but not in the long term. The main challenge that this type of devices, and consequently visual lifelogs, face is the processing of such tremendous amounts of data [18]. It is essential to develop techniques that are able to automatically label, segment, and present relevant images in a meaningful sequence.

Pauly-Takacs et al [31] used the images captured by SenseCam during a walk to assist a boy aged 13 years, with profound episodic memory difficulties in remembering those moments. The result of this experiment shows the ability of the images to support the formation of personal semantic memories and memory rehabilitation. In addition to helping in the improvement of retrospective memory, SenseCam can also be applied to patients with dementia, but as a cognitive stimulation therapy. A case study was conducted with the aim of mentally stimulating the patient and encouraging factual and opinionated communication [24].

It is obvious that visual lifelogs are essential as memory reminders to reconstruct previous life experiences, but these lifelogs can be used in other use cases, such as general lifestyle analysis. Doherty et al [28,29] proposed a method to automatically classify visual lifelogs into different lifestyle traits using images collected by SenseCam. The camera captures details of the individual's everyday activities, in an approach to build a memory of the past. Moreover, Doherty et al [54] used SenseCam images to complement accelerometry measures to identify behavior type and context information across a range of activity episodes.

It is essential to develop techniques that are capable of summarizing the large number of images collected through visual lifelogging. Similarly, Wang and Smeaton [32] proposed a technique for identifying everyday activities captured using SenseCam. It is worth noting that these findings are consistent with previous literature [2,21]. In terms of daily human activities, a very wide range of semantic concepts can be identified in visual lifelogs. For the same activity, a variety of semantic concepts can be observed across individuals. Wang et al [33] characterized everyday activities and behaviors of individuals based on the detection of semantic concepts that appear in visual lifelogs obtained from events that have been automatically segmented based on the technique introduced in the study by Lee et al [65].

In another study conducted using SenseCam, a day of a user was recorded by taking a photo every 30 seconds [35]. Following the lifelogging process, the user reviewed the collected data and classified the day into 12 events to create a ground truth. This method has the potential to retrieve autobiographical events, enabled by the creation of visual lifelogs. Therefore, the use of a wearable camera along with the methods mentioned in this paper constitutes a promising approach to help people retrieve their memories.

In the study by Song et al [34], several egocentric videos were recorded using Google Glass, which captured the diversity and complexity of different daily human activities from a first-person perspective. These videos were collected from 10 different individuals and contained 13 categories of activities relevant to lifelogging applications. Song et al [34] performed several experiments through which they accurately recognized these activities by adopting the dense trajectory approach.

Bolanos et al [36] proposed a method for creation of visual summaries of a set of egocentric images captured by a wearable camera, the Narrative Clip. This summarization aims to support people with neuronal degradation. Other similar studies have been proposed based on the same methodology of clustering-based event segmentation [37] and summarization using contextual and semantic information [38].

Recently, methods based on deep learning to extract visual concepts from images have grown rapidly, making it possible to automatically extract and annotate visual lifelogs accurately. Gupta and Gurrin [39] proposed event segmentation of visual lifelogs based on 2 different approaches for visual concept extraction and image classification, such as objects and activities. The visual lifelogs were collected using a wearable camera, OMG Autographer.

Fan et al [40] proposed the compilation of a journal using the captions of photo streams acquired through camera-based lifelogs. This type of lifelogging collects a large number of images, which in turn are of low quality, noisy, and ambiguous, as they are taken automatically. In this study, 2 authors used Narrative Clip cameras for 5 months to create a data set.

Most studies that used visual lifelogs collected images or videos and created data sets that often contain very limited data, which results in insufficient data to train machine and deep learning algorithms efficiently. In the study by Garcia del Molino et al [41], a large-scale data set with a first-person perspective was created with >1.5 million images captured by 57 users using a wearable camera to train a visual context predictor. This approach can be used to model daily activities and learn the associations between different scenes.

Furnari et al [42] presented a method for temporal segmentation based on personal locations. This study is very promising because it achieves results that are as accurate as those of other methods in the literature. Oliveira-Barra et al [43] proposed a comprehensive methodology for egocentric photo stream analysis. They performed a summary of autobiographical episodes and a semantic key-frame selection and, finally, implemented text-based inverted index retrieval techniques. The episode temporal segmentation was based on semantic regularized–clustering [38]. This model was applied to a data set, and the results suggest that this system stimulates the



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memory of patients with mild cognitive impairment; for example, patients with dementia.

### *Audio*

As stated in Table 1, a lifelogging application can also use audio lifelogs, generally captured by wearable audio recorders, smartphones, or video cameras that can record audio for several hours or days using a microphone. In the MyLifeBits project [12,13], Gordon Bell used a wearable microphone to record audio clips and stored them in his personal lifelogs. Ellis and Lee [44] described several practical advantages of using audio lifelogs and conducted experiments with different equipment and techniques. Totally, there are 3 major advantages of using audio lifelogs [44]: audio devices, such as microphones, are less sensitive to positioning or motion than cameras; audio data are smaller in file size than videos or image sequences; and audio archives can provide a wide range of useful information, such as location, activities, people, and words.

Audio lifelogs can provide useful information to lifelogging systems, and human activities are reflected in a rich variety of acoustic events and environmental sound cues. Shaikh et al [45] proposed a method to detect and classify activities of daily living, such as laughing, talking, cooking, and so on, and location of the person, such as inside a train, at home, at school, and so on, from the environmental sound cues. Shah et al [46] proposed a lifelogging system using audio records that included speech, music, and environmental sounds. In large audio lifelogs, manual browsing and searching for events or specific audio clips is time-consuming. Therefore, to deal with several types of audio and build an easy, intuitive, and efficient lifelogging application, a generalized and more complex approach was presented in the study by Shah et al [46].

Other studies have used audio lifelogs to segment and classify them according to several characteristics. For example, Yamano and Itou [47] recorded audio lifelogs using wearable microphones and conducted several experiments that enabled browsing these lifelogs. The audio lifelogs were segmented and clustered into events to classify them according to place, speaker, and time. Ziaei et al [48] proposed an analysis system, which automatically estimates the number of unique people and environments using personal audio records.

### *Location*

Lifelogs based on locations can be recognized in 2 different ways: GPS coordinates, such as longitude and latitude, and physical or semantic locations characterized by the place or environment, such as home, office, or more specific locations such as the University of Aveiro. Literature indicates that GPS tracking devices and wearable devices improve the users' self-esteem when evaluating the effects on the quality of life [66,67]. It is important to note that in this case, the data from GPS tracking devices were not intended to retrieve memories. Nevertheless, the location information may complement visual lifelogs by identifying where the images were taken. This information is usually expressed as coordinates. Moreover, lifelogs offer the option to register relevant locations under intuitive names such as *my son's house* [42,49]. When the user checks her lifelog, both the image and the location are displayed. Thus, the user may recall the corresponding memory more easily, even if no spatial cues are visible in the image.

Li et al [49] proposed a method for relating user activities to their location. The authors used spatial and temporal constraints to infer where the user worked or studied. Although this method does not correctly identify all the activities, the results are promising. Furthermore, the proposed method points to the possible automatic compilation of a journal with the places and activities of everyday life by just using a smartphone, which, in turn, can aid memory retrieval.

In the study by Tanaka et al [50], a method for daily context recognition by recording lifelogs based on GPS location from a smartphone was proposed. The proposed method recognizes the lifelogger's location and activity as contexts. It can also recognize several contexts at the same location; for example, in a shopping mall, the method can distinguish between shopping, eating a meal, or watching a movie at the cinema. By using a smartphone, the lifeloggers can track their activities over time and observe their daily life in more detail.

### *Physical Activity*

Physical activity is fundamental for human beings and is associated with better general health status and improved quality of life. Accelerometers, gyroscopes, goniometers, force sensors, and pressure sensors enable the collection of diverse information. When strategically placed on the user, these sensors can assess the gait and detect falls [68]. Moreover, these sensors are often incorporated into smartwatches or smart bands to monitor physical activity [40]. In addition to counting steps and estimating walked distance, smartwatches and wristbands can record the heart rate and detect stair climbing, arousal, stress, and excitement through electrodermal activity [21].

Doherty et al [54], following their previous study on event-based segmentation [28] and recognition of human activities [29], proposed the use of accelerometers combined with images from wearable cameras to identify certain physical activity behaviors. In this approach, the accelerometer data determined the event boundaries, and the authors could identify sedentary and light, moderate, and vigorous intensity physical activities.

With the easy accessibility of sensors such as accelerometers, which measure the acceleration forces acting on an object or person to determine the object's position in space and monitor the movement, Hurvitz et al [55] proposed methods to measure and analyze activity behaviors using data, such as location, activity, and environment, collected from the combination of accelerometers, GPS data, and travel diaries. The authors also provided an interface tool to structure and visualize location and physical activity data simultaneously.

Yang et al [56,57] studied several existing lifelogging physical activity measurement devices and identified some measurement uncertainties in an Internet of Things environment that impact the efficiency and accuracy of lifelogging and health applications.

Several diseases such as obesity, hypertension, and cardiovascular diseases are correlated with insufficient physical activity. Dobbins et al [58] proposed an approach to collect and



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process data from triaxial accelerometers and a heart rate monitor to classify physical activities, such as lying, sitting, running, working on computer, and walking, into different activity levels. In addition to this classification, a visual interface was provided to display the classification of daily physical activities of the user on a smartwatch.

Recently, Ni et al [59] explored a 2-stage hybrid model to predict human physical activity status from lifelogging data collected by wearable sensors. Their goal was to provide health care analytics to support individual decisions in real-time monitoring and statistical analysis, provide personalized advice to individuals, and ultimately, encourage positive attitudes toward healthy lifestyles.

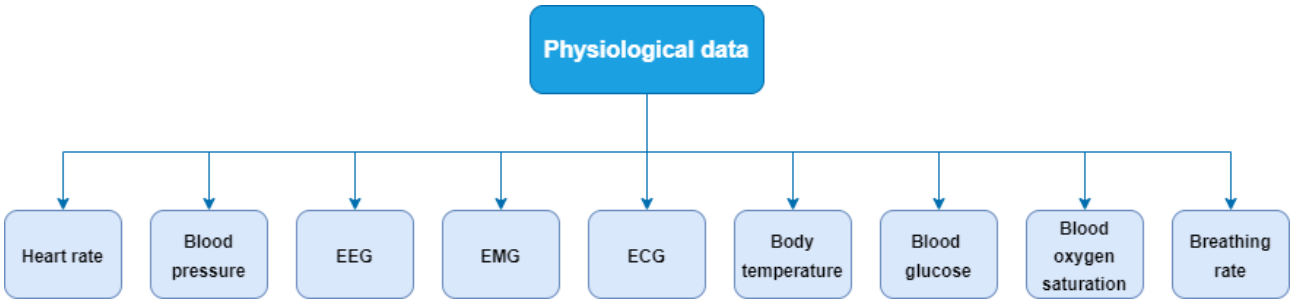
### *Physiological Signals*

Physiological data are inevitably related to the health care service area. These data have been increasingly used in lifelogs over the years, which can be explained by the expansion of the fitness industry [21,60]. The main physiological data are presented in Figure 3. The most relevant data are heart rate, blood pressure, electroencephalogram, electromyogram, electrocardiogram, blood oxygen saturation, blood glucose, body temperature, and breathing rate [61,68,69]. However, the sensors needed to collect most of these data still have to be incorporated into more practical devices before they become prominent in lifelogging applications.

Heart rate is related to user activity; therefore, it plays a relevant role; for example, when the intention is to identify user activities from visual lifelogs. In the study by Dobbins et al [58], the use of heart rate information was combined with an accelerometer to detect physical activity and support people with diseases such as obesity. Another relevant biological signal is blood pressure, and similar to heart rate, the respective sensors can be incorporated into wearable devices, particularly smartwatches [69].

Dobbins and Fairclough [62] collected lifelogging data from multiple sources including physiological signals, such as ECC and photoplethysmogram data, and driving data, such as the speed of the vehicle, location, and first-person environment images, to develop several classifiers for detecting stress in real-world driving.

**Figure 3.** Summary of the main physiological data. ECG: electrocardiogram; EEG: electroencephalogram; EMG: electromyogram.




## Challenges and Data Sets

Over the past years, the term *lifelogging* has received significant attention from both research and commercial communities. The events that introduced the lifelogging concept to the academic community were the Association for Computing Machinery Continuous Archiving of Personal Experiences workshops from 2004 to 2006 [70-72]. These workshops were essential for those who previously designed and developed solutions independently [6,44,73,74], share tools and experiences, and lead lifelogging as an emerging research area.

Table 2 presents the most relevant data sets existing in the literature for lifelog research.

**Table 2.** Data sets.

| Data sets | Visual | Audio | Location | Physical activity | Physiological signals |
|---|---|---|---|---|---|
| NTCIR[a]-12 lifelog [75] | ✓ (OMG Autographer) | —[b] | ✓ (semantic) | ✓ (smartphone) | — |
| NTCIR-13 lifelog [76] | ✓ (Narrative Clip) | ✓ (music listened) | ✓ (semantic) | ✓ (smartphone) | ✓ (multiple sensors) |
| NTCIR-14 lifelog [77] | ✓ (OMG Autographer) | ✓ (music listened) | ✓ (semantic) | ✓ (smartphone) | ✓ (multiple sensors) |
| EDUB[c] [78] | ✓ (Narrative Clip) | — | — | — | — |

[a]NTCIR: National Institute of Informatics Testbeds and Community for Information Access Research.

[b]The data set does not contain this type of data.

[c]EDUB: Egocentric Dataset of the University of Barcelona.

In 2016, the first test collection for personal lifelog data was introduced [75], which has been used for the National Institute of Informatics Testbeds and Community for Information Access Research (NTCIR)-12–Lifelog task [79]. It promoted a comparative evaluation of information access and retrieval systems operating over personal lifelogs. The lifelogs in this test collection consisted of images from 3 lifeloggers using the wearable camera, OMG Autographer. It also contained several semantic locations, such as home, work, and so on, and physical activities, such as walking, transport, and running. The data set was anonymized to ensure the privacy of both lifeloggers and individuals by removing identifiable content, such as



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recognizable faces and absolute GPS locations. The test collection also included a set of topic descriptions, which represent the retrieval and reflection reason of the lifelogger for accessing memories [75].

Consequently, challenges regarding lifelogging started emerging. The First Workshop on Lifelogging Tools and Applications in 2016 [80] aimed to discuss approaches to lifelog data capture, analytics, and applications, thus identifying opportunities and challenges for researchers in this new and challenging area. In 2017, the Second Workshop on Lifelogging Tools and Applications was organized simultaneously with the lifelog evaluation tasks, NTCIR-13 Lifelog-2 Task [76] and ImageCLEFlifelog 2017 Task [81].

The ImageCLEFlifelog 2017 challenge was introduced with the NTCIR-12–Lifelog data set [75], but different subtasks were proposed to the participants. However, in the NTCIR-13 Lifelog-2 Task, the organizers created a new data set based on the requirements of the first test collection for personal lifelog data. In addition to the tasks of NTCIR-12–Lifelog, they addressed 2 different challenges for lifelog data organization and retrieval [76].

Since then, workshops and tasks have been organized to advance research on some of the key challenges: ImageCLEFlifelog challenges [82-84]; Lifelog Search Challenge [85-87], which aims to encourage the development of efficient interactive lifelog retrieval systems; and NTCIR Lifelog Tasks [77]. Over the years, these challenges have focused on creating a comparative benchmark activity for lifelogging applications, and data sets used in each of them are very similar or even the same. These data sets start with the first test collection for personal lifelog data [75], which they extend or improve.

In addition to the data sets used in these challenges, several other data sets containing egocentric data are available [34,42,78,88]. However, most of these data sets focus on different and smaller amounts of data for specific use case applications and not on capturing all the daily activities and behaviors of a lifelogger. An example of these data sets is the Egocentric Dataset of the University of Barcelona (EDUB) [78], which is divided into different sub–data sets depending on the data annotations, such as EDUB-Obj data set for object localization or segmentation [89], EDUB-Seg data set for egocentric event segmentation [37,38], and EDUB-SegDesc data set that can be used either for egocentric event segmentation or for egocentric sequence description [90].

### Lifelog Retrieval Software Tools

Throughout the referred challenges and workshops, several applications were presented. The Lifelog Search Challenge has been one of the challenges in which several lifelogging systems have been presented with several utilities for real-world use, unlike other challenges, such as ImageCLEFlifelog challenges, which present very specific tasks.

A retrieval and exploration lifelogging system, called lifeXplore, which allows to search and browse features that have been optimized for lifelog data, was presented by Münzer et al [91]. It was based on a video search system, diveXplore [92-94], previously developed for video retrieval competitions. Besides efficient presentation and summarization of lifelog data, it includes different methods of retrieving and visualizing content, such as feature map, day inspector, lifelog filter, sketch search, and similarity search. Over time, the lifeXplore system was improved by including location-based filtering, automatic feature map browsing, and optical character recognition. Moreover, uniform sampling was used as an alternative method for segmenting videos [95,96].

Other tools obtained from video retrieval competitions are the VIRET tool [97-100], which is an updated version of the SIRET interactive video retrieval tool [101] addressing specific properties of visual lifelogs, and vitrivr [102,103], which was developed for video retrieval [104] and later adapted to support multimodal data [105], such as lifelogs.

Zhou et al [106] proposed an iterative lifelog search engine called LIFER, which is queried based on several different forms of lifelog data, such as visual concepts, activities, locations, time, and so on. Despite some limitations of LIFER, this application allows users to retrieve the moments from their personal life archives in a reliable and efficient manner. Enhanced versions of LIFER, such as LIFER 2.0 [107] and LIFER 3.0 [108], were proposed with additional visual features to solve several tasks of ImageCLEFlifelog 2019 and 2020, respectively. It should be noted that many other applications have been proposed in the challenges and workshops mentioned previously [109-114].

In addition to the mentioned applications, other applications have been incorporated into the context of health care. Health lifelogs focus on medical and clinical perspectives. In this case, lifelogs exploit other sensors to gather information. Physical activity, heart rate, blood pressure, and body temperature are examples of measurements that may be valuable from a clinical perspective [61,115,116]. Lifelogs can be used to create platforms that provide a collection of digital memories in a structured and searchable manner, similar to the DigMem system [117]. Another example of an application is the compilation of a diary based on information extracted from the lifelogs [40].

A recent study introduced the use of lifelog monitoring for the early detection of complications in pregnancy [116]. These lifelogs feature physiological data and self-reported information. The authors aimed to detect physiological changes and, together with the multiomics data, try to understand the mechanisms responsible for pregnancy-related diseases. Kim et al [118] proposed the development of a ubiquitous health care system based on biological and lifelog data. This system was designed to assist the care of patients with chronic medical conditions. A Japanese study discussed the viability of a platform (PeOPLe) containing self-recorded lifelogs and medical records to support health care applications [115]. Each patient should provide lifelogs to the platform to assist the health management of the patients who are old and request physician support based on automatic predictions. Similar to PeOPLe, the study presented by Choi et al [61] identified machine learning and mobile learning as helpful tools to examine big data resulting from lifelogs.

In addition to developing diagnostic and health care systems, as illustrated by the examples mentioned previously, lifelogging



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can assist the change of lifestyle and behaviors [119]. The awareness provided by self-monitoring encourages users to make healthy choices, and if the progression is noticeable, they feel motivated to continue. This applies to nutrition, physical activity, sports, active travel, and psychological well-being [2,40,64,115,120].

## Applications

Lifelogs comprise data of different natures, and consequently, they present an extensive range of possible applications within different use cases, as presented in Table 3. It is noteworthy that work or other procedures may be recorded through lifelogging. An example is the visual lifelogging of a workday by health care professionals [2]. Despite the popularity of wearable lifelogging devices, other sensors can be strategically placed to monitor user activity. These sensors can be used for older people with assisted living needs, and the data acquired by them can be recorded as a lifelog.

In summary, besides memory assistance, monitoring is the main application of lifelogging in health care. This is specifically relevant for the older population, but not exclusively. In addition, monitoring prompts self-reflection by the user, resulting in the motivation for self-improvement.



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**Table 3.** Applications of the research presented in the selected publications considering 5 major areas.

| Study | Daily activities | Event segmentation | Health care | Summarization | Retrieval |
|---|---|---|---|---|---|
| Piasek et al [24] | __[a] | — | ✓ | — | — |
| Hodges et al [17] | — | — | ✓ | — | — |
| Doherty et al [29] | ✓ | — | — | — | — |
| Gurrin et al [30] | ✓ | — | — | — | — |
| Pauly-Takacs et al [31] | — | — | ✓ | — | — |
| Wang et al [32,33] | ✓ | — | — | — | — |
| Song et al [34] | ✓ | — | — | — | — |
| Li et al [35] | — | ✓ | — | — | — |
| Bolanos et al [36] | — | ✓ | — | ✓ | — |
| Talavera et al [37] | — | ✓ | — | — | — |
| Dimiccoli et al [38] | — | ✓ | — | — | — |
| Gupta and Gurrin [39] | — | ✓ | — | — | — |
| Fan et al [40] | — | — | — | ✓ | — |
| Garcia del Molino et al [41] | — | ✓ | — | — | — |
| Furnari et al [42] | — | ✓ | — | — | — |
| Oliveira-Barra et al [43] | — | — | — | ✓ | ✓ |
| Ellis and Lee [44] | — | ✓ | — | — | — |
| Shaikh et al [45] | ✓ | — | — | — | — |
| Shah et al [46] | — | — | — | — | ✓ |
| Yamano and Itou [47] | — | ✓ | — | — | — |
| Ziaei et al [48] | — | ✓ | — | — | — |
| Li et al [49] | ✓ | — | — | — | — |
| Tanaka et al [50] | ✓ | — | — | — | — |
| Doherty et al [54] | ✓ | — | — | ✓ | — |
| Hurvitz et al [55] | ✓ | — | — | — | — |
| Yang et al [56,57] | ✓ | — | ✓ | — | — |
| Dobbins et al [58] | ✓ | — | ✓ | — | — |
| Ni et al [59] | ✓ | — | ✓ | — | — |
| Kim et al [60] | — | — | — | — | ✓ |
| Choi et al [61] | — | — | ✓ | — | ✓ |
| Dobbins and Fairclough [62] | — | — | ✓ | — | — |
| Leibetseder and Schoeffmann [96] | — | — | — | ✓ | ✓ |
| Kovalčík et al [100] | — | — | — | — | ✓ |
| Gasser et al [105] | — | — | — | — | ✓ |
| Le et al [108] | — | — | — | — | ✓ |
| Le et al [110] | — | — | — | — | ✓ |
| Ribeiro et al [109] | — | — | — | — | ✓ |
| Mai-Nguyen et al [111] | — | ✓ | — | — | ✓ |
| Tran et al [112] | — | ✓ | — | — | ✓ |
| Rossetto et al [113] | — | — | — | — | ✓ |
| Khan et al [114] | — | — | — | — | ✓ |
| Dobbins et al [117] | — | — | — | — | ✓ |



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| Study | Daily activities | Event segmentation | Health care | Summarization | Retrieval |
|---|---|---|---|---|---|
| Karako et al [115] | — | — | ✓ | — | — |
| Sugawara et al [116] | — | — | ✓ | — | — |
| Kim et al [118] | — | — | ✓ | — | — |
| Dobbins and Fairclough [64] | — | — | ✓ | — | — |

[a]The computational tool does not focus on this application.

### Privacy and Concerns

One of the most evident challenges associated with lifelogging is infringement of privacy [2,108]. The nonconsensual logging of bystanders and even the logging of aware friends and family exposes them. A possible solution for visual lifelogs is to blur faces [21,121]. However, when visual lifelogs are used as a memory aid, blurring the faces may hinder this function. Moreover, lifelogs may pose a privacy threat to the surrounding people. Lifeloggers are also susceptible to privacy issues, as lifelogs may constitute valuable information for corporations, including advertisers, which reinforces the necessity of the General Data Protection Regulation. Nevertheless, unobtrusive recording of audio or capturing of images without the explicit consent of everyone involved is prohibited by law.

The use of smartwatches by lifeloggers can be advantageous for recording health data. Kim et al [60] proposed a method to collect data from smartwatches while preserving the user's privacy. This study is of interest as it attempts to circumvent privacy issues regarding the use of smartwatches. These principles can serve as inspiration for similar approaches for other devices.

Lifelogs may affect our perception of reality; for example, memories may seem more recent than they actually are [119]. Furthermore, despite all the efforts, lifelogs can only capture a small fraction of reality, and as such, only concrete information about subjective experiences can be recorded. Consequently, lifelogs cannot be considered as the ground truth, as there may be failures that prevent full documentation [21].

Another result of our analysis was the permanent character inherent in lifelogs. Although this is advantageous for applications such as memory retrieval, it may become problematic. For example, people with mental illnesses may be obsessed with some memories and dwell on them [7]. Furthermore, even for healthy people, this permanent record may put them under the impression that they are not allowed to change [119]. Therefore, it has been proposed in the literature that lifelogs should try to mimic human memory and implement a forgetting functionality [2,21,64].

Another pertinent concern regarding lifelogging is the possibility that people may rely excessively on lifelogs to remember [119]. This is specifically relevant for future research, as the goal is to enhance the memory of healthy people or improve the memory of people with dementia.

With the popularization of lifelogs and adherence by most of the population, surveillance may become an issue. On one hand, law enforcement may consider lifelogs as a viable method to investigate criminals, which may result in intrusion of the privacy of innocent people [21]. On the other hand, lifelogs may be admitted as proof of innocence. In addition, lifelogs can also potentially empower surveillance by authorities. A legitimate ethical question that emerges from this surveillance is whether illegal behaviors perpetrated by bystanders should be reported by lifeloggers [2].

## Discussion

### Principal Findings

In lifelogging, devices should be ubiquitous, and data capture should occur without requiring any action on the part of the wearer. Currently, everything and everybody with network connectivity can be turned into sensors that continuously generate data. Mobile and wearable devices have been integrated into everyday activities in a seamless and ubiquitous manner. It has become increasingly possible to remotely monitor behaviors using our smartphones or wearable devices.

Lifelogs are personal data created through life experiences and behaviors of individuals during their daily life, such as images, videos, audio, biometric data, or locations, that are collected by physical sensors. Lifelogs are prone to become a powerful tool to retrieve memories or increase the knowledge about an individual's experiences or behaviors. However, regarding human digital memories (or personal digital memories), different viewpoints arise. Although some refer to human digital memories interchangeably with lifelogs, it is valid to argue that human digital memories are the result of the processing and organization of lifelogs [2,122,123].

Visual lifelogs are one of the most used data in lifelogging approaches and applications. These lifelogs provide important visual information such as environment, objects, activity, and behavior, which are performed and visualized by the lifelogger. As human beings, we can distinguish this visual information and interpret it to reconstruct a memory that was previously experienced. However, for machines such as our computers, this information is only pixels or numbers, which requires the development of algorithms and methods for the interpretation and analysis of these data to retrieve a specific memory efficiently. One of the main advantages of visual lifelogging is the resulting feeling of security. The users are not worried about remembering because they know that everything is being documented [21]. It should be noted that visual lifelogs are usually accompanied by supplementary information, as illustrated by the examples analyzed in the previous sections. These data can help in memory retrieval, because the richer the lifelogs, the more likely they are to hold relevant cues.



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Audio lifelogs are less used in lifelogging applications than visual lifelogs because of the additional challenges that they bring to the application. They can be uncomfortable for the lifelogger. However, audio lifelogs may contain important information for lifelogging applications, such as conversations, speeches, music, or several environmental sounds. Moreover, visual entry lifelogs can take advantage of sound records, as illustrated in the cases mentioned in the *Results* section. Although audio devices are mainly used as reminder devices, voice records can be used to document important events as the user is experiencing them or shortly thereafter. However, there is a lack of studies on the use of audio lifelogs and their relevance in lifelogging applications for people with dementia.

Location-based lifelogs allow people to retrieve information about the environment and activities that may occur in that location. Regarding memory retrieval, the locations complemented by other information, such as visual lifelogs or temporal features, facilitate the search for these data and make a lifelogging system more accurate [21]. For example, people with dementia tend to lose their ability to recognize familiar places or locations or become lost and confused about their location. Such information can be retrieved together with visual lifelogs and, therefore, stimulate the memory of these people.

Extracting physical activities only from images is a complex process and sometimes inaccurate, because certain objects or scenes can be associated with a wide range of activities. However, lifelog data such as heart rate and accelerometer data can be used to recognize activities of the lifelogger. By using semantic concepts extracted from the images and locations, the classification of these activities can improve significantly. Human physiological signals have several potential benefits in lifelogging applications, such as for health care and daily life monitoring. However, to use a wide range of these data, several sensors are necessary, and most existing lifelogging technologies do not incorporate all these sensors. For example, multiple devices are required to collect these signals from an individual in real time, which becomes challenging for data synchronization and filtering [64].

Physiological data are rarely used in isolation, and generally, these data alone rarely show cues to retrieve memories, particularly in patients with dementia, as their memories are triggered mainly by visual information. The main utility of physiological data in lifelogging is for medical records and physical activity. However, they may also be used to detect emotions, and similar to visual lifelogs, they can form a more complete digital memory [117].

Regarding privacy and concerns, lifeloggers must have access to their data and opportunities to rectify, remove, and control the data that is collected. In addition, lifeloggers should be aware of how their data are stored and used, who owns the lifelogs, and who owns the information obtained from their lifelogs [119]. Gurrin et al [2] assume that the data gatherer owns the lifelogs, which raises the question, “What happens to lifelogs when the correspondent lifelogger dies?” On one hand, lifelogs contain a lifetime of personal information. However, if they are stored in databases, it can help to improve research approaches. Thus, it is necessary to establish regulations on how to approach these concerning issues.

## Conclusions

The integration of lifelogging into people’s lives can be beneficial to improve the quality of their life, either by serving as a tool for memory augmentation or by providing support when having memory issues. Lifelogging systems can create relevant digital memories. Through this narrative review, we understand that contextual information can be extracted from lifelogs, which provides an understanding of a person’s daily activities based on events, experiences, and behaviors.

Initially, the scientific community in the lifelogging research field focused their attention on the design and development of solutions or devices capable of acquiring and storing data without interfering with one’s daily life. However, with the increase in wearable devices available for personal data acquisition and the large amount of data to be stored and retrieved, new challenges and issues arose regarding the storage, processing, organization, and retrieval of lifelogs.

An important conclusion of this research exercise is that visual lifelogs are most prevalent when the goal is to create digital memories as surrogate memories. Nevertheless, there is a tendency to associate visual lifelogs with other lifelog data such as audio, location, physical activities, and physiological signals. Audio lifelogs can provide relevant information, such as speeches or environmental sounds, which encode information about locations, activities, and overall context. Along with these personal data, location-based lifelogs can provide additional information. Physical activity and physiological lifelog data are often associated with health care and quality of life. The several sensors that can be incorporated in wearable and easy-to-use devices provide useful information for the recognition and classification of the activities and behaviors of a user. These data used in isolation have some benefits for health care and personal monitoring. Nevertheless, when combined with other lifelogs, they potentially provide important cues to retrieve and form more complete personal digital memories. In addition to creating human digital memories, the acquisition and processing of these lifelogs can be used for monitoring daily life and self-improvement. As they comprise data of different natures, they present an extensive range of possible applications within different use cases. In addition to their relevance in health care, several other applications have been explored such as daily activity analysis, event segmentation, summarization, and information retrieval.

The practice of lifelogging requires tracking and recording of lifelogs in everyday life, for which it is necessary to capture personal data over long periods or even the lifelogger’s entire life. These lifelogs can be combined to develop methods to recognize several contextual data to provide a broader understanding of the lifelogger’s life, such as events, experiences, behaviors, and moments. However, the lifelogs must be synchronized with each other, which can be achieved through time features recorded at the time of lifelog acquisition.

Nevertheless, when these lifelogs are introduced into a lifelogging application, some of them are not relevant or do not



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contain useful information for further processing and visualization. Therefore, preprocessing methods can be applied to select only relevant lifelogs and remove or correct those that may introduce errors and noise into the system. To retrieve and visualize the previously selected lifelogs, the lifelogging system must be able to interpret these lifelogs in a way similar to that of the lifelogger. Therefore, it is important to annotate, organize, and store the lifelogs with semantic concepts that provide more information about the environment and activities of the lifelogger. These semantic concepts are useful to understand the lifelogger's behavior and define events and specific moments, which may be required and visualized in the future as surrogate memories.

This narrative review shows that there is a considerable number of published studies on lifelogging. However, we identified several open questions through the analysis and possible lines of investigation in this currently important topic.

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## Authors' Contributions

RR, AT, and AJRN designed and conceptualized the study. RR was responsible for data collection and literature screening. RR drafted the manuscript. AT and AJRN contributed to the critical revision of this manuscript. All authors reviewed the manuscript and approved for publication.

## Conflicts of Interest

None declared.

## References

1. Dodge M, Kitchin R. 'Outlines of a world coming into existence': pervasive computing and the ethics of forgetting. Environ Plann B Plann Des 2016 Jul 22;34(3):431-445. [doi: 10.1068/b32041t]
2. Gurrin C, Smeaton AF, Doherty AR. LifeLogging: personal big data. FNT Inf Retrieval 2014;8(1):1-125. [doi: 10.1561/1500000033]
3. Bush V. As we may think. Interactions 1996 Mar;3(2):35-46. [doi: 10.1145/227181.227186]
4. Mann S. Wearable computing: a first step toward personal imaging. Computer 1997;30(2):25-32. [doi: 10.1109/2.566147]
5. Mann S. 'WearCam' (The wearable camera): personal imaging systems for long-term use in wearable tetherless computer-mediated reality and personal photo/videographic memory prosthesis. In: Proceedings of the Digest of Papers. Second International Symposium on Wearable Computers (Cat. No.98EX215). 1998 Presented at: Digest of Papers. Second International Symposium on Wearable Computers (Cat. No.98EX215); Oct 19-20, 1998; Pittsburgh, PA, USA. [doi: 10.1109/iswc.1998.729538]
6. Mann S. Continuous lifelong capture of personal experience with EyeTap. In: Proceedings of the the 1st ACM workshop on Continuous archival and retrieval of personal experiences. 2004 Presented at: MM04: 2004 12th Annual ACM International Conference on Multimedia; Oct 15, 2004; New York, USA. [doi: 10.1145/1026653.1026654]
7. Mann S, Fung J, Aimone C, Sehgal A, Chen D. Designing EyeTap digital eyeglasses for continuous lifelong capture and sharing of personal experiences. 2005 Presented at: CHI 2005; April 2-7, 2005; Portland, Oregon.
8. Mann S, Huang J, Janzen R, Lo R, Rampersad V, Chen A, et al. Blind navigation with a wearable range camera and vibrotactile helmet. In: Proceedings of the 19th ACM international conference on Multimedia. 2011 Presented at: MM '11: ACM Multimedia Conference; Nov 28 -Dec 1, 2011; Scottsdale Arizona USA. [doi: 10.1145/2072298.2072005]
9. Mann S, Lo R, Ovtcharov K, Gu S, Dai D, Ngan C, et al. Realtime HDR (High Dynamic Range) video for eyetap wearable computers, FPGA-based seeing aids, and glasseyes (EyeTaps). In: Proceedings of the 2012 25th IEEE Canadian Conference on Electrical and Computer Engineering (CCECE). 2012 Presented at: 2012 25th IEEE Canadian Conference on Electrical and Computer Engineering (CCECE); Apr 29- May 2, 2012; Montreal, QC, Canada. [doi: 10.1109/ccece.2012.6335012]
10. Mann S, Ali M, Lo R, Wu H. FreeGlass for developers, "haccessibility", and Digital Eye Glass + Lifeglogging research in a (sur/sous)veillance society. In: Proceedings of the International Conference on Information Society (i-Society 2013). 2013 Presented at: International Conference on Information Society (i-Society 2013); Jun 24-26, 2013; Toronto, ON, Canada.
11. Mann S, Mann C, Lam D, Mathewson K, Stairs J, Pierce C, et al. The human eye as a camera. In: Proceedings of the 2019 IEEE International Conference on E-health Networking, Application & Services (HealthCom). 2019 Presented at: 2019 IEEE International Conference on E-health Networking, Application & Services (HealthCom); Oct 14-16, 2019; Bogota, Colombia. [doi: 10.1109/healthcom46333.2019.9009592]



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12. Gemmell J, Bell G, Lueder R, Drucker S, Wong C. Mylifebits: fulfilling the memex vision. In: Proceedings of the tenth ACM international conference on Multimedia. 2002 Presented at: MM02: ACMM02: ACM Multimedia 2002M Multimedia 2002; Dec 1 - 6, 2002; Juan-les-Pins France. [doi: 10.1145/641007.641053]
13. Gemmell J, Lueder R, Bell G. The mylifebits lifetime store. In: Proceedings of the 2003 ACM SIGMM workshop on Experiential telepresence. 2003 Presented at: ETP '03: Proceedings of the 2003 ACM SIGMM workshop on Experiential telepresence; Nov 7, 2003; Berkeley California. [doi: 10.1145/982484.982500]
14. Gemmell J, Bell G, Lueder R. MyLifeBits. Commun ACM 2006 Jan;49(1):88-95. [doi: 10.1145/1107458.1107460]
15. Bell G, Gemmell J. A digital life. Sci Am 2007 Mar;296(3):58-65. [doi: 10.1038/scientificamerican0307-58]
16. Bell G, Gemmell J. Total Recall: How the E-Memory Revolution Will Change Everything. New York, NY: Dutton Penguin; 2009.
17. Hodges S, Williams L, Berry E, Izadi S, Srinivasan J, Butler A, et al. SenseCam: a retrospective memory aid. In: Dourish P, Friday A, editors. UbiComp 2006: Ubiquitous Computing. UbiComp 2006. Lecture Notes in Computer Science, vol 4206. Berlin, Heidelberg: Springer; 2006:177-193.
18. Hodges S, Berry E, Wood K. SenseCam: a wearable camera that stimulates and rehabilitates autobiographical memory. Memory 2011 Oct;19(7):685-696. [doi: 10.1080/09658211.2011.605591] [Medline: 21995708]
19. Chen M, Mao S, Liu Y. Big data: a survey. Mobile Netw Appl 2014 Jan 22;19(2):171-209. [doi: 10.1007/s11036-013-0489-0]
20. Gurrin C, Smeaton AF, Byrne D, O'Hare N, Jones GJF, O'Connor N. An examination of a large visual lifelog. In: Li H, Liu T, Ma WY, Sakai T, Wong KF, Zhou G, editors. Information Retrieval Technology. AIRS 2008: Lecture Notes in Computer Science, vol 4993. Berlin, Heidelberg: Springer; 2008:537-542.
21. Harvey M, Langheinrich M, Ward G. Remembering through lifelogging: a survey of human memory augmentation. Pervasive Mobile Comput 2016 Apr;27:14-26. [doi: 10.1016/j.pmcj.2015.12.002]
22. World Population Ageing 2017 Highlights. Geneva: United Nations; 2019.
23. Global Action Plan on the Public Health Response to Dementia 2017 - 2025. Geneva: World Health Organization; 2017.
24. Piasek P, Irving K, Smeaton AF. Case study in SenseCam use as an intervention technology for early-stage dementia. Int J Comput Healthcare 2012;1(4):304. [doi: 10.1504/ijcih.2012.051798]
25. Ferrari R. Writing narrative style literature reviews. Med Writing 2015 Dec 23;24(4):230-235. [doi: 10.1179/2047480615z.000000000329]
26. Greenhalgh T, Thorne S, Malterud K. Time to challenge the spurious hierarchy of systematic over narrative reviews? Eur J Clin Invest 2018 Jun 16;48(6):e12931 [FREE Full text] [doi: 10.1111/eci.12931] [Medline: 29578574]
27. Page M, McKenzie J, Bossuyt P, Boutron I, Hoffmann T, Mulrow C, et al. Updating guidance for reporting systematic reviews: development of the PRISMA 2020 statement. J Clin Epidemiol 2021 (forthcoming). [doi: 10.31222/osf.io/jb4dx]
28. Doherty AR, Smeaton AF. Automatically segmenting lifelog data into events. In: Proceedings of the 2008 Ninth International Workshop on Image Analysis for Multimedia Interactive Services. 2008 Presented at: 2008 Ninth International Workshop on Image Analysis for Multimedia Interactive Services; May 7-9, 2008; Klagenfurt, Austria. [doi: 10.1109/wiamis.2008.32]
29. Doherty AR, Caprani N, Conaire CO, Kalnikaite V, Gurrin C, Smeaton AF, et al. Passively recognising human activities through lifelogging. Comput Human Behav 2011 Sep;27(5):1948-1958. [doi: 10.1016/j.chb.2011.05.002]
30. Gurrin C, Qiu Z, Hughes M, Caprani N, Doherty AR, Hodges SE, et al. The smartphone as a platform for wearable cameras in health research. Am J Prev Med 2013 Mar;44(3):308-313. [doi: 10.1016/j.amepre.2012.11.010] [Medline: 23415130]
31. Pauly-Takacs K, Moulin CJ, Estlin EJ. SenseCam as a rehabilitation tool in a child with anterograde amnesia. Memory 2011 Oct;19(7):705-712. [doi: 10.1080/09658211.2010.494046] [Medline: 20658434]
32. Wang P, Smeaton AF. Using visual lifelogs to automatically characterize everyday activities. Inf Sci 2013 May;230:147-161. [doi: 10.1016/j.ins.2012.12.028]
33. Wang P, Sun L, Yang S, F. Smeaton A, Gurrin C. Characterizing everyday activities from visual lifelogs based on enhancing concept representation. Comput Vision Image Understanding 2016 Jul;148:181-192. [doi: 10.1016/j.cviu.2015.09.014]
34. Song S, Chandrasekhar V, Cheung N, Narayan S, Li L, Lim J. Activity recognition in egocentric life-logging videos. In: Computer Vision - ACCV 2014 Workshops. Cham: Springer; 2015.
35. Li N, Crane M, Ruskin HJ, Gurrin C. Application of statistical physics for the identification of important events in visual lifelogs. In: Proceedings of the 2013 IEEE International Conference on Bioinformatics and Biomedicine. 2013 Presented at: 2013 IEEE International Conference on Bioinformatics and Biomedicine; Dec 18-21, 2013; Shanghai, China. [doi: 10.1109/bibm.2013.6732563]
36. Balonas M, Mestre B, Talavera E, Giró-i-Nieto X, Radeva P. Visual summary of egocentric photostreams by representative keyframes. In: Proceedings of the 2015 IEEE International Conference on Multimedia & Expo Workshops (ICMEW). 2015 Presented at: 2015 IEEE International Conference on Multimedia & Expo Workshops (ICMEW); Jun 29- Jul 3, 2015; Turin, Italy. [doi: 10.1109/icmew.2015.7169863]
37. Talavera E, Bolanos M, Dimiccoli M, Aghaei M, Radeva P. R-clustering for egocentric video segmentation. In: Pattern Recognition and Image Analysis. Cham: Springer; 2015 Presented at: 7th Iberian Conference, IbPRIA 2015; June 17-19, 2015; Santiago de Compostela, Spain. [doi: 10.1007/978-3-319-19390-8_37]




XSL•FO
RenderX

38. Dimiccoli M, Bolaños M, Talavera E, Aghaei M, Nikolov SG, Radeva P. SR-clustering: semantic regularized clustering for egocentric photo streams segmentation. Comput Vision Image Understanding 2017 Feb;155:55-69. [doi: 10.1016/j.cviu.2016.10.005]
39. Gupta R, Gurrin C. Approaches for event segmentation of visual lifelog data. In: MultiMedia Modeling. MMM 2018. Lecture Notes in Computer Science, vol 10704. Cham: Springer; 2018.
40. Fan C, Zhang Z, Crandall DJ. Deepdiary: lifelogging image captioning and summarization. J Visual Commun Image Representation 2018 Aug;55:40-55. [doi: 10.1016/j.jvcir.2018.05.008]
41. Garcia del Molino A, Lim JH, Tan AH. Predicting visual context for unsupervised event segmentation in continuous photostreams. In: Proceedings of the 26th ACM international conference on Multimedia. 2018 Presented at: MM '18: ACM Multimedia Conference; Oct 22 - 26, 2018; Seoul Republic of Korea. [doi: 10.1145/3240508.3240624]
42. Furnari A, Battiato S, Farinella GM. Personal-location-based temporal segmentation of egocentric videos for lifelogging applications. J Visual Commun Image Representation 2018 Apr;52:1-12. [doi: 10.1016/j.jvcir.2018.01.019]
43. Oliveira-Barra G, Bolanos M, Talavera E, Gelonch O, Garolera M, Radeva P. Lifelog retrieval for memory stimulation of people with memory impairment. In: Alameda-Pineda X, Ricci E, Sebe N, editors. Multimodal Behavior Analysis in the Wild: Advances and Challenges. Cambridge, Massachusetts: Academic Press; 2019:135-158.
44. Ellis D, Lee K. Minimal-impact audio-based personal archives. In: Proceedings of the the 1st ACM workshop on Continuous archival and retrieval of personal experiences. 2004 Presented at: MM04: 2004 12th Annual ACM International Conference on Multimedia; Oct 15, 2004; New York, USA. [doi: 10.1145/1026653.1026659]
45. Shaikh MA, Molla MK, Hirose K. Automatic life-logging: a novel approach to sense real-world activities by environmental sound cues and common sense. In: Proceedings of the 2008 11th International Conference on Computer and Information Technology. 2008 Presented at: 2008 11th International Conference on Computer and Information Technology; Dec 24-27, 2008; Khulna, Bangladesh. [doi: 10.1109/iccitechn.2008.4803018]
46. Shah M, Mears B, Chakraborty C, Spanias A. Lifelogging: archival and retrieval of continuously recorded audio using wearable devices. In: Proceedings of the 2012 IEEE International Conference on Emerging Signal Processing Applications. 2012 Presented at: 2012 IEEE International Conference on Emerging Signal Processing Applications; Jan 12-14, 2012; Las Vegas, NV, USA. [doi: 10.1109/espa.2012.6152455]
47. Yamano K, Itou K. Browsing audio lifelog data using acoustic and location information. In: Proceedings of the 2009 Third International Conference on Mobile Ubiquitous Computing, Systems, Services and Technologies. 2009 Presented at: 2009 Third International Conference on Mobile Ubiquitous Computing, Systems, Services and Technologies; Oct 11-16, 2009; Sliema, Malta. [doi: 10.1109/ubicomm.2009.57]
48. Ziaei A, Sangwan A, Hansen JH. Prof-life-log: Personal interaction analysis for naturalistic audio streams. In: Proceedings of the 2013 IEEE International Conference on Acoustics, Speech and Signal Processing. 2013 Presented at: 2013 IEEE International Conference on Acoustics, Speech and Signal Processing; May 26-31, 2013; Vancouver, BC, Canada. [doi: 10.1109/icassp.2013.6639176]
49. Li D, Gu Y, Kamijo S. Smartphone based lifelog with meaningful place detection. In: Proceedings of the 2018 IEEE International Conference on Consumer Electronics (ICCE). 2018 Presented at: 2018 IEEE International Conference on Consumer Electronics (ICCE); Jan 12-14, 2018; Las Vegas, NV, USA. [doi: 10.1109/icce.2018.8326116]
50. Tanaka G, Okada M, Mineno H. GPS-based daily context recognition for lifelog generation using smartphone. Int J Advanced Comput Sci App 2015;6(2):104-112. [doi: 10.14569/ijacsa.2015.060216]
51. Aizawa K, Ishijima K, Shiina M. Summarizing wearable video. In: Proceedings 2001 International Conference on Image Processing (Cat. No.01CH37205). 2001 Presented at: Proceedings 2001 International Conference on Image Processing (Cat. No.01CH37205); Oct 7-10, 2001; Thessaloniki, Greece. [doi: 10.1109/icip.2001.958135]
52. Hori T, Aizawa K. Context-based video retrieval system for the life-log applications. In: Proceedings of the 5th ACM SIGMM international workshop on Multimedia information retrieval. 2003 Presented at: Proceedings of the 5th ACM SIGMM international workshop on Multimedia information retrieval; Nov 7, 2003; Berkeley California. [doi: 10.1145/973264.973270]
53. Datchakorn T, Toshihiko Y, Kiyoharu A. Practical experience recording and indexing of life log video. In: Proceedings of the 2nd ACM workshop on Continuous archival and retrieval of personal experiences. 2005 Presented at: ICMI05: Seventh International Conference on Multimodal Interfaces 2005; Nov 11, 2005; Hilton Singapore. [doi: 10.1145/1099083.1099092]
54. Doherty AR, Kelly P, Kerr J, Marshall S, Oliver M, Badland H, et al. Using wearable cameras to categorise type and context of accelerometer-identified episodes of physical activity. Int J Behav Nutr Phys Act 2013 Feb 13;10(1):22 [FREE Full text] [doi: 10.1186/1479-5868-10-22] [Medline: 23406270]
55. Hurvitz PM, Moudon AV, Kang B, Saelens BE, Duncan GE. Emerging technologies for assessing physical activity behaviors in space and time. Front Public Health 2014;2:2. [doi: 10.3389/fpubh.2014.00002] [Medline: 24479113]
56. Yang P, Hanneghan M, Qi J, Deng Z, Dong F, Fan D. Improving the validity of lifelogging physical activity measures in an internet of things environment. In: Proceedings of the 2015 IEEE International Conference on Computer and Information Technology; Ubiquitous Computing and Communications; Dependable, Autonomic and Secure Computing; Pervasive Intelligence and Computing. 2015 Presented at: 2015 IEEE International Conference on Computer and Information




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Technology; Ubiquitous Computing and Communications; Dependable, Autonomic and Secure Computing; Pervasive Intelligence and Computing; Oct 26-28, 2015; Liverpool, UK. [doi: 10.1109/cit/iucc/dasc/picom.2015.341]
57. Yang P, Stankevicius D, Marozas V, Deng Z, Liu E, Lukosevicius A, et al. Lifelogging data validation model for internet of things enabled personalized healthcare. IEEE Trans Syst Man Cybern Syst 2018 Jan;48(1):50-64. [doi: 10.1109/tsmc.2016.2586075]
58. Dobbins C, Rawassizadeh R, Momeni E. Detecting physical activity within lifelogs towards preventing obesity and aiding ambient assisted living. Neurocomputing 2017 Mar;230:110-132. [doi: 10.1016/j.neucom.2016.02.088]
59. Ni J, Chen B, Allinson NM, Ye X. A hybrid model for predicting human physical activity status from lifelogging data. Eur J Operational Res 2020 Mar;281(3):532-542. [doi: 10.1016/j.ejor.2019.05.035]
60. Kim JW, Lim JH, Moon SM, Jang B. Collecting health lifelog data from smartwatch users in a privacy-preserving manner. IEEE Trans Consum Electron 2019 Aug;65(3):369-378. [doi: 10.1109/tce.2019.2924466]
61. Choi J, Choi C, Ko H, Kim P. Intelligent healthcare service using health lifelog analysis. J Med Syst 2016 Aug 28;40(8):188. [doi: 10.1007/s10916-016-0534-1] [Medline: 27352004]
62. Dobbins C, Fairclough S. Signal processing of multimodal mobile lifelogging data towards detecting stress in real-world driving. IEEE Trans Mobile Comput 2019 Mar 1;18(3):632-644. [doi: 10.1109/tmc.2018.2840153]
63. Doherty A, Pauly-Takacs K, Caprani N, Gurrin C, Moulin CJ, O'Connor N, et al. Experiences of aiding autobiographical memory using the SenseCam. Human Comput Interact 2012;27(1-2):174. [doi: 10.1080/07370024.2012.656050]
64. Dobbins C, Fairclough S. Lifelogging technologies to detect negative emotions associated with cardiovascular disease. In: Applied Computing in Medicine and Health. Burlington, Massachusetts: Morgan Kaufmann; 2016:27-44.
65. Lee H, Smeaton AF, O'Connor NE, Jones G, Blighe M, Byrne D, et al. Constructing a SenseCam visual diary as a media process. Multimedia Syst 2008 Jul 12;14(6):341-349. [doi: 10.1007/s00530-008-0129-x]
66. Gibson G, Newton L, Pritchard G, Finch T, Brittain K, Robinson L. The provision of assistive technology products and services for people with dementia in the United Kingdom. Dementia (London) 2016 Jul 05;15(4):681-701. [doi: 10.1177/1471301214532643] [Medline: 24803646]
67. Sanders D, Scott P. Literature review: technological interventions and their impact on quality of life for people living with dementia. BMJ Health Care Inform 2020 Jan 15;27(1):e100064 [FREE Full text] [doi: 10.1136/bmjhci-2019-100064] [Medline: 31948938]
68. Rodgers MM, Pai VM, Conroy RS. Recent advances in wearable sensors for health monitoring. IEEE Sensors J 2015 Jun;15(6):3119-3126. [doi: 10.1109/jsen.2014.2357257]
69. Zheng Y, Ding X, Poon CC, Lo BP, Zhang H, Zhou X, et al. Unobtrusive sensing and wearable devices for health informatics. IEEE Trans Biomed Eng 2014 May;61(5):1538-1554. [doi: 10.1109/tbme.2014.2309951]
70. Gemmell J, Sundaram H. CARPE'04: Proceedings of the the 1st ACM workshop on Continuous archival and retrieval of personal experiences. New York, NY, USA: Association for Computing Machinery; 2004.
71. Gemmell J, Sundaram H. CARPE '05: Proceedings of the 2nd ACM workshop on Continuous archival and retrieval of personal experiences. New York, NY, USA: Association for Computing Machinery; 2005.
72. Mase K. CARPE '06: Proceedings of the 3rd ACM workshop on Continuous archival and retrival of personal experences. New York, NY, USA: Association for Computing Machinery; 2006.
73. GemmellJ G, Williams L, Wood K, Lueder R, Bell G. Passive capture and ensuing issues for a personal lifetime store. In: Proceedings of the the 1st ACM workshop on Continuous archival and retrieval of personal experiences. 2004 Presented at: MM04: 2004 12th Annual ACM International Conference on Multimedia; Oct 15, 2004; New York USA. [doi: 10.1145/1026653.1026660]
74. Aizawa K, Tancharoen D, Kawasaki S, Yamasaki T. Efficient retrieval of life log based on context and content. In: Proceedings of the the 1st ACM workshop on Continuous archival and retrieval of personal experiences. 2004 Presented at: MM04: 2004 12th Annual ACM International Conference on Multimedia; Oct 15, 2004; New York, USA. [doi: 10.1145/1026653.1026656]
75. Gurrin C, Joho H, Hopfgartner F, Zhou L, Albatal R. NTCIR lifelog: the first test collection for lifelog research. In: Proceedings of the 39th International ACM SIGIR conference on Research and Development in Information Retrieval. 2016 Presented at: SIGIR '16: The 39th International ACM SIGIR conference on research and development in Information Retrieval; Jul 17 - 21, 2016; Pisa Italy. [doi: 10.1145/2911451.2914680]
76. Gurrin C, Joho H, Hopfgartner F, Zhou L, Gupta R, Albatal R, et al. Overview of NTCIR-13 Lifelog-2 Task. In: Proceedings of the The Thirteenth NTCIR conference (NTCIR-13). 2017 Presented at: The Thirteenth NTCIR conference (NTCIR-13); Dec 5-8, 2017,; Tokyo, Japan.
77. Gurrin C, Joho H, Hopfgartner F, Zhou L, Ninh HT, Le TK, et al. Overview of the NTCIR-14 Lifelog-3 task. In: Proceedings of the 14th NTCIR Conference on Evaluation of Information Access Technologies. 2019 Presented at: 14th NTCIR Conference on Evaluation of Information Access Technologies; Jun 10-13, 2019; Tokyo Japan URL: https://doras.dcu.ie/25867/
78. Bolanos M, Dimiccoli M, Radeva P. Toward storytelling from visual lifelogging: an overview. IEEE Trans Human Mach Syst 2017;47(1):77-90. [doi: 10.1109/thms.2016.2616296]



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79. Gurrin C, Joho H, Hopfgartner F, Zhou L, Albatal R. Overview of NTCIR-12 lifelog task. In: Proceedings of the 12th NTCIR Conference on Evaluation of Information Access Technologies. 2016 Presented at: Proceedings of the 12th NTCIR Conference on Evaluation of Information Access Technologies; Jun 7-10, 2016; Tokyo Japan URL: https://research.nii.ac.jp/ntcir/workshop/OnlineProceedings12/pdf/ntcir/OVERVIEW/01-NTCIR12-OV-LIFELOG-GurrinC.pdf [doi: 10.1145/2911451.2914680]
80. Gurrin C, Giro-i-Nieto X, Radeva P, Dimiccoli M, Johansen H, Joho H, et al. LTA 2016: the first workshop on lifelogging tools and applications. In: Proceedings of the 24th ACM international conference on Multimedia. 2016 Presented at: MM '16: ACM Multimedia Conference; Oct 15 - 19, 2016; Amsterdam The Netherlands. [doi: 10.1145/2964284.2980534]
81. Dang-Nguyen D, Piras P, Riegler M, Boato G, Zhou L, Gurrin C. Overview of ImageCLEF lifelog 2017: lifelog retrieval and summarization. In: ImageCLEF. Central Europe: CEUR-WS; 2017.
82. Dang-Nguyen DT, Piras L, Riegler M, Zhou L, Lux M, Gurrin C. Overview of ImageCLEFlifelog 2018: daily living understanding and lifelog moment retrieval. In: Proceedings of the Conference and Labs of the Evaluation Forum. 2018 Presented at: Conference and Labs of the Evaluation Forum; Sep 10-14, 2018; Avignon, France URL: http://ceur-ws.org>
83. Dang-Nguyen DT, Piras L, Riegler M, Zhou L, Lux M, Tran MT, et al. Overview of ImageCLEFlifelog 2019: solve my life puzzle and lifelog moment retrieval. In: Proceedings of CLEF 2019. 2019 Presented at: CLEF 2019; Sep 9-12, 2019; Lugano, Switzerland URL: http://ceur-ws.org/Vol-2380/paper_223.pdf
84. Ninh VT, Le TK, Zhou L, Piras L, Riegler M, Halvorsen P, et al. Overview of ImageCLEF Lifelog 2020: lifelog moment retrieval and sport performance lifelog. In: Proceedings of CLEF 2020. 2020 Presented at: CLEF 2020; Sep 20-25, 2020; Thessalonik, Greece URL: http://ceur-ws.org/Vol-2696/paper_65.pdf [doi: 10.1145/3379172.3391724]
85. Gurrin C, Schoeffmann K, Joho H, Dang-Nguyen DT, Riegler M, Piras L. LSC '18: Proceedings of the 2018 ACM Workshop on The Lifelog Search Challenge. New York, NY, USA: Association for Computing Machinery; 2018.
86. Gurrin C, Schoeffmann K, Joho H, Dang-Nguyen DT, Riegler M, Piras L. LSC '19: Proceedings of the ACM Workshop on Lifelog Search Challenge. New York, NY, USA: Association for Computing Machinery; 2019.
87. Gurrin C, Schoeffmann K, Jónsson B, Dang-Nguyen DT, Lokoč J, Tran MT, et al. LSC '20: Proceedings of the Third Annual Workshop on Lifelog Search Challenge. New York, NY, USA: Association for Computing Machinery; 2020.
88. Rawassizadeh R, Tomitsch M, Wac K, Tjoa AM. UbiqLog: a generic mobile phone-based life-log framework. Pers Ubiquit Comput 2012 Apr 3;17(4):621-637. [doi: 10.1007/s00779-012-0511-8]
89. Bolaños M, Radeva P. Ego-object discovery. arXiv 2015:1639.
90. Bolaños M, Peris A, Casacuberta F, Soler S, Radeva P. Egocentric video description based on temporally-linked sequences. J Visual Commun Image Representation 2018 Jan;50:205-216. [doi: 10.1016/j.jvcir.2017.11.022]
91. Münzer B, Leibetseder A, Kletz S, Primus MJ, Schoeffmann K. lifeXplore at the lifelog search challenge 2018. In: Proceedings of the 2018 ACM Workshop on The Lifelog Search Challenge. 2018 Presented at: ICMR '18: International Conference on Multimedia Retrieval; Jun 11, 2018; Yokohama Japan. [doi: 10.1145/3210539.3210541]
92. Schoeffmann K, Primus MJ, Muenzer B, Petscharnig S, Karisch C, Qing X, et al. Collaborative feature maps for interactive video search. In: Amsaleg L, Guðmundsson G, Gurrin C, Jónsson B, Satoh S, editors. MultiMedia Modeling. MMM 2017. Lecture Notes in Computer Science, vol 10133. Cham: Springer; 2017:457-462.
93. Primus MJ, Münzer B, Leibetseder A, Schoeffmann K. The ITEC collaborative video search system at the video browser showdown 2018. In: MultiMedia Modeling. MMM 2018. Lecture Notes in Computer Science, vol 10705. Cham: Springer; 2018:438-443.
94. Leibetseder A, Münzer B, Primus MJ, Kletz S, Schoeffmann K. diveXplore 4.0: the ITEC deep interactive video exploration system at VBS 2020. In: MultiMedia Modeling. Berlin, Heidelberg: Springer-Verlag; 2020 Presented at: 26th International Conference on MultiMedia Modeling; January 5-8; Daejeon, South Korea p. 753-759. [doi: 10.1007/978-3-030-37734-2_65]
95. Leibetseder A, Münzer B, Primus MJ, Kletz S, Schoeffmann K, Berns F, et al. Lifexplore at the lifelog search challenge 2019. In: Proceedings of the ACM Workshop on Lifelog Search Challenge. 2019 Presented at: ICMR '19: International Conference on Multimedia Retrieval; Jun 10 - 13, 2019; Ottawa ON Canada. [doi: 10.1145/3326460.3329157]
96. Leibetseder A, Schoeffmann K. Lifexplore at the lifelog search challenge 2020. In: Proceedings of the Third Annual Workshop on Lifelog Search Challenge. 2020 Presented at: ICMR '20: International Conference on Multimedia Retrieval; Jun 9, 2020; Dublin Ireland. [doi: 10.1145/3379172.3391721]
97. Lokoč J, Souček T, Kovalčik G. Using an interactive video retrieval tool for lifelog data. In: Proceedings of the 2018 ACM Workshop on The Lifelog Search Challenge. 2018 Presented at: ICMR '18: International Conference on Multimedia Retrieval; Jun 11, 2018; Yokohama Japan. [doi: 10.1145/3210539.3210543]
98. Lokoč J, Kovalčík G, Souček T, Moravec J, Čech P. Viret: a video retrieval tool for interactive known-item search. In: Proceedings of the 2019 on International Conference on Multimedia Retrieval. 2019 Presented at: ICMR '19: International Conference on Multimedia Retrieval; Jun 10 - 13, 2019; Ottawa ON Canada. [doi: 10.1145/3323873.3325034]
99. Lokoč J, Souček T, Čech P, Kovalčík G. Enhanced VIRET tool for lifelog data. In: Proceedings of the ACM Workshop on Lifelog Search Challenge. 2019 Presented at: ICMR '19: International Conference on Multimedia Retrieval; Jun 10 - 13, 2019; Ottawa ON Canada. [doi: 10.1145/3326460.3329159]




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100. Kovalčík G, Škrhak V, Souček T, Lokoč J. VIRET tool with advanced visual browsing and feedback. In: Proceedings of the Third Annual Workshop on Lifelog Search Challenge. 2020 Presented at: ICMR '20: International Conference on Multimedia Retrieval; Jun 9, 2020; Dublin Ireland. [doi: 10.1145/3379172.3391725]
101. Lokoč J, Kovalcík G, Soucek T. Revisiting SIRET video retrieval tool. In: International Conference on Multimedia Modeling. Cham: Springer; 2018:419-424.
102. Rossetto L, Gasser R, Heller S, Parian M, Schuldt H. Retrieval of structured and unstructured data with vitrivr. In: Proceedings of the ACM Workshop on Lifelog Search Challenge. 2019 Presented at: ICMR '19: International Conference on Multimedia Retrieval; Jun 10 - 13, 2019; Ottawa ON Canada. [doi: 10.1145/3326460.3329160]
103. Heller S, Parian M, Gasser R, Sauter L, Schuldt H. Interactive lifelog retrieval with vitrivr. In: Proceedings of the Third Annual Workshop on Lifelog Search Challenge. 2020 Presented at: ICMR '20: International Conference on Multimedia Retrieval; Jun 9, 2020; Dublin Ireland. [doi: 10.1145/3379172.3391715]
104. Rossetto L, Giangreco I, Tanase C, Schuldt H. Vitrivr: a flexible retrieval stack supporting multiple query modes for searching in multimedia collections. In: Proceedings of the 24th ACM international conference on Multimedia. 2016 Presented at: MM '16: ACM Multimedia Conference; Oct 15 - 19, 2016; Amsterdam The Netherlands. [doi: 10.1145/2964284.2973797]
105. Gasser R, Rossetto L, Schuldt H. Multimodal multimedia retrieval with vitrivr. In: Proceedings of the 2019 on International Conference on Multimedia Retrieval. 2019 Presented at: ICMR '19: International Conference on Multimedia Retrieval; Jun 10 - 13, 2019; Ottawa ON Canada. [doi: 10.1145/3323873.3326921]
106. Zhou L, Hinbarji Z, Dang-Nguyen DT, Gurrin C. Lifer: an interactive lifelog retrieval system. In: Proceedings of the 2018 ACM Workshop on The Lifelog Search Challenge. 2018 Presented at: ICMR '18: International Conference on Multimedia Retrieval; Jun 11, 2018; Yokohama Japan. [doi: 10.1145/3210539.3210542]
107. Ninh VT, Le TK, Zhou L, Piras L, Riegler M, Lux M, et al. LIFER 2.0: discovering personal lifelog insights using an interactive lifelog retrieval system. In: Proceedings of the CLEF 2019. 2019 Presented at: CLEF 2019; Sep 9-12, 2019; Lugano, Switzerland. [doi: 10.1145/3210539.3210542]
108. Le TK, Ninh VT, Zhou L, Nguyen-Ngoc MH, Trinh HD, Tran NH, et al. Organiser team at ImageCLEF Lifelog 2020: a baseline approach for moment retrieval and athlete performance prediction using lifelog data. In: Proceedings of the CLEF 2020. 2020 Presented at: CLEF 2020; Sep 22-25, 2020; Thessaloniki, Greece URL: http://ceur-ws.org/Vol-2696/paper_104.pdf [doi: 10.1145/3379172.3391724]
109. Ribeiro R, Silva J, Trifan A, Oliveira JL, Neves AJ. UA.PT Bioinformatics at ImageCLEF 2020: lifelog moment retrieval web based tool. In: Proceedings of the CLEF 2020. 2020 Presented at: CLEF 2020; Sep 22-25, 2020; Thessaloniki, Greece.
110. Le TK, Ninh VT, Tran MT, Nguyen TA, Nguyen HD, Zhou L, et al. LifeSeeker 2.0: interactive lifelog search engine at LSC 2020. In: Proceedings of the Third Annual Workshop on Lifelog Search Challenge. 2020 Presented at: ICMR '20: International Conference on Multimedia Retrieval; Jun 9, 2020; Dublin Ireland. [doi: 10.1145/3379172.3391724]
111. Mai-Nguyen AV, Phan TD, Vo AK, Tran VL, Dao MS, Zettsu K. BIDAL-HCMUS@LSC2020: an interactive multimodal lifelog retrieval with query-to-sample attention-based search engine. In: Proceedings of the Third Annual Workshop on Lifelog Search Challenge. 2020 Presented at: ICMR '20: International Conference on Multimedia Retrieval; Jun 9, 2020; Dublin Ireland. [doi: 10.1145/3379172.3391722]
112. Tran MT, Nguyen TA, Tran QC, Tran MK, Nguyen K, Ninh VT, et al. FIRST - Flexible Interactive Retrieval SysTem for visual lifelog exploration at LSC 2020. In: Proceedings of the Third Annual Workshop on Lifelog Search Challenge. 2020 Presented at: ICMR '20: International Conference on Multimedia Retrieval; Jun 9, 2020; Dublin Ireland. [doi: 10.1145/3379172.3391726]
113. Rossetto L, Baumgartner M, Ashena N, Ruosch F, Pernischová R, Bernstein A. LifeGraph: a knowledge graph for lifelogs. In: Proceedings of the Third Annual Workshop on Lifelog Search Challenge. 2020 Presented at: ICMR '20: International Conference on Multimedia Retrieval; Jun 9, 2020; Dublin Ireland. [doi: 10.1145/3379172.3391717]
114. Khan OS, Larsen MD, Poulsen LA, Jónsson B, Zahálka J, Rudinac S, et al. Exquisitor at the lifelog search challenge 2020. In: Proceedings of the Third Annual Workshop on Lifelog Search Challenge. 2020 Presented at: ICMR '20: International Conference on Multimedia Retrieval; Jun 9, 2020; Dublin Ireland. [doi: 10.1145/3379172.3391718]
115. Karako K, Chen Y, Song P, Tang W. Super-aged society: constructing an integrated information platform of self-recording lifelogs and medical records to support health care in Japan. Biosci Trends 2019;13(3):276-278 [FREE Full text] [doi: 10.5582/bst.2019.01124] [Medline: 31327796]
116. Sugawara J, Ochi D, Yamashita R, Yamauchi T, Saigusa D, Wagata M, et al. Maternity Log study: a longitudinal lifelog monitoring and multiomics analysis for the early prediction of complicated pregnancy. BMJ Open 2019 Feb 19;9(2):e025939 [FREE Full text] [doi: 10.1136/bmjopen-2018-025939] [Medline: 30782942]
117. Dobbins C, Merabti M, Fergus P, Llewellyn-Jones D, Bouhafs F. Exploiting linked data to create rich human digital memories. Comput Commun 2013 Sep;36(15-16):1639-1656. [doi: 10.1016/j.comcom.2013.06.008]
118. Kim S, Yeom S, Kwon O, Shin D, Shin D. Ubiquitous healthcare system for analysis of chronic patients' biological and lifelog data. IEEE Access 2018;6:8909-8915. [doi: 10.1109/access.2018.2805304]




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119. Jacquemard T, Novitzky P, O'Brolcháin F, Smeaton AF, Gordijn B. Challenges and opportunities of lifelog technologies: a literature review and critical analysis. Sci Eng Ethics 2014 Jun 9;20(2):379-409. [doi: 10.1007/s11948-013-9456-1] [Medline: 23836154]
120. Doherty AR, Hodges SE, King AC, Smeaton AF, Berry E, Moulin CJ, et al. Wearable cameras in health: the state of the art and future possibilities. Am J Prev Med 2013 Mar;44(3):320-323. [doi: 10.1016/j.amepre.2012.11.008] [Medline: 23415132]
121. Florez-Revuelta F, Mihailidis A, Ziefle M, Colonna L, Spinsante S. Privacy-aware and acceptable lifelogging services for older and frail people: The PAAL project. In: Proceedings of the 2018 IEEE 8th International Conference on Consumer Electronics - Berlin (ICCE-Berlin). 2018 Presented at: 2018 IEEE 8th International Conference on Consumer Electronics - Berlin (ICCE-Berlin); Sep 2-5, 2018; Berlin, Germany. [doi: 10.1109/icce-berlin.2018.8576191]
122. Sellen AJ, Whittaker S. Beyond total capture. Commun ACM 2010 May;53(5):70-77. [doi: 10.1145/1735223.1735243]
123. Dobbins C, Merabti M, Fergus P, Llewellyn-Jones D. Creating human digital memories with the aid of pervasive mobile devices. Pervasive Mobile Comput 2014 Jun;12:160-178. [doi: 10.1016/j.pmcj.2013.10.009]


## Abbreviations

**EDUB:** Egocentric Dataset of the University of Barcelona
**NTCIR:** National Institute of Informatics Testbeds and Community for Information Access Research
**PRISMA:** Preferred Reporting Items for Systematic Reviews and Meta-Analyses


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Review

# Consumer Devices for Patient-Generated Health Data Using Blood Pressure Monitors for Managing Hypertension: Systematic Review

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## Abstract

**Background:** In the era of digital health information technology, there has been a proliferation of devices that collect patient-generated health data (PGHD), including consumer blood pressure (BP) monitors. Despite their widespread use, it remains unclear whether such devices can improve health outcomes.

**Objective:** We performed a systematic review of the literature on consumer BP monitors that collect PGHD for managing hypertension to summarize their clinical impact on health and surrogate outcomes. We focused particularly on studies designed to measure the specific effect of using a BP monitor independent of cointerventions. We have also summarized the process and consumer experience outcomes.

**Methods:** An information specialist searched PubMed, MEDLINE, and Embase for controlled studies on consumer BP monitors published up to May 12, 2020. We assessed the risk of bias using an adapted 9-item appraisal tool and performed a narrative synthesis of the results.

**Results:** We identified 41 different types of BP monitors used in 49 studies included for review. Device engineers judged that 38 (92%) of those devices were similar to the currently available consumer BP monitors. The median sample size was 222 (IQR 101-416) participants, and the median length of follow-up was 6 (IQR 3-12) months. Of the included studies, 18 (36%) were designed to isolate the clinical effects of BP monitors; 6 of the 18 (33%) studies evaluated health outcomes (eg, mortality, hospitalizations, and quality of life), and data on those outcomes were unclear. The lack of clarity was due to low event rates, short follow-up duration, and risk of bias. All 18 studies that isolated the effect of BP monitors measured both systolic and diastolic BP and generally demonstrated a decrease of 2 to 4 mm Hg in systolic BP and 1 to 3 mm Hg in diastolic BP compared with non–BP monitor groups. Adherence to using consumer BP monitors ranged from 38% to 89%, and ease of use and satisfaction ratings were generally high. Adverse events were infrequent, but there were a few technical problems with devices (eg, incorrect device alerts).

**Conclusions:** Overall, BP monitors offer small benefits in terms of BP reduction; however, the health impact of these devices continues to remain unclear. Future studies are needed to examine the effectiveness of BP monitors that transmit data to health care providers. Additional data from implementation studies may help determine which components are critical for sustained BP improvement, which in turn may improve prescription decisions by clinicians and coverage decisions by policy makers.

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**KEYWORDS**

patient-generated health data; consumer devices; hypertension; blood pressure monitors; digital health; cardiovascular diseases; wearable devices; health information; mobile phone



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## Introduction

In 2018, nearly half a million deaths in the United States included hypertension as a primary or contributing cause [1]. Current data support the use of out-of-office blood pressure (BP) monitoring for hypertension management because it provides clinical information beyond in-office BP monitoring and enhances titration of the medication dose [2-4]. This evidence has led to the proliferation of consumer patient-generated health data (PGHD) devices for hypertension management.

The Office of the National Coordinator for Health Information Technology defines PGHD as "health-related data created, recorded, or gathered by or from patients (or family members or other caregivers) to help address a health concern" [5]. These health-related data are captured by the patient, who may also need to share this information with a health care provider or others (if data transmission is not automatic). The adoption curve of consumer PGHD devices for hypertension management is maturing due to the rising numbers of wearables and BP monitors on the market. The global market size of automated home BP monitors is expected to gain market growth between 2020 and 2025, with a compound annual growth rate of 2.3%, forecasting US $1068.3 million by 2025, from US $975.6 million in 2019 [6].

Consumer PGHD devices can improve the health outcomes of patients and play an important role in managing hypertension. This review summarizes findings on hypertension from a larger report that addressed PGHD for 11 chronic conditions. The full report can be downloaded from the website of the Effective Healthcare Program at the Agency for Healthcare Research and Quality (AHRQ) [7]. In this paper, we summarize the clinical effectiveness of consumer BP monitors in collecting PGHD on health and surrogate outcomes. We also summarize the process outcomes (eg, medication titration) and consumer experience outcomes (eg, device adherence, ease of use, and technical problems).

## Methods

### Search Strategy

A professional information specialist searched MEDLINE and Embase, in-process MEDLINE and PubMed unique content, and the Cochrane Database of Systematic Reviews for systematic reviews or controlled trials published from inception until May 12, 2020. We also searched ClinicalTrials.gov for active studies until June 19, 2020. The review protocol is posted on the PROSPERO website [7].

### Selection Criteria

Textbox 1 shows study eligibility criteria for studies evaluating the effects of BP monitors on hypertension. Device engineers examined the devices from the screened studies (manufacturer and model names) and determined whether each device was available for direct purchase by consumers. Studies that included nonconsumer devices (eg, devices requiring a prescription) were excluded. The technology had to collect and store consumer data without requiring manual input and potentially could be sent to a health care professional, although data transmission was not required for study inclusion. We included both US-marketed and non–US-marketed technologies that met the criteria. However, any technology subject to Food and Drug Administration (FDA) clearance must have received FDA clearance to be included.

We carefully examined the interventions provided to each treatment group and determined whether the study design isolated the effect of the BP monitor. This occurred when the intervention group received the BP monitor whereas other comparison groups did not, and any additional treatments were the same between groups. In cases where clinicians made changes to treatment plans (eg, medication or dose adjustments) based on feedback from the BP monitor, we considered it as part of the BP monitor's effect because such adjustments were only possible due to the device. The comparison groups commonly received usual care, which would not preclude the clinician's decisions to modify hypertension treatment plans based on BP measurements in other contexts and settings.

Using DistillerSR (Evidence Partners), 3 reviewers (JRT, BR, and JR) screened the titles, and all 6 screened abstracts and full-text articles. For titles, only 1 reviewer assessed the general relevance to the topic. For abstract screening, 2 reviewers were necessary to exclude an article from further consideration; however, only 1 reviewer was necessary to order the full text. Regarding full texts, 2 reviewers assessed the study against the inclusion criteria, and disagreements were resolved by a (senior-level) third reviewer (JRT or JR). Full-text screening also involved determining which articles were associated with other included articles of the same trial.



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**Textbox 1.** Eligibility criteria.

**Category and criteria**

- Populations
  - Include individuals who have (or may potentially develop) hypertension
  - Exclude individuals with other conditions and pregnant and postpartum women
- Interventions
  - Include consumer blood pressure (BP) monitors for the prevention or treatment of hypertension. The monitor must collect and store the patient data without manual input, which could be used by the patient or sent to a health care professional (data transmission was not required but could be via the same or a different technology)
- Comparators
  - Include non–patient-generated health data (PGHD) interventions, other PGHD interventions, or no intervention
  - Exclude comparators that used the same PGHD intervention
- Outcomes
  - Include health outcomes: direct measures of health (eg, mortality, emergency room visits, hospitalizations, disease progression, and quality of life)
  - Include blood pressure: systolic or diastolic BP change and change in BP control
  - Include potential harms: serious adverse events (eg, hospitalization or delay in care) and other potential harms such as underuse or overuse of medications secondary to inaccurate BP data
  - Include process outcomes (if 1 of the first 3 outcome categories were reported): medication changes
  - Include consumer outcomes (if 1 of the first 3 outcome categories were reported): BP measurement adherence, interoperability, functions, acceptability/usability, sustainability, feasibility, fidelity, and integration into electronic health records
  - Include costs (if 1 of the first 3 outcome categories were reported): total cost and cost-effectiveness
  - Exclude surrogates such as prescription filling behavior, biomarkers that do not define the condition, adherence, disease knowledge, beliefs, opinions, dietary behavior, activity level, and steps per day
- Timing/setting
  - Include no limitations on timing. The setting must be at home or otherwise outside of a hospital or health care center.
- Study designs
  - Include any study design with a separate comparison group of patients who received a different intervention strategy or single-arm registry studies. Systematic reviews were only used to screen their included studies to ensure none were missed by the database searches.
  - Exclude reviews, case reports, editorials, comments, letters, meeting abstracts, and studies with <10 patients per arm at follow-up.
- Language
  - Include studies published in English.

## Data Extraction

For each included trial, 1 reviewer (BR or NM) extracted the general trial information, patient characteristics (eg, baseline BP), treatment details (including specific PGHD devices), risk-of-bias items, and outcome data. We examined data on the following reported health outcomes: mortality, emergency room visits, hospitalization, quality of life (QoL), and adverse events (AEs). Surrogate outcomes for hypertension consisted of systolic BP (SBP) and diastolic BP (DBP). Process outcomes included medication changes, dose adjustments, physician consultations, and office visits. We also extracted data on consumer experience, including device adherence, the number of BP readings taken or transmitted, device alerts, ease of use, patient satisfaction, and technical problems.

## Risk-of-Bias Assessment

We assessed the overall risk of bias based on 9 items, including randomization, allocation concealment, baseline similarity between groups, and masking of outcome assessors. The items were adapted from the AHRQ report titled “Mobile Applications for Self-Management of Diabetes” [8]. In addition, we included an item about whether the device’s effects could be isolated (ie, consumer BP monitor alone vs usual care). After considering all 9 items, we categorized each trial as at low, moderate, or high risk of bias.

## Device Similarity

Given that the included studies were published as early as 1997, for each BP monitor used within the included studies, device



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engineers assessed the similarity to devices currently on the market from that manufacturer. They used the following scale: (1) this model is *similar* to a device available from this manufacturer; (2) this model is *somewhat different* than any device available from this manufacturer; (3) this model is *very different* from any device available from this manufacturer; and (4) we could not reliably determine the similarity of this model with the ones currently available from this manufacturer.

### Results Classification

For isolated effects on health outcomes, we narratively synthesized the summary effect into one of four categories: (1) likely no effect, (2) unclear, (3) possible positive effect, or (4) likely positive effect. If the results consistently demonstrated the lack of an effect (via narrow CIs around a null effect), we coded it as likely no effect. If the results were inconsistent in the direction of effect or study authors could not reach a conclusion, the findings were coded as *unclear* for that outcome. If ≥1 outcomes had minor inconsistency in findings, but at least 1 study with moderate or low risk of bias showed a positive effect, the findings were coded as *possible positive effect*. If the results had a consistent positive effect, we coded it as *likely positive effect*.

When we categorized health outcome data as *unclear*, we then examined surrogate outcomes, which for hypertension were SBP and DBP. To help interpret the SBP/DBP outcomes, we used a minimally important difference of 2 mm Hg [9,10].

For studies of multicomponent interventions, we did not attempt to classify the data in the manner described earlier because the effect of BP monitoring in those studies could not be determined.

## Results

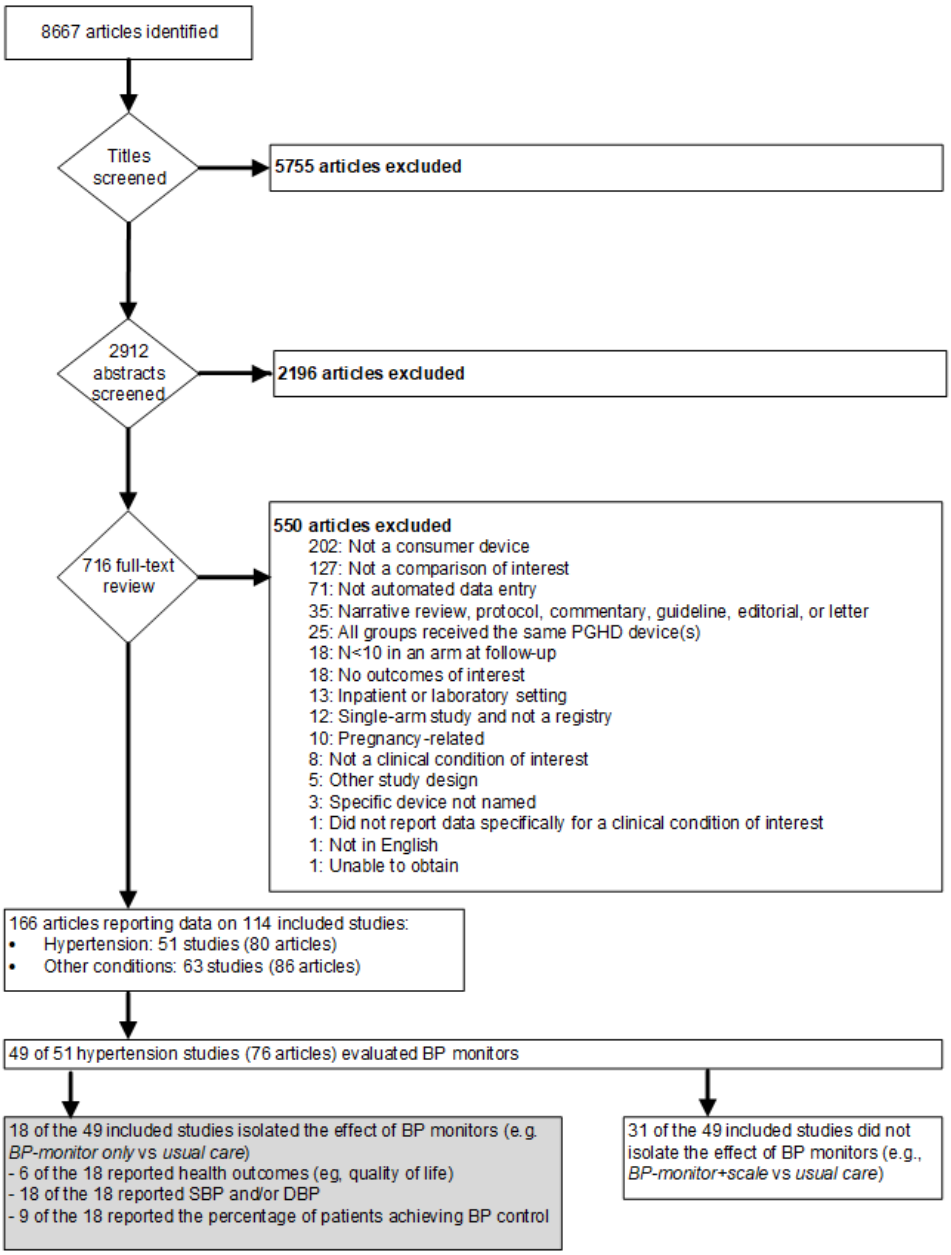
### Literature Search

For the full report (ie, 11 clinical conditions), our searches identified 8667 potentially relevant articles, of which we excluded 5755 (66.40%) at the title level (not relevant) and 2196 (25.33%) at the abstract level (Figure 1). We dual-screened the full texts of the remaining 716 articles (8.26%). The review team included 126 (17.6%) of these studies, but upon further review of the devices by device engineers, 12 studies (1.7%) had used only nonconsumer devices and were therefore excluded from the full report (none of the 12 addressed hypertension). A total of 114 unique studies were described in 166 articles. For the subset of screened studies enrolling patients with hypertension, we included 51 studies reported in 80 articles. This review focuses on 49 (96%; 79 articles) of those 51 studies that used BP monitors to generate PGHD for managing hypertension; 2 studies did not use BP monitors to manage hypertension, 1 evaluated a pedometer [11], and the other compared 2 mobile apps [12]. Of the 49 studies, 18 (36.7%) used designs that isolated the effect of BP monitors (eg, BP monitor alone vs usual care or BP monitor+scale vs scale alone), whereas the other 31 (63.3%) used multicomponent designs that did not permit conclusions about the impact on outcomes specific to BP monitors (eg, BP monitor+scale vs usual care).



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**Figure 1.** Study flow diagram. BP: blood pressure; DBP: diastolic blood pressure; PGHD: patient-generated health data; SBP: systolic blood pressure.




## Study Characteristics

Key characteristics of the studies using BP monitors for hypertension are shown in Table 1 (18 isolated-effect studies) and Multimedia Appendix 1 (Table S1; 31 multicomponent studies). Of the 49 studies, 47 (96%) were randomized trials, and 2 (4%) were nonrandomized; 21 (43%) studies were conducted in the United States, and other notable countries included the United Kingdom (n=6 studies, 12%), Canada (n=3 studies, 6%), Denmark (n=2 studies. 4%), Finland (n=2 studies, 4%), and South Korea (n=2 studies, 4%). The median number of patients per study at baseline was 222 (IQR 80-433). Patient enrollment dates were reported in 29 (59%) studies and ranged from May 1999 to June 2017. The median length of follow-up was 6 months (IQR 4-12).

Study group comparisons are shown in Table 2 and Multimedia Appendix 1 (Table S1). Of the 49 studies, 42 (86%) had 2 study groups, 4 (8%) studies had 3 groups, and 3 (6%) studies had 4 groups. A usual care control group was used in 43 (88%) studies, whereas 3 (6%) studies used a consumer device in the control group, and 4 (8%) other studies used active comparators without a consumer device (eg, counseling alone). Statistical power analyses were conducted a priori in 39 of the 49 (80%) studies, and 29 of these 39 (74%) studies were based on SBP, DBP, or BP control. Note that 31 of the 49 (62%) studies used only multicomponent interventions, making it impossible to discern the impact specific to the BP monitor. Among these 31 studies, 25 (81%) used a BP monitor along with nondevice interventions, 3 (10%) studies used a BP monitor along with another device, and the other 4 (12%) studies used a BP monitor along with ≥2 other devices.



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**Table 1.** General characteristics of studies isolating the effect of blood pressure monitors.

| Study | Design | Country | N at baseline | Study duration | Study groups (BP[a] monitor manufacturer and model) | Outcomes |
|---|---|---|---|---|---|---|
| Aekplakorn et al (2016) [13] | RCT[b] | Thailand | 224 | 12 months | • PGHD[c] (Omron HEM 7117)<br>• Usual care | • Surrogate (SBP[d], DBP[e], or BP control)<br>• Process<br>• Consumer experience |
| Bosworth et al (2009) [14] | RCT | United States | 636 | 2 years | • PGHD (Omron 773AC or 637)<br>• Behavioral intervention<br>• Combination (PGHD+behavioral)<br>• Usual care | • Health (hospitalizations)<br>• Surrogate (SBP, DBP, or BP control)<br>• Process<br>• Adverse events<br>• Consumer experience |
| Bosworth et al (2011) [15-17] | RCT | United States | 636 | 24 months | • PGHD (Omron 773AC or 637)<br>• Behavioral intervention<br>• Combination (PGHD+behavioral)<br>• Usual care | • Surrogate (SBP or DBP) |
| Broege 2001 [18] | RCT | United States | 40 | 3 months | • PGHD (Omron HEM-702)<br>• Usual care | • Health (QoL[f])<br>• Surrogate (SBP or DBP)<br>• Consumer experience |
| Fuchs et al (2012) [19] | RCT | Brazil | 121 | 60 days | • PGHD (Omron HEM-705 CP)<br>• Usual care | • Surrogate (SBP or DBP)<br>• Consumer experience |
| Green et al (2008) [20,21] | RCT | United States | 778 | 1 year | • PGHD (Omron HEM-705 CP)<br>• Combination (PGHD+pharmacist care)<br>• Usual care | • Health (QoL)<br>• Surrogate (SBP, DBP, or BP control)<br>• Adverse events |
| Hebert et al (2012) [22] | RCT | United States | 416 | 18 months | • PGHD (Omron HEM-712C)<br>• Combination (PGHD+nurse management)<br>• Usual care | • Health (mortality)<br>• Surrogate (SBP, DBP, or BP control)<br>• Process |
| Hoffmann-Petersen et al (2017) [23] | RCT | Denmark | 356 | 3 months | • PGHD (A&D 767PlusBT or Omron 705IT)<br>• Usual care | • Surrogate (SBP, DBP, or BP control)<br>• Process |
| Hosseininasab et al (2014) [24] | RCT | Iran | 194 | 24 weeks | • PGHD (Samsung SHB-200w)<br>• Usual care | • Surrogate (SBP or DBP) |
| Kaihara et al (2014) [25] | RCT | Japan | 57 | 2 weeks | • PGHD (Omron HEM-7251G)<br>• Conventional BP monitor | • Surrogate (SBP or DBP)<br>• Consumer experience |
| Kauric-Klein et al (2007) [26] | RCT | United States | 34 | 12 weeks | • PGHD (Omron IC)<br>• Usual care | • Surrogate (SBP or DBP) |
| Kim et al (2016) [27,28] | RCT | United States | 160 | 6 months | • PGHD (Withings)<br>• Usual care | • Surrogate (SBP, DBP, or BP control)<br>• Consumer experience |
| Lakshminarayan et al (2018) [29] | RCT | United States | 50 | 13 weeks | • PGHD (upper arm Withings [Nikia] wireless BP monitor)<br>• Conventional BP monitor | • Surrogate (SBP)<br>• Consumer experience |
| Márquez-Contreras et al (2006) [30] | RCT | Spain | 250 | 6 months | • PGHD (Omron M4 automatic monitor)<br>• Usual care | • Surrogate (SBP, DBP, or BP control) |



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| Study | Design | Country | N at baseline | Study duration | Study groups (BP[a] monitor manufacturer and model) | Outcomes |
|---|---|---|---|---|---|---|
| McManus et al (2018) [4,31-33] | RCT | United Kingdom | 1173 | 12 months | • PGHD (Omron M10-IT)<br>• Combination (PGHD+telemonitoring)<br>• Usual care | • Health (QoL)<br>• Surrogate (SBP or DBP); process<br>• Adverse events |
| Qi et al (2017) [34] | RCT | China | 1032 | 5 years | • PGHD (Omron HEM-7121)<br>• Control group | • Surrogate (SBP, DBP, or BP control) |
| Zaleski et al (2019) [35] | RCT | United States | 24 | 4 months | • PGHD (BP Omron 705 CPN)<br>• Usual care | • Surrogate (SBP or DBP)<br>• Adverse events<br>• Consumer experience |
| Zha et al (2019) [36] | RCT | United States | 25 | 6 months | • PGHD (iHealth BP 7 wireless BP wrist monitor)<br>• Usual care | • Health (QoL)<br>• Surrogate (SBP, DBP, or BP control)<br>• Consumer experience |

[a]BP: blood pressure.

[b]RCT: randomized controlled trial.

[c]PGHD: patient-generated health data.

[d]SBP: systolic blood pressure.

[e]DBP: diastolic blood pressure.

[f]QoL: quality of life.



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**Table 2.** Patient characteristics in studies isolating the effect of blood pressure monitors.

| Study | Age (years), mean | Sample (female), n | Female, n (%) | Baseline disease severity |
|---|---|---|---|---|
| Aekplakorn et al (2016) [13] | 59 | 224 | 148 (66) | • Mean SBP[a] PGHD[b]: 149.4 mm Hg<br>• Mean DBP[c] PGHD: 83.4 mm Hg<br>• Mean SBP UC[d]: 147.2 mm Hg<br>• Mean DBP UC: 82.2 mm Hg |
| Bosworth et al (2009) [14] | 61 | 636 | 420 (66) | • BP controlled at baseline 73%<br>• Mean SBP: 125 mm Hg<br>• Mean DBP: 71 mm Hg |
| Bosworth et al (2011) [15]; Bosworth et al (2007) [16]; Bosworth et al (2008) [17] | 61 | 636 | 407 (64) | • Mean SBP: 125 mm Hg<br>• Mean DBP: 71 mm Hg |
| Broege et al (2001) [18] | 73 | 40 | 28 (70) | • Mean ambulatory awake SBP: 147 mm Hg<br>• Mean ambulatory awake DBP: 82 mm Hg |
| Fuchs et al (2012) [19] | 59.0 | 121 | 73 (60) | • Mean office SBP: 158.6 mm Hg<br>• Mean office DBP: 89.5 mm Hg<br>• Mean 24-hour systolic ABPM[e]: 148.8 mm Hg<br>• Mean 24-hour diastolic ABPM: 87.5 mm Hg |
| Green et al (2008) [20,21] | 59.1 | 778 | 405 (52) | • Mean SBP: 151.9 mm Hg<br>• Mean DBP: 89.1 mm Hg |
| Hebert et al (2012) [22] | 60.8 | 416 | 295 (71) | • Mean SBP: 153 mm Hg<br>• Mean DBP: 86.0 mm Hg |
| Hoffmann-Petersen et al (2017) [23] | 60.5 | 356 | 164 (46) | • Mean office SBP: 154.6 mm Hg<br>• Mean office DBP: 93.2 mm Hg |
| Hosseininasab et al (2014) [24] | 58.7 | 194 | 118 (61) | • Mean SBP: 145.2 mm Hg<br>• Mean DBP: 85.3 mm Hg |
| Kaihara et al (2014) [25] | 64.4 | 57 | 37 (65) | • Mean SBP: 144 mm Hg<br>• Mean DBP: 83 mm Hg |
| Kauric-Kleinet et al (2007) [26] | 48.7 | 34 | 23 (68) | • Mean SBP PGHD: 161 mm Hg and 162 mm Hg in the UC group<br>• Mean DBP PGHD: 94 mm Hg<br>• Mean DBP UC: 100 mm Hg<br>• Patients were chronic hemodialysis patients |
| Kim et al (2016) [27]; Bloss (2016) [28] | 57.6 | 160 | 104 (65) | • Mean SBP: 140.6 mm Hg<br>• Mean DBP: 89.4 mm Hg<br>• Mean number of antihypertensive medications: 2 |
| Lakshminarayan et al (2018) [29] | 66 | 50 | 14 (28) | • Mean SBP: 140 mm Hg<br>• Mean DBP: not reported |
| Márquez-Contreras et al (2006) [30] | 59.1 | 250 | 123 (49) | • Mean SBP: 157.4 mm Hg<br>• Mean DBP: 91.7 mm Hg |
| McManus et al (2018) [4,31-33] | 66.9 | 1173 | 540 (46) | • Mean SBP: 153.1 mm Hg<br>• Mean DBP: 85.5 mm Hg |
| Qi et al (2017) [34] | 64.0 | 1032 | 464 (45) | • Mean SBP: 140.0 mm Hg<br>• Mean DBP: 92.5 mm Hg |



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| Study | Age (years), mean | Sample (female), n | Female, n (%) | Baseline disease severity |
|---|---|---|---|---|
| Zaleski et al (2019) [35] | 52.3 | 24 | 13 (54) | • Mean SBP: 136.2 mm Hg<br>• Mean DBP: 85.2 mm Hg<br>• Mean duration of hypertension: 6.2 years |
| Zha et al (2019) [36] | 52.2 | 25 | 22 (88) | • Mean SBP: 145.72 mm Hg<br>• Mean DBP: 90.57 mm Hg |

[a]SBP: systolic blood pressure.

[b]PGHD: patient-generated health data.

[c]DBP: diastolic blood pressure.

[d]UC: usual care.

[e]ABPM: ambulatory blood pressure monitoring.

Table 2 (isolated-effect studies) and Multimedia Appendix 1 (Table S2; multicomponent studies) show the patient characteristics from the 49 studies. The mean age ranged from 49 to 73 years, and the percentage of females ranged from 5% to 88%. The mean baseline SBP was reported in 44 (90%) studies and ranged from 125 to 161 mm Hg. The mean baseline DBP was reported in 42 (86%) studies and ranged from 71 to 97 mm Hg. Only 3 (6%) studies were conducted in rural populations [25,37,38], whereas 24 (49%) were not of rural populations [22,23,26,29,30,35,36,39-62] and the other 22 (44%) did not specify.

Only 21 of the 49 (43%) studies reported health outcomes, which included mortality (n=3 studies, 6%), hospitalizations or emergency room visits (n=2 studies, 4%), QoL (n=13 studies, 26%), and AEs (n=13 studies, 26%). No studies reported other health outcomes related to hypertension, such as major adverse cardiovascular events. All studies reported SBP, DBP, or BP control.

## Device Characteristics

The included studies used 41 different BP monitoring devices (see specifics in Table 1). Of these, 34 (83%) were arm devices and 2 (5%) were wrist devices, and the wrist or arm was unclear in the other 5 (12%) studies. A total of 38 (93%) BP monitors were judged as similar to devices currently on the market from the corresponding manufacturer, 1 (2%) was judged as somewhat different, and 2 (5%) were of unknown similarity.

Regarding the transmission of data (eg, to a website, to study staff, or to health care providers), 19 of 49 (39%) studies used automatic transmission, 6 (12%) used manual data entry for transmission, 20 (41%) had no electronic data transmission, and the other 4 (8%) did not report whether or how data were transmitted.

## Isolated Effects on Health Outcomes

The isolated effects of a consumer BP monitor device on health outcomes were evaluated in 6 of the 49 (12%) studies. The consumer BP monitors examined included the iHealth BP 7 Wireless Wrist Monitor, Omron 637, Omron 773AC, Omron HEM-705 CP, Omron HEM-712C, and Omron M10-IT. Only 1 of the 6 (17%) studies reported mortality [22], 1 (17%) reported hospitalization [14], and the other 4 (67%) reported QoL [4,18,20,21,31-33,36].

- For mortality, Hebert et al [22] followed patients for 18 months and found that 8 deaths occurred in the 3 study groups (Omron HEM-712C BP monitor, Omron HEM-712C BP monitor plus nurse management, and usual care). Mortality rates did not differ significantly across the groups (group-specific rates were not reported).
- For hospitalizations, Bosworth et al [14] reported no statistically significant differences in hospitalization rates among the 4 study groups. The rates ranged from 19% to 23% (group-specific rates were not reported). The groups received Omron 773AC or 637 (depending on patient arm circumference) compared with usual care, behavioral management alone, or a combination of BP monitoring and behavioral management.
- For QoL, 3 of the 4 (75%) studies found no statistically significant differences between groups at follow-ups ranging from 3 to 12 months. To measure QoL, the studies used the Short Form Health Survey 36 (SF-36) [18], the Short Form Health Survey-12 [20,21], or the EQ-5D [4,31-33]. The fourth study [36] found that at both baseline and the 6-month follow-up, there was a statistically significant difference in SF-36 scores favoring the usual care group over the BP monitor group (suggesting a problem with randomization rather than an effect of the BP monitor).

## Isolated Effects on Surrogate Outcomes

Of the 49 studies, 18 (37%) [4,13-26,28-36] examined the isolated effects of consumer BP monitors on blood pressure. All evaluated the effects compared with usual care (ie, no BP monitor), except for 2 (11%) studies [25,29], each of which compared BP monitors with automatic data transmission with BP monitors without automatic transmission.

All 16 studies on comparisons with usual care reported the effects of PGHD interventions on SBP (Figure 2). The top 4 points were from studies using automatic transmission of BP data, and the remaining 28 points were from studies that did not use automatic transmission. Six studies [4,15-17,19-21,26,31-34] found a statistically significant reduction in SBP favoring the BP monitoring group compared with the control group. However, the results were somewhat inconsistent. For example, Bosworth et al [15-17] found significant improvement only in non-White patients at 12 months; differences were not statistically significant for White



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patients at any time point or 24 months for any subgroup. The point estimates for SBP are shown in Figure 2, corresponding to 32 reported outcomes from 16 studies. Moreover, 4 of 32 (13%) SBP outcomes identified a reduction of 6 mm Hg or more favoring the consumer BP monitor group compared with usual care; 12 (38%) identified an SBP reduction between 2 mm Hg and 6 mm Hg favoring the consumer BP monitor, 10 (31%) identified SBP differences from −2 mm Hg to +2 mm Hg, and the remaining 3 (9%) found an SBP reduction ≥2 mm Hg favoring the usual care groups. Whether the BP monitor automatically transmitted data (comparing the top 4 points with the other points) did not appear to modify the effect on SBP.

The overall findings for DBP were similar to those for SBP; 5 (31%) [4,15,19,30-34] studies found that consumer BP monitors significantly reduced DBP compared with controls. However, similar to SBP, the results were inconsistent, and statistical significance was found only for particular subgroups or time points in a study. The 32 point estimates for DBP are shown in Figure 3 (restricted to studies with usual care comparison groups). Of these, 1 (3%) identified a DBP reduction of 6 mm Hg or more favoring the consumer BP monitor, 9 (28%) identified a DBP reduction between 2 mm Hg and 6 mm Hg, favoring the consumer BP monitor, and the remaining 19 (59%) identified DBP differences from −2 mm Hg to +2 mm Hg. Whether the BP monitor automatically transmitted data did not appear to modify its effect on DBP.

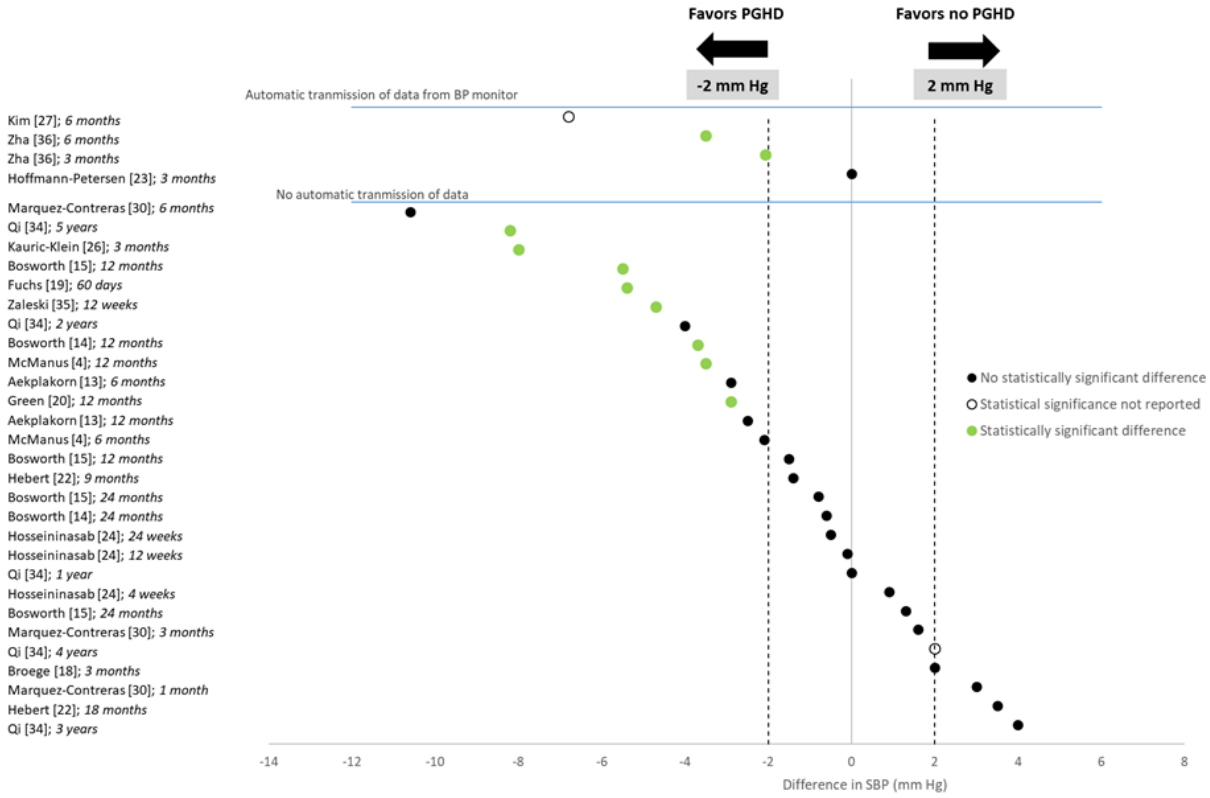
Regarding the 2 studies examining the effect of data transmission (eg, BP monitor with vs without data transmission), Kaihara et al [25] found that data transmission resulted in an estimated 6 mm Hg lower SBP but no statistically significant effect on DBP. Lakshminarayan et al [29] found a statistically nonsignificant difference of 3.7 mm Hg in favor of data transmission and did not report data on DBP.

BP control was examined in 9 (15%) studies of the isolated effects of consumer BP monitors [13,14,19-23,27,28,30,34]. Most defined BP control as SBP <140 mm Hg and DBP <90 mm Hg, but 1 study [23] used <135/<85 mm Hg; 2 [14,23] studies included a separate definition of <130/80 mm Hg for patients with diabetes. Only 2 of the 9 (22%) studies [19,34] reported statistically significantly higher rates of BP control with BP monitors than with controls.

- Fuchs et al [19] found that at 60 days, the BP control rates measured in the office were similar for BP-monitored patients and usual care patients (43% and 41%, respectively), but for 24-hour BP, 32% of BP-monitored patients had BP control compared with only 16% of usual care patients;
- Qi et al [34] found that at 5 years, 85% of BP-monitored patients had BP control compared with 80% of usual care patients.

The remaining 7 (78%) studies found nonsignificant differences in BP control rates between BP-monitored and control patients.

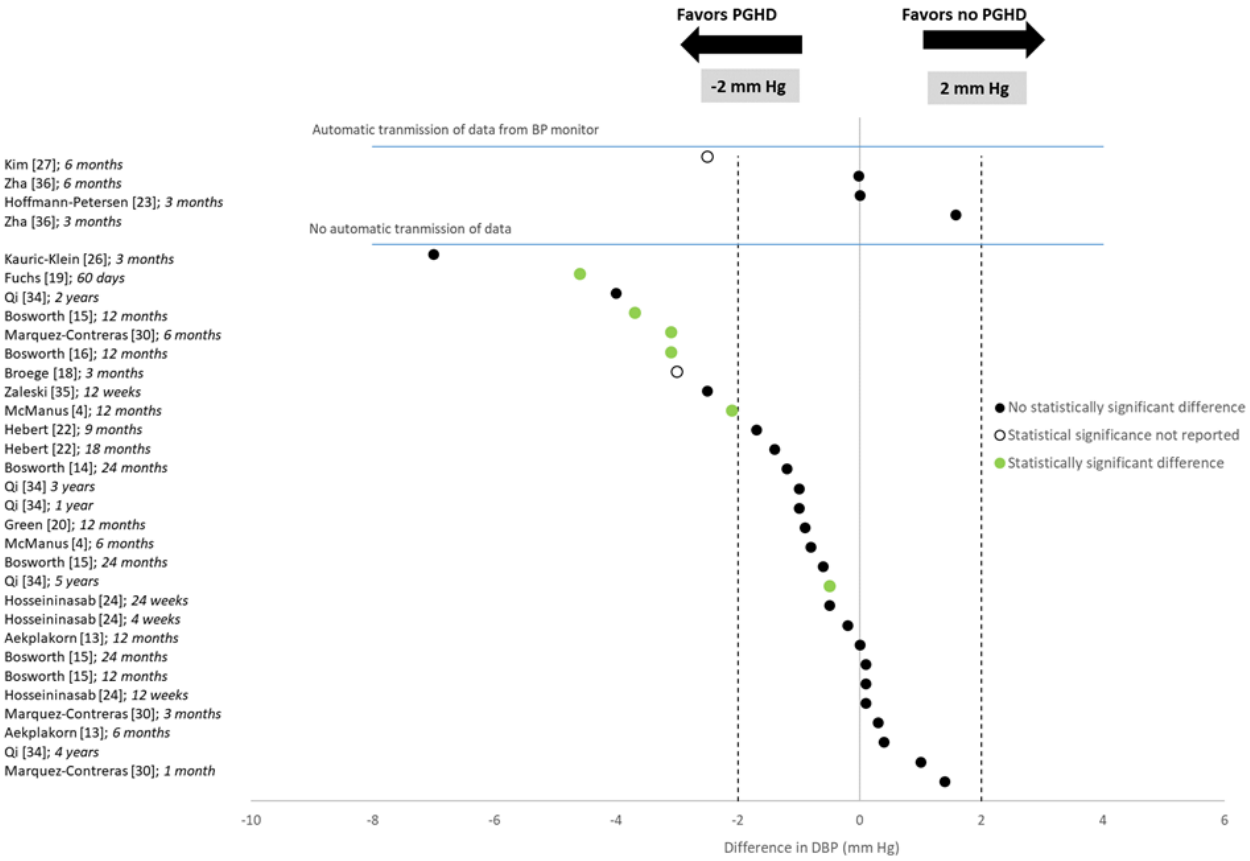
**Figure 2.** Systolic blood pressure (SBP) differences in studies of isolated effects of blood pressure (BP) monitors. PGHD: patient-generated health data.






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**Figure 3.** Diastolic blood pressure (DBP) differences in studies of isolated effects of blood pressure (BP) monitors. PGHD: patient-generated health data.




## Isolated Effects on Process Outcomes

Of the 18 studies on isolated effects of BP monitors, 5 (28%) reported process outcomes, and the results were mixed. For medication prescribing, McManus et al [4,31-33] found that those in the BP monitor group were prescribed statistically significantly more antihypertensive drugs than those in the usual care group (difference 0.11; 95% CI 0.02-0.19), and 3 other studies found no statistically significant impact of BP monitoring on prescriptions.

- Hebert et al [22] reported that the percentage of patients who had no change in medications at 9 months was not statistically significantly different among those who had BP monitoring (44%) compared with the control group (38%).
- Hoffmann-Petersen et al [23] found that at baseline, 59% of the BP-monitored group and 61% of the control group did not receive any antihypertensive medication. At follow-up, these percentages were reduced to 23% in the BP-monitored group and 22% in the control group (not a significant difference).
- Aekplakorn et al [13] found that prescription of antihypertensive medications increased in both groups, but there were no significant between-group differences in drug items or drug classes (the authors did not report the number of prescriptions at follow-up).

However, these studies were not statistically powered to detect such effects, so they did not rule out the possibility of an impact on prescriptions.

In addition, Bosworth et al (2009) [14] found no between-group differences in the number of outpatient encounters (medians ranged from 13 to 15).

With regard to data transmission, 5 of the 18 (28%) studies used automatic data transmission, 2 (11%) used manual entry, 10 (31%) had no electronic data transmission, and 1 (3%) did not report whether or how data were transmitted. Of those using automatic data transmission, in Hoffmann-Petersen et al [23], data were transmitted using a Tunstall RTX3371 or Numera telehealth monitor to a study database or an electronic health record after BP measurements.

In Kaihara et al [25], the BP monitor wirelessly transmitted data to a study database over the internet.

In Kim et al [27], the BP monitor readings were wirelessly transmitted via the HealthCircles app on a smartphone to a website.

In Lakshminarayan et al [29], a smartphone transmitted daily BP measurements to a study database. Participants in the PGHD group transmitted data on an average of 89% of the study days and rated the ease of use of the system favorably.

In Zha et al [36], the wireless BP wrist monitor would transmit data to a website using the iHealth MyVitals app on a smartphone.



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Of the 18 studies, 2 (18%) studies used manual data transmission [4,35]. In these 2 studies, participants sent BP readings via an SMS text message service or web-based form to a website [4] or entered their BP measurements on a BP-tracking website [35].

### Adverse Events

Of the 49 studies, 12 (24%) reported on AEs and generally found them to occur infrequently, and 4 [4,14,20,21,31-33,35] of the 18 (22%) studies on isolated effects of BP monitoring reported on AEs; 2 (17%) studies reported that no AEs occurred during the course of the study. A study [20,21] found that serious AEs, including nonfatal cardiovascular events, were rare and not substantially different between the BP monitoring and control groups. Another study [4,31-33] reported on various other AEs, including pain, fatigue, and dry mouth. Only dry mouth occurred significantly more frequently in the BP monitor group than in the usual care group. Of the 49 studies, 11 (22%) [4,14,20,21,31-33,38,44-46,50-56,60,63-74] reported on AEs in studies with multicomponent device groups. Only one of those studies [69-73] reported a significant increase of an AE, swelling of legs, in a multicomponent intervention group that included a BP monitor compared with usual care.

### Consumer Experience

Of the 49 studies, 26 (53%) reported the outcomes of consumer experience. Adherence to the use of BP monitors ranged from 38% to 89%, but device adherence had variable definitions. For example, Logan et al [47] defined adherence as a minimum of 8 readings per week. Zaleski et al [35] only determined whether patients said they were still monitoring their BP. Zha et al [36] measured adherence by dividing the number of received readings by expected readings.

Some studies reported that adherence declined throughout the study. For example, Bosworth et al [14] reported that during the first 2 months, 91% of those using a BP monitor were adherent, whereas 64% were adherent during the last 2 months. The studies also measured BP monitor use in various ways, including the total number of transmissions during the study and the average number of transmissions per week.

Studies measuring the ease of use or satisfaction with consumer BP monitors found favorable ratings. For example, Magid et al [49] reported that 68% of patients using the monitor found it very or extremely easy to use. Rifkin et al [75] reported that 96% of patients would continue to use the BP monitor.

Only 2 studies reported problems with BP monitors. Bosworth et al [63-65] found that 35 alerts were triggered by the monitoring system due to BP monitor problems, which represented 5% of the total alerts that occurred during the study. Lakshminarayan et al [29] found that some patients experienced issues with the BP monitor and the smartphone provided to transmit BP data, including an inability to hold a charge and difficulty using the phone app to see BP data.

### Multicomponent Effects

Of the 31 multicomponent studies [38-87], 11 (35%) examined the multicomponent effect of BP monitors on health outcomes, and all 31 evaluated multicomponent PGHD for surrogate outcomes including SBP, DBP, and BP control. These study designs did not permit any determination of the effectiveness specific to BP monitors.

### Risk of Bias

Of the 18 studies of isolated effects, we rated 6 (33%) as low risk of bias, 9 (50%) as moderate risk of bias, and 3 (17%) as high risk of bias. In contrast, of the 31 studies of multicomponent effects, we rated 6 (19%) as low risk of bias, 13 (42%) as moderate risk of bias, and 12 (39%) as high risk of bias. The full AHRQ report (in its Appendix Table C-26) contains the item-level and overall risk-of-bias ratings for each study [7].

## Discussion

### Principal Findings

This systematic review summarizes 49 comparative studies that used consumer BP monitors for hypertension management. However, the effects of these devices on health outcomes remain unclear. Only 18 studies were designed to isolate the BP monitor effect, and only 6 of these 18 (33%) studies reported any health outcome, such as mortality, hospitalization, and QoL. One study [36] found a statistically significant difference in QoL at follow-up favoring usual care over BP monitoring, but QoL also favored usual care at baseline (suggesting a problem in the randomization process). None of the 5 remaining studies found statistically significant effects on health outcomes, possibly because they were powered to detect differences in BP measurements and not necessarily differences in health outcomes. Many studies had only 6 months of follow-up, which may also explain the uncertain effect of BP monitors on health outcomes.

We found consistent benefits of BP monitoring on both surrogate outcomes, SBP and DBP. SBP reductions typical of included studies ranged between 2 and 4 mm Hg, and DBP reductions ranged from 1 to 3 mm Hg. It is unclear whether these modest changes in BP related to consumer BP monitors lead to lower risks of hypertension-related complications or mortality. Many factors may have potentially modified BP reduction in these studies. BP self-monitoring may support behavioral changes or reminder strategies to assist with lifestyle changes or medication adherence [2-4]. In addition, select BP monitors transmit data to health care providers and can improve BP control by facilitating timely recommendations from providers to patients to better manage their BP [87,88]. However, only 5 [23,25,27-29,36] of the 18 (27%) studies on isolated effects of BP monitors used automatic data transmission, and the effects on provider behavior change were rarely described among the included studies. This indicates that many studies did not use the advanced capabilities of modern BP monitors and may explain the unclear impact on health outcomes.

Most studies reported adherence to BP monitor use that ranged from 38% to 89%, but adherence was inconsistently measured. There was also a large gap between self-reported and measured adherence, such as a set number of recordings per week, as self-reported information is not always reliable. In addition, adherence can be affected by a variety of factors, such as daily



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access to the device, consumer comfort with the device, or self-motivation factors [89]. Spillover to other adherence factors, such as medication adherence or compliance with lifestyle behavior changes to manage hypertension, were not reported but may ultimately be a mechanism by which consumers of BP monitors improve their hypertension. Another consumer experience outcome, overall satisfaction, was reported as highly favorable among the included studies, thus validating the current rising consumer market for these devices.

Many studies evaluated multicomponent interventions, with BP monitors representing only 1 component, and did not separately evaluate the impact of the BP monitor. In our evidence base, only 18 of the 49 (37%) studies permitted such a direct assessment of BP monitor impact. Many PGHD technologies are intended to be used in combination with other interventions for chronic disease management, such as additional devices, exercise sessions, or health education sessions with medical personnel. These interventions may also influence outcomes; therefore, studies should be designed to measure the impact of isolated PGHD technology when added to other components.

### Strengths and Limitations

This systematic review has several strengths. To our knowledge, this is the first systematic review to synthesize the patient-centered health effects of consumer BP monitors for hypertension management, in addition to their effects on BP. We closely followed the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) reporting standards and used robust AHRQ Evidence-based Practice Center systematic review methodology, including duplicate literature screening and data extraction. The findings of our review mirror those from 2 recent meta-analyses of systematic reviews of individual patient data [90,91] and contribute summary-level data on health effects as well as key data on medication management and consumer experience. Furthermore, in this review, we used device engineers to verify the consumer availability of BP monitors used in studies and their similarity to currently available models.

This systematic review has limitations related to both the review methodology and the generalizability of the available literature. We judged the overall risk of bias using an adapted tool designed for mobile apps in managing diabetes [8] and therefore may not have detected some biases. We did not assess the possibility of publication bias, which may be a key problem in studies funded by manufacturers of devices that collect PGHD. The included studies rarely provided sufficient detail to delineate the contributions of cointerventions to outcomes, particularly those related to changes in BP. This limits the generalizability of our findings to patients with limited access to care or underserved patient populations. This may also further limit the confidence in the validity of our findings not otherwise captured in our risk-of-bias assessment. Studies with *usual care* groups often provided few details about what happened with these patients, which may potentially explain the wide variation in BP results among studies. The inclusion criteria of multiple studies were specific to consumers who had access to and familiarity with technology, which could include using the internet, smartphones or computers, arm or wrist devices, or access to electricity. Less technically adept consumers may not experience the same benefits as those enrolled in these studies. In addition, only 3 [25,37,38] of the 49 (6%) studies focused on rural populations, suggesting that these populations are underrepresented. Only 19 of the 49 (39%) studies used automatic data transmission from PGHD devices to health care providers.

Future studies are needed to examine the effectiveness of BP monitors that transmit data to health care providers (which are then used to inform medical decisions). Additional data from implementation studies may help determine which components are critical for sustained BP improvement, which in turn may improve prescription decisions by clinicians and coverage decisions by policy makers. In addition, challenges related to data accuracy, interoperability, privacy, and security should be explored as this field continues to grow.

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## Conflicts of Interest

None declared.

Multimedia Appendix 1
Tables showing general characteristics and patients characteristics of the 31 multicomponent studies.
[DOCX File , 27 KB - mhealth_v10i5e33261_app1.docx ]

## References

1. Centers FDC. About underlying cause of death, 1999-2018. Centers for Disease Control and Prevention. 2018. URL: https://wonder.cdc.gov/ucd-icd10.html [accessed 2020-11-03]



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2. Ward AM, Takahashi O, Stevens R, Heneghan C. Home measurement of blood pressure and cardiovascular disease: systematic review and meta-analysis of prospective studies. J Hypertens 2012 Mar;30(3):449-456. [doi: 10.1097/HJH.0b013e32834e4aed] [Medline: 22241136]
3. Mancia G, Facchetti R, Bombelli M, Grassi G, Sega R. Long-term risk of mortality associated with selective and combined elevation in office, home, and ambulatory blood pressure. Hypertension 2006 May;47(5):846-853. [doi: 10.1161/01.HYP.0000215363.69793.bb] [Medline: 16567588]
4. McManus RJ, Mant J, Franssen M, Nickless A, Schwartz C, Hodgkinson J, TASMINH4 investigators. Efficacy of self-monitored blood pressure, with or without telemonitoring, for titration of antihypertensive medication (TASMINH4): an unmasked randomised controlled trial. Lancet 2018 Mar 10;391(10124):949-959 [FREE Full text] [doi: 10.1016/S0140-6736(18)30309-X] [Medline: 29499873]
5. National Learning Consortium. Patient-generated health data fact sheet. The Office of the National Coordinator for Health Information Technology (ONC). 2014. URL: https://www.healthit.gov/sites/default/files/patient_generated_data_factsheet.pdf [accessed 2020-08-17]
6. Global automated home blood pressure monitors market 2020 by manufacturers, type and application, forecast to 2025. Markets and Research. 2020. URL: https://www.marketsandresearch.biz/report/95547/global-automated-home-blood-pressure-monitors-market-2020-by-manufacturers-type-and-application-forecast-to-2025 [accessed 2020-11-03]
7. Treadwell JR, Reston JT, Rouse B, Fontanarosa J, Patel N, Mull NK. Automated-entry patient-generated health data for chronic conditions: the evidence on health outcomes. Technical brief No. 38. Agency for Healthcare Research and Quality. 2021 Mar 1. URL: https://effectivehealthcare.ahrq.gov/products/health-data-mapping/report [accessed 2020-04-02]
8. Veazie S, Winchell K, Gilbert J, Paynter R, Ivlev I, Eden K, et al. Mobile Applications for Self-Management of Diabetes. Technical Brief No. 31. Agency for Healthcare Research and Quality. 2018 May. URL: https://effectivehealthcare.ahrq.gov/products/diabetes-mobile-devices/technical-brief [accessed 2022-04-02]
9. Makai P, IntHout J, Deinum J, Jenniskens K, van der Wilt GJ. A network meta-analysis of clinical management strategies for treatment-resistant hypertension: making optimal use of the evidence. J Gen Intern Med 2017 Aug;32(8):921-930 [FREE Full text] [doi: 10.1007/s11606-017-4000-7] [Medline: 28275946]
10. Whelton PK, He J, Appel LJ, Cutler JA, Havas S, Kotchen TA, National High Blood Pressure Education Program Coordinating Committee. Primary prevention of hypertension: clinical and public health advisory from The National High Blood Pressure Education Program. JAMA 2002 Oct 16;288(15):1882-1888. [doi: 10.1001/jama.288.15.1882] [Medline: 12377087]
11. Bennett GG, Steinberg D, Askew S, Levine E, Foley P, Batch BC, et al. Effectiveness of an app and provider counseling for obesity treatment in primary care. Am J Prev Med 2018 Dec;55(6):777-786 [FREE Full text] [doi: 10.1016/j.amepre.2018.07.005] [Medline: 30361140]
12. Chandler J, Sox L, Diaz V, Kellam K, Neely A, Nemeth L, et al. Impact of 12-month smartphone breathing meditation program upon systolic blood pressure among non-medicated stage 1 hypertensive adults. Int J Environ Res Public Health 2020 Mar 17;17(6):1955 [FREE Full text] [doi: 10.3390/ijerph17061955] [Medline: 32192020]
13. Aekplakorn W, Suriyawongpaisal P, Tansirisithikul R, Sakulpipat T, Charoensuk P. Effectiveness of self-monitoring blood pressure in primary care: a randomized controlled trial. J Prim Care Community Health 2016 Apr;7(2):58-64 [FREE Full text] [doi: 10.1177/2150131915614069] [Medline: 26574566]
14. Bosworth HB, Olsen MK, Grubber JM, Neary AM, Orr MM, Powers BJ, et al. Two self-management interventions to improve hypertension control: a randomized trial. Ann Intern Med 2009 Nov 17;151(10):687-695 [FREE Full text] [doi: 10.7326/0003-4819-151-10-200911170-00148] [Medline: 19920269]
15. Bosworth HB, Olsen MK, Grubber JM, Powers BJ, Oddone EZ. Racial differences in two self-management hypertension interventions. Am J Med 2011 May;124(5):468.e1-468.e8 [FREE Full text] [doi: 10.1016/j.amjmed.2010.11.024] [Medline: 21531237]
16. Bosworth HB, Olsen MK, Dudley T, Orr M, Neary A, Harrelson M, et al. The Take Control of Your Blood pressure (TCYB) study: study design and methodology. Contemp Clin Trials 2007 Jan;28(1):33-47. [doi: 10.1016/j.cct.2006.08.006] [Medline: 16996808]
17. Bosworth HB, Olsen MK, Neary A, Orr M, Grubber J, Svetkey L, et al. Take Control of Your Blood Pressure (TCYB) study: a multifactorial tailored behavioral and educational intervention for achieving blood pressure control. Patient Educ Couns 2008 Mar;70(3):338-347 [FREE Full text] [doi: 10.1016/j.pec.2007.11.014] [Medline: 18164894]
18. Broege PA, James GD, Pickering TG. Management of hypertension in the elderly using home blood pressures. Blood Press Monit 2001 Jun;6(3):139-144. [doi: 10.1097/00126097-200106000-00004] [Medline: 11518836]
19. Fuchs SC, Ferreira-da-Silva AL, Moreira LB, Neyeloff JL, Fuchs FC, Gus M, et al. Efficacy of isolated home blood pressure monitoring for blood pressure control: randomized controlled trial with ambulatory blood pressure monitoring - MONITOR study. J Hypertens 2012 Jan;30(1):75-80. [doi: 10.1097/HJH.0b013e32834e5a4f] [Medline: 22134392]
20. Green BB, Cook AJ, Ralston JD, Fishman PA, Catz SL, Carlson J, et al. Effectiveness of home blood pressure monitoring, web communication, and pharmacist care on hypertension control: a randomized controlled trial. JAMA 2008 Jun 25;299(24):2857-2867 [FREE Full text] [doi: 10.1001/jama.299.24.2857] [Medline: 18577730]




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21. Ralston JD, Cook AJ, Anderson ML, Catz SL, Fishman PA, Carlson J, et al. Home blood pressure monitoring, secure electronic messaging and medication intensification for improving hypertension control: a mediation analysis. Appl Clin Inform 2014;5(1):232-248 [FREE Full text] [doi: 10.4338/ACI-2013-10-RA-0079] [Medline: 24734136]
22. Hebert PL, Sisk JE, Tuzzio L, Casabianca JM, Pogue VA, Wang JJ, et al. Nurse-led disease management for hypertension control in a diverse urban community: a randomized trial. J Gen Intern Med 2012 Jun;27(6):630-639 [FREE Full text] [doi: 10.1007/s11606-011-1924-1] [Medline: 22143452]
23. Hoffmann-Petersen N, Lauritzen T, Bech JN, Pedersen EB. Short-term telemedical home blood pressure monitoring does not improve blood pressure in uncomplicated hypertensive patients. J Hum Hypertens 2017 Feb;31(2):93-98. [doi: 10.1038/jhh.2016.43] [Medline: 27334521]
24. Hosseininasab M, Jahangard-Rafsanjani Z, Mohagheghi A, Sarayani A, Rashidian A, Javadi M, et al. Self-monitoring of blood pressure for improving adherence to antihypertensive medicines and blood pressure control: a randomized controlled trial. Am J Hypertens 2014 Nov;27(11):1339-1345 [FREE Full text] [doi: 10.1093/ajh/hpu062] [Medline: 24771706]
25. Kaihara T, Eguchi K, Kario K. Home BP monitoring using a telemonitoring system is effective for controlling BP in a remote island in Japan. J Clin Hypertens (Greenwich) 2014 Nov;16(11):814-819 [FREE Full text] [doi: 10.1111/jch.12421] [Medline: 25267008]
26. Kauric-Klein Z, Artinian N. Improving blood pressure control in hypertensive hemodialysis patients. CANNT J 2007;17(4):24-38. [Medline: 18271430]
27. Kim JY, Wineinger NE, Steinhubl SR. The influence of wireless self-monitoring program on the relationship between patient activation and health behaviors, medication adherence, and blood pressure levels in hypertensive patients: a substudy of a randomized controlled trial. J Med Internet Res 2016 Jun 22;18(6):e116 [FREE Full text] [doi: 10.2196/jmir.5429] [Medline: 27334418]
28. Bloss CS, Wineinger NE, Peters M, Boeldt DL, Ariniello L, Kim JY, et al. A prospective randomized trial examining health care utilization in individuals using multiple smartphone-enabled biosensors. PeerJ 2016 Jan 14;4:e1554 [FREE Full text] [doi: 10.7717/peerj.1554] [Medline: 26788432]
29. Lakshminarayan K, Westberg S, Northuis C, Fuller CC, Ikramuddin F, Ezzeddine M, et al. A mHealth-based care model for improving hypertension control in stroke survivors: pilot RCT. Contemp Clin Trials 2018 Jul;70:24-34 [FREE Full text] [doi: 10.1016/j.cct.2018.05.005] [Medline: 29763657]
30. Márquez-Contreras E, Martell-Claros N, Gil-Guillén V, de la Figuera-Von Wichmann M, Casado-Martínez JJ, Martin-de Pablos JL, Compliance Group of the Spanish Society of Hypertension (SEE). Efficacy of a home blood pressure monitoring programme on therapeutic compliance in hypertension: the EAPACUM-HTA study. J Hypertens 2006 Jan;24(1):169-175. [doi: 10.1097/01.hjh.0000198023.53859.a2] [Medline: 16331115]
31. Franssen M, Farmer A, Grant S, Greenfield S, Heneghan C, Hobbs R, et al. Telemonitoring and/or self-monitoring of blood pressure in hypertension (TASMINH4): protocol for a randomised controlled trial. BMC Cardiovasc Disord 2017 Feb 13;17(1):58 [FREE Full text] [doi: 10.1186/s12872-017-0494-5] [Medline: 28193176]
32. Grant S, Hodgkinson J, Schwartz C, Bradburn P, Franssen M, Hobbs FR, et al. Using mHealth for the management of hypertension in UK primary care: an embedded qualitative study of the TASMINH4 randomised controlled trial. Br J Gen Pract 2019 Sep;69(686):e612-e620 [FREE Full text] [doi: 10.3399/bjgp19X704585] [Medline: 31262847]
33. Monahan M, Jowett S, Nickless A, Franssen M, Grant S, Greenfield S, et al. Cost-effectiveness of telemonitoring and self-monitoring of blood pressure for antihypertensive titration in primary care (TASMINH4). Hypertension 2019 Jun;73(6):1231-1239 [FREE Full text] [doi: 10.1161/HYPERTENSIONAHA.118.12415] [Medline: 31067190]
34. Qi L, Qiu Y, Zhang W. Home blood pressure monitoring is a useful measurement for patients with hypertension: a long-term follow-up study. Biomed Res 2017;28(7):2898-2902.
35. Zaleski AL, Taylor BA, Park CL, Santos LP, Panza G, Kramarz M, et al. Using the immediate blood pressure benefits of exercise to improve exercise adherence among adults with hypertension: a randomized clinical trial. J Hypertens 2019 Sep;37(9):1877-1888. [doi: 10.1097/HJH.0000000000002115] [Medline: 31058797]
36. Zha P, Qureshi R, Porter S, Chao YY, Pacquiao D, Chase S, et al. Utilizing a mobile health intervention to manage hypertension in an underserved community. West J Nurs Res 2020 Mar;42(3):201-209. [doi: 10.1177/0193945919847937] [Medline: 31057081]
37. Bernocchi P, Scalvini S, Bertacchini F, Rivadossi F, Muiesan ML. Home based telemedicine intervention for patients with uncontrolled hypertension--a real life non-randomized study. BMC Med Inform Decis Mak 2014 Jun 12;14:52 [FREE Full text] [doi: 10.1186/1472-6947-14-52] [Medline: 24920046]
38. Petrella RJ, Stuckey MI, Shapiro S, Gill DP. Mobile health, exercise and metabolic risk: a randomized controlled trial. BMC Public Health 2014 Oct 18;14:1082 [FREE Full text] [doi: 10.1186/1471-2458-14-1082] [Medline: 25326074]
39. Bove AA, Homko CJ, Santamore WP, Kashem M, Kerper M, Elliott DJ. Managing hypertension in urban underserved subjects using telemedicine--a clinical trial. Am Heart J 2013 Apr;165(4):615-621. [doi: 10.1016/j.ahj.2013.01.004] [Medline: 23537980]
40. Dorough AE, Winett RA, Anderson ES, Davy BM, Martin EC, Hedrick V. DASH to wellness: emphasizing self-regulation through e-health in adults with prehypertension. Health Psychol 2014 Mar;33(3):249-254. [doi: 10.1037/a0030483] [Medline: 23181455]




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RenderX

41. Earle KA, Istepanian RS, Zitouni K, Sungoor A, Tang B. Mobile telemonitoring for achieving tighter targets of blood pressure control in patients with complicated diabetes: a pilot study. Diabetes Technol Ther 2010 Jul;12(7):575-579. [doi: 10.1089/dia.2009.0090] [Medline: 20597833]
42. Green BB, Anderson ML, Cook AJ, Catz S, Fishman PA, McClure JB, et al. e-Care for heart wellness: a feasibility trial to decrease blood pressure and cardiovascular risk. Am J Prev Med 2014 Apr;46(4):368-377 [FREE Full text] [doi: 10.1016/j.amepre.2013.11.009] [Medline: 24650839]
43. He J, Irazola V, Mills KT, Poggio R, Beratarrechea A, Dolan J, HCPIA Investigators. Effect of a community health worker-led multicomponent intervention on blood pressure control in low-income patients in Argentina: a randomized clinical trial. JAMA 2017 Sep 19;318(11):1016-1025 [FREE Full text] [doi: 10.1001/jama.2017.11358] [Medline: 28975305]
44. Kerry SM, Markus HS, Khong TK, Cloud GC, Tulloch J, Coster D, et al. Home blood pressure monitoring with nurse-led telephone support among patients with hypertension and a history of stroke: a community-based randomized controlled trial. CMAJ 2013 Jan 08;185(1):23-31 [FREE Full text] [doi: 10.1503/cmaj.120832] [Medline: 23128283]
45. Kerry S, Markus H, Khong T, Doshi R, Conroy R, Oakeshott P. Community based trial of home blood pressure monitoring with nurse-led telephone support in patients with stroke or transient ischaemic attack recently discharged from hospital. Trials 2008 Mar 19;9:15 [FREE Full text] [doi: 10.1186/1745-6215-9-15] [Medline: 18353175]
46. Ovaisi S, Oakeshott P, Kerry S, Crabtree AE, Kyei G, Kerry SM. Home blood pressure monitoring in hypertensive stroke patients: a prospective cohort study following a randomized controlled trial. Fam Pract 2013 Aug;30(4):398-403. [doi: 10.1093/fampra/cmt018] [Medline: 23629739]
47. Logan AG, Irvine MJ, McIsaac WJ, Tisler A, Rossos PG, Easty A, et al. Effect of home blood pressure telemonitoring with self-care support on uncontrolled systolic hypertension in diabetics. Hypertension 2012 Jul;60(1):51-57. [doi: 10.1161/HYPERTENSIONAHA.111.188409] [Medline: 22615116]
48. Magid DJ, Ho PM, Olson KL, Brand DW, Welch LK, Snow KE, et al. A multimodal blood pressure control intervention in 3 healthcare systems. Am J Manag Care 2011 Apr;17(4):e96-103. [Medline: 21774100]
49. Magid DJ, Olson KL, Billups SJ, Wagner NM, Lyons EE, Kroner BA. A pharmacist-led, American Heart Association Heart360 web-enabled home blood pressure monitoring program. Circ Cardiovasc Qual Outcomes 2013 Mar 01;6(2):157-163. [doi: 10.1161/CIRCOUTCOMES.112.968172] [Medline: 23463811]
50. Margolis KL, Asche SE, Bergdall AR, Dehmer SP, Groen SE, Kadrmas HM, et al. Effect of home blood pressure telemonitoring and pharmacist management on blood pressure control: a cluster randomized clinical trial. JAMA 2013 Jul 03;310(1):46-56 [FREE Full text] [doi: 10.1001/jama.2013.6549] [Medline: 23821088]
51. Margolis KL, Asche SE, Bergdall AR, Dehmer SP, Maciosek MV, Nyboer RA, et al. A successful multifaceted trial to improve hypertension control in primary care: why did it work? J Gen Intern Med 2015 Nov;30(11):1665-1672 [FREE Full text] [doi: 10.1007/s11606-015-3355-x] [Medline: 25952653]
52. Beran M, Asche SE, Bergdall AR, Crabtree B, Green BB, Groen SE, et al. Key components of success in a randomized trial of blood pressure telemonitoring with medication therapy management pharmacists. J Am Pharm Assoc (2003) 2018;58(6):614-621 [FREE Full text] [doi: 10.1016/j.japh.2018.07.001] [Medline: 30077564]
53. Dehmer SP, Maciosek MV, Trower NK, Asche SE, Bergdall AR, Nyboer RA, et al. Economic evaluation of the home blood pressure telemonitoring and pharmacist case management to control hypertension (Hyperlink) trial. J Am Coll Clin Pharm 2018 Oct;1(1):21-30 [FREE Full text] [doi: 10.1002/jac5.1001] [Medline: 30320302]
54. Margolis KL, Kerby TJ, Asche SE, Bergdall AR, Maciosek MV, O'Connor PJ, et al. Design and rationale for home blood pressure telemonitoring and case management to control hypertension (HyperLink): a cluster randomized trial. Contemp Clin Trials 2012 Jul;33(4):794-803 [FREE Full text] [doi: 10.1016/j.cct.2012.03.014] [Medline: 22498720]
55. Margolis KL, Asche SE, Dehmer SP, Bergdall AR, Green BB, Sperl-Hillen JM, et al. Long-term outcomes of the effects of home blood pressure telemonitoring and pharmacist management on blood pressure among adults with uncontrolled hypertension: follow-up of a cluster randomized clinical trial. JAMA Netw Open 2018 Sep 07;1(5):e181617 [FREE Full text] [doi: 10.1001/jamanetworkopen.2018.1617] [Medline: 30646139]
56. Kerby TJ, Asche SE, Maciosek MV, O'Connor PJ, Sperl-Hillen JM, Margolis KL. Adherence to blood pressure telemonitoring in a cluster-randomized clinical trial. J Clin Hypertens (Greenwich) 2012 Oct;14(10):668-674 [FREE Full text] [doi: 10.1111/j.1751-7176.2012.00685.x] [Medline: 23031143]
57. Mehos BM, Saseen JJ, MacLaughlin EJ. Effect of pharmacist intervention and initiation of home blood pressure monitoring in patients with uncontrolled hypertension. Pharmacotherapy 2000 Nov;20(11):1384-1389. [doi: 10.1592/phco.20.17.1384.34891] [Medline: 11079287]
58. Mendelson M, Vivodtzev I, Tamisier R, Laplaud D, Dias-Domingos S, Baguet JP, et al. CPAP treatment supported by telemedicine does not improve blood pressure in high cardiovascular risk OSA patients: a randomized, controlled trial. Sleep 2014 Nov 01;37(11):1863-1870 [FREE Full text] [doi: 10.5665/sleep.4186] [Medline: 25364081]
59. Niiranen TJ, Leino K, Puukka P, Kantola I, Karanko H, Jula AM. Lack of impact of a comprehensive intervention on hypertension in the primary care setting. Am J Hypertens 2014 Mar;27(3):489-496. [doi: 10.1093/ajh/hpt204] [Medline: 24186848]




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60. Ogedegbe G, Tobin JN, Fernandez S, Cassells A, Diaz-Gloster M, Khalida C, et al. Counseling African Americans to control hypertension: cluster-randomized clinical trial main effects. Circulation 2014 May 20;129(20):2044-2051 [FREE Full text] [doi: 10.1161/CIRCULATIONAHA.113.006650] [Medline: 24657991]
61. Sarfo FS, Treiber F, Gebregziabher M, Adamu S, Nichols M, Singh A, PINGS Team. Phone-based intervention for blood pressure control among Ghanaian stroke survivors: a pilot randomized controlled trial. Int J Stroke 2019 Aug;14(6):630-638. [doi: 10.1177/1747493018816423] [Medline: 30465630]
62. Yoo HJ, Park MS, Kim TN, Yang SJ, Cho GJ, Hwang TG, et al. A ubiquitous chronic disease care system using cellular phones and the internet. Diabet Med 2009 Jun;26(6):628-635. [doi: 10.1111/j.1464-5491.2009.02732.x] [Medline: 19538239]
63. Bosworth HB, Powers BJ, Olsen MK, McCant F, Grubber J, Smith V, et al. Home blood pressure management and improved blood pressure control: results from a randomized controlled trial. Arch Intern Med 2011 Jul 11;171(13):1173-1180. [doi: 10.1001/archinternmed.2011.276] [Medline: 21747013]
64. Maciejewski ML, Bosworth HB, Olsen MK, Smith VA, Edelman D, Powers BJ, et al. Do the benefits of participation in a hypertension self-management trial persist after patients resume usual care? Circ Cardiovasc Qual Outcomes 2014 Mar;7(2):269-275. [doi: 10.1161/CIRCOUTCOMES.113.000309] [Medline: 24619321]
65. McCant F, McKoy G, Grubber J, Olsen MK, Oddone E, Powers B, et al. Feasibility of blood pressure telemonitoring in patients with poor blood pressure control. J Telemed Telecare 2009;15(6):281-285. [doi: 10.1258/jtt.2009.090202] [Medline: 19720764]
66. McKinstry B, Hanley J, Wild S, Pagliari C, Paterson M, Lewis S, et al. Telemonitoring based service redesign for the management of uncontrolled hypertension: multicentre randomised controlled trial. BMJ 2013 May 24;346:f3030 [FREE Full text] [doi: 10.1136/bmj.f3030] [Medline: 23709583]
67. Hanley J, Ure J, Pagliari C, Sheikh A, McKinstry B. Experiences of patients and professionals participating in the HITS home blood pressure telemonitoring trial: a qualitative study. BMJ Open 2013 May 28;3(5):e002671 [FREE Full text] [doi: 10.1136/bmjopen-2013-002671] [Medline: 23793649]
68. Stoddart A, Hanley J, Wild S, Pagliari C, Paterson M, Lewis S, et al. Telemonitoring-based service redesign for the management of uncontrolled hypertension (HITS): cost and cost-effectiveness analysis of a randomised controlled trial. BMJ Open 2013 May 28;3(5):e002681 [FREE Full text] [doi: 10.1136/bmjopen-2013-002681] [Medline: 23793650]
69. McManus RJ, Mant J, Bray EP, Holder R, Jones MI, Greenfield S, et al. Telemonitoring and self-management in the control of hypertension (TASMINH2): a randomised controlled trial. Lancet 2010 Jul 17;376(9736):163-172. [doi: 10.1016/S0140-6736(10)60964-6] [Medline: 20619448]
70. Bray EP, Jones MI, Banting M, Greenfield S, Hobbs FD, Little P, et al. Performance and persistence of a blood pressure self-management intervention: telemonitoring and self-management in hypertension (TASMINH2) trial. J Hum Hypertens 2015 Jul;29(7):436-441. [doi: 10.1038/jhh.2014.108] [Medline: 25566874]
71. McManus RJ, Bray EP, Mant J, Holder R, Greenfield S, Bryan S, et al. Protocol for a randomised controlled trial of telemonitoring and self-management in the control of hypertension: telemonitoring and self-management in hypertension. [ISRCTN17585681]. BMC Cardiovasc Disord 2009 Feb 16;9:6 [FREE Full text] [doi: 10.1186/1471-2261-9-6] [Medline: 19220913]
72. Kaambwa B, Bryan S, Jowett S, Mant J, Bray EP, Hobbs FD, et al. Telemonitoring and self-management in the control of hypertension (TASMINH2): a cost-effectiveness analysis. Eur J Prev Cardiol 2014 Dec;21(12):1517-1530. [doi: 10.1177/2047487313501886] [Medline: 23990660]
73. Jones MI, Greenfield SM, Bray EP, Hobbs FR, Holder R, Little P, et al. Patient self-monitoring of blood pressure and self-titration of medication in primary care: the TASMINH2 trial qualitative study of health professionals' experiences. Br J Gen Pract 2013 Jun;63(611):e378-e385 [FREE Full text] [doi: 10.3399/bjgp13X668168] [Medline: 23735408]
74. McManus RJ, Mant J, Haque MS, Bray EP, Bryan S, Greenfield SM, et al. Effect of self-monitoring and medication self-titration on systolic blood pressure in hypertensive patients at high risk of cardiovascular disease: the TASMIN-SR randomized clinical trial. JAMA 2014 Aug 27;312(8):799-808. [doi: 10.1001/jama.2014.10057] [Medline: 25157723]
75. Rifkin DE, Abdelmalek JA, Miracle CM, Low C, Barsotti R, Rios P, et al. Linking clinic and home: a randomized, controlled clinical effectiveness trial of real-time, wireless blood pressure monitoring for older patients with kidney disease and hypertension. Blood Press Monit 2013 Feb;18(1):8-15 [FREE Full text] [doi: 10.1097/MBP.0b013e32835d126c] [Medline: 23275313]
76. Kao CW, Chen TY, Cheng SM, Lin WS, Chang YC. A Web-based self-titration program to control blood pressure in patients with primary hypertension: randomized controlled trial. J Med Internet Res 2019 Dec 05;21(12):e15836 [FREE Full text] [doi: 10.2196/15836] [Medline: 31804186]
77. Zarnke KB, Feagan BG, Mahon JL, Feldman RD. A randomized study comparing a patient-directed hypertension management strategy with usual office-based care. Am J Hypertens 1997 Jan;10(1):58-67. [doi: 10.1016/s0895-7061(96)00305-6] [Medline: 9008249]
78. Istepanian RS, Zitouni K, Harry D, Moutosammy N, Sungoor A, Tang B, et al. Evaluation of a mobile phone telemonitoring system for glycaemic control in patients with diabetes. J Telemed Telecare 2009;15(3):125-128. [doi: 10.1258/jtt.2009.003006] [Medline: 19364893]




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79. Halme L, Vesalainen R, Kaaja M, Kantola I, HOme MEasuRement of blood pressure study group. Self-monitoring of blood pressure promotes achievement of blood pressure target in primary health care. Am J Hypertens 2005 Nov;18(11):1415-1420. [doi: 10.1016/j.amjhyper.2005.05.017] [Medline: 16280273]
80. Kim YN, Shin DG, Park S, Lee CH. Randomized clinical trial to assess the effectiveness of remote patient monitoring and physician care in reducing office blood pressure. Hypertens Res 2015 Jul;38(7):491-497. [doi: 10.1038/hr.2015.32] [Medline: 25787041]
81. Klarskov P, Bang LE, Schultz-Larsen P, Gregers Petersen H, Benee Olsen D, Berg RM, et al. Intensive versus conventional blood pressure monitoring in a general practice population. The Blood Pressure Reduction in Danish General Practice trial: a randomized controlled parallel group trial. Fam Pract 2018 Jul 23;35(4):433-439. [doi: 10.1093/fampra/cmx106] [Medline: 29351658]
82. Neumann CL, Menne J, Rieken EM, Fischer N, Weber MH, Haller H, et al. Blood pressure telemonitoring is useful to achieve blood pressure control in inadequately treated patients with arterial hypertension. J Hum Hypertens 2011 Dec;25(12):732-738. [doi: 10.1038/jhh.2010.119] [Medline: 21228822]
83. Neumann CL, Menne J, Schettler V, Hagenah GC, Brockes C, Haller H, et al. Long-term effects of 3-month telemetric blood pressure intervention in patients with inadequately treated arterial hypertension. Telemed J E Health 2015 Mar;21(3):145-150. [doi: 10.1089/tmj.2014.0058] [Medline: 25569481]
84. Rogers MA, Small D, Buchan DA, Butch CA, Stewart CM, Krenzer BE, et al. Home monitoring service improves mean arterial pressure in patients with essential hypertension. A randomized, controlled trial. Ann Intern Med 2001 Jun 05;134(11):1024-1032. [doi: 10.7326/0003-4819-134-11-200106050-00008] [Medline: 11388815]
85. Sarfo F, Treiber F, Gebregziabher M, Adamu S, Patel S, Nichols M, et al. PINGS (Phone-based Intervention under Nurse Guidance after Stroke): interim results of a pilot randomized controlled trial. Stroke 2018 Jan;49(1):236-239 [FREE Full text] [doi: 10.1161/STROKEAHA.117.019591] [Medline: 29222227]
86. Stewart K, George J, Mc Namara KP, Jackson SL, Peterson GM, Bereznicki LR, et al. A multifaceted pharmacist intervention to improve antihypertensive adherence: a cluster-randomized, controlled trial (HAPPy trial). J Clin Pharm Ther 2014 Oct;39(5):527-534. [doi: 10.1111/jcpt.12185] [Medline: 24943987]
87. Rodriguez S, Hwang K, Wang J. Connecting home-based self-monitoring of blood pressure data into electronic health records for hypertension care: a qualitative inquiry with primary care providers. JMIR Form Res 2019 May 23;3(2):e10388 [FREE Full text] [doi: 10.2196/10388] [Medline: 31124468]
88. Asayama K, Ohkubo T, Metoki H, Obara T, Inoue R, Kikuya M, Hypertension Objective Treatment Based on Measurement by Electrical Devices of Blood Pressure (HOMED-BP). Cardiovascular outcomes in the first trial of antihypertensive therapy guided by self-measured home blood pressure. Hypertens Res 2012 Nov;35(11):1102-1110. [doi: 10.1038/hr.2012.125] [Medline: 22895063]
89. Burke LE, Ma J, Azar KM, Bennett GG, Peterson ED, Zheng Y, American Heart Association Publications Committee of the Council on Epidemiology and Prevention, Behavior Change Committee of the Council on Cardiometabolic Health, Council on Cardiovascular and Stroke Nursing, Council on Functional Genomics and Translational Biology, Council on Quality of Care and Outcomes Research, and Stroke Council. Current science on consumer use of mobile health for cardiovascular disease prevention: a scientific statement from the American Heart Association. Circulation 2015 Sep 22;132(12):1157-1213 [FREE Full text] [doi: 10.1161/CIR.0000000000000232] [Medline: 26271892]
90. Sheppard JP, Tucker KL, Davison WJ, Stevens R, Aekplakorn W, Bosworth HB, et al. Self-monitoring of blood pressure in patients with hypertension-related multi-morbidity: systematic review and individual patient data meta-analysis. Am J Hypertens 2020 Mar 13;33(3):243-251 [FREE Full text] [doi: 10.1093/ajh/hpz182] [Medline: 31730171]
91. Tucker KL, Sheppard JP, Stevens R, Bosworth HB, Bove A, Bray EP, et al. Self-monitoring of blood pressure in hypertension: a systematic review and individual patient data meta-analysis. PLoS Med 2017 Sep;14(9):e1002389 [FREE Full text] [doi: 10.1371/journal.pmed.1002389] [Medline: 28926573]


## Abbreviations

**AE:** adverse event
**AHRQ:** Agency for Healthcare Research and Quality
**BP:** blood pressure
**DBP:** diastolic blood pressure
**FDA:** Food and Drug Administration
**PGHD:** patient-generated health data
**PRISMA:** Preferred Reporting Items for Systematic Reviews and Meta-Analyses
**QoL:** quality of life
**SBP:** systolic blood pressure
**SF-36:** Short Form Health Survey 36



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Review

# Sociotechnical Factors Affecting Patients' Adoption of Mobile Health Tools: Systematic Literature Review and Narrative Synthesis

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## Abstract

**Background:** Mobile health (mHealth) tools have emerged as a promising health care technology that may contribute to cost savings, better access to care, and enhanced clinical outcomes; however, it is important to ensure their acceptance and adoption to harness this potential. Patient adoption has been recognized as a key challenge that requires further exploration.

**Objective:** The aim of this review was to systematically investigate the literature to understand the factors affecting patients' adoption of mHealth tools by considering sociotechnical factors (from technical, social, and health perspectives).

**Methods:** A structured search was completed following the participants, intervention, comparators, and outcomes framework. We searched the MEDLINE, PubMed, Cochrane Library, and SAGE databases for studies published between January 2011 and July 2021 in the English language, yielding 5873 results, of which 147 studies met the inclusion criteria. The PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines and the Cochrane Handbook were followed to ensure a systematic process. Extracted data were analyzed using NVivo (QSR International), with thematic analysis and narrative synthesis of emergent themes.

**Results:** The technical factors affecting patients' adoption of mHealth tools were categorized into six key themes, which in turn were divided into 20 subthemes: usefulness, ease of use, data-related, monetary factors, technical issues, and user experience. Health-related factors were categorized into six key themes: the disease or health condition, the care team's role, health consciousness and literacy, health behavior, relation to other therapies, integration into patient journey, and the patients' insurance status. Social and personal factors were divided into three key clusters: demographic factors, personal characteristics, and social and cultural aspects; these were divided into 19 subthemes, highlighting the importance of considering these factors when addressing potential barriers to mHealth adoption and how to overcome them.

**Conclusions:** This review builds on the growing body of research that investigates patients' adoption of mHealth services and highlights the complexity of the factors affecting adoption, including personal, social, technical, organizational, and health care aspects. We recommend a more patient-centered approach by ensuring the tools' fit into the overall patient journey and treatment plan, emphasizing inclusive design, and warranting comprehensive patient education and support. Moreover, empowering and mobilizing clinicians and care teams, addressing ethical data management issues, and focusing on health care policies may facilitate adoption.

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**KEYWORDS**

telemedicine; smartphone; mobile phone; electronic health record; public health practice; technology; perception; health education; mHealth; mobile health; telehealth; eHealth; patients

## Introduction

Mobile health (mHealth) tools have emerged as a promising health care technology that may contribute to better access to health services, enhanced quality of care, and cost savings [1-6]. These novel technologies may also present an opportunity to enhance communication between patients and their health care providers and facilitate self-monitoring and self-management [7-9], leading to better treatment outcomes. Patients' adoption is a key factor for mHealth success; however, it has been recognized as one of the key challenges.

Results from several trials showed that up to 70% of patients who were invited to use mHealth technologies either declined to participate or dropped using the tools prematurely [10]. Trials that reported higher retention rates were usually conducted over a short time frame and may not necessarily reflect the situation in real-world adoption [11]. A survey study on the topic stated that >50% of the surveyed clinicians cited patient resistance as one of the key barriers to adoption [12]. Furthermore, several studies have established that only a small fraction of patients kept using mHealth tools in the long term, and that up to 80% of users would only show minimal engagement, using the tools <2 times [13,14]. Another study conducted on a large real-world cohort of 189,770 people reported that only 2.58% of the people who downloaded the app sustained its active use, concluding that the impact of such apps may remain minimal if they fail to reach the patients who need them most [15].

The scope of this study is to build a better understanding of the different factors that may affect patients' adoption of mHealth technologies. This study defines mHealth as "medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, Personal Digital Assistants (PDAs), and other wireless devices" as per the World Health Organization's Global Observatory of eHealth, which considers mHealth a subcategory of eHealth. Telemedicine is, in turn, a subcategory of mHealth and defined as "the communication or consultation between health professionals about patients using voice, text, data, imaging, or video functions of a mobile device. But it can be applied to other situations; the management of chronic diseases of patients living at home being one example" [16].

Accordingly, a systematic review was conducted to provide a precise and up-to-date description of factors that affect patients' adoption of mHealth tools from a technology, social, and health perspective. It also reflects on potential implications and suggests directions for relevant stakeholders to overcome barriers to adoption and thus facilitate the use of mHealth by a broader population. This work is part of an ongoing research project that explores the clinicians' perspective and supplements its initial findings, which have already been published [17].

Findings from this study will help inform health care professionals, technology providers, and policy makers by presenting them with an up-to-date and comprehensive review of key factors affecting patients' adoption of mHealth tools, as reported in the academic literature. This can guide them in making more informed decisions to promote adoption and harness the potential advantages of these tools.

## Methods

### Overview

The methods for this review were drawn from the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines [18] and the Cochrane Handbook [19], both of which provide guidance toward a rigorous and reliable literature review methodology. The review methods were defined in advance and the protocol was published in the PROSPERO (International Prospective Register of Systematic Reviews) and is available on the web [20]. The analysis did not require any major divergence from the initial protocol. The research question that guided this review was the following: "According to the literature, what are the social, technical and health factors impacting patients' adoption of mHealth tools?"

### Search Strategy

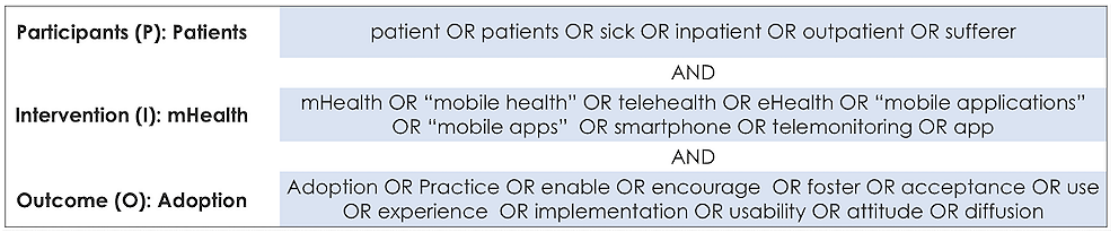
A search of MEDLINE, PubMed, Cochrane Library, and SAGE databases in July 2021 identified the relevant studies. The scope of this review was narrowed to studies published in English between January 2011 and July 2021. Only original, peer-reviewed, and published papers were included in this study. Other forms, such as editorials, unsystematic reviews, interviews, comments, unstructured observations, and position papers, were excluded. We decided not to include articles on the basis of manual searches of reference lists for causes summarized in the Cochrane Handbook: "positive studies are more likely to be cited" and "retrieving literature by scanning reference lists may thus produce a biased sample of studies" [19].

The search string shown in Figure 1 was developed according to the participants, intervention, comparators, and outcome framework [21]. There were no limitations to the types of conditions that qualified for inclusion, and both qualitative and quantitative studies were included. Comparators were not applicable to this study. Participants included studies that focused on patients. Interventions (mHealth) included studies involving smart device use such as mHealth apps or telehealth. Outcomes (adoption) included studies addressing the factors affecting mHealth technology adoption or use.



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**Figure 1.** The search string according to the participants, intervention, comparator, and outcome (PICO) framework. mHealth: mobile health.




## Study Selection

Two researchers (CJ and ES) were involved in the screening, eligibility, and inclusion phases, and any divergence was agreed upon in the discussion between them. In cases in which they could not reach an agreement, a third reviewer (ASV or CI) discussed it with them and made the final decision. The research team used the open-source app Rayyan QCRI (Qatar Computing Research Institute) to facilitate collaborative screening [22]. Screening lasted from June to September 2021.

The inclusion and exclusion criteria, detailed in Textbox 1, were developed according to the participants, intervention, comparators, and outcome framework. Studies were excluded if they did not involve the use of mHealth or smart devices; focused solely on, for example, clinicians, caregivers, or technology providers; did not include patients; were not peer-reviewed; were editorials, interviews, comments, unstructured observations, or position papers; did not address the factors affecting adoption; or if the full text was not available, freely available, or available in English.

**Textbox 1.** Inclusion and exclusion criteria according to the PICO (participants, intervention, comparator, and outcome) framework.

**Inclusion and exclusion criteria**

**Population**

- Include: focused on patients
- Exclude: focused only on clinicians, caregivers, or technology providers

**Intervention**

- Include: focused on solutions involving a smart device (eg, mobile health [mHealth] apps and telehealth)
- Exclude: using other technologies (eg, virtual reality and machine learning)

**Comparators**

- Does not apply

**Outcome**

- Include: addresses factors impacting patients' adoption, acceptance, use, experience, usability, or attitude of using mHealth, regardless of the condition
- Exclude: focused only on mHealth success or development in general

**Publication type**

- Include: original, peer-reviewed, and published paper
- Exclude: editorials, interviews, comments, unstructured observations, and position papers

After completing the screening and resolving any conflicting views among the researchers, the selected full texts were assessed for eligibility independently by CJ and ES. Any disagreements were resolved through discussion with ASV or CI. The risk of bias was assessed using the Critical Appraisal Skills Program tool [23]. The checklist is included in Multimedia Appendix 1, and a Microsoft Excel sheet with the appraisal of the included studies can be accessed in Multimedia Appendix 2.

## Data Collection and Synthesis

The variety of procedures and results that were identified in the included studies was not homogeneous enough to enable a quantitative analysis of the data. Therefore, a narrative synthesis was used and structured around the social, health, and technical factors affecting patients' adoption of mHealth solutions. NVivo (QSR International), a computer-assisted qualitative data analysis software, was used to assist with this task.

Data coding began with a preliminary data extraction grid that included themes based on previous research and technology acceptance frameworks; the initial codebook was informed by



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our previous work that aggregated the factors used in the most used frameworks [24]. More codes were added as they emerged during the review process. Thematic analysis by Braun and Clarke [25] was used to identify and extract themes under social, technical, and health factors addressed in the research question. Social factors include any social-related elements, such as the effects of people and groups influencing one another through culture; technical factors include elements related to the material sides of the technology, such as its ease of use and usability; and health-related factors were linked to elements such as the health condition itself and the patient's health literacy. The phases of the thematic analysis are explained in detail in Multimedia Appendix 3. This process lasted from September to November 2021.

### Theoretical Framework

Health care technologies are generally more complex than tools that address individual user needs, as they usually support patients with comorbidities who are typically treated by multidisciplinary teams who might even work in different health care organizations. The special nature of how the health care sector operates and its high degree of regulation, normalized budget deficits, and the interdependence between health care organizations necessitate some crucial expansions to existing theoretical frameworks usually used when studying adoption.

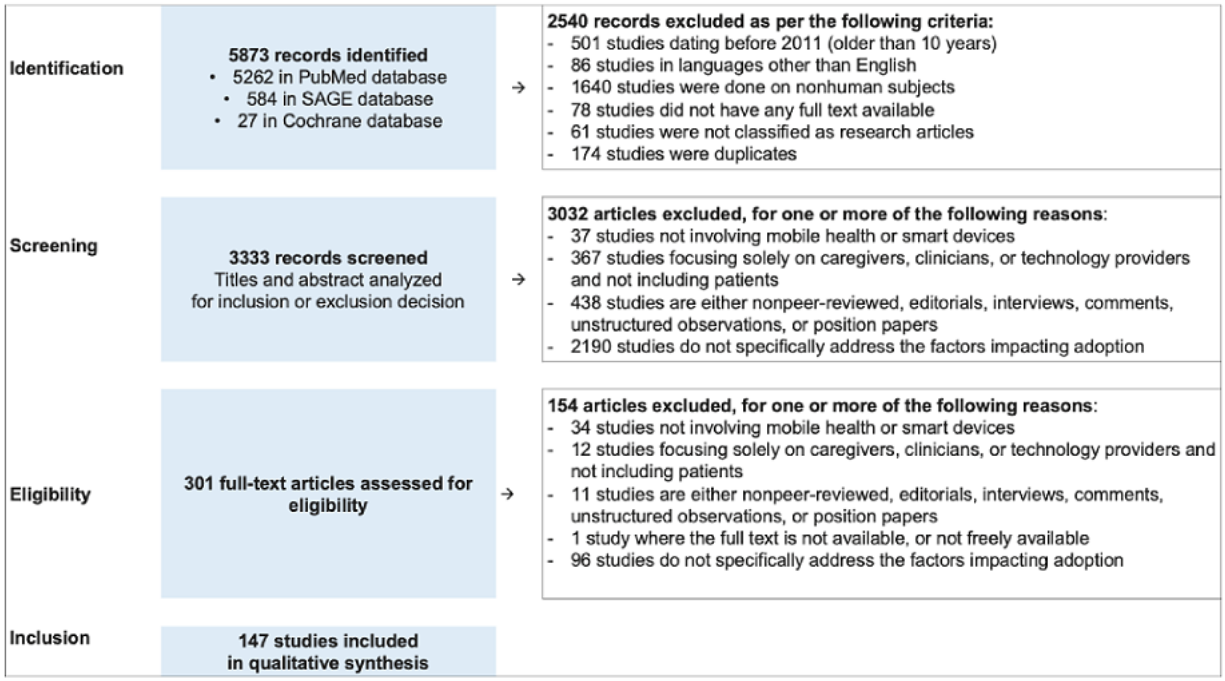
Therefore, the authors were guided in their thinking about technology adoption by theoretical frameworks in the field of social studies of technology and sociotechnical theory; they view technology, roles, and practices and organizational structures as interacting parts of a mutually constituting ensemble of elements [26]. They used a consolidated model that the research team had previously published [24], in which they reviewed and aggregated the most used frameworks applied to technology adoption in health care. Most factors could be linked to one framework or another, but there was no single framework that could adequately cover all relevant and specific factors without some expansion. This led the authors to suggest a shift toward an extended framework that considers the complexity of the health care landscape, its highly regulated nature, and the interdependence between its different stakeholders [24]. This is aligned with what other scholars have also suggested, explaining that many of the broadly used frameworks adopt a technology-centered view focusing on the tool itself [27-30], and proposed a move to multidimensional models that go past usability to encompass the surrounding context, as well as societal and implementation challenges [27,28,30-33].

## Results

### Overview

As shown in the study selection flow diagram (Figure 2), the search string yielded 5873 studies, of which 5262 (89.6%) were from PubMed, 584 (9.9%) from SAGE, and 27 (0.5%) from the Cochrane database. Of these 5873 studies, 2540 (43.2%) were excluded after limiting the scope to studies published in English and published after January 2011, leaving 3333 (56.8%) studies for screening. Screening of the titles and abstracts excluded another 3032 articles because 37 of them did not involve mHealth or smart devices; 367 focused solely on nonpatient populations such as clinicians, caregivers, or technology providers; 438 were editorials, interviews, comments, unstructured observations, position, or non–peer-reviewed papers; and 2190 did not address factors affecting adoption.

**Figure 2.** Study selection flow diagram on the basis of the PRISMA (Preferred Reporting Items for Systematic Review and Meta-Analysis) guidelines.






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In the eligibility phase, 301 articles were included for full-text assessment. A total of 154 articles were excluded for the following reasons: 34 for not involving mHealth or smart devices; 12 for focusing solely on nonpatient populations such as clinicians, caregivers, or technology providers; 11 for being editorials, interviews, comments, unstructured observations, position, or non–peer-reviewed papers; 1 because the full text was not available; and 96 for not addressing the factors affecting adoption. This resulted in the inclusion of 147 articles for the qualitative synthesis [34-180].

## Characteristics of Included Studies

Multimedia Appendix 4 presents the sample characteristics of the included articles. Overall, 85 studies focused on patients, 24 on both healthy and sick people, 24 on patients and health care professionals, 4 on patients and caregivers, and 10 included patients and other populations, such as clinicians, researchers, policy makers, and medical students. From a disease area perspective, some were more represented than others in the included studies; 16 studies focused on diabetes and obesity, 13 on cardiovascular disease and heart failure, 13 on mental health, 11 on surgery, 10 on oncology, 9 on chronic diseases, 8 on primary care, and 6 on neurology and neurosurgery, whereas the other disease areas were represented ≤4 times in the included studies.

Most of the publications did not mention the use of a theoretical framework. Among those that used one, the Unified Theory of Acceptance and Use of Technology was the most common (n=12), followed by the Technology Acceptance Model (n=11) and the Diffusion of Innovation Theory (n=2). Other models were used only once, as described in Multimedia Appendix 4.

From a geographical perspective: 46 studies were conducted in the United States, 12 in China, 10 in the United Kingdom, 8 in Canada, 5 in Australia, 5 in Germany, 5 in Singapore, whereas other geographies were covered in ≤4 studies. From a sample size perspective, most of the included studies had a sample size >100 participants (n=80), whereas most studies that included smaller samples were qualitative in nature and did not necessitate the larger samples that are typically required in quantitative approaches.

## Critical Appraisal

On the basis of the critical appraisal, 42.8% (63/147) studies did not clearly justify their choice of study design, but still used a design that is suitable for their objectives, 4.8% (7/147) did not report a clear participant recruitment strategy, 0.7% (1/147) did not provide sufficient details on the data collection techniques, 19% (28/147) did not report if the study procedure was reviewed for ethics approval, 18.4% (27/147) were not clear enough about their data analysis strategy and whether it was sufficiently rigorous, and 8.2% (12/147) did not sufficiently discuss the practical or policy implications of their findings. However, articles were not excluded based on technical quality to enable researchers to capture both theoretical and empirical contributions from the published studies.

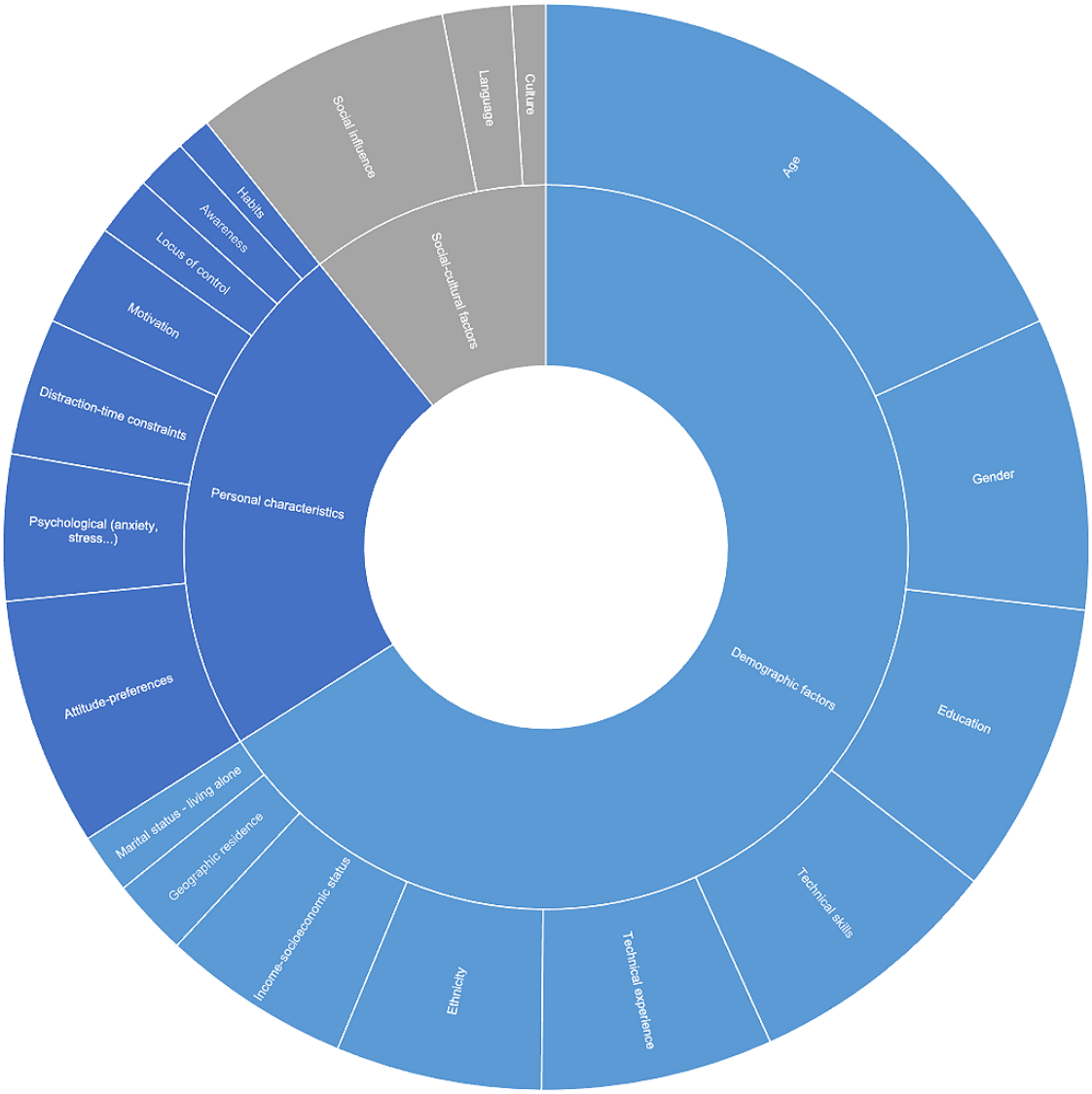
## Social and Personal Factors

The social and personal factors affecting patients' adoption of mHealth were categorized into three key themes: demographic factors, personal characteristics, and cultural and social elements. These were, in turn, subdivided into 19 subthemes. Figure 3 provides an overview of these social and personal factor themes and subthemes and their respective occurrence.



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**Figure 3.** Overview of social and personal factors and their occurrence.



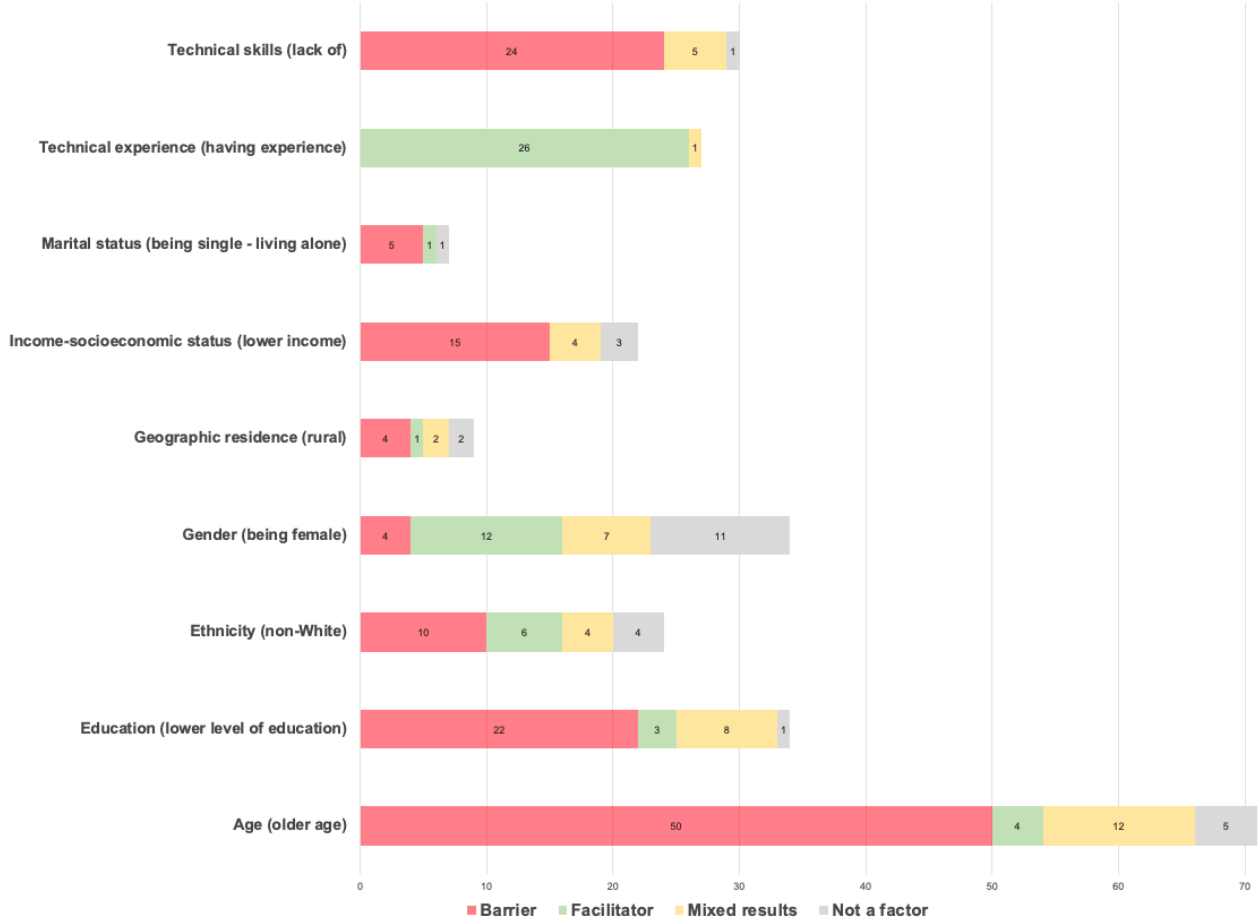

Demographic factors were the most prominent, often related to matters such as age (n=71), gender (n=34), education (n=34), technology skills (n=30), technology experience (n=27), ethnicity (n=24), socioeconomic factors (n=22), geographic residence (n=9), and marital status (n=7). An in-depth analysis of the demographic factors was also done to clarify which factors were mostly cited as barriers (they hinder adoption), facilitators (they facilitate adoption), mixed results (their relationship to adoption is not linear and may vary based on context), or had no impact on adoption according to the included studies, this subanalysis is visualized in Figure 4.

Personal characteristics also played a central role, with factors such as patient attitudes and preferences (n=29), psychological factors (n=17), time constrain and distraction (n=16), and motivation (n=12) being in the center. Other personal characteristics were also mentioned, including the locus of control (n=7), awareness (n=6), and habits (n=5). These factors were complemented by cultural and social elements including social influence (n=30), language (n=8), and culture (n=4). Multimedia Appendix 5A details the social and personal factors affecting adoption, their occurrence, and the respective studies where they were identified.



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**Figure 4.** Subanalysis of the demographic factors according to their classification in the included studies.




## Technical and Material Factors

The technical and material factors affecting patients' adoption of mHealth were categorized into six key themes, which were in turn divided into 20 subthemes: usefulness, ease of use, data-related, monetary factors, technical issues, and user experience. Figure 5 provides an overview of these technical and material themes and subthemes and their respective occurrence.

Usefulness was the most prominent factor in the technical and material clusters and was often related to matters such as perceived benefits and performance expectancy (n=55), convenience and accessibility (n=40), communication (n=36), health education (n=33), self-management (n=31), quality of care (n=12), health benefits (n=12), monitoring (n=11), early detection of symptoms (n=6), personalized feedback (n=5), and quality of life and well-being (n=4). Ease of use (n=54) was also very prevalent, as were data-related factors, mostly evolving around privacy and security (n=51), quality and credibility (n=20), and relevance (n=6).

There was also a frequent mention of monetary factors (n=35), such as cost and reimbursement, as well as user experience, where the focus was mostly on the usability of the tools (n=19) and personalization (n=17). Technical factors evolved around technical issues such as infrastructure and log-in problems (n=43), access to technology (n=20), training (n=13), and technical support (n=5). Multimedia Appendix 5B details the technical and material factors affecting adoption, their occurrence, and the respective studies where they were identified.



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**Figure 5.** Overview of technical and material factors and their occurrence.




## Health-Related Factors

Health-related factors affecting patients' adoption of mHealth were categorized into six key themes: the disease or health condition, the care team's role, health consciousness and literacy, health behavior, relation to other therapies and integration into patient journey, and the patients' insurance status. Figure 6 provides an overview of these health-related themes and subthemes and their respective occurrences.

The disease or health condition that the patient had was not only the most prominent factor, often related to matters such as perceiving the worse condition as a barrier to adoption (n=21), but also a facilitator in other contexts (n=11). The disease type itself may also be a factor (n=7) and the patient's risk perception of their health condition (n=5), whereas other studies found that the health condition was not a factor (n=3). Similarly, the care team's role was mostly reported as a facilitator (n=14), but also sometimes as a barrier (n=8), although some papers reported mixed results (n=4).

Other health-related aspects such as health consciousness and literacy (n=17), relation to other therapies, and the integration of mHealth into the patient journey (n=15), as well as the patient's baseline health behavior (n=7) and insurance status (n=5) were cited as potential factors that may affect health technology adoption. Multimedia Appendix 5C details the health factors affecting adoption, their occurrence, and the respective studies where they were identified.



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**Figure 6.** Overview of health-related factors and their occurrence.




## Principal Findings

The main findings of this review emphasize the central factors affecting patients' adoption of mHealth tools. Analyzing the prevalence of the different factors sheds light on the significance of social and health-related factors that go beyond technical features, stressing their importance when developing and deploying these tools.

## Social and Personal Factors

The prominence of social and personal factors in the included studies highlights how mHealth adoption is closely connected to and shaped by the societal dynamics in which they are embedded. Demographic factors, personal characteristics, and other social and cultural elements may play a key role in patients' willingness to adopt an mHealth tool.

## Demographic Factors

Age was the most prominent demographic factor, with older age mostly cited as a barrier, and many studies have reported a negative relationship between age and willingness to use such tools [34-55]. Some studies further explained that this may not be because of age per se but indirectly because of other factors such as older individuals facing physical or cognitive challenges [56,57], unfamiliarity with the use of technology or smartphones in general [58-63], or lack of phone ownership [64-66]. In the case of solutions dedicated to child patients, parents' age was negatively associated with their willingness to use digital tools,



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whereas children's age was positively associated with their willingness to adopt these tools [67].

Nevertheless, older age was cited as a facilitator in some studies, with older patients being among the highest adopters and the most adherent users [68-70], especially in cases where there is a clear need such as during the COVID-19 pandemic when a remote health service may help older patients minimize infection risk [71]. Other researchers have reported that age is not a factor, and that older patients are as interested as their younger counterparts, especially after adjusting for other factors, such as technology skills and experience [72-76]. This may explain why some studies concluded that increasing age should not necessarily be considered a limitation because it mostly depends on the context and other related factors [77-80], suggesting that ensuring ease of use and delivering better training could help close this gap [81-83], and that a better understanding of how the tools may help them improve their condition could motivate the adoption decision [84,85].

Gender was also a prominent demographic factor, with being female mostly cited as a facilitator, and many studies reporting on the positive relationship between being female and the willingness to use such tools [39,51,55,71,85-88], with some researchers describing that this may be because of gender-specific behavioral patterns, as women frequently undertook the role of *health care liaison* for their families [82], that mothers may experience more anxiety than fathers and are therefore more likely to seek alternative solutions [67]; therefore, these gender-related use patterns may very well be because of the care role that society assigns to women rather than gender per se [54,83]. Furthermore, this may be because of trial bias and self-selection bias presented by female participants, as seen in the patient characteristics of many mHealth studies. However, it is worth noting that an equally prevalent number of studies reported that gender was not significantly associated with the adoption decision [36,40,45,50,53,62,68,73,89-91].

Conversely, some studies have concluded that adoption is more widespread among male users [43,92,93], sometimes because of other related factors, such as more prevalent phone ownership among male members of a specific society [65]. Moreover, other researchers have established that gender is not necessarily a decisive factor, and that adoption may vary according to the context and other factors [49,94,95]. For instance, Abelson et al [77] explained that while women in their study were more likely than their male counterparts to be anxious about losing face-to-face communication with their care providers, they were also more likely to welcome the benefit of avoiding unwarranted clinic visits. Other studies noted that women may tend to be more adopters of specific types of digital tools compared with others. For example, Beard et al [35] noted that women are more likely to adopt mental health apps, but less likely to adopt other types of apps that use entertainment, for example, compared with men. Gender-specific behavior may also differ according to the health condition in question, as reported by Foster et al [69], where adopters were most likely females in the depression trial and most likely males in the cardiovascular disease risk trial.

Education was another prominent demographic factor, with lower levels of education mostly cited as a barrier, and many studies have reported a positive relationship between the level of education and the willingness to use mHealth tools [35,49,53,55,64,65,72,84,92,96-98]. This was explained in some studies by lower access to, and skills in using technology [89,90], and lower eHealth literacy among the less educated in some contexts [44]. Only one study reported that education was not significantly correlated with adoption [68].

Unexpectedly, some studies concluded that lower education may, in some cases, facilitate adoption [45]. For example, people with less education may have higher health information needs that, in turn, foster their digital information–seeking behaviors and consequently promote adoption [88], or they may be more likely to seek alternative or supplementary solutions when care problems occur [99]. Other researchers established that education is not necessarily a conclusive factor, and that adoption may vary according to the context and other factors [95], such as lower rates of computer and internet access among the less educated [82], lower technical skills [78], and differences depending on the type of solution at hand [39,51]. Furthermore, Torrent-Sellens [83] found that the relationship between education and adoption was not linear but rather U-shaped, with usage being greater among participants with a secondary education and lower among those with primary and tertiary education.

Technology-related skills were predictably among the most prominent factors, with the lack of technology skills being cited as a barrier, and numerous studies have reported a positive relationship between technology skills and the willingness to use mHealth tools [52,62,74,80,100-103], especially among older patients who may lack these skills [61,69,77,79,103-105]. Some studies concluded that a lack of technical skills may be the underlying cause of lower adoption in older age groups, not their age as such [72]. However, one study stated that self-efficacy and a person's perception of their own skills did not have an impact on adoption [36]. Although the lack of technical skills was typically perceived as a hindrance to adoption in the included articles, some studies reported that it is not necessarily the case; for example, if the person believes that everything can be learned, it is no longer considered a hindrance, meaning that the adoption decision also depends on the person's attitude and openness to learn new skills [106] and on other contextual factors such as the availability of training and some additional help or support [58,64,66,107].

Similarly, technological experience was prominent, with all studies except one reporting a positive relationship between previous technology experience and adoption decisions, stating that factors such as previous smartphone use or ownership [84,92,96,107], ownership of wearable devices [49], use of health apps [38,46,54,56,83,97,109-113] or apps in general [40,48,78,85], and broad experience with digital technologies [102,114-118] may increase the odds of mHealth acceptance and adoption. However, Zhang et al [127] pointed out that even users with previous technology experience may still choose not to adopt a tool that they perceive as irrelevant or less useful compared with their traditional methods in receiving health care.



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Ethnicity came up in several studies, with being non-White mostly reported as a barrier to adoption, and a negative relationship between mHealth acceptance and being of non-White ethnicity [35,71,84,119,120], sometimes relating the impact of ethnicity to other indirect factors, such as socioeconomic factors [62], lower health literacy [121], less access to technology [64,66], and insurance status [122]. However, some studies have reported mixed results [95], with ethnicity being a significant factor in some contexts and not a factor in others, as described by Foster et al [69], who highlighted that the relevance of ethnicity varied in the different trials they conducted depending on the health condition in question. Other researchers who also reported mixed results pointed out that ethnicity itself may not be the real factor, but rather other underlying triggers such as systemic racism and the existing disparities in health services that may have increased the need for such alternative solutions among non-White patients [123]. In other contexts, being non-White was reported as a facilitator of adoption [43,51,124,125], which was sometimes linked to other contextual factors such as non-White patients being less concerned about privacy issues compared with their White counterparts [77], or more use of mobile apps in general and the perception that mobile phones are essential, predominantly because of the lack of home landlines [44]. However, some studies concluded that ethnicity had no impact on patients' decisions to adopt mHealth [50,53,86,90].

Although some researchers have established that socioeconomic factors such as income have no impact on mHealth acceptance [48,50,52], lower or insufficient income has often been reported as a barrier to adoption [37,43,44,57,63,77,83,84,90,91,126], frequently citing other interrelated factors such as insurance status, skills and education, or access to technology [51,82,89,127]. There are also studies that have reported mixed results where income may be a factor in some contexts but not in others [41,95], sometimes depending on other elements such as the level of education [62] or the specific health condition [39].

Geographic residence seems to also sometimes affect adoption, and several papers reported that living in a rural area is mostly considered a barrier to adoption [71,83], sometimes owing to lower technology access because of a less developed infrastructure in some rural areas [89]. Jaffe et al [50] reported that the prevalence of mHealth use in some regions more than others may also be related to other interrelated factors such as a lower number of COVID-19 infections in the regions that had lower adoption rates, most likely because there was less need for mHealth use in those regions with fewer cases. Rush et al [113] is the only study that concluded that living in a rural location may be a facilitator because of the long distances that a patient has to travel to access health care services and the life-saving effect that a remote service may have in such cases. Nevertheless, some studies have reported mixed results [76,95], whereas others have found that geographic residence was not a factor affecting adoption decisions [90,91].

Interestingly, marital status was also reported as a potential demographic factor affecting the adoption of these tools; seemingly, being single or living alone was usually a barrier [43,83,119], most likely because of the absence of accountability and support that a significant other may offer [82,95]. One study concluded that marital status has no impact on adoption [53], and another study reported that living alone or being single, divorced, or widowed may increase the odds of using mobile health [50].

### Personal Characteristics

Patients' attitudes and preferences are among the most prevalent personal characteristics that may affect mHealth acceptance. For instance, preference for face-to-face interactions with their care team [37,77,115,119,127,128], resistance or openness to change [36,45,129,130], negative or positive perceptions of mHealth [41,43,56,60,62,83,87,102,114,131-134], lack of interest [55,58,69,101,103], and fear of technology [135] are all elements that play a role in whether a patient is more or less receptive to these technologies.

There are also important psychological aspects to consider, such as individual-level processes and meanings that influence mental states. For instance, although mHealth may increase the feeling of safety for some patients as they know they are being monitored or have access to additional safety measures [67,80], it may trigger a sense of anxiety and stress in others for many reasons, such as being constantly reminded of their symptoms and so their disease [80,101,107,118,136-139], with these feelings sometimes subsiding when patients become more comfortable managing their own condition [112]. Furthermore, sometimes patients may give up the use of mHealth because they are overwhelmed or struggling to cope with their condition [140], they do not want the additional stress of managing their condition and prefer relying on their care team [73,79], or they may lack the emotional capacity to even try to use the tools [69]. Interestingly, users may also abandon digital tools and choose face-to-face examinations because of their emotional need to have physical contact and get out of the house [115]. Conversely, mHealth may help overcome some psychological challenges by enabling patients to receive health care services in a more private way, particularly in stigmatized areas such as mental health services [85].

Distraction and time constraints may also interfere with mHealth adoption, some patients drop the apps because they tend to forget to use them [100,110,133], get too busy with other competing priorities that take up all their time [69,80,91,100,112,115,116,137,138,140,141], find the tools too time consuming [55], or get annoyed by the interference of the app with their daily life through frequent reminders at unsuitable times that cannot be customized to their schedules [118,120]. This factor may also relate to a patient's existing habits [57] and how a successful adoption is tied to the person's willingness to embed the mHealth tools in their day-to-day routines to become a natural part of their existing agendas [70,140]. Haldane et al [110] pointed out that it might be easier for newly diagnosed patients to adopt these tools compared with established patients who have been managing their conditions using traditional methods for a long time. Conversely, other scholars have concluded that habit may not necessarily be a hindrance to adoption in the case of user-friendly tools that only require minimal effort and no major change in the user's daily habits and routines [142].



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Motivation is another personal characteristic that emerged as a noteworthy determining factor of behavioral intention to use new health technologies [140,142,143]; hence, motivating patients to use mHealth may be a challenge, especially if they perceive the tools as a burden or as not useful to them [130,144]. The lack of motivation in general [100,107,145] or lack of engaging mechanisms within the apps themselves may also be a challenge to adoption [146], whereas apps that include motivational elements such as rewards or interactivity may encourage adoption [101,114,147]. Similarly, self-efficacy and locus of control may also affect patients' decisions to adopt mHealth; people who feel that they are more in control of their life and their condition are more intrinsically motivated to adopt self-management tools [80,140,148], and they are more likely to adhere to the tools when they feel responsible for their health and see it as an important purpose [110,143]. Furthermore, the lack of awareness and knowledge of mHealth apps may negatively affect patients' intentions to use them [58,60,102,127], especially with the vast number of apps available, which makes it difficult for patients to choose the one that suits them most [78,135].

### Social Influence and Cultural Factors

Several scholars argued that patients are often subject to the social influence surrounding them when making their health technology decisions [78,129,131,140,149,150], such as the presence or absence of caregivers who can encourage and support them in using the apps [70,107,108,115,128,132,151,152], particularly in the case of people with less technology experience or those surrounded by a social circle that lacks technology experience [95,110,142]. Interestingly, the presence of strong social support and people who constantly care for the patient may sometimes discourage adoption as the person gets enough help from their caregiver and deems mHealth unnecessary [102]. It is also worth noting that social influence was not limited to the patient's personal social network but also to the care team's endorsement [81,153], input and support from other fellow patients who had undergone similar experiences through online communities and forums [104,113,118,154-157], or membership of a patient association [57]. Khalemsky et al [67] pointed out that this factor may also depend on the level of a person's emotional autonomy, especially in the case of sick children and their relationship with their parents. In other contexts, researchers found no impact of social influence on adoption decisions [36].

Language barriers such as lack of language options in the tools may hinder adoption and compromise user experience [61,106,110,158], especially in the case of patients with low literacy [159,160]. This also applies to tools that use a complicated medical or technical language that is not easy for the patient to understand [78,158]. Conversely, Spooner et al [44] argued that the brevity and accessibility of some forms of mHealth tools, such as those using text messaging, may help overcome language barriers as they require less fluency compared with in-person or phone communication. Culture may also be an influencing factor, accounting for cultural nuances and tailoring the content to specific cultural beliefs and attitudes may foster adoption [95,118,121]. Gender issues in some cultural contexts may be a challenge; Duclos et al [115], for example, explains how male dominance may compromise mHealth implementation in some countries, as husbands prevent their wives from owning or using a phone.

### Technical and Material Factors

It is no surprise that technical factors related to mHealth tool features and capabilities also played a central role in adoption. Factors such as usefulness and ease of use are crucial for patient acceptance, as well as user experience and personalization, data-related factors, monetary factors such as cost and funding, and technical factors including access to technology and technical challenges.

### Usefulness

Perceived benefit and performance expectancy were among the key factors affecting patient acceptance of health care technologies, indicating that user adoption has much to do with the tool's performance [40,76,78,81,92,94,101,110,114,129,134,140,142,146,147,150,156,161,162], especially if they find it more useful compared with their current methods [87,106,117,141,157]. This perceived usefulness is not always related to the disease itself, but may also extend to other benefits such as better relaxation, an enhanced quality of sleep, or a sense of achievement [100,107,163]. In this context, it is important to note that a good understanding of the tool's purpose and how it aims to help the patients may lead to higher adoption [60,132,137,164]. Furthermore, evidence of effectiveness may also encourage patients to start using the apps [43]. Similarly, lack of functionality or information [154] and lack of necessity or suitability [79,102,127,165,166] may lead to the tool's abandonment. Surprisingly, Koivumäki et al [167] reported that their study found no impact of a tool's performance on its adoption, contrary to most other studies.

Convenience and better access to care are typically facilitators to adoption [38,70,75,107,111,120,130,135,167,168], as mHealth tools may help save time and the cost of frequent clinic visits [77,105,128,137,151,169], are more flexible and may fit better in the patients' schedule [61,92,115,170], and immediate access to care may also be convenient, especially when it is not easy to reach a physician on weekends or in the evening, for example [79,127,141,144]. Some studies specified that longer travel times [34,65,96,103,116] and difficulties accessing traditional care services are similarly positively related to health app adoption [54,74,99,113,152]. Conversely, Kemp et al [119] reported that travel distance does not have a significant impact on adoption decisions.

Communication between patients and their care team and whether it is positively or negatively affected by the use of mHealth apps also affects patient acceptance [70,75,152,160,171]. Several studies have reported that mHealth may positively affect communications [128,130,131,136,141,154,171], for instance, by enabling a quicker and easier exchange with their care team [60,61,79,80,98,104,113,116,118], and hence foster adoption. In contrast, other scholars concluded that in some contexts, users may perceive a negative impact on their communication with their care team [69,92,111,115,173], as it is less personal [52,107,146,165,168,169], leading to lower acceptance and adoption. It is worth



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noting that some studies have pointed out the importance of combining web-based and offline communication to encourage adoption, suggesting that mHealth should complement traditional care and not replace it [79,137].

Health education was perceived as a facilitator of mHealth adoption in all included studies [88,105,107,113,116,118,147,152], and the educational and informative content in the apps may address knowledge gaps, raise disease awareness, and encourage healthier behaviors. Such benefits may encourage patients to accept these tools as they help them better understand their medication and possible drug interactions [40,42,79,104,130], their symptoms [101,136], and their specific condition [38,53,80,102,141,149,154,155,170,174,175], and hence achieve better health results [140,145,157].

Self-management is another factor that is predominantly perceived as a facilitator [104], helping patients be more proactive in coping with their condition [43,164], more conscious of their health condition and behaviors [60,117,141,145,157], more engaged in self-care [61,70,75,79,80,101,109,113,118,139,140,152,163], and feeling more secure and confident in managing their disease [120,131,136,149,161]. This particularly applies in the case of newly diagnosed patients, as it may help them build and adopt new habits to better manage their condition [144]. Woo and Dowding [102] found that patients who have been successfully managing their condition using traditional methods for a long time may be reluctant to adopt mHealth tools as they may fail to see their value. Conversely, Fairbrother et al [175] reported that patients may not engage in self-management as they perceive this to be the responsibility of their care team, so they may choose to adopt mHealth to enable their care teams to better monitor them but not to engage in proactive management of their own condition.

Several studies have reported that mHealth adoption may improve health outcomes [42,55,114,149]. Patients who perceive potential health benefits such as better health effects and enhanced health behaviors resulting from the use of these apps are more likely to adopt them [49,58,98,107,117,138,140,141]. Similarly, tools that target a better overall quality of life that go beyond solely focusing on the disease or health condition are usually highly appreciated and may have better chances of being accepted by patients [70,103,135,176].

Continuous monitoring may encourage adoption as it increases patients' feeling of safety because their care team constantly monitors them [77,79,80,120,170,174], allowing for treatment optimization and better control of the condition [107,145], and a clearer overview of patients' development for better follow-up [104,155]. Early detection of symptoms and health care issues is another benefit closely related to monitoring and may foster adoption, as the tools allow the care team to stay in the loop between clinic visits and intervene in case of symptom deterioration [40,80,87,101,107,144].

Seeking a better quality of care as an outcome of mHealth adoption may motivate user acceptance, several studies reported on quality improvement and better continuity of care [42,118,168-170,172], streamlining the processes of follow-up and care management [61,113,163], enhanced documentation and evidence-based health decisions [174], and a more holistic and individualized care approach [79,135], as potential facilitators. Personalized feedback is a closely related factor that may also enhance the overall quality of care and facilitate adoption as it enables a more patient-centric approach tailored to each patient's individual needs [95,101,147,170].

### Ease of Use

Ease of use is one of the leading factors affecting mHealth adoption [70,104,107,117,150,160,161,163,177], patients would typically abandon tools that are complex or require a lot of effort [55,56,59,60,97,120,135,142,162,165,175], especially when they are already burdened by their condition [77,129]. In contrast, easy-to-use technologies that do not overburden patients have higher odds of being accepted and adopted [36,38,49,57,58,76,78,94,101,102,112,114,130,131,134,136,139,149,157,170]. Some studies have suggested that users' perception of ease of use may be enhanced with good training material that shows the user how to optimize their use of these technologies [72,110,132,147], and by applying a more participatory approach to design that ensures the inclusion of patients in the development of tools [81,95].

### User Experience

Usability was often mentioned in the included study, especially with the multitude of tools available to patients to choose from; they would most likely adopt tools that give them the best user experience [40,60,107,129,137,139,173]. Elements such as app appearance and attractiveness, including font size, navigation, layout, colors, text length, automated features, and interactive design, may play a role in the adoption decision [78,130,135,146,152,154,157,162,178]. Some studies have pointed out that design factors such as font size, color brightness, and screen size may play a particularly important role with more senior users and therefore must be tailored to their cognitive and physical capabilities [101,110,136].

Personalization has been specifically mentioned in several studies; for instance, the inability to personalize the app according to their specific needs (eg, diagnosis, symptoms, medication, stage of treatment) may lead to lower adoption or even abandonment of the tool [98,146,162,164]. Patients often prefer to be able to adjust the tools to their specific needs [101,104,107,118,130,138,154,157,160]; for instance, the timing of prompts and frequency of reminders [164], adjusting the app to their preferred goals and activities [147,165], and adjusting visual features such as colors and text size [78,118]. It is worth noting that Zhang et al [133] pointed out that patients' desire to have more personalized solutions may be related to a decrease in their privacy concerns.

### Data-Related Factors

Privacy and security are without a doubt very important factors; they were mostly perceived as a concern and a barrier to adoption, with many studies reporting on the importance patients put on the protection of their personal health information [38,40,43,52,55,61,85,87,97,101,108,128,130,137,139,168,169,175], typically requesting to know who will have access to their data and how the data will be protected against cybercrime [77,104,107,116-118,129,141,146,147,152,160,165], and



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sometimes voicing concerns or demanding control on whom to access their information, including other family members [58,155,157].

Conversely, some studies found that privacy may also facilitate adoption when patients perceive the apps to be secure and to offer a private way of sharing their health data [57,167], especially with users who already practice high privacy measures such as locking their phones with strong passwords [96]. Interestingly, van Heerden et al [174] pointed out that clinicians and patients are already using their smartphones to communicate and exchange information, which makes mHealth tools a more private and secure option compared with generic communication apps.

Other studies reported mixed outcomes regarding data privacy and security, expressing that not all participants perceived this factor as a barrier or as a facilitator but recognized both the advantages and the threats that it brings and highlighted the importance of securing the data [78,92,154,172]. For instance, Amann et al [144] explained that although some participants expressed concerns about data privacy, they also acknowledged that it is necessary to obtain the support they need through the app. Bauer et al [164] reported that although patients felt reassured knowing that their care team could access data about their symptoms through the app, they were simultaneously concerned about who else could have access to these data. Lupiáñez-Villanueva et al [93] concluded that patients do not have the same sensitivity to data privacy, and that their level of sensitivity may differ from one context to another. Interestingly, their study found that even users who are quite concerned about privacy are not necessarily willing to pay for it but rather would prefer their data to be protected by legal requirements [93]. Nonetheless, a few studies reported that they found no, or very minimal, impact of data privacy concerns on the adoption decision [69,94,120].

Quality, credibility, and reliability of the data available through mHealth tools may also play a role in the adoption decision [107,109,127,130,179]. The credibility of the information on the tool from the patients' perspective often increases when it is provided or endorsed by trusted sources [40,58,78,93,110,116,154,175], reassurance that the information on the app is up-to-date to ensure its accuracy [144], and scientific evidence that warrants the app's safety and reliability [57,59,101,113,118]. Relevance and appropriateness of the information offered by the app may also affect patient acceptance; content that is appropriate for users may foster adoption [118,146], whereas information that is not relevant, inappropriate, or not tailored to patients' needs may discourage adoption [117,137,162]. For instance, Connor et al [154] explained that even an inappropriate tone, such as pushing too many tips through an app, could lead users to abandon it, especially if they are very sick.

### Monetary Factors

Monetary factors such as app costs and lack of reimbursement were mostly perceived as barriers to adoption [61,91,131,169]. Several researchers have reported that patients may not be ready to pay for health apps or choose to pay only for the features that they find crucial for their perceived health benefits [78,104,106]. Hidden costs generated through extra data use were also mentioned as a potential barrier to adoption [55,58,97,118,152], which is particularly relevant in specific socioeconomic contexts where prepaid mobile services are the norm, and an overuse of the data package may result in service discontinuity [166]. Additional costs resulting from the patient's need to buy new technology to facilitate mHealth use may also deter adoption [52]. Conversely, mHealth affordability was reported as one of the facilitating factors in other studies [111,116,167], and it could even help save costs, mostly by saving travel time and expenses [43,80,105,113,151,172]. Interestingly, other researchers have reported no impact of mHealth costs on patients' intentions to use mHealth [81,129,142]. Other scholars reported mixed or inconclusive results, stating that some users may be more cost-sensitive than others [42,65,92,93,126,168], for instance, younger users may be less willing to pay for health apps [65,168].

### Technical Factors

Technical issues were frequently cited as a barrier, with issues such as technology failure, insufficient phone storage, battery drain, syncing, and technical difficulties creating frustration and discouraging adoption [37,68,70,77,80,100,114,118-120,130-132,135,137,138,141,151,178]. Poor technology infrastructure, including connectivity, network availability, and Wi-Fi issues [65,77,78,102,112,116,118,120,132,148,152,155,158,166] as well as log-in difficulties [78,152,170] were also prevalent in the included studies. Access to technology is another important technical factor that should not be overlooked. Several studies have reported that the lack of patient access to technologies such as smartphones, computers, or specific apps [34,43,66,85,92,100,103,107,108,115,128,132,166], or lack of internet access [37,52,69,95,127], especially among older patients [135,157] could be barriers to mHealth adoption.

Training emerged in several studies as a particularly important factor for adoption given the disparity of technical skills among patients, especially in the older age groups and users with low levels of education [70,79,80,100,108,116,117,131,157,162]. The lack of such training may be a major concern and a real barrier to adoption [61,171,174]. Furthermore, technical support has often been cited as a facilitator to patient adoption if it is available and efficient in helping users overcome their technical issues [70,102,131], but it could also be a barrier if it is not adequate, leading users to abandon the tools when they do not feel supported when they face technical difficulties [55,117].

### Health-Related Factors

Health- and health care–related factors were equally central in the included studies. Elements such as the specific disease a patient has, the severity of their health condition, their health behavior, health consciousness and literacy, the relation of the mHealth tool to other therapies, and the role that the care team plays may affect a patient's willingness to use mHealth tools. The patients' disease and health condition may affect their decision to adopt mHealth. The severity of symptoms and complexity of the health condition were prevalent factors in the included studies; however, there were mixed results on whether they were a barrier or a facilitator. It is worth noting that the studies that established that more severe disease could be a



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barrier to adoption were about twice the number of studies that found it to be a facilitator.

Several researchers have reported that their studies found that patients with low baseline health, worse baseline clinical disease activity, higher prevalence of chronic conditions, high level of comorbidity, higher levels of pain and fatigue, higher frequency of hospital readmission, and those who were hospitalized or in the end-of-life phase were less likely to use the apps [52,64-66,68,73,76,80,107,112,114,115,119,148,159,161]. This could sometimes be explained by the closer follow-up usually needed by patients with a worse condition, resulting in a reduced need for mHealth [57]. In some specific cases, such as mental health disease, patients having a depressive episode, or those with more depressive symptoms, for example, may experience a sense of hopelessness that makes them disengaged in many aspects of life, including health care apps [104,121]; similarly, patients with severe psychotic symptoms may have an exaggerated sense of fear of the potential surveillance resulting from remote monitoring apps [117].

Conversely, other studies found that patients who are more affected by their disease or health state may be more motivated to use mHealth to manage their condition better [39,41,49,83,89,98,132]. For instance, Ross et al [138] reported that patients with higher pain ratings had a higher adoption rate, most likely because their perceived benefit from the app is higher compared with those who have pain levels under control. Similarly, Runz-Jørgensen et al [79] explained that patients with a higher burden of illness placed a higher value on the benefits that they could obtain from mHealth. Interestingly, 3 studies concluded that disease and health condition did not have a significant impact on patients' decision to use mHealth [35,48,100].

Some studies have also reported that the disease type may be a factor that affects patients' intentions to adopt health apps [83,90,91,120]. For instance, health care technologies seem to be more accepted among mental health patients compared with other conditions [50,74]. Bauer et al [86] reported that mHealth use appears to be more common among primary care patients compared with those with chronic conditions; however, they rationalized that this pattern may be explained by other factors such as older age in chronic disease patients and not their health condition as such. Torrent-Sellens et al [83] affirmed that the presence of specific types of diseases such as diabetes, stroke or cerebral hemorrhage, cancer, and cataract may increase the odds of mHealth adoption. Patients' perception of the risk or health threat caused by their disease could also play a role in their adoption decision. A higher perception of risk or health threat may positively affect the adoption of health care technologies [36,110,123,129]. In addition, a higher stigma perception of the disease, such as in the case of HIV, may foster mHealth adoption [92].

The role of the care team is also central for adoption. It has mostly been reported as a facilitator, especially when the health app has been recommended by the health care provider [59,60,70,78,81,93,97,180], when patients notice how their care team responds to the data they feed into the apps and integrate it into their care [136,164], and when the care team offers coaching and support toward patients' self-management [132,134,143]. However, Gupta et al [85] warned that clinicians should be careful not to overdo the reminders to use the tools, especially with patients with high disease burden, such as patients with cancer, to avoid overwhelming them. Several studies concluded that the care team could be a barrier to adoption if they lacked the necessary skills [107,168], if they did not proactively support mHealth use [44,62,101,118,154], or if they did not monitor the information that patients submit to the apps [80].

Interestingly, some studies reported mixed results; for example, clinician engagement and support of mHealth use may depend on their medical specialty, with specialists more engaged than general practitioners in health care app use, perhaps because of their higher involvement in shared decision-making and clinician-patient communication [135,153]. It may also be confusing to patients when the care team encourages them to use the technology, but then fails to actively monitor the data they feed into the apps, which eventually leads to app abandonment even if the user initially agrees to adopt the tool [145]. Magnol et al [57] explained that although physician's recommendation could initially foster mHealth adoption, their potential lack of information on the range of available apps may also be a limitation.

Health consciousness and literacy could play a role in patients' adoption of health care technologies [40,49,51,65,72,98,107,121,134,159], as people with higher levels of health consciousness and literacy are typically more cognizant of their health issues and behaviors [93,110,142,156]. However, some studies have concluded that health literacy is not necessarily a significant predictor of mHealth use [73,81,86]. Health behavior is another factor with mixed results. Studies have reported that patients with a positive baseline health behavior, such as better medication adherence rate or a higher physical activity level, were more likely to adopt the tools [41,49,75,106]. Conversely, other researchers found that users with poorer baseline health behavior, such as a lower treatment adherence rate, felt a higher need for the app and used it more frequently [67]. Although Meyerowitz-Katz et al [98] reported a low adoption rate among those who were already healthy eaters before the initiation of mHealth use; Browning et al [48] found no correlation between baseline health behavior and mHealth use in their research.

Relation to other therapies and how the app fits into the overall patient journey and treatment path could play a role in the adoption decision. Several researchers have pointed out that although patients may appreciate the benefits they receive from mHealth, they still perceive it as a complement rather than a replacement for other components and modes of treatment [100]. When mHealth apps are used in isolation from other parts of the treatment and are not integrated into the overall patient journey, adoption rates may suffer [112-114,141,162]. Similarly, it is very important to consider any underlying comorbidities that the patients may have from before using mHealth to ensure a holistic understanding of the data they submit in the apps [80]. The type and burden of other medications may also play a role; for instance, the high burden of cancer treatment can be overwhelming, preventing patients from using an additional tool such as a health app [85]. Furthermore, patients who take



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multiple long-term medications and those who engage in multiple interventions may be less likely to adopt these tools [52,98]. Jemere et al [96] found that study participants who took medication in the form of a pill were over 3 times more likely to adopt mHealth compared with those who took medication in the form of an injection. It is also worth noting that some studies found that patients who have easy access to satisfactory care services or those who need frequent hospital follow-ups or hospitalization may have a lower mHealth adoption rate because they are often in direct contact with their care team [54,57,102,179].

Insurance status and its impact on mHealth adoption was inconclusive in the included studies. For instance, being publicly insured has been reported as a facilitator in a study by Pierce et al [71] but as a barrier in a study by Warinner et al [90]. Similarly, Anosike et al [126] found that some insured patients are less likely to use mHealth tools if they are not covered by their insurance, and Pierce et al [71] reported that privately insured patients are less likely to use these tools compared with Medicare, Medicaid, and self-pay patients. Others reported that patients who had commercial insurance or preferred provider organization insurance were more likely to use these services [37,82]. It is worth noting that adoption decisions related to patients' insurance status may differ from one country to another depending on elements such as the legal requirements of minimum insurance cover and local policies on mHealth reimbursement.

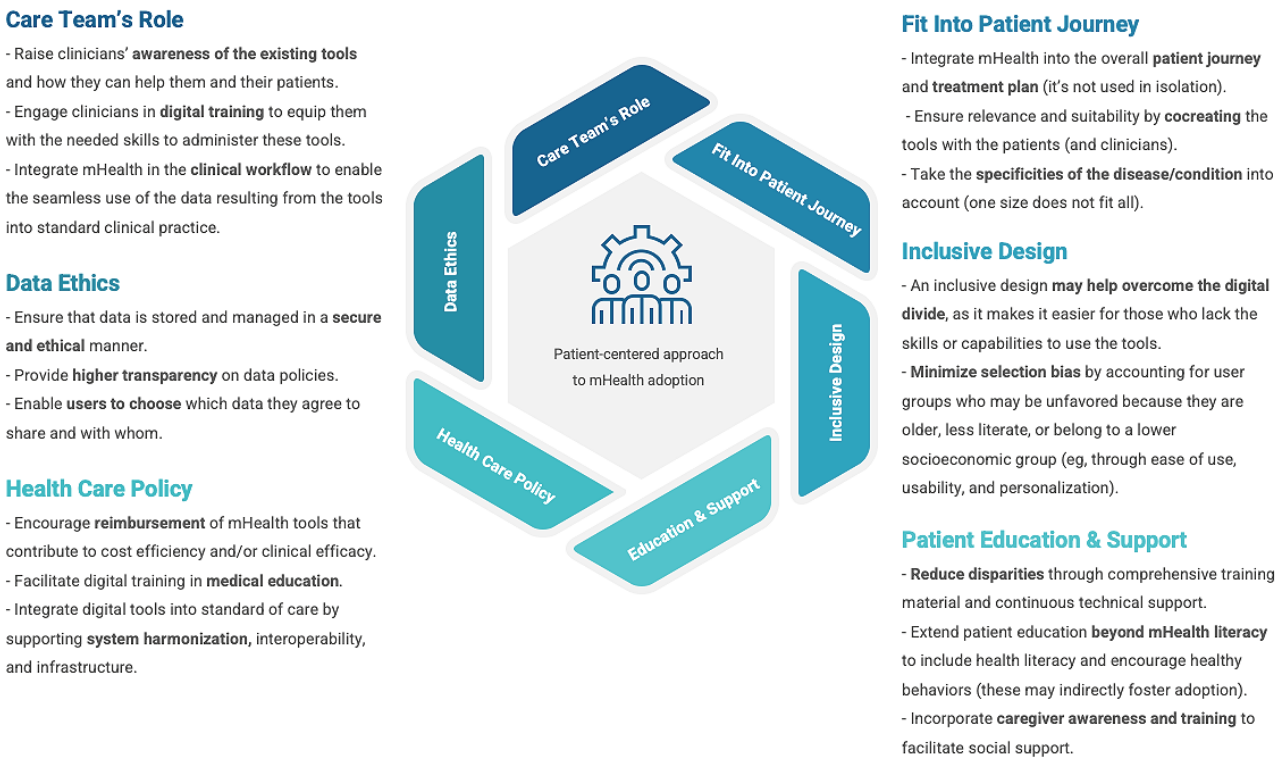
# Discussion

## Practical Implications

This review builds on the growing body of research that investigates patients' adoption of mHealth services and highlights the complexity of the factors affecting adoption, spanning personal, social, technical, organizational, and health care aspects. This implies that to achieve successful adoption and implementation of these tools, the different players in the health care landscape need to work together to overcome the barriers and harness the potential benefits of novel technologies in health care. Our findings show that mHealth developers and technology providers alone are not likely to achieve success by focusing on creating tools that are technically superior; there are social, organizational, health care, and policy-related factors that must be considered, underlining the central role of care teams and health care policy in promoting adoption.

Although some factors may be very hard to influence (eg, intrinsic motivation or a person's locus of control), others could be shifted. Figure 7 summarizes our recommendations for a more patient-centered approach to mHealth adoption, covering aspects that may help overcome some of the key barriers reported in this systematic review. This shift may be possible by ensuring the tools' fit into the overall patient journey and treatment plan, emphasizing inclusive design, warranting comprehensive patient education and support, empowering and mobilizing clinicians and care teams, addressing ethical data management issues, and focusing on health care policies that may facilitate adoption.

**Figure 7.** Recommendations for a patient-centered approach to mobile health (mHealth) adoption.






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Ensuring the tools' *fit into the overall patient journey and treatment plan***,** based on the understanding that mHealth apps are not used in isolation, is crucial for sustainable adoption. Technology providers may opt to co-create the tools with patients (and clinicians) to ensure that they have taken their overall journey into account and established how their tool relates to other treatments that the patients are receiving, any comorbidities, and how their specific health condition may influence the way they use the technology [181]. Embedding users as equal partners in all phases of the development process may increase the usefulness, relevance, and appropriateness of the resulting tools, ensuring that they reflect the specificities of each disease and the overall context of the patients, increasing the odds of their adoption.

*Inclusive design* principles may help developers address the needs of the most vulnerable patient populations who may not be engaging with mHealth owing to their age or health-related physical and cognitive challenges, educational level, socioeconomic status, or their technological skills and experience. Numerous studies have concluded that many demographic factors are typically not the root cause for the lack of adoption per se, but rather other underlying causes were at play, mainly pointing back to a lack of skills and literacy that were typically correlated to more older patients, those with a lower level of education, or those belonging to lower socioeconomic classes. Designing for inclusivity does not ignore the unique features, environments, and cultural contexts of users. Research has shown that many aspects of the digital divide may be addressed through an inclusive design that incorporates cultural appropriateness, easy-to-understand lay language that does not need high literacy levels, and ease-of-use that does not require any sophisticated technical skills. For instance, a design that enables offline use may encourage patients in lower socioeconomic classes who are weary of the overuse of their data package to use the tool. Increasing the personal relevance of tools through personalization may also help address the varying needs of different users, allowing technology providers to cater to different patient populations that may vary in their level of skills, physical or mental capabilities, and literacy.

Another element that may help to reduce disparities in adoption is *patient education and support*. Comprehensive training materials and continuous technical support may assist some of the most unfavorable patient populations to benefit from these tools. Several studies have reported that the availability of training enables user groups that do not necessarily have the skills or literacy levels to acquire the knowledge that they need to use the tools more easily, especially when it increases their understanding of how the tool may help them improve their condition, step-by-step instructions on how it works, and knowing whom to contact in case of issues or questions. It is worth noting that extending patient education and awareness programs to go beyond mHealth literacy to include health literacy in general and encourage healthy behaviors may foster adoption, as research has shown that these factors may indirectly promote the tools' uptake. Furthermore, given the important role of social influence, raising caregivers' awareness may contribute to more successful adoption.

*Data ethics* is one of the most prominent factors in almost all health technology–related discussions, mostly as a barrier to adoption. Fostering patient adoption necessitates addressing their main fears and concerns by ensuring that their health data are stored and managed in a secure and ethical manner, providing higher transparency on data policies, and, whenever possible, enabling users to choose which data they agree to share and with whom.

*Care teams' role* is central to patient adoption, as research shows that the endorsement of the clinician is a key facilitator of patient acceptance of the tools. However, lack of knowledge, skills, or active engagement with mHealth from the care team may discourage patient adoption. Therefore, raising clinicians' awareness of the existing tools and how they can help them and their patients and engaging them in digital training to equip them with the necessary skills to administer these tools is central to success. Moreover, integrating mHealth in the clinical workflow to enable the seamless use of the data resulting from the tools in standard clinical practice is crucial, as previous studies have reported that patients would often abandon the tools if they feel that their care team is not actively engaging with the data that they feed on these apps.

Furthermore, recognizing potential barriers has essential *policy implications* for mHealth adoption to improve access to health care services and patient support. Encouraging the reimbursement of mHealth tools that contribute to cost efficiency and clinical efficacy may help overcome the cost-related barriers that were often reported in the studies. Facilitating digital training in medical education may help equip care teams with the necessary skills to implement and administer new technologies. Facilitating the integration of digital tools into the standard of care by supporting system harmonization, interoperability, and infrastructure may play a vital role in overcoming some of the key technical barriers that hinder adoption.

## Limitations and Recommendations for Future Research

Although this study contributes to the understanding of the factors affecting patients' adoption of mHealth services, some limitations must be acknowledged. This review may not have included relevant studies that were not indexed in the searched databases, written in a language other than English, and gray literature searches that could have also allowed the identification of additional relevant insights. However, this study focused on peer-reviewed scientific papers.

In addition, this analysis only considered published studies, and no further contacts were made with the authors of the papers to obtain additional information or to validate our thematic analysis. Consequently, it is possible that other mHealth adoption factors may have been missed. Future reviews could include studies in other languages to gain a better grasp of any interregional or intercultural differences, and to have more studies in developed countries.

## Conclusions

This systematic literature review and narrative synthesis builds on and expands the growing body of literature investigating



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patients' adoption of mHealth services. Our findings highlight the complexity of the factors affecting adoption, including personal, social, technical, organizational, and health care aspects. We recommend improving patient-centered approaches and taking a more holistic view of adoption factors beyond technical aspects by ensuring the tools' fit into the overall patient journey and treatment plan. We emphasize the crucial role of inclusive design, which enables comprehensive patient education and support programs. Moreover, we stress the importance of empowering and mobilizing clinicians and care teams, addressing ethical data management issues, and focusing on health care policies that may facilitate adoption such as mHealth reimbursement.

## Conflicts of Interest

None declared.

Multimedia Appendix 1
Critical Appraisal Skills Program checklist.
[PDF File (Adobe PDF File), 440 KB - mhealth_v10i5e36284_app1.pdf ]

Multimedia Appendix 2
Critical appraisal of the included studies.
[XLSX File (Microsoft Excel File), 101 KB - mhealth_v10i5e36284_app2.xlsx ]

Multimedia Appendix 3
Phases of thematic analysis based on Braun and Clarke [25].
[PDF File (Adobe PDF File), 48 KB - mhealth_v10i5e36284_app3.pdf ]

Multimedia Appendix 4
Characteristics of included studies.
[PDF File (Adobe PDF File), 117 KB - mhealth_v10i5e36284_app4.pdf ]

Multimedia Appendix 5
(A) Social and personal factors and their occurrence. (B) Technical and material factors and their occurrence. (C) Health-related factors and their occurrence.
[PDF File (Adobe PDF File), 146 KB - mhealth_v10i5e36284_app5.pdf ]

## References

1. Armstrong AW, Kwong MW, Chase EP, Ledo L, Nesbitt TS, Shewry SL. Teledermatology operational considerations, challenges, and benefits: the referring providers' perspective. Telemed J E Health 2012 Oct;18(8):580-584. [doi: 10.1089/tmj.2011.0241] [Medline: 22881579]
2. Avey JP, Hobbs RL. Dial in: fostering the use of telebehavioral health services in frontier Alaska. Psychol Serv 2013 Aug;10(3):289-297. [doi: 10.1037/a0028231] [Medline: 22924798]
3. Anderson K, Francis T, Ibanez-Carrasco F, Globerman J. Physician's perceptions of telemedicine in HIV care provision: a cross-sectional web-based survey. JMIR Public Health Surveill 2017 May 30;3(2):e31 [FREE Full text] [doi: 10.2196/publichealth.6896] [Medline: 28559226]
4. Bhatta R, Aryal K, Ellingsen G. Opportunities and challenges of a rural-telemedicine program in Nepal. J Nepal Health Res Counc 2015;13(30):149-153. [Medline: 26744201]
5. Mileski M, Kruse CS, Catalani J, Haderer T. Adopting telemedicine for the self-management of hypertension: systematic review. JMIR Med Inform 2017 Oct 24;5(4):e41 [FREE Full text] [doi: 10.2196/medinform.6603] [Medline: 29066424]
6. Puszka S, Dingwall KM, Sweet M, Nagel T. E-mental health innovations for aboriginal and Torres Strait Islander Australians: a qualitative study of implementation needs in health services. JMIR Ment Health 2016 Sep 19;3(3):e43 [FREE Full text] [doi: 10.2196/mental.5837] [Medline: 27644259]
7. Talboom-Kamp EP, Verdijk NA, Kasteleyn MJ, Numans ME, Chavannes NH. From chronic disease management to person-centered eHealth; a review on the necessity for blended care. Clin eHealth 2018 Mar;1(1):3-7. [doi: 10.1016/j.ceh.2018.01.001]
8. Tistad M, Lundell S, Wiklund M, Nyberg A, Holmner A, Wadell K. Usefulness and relevance of an ehealth tool in supporting the self-management of chronic obstructive pulmonary disease: explorative qualitative study of a cocreative process. JMIR Hum Factors 2018 Oct 26;5(4):e10801 [FREE Full text] [doi: 10.2196/10801] [Medline: 30368440]



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9. Stellefson M, Chaney B, Barry AE, Chavarria E, Tennant B, Walsh-Childers K, et al. Web 2.0 chronic disease self-management for older adults: a systematic review. J Med Internet Res 2013 Feb 14;15(2):e35 [FREE Full text] [doi: 10.2196/jmir.2439] [Medline: 23410671]
10. Achelrod D. Policy expectations and reality of telemedicine – a critical analysis of health care outcomes, costs and acceptance for congestive heart failure. J Telemed Telecare 2014 May 06;20(4):192-200. [doi: 10.1177/1357633x14533894]
11. Wang Y, Xue H, Huang Y, Huang L, Zhang D. A systematic review of application and effectiveness of mHealth interventions for obesity and diabetes treatment and self-management. Adv Nutr 2017 May 15;8(3):449-462 [FREE Full text] [doi: 10.3945/an.116.014100] [Medline: 28507010]
12. Shivkumar V, Subramanian T, Agarwal P, Mari Z, Mestre TA, Parkinson Study Group. Uptake of telehealth in Parkinson's disease clinical care and research during the COVID-19 pandemic. Parkinsonism Relat Disord 2021 May;86:97-100. [doi: 10.1016/j.parkreldis.2021.03.032] [Medline: 33895540]
13. Pfammatter AF, Mitsos A, Wang S, Hood SH, Spring B. Evaluating and improving recruitment and retention in an mHealth clinical trial: an example of iterating methods during a trial. Mhealth 2017 Nov 01;3:49 [FREE Full text] [doi: 10.21037/mhealth.2017.09.02] [Medline: 29184901]
14. Fleming T, Bavin L, Lucassen M, Stasiak K, Hopkins S, Merry S. Beyond the trial: systematic review of real-world uptake and engagement with digital self-help interventions for depression, low mood, or anxiety. J Med Internet Res 2018 Jun 06;20(6):e199 [FREE Full text] [doi: 10.2196/jmir.9275] [Medline: 29875089]
15. Helander E, Kaipainen K, Korhonen I, Wansink B. Factors related to sustained use of a free mobile app for dietary self-monitoring with photography and peer feedback: retrospective cohort study. J Med Internet Res 2014 Apr 15;16(4):e109 [FREE Full text] [doi: 10.2196/jmir.3084] [Medline: 24735567]
16. MHealth New Horizons for Health Through Mobile Technologies. Geneva: World Health Organization; 2011.
17. Jacob C, Sanchez-Vazquez A, Ivory C. Social, organizational, and technological factors impacting clinicians' adoption of mobile health tools: systematic literature review. JMIR Mhealth Uhealth 2020 Feb 20;8(2):e15935. [doi: 10.2196/15935]
18. Moher D, Liberati A, Tetzlaff J, Altman DG, PRISMA Group. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. PLoS Med 2009 Jul 21;6(7):e1000097 [FREE Full text] [doi: 10.1371/journal.pmed.1000097] [Medline: 19621072]
19. Higgins J. Cochrane Handbook for Systematic Reviews of Interventions: Cochrane Book Series. Hoboken, New Jersey: Wiley; 2011.
20. Jacob C, Ivory C, Sezgin E. Sociotechnical factors impacting patients' adoption of mHealth tools: a systematic review of the literature [Internet]. PROSPERO. 2021. URL: https://www.crd.york.ac.uk/prospero/display_record.php?RecordID=266484
21. Richardson WS, Wilson MC, Nishikawa J, Hayward RS. The well-built clinical question: a key to evidence-based decisions. ACP J Club 1995;123(3):A12-A13. [Medline: 7582737]
22. Ouzzani M, Hammady H, Fedorowicz Z, Elmagarmid A. Rayyan-a web and mobile app for systematic reviews. Syst Rev 2016 Dec 05;5(1):210 [FREE Full text] [doi: 10.1186/s13643-016-0384-4] [Medline: 27919275]
23. CASP Checklist. CASP. URL: https://casp-uk.net/casp-tools-checklists/ [accessed 2022-04-09]
24. Jacob C, Sanchez-Vazquez A, Ivory C. Understanding clinicians' adoption of mobile health tools: a qualitative review of the most used frameworks. JMIR Mhealth Uhealth 2020 Jul 06;8(7):e18072 [FREE Full text] [doi: 10.2196/18072] [Medline: 32442132]
25. Braun V, Clarke V. Using thematic analysis in psychology. Qual Res Psychol 2006 Jan;3(2):77-101. [doi: 10.1191/1478088706qp063oa]
26. Leonardi P. Methodological guidelines for the study of materiality and affordances. In: The Routledge Companion to Qualitative Research in Organization Studies. Milton Park, Abingdon-on-Thames, Oxfordshire, England, UK: Routledge; 2017.
27. Ammenwerth E. Technology acceptance models in health informatics: TAM and UTAUT. Stud Health Technol Inform 2019 Jul 30;263:64-71. [doi: 10.3233/SHTI190111] [Medline: 31411153]
28. Ward R. The application of technology acceptance and diffusion of innovation models in healthcare informatics. Health Policy Technol 2013 Dec;2(4):222-228. [doi: 10.1016/j.hlpt.2013.07.002]
29. Rahimi B, Nadri H, Lotfnezhad Afshar H, Timpka T. A systematic review of the technology acceptance model in health informatics. Appl Clin Inform 2018 Jul 15;9(3):604-634 [FREE Full text] [doi: 10.1055/s-0038-1668091] [Medline: 30112741]
30. Shachak A, Kuziemsky C, Petersen C. Beyond TAM and UTAUT: future directions for HIT implementation research. J Biomed Inform 2019 Dec;100:103315 [FREE Full text] [doi: 10.1016/j.jbi.2019.103315] [Medline: 31629923]
31. Sittig DF, Singh H. A new sociotechnical model for studying health information technology in complex adaptive healthcare systems. Qual Saf Health Care 2010 Oct;19 Suppl 3:68-74 [FREE Full text] [doi: 10.1136/qshc.2010.042085] [Medline: 20959322]
32. Riley WT, Rivera DE, Atienza AA, Nilsen W, Allison SM, Mermelstein R. Health behavior models in the age of mobile interventions: are our theories up to the task? Transl Behav Med 2011 Mar;1(1):53-71 [FREE Full text] [doi: 10.1007/s13142-011-0021-7] [Medline: 21796270]




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33. Karsh B. Beyond usability: designing effective technology implementation systems to promote patient safety. Qual Saf Health Care 2004 Oct;13(5):388-394 [FREE Full text] [doi: 10.1136/qhc.13.5.388] [Medline: 15465944]
34. Dai M, Xu J, Lin J, Wang Z, Huang W, Huang J. Willingness to use mobile health in Glaucoma patients. Telemed J E Health 2017 Oct;23(10):822-827. [doi: 10.1089/tmj.2016.0254] [Medline: 28418773]
35. Beard C, Silverman AL, Forgeard M, Wilmer MT, Torous J, Björgvinsson T. Smartphone, social media, and mental health app use in an acute transdiagnostic psychiatric sample. JMIR Mhealth Uhealth 2019 Jun 07;7(6):e13364 [FREE Full text] [doi: 10.2196/13364] [Medline: 31199338]
36. Breil B, Kremer L, Hennemann S, Apolinário-Hagen J. Acceptance of mHealth apps for self-management among people with hypertension. Stud Health Technol Inform 2019 Sep 03;267:282-288. [doi: 10.3233/SHTI190839] [Medline: 31483283]
37. Darcourt JG, Aparicio K, Dorsey PM, Ensor JE, Zsigmond EM, Wong ST, et al. Analysis of the implementation of telehealth visits for care of patients with cancer in Houston during the COVID-19 pandemic. JCO Oncol Pract 2021 Jan;17(1):e36-e43 [FREE Full text] [doi: 10.1200/OP.20.00572] [Medline: 33026951]
38. de Vries ST, Denig P, Lasheras Ruiz C, Houÿez F, Wong L, Sutcliffe A, IMI Web-RADR Work Package 3b Consortium. Interest in a mobile app for two-way risk communication: a survey study among European healthcare professionals and patients. Drug Saf 2018 Jul 2;41(7):697-712 [FREE Full text] [doi: 10.1007/s40264-018-0648-0] [Medline: 29500800]
39. Hansen AH, Bradway M, Broz J, Claudi T, Henriksen O, Wangberg SC, et al. Inequalities in the use of eHealth between socioeconomic groups among patients with type 1 and type 2 diabetes: cross-sectional study. J Med Internet Res 2019 May 29;21(5):e13615 [FREE Full text] [doi: 10.2196/13615] [Medline: 31144669]
40. Knitza J, Simon D, Lambrecht A, Raab C, Tascilar K, Hagen M, et al. Mobile health usage, preferences, barriers, and eHealth literacy in rheumatology: patient survey study. JMIR Mhealth Uhealth 2020 Aug 12;8(8):e19661 [FREE Full text] [doi: 10.2196/19661] [Medline: 32678796]
41. Lee K, Bejerano IL, Han M, Choi HS. Willingness to use smartphone apps for lifestyle management among patients with schizophrenia. Arch Psychiatr Nurs 2019 Aug;33(4):329-336. [doi: 10.1016/j.apnu.2019.01.002] [Medline: 31280776]
42. Reinecke F, Dittrich F, Dudda M, Stang A, Polan C, Müller R, et al. Acceptance, barriers, and future preferences of mobile health among patients receiving trauma and orthopedic surgical care: paper-based survey in a prospective multicenter study. JMIR Mhealth Uhealth 2021 Apr 21;9(4):e23784 [FREE Full text] [doi: 10.2196/23784] [Medline: 33881401]
43. Sin DY, Guo X, Yong DW, Qiu TY, Moey PK, Falk M, et al. Assessment of willingness to tele-monitoring interventions in patients with type 2 diabetes and/or hypertension in the public primary healthcare setting. BMC Med Inform Decis Mak 2020 Jan 28;20(1):11 [FREE Full text] [doi: 10.1186/s12911-020-1024-4] [Medline: 31992288]
44. Spooner KK, Salemi JL, Salihu HM, Zoorob RJ. eHealth patient-provider communication in the United States: interest, inequalities, and predictors. J Am Med Inform Assoc 2017 Apr 01;24(e1):e18-e27 [FREE Full text] [doi: 10.1093/jamia/ocw087] [Medline: 27497797]
45. Su J, Dugas M, Guo X, Gao G. Influence of personality on mHealth use in patients with diabetes: prospective pilot study. JMIR Mhealth Uhealth 2020 Aug 10;8(8):e17709 [FREE Full text] [doi: 10.2196/17709] [Medline: 32773382]
46. Sun L, Jiao C, Wang Y, Xiao Q, Zhang Y, Wu Y. A survey on the willingness to use physical activity smartphone applications (Apps) in patients with chronic diseases. Stud Health Technol Inform 2016;225:1032-1033. [Medline: 27332468]
47. Aghazadeh H, Crump T, Tennant M, Weis E. Use of mobile health (mHealth) technologies in ophthalmology patients in Alberta. Can J Ophthalmol 2019 Apr;54(2):164-170. [doi: 10.1016/j.jcjo.2018.05.010] [Medline: 30975338]
48. Browning RB, McGillicuddy JW, Treiber FA, Taber DJ. Kidney transplant recipients' attitudes about using mobile health technology for managing and monitoring medication therapy. J Am Pharm Assoc (2003) 2016;56(4):450-4.e1 [FREE Full text] [doi: 10.1016/j.japh.2016.03.017] [Medline: 27450140]
49. Ernsting C, Stühmann LM, Dombrowski SU, Voigt-Antons J, Kuhlmey A, Gellert P. Associations of health app use and perceived effectiveness in people with cardiovascular diseases and diabetes: population-based survey. JMIR Mhealth Uhealth 2019 Mar 28;7(3):e12179 [FREE Full text] [doi: 10.2196/12179] [Medline: 30920383]
50. Jaffe DH, Lee L, Huynh S, Haskell TP. Health inequalities in the use of telehealth in the United States in the lens of COVID-19. Popul Health Manag 2020 Oct 01;23(5):368-377. [doi: 10.1089/pop.2020.0186] [Medline: 32816644]
51. Kontos E, Blake KD, Chou WS, Prestin A. Predictors of eHealth usage: insights on the digital divide from the health information national trends survey 2012. J Med Internet Res 2014 Jul 16;16(7):e172 [FREE Full text] [doi: 10.2196/jmir.3117] [Medline: 25048379]
52. Mangin D, Parascandalo J, Khudoyarova O, Agarwal G, Bismah V, Orr S. Multimorbidity, eHealth and implications for equity: a cross-sectional survey of patient perspectives on eHealth. BMJ Open 2019 Feb 12;9(2):e023731 [FREE Full text] [doi: 10.1136/bmjopen-2018-023731] [Medline: 30760515]
53. Potdar R, Thomas A, DiMeglio M, Mohiuddin K, Djibo DA, Laudanski K, et al. Access to internet, smartphone usage, and acceptability of mobile health technology among cancer patients. Support Care Cancer 2020 Nov 12;28(11):5455-5461. [doi: 10.1007/s00520-020-05393-1] [Medline: 32166381]
54. Ye Q, Deng Z, Chen Y, Liao J, Li G, Lu Y. How resource scarcity and accessibility affect patients' usage of mobile health in China: resource competition perspective. JMIR Mhealth Uhealth 2019 Aug 09;7(8):e13491 [FREE Full text] [doi: 10.2196/13491] [Medline: 31400104]




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55. Qan'ir Y, Khalifeh A, Eid M, Hammad B, Al-Batran M. Mobile health apps use among Jordanian outpatients: a descriptive study. Health Informatics J 2021;27(2):14604582211017940 [FREE Full text] [doi: 10.1177/14604582211017940] [Medline: 34030504]
56. Ali EE, Leow JL, Chew L, Yap KY. Patients' perception of app-based educational and behavioural interventions for enhancing oral anticancer medication adherence. J Cancer Educ 2018 Dec 14;33(6):1306-1313. [doi: 10.1007/s13187-017-1248-x] [Medline: 28707206]
57. Magnol M, Eleonore B, Claire R, Castagne B, Pugibet M, Lukas C, et al. Use of ehealth by patients with rheumatoid arthritis: observational, cross-sectional, multicenter study. J Med Internet Res 2021 Jan 29;23(1):e19998 [FREE Full text] [doi: 10.2196/19998] [Medline: 33512320]
58. Alwashmi MF, Fitzpatrick B, Farrell J, Gamble J, Davis E, Nguyen HV, et al. Perceptions of patients regarding mobile health interventions for the management of chronic obstructive pulmonary disease: mixed methods study. JMIR Mhealth Uhealth 2020 Jul 23;8(7):e17409 [FREE Full text] [doi: 10.2196/17409] [Medline: 32706697]
59. Byambasuren O, Beller E, Hoffmann T, Glasziou P. Barriers to and facilitators of the prescription of mHealth apps in Australian general practice: qualitative study. JMIR Mhealth Uhealth 2020 Jul 30;8(7):e17447 [FREE Full text] [doi: 10.2196/17447] [Medline: 32729839]
60. Cook EJ, Randhawa G, Sharp C, Ali N, Guppy A, Barton G, et al. Exploring the factors that influence the decision to adopt and engage with an integrated assistive telehealth and telecare service in Cambridgeshire, UK: a nested qualitative study of patient 'users' and 'non-users'. BMC Health Serv Res 2016 Apr 19;16:137 [FREE Full text] [doi: 10.1186/s12913-016-1379-5] [Medline: 27095102]
61. Eno AK, Ruck JM, Van Pilsum Rasmussen SE, Waldram MM, Thomas AG, Purnell TS, et al. Perspectives on implementing mobile health technology for living kidney donor follow-up: in-depth interviews with transplant providers. Clin Transplant 2019 Aug 26;33(8):e13637. [doi: 10.1111/ctr.13637] [Medline: 31194892]
62. Fischer SH, Ray KN, Mehrotra A, Bloom EL, Uscher-Pines L. Prevalence and characteristics of telehealth utilization in the United States. JAMA Netw Open 2020 Oct 01;3(10):e2022302 [FREE Full text] [doi: 10.1001/jamanetworkopen.2020.22302] [Medline: 33104208]
63. Reddy R, Majmudar M, Dhopeshwarkar N, Vacaro V, Isselbacher E, Bhatt AB. Mobile health apps preferences and practice among ambulatory cardiovascular patients. Future Cardiol 2018 Sep;14(5):381-388. [doi: 10.2217/fca-2018-0005] [Medline: 30232910]
64. Gordon NP, Hornbrook MC. Differences in access to and preferences for using patient portals and other eHealth technologies based on race, ethnicity, and age: a database and survey study of seniors in a large health plan. J Med Internet Res 2016 Mar 04;18(3):e50 [FREE Full text] [doi: 10.2196/jmir.5105] [Medline: 26944212]
65. Kamis K, Janevic MR, Marinec N, Jantz R, Valverde H, Piette JD. A study of mobile phone use among patients with noncommunicable diseases in La Paz, Bolivia: implications for mHealth research and development. Global Health 2015 Jul 04;11:30 [FREE Full text] [doi: 10.1186/s12992-015-0115-y] [Medline: 26141528]
66. Gordon NP, Hornbrook MC. Older adults' readiness to engage with eHealth patient education and self-care resources: a cross-sectional survey. BMC Health Serv Res 2018 Mar 27;18(1):220 [FREE Full text] [doi: 10.1186/s12913-018-2986-0] [Medline: 29587721]
67. Khalemsky M, Schwartz DG, Silberg T, Khalemsky A, Jaffe E, Herbst R. Childrens' and parents' willingness to join a smartphone-based emergency response community for anaphylaxis: survey. JMIR Mhealth Uhealth 2019 Aug 27;7(8):e13892 [FREE Full text] [doi: 10.2196/13892] [Medline: 31456582]
68. Colls J, Lee Y, Xu C, Corrigan C, Lu F, Marquez-Grap G, et al. Patient adherence with a smartphone app for patient-reported outcomes in rheumatoid arthritis. Rheumatology (Oxford) 2021 Jan 05;60(1):108-112. [doi: 10.1093/rheumatology/keaa202] [Medline: 32572490]
69. Foster A, Horspool KA, Edwards L, Thomas CL, Salisbury C, Montgomery AA, et al. Who does not participate in telehealth trials and why? A cross-sectional survey. Trials 2015 Jun 05;16(1):258 [FREE Full text] [doi: 10.1186/s13063-015-0773-3] [Medline: 26044763]
70. Ware P, Dorai M, Ross HJ, Cafazzo JA, Laporte A, Boodoo C, et al. Patient adherence to a mobile phone-based heart failure telemonitoring program: a longitudinal mixed-methods study. JMIR Mhealth Uhealth 2019 Feb 26;7(2):e13259 [FREE Full text] [doi: 10.2196/13259] [Medline: 30806625]
71. Pierce R, Stevermer J. Disparities in use of telehealth at the onset of the COVID-19 public health emergency. J Telemed Telecare 2020 Oct 21:1357633X2096389 [FREE Full text] [doi: 10.1177/1357633x20963893]
72. Jiang J, Zhu Q, Zheng Y, Zhu Y, Li Y, Huo Y. Perceptions and acceptance of mHealth in patients with cardiovascular diseases: a cross-sectional study. JMIR Mhealth Uhealth 2019 Feb 04;7(2):e10117 [FREE Full text] [doi: 10.2196/10117] [Medline: 30714942]
73. Wiggers A, Peek N, Kraaijenhagen R, Jaspers M. Determinants of eligibility and use of ehealth for cardiac rehabilitation patients: preliminary results. Stud Health Technol Inform 2014;205:818-822. [Medline: 25160301]
74. Edwards L, Thomas C, Gregory A, Yardley L, O'Cathain A, Montgomery AA, et al. Are people with chronic diseases interested in using telehealth? A cross-sectional postal survey. J Med Internet Res 2014 May 08;16(5):e123 [FREE Full text] [doi: 10.2196/jmir.3257] [Medline: 24811914]




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75. Hasenöhrl T, Windschnurer T, Dorotka R, Ambrozy C, Crevenna R. Prescription of individual therapeutic exercises via smartphone app for patients suffering from non-specific back pain : a qualitative feasibility and quantitative pilot study. Wien Klin Wochenschr 2020 Mar 14;132(5-6):115-123 [FREE Full text] [doi: 10.1007/s00508-020-01616-x] [Medline: 32060724]
76. Jaana M, Paré G. Comparison of mobile health technology use for self-tracking between older adults and the general adult population in Canada: cross-sectional survey. JMIR Mhealth Uhealth 2020 Nov 27;8(11):e24718 [FREE Full text] [doi: 10.2196/24718] [Medline: 33104517]
77. Abelson J, Kaufman E, Symer M, Peters A, Charlson M, Yeo H. Barriers and benefits to using mobile health technology after operation: a qualitative study. Surgery 2017 Sep;162(3):605-611. [doi: 10.1016/j.surg.2017.05.007] [Medline: 28651777]
78. de Vries ST, Wong L, Sutcliffe A, Houÿez F, Ruiz CL, Mol PG, IMI Web-RADR Work Package 3b Consortium. Factors influencing the use of a mobile app for reporting adverse drug reactions and receiving safety information: a qualitative study. Drug Saf 2017 May;40(5):443-455 [FREE Full text] [doi: 10.1007/s40264-016-0494-x] [Medline: 28035492]
79. Runz-Jørgensen SM, Schiøtz ML, Christensen U. Perceived value of eHealth among people living with multimorbidity: a qualitative study. J Comorb 2017;7(1):96-111 [FREE Full text] [doi: 10.15256/joc.2017.7.98] [Medline: 29359124]
80. De La Cruz Monroy MF, Mosahebi A. The use of smartphone applications (apps) for enhancing communication with surgical patients: a systematic review of the literature. Surg Innov 2019 Apr;26(2):244-259. [doi: 10.1177/1553350618819517] [Medline: 30602332]
81. Cajita MI, Hodgson NA, Budhathoki C, Han H. Intention to use mHealth in older adults with heart failure. J Cardiovasc Nurs 2017;32(6):E1-E7 [FREE Full text] [doi: 10.1097/JCN.0000000000000401] [Medline: 28248747]
82. Darrat I, Tam S, Boulis M, Williams AM. Socioeconomic disparities in patient use of telehealth during the Coronavirus disease 2019 surge. JAMA Otolaryngol Head Neck Surg 2021 Mar 01;147(3):287-295 [FREE Full text] [doi: 10.1001/jamaoto.2020.5161] [Medline: 33443539]
83. Torrent-Sellens J, Díaz-Chao Á, Soler-Ramos I, Saigí-Rubió F. Modelling and predicting eHealth usage in Europe: a multidimensional approach from an online survey of 13,000 European Union internet users. J Med Internet Res 2016 Jul 22;18(7):e188 [FREE Full text] [doi: 10.2196/jmir.5605] [Medline: 27450189]
84. Abelson JS, Symer M, Peters A, Charlson M, Yeo H. Mobile health apps and recovery after surgery: what are patients willing to do? Am J Surg 2017 Oct;214(4):616-622. [doi: 10.1016/j.amjsurg.2017.06.009] [Medline: 28666581]
85. Gupta A, Ocker G, Chow P. Recruiting breast cancer patients for mHealth research: obstacles to clinic-based recruitment for a mobile phone app intervention study. Clin Trials 2020 Dec;17(6):675-683 [FREE Full text] [doi: 10.1177/1740774520939247] [Medline: 32660354]
86. Bauer AM, Rue T, Keppel GA, Cole AM, Baldwin L, Katon W. Use of mobile health (mHealth) tools by primary care patients in the WWAMI region Practice and Research Network (WPRN). J Am Board Fam Med 2014 Nov 07;27(6):780-788 [FREE Full text] [doi: 10.3122/jabfm.2014.06.140108] [Medline: 25381075]
87. Scherer J, Keller F, Pape H, Osterhoff G. Would patients undergo postoperative follow-up by using a smartphone application? BMC Surg 2020 Oct 07;20(1):229 [FREE Full text] [doi: 10.1186/s12893-020-00889-3] [Medline: 33028309]
88. Theis S, Schäfer D, Bröhl C, Schäfer K, Rasche P, Wille M, et al. Predicting technology usage by health information need of older adults: implications for eHealth technology. Work 2019 Mar 19;62(3):443-457. [doi: 10.3233/WOR-192878] [Medline: 30909259]
89. Liu X, Wang R, Zhou D, Hong Z. Feasibility and acceptability of smartphone applications for seizure self-management in China: questionnaire study among people with epilepsy. Epilepsy Behav 2016 Feb;55:57-61. [doi: 10.1016/j.yebeh.2015.11.024] [Medline: 26745631]
90. Warinner C, Hayirli T, Bergmark R, Sethi R, Rettig E. Patterns of technology use among patients with head and neck cancer and implications for telehealth. OTO Open 2021 Jun 07;5(2):2473974X2110186 [FREE Full text] [doi: 10.1177/2473974x211018612]
91. Zhang Y, Li X, Luo S, Liu C, Xie Y, Guo J, et al. Use, perspectives, and attitudes regarding diabetes management mobile apps among diabetes patients and diabetologists in China: national web-based survey. JMIR Mhealth Uhealth 2019 Feb 08;7(2):e12658 [FREE Full text] [doi: 10.2196/12658] [Medline: 30735147]
92. Dandachi D, Dang BN, Lucari B, Teti M, Giordano TP. Exploring the attitude of patients with HIV about using telehealth for HIV care. AIDS Patient Care STDS 2020 Apr 01;34(4):166-172. [doi: 10.1089/apc.2019.0261] [Medline: 32324481]
93. Lupiáñez-Villanueva F, Folkvord F, Vanden Abeele M. Influence of the business revenue, recommendation, and provider models on mobile health app adoption: three-country experimental vignette study. JMIR Mhealth Uhealth 2020 Jun 04;8(6):e17272 [FREE Full text] [doi: 10.2196/17272] [Medline: 32496204]
94. Hoque MR, Bao Y, Sorwar G. Investigating factors influencing the adoption of e-Health in developing countries: a patient's perspective. Inform Health Soc Care 2017 Jan;42(1):1-17. [doi: 10.3109/17538157.2015.1075541] [Medline: 26865037]
95. Reiners F, Sturm J, Bouw LJ, Wouters EJ. Sociodemographic factors influencing the use of eHealth in people with chronic diseases. Int J Environ Res Public Health 2019 Feb 21;16(4):645 [FREE Full text] [doi: 10.3390/ijerph16040645] [Medline: 30795623]




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96. Jemere AT, Yeneneh YE, Tilahun B, Fritz F, Alemu S, Kebede M. Access to mobile phone and willingness to receive mHealth services among patients with diabetes in Northwest Ethiopia: a cross-sectional study. BMJ Open 2019 Jan 24;9(1):e021766 [FREE Full text] [doi: 10.1136/bmjopen-2018-021766] [Medline: 30679284]
97. Sun L, Wang Y, Greene B, Xiao Q, Jiao C, Ji M, et al. Facilitators and barriers to using physical activity smartphone apps among Chinese patients with chronic diseases. BMC Med Inform Decis Mak 2017 Apr 19;17(1):44 [FREE Full text] [doi: 10.1186/s12911-017-0446-0] [Medline: 28420355]
98. Meyerowitz-Katz G, Ravi S, Arnolda L, Feng X, Maberly G, Astell-Burt T. Rates of attrition and dropout in app-based interventions for chronic disease: systematic review and meta-analysis. J Med Internet Res 2020 Sep 29;22(9):e20283 [FREE Full text] [doi: 10.2196/20283] [Medline: 32990635]
99. Senft N, Everson J. eHealth engagement as a response to negative healthcare experiences: cross-sectional survey analysis. J Med Internet Res 2018 Dec 05;20(12):e11034 [FREE Full text] [doi: 10.2196/11034] [Medline: 30518513]
100. Ball E, Newton S, Rohricht F, Steed L, Birch J, Dodds J, et al. mHealth: providing a mindfulness app for women with chronic pelvic pain in gynaecology outpatient clinics: qualitative data analysis of user experience and lessons learnt. BMJ Open 2020 Mar 12;10(3):e030711 [FREE Full text] [doi: 10.1136/bmjopen-2019-030711] [Medline: 32165550]
101. Korpershoek YJ, Vervoort SC, Trappenburg JC, Schuurmans MJ. Perceptions of patients with chronic obstructive pulmonary disease and their health care providers towards using mHealth for self-management of exacerbations: a qualitative study. BMC Health Serv Res 2018 Oct 04;18(1):757 [FREE Full text] [doi: 10.1186/s12913-018-3545-4] [Medline: 30286761]
102. Woo K, Dowding DW. Decision-making factors associated with telehealth adoption by patients with heart failure at home: a qualitative study. Comput Inform Nurs 2020 Apr;38(4):204-214 [FREE Full text] [doi: 10.1097/CIN.0000000000000589] [Medline: 31929355]
103. Hawley CE, Genovese N, Owsiany MT, Triantafylidis LK, Moo LR, Linsky AM, et al. Rapid integration of home telehealth visits amidst COVID-19: what do older adults need to succeed? J Am Geriatr Soc 2020 Nov 04;68(11):2431-2439 [FREE Full text] [doi: 10.1111/jgs.16845] [Medline: 32930391]
104. Patoz M, Hidalgo-Mazzei D, Blanc O, Verdolini N, Pacchiarotti I, Murru A, et al. Patient and physician perspectives of a smartphone application for depression: a qualitative study. BMC Psychiatry 2021 Jan 29;21(1):65 [FREE Full text] [doi: 10.1186/s12888-021-03064-x] [Medline: 33514333]
105. Smith R, Menon J, Rajeev JG, Feinberg L, Kumar RK, Banerjee A. Potential for the use of mHealth in the management of cardiovascular disease in Kerala: a qualitative study. BMJ Open 2015 Nov 17;5(11):e009367 [FREE Full text] [doi: 10.1136/bmjopen-2015-009367] [Medline: 26576813]
106. Ali E, Chan S, Leow J, Chew L, Yap KY. User acceptance of an app-based adherence intervention: perspectives from patients taking oral anticancer medications. J Oncol Pharm Pract 2019 Mar;25(2):390-397 [FREE Full text] [doi: 10.1177/1078155218778106] [Medline: 29792123]
107. Simblett S, Matcham F, Siddi S, Bulgari V, Barattieri di San Pietro C, Hortas López J, RADAR-CNS Consortium. Barriers to and facilitators of engagement with mHealth technology for remote measurement and management of depression: qualitative analysis. JMIR Mhealth Uhealth 2019 Jan 30;7(1):e11325 [FREE Full text] [doi: 10.2196/11325] [Medline: 30698535]
108. Wiseman JT, Fernandes-Taylor S, Barnes ML, Tomsejova A, Saunders RS, Kent KC. Conceptualizing smartphone use in outpatient wound assessment: patients' and caregivers' willingness to use technology. J Surg Res 2015 Sep;198(1):245-251 [FREE Full text] [doi: 10.1016/j.jss.2015.05.011] [Medline: 26025626]
109. Chen P, Xiao L, Gou Z, Xiang L, Zhang X, Feng P. Telehealth attitudes and use among medical professionals, medical students and patients in China: a cross-sectional survey. Int J Med Inform 2017 Dec;108:13-21. [doi: 10.1016/j.ijmedinf.2017.09.009] [Medline: 29132618]
110. Haldane V, Tan YG, Teo KW, Koh JJK, Srivastava A, Cheng RX, et al. Perspectives on acceptance and use of a mobile health intervention for the prevention of atherosclerotic cardiovascular disease in Singapore: mixed-methods study. JMIR Mhealth Uhealth 2019 Mar 14;7(3):e11108 [FREE Full text] [doi: 10.2196/11108] [Medline: 30869651]
111. Javanparast S, Roeger L, Kwok Y, Reed RL. The experience of Australian general practice patients at high risk of poor health outcomes with telehealth during the COVID-19 pandemic: a qualitative study. BMC Fam Pract 2021 Apr 08;22(1):69 [FREE Full text] [doi: 10.1186/s12875-021-01408-w] [Medline: 33832422]
112. Papoutsi C, A'Court C, Wherton J, Shaw S, Greenhalgh T. Explaining the mixed findings of a randomised controlled trial of telehealth with centralised remote support for heart failure: multi-site qualitative study using the NASSS framework. Trials 2020 Oct 27;21(1):891 [FREE Full text] [doi: 10.1186/s13063-020-04817-x] [Medline: 33109254]
113. Rush K, Hatt L, Gorman N, Janicki L, Polasek P, Shay M. Planning telehealth for older adults with atrial fibrillation in rural communities: understanding stakeholder perspectives. Clin Nurs Res 2019 Feb;28(2):130-149 [FREE Full text] [doi: 10.1177/1054773818758170] [Medline: 29460639]
114. Bentley CL, Powell L, Potter S, Parker J, Mountain GA, Bartlett YK, et al. The use of a smartphone app and an activity tracker to promote physical activity in the management of chronic obstructive pulmonary disease: randomized controlled feasibility study. JMIR Mhealth Uhealth 2020 Jun 03;8(6):e16203 [FREE Full text] [doi: 10.2196/16203] [Medline: 32490838]




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115. James N, Power E, Hogden A, Vucic S. Patients' perspectives of multidisciplinary home-based e-Health service delivery for motor neurone disease. Disabil Rehabil Assist Technol 2019 Oct;14(7):737-743. [doi: 10.1080/17483107.2018.1499139] [Medline: 30182780]
116. Margineanu I, Louka C, Vincenti-Gonzalez M, Saktiawati AM, Schierle J, Abass KM, et al. Patients and medical staff attitudes toward the future inclusion of ehealth in tuberculosis management: perspectives from six countries evaluated using a qualitative framework. JMIR Mhealth Uhealth 2020 Nov 02;8(11):e18156 [FREE Full text] [doi: 10.2196/18156] [Medline: 33136052]
117. Steare T, Giorgalli M, Free K, Harju-Seppänen J, Akther S, Eskinazi M, et al. A qualitative study of stakeholder views on the use of a digital app for supported self-management in early intervention services for psychosis. BMC Psychiatry 2021 Jun 19;21(1):311 [FREE Full text] [doi: 10.1186/s12888-021-03317-9] [Medline: 34147075]
118. Vo V, Auroy L, Sarradon-Eck A. Patients' perceptions of mHealth apps: meta-ethnographic review of qualitative studies. JMIR Mhealth Uhealth 2019 Jul 10;7(7):e13817 [FREE Full text] [doi: 10.2196/13817] [Medline: 31293246]
119. Kemp MT, Williams AM, Sharma SB, Biesterveld BE, Wakam GK, Matusko N, et al. Barriers associated with failed completion of an acute care general surgery telehealth clinic visit. Surgery 2020 Nov;168(5):851-858. [doi: 10.1016/j.surg.2020.06.029] [Medline: 32782115]
120. Thomas NA, Drewry A, Racine Passmore S, Assad N, Hoppe KK. Patient perceptions, opinions and satisfaction of telehealth with remote blood pressure monitoring postpartum. BMC Pregnancy Childbirth 2021 Feb 19;21(1):153 [FREE Full text] [doi: 10.1186/s12884-021-03632-9] [Medline: 33607957]
121. Nelson LA, Mulvaney SA, Gebretsadik T, Ho Y, Johnson KB, Osborn CY. Disparities in the use of a mHealth medication adherence promotion intervention for low-income adults with type 2 diabetes. J Am Med Inform Assoc 2016 Jan;23(1):12-18 [FREE Full text] [doi: 10.1093/jamia/ocv082] [Medline: 26186935]
122. Weber E, Miller S, Astha V, Janevic T, Benn E. Characteristics of telehealth users in NYC for COVID-related care during the coronavirus pandemic. J Am Med Inform Assoc 2020 Dec 09;27(12):1949-1954 [FREE Full text] [doi: 10.1093/jamia/ocaa216] [Medline: 32866249]
123. Campos-Castillo C, Anthony D. Racial and ethnic differences in self-reported telehealth use during the COVID-19 pandemic: a secondary analysis of a US survey of internet users from late March. J Am Med Inform Assoc 2021 Jan 15;28(1):119-125 [FREE Full text] [doi: 10.1093/jamia/ocaa221] [Medline: 32894772]
124. Almandoz J, Xie L, Schellinger J, Mathew M, Edwards K, Ofori A, et al. Telehealth utilization among multi-ethnic patients with obesity during the COVID-19 pandemic. J Telemed Telecare 2021 Mar 04:1357633X2199821 [FREE Full text] [doi: 10.1177/1357633x21998211]
125. Raghunathan NJ, Korenstein D, Li QS, Tonorezos ES, Mao JJ. Determinants of mobile technology use and smartphone application interest in cancer patients. Cancer Med 2018 Nov;7(11):5812-5819 [FREE Full text] [doi: 10.1002/cam4.1660] [Medline: 30280495]
126. Anosike C, Adibe M, Isah A, Ukoha-Kalu O. Willingness to pay for pharmacist-provided home telemonitoring among patients with chronic diseases in Enugu metropolis. Health Informatics J 2020 Jun;26(2):829-840 [FREE Full text] [doi: 10.1177/1460458219852534] [Medline: 31195915]
127. Zhang X, Yu P, Yan J, Ton A M Spil I. Using diffusion of innovation theory to understand the factors impacting patient acceptance and use of consumer e-health innovations: a case study in a primary care clinic. BMC Health Serv Res 2015 Feb 21;15:71 [FREE Full text] [doi: 10.1186/s12913-015-0726-2] [Medline: 25885110]
128. Geronimo A, Wright C, Morris A, Walsh S, Snyder B, Simmons Z. Incorporation of telehealth into a multidisciplinary ALS Clinic: feasibility and acceptability. Amyotroph Lateral Scler Frontotemporal Degener 2017 Nov 05;18(7-8):555-561. [doi: 10.1080/21678421.2017.1338298] [Medline: 28678542]
129. Alaiad A, Alsharo M, Alnsour Y. The determinants of m-health adoption in developing countries: an empirical investigation. Appl Clin Inform 2019 Oct 30;10(5):820-840 [FREE Full text] [doi: 10.1055/s-0039-1697906] [Medline: 31667819]
130. DiDonato KL, Liu Y, Lindsey CC, Hartwig DM, Stoner SC. Community pharmacy patient perceptions of a pharmacy-initiated mobile technology app to improve adherence. Int J Pharm Pract 2015 Oct 09;23(5):309-319. [doi: 10.1111/ijpp.12168] [Medline: 25572628]
131. Helleman J, Kruitwagen ET, van den Berg LH, Visser-Meily JM, Beelen A. The current use of telehealth in ALS care and the barriers to and facilitators of implementation: a systematic review. Amyotroph Lateral Scler Frontotemporal Degener 2020 May;21(3-4):167-182. [doi: 10.1080/21678421.2019.1706581] [Medline: 31878794]
132. Louissaint J, Lok AS, Fortune BE, Tapper EB. Acceptance and use of a smartphone application in cirrhosis. Liver Int 2020 Jul;40(7):1556-1563. [doi: 10.1111/liv.14494] [Medline: 32343467]
133. Zhang X, Guo X, Guo F, Lai K. Nonlinearities in personalization-privacy paradox in mHealth adoption: the mediating role of perceived usefulness and attitude. Technol Health Care 2014 Aug 01;22(4):515-529. [doi: 10.3233/thc-140811]
134. Zolait A, Radhi N, Alhowaishi MM, Sundram VP, Aldoseri LM. Can Bahraini patients accept e-health systems? Int J Health Care Qual Assur 2019 May 13;32(4):720-730. [doi: 10.1108/ijhcqa-05-2018-0106]
135. Nabi J, Cone EB, Vasavada A, Sun M, Kilbridge KL, Kibel AS, et al. Mobile health app for prostate cancer patients on androgen deprivation therapy: qualitative usability study. JMIR Mhealth Uhealth 2020 Nov 03;8(11):e20224 [FREE Full text] [doi: 10.2196/20224] [Medline: 33141104]




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136. Li J, Varnfield M, Jayasena R, Celler B. Home telemonitoring for chronic disease management: perceptions of users and factors influencing adoption. Health Informatics J 2021;27(1):1460458221997893 [FREE Full text] [doi: 10.1177/1460458221997893] [Medline: 33685279]
137. Lie SS, Karlsen B, Oord ER, Graue M, Oftedal B. Dropout from an eHealth intervention for adults with type 2 diabetes: a qualitative study. J Med Internet Res 2017 May 30;19(5):e187 [FREE Full text] [doi: 10.2196/jmir.7479] [Medline: 28559223]
138. Ross EL, Jamison RN, Nicholls L, Perry BM, Nolen KD. Clinical integration of a smartphone app for patients with chronic pain: retrospective analysis of predictors of benefits and patient engagement between clinic visits. J Med Internet Res 2020 Apr 16;22(4):e16939 [FREE Full text] [doi: 10.2196/16939] [Medline: 32297871]
139. Leenen LA, Wijnen BF, de Kinderen RJ, van Heugten CM, Evers SM, Majoie MH. Are people with epilepsy using eHealth-tools? Epilepsy Behav 2016 Nov;64(Pt A):268-272. [doi: 10.1016/j.yebeh.2016.08.007] [Medline: 27780086]
140. Desveaux L, Shaw J, Saragosa M, Soobiah C, Marani H, Hensel J, et al. A mobile app to improve self-management of individuals with type 2 diabetes: qualitative realist evaluation. J Med Internet Res 2018 Mar 16;20(3):e81 [FREE Full text] [doi: 10.2196/jmir.8712] [Medline: 29549070]
141. Edbrooke-Childs J, Edridge C, Averill P, Delane L, Hollis C, Craven MP, et al. A feasibility trial of power up: smartphone app to support patient activation and shared decision making for mental health in young people. JMIR Mhealth Uhealth 2019 Jun 04;7(6):e11677 [FREE Full text] [doi: 10.2196/11677] [Medline: 31165709]
142. Alam MM, Alam MZ, Rahman SA, Taghizadeh SK. Factors influencing mHealth adoption and its impact on mental well-being during COVID-19 pandemic: a SEM-ANN approach. J Biomed Inform 2021 Apr;116:103722 [FREE Full text] [doi: 10.1016/j.jbi.2021.103722] [Medline: 33705856]
143. Graffigna G, Barello S, Bonanomi A, Menichetti J. The motivating function of healthcare professional in eHealth and mHealth interventions for type 2 diabetes patients and the mediating role of patient engagement. J Diabetes Res 2016;2016:2974521 [FREE Full text] [doi: 10.1155/2016/2974521] [Medline: 26881243]
144. Amann J, Fiordelli M, Scheel-Sailer A, Brach M, Rubinelli S. Opportunities and challenges of a self-management app to support people with spinal cord injury in the prevention of pressure injuries: qualitative study. JMIR Mhealth Uhealth 2020 Dec 09;8(12):e22452 [FREE Full text] [doi: 10.2196/22452] [Medline: 33295876]
145. Chang C, Lee T, Mills ME. Experience of home telehealth technology in older patients with diabetes. Comput Inform Nurs 2017 Oct;35(10):530-537. [doi: 10.1097/CIN.0000000000000341] [Medline: 28291156]
146. Anastasiadou D, Folkvord F, Serrano-Troncoso E, Lupiañez-Villanueva F. Mobile health adoption in mental health: user experience of a mobile health app for patients with an eating disorder. JMIR Mhealth Uhealth 2019 May 31;7(6):e12920 [FREE Full text] [doi: 10.2196/12920] [Medline: 31199329]
147. Blonigen D, Harris-Olenak B, Kuhn E, Humphreys K, Timko C, Dulin P. From "Step away" to "Stand down": tailoring a smartphone app for self-management of hazardous drinking for veterans. JMIR Mhealth Uhealth 2020 Feb 13;8(2):e16062 [FREE Full text] [doi: 10.2196/16062] [Medline: 32053118]
148. Shaw RJ, Steinberg DM, Bonnet J, Modarai F, George A, Cunningham T, et al. Mobile health devices: will patients actually use them? J Am Med Inform Assoc 2016 May 17;23(3):462-466 [FREE Full text] [doi: 10.1093/jamia/ocv186] [Medline: 26911820]
149. Jaana M, Sherrard H, Paré G. A prospective evaluation of telemonitoring use by seniors with chronic heart failure: adoption, self-care, and empowerment. Health Informatics J 2019 Dec;25(4):1800-1814 [FREE Full text] [doi: 10.1177/1460458218799458] [Medline: 30247080]
150. Rho MJ, Kim H, Sun C, Wang G, Yoon K, Choi IY. Comparison of the acceptance of telemonitoring for glucose management between South Korea and China. Telemed J E Health 2017 Nov;23(11):881-890. [doi: 10.1089/tmj.2016.0217] [Medline: 28598260]
151. Powell RE, Henstenburg JM, Cooper G, Hollander JE, Rising KL. Patient perceptions of telehealth primary care video visits. Ann Fam Med 2017 May;15(3):225-229 [FREE Full text] [doi: 10.1370/afm.2095] [Medline: 28483887]
152. Serafica R, Inouye J, Lukkahatai N, Braginsky N, Pacheco M, Daub K. The use of mobile health to assist self-management and access to services in a rural community. Comput Inform Nurs 2019 Feb;37(2):62-72. [doi: 10.1097/CIN.0000000000000494] [Medline: 30543532]
153. Brew-Sam N, Chib A, Rossmann C. Differential influences of social support on app use for diabetes self-management - a mixed methods approach. BMC Med Inform Decis Mak 2020 Jul 07;20(1):151 [FREE Full text] [doi: 10.1186/s12911-020-01173-3] [Medline: 32635919]
154. Connor K, Wambach K, Baird MB. Descriptive, qualitative study of women who use mobile health applications to obtain perinatal health information. J Obstet Gynecol Neonatal Nurs 2018 Nov;47(6):728-737. [doi: 10.1016/j.jogn.2018.04.138] [Medline: 29856963]
155. Duclos V, Yé M, Moubassira K, Sanou H, Sawadogo NH, Bibeau G, et al. Situating mobile health: a qualitative study of mHealth expectations in the rural health district of Nouna, Burkina Faso. Health Res Policy Syst 2017 Jul 12;15(Suppl 1):47 [FREE Full text] [doi: 10.1186/s12961-017-0211-y] [Medline: 28722558]




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156. Guo X, Chen S, Zhang X, Ju X, Wang X. Exploring patients' intentions for continuous usage of mHealth services: elaboration-likelihood perspective study. JMIR Mhealth Uhealth 2020 Apr 06;8(4):e17258 [FREE Full text] [doi: 10.2196/17258] [Medline: 32250277]
157. Schulte M, Liang D, Wu F, Lan Y, Tsay W, Du J, et al. A smartphone application supporting recovery from heroin addiction: perspectives of patients and providers in China, Taiwan, and the USA. J Neuroimmune Pharmacol 2016 Sep 4;11(3):511-522 [FREE Full text] [doi: 10.1007/s11481-016-9653-1] [Medline: 26846506]
158. Aisyah DN, Ahmad RA, Artama WT, Adisasmito W, Diva H, Hayward AC, et al. Knowledge, attitudes, and behaviors on utilizing mobile health technology for TB in Indonesia: a qualitative pilot study. Front Public Health 2020;8:531514 [FREE Full text] [doi: 10.3389/fpubh.2020.531514] [Medline: 33123508]
159. Hinami K, Harris BA, Uriostegui R, Jasmin W, Lopez M, Trick WE. Patient-level exclusions from mHealth in a safety-net health system. J Hosp Med 2017 Feb 01;12(2):90-93. [doi: 10.12788/jhm.2686] [Medline: 28182803]
160. Kumar AA, De Costa A, Das A, Srinivasa G, D'Souza G, Rodrigues R. Mobile health for tuberculosis management in South India: is video-based directly observed treatment an acceptable alternative? JMIR Mhealth Uhealth 2019 Apr 03;7(4):e11687 [FREE Full text] [doi: 10.2196/11687] [Medline: 30942696]
161. Salgado T, Tavares J, Oliveira T. Drivers of mobile health acceptance and use from the patient perspective: survey study and quantitative model development. JMIR Mhealth Uhealth 2020 Jul 09;8(7):e17588 [FREE Full text] [doi: 10.2196/17588] [Medline: 32673249]
162. Zini EM, Lanzola G, Quaglini S, Bossi P, Licitra L, Resteghini C. A pilot study of a smartphone-based monitoring intervention on head and neck cancer patients undergoing concurrent chemo-radiotherapy. Int J Med Inform 2019 Sep;129:404-412. [doi: 10.1016/j.ijmedinf.2019.06.004] [Medline: 31445284]
163. Su Y, Huang S, Wu Y, Chen C. Factors affecting patients' acceptance of and satisfaction with cloud-based telehealth for chronic disease management: a case study in the workplace. Appl Clin Inform 2020 Mar 15;11(2):286-294 [FREE Full text] [doi: 10.1055/s-0040-1708838] [Medline: 32294772]
164. Bauer AM, Iles-Shih M, Ghomi RH, Rue T, Grover T, Kincler N, et al. Acceptability of mHealth augmentation of collaborative care: a mixed methods pilot study. Gen Hosp Psychiatry 2018;51:22-29 [FREE Full text] [doi: 10.1016/j.genhosppsych.2017.11.010] [Medline: 29272712]
165. Čuš A, Edbrooke-Childs J, Ohmann S, Plener PL, Akkaya-Kalayci T. "Smartphone Apps Are Cool, But Do They Help Me?": a qualitative interview study of adolescents' perspectives on using smartphone interventions to manage nonsuicidal self-injury. Int J Environ Res Public Health 2021 Mar 22;18(6):3289 [FREE Full text] [doi: 10.3390/ijerph18063289] [Medline: 33810106]
166. Jain N, Singh H, Koolwal GD, Kumar S, Gupta A. Opportunities and barriers in service delivery through mobile phones (mHealth) for Severe Mental Illnesses in Rajasthan, India: a multi-site study. Asian J Psychiatr 2015 Apr;14:31-35. [doi: 10.1016/j.ajp.2015.01.008] [Medline: 25701069]
167. Koivumäki T, Pekkarinen S, Lappi M, Väisänen J, Juntunen J, Pikkarainen M. Consumer adoption of future MyData-based preventive eHealth services: an acceptance model and survey study. J Med Internet Res 2017 Dec 22;19(12):e429 [FREE Full text] [doi: 10.2196/jmir.7821] [Medline: 29273574]
168. Caplan S, Sosa Lovera A, Veloz Comas E, Attilus J. A mobile app to prevent depression among low-income primary care patients in the Dominican Republic: sociocultural adaptations. J Transcult Nurs 2020 Jul 19;31(4):413-424. [doi: 10.1177/1043659620912315] [Medline: 32188342]
169. Muigg D, Duftschmid G, Kastner P, Modre-Osprian R, Haluza D. Telemonitoring readiness among Austrian diabetic patients: a cross-sectional validation study. Health Informatics J 2020 Dec;26(4):2332-2343 [FREE Full text] [doi: 10.1177/1460458219894094] [Medline: 32046567]
170. Muigg D, Kastner P, Modre-Osprian R, Haluza D, Duftschmid G. Is Austria ready for telemonitoring? A readiness assessment among doctors and patients in the field of diabetes. Stud Health Technol Inform 2018;248:322-329. [Medline: 29726454]
171. Helleman J, Van Eenennaam R, Kruitwagen ET, Kruithof WJ, Slappendel MJ, Van Den Berg LH, et al. Telehealth as part of specialized ALS care: feasibility and user experiences with "ALS home-monitoring and coaching". Amyotroph Lateral Scler Frontotemporal Degener 2020 May;21(3-4):183-192. [doi: 10.1080/21678421.2020.1718712] [Medline: 32003245]
172. Müller SD, Wehner D, Konzag H, Vesterby M, Høybye MT. The paradox of project success despite lack of the "My Pathway" telehealth platform usage. Health Informatics J 2021;27(1):1460458220976734 [FREE Full text] [doi: 10.1177/1460458220976734] [Medline: 33438499]
173. Chang LW, Njie-Carr V, Kalenge S, Kelly JF, Bollinger RC, Alamo-Talisuna S. Perceptions and acceptability of mHealth interventions for improving patient care at a community-based HIV/AIDS clinic in Uganda: a mixed methods study. AIDS Care 2013 May 08;25(7):874-880 [FREE Full text] [doi: 10.1080/09540121.2013.774315] [Medline: 23452084]
174. van Heerden A, Harris DM, van Rooyen H, Barnabas RV, Ramanathan N, Ngcobo N, et al. Perceived mHealth barriers and benefits for home-based HIV testing and counseling and other care: qualitative findings from health officials, community health workers, and persons living with HIV in South Africa. Soc Sci Med 2017 Jun;183:97-105 [FREE Full text] [doi: 10.1016/j.socscimed.2017.04.046] [Medline: 28475904]




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175. Fairbrother P, Ure J, Hanley J, McCloughan L, Denvir M, Sheikh A, Telescot programme team. Telemonitoring for chronic heart failure: the views of patients and healthcare professionals - a qualitative study. J Clin Nurs 2014 Jan;23(1-2):132-144. [doi: 10.1111/jocn.12137] [Medline: 23451899]
176. Schnall R, Higgins T, Brown W, Carballo-Dieguez A, Bakken S. Trust, perceived risk, perceived ease of use and perceived usefulness as factors related to mHealth technology use. Stud Health Technol Inform 2015;216:467-471 [FREE Full text] [Medline: 26262094]
177. Siebenhüner AR, Mikolasek M, Witt C, Barth J. Improvements in health might contradict adherence to mobile health interventions: findings from a self-care cancer app study. J Altern Complement Med 2021 Mar;27(S1):S115-S123. [doi: 10.1089/acm.2020.0111] [Medline: 33788602]
178. Murphy J, Uttamlal T, Schmidtke KA, Vlaev I, Taylor D, Ahmad M, et al. Tracking physical activity using smart phone apps: assessing the ability of a current app and systematically collecting patient recommendations for future development. BMC Med Inform Decis Mak 2020 Feb 03;20(1):17 [FREE Full text] [doi: 10.1186/s12911-020-1025-3] [Medline: 32013996]
179. Zhou M, Zhao L, Kong N, Campy KS, Qu S, Wang S. Factors influencing behavior intentions to telehealth by Chinese elderly: an extended TAM model. Int J Med Inform 2019 Jun;126:118-127. [doi: 10.1016/j.ijmedinf.2019.04.001] [Medline: 31029253]
180. Bennett BL, Goldstein CM, Gathright EC, Hughes JW, Latner JD. Internal health locus of control predicts willingness to track health behaviors online and with smartphone applications. Psychol Health Med 2017 Dec 17;22(10):1224-1229 [FREE Full text] [doi: 10.1080/13548506.2017.1317354] [Medline: 28415852]
181. Sezgin E, Weiler M, Weiler A, Lin S. Proposing an ecosystem of digital health solutions for teens with chronic conditions transitioning to self-management and independence: exploratory qualitative study. J Med Internet Res 2018 Sep 06;20(9):e10285 [FREE Full text] [doi: 10.2196/10285] [Medline: 30190253]

## Abbreviations

**mHealth:** mobile health
**PRISMA:** Preferred Reporting Items for Systematic Reviews and Meta-Analyses
**QCRI:** Qatar Computing Research Institute

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Review

# mHealth Interventions to Reduce Physical Inactivity and Sedentary Behavior in Children and Adolescents: Systematic Review and Meta-analysis of Randomized Controlled Trials

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## Abstract

**Background:** Children and adolescents increasingly do not meet physical activity (PA) recommendations. Hence, insufficient PA (IPA) and sedentary behavior (SB) among children and adolescents are relevant behavior change domains for using individualized mobile health (mHealth) interventions.

**Objective:** This review and meta-analysis investigated the effectiveness of mHealth interventions on IPA and SB, with a special focus on the age and level of individualization.

**Methods:** PubMed, Scopus, Web of Science, SPORTDiscus, and Cochrane Library were searched for randomized controlled trials published between January 2000 and March 2021. mHealth interventions for primary prevention in children and adolescents addressing behavior change related to IPA and SB were included. Included studies were compared for content characteristics and methodological quality and summarized narratively. In addition, a meta-analysis with a subsequent exploratory meta-regression examining the moderating effects of age and individualization on overall effectiveness was performed.

**Results:** On the basis of the inclusion criteria, 1.3% (11/828) of the preliminary identified studies were included in the qualitative synthesis, and 1.2% (10/828) were included in the meta-analysis. Trials included a total of 1515 participants (mean age (11.69, SD 0.788 years; 65% male and 35% female) self-reported (3/11, 27%) or device-measured (8/11, 73%) health data on the duration of SB and IPA for an average of 9.3 (SD 5.6) weeks. Studies with high levels of individualization significantly decreased insufficient PA levels (Cohen $d$=0.33; 95% CI 0.08-0.58; $Z$=2.55; $P$=.01), whereas those with low levels of individualization (Cohen $d$=−0.06; 95% CI −0.32 to 0.20; $Z$=0.48; $P$=.63) or targeting SB (Cohen $d$=−0.11; 95% CI −0.01 to 0.23; $Z$=1.73; $P$=.08) indicated no overall significant effect. The heterogeneity of the studies was moderate to low, and significant subgroup differences were found between trials with high and low levels of individualization ($\chi^2_1$=4.0; $P$=.04; $I^2$=75.2%). Age as a moderator variable showed a small effect; however, the results were not significant, which might have been because of being underpowered.

**Conclusions:** Evidence suggests that mHealth interventions for children and adolescents can foster moderate reductions in IPA but not SB. Moreover, individualized mHealth interventions to reduce IPA seem to be more effective for adolescents than for children. Although, to date, only a few mHealth studies have addressed inactive and sedentary young people, and their quality of evidence is moderate, these findings indicate the relevance of individualization on the one hand and the difficulties in reducing SB using mHealth interventions on the other.



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**Trial Registration:** PROSPERO CRD42020209417; https://www.crd.york.ac.uk/prospero/display_record.php?RecordID=209417

***(JMIR Mhealth Uhealth 2022;10(5):e35920)*** doi:10.2196/35920

**KEYWORDS**

health behavior change; individualization; sedentary behavior; physical activity; tailored interventions; personalized medicine; health app; mobile phone

## Introduction

### Rationale

"Inactivity is the epidemic of the 21st century" [1]. The prevalence of insufficient physical activity (IPA; defined as not meeting the specified physical activity [PA] guidelines [2]) in children and adolescents is >80% worldwide, which is mainly attributable to time spent on sedentary behavior (SB; defined as any waking behavior characterized by an energy expenditure ≤1.5 metabolic equivalents of task [METs] while in a sitting, reclining, or lying posture [2,3]) and has increased continuously over the past decades [4]. This trend remains unbroken, although the health benefits of at least 60 minutes of moderate to vigorous PA (MVPA; defined as any activity with a MET value between 3 and 5.9; vigorous-intensity PA is defined as ≥6 METs [5,6]) on average per day for children and adolescents are well-established [7].

Although SB and IPA may be used synonymously, and indeed by definition, they refer to the same energy expenditure spectrum, it should still be noted that they are not necessarily correlated [8], and both have severe health consequences [9]. For example, children and adolescents may exhibit high levels of SB (driving to school, sitting in class all day, and playing video games in the evening) while simultaneously meeting the recommended PA guidelines (going to soccer practice for an hour in the evening). In this case, the health consequences of SB time would be occurring, although the PA level is sufficient. If IPA and SB are performed in childhood and adolescence, it is assumed that these behavioral patterns will endure until adulthood [10], which is why, from a global perspective, it is important to target young populations with strong IPA and SB patterns in the context of primary prevention.

Given the increasing digitization in health care and the proliferation of smartphones [11], mobile health (mHealth) interventions have been shown to be effective and of scope in reducing IPA and SB in children and adolescents [12], as well as in adults [13]. A more detailed glance at the contents of mHealth interventions reveals that SMS text messaging interventions are one of the most common methods used for delivering mHealth interventions [14], which has been recently criticized [15]. Instead, personalized approaches should focus on responding appropriately to the realities of everyday life and addressing the diversity of modern societies [16]. Key facets of effective mHealth interventions depict the integration of behavior change techniques (BCTs) [17] and the foundation upon existing theoretical approaches [18]. Furthermore, there is empirical evidence that just-in-time interventions [19,20], individualized or tailored interventions [21], and interventions that incorporate multiple BCTs [22] show large potential in this respect. However, Chen et al [23] highlight that the design of mHealth interventions often lacks a theory-driven approach [24,25], and there is little emphasis on evidence-based content [26]. Another difficulty with mHealth interventions occurs when existing evidence is summarized in meta-analyses and refers to outcomes that are coreported as secondary outcomes but do not constitute the core of the intervention [27].

Until recently, there have been far more mHealth interventions for healthy adults aiming to reduce IPA and SB than for healthy children and adolescents [13,28]. In one of the very few reviews on healthy children and adolescent target groups, Schoeppe et al [12] demonstrated an overall moderate quality of health apps and found a positive correlation between app quality and the number of app features and BCTs, therefore suggesting that future apps should target user engagement, be tailored to specific populations, and be guided by health behavior theories. Böhm et al [28] furthermore criticize the quality of mHealth interventions for children and adolescents in this respect and suggest that more age-appropriate solutions are needed. The results of other reviews indicate that smartphone-based mHealth interventions (especially apps) are a versatile strategy for increasing PA and steps in children and adolescents [29]. For example, Laranjo et al [30] found an average increase of 1850 steps per day after an mHealth intervention. However, it is also occasionally mentioned that the use of mHealth could lead to a further increase in the already high screen time of children and adolescents [31,32], which needs to be taken into consideration when planning and implementing mHealth apps. Although mHealth can increase screen time, it may not necessarily do so. The representative and longitudinal Motorik-Modul study demonstrated that increased screen time does not correlate with PA minutes, opening various opportunities for digital interventions and potential ways for new approaches to target the IPA and SB of children and adolescents [33,34].

In the context of mHealth, individualization is defined as an adaptation to the needs or special circumstances of an individual and is cited as one of the main barriers that prevent patients from changing their health behavior [23,35]. Individualized interventions (sometimes also called adaptive, needs-specific, target group–specific, tailored, or personalized interventions) offer a potential way of delivering person-centered interventions by varying levels of individual needs and empowering individuals to monitor their health actively [21]. Non-mHealth interventions have sometimes used individualized one-on-one meetings, showing high effectiveness but consuming much time and resources. Therefore, this approach has been criticized as time consuming and resource burdening [36,37]. Apps can apply this approach in a much more ecological way by being easily accessible to a wide variety of populations. The enhanced efficacy of individualized interventions compared with



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nonindividualized interventions has been repeatedly demonstrated in various populations [30,38,39], especially in adults [40], but not yet in children or adolescents, although several randomized controlled trials address this matter. For example, the MOPO study examined the effects of a gamified and individualized mHealth intervention and has not been cited in any meta-analysis to date [41]. Another example of this is the intervention of Moreau et al [42], which is a fully automated, theory-driven, tailored intervention. In addition, there is no existing taxonomy for individualized app elements as there is, for example, for behavior change mechanisms [17], from which derives the urgent need for further systematic reviews and development of a taxonomy for individualized elements.

### Objective

Although several reviews [12,28,29,43] have been published on mHealth-based PA promotion in children and adolescents, and some of them also include studies with IPA and SB as outcomes, none of the existing reviews ensures (1) a clear focus on the at-risk target group of children and adolescents with high IPA and SB levels and (2) a separate analysis of effects of mHealth on IPA and SB. Therefore, this review might contribute to a better understanding of the needs of children and adolescents who engage in IPA and high SB. For this reason, this review's aims were 3-fold.

First, there is a need to identify and describe existing SB and IPA mHealth interventions that address PA for children and adolescents. Second, this review sought to answer whether and how mHealth interventions are effective in reducing IPA and SB in healthy children and adolescents. Third, there is a need to explore whether age and individualization are moderators of the overall effectiveness of the mHealth interventions. This leads to the following main research questions:

1. What are the characteristics of effective existing mHealth interventions for children and adolescents to reduce SB and IPA?
2. How effective are existing mHealth interventions for children and adolescents in reducing SB and IPA?
3. What moderating effects do individualization and age have on the effectiveness of mHealth interventions for children and adolescents to reduce SB and IPA?

## Methods

This systematic review and meta-analysis was conducted according to Cochrane methodology, and the results were reported following the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) 2020 statement [44].

### Eligibility Criteria

The criteria for eligible studies are defined in accordance with the population, intervention, comparison, and outcomes criteria [45] and are presented in Textbox 1. In line with World Health Organization (WHO) recommendations [5], IPA was defined as <60 minutes of MVPA per day or insufficient step count per day (<5000 steps per day) [46], and SB was defined as any waking behavior characterized by an energy expenditure of ≤1.5 METs while in a sitting, reclining, or lying posture [2,3]. Alternative measures can be screen time and sitting time.



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**Textbox 1.** Summary of the population, intervention, comparison, and outcomes and eligibility criteria.

**Participants and population**

- Inclusion: healthy children and adolescents (aged 0-21 years) without physical or psychological morbidities that would influence the realization of behaviors targeted by the respective interventions and studies that include participants with any physical or psychological morbidities (eg, populations with obesity) and provides a subgroup analysis for the healthy population separately
- Exclusion: children and adolescents with any physical or psychological morbidities, populations with mean age >21 years, studies conducted within clinical settings, and studies focusing on populations whose insufficient physical activity (IPA) or sedentary behavior (SB) is influenced by disease-specific recommendations or health status

**Intervention or interventions and exposure or exposures**

- Inclusion: mobile health (mHealth) interventions with healthy children and adolescents where the primary or secondary outcome measure was IPA or SB, mixed interventions, and family-based interventions
- Exclusion: studies without mHealth interventions

**Comparator(s) and control**

- Inclusion: active or passive control groups
- Exclusion: studies without a control group

**Outcomes**

- Inclusion:
  - IPA, which is defined as <60 minutes of self-reported or accelerometry-measured moderate to vigorous physical activity per day or insufficient step count per day (<5000 steps per day); therefore, various physical activity measures (min/week of physical activity, steps, counts, metabolic equivalents of task [MET] minutes, screen time, and sitting time) need to be included
  - SB, which is defined as any waking behaviors characterized by an energy expenditure of ≤1.5 METs while in a sitting, reclining, or lying posture; alternative measures can be screen time and sitting time
- Exclusion: mHealth intervention studies that do not involve IPA or SB as a primary or secondary outcome

**Types of study to be included**

- Inclusion: randomized controlled trials (RCTs) that include individual or cluster randomization, clinical trials, feasibility studies with an RCT design, and just-in-time adaptive interventions; for a potential meta-analysis, only RCTs were included
- Exclusion: nonexperimental study designs (eg, observational or case studies, studies reporting prevalence or trend data, measurement studies, and theoretical papers), non–peer-reviewed studies, and nonprimary studies (eg, letters, comments, conference proceedings, reviews, and narrative articles)

## Information Sources

After group discussion among the research team, a systematic search for randomized controlled trials in English between January 1, 2000, and January 29, 2021. was conducted using the 5 databases of PubMed, Scopus, Web of Science, SPORTDiscus, and Cochrane Library.

## Search Strategy

The search terms were reviewed by 3 authors (HB, JF, and KW), and the search was conducted by 1 author (HB) in March 2021. The following vital constructs, as well as numerous synonyms, were used: (*children* OR *adolescents*) AND (*mHealth*) AND (*IPA* OR *SB*). The entire search strategy can be found in the *Availability of Data, Code, and Other Materials* section.

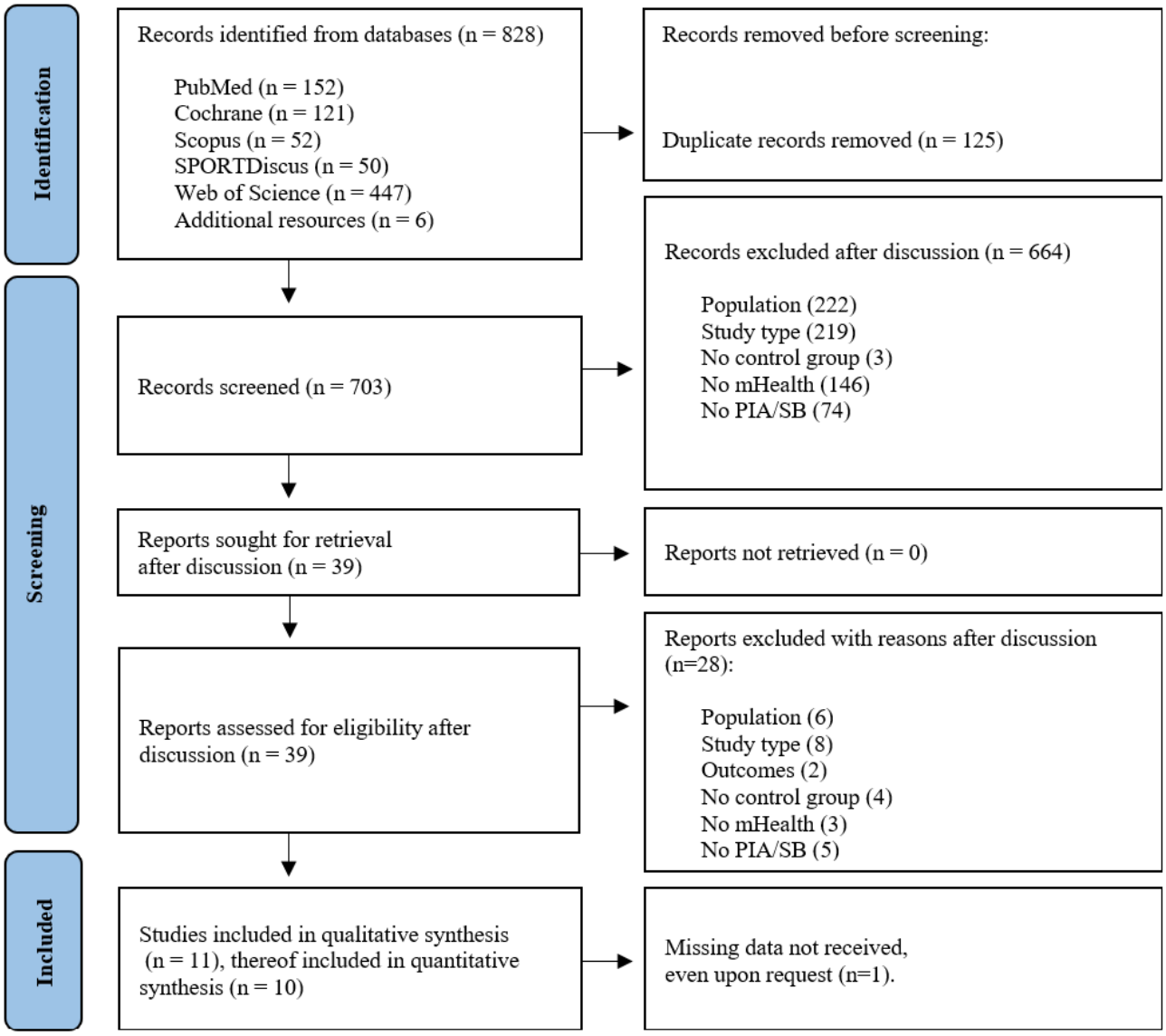
## Selection Process

The identified literature was imported to the reference management software Zotero (Roy Rosenzweig Center for History and New Media). After removing duplicates, the first author (HB) and a coauthor (JF) screened titles and abstracts to identify all potentially eligible studies based on the inclusion and exclusion criteria (the detailed study flow is presented in the PRISMA flowchart in Figure 1). Full-text articles were retrieved for eligible abstracts and reviewed by the same 2 authors before inclusion in the review. The first author (HB) and a second reviewer (JF) independently assessed full paper copies of remaining potentially eligible studies to determine included studies, and if no consent was reached, a third reviewer (KW) resolved the disagreement by discussion and arbitration.



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**Figure 1.** Flowchart and study selection process (adapted from Page et al [45]). IPA: insufficient physical activity; SB: sedentary behavior.




## Data Collection Process and Data Items

On a study level, data, including the name of the author, year of publication, study type, study aim, information about the mHealth intervention, duration of intervention, follow-up period, target population or setting, integration of parents, country, sample size, age (range, mean, and SD), gender, IPA or SB criterion, relevant outcomes, measurement method, treatment effects, individualized elements, BCT elements, and theoretical foundation were extracted. To identify interventions with high and low levels of individualization, we quantified the individualized elements and defined *low level of individualization* as the number of individualized items below the IQR of the evaluated interventions and *high level of individualization* as the number of individualized items within or above the IQR of the evaluated interventions.

## Study Risk of Bias Assessment

The risk of bias (ROB) in individual studies was evaluated independently by 2 reviewers (HB and KW) using the 5-dimensional ROB 2 tool [47]. In this procedure, the overall ROB is classified as low if all dimensions indicate low risk. Once ≥1 dimension is rated as unclear, the entire trial is rated the same way. Furthermore, if ≥1 dimension is classified as being high risk, the overall ROB is rated high. Disagreements between the authors concerning the ROB were resolved by discussion, with the involvement of another author where necessary.

## Effect Measures

To perform a meta-analysis, the sample sizes, means, and SDs of measurement time points 1 and 2 were extracted from the intervention and control groups of all included studies (or study arms) for both IPA and SB. For reasons of comparability in the meta-analysis, follow-up data were not extracted, as not all studies included a third or fourth measurement point. When multiple primary outcome measures were presented, the most conclusive measure to our research questions was identified by JF and HB. Quality of information and the orientation toward WHO guidelines played a critical role in this process. It was defined that IPA was most likely to be modeled by *minutes of MVPA per day*, as suggested by the WHO, followed by *minutes of light MVPA per day*, *minutes of PA per day*, and *number of steps per day*. For SB, *minutes in SB per day* was preferred over



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the proxy measures of *minutes of sitting time per day* and *minutes of screen time per day*.

### Synthesis Methods

If data for the meta-analysis were not available in the original manuscripts, the study authors were contacted. The last search was conducted in March 2021. Extracted data were then weighted by sample size (splitted shared group procedure was used in studies with multiple study arms to avoid unit of analysis error [48]), converted into Cohen *d*, and integrated into a meta-analysis with random effects using RevmanWeb [49] calculator. We used the following benchmark to interpret the effect sizes: effect sizes >0.50 are interpreted as large, effect sizes of 0.50 to 0.30 as moderate, and effect sizes of 0.30 to 0.10 as small or <0.10 as trivial [50]. Tests for heterogeneity, overall effects, and subgroup differences were also calculated using RevmanWeb.

### Reporting Bias Assessment and Certainty Assessment

To assess publication bias, funnel plots were compiled using RevmanWeb to determine asymmetric shapes within the natural statistical dispersion [51]. If the plot is asymmetric because of many large effect sizes on one side of the mean, it strongly suggests unpublished or unconducted studies with contrary results. To provide certainty of the evidence, the Grading of Recommendations, Assessment, Development, and Evaluations approach [52] was used as an extension of the ROB assessment. The following five factors were examined to obtain a well-founded assessment: individual study limitations (ROB), inconsistency of results (heterogeneity), indirectness of evidence (external validity), imprecision (small sample size and wide CI), and publication bias.

### Additional Analyses

An additional meta-regression was performed in R-Studio [53] using the *Metafor* package [54] to relate the estimated effect sizes to the mean age of the samples. We distinguished between primary outcome (IPA or SB) and level of individualization (low or high). The included trials (and their multiple arms) were divided into trials with high (number of individualized items within or above the IQR of evaluated interventions) and low levels of individualization (number of individualized items below the IQR of evaluated interventions) to conduct a meta-analysis. For both IPA and SB outcomes, a separate meta-analysis was conducted to provide the comparability of effects. To visualize the results, a grouped bubble plot was created in Microsoft Excel [55], plotting the weighted standardized mean differences of the individual trials and the average age of the participants. Group differentiation was based on the primary outcome (IPA and SB).

### Registration and Protocol

The protocol for this systematic review and meta-analysis was prospectively registered on PROSPERO (International Prospective Register of Systematic Reviews) and can be accessed using registration number CRD42020209417.

### Availability of Data, Code, and Other Materials

The search string (Medical Subject Headings) was as follows:

> *(Child [MeSH] OR Adolescent [MeSH]) AND (Health Promotion[MeSH] OR School Health Services[MeSH] OR Primary Prevention[MeSH] OR Health Behavior Change) AND (Telemedicine [MeSH] OR Patient-Specific Modeling[MeSH] OR Individuali* OR tailored Intervention OR digital health OR Mobile Applications[MeSH] OR mobile phone* OR smartphone* OR iPhone* OR iPad* OR tablet* OR android OR SMS OR text message* OR App OR Reminder Systems [MeSH]) AND (SB[MeSH] OR Physical Fitness[MESH] OR Exercise[MESH] OR energy expenditure) / Filter applied: years 2010-2020, only RCT and Clinical Trials*

## Results

### Study Selection

The initial database search generated 828 articles, of which 125 (15.1%) were duplicates (Figure 1), and the study screening identified 11 (1.35) studies as eligible for qualitative analysis and 10 (1.2%) articles for quantitative synthesis.

### Study Characteristics

A total of 11 randomized controlled trials were included (n=10, 91%, parallel and n=1, 9%, crossover trial), with a duration of 9.3 (SD 5.6) weeks, of which 3 (27%) [56-58] included a follow-up measurement. Eligible trials included samples of 40 to 496 participants (mean 138, SD 145), with a mean age range of 3.5 to 17.8 years (Table 1). In 9% (10/11) of studies, both genders were approximately equally represented. A single study [41] only included male adolescents, resulting in an overall gender distribution of 975 boys and young men to 540 girls and young women. Approximately 27% (3/11) of trials with young children (aged <5 years) included parent integration, whereas others focused on children and adolescents only. The target population and study aims varied across studies, and the countries were exclusively Western nations. The mHealth interventions ranged from basic SMS text messaging interventions to web-based mobile interventions, individualized and gamified apps, and wearable interventions. In addition, of the 15 interventions, 3 (20%) used self-reported measures, and 8 (53%) interventions used device-based measures of health data on the duration of SB and IPA. Furthermore, it should be mentioned that not all studies focused on reducing SB or IPA as their primary objective. Approximately 45% (5/11) of studies aimed to promote PA [41,57-60], 9% (1/11) aimed to improve fat mass index [61], 9% (1/11) aimed to reduce BMI [62], and 9% (1/11) aimed to change behavior [56] as a primary study aim.

The quantitative results of the individual studies are presented in the forest plots in Figures 2 and 3. To describe each intervention (or study arm) in detail, the number and content of individualized elements, BCTs, and theoretical foundations are presented in Table 2.



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**Table 1.** Study characteristics.

| Study | Study type (duration in weeks) | Study aim | Description of mHealth[a] intervention | Population (setting), region, and country | Sample size (N) | Age (years) | | SB[b] (unit) and IPA[c] outcomes (unit); measurement method |
|---|---|---|---|---|---|---|---|---|
| | | | | | | Values, mean (SD) | Values, range | |
| Chen et al [62] | 2-arm parallel RCT[d] with follow-up (12) | Decrease BMI | iStart Smart for Teens: a smartphone-based, culturally appropriate, and tailored educational program for weight management | Chinese American adolescents who are overweight, California, United States | 40 (male 23 and female 17) | 14.9 (1.67) | 13-18 | SB (hours per day) and PA[e] (days per week); questionnaire (California Health Interview Survey) |
| Nyström et al [61] | 2-arm parallel RCT (24) | Reduce obesity (improve fat mass index) | Web-based app to deliver MINISTOP intervention, which provided an extensive program of information and behavioral support | Healthy children (preschool; parental support), Östergötland, Sweden | 313 (male 170 and female 143) | 4.5 (0.1) | 4-5 | SB (min/day) and MVPA[f] (minutes per day); ActiGraph wGT3x-BT accelerometer |
| Direito et al [58] | 3-arm parallel RCT (8) | Improve PA levels in healthy young people who are insufficiently active | AIMFIT trial compared the apps "Zombies, run" and "Get Running" with a control group (device measured) | Healthy adolescents, Auckland, New Zealand | 51 (male 22 and female 29) | 15.67 (1.2) | 14-17 | SB (minutes per day) and MVPA (minutes per day); accelerometer (ActiGraph GT1M) and PAQ-A[g] |
| Downing et al [63] | 2-arm pilot RCT (6) | Reducing children's SB in early age | Mini-Movers: SMS text messaging intervention to provide information and practical support | Young children (playgroups; parental support), Melbourne, Australia | 57 (male 26 and female 31) | 3.05 (0.75) | 2-4 | Sitting time (minutes per day) and no IPA outcome; ActivePAL |
| Fassnacht et al [59] | 2-arm parallel RCT (8) with 2 follow-ups (4 and 4) | Promote health behavior in school-aged children | Daily behavior reporting and feedback vis SMS text messaging | Healthy children (elementary school), Braga, Portugal | 49 (male 23 and female 26) | 9.6 (0.4) | 8-19 | Screen time (hours per day) and PA (hours per day); Family Eating and Activity Habits questionnaire |
| Gaudet et al [57] | Crossover RCT (6) | Increase PA in young adolescents | Wrist-worn PA tracker (Fitbit, model Charge HR)+web-based Fitbit user account | Young adolescents (school), New Brunswick, Canada | 46, (male 22 and female 24) | 13.0 (0.35) | 13-14 | SB (minutes per day) and MVPA (minutes per day); Actical accelerometer |
| Hammersley et al [64] | 2-arm parallel RCT (11) with 2 follow-ups (12 and 24) | Reduce obesity behaviors in preschool children | Parent focused; Time2bHealthy Online Program with Fakebook integration | Children who are overweight (preschool; parental support), Wollongong, Australia | 86 (male 43 and female 43) | 3.46 (0.92) | 2-5 | SB (minutes per day) and MVPA (minutes per day); ActiGraph GT3X+ accelerometer |
| Mendoza et al [60] | 2-arm parallel RCT (10) | Promote PA among adolescent and young adult survivors | Wearable PA-tracking device (Fitbit Flex) and a peer-based web-based support group (a Facebook group) | Childhood survivors of cancer, Seattle, United States | 59 (male 24 and female 35) | 16.6 (1.5) | 14-18 | SB (minutes per day) and MVPA (minutes per day); ActiGraph GT3X+ accelerometer |
| Pyky et al [41] | 2-arm parallel RCT (6) | Promote PA and social activity | Game-based persuasion, for example, by physically moving within the districts of the city; players could earn points and claim areas for their clan in-game | Young adolescent men (military), Oulu, Finland | 496 (male 496 and female 0) | 17.8 (0.6) | 16-20 | SB (minutes per day) and MVPA (minutes per day); Polar Active Accelerometer |



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| Study | Study type (duration in weeks) | Study aim | Description of mHealth[a] intervention | Population (setting), region, and country | Sample size (N) | Age (years) | | SB[b] (unit) and IPA[c] outcomes (unit); measurement method |
|---|---|---|---|---|---|---|---|---|
| | | | | | | Values, mean (SD) | Values, range | |
| Sirriyeh et al [56] | 4-arm exploratory RCT (2) | PA behavior change | Daily SMS text messages, which included manipulations of affective or beneficial beliefs | Late adolescents (state schools), Yorkshire, United Kingdom | 128 (male 38 and female 90) | 17.3 (0.68) | 16-19 | IPAQ[h] questionnaire; no outcomes; time point 0 data missing |
| Van Woudenberg et al [65] | 2-arm clustered RCT (10) | Promote PA | Smartphone-based SNI[i] with MyMovez2 Wearable Lab—a smartphone with a tailor-made research app | Influential adolescents (school), Venlo, Netherlands | 190 (male 88 and female 102) | 12.7 (0.50) | 11-19 | SB (minutes per day) and MVPA (minutes per day); accelerometer (Fitbit Flex) |

[a]mHealth: mobile health.

[b]SB: sedentary behavior.

[c]IPA: insufficient physical activity.

[d]RCT: randomized controlled trial.

[e]PA: physical activity.

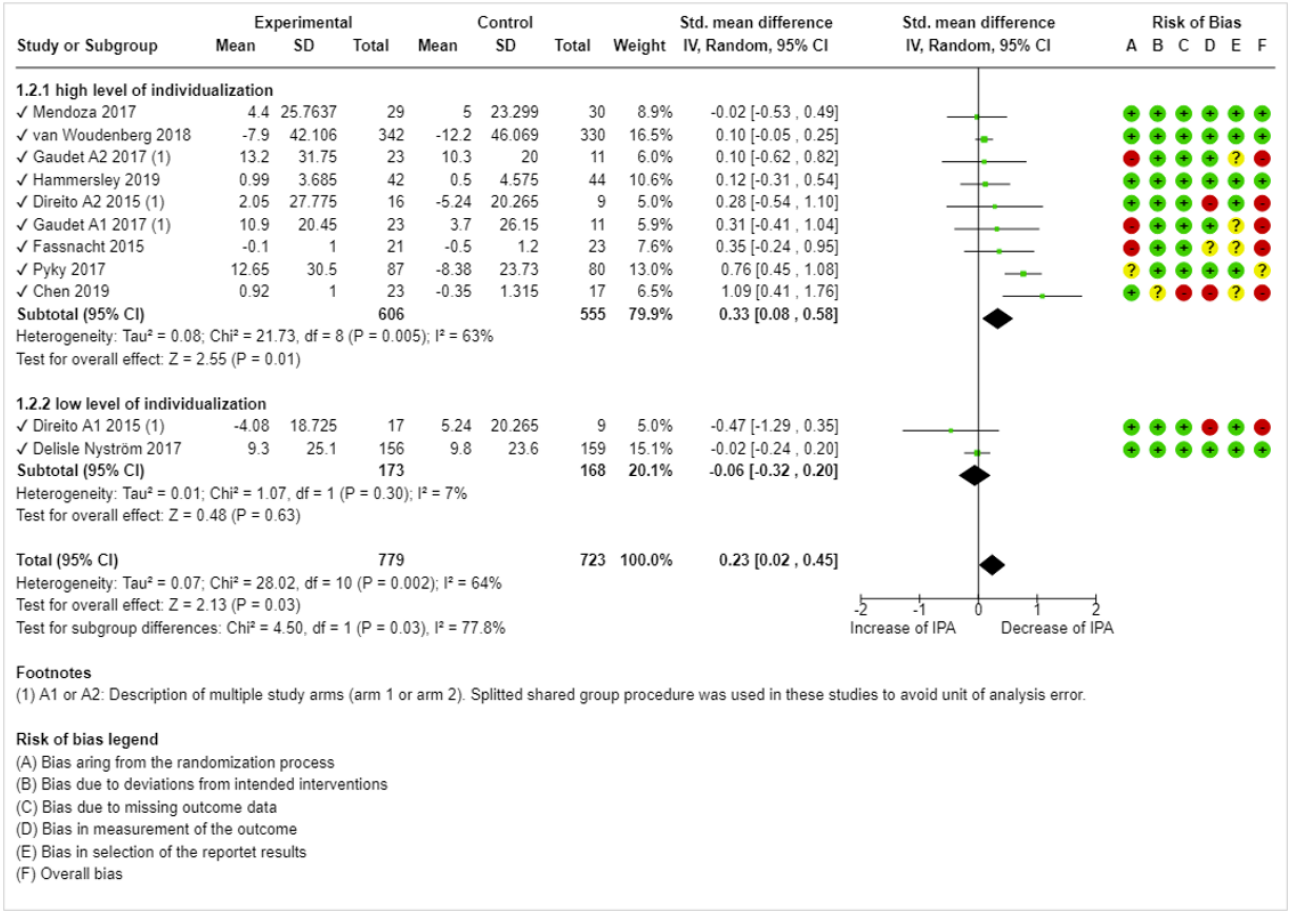
[f]MVPA: moderate to vigorous physical activity.

[g]PAQ-A: Physical Activity Questionnaire for Adolescents.

[h]IPAQ: International Physical Activity Questionnaire.

[i]SNI: social network intervention.

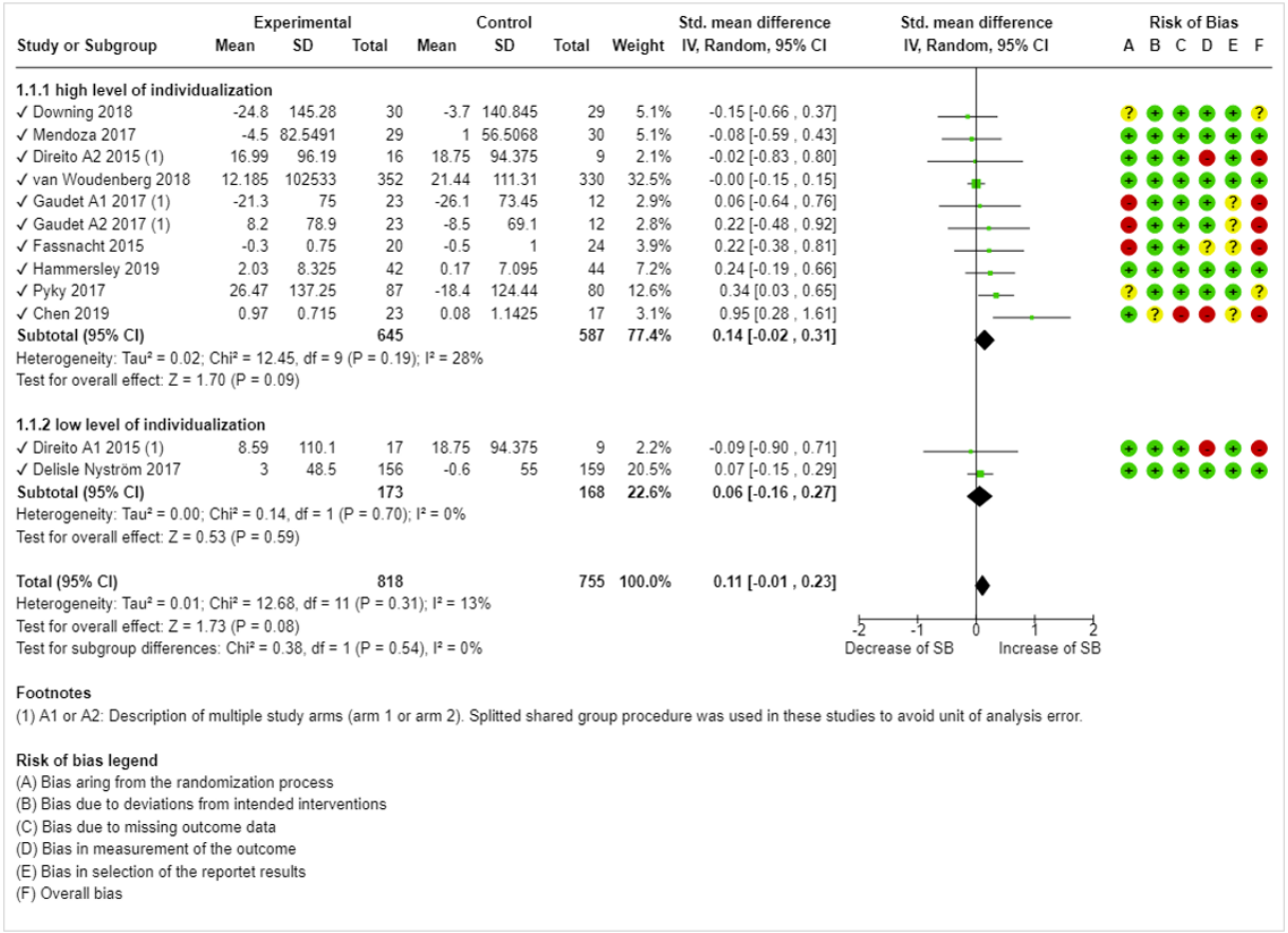
**Figure 2.** Forest plot for effect size comparison of high-individualized versus low-individualized mobile health interventions on decreasing IPA [42,58-63,66]. IPA: insufficient physical activity.






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**Figure 3.** Forest plot for effect size comparison of high-individualized versus low-individualized mobile health interventions on decreasing SB [42,58-64,66]. RCT: randomized controlled trial; SB: sedentary behavior.






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**Table 2.** Mobile health intervention characteristics: study aims, BCT[a] cluster, theoretical foundation, and individualization.

| Study (RCT[b] and protocol) and intervention (study arm) | BCT taxonomy cluster, according to Michie et al [17] (N) | Theoretical foundation (N) | Individualization (N) | Level of individualization |
|---|---|---|---|---|
| **Chen et al [62]** | | | | |
| Fitbit app and Facebook | Goals and planning, feedback and monitoring, social support, shaping knowledge, comparison of behavior, reward and threat, and associations (7) | Not mentioned (0) | Competitions with community or friends, individual goal setting, task adjustment in relation to BMI, direct biofeedback and real-time coaching, goal-specific motivational coaching, personalized advice, and guidance (6) | High |
| **Nyström et al [61,66]** | | | | |
| MINISTOP app | Feedback and monitoring and associations (2) | Not mentioned (0) | Individual feedback (1) | Low |
| **Direito et al [58]** | | | | |
| Zombies, Run! app (1) | Goals and planning and feedback and monitoring (2) | Self-regulatory behavior change theory [67] (1) | Audio instructions, missions and defense bases, and web-based races (3) | Low |
| Get Running app (2) | Goals and planning, feedback and monitoring, comparison of behavior, and reward and threat (4) | Self-regulatory behavior change theory [67] (1) | Human voice coach, training path, friend integration, low threshold approach, recovery periods, and music (6) | High |
| **Downing et al [63,68]** | | | | |
| Mini-Movers SMS text messaging–based intervention | Goals and planning, feedback and monitoring, and reward and threat (3) | Social cognitive theory [69], SMART[c] goal framework [70], and CALO-RE[d] taxonomy [71] (3) | Individual goal setting; goal-specific feedback; tailored SMS text messages; and just-in-time delivery of SMS text messages based on preferred time, date, and activity (4) | High |
| **Fassnacht et al [59]** | | | | |
| SMS text messaging–based feedback intervention | Goals and planning, feedback and monitoring, and associations (3) | Not mentioned (0) | Individual goal setting, task adjustment in relation to BMI, tailored feedback messages, and goal-specific motivational coaching (4) | High |
| **Gaudet et al [57]** | | | | |
| FitBit app immediate intervention (1) | Goals and planning, feedback and monitoring, social support, shaping knowledge, comparison of behavior, reward and threat, and associations (7) | Not mentioned (0) | Competitions with community or friends, individual goal setting, task adjustment in relation to BMI, direct biofeedback and real-time coaching, goal-specific motivational coaching, personalized advice, and guidance (6) | High |
| FitBit app delayed intervention (2) | Goals and planning, feedback and monitoring, social support, shaping knowledge, comparison of behavior, reward and threat, and associations (7) | Not mentioned (0) | Competitions with community or friends, individual goal setting, task adjustment in relation to BMI, direct biofeedback and real-time coaching, goal-specific motivational coaching, personalized advice, and guidance (6) | High |
| **Hammersley et al [64,72]** | | | | |
| Time2b-Healthy Facebook and on the web | Goal setting, revision of goals, feedback, and challenges (4) | Self-efficacy model [73] and SMART goals framework [70] (2) | Tailored reminder emails, a Facebook group with individual goal setting, and goal-specific motivational coaching (4) | High |
| **Mendoza et al [60]** | | | | |



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| Study (RCT[b] and protocol) and intervention (study arm) | BCT taxonomy cluster, according to Michie et al [17] (N) | Theoretical foundation (N) | Individualization (N) | Level of individualization |
|---|---|---|---|---|
| Fitbit app and Facebook | Goals and planning, feedback and monitoring, social support, shaping knowledge, comparison of behavior, reward and threat, and associations (7) | Not mentioned (0) | Individual awards in a Facebook group, competitions with community or friends, individual goal setting, task adjustment in relation to BMI, direct biofeedback and real-time coaching, goal-specific motivational coaching, personalized advice, and guidance (7) | High |
| **Pyky et al [41,74,75]** | | | | |
| Clans of Oulu gamified app and web-based MOPO portal | Goals and planning, feedback and monitoring, social support, comparison of behavior, comparison of outcomes, reward and threat, associations, identity, and covert learning (9) | Transtheoretical Model of Behavior Change [76] (1) | Stage of behavior change, individual feedback on physical activity and sitting time, GPS-based tasks, competitions with community, and peer-referenced comparison (5) | High |
| **Woudenberg et al [65,77]** | | | | |
| App-based social network intervention—MyMovez | Comparison of behavior, reward and threat, and identity (3) | Theory of Planned Behavior [78], Self-Determination Theory [79], and Self-Persuasion Theory [80] (3) | Content tailored to influential youths, comparing individual scores with others, individual rewards, and individual identification with health behavior (4) | High |
| **Sirriyeh et al [56]** | | | | |
| Instrumental SMS text message intervention | Goals and planning, shaping knowledge, and identity (3) | Theory of Planned Behavior [78] (1) | Individual goal setting (1) | Low |
| Affective SMS text message intervention | Goals and planning, self-belief, and identity (3) | Theory of Planned Behavior [78] (1) | Individual goal setting (1) | Low |
| Combined SMS text message intervention | Goals and planning, shaping knowledge, self-belief, and identity (4) | Theory of Planned Behavior [78] (1) | Individual goal setting (1) | Low |

[a]BCT: behavior change technique.

[b]RCT: randomized controlled trial.

[c]SMART: Specific, Measurable, Achievable, Relevant, and Time-Bound.

[d]CALO-RE: Coventry, Aberdeen, and London-Refined.

Among the 11 included studies, 3 (27%) had multiple study arms [56-58], resulting in a total of 15 mHealth interventions. In studies with multiple arms, each study arm represented a subintervention. Unfortunately, the subtrials of Sirriyeh et al [56] could not be integrated into the meta-analysis because of missing data. Overall, 33% (5/15) indicated a low level of individualization, and 66% (10/15) of interventions showed a high level of individualization. Individual goal setting was the most common technique used to individualize mHealth interventions. If the level of individualization in the studies was low, there was also a low use of BCTs in these interventions. The reporting of the theoretical foundation was not mentioned in 40% (6/15) of interventions and was therefore generally poor, although the interventions of Downing et al [68] and Woudenberg et al [65] were each based on 3 underlying theories. The most common theories were self-regulatory BCT [67]; Specific, Measurable, Achievable, Relevant, and Time-Bound goals framework [70]; Theory of Planned Behavior [78]; Self-Determination Theory [79]; Self-Persuasion Theory [80]; Transtheoretical Model of Behavior Change [76]; social cognitive theory [69]; and the Coventry, Aberdeen, and London-Refined taxonomy [71]. The number of behavior change elements correlated with the number of individualized elements. Of the 12 included interventions, 2 (17%) were SMS text messaging based, 5 (42%) included some form of social media (eg, Facebook), and 4 (33%) used the Fitbit app.

## ROB in Studies

Across the 11 studies, 7 out of 60 ratings (5 dimensions ×12 studies) indicated high ROB, and 7 ratings showed an unclear ROB, resulting in an overall rating of 3 (27%) studies with low, 2 (18%) studies with unclear, and 6 (55%) studies with a high ROB. Potential biases frequently occurred in dimensions A (bias arising from the randomization process) and D (bias in the measurement of the outcome). More detailed ROB information for each study can be found in Multimedia Appendix 1 [41,57-65] and Multimedia Appendix 2 and is also integrated into the forest plots for the meta-analysis.



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## Synthesis of Results

### *Effects of High-Individualized and Low-Individualized mHealth Interventions on Decreasing IPA*

Approximately 82% (9/11) of studies evaluated the effects of mHealth interventions on decreasing IPA levels, of which 22% (2/9) included multiple study arms [57,58]. Notably, the nonimmersive app of Direito et al [58] (arm 2) contributed to a reduction in IPA, whereas the immersive app (arm 1) increased IPA. One of the trials [56] was not included because of missing data on IPA. Splitted shared group procedure was used in studies with multiple study arms to avoid unit of analysis error [48]. As shown in Figure 2, the meta-analysis of IPA demonstrated a significant, small overall effect size (Cohen $d$=0.23; 95% CI 0.02-0.45; $Z$=2.13; $P$=.03). Trials with high levels of individualization (9/11, 82% of studies) significantly decreased IPA levels, with a moderate effect size (Cohen $d$=0.33; 95% CI 0.08-0.58; $Z$=2.55; $P$=.01). In contrast, those with low levels of individualization (2/11, 18% of studies) indicated no overall effect or even a nonsignificant increase in IPA (Cohen $d$=−0.06; 95% CI −0.32 to 0.20; $Z$=0.48; $P$=.63). A test for subgroup differences indicated that the described difference between interventions with high and low levels of individualization was statistically significant ($\chi^2_1$=4.0; $P$=.04; $I^2$=75.2%). The overall heterogeneity was moderate ($\tau^2$=0.02; $\chi^2_9$=1.1; $P$=.002; $I^2$=64%), and several ROB dimensions indicated a high ROB. As can be seen in Figure 2, dimensions A (bias arising from the randomization process), C (bias because of missing outcome date), and D (bias in the measurement of the outcome) were most frequently represented.

### *Effects of High-Individualized and Low-Individualized mHealth Interventions on Decreasing SB*

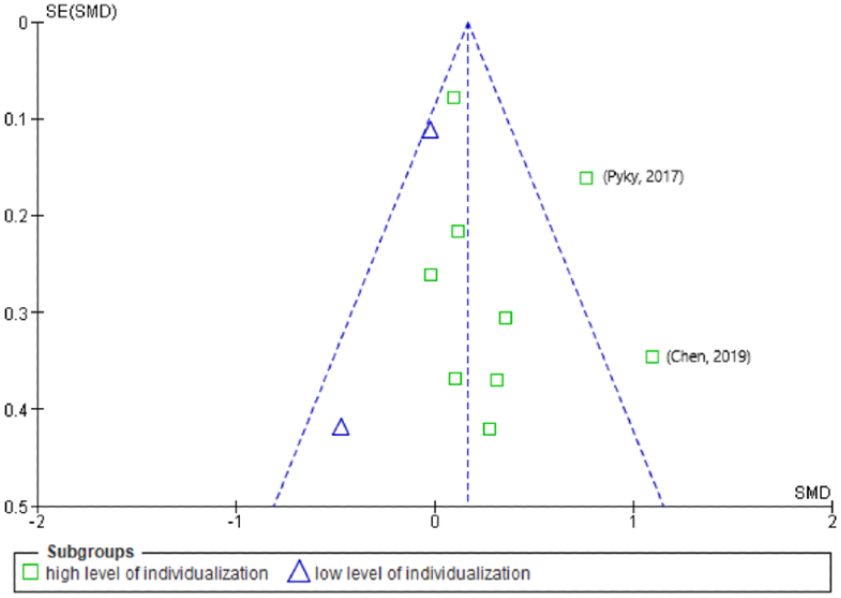
Overall, all 10 included studies evaluated the effects of mHealth interventions on decreasing SB time, and 2 (20%) studies included multiple study arms [57,58]. The results showed a difference in positive effect sizes between the 2 arms of the Gaudet et al [57] study, although it was a crossover trial. In contrast, the Direito et al [58] immersive app (arm 1) showed a slight reduction in SB, whereas the nonimmersive app (arm 2) showed a slight increase. In contrast to the meta-analytic outcome measure IPA, the analysis indicated neither a significant subgroup difference between interventions with low and high levels of individualization ($\chi^2_1$=0.4; $P$=.54; $I^2$=0%) nor a general, significant effect within each subgroup ($Z$=1.70, $P$=.09; $Z$=.53, $P$=.59). Of the 15 interventions, 8 (53%) demonstrated a small increase in SB time. The heterogeneity of the included studies was overall low to moderate ($\tau^2$=0.01; $\chi^2_{11}$=12.7; $P$=.31; $I^2$=13%) but varied by subgroup (trials with high levels of individualization: $\tau^2$=0.02, $\chi^2_9$=12.5, $P$=.19, $I^2$=28%; trials with low level of individualization: $\tau^2$=0.00, $\chi^2_1$=0.1, $P$=.70, $I^2$=0%). As demonstrated in Figure 3, several ROB dimensions indicated an unclear or high ROB. Dimensions A (bias arising from the randomization process), C (bias because of missing outcome date), and D (bias in the outcome measurement) were the most frequently represented.

## Reporting Biases

Publication bias between studies was assessed using funnel plots for the 2 outcomes of IPA and SB. Statistical tests (eg, Egger regression [81]) for publication bias were not performed because of the small number of included studies.

Visual inspection of funnel plots (Figures 4 and 5) indicated no serious publication bias in either case. The results of the study by Chen et al [62] occurred outside of the 95% CIs for both outcomes but for high-individualized trials only. Low-level individualization showed a smaller effect, and no results were outside the 95% CI. This also applies to the result of Pyky et al [41] for the IPA outcome. Therefore, it is particularly important to critically reflect on the results reported by Chen et al [62] and Pyky et al [41].

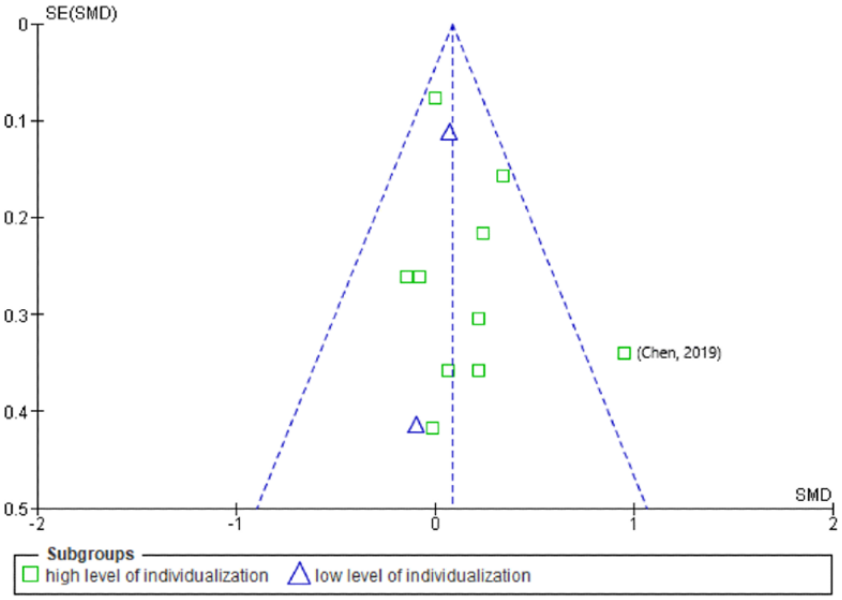
**Figure 4.** Funnel plot of comparison: insufficient physical activity outcomes. SMD: standardized mean difference.






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**Figure 5.** Funnel plot of comparison: sedentary behavior outcomes. SMD: standardized mean difference.




## Certainty of Evidence

As shown in Table 3, moderate confidence was evident in the meta-analysis effect estimate for IPA. The true effect is likely to be close to the estimate; however, there is a possibility that it is substantially different. By contrast, our confidence in the estimated effect is very limited for the primary outcome of SB, and the true effect may be substantially different. This potential bias is reinforced by the studies of Chen et al [62] and Pyky et al [41], which have above-average effect sizes while being severely weighted.

**Table 3.** Summary of findings based on Grading of Recommendations, Assessment, Development, and Evaluations approach (N=11).

| Subgroup | Studies, n (%) | Study design | Risk of bias | Inconsistency | Indirectness | Imprecision | Publication bias | Relative risk (95% CI) | Certainty |
|---|---|---|---|---|---|---|---|---|---|
| IPA[a], high level of individualization | 7 (64) | RCT[b] | Not serious | Not serious | Not serious | Serious (−1) | Probably not | 0.25 (0.02 to 0.47) | Moderate |
| IPA, low level of individualization | 3 (27) | RCT | Not serious | Not serious | Not serious | Serious (−1) | Probably not | −0.05 (−0.24 to 0.15) | Moderate |
| SB[c], high level of individualization | 8 (73) | RCT | Not serious | Not serious | Not serious | Serious (−1) | Probably yes (−1) | 0.12 (−0.07 to 0.32) | Low |
| SB, low level of individualization | 4 (36) | RCT | Not serious | Serious (−1) | Not serious | Serious (−1) | Probably yes (−1) | 0.74 (−1.08 to 2.55) | Very low |

[a]IPA: insufficient physical activity.

[b]RCT: randomized controlled trial.

[c]SB: sedentary behavior.

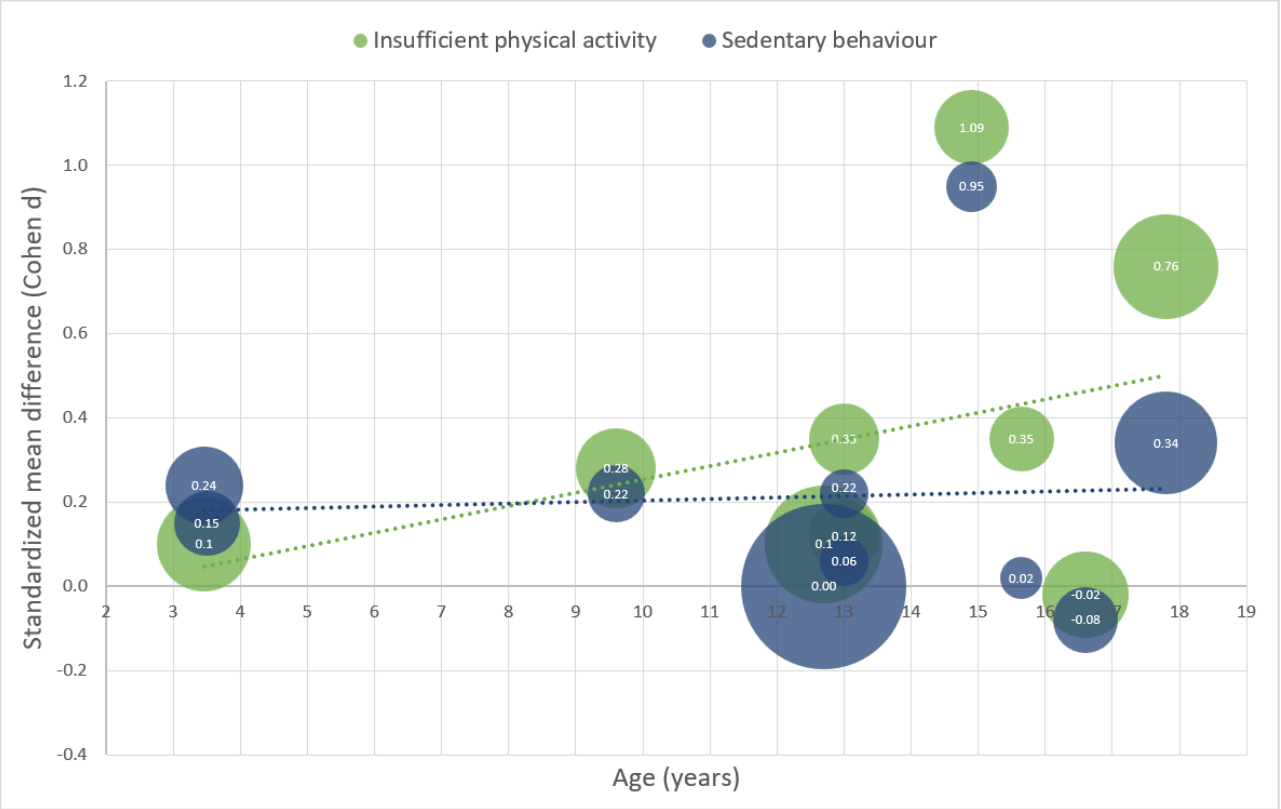
## Additional Analyses

In an exploratory approach, the effect sizes obtained from the highly individualized interventions were further explored in a meta-regression analysis with age as a moderator variable to explain the moderate heterogeneity between studies and incorporate developmental psychological aspects of children and adolescents. Therefore, Figure 6 shows a weighted grouped scatter plot of the standardized mean differences (Cohen *d*) of individual interventions (including multiple study arms) and the mean age of participants. Group differentiation was based on the primary outcomes (IPA and SB). Meta-regression analysis results indicated that effect sizes were negligible for children (aged 1-14 years). There were nonsignificant differences in IPA in the adolescent age groups (14-18 years). Although the effect size (Cohen *d*) of highly individualized interventions with respect to SB remained approximately the same across age ($\tau^2$=0.0115, SE 0.0226; $\tau$=0.1071; $I^2$=21.23%; $H^2$=1.72; $R^2$=0.00%; test for residual heterogeneity: $QE_{10}$=11.8472, $P$=.30; test of moderators: $QM_1$=0.1451, $P$=.70) the effectiveness of highly individualized interventions of IPA increased slightly but not significantly across age ($\tau^2$=0.0564, SE 0.0546; $\tau$=0.2375; $I^2$=57.01%; $H^2$=2.33; $R^2$=28.47%; test for residual heterogeneity: $QE_9$=20.3088, $P$=.02; test of moderators: $QM_1$=2.0165, $P$=.16). Although the small number of included interventions allowed only descriptive conclusions to be drawn, the underlying tendency is evident in the data and needs to be examined in future studies.



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**Figure 6.** Grouped bubble plot of weighted standardized mean differences of individual trials and mean age of participants. Group differentiation based on the primary outcome (IPA and SB). High-individualized trials included only.




## Discussion

### Principal Findings

This review and meta-analysis aimed to identify and characterize existing mHealth interventions for children and adolescents in the context of primary prevention of IPA and SB. In addition, this analysis aimed to provide clarity on whether and how effective mHealth interventions are in reducing IPA and SB in healthy children and adolescents. As a broad objective, we aimed to examine whether age and individualization influenced the overall effectiveness of mHealth interventions.

### Summary of Evidence

Out of 828 identified studies, a total of 11 (1.3%) were included for the qualitative synthesis and 10 (1.2%) for the meta-analysis based on the inclusion criteria. Trials included 1515 participants (mean age 11.69, SD 0.788 years; 65% male and 35% female) with self-reported (3/11, 27%) or device-measured (8/11, 73%) health data on the duration of SB and IPA for an average intervention period of 9.3 (SD 5.6) weeks (excluding follow-ups). Studies with high levels of individualization decreased IPA levels significantly (Cohen *d*=0.33; 95% CI 0.08-0.58; *Z*=2.55; *P*=.01), whereas those with low levels of individualization (Cohen *d*=−0.06; 95% CI −0.32 to 0.20; *Z*=0.48; *P*=.63) or addressing SB (Cohen *d*=−0.11; 95% CI −0.01 to 0.23; *Z*=1.73; *P*=.08) indicated no overall significant effect. Heterogeneity was moderate to low, and a test for subgroup differences indicated significant differences between trials with high and low levels of individualization ($\chi^2_1$=4.0; *P*=.04; $I^2$=75.2%). Age as a moderator variable showed a minor moderating effect; however, the results were not significant, which might have been because of being underpowered. This review is the first to examine the age- and individualization-dependent effectiveness of mHealth interventions to reduce IPA and SB in children and adolescents and strengthens the evidence of moderate mHealth effectiveness. This is in line with existing research on mHealth for children and adolescents [12,28].

### Characteristics of Observed mHealth Interventions

One of the main qualitative results concerning the first research question is that gamified approaches tend to have a higher effect in this population, and several previous interventions have already been shown to be effective [82,83]. The 18% (2/11) of trials showing the highest effectiveness in this meta-analysis (*Fitbit and Facebook intervention* by Chen et al [62] and the *Clans of Oulu intervention* by Pyky et al [41]) used this approach. However, it should be mentioned that the intervention *Zombies, Run!* by Direito et al [58], which showed a very low effect size, was also a gamified approach; however, it is hardly individualized and uses few BCTs. Therefore, the results suggest (in line with existing research [82]) that gamified approaches can be effective for children and adolescents but only if individualization, theoretical foundation, and integration of BCTs occur simultaneously. However, the 2 most effective interventions mentioned above are united by a distinguishing feature in addition to gamification. Both involve the social component and integrate community-based systems of social participation and association with real-world PAs in the surrounding environment. Hammersley et al [72] and van Woudenberg et al [65] integrated similar approaches. This may



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suggest that friends, family, and surrounding environments are relevant determinants for children and adolescents in the context of mHealth and should be considered in the development of mHealth interventions to reduce inadequate PA and SB.

This review also demonstrates that mHealth interventions for children and adolescents are rarely theory based [18,24,25], although theories were occasionally mentioned, and therefore reinforce the need for enhanced theoretical substantiation in the development of mHealth interventions. The consequences of non–theory-based approaches include low effect sizes and methodological deficiencies, at least in self-developed interventions [59,61]. No negative effect of missing theoreticity could be shown when already existing and evaluated apps (eg, Fitbit app) were used [57,60]. In this respect, another striking aspect of the results is that most of the considered interventions used commercially available apps (especially Fitbit models and the corresponding app) or self-developed approaches. Models from other well-known commercial providers were not used. Data transfer software was often cited as a reason in some studies. From a scientific point of view, one of the problems may be that Fitbit does not disclose the mechanisms and underlying theories behind its development.

Regarding the quality of the integrated data, it should be mentioned that many trials addressed multiple outcomes [84] and used questionnaire data as outcome parameters [85]. A more appropriate approach would be to focus only on objective data or consider a combination of objective and subjective data, similar to the approach of Chen et al [62]. The use of only qualitative data can become a problem if an objective comparison with WHO recommendations has to be provided [86]. Therefore, we encourage researchers in the field of mHealth to use accelerometry-based measurements and more standardized outcome measures in future intervention studies.

Another key aspect of qualitative analysis is the individualization of the included mHealth interventions. It is noticeable that the type of individualization varies considerably between techniques that are frequently used (eg, *individual goal setting*) and other techniques that are unique to one of the interventions (eg, individualization based on the stage of behavior change). Similar to existing ideas in the field of behavior change mechanisms [17], a consistent taxonomy is needed and should be a part of future research.

## Effectiveness of Observed mHealth Interventions

Across all interventions, it appears that mHealth interventions to reduce IPA in children and adolescents showed an overall significant moderate effectiveness, whereas interventions to reduce SB showed no overall significant effect. Accordingly, it appears easier to change IPA than SB in children and adolescents. More structural changes are probably necessary to reduce SB, which include educational policies for schools. For instance, it is harder to reduce sitting time in class, at lunch, at home while doing homework, or during transportation than it is to do another hour of sports in the evening. Potential ideas that could be implemented in the context of mHealth would be *just-in-time adaptive interventions* with reminders for small exercise breaks [20]; in the school context, the use of automated standing desks to interrupt sitting times; or the assignment of physically activating homework that encourages children and adolescents to explore their invigorated environment.

It should be further discussed that the considered mHealth interventions had no or even a small reverse effect on the reduction of SB. Although it has been shown that screen time and PA are independent constructs [33,34], it becomes evident that the use of apps leads to as much or slightly more time spent in SB, although IPA decreases. Thus, there is presumably a shift in time resources among children and adolescents through the use of mHealth intervention. A similar finding emerged for the game Pokémon Go [82]. The consequences of this finding are far-reaching and suggest that the use of mHealth in adolescence and childhood deserves careful consideration. For younger age groups, in particular, the use of an app as a family or with parental support could make sense but results in low effect sizes, as shown by 20% (3/15) of the considered interventions [61,64,68].

## Moderating Effects of Individualization and Age

Looking at the average age of the target groups in the interventions used in the meta-regression, it is noteworthy that the highest effect sizes were evident in adolescent age groups. Therefore, it is reasonable to assume that participants in different age groups are differently impressionable by mHealth. There are multiple explanations for this finding. First, as children age, unhealthy behaviors may be established, and apps may need to become more individualized to be effective [21]. Second, the more the child evolves into an individual, the more important it becomes to address their individuality in health interventions. The second hypothesis is supported by one of the key findings of the meta-analysis that individualized mHealth interventions to reduce IPA differ significantly from nonindividualized interventions with the same objective. This is in line with previous research on other populations [21]. However, it is interesting to note that interventions with the most individualized elements are not the most effective [60]. Thus, more individualization does not necessarily lead to higher effectiveness; rather, the selection of particular relevant parameters in combination with the rest of the intervention characteristics seems to result in an effective intervention. For example, the development of a new intervention could be accompanied by a kind of intervention mapping [87] accompanied by a target group analysis. This would reveal the needs and requirements of the target group of an mHealth intervention. Future research should aim to deepen these partially exploratory findings and identify the underlying psychological mechanisms. We hypothesize that there is a sweet spot at which the addition of further mechanisms for individualization and behavior change no longer leads to a larger effect, which would have severe implications for the development of mHealth interventions. Furthermore, based on the results of this review, we would like to point out that the content and functions of mHealth interventions for children and adolescents should always be adapted to the age of the target group to avoid possible developmental psychological difficulties and associated low effect sizes. It should also be mentioned that the results of the meta-regression, as suggested in the Introduction section, again indicate that SB and IPA are not correlated constructs. Therefore, PA promotion does not



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necessarily imply SB reduction. Therefore, mHealth should be addressed separately.

### Strengths and Limitations

This review is the first to differentiate between SB and IPA when considering the effects of mHealth on children and adolescents and contrast both study effects and bias. Moreover, no other review in the field to date includes a narrative analysis of individualized elements in mHealth interventions and relates them to intervention effectiveness. Another unique feature is the exploratory meta-regression. In addition to these strengths, this review has numerous limitations, both at the study and review levels.

At the study level, apart from the studies by von Pyky et al [41], van Woudenberg et al [65], and Nyström et al [61], the sample size was generally moderate to small, which may have biased the results. It should also be noted that most of the studies included multiple outcome parameters and that the primary objective of these studies was not to decrease IPA and SB. As a consequence, we assume that the observed effect sizes do not fully reflect the magnitude of the true effect. If all the included mHealth interventions were targeted at reducing IPA or SB alone, the results would certainly be more conclusive. Conspicuous among studies with small sample sizes compared with those with larger samples is the lower rating in the ROB assessment. In addition, there was a small number of included studies and partly considerable heterogeneity because of deviants, for example, the results of the study by Pyky et al [41]. This could be because of the major variability in the study design or the diverse target and age groups.

At the review level, the asymmetries observed in the funnel plot of the SB outcome indicate a publication bias. This is probably because of the study by Pyky et al [41], although the ROB assessment in this study was positive. Furthermore, it should be noted that the study results of Sirriyeh et al [56] could not be included in the meta-analysis because of a lack of reporting and as the authors did not provide any data when asked repeatedly. As the study was a 4-arm randomized controlled trial, this would certainly have been insightful for the review. In the included studies with several study arms, such as that of Direito et al [58], it was observed that the results of individual studies sometimes differed considerably. In this case, the immersive app *Zombies, Run* showed a substantially smaller effect than the nonimmersive app *Get Running*. Although other existing meta-analyses in the field of mHealth for children and adolescents similarly integrate multiple study arms (eg, He et al [29]) and we attempted to avoid potential overpowering by using the splitted shared group procedure [48], this approach should be considered controversial. Arguably, 1 author team was responsible for an excessive degree of evidence. For example, if a study shows a high ROB and includes 4 study arms, it leads to a globally insufficient certainty of evidence. As the only way to avoid this potential bias is to deliberately exclude existing evidence, further research should focus on minimizing the number of study arms and developing new statistical methods to address this issue. Another limitation of this review was that follow-up data were not extracted. As mHealth in children and adolescents is still a relatively young field of research, we did not consider there to be enough studies with follow-up measurements for a meta-analysis and therefore decided not to include follow-up measurements for reasons of evidence comparability. However, concerning mHealth in adults, it has already been shown that the effects of the interventions decrease in the long term [13]. If more mHealth trials with children and adolescents become published, we suggest replicating this review, including its follow-up effects. We assume that the long-term effects are considerably stronger in children and adolescents than in adults, as they may not yet be as well-established as for adults.

In general, the results of this review and meta-analysis should be interpreted with caution, as only moderate to low certainty of evidence is warranted based on the Grading of Recommendations, Assessment, Development, and Evaluations rating. In addition, many publications identified in the systematic literature screening were excluded as they were study protocols or small pilot studies. Therefore, this review should be updated at a later date. Furthermore, there is also limited comparability between the included studies, as the mechanisms of the considered mHealth interventions certainly move along disparate causal pathways in different age groups.

### Conclusions

The findings of this review suggest that the considered mHealth interventions for healthy children and adolescents can foster low to moderate reductions in IPA but not SB. As no significant effects were shown for SB, future studies should identify how targeted SB can be reduced using mHealth. In the future, it may also be useful to test the described interventions in clinical populations (eg, children and adolescents diagnosed with obesity or metabolic syndrome), as distressing pressure may be greater here, potentially increasing adherence to use. Moreover, individualized mHealth interventions to reduce IPA are more effective for adolescents than for children. Although only a few mHealth studies have addressed inactive and sedentary young people, and their quality of evidence is moderate, these findings indicate the relevance of individualization in the period of adolescence on the one hand and the difficulties in reducing SB with mHealth interventions on the other. Future research and policy makers should aim to strengthen the evidence and systematically evaluate individualized mHealth interventions for children and adolescents. Especially in multidisciplinary collaborations among app development, science, and engineering, there is great potential for high-quality mHealth intervention development.

## Acknowledgments

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## Conflicts of Interest

None declared.

Multimedia Appendix 1
Risk of bias in individual studies.
[PNG File , 125 KB - mhealth_v10i5e35920_app1.png ]

Multimedia Appendix 2
Risk of bias across studies.
[PNG File , 49 KB - mhealth_v10i5e35920_app2.png ]

## References


1. Hall G, Laddu DR, Phillips SA, Lavie CJ, Arena R. A tale of two pandemics: how will COVID-19 and global trends in physical inactivity and sedentary behavior affect one another? Prog Cardiovasc Dis 2021;64:108-110 [FREE Full text] [doi: 10.1016/j.pcad.2020.04.005] [Medline: 32277997]
2. Tremblay MS, Aubert S, Barnes JD, Saunders TJ, Carson V, Latimer-Cheung AE, SBRN Terminology Consensus Project Participants. Sedentary Behavior Research Network (SBRN) - terminology consensus project process and outcome. Int J Behav Nutr Phys Act 2017 Jun 10;14(1):75 [FREE Full text] [doi: 10.1186/s12966-017-0525-8] [Medline: 28599680]
3. Tremblay MS, Gray CE, Akinroye K, Harrington DM, Katzmarzyk PT, Lambert EV, et al. Physical activity of children: a global matrix of grades comparing 15 countries. J Phys Act Health 2014 May;11 Suppl 1:S113-S125. [doi: 10.1123/jpah.2014-0177] [Medline: 25426906]
4. Guthold R, Stevens GA, Riley LM, Bull FC. Worldwide trends in insufficient physical activity from 2001 to 2016: a pooled analysis of 358 population-based surveys with 1·9 million participants. Lancet Glob Health 2018 Oct;6(10):e1077-e1086 [FREE Full text] [doi: 10.1016/S2214-109X(18)30357-7] [Medline: 30193830]
5. WHO Guidelines on physical activity and sedentary behavior. World Health Organisation. 2020. URL: https://apps.who.int/iris/bitstream/handle/10665/336656/9789240015128-eng.pdf?sequence=1&isAllowed=y [accessed 2021-01-12]
6. World Health Organization. Global Recommendations on Physical Activity for Health. Geneva, Switzerland: World Health Organization; Jan 1, 2010.
7. Farooq A, Martin A, Janssen X, Wilson MG, Gibson AM, Hughes A, et al. Longitudinal changes in moderate-to-vigorous-intensity physical activity in children and adolescents: a systematic review and meta-analysis. Obes Rev 2020 Jan;21(1):e12953 [FREE Full text] [doi: 10.1111/obr.12953] [Medline: 31646739]
8. van der Ploeg HP, Hillsdon M. Is sedentary behaviour just physical inactivity by another name? Int J Behav Nutr Phys Act 2017 Oct 23;14(1):142 [FREE Full text] [doi: 10.1186/s12966-017-0601-0] [Medline: 29058587]
9. Biddle SJ, Asare M. Physical activity and mental health in children and adolescents: a review of reviews. Br J Sports Med 2011 Sep;45(11):886-895. [doi: 10.1136/bjsports-2011-090185] [Medline: 21807669]
10. Sallis JF, Prochaska JJ, Taylor WC. A review of correlates of physical activity of children and adolescents. Med Sci Sports Exerc 2000 May;32(5):963-975. [doi: 10.1097/00005768-200005000-00014] [Medline: 10795788]
11. Glauner P, Plugmann P, Lerzynski G. Digitalization in Healthcare: Implementing Innovation and Artificial Intelligence. Cham, Switzerland: Springer; 2021.
12. Schoeppe S, Alley S, Rebar AL, Hayman M, Bray NA, Van Lippevelde W, et al. Apps to improve diet, physical activity and sedentary behaviour in children and adolescents: a review of quality, features and behaviour change techniques. Int J Behav Nutr Phys Act 2017 Jun 24;14(1):83 [FREE Full text] [doi: 10.1186/s12966-017-0538-3] [Medline: 28646889]
13. Mönninghoff A, Kramer JN, Hess AJ, Ismailova K, Teepe GW, Tudor Car L, et al. Long-term effectiveness of mHealth physical activity interventions: systematic review and meta-analysis of randomized controlled trials. J Med Internet Res 2021 Apr 30;23(4):e26699 [FREE Full text] [doi: 10.2196/26699] [Medline: 33811021]
14. Whittaker R, McRobbie H, Bullen C, Rodgers A, Gu Y. Mobile phone-based interventions for smoking cessation. Cochrane Database Syst Rev 2016 Apr 10;4(4):CD006611 [FREE Full text] [doi: 10.1002/14651858.CD006611.pub4] [Medline: 27060875]
15. Walthouwer MJ, Oenema A, Lechner L, de Vries H. Comparing a video and text version of a Web-based computer-tailored intervention for obesity prevention: a randomized controlled trial. J Med Internet Res 2015 Oct 19;17(10):e236 [FREE Full text] [doi: 10.2196/jmir.4083] [Medline: 26481772]
16. Davis A, Sweigart R, Ellis R. A systematic review of tailored mHealth interventions for physical activity promotion among adults. Transl Behav Med 2020 Oct 12;10(5):1221-1232. [doi: 10.1093/tbm/ibz190] [Medline: 33044542]
17. Michie S, Richardson M, Johnston M, Abraham C, Francis J, Hardeman W, et al. The behavior change technique taxonomy (v1) of 93 hierarchically clustered techniques: building an international consensus for the reporting of behavior change interventions. Ann Behav Med 2013 Aug;46(1):81-95. [doi: 10.1007/s12160-013-9486-6] [Medline: 23512568]




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18. Fiedler J, Eckert T, Wunsch K, Woll A. Key facets to build up eHealth and mHealth interventions to enhance physical activity, sedentary behavior and nutrition in healthy subjects - an umbrella review. BMC Public Health 2020 Oct 23;20(1):1605 [FREE Full text] [doi: 10.1186/s12889-020-09700-7] [Medline: 33097013]
19. Hardeman W, Houghton J, Lane K, Jones A, Naughton F. A systematic review of just-in-time adaptive interventions (JITAIs) to promote physical activity. Int J Behav Nutr Phys Act 2019 Apr 03;16(1):31 [FREE Full text] [doi: 10.1186/s12966-019-0792-7] [Medline: 30943983]
20. Wunsch K, Eckert T, Fiedler J, Woll A. Just-in-time adaptive interventions in mobile physical activity interventions – a synthesis of frameworks and future directions. Eur Health Psychol 2022;22(4):834-842.
21. Tong HL, Quiroz JC, Kocaballi AB, Fat SC, Dao KP, Gehringer H, et al. Personalized mobile technologies for lifestyle behavior change: a systematic review, meta-analysis, and meta-regression. Prev Med 2021 Jul;148:106532. [doi: 10.1016/j.ypmed.2021.106532] [Medline: 33774008]
22. Dugas M, Gao GG, Agarwal R. Unpacking mHealth interventions: a systematic review of behavior change techniques used in randomized controlled trials assessing mHealth effectiveness. Digit Health 2020 Feb 20;6:2055207620905411 [FREE Full text] [doi: 10.1177/2055207620905411] [Medline: 32128233]
23. Chen Y, Ji M, Wu Y, Deng Y, Wu F, Lu Y. Individualized mobile health interventions for cardiovascular event prevention in patients with coronary heart disease: study protocol for the iCARE randomized controlled trial. BMC Cardiovasc Disord 2021 Jul 13;21(1):340 [FREE Full text] [doi: 10.1186/s12872-021-02153-9] [Medline: 34256698]
24. Direito A, Walsh D, Hinbarji M, Albatal R, Tooley M, Whittaker R, et al. Using the intervention mapping and behavioral intervention technology frameworks: development of an mHealth intervention for physical activity and sedentary behavior change. Health Educ Behav 2018 Jun;45(3):331-348. [doi: 10.1177/1090198117742438] [Medline: 29216765]
25. Han M, Lee E. Effectiveness of mobile health application use to improve health behavior changes: a systematic review of randomized controlled trials. Healthc Inform Res 2018 Jul;24(3):207-226 [FREE Full text] [doi: 10.4258/hir.2018.24.3.207] [Medline: 30109154]
26. Dawson RM, Felder TM, Donevant SB, McDonnell KK, Card 3rd EB, King CC, et al. What makes a good health 'app'? Identifying the strengths and limitations of existing mobile application evaluation tools. Nurs Inq 2020 Apr;27(2):e12333 [FREE Full text] [doi: 10.1111/nin.12333] [Medline: 31854055]
27. Copas JB, Jackson D, White IR, Riley RD. The role of secondary outcomes in multivariate meta-analysis. J R Stat Soc Ser C Appl Stat 2018 Nov;67(5):1177-1205 [FREE Full text] [doi: 10.1111/rssc.12274] [Medline: 30344346]
28. Böhm B, Karwiese SD, Böhm H, Oberhoffer R. Effects of mobile health including wearable activity trackers to increase physical activity outcomes among healthy children and adolescents: systematic review. JMIR Mhealth Uhealth 2019 Apr 30;7(4):e8298 [FREE Full text] [doi: 10.2196/mhealth.8298] [Medline: 31038460]
29. He Z, Wu H, Yu F, Fu J, Sun S, Huang T, et al. Effects of smartphone-based interventions on physical activity in children and adolescents: systematic review and meta-analysis. JMIR Mhealth Uhealth 2021 Feb 01;9(2):e22601 [FREE Full text] [doi: 10.2196/22601] [Medline: 33522980]
30. Laranjo L, Ding D, Heleno B, Kocaballi B, Quiroz JC, Tong HL, et al. Do smartphone applications and activity trackers increase physical activity in adults? Systematic review, meta-analysis and metaregression. Br J Sports Med 2021 Apr;55(8):422-432. [doi: 10.1136/bjsports-2020-102892] [Medline: 33355160]
31. Carson V, Hunter S, Kuzik N, Gray CE, Poitras VJ, Chaput JP, et al. Systematic review of sedentary behaviour and health indicators in school-aged children and youth: an update. Appl Physiol Nutr Metab 2016 Jun;41(6 Suppl 3):S240-S265 [FREE Full text] [doi: 10.1139/apnm-2015-0630] [Medline: 27306432]
32. Csibi S, Griffiths MD, Demetrovics Z, Szabo A. Analysis of problematic smartphone use across different age groups within the 'Components Model of Addiction'. Int J Ment Health Addiction 2021;19(3):616-631. [doi: 10.1007/s11469-019-00095-0]
33. Pearson N, Braithwaite RE, Biddle SJ, van Sluijs EM, Atkin AJ. Associations between sedentary behaviour and physical activity in children and adolescents: a meta-analysis. Obes Rev 2014 Aug;15(8):666-675 [FREE Full text] [doi: 10.1111/obr.12188] [Medline: 24844784]
34. Schmidt SC, Anedda B, Burchartz A, Kolb S, Oriwol D, Woll A. Der Zusammenhang zwischen körperlicher Aktivität und Mediennutzung bei Kindern und Jugendlichen in Deutschland. In: Arampatzis A, Braun S, Schmitt K, Wolfarth B, editors. Sport im öffentlichen Raum: 24. dvs-Hochschultag, Berlin, 18.-20. September 2019 ; Abstracts. Vol. 282. Hamburg, Germany: Feldhaus; 2019:95-96.
35. Maron DJ, Boden WE, O'Rourke RA, Hartigan PM, Calfas KJ, Mancini GB, COURAGE Trial Research Group. Intensive multifactorial intervention for stable coronary artery disease: optimal medical therapy in the COURAGE (Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation) trial. J Am Coll Cardiol 2010 Mar 30;55(13):1348-1358 [FREE Full text] [doi: 10.1016/j.jacc.2009.10.062] [Medline: 20338496]
36. Mistry H, Morris S, Dyer M, Kotseva K, Wood D, Buxton M, EUROACTION study group. Cost-effectiveness of a European preventive cardiology programme in primary care: a Markov modelling approach. BMJ Open 2012 Oct 11;2(5):e001029 [FREE Full text] [doi: 10.1136/bmjopen-2012-001029] [Medline: 23065443]
37. Kereiakes DJ, Teirstein PS, Sarembock IJ, Holmes Jr DR, Krucoff MW, O'Neill WW, et al. The truth and consequences of the COURAGE trial. J Am Coll Cardiol 2007 Oct 16;50(16):1598-1603 [FREE Full text] [doi: 10.1016/j.jacc.2007.07.063] [Medline: 17936161]




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38. Krebs P, Prochaska JO, Rossi JS. A meta-analysis of computer-tailored interventions for health behavior change. Prev Med 2010;51(3-4):214-221 [FREE Full text] [doi: 10.1016/j.ypmed.2010.06.004] [Medline: 20558196]
39. Broekhuizen K, Kroeze W, van Poppel MN, Oenema A, Brug J. A systematic review of randomized controlled trials on the effectiveness of computer-tailored physical activity and dietary behavior promotion programs: an update. Ann Behav Med 2012 Oct;44(2):259-286 [FREE Full text] [doi: 10.1007/s12160-012-9384-3] [Medline: 22767052]
40. Lau Y, Chee DG, Chow XP, Cheng LJ, Wong SN. Personalised eHealth interventions in adults with overweight and obesity: a systematic review and meta-analysis of randomised controlled trials. Prev Med 2020 Mar;132:106001. [doi: 10.1016/j.ypmed.2020.106001] [Medline: 31991155]
41. Pyky R, Koivumaa-Honkanen H, Leinonen AM, Ahola R, Hirvonen N, Enwald H, et al. Effect of tailored, gamified, mobile physical activity intervention on life satisfaction and self-rated health in young adolescent men: a population-based, randomized controlled trial (MOPO study). Comput Human Behav 2017 Jul;72:13-22. [doi: 10.1016/j.chb.2017.02.032]
42. Moreau M, Gagnon MP, Boudreau F. Development of a fully automated, web-based, tailored intervention promoting regular physical activity among insufficiently active adults with type 2 diabetes: integrating the I-change model, self-determination theory, and motivational interviewing components. JMIR Res Protoc 2015 Feb 17;4(1):e25 [FREE Full text] [doi: 10.2196/resprot.4099] [Medline: 25691346]
43. Lee AM, Chavez S, Bian J, Thompson LA, Gurka MJ, Williamson VG, et al. Efficacy and effectiveness of mobile health technologies for facilitating physical activity in adolescents: scoping review. JMIR Mhealth Uhealth 2019 Feb 12;7(2):e11847 [FREE Full text] [doi: 10.2196/11847] [Medline: 30747716]
44. Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021 Mar 29;372:n71 [FREE Full text] [doi: 10.1136/bmj.n71] [Medline: 33782057]
45. Blümle A, Gechter D, Nothacker M, Schaefer C, Motschall E, Boeker M, et al. Manual: systematische Recherche für Evidenzsynthesen und Leitlinien, Version 2.1. Association of the Scientific Medical Societies in Germany. 2020. URL: https://www.awmf.org/fileadmin/user_upload/Leitlinien/Werkzeuge/20201214_Manual_Recherche_Evidenzsynthesen_Leitlinien_V2.1.pdf [accessed 2021-08-15]
46. Kraus WE, Janz KF, Powell KE, Campbell WW, Jakicic JM, Troiano RP, 2018 Physical Activity Guidelines Advisory Committee*. Daily step counts for measuring physical activity exposure and its relation to health. Med Sci Sports Exerc 2019 Jun;51(6):1206-1212 [FREE Full text] [doi: 10.1249/MSS.0000000000001932] [Medline: 31095077]
47. Sterne JA, Savović J, Page MJ, Elbers RG, Blencowe NS, Boutron I, et al. RoB 2: a revised tool for assessing risk of bias in randomised trials. BMJ 2019 Aug 28;366:l4898. [doi: 10.1136/bmj.l4898] [Medline: 31462531]
48. Rücker G, Cates CJ, Schwarzer G. Methods for including information from multi-arm trials in pairwise meta-analysis. Res Synth Methods 2017 Dec;8(4):392-403. [doi: 10.1002/jrsm.1259] [Medline: 28759708]
49. RevMan. Cochrane Training. 2020. URL: https://training.cochrane.org/online-learning/core-software-cochrane-reviews/revman [accessed 2021-11-30]
50. Döring N, Bortz J. Forschungsmethoden und Evaluation in den Sozial- und Humanwissenschaften. 5th edition. Berlin, Germany: Springer; 2016.
51. Deaton A, Cartwright N. Understanding and misunderstanding randomized controlled trials. Soc Sci Med 2018 Aug;210:2-21 [FREE Full text] [doi: 10.1016/j.socscimed.2017.12.005] [Medline: 29331519]
52. Andrews JC, Schünemann HJ, Oxman AD, Pottie K, Meerpohl JJ, Coello PA, et al. GRADE guidelines: 15. Going from evidence to recommendation-determinants of a recommendation's direction and strength. J Clin Epidemiol 2013 Jul;66(7):726-735. [doi: 10.1016/j.jclinepi.2013.02.003] [Medline: 23570745]
53. Integrated Development for R. R Studio. 2021. URL: https://www.rstudio.com/categories/integrated-development-environment/ [accessed 2021-12-14]
54. Viechtbauer W. Conducting meta-analyses in R with the metafor package. J Stat Soft 2010;36(3):1-48. [doi: 10.18637/jss.v036.i03]
55. Excel. Microsoft Corporation. 2021. URL: https://www.microsoft.com/en-in/microsoft-365/excel [accessed 2022-04-12]
56. Sirriyeh R, Lawton R, Ward J. Physical activity and adolescents: an exploratory randomized controlled trial investigating the influence of affective and instrumental text messages. Br J Health Psychol 2010 Nov;15(Pt 4):825-840. [doi: 10.1348/135910710X486889] [Medline: 20156396]
57. Gaudet J, Gallant F, Bélanger M. A bit of fit: minimalist intervention in adolescents based on a physical activity tracker. JMIR Mhealth Uhealth 2017 Jul 06;5(7):e92 [FREE Full text] [doi: 10.2196/mhealth.7647] [Medline: 28684384]
58. Direito A, Jiang Y, Whittaker R, Maddison R. Apps for IMproving FITness and increasing physical activity among young people: the AIMFIT pragmatic randomized controlled trial. J Med Internet Res 2015 Aug 27;17(8):e210 [FREE Full text] [doi: 10.2196/jmir.4568] [Medline: 26316499]
59. Fassnacht DB, Ali K, Silva C, Gonçalves S, Machado PP. Use of text messaging services to promote health behaviors in children. J Nutr Educ Behav 2015;47(1):75-80. [doi: 10.1016/j.jneb.2014.08.006] [Medline: 25282200]
60. Mendoza JA, Baker KS, Moreno MA, Whitlock K, Abbey-Lambertz M, Waite A, et al. A Fitbit and Facebook mHealth intervention for promoting physical activity among adolescent and young adult childhood cancer survivors: a pilot study. Pediatr Blood Cancer 2017 Dec;64(12):e26660. [doi: 10.1002/pbc.26660] [Medline: 28618158]




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61. Nyström CD, Sandin S, Henriksson P, Henriksson H, Trolle-Lagerros Y, Larsson C, et al. Mobile-based intervention intended to stop obesity in preschool-aged children: the MINISTOP randomized controlled trial. Am J Clin Nutr 2017 Jun;105(6):1327-1335. [doi: 10.3945/ajcn.116.150995] [Medline: 28446496]
62. Chen J, Guedes CM, Lung AE. Smartphone-based healthy weight management intervention for Chinese American adolescents: short-term efficacy and factors associated with decreased weight. J Adolesc Health 2019 Apr;64(4):443-449. [doi: 10.1016/j.jadohealth.2018.08.022] [Medline: 30409751]
63. Downing KL, Salmon J, Hinkley T, Hnatiuk JA, Hesketh KD. Feasibility and efficacy of a parent-focused, text message-delivered intervention to reduce sedentary behavior in 2- to 4-year-old children (Mini Movers): pilot randomized controlled trial. JMIR Mhealth Uhealth 2018 Feb 09;6(2):e39 [FREE Full text] [doi: 10.2196/mhealth.8573] [Medline: 29426816]
64. Hammersley ML, Okely AD, Batterham MJ, Jones RA. An internet-based childhood obesity prevention program (Time2bHealthy) for parents of preschool-aged children: randomized controlled trial. J Med Internet Res 2019 Feb 08;21(2):e11964 [FREE Full text] [doi: 10.2196/11964] [Medline: 30735139]
65. van Woudenberg TJ, Bevelander KE, Burk WJ, Smit CR, Buijs L, Buijzen M. A randomized controlled trial testing a social network intervention to promote physical activity among adolescents. BMC Public Health 2018 Apr 23;18(1):542 [FREE Full text] [doi: 10.1186/s12889-018-5451-4] [Medline: 29685112]
66. Delisle C, Sandin S, Forsum E, Henriksson H, Trolle-Lagerros Y, Larsson C, et al. A web- and mobile phone-based intervention to prevent obesity in 4-year-olds (MINISTOP): a population-based randomized controlled trial. BMC Public Health 2015 Feb 07;15:95 [FREE Full text] [doi: 10.1186/s12889-015-1444-8] [Medline: 25886009]
67. Bamberg S. Changing environmentally harmful behaviors: a stage model of self-regulated behavioral change. J Environ Psychol 2013 Jun;34:151-159. [doi: 10.1016/j.jenvp.2013.01.002]
68. Downing KL, Salmon J, Hinkley T, Hnatiuk JA, Hesketh KD. A mobile technology intervention to reduce sedentary behaviour in 2- to 4-year-old children (Mini Movers): study protocol for a randomised controlled trial. Trials 2017 Mar 03;18(1):97 [FREE Full text] [doi: 10.1186/s13063-017-1841-7] [Medline: 28253904]
69. Bandura A. Self-efficacy: toward a unifying theory of behavioral change. Psychol Rev 1977;84(2):191-215. [doi: 10.1037/0033-295X.84.2.191]
70. Bowman J, Mogensen L, Marsland E, Lannin N. The development, content validity and inter-rater reliability of the SMART-Goal Evaluation Method: a standardised method for evaluating clinical goals. Aust Occup Ther J 2015 Dec;62(6):420-427. [doi: 10.1111/1440-1630.12218] [Medline: 26286379]
71. Michie S, Ashford S, Sniehotta FF, Dombrowski SU, Bishop A, French DP. A refined taxonomy of behaviour change techniques to help people change their physical activity and healthy eating behaviours: the CALO-RE taxonomy. Psychol Health 2011 Nov;26(11):1479-1498. [doi: 10.1080/08870446.2010.540664] [Medline: 21678185]
72. Hammersley ML, Jones RA, Okely AD. Time2bHealthy - an online childhood obesity prevention program for preschool-aged children: a randomised controlled trial protocol. Contemp Clin Trials 2017 Oct;61:73-80. [doi: 10.1016/j.cct.2017.07.022] [Medline: 28739536]
73. Bandura A. On the functional properties of perceived self-efficacy revisited. J Manag 2012 Jan 1;38(1):9-44. [doi: 10.1177/0149206311410606]
74. Ahola R, Pyky R, Jämsä T, Mäntysaari M, Koskimäki H, Ikäheimo TM, et al. Gamified physical activation of young men--a Multidisciplinary Population-Based Randomized Controlled Trial (MOPO study). BMC Public Health 2013 Jan 14;13:32 [FREE Full text] [doi: 10.1186/1471-2458-13-32] [Medline: 23311678]
75. Leinonen AM, Pyky R, Ahola R, Kangas M, Siirtola P, Luoto T, et al. Feasibility of gamified mobile service aimed at physical activation in young men: population-based randomized controlled study (MOPO). JMIR Mhealth Uhealth 2017 Oct 10;5(10):e146 [FREE Full text] [doi: 10.2196/mhealth.6675] [Medline: 29017991]
76. Prochaska JO, Velicer WF. The transtheoretical model of health behavior change. Am J Health Promot 1997;12(1):38-48. [doi: 10.4278/0890-1171-12.1.38] [Medline: 10170434]
77. Bevelander KE, Smit CR, van Woudenberg TJ, Buijs L, Burk WJ, Buijzen M. Youth's social network structures and peer influences: study protocol MyMovez project - Phase I. BMC Public Health 2018 Apr 16;18(1):504 [FREE Full text] [doi: 10.1186/s12889-018-5353-5] [Medline: 29661223]
78. Ajzen I. The theory of planned behavior. Organ Behav Hum Decis Process 1991 Dec;50(2):179-211. [doi: 10.1016/0749-5978(91)90020-T]
79. Deci EL, Ryan RM. Self-determination theory. In: Van Lange PA, Kruglanski AW, Higgins ET, editors. Handbook of Theories of Social Psychology: Volume 1. Los Angeles, CA, USA: Sage Publications; 2012:416-437.
80. Aronson E. The power of self-persuasion. Am Psychol 1999 Nov;54(11):875-884 [FREE Full text] [doi: 10.1037/h0088188]
81. Egger M, Davey Smith G, Schneider M, Minder C. Bias in meta-analysis detected by a simple, graphical test. BMJ 1997 Sep 13;315(7109):629-634 [FREE Full text] [doi: 10.1136/bmj.315.7109.629] [Medline: 9310563]
82. Khamzina M, Parab KV, An R, Bullard T, Grigsby-Toussaint DS. Impact of Pokémon Go on physical activity: a systematic review and meta-analysis. Am J Prev Med 2020 Feb;58(2):270-282. [doi: 10.1016/j.amepre.2019.09.005] [Medline: 31836333]




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83. Sardi L, Idri A, Fernández-Alemán JL. A systematic review of gamification in e-Health. J Biomed Inform 2017 Jul;71:31-48 [FREE Full text] [doi: 10.1016/j.jbi.2017.05.011] [Medline: 28536062]
84. Mayo-Wilson E, Fusco N, Li T, Hong H, Canner JK, Dickersin K, MUDS investigators. Multiple outcomes and analyses in clinical trials create challenges for interpretation and research synthesis. J Clin Epidemiol 2017 Jun;86:39-50 [FREE Full text] [doi: 10.1016/j.jclinepi.2017.05.007] [Medline: 28529187]
85. de Moraes Ferrari GL, Kovalskys I, Fisberg M, Gómez G, Rigotti A, Sanabria LY, ELANS Study Group. Comparison of self-report versus accelerometer - measured physical activity and sedentary behaviors and their association with body composition in Latin American countries. PLoS One 2020 Apr 28;15(4):e0232420 [FREE Full text] [doi: 10.1371/journal.pone.0232420] [Medline: 32343753]
86. Fiedler J, Eckert T, Burchartz A, Woll A, Wunsch K. Comparison of self-reported and device-based measured physical activity using measures of stability, reliability, and validity in adults and children. Sensors (Basel) 2021 Apr 10;21(8):2672 [FREE Full text] [doi: 10.3390/s21082672] [Medline: 33920145]
87. Koutoukidis DA, Lopes S, Atkins L, Croker H, Knobf MT, Lanceley A, et al. Use of intervention mapping to adapt a health behavior change intervention for endometrial cancer survivors: the shape-up following cancer treatment program. BMC Public Health 2018 Mar 27;18(1):415 [FREE Full text] [doi: 10.1186/s12889-018-5329-5] [Medline: 29587699]


## Abbreviations

**BCT:** behavior change technique
**IPA:** insufficient physical activity
**MET:** metabolic equivalent of task
**mHealth:** mobile health
**MVPA:** moderate to vigorous physical activity
**PA:** physical activity
**PRISMA:** Preferred Reporting Items for Systematic Reviews and Meta-Analyses
**PROSPERO:** International Prospective Register of Systematic Reviews
**ROB:** risk of bias
**SB:** sedentary behavior
**WHO:** World Health Organization


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Original Paper

# Physical Activity Behavior of Patients at a Skilled Nursing Facility: Longitudinal Cohort Study

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## Abstract

**Background:** On-body wearable sensors have been used to predict adverse outcomes such as hospitalizations or fall, thereby enabling clinicians to develop better intervention guidelines and personalized models of care to prevent harmful outcomes. In our previous work, we introduced a generic remote patient monitoring framework (Sensing At-Risk Population) that draws on the classification of human movements using a 3-axial accelerometer and the extraction of indoor localization using Bluetooth low energy beacons, in concert. Using the same framework, this paper addresses the longitudinal analyses of a group of patients in a skilled nursing facility. We try to investigate if the metrics derived from a remote patient monitoring system comprised of physical activity and indoor localization sensors, as well as their association with therapist assessments, provide additional insight into the recovery process of patients receiving rehabilitation.

**Objective:** The aim of this paper is twofold: (1) to observe longitudinal changes of sensor-based physical activity and indoor localization features of patients receiving rehabilitation at a skilled nursing facility and (2) to investigate if the sensor-based longitudinal changes can complement patients' changes captured by therapist assessments over the course of rehabilitation in the skilled nursing facility.

**Methods:** From June 2016 to November 2017, patients were recruited after admission to a subacute rehabilitation center in Los Angeles, CA. Longitudinal cohort study of patients at a skilled nursing facility was followed over the course of 21 days. At the time of discharge from the skilled nursing facility, the patients were either readmitted to the hospital for continued care or discharged to a community setting. A longitudinal study of the physical therapy, occupational therapy, and sensor-based data assessments was performed. A generalized linear mixed model was used to find associations between functional measures with sensor-based features. Occupational therapy and physical therapy assessments were performed at the time of admission and once a week during the skilled nursing facility admission.



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**Results:** Of the 110 individuals in the analytic sample with mean age of 79.4 (SD 5.9) years, 79 (72%) were female and 31 (28%) were male participants. The energy intensity of an individual while in the therapy area was positively associated with transfer activities (β=.22; SE 0.08; *P*=.02). Sitting energy intensity showed positive association with transfer activities (β=.16; SE 0.07; *P*=.02). Lying down energy intensity was negatively associated with hygiene activities (β=–.27; SE 0.14; *P*=.04). The interaction of sitting energy intensity with time (β=–.13; SE 0.06; *P*=.04) was associated with toileting activities.

**Conclusions:** This study demonstrates that a combination of indoor localization and physical activity tracking produces a series of features, a subset of which can provide crucial information to the story line of daily and longitudinal activity patterns of patients receiving rehabilitation at a skilled nursing facility. The findings suggest that detecting physical activity changes within locations may offer some insight into better characterizing patients' progress or decline.

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**KEYWORDS**

physical medicine and rehabilitation; geriatrics; remote sensing technology; physical activity; frailty; health care delivery models; wearable sensors; indoor localization; Bluetooth low energy beacons; smartwatches

## Introduction

The population aged 65 years and older is projected to double in size to 83.7 million by 2050 only in the United States [1]. With the increase in the geriatric population, health care use is expected to increase drastically with the concomitant demand for rehabilitation and in-home care after hospitalization. Many hospitalized older adults are discharged with new or worse participation in activities of daily living (ADL). Identification of patients' unmet ADL needs in terms of functional status at the time of discharge and after they return home could help address vulnerabilities prior to hospital discharge. Functional disability, prevalent among geriatrics, is a multidimensional concept that involves factors reflected in a person's basic actions including mobility, ADL, cognition, and vision. Whether a patient has sufficient ability to perform their ADL and mobility can be a predictor of whether they are able to remain in the community. Functional status is an important predictor of health outcomes, and emphasis on better quantifying it and understanding its limitations over longer periods of time is warranted [2-5].

In rehabilitation settings, patients work with physical and occupational therapists depending on their disability. Their functional status is measured by standardized scales to evaluate impaired motor functions, limitations in performing daily activities, reaching, grasping capabilities, and so on. While such scales may not always fully capture the motor functions, completion of a task by patients may also not always reflect improvement in motor functions in that patients learn to adopt different "synergistic patterns to compensate for lost functions" [2]. In such scenarios, physical activity wearable sensors can provide quantifiable and accurate measures of human body movements through which the effect of an injury or a disease on the movement system can be investigated. However, despite the widespread use of such technologies, their clinical use has yet to translate from "bench to bedside" [2-16].

With the advent of commercially available low-cost and lightweight sensors over the past decade, the development of remote health monitoring systems has been extensively fostered and largely investigated as a tool to provide constant vigilance to patients. Their portability and ease of use make them widely practical and applicable in a variety of living settings, providing a comprehensive illustration of activities of daily living for patients living with mobility deficits as well as healthy individuals.

In a previous study [16] we reported on the performance of our developed remote monitoring system, Sensing At-Risk Population (SARP), which is comprised of activity tracking wearable sensors and indoor localization sensors. We monitored the first 3 days of patients in subacute rehabilitation environment (baseline) using SARP. This paper extends that analysis by looking at the longitudinal data captured by SARP system in a skilled nursing facility. The goal of our analysis was to determine if longitudinal changes of sensor-based physical activity and indoor localization features of patients receiving rehabilitation can complement changes captured by therapist assessments over the course of rehabilitation in the skilled nursing facility.

## Methods

### Participants

From June 2016 to November 2017, patients were recruited after admission to a subacute rehabilitation center in Los Angeles. A longitudinal study of the physical therapy, occupational therapy, and sensor-based data assessments was performed. The study cohort contains patients admitted to a skilled nursing facility for an intended rehabilitation course of no more than 21 days. After this period, patients were either re-admitted to hospital or stayed in the community or in their residence in long-term care.

Participants were eligible if older than 60 years of age, English speaking, and able to sign a consent form approved by University of California, Los Angeles, Institutional Review Board (IRB# 16-000166 entitled Sensing in At-Risk Populations). Exclusion criteria were movement disorders or complete paralysis of the upper or lower extremities. The diversity of cohort comprised patients who were postsurgical and poststroke and had functional limitations because of medical illnesses.

### Study Design

Patients were given a smartwatch every morning at 9 am, and the watches were collected from them at around 6 PM daily.



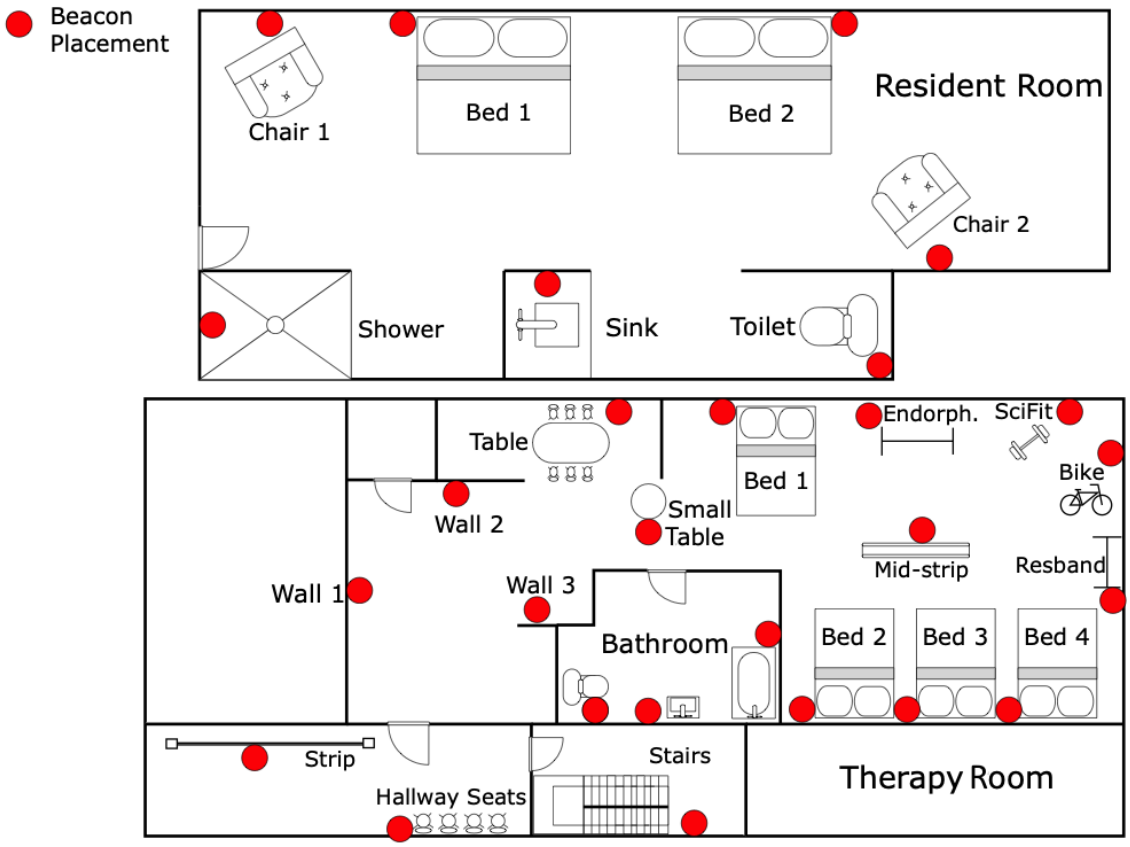
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Sensors placed throughout the facility collected data passively without any interaction required from patients. Patients normally stayed in the *resident room* (bedroom) and were scheduled for an hour of daily exercise and activity in the *therapy area of the nursing home*.

## SARP System Overview

The core of SARP is comprised of the following: hardware—(1) commercially available Sony SmartWatch 3 with built-in EM7180 ± 2 g triaxial accelerometer, 420mA battery, and BCM43340 Bluetooth module; (2) proximity beacons (MCU ARM Cortex-M4 32-bit processor) mounted at *locations of interest* within resident rooms (bedrooms) and therapy area, shown with red color dots in Figure 1; clinically validated software—activity recognition, indoor localization, and data visualization algorithms, all encompassed within a Health Insurance Portability and Accountability Act–compliant infrastructure.

**Figure 1.** Skilled nursing facility map with beacon placements shown with red dots [16].




Details of the system architecture can be found in [16-20], and the patent is described in [21]. Activity tracking and indoor localization models were built, validated, and refined prior to this study on a separate cohort of patients [17].

## Measures

### *Clinical Features*

Clinical assessments in this study are 2-fold: physical therapy (PT) and occupational therapy (OT). PT and OT metrics included functional activities such as bed mobility (includes rolling, moving between supine and sitting, scooting in supine, scooting on the edge of the bed), gait (movement patterns that make up walking and associated interpretations), transfers (moving body from one surface to another without walking), hygiene, toileting, and lower body dressing. Those activities were scored based on the functional levels (1 to 6), from independent to completely dependent [22]. A comprehensive collection of PT and OT key metrics were performed every week; hence, patients were expected to have ≥3 PT or OT assessments within 21 days. In this study, a subset of clinical features was chosen; these features were common in more than 65% (n=72) of patients' PT and OT visits. The most common PT functional activities, performed by more than 65% of the cohort, are as follows: gait distance (in feet), transfer activity, and bed mobility, including movement from supine to sit. Common OT functional activities are comprised of lower body dressing, toileting activity, hygiene, and overall ability to tolerate daily activities (activity tolerance).

### *Sensor-Based Features*

Time and frequency domain characteristics of the accelerometer signal (main, median, variance, skewness, kurtosis, peak frequency, and peak power) were used to determine physical activities. Indoor localization was achieved by using beacons mounted on locations of interest.

The metrics captured from smartwatches and beacons were used to infer the following features: (1) activity recognition measures such as sitting time and standing time; (2) indoor localizations,



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such as time in bed, time in the bathroom, or therapy area; and (3) raw acceleration quantification (ie, mean absolute deviation, which is approximately equal to energy spent). By combining these attributes, we achieved features such as sitting time in bed, energy spent while walking, lying down time in bed, and so on. Equations resulted in sensor-based feature quantifications can be found in Table 1.

To simplify the result and avoid unnecessary complexity, we focused on the most comprehensive and significant sensor-based feature (ie, energy intensity trends), consistent with analysis shown in [16].

**Table 1.** Sensor-based features.

| Number | Equation | Summary |
|---|---|---|
| (1) | | Signal magnitude |
| (2) | | MAD[a] of accelerometer magnitude signal≈energy spent |
| (3) | | Hand displacement in 10 s when threshold on MAD=0.02 m/s$^2$ |
| (4) | | Energy spent in *walking, sitting, standing, laying,* or in *locations of interest* divided by their corresponding *time spent.* In addition to energy intensity spent at each location, we calculated the total energy intensity in *resident* room and *therapy* room. is resident room. Energy intensity for therapy room was similarly calculated. |

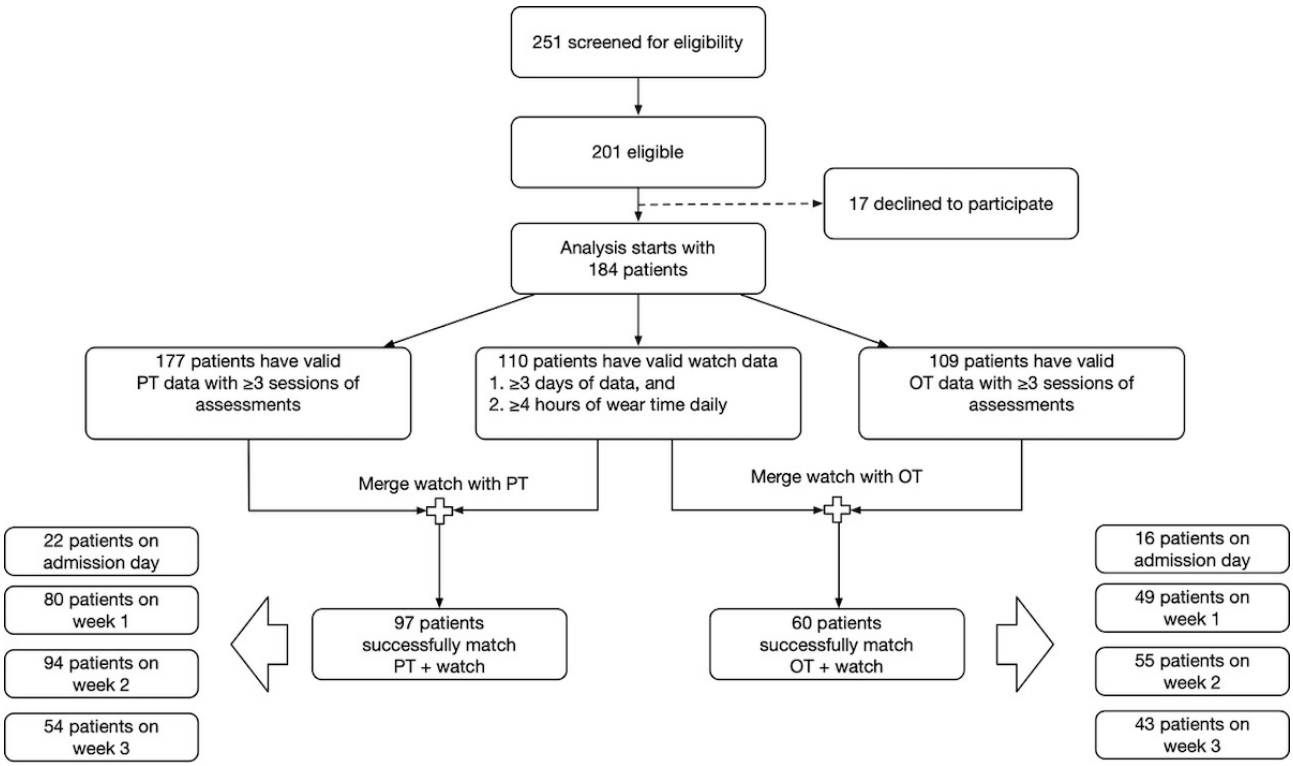
[a]MAD: mean absolute deviation.

## Analysis Inclusion Criteria

Analysis inclusion criteria were defined to ensure all patients satisfy a minimum amount of daily sensor data and collected PT and OT assessments. Analysis criteria include patients with the following data: (1) ≥3 days of watch data; (2) each day ≥4 hours of watch wear time; and (3) ≥3 sessions of PT or OT or a combination of both PT and OT.

Cohort data were agglomerated for analyses according to the consort diagram shown in Figure 2.

**Figure 2.** Diagram describing the analysis cohort. OT: occupational therapy; PT: physical therapy.






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### Statistical Analyses

Visualization of prior analysis was generated to unveil any longitudinal patterns. The time trends of sensor-based features appeared to be approximately linear; hence, we decided to use linear models for longitudinal analysis.

Descriptive statistics (medians and IQR) were computed for clinical assessments (ie, PT and OT) at each session. Generalized linear mixed effect model was used to understand the longitudinal relationships between the clinical measures and the sensor-based features [23-26]. Due to the frequency difference in which sensor and clinical assessments were collected, we merged a day of clinical assessment data with its corresponding day or closest day containing the sensor data (SD 3 days). Note that a valid day of sensor data should satisfy the analysis inclusion criteria 1 and 2.

Three models, each with different sets of sensor-based features, were constructed for each clinical outcome. Model 1 included overall energy intensity as covariate. Model 2 considered energy intensity at resident room and energy intensity at therapy area as covariates. Additionally, sensor-based activity parameters (eg, energy intensity of sitting) were used in model 3. Linear time indicates the number of weeks since the enrollment day. Interaction effects of sensor features with time were also included.

### Ethics Approval

The Ethics Board reviewed this study. The following was their determination: “The UCLA Institutional Review Board (UCLA IRB) has approved IRB#16-000166 entitled ‘Sensing At Risk Populations (SARP).’ UCLA's Federal wide Assurance (FWA) with Department of Health and Human Services is FWA00004642. The UCLA IRB waived the requirement for HIPAA Research Authorization to identify potential research participants. The UCLA IRB waived the requirement for informed consent for the review of medical records to identify potential research participants under 45 CFR 46.116(d). The UCLA IRB waived the requirement for signed informed consent for participants admitted to the BECH for acute care under 45 CFR 46.117(2).”

## Results

### Demographic Analysis

From 184 consented patients, 110 (60%) met the watch wearing time protocol with mean age of 79.4 (SD 5.9) years. Moreover, 97 (88%) patients were included in PT-watch paired analysis and 60 (54%) in OT with watch analytics. Most participants were female (n=79, 72%) and of White race or ethnicity (n=84, 76%). Additionally, 62% (n=69) of the patients had pain, 99% (n=109) of them needed some level of assistance with functional mobility activities (transfer activity), and 75% (n=83) needed assistive devices for walking. Table 2 presents detailed sociodemographic and clinical characteristics of the 110 patients. ADL parameters and their significance in determining the outcome are presented based on initial assessments, at the time of admission, or within one day.



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**Table 2.** Sociodemographic and clinical characteristics (initial assessment) of the cohort of 110 patients.

| Parameters | Community | Hospital | Parameter discriminative power (*P* value) |
|---|---|---|---|
| Subject, n (%) | 105 (95.5) | 5 (4.5) | N/A[a] |
| Age (years), mean (SD) | 78.0 (5.7) | 84.1 (6.8) | .03 |
| **Gender, n (%)** | | | >.99 |
| Female | 76 (72.4) | 3 (60) | |
| Male | 29 (27.6) | 2 (40) | |
| **Race or ethnicity, n (%)** | | | >.99 |
| Asian | 5 (4.8) | 0 (0) | |
| Black or African American | 12 (11.4) | 1 (20) | |
| Hispanic or Latino | 2 (1.9) | 0 (0) | |
| Native or Hawaiian Pacific Islander | 2 (1.9) | 0 (0) | |
| White | 84 (80) | 4 (80) | |
| **Pain present, n (%)** | | | .95 |
| No | 29 (30) | 2 (50) | |
| Yes | 67 (70) | 2 (50) | |
| **Active diagnoses, n (%)** | | | .86 |
| <10 | 22 (21) | 0 (0) | |
| ≥10 | 83 (79) | 5 (100) | |
| **Transfers, n (%)[b]** | | | .87 |
| Supervision | 1 (1) | 0 (0) | |
| Limited assistance | 57 (55) | 1 (20) | |
| Extensive assistance | 46 (44) | 4 (80) | |
| **Dressing, lower body, n (%)** | | | .93 |
| Independent | 1 (1) | 0 (0) | |
| Limited assistance | 28 (27) | 0 (0) | |
| Extensive assistance | 75 (72) | 5 (100) | |
| **Eating, n (%)** | | | .93 |
| Independent | 94 (90) | 4 (80) | |
| Supervision | 4 (4) | 1 (20) | |
| Limited assistance | 4 (4) | 0 (0) | |
| Extensive assistance | 2 (2) | 0 (0) | |
| **Toileting, n (%)** | | | .70 |
| Independent | 1 (1) | 0 (0) | |
| Limited assistance | 45 (43) | 0 (0) | |
| Extensive assistance | 58 (56) | 5 (100) | |
| **Walk room, n (%)** | | | .91 |
| Supervision | 1 (1) | 0 (0) | |
| Limited assistance | 61 (59) | 1 (20) | |
| Extensive assistance | 34 (32) | 3 (60) | |
| Activity did not occur | 8 (8) | 1 (20) | |
| **Walk hall, n (%)** | | | .92 |
| Supervision | 1 (1) | 0 (0) | |



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| Parameters | Community | Hospital | Parameter discriminative power (*P* value) |
|---|---|---|---|
| Limited assistance | 62 (60) | 1 (20) | |
| Extensive assistance | 35 (33) | 4 (80) | |
| Activity occurred only once or twice | 1 (1) | 0 (0) | |
| Activity did not occur | 5 (5) | 0 (0) | |
| **Walk on unit, n (%)** | | | .78 |
| Supervision | 1 (1) | 0 (0) | |
| Limited assistance | 62 (60) | 1 (20) | |
| Extensive assistance | 41 (39) | 4 (80) | |
| **Hygiene, n (%)** | | | .84 |
| Independent | 1 (1) | 0 (0) | |
| Limited assistance | 59 (57) | 2 (40) | |
| Extensive assistance | 44 (42) | 3 (60) | |
| **Bed mobility, n (%)** | | | .96 |
| Supervision | 1 (1) | 0 (0) | |
| Limited assistance | 68 (65) | 2 (40) | |
| Extensive assistance | 35 (34) | 3 (60) | |
| **Urinary continence, n (%)**[b] | | | .002 |
| Always continent | 85 (82) | 1 (20) | |
| Occasionally incontinent | 3 (3) | 0 (0) | |
| Frequently incontinent | 7 (6) | 1 (20) | |
| Always incontinent | 4 (4) | 3 (60) | |
| Not rated | 5 (5) | 0 (0) | |
| **Bowel continence, n (%)**[b] | | | .006 |
| Always continent | 91 (87) | 2 (40) | |
| Occasionally incontinent | 3 (3) | 0 (0) | |
| Frequently incontinent | 5 (5) | 0 (0) | |
| Always incontinent | 5 (5) | 3 (60) | |
| **Assistive devices, n (%)** | | | >.99 |
| Wheelchair | 3 (4) | 0 (0) | |
| Walker and wheelchair | 75 (95) | 4 (100) | |
| Cane and wheelchair | 1 (1) | 0 (0) | |

[a]N/A: not applicable.

[b]Parameters with $P<.05$.

## Longitudinal Analysis of All Features (Sensor and Clinical Measurements)

The community group spent higher overall energy intensity and energy intensity at the resident room compared to the hospital group, as seen in Figures S1 (a) and S1 (b) of Multimedia Appendix 1. However, energy intensity during therapy sessions tends to have similar values between two groups, especially toward the end of the rehabilitation period, as seen in Figure S1 (c) of Multimedia Appendix 1.

The descriptive statistics of clinical parameters are summarized in Table 3. It shows that “gait distance feet” increases over time (median and IQR after the first week), and “activity tolerance” increases (IQR after first week and median after second week). The table indicates no clear improvements in other clinical-based measures gauged by PT and OT functional levels within 3 weeks.



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**Table 3.** Descriptive statistics of all measures.

| Measures | Admission day | | | Week 1 | | | Week 2 | | | Week 3 | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | N | Median | IQR | N | Median | IQR | N | Median | IQR | N | Median | IQR |
| **Sensor features** | | | | | | | | | | | | |
| Overall_EI[a] | 110 | 17.97 | 13.00~23.74 | 110 | 18.88 | 13.76~25.17 | 83 | 19.30 | 14.97~25.05 | 57 | 18.43 | 15.10~23.37 |
| Resident_room_EI | 110 | 19.41 | 14.90~24.74 | 110 | 19.94 | 15.58~25.85 | 83 | 20.65 | 16.12~25.66 | 57 | 19.45 | 15.69~24.39 |
| Therapy_room_EI | 110 | 15.09 | 9.02~25.36 | 110 | 15.29 | 9.83~25.01 | 83 | 17.19 | 10.30~24.34 | 57 | 14.96 | 11.20~20.50 |
| **Occupational therapy features** | | | | | | | | | | | | |
| Dressing, lower body | 16 | 3.00 | 2.75~3.00 | 39 | 4.00 | 3.00~4.00 | 40 | 4.00 | 4.00~4.00 | 31 | 4.00 | 4.00~4.00 |
| Toileting general | 16 | 4.00 | 2.75~4.00 | 37 | 4.00 | 3.00~4.00 | 40 | 4.00 | 4.00~4.00 | 29 | 4.00 | 4.00~4.00 |
| Activity tolerance general (min) | 11 | 8.00 | 5.00~9.00 | 34 | 15.00 | 10.00~15.00 | 37 | 15.00 | 15.00~20.00 | 29 | 20.00 | 15.00~20.00 |
| Hygiene grooming | 4 | 4 | 4.00~4.00 | 15 | 4.00 | 4.00~4.00 | 19 | 4.00 | 4.00~4.00 | 15 | 4.00 | 4.00~4.00 |
| **Physical therapy features** | | | | | | | | | | | | |
| Transfer general | 20 | 4.00 | 3.75~4.00 | 72 | 4.00 | 4.00~4.00 | 86 | 4.00 | 4.00~4.00 | 50 | 4.00 | 4.00~4.00 |
| Gait distance, feet | 20 | 40.00 | 18.75~50.00 | 70 | 100.00 | 71.25~150.00 | 80 | 150.00 | 100.00~200.00 | 44 | 150.00 | 97.50~200.00 |
| Gait assistive device | 21 | 2.00 | 1.00~2.00 | 60 | 2.00 | 2.00~2.00 | 69 | 2.00 | 2.00~2.00 | 38 | 2.00 | 2.00~2.00 |
| Gait level surface | 18 | 4.00 | 4.00~4.00 | 61 | 4.00 | 4.00~4.00 | 71 | 4.00 | 4.00~4.00 | 40 | 4.00 | 4.00~4.00 |
| Bed mobility supine sit | 21 | 4.00 | 3.00~4.00 | 72 | 4.00 | 4.00~4.00 | 84 | 4.00 | 4.00~4.00 | 49 | 4.00 | 4.00~4.00 |

[a]EI: energy intensity.

## Longitudinal Association Between Clinical Measures and Sensor-Based Features

The associations of repeated PT, OT, and sensor-based measurements are modeled through three generalized linear mixed models. On PT and sensor associations, according to Table 4, the results of model 1 revealed that gait distance feet (β=.28; SE=0.06; *P*<.001), gait level surface β=.17; SE=0.04; *P*<.001, and bed mobility including supine to sit (β=.26; SE=0.05; *P*<.001) improved over time. Higher overall energy intensity indicates a higher score of transfer activity (β=.22; SE=0.08; *P*=.03).

In model 2, energy intensity at the therapy room was positively associated with transfer activity (β=.19; SE=0.08; *P*=.02). In addition, gait distance feet (β=.28; SE=0.05; *P*<.001), gait level surface (β=.17; SE=0.04; *P*<.001) and bed mobility including supine to sit (β=.26; SE=0.05; *P*<.001) improved every week.

In model 3, sitting energy intensity showed positive association with transfer activity (β=.16; SE=0.07; *P*=.02). Meanwhile, according to model 3, participants showed weekly improvements in gait distance (measured in feet; β=.27; SE=0.06; *P*<.001), gait level surface (β=.16; SE=0.05; *P*<.001), and bed mobility including supine to sit (β=.26; SE=0.05; *P*<.001).

On OT and sensor associations, Table 4 shows that lower body dressing, toileting activity, and activity tolerance in general improved every week in all three models. The higher value of overall energy intensity in model 1 implied a higher functional score of lower body dressing (β=.19; SE=0.09; *P*=.03) and toileting activity (β=.23; SE=0.09; *P*=.01).



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**Table 4.** Generalized linear mixed model association between physical therapy and occupational therapy assessments with sensor-based features.

| Models | Gait distance feet | | Transfer general | | Gait level surfaces | | Bed mobility supine sit | | Dressing lower body | | Toileting general | | Activity tolerance general | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Estimate β | SE | Estimate β | SE | Estimate β | SE | Estimate β | SE | Estimate β | SE | Estimate β | SE | Estimate β | SE |
| **Model 1** | | | | | | | | | | | | | | |
| Intercept | –.01 | 0.09 | –.01 | 0.09 | .02 | 0.11 | .01 | 0.09 | <.01 | 0.10 | .01 | 0.13 | <.01 | 0.10 |
| Time (weeks) | .28 | 0.06[a] | .08 | 0.05 | .17 | 0.04[a] | .26 | 0.05[a] | .30 | 0.07[a] | .16 | 0.05[b] | .59 | 0.06[a] |
| Overall EI[c] | .14 | 0.08 | .22 | 0.08[b] | .11 | 0.08 | .18 | 0.08[b] | .19 | 0.09[b] | .23 | 0.09[b] | –.08 | 0.08 |
| Time × overall EI | .01 | 0.06 | –.05 | 0.05 | –.07 | 0.05 | –.09 | 0.05 | –.09 | 0.07 | –.04 | 0.06 | –.01 | 0.07 |
| **Model 2** | | | | | | | | | | | | | | |
| Intercept | <–.01 | 0.08 | –.02 | 0.09 | .01 | 0.10 | .01 | 0.09 | <–.01 | 0.10 | .01 | 0.13 | <.01 | 0.10 |
| Time (weeks) | .28 | 0.05[a] | .08 | 0.05 | .17 | 0.04[a] | .26 | 0.05[a] | .29 | 0.07[a] | .15 | 0.05[b] | .59 | 0.06[a] |
| Resident room EI | .16 | 0.10 | .06 | 0.09 | .02 | 0.10 | .14 | 0.09 | .07 | 0.10 | .14 | 0.10 | .04 | 0.29 |
| Therapy room EI | –.05 | 0.08 | .19 | 0.08[b] | .10 | 0.08 | .07 | 0.07 | .16 | 0.10 | .15 | 0.08 | –.02 | 0.24 |
| Resident room EI × time | .07 | 0.07 | –.04 | 0.07 | .01 | 0.06 | –.08 | 0.06 | –.07 | 0.09 | –.06 | 0.07 | –.02 | 0.12 |
| Therapy room EI × time | –.08 | 0.07 | .02 | 0.07 | –.10 | 0.06 | –.01 | 0.06 | .02 | 0.09 | .05 | 0.08 | –.01 | 0.10 |
| **Model 3** | | | | | | | | | | | | | | |
| Intercept | –.01 | 0.08 | –.01 | 0.09 | .02 | 0.11 | .01 | 0.09 | –.01 | 0.11 | .02 | 0.14 | <.01 | 0.10 |
| Time (weeks) | .27 | 0.06[a] | .06 | 0.05 | .16 | 0.05[a] | .26 | 0.05[a] | .32 | 0.07[a] | .18 | 0.05[a] | .59 | 0.06[a] |
| Sitting EI | .03 | 0.07 | .16 | 0.07[b] | .03 | 0.06 | <.01 | 0.06 | .13 | 0.09 | .09 | 0.07 | .10 | 0.07 |
| Standing EI | –.01 | 0.09 | .06 | 0.08 | .07 | 0.07 | –.03 | 0.08 | .07 | 0.11 | .03 | 0.08 | –.03 | 0.09 |
| Laying down EI | .13 | 0.09 | .06 | 0.09 | .06 | 0.08 | .14 | 0.08 | .03 | 0.11 | .10 | 0.11 | –.14 | 0.09 |
| Sitting EI × time | .03 | 0.06 | –.04 | 0.05 | –.01 | 0.05 | –.02 | 0.05 | –.15 | 0.08 | –.13 | 0.06[b] | –.13 | 0.07 |
| Standing EI × time | .08 | 0.07 | .11 | 0.07 | .02 | 0.06 | .04 | 0.06 | –.05 | 0.10 | –.07 | 0.07 | .04 | 0.09 |
| Laying down EI × time | –.01 | 0.08 | –.13 | 0.07 | –.09 | 0.06 | –.09 | 0.07 | .11 | 0.11 | .15 | 0.09 | –.10 | 0.08 |

[a]$P<.001$.

[b]$P<.05$.

[c]EI: energy intensity.

## Longitudinal Analyses of Location Occurrences Between 2 Outcome Categories of Patients

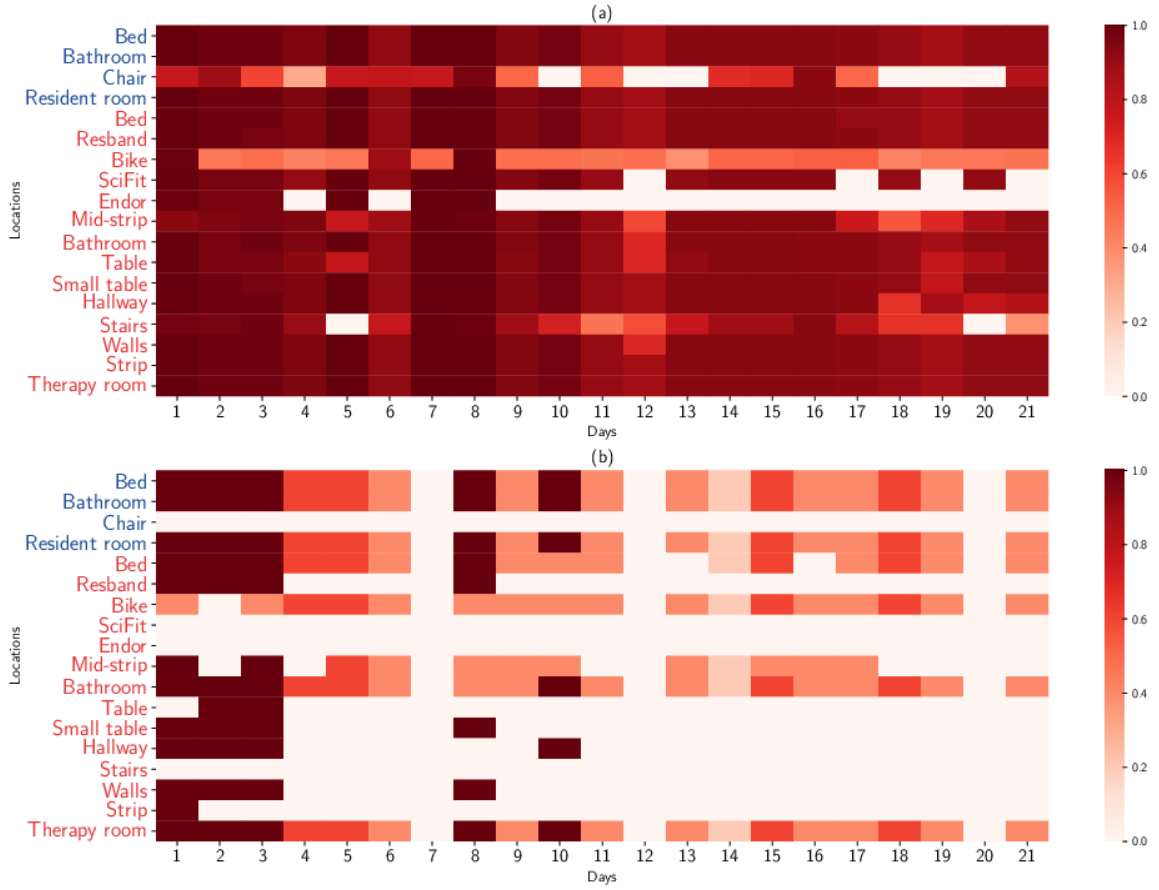
The occurrence of a location is equal to the number of times a patient spends more than 40 continuous seconds within that specific location. In other words, if the smartwatch receives Bluetooth low energy signal of a beacon corresponding a location for 40 seconds, the occurrence of that location increases by one unit. Figure 3 (a and b) shows total occurrences of patients in various nursing facility locations (daily) normalized by the number of patients in each category. Darker colors indicate higher frequency of patients visiting a particular



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location. In short, patients in outcome category "home" traveled within the facility (resident and therapy area) much more frequently than patients eventually admitted to a longer-term care or the "hospital" group. Additionally, no patient in the hospital category used upper body exercise (SciFit), Endorphin, and stair equipment in the therapy area.

**Figure 3.** Normalized observation counts per patient by location within 21 days; (a): 105 patients in the "community" group; (b): 5 patients in the "hospital" group.




## Discussion

### Overview

To the best of our knowledge, this paper and what we described in [13] are first to explore a combination of indoor localization and physical activity tracking to assess older residents. Following baseline investigations [13], in this paper, we highlight significant findings in longitudinal analyses of clinical and sensor-based features.

### Activity With Therapist Versus Resident Time Alone and the Value of Indoor Localization

One of the principal findings of this study is that the energy intensity spent in therapy sessions, unlike in resident room, tend to have similar values in both outcome groups, more significantly toward the end of the rehabilitation period (Figure S1 in Multimedia Appendix 1). Perhaps the therapists in both patient groups are encouraged to complete their therapy activities and are part of an individually designed therapeutic program that aimed to improve functional activity. Moreover, energy intensity spent in the resident room is very similar to overall energy intensity in that patients generally spend most of their time in the resident room. Resident room activity levels are likely to be crucial in determining the outcome of patients, even at early stages of their rehabilitation. Further understanding of the therapeutic skills learned during therapeutic intervention and carryover into the resident room warrants further study.

Based on Table 3, the PT and OT features investigated in this study all improved over time along with the sensor-based feature, energy intensity. However, improvements are more distinguishable between admission day and weeks 1 and 2. On week 3, the mean value for sensor-based features such as overall energy intensity declines. Similarly, OT and PT features show less change compared to week 1 and admission day. One possible reason could be the drop in sample size after week 2 as patients are likely to be discharged earlier. Note that despite the steady PT and OT functional scores in later times, the interquartile range decreases over time, which indicates less variations in functional levels. This could mean that residents achieved their functional goals or plateaued in functional progression. Other aspects that limit a resident's functional ability need to be examined to determine if nonmotor parameters are limiting a resident's progress. Cognition, vision, and



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psychological factors are some of the areas that may limit functional progression.

Table 3 also shows that except the "gait distance in feet," the improvement of features was not evident after the 2nd and 3rd week. Further exploration of therapy treatment intensity or type of intervention is warranted. Significant improvements in "gait distance in feet" suggest the importance of this feature in clinical assessment. The rest of the gait measures showed they were less likely to change over time. Dynamic gait parameters and their relation to mobility in daily activities need more investigation.

### Sensor-Based Features and Changes in Clinical Assessments

The captured sensor-based longitudinal changes such as lying down, sitting, and overall energy intensity reflect changes in PT and OT features (Table 4). This finding confirms the benefit of remote patient monitoring systems as adjunct tools to further reveal patients' daily story lines. Such systems can bear valuable information in further understanding the type and intensity of therapy interventions that impact overall functional outcome. Brisk features remained surprisingly unchanged over time when patients were expected to become less sedentary during recovery of functional abilities, at least partially. Average sedentary time among all patients was more than 99.8% and remained unchanged. In other words, the cohort was walking less than 0.2% of the time, measured objectively by the SARP wrist-worn sensor. This finding strongly suggests that focusing on sedentary features among elderly patients is beneficial, confirming the studies in [27-29], contrary to the emphasis many patient monitoring systems place on using activity trackers to count steps [30,31]. This study shows the importance of translating all movements into measurements such as energy, or energy intensity, rather than solely relying on steps. This may shed light on the type of intervention needed for improving the mobility of the elderly resident population.

### Study Limitations

This study had some limitations. Wrist-worn accelerometers used for activity recognition are popular due to their ease of use and ability to capture a comprehensive set of activities. However, interpreting users' data in sedentary positions such as sitting or standing can be quite challenging. Movements (or lack thereof) in sedentary positions are hard to be distinguished by wrist-worn sensors [32]. Compliance to technology is another obstacle faced in this study. Patients accepting to use the technology is a challenge expected to be generic and present in similar studies.

Battery consumption of smart watches can be problematic when trying to transmit data, hourly or daily. Battery lifetimes are normally insufficient in almost all smartwatch manufacturing brands. Their operating systems are designed to perform sophisticated tasks, many of which are not needed for patient remote monitoring such as receiving messages and calls. Furthermore, consumer-grade wearables have wide variability in their accuracy across a range of functional activities depending on their placement, the individuals' movement characteristics, speed of walking, using assistive devices, and so on. The best way to tackle this problem is to use wearable sensors specifically designed (hardware and software) for patient monitoring. However, commercially available research-grade sensors are very expensive and not yet clinician and patient friendly [33].

The study cohort had two outcome groups that were not equally presented. The data set predominantly comprised majority class instances and contained only a few instances of patients who were re-admitted to a long-term care. Akin to most imbalanced medical data sets, analyzing such data poses a great challenge [34].

## Conclusions

This study aimed to show that wearable activity trackers, despite raising concerns about their efficacy in quantifying residents' health, can result in a better understanding of patients' well-being when tailored for a specific cohort. Such studies can hopefully pave the way in early prediction of hospitalization, developing intervention alerts and improving overall quality of care. As discussed, our remote patient monitoring system, SARP, captures a combination of indoor localization and physical activity features. SARP information on daily and longitudinal activity patterns can be incorporated into mobile health technology platforms to provide a better assessment of underrepresented, particularly frail, populations.

## Acknowledgments

We would like to express their gratitude to the researchers cited here and apologize to those whose work, because of page restrictions, could not be mentioned. Special thanks to Amy Hoang at University of California, Los Angeles for patient recruitment and data abstraction. We highly appreciate Berkley East Convalescent Hospital. This research was mainly funded by a National Institutes of Health (NIH) grant, Department of Health and Human Services Agency for Health Care Research and Quality: RO1 HS024394.

## Conflicts of Interest

The Sensing At-Risk Population system is protected by a patent (US patent 10937547) [21] owned by the University of California, Los Angeles, in which RR, AN, and MS are listed as co-inventors. RR and AN are cofounders of InvistaHealth LLC. Other authors have declared no potential conflicts of interest regarding the publication of this paper.

Multimedia Appendix 1



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Energy intensity averaged per days in 21 days. Note, the numbers shown on top of the point plots indicate the sample size on the corresponding day specified on the x-axis. Overall energy intensity and energy intensity in resident room and therapy room all improve over time, except at week 3, with a drop in sample size from 83 to 57 participants.
[PNG File , 338 KB - mhealth_v10i5e23887_app1.png ]

## References


1. Ortman JM, Velkoff VA, Hogan H. An Aging Nation: The Older Population in the United States. Census.gov. 2014. URL: https://www.census.gov/content/dam/Census/library/publications/2014/demo/p25-1140.pdf [accessed 2022-04-27]
2. Maceira-Elvira P, Popa T, Schmid A, Hummel FC. Wearable technology in stroke rehabilitation: towards improved diagnosis and treatment of upper-limb motor impairment. J Neuroeng Rehabil 2019 Nov 19;16(1):142 [FREE Full text] [doi: 10.1186/s12984-019-0612-y] [Medline: 31744553]
3. Boyd CM, Landefeld CS, Counsell SR, Palmer RM, Fortinsky RH, Kresevic D, et al. Recovery of activities of daily living in older adults after hospitalization for acute medical illness. J Am Geriatr Soc 2008 Dec;56(12):2171-2179 [FREE Full text] [doi: 10.1111/j.1532-5415.2008.02023.x] [Medline: 19093915]
4. Sands L, Wang Y, McCabe GP, Jennings K, Eng C, Covinsky KE. Rates of acute care admissions for frail older people living with met versus unmet activity of daily living needs. J Am Geriatr Soc 2006 Feb;54(2):339-344. [doi: 10.1111/j.1532-5415.2005.00590.x] [Medline: 16460389]
5. Depalma G, Xu H, Covinsky KE, Craig BA, Stallard E, Thomas J, et al. Hospital readmission among older adults who return home with unmet need for ADL disability. Gerontologist 2013 Jun;53(3):454-461 [FREE Full text] [doi: 10.1093/geront/gns103] [Medline: 22859438]
6. Chumney D, Nollinger K, Shesko K, Skop K, Spencer M, Newton R. Ability of Functional Independence Measure to accurately predict functional outcome of stroke-specific population: systematic review. J Rehabil Res Dev 2010;47(1):17-29 [FREE Full text] [doi: 10.1682/jrrd.2009.08.0140] [Medline: 20437324]
7. Murphy J, Uttamlal T, Schmidtke KA, Vlaev I, Taylor D, Ahmad M, et al. Tracking physical activity using smart phone apps: assessing the ability of a current app and systematically collecting patient recommendations for future development. BMC Med Inform Decis Mak 2020 Feb 03;20(1):17 [FREE Full text] [doi: 10.1186/s12911-020-1025-3] [Medline: 32013996]
8. Jennifer M, David T, Mian A, Suzanne A, Sanjay P, Samantha S, et al. Quantified-self for obesity: Physical activity behaviour sensing to improve health outcomes. Front. Public Health 2016;4. [doi: 10.3389/conf.fpubh.2016.01.00026]
9. Remote health monitoring and maintenance system. Free Patents Online. 2010. URL: http://www.freepatentsonline.com/7853455.html [accessed 2022-04-27]
10. Suh M, Chen C, Woodbridge J, Tu MK, Kim JI, Nahapetian A, et al. A remote patient monitoring system for congestive heart failure. J Med Syst 2011 Oct 25;35(5):1165-1179 [FREE Full text] [doi: 10.1007/s10916-011-9733-y] [Medline: 21611788]
11. Porciuncula F, Roto AV, Kumar D, Davis I, Roy S, Walsh CJ, et al. Wearable Movement Sensors for Rehabilitation: A Focused Review of Technological and Clinical Advances. PM R 2018 Sep 27;10(9 Suppl 2):S220-S232 [FREE Full text] [doi: 10.1016/j.pmrj.2018.06.013] [Medline: 30269807]
12. Toosizadeh N, Najafi B, Reiman EM, Mager RM, Veldhuizen JK, O'Connor K, et al. Upper-Extremity Dual-Task Function: An Innovative Method to Assess Cognitive Impairment in Older Adults. Front Aging Neurosci 2016 Jul 07;8:167 [FREE Full text] [doi: 10.3389/fnagi.2016.00167] [Medline: 27458374]
13. Najafi B, Aminian K, Paraschiv-Ionescu A, Loew F, Bula C, Robert P. Ambulatory system for human motion analysis using a kinematic sensor: monitoring of daily physical activity in the elderly. IEEE Trans. Biomed. Eng 2003 Jun;50(6):711-723. [doi: 10.1109/tbme.2003.812189]
14. Razjouyan J, Naik A, Horstman M, Kunik M, Amirmazaheri M, Zhou H, et al. Wearable Sensors and the Assessment of Frailty among Vulnerable Older Adults: An Observational Cohort Study. Sensors (Basel) 2018 Apr 26;18(5):1336 [FREE Full text] [doi: 10.3390/s18051336] [Medline: 29701640]
15. Wong K, Shen J, Ramezani R, Zhang W, Xie Z, Naeim A, et al. A pilot study of a wearable monitoring system as an adjunct to geriatric assessment in older adults with cancer. J Clin Oncol 2020 May 20;38(15 suppl):2062. [doi: 10.1200/JCO.2020.38.15_suppl.2062]
16. Ramezani R, Zhang W, Xie Z, Shen J, Elashoff D, Roberts P, et al. A Combination of Indoor Localization and Wearable Sensor-Based Physical Activity Recognition to Assess Older Patients Undergoing Subacute Rehabilitation: Baseline Study Results. JMIR Mhealth Uhealth 2019 Jul 10;7(7):e14090 [FREE Full text] [doi: 10.2196/14090] [Medline: 31293244]
17. Moatamed B, Arjun, Shahmohammadi F, Ramezani R, Naeim A, Sarrafzadeh M. Low-Cost Indoor Health Monitoring System. 2016 Presented at: Inth International Conference on Wearable and Implantable Body Sensor Networks (BSN); 14-17 June 2016; San Francisco, CA, USA p. 14-17. [doi: 10.1109/bsn.2016.7516252]
18. Bouchard K, Ramin R, Arash N. Features based proximity localization with Bluetooth emitters. 2016 Presented at: IEEE 7th Annual Ubiquitous Computing, Electronics & Mobile Communication Conference (UEMCON); 12 December 2016; New York, NY, USA. [doi: 10.1109/uemcon.2016.7777845]




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19. Bouchard K, Ramin R, Arash N. Evaluation of Bluetooth beacons behavior. 2016 Presented at: IEEE 7th Annual Ubiquitous Computing, Electronics & Mobile Communication Conference (UEMCON); 12 December 2016; New York, NY, USA. [doi: 10.1109/uemcon.2016.7777846]
20. Bouchard K, Eusufzai MR, Ramezani R, Naeim A. Generalizable spatial feature for human positioning based on Bluetooth beacons. 2016 Presented at: IEEE 7th Annual Ubiquitous Computing, Electronics & Mobile Communication Conference (UEMCON); 12 December 2016; New York, NY, USA. [doi: 10.1109/uemcon.2016.7777884]
21. Ramezani R, Moatamed B, Naeim A, Sarrafzadeh M. Subject assessment using localization, activity recognition and a smart questionnaire. Google Patents. 2021 Mar 02. URL: https://patents.google.com/patent/WO2016205212A1/en [accessed 2022-04-27]
22. Minimum Data Set 3.0 Public Reports. CMS.gov. URL: https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/Minimum-Data-Set-3-0-Public-Reports [accessed 2022-04-27]
23. Locascio JJ, Atri A. An overview of longitudinal data analysis methods for neurological research. Dement Geriatr Cogn Dis Extra 2011 Jan;1(1):330-357 [FREE Full text] [doi: 10.1159/000330228] [Medline: 22203825]
24. Tieges Z, Mead G, Allerhand M, Duncan F, van Wijck F, Fitzsimons C, et al. Sedentary behavior in the first year after stroke: a longitudinal cohort study with objective measures. Arch Phys Med Rehabil 2015 Jan;96(1):15-23. [doi: 10.1016/j.apmr.2014.08.015] [Medline: 25220942]
25. Breslow NE, Clayton DG. Approximate Inference in Generalized Linear Mixed Models. Journal of the American Statistical Association 1993 Mar;88(421):9. [doi: 10.2307/2290687]
26. Wuensch KL, Evans JD. Straightforward Statistics for the Behavioral Sciences. Journal of the American Statistical Association 1996 Dec;91(436):1750. [doi: 10.2307/2291607]
27. Barrett M, Snow JC, Kirkland MC, Kelly LP, Gehue M, Downer MB, et al. Excessive sedentary time during in-patient stroke rehabilitation. Top Stroke Rehabil 2018 Jul 03;25(5):366-374. [doi: 10.1080/10749357.2018.1458461] [Medline: 29609499]
28. Mesquita R, Meijer K, Pitta F, Azcuna H, Goërtz YMJ, Essers JM, et al. Changes in physical activity and sedentary behaviour following pulmonary rehabilitation in patients with COPD. Respir Med 2017 May;126:122-129 [FREE Full text] [doi: 10.1016/j.rmed.2017.03.029] [Medline: 28427543]
29. Ramadi A, Haennel RG. Sedentary behavior and physical activity in cardiac rehabilitation participants. Heart Lung 2019 Jan;48(1):8-12. [doi: 10.1016/j.hrtlng.2018.09.008] [Medline: 30366574]
30. Bassett DR, Toth LP, LaMunion SR, Crouter SE. Step Counting: A Review of Measurement Considerations and Health-Related Applications. Sports Med 2017 Jul 22;47(7):1303-1315 [FREE Full text] [doi: 10.1007/s40279-016-0663-1] [Medline: 28005190]
31. Vähä-Ypyä H, Vasankari T, Husu P, Suni J, Sievänen H. A universal, accurate intensity-based classification of different physical activities using raw data of accelerometer. Clin Physiol Funct Imaging 2015 Jan 07;35(1):64-70. [doi: 10.1111/cpf.12127] [Medline: 24393233]
32. Rosenberger ME, Haskell WL, Albinali F, Mota S, Nawyn J, Intille S. Estimating Activity and Sedentary Behavior from an Accelerometer on the Hip or Wrist. Medicine & Science in Sports & Exercise 2013;45(5):964-975. [doi: 10.1249/mss.0b013e31827f0d9c]
33. Lang CE, Barth J, Holleran CL, Konrad JD, Bland MD. Implementation of Wearable Sensing Technology for Movement: Pushing Forward into the Routine Physical Rehabilitation Care Field. Sensors (Basel) 2020 Oct 10;20(20):5744 [FREE Full text] [doi: 10.3390/s20205744] [Medline: 33050368]
34. Li D, Liu C, Hu SC. A learning method for the class imbalance problem with medical data sets. Comput Biol Med 2010 May;40(5):509-518. [doi: 10.1016/j.compbiomed.2010.03.005] [Medline: 20347072]


## Abbreviations

**ADL:** activities of daily living
**OT:** occupational therapy
**PT:** physical therapy
**SARP:** Sensing At-Risk Population



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Original Paper

# Adolescent Health Promotion Interventions Using Well-Care Visits and a Smartphone Cognitive Behavioral Therapy App: Randomized Controlled Trial

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## Abstract

**Background:** Adolescent health promotion is important in preventing risk behaviors and improving mental health. Health promotion during adolescence has been shown to contribute to the prevention of late onset of the mental health disease. However, scalable interventions have not been established yet.

**Objective:** This study was designed to test the efficacy of two adolescent health promotion interventions: a well-care visit (WCV) with a risk assessment interview and counseling and self-monitoring with a smartphone cognitive behavioral therapy (CBT) app. Our hypothesis was that participants who had received both WCV and the CBT app would have better outcomes than those who had received only WCV or those who had not received any intervention. We conducted a prospective multi-institutional randomized controlled trial.

**Methods:** Participants were 217 adolescents aged 13-18 years. They were randomly divided into two intervention groups (WCV group and WCV with CBT app group) and a nonintervention group. WCV comprised a standardized physical examination along with a structured interview and counseling for youth risk assessment, which was designed with reference to the Guideline for Health Supervision of Adolescents of Bright Futures. A smartphone-based CBT program was developed based on the CBT approach. The CBT app comprised a 1-week psychoeducation component and a 1-week self-monitoring component. During the CBT program, participants created several self-monitoring sheets based on the CBT model with five window panels: event, thoughts, feelings, body response, and actions. The primary outcome was the change in scores for depressive symptoms. Secondary outcomes included changes in scores for self-esteem, quality of life, self-monitoring, and an adolescent health promotion scale.



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These outcomes were evaluated at baseline and at 1, 2, and 4 months after baseline. The exploratory outcome was the presence of suicidal ideation during the observation period. Intervention effects were estimated using mixed effect models.

**Results:** In total, 94% (204/217) of the participants completed the 4-month evaluation. Both intervention groups showed a significant effect in the form of reduced scores for depressive symptoms at 1 month in high school students; however, these effects were not observed at 2 and 4 months. The intervention effect was significantly more predominant in those scoring above cutoff for depressive symptoms. There was significantly less suicidal ideation in the intervention groups. As for secondary outcomes, there was significant increase in health promotion scale scores at the 4-month follow-up among junior high school students in the WCV group. Moreover, the CBT app was significantly effective in terms of obtaining self-monitoring skills and reducing depressive symptoms.

**Conclusions:** Although adolescent health promotion interventions may have short-term benefits, the frequency of WCV and further revision of the CBT app should be considered to evaluate long-term effectiveness.

**Trial Registration:** University Hospital Medical Information Network Clinical Trials Registry UMIN 000036343; https://center6.umin.ac.jp/cgi-open-bin/ctr/ctr_view.cgi?recptno=R000041246

***(JMIR Mhealth Uhealth 2022;10(5):e34154)*** doi:10.2196/34154

**KEYWORDS**

health promotion; well-care visit; cognitive behavioral therapy; app; randomized controlled trial; RCT; mobile phone

## Introduction

### Background

Care settings for young children and adolescents are changing from treating acute diseases to managing chronic diseases as vaccinations are developed and deployed and as medical treatment advances. With reductions in serious illnesses, physicians can place greater importance on lifestyle-related diseases, mental health disorders, and developmental behavioral disorders [1,2]. The Ministry of Health, Labour and Welfare, Japan, published its first report concerning disability-adjusted life years of Japanese adolescents in 2018, which indicated that mental health disorders accounted for approximately 20% of the burden of disease [3]. Mental health disorders such as depression affect approximately 5% of adolescents in Japan, and suicide is the leading cause of death among adolescents [4]. Therefore, health supervision for young children and adolescents is becoming increasingly important in medical settings.

### Primary Care Visits

The American Academy of Pediatrics recommended the delivery of preventive services and anticipatory guidance for adolescents aged ≤21 years through annual primary care visits [5,6]. These visits offer an important opportunity that may lead to reduced risk behaviors among adolescents [7,8]. Evidence shows that although preventive interventions resulted in various significant improvements such as reduced smoking, increased helmet use, and increased condom use, there are insufficient effects in terms of reduced substance and alcohol use and change in the rate of sexual intercourse [9,10]. Furthermore, the screening rate for major depression disorder (MDD) among adolescents is insufficient in the context of annual primary care visits [11]. The low MDD screening rate may result from insufficient training of pediatric health care providers. Fallucco et al [12] reported that the MDD screening rate significantly increased after primary care providers received adequate training in depression care. As the primary care visit rate among adolescents is <50%, it is important to provide opportunities for routine visits to reduce risk behaviors and promote health in this population.

### Internet-Based Cognitive Behavioral Therapy

A universal intervention program based on cognitive behavioral therapy (CBT) using an internet-based setting has shown potential to prevent depressive symptoms among adolescents [13-19]. These intervention techniques have been proposed as self-help strategies to relieve depressive symptoms for adolescents, as young children and adolescents with depressive symptoms often do not receive medical treatment owing to lack of symptom awareness, poor access to services, and perceived stigma [20]. Several randomized controlled trials have demonstrated the efficacy of internet-based therapies for depression. Moritz et al [13] reported an 8-week internet-based program that encompassed 10 content modules focused on evidence-based cognitive behavioral techniques (eg, psychoeducation, behavioral activation, and problem solving) and showed a significant decline in symptoms of depression in adulthood. However, the efficacy of internet-based CBT for adolescent depression remains inconclusive. Pennant et al [18] systematically reviewed the evidence for internet-based CBT interventions for adolescents and showed a small positive effect for depression in a general population study. Kauer et al [15] reported that an internet-based CBT intervention for adolescents had a significant effect on depressive symptoms. The differences in study findings may be attributable to the duration and strength of the intervention, contamination effect, degree of depressive symptoms, and amount of guidance provided to the participants.

### Objectives

Both primary care visits and internet-based CBT programs may be beneficial in promoting adolescent health. Interestingly, these intervention procedures are delivered in completely opposite ways; the former is characterized by a face-to-face encounter, whereas the latter is based on self-help therapy without an interview. Face-to-face encounters have the advantage of providing health education securely and allow providers to respond to individual requirements, but have disadvantages in terms of cost and time. Although internet-based programs have



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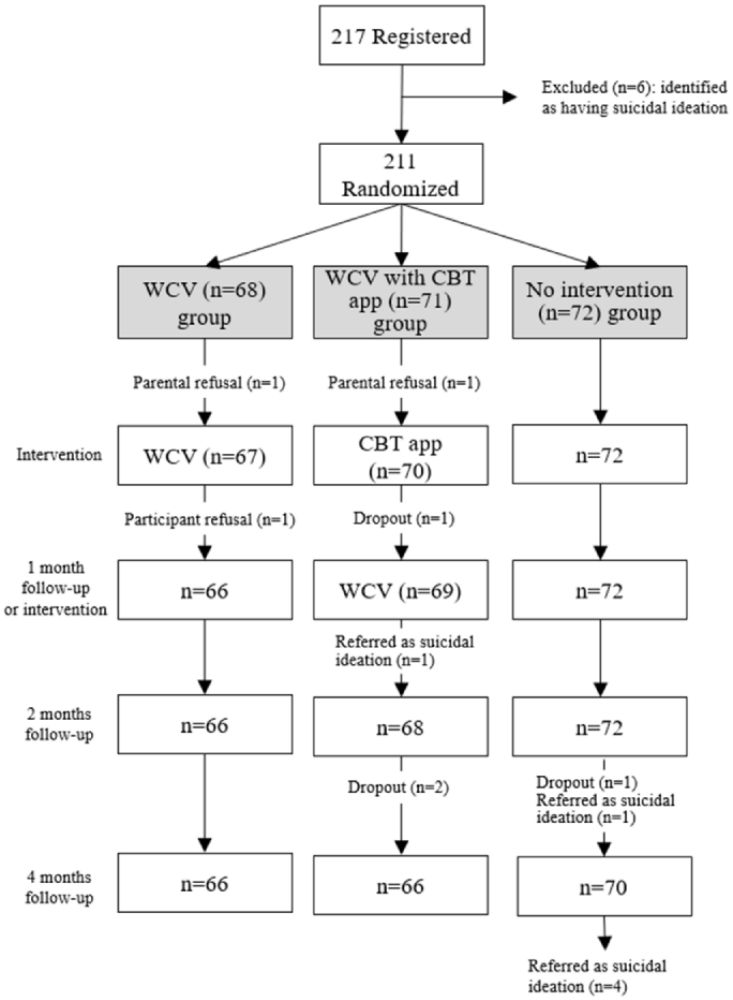
various advantages such as accessibility to large groups, cost-effectiveness, and less labor, a major disadvantage is that they depend on user motivation. In this study, we conduct a randomized controlled trial with a well-care visit (WCV) combined with a risk assessment interview and counseling and self-monitoring using a smartphone CBT app to promote adolescent health. The primary outcome of the interventions is improvement in depressive symptoms, and the secondary outcome is increase in health promotion score. Our hypothesis is that participants who receive both WCV and the CBT app would have better outcomes than those who receive only WCV or those who did not receive any intervention.

## Methods

### Study Design

We conducted a prospective multi-institutional randomized controlled trial involving 217 adolescents (aged 13-18 years) from Fukuoka, Saitama, and Okayama prefectures and Tokyo. The trial was registered in the University Hospital Medical Information Network Clinical Trials Registry (UMIN 000036343). Participants were enrolled in the trial and randomized into two intervention groups (WCV only or WCV with CBT app) or a nonintervention (control) group. Outcome data were collected at baseline, after the intervention (4 weeks), and at 2- and 4-month follow-ups. Figure 1 shows a participant flow chart demonstrating participant allocation, intervention menu, and data collection. Participants in the nonintervention group were offered the intervention immediately after this study was completed.

**Figure 1.** Participant flow chart. CBT: cognitive behavioral therapy; WCV: well-care visit.




### Ethics Approval

The design of this study and procedures for obtaining informed consent were approved by the Medical Ethics Committee of the Kurume University School of Medicine (#18138).

### Procedure

The principal investigator and coinvestigators in each prefecture explained the purpose of this study and the study design to each regional educational committee and school principals' association. School principals who were interested in the study informed students in their school about the content of this study using a leaflet. The leaflet was developed by the principal



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investigator and covered the purpose of the study, study design, participant recruitment, and the URL for the study's home page. Students who were interested in this study could talk with their parents about enrollment. To receive a detailed explanation of the study design, the student or their parents applied for an appointment with an investigator at the relevant research facility (hospital outpatient clinic) through the study's home page. During these appointments, students and their parents received detailed information about the study and provided informed consent. A total of 240 students from 23 junior high schools and 25 high schools received appointments, and 217 (90.4%) of them agreed to participate in this study. The inclusion criteria were the following: (1) aged 13-18 years, (2) able to visit a research facility with their parent or caregiver twice to receive a WCV or for installation of the CBT program, and (3) had access to a smartphone or Wi-Fi network (smartphones were available to rent if a participant had no smartphone). The exclusion criterion was the presence of severe depressive symptoms or suicidal ideation. After the participants and parents signed the informed consent form, screening for severe depressive symptoms or suicidal ideation was performed using the 9-item Patient Health Questionnaire (PHQ-9) [21]. A PHQ-9 item asks how often responders had thoughts of hurting themselves or thoughts that it would be better if they were dead over the past 2 weeks. For individuals who scored 2 or 3 ("more than half" or "almost every day," respectively), participation was suspended before randomization, and they were referred to mental health services. Group allocation was stratified by sex and school type (junior high school or high school). A research assistant, who was not otherwise engaged in this study, generated the random dynamic allocation sequence using a minimization method. After each participant provided informed consent, they were automatically allocated to an intervention group or the nonintervention group within 2 weeks. Allocation was concealed from the principal investigator and all coinvestigators dealing with the participants.

## Interventions

### *Overview*

This study had two intervention groups (WCV group and WCV with CBT app group) and a nonintervention group. Participants in all groups were asked to complete a questionnaire that included several outcome measures at four time points: at baseline and at 1, 2, and 4 months after baseline. The participant flow chart is shown in Figure 1. Participants in the WCV group visited the research facility twice (at baseline and 1 month after their first visit) to undergo a health checkup along with a risk assessment interview and counseling. They completed the baseline and 1-month outcome questionnaires before the respective visit to the research facility. The questionnaires for the 2- and 4-month measurements were delivered to the participants' homes, and completed questionnaires were returned to the respective research facility. Participants in the WCV with CBT app group visited a research facility twice (at baseline and 1 month after the first visit). During the first visit, the participants completed the baseline questionnaire and installed the CBT app program on their smartphone. As the CBT app involved a 2-week program, participants had a second visit after 1 month to receive their health checkup. These participants were required to complete the smartphone CBT program before undergoing their health checkup. They completed the baseline and 1-month questionnaires at the research facility and the 2- and 4-month questionnaires at their homes. For the nonintervention group, the questionnaires were delivered to participants' homes at each time point and the completed questionnaires were returned. After the intervention period (4 months), participants in the nonintervention group received either WCV or the CBT app (or both) as needed.

### *Contents of WCV*

The WCV was designed with reference to the Guideline for Health Supervision of Adolescents of Bright Futures. The purpose of the WCV was to address the individual's concerns or stressors, check social determinants of health, and provide anticipatory guidance through an interview. We used the Home, Education, Eating, Activities, Drugs, Sexuality, Suicide, Safety (HEEADSSS) framework to help structure the WCV interviews [22]. A complete physical examination was also included in the WCV, which involves measuring blood pressure, height, and weight; checking BMI, scoliosis, and acne; and rating sexual maturity. Before the WCV, participants were asked to complete the outcome questionnaire. The WCV consisted of a 40-minute session: checking individual history and the participant's concerns or stressors using check sheets (5 minutes), risk assessment interview using the HEEADSSS framework (20 minutes), physical examination (5 minutes), and discussing anticipatory guidance (10 minutes). Guidance was also provided to participants' parents or guardians, as needed. After the individual risk assessment, participants received educational handouts that described how to avoid and manage risk behaviors. We prepared 20 different handouts, covering the following aspects: sleep hygiene, appropriate eating, dieting, obesity, screen time, exercising, headache, oral health, constipation, acne, menstruation, sports injury, helmets or seat belts, school record, relationships with friends, mental health, tobacco, alcohol, sexual behavior, and the internet. During the second WCV, the participants discussed issues that had been determined during their first WCV. For example, if prolonged screen time was noted during the first WCV, the participant's effort to improve this was discussed during the second WCV. To standardize the WCV procedure among research facilities, all the investigators providing WCVs received training using a demonstration video developed by one of the coauthors, and then, all the investigators gathered at 1 research facility and were further trained through role-play.

### *CBT App*

A smartphone-based CBT program for iPhones, named *Mugimaru*, was developed based on the CBT approach. The program comprised a psychoeducation session (week 1) and a self-monitoring session (week 2). Mugimaru presented psychoeducation in a story-like manner, so that the adolescents can easily understand the rationale of CBT and were motivated to continue using the app. The story featured an adolescent boy, an adolescent girl, and a cat (the name of this cat is *Mugimaru*). In the story, the boy and girl have troubles in relationships with friends or about their future. Mugimaru teaches them how the feelings, thoughts, and actions are mutually affected. They also



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learn that their feelings are associated with their thoughts and actions. The story consisted of 10 scenarios, and participants could browse 1 to 2 scenarios each day. After reading one scenario, a new scenario could be read after 24 hours. The ending of the story was available 1 week after the participants read the whole story. During the intervention period, participants created several self-monitoring sheets based on the CBT model with five window panels: event, thoughts, feelings, body response, and actions. The participant inputted their thoughts, feelings, body responses, and actions when they experienced a daily event. In another window, the adolescents could input comments or advice if their friend had experienced the same event. This input was used by adolescents to practice cognitive reappraisal and problem solving. Figure 2 shows the CBT app screenshots from the smartphone. By repeatedly creating these monitoring sheets, the adolescents could monitor their own experiences and develop solutions to make necessary changes. The shortest time in which Mugimaru can be completed was 2 weeks. All the data were stored in the main server, and the participants were informed in advance that only the principal investigator could view the data.

**Figure 2.** Screenshots of the smartphone cognitive behavioral therapy app.




### *Depression Self-Rating Scale for Children*

The primary outcome of this intervention was improvement in depressive symptoms. The Depression Self-Rating Scale for Children (DSRS-C), an 18-item self-report questionnaire that measures depressive symptoms, was used to measure depressive symptoms in this study [23]. Participants are asked to select one of three response options: “most of the time” (score=2), “sometimes” (score=1), or “never” (score=0). The maximum score is 36, and higher scores indicate stronger depressive tendencies. The Japanese version of the DSRS-C has good reliability and validity [24]. The cutoff score for the Japanese version is 16 points.

### *Adolescent Health Promotion Short Form*

The Adolescent Health Promotion Short Form (AHP-SF) is a self-administered instrument that was designed by Chen et al [25] to measure adolescent health-promoting behaviors. The instrument uses a 5-point Likert scale to obtain data regarding the frequency of reported behaviors. Scores range from 1 (“never”) to 5 (“always”). The AHP-SF has 21 items on six subscales: nutrition, social support, health responsibility, life appreciation, exercise, and stress management. The total score ranges from 21 to 105. We obtained permission from the original authors to develop a Japanese version of the AHP-SF.

### *Rosenberg Self-Esteem Scale*

The Rosenberg Self-Esteem Scale (RSES) is the most recognized and widely used measure to quantify global positive and negative attitudes toward the self [26]. It comprises 10 items with responses on a 4-point Likert scale: “strongly agree” (score=4), “agree” (score=3), “disagree” (score=2), and “strongly disagree” (score=1). Negatively worded items are reverse scored, and total score ranges from 10 to 40. Higher scores reflect greater levels of self-esteem. The Japanese version of the RSES has good reliability and validity [27].

### *Pediatric Quality of Life Inventory*

The Pediatric Quality of Life Inventory (PedsQL) is a brief measure of adolescents’ health-related quality of life [28]. The 23 items comprise four generic core scales: physical functioning, emotional functioning, social functioning, and school functioning. Items are scored as 0 (“never”; score=100), 1 (“almost never”; score=75), 2 (“sometimes”; score=50), 3



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("often"; score=25), and 4 ("almost always"; score=0). The total scale score is calculated from the mean of all the items and transformed to a 0-100 scale. Higher scores indicate better health-related quality of life. The Japanese version of the PedsQL has good reliability and validity [29].

### Exploratory Outcome Measures

#### *Suicidal Ideation*

We counted the number of participants presenting suicidal ideation on the PHQ-9 during the observation period in each group. We defined participants as having suicidal ideation if they scored 2 or 3 ("more than half" or "almost every day," respectively) on item 9 of the PHQ-9 [21].

#### *Trait Emotional Intelligence Questionnaire–Adolescent Short Form*

The Trait Emotional Intelligence Questionnaire–Adolescent Short Form (TEIQue-ASF) assesses how adolescents perceive their ability to deal with their emotions while communicating with others [30,31]. The TEIQue-ASF has 30 items with responses on a 7-point Likert scale, from "strongly disagree" (score=1) to "strongly agree" (score=7). Some items, such as "I'm usually able to find ways to control my emotions when I want to" and "On the whole, I'm able to deal with stress," from the self-control subscale were used to assess the efficacy of the CBT app.

#### *Participants' Use of the CBT App and the Number of Worksheets Created in the CBT App*

Participants' use of the CBT app was confirmed using server data on the number of days they browsed the CBT app (Mugimaru) and the number of self-monitoring sheets they created during the CBT app intervention period.

### Sample Size Consideration

The sample size for this study was calculated based on the results from previous studies that set depressive symptoms as the primary outcome [13,19,32-34]. We estimated that approximately 75 participants were required to detect group differences in the DSRS-C (mean difference 2.8, SD 6) at 1 month, with 80% power at $P$=.05.

### Data Analysis

#### *Primary and Secondary Outcome Measures*

To investigate the effect of the intervention on the primary outcome measure (depressive symptoms), data analysis was performed using 2 strategies. First, we assessed changes in the mean depressive scores from baseline to the 1-month evaluation and from baseline to the 4-month evaluation as the immediate effect and maintenance effect of the intervention, respectively. Changes were statistically compared among the WCV, WCV with CBT app, and nonintervention groups using mixed effect models, accounting for the within-participant serial correlation of repeated measures. We also investigated the intervention effect separately for junior high school students and high school students. Second, we examined the associations between baseline depressive symptoms and the intervention. Therefore, participants in both intervention groups were classified into a group with baseline DSRS-C score >16 and another group with baseline DSRS-C score ≤16. An analysis similar to that described above was used to examine the immediate and maintenance effects of the intervention. The nonintervention group was excluded from this assessment. For the secondary outcome measures (including AHP-SF, RSES, and PedsQL scores), the changes in each score from baseline to the 1-, 2-, and 4-month evaluations were compared among the 3 groups using mixed effect models.

Furthermore, to assess the effect of the CBT app on depressive scores, the association between the number of self-monitoring sheets created by participants on their smartphone and the changes in depressive scores at the 1-, 2-, and 4-month evaluations were investigated using correlation coefficients. Similarly, to clarify the self-monitoring efficacy of the CBT app, we assessed the changes in TEIQue-ASF scores from baseline to the 1-, 2-, and 4-month evaluations.

#### *Exploratory Outcome Measures*

At every measurement point, the presence of suicidal ideation in participants was assessed using PHQ-9. The prevalence of suicidal ideation between the intervention groups and nonintervention group was compared using chi-square test.

As this study was an exploratory investigation of the proposed intervention, no adjustment was used in multiple comparisons. All data analyses were performed using SAS (version 9.4; SAS Institute Inc).

## Results

### Participants and Follow-up Rate

A total of 217 participants from 48 schools (23 junior high schools and 25 high schools) were enrolled in this study and randomized into the 3 groups. From the 217 participants, 6 (2.7%) participants were excluded owing to the presence of suicidal ideation. Thus, 97.2% (211/217) of the participants were included in our analyses (WCV group: 68/211, 32.2%; WCV with CBT app group: 71/211, 33.6%; and nonintervention group: 72/211, 34.1%). There were 37.9% (80/211) male participants and 62.1% (131/211) female participants, with 38.9% (82/211) of the participants from junior high school and 61.1% (129/211) of the participants from high school. During the follow-up period, 1.4% (3/211) of the participants (3/3, 100% women; 2/3, 67% from the WCV group; and 1/3, 33% from the WCV with CBT app group) canceled their study attendance, and 1.9% (4/211) of the participants (1/4, 25% men and 3/4, 75% women; 3/4, 75% from the WCV with CBT app group and 1/4, 25% from the nonintervention group) dropped out of the study without giving any reason. Consequently, the follow-up rate was 96.7% (204/211). The flow of participants is shown in Figure 1.

### DSRS-C Scores

For all participants, the mean changes in DSRS-C scores from baseline to 1, 2, and 4 months did not significantly differ among the WCV group, WCV with CBT app group, and nonintervention group (Table 1).



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**Table 1.** Continuous outcome scores from baseline to the follow-up period for each group.

| Outcome measure and follow-up (months) | WCV[a] group (n=68) | | | WCV with CBT[b] app group (n=71) | | | Nonintervention group (n=72) | | |
|---|---|---|---|---|---|---|---|---|---|
| | Participants, n (%) | Score, mean (SD) | Change in score, mean (SD) | Participants, n (%) | Score, mean (SD) | Change in score, mean (SD) | Participants, n (%) | Score, mean (SD) | Change in score, mean (SD) |
| **DSRS-C[c]** | | | | | | | | | |
| 0 | 67 (99) | 8.43 (5.51) | N/A[d] | 70 (99) | 9.26 (6.46) | N/A | 72 (100) | 11.21 (5.97) | N/A |
| 1 | 66 (97) | 7.18 (5.34) | −1.18 (3.18) | 69 (97) | 8.12 (5.60) | −1.10 (4.11) | 72 (100) | 11.20 (6.03) | −0.01 (4.49) |
| 2 | 66 (97) | 8.12 (6.04) | −0.29 (4.05) | 68 (96) | 9.46 (6.85) | 0.25 (4.58) | 72 (100) | 10.54 (6.80) | −0.46 (3.98) |
| 4 | 66 (97) | 7.40 (6.10) | −1.08 (4.11) | 66 (93) | 9.14 (6.68) | −0.02 (4.37) | 70 (97) | 10.76 (6.81) | −0.17 (4.81) |
| **AHP−SF[e]** | | | | | | | | | |
| 0 | 67 (99) | 71.11 (13.38) | N/A | 70 (99) | 72.24 (12.43) | N/A | 72 (100) | 68.30 (15.30) | N/A |
| 1 | 66 (97) | 71.05 (14.73) | 0.34 (9.79) | 69 (97) | 73.14 (13.97) | 1.14 (8.72) | 72 (100) | 69.30 (14.59) | 0.94 (7.76) |
| 2 | 66 (97) | 74.02 (14.39) | 3.28 (9.85) | 68 (96) | 74.64 (13.54) | 1.97 (9.75) | 72 (100) | 69.55 (15.79) | 0.88 (8.32) |
| 4 | 66 (97) | 75.13 (15.61) | 3.93 (11.97) | 66 (93) | 75.94 (14.08) | 2.98 (9.63) | 70 (97) | 70.60 (16.71) | 2.61 (9.32) |
| **RSES[f]** | | | | | | | | | |
| 0 | 67 (99) | 28.62 (5.90) | N/A | 70 (99) | 27.44 (5.56) | N/A | 72 (100) | 26.39 (6.48) | N/A |
| 1 | 66 (97) | 29.75 (5.58) | 1.03 (3.17) | 68 (96) | 28.54 (4.88) | 1.21 (2.70) | 72 (100) | 26.77 (6.39) | 0.32 (3.31) |
| 2 | 66 (97) | 29.29 (6.48) | 0.58 (3.22) | 68 (96) | 28.71 (5.95) | 1.17 (3.39) | 72 (100) | 26.89 (6.25) | 0.47 (3.34) |
| 4 | 66 (97) | 29.44 (6.22) | 0.77 (2.78) | 66 (93) | 28.64 (6.43) | 0.92 (3.64) | 70 (97) | 27.28 (5.90) | 0.91 (3.91) |
| **PedsQL[g]** | | | | | | | | | |
| 0 | 67 (99) | 90.88 (11.99) | N/A | 70 (99) | 89.65 (11.40) | N/A | 72 (100) | 85.30 (13.13) | N/A |
| 1 | 66 (97) | 93.48 (9.18) | 2.60 (8.75) | 69 (97) | 90.61 (9.49) | 0.94 (7.19) | 72 (100) | 85.89 (13.27) | 0.54 (8.32) |
| 2 | 66 (97) | 91.17 (14.92) | 0.37 (10.17) | 68 (96) | 90.82 (10.46) | 0.98 (10.85) | 72 (100) | 86.82 (14.99) | 0.96 (12.15) |
| 4 | 66 (97) | 92.43 (14.08) | 1.37 (11.10) | 66 (93) | 90.41 (12.42) | 0.69 (12.59) | 70 (97) | 87.63 (13.83) | 2.31 (9.66) |

[a]WCV: well-care visit.

[b]CBT: cognitive behavioral therapy.

[c]DSRS-C: Depression Self-Rating Scale for Children.

[d]N/A: not applicable.

[e]AHP-SF: Adolescent Health Promotion Short Form.

[f]RSES: Rosenberg Self-Esteem Scale.

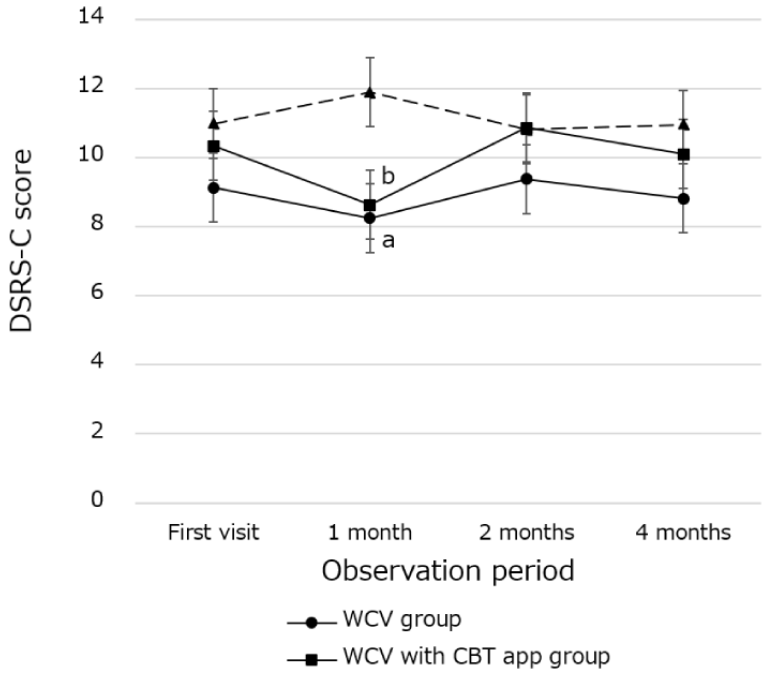
[g]PedsQL: Pediatric Quality of Life Inventory.



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No immediate or maintenance effects by intervention was observed. However, in high school students, there were significant differences in the changes in DSRS-C scores from baseline to 1 month between the WCV group (mean −0.88, SD 3.16) and the nonintervention group (mean 0.90, SD 4.49) and between the WCV with CBT app group (mean −1.67, SD 3.80) and the nonintervention group (Figure 3).

**Figure 3.** Changes in Depression Self-Rating Scale for Children (DSRS-C) scores in the intervention and nonintervention groups during the follow-up period; a: There were significant differences in the changes in DSRS-C scores from baseline to 1 month between the WCV group and the nonintervention group (*P*=.045); b: there were significant differences in the changes in DSRS-C scores from baseline to 1 month between the WCV with CBT app group and the nonintervention group (*P*=.004). Vertical bars show the SE. CBT: cognitive behavioral therapy; WCV: well-care visit.

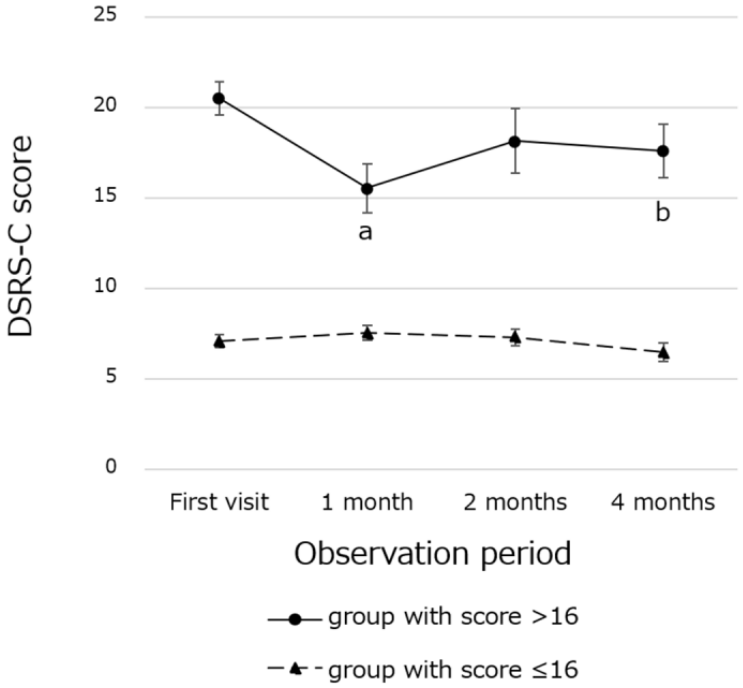



Furthermore, an intervention effect was observed in the classification of participants who scored above the DSRS-C cutoff score (16 points). The mean DSRS-C score for participants scoring >16 in the intervention groups was significantly decreased at 1 month (mean 15.56, SD 5.68) and at 4 months (mean 17.63, SD 5.88) compared with the mean score at their first visit (mean 20.53, SD 3.79). However, no such differences were observed in participants with DSRS-C score ≤16 in the intervention groups (Figure 4).



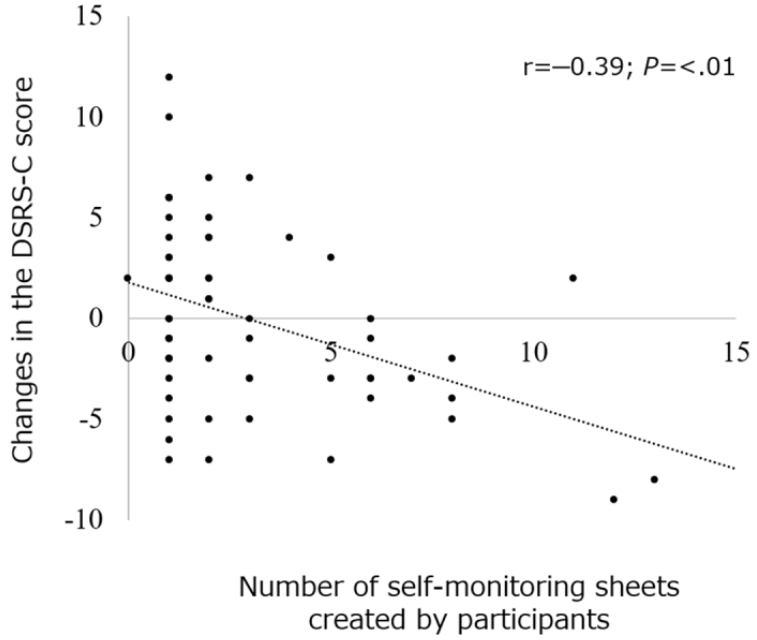
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**Figure 4.** Changes in Depression Self-Rating Scale for Children (DSRS-C) scores for participants in the intervention groups by the DSRS-C cutoff score; a: the mean DSRS-C score for participants scoring >16 in the intervention groups was significantly decreased at 1 month compared with the mean score at their first visit (*P*=.004); b: the mean DSRS-C score for participants scoring >16 in the intervention groups was significantly decreased at 4 month compared with the mean score at their first visit (*P*=.03). Vertical bars show SE.




Regarding the effect of the CBT app on changes in the DSRS-C score, participants who created more self-monitoring sheets had better DSRS-C scores at the 4-month follow-up. The relationship between the number of self-monitoring sheets and the changes in DSRS-C score showed a significant negative correlation at 4 months (Figure 5).

**Figure 5.** Correlation between the number of self-monitoring sheets created by participants and the changes in Depression Self-Rating Scale for Children (DSRS-C) scores in the well-care visit with cognitive behavioral therapy app group. Significant negative correlation was observed between the changes in DSRS-C scores and number of self-monitoring sheets created by participants at 4 months.





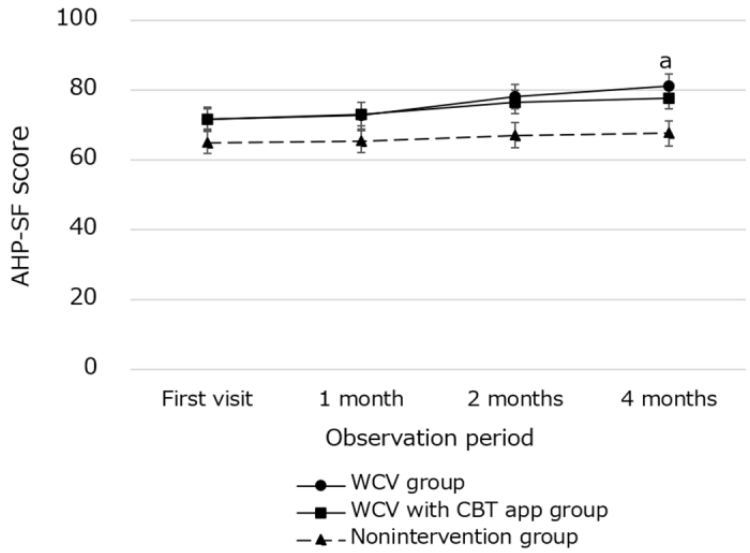

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## Secondary Outcome Result

### *AHP-SF Scores*

For all participants, the mean changes in AHP-SF scores from baseline to 1, 2, and 4 months did not significantly differ among the 3 groups (Table 1). However, in junior high school students, the changes in AHP-SF scores from baseline to 4 months were significantly different between the WCV group (mean 11.87, SD 19.06) and the nonintervention group (mean 3.33, SD 9.60; Figure 6).

**Figure 6.** Changes in Adolescent Health Promotion Short Form (AHP-SF) scores in the intervention and nonintervention groups during the follow-up period; a: the changes in AHP-SF scores from baseline to 4 months were significantly different between the WCV group and the nonintervention group (*P*=.046). Vertical bars show the SE. CBT: cognitive behavioral therapy; WCV: well-care visit.




### *RSES Scores*

For all participants, the mean changes in RSES scores from baseline to 1, 2, and 4 months did not significantly differ among the 3 groups (Table 1). No significant difference was observed in junior high school students or high school students.

### *PedsQL Scores*

For all participants, there was no significant difference in the mean changes in PedsQL scores from baseline to 1, 2, and 4 months among the 3 groups (Table 1). No significant difference was observed in junior high school students or high school students.

## Exploratory Outcome Measures

### *Suicidal Ideation*

A total of 5.5% (12/217) of the participants presented with suicidal ideation during the observation period. Of these 12 participants, 6 (50%) participants were identified before entry, 5 (42%) participants were identified in the nonintervention group, and 1 (8%) participant was identified in the WCV with CBT app group. This showed a significant intervention effect for the prevention of suicidal ideation (Figure 1; *P*<.001).

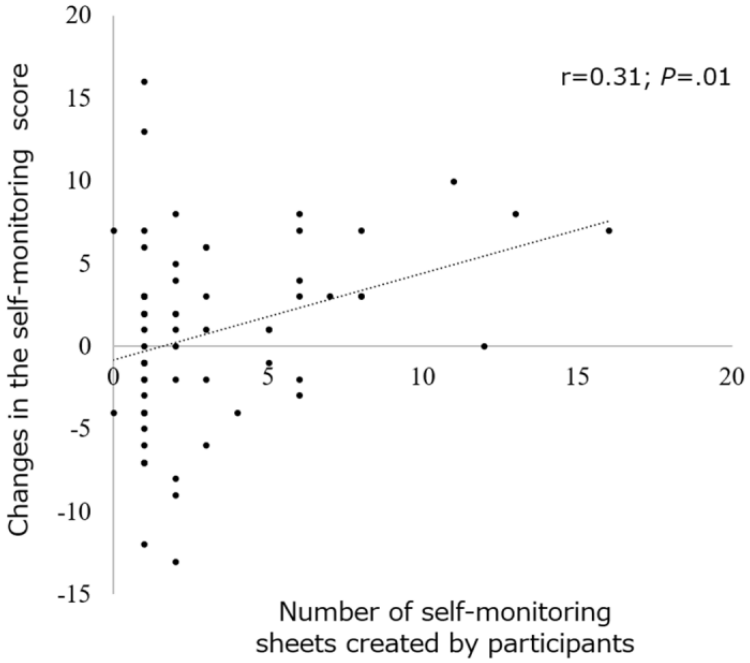
### *Self-monitoring Effect of the CBT App*

Regarding the effect of the CBT app on changes in participants' self-monitoring scores, the more participants created self-monitoring sheets, the better their self-monitoring scores were at the 1-month follow-up. The relationship between the number of self-monitoring sheets created by the participants and the changes in self-monitoring scores showed significant positive correlation (Figure 7).



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**Figure 7.** Correlation between the number of self-monitoring sheets created by participants and the changes in self-monitoring scores in the well-care visit with cognitive behavioral therapy app group. Significant positive correlation was observed between changes in self-monitoring scores and number of self-monitoring sheets created by participants at the 1-month visit.




## Discussion

### Principal Findings

In this randomized controlled trial, we were unable to demonstrate an effect of universal intervention with either the WCV intervention or the WCV with CBT app intervention in terms of changes in adolescents' depressive symptoms; however, both interventions showed a temporary effect in improving depressive symptoms in high school students. Furthermore, the effect was significant for individuals who scored above the cutoff point for depressive symptoms. In addition, the interventions significantly reduced suicidal ideation during the observation period. However, our hypothesis of obtaining better outcomes in the WCV with CBT app group was not supported.

Initially, the interventions showed a significant temporary effect of improving depressive symptoms in high school students irrespective of intervention type (WCV only or WCV with CBT app). However, the second WCV session showed no effect on depressive symptoms in either intervention group after 1 month. This result may reflect volunteer bias, whereby participants' responses met the expectations of the researchers. As volunteers who participate in research studies are generally high-functioning individuals with higher willingness [35,36], their responses tend to produce better results despite the intervention pattern. Although there was a possibility of volunteer bias, the intervention itself may have been effective for participants with a high level of depressive symptoms. The intervention effect was significant and prominent in participants who scored above the DSRS-C cutoff point (16 points) compared with those who scored ≤16. A similar intervention effect for adolescents using a CBT program was reported by Tomyn et al [33], where the intervention showed no average improvement in universal participants, except for those with elevated depression symptoms. This may mean that achieving improvements when participants have few depressive symptoms is challenging. However, our study indicated that better results may be obtained by targeting interventions to individuals with more depressive symptoms rather than a school-based universal intervention for all students with and those without depressive symptoms.

### Effect in Reducing Suicidal Ideation

This study revealed significant effect in terms of reduced suicidal ideation in adolescents during the 4-month observation period in both the WCV group and the WCV with CBT app group. Although 7% (5/72) of the participants were identified as having suicidal ideation in the nonintervention group during the study period, only 0.8% (1/132) of the participants in the intervention groups was identified as having suicidal ideation. This result suggested that the intervention may potentially be effective, and the WCV with or WCV without the CBT app may be an effective means to prevent children from committing suicide. As adolescent suicide is a global mental health concern [6,37], school-based universal prevention programs have focused on reducing the number of suicide attempts and suicidal ideation [37-42]. A European multicentral randomized controlled trial involving 11,110 adolescents (median age 15 years) from 168 schools showed that a short (5 hours over 4 weeks) school-based intervention including role-play sessions and interactive lectures about mental health was significantly effective in preventing new cases of suicide attempts and suicidal ideation at the 12-month follow-up [37]. The study accounted for its significant effect by the role-play sessions and interactive lectures, providing adolescents with opportunity to think, verbalize, and discuss a range of issues related to mental health. Checking social determinants of health and providing anticipatory



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guidance through the HEEADSSS-based interviews, as used in our study, may have offered adolescents the opportunity to identify their emotions and feelings. Therefore, their suicidal ideation may have been suppressed compared with those in the nonintervention group.

### Effect of a Smartphone CBT App

We developed a smartphone CBT app for adolescents, which contained psychoeducation and self-monitoring and was expected to improve their depressive symptoms. App users were coached to observe their own thoughts, feelings, body response, actions, and relationships relating to daily events by repeatedly creating monitoring sheets, and they could monitor their own mind and develop solutions for changing their cognitive processes throughout the sessions. The CBT app was significantly effective in terms of obtaining self-monitoring skills and reducing depressive symptoms, which was confirmed by the association between the number of self-monitoring sheets created and the changes in self-monitoring and depressive symptoms scores. This effect may have contributed to the suppression of the adolescents' suicidal ideation similar to the WCV. An increasing number of mobile apps are available for adolescents with mental health problems, many of which are equipped with CBT programs. However, currently, there is insufficient research evidence to support the effectiveness of these apps for adolescents [17,18]. Stallard et al [16] developed a smartphone app that provided a personalized toolbox of strategies based on CBT in conjunction with a face-to-face intervention to reduce self-harm and support psychological functioning. They found that 73% of individuals who had recently harmed themselves reported reductions in self-harm and depressive scores; however, a flaw in their study design was the absence of a comparison group. Few randomized controlled trials have focused on smartphone apps for adolescents' mental health, and most available studies have failed to demonstrate significant effects on the intended outcomes [43]. Although our study was designed as a randomized controlled trial, both intervention groups included face-to-face interview (WCV) and our hypothesis of obtaining better outcomes in individuals who receive both WCV with CBT app was not supported. Thus, more scientific evidence for the significance of CBT apps is needed from future research. However, our finding of a significant association between the number of self-monitoring sheets created and the changes in self-monitoring scores and depressive symptoms offered a further perspective of implementation of apps for adolescent mental health services. In addition, a deep learning approach using text mining data created in the 5 window panels of the smartphone app in this study could help health care professionals to find adolescents in need of medical care at an advantage.

### Effect of HEEADSSS

Another important finding in this study was the significant increase in health promotion scale scores at the 4-month follow-up in junior high school students in the WCV group. This indicated that they may have become interested in health promotion activities, such as nutrition, exercise, and stress management. Participants in the WCV group participated in risk assessment interviews and received counseling (HEEADSSS) twice (at baseline and 1 month after the first visit). Although several school-based interventions to promote adolescent health revealed both significant and nonsignificant effects in reducing health problems [37,38,40,41], no evidence of effectiveness was available for individual interventions in primary care settings. Our WCV with a HEEADSSS-based interview allocated sufficient intervention time (>30 minutes), which enabled participants to talk and think about their own health through the HEEADSSS framework. As the HEEADSSS framework in a face-to-face interview requires time, an electronic HEEADSSS screening system has been widely accepted [44]. Although annual health checkup for adolescents in Japan have been performed at each school by the school physicians under the supervision of the Ministry of Education of Japan, the school health examination only includes a physical examination (eg, measuring height and body weight; checking visual acuity, hearing, and scoliosis; and urinalysis). Therefore, screening and preventing mental health problems using a HEEADSSS-based interview is required at primary care clinics.

### Limitations

This study had some limitations that need to be addressed. First, the follow-up period in this study (4 months) was a relatively short observation period to draw conclusions about a universal intervention effect. Although there were significant differences in the prevalence of suicidal ideation between the intervention and nonintervention groups during the observation period, participants may have developed suicidal ideation after the observation period, even in the intervention groups. However, many adolescent intervention studies have used relatively short assessment durations (eg, 4-12 weeks) [13,15,34]. As adolescents' mental health conditions may easily change based on daily events, regular additional interventions may be necessary to obtain significant outcomes in longer observation periods. Second, although this study found significant associations between the number of self-monitoring sheets created and improvement in depressive symptoms and self-monitoring skills, a revised version of the CBT app is required to enhance feasibility and adherence. Many participants in the WCV with CBT app group created only a couple of self-monitoring sheets during the observation period, and the efficacy of the CBT app may be enhanced if they could be challenged to make more self-monitoring sheets using an additional method such as gamification [45,46]. Furthermore, our CBT app consisted of two modules (psychoeducation and self-monitoring), and additional modules including cognitive restructuring and behavioral activation modules are necessary to increase the strength of CBT. Finally, although the 217 participants in this study were from 48 junior high schools and high schools, which could avoid the bias caused by sharing CBT app information in single school [32], there was a possibility of volunteer bias because highly motivated participants may have been more interested in participating. Therefore, we should plan to implement a further school-based intervention study.

### Conclusions

In conclusion, this study contributes by informing research directions to promote adolescent health. A standard interview framework for adolescent health promotion (ie, HEEADSSS)



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may be applied in primary care settings in Japan to improve adolescents' mental health, as there are no screening and intervention systems in the regular school-based health checkup. To minimize the time required for this screening, development of either a short form of the HEEADSSS or electronic HEEADSSS screening may be required. Furthermore, our CBT app, which uses a mobile device, may emerge as a new health promotion tool for adolescents if more CBT modules are added. Integrating direct and indirect interventions (HEEADSSS and CBT apps, respectively) may further promote adolescent health.

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## Authors' Contributions

SN, MH, KS, RS, AO, and KM participated in the design of this study, and SN compiled the manuscript. SN, KS, RS, and AO were the representatives in each research facility and recruited the participants. MH, A Kanie, MI, A Katayanagi, and T Katayama designed the cognitive behavioral therapy app. T Kakuma conducted the statistical analyses. All authors except MH, A Kanie, MI, A Katayanagi, T Katayama, and T Kakuma examined and interviewed the participants using the Home, Education, Eating, Activities, Drugs, Sexuality, Suicide, Safety method. All authors read and approved the manuscript. YY supervised the preparation of the manuscript.

## Conflicts of Interest

MI received royalties from several publishing companies for books related to cognitive behavioral therapy. He also received honorariums for workshops and supervisions regarding cognitive behavioral therapy.

Multimedia Appendix 1
CONSORT e-HEALTH checklist (V 1.6.1).
[PDF File (Adobe PDF File), 360 KB - mhealth_v10i5e34154_app1.pdf ]

## References

1. Dalsgaard S, Thorsteinsson E, Trabjerg BB, Schullehner J, Plana-Ripoll O, Brikell I, et al. Incidence rates and cumulative incidences of the full spectrum of diagnosed mental disorders in childhood and adolescence. JAMA Psychiatry 2020 Feb 01;77(2):155-164 [FREE Full text] [doi: 10.1001/jamapsychiatry.2019.3523] [Medline: 31746968]
2. Potrebny T, Wiium N, Lundegård M. Temporal trends in adolescents' self-reported psychosomatic health complaints from 1980-2016: a systematic review and meta-analysis. PLoS One 2017 Nov 28;12(11):e0188374 [FREE Full text] [doi: 10.1371/journal.pone.0188374] [Medline: 29182644]
3. 子どもの身体的 精神的 社会的（biopsychosocial）な健康課題に関する調査研究. 研究報告書. URL: https://www.mhlw.go.jp/content/11900000/000520474.pdf [accessed 2022-04-06]
4. Saito T, Reines EH, Florea I, Dalsgaard MK. Management of depression in adolescents in Japan. J Child Adolesc Psychopharmacol 2019 Dec 01;29(10):753-763. [doi: 10.1089/cap.2019.0023] [Medline: 31268356]
5. Giovanelli A, Adams SH, Jane Park M, Ozer EM. Delivering Anticipatory Guidance About Technology Use to Adolescents in Primary Care: Rates in a Representative California Sample. J Adolesc Health 2021 Dec;69(6):1044-1047 [FREE Full text] [doi: 10.1016/j.jadohealth.2021.06.007] [Medline: 34301469]
6. Nagamitsu S, Mimaki M, Koyanagi K, Tokita N, Kobayashi Y, Hattori R, et al. Prevalence and associated factors of suicidality in Japanese adolescents: results from a population-based questionnaire survey. BMC Pediatr 2020 Oct 06;20(1):467 [FREE Full text] [doi: 10.1186/s12887-020-02362-9] [Medline: 33023527]
7. Adams SH, Park MJ, Twietmeyer L, Brindis CD, Irwin CE. Association between adolescent preventive care and the role of the affordable care act. JAMA Pediatr 2018 Jan 01;172(1):43-48 [FREE Full text] [doi: 10.1001/jamapediatrics.2017.3140] [Medline: 29114725]
8. Peddecord KM, Wang W, Wang L, Ralston K, Ly E, Friedman L, et al. Adolescents' self-reported recall of anticipatory guidance provided during well-visits at nine medical clinics in San Diego, California, 2009-2011. J Adolesc Health 2016 Mar;58(3):267-275. [doi: 10.1016/j.jadohealth.2015.10.007] [Medline: 26699230]
9. Ozer EM, Adams SH, Orrell-Valente JK, Wibbelsman CJ, Lustig JL, Millstein SG, et al. Does delivering preventive services in primary care reduce adolescent risky behavior? J Adolesc Health 2011 Nov;49(5):476-482. [doi: 10.1016/j.jadohealth.2011.02.011] [Medline: 22018561]



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10. Kamb ML, Fishbein M, Douglas JM, Rhodes F, Rogers J, Bolan G, et al. Efficacy of risk-reduction counseling to prevent human immunodeficiency virus and sexually transmitted diseases: a randomized controlled trial. Project RESPECT Study Group. JAMA 1998 Oct 07;280(13):1161-1167. [doi: 10.1001/jama.280.13.1161] [Medline: 9777816]
11. Sekhar DL, Ba DM, Liu G, Kraschnewski JL. Major depressive disorder screening remains low even among privately insured adolescents. J Pediatr 2019 Jan;204:203-207. [doi: 10.1016/j.jpeds.2018.07.086] [Medline: 30244990]
12. Fallucco EM, James L, Smotherman C, Greco P. Impact of experiential training with standardized patients on screening and diagnosis of adolescent depression in primary care. J Adolesc Health 2019 Jul;65(1):57-62. [doi: 10.1016/j.jadohealth.2018.12.022] [Medline: 30879884]
13. Moritz S, Schilling L, Hauschildt M, Schröder J, Treszl A. A randomized controlled trial of internet-based therapy in depression. Behav Res Ther 2012 Aug;50(7-8):513-521. [doi: 10.1016/j.brat.2012.04.006] [Medline: 22677231]
14. Malinauskas R, Malinauskiene V. A meta-analysis of psychological interventions for internet/smartphone addiction among adolescents. J Behav Addict 2019 Dec 01;8(4):613-624 [FREE Full text] [doi: 10.1556/2006.8.2019.72] [Medline: 31891316]
15. Kauer SD, Reid SC, Crooke AH, Khor A, Hearps SJ, Jorm AF, et al. Self-monitoring using mobile phones in the early stages of adolescent depression: randomized controlled trial. J Med Internet Res 2012 Jun 25;14(3):e67 [FREE Full text] [doi: 10.2196/jmir.1858] [Medline: 22732135]
16. Stallard P, Porter J, Grist R. A Smartphone App (BlueIce) for young people who self-harm: open phase 1 pre-post trial. JMIR Mhealth Uhealth 2018 Jan 30;6(1):e32 [FREE Full text] [doi: 10.2196/mhealth.8917] [Medline: 29382632]
17. Grist R, Porter J, Stallard P. Mental health mobile apps for preadolescents and adolescents: a systematic review. J Med Internet Res 2017 May 25;19(5):e176 [FREE Full text] [doi: 10.2196/jmir.7332] [Medline: 28546138]
18. Pennant ME, Loucas CE, Whittington C, Creswell C, Fonagy P, Fuggle P, Expert Advisory Group. Computerised therapies for anxiety and depression in children and young people: a systematic review and meta-analysis. Behav Res Ther 2015 Apr;67:1-18. [doi: 10.1016/j.brat.2015.01.009] [Medline: 25727678]
19. Vigerland S, Lenhard F, Bonnert M, Lalouni M, Hedman E, Ahlen J, et al. Internet-delivered cognitive behavior therapy for children and adolescents: a systematic review and meta-analysis. Clin Psychol Rev 2016 Dec;50:1-10 [FREE Full text] [doi: 10.1016/j.cpr.2016.09.005] [Medline: 27668988]
20. Thornicroft G. Most people with mental illness are not treated. Lancet 2007 Sep;370(9590):807-808. [doi: 10.1016/S0140-6736(07)61392-0]
21. Muramatsu K, Miyaoka H, Kamijima K, Muramatsu Y, Tanaka Y, Hosaka M, et al. Performance of the Japanese version of the Patient Health Questionnaire-9 (J-PHQ-9) for depression in primary care. Gen Hosp Psychiatry 2018;52:64-69. [doi: 10.1016/j.genhosppsych.2018.03.007] [Medline: 29698880]
22. Cohen E, Mackenzie RG, Yates GL. HEADSS, a psychosocial risk assessment instrument: implications for designing effective intervention programs for runaway youth. J Adolescent Health 1991 Nov;12(7):539-544. [doi: 10.1016/0197-0070(91)90084-y]
23. Poznanski EO, Grossman JA, Buchsbaum Y, Banegas M, Freeman L, Gibbons R. Preliminary studies of the reliability and validity of the children's depression rating scale. J Am Acad Child Psychiatry 1984 Mar;23(2):191-197. [doi: 10.1097/00004583-198403000-00011] [Medline: 6715741]
24. Murata T, Shimizu A, Mori Y, Oushima S. Childhood depressive state in the school situation-consideration from the Birleson's Scale. Jpn J Psychiatry 1996;1:131-138.
25. Chen M, Lai L, Chen H, Gaete J. Development and validation of the short-form Adolescent Health Promotion Scale. BMC Public Health 2014 Oct 26;14(1):1106 [FREE Full text] [doi: 10.1186/1471-2458-14-1106] [Medline: 25344693]
26. Rosenberg M. Society and the Adolescent Self-Image. Princeton: Princeton University Press; 1965.
27. Mimura C, Griffiths P. A Japanese version of the Rosenberg Self-Esteem Scale: translation and equivalence assessment. J Psychosom Res 2007 May;62(5):589-594. [doi: 10.1016/j.jpsychores.2006.11.004] [Medline: 17467414]
28. Varni JW, Seid M, Rode CA. The PedsQL: measurement model for the pediatric quality of life inventory. Med Care 1999 Feb;37(2):126-139. [doi: 10.1097/00005650-199902000-00003] [Medline: 10024117]
29. Kobayashi K, Kamibeppu K. Measuring quality of life in Japanese children: development of the Japanese version of PedsQL. Pediatr Int 2010 Feb;52(1):80-88. [doi: 10.1111/j.1442-200X.2009.02889.x] [Medline: 19496977]
30. Mavroveli S, Petrides KV, Shove C, Whitehead A. Investigation of the construct of trait emotional intelligence in children. Eur Child Adolesc Psychiatry 2008 Dec 18;17(8):516-526. [doi: 10.1007/s00787-008-0696-6] [Medline: 18563477]
31. Abe K, Niwa M, Fujisaki K, Suzuki Y. Associations between emotional intelligence, empathy and personality in Japanese medical students. BMC Med Educ 2018 Mar 27;18(1):47 [FREE Full text] [doi: 10.1186/s12909-018-1165-7] [Medline: 29587725]
32. Whittaker R, Stasiak K, McDowell H, Doherty I, Shepherd M, Chua S, et al. MEMO: an mHealth intervention to prevent the onset of depression in adolescents: a double-blind, randomised, placebo-controlled trial. J Child Psychol Psychiatry 2017 Sep 02;58(9):1014-1022. [doi: 10.1111/jcpp.12753] [Medline: 28573672]
33. Tomyn JD, Fuller-Tyszkiewicz M, Richardson B, Colla L. A comprehensive evaluation of a universal school-based depression prevention program for adolescents. J Abnorm Child Psychol 2016 Nov 12;44(8):1621-1633. [doi: 10.1007/s10802-016-0136-x] [Medline: 26873012]




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34. Das JK, Salam RA, Lassi ZS, Khan MN, Mahmood W, Patel V, et al. Interventions for adolescent mental health: an overview of systematic reviews. J Adolesc Health 2016 Oct;59(4S):S49-S60 [FREE Full text] [doi: 10.1016/j.jadohealth.2016.06.020] [Medline: 27664596]
35. Dodge HH, Katsumata Y, Zhu J, Mattek N, Bowman M, Gregor M, et al. Characteristics associated with willingness to participate in a randomized controlled behavioral clinical trial using home-based personal computers and a webcam. Trials 2014 Dec 23;15(1):508 [FREE Full text] [doi: 10.1186/1745-6215-15-508] [Medline: 25539637]
36. Ganguli M, Lytle ME, Reynolds MD, Dodge HH. Random versus volunteer selection for a community-based study. J Gerontol Series A Biological Sci Med Sci 1998 Jan 01;53A(1):M39-M46. [doi: 10.1093/gerona/53A.1.M39]
37. Wasserman D, Hoven CW, Wasserman C, Wall M, Eisenberg R, Hadlaczky G, et al. School-based suicide prevention programmes: the SEYLE cluster-randomised, controlled trial. Lancet 2015 Apr;385(9977):1536-1544. [doi: 10.1016/S0140-6736(14)61213-7]
38. Araya R, Fritsch R, Spears M, Rojas G, Martinez V, Barroilhet S, et al. School intervention to improve mental health of students in Santiago, Chile: a randomized clinical trial. JAMA Pediatr 2013 Nov 01;167(11):1004-1010. [doi: 10.1001/jamapediatrics.2013.2361] [Medline: 23999656]
39. Xu T, Tomokawa S, Gregorio ER, Mannava P, Nagai M, Sobel H. School-based interventions to promote adolescent health: a systematic review in low- and middle-income countries of WHO Western Pacific Region. PLoS One 2020 Mar 5;15(3):e0230046 [FREE Full text] [doi: 10.1371/journal.pone.0230046] [Medline: 32134985]
40. Shinde S, Weiss HA, Khandeparkar P, Pereira B, Sharma A, Gupta R, et al. A multicomponent secondary school health promotion intervention and adolescent health: an extension of the SEHER cluster randomised controlled trial in Bihar, India. PLoS Med 2020 Feb 11;17(2):e1003021 [FREE Full text] [doi: 10.1371/journal.pmed.1003021] [Medline: 32045409]
41. Silverstone PH, Bercov M, Suen VY, Allen A, Cribben I, Goodrick J, et al. Initial findings from a novel school-based program, EMPATHY, which may help reduce depression and suicidality in youth. PLoS One 2015 May 14;10(5):e0125527 [FREE Full text] [doi: 10.1371/journal.pone.0125527] [Medline: 25974146]
42. Silverstone PH, Bercov M, Suen VY, Allen A, Cribben I, Goodrick J, et al. Long-term results from the empowering a multimodal pathway toward healthy youth program, a multimodal school-based approach, show marked reductions in suicidality, depression, and anxiety in 6,227 students in grades 6-12 (aged 11-18). Front Psychiatry 2017 May 15;8:81 [FREE Full text] [doi: 10.3389/fpsyt.2017.00081] [Medline: 28555115]
43. García-Escalera J, Valiente RM, Sandín B, Ehrenreich-May J, Prieto A, Chorot P. The unified protocol for transdiagnostic treatment of emotional disorders in adolescents (UP-A) adapted as a school-based anxiety and depression prevention program: an initial cluster randomized wait-list-controlled trial. Behav Ther 2020 May;51(3):461-473. [doi: 10.1016/j.beth.2019.08.003] [Medline: 32402261]
44. Saw C, Smit A, Silva D, Bulsara M, Nguyen ET. Service evaluation and retrospective audit of electronic HEEADSSS (e-HEEADSSS) screening device in paediatric inpatient service in Western Australia. Int J Adolesc Med Health 2020 Sep 22;22:2020-2120. [doi: 10.1515/ijamh-2020-0120] [Medline: 32960776]
45. Furukawa TA, Horikoshi M, Fujita H, Tsujino N, Jinnin R, Kako Y, et al. Cognitive and behavioral skills exercises completed by patients with major depression during smartphone cognitive behavioral therapy: secondary analysis of a randomized controlled trial. JMIR Ment Health 2018 Jan 11;5(1):e4 [FREE Full text] [doi: 10.2196/mental.9092] [Medline: 29326098]
46. Watanabe N, Horikoshi M, Yamada M, Shimodera S, Akechi T, Miki K, Steering Committee of the Fun to Learn to ActThink through Technology Project. Adding smartphone-based cognitive-behavior therapy to pharmacotherapy for major depression (FLATT project): study protocol for a randomized controlled trial. Trials 2015 Jul 07;16:293 [FREE Full text] [doi: 10.1186/s13063-015-0805-z] [Medline: 26149441]


## Abbreviations

**AHP-SF:** Adolescent Health Promotion Short Form
**CBT:** cognitive behavioral therapy
**DSRS-C:** Depression Self-Rating Scale for Children
**HEEADSSS:** Home, Education, Eating, Activities, Drugs, Sexuality, Suicide, Safety
**MDD:** major depression disorder
**PedsQL:** Pediatric Quality of Life Inventory
**PHQ-9:** 9-item Patient Health Questionnaire
**RSES:** Rosenberg Self-Esteem Scale
**TEIQue-ASF:** Trait Emotional Intelligence Questionnaire–Adolescent Short Form
**WCV:** well-care visit



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Original Paper

# The Effectiveness of a Mobile Health Care App and Human Coaching Program in Primary Care Clinics: Pilot Multicenter Real-World Study

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## Abstract

**Background:** As the global burden of chronic conditions increases, their effective management is a concern. Although the need for chronic disease management using mobile self-management health care apps is increasing, there are still many barriers to their practical application in the primary care field.

**Objective:** This study evaluated the effectiveness of primary care services combining a mobile self-management health care app with human coaching for patients with chronic diseases in the current primary care system.

**Methods:** A total of 110 patients (mean age 53.2, SD 9.2 years; 64 of 110, 58.2% female) with hypertension, diabetes, dyslipidemia, or metabolic syndrome who visited one of 17 participating primary care clinics from September to November 2020 were included in this study. All participants recorded data regarding changes in body weight, sleep conditions, quality of life, depression, anxiety, stress, BMI, waist circumference, blood sugar levels, blood pressure, and blood lipids levels. The app user group (n=65) used a mobile self-management health care app with human coaching for 12 weeks, and the control group (n=45) underwent conventional self-managed health care.

**Results:** Patients in the app user group reported significantly more weight loss than those in the control group—the body weight of the app user group decreased by 1.43 kg (95% CI –2.07 to –0.79) and that of the control group decreased by 0.13 kg (95% CI –0.67 to 0.41; *P*=.002). The weight loss was markedly greater after using the app for 9 weeks than that when used for 4 weeks or 5-8 weeks (*P*=.002). Patients in the app user group reported better sleep quality (*P*=.04) and duration (*P*=.004) than those in the control group.

**Conclusions:** The combination of primary care clinics and a mobile self-management health care app with human coaching results in better management of chronic conditions. This study shows that the primary care services combining a mobile self-management health care app with human coaching are effective in the current primary care system. An implication of this study is the possibility that a mobile self-management health care app with human coaching is a treatment option in the current primary care system.

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**KEYWORDS**

healthcare; health care; mobile application; app; self-management; primary care; chronic conditions



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## Introduction

The burden of chronic conditions has increased markedly [1], and the incidence of conditions such as hypertension, diabetes, and hyperlipidemia is rising in South Korea. Health care systems worldwide are challenged with clinical and economic burdens of chronic and complex conditions, resulting in major obstacles in the provision of optimal health care [2]. Determining the potential benefits of lifestyle modifications and patient participation in health-related decisions is necessary owing to the increased demands on primary care clinics and health care systems [3,4].

The effects of lifestyle modifications on patients with chronic conditions have been identified in previous studies [5-9]. However, a model that supports lifestyle modifications in an evidence-based manner in a format that can be integrated into clinical practice is necessary for primary care providers. Patient involvement is critical for the clinical integration of such models; patient participation in treatment planning, knowledge exchanges, setting goals, and performing self-care activities is necessary for effective lifestyle modifications [10,11]. Patient participation is valuable for symptom control and the management of chronic health conditions [12]. Self-management strategies for lifestyle modifications are increasingly recognized as important tools for chronic disease management and secondary prevention [13].

Technical innovations have increased access and improved health care quality as they have enabled the dissemination and improvement of health care via nontraditional channels at an unprecedented rate with the removal of practical barriers [14]. Technical innovations, such as the transmission of medical records, teleconsulting, telemonitoring, telemedicine, and teleprescription, have led to the development and utilization of tools to promote lifestyle modifications in the health care industry [15,16]. Strategies for implementing lifestyle modifications include self-management aimed at behavior changes, educational interventions, and motivation to participate in self-management [17]. Mobile health technology allows mobile devices, such as tablets, smartphones, and laptops, to play an important role in the collection, storage, and transmission of health data; supports real-time monitoring and the self-management of patients; and has made a huge difference in lifestyle modification interventions [18,19]. Previous studies have shown the efficacy of lifestyle modifications using various mobile tools [15,20,21]. A meta-analysis that evaluated the effectiveness of mobile self-management health care apps for lifestyle modifications in patients with type 2 diabetes found that the use of most apps resulted in significant changes in hemoglobin $A_{1c}$ ($HbA_{1c}$) levels [15]. Another study reported that combining a health care app with a wearable device result in lifestyle modifications that affect the BMI and cholesterol level of patients [20]. Moreover, digital interventions using technologies, such as the internet, SMS, software applications, and mobile sensors may improve positive behavioral factors (physical activity, diet, and medication adherence), and these are even more effective when used to treat multiple behavioral outcomes simultaneously [21].

The lifestyle modification tools provided with recent technological advances allow for sustainable changes by supporting self-care and providing more personalized health care. However, previous studies regarding these tools are limited. Primary health care physicians are usually the first point of contact between the health care system and patient [22], including patients with chronic diseases who utilize the health care system regularly. However, evidence-based models, especially those using information technology, are currently not available for primary care providers to effectively support lifestyle modifications and promote changes in patient behavior. Most previous studies include patients from clinical settings who are already using health care tools or those who are exceptionally motivated to do so [23,24]. Previous studies suggested an integrated whole-systems approach at the patient, primary care, and service organization levels [25]. The effective implementation of these models is necessary for ensuring feasibility, sustainability, and scalability [26]. However, not all patients are eligible for participation in these models owing to their socioeconomic status, lack of access to the internet, and other technologies. Moreover, systematic and comprehensive data on the implementation and utilization aspects of mobile self-management apps, especially in primary care settings, are lacking.

This study evaluated the effectiveness of primary care services combining a mobile self-management health care app with human coaching in the current primary care system for patients with hypertension, diabetes, dyslipidemia, or metabolic syndrome, and on changes in body weight, sleep condition and quality of life, mental health (depression, anxiety, and stress), and cardiovascular risk factors (BMI, waist circumference, blood sugar level, blood pressure, and blood lipid levels).

## Methods

### Study Population

Patients aged ≥19 years who visited any of the 17 primary care clinics between September 2020 and November 2020 and were diagnosed with hypertension, diabetes, dyslipidemia, or metabolic syndrome were included in this study. Patients who met the following criteria were excluded from the study: (1) having a condition that might compromise adherence to using mobile phones (such as those with visual or hearing limitations); (2) having comorbid conditions (such as breathing difficulties, uncontrolled congestive heart failure, or angina); (3) inability to communicate in the Korean language; and (4) those who were currently using or had used mobile self-management health care apps or weight loss medications within one month of the study. Physicians from 17 primary care clinics identified potential participants using medical records.

### Study Design

This study is a multicenter real-world study that evaluated the effectiveness of the mobile self-management health care apps with combined primary care in the current primary care environment. The patients were divided into an app user group, which received a mobile self-management health care app called Noom (Noom Inc; Figure 1), and a control group. For group assignment, when a physician suggests to use the app to patient

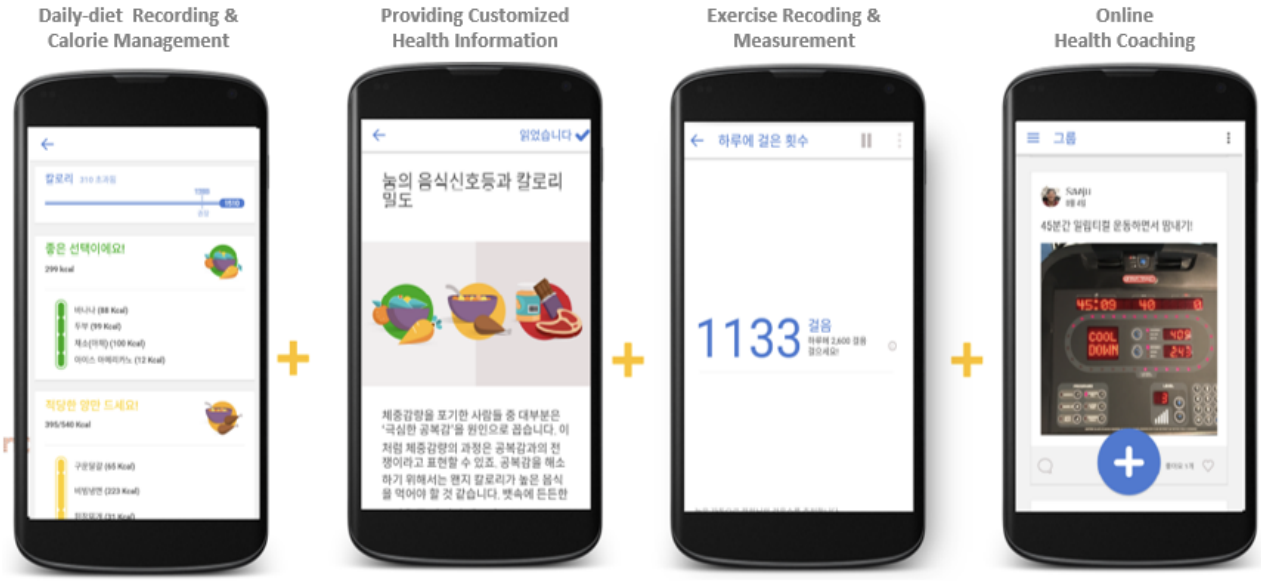


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who needs continuous lifestyle modification during the treatment in the clinic, a researcher dispatched to the primary care center explains the intervention program to the patient and if the patient agrees to use the application assigned to the application use group, and if they did not agree, they were assigned to the control group. The goal of the Noom app is to enable users to lose weight and develop healthier habits via a behavioral approach. Users of the Noom app have access to built-in tools to track their daily activity, food intake, blood pressure, and blood sugar levels. It is one of the most used mobile self-management health care apps in South Korea and has been recognized by the Diabetes Prevention Program of the Centers for Disease Control and Prevention. The mobile self-management health care program used in this study lasted for 12 weeks and included human coaching sessions twice a week. The coaches were trained nutritionists who helped users set and implement achievable goals. Upon installation of the Noom app, the user answered a series of questions regarding their current weight, health problems, and lifestyle (such as, “Do you cook or eat out more?” and “How active you are during the day?”). The human coaches used patients’ responses to make dietary recommendations and to provide lifestyle advice to the patients.

The patients in the app user group recorded their diet and exercise using the app. They received personalized feedback and education from their human coach through mobile messages sent through the Noom app thrice a week, along with 1 or 2 primary care consultations over 12 weeks after the primary visit. For example, the human coach explains to the patients in the app user group what they are doing well and where they are not and sends related articles or videos. It also sets goals for the next step. The intervention program applied to the study is the same program as the existing Noom app program sold, but additionally, the participants shared their life log data recorded in the Noom app with their attending physician. The physicians received the app history data of participants in the form of reports from Noom on the launched website and provided professional feedback for lifestyle management in the clinic. The control group received conventional care, including lifestyle correction counseling to help self-manage chronic disease and providing a basic information booklet on chronic disease once or twice for 12 weeks.

**Figure 1.** Example to track their daily activity, food intake, blood pressure, and blood sugar and chat human coaching.




## Study Outcome Measurement

The primary outcome of this study was the difference in weight loss between the 2 groups after 12 weeks. The secondary outcomes included differences in the changes in sleep condition, quality of life, depression, anxiety, stress, BMI, waist circumference, blood sugar levels, blood pressure, and blood lipid levels in the application user group after using the Noom app for 12 weeks.

Sleep conditions were evaluated by sleep quality and average sleep duration. The sleep quality was measured by patients using the following Likert Scale of five categories: (1) very bad, (2) bad, (3) neutral, (4) good, and (5) very good; furthermore, sleep duration was also recorded. The patients’ quality of life, indicating the extent to which patients are satisfied with their lives, was assessed using the Short Form-12 Health Survey (SF-12) questionnaire [27]. Depression was assessed using the Patient Health Questionnaire-2 (PHQ-2) [28], and anxiety was assessed using the Generalized Anxiety Disorder, 2-item (GAD-2) questionnaire [29]. Stress was assessed using the 10-level perceived stress scale [30]. Other measurements (body weight, BMI, and waist circumference) and laboratory tests (blood sugar levels, blood pressure, and blood lipid levels) were obtained at the participating primary care facilities and performed on only a subset of participating patients as judged necessary by the primary care physicians (64/110, 58.2%).

## Statistical Analyses

Baseline participant characteristics were compared between the study arms and tested for significance using the *t* test for continuous variables and chi-square test for categorical variables. An analysis of variance was used to identify



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differences between patients in the app user group who used the app for different lengths of time. Statistical significance was set at $P<.05$. Before analysis, propensity score (PS) matching was performed on variables such as age, sex, educational status, and underlying diseases to adjust the basic characteristics of the two groups. PS matching logit method was used at a ratio of 1:2. All statistical tests were 2-sided and conducted using Stata 16 (StataCorp).

### Ethical Considerations

The clinical research coordinator at Seoul National University Hospital explained the details of the study to the participants, and informed consent was obtained from each participant willing to participate. The institutional review board of Seoul National University Hospital approved the study (approval number H-2102-136-1199). The clinical study was conducted in accordance with the Good Clinical Practice guidelines and the tenets of the Declaration of Helsinki.

## Results

Although this study included 128 patients in the app user group and 50 patients in the control group who completed the program for 12 weeks (after recruiting a total of 218 patients from 17 primary care centers, those lost to follow-up were excluded), PS matching was conducted by considering the confounding as age, sex, educational status, and underlying diseases. The final analysis included 65 patients in the app user group and 45 in the control group after adjusting for baseline characteristics.

The baseline characteristics of the two groups were similar (Table 1). Although patients in the app user group were younger and had a higher level of education, the differences were not significant. Patient body weight ($P<.001$), sleep condition (sleep quality, $P<.001$; sleep duration, $P<.001$), stress ($P=.01$), BMI ($P=.04$), waist circumference ($P=.03$), $HbA_{1c}$ levels ($P=.04$), high-density lipoprotein (HDL) cholesterol levels ($P=.02$), and triglyceride levels ($P=.003$) were significantly improved after 12 weeks in the app user group. There were no significant differences in the control group after 12 weeks (Tables 2 and 3).

**Table 1.** Demographic and clinical characteristics of participants (N=110).

| Demographic description | Intervention group (n=65) | Control group (n=45) | *P* value |
|---|---|---|---|
| Age (years), mean (SD) | 51.93 (8.06) | 55.24 (10.46) | .08 |
| **Sex, n (%)** | | | .39 |
| Male | 25 (38.46) | 21 (46.67) | |
| Female | 40 (61.54) | 24 (53.33) | |
| **Education status, n (%)** | | | .07 |
| High school or lower | 32 (49.23) | 30 (66.67) | |
| College or university | 33 (50.77) | 15 (33.33) | |
| **Disease or condition, n (%)** | | | .36 |
| Hypertension | 22 (34.00) | 15 (33.00) | |
| Diabetes mellitus | 35 (54.00) | 24 (53.00) | |
| Hyperlipidemia | 3 (5.00) | 3 (7.00) | |
| Metabolic syndrome | 5 (8.00) | 6 (13.00) | |



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**Table 2.** Changes in clinical characteristics after 12 weeks.

| Clinical characteristics | Intervention group (n=65), mean (SD) | *P* value | Control group (n=45), mean (SD) | *P* value |
|---|---|---|---|---|
| **Body weight** | | <.001 | | .63 |
| Baseline | 78.10 (17.46) | | 74.05 (15.30) | |
| After 12 weeks | 76.67 (17.10) | | 73.92 (15.03) | |
| **Sleep quality** | | <.001 | | .72 |
| Baseline | 3.12 (1.00) | | 3.20 (0.89) | |
| After 12 weeks | 3.49 (0.95) | | 3.15 (0.87) | |
| **Sleep duration** | | <.001 | | .65 |
| Baseline | 6.23 (1.17) | | 6.18 (1.04) | |
| After 12 weeks | 6.59 1.12 | | 6.14 (1.12) | |
| **Short Form-12 Health Survey (physical composite) score** | | .12 | | .25 |
| Baseline | 43.17 (4.51) | | 43.91 (4.63) | |
| After 12 weeks | 43.94 (5.01) | | 44.86 (4.82) | |
| **Short Form-12 Health Survey (mental composite) score** | | .12 | | .03 |
| Baseline | 39.91 (5.56) | | 38.46 (5.98) | |
| After 12 weeks | 41.04 (4.97) | | 40.83 (7.60) | |
| **Patient Health Questionnaire-2 score** | | .87 | | .86 |
| Baseline | 1.29 (1.71) | | 0.88 (1.54) | |
| After 12 weeks | 1.26 (1.53) | | 0.93 (1.48) | |
| **Generalized Anxiety Disorder-2 scale score** | | .26 | | .49 |
| Baseline | 1.16 (1.68) | | 0.80 (1.37) | |
| After 12 weeks | 0.98 (1.52) | | 0.66 (1.39) | |
| **Propensity score** | | .01 | | .92 |
| Baseline | 16.38 (6.89) | | 14.02 (5.61) | |
| After 12 weeks | 14.43 (5.9) | | 14.11 (6.03) | |



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**Table 3.** Changes in physical and laboratory measurements after 12 weeks[a].

| Measurements | Intervention group (n=42), mean (SD) | *P* value | Control group (n=24), mean (SD) | *P* value |
|---|---|---|---|---|
| **Waist circumference** | | .03 | | .53 |
| Baseline | 93.41 (11.09) | | 89.99 (9.08) | |
| After 12 weeks | 91.75 (11.57) | | 89.64 (9.14) | |
| **BMI** | | .04 | | .66 |
| Baseline | 28.60 (4.47) | | 27.65 (4.12) | |
| After 12 weeks | 27.83 (4.23) | | 27.58 (4.04) | |
| **Systolic blood pressure** | | .09 | | .76 |
| Baseline | 123.95 (12.35) | | 127.75 (12.02) | |
| After 12 weeks | 127.02 (15.00) | | 126.75 (10.77) | |
| **Diastolic blood pressure** | | .06 | | .76 |
| Baseline | 77.71 (7.83) | | 77.87 (8.30) | |
| After 12 weeks | 81.19 (11.51) | | 78.37 (9.70) | |
| **Hemoglobin $A_{1c}$ levels** | | .04 | | .89 |
| Baseline | 6.69 (1.06) | | 6.73 (0.94) | |
| After 12 weeks | 6.51 (0.91) | | 6.72 (0.93) | |
| **Total cholesterol** | | .83 | | .73 |
| Baseline | 165.80 (46.49) | | 159.29 (36.22) | |
| After 12 weeks | 167.26 (35.68) | | 157.08 (41.57) | |
| **High-density lipoprotein cholesterol levels** | | .02 | | .67 |
| Baseline | 48.50 (11.30) | | 47.17 (10.82) | |
| After 12 weeks | 51.23 (12.36) | | 47.78 (8.04) | |
| **Low-density lipoprotein cholesterol levels** | | .37 | | .54 |
| Baseline | 85.83 (30.32) | | 78.73 (30.13) | |
| After 12 weeks | 89.49 (30.97) | | 76.01 (35.83) | |
| **Triglyceride levels** | | .003 | | .47 |
| Baseline | 176.38 (109.02) | | 193.33 (199.90) | |
| After 12 weeks | 136.07 (54.2) | | 166.37 (60.93) | |

[a]All physical and laboratory measurements were obtained at the participating primary care center and only for a subset of participating patients as judged necessary by the primary care physicians. Hence, this table shows only 42 and 24 participants in the intervention and control groups, respectively.

## Primary Outcome

The app user group had significantly more weight loss than the control group: the body weight of the app user group decreased by 1.43 kg (95% CI –2.07 to –0.79) and that of the control group decreased by 0.13 kg (95% CI –0.67 to 0.41; *P*=.002; Table 4). Patients in the app user group who used the Noom app for at least 9 weeks had a significantly higher weight loss than those who used the app for 5-8 weeks and those who used the app for ≤4 weeks (*P*=.002; Table 5).



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**Table 4.** Comparison of measurements changes between baseline and after 12 weeks by the group.

| Measurements | Intervention group (n=65), mean (SD) | Control group (n=45), mean (SD) | *P* value |
|---|---|---|---|
| Body weight (kg) | –1.43 (2.59) | –0.13 (1.78) | .002 |
| Sleep quality score | 0.36 (0.71) | –0.04 (0.82) | .007 |
| Sleep duration (hours) | 0.35 (0.78) | –0.04 (0.64) | .004 |
| Short-Form-12 Health Survey (physical composite) score | 1.91 (5.64) | 0.94 (5.44) | .37 |
| Short-Form-12 Health Survey (mental composite) score | 1.12 (5.74) | 2.37 (7.21) | .34 |
| Patient Health Questionnaire-2 score | –0.03 (1.46) | 0.04 (1.71) | .81 |
| Generalized Anxiety Disorder-2 scale score | –0.18 (1.30) | –0.13 (1.27) | .84 |
| Propensity score | –1.95 (6.01) | 0.08 (5.99) | .08 |
| Waist circumference (cm)[a] | –1.82 (4.53) | –0.15 (3.59) | .04 |
| BMI ($kg/m^2$)[a] | –0.53 (0.99) | –0.04 (0.64) | .002 |
| Systolic blood pressure (mm Hg)[a] | 3.35 (11.02) | 1.23 (17.36) | .51 |
| Diastolic blood pressure (mm Hg)[a] | 3.23 (11.34) | 0.05 (8.78) | .14 |
| Hemoglobin $A_{1c}$ levels (%)[a] | –0.17 (0.60) | –0.01 (0.42) | .14 |
| Total cholesterol levels (mg/dl)[a] | 4.09 (42.65) | –0.82 (27.43) | .52 |
| High-density lipoprotein cholesterol levels (mg/dL)[a] | 3.16 (7.10) | 2.03 (6.99) | .47 |
| Low-density lipoprotein cholesterol levels (mg/dL)[a] | 6.99 (30.85) | –0.94 (20.28) | .16 |
| Triglyceride levels (mg/dL)[a] | –37.94 (89.18) | –51.05 (182.82) | .70 |

[a]All physical and laboratory measurements were obtained at the participating primary center and only for a subset of participating patients (intervention group, n=42; control group, n=24) as judged necessary by the primary care physicians.

**Table 5.** Comparison of measurements change between baseline and after 3 months by app use period.

| Measurements | Control group (n=45), mean (SD) | Intervention group (n=65), mean (SD) | | | *P* value |
|---|---|---|---|---|---|
| | | Less than 4 weeks (n=18) | 5-8 weeks (n=11) | Greater than 9 weeks (n=36) | |
| Body weight (kg) | –0.13 (1.78) | –0.90 (1.75) | –0.33 (1.55) | –2.02 (3.03) | .002 |
| Sleep quality score | –0.04 (0.82) | 0.16 (0.38) | 0.27 (0.46) | 0.50 (0.87) | .02 |
| Sleep duration (hours) | –0.04 (0.64) | 0.25 (0.55) | 0.36 (0.77) | 0.40 (0.89) | .045 |
| Waist circumference (cm) | –0.15 (3.59) | –1.18 (1.93) | –1.37 (1.93) | –2.21 (5.84) | .22 |
| BMI ($kg/m^2$) | –0.04 (0.64) | –0.33 (0.69) | –0.13 (0.64) | –0.75 (1.15) | .003 |

### Secondary Outcomes

The subjective assessments of sleep quality (*P*=.007), sleep duration (*P*=.004), waist circumference (*P*=.04), and BMI (*P*=.002) were significantly more favorable in the app user group than in the control group after 12 weeks (Table 4). Patients in the app user group tended to display a greater change in stress scores than those in the control group, although the differences were not significant after 12 weeks (Table 4). The sleep conditions and BMI also improved as patients in the app user group using the app for 9 weeks or more (Table 5).

## Discussion

### Principal Findings

After 12 weeks of using the Noom app, patients in the app user group reported significantly greater weight loss and improved sleep quality and duration than those in the control group. This is the first Korean study to determine the efficacy of a mobile app for the self-management of chronic conditions in the current primary care setting.

The results of this study are similar to those of a previous study regarding the use of an app and medical provider management for patients with obesity and hypertension, diabetes, or hyperlipidemia [31]. The weight loss observed in this study was greater than that reported previously when considering the



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duration of both these studies. This is likely since this study combined the use of a mobile app with human coaching to enhance the patients' self-management competency. The Opportunities for Weight Reduction (POWER) study combined telephone-based coaching and web-based training modules with self-managed interventions and resulted in weight reduction that was comparable to that in this study [32]. Taken together, the results of these studies suggest that a self-management program using a mobile app, human coaching, and provider counseling is effective for weight loss in patients with hypertension, diabetes, or hyperlipidemia. Furthermore, the results of this study show that the results of these studies are also linked to the current primary care setting.

Several previous studies have evaluated the effectiveness of mobile self-management health care apps with varied results. While some studies have shown that using mobile self-management health care apps is effective for weight loss in patients with chronic diseases and improving blood pressure control, total cholesterol and triglyceride levels, and waist circumference [33-36]. However, results from another study indicate that the weight change was minimal and insignificant compared with a control group [37]. In addition, the use of mobile self-management health care apps allowed patients to maintain a healthy lifestyle after 12 months, though long-term differences between the app user groups and the control groups were not reported in a previous study [38]. Previous South Korean studies on the effectiveness of mobile self-management health care apps focused on weight loss [39,40].

The Noom app can be used to alleviate the difficulties related to continuous self-monitoring, provide patient education, customize feedback [41], and manage meetings with physicians. However, to make the intervention cost-effective, a low-cost digital technique (interactive text, questions and answers, and feedback text messaging) was used in this study. This method may limit the use in the elderly population that is on the rise. In addition, even when the low-cost digital methods of communication were used, the maintenance cost of the methods used in this study was higher than the cost of using only the app. This resulted from the providing app and provider counseling that involved a human coach. Previous studies have shown that the inclusion of human counseling results in more favorable outcomes when using digital health interventions [42,43]. Patient data algorithms were used in this study to analyze patient data to produce short medical consultation reports for clinicians, data dashboards that organize the coaching process and show the patients' lifestyles, and personalized feedback for the patients.

### Limitations and Strengths

This study has several strengths. The greatest advantage of this study was that it involved a multicenter primary clinic of the current primary care setting. This has shown that the primary care services combining a mobile self-management health care app with human coaching are effective in the current primary care system where there are barriers such as patient perception. Second, it was based on using a mobile phone app instead of a web-based program. Mobile phone interventions result in increased involvement of the participant compared with web-based programs. Third, the human coaching component included in this study provided individualized, one-on-one feedback based on self-monitoring data provided by the patient. When the patient entered data on his/her diet and activities, the coach confirmed the data and helped the patients use the app better and improve their health management skills via individualized feedback. Last, the human coaches provided summary data to the primary care provider, allowing the primary care staff to provide feedback regarding the patient's lifestyle while providing medical care. This allowed for the reinforcement of lifestyle modifications from various sources and extended the responsibilities of the medical staff.

However, this study also had some limitations. The first limitation of this study is the nonrandomized. This could lead to a selection bias based on mobile approach properties, and patients who participated in the application user group actually tended to be younger and more educated than the control group. To compensate for this limitation, this study attempted to minimize this bias by implementing PS matching by adjusting the basic characteristics such as age, sex, educational status, and underlying diseases. Nevertheless, it may have influenced the assignment of patients to interventions and controls. Second, owing to the study design, it was not possible to isolate the specific effects of each component of the intervention. It may be unclear whether the effect of the study is a representation on the use of mobile self-management health care app, an effect on human coaching, or an effect on primary care. Finally, the sample size is small for generalization.

## Conclusions

The combination of primary care services combining a mobile self-management health care app with human coaching is more effective than conventional primary care for weight loss and improving sleep in patients with chronic diseases in primary care clinics. An implication of this is the possibility that a mobile self-management health care app with human coaching is a treatment option in the current primary care system. In the future, for a mobile self-management health care app to become a general treatment option, large-scale randomized studies on the long-term effects of interventions in the current primary care settings are needed.

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or approval of the manuscript; and decision to submit the manuscript for publication. This study was supported by the Korea Health Industry Development Institute (grant Nutrition-2020-70).

## Authors' Contributions

HRJ, EKK, and BC conceptualized and constructed the clinical structure for these digital interventions during the implementation stage. YIK and HYK provided practical and on-site research insights when constructing the digital intervention. HRJ, EKK, and BC contributed to the study design and HRJ, EKK, YIK, and HYK collected research data. HRJ mainly analyzed the data, and all authors interpreted the data. HRJ and EKK wrote the manuscript, and BC edited the contents of the manuscript. YIK and HYK reviewed the manuscript. All authors approved the final version of the manuscript for submission.

## Conflicts of Interest

YIK and HYK are employees of Noom.

## References

1. Noncommunicable diseases country profiles 2018. World Health Organization. 2018 Sep 24. URL: https://apps.who.int/iris/handle/10665/274512 [accessed 2022-04-29]
2. Montgomery H, Haines A, Marlow N, Pearson G, Mythen M, Grocott M, et al. The future of UK healthcare: problems and potential solutions to a system in crisis. Ann Oncol 2017 Aug 01;28(8):1751-1755 [FREE Full text] [doi: 10.1093/annonc/mdx136] [Medline: 28453610]
3. Luhr K, Holmefur M, Theander K, Eldh AC. Patient participation during and after a self-management programme in primary healthcare - The experience of patients with chronic obstructive pulmonary disease or chronic heart failure. Patient Educ Couns 2018 Jun;101(6):1137-1142. [doi: 10.1016/j.pec.2017.12.020] [Medline: 29290329]
4. Bell J, Dziekan G, Pollack C, Mahachai V. Self-Care in the Twenty First Century: A Vital Role for the Pharmacist. Adv Ther 2016 Oct;33(10):1691-1703 [FREE Full text] [doi: 10.1007/s12325-016-0395-5] [Medline: 27535290]
5. Lambrinou E, Hansen TB, Beulens JW. Lifestyle factors, self-management and patient empowerment in diabetes care. Eur J Prev Cardiol 2019 Dec;26(2_suppl):55-63. [doi: 10.1177/2047487319885455] [Medline: 31766913]
6. Samadian F, Dalili N, Jamalian A. Lifestyle Modifications to Prevent and Control Hypertension. Iran J Kidney Dis 2016 Sep;10(5):237-263 [FREE Full text] [Medline: 27721223]
7. Zachariah JP, Chan J, Mendelson MM, Regh T, Griggs S, Johnson PK, et al. Adolescent Dyslipidemia and Standardized Lifestyle Modification: Benchmarking Real-World Practice. J Am Coll Cardiol 2016 Nov 08;68(19):2122-2123 [FREE Full text] [doi: 10.1016/j.jacc.2016.08.041] [Medline: 27810053]
8. Robbins CL, Dietz PM, Bombard J, Tregear M, Schmidt SM, Tregear SJ. Lifestyle interventions for hypertension and dyslipidemia among women of reproductive age. Prev Chronic Dis 2011 Nov;8(6):A123 [FREE Full text] [Medline: 22005616]
9. Takahara M, Shimomura I. Metabolic syndrome and lifestyle modification. Rev Endocr Metab Disord 2014 Dec;15(4):317-327. [doi: 10.1007/s11154-014-9294-8] [Medline: 25263290]
10. Rikabi GE, Story LJ, Rikabi K. Patient-Centered Care: Lifestyle Modifications Among Adult Participants With Dyslipidemia. J Dr Nurs Pract 2019 Apr 01;12(1):31-40. [doi: 10.1891/2380-9418.12.1.31] [Medline: 32745053]
11. Thórarinsdóttir K, Kristjánsson K. Patients' perspectives on person-centred participation in healthcare: a framework analysis. Nurs Ethics 2014 Mar;21(2):129-147. [doi: 10.1177/0969733013490593] [Medline: 23812560]
12. McWilliam CL. Patients, persons or partners? Involving those with chronic disease in their care. Chronic Illn 2009 Dec;5(4):277-292. [doi: 10.1177/1742395309349315] [Medline: 19933246]
13. Jordan JE, Briggs AM, Brand CA, Osborne RH. Enhancing patient engagement in chronic disease self-management support initiatives in Australia: the need for an integrated approach. Med J Aust 2008 Nov 17;189(S10):S9-S13. [doi: 10.5694/j.1326-5377.2008.tb02202.x] [Medline: 19143585]
14. Walker DM, Diana ML. Hospital Adoption of Health Information Technology to Support Public Health Infrastructure. J Public Health Manag Pract 2016;22(2):175-181. [doi: 10.1097/PHH.0000000000000198] [Medline: 26811967]
15. Wu X, Guo X, Zhang Z. The Efficacy of Mobile Phone Apps for Lifestyle Modification in Diabetes: Systematic Review and Meta-Analysis. JMIR Mhealth Uhealth 2019 Jan 15;7(1):e12297 [FREE Full text] [doi: 10.2196/12297] [Medline: 30664494]
16. Lunde P, Nilsson BB, Bergland A, Kværner KJ, Bye A. The Effectiveness of Smartphone Apps for Lifestyle Improvement in Noncommunicable Diseases: Systematic Review and Meta-Analyses. J Med Internet Res 2018 May 04;20(5):e162 [FREE Full text] [doi: 10.2196/jmir.9751] [Medline: 29728346]
17. Bourbeau J, Lavoie KL, Sedeno M. Comprehensive Self-Management Strategies. Semin Respir Crit Care Med 2015 Aug;36(4):630-638. [doi: 10.1055/s-0035-1556059] [Medline: 26238647]
18. Weinstein RS, Lopez AM, Joseph BA, Erps KA, Holcomb M, Barker GP, et al. Telemedicine, telehealth, and mobile health applications that work: opportunities and barriers. Am J Med 2014 Mar;127(3):183-187. [doi: 10.1016/j.amjmed.2013.09.032] [Medline: 24384059]



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19. Zhao Y, Ni Q, Zhou R. What factors influence the mobile health service adoption? A meta-analysis and the moderating role of age. Int J Inf Manage 2018 Dec;43:342-350. [doi: 10.1016/j.ijinfomgt.2017.08.006]
20. Lee J, Kang M, Lee S. Effects of the e-Motivate4Change Program on Metabolic Syndrome in Young Adults Using Health Apps and Wearable Devices: Quasi-Experimental Study. J Med Internet Res 2020 Jul 30;22(7):e17031 [FREE Full text] [doi: 10.2196/17031] [Medline: 32729838]
21. Akinosun AS, Polson R, Diaz-Skeete Y, De Kock JH, Carragher L, Leslie S, et al. Digital Technology Interventions for Risk Factor Modification in Patients With Cardiovascular Disease: Systematic Review and Meta-analysis. JMIR Mhealth Uhealth 2021 Mar 03;9(3):e21061 [FREE Full text] [doi: 10.2196/21061] [Medline: 33656444]
22. Jung H, Jo M, Kim HJ, Jang WM, Eun SJ, Lee JY. General Public's Perspectives on Medical Doctors and Local Clinics in South Korea. Int J Environ Res Public Health 2019 Jun 07;16(11) [FREE Full text] [doi: 10.3390/ijerph16112030] [Medline: 31181626]
23. Kang S, Kim S, Cho JH, Yoon C, Hwang S, Lee H, et al. Prevalence, Awareness, Treatment, and Control of Hypertension in Korea. Sci Rep 2019 Jul 29;9(1):10970 [FREE Full text] [doi: 10.1038/s41598-019-46965-4] [Medline: 31358791]
24. Logan AG, Irvine MJ, McIsaac WJ, Tisler A, Rossos PG, Easty A, et al. Effect of home blood pressure telemonitoring with self-care support on uncontrolled systolic hypertension in diabetics. Hypertension 2012 Jul;60(1):51-57. [doi: 10.1161/HYPERTENSIONAHA.111.188409] [Medline: 22615116]
25. Kennedy A, Bower P, Reeves D, Blakeman T, Bowen R, Chew-Graham C, Salford National Institute for Health Research Gastrointestinal programme Grant Research Group. Implementation of self management support for long term conditions in routine primary care settings: cluster randomised controlled trial. BMJ 2013 May 13;346:f2882 [FREE Full text] [doi: 10.1136/bmj.f2882] [Medline: 23670660]
26. O'Connell S, Mc Carthy VJC, Savage E. Frameworks for self-management support for chronic disease: a cross-country comparative document analysis. BMC Health Serv Res 2018 Jul 25;18(1):583 [FREE Full text] [doi: 10.1186/s12913-018-3387-0] [Medline: 30045721]
27. Kim S, Jo M, Ahn J, Ock M, Shin S, Park J. Assessment of psychometric properties of the Korean SF-12 v2 in the general population. BMC Public Health 2014 Oct 18;14:1086 [FREE Full text] [doi: 10.1186/1471-2458-14-1086] [Medline: 25326684]
28. Shin J, Kim H, Jung C, Kim J, Jung S, Cho H, et al. The Standardization of the Korean Version of the Patient Health Questionnaire-2. J Korean Neuropsychiatr Assoc 2013;52(3):115. [doi: 10.4306/jknpa.2013.52.3.115]
29. Plummer F, Manea L, Trepel D, McMillan D. Screening for anxiety disorders with the GAD-7 and GAD-2: a systematic review and diagnostic metaanalysis. Gen Hosp Psychiatry 2016;39:24-31. [doi: 10.1016/j.genhosppsych.2015.11.005] [Medline: 26719105]
30. Hong GS, Kang H, Oh E, Park Y, Kim H. Reliability and Validity of the Korean Version of the Perceived Stress Scale-10 (K-PSS-10) in Older Adults. Res Gerontol Nurs 2016;9(1):45-51. [doi: 10.3928/19404921-20150806-72] [Medline: 26366581]
31. Bennett GG, Steinberg D, Askew S, Levine E, Foley P, Batch BC, et al. Effectiveness of an App and Provider Counseling for Obesity Treatment in Primary Care. Am J Prev Med 2018 Dec;55(6):777-786 [FREE Full text] [doi: 10.1016/j.amepre.2018.07.005] [Medline: 30361140]
32. Wadden TA, Volger S, Sarwer DB, Vetter ML, Tsai AG, Berkowitz RI, et al. A two-year randomized trial of obesity treatment in primary care practice. N Engl J Med 2011 Nov 24;365(21):1969-1979 [FREE Full text] [doi: 10.1056/NEJMoa1109220] [Medline: 22082239]
33. Kouwenhoven-Pasmooij TA, Robroek SJW, Kraaijenhagen RA, Helmhout PH, Nieboer D, Burdorf A, et al. Effectiveness of the blended-care lifestyle intervention 'PerfectFit': a cluster randomised trial in employees at risk for cardiovascular diseases. BMC Public Health 2018 Jun 19;18(1):766 [FREE Full text] [doi: 10.1186/s12889-018-5633-0] [Medline: 29921255]
34. Bennett GG, Steinberg D, Askew S, Levine E, Foley P, Batch BC, et al. Effectiveness of an App and Provider Counseling for Obesity Treatment in Primary Care. Am J Prev Med 2018 Dec;55(6):777-786 [FREE Full text] [doi: 10.1016/j.amepre.2018.07.005] [Medline: 30361140]
35. Recio-Rodríguez JI, Rodriguez-Sanchez E, Martin-Cantera C, Martinez-Vizcaino V, Arietaleanizbeaskoa MS, Gonzalez-Viejo N, EVIDENT Investigators group. Combined use of a healthy lifestyle smartphone application and usual primary care counseling to improve arterial stiffness, blood pressure and wave reflections: a Randomized Controlled Trial (EVIDENT II Study). Hypertens Res 2019 Jun;42(6):852-862. [doi: 10.1038/s41440-018-0182-6] [Medline: 30587857]
36. Gomez-Marcos MA, Patino-Alonso MC, Recio-Rodriguez JI, Agudo-Conde C, Romaguera-Bosch M, Magdalena-Gonzalez O, on behalf the EVIDENT Investigators 11. Short- and long-term effectiveness of a smartphone application for improving measures of adiposity: A randomised clinical trial - EVIDENT II study. Eur J Cardiovasc Nurs 2018 Aug 28;17(6):552-562 [FREE Full text] [doi: 10.1177/1474515118761870] [Medline: 29488798]
37. Laing BY, Mangione CM, Tseng C, Leng M, Vaisberg E, Mahida M, et al. Effectiveness of a smartphone application for weight loss compared with usual care in overweight primary care patients: a randomized, controlled trial. Ann Intern Med 2014 Nov 18;161(10 Suppl):S5-12 [FREE Full text] [doi: 10.7326/M13-3005] [Medline: 25402403]




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38. Recio-Rodriguez JI, Agudo Conde C, Calvo-Aponte MJ, Gonzalez-Viejo N, Fernandez-Alonso C, Mendizabal-Gallastegui N, EVIDENT Investigators. The Effectiveness of a Smartphone Application on Modifying the Intakes of Macro and Micronutrients in Primary Care: A Randomized Controlled Trial. The EVIDENT II Study. Nutrients 2018 Oct 10;10(10) [FREE Full text] [doi: 10.3390/nu10101473] [Medline: 30309008]
39. Toro-Ramos T, Lee D, Kim Y, Michaelides A, Oh TJ, Kim KM, et al. Effectiveness of a Smartphone Application for the Management of Metabolic Syndrome Components Focusing on Weight Loss: A Preliminary Study. Metab Syndr Relat Disord 2017 Nov;15(9):465-473. [doi: 10.1089/met.2017.0062] [Medline: 29035677]
40. Kim Y, Oh B, Shin H. Effect of mHealth With Offline Antiobesity Treatment in a Community-Based Weight Management Program: Cross-Sectional Study. JMIR Mhealth Uhealth 2020 Jan 21;8(1):e13273 [FREE Full text] [doi: 10.2196/13273] [Medline: 31961335]
41. Kim M, Kim Y, Go Y, Lee S, Na M, Lee Y, et al. Multidimensional Cognitive Behavioral Therapy for Obesity Applied by Psychologists Using a Digital Platform: Open-Label Randomized Controlled Trial. JMIR Mhealth Uhealth 2020 Apr 30;8(4):e14817 [FREE Full text] [doi: 10.2196/14817] [Medline: 32352391]
42. van der Weegen S, Verwey R, Spreeuwenberg M, Tange H, van der Weijden T, de Witte L. The development of a mobile monitoring and feedback tool to stimulate physical activity of people with a chronic disease in primary care: a user-centered design. JMIR Mhealth Uhealth 2013 Jul 02;1(2):e8 [FREE Full text] [doi: 10.2196/mhealth.2526] [Medline: 25099556]
43. Silberman JM, Kaur M, Sletteland J, Venkatesan A. Outcomes in a digital weight management intervention with one-on-one health coaching. PLoS One 2020;15(4):e0232221 [FREE Full text] [doi: 10.1371/journal.pone.0232221] [Medline: 32353035]


## Abbreviations

**GAD-2:** Generalized Anxiety Disorder, 2-item
**$HbA_{1c}$:** hemoglobin $A_{1c}$
**HDL:** high-density lipoprotein
**PHQ-2:** Patient Health Questionnaire-2
**POWER:** Opportunities for Weight Reduction
**PS:** propensity score
**SF-12:** Short Form-12 Health Survey


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Original Paper

# Evaluation of the Effect of Patient Education and Strengthening Exercise Therapy Using a Mobile Messaging App on Work Productivity in Japanese Patients With Chronic Low Back Pain: Open-Label, Randomized, Parallel-Group Trial

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## Abstract

**Background:** Artificial intelligence–assisted interactive health promotion systems are useful tools for the management of musculoskeletal conditions.

**Objective:** This study aimed to explore the effects of web-based video patient education and strengthening exercise therapy, using a mobile messaging app, on work productivity and pain in patients with chronic low back pain (CLBP) receiving pharmacological treatment.

**Methods:** Patients with CLBP were randomly allocated to either the exercise group, who received education and exercise therapy using a mobile messaging app, or the conventional group. For patient education, a web-based video program was used to provide evidence-based thinking regarding the importance of a cognitive behavioral approach for CLBP. The exercise therapy was developed in accordance with the recommendations for alignment, core muscles, and endogenous activation, including *improvement of posture and mobility for proper alignment*, *stimulation and/or strengthening of deep muscles for spinal stability*, and *operation of intrinsic pain* for the *activation of endogenous substances by aerobic exercise*. Both groups continued to receive the usual medical care with pharmacological treatment. The end points were changes in work productivity, pain intensity, quality of life, fear of movement, and depression. The observation period for this study was 12 weeks. An analysis adjusted for baseline values, age at the time of consent acquisition, sex, and willingness to strengthen the exercise therapy was performed.

**Results:** The exercise and conventional groups included 48 and 51 patients, with a mean age of 47.9 years (SD 10.2 years; n=27, 56.3% male patients) and 46.9 years (SD 12.3 years; n=28, 54.9% male patients) in the full analysis set, respectively. No significant impact of these interventions on work productivity was observed in the exercise group compared with the conventional group (primary end point: Quantity and Quality method; 0.062 vs 0.114; difference between groups −0.053, 95% CI −0.184 to 0.079; *P*=.43). However, the exercise group showed consistently better trends for the other end points than did the conventional group. Compared with the conventional group, the exercise group showed a significant improvement in the symptoms of low back pain (3.2 vs 3.8; difference between groups −0.5, 95% CI −1.1 to 0.0; *P*=.04), quality of life (EuroQoL 5 Dimensions 5 Level: 0.068 vs 0.006; difference between groups 0.061, 95% CI 0.008 to 0.114; *P*=.03), and fear of movement at week 12 (−2.3 vs 0.5; difference between groups −2.8, 95% CI −5.5 to −0.1; *P*=.04).



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**Conclusions:** This study suggests that patient education and strengthening exercise therapy using a mobile messaging app may be useful for treating CLBP. This study does not reveal the effect of therapeutic interventions on CLBP on work productivity. Thus, further research is required to assess work productivity with therapeutic interventions.

**Trial Registration:** University Hospital Medical Information Network Clinical Trials Registry UMIN000041037; https://center6.umin.ac.jp/cgi-open-bin/ctr_e/ctr_view.cgi?recptno=R000046866

***(JMIR Mhealth Uhealth 2022;10(5):e35867)*** doi:10.2196/35867

**KEYWORDS**

mobile app; patient education; chronic low back pain; exercise regimen; mobile phone

## Introduction

### Background

Chronic low back pain (CLBP) is common in adults, with prevalence rates as high as >80% [1,2]. In Japan, the low back is the most common site for pain in 31% of Japanese adults aged ≥20 years [3].

Low back pain (LBP) is associated with high disability. In the Global Burden of Diseases, Injuries, and Risk Factors Study 2017, LBP ranked highest in terms of years lived with disability among the 354 conditions studied over the period of 28 years [4]. Recurrence of pain, limitation of activity, loss of productivity, and work absenteeism contribute to the associated huge socioeconomic burden of CLBP [5-7].

In a retrospective, cross-sectional study using the 2014 Japan National Health and Wellness Survey data, 77.4% of 30,000 Japanese adults with CLBP reported presenteeism and had a poor quality of life (QoL) compared with those without presenteeism [8]. A cross-sectional survey of 392 patients with CLBP in Japan estimated the costs for lost productivity as approximately ¥1.2 trillion (US $10 billion) per year [7]. A recent internet-based survey of 10,000 Japanese workers reported that 36.8% of the participants had a health problem that interfered with their work during the past 4 weeks. Among the symptoms that most affect presentism, neck pain or shoulder stiffness, LBP, and mental illnesses accounted for approximately 35.7%. The annualized costs of presenteeism per capita for these conditions were US $414.05, US $407.59, and US $469.67, respectively [9].

Several studies have reported that exercise alleviates CLBP and disability [10-12]. Furthermore, exercise regimens have been reported to reduce disability [13] and improve the QoL of individuals with CLBP [14,15]. Patients with chronic pain, including CLBP, exhibit various symptoms and signs as the duration of the pain increases. When the pain lingers, it becomes intractable and serious through a cyclical interaction with psychosocial factors. As illustrated by the fear-avoidance model of pain, pain often involves catastrophizing when it becomes intractable [16]. There are also several psychological treatments or therapies for musculoskeletal symptoms [17]. In a study on patients with CLBP, both groups—one that received only exercise therapy and the other that received a combination of cognitive behavioral therapy and exercise therapy—showed improvements in pain intensity and QoL compared with baseline [18].

Despite these encouraging results, patients often show noncompliance with exercise therapy. Perceptions of the underlying illness and exercise therapy, lack of positive feedback, and degree of helplessness are factors related to noncompliance with exercise therapy [19]. In recent years, digital devices have become popular for supporting exercise therapy for musculoskeletal pain [20-22]. These digital devices have been reported to improve adherence [23,24]. Most studies have supported the role of digital interventions for LBP alleviation [24-27].

The mobile messaging app Secaide (Travoss Co, Ltd) is a digital device designed to enhance the patient's understanding of CLBP and enable remote exercise therapy for more accessible and personalized home-based pain management. The app was nicknamed *se · ca · ide* by the *self-care guide service*. *Secaide* also means *in the world* when read in Japanese. The usefulness of mobile messaging app–based interventions in managing neck and/or shoulder stiffness and LBP is established in workers in randomized controlled trials [28].

### Objectives

Previous studies have not clarified the impact of intervention in CLBP treatment on presenteeism in patients. As a hypothesis, we expected that therapeutic intervention for CLBP would have a positive effect on presenteeism. This study aims to explore the effects of patient education and strengthening exercise therapy on work productivity, symptoms, and QoL in patients with CLBP who were receiving medication and who continued to experience pain despite treatment. In a new attempt, we used web-based videos for patient education and a mobile messaging app to support the continuation of exercise therapy. Because of the COVID-19 pandemic, we devised methods for study continuation without any visits to clinics by the intervention in web-based remote exercise therapy and by using patient-reported outcomes (PROs) as an outcome evaluation method.

## Methods

### Study Design

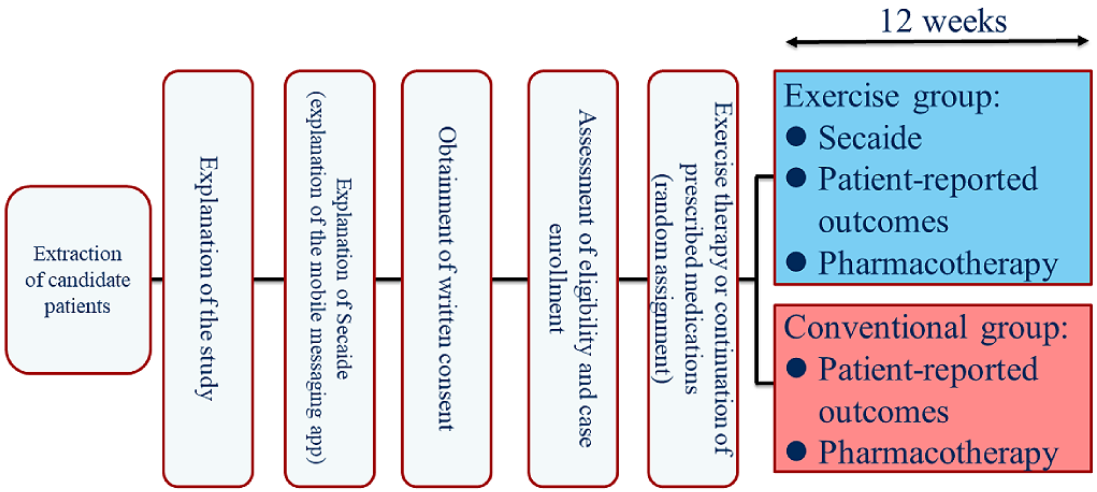
This was a multicenter, open-label, randomized, parallel-group study conducted in Japan from June 2020 to March 2021 at 16 clinics (Multimedia Appendix 1). The main clinical specialty of the 16 community-based clinics included 8 (50%) orthopedic facilities, 3 (19%) pain clinics, and 5 (31%) primary care facilities. In this study, patients were followed up for 12 weeks (Figure 1). Patients who met the eligibility criteria were randomly assigned using a stochastic minimization procedure



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with allocation regulators, such as age (<45 or ≥45 years), sex (male or female), and willingness to enhance exercise therapy (yes or no).

**Figure 1.** Study design.




## Ethics Approval

The study was conducted in accordance with all the international and local laws, the principles of the *Declaration of Helsinki*, and the SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) statement [29]. Written informed consent was obtained from all patients before enrollment in the study. The study protocol and all subsequent amendments were approved by the institutional review board of Takahashi Clinic (clinical research implementation plan MA2020-P-002). The study was registered with the University Hospital Medical Information Network Clinical Trials Registry (UMIN000041037).

## Study Population

Patients who met the following criteria were included in the study: (1) having LBP for >3 months, (2) aged 20 to 64 years, (3) receiving prescribed pharmacological treatment for the pain, (4) not likely to experience any unexpected pain flare-ups for 12 weeks, (5) able to walk independently, (6) engaging in work for >3 days per week in either full-time or part-time capacity for >3 hours a day, and (7) having the skill and understanding to operate mobile communications. The CLBP diagnosis was established by qualified practicing physicians.

The key exclusion criteria were as follows: (1) aged >65 years, (2) having CLBP unrelated to a musculoskeletal condition, (3) with radiculopathy or constructive spinal deformity, (4) having LBP with red flags (with chest pain, malignant tumor, HIV infection, malnutrition, significant weight loss of ≥5% within 1 month, extensive neurological symptoms, or fever of ≥37.5 °C), (5) using over-the-counter medications for CLBP, (6) pregnant women and those who were willing to be pregnant during the clinical trial period, (7) receiving steroids (intravenous injection or oral administration) or opioids, and (8) unable to understand the Japanese language.

## Study Treatment, Education, and Therapy

The patients received the prescribed pharmacological treatment, surgical treatment, and/or patient education and exercise therapy for the management of CLBP.

### *Pharmacological Treatment*

Information about the use of medications for pain was obtained from an electronic medical record system (Mebix, Inc). Pharmacological treatment included nonsteroidal anti-inflammatory drugs, acetaminophen, weak opioids, blood flow improvers, muscle relaxants, medications for osteoporosis, antidepressant drugs, steroids, antiepileptic drugs, and nerve-blocking agents, such as local anesthetic drugs. Medications were assessed at randomization; weeks 4, 8, and 12; and study discontinuation.

### *Surgical Treatment*

Any surgeries for pain relief were recorded at randomization; weeks 4, 8, and 12; and study discontinuation.

### *Patient Education and Exercise Therapy*

A web-based video program was used to provide evidence-based thinking regarding the importance of a cognitive behavioral approach for patients with CLBP. The exercise therapy was developed by Travoss Co, Ltd, in accordance with the recommendations for alignment, core muscles, and endogenous activation, including *improvement of posture and mobility for proper alignment*, *stimulation and/or strengthening of deep muscles for spinal stability*, and *operation of intrinsic pain* for the *activation of endogenous substances by aerobic exercise* [30,31].

Secaide, a mobile messaging app for mobile communication devices such as smartphones and tablets, with download enabled by a QR code, is an aid to exercise therapy. In Japan, this mobile messaging app is used for SMS text messaging and voice calls [28]. Patient education and exercise therapy announcements were conducted as follows. The artificial intelligence–assisted



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chatbot was programmed to send messages to users with exercise instructions and some tips on what they can do in their daily lives to improve their symptoms. The messages were sent every day at a fixed time through the LINE app (a smartphone app widely used for sending and receiving SMS text messages, images, and videos, and making voice calls in Japan; LINE Corporation). The notification time can be changed by users to a time convenient for them. The exercise was performed during the patient's favorite time. The participants can complete their exercise within approximately 1 to 3 minutes each day (Figures 2-4). During the first week, Secaide provided evidence-based thinking about the importance of a cognitive-behavioral approach for CLBP to patient education. Secaide also provided guidance to carry out six simple exercise menus for 60 days. After the 14th, information on two types of exercise was optionally added to patients who desire further exercise. At each clinic, the conventional group received only routine medical care. In the exercise therapy group, in addition to the routine medical care, patient education and strengthening of exercise were provided. To avoid cross-contamination between the 2 groups, only the exercise group received patient education and daily exercise therapy via Secaide (Figures 2-4).

**Figure 2.** Examples of exercises with instructions from the artificial intelligence–assisted health program (Secaide).

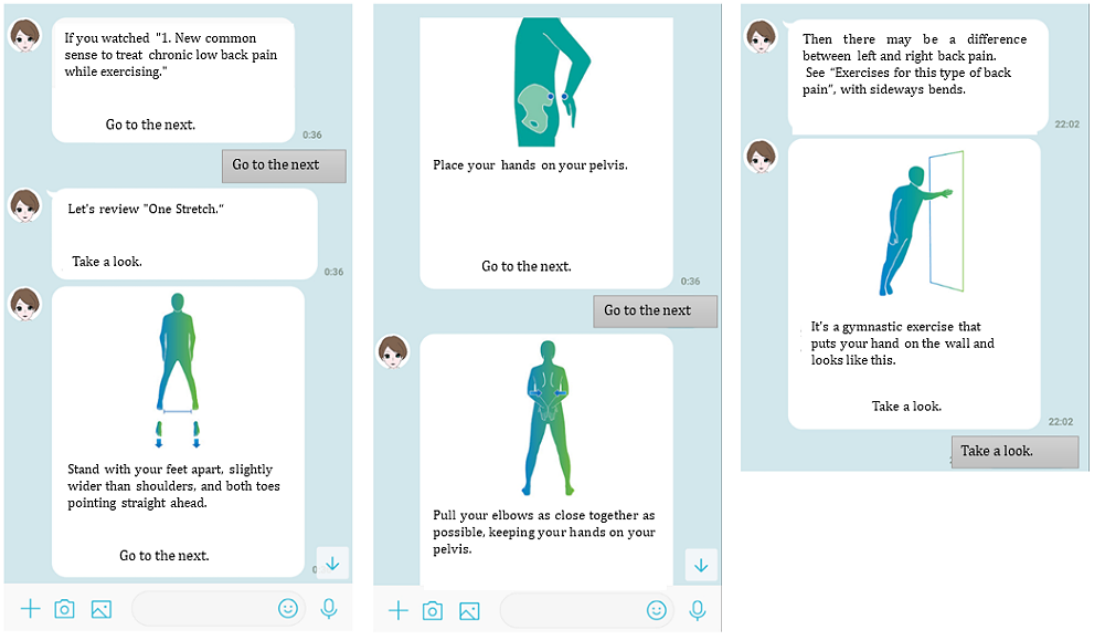
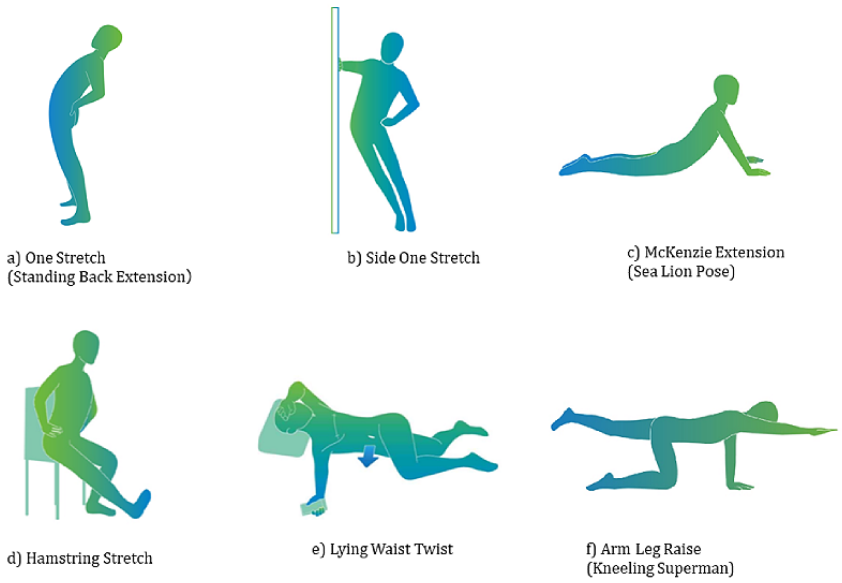


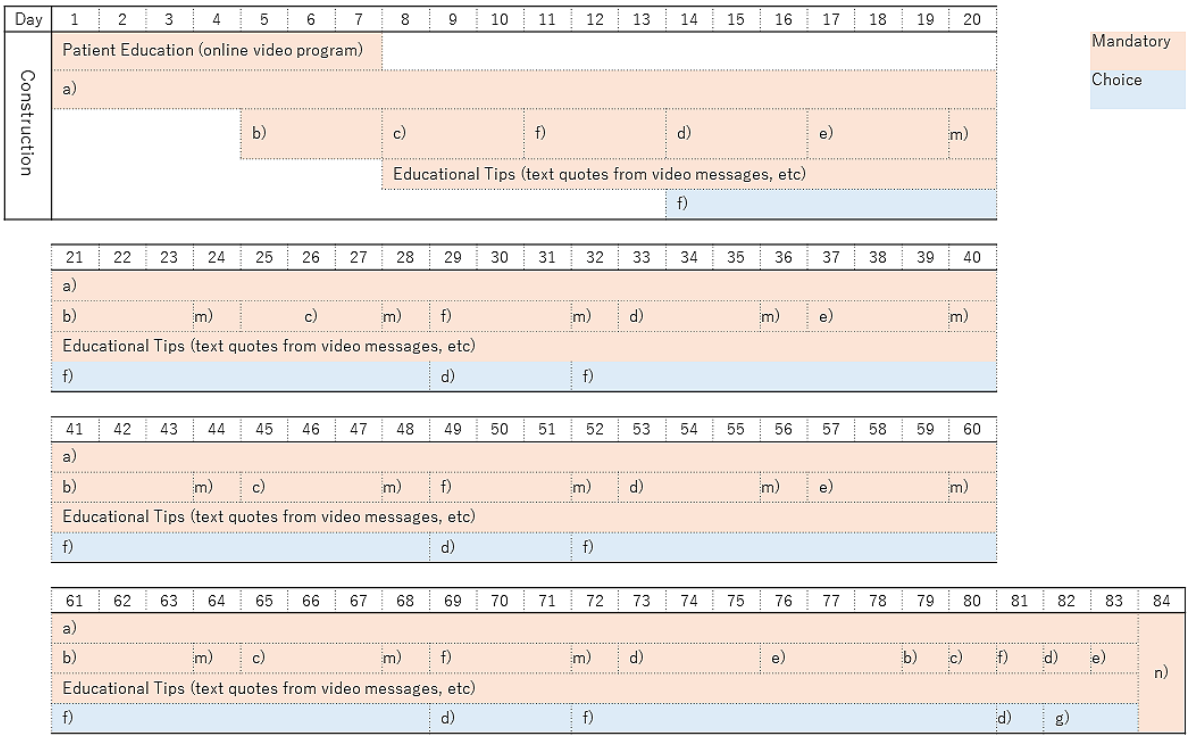

**Figure 3.** Exercise menu on Secaide.






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**Figure 4.** Exercise schedule on Secaide. a) One Stretch (Standing Back Extension), b) Side One Stretch, c) McKenzie Extension (Sea Lion Pose), d) Hamstring Stretch, e) Lying Waist Twist, f) Arm Leg Raise (Kneeling Superman), m) Mindfulness, n) Questionnaire.




## Survey

All patients were required to respond to a web-based survey that captured demographic and background information, including occupation and exercise habits. Furthermore, pharmacological and surgical treatment for CLBP and the number of institutional visits in the last 30 days were collected at weeks 0 to 4, weeks 4 to 8, and weeks 8 to 12 and at study discontinuation.

Adherence to the use of mobile messaging app–based exercise therapy was measured by the rate of implementation (%), calculated as follows: (access days/observation period)×100. Category aggregation for the adherence rate was performed by 0% to 25%, by 25% to 50%, by 50% to 75%, and by ≥75%. Assessments were made from the log information (date) of Secaide and the PRO response date, that is, weeks 0 to 4, weeks 4 to 8, weeks 8 to 12, and weeks 0 to 12.

## Study End Points

### *Primary End Point*

The primary end point was the change in work productivity at week 12. The work productivity was measured using the Quantity and Quality method (QQ method), which evaluates work productivity in terms of quality, quantity, and efficiency and is an evaluation index for absenteeism [32].

### *Secondary End Points*

The secondary end points were changes in work productivity measured using the Work Productivity and Activity Impairment Questionnaire: General Health (WPAI-GH) [33], CLBP and shoulder stiffness (Numerical Rating Scale [NRS]) [34], subjective ratings of stiffness and LBP on a scale of 1 to 5 [28], disease-specific QoL (Roland-Morris Disability Questionnaire [RDQ-24]) [35,36], health-related QoL (EuroQoL 5 Dimensions 5 Level [EQ-5D-5L]) [37,38], fear of movement (Tampa Scale for Kinesiophobia [TSK-11]) [39,40], degree of depression (Kessler Screening Scale for Psychological Distress [K-6]) [41], drug use, and consultation status at medical institutions. All the secondary end points were measured at baseline and week 12. In addition, changes in LBP and drug use were measured at weeks 4 and 8 during the study period.

## Statistical Analysis

The data related to changes in WPAI-GH in a 6-week randomized study of patients with LBP were used to calculate the sample size of 100 participants [42]. The required sample size in this study was estimated to be 90 patients for 80% power at an intergroup difference of 2.7, a common SD of the 2 groups of 4.5, and an $\alpha$ level of .05, using the 2-sample, 2-tailed *t* test. Considering a dropout rate of 10%, the total sample size was 100 (n=50, 50% patients in each group). For allocation, a minimization method was used, with adjustments for age, sex, and willingness to adopt the exercise therapy.

Data were summarized using descriptive statistics of the mean (SE) for continuous variables and frequencies and percentages for categorical variables. To compare continuous data in the 2 groups, an analysis of covariance model (covariates: treatment, baseline, age, sex, and willingness to adopt the exercise therapy) or mixed-effects model for repeated measures (covariates: treatment, baseline, time, time×treatment, age, sex, and willingness to adopt the exercise therapy) was used for the primary and secondary end points, depending on the times of



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measurements. The Fisher exact test was used to compare the percentages in the 2 groups.

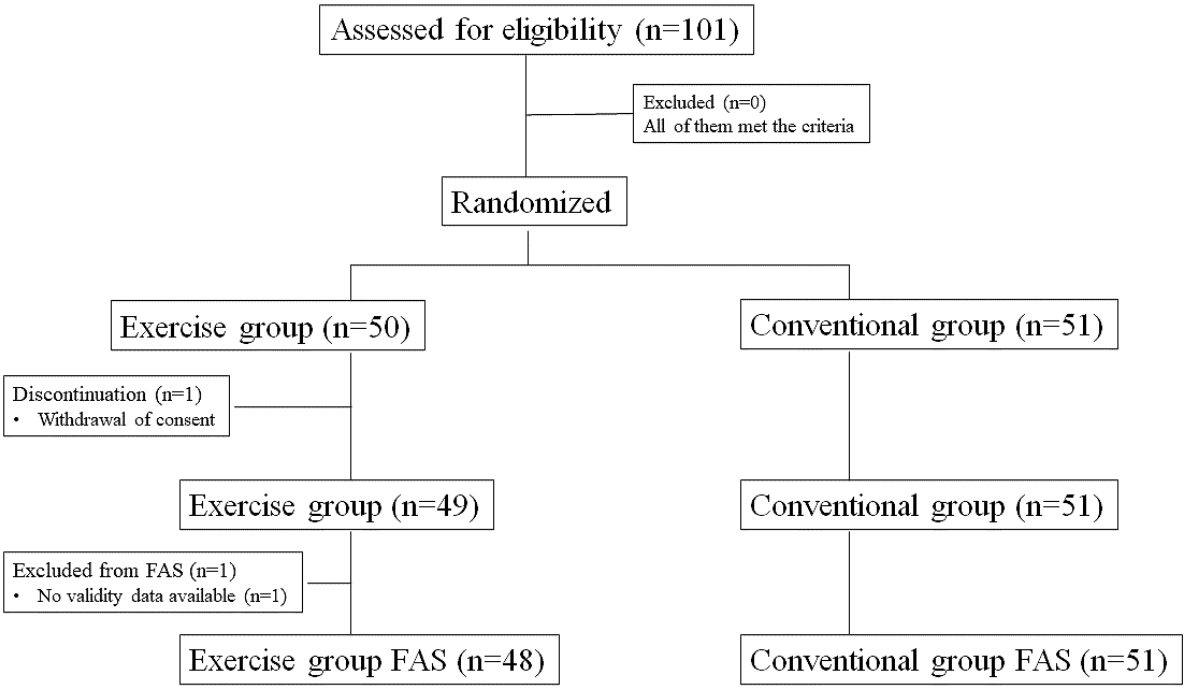
In patients who had data reported at week 12, post hoc analyses were performed to check the impact of the treatment compliance (<75% and ≥75% exercise groups and conventional group) on the primary end point (work productivity) and secondary end points (NRS of CLBP and RDQ-24). Data were analyzed using SAS (version 9.4; SAS Institute Inc).

## Results

### Study Population

A total of 101 patients with CLBP were recruited, and consenting participants were randomly allocated to either the exercise group (n=50, 49.5% randomized; n=48, 47.5% analyzed for efficacy), who used the web-based videos and Secaide for exercise therapy, or the conventional group (n=51, 50.5% randomized and analyzed; Figure 5). Both groups continued with the prescribed pharmacological treatments.

**Figure 5.** Patient disposition. FAS: full analysis set.




The baseline characteristics of patients in the exercise and conventional groups are shown in Table 1. No difference in many characteristics was observed between the 2 groups. However, variability in work productivity was observed (WPAI-GH). In addition, >85% of the patients in both groups requested exercise therapy (exercise group: 42/48, 88% patients; conventional group: 45/51, 88% patients), which was a group highly conscious of exercise. Of the 48 participants in the exercise group, 37 (77%) were adherent to the use of mobile messaging app–based exercise therapy in weeks 0 to 4, 31 (65%) in weeks 4 to 8, and 32 (67%) in weeks 8 to 12 (Figure 6).



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**Table 1.** Baseline characteristics (full analysis set).

| | Exercise group (n=48) | Conventional group (n=51) |
|---|---|---|
| **Age (years), mean (SD)** | 47.9 (10.2) | 46.9 (12.3) |
| <45 | 18 (37.5) | 20 (39.2) |
| ≥45 | 30 (62.5) | 31 (60.8) |
| **Sex, n (%)** | | |
| Women | 21 (44) | 23 (45) |
| Men | 27 (56) | 28 (55) |
| BMI (kg/m$^2$), mean (SD) | 24.42 (4.05) | 23.39 (4.18) |
| **Duration of CLBP[a] (years), n (%)** | | |
| <0.5 | 3 (6) | 5 (10) |
| 0.5 to <1 | 3 (6) | 6 (12) |
| ≥1 | 42 (88) | 40 (78) |
| **Exercise habits, n (%)** | | |
| Yes | 14 (29) | 19 (37) |
| No | 14 (29) | 19 (37) |
| Sometimes | 20 (42) | 13 (25) |
| **Hope for exercise therapy, n (%)** | | |
| Yes | 42 (88) | 45 (88) |
| No | 6 (13) | 6 (12) |
| **Work engagement, n (%)** | | |
| Full time (>40 hours per week) | 34 (71) | 40 (78) |
| Part time | 14 (29) | 11 (22) |
| **Family structure, n (%)** | | |
| Living alone | 10 (21) | 9 (18) |
| Living with children only | 1 (2) | 4 (8) |
| Living with adults only | 18 (38) | 18 (35) |
| Living with adults and children | 19 (40) | 20 (39) |
| **Income (¥ [US $]), n (%)** | | |
| <3 million (24,000) | 15 (31) | 10 (20) |
| 3 million to <5 million (24,000 to 40,000) | 14 (29) | 16 (31) |
| 5 million to <8 million (40,000 to 64,000) | 9 (19) | 13 (25) |
| ≥8 million (64,000) | 8 (17) | 7 (14) |
| Decline to answer | 2 (4) | 5 (10) |
| Education level (completed university education), mean (SD) | 25 (52.1) | 22 (43.1) |
| **Drink alcohol, n (%)** | | |
| Yes | 17 (35) | 18 (35) |
| No | 12 (25) | 22 (43) |
| Sometimes | 19 (40) | 11 (22) |
| **Smoking, n (%)** | | |
| Never smoked | 23 (48) | 26 (51) |
| Former smoker | 14 (29) | 15 (29) |
| Current smoker | 11 (23) | 10 (20) |



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| | Exercise group (n=48) | Conventional group (n=51) |
|---|---|---|
| **Work productivity, QQ method,[b] mean (SD)** | | |
| Performance degradation | 0.51 (0.303) | 0.516 (0.314) |
| Days of work loss due to poor performance | 10.466 (8.485) | 12.409 (9.956) |
| **Work productivity (WPAI-GH[c]), mean (SD)** | | |
| Work time | 4.3 (12.4) | 8.2 (21.8) |
| Impairment while working | 35.3 (29.8) | 45.6 (33.2) |
| Overall work impairment | 37.0 (30.7) | 47.7 (34.4) |
| Activity impairment | 47.2 (31.6) | 50.4 (29) |
| **NRS,[d] mean (SD)** | | |
| CLBP | 5 (2.4) | 5.1 (2.1) |
| Shoulder stiffness | 4.5 (3.0) | 4.5 (2.8) |
| RDQ-24,[e] mean (SD) | 8.6 (5.3) | 7.4 (4.7) |
| EQ-5D-5L,[f] mean (SD) | 0.720 (0.195) | 0.746 (0.142) |
| TSK-11,[g] mean (SD) | 26.4 (6.1) | 24.6 (6.6) |
| K-6,[h] mean (SD) | 6.2 (5.6) | 5 (4.9) |
| **Medical institution consultation status (in the last 30 days), mean (SD)** | | |
| Hospital | 1.9 (1.7) | 2.1 (2.3) |
| Clinic | 0.8 (1.6) | 1.1 (2.5) |
| Acupuncture and moxibustion clinic | 0.2 (0.8) | 0.1 (0.2) |
| Manipulative clinic | 0.8 (1.7) | 0.8 (1.9) |
| Others | 0.3 (1.0) | 0.4 (0.9) |

[a]CLBP: chronic low back pain.

[b]QQ method: Quantity and Quality method.

[c]WPAI-GH: Work Productivity and Activity Impairment Questionnaire: General Health.

[d]NRS: Numerical Rating Scale.

[e]RDQ-24: Roland-Morris Disability Questionnaire.

[f]EQ-5D-5L: EuroQoL 5 Dimensions 5 Level.

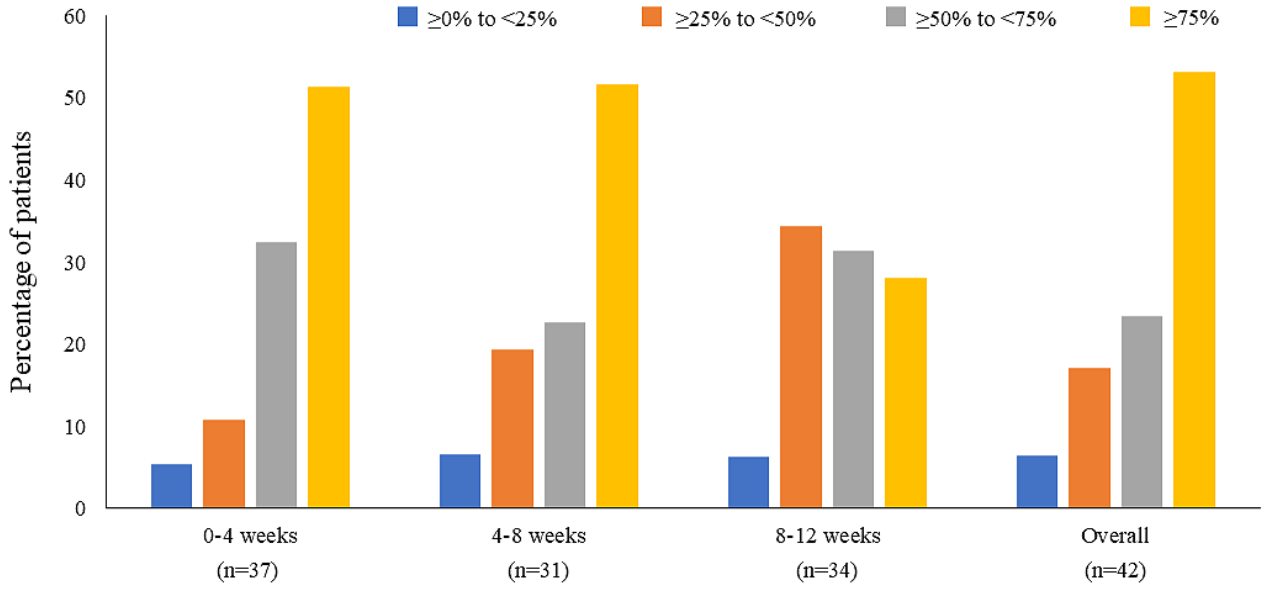
[g]TSK-11: Tampa Scale for Kinesiophobia.

[h]K-6: Kessler Screening Scale for Psychological Distress.



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**Figure 6.** Compliance rates for the use of mobile messaging app–based exercise therapy during the study duration. Exercise status is evaluated by access log to Secaide within a specified period. Percentage of patients (%)=(access days/observation period)×100. Category aggregation for the rate of adherence was performed by 0% to 25% (blue), 25% to 50% (orange), 50% to 75% (gray), and ≥75% (yellow).




## Primary End Point

At week 12, the mean change (SE) in work productivity (QQ method) in the exercise group (n=37) and the conventional group (n=32) was 0.062 (0.069) and 0.114 (0.069), respectively (difference between groups −0.053, 95% CI −0.184 to 0.079; *P*=.43). No significant difference was observed at the primary end point.

## Secondary End Points

### *Work Productivity*

Changes in the WPAI-GH parameters in the 2 groups at week 12 are shown in Table 2. Percent overall work impairment due to health in the exercise group (n=36) and the conventional group (n=26) was −13.3 (SE 6.8) and −4.7 (SE 7.6), respectively (difference between groups −8.6, 95% CI −23.6 to 6.5; *P*=.26).

**Table 2.** Changes in Work Productivity and Activity Impairment Questionnaire: General Health parameters and QoL[a] at week 12.

| Parameter | Exercise group, least squares mean (SE) | Conventional group, least squares mean (SE) | Difference between groups in the 12 weeks, least squares mean (95% CI) | *P* value |
|---|---|---|---|---|
| **Work Productivity, n (%)** | 36[b] (100) | 26 (100) | N/A[c] | |
| Work time | 3.8 (3.4) | 1.2 (4.1) | 2.7 (−5.4 to 10.7) | .51 |
| Impairment while working | −16.5 (6.2) | −6.8 (6.9) | −9.6 (−23.3 to 4.1) | .17 |
| Overall work impairment | −13.3 (6.8) | −4.7 (7.6) | −8.6 (−23.6 to 6.5) | .26 |
| Activity impairment | −16.7 (5.7) | −6.4 (6.7) | −10.3 (−23.6 to 3.0) | .13 |
| **QoL scale, n (%)** | 38 (100) | 34 (100) | N/A | |
| RDQ-24[d] | −2.1 (0.8) | −0.3 (0.9) | −1.9 (−3.7 to 0.0) | .05 |
| EQ-5D-5L[e] | 0.068 (0.024) | 0.006 (0.026) | 0.061 (0.008 to 0.114) | .03 |

[a]QoL: quality of life.

[b]Data for activity impairment due to health were analyzed for 37 patients.

[c]N/A: not applicable.

[d]RDQ-24: Roland-Morris Disability Questionnaire.

[e]EQ-5D-5L: EuroQoL 5 Dimensions 5 Level.

### *Low Back Pain*

At week 12, although no statistically significant difference in the reduction of the NRS scores was observed between the exercise (mean −1.1, SE 0.3) and conventional groups (mean −0.7, SE 0.4; *P*=.26), the mean subjective improvement in CLBP symptoms was significantly greater in the exercise group (mean 3.2, SE 0.2) than in the conventional group (mean 3.8, SE 0.3; difference between groups −0.5, 95% CI −1.1 to 0.0; *P*=.04).



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### *Quality of Life*

At week 12, no statistically significant differences in the RDQ-24 scores were observed between the exercise and conventional groups. A significant improvement in EQ-5D-5L at week 12 was observed in the exercise group compared with that in the conventional group (Table 2).

### *Kinesiophobia*

At week 12, a significant improvement in the TSK-11 score was observed in the exercise group (mean −2.3, SE 1.2) compared with that in the conventional group (mean 0.5, SE 1.3; difference between groups −2.8, 95% CI −5.5 to −0.1; *P*=.04).

### *Depression*

At week 12, no significant improvement in the K-6 score was observed in the exercise group (mean −1.5, SE 0.8) compared with that in the conventional group (mean −0.6, SE 0.9; difference between groups −0.9; 95% CI −2.7 to 0.9; *P*=.34).

### *Change in Consultation Status*

Visits to clinics were significantly reduced in the exercise group at weeks 4, 8, and 12. Similarly, a significant reduction in visits to the acupuncture and moxibustion clinics was observed in the exercise group at weeks 4 and 8 (Multimedia Appendix 2).

### *Surgical Treatment and Change in Drug Use*

No differences for surgical treatment or changes in drug use were observed in the conventional or exercise group throughout the study period.

### *Post Hoc Analysis*

In this study, no significant difference in work productivity (QQ method), pain intensity, and RDQ-24 was observed in the exercise group. As a post hoc analysis, the effects of exercise therapy on work productivity (QQ method), pain intensity, and RDQ-24 were examined in the group with a high compliance rate of exercise (≥75%) and the other groups (<75% compliance). At week 12, patients who showed a higher (≥75%) adherence to the exercise regimen had a greater improvement in work productivity (QQ method), NRS scores, and RDQ-24 than those with <75% adherence or the conventional group (Table 3).

**Table 3.** Change from baseline of work productivity, CLBP,[a] and quality of life among treatment compliances at week 12 (post hoc analysis).[b]

| Parameters | Exercise group compliance ≥75% (n=18), least squares mean (95% CI) | Exercise group compliance <75% (n=20), least squares mean (95% CI) | Conventional group (n=34), least squares mean (95% CI) |
|---|---|---|---|
| Work productivity (QQ method[c]) | 0.00 (−0.14 to 0.15) | 0.05 (−0.11 to 0.21) | 0.08 (−0.03 to 0.18) |
| CLBP (NRS[d]) | −2.28 (−3.47 to −1.09) | −0.15 (−1.03 to 0.73) | −0.91 (−1.48 to −0.34) |
| Quality of life (RDQ-24[e]) | −3.06 (−4.45 to −1.66) | −2.20 (−4.51 to 0.11) | −0.76 (−2.15 to 0.62) |

[a]CLBP: chronic low back pain.

[b]No statistical tests were performed.

[c]QQ method: Quantity and Quality method.

[d]NRS: Numerical Rating Scale.

[e]RDQ-24: Roland-Morris Disability Questionnaire.

## *Discussion*

### Principal Findings

The exercise intervention is considered an integral part of CLBP management and has been reported to reduce pain and improve function in patients with CLBP; however, there are challenges in exploring effective exercise types and continuing exercise [43,44]. In recent years, various digital interventions have attempted to address these challenges [45-49].

The web-based video patient education and strengthening exercise therapy using the mobile messaging app did not show any significant changes in work productivity or loss of workdays due to CLBP at week 12 compared with the conventional pharmacological treatment in this study. To the best of our knowledge, there is no randomized controlled trial with the intervention outcome to improve work productivity in patients with CLBP; therefore, this result cannot be compared with previous studies. It is possible that drastic changes in the working environment during the COVID-19 pandemic affected the assessment of work productivity. During the research period, the Government of Japan began to recommend remote work as a national policy. In the evaluation of work productivity, the quantity and quality of work at the time of evaluation were compared with those in the absence of CLBP. The effect of changes in working style might be greater than that of exercise therapy on work productivity. A survey of workers in remote work before and during the COVID-19 pandemic conducted in Japan in 2020 also reported that full remote work of 5 days a week reduced work productivity [50]. Therefore, the difference in work productivity between the 2 groups due to exercise therapy may not have been observed. In fact, many secondary end points showed a significant improvement in exercise therapy. However, the work productivities did not show a significant improvement. The work productivity assessments may have been particularly susceptible to COVID-19 compared with outcomes such as pain intensity and QoL. To assess the impact of exercise therapy on work productivity in patients with CLBP, further improved clinical studies will be considered.



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The use of mobile devices can enhance patient engagement in self-management of CLBP and improve exercise compliance [51]. In this study, >50% (36/47) of the participants had ≥75% compliance with the use of the mobile messaging app–based exercise therapy. In previous studies, similar adherence rates of about 50% to 70% for home-based exercise programs have been reported [52,53]. The results of this study also showed high adherence to the continuation of exercise therapy using mobile devices. A problem with exercise therapy is the low level of adherence to the prescribed exercises. Two systematic reviews have reported that up to 70% of participants did not adhere to the prescribed exercises [54,55]. It has been suggested that using digital devices may improve the patient's noncompliance with exercise therapy, which is considered to have the highest level of evidence for CLBP.

In this study, many end points, rather than the primary end point, showed results similar to those of previous studies. In particular, the degree of the subjective score of pain was significantly improved in workers who received exercise therapy, which is consistent with a previous study using Secaide [28]. The end point of QoL (EQ-5D-5L) showed a significant improvement, as in previous studies using digital interventions [47,56].

Kinesiophobia is a therapeutic target with exercise regimens in the management of CLBP [57-59]. To the best of our knowledge, no study has evaluated the impact of mobile-based apps on pain-related fear in patients with CLBP. In this study, we evaluated kinesiophobia using the TSK-11 scale, which has been validated for use in patients with CLBP [60]. At week 12, a significant improvement in the TSK-11 score was observed in the exercise group. From the above results, it is considered that the effect of exercise therapy was supported in this study, as well as in previous studies.

In addition, a post hoc analysis was used to evaluate the relationship between exercise therapy adherence and outcomes. High adherence showed good outcomes in work productivity (QQ method), CLBP score (NRS), and RDQ-24 score. Recently, evaluation using PROs has attracted attention in clinical trials [61]. The concept of minimal clinically significant difference (MCID) is established, and its importance is recognized. MCID is not a statistically significant difference, but it is an indicator of the clinical benefits to patients. The MCID has been reported as an NRS ≥2 for LBP [62] and a 30% change in score for RDQ-24 (if the score is <7) [63]. In the post hoc analysis, patients with high adherence to exercise therapy showed an improvement of 2.28 in NRS in CLBP as a change from baseline and an improvement of approximately 38% in RDQ-24. These scores achieved MCID. This improvement was clinically meaningful. Previous studies have reported that apps improve exercise therapy adherence; therefore, Secaide used in this study may also play an important role in achieving better outcomes.

In this study, we adopted the Secaide app [28], an interactive health promotion system, to aid education and exercise therapy in patients with CLBP. Furthermore, adopting web-based education and mobile messaging app–based exercise therapy may reduce the number of facility visits, ensure safety, and ensure continued patient care. Pain treatment based on traditional visits in clinics may be difficult because of the COVID-19 pandemic. PROs are becoming increasingly important, and the need for remote medical care, such as digital health programs, is increasing. The use of technology can be advantageous, enabling the remote collection of data during such unprecedented times. Using digital devices, the enhancement of exercise therapy yielded better results in more end points than in routine clinical practice. These results and compliance rates are due to research conditions. Although the impact of these on treatment cannot be evaluated correctly, it is hoped that they will provide an opportunity to consider the usefulness of remote medical care in CLBP.

## Limitations

This study had certain limitations. Changes in work quality and quantity were used as outcomes for work productivity. This study was conducted during the COVID-19 pandemic, when the social working environment has evolved with the adoption of remote working. Furthermore, these changes in the work environment may have influenced the evaluation of work productivity. The study design has the inherent limitations of a short duration (12 weeks) and a small sample size (50 in each group). There have been no previous studies with the same patient population and end point, and the required number of cases was calculated using the results of secondary end point of this study. As a result, the statistical power of this study may be lower than expected. We did not assess the rate of adherence to prescribed medications, which could possibly impact work productivity outcomes with exercise therapy using the mobile messaging app. The data for the study outcomes were self-reported, and a response bias could have led to varying estimates of the severity of CLBP. Comparison of the high adherence group with the other groups should be interpreted in a limited manner because of the results of the post hoc analysis.

## Conclusions

Web-based patient education and strengthening exercise therapy using the Secaide app may be useful for enhancing the effectiveness of exercise therapy in the treatment of CLBP. In this exploratory study, the exercise group showed consistently better trends for most end points than did the conventional group. The adherence to exercise therapy improved work productivity, NRS for CLBP, and RDQ-24, suggesting that the mobile messaging app is useful for CLBP treatment.

This study did not reveal the effect of therapeutic interventions on CLBP on work productivity. Further research is required to assess work productivity with therapeutic interventions.

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## Conflicts of Interest

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Multimedia Appendix 1
Study clinics and investigators.
[DOCX File , 38 KB - mhealth_v10i5e35867_app1.docx ]

Multimedia Appendix 2
Change from baseline in the mean number of consultations in the exercise and conventional groups.
[PNG File , 185 KB - mhealth_v10i5e35867_app2.png ]

Multimedia Appendix 3
CONSORT-EHEALTH checklist (V 1.6.2).
[PDF File (Adobe PDF File), 143 KB - mhealth_v10i5e35867_app3.pdf ]

## References

1. Meucci RD, Fassa AG, Faria NM. Prevalence of chronic low back pain: systematic review. Rev Saude Publica 2015;49:1 [FREE Full text] [doi: 10.1590/S0034-8910.2015049005874] [Medline: 26487293]
2. Fujii T, Matsudaira K. Prevalence of low back pain and factors associated with chronic disabling back pain in Japan. Eur Spine J 2013 Feb;22(2):432-438 [FREE Full text] [doi: 10.1007/s00586-012-2439-0] [Medline: 22868456]
3. Inoue S, Kobayashi F, Nishihara M, Arai YC, Ikemoto T, Kawai T, et al. Chronic pain in the Japanese community--prevalence, characteristics and impact on quality of life. PLoS One 2015 Jun 15;10(6):e0129262 [FREE Full text] [doi: 10.1371/journal.pone.0129262] [Medline: 26076135]
4. GBD 2017 Disease and Injury Incidence and Prevalence Collaborators. Global, regional, and national incidence, prevalence, and years lived with disability for 354 diseases and injuries for 195 countries and territories, 1990-2017: a systematic analysis for the Global Burden of Disease Study 2017. Lancet 2018 Nov 10;392(10159):1789-1858 [FREE Full text] [doi: 10.1016/S0140-6736(18)32279-7] [Medline: 30496104]
5. Frymoyer JW. Predicting disability from low back pain. Clin Orthop Relat Res 1992 Jun(279):101-109. [Medline: 1534720]
6. Dutmer A, Schiphorst Preuper HR, Soer R, Brouwer S, Bültmann U, Dijkstra PU, et al. Personal and societal impact of low back pain: the Groningen spine cohort. Spine (Phila Pa 1976) 2019 Dec 15;44(24):E1443-E1451. [doi: 10.1097/BRS.0000000000003174] [Medline: 31369481]
7. Montgomery W, Sato M, Nagasaka Y, Vietri J. The economic and humanistic costs of chronic lower back pain in Japan. Clinicoecon Outcomes Res 2017 Jun 23;9:361-371 [FREE Full text] [doi: 10.2147/CEOR.S134130] [Medline: 28694702]
8. Tsuji T, Matsudaira K, Sato H, Vietri J, Jaffe DH. Association between presenteeism and health-related quality of life among Japanese adults with chronic lower back pain: a retrospective observational study. BMJ Open 2018 Jun 27;8(6):e021160 [FREE Full text] [doi: 10.1136/bmjopen-2017-021160] [Medline: 29950467]
9. Yoshimoto T, Oka H, Fujii T, Nagata T, Matsudaira K. The economic burden of lost productivity due to presenteeism caused by health conditions among workers in Japan. J Occup Environ Med 2020 Oct;62(10):883-888 [FREE Full text] [doi: 10.1097/JOM.0000000000002001] [Medline: 32826548]



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10. van der Velde G, Mierau D. The effect of exercise on percentile rank aerobic capacity, pain, and self-rated disability in patients with chronic low-back pain: a retrospective chart review. Arch Phys Med Rehabil 2000 Nov;81(11):1457-1463. [doi: 10.1053/apmr.2000.9629] [Medline: 11083348]
11. Rainville J, Sobel J, Hartigan C, Monlux G, Bean J. Decreasing disability in chronic back pain through aggressive spine rehabilitation. J Rehabil Res Dev 1997 Oct;34(4):383-393. [Medline: 9323642]
12. Marshall PW, Murphy BA. Evaluation of functional and neuromuscular changes after exercise rehabilitation for low back pain using a Swiss ball: a pilot study. J Manipulative Physiol Ther 2006 Sep;29(7):550-560. [doi: 10.1016/j.jmpt.2006.06.025] [Medline: 16949944]
13. Pinto RZ, Ferreira PH, Kongsted A, Ferreira ML, Maher CG, Kent P. Self-reported moderate-to-vigorous leisure time physical activity predicts less pain and disability over 12 months in chronic and persistent low back pain. Eur J Pain 2014 Sep;18(8):1190-1198. [doi: 10.1002/j.1532-2149.2014.00468.x] [Medline: 24577780]
14. Tekur P, Nagarathna R, Chametcha S, Hankey A, Nagendra HR. A comprehensive yoga programs improves pain, anxiety and depression in chronic low back pain patients more than exercise: an RCT. Complement Ther Med 2012 Jun;20(3):107-118. [doi: 10.1016/j.ctim.2011.12.009] [Medline: 22500659]
15. Durmus D, Unal M, Kuru O. How effective is a modified exercise program on its own or with back school in chronic low back pain? A randomized-controlled clinical trial. J Back Musculoskelet Rehabil 2014;27(4):553-561. [doi: 10.3233/BMR-140481] [Medline: 24867906]
16. Baliki MN, Mansour AR, Baria AT, Apkarian AV. Functional reorganization of the default mode network across chronic pain conditions. PLoS One 2014 Sep 2;9(9):e106133 [FREE Full text] [doi: 10.1371/journal.pone.0106133] [Medline: 25180885]
17. Babatunde OO, Jordan JL, Van der Windt DA, Hill JC, Foster NE, Protheroe J. Effective treatment options for musculoskeletal pain in primary care: a systematic overview of current evidence. PLoS One 2017 Jun 22;12(6):e0178621 [FREE Full text] [doi: 10.1371/journal.pone.0178621] [Medline: 28640822]
18. Khan M, Akhter S, Soomro RR, Ali SS. The effectiveness of Cognitive Behavioral Therapy (CBT) with general exercises versus general exercises alone in the management of chronic low back pain. Pak J Pharm Sci 2014 Jul;27(4 Suppl):1113-1116. [Medline: 25016276]
19. Sluijs EM, Kok GJ, van der Zee J. Correlates of exercise compliance in physical therapy. Phys Ther 1993 Nov;73(11):771-786. [doi: 10.1093/ptj/73.11.771] [Medline: 8234458]
20. Nicholl BI, Sandal LF, Stochkendahl MJ, McCallum M, Suresh N, Vasseljen O, et al. Digital support interventions for the self-management of low back pain: a systematic review. J Med Internet Res 2017 May 21;19(5):e179 [FREE Full text] [doi: 10.2196/jmir.7290] [Medline: 28550009]
21. Hewitt S, Sephton R, Yeowell G. The effectiveness of digital health interventions in the management of musculoskeletal conditions: systematic literature review. J Med Internet Res 2020 Jun 05;22(6):e15617 [FREE Full text] [doi: 10.2196/15617] [Medline: 32501277]
22. Bailey JF, Agarwal V, Zheng P, Smuck M, Fredericson M, Kennedy DJ, et al. Digital care for chronic musculoskeletal pain: 10,000 participant longitudinal cohort study. J Med Internet Res 2020 May 11;22(5):e18250 [FREE Full text] [doi: 10.2196/18250] [Medline: 32208358]
23. Cranen K, Drossaert CH, Brinkman ES, Braakman-Jansen AL, Ijzerman MJ, Vollenbroek-Hutten MM. An exploration of chronic pain patients' perceptions of home telerehabilitation services. Health Expect 2012 Dec;15(4):339-350 [FREE Full text] [doi: 10.1111/j.1369-7625.2011.00668.x] [Medline: 21348905]
24. Irvine AB, Russell H, Manocchia M, Mino DE, Cox Glassen T, Morgan R, et al. Mobile-web app to self-manage low back pain: randomized controlled trial. J Med Internet Res 2015 Jan 02;17(1):e1 [FREE Full text] [doi: 10.2196/jmir.3130] [Medline: 25565416]
25. Del Pozo-Cruz B, Adsuar JC, Parraca J, Del Pozo-Cruz J, Moreno A, Gusi N. A web-based intervention to improve and prevent low back pain among office workers: a randomized controlled trial. J Orthop Sports Phys Ther 2012 Oct;42(10):831-841. [doi: 10.2519/jospt.2012.3980] [Medline: 22951407]
26. Shebib R, Bailey JF, Smittenaar P, Perez DA, Mecklenburg G, Hunter S. Randomized controlled trial of a 12-week digital care program in improving low back pain. NPJ Digit Med 2019 Jan 7;2:1 [FREE Full text] [doi: 10.1038/s41746-018-0076-7] [Medline: 31304351]
27. Toelle TR, Utpadel-Fischler DA, Haas K, Priebe JA. App-based multidisciplinary back pain treatment versus combined physiotherapy plus online education: a randomized controlled trial. NPJ Digit Med 2019 May 3;2:34 [FREE Full text] [doi: 10.1038/s41746-019-0109-x] [Medline: 31304380]
28. Anan T, Kajiki S, Oka H, Fujii T, Kawamata K, Mori K, et al. Effects of an artificial intelligence-assisted health program on workers with neck/shoulder pain/stiffness and low back pain: randomized controlled trial. JMIR Mhealth Uhealth 2021 Sep 24;9(9):e27535 [FREE Full text] [doi: 10.2196/27535] [Medline: 34559054]
29. Chan AW, Tetzlaff JM, Altman DG, Laupacis A, Gøtzsche PC, Krleža-Jerić K, et al. SPIRIT 2013 statement: defining standard protocol items for clinical trials. Ann Intern Med 2013 Feb 05;158(3):200-207 [FREE Full text] [doi: 10.7326/0003-4819-158-3-201302050-00583] [Medline: 23295957]




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30. Jinnouchi H, Matsudaira K, Kitamura A, Kakihana H, Oka H, Hayama-Terada M, et al. Effects of low-dose therapist-led self-exercise education on the management of chronic low back pain: protocol for a community-based, randomized, 6-month parallel-group study. Spine Surg Relat Res 2019 Apr 26;3(4):377-384 [FREE Full text] [doi: 10.22603/ssrr.2019-0005] [Medline: 31768459]
31. Jinnouchi H, Matsudaira K, Kitamura A, Kakihana H, Oka H, Hayama-Terada M, CIRCS Investigators. Effects of brief self-exercise education on the management of chronic low back pain: a community-based, randomized, parallel-group pragmatic trial. Mod Rheumatol 2021 Jul;31(4):890-898 [FREE Full text] [doi: 10.1080/14397595.2020.1823603] [Medline: 32930621]
32. Brouwer WB, Koopmanschap MA, Rutten FF. Productivity losses without absence: measurement validation and empirical evidence. Health Policy 1999 Jul;48(1):13-27. [doi: 10.1016/s0168-8510(99)00028-7] [Medline: 10539583]
33. Reilly MC, Zbrozek AS, Dukes EM. The validity and reproducibility of a work productivity and activity impairment instrument. Pharmacoeconomics 1993 Nov;4(5):353-365. [doi: 10.2165/00019053-199304050-00006] [Medline: 10146874]
34. Jensen MP, Karoly P, Braver S. The measurement of clinical pain intensity: a comparison of six methods. Pain 1986 Oct;27(1):117-126. [doi: 10.1016/0304-3959(86)90228-9] [Medline: 3785962]
35. Roland M, Morris R. A study of the natural history of back pain. Part I: development of a reliable and sensitive measure of disability in low-back pain. Spine (Phila Pa 1976) 1983 Mar;8(2):141-144. [doi: 10.1097/00007632-198303000-00004] [Medline: 6222486]
36. Stratford PW, Riddle DL. A Roland Morris disability questionnaire target value to distinguish between functional and dysfunctional states in people with low back pain. Physiother Can 2016;68(1):29-35 [FREE Full text] [doi: 10.3138/ptc.2014-85] [Medline: 27504045]
37. EuroQol Group. EuroQol--a new facility for the measurement of health-related quality of life. Health Policy 1990 Dec;16(3):199-208. [doi: 10.1016/0168-8510(90)90421-9] [Medline: 10109801]
38. Cheung PW, Wong CK, Samartzis D, Luk KD, Lam CL, Cheung KM, et al. Psychometric validation of the EuroQoL 5-Dimension 5-Level (EQ-5D-5L) in Chinese patients with adolescent idiopathic scoliosis. Scoliosis Spinal Disord 2016 Aug 4;11:19 [FREE Full text] [doi: 10.1186/s13013-016-0083-x] [Medline: 27525314]
39. Lundberg MK, Styf J, Carlsson SG. A psychometric evaluation of the Tampa Scale for Kinesiophobia — from a physiotherapeutic perspective. Physiother Theory Pract 2004;20(2):121-133. [doi: 10.1080/09593980490453002]
40. Lundberg M, Styf J, Jansson B. On what patients does the Tampa Scale for Kinesiophobia fit? Physiother Theory Pract 2009 Oct;25(7):495-506. [doi: 10.3109/09593980802662160] [Medline: 19925172]
41. Kessler RC, Andrews G, Colpe LJ, Hiripi E, Mroczek DK, Normand SL, et al. Short screening scales to monitor population prevalences and trends in non-specific psychological distress. Psychol Med 2002 Aug;32(6):959-976. [doi: 10.1017/s0033291702006074] [Medline: 12214795]
42. Han HI, Choi HS, Shin WS. Effects of hamstring stretch with pelvic control on pain and work ability in standing workers. J Back Musculoskelet Rehabil 2016 Nov 21;29(4):865-871. [doi: 10.3233/BMR-160703] [Medline: 27197706]
43. Searle A, Spink M, Ho A, Chuter V. Exercise interventions for the treatment of chronic low back pain: a systematic review and meta-analysis of randomised controlled trials. Clin Rehabil 2015 Dec;29(12):1155-1167. [doi: 10.1177/0269215515570379] [Medline: 25681408]
44. Hayden JA, van Tulder MW, Malmivaara A, Koes BW. Exercise therapy for treatment of non-specific low back pain. Cochrane Database Syst Rev 2005 Jul 20(3):CD000335. [doi: 10.1002/14651858.CD000335.pub2] [Medline: 16034851]
45. Martínez de la Cal J, Fernández-Sánchez M, Matarán-Peñarrocha GA, Hurley DA, Castro-Sánchez AM, Lara-Palomo IC. Physical therapists' opinion of e-health treatment of chronic low back pain. Int J Environ Res Public Health 2021 Feb 16;18(4):1889 [FREE Full text] [doi: 10.3390/ijerph18041889] [Medline: 33669249]
46. Peterson S. Telerehabilitation booster sessions and remote patient monitoring in the management of chronic low back pain: a case series. Physiother Theory Pract 2018 May;34(5):393-402. [doi: 10.1080/09593985.2017.1401190] [Medline: 29125371]
47. Chhabra HS, Sharma S, Verma S. Smartphone app in self-management of chronic low back pain: a randomized controlled trial. Eur Spine J 2018 Nov;27(11):2862-2874. [doi: 10.1007/s00586-018-5788-5] [Medline: 30324496]
48. Mork PJ, Bach K, selfBACK Consortium. A decision support system to enhance self-management of low back pain: protocol for the selfBACK project. JMIR Res Protoc 2018 Jul 20;7(7):e167 [FREE Full text] [doi: 10.2196/resprot.9379] [Medline: 30030208]
49. Hornung AL, Rudisill SS, Suleiman RW, Siyaji ZK, Sood S, Siddiqui S, et al. Low back pain: what is the role of YouTube content in patient education? J Orthop Res 2022 Apr;40(4):901-908. [doi: 10.1002/jor.25104] [Medline: 34057762]
50. Shimura A, Yokoi K, Ishibashi Y, Akatsuka Y, Inoue T. Remote work decreases psychological and physical stress responses, but full-remote work increases presenteeism. Front Psychol 2021 Sep 30;12:730969 [FREE Full text] [doi: 10.3389/fpsyg.2021.730969] [Medline: 34659039]
51. Hamine S, Gerth-Guyette E, Faulx D, Green BB, Ginsburg AS. Impact of mHealth chronic disease management on treatment adherence and patient outcomes: a systematic review. J Med Internet Res 2015 Feb 24;17(2):e52 [FREE Full text] [doi: 10.2196/jmir.3951] [Medline: 25803266]




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52. Palazzo C, Klinger E, Dorner V, Kadri A, Thierry O, Boumenir Y, et al. Barriers to home-based exercise program adherence with chronic low back pain: patient expectations regarding new technologies. Ann Phys Rehabil Med 2016 Apr;59(2):107-113 [FREE Full text] [doi: 10.1016/j.rehab.2016.01.009] [Medline: 27050664]
53. Argent R, Daly A, Caulfield B. Patient involvement with home-based exercise programs: can connected health interventions influence adherence? JMIR Mhealth Uhealth 2018 Mar 01;6(3):e47 [FREE Full text] [doi: 10.2196/mhealth.8518] [Medline: 29496655]
54. Beinart NA, Goodchild CE, Weinman JA, Ayis S, Godfrey EL. Individual and intervention-related factors associated with adherence to home exercise in chronic low back pain: a systematic review. Spine J 2013 Dec;13(12):1940-1950. [doi: 10.1016/j.spinee.2013.08.027] [Medline: 24169445]
55. Essery R, Geraghty AW, Kirby S, Yardley L. Predictors of adherence to home-based physical therapies: a systematic review. Disabil Rehabil 2017 Mar;39(6):519-534. [doi: 10.3109/09638288.2016.1153160] [Medline: 27097761]
56. Du S, Liu W, Cai S, Hu Y, Dong J. The efficacy of e-health in the self-management of chronic low back pain: a meta analysis. Int J Nurs Stud 2020 Jun;106:103507. [doi: 10.1016/j.ijnurstu.2019.103507] [Medline: 32320936]
57. Vincent HK, Seay AN, Montero C, Conrad BP, Hurley RW, Vincent KR. Kinesiophobia and fear-avoidance beliefs in overweight older adults with chronic low-back pain: relationship to walking endurance--part II. Am J Phys Med Rehabil 2013 May;92(5):439-445 [FREE Full text] [doi: 10.1097/PHM.0b013e318287633c] [Medline: 23478452]
58. Cruz-Díaz D, Romeu M, Velasco-González C, Martínez-Amat A, Hita-Contreras F. The effectiveness of 12 weeks of Pilates intervention on disability, pain and kinesiophobia in patients with chronic low back pain: a randomized controlled trial. Clin Rehabil 2018 Sep;32(9):1249-1257. [doi: 10.1177/0269215518768393] [Medline: 29651872]
59. da Luz MA, Costa LO, Fuhro FF, Manzoni AC, Oliveira NT, Cabral CM. Effectiveness of mat Pilates or equipment-based Pilates exercises in patients with chronic nonspecific low back pain: a randomized controlled trial. Phys Ther 2014 May;94(5):623-631. [doi: 10.2522/ptj.20130277] [Medline: 24435105]
60. Vlaeyen JW, Kole-Snijders AM, Boeren RG, van Eek H. Fear of movement/(re)injury in chronic low back pain and its relation to behavioral performance. Pain 1995 Sep;62(3):363-372. [doi: 10.1016/0304-3959(94)00279-N] [Medline: 8657437]
61. Calvert M, Blazeby J, Altman DG, Revicki DA, Moher D, Brundage MD, CONSORT PRO Group. Reporting of patient-reported outcomes in randomized trials: the CONSORT PRO extension. JAMA 2013 Feb 27;309(8):814-822. [doi: 10.1001/jama.2013.879] [Medline: 23443445]
62. Childs JD, Piva SR, Fritz JM. Responsiveness of the numeric pain rating scale in patients with low back pain. Spine (Phila Pa 1976) 2005 Jun 01;30(11):1331-1334. [doi: 10.1097/01.brs.0000164099.92112.29] [Medline: 15928561]
63. Jordan K, Dunn KM, Lewis M, Croft P. A minimal clinically important difference was derived for the Roland-Morris Disability Questionnaire for low back pain. J Clin Epidemiol 2006 Jan;59(1):45-52. [doi: 10.1016/j.jclinepi.2005.03.018] [Medline: 16360560]


## Abbreviations

**CLBP:** chronic low back pain
**EQ-5D-5L:** EuroQoL 5 Dimensions 5 Level
**LBP:** low back pain
**MCID:** minimal clinically significant difference
**NRS:** Numerical Rating Scale
**PRO:** patient-reported outcome
**QoL:** quality of life
**QQ method:** Quantity and Quality method
**RDQ-24:** Roland-Morris Disability Questionnaire
**SPIRIT:** Standard Protocol Items: Recommendations for Interventional Trials
**TSK-11:** Tampa Scale for Kinesiophobia
**WPAI-GH:** Work Productivity and Activity Impairment Questionnaire: General Health


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Original Paper

# Nonusage Attrition of Adolescents in an mHealth Promotion Intervention and the Role of Socioeconomic Status: Secondary Analysis of a 2-Arm Cluster-Controlled Trial

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## Abstract

**Background:** Mobile health (mHealth) interventions may help adolescents adopt healthy lifestyles. However, attrition in these interventions is high. Overall, there is a lack of research on nonusage attrition in adolescents, particularly regarding the role of socioeconomic status (SES).

**Objective:** The aim of this study was to focus on the role of SES in the following three research questions (RQs): When do adolescents stop using an mHealth intervention (RQ1)? Why do they report nonusage attrition (RQ2)? Which intervention components (ie, self-regulation component, narrative, and chatbot) prevent nonusage attrition among adolescents (RQ3)?

**Methods:** A total of 186 Flemish adolescents (aged 12-15 years) participated in a 12-week mHealth program. Log data were monitored to measure nonusage attrition and usage duration for the 3 intervention components. A web-based questionnaire was administered to assess reasons for attrition. A survival analysis was conducted to estimate the time to attrition and determine whether this differed according to SES (RQ1). Descriptive statistics were performed to map the attrition reasons, and Fisher exact tests were used to determine if these reasons differed depending on the educational track (RQ2). Mixed effects Cox proportional hazard regression models were used to estimate the associations between the use duration of the 3 components during the first week and attrition. An interaction term was added to the regression models to determine whether associations differed by the educational track (RQ3).

**Results:** After 12 weeks, 95.7% (178/186) of the participants stopped using the app. 30.1% (56/186) of the adolescents only opened the app on the installation day, and 44.1% (82/186) stopped using the app in the first week. Attrition at any given time during the intervention period was higher for adolescents from the nonacademic educational track compared with those from the academic track. The other SES indicators (family affluence and perceived financial situation) did not explain attrition. The most common reasons for nonusage attrition among participants were perceiving that the app did not lead to behavior change, not liking the app, thinking that they already had a sufficiently healthy lifestyle, using other apps, and not being motivated by the environment. Attrition reasons did not differ depending on the educational track. More time spent in the self-regulation and narrative components during the first week was associated with lower attrition, whereas chatbot use duration was not associated with attrition rates. No moderating effects of SES were observed in the latter association.



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**Conclusions:** Nonusage attrition was high, especially among adolescents in the nonacademic educational track. The reported reasons for attrition were diverse, with no statistical differences according to the educational level. The duration of the use of the self-regulation and narrative components during the first week may prevent attrition for both educational tracks.

**Trial Registration:** ClinicalTrials.gov NCT04719858; http://clinicaltrials.gov/ct2/show/NCT04719858

***(JMIR Mhealth Uhealth 2022;10(5):e36404)*** doi:10.2196/36404

**KEYWORDS**

mHealth; nonusage attrition; adolescents; socioeconomic status; mobile phone

## Introduction

Mobile health (mHealth) interventions seem promising for behavior change [1-6]. mHealth is a part of the broad category of digital health interventions and is defined as the support of health practices through mobile devices, such as mobile phones, patient monitoring devices, PDAs, and other wireless devices [7]. mHealth offers the opportunity to reach a large part of the population in a tailored, cost-effective manner [2,8-11]. Despite its potential, many mHealth interventions report trivial-to-small effects or effects that are not sustained in the long term [1,2,9,12-14]. Evidence suggests that this is partly because of low levels of adherence and high nonusage attrition rates, which are common in digital health interventions [15-19]. Nonusage attrition refers to participants who stop using the digital intervention, although they could still be participating in the research protocol (eg, filling out questionnaires) [18]. Nonusage attrition to commercial apps used in real-world settings reaches an average rate of 62%, with 21% of users abandoning an app after the first use [20]. Nonusage attrition to research-based mHealth interventions ranges from 32% to 75%, often depending on how long an intervention lasts and whether a study occurs in a real-world rather than controlled context [21-24].

Unfortunately, most research on this topic has focused on adults. There is a dearth of research on attrition rates of adolescents, although there has been a sharp increase in the use of digital interventions for behavior change within this age group [14,25]. A notable exception is the study by Egilsson et al [26], who developed the social health game *SidekickHealth*. This app focuses on three health categories: food and drink intake, physical activity, and mental health. Young people can set goals and complete missions (ie, gamification) both individually and in small groups. Attrition rates were reviewed weekly to check whether adolescents completed at least three health exercises within the app. During their pilot study among Icelandic adolescents aged between 15 and 16 years, the authors reported a nonusage attrition rate of 35% from initiation to the 6-week follow-up. The average frequency of completing in-app health exercises decreased significantly in the first week (from an average of 55.25 to 13.63 exercises), notwithstanding the large effort to keep the app entertaining and fun (eg, by adding a reward system and storyline highlighting progress) [26].

Various behavior change techniques are typically used in mHealth interventions [1,27-29], among which are goal setting and self-monitoring (ie, self-regulation techniques) [1,27,29,30]. Similarly, other techniques are required, not necessary to foster behavior change, but rather engagement (eg, a reward system). Research indicates that when adolescents are more engaged, there is a reduced risk of attrition, leading to a higher probability of intervention effectiveness [22,31]. In this regard, it has been suggested that narratives (ie, stories that portray human thought and action with a beginning, middle, and end) [32-34] and chatbots [35] might increase user engagement with digital health interventions. These intervention components can be of particular interest to adolescents from lower socioeconomic status (SES), as this group tends to have lower digital health literacy [36]. Narratives are less language demanding, and chatbots provide the opportunity to replace researchers offering direct communication during a study, which could mitigate the problems of health literacy because participants can ask questions based on their own use of language [37,38].

Special efforts to engage adolescents from lower SES backgrounds are needed, as these adolescents tend to have lower health outcomes than those from higher SES groups [39-45]. It further appears that digital health tools are currently only used to a small extent by people with low SES [37,46], although many of them do own a smartphone (eg, smartphone ownership of Flemish adolescents of all different socioeconomic backgrounds amounts to 93% [47]). Furthermore, digital interventions do not show equivalent efficacy for people of low and high SES, meaning that there is no evidence that digital interventions are effective for people with low SES, whereas this appears to be the case for their higher SES counterparts [36]. The fact that high-SES groups engage more with digital tools and that they prove to be effective only for them may further widen the health gap between higher and lower SES groups [46]. Past studies have consequently recommended adapting interventions to adolescents with lower SES [36,39-41,45,48]. However, no studies have investigated the SES differences in nonusage attrition among adolescents in mHealth interventions and whether intervention components aimed at increasing engagement also effectively lead to longer use of the intervention in this target group.

To counteract small intervention effects (Cohen $d$=0.22 in mHealth interventions for youth [2]) or prevent only the short-term use of mHealth interventions for adolescents, it is necessary to further identify when and why adolescents stop using an intervention (RQ1 and RQ2). Within this context, it is also important to investigate the intervention components that positively impact attrition (RQ3). All RQs also examine whether the results differ according to SES, as engaging vulnerable groups is key to tackling socioeconomic health inequalities [46].



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## Methods

### Study Design

This study concerns secondary analyses of a larger 2-arm cluster-controlled trial that evaluated the effectiveness of the #LIFEGOALS intervention. A total of 6 schools with 223 participants were assigned to the intervention group and 5 schools with 118 participants were assigned to the control group. The intervention group received the #LIFEGOALS intervention to promote a healthy lifestyle for 12 weeks (ie, 85 days). The control group received no intervention. A more detailed description of the study is provided in the flowchart in Multimedia Appendix 1. In this paper, only data from the intervention group will be described, as the focus is on nonusage attrition with the app. Written informed consent was obtained from the participants and their parents before participation in the study.

### Ethics Approval

This study was approved by the Ethical Committee of the Faculty of Psychology and Educational Sciences of Ghent University (2020/2070 Laura Maenhout).

### Participants and Recruitment

Participants were recruited through schools via convenience sampling in August and September 2020. The inclusion criteria were adolescents of the seventh, eighth, or ninth grade of general education. The exclusion criteria were schools of special needs education and education for nonnative speakers (in preparation for regular education). A total of 27 Flemish schools were contacted via email to participate in this study. When the schools did not respond within 2 weeks, they were contacted by phone. Of the 27 schools, 12 (ie, response rate 44%) agreed to participate in the study. To allow for clustering in the analysis of the effect study, a target number of 30 adolescents per school was set. The school selected the classes, but the researchers actively monitored that there was an equal mix of grades and educational tracks (academic vs nonacademic) across the intervention and control groups. Because of the COVID-19 measures, of the 6 schools, 1 (17%) withdrew from the intervention group, resulting in 1 school from the control group being assigned to the intervention group. This resulted in an overrepresentation of adolescents in the academic track (114/186, 61.3%) than in the nonacademic track (72/186, 38.7%) in the intervention group. The researchers sent information letters and informed consent for both adolescents and parents to the school contact person by mail in advance. The contact person distributed informed consent to the participating classes, with the intention that both signed consent forms could be collected at the first class visit. Adolescents who provided both signed consent forms during the first class visit were rewarded with a power bank. Adolescents who lacked one of the consent forms were encouraged to have the forms signed by the second class visit. If adolescents submitted their consent forms during subsequent class visits, they could still participate and receive their power bank. In addition, cinema tickets (ie, incentive at the end of the intervention period) were never distributed if consent forms had not yet been submitted. Finally, adolescents for whom consent forms were still missing at the end of the intervention period were removed from the data (21/186, 11.3%).

### Intervention

#LIFEGOALS is an mHealth intervention developed for Flemish adolescents aged between 12 and 15 years to improve their mental health by promoting healthy lifestyle behaviors (ie, sufficient sleep and physical activity, daily breakfast intake, and sedentary behavior reduction) [45,49-52]. #LIFEGOALS is theory-based (ie, based on the Health Action Process Approach [53], Elaboration Likelihood Model [54], and Persuasive Systems Design [55]) and developed in close collaboration with target users and stakeholders. In total, 249 adolescents were involved during intervention development [56]: adolescents' views on a health app and chatbot were identified through focus group discussions (112/249, 44.9%); a class of adolescents was involved in developing and filming of the narrative (47/249, 18.9%); prototypes of the app and chatbot were tested regularly to detect bugs (11/249, 4.4%); a steering committee was set up and consulted at various times throughout the process (14/249, 5.6%); and finally, a pilot study with process evaluation interviews was conducted in January 2020, after which final adjustments were made toward the effect study (65/249, 26.1%). #LIFEGOALS includes (1) a self-regulation component associated with Fitbit for goal settings, action planning, coping planning, monitoring, and providing feedback; (2) a narrative component (ie, every week participants receive a new episode [2-5 minutes] of a dedicated youth series made for this intervention) for modeling, attitude change, and increased engagement; and (3) a chatbot component (ie, a web-based coach that provides an automated answer to user questions and sends 2 encouraging messages per week) for social support and sustained engagement with the intervention [56]. In addition, information (eg, on the benefits of health behaviors and relevant [youth] health organizations for further information or support) and a reward system (in which coins can be earned to achieve goals, which the participants can then use to personalize their personal avatar) are included in the intervention. The participants were free to choose which lifestyle behaviors they wanted to target, and to what extent they wanted to use the app. A screenshot of the app can be found in Multimedia Appendix 2.

### Procedure

Three waves of data collection were conducted from October 2020 to May 2021. The first wave (intervention group, 67/186, 36%) began in October 2020, the second wave (55/186, 29.6%) in November 2020, and the third wave (64/186, 34.4%) in January 2021. The researchers visited the intervention schools 4 times. During the first school visit, adolescents received information about the project and were provided with an accelerometer (ie, Axivity [AX3; Axivity Ltd]), which they were instructed to wear for 1 week (beyond the scope of this study). They were also asked to complete a prequestionnaire including sociodemographic factors. During the next visit (1 week later), the accelerometers were retrieved, and temporary devices were provided to those without a smartphone or Fitbit (charge 2 or 3) for the duration of the study. Subsequently, the #LIFEGOALS app was installed on participants' smartphones



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and connected with the associated Fitbit. The participants were asked to use the app for 12 consecutive weeks. Roll-up banners were set as cues in visible places (ie, in the classroom where adolescents were primarily taught) to encourage the app use (Multimedia Appendix 3). After 12 weeks, the participants completed the postquestionnaire and wore the accelerometers for another week. During the last visit (1 week later), accelerometers were retrieved and incentives (ie, cinema tickets) were provided to those who completed all the questionnaires and wore the accelerometer. To gain insights into when adolescents stopped using the app, their log data were monitored during the entire intervention period. To explore the reasons why participants stopped using the app, a web-based questionnaire was sent by text message (or by email for those not providing their phone number; 12/186, 6.5%) after a participant had not used the app (including narrative and chatbot) for 3 weeks. Participants who indicated in the web-based questionnaire that they still had the intention to use the app were not asked further questions but were contacted again when they had not used the app for another 3 weeks. Participants who did not complete the questionnaire were considered nonusers without any information about their attrition reasons. Participation in the web-based questionnaire was encouraged by reminding adolescents of cinema tickets via SMS text messaging.

## Measures

### General Sociodemographic Information

Sociodemographic information was reported by the adolescents themselves, including gender (boy, girl, or other), age (date of birth), language spoken at home (Dutch, French, Turkish, Arabic, English, or other), grade (seventh, eighth, or ninth), and SES. All items were answered by the adolescents themselves. Various indicators were used to measure SES, as currently no consensus is reached in the literature on the most appropriate indicator [57]. First, adolescent's educational track was asked. For the seventh and eighth grades, response options were A track (ie, mainstream education) or B track (ie, for academically less-performing students that prepares them for vocational education), and for the ninth grade, response options were general academic, technical, vocational, or arts education. The 3 grades were subsequently recoded into academic and nonacademic tracks. It is hypothesized that adolescents from the nonacademic track would have lower SES compared with adolescents from the academic track, analogous to the Flemish Health Behavior in School-Aged Children (HBSC) questionnaire [58]. Second, the educational level of both the father and mother (not applicable, I do not know, no diploma, primary school [until aged 12 years], secondary school [until aged 18 years], high school or nonuniversity, or university) was assessed. Third, family affluence was estimated using the Family Affluence Scale (FAS) III. This scale is an international indicator of adolescents' SES used in the HBSC questionnaire [59] and is defined as a socioeconomic proxy for family wealth [60]. This scale has been widely used [61] and validated alongside other SES measures (eg, parental occupation) and objective measures of country wealth (eg, per-capita income and gross domestic product) [60,62,63]. The FAS III consists of the following six items [60]: *Does your family own a car or another motorized vehicle?* (No=0; Yes, one=1; Yes, 2 or more=2), *Do you have your own bedroom?* (No=0; Yes=1), *How many computers (including laptops and tablets, not including game consoles and smartphones) does your family own?* (None=0; One=1; Two=2; More than two=3), *How many bathrooms (room with a bath/shower or both) are there in your home?* (None=0; One=1; Two=2; More than two=3), *Does your family have a dishwasher?* (No=0; Yes=1), and *How many times did you and your family travel out of Belgium for holiday/vacation last year?* (Never=0; Once=1; Twice=2; More than twice=3). A composite FAS score (ranging from 0 to 13) was calculated for each adolescent based on their responses to these 6 items [59]. Consequently, three groups were created according to the cutoff points of the Flemish HBSC questionnaire (0-7=low FAS score, 8-11=medium FAS score, and 12-13=high FAS score) [64]. Finally, the perceived financial situation was measured using the following question: *How easily can your family pay for everything you need in a month (eg, food, rent, things for school, and so on)?* of the Flemish Youth Research Platform (Jongeren Overleg Platform School Monitor 2018 [65]). Answer options were rated on a 6-point Likert scale ranging from very difficult to very easy. A total of two categories were created based on the median (1=very difficult to quite easy and 2=easy to very easy). These 4 SES measures referred both to the level of education, which can be seen as an indication of certain knowledge and skills and to material prosperity (ie, the FAS and perceived financial situation). Moreover, several dimensions can be distinguished in different SES measures: the adolescent, the parents, and the whole family.

### Log Data Variables

Log data of the #LIFEGOALS app to measure (1) nonusage attrition and (2) the use of the three intervention components (ie, self-regulation, narrative, and chatbot) were stored on the cloud server of Ghent University, Department of Information and Communication Technology. Nonusage attrition was operationalized as the number of days from the start of the intervention (ie, the day adolescents installed the app on their smartphone) to the last day that the app activity was recorded. For the use of the 3 intervention components, the duration (in minutes) participants spent using the self-regulation component, watching the narrative, and interacting with the chatbot during the first week was extracted. The duration started when one of the app components (ie, self-regulation component, narrative, and chatbot) was clicked and ended when the adolescent called up another app component, left the app, or if the smartphone went into sleeping or inactive mode. As the self-regulation component consisted of several elements (eg, goal setting [Set Mission], coping planning [Tools], self-monitoring [Graphs], and agenda [My Agenda]), the sum score of the time spent on all these elements was calculated.

### User-Reported Reasons for Attrition

A total of 14 items were formulated based on the literature [18,66-68] and discussions with the research team. Participants indicated whether they agreed with the reason for attrition on a 5-point Likert scale, ranging from strongly disagree to strongly agree. Furthermore, participants were free to give another reason for not using the #LIFEGOALS app anymore via an open



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answer option. Finally, they were asked whether they would recommend the app to their friends (yes, no, or not applicable).

### Analysis

Descriptive statistics were provided for participants' characteristics and reasons for nonusage attrition. Survival analysis (ie, Kaplan-Meier plots and logrank test statistics) [69,70] was used to estimate the time to attrition and assess statistically significant differences among the SES groups (RQ1). The number of days between the start of the intervention (ie, the day adolescents installed the app on their smartphone) and the last day of app use was the time variable, and the event variable was specified as attrition before the end of the 12-week (ie, 85 days) intervention. Cases were classified as censored when the app was still being used by the end of the 12-week intervention period. To test for significant differences in participant characteristics between responders and nonresponders in the attrition questionnaire, an independent samples 2-tailed *t* test was used for the continuous variable (ie, age) and chi-square tests were conducted for categorical variables (ie, gender, grade, and type of education). Fisher exact tests were used to determine if there were significant differences between attrition reasons and educational tracks (RQ2). Therefore, the 14 variables with attrition reasons were recoded into variables with two categories: strongly disagree-neutral and agree-strongly agree. Mixed effects Cox proportional hazard regression models with clusters (ie, classes) as a random factor [71] were used to identify whether the duration of the self-regulation, narrative, or chatbot component during the first week could predict attrition (RQ3). It was chosen to run the models with clusters to control for the random effects of the class in which each adolescent was nested (eg, the attention given to the project by the teacher). However, given the correlation between *class* and *educational track* of the adolescent, the standard Cox proportional hazard regression model was also run as sensitivity analysis (Multimedia Appendix 4). First, single-predictor models were fitted for each potential confounding variable (ie, age, grade, gender, home language, educational track, family affluence, and perceived financial situation) and for the duration in the different intervention components (ie, self-regulation component, narrative, and chatbot) during the first week. Second, a multiple-predictor model was fitted with the significant confounding variables from the previous step and the duration of each intervention component during the first week. Finally, an interaction term was added to the fully adjusted multiple-predictor model to test whether the associations between the duration of each intervention component in the first week and nonusage attrition differed among SES groups. Statistical analyses were performed using the coxme package in R (version 4.1.0; R Foundation for Statistical Computing). An $\alpha$ level of .05 was used to assess the statistical significance.

## Results

### Participant Characteristics

In total, the intervention group consisted of 186 adolescents (ie, participation rate, 83%). The characteristics of the sample are presented in Table 1. The log data related to duration in the different components during the first week showed that there were large differences among the participants in terms of use duration, but most of the adolescents hardly spent any time in the app, with a median of 1.41 minutes per week for the self-regulation component, 0.03 minutes per week for the narrative, and 0.39 minutes per week for the chatbot.



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**Table 1.** Participant characteristics of the #LIFEGOALS intervention group (n=186).

| Sociodemographic characteristic | Value |
|---|---|
| Age (years), mean (SD; range) | 13.51 (0.96; 11.83-15.66) |
| **Gender, n (%)** | |
| Adolescent male | 90 (48.4) |
| Adolescent female | 94 (50.5) |
| Other | 2 (1.1) |
| **Home language, n (%)** | |
| Dutch | 148 (79.6) |
| French | 6 (3.2) |
| Turkish | 10 (5.4) |
| Arabic | 8 (4.3) |
| English | 1 (0.5) |
| Other | 13 (7) |
| **Grade, n (%)** | |
| Seventh | 67 (36) |
| Eighth | 60 (32.3) |
| Ninth | 59 (31.7) |
| **Type of education, n (%)** | |
| Academic track | 114 (61.3) |
| Nonacademic track | 72 (38.7) |
| **Educational degree of the father, n (%)** | |
| Not applicable | 4 (2.2) |
| I do not know | 110 (59.1) |
| No diploma | 1 (0.5) |
| Primary school (until 12 years of age) | 3 (1.6) |
| Secondary school (until 18 years of age) | 24 (12.9) |
| High school, nonuniversity | 21 (11.3) |
| University | 23 (12.4) |
| **Educational degree of the mother, n (%)** | |
| Not applicable | 2 (1.1) |
| I do not know | 101 (54.3) |
| No diploma | 4 (2.2) |
| Primary school (until 12 years of age) | 4 (2.2) |
| Secondary school (until 18 years of age) | 17 (9.1) |
| High school, nonuniversity | 35 (18.8) |
| University | 23 (12.4) |
| **Family affluence, mean (SD; range)** | 9.09 (2.03; 2-13) |
| Low FAS[a] score, n (%) | 38 (20.4) |
| Medium FAS score, n (%) | 128 (68.8) |
| High FAS score, n (%) | 20 (10.8) |
| **Perceived financial situation, n (%)** | |
| Very difficult | 0 (0) |
| Difficult | 5 (2.7) |



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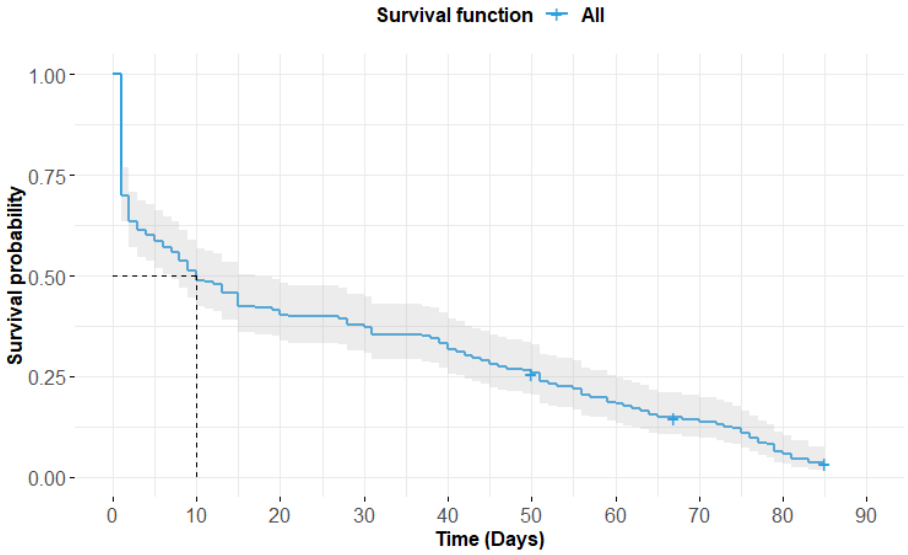
| Sociodemographic characteristic | Value |
|---|---|
| Quite difficult | 3 (1.6) |
| Quite easy | 30 (16.1) |
| Easy | 92 (49.5) |
| Very easy | 56 (30.1) |
| **Log data–derived variables (in minutes), median (IQR; range)** | |
| Duration of self-regulation during the first week | 1.41 (5.36; 0-34.21) |
| Duration of narrative during the first week | 0.03 (0.77; 0-16.35) |
| Duration of engaging with the chatbot during the first week | 0.39 (2.52; 0-43.33) |

[a]FAS: Family Affluence Scale.

## Attrition Patterns

The attrition pattern of the entire 12-week study period is presented by the Kaplan-Meier plot in Figure 1. Across the study period, there was a 4.3% (8/186) completion rate, with the remaining 95.7% (178/186) of the participants stopping the use of the app before the end of the study. The median survival time was 10 (95% CI 7-17) days. Of the 186 adolescents, 56 (30.1%) only opened the app on the installation day (ie, day 1) and 82 (44.1%) stopped using the app in the first week.

**Figure 1.** Attrition pattern of the #LIFEGOALS intervention.




Next, we examined whether the attrition rate differed according to SES indicators included in the study. Because more than half of the adolescents reported not knowing the degree of education of their fathers (110/186, 59.1%) and/or mothers (101/186, 54.3%), the difference in the attrition rate based on this indicator was not examined. Figures 2-4 show the Kaplan-Meier plots according to (1) educational track, (2) family affluence, and (3) perceived financial situation. According to the logrank tests (Table 2), only the educational track showed a significant difference ($P$<.001), meaning that attrition at any given time during the intervention period was significantly higher for adolescents from the nonacademic track compared with the academic track.



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**Figure 2.** Kaplan-Meier plots according to socioeconomic status indicator (educational track).

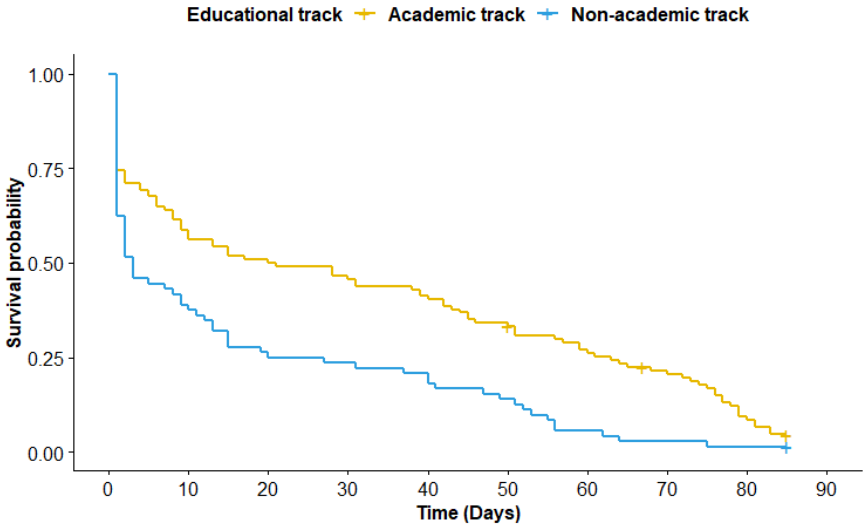



**Figure 3.** Kaplan-Meier plots according to socioeconomic status indicator. FAS: Family Affluence Scale.

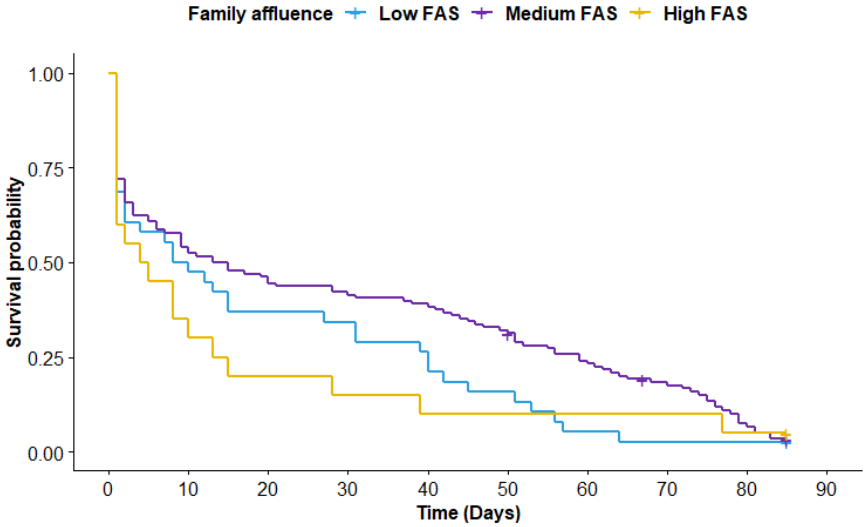
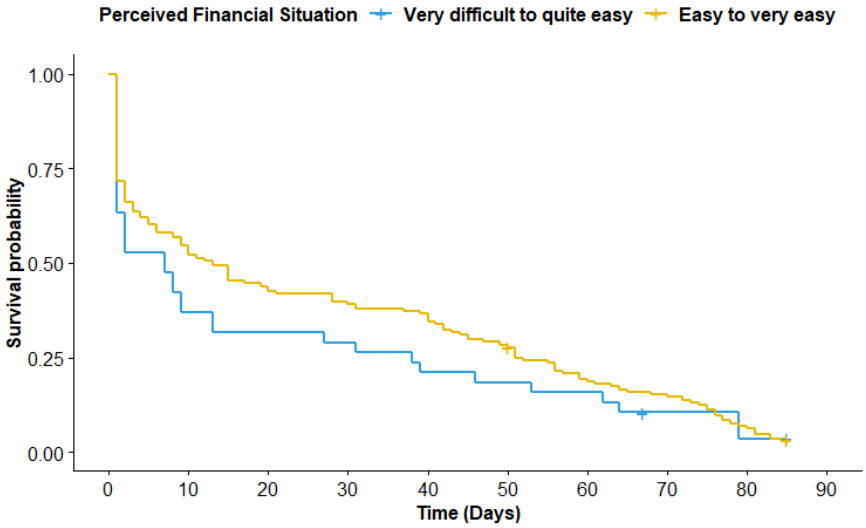



**Figure 4.** Kaplan-Meier plots according to socioeconomic status indicator (perceived financial situation).






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**Table 2.** Logrank tests according to socioeconomic status (SES) indicators.

| SES indicator | Logrank value ($\chi^2$) (*df*) | *P* value |
|---|---|---|
| Educational track | 16.7 (1) | *<.001* [a] |
| Family affluence | 5.2 (2) | .07 |
| Perceived financial situation | 1.3 (1) | .3 |

[a]Italicization indicates *P*<.05.

## Reasons for Nonusage Attrition

Of the 186 adolescents, 175 (94.1%) received the attrition questionnaire at least once during the intervention period (meaning they had not used the app for 3 weeks). Finally, 25.1% (44/175) of adolescents completed an attrition questionnaire. Table 3 shows the participant characteristics of receivers, responders, and nonresponders. There was a significant difference between responders and nonresponders according to the educational track, with more adolescents from the academic track answering the attrition questionnaire than adolescents from the nonacademic track (*P*=.046).

**Table 3.** Participants' characteristics with regard to the attrition questionnaire.

| Sociodemographic characteristic | Values | | | Significance of difference | | |
|---|---|---|---|---|---|---|
| | Receivers (n=175) | Responders (n=44) | Nonresponders (n=131) | *t* test (*df*)[a] | Chi-square (*df*) | *P* value |
| Age (years), mean (SD; range) | 13.42 (0.97; 11.83-15.66) | 13.55 (0.94; 11.96-15.47) | 13.45 (0.98; 11.83-15.66) | −0.55 (173) | N/A[b] | .59 |
| **Gender, n (%)** | | | | N/A | 2.60 (1) | .11 |
| Adolescent male | 86 (49.1) | 17 (38.6) | 69 (52.7) | | | |
| Adolescent female | 87 (49.7) | 27 (61.4) | 60 (45.8) | | | |
| Other | 2 (0.2) | 0 (0) | 2 (1.5) | | | |
| **Grade, n (%)** | | | | N/A | 1.68 (2) | .43 |
| Seventh | 66 (37.7) | 13 (29.5) | 53 (40.5) | | | |
| Eighth | 57 (32.6) | 16 (36.4) | 41 (31.3) | | | |
| Ninth | 52 (29.7) | 15 (34.1) | 37 (28.2) | | | |
| **Type of education, n (%)** | | | | N/A | 3.97 (1) | *.046*[c] |
| Academic track | 105 (60) | 32 (72.7) | 73 (55.7) | | | |
| Nonacademic track | 70 (40) | 12 (27.3) | 58 (44.3) | | | |

[a]Independent samples 2-tailed *t* test.

[b]N/A: not applicable.

[c]Italicization indicates *P*<.05.

The most common reasons for the nonusage attrition of the #LIFEGOALS app were (percentages from agree to strongly agree; Table 4) (1) My behavior did not change by using the app (24/44, 55%), (2) I did not like the app (17/44, 39%), (3) I already use other apps to track and/or improve my lifestyle (17/44, 39%), (4) I already live a sufficiently healthy life (16/44, 36%), and (5) I was not motivated by my environment to keep using the app (eg, at home and by friends; 15/44, 34%). There were no statistically significant differences in the attrition reasons depending on the educational track; only a borderline significant difference for the reason that there are other things in the adolescent's life that they consider more important than their health (*P*=.08), where more adolescents from the nonacademic track had indicated this reason compared with those from the academic track. A comprehensive descriptive table of what the adolescents indicated per answer category for each attrition reason, including the division according to educational track, can be found in Multimedia Appendix 5.

In addition to the items included in the questionnaire, adolescents could also fill in their own reasons for no longer using the app. Other reasons given by adolescents were forgetting to use the app because of tight schedules with other things (5/44, 11%); not having enough storage on the smartphone (n=1); being more engaged with the Fitbit itself than with the app (n=1); feeling difficult to be motivated (n=1); feeling no intrinsic trigger to use the app compared with other apps (n=1); and using an app feels rather obligatory (eg, filling in a goal); therefore, preferring to work on their health *on their own* rather than using an app (n=2).

Of the 44 adolescents, 25 (57%) would not recommend the app to their friends and 19 (43%) would.



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**Table 4.** Reasons why adolescents stopped using the #LIFEGOALS app and a test of significance according to the educational track (n=44).

| I do not use the #LIFEGOALS app anymore because... | Strongly disagree to neutral, n (%) | Agree to strongly agree, n (%) | Significance of difference (*P* value, 2-tailed)[a] |
|---|---|---|---|
| The app takes too much time. | 31 (70) | 13 (30) | .30 |
| I am not allowed to use my mobile phone much at home. | 39 (89) | 5 (11) | .99 |
| I already live a sufficiently healthy life. | 28 (64) | 16 (36) | .99 |
| There were technical problems with the app. | 35 (80) | 9 (20) | .41 |
| The app was too complicated. | 33 (75) | 11 (25) | .14 |
| I did not like the app. | 27 (61) | 17 (39) | .74 |
| My behavior did not change by using the app. | 20 (45) | 24 (55) | .50 |
| The app did not meet my expectations. | 37 (84) | 7 (16) | .65 |
| My friends did not use the app either. | 37 (84) | 7 (16) | .37 |
| I did not get enough reminders to use the app. | 34 (77) | 10 (23) | .24 |
| I was not motivated by my environment to keep using the app (eg, at home and by friends). | 29 (66) | 15 (34) | .17 |
| I already use other apps to track or improve my lifestyle (eg, Fitbit app). | 27 (61) | 17 (39) | .74 |
| There are other things in my life I consider more important than my health. | 37 (84) | 7 (16) | .08 |
| The chatbot often answered my questions incorrectly. | 38 (86) | 6 (14) | .53 |

[a]Fisher exact tests.

## Cox Proportional Hazard Regression Models

The results of both the single- and multiple-predictor mixed effects Cox proportional hazard regression models are presented in Table 5. As shown in the single-predictor models, no sociodemographic variables were significantly related to attrition, except educational track (*P*=.02). Conversely, the use duration in all 3 components during the first week was found to be significantly related to survival time. Subsequently, a multiple-predictor model was constructed in which the educational track was included as a confounding variable and the duration of all 3 components as independent variables. Significant predictors of attrition were duration in the self-regulation component during the first week (*P*<.001) and duration in the narrative component during the first week (*P*=.03). When adolescents used the self-regulation (hazard ratio 0.902, 95% CI 0.867-0.939) and narrative component (hazard ratio 0.924, 95% CI 0.858-0.994) more often during the first week, they were less likely to drop out 12 weeks later. The duration of the chatbot component during the first week did not contribute significantly to the overall model. Furthermore, the effect of duration in the 3 components during the first week on attrition was not significantly different according to SES (ie, educational track).



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**Table 5.** Results of the clustered Cox proportional hazard regression models.

| | Single-predictor models | | | Multiple-predictor models | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | Coefficient (SE) | HR[a] (95% CI) | *P* value | Without an interaction term | | | With an interaction term | | |
| | | | | Coefficient (SE) | HR (95% CI) | *P* value | Coefficient (SE) | HR (95% CI) | *P* value |
| **Sociodemographic variables** | | | | | | | | | |
| Age (in years) | 0.057 (0.125) | 1.059 (0.828-1.354) | .65 | N/A[b] | N/A | N/A | N/A | N/A | N/A |
| **Gender (reference: adolescent male)** | | | | N/A | N/A | N/A | N/A | N/A | N/A |
| Adolescent female | −0.045 (0.192) | 0.956 (0.656-1.393) | .81 | | | | | | |
| Other | 0.754 (0.754) | 2.126 (0.485-9.328) | .32 | | | | | | |
| **Grade (reference: seventh grade)** | | | | N/A | N/A | N/A | N/A | N/A | N/A |
| Eighth grade | −0.161 (0.362) | 0.851 (0.419-1.730) | .66 | | | | | | |
| Ninth grade | −0.325 (0.333) | 0.722 (0.376-1.388) | .33 | | | | | | |
| Home language (reference: Dutch) | 0.361 (0.199) | 1.435 (0.971-2.120) | .07 | N/A | N/A | N/A | N/A | N/A | N/A |
| Educational track (reference: academic track) | 0.555 (0.228) | 1.742 (1.115-2.722) | *.02* [c] | 0.750 (0.211) | 2.117 (1.399-3.202) | *<.001* | 0.794 (0.262) | 2.211 (1.324-3.695) | *.002* |
| **Family affluence (reference: low FAS[d] score)** | | | | N/A | N/A | N/A | N/A | N/A | N/A |
| Medium FAS score | −0.244 (0.201) | 0.784 (0.529-1.161) | .22 | | | | | | |
| High FAS score | 0.241 (0.291) | 1.272 (0.720-2.249) | .41 | | | | | | |
| Perceived financial situation | −0.225 (0.194) | 0.798 (0.546-1.167) | .24 | N/A | N/A | N/A | N/A | N/A | N/A |
| **Log data–derived variables** | | | | | | | | | |
| Duration of self-regulation during the first week | −0.109 (0.019) | 0.897 (0.864-0.931) | *<.001* | −0.103 (0.021) | 0.902 (0.867-0.939) | *<.001* | −0.097 (0.024) | 0.907 (0.866-0.951) | *<.001* |
| Duration of narrative during the first week | −0.111 (0.039) | 0.895 (0.828-0.966) | *.01* | −0.079 (0.037) | 0.924 (0.858-0.994) | *.03* | −0.033 (0.046) | 0.968 (0.885-1.058) | .47 |
| Duration of engaging with the chatbot during the first week | −0.065 (0.029) | 0.937 (0.885-0.993) | *.03* | 0.006 (0.029) | 1.007 (0.951-1.065) | .82 | −0.022 (0.043) | 0.979 (0.900-1.064) | .61 |
| **Interaction with socioeconomic status** | N/A | N/A | N/A | N/A | N/A | N/A | | | |
| Duration of self-regulation during the first week—educational track (reference: academic track) | | | | | | | −0.011 (0.046) | 0.989 (0.904-1.082) | .81 |
| Duration narrative during first week—educational track (reference: academic track) | | | | | | | −0.102 (0.081) | 0.903 (0.770-1.060) | .21 |
| Duration chatbot during first week—educational track (reference academic track) | | | | | | | 0.048 (0.059) | 1.049 (0.935-1.177) | .41 |

[a]HR: hazard ratio.

[b]N/A: not applicable.



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[c]Italicization indicates $P<.05$.

[d]FAS: Family Affluence Scale.

## Discussion

### Principal Findings

This study investigated when and why adolescents stop using an mHealth intervention (RQ1 and RQ2) and explored whether the use duration of specific intervention components during the first week can predict attrition (RQ3). All RQs examined whether this differed according to SES.

Although mHealth interventions can be seen as potentially revolutionary, we are still in the age of promise rather than delivery [72]. One of the main challenges that still lies ahead is low adherence to and engagement with mHealth interventions [15-19,72]. Despite attempts to increase adherence and engagement in the current intervention (ie, participatory development, adding a narrative and chatbot, and reward system), the results of the #LIFEGOALS intervention showed that 95.7% (178/186) of the participants stopped using the app before the end of the study period. These numbers are high compared with the attrition rates obtained by other research-based mHealth interventions (ie, 32%-75%) [21-24]. Although most of these studies focused on adults, the study by Egilsson et al [26], focusing on adolescents, also reported a much lower attrition rate (ie, an attrition rate of 35% after 6 weeks). A possible explanation for our higher rates than those reported by Egilsson et al [26] might be the difference in recruitment strategy; in this study, whole classes were recruited in which all pupils were asked to participate during a class visit, whereas in the study by Egilsson et al [26], an email was sent via school officials to parents and legal guardians asking for children interested to participate. A nonresponse bias may be at play in the study by Egilsson et al [26], meaning that the most motivated adolescents might have signed up to participate, resulting in lower attrition rates. From a practical point of view, we can conclude that the school is an ideal place to reach adolescents, but it may not be the right entry point for health interventions. If the intervention had been delivered through social media or through an influencer using popular youth channels such as YouTube or TikTok, it might have appealed to more adolescents [73,74]. Moreover, existing research stipulates that *health* is not a motivating factor for adolescents in health interventions [74]. Therefore, interventions that focus solely on improving health might be unlikely to engage adolescents. Rather, interventions should align with the values and priorities specified by adolescents, such as being with their friends and doing what they enjoy and are good at [74]. #LIFEGOALS was presented as an app that could motivate participants to increase healthy lifestyle behaviors. As a result, the intervention could have benefited from another framing, meaning that the current framing might not have appealed to adolescents' motivation to use the app or their intention to change behavior (ie, no intention to change behavior=motivational phase within the Health Action Process Approach [53]). As most adolescents have only used the intervention for a short time (ie, median survival time of 10 days, 95% CI 7-17 days), it is not surprising that they could not yet experience any change as behavior change is a long-term process that usually involves several stages to ultimately bring about change [53].

Consistent with previous research, high attrition rates occurred in the very early phases of the intervention [18,26,68,75,76]: 30.1% (56/186) had only opened the app on the installation day (ie, day 1), and almost half of the adolescents (82/186, 44.1%) stopped using the app in the first week. It seems like many adolescents (approximately one-third; 56/186, 30.1%) had not given the intervention a chance. The attrition questionnaire showed that adolescents did not like the app. Despite involving the target group (ie, 249 adolescents), a graphic designer, and a retired professor passionate about software design during the development process, the numbers are not surprising, as this was still an app with research purposes. It is possible that the current generation of adolescents who have grown up with apps have much higher expectations of apps than the app presented to them as part of the study. Previous research concluded that the power of design features should not be underestimated [77]. The #LIFEGOALS app is, in that perspective, rather basic compared with existing commercial health apps, which adolescents indicated they were already using instead of the #LIFEGOALS app to track or improve their health. However, these commercial apps should be viewed with caution, as they are often not evidence-based [78]. Furthermore, previous research has shown that adolescents may assume that using health apps could make them unpopular among their peers [73], which may also have played a role in why adolescents did not like the app.

Another reason for adolescents to stop using the #LIFEGOALS app was already leading a sufficiently healthy lifestyle. However, a first glance at the baseline data from the questionnaire and the accelerometers of this sample (intervention group only) showed that 90.9% (169/186) did not reach the recommended guidelines of 60 minutes per day of moderate to vigorous physical activity, 47.8% (89/186) were sitting for >8 hours per day, 71% (132/186) did not meet the Flemish HBSC-norm of 8-hour of sleep, and 52.8% (95/180) of adolescents did not take breakfast daily. Thus, a more realistic reflection might be that adolescents have a false image of their own health behavior, overestimating themselves. Future research with this age group should focus more on the correct assessment of their own lifestyle behavior or pay more attention to communicating the guidelines, as it is unclear whether adolescents sufficiently know these.

It has been proposed that *e-attainment* may be the cause of nonadherence, which means that participants may stop using an intervention when they feel they have achieved as much as they wish from it (eg, living a sufficiently healthy life) [79-81]. In that regard, *attrition* should not always have a negative connotation. For some users and contexts, only one in-depth period of engagement with the digital intervention may be sufficient to initiate new habits or teach new skills (ie, effective engagement) [72,82]. However, this seems to be unlikely here because of the low actual use of the app components in the



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number of minutes. In any case, the hypothesis of e-attainment cannot be answered conclusively at this time, as the effect evaluation (in preparation) still needs to determine whether any effect of the intervention can be observed on the healthy lifestyle behaviors of adolescents.

Finally, adolescents indicated that they were not motivated by their environment to use the app. Previous research has already demonstrated that there would be a higher risk of attrition when the interventions are stand-alone apps than when they involve guidance or support [11,15-17,83]. Attrition rates to the #LIFEGOALS app could potentially be reduced if some (human) guidance or support was provided by integrating social elements [84].

Traditionally, adolescents' SES has been measured using information about parents' income, educational level, or occupation [85]. However, adolescents often find these measures difficult to answer [61,86]. This was confirmed here, as more than half of the adolescents indicated that they did not know the educational level of their fathers (110/186, 59.1%) and mothers (101/186, 54.3%). Furthermore, it raised the question of whether it would not be better to survey the SES of adolescents themselves rather than parental SES, as adolescence is seen as a developmental stage in which one strives to find one's own identity, independent of one's parents [85]. Therefore, various SES indicators were included in this study to explore whether there was a difference in attrition according to SES. In line with previous research [75,82,87,88], the results showed that adolescents' educational level had a significant impact on attrition: attrition at any given time during the intervention period was significantly higher for adolescents from the nonacademic track compared with the academic track. The other SES indicators, family affluence and perceived financial situation, did not significantly affect attrition rates. Previous research has shown that different SES indicators have a different impact on the healthy lifestyle behaviors of adolescents [45,57,89-91]. This study shows that different SES indicators can play a different role within attrition rates as well. It is possible that the values, norms, knowledge, and skills of adolescents differ according to educational track, and that this has a greater impact on their attrition rates than their financial situation at home. Educational level is most often used as a proxy for health literacy [92], which may thus be more important for this RQ than financial resources. In this regard, surveying *cultural (health) capital* might also be an interesting SES indicator among adolescents because it maps out the values, norms, knowledge, and skills accumulated through education and lifelong socialization [92,93]. The difference in attrition according to educational level may indicate several things. First, adolescents in a nonacademic educational track may be less motivated to change health-related behavior. Second, the app (despite the integration of the narrative and chatbot) may not have been adequately tailored to the needs and preferences of adolescents in the nonacademic track [82,94]. For example, the chatbot development paper [56] showed that adolescents from the nonacademic track were involved; however, they had less input, especially during the focus groups that required some abstract thinking, than adolescents from the academic track. Therefore, we cannot say with certainty that the components adequately addressed their needs. A possible way of tailoring an intervention to people of lower affluence that has been posited in the literature is to provide a support person during the intervention period. Someone with whom they can have much more direct contact and who continues to motivate them throughout the study period, for example, by setting goals together and encouraging each other to achieve those goals [37,46]. Although this study did not find any significant differences in attrition reasons according to SES (in this study, educational track), we definitely recommend doing further (qualitative) research into this, as the number of responders from the nonacademic track was very small to make conclusive statements (12/44, 27%).

As a third RQ, this study investigated whether the duration of the 3 different intervention components during the first week had an impact on adolescents' attrition rates and whether this differed according to SES. The results indicated that the time spent in the self-regulation and narrative components during the first week had an influence on attrition (ie, the longer time they spent in those components, the less likely they were to drop out), whereas duration in the chatbot component during the first week had no impact on the attrition rates. This may be because the chatbot could not yet answer adolescents' questions accurately (enough), leading to user frustration and early cessation of use [56]. These links should, however, be viewed with caution, given the limited time spent in each of the components in the first week (median of 1.41, 0.03, and 0.39 minutes, respectively). Furthermore, no differences were found according to SES (ie, educational track of the adolescent), meaning that the duration use of the 3 components during the first week has the same impact on attrition for each of the two groups (academic track vs nonacademic track). At present, there is limited research within mHealth on the components that contribute to attrition. Just as it is important to investigate which mHealth components contribute to engagement [95,96], it also seems important to explore this for attrition, although participants' engagement and attrition are undoubtedly closely linked: the stronger the engagement, the less likely it is to drop out [22].

## Limitations and Strengths

This study had some limitations. First, there was an overrepresentation of adolescents from the academic track compared with the nonacademic track in the intervention group, as well as in the respondents of the attrition questionnaire. This means that few conclusions can be drawn regarding the attrition reasons of nonacademic track adolescents. Additional research (eg, process evaluation interviews) is needed to thoroughly assess the reasons, especially in nonacademic track adolescents so that future interventions can be adopted accordingly. Second, most of our sample (128/186, 68.8%) was of medium affluence according to the Flemish HBSC cut points (mean of 9.12 on family affluence), consistent with the rather high affluence of the country [45]. This may limit the generalizability of our findings to other countries with a lower national level of affluence. Third, the last item of the FAS III regarding traveling out of Belgium for a holiday or vacation last year may be biased because of the COVID-19 pandemic and the associated travel restrictions. Fourth, no item was added to the attrition



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questionnaire that gauged the general motivation or need of adolescents for behavior change; therefore, we cannot say with certainty that adolescents did not use the app because they were not motivated to change their behavior. Fifth, the attrition pattern may have been influenced by sending the attrition questionnaire because the log data showed that many nonusers used the app briefly on the day they received the attrition questionnaire. Sixth, teachers did not receive specific instructions to remind or motivate adolescents to use the app during the intervention period. However, if teachers in several schools handled this differently, this might have had an impact on attrition rates. In this study, no statements could be made about this, because the specific input of the teacher, or the differences of the teachers' input among the schools, was not questioned. The main strength is that this study added to the scarce research on attrition rates in an mHealth intervention for youth. The log data of a large group (N=186) of adolescents aged between 12 and 15 years could be tracked to gain insights into their attrition pattern. Second, SES was measured using 3 self-reported indicators. As different indicators measure different dimensions of SES, this study was able to identify which indicator plays a (greater) influence within attrition.

## Conclusions

Nonusage attrition rates in this study were high. Of the total number of adolescents, 30.1% (56/186) only opened the app on the installation day, indicating low motivation among the adolescents to use the health app. Despite the efforts made by researchers to engage low-SES adolescents, adolescents from a nonacademic educational track were more likely to drop out earlier than adolescents from an academic track. The reasons for attrition greatly varied. Duration in the self-regulation and narrative components during the first week may have a positive impact on attrition rates, both for adolescents in academic and nonacademic educational tracks.

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## Data Availability

The data sets used or analyzed during this study are available from the corresponding author upon reasonable request.

## Authors' Contributions

LM and SC conceptualized this study. LM and CP collected data. LM drafted the original manuscript. SC, CP, G Cardon, G Crombez, and ADS edited the manuscript and provided feedback. All authors have read and approved the final manuscript.

## Conflicts of Interest

None declared.

Multimedia Appendix 1
Flowchart of the #LIFEGOALS intervention.
[PNG File , 92 KB - mhealth_v10i5e36404_app1.png ]

Multimedia Appendix 2
Screenshot of the #LIFEGOALS app.
[PDF File (Adobe PDF File), 75 KB - mhealth_v10i5e36404_app2.pdf ]

Multimedia Appendix 3
Roll-up banner.
[PNG File , 397 KB - mhealth_v10i5e36404_app3.png ]

Multimedia Appendix 4
Results of the standard Cox proportional hazard regression models (without clustering).
[DOCX File , 26 KB - mhealth_v10i5e36404_app4.docx ]

Multimedia Appendix 5
Reasons why adolescents stopped using the #LIFEGOALS app.
[PDF File (Adobe PDF File), 168 KB - mhealth_v10i5e36404_app5.pdf ]



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## References


1. Direito A, Carraça E, Rawstorn J, Whittaker R, Maddison R. mHealth technologies to influence physical activity and sedentary behaviors: behavior change techniques, systematic review and meta-analysis of randomized controlled trials. Ann Behav Med 2017 Apr;51(2):226-239. [doi: 10.1007/s12160-016-9846-0] [Medline: 27757789]
2. Fedele DA, Cushing CC, Fritz A, Amaro CM, Ortega A. Mobile health interventions for improving health outcomes in youth: a meta-analysis. JAMA Pediatr 2017 May 01;171(5):461-469 [FREE Full text] [doi: 10.1001/jamapediatrics.2017.0042] [Medline: 28319239]
3. Rathbone AL, Prescott J. The use of mobile apps and SMS messaging as physical and mental health interventions: systematic review. J Med Internet Res 2017 Aug 24;19(8):e295 [FREE Full text] [doi: 10.2196/jmir.7740] [Medline: 28838887]
4. Mclaughlin M, Delaney T, Hall A, Byaruhanga J, Mackie P, Grady A, et al. Associations between digital health intervention engagement, physical activity, and sedentary behavior: systematic review and meta-analysis. J Med Internet Res 2021 Feb 19;23(2):e23180. [doi: 10.2196/23180]
5. Flores Mateo G, Granado-Font E, Ferré-Grau C, Montaña-Carreras X. Mobile phone apps to promote weight loss and increase physical activity: a systematic review and meta-analysis. J Med Internet Res 2015 Nov 10;17(11):e253 [FREE Full text] [doi: 10.2196/jmir.4836] [Medline: 26554314]
6. Romeo A, Edney S, Plotnikoff R, Curtis R, Ryan J, Sanders I, et al. Can smartphone apps increase physical activity? Systematic review and meta-analysis. J Med Internet Res 2019 Mar 19;21(3):e12053 [FREE Full text] [doi: 10.2196/12053] [Medline: 30888321]
7. mHealth: New Horizons for Health Through Mobile Technologies: Second Global Survey on eHealth. Geneva: World Health Organization; 2011.
8. McIntosh JR, Jay S, Hadden N, Whittaker PJ. Do E-health interventions improve physical activity in young people: a systematic review. Public Health 2017 Jul;148:140-148. [doi: 10.1016/j.puhe.2017.04.001] [Medline: 28482322]
9. Lau PW, Lau EY, Wong DP, Ransdell L. A systematic review of information and communication technology-based interventions for promoting physical activity behavior change in children and adolescents. J Med Internet Res 2011 Jul 13;13(3):e48 [FREE Full text] [doi: 10.2196/jmir.1533] [Medline: 21749967]
10. eHealth Research, Theory and Development A Multidisciplinary Approach. London, United Kingdom: Routledge; 2018.
11. Turner T, Spruijt-Metz D, Wen CK, Hingle MD. Prevention and treatment of pediatric obesity using mobile and wireless technologies: a systematic review. Pediatr Obes 2015 Dec;10(6):403-409 [FREE Full text] [doi: 10.1111/ijpo.12002] [Medline: 25641770]
12. Gomez Quiñonez S, Walthouwer MJ, Schulz DN, de Vries H. mHealth or eHealth? Efficacy, use, and appreciation of a web-based computer-tailored physical activity intervention for Dutch adults: a randomized controlled trial. J Med Internet Res 2016 Nov 09;18(11):e278 [FREE Full text] [doi: 10.2196/jmir.6171] [Medline: 27829576]
13. Laura L. Technology as a platform for improving healthy behaviors and weight status in children and adolescents: a review. Obesity 2015;1(3). [doi: 10.16966/2380-5528.109]
14. Rose T, Barker M, Maria Jacob C, Morrison L, Lawrence W, Strömmer S, et al. A systematic review of digital interventions for improving the diet and physical activity behaviors of adolescents. J Adolesc Health 2017 Dec;61(6):669-677 [FREE Full text] [doi: 10.1016/j.jadohealth.2017.05.024] [Medline: 28822682]
15. Clarke AM, Kuosmanen T, Barry MM. A systematic review of online youth mental health promotion and prevention interventions. J Youth Adolesc 2015 Jan;44(1):90-113. [doi: 10.1007/s10964-014-0165-0] [Medline: 25115460]
16. Neil AL, Batterham P, Christensen H, Bennett K, Griffiths KM. Predictors of adherence by adolescents to a cognitive behavior therapy website in school and community-based settings. J Med Internet Res 2009 Feb 23;11(1):e6 [FREE Full text] [doi: 10.2196/jmir.1050] [Medline: 19275982]
17. Christensen H, Reynolds J, Griffiths KM. The use of e-health applications for anxiety and depression in young people: challenges and solutions. Early Interv Psychiatry 2011 Feb;5 Suppl 1:58-62. [doi: 10.1111/j.1751-7893.2010.00242.x] [Medline: 21208393]
18. Eysenbach G. The law of attrition. J Med Internet Res 2005 Mar 31;7(1):e11 [FREE Full text] [doi: 10.2196/jmir.7.1.e11] [Medline: 15829473]
19. Lubans DR, Smith JJ, Skinner G, Morgan PJ. Development and implementation of a smartphone application to promote physical activity and reduce screen-time in adolescent boys. Front Public Health 2014;2:42 [FREE Full text] [doi: 10.3389/fpubh.2014.00042] [Medline: 24904909]
20. 21% of users abandon an app after one use. Localytics. URL: http://info.localytics.com/blog/21-percent-of-users-abandon-apps-after-one-use [accessed 2022-04-12]
21. Guertler D, Vandelanotte C, Kirwan M, Duncan MJ. Engagement and nonusage attrition with a free physical activity promotion program: the case of 10,000 steps Australia. J Med Internet Res 2015 Jul 15;17(7):e176 [FREE Full text] [doi: 10.2196/jmir.4339] [Medline: 26180040]
22. Edney S, Ryan JC, Olds T, Monroe C, Fraysse F, Vandelanotte C, et al. User engagement and attrition in an app-based physical activity intervention: secondary analysis of a randomized controlled trial. J Med Internet Res 2019 Nov 27;21(11):e14645 [FREE Full text] [doi: 10.2196/14645] [Medline: 31774402]




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23. Meyerowitz-Katz G, Ravi S, Arnolda L, Feng X, Maberly G, Astell-Burt T. Rates of attrition and dropout in app-based interventions for chronic disease: systematic review and meta-analysis. J Med Internet Res 2020 Sep 29;22(9):e20283 [FREE Full text] [doi: 10.2196/20283] [Medline: 32990635]
24. Vandelanotte C, Duncan MJ, Kolt GS, Caperchione CM, Savage TN, Van Itallie A, et al. More real-world trials are needed to establish if web-based physical activity interventions are effective. Br J Sports Med 2019 Dec 03;53(24):1553-1554. [doi: 10.1136/bjsports-2018-099437] [Medline: 29970409]
25. Shin Y, Kim SK, Lee M. Mobile phone interventions to improve adolescents' physical health: a systematic review and meta-analysis. Public Health Nurs 2019 Nov;36(6):787-799. [doi: 10.1111/phn.12655] [Medline: 31456259]
26. Egilsson E, Bjarnason R, Njardvik U. Usage and weekly attrition in a smartphone-based health behavior intervention for adolescents: pilot randomized controlled trial. JMIR Form Res 2021 Feb 17;5(2):e21432 [FREE Full text] [doi: 10.2196/21432] [Medline: 33481750]
27. Dugas M, Gao GG, Agarwal R. Unpacking mHealth interventions: a systematic review of behavior change techniques used in randomized controlled trials assessing mHealth effectiveness. Digit Health 2020;6:2055207620905411 [FREE Full text] [doi: 10.1177/2055207620905411] [Medline: 32128233]
28. Michie S, West R, Sheals K, Godinho CA. Evaluating the effectiveness of behavior change techniques in health-related behavior: a scoping review of methods used. Transl Behav Med 2018 Mar 01;8(2):212-224 [FREE Full text] [doi: 10.1093/tbm/ibx019] [Medline: 29381786]
29. Direito A, Dale LP, Shields E, Dobson R, Whittaker R, Maddison R. Do physical activity and dietary smartphone applications incorporate evidence-based behaviour change techniques? BMC Public Health 2014 Jun 25;14:646 [FREE Full text] [doi: 10.1186/1471-2458-14-646] [Medline: 24965805]
30. Schroé H, Van Dyck D, De Paepe A, Poppe L, Loh WW, Verloigne M, et al. Which behaviour change techniques are effective to promote physical activity and reduce sedentary behaviour in adults: a factorial randomized trial of an e- and m-health intervention. Int J Behav Nutr Phys Act 2020 Oct 07;17(1):127 [FREE Full text] [doi: 10.1186/s12966-020-01001-x] [Medline: 33028335]
31. Perski O, Blandford A, West R, Michie S. Conceptualising engagement with digital behaviour change interventions: a systematic review using principles from critical interpretive synthesis. Transl Behav Med 2017 Jun;7(2):254-267 [FREE Full text] [doi: 10.1007/s13142-016-0453-1] [Medline: 27966189]
32. Hinyard LJ, Kreuter MW. Using narrative communication as a tool for health behavior change: a conceptual, theoretical, and empirical overview. Health Educ Behav 2007 Oct 30;34(5):777-792. [doi: 10.1177/1090198106291963] [Medline: 17200094]
33. Slater MD, Rouner D. Entertainment-education and elaboration likelihood: understanding the processing of narrative persuasion. Commun Theory 2002 May;12(2):173-191. [doi: 10.1111/j.1468-2885.2002.tb00265.x]
34. Murphy ST, Frank LB, Chatterjee JS, Baezconde-Garbanati L. Narrative versus non-narrative: the role of identification, transportation and emotion in reducing health disparities. J Commun 2013 Feb 07;63(1):116-137 [FREE Full text] [doi: 10.1111/jcom.12007] [Medline: 24347679]
35. Perski O, Crane D, Beard E, Brown J. Does the addition of a supportive chatbot promote user engagement with a smoking cessation app? An experimental study. Digit Health 2019;5:2055207619880676 [FREE Full text] [doi: 10.1177/2055207619880676] [Medline: 31620306]
36. Western MJ, Armstrong ME, Islam I, Morgan K, Jones UF, Kelson MJ. The effectiveness of digital interventions for increasing physical activity in individuals of low socioeconomic status: a systematic review and meta-analysis. Int J Behav Nutr Phys Act 2021 Nov 09;18(1):148 [FREE Full text] [doi: 10.1186/s12966-021-01218-4] [Medline: 34753490]
37. Arsenijevic J, Tummers L, Bosma N. Adherence to electronic health tools among vulnerable groups: systematic literature review and meta-analysis. J Med Internet Res 2020 Feb 06;22(2):e11613 [FREE Full text] [doi: 10.2196/11613] [Medline: 32027311]
38. Fadhil A, Gabrielli S. Addressing challenges in promoting healthy lifestyles: the al-chatbot approach. In: Proceedings of the 11th EAI International Conference on Pervasive Computing Technologies for Healthcare. 2017 Presented at: PervasiveHealth '17: Proceedings of the 11th EAI International Conference on Pervasive Computing Technologies for Healthcare; May 23 - 26, 2017; Barcelona Spain. [doi: 10.1145/3154862.3154914]
39. Richter M, Erhart M, Vereecken CA, Zambon A, Boyce W, Nic Gabhainn S. The role of behavioural factors in explaining socio-economic differences in adolescent health: a multilevel study in 33 countries. Soc Sci Med 2009 Aug;69(3):396-403. [doi: 10.1016/j.socscimed.2009.05.023] [Medline: 19540029]
40. Sigmundová D, Sigmund E, Tesler R, Ng KW, Hamrik Z, Mathisen FK, et al. Vigorous physical activity in relation to family affluence: time trends in Europe and North America. Int J Public Health 2019 Sep;64(7):1049-1058 [FREE Full text] [doi: 10.1007/s00038-019-01271-8] [Medline: 31278436]
41. Omorou AY, Manneville F, Langlois J, Legrand K, Böhme P, Muller L, PRALIMAP-INÈS Trial Group. Physical activity rather than sedentary behaviour is socially determined in French adolescents with overweight and obesity. Prev Med 2020 May;134:106043. [doi: 10.1016/j.ypmed.2020.106043] [Medline: 32097754]




XSL•FO
RenderX

42. Jiménez Pavón D, Ortega FP, Ruiz JR, España Romero V, García Artero E, Moliner Urdiales D, HELENA Study Group. Socioeconomic status influences physical fitness in European adolescents independently of body fat and physical activity: the HELENA study. Nutr Hosp 2010;25(2):311-316. [Medline: 20449543]
43. Elgar FJ, Pförtner T, Moor I, De Clercq B, Stevens GW, Currie C. Socioeconomic inequalities in adolescent health 2002–2010: a time-series analysis of 34 countries participating in the Health Behaviour in School-aged Children study. The Lancet 2015 May;385(9982):2088-2095. [doi: 10.1016/s0140-6736(14)61460-4]
44. Spotlight on adolescent health and well-being. Findings from the 2017/2018 Health Behaviour in School-aged Children (HBSC) survey in Europe and Canada. International report. Volume 1. Key findings 14. Denmark: World Health Organization; 2020.
45. Maenhout L, Peuters C, Cardon G, Compernolle S, Crombez G, DeSmet A. The association of healthy lifestyle behaviors with mental health indicators among adolescents of different family affluence in Belgium. BMC Public Health 2020 Jun 18;20(1):958 [FREE Full text] [doi: 10.1186/s12889-020-09102-9] [Medline: 32552853]
46. Latulippe K, Hamel C, Giroux D. Social health inequalities and eHealth: a literature review with qualitative synthesis of theoretical and empirical studies. J Med Internet Res 2017 Apr 27;19(4):e136 [FREE Full text] [doi: 10.2196/jmir.6731] [Medline: 28450271]
47. Onderzoeksrapport Apestaartjaren : de digitale leefwereld van jongeren. Mediaraven. URL: https://biblio.ugent.be/publication/8667985 [accessed 2022-04-13]
48. van Lenthe FJ, de Bourdeaudhuij I, Klepp K, Lien N, Moore L, Faggiano F, et al. Preventing socioeconomic inequalities in health behaviour in adolescents in Europe: background, design and methods of project TEENAGE. BMC Public Health 2009 May 08;9(1):125 [FREE Full text] [doi: 10.1186/1471-2458-9-125] [Medline: 19426476]
49. Velten J, Lavallee KL, Scholten S, Meyer AH, Zhang X, Schneider S, et al. Lifestyle choices and mental health: a representative population survey. BMC Psychol 2014 Dec 23;2(1):58 [FREE Full text] [doi: 10.1186/s40359-014-0055-y] [Medline: 25628891]
50. Walsh R. Lifestyle and mental health. Am Psychol 2011 Oct;66(7):579-592. [doi: 10.1037/a0021769] [Medline: 21244124]
51. Biddle SJ, Asare M. Physical activity and mental health in children and adolescents: a review of reviews. British J Sports Med 2011 Aug 01;45(11):886-895. [doi: 10.1136/bjsports-2011-090185] [Medline: 21807669]
52. Rodriguez-Ayllon M, Cadenas-Sánchez C, Estévez-López F, Muñoz NE, Mora-Gonzalez J, Migueles JH, et al. Role of physical activity and sedentary behavior in the mental health of preschoolers, children and adolescents: a systematic review and meta-analysis. Sports Med 2019 Sep 16;49(9):1383-1410. [doi: 10.1007/s40279-019-01099-5] [Medline: 30993594]
53. Schwarzer R. Modeling health behavior change: how to predict and modify the adoption and maintenance of health behaviors. Applied Psychol 2008 Jan;57(1):1-29. [doi: 10.1111/j.1464-0597.2007.00325.x]
54. Communication and Persuasion Central and Peripheral Routes to Attitude Change. New York: Springer; 1986.
55. Oinas-Kukkonen H, Harjumaa M. Persuasive systems design: key issues, process model, and system features. Commun Assoc Inf Syst 2009;24(1):28. [doi: 10.17705/1cais.02428]
56. Maenhout L, Peuters C, Cardon G, Compernolle S, Crombez G, DeSmet A. Participatory development and pilot testing of an adolescent health promotion chatbot. Front Public Health 2021 Nov 11;9:724779 [FREE Full text] [doi: 10.3389/fpubh.2021.724779] [Medline: 34858919]
57. Braveman PA, Cubbin C, Egerter S, Chideya S, Marchi KS, Metzler M, et al. Socioeconomic status in health research: one size does not fit all. JAMA 2005 Dec 14;294(22):2879-2888. [doi: 10.1001/jama.294.22.2879] [Medline: 16352796]
58. Gezondheid en welzijn. Health Behaviour in School-Aged Children. URL: http://www.jongeren-en-gezondheid.ugent.be/materialen/factsheets-vlaanderen/gezondheid-en-welzijn/ [accessed 2022-04-13]
59. Hartley JE, Levin K, Currie C. A new version of the HBSC Family Affluence Scale - FAS III: Scottish qualitative findings from the international FAS development study. Child Indic Res 2016 Aug 2;9(1):233-245 [FREE Full text] [doi: 10.1007/s12187-015-9325-3] [Medline: 26925177]
60. Health Behaviour in School-aged Children (Hbsc) Study Protocol: Background, Methodology and Mandatory Items for the 2017/18 Survey. St Andrews: CAHRU; 2018.
61. Currie C, Molcho M, Boyce W, Holstein B, Torsheim T, Richter M. Researching health inequalities in adolescents: the development of the health Behaviour in School-Aged Children (HBSC) family affluence scale. Soc Sci Med 2008 Mar;66(6):1429-1436. [doi: 10.1016/j.socscimed.2007.11.024] [Medline: 18179852]
62. Torsheim T, Cavallo F, Levin KA, Schnohr C, Mazur J, Niclasen B, FAS Development Study Group. Psychometric validation of the revised family affluence scale: a latent variable approach. Child Indic Res 2016;9:771-784 [FREE Full text] [doi: 10.1007/s12187-015-9339-x] [Medline: 27489572]
63. Boyce W, Torsheim T, Currie C, Zambon A. The family affluence scale as a measure of national wealth: validation of an adolescent self-report measure. Soc Indic Res 2006 Apr 20;78(3):473-487. [doi: 10.1007/s11205-005-1607-6]
64. Factsheet demografische context. HSBC. URL: https://www.jongeren-en-gezondheid.ugent.be/wordpress/wp-content/uploads/2019/09/HBSC201718_Facstheet_sociodemografie.pdf [accessed 2022-04-13]
65. Technisch verslag JOP-schoolmonitor 2018. jeugdonderzoeksplatform. URL: https://www.jeugdonderzoeksplatform.be/files/Technischverslag_JOP-schoolmonitor_2018.pdf [accessed 2022-04-13]




XSL•FO
RenderX

66. Postel MG, de Haan HA, ter Huurne ED, van der Palen J, Becker ES, de Jong CA. Attrition in web-based treatment for problem drinkers. J Med Internet Res 2011 Dec 27;13(4):e117 [FREE Full text] [doi: 10.2196/jmir.1811] [Medline: 22201703]
67. Van der Mispel C, Poppe L, Crombez G, Verloigne M, De Bourdeaudhuij I. A self-regulation-based eHealth intervention to promote a healthy lifestyle: investigating user and website characteristics related to attrition. J Med Internet Res 2017 Jul 11;19(7):e241 [FREE Full text] [doi: 10.2196/jmir.7277] [Medline: 28698168]
68. Schroé H, Crombez G, De Bourdeaudhuij I, Van Dyck D. Investigating when, which, and why users stop using a digital health intervention to promote an active lifestyle: secondary analysis with a focus on health action process approach-based psychological determinants. JMIR Mhealth Uhealth 2022 Jan 31;10(1):e30583 [FREE Full text] [doi: 10.2196/30583] [Medline: 35099400]
69. Rich JT, Neely JG, Paniello RC, Voelker CC, Nussenbaum B, Wang EW. A practical guide to understanding Kaplan-Meier curves. Otolaryngol Head Neck Surg 2010 Sep;143(3):331-336 [FREE Full text] [doi: 10.1016/j.otohns.2010.05.007] [Medline: 20723767]
70. Clark TG, Bradburn MJ, Love SB, Altman DG. Survival analysis part I: basic concepts and first analyses. Br J Cancer 2003 Jul 21;89(2):232-238 [FREE Full text] [doi: 10.1038/sj.bjc.6601118] [Medline: 12865907]
71. Bradburn MJ, Clark TG, Love SB, Altman DG. Survival analysis part II: multivariate data analysis--an introduction to concepts and methods. Br J Cancer 2003 Aug 04;89(3):431-436 [FREE Full text] [doi: 10.1038/sj.bjc.6601119] [Medline: 12888808]
72. Michie S, Yardley L, West R, Patrick K, Greaves F. Developing and evaluating digital interventions to promote behavior change in health and health care: recommendations resulting from an international workshop. J Med Internet Res 2017 Jun 29;19(6):e232 [FREE Full text] [doi: 10.2196/jmir.7126] [Medline: 28663162]
73. Chan A, Kow R, Cheng JK. Adolescents' perceptions on smartphone applications (Apps) for health management. J Mobile Technol Med 2017 Aug;6(2):47-55. [doi: 10.7309/jmtm.6.2.6]
74. Strömmer S, Shaw S, Jenner S, Vogel C, Lawrence W, Woods-Townsend K, et al. How do we harness adolescent values in designing health behaviour change interventions? A qualitative study. Br J Health Psychol 2021 Nov 04;26(4):1176-1193. [doi: 10.1111/bjhp.12526] [Medline: 33945194]
75. Geraghty AW, Torres LD, Leykin Y, Pérez-Stable EJ, Muñoz RF. Understanding attrition from international internet health interventions: a step towards global eHealth. Health Promot Int 2013 Sep;28(3):442-452 [FREE Full text] [doi: 10.1093/heapro/das029] [Medline: 22786673]
76. Christensen H, Griffiths KM, Mackinnon AJ, Brittliffe K. Online randomized controlled trial of brief and full cognitive behaviour therapy for depression. Psychol Med 2006 Dec;36(12):1737-1746. [doi: 10.1017/S0033291706008695] [Medline: 16938144]
77. Ludden GD, van Rompay TJ, Kelders SM, van Gemert-Pijnen JE. How to increase reach and adherence of web-based interventions: a design research viewpoint. J Med Internet Res 2015 Jul 10;17(7):e172 [FREE Full text] [doi: 10.2196/jmir.4201] [Medline: 26163456]
78. Kirkova-Bogdanova A. Standards in mobile health and fitness applications. Knowl Int J 2021;46(3):441-444.
79. Nicholas J, Proudfoot J, Parker G, Gillis I, Burckhardt R, Manicavasagar V, et al. The ins and outs of an online bipolar education program: a study of program attrition. J Med Internet Res 2010 Dec 19;12(5):e57 [FREE Full text] [doi: 10.2196/jmir.1450] [Medline: 21169169]
80. Christensen H, Mackinnon A. The law of attrition revisited. J Med Internet Res 2006 Sep 29;8(3):e20; author reply e21 [FREE Full text] [doi: 10.2196/jmir.8.3.e20] [Medline: 17032636]
81. Sieverink F. Opening the Black Box of eHealth: A Mixed Methods Approach for the Evaluation of Personal Health Records. Enschede: University of Twente; 2017.
82. Yardley L, Spring BJ, Riper H, Morrison LG, Crane DH, Curtis K, et al. Understanding and promoting effective engagement with digital behavior change interventions. Am J Prev Med 2016 Nov;51(5):833-842. [doi: 10.1016/j.amepre.2016.06.015] [Medline: 27745683]
83. Torous J, Lipschitz J, Ng M, Firth J. Dropout rates in clinical trials of smartphone apps for depressive symptoms: a systematic review and meta-analysis. J Affect Disord 2020 Feb 15;263:413-419. [doi: 10.1016/j.jad.2019.11.167] [Medline: 31969272]
84. Mendonça G, Cheng LA, Mélo EN, de Farias Júnior JC. Physical activity and social support in adolescents: a systematic review. Health Educ Res 2014 Oct;29(5):822-839. [doi: 10.1093/her/cyu017] [Medline: 24812148]
85. Hagquist CE. Health inequalities among adolescents: the impact of academic orientation and parents' education. Eur J Public Health 2007 Feb 14;17(1):21-26. [doi: 10.1093/eurpub/ckl087] [Medline: 16777839]
86. Svedberg P, Nygren JM, Staland-Nyman C, Nyholm M. The validity of socioeconomic status measures among adolescents based on self-reported information about parents occupations, FAS and perceived SES; implication for health related quality of life studies. BMC Med Res Methodol 2016 Apr 29;16:48 [FREE Full text] [doi: 10.1186/s12874-016-0148-9] [Medline: 27130331]
87. Bannink R, Broeren S, Joosten-van Zwanenburg E, van As E, van de Looij-Jansen P, Raat H. Effectiveness of a web-based tailored intervention (E-health4Uth) and consultation to promote adolescents' health: randomized controlled trial. J Med Internet Res 2014 May 30;16(5):e143 [FREE Full text] [doi: 10.2196/jmir.3163] [Medline: 24878521]




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88. Kohl LF, Crutzen R, de Vries NK. Online prevention aimed at lifestyle behaviors: a systematic review of reviews. J Med Internet Res 2013 Jul 16;15(7):e146 [FREE Full text] [doi: 10.2196/jmir.2665] [Medline: 23859884]
89. Richter M, Vereecken CA, Boyce W, Maes L, Gabhainn SN, Currie CE. Parental occupation, family affluence and adolescent health behaviour in 28 countries. Int J Public Health 2009;54(4):203-212. [doi: 10.1007/s00038-009-8018-4] [Medline: 19347249]
90. Richter M, Kuntsche E, de Looze M, Pförtner TK. Trends in socioeconomic inequalities in adolescent alcohol use in Germany between 1994 and 2006. Int J Public Health 2013 Oct 9;58(5):777-784. [doi: 10.1007/s00038-013-0486-x] [Medline: 23835868]
91. Galobardes B, Shaw M, Lawlor DA, Lynch JW, Davey Smith G. Indicators of socioeconomic position (part 1). J Epidemiol Community Health 2006 Jan 01;60(1):7-12 [FREE Full text] [doi: 10.1136/jech.2004.023531] [Medline: 16361448]
92. Missinne S, Neels K, Bracke P. Reconsidering inequalities in preventive health care: an application of cultural health capital theory and the life-course perspective to the take-up of mammography screening. Sociol Health Illn 2014 Nov;36(8):1259-1275. [doi: 10.1111/1467-9566.12169] [Medline: 25470325]
93. Gagné T, Frohlich KL, Abel T. Cultural capital and smoking in young adults: applying new indicators to explore social inequalities in health behaviour. Eur J Public Health 2015 Oct;25(5):818-823. [doi: 10.1093/eurpub/ckv069] [Medline: 25862433]
94. Cushing CC, Bejarano CM, Ortega A, Sayre N, Fedele DA, Smyth JM. Adaptive mHealth intervention for adolescent physical activity promotion. J Pediatr Psychol 2021 Jun 03;46(5):536-546. [doi: 10.1093/jpepsy/jsaa125] [Medline: 33484137]
95. van Gemert-Pijnen JE, Nijland N, van Limburg M, Ossebaard HC, Kelders SM, Eysenbach G, et al. A holistic framework to improve the uptake and impact of eHealth technologies. J Med Internet Res 2011 Dec 05;13(4):e111 [FREE Full text] [doi: 10.2196/jmir.1672] [Medline: 22155738]
96. Vandelanotte C, Müller AM, Short CE, Hingle M, Nathan N, Williams SL, et al. Past, present, and future of eHealth and mHealth research to improve physical activity and dietary behaviors. J Nutrition Educ Behav 2016 Mar;48(3):219-28.e1. [doi: 10.1016/j.jneb.2015.12.006] [Medline: 26965100]


## Abbreviations

**FAS:** Family Affluence Scale
**HBSC:** Health Behavior in School-Aged Children
**mHealth:** mobile health
**RQ:** research question
**SES:** socioeconomic status


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Original Paper

# Early Detection of Neurodevelopmental Disorders of Toddlers and Postnatal Depression by Mobile Health App: Observational Cross-sectional Study

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## Abstract

**Background:** Delays in the diagnosis of neurodevelopmental disorders (NDDs) in toddlers and postnatal depression (PND) in mothers are major public health issues. In both cases, early intervention is crucial.

**Objective:** We aimed to assess if a mobile app named Malo can reduce delay in the recognition of NDD and PND.

**Methods:** We performed an observational, cross-sectional, data-based study in a population of young parents with a minimum of 1 child under 3 years of age at the time of inclusion and using Malo on a regular basis. We included the first 4000 users matching the criteria and agreeing to participate between November 11, 2021, and January 14, 2022. Parents received monthly questionnaires via the app, assessing skills on sociability, hearing, vision, motricity, language of their infants, and possible autism spectrum disorder. Mothers were also requested to answer regular questionnaires regarding PND, from 4-28 weeks after childbirth. When any patient-reported outcomes matched predefined criteria, an in-app notification was sent to the user, recommending the booking of an appointment with their family physician or pediatrician. The main outcomes were the median age of the infant at the time of notification for possible NDD and the median time of PND notifications after childbirth. One secondary outcome was the relevance of the NDD notification for a consultation as assessed by the physicians.

**Results:** Among 4242 children assessed by 5309 questionnaires, 613 (14.5%) had at least 1 disorder requiring a consultation. The median age of notification for possible autism spectrum, vision, audition, socialization, language, or motor disorders was 11, 9, 17, 12, 22, and 4 months, respectively. The sensitivity of the alert notifications of suspected NDDs as assessed by the physicians was 100%, and the specificity was 73.5%. Among 907 mothers who completed a PND questionnaire, highly probable PND was detected in 151 (16.6%) mothers, and the median time of detection was 8-12 weeks.

**Conclusions:** The algorithm-based alert suggesting NDD was highly sensitive with good specificity as assessed by real-life practitioners. The app was also efficient in the early detection of PND. Our results suggest that the regular use of this multidomain familial smartphone app would permit the early detection of NDD and PND.

**Trial Registration:** ClinicalTrials.gov NCT04958174; https://clinicaltrials.gov/ct2/show/NCT04958174



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*(JMIR Mhealth Uhealth 2022;10(5):e38181)* doi:10.2196/38181

**KEYWORDS**

early detection; NDD; neurodevelopmental disorder; ASD; autism spectrum disorder; PND; postnatal depression; mHealth; mobile health; real-world study; autism; parenting; pediatric; children; mobile phone; smartphone; mobile health app; digital health intervention; digital product; algorithm

## Introduction

Electronic patient-reported outcomes (ePROs) by smartphone apps have demonstrated their value in the early detection of disease and relapse as well as for prevention or triage of patients in several diseases [1-3]. Patients report symptoms using a dedicated questionnaire. When some criteria meet a pre-established threshold, the prescribing professional is notified and can intervene. Thus, ePROs can reduce delays in diagnosis and treatment while alleviating the burden of monitoring.

After birth, the mother-child dyad can be impacted by impairments that are either undetected or detected too late. Among these impairments, a neurodevelopmental disorder (NDD) such as autism spectrum disorder (ASD) affects 1 in 166 children [4]. The average time to diagnosis is approximately 4 years, whereas consensus statements indicate that a diagnosis could be made as early as 12 or 18 months of age [5-9]. Interestingly, parents are the main contributors to the NDD screening of their children [10]. Other disorders that deserve early screening are hearing disorders, which are observed in 1 in 300 children at age 3 years, and the main visual disorder in toddlers, amblyopia, which is observed with a prevalence of 3% [11-14]. It is, therefore, crucial to provide parents with screening tools and to recommend that they consult a physician at the first symptoms.

Postnatal depression (PND) of mothers is another good example of an underdiagnosed disorder with severe consequences. PND—an episode of depression occurring during the first year after childbirth—has a prevalence of 17.7% and may have a negative impact on the synchrony or receptivity loop that is crucial to the proper neurodevelopment of the baby [15,16].

All these disorders can benefit tremendously from early detection by ePRO questionnaires for parents and their children, which would enable early intervention.

We thus developed Malo, an “all-in-one” multidomain digital health record ePRO app for smartphones, aiming to facilitate early screening of NDDs in children from birth to age 3 years and PND in mothers. We assessed the performance of this app in an observational cross-sectional, data-based study.

## Methods

### Ethics Approval

We ran an ecological, observational, cross-sectional, data-based study. Our study was approved by the French National Health Data Institute (HDH approval number F20210420115840), which ensures ethical conduct in human subject research regarding data confidentiality and safety.

### Population

Our users were recruited during a 2-month period, following a French national media campaign that was disseminated through social media between November 11 and 18, 2021. We selected a wide array of networks, both professional (eg, LinkedIn) and nonprofessional (eg, Facebook, Instagram, TikTok, and Twitter). A national and regional press campaign also relayed the following message (in print, audio, and television): “Use Malo to improve follow-up of neurodevelopment of your toddler and your mental burden.” Finally, we also used Google ads and Facebook ads to encourage recruitment for this study. To participate, individuals were required to download the app (Malo) on the Android or Apple app stores, create an account and electronically confirm their agreement to the applicable terms and conditions of the app, then opt in to our research. Enrollment in the study was strictly optional. Recruitment was open with no exclusion criteria. The only inclusion criteria were to download the app and give informed consent (in-app). The study population target was 4000 users to obtain at least 30 possible cases of ASD screened by the app.

### Data Collection

Data collection was embedded in the app. Data were anonymously collected in a French labelled health data cloud. The approval number for our human subjects review was F20210420115840. Respondents anonymously self-entered the age and gender of their infants. The app also allowed for the entry of the children’s height, weight, vaccination status, medical background, and ongoing or previous treatments. Questionnaires and scales, each containing 25-50 questions assessing neurodevelopment skills, were automatically submitted every month from birth to 9 months, then at 11, 12, 16, 18, 21, 24, 30, and 36 months, and were focused on language, socialization, hearing and vision, and motricity.

Questionnaires and notifications were based on French health authorities’ reports, international recommendations, and experts’ agreements [17,18].

The questionnaire for the screening of postnatal depression was submitted every 21 days between 4 and 28 weeks after childbirth, using a modified questionnaire of the Edinburgh Postnatal Depression Scale adapted to self-assessment.

### Threshold-Based In-App Notification

Notifications were sent automatically to the user if some symptoms matched predefined criteria and a physician consultation was recommended.

Regarding NDDs, once a threshold of concern was reached, 2 types of notifications were sent: type A notifications recommended discussing their symptoms with a general practitioner (GP) and type B notifications recommended contacting a pediatrician.



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Regarding maternal depression, there were 3 grades of notifications sent to the mother: grade 0 (score lower than 25) was associated with a message indicating that everything is ok; grade 1 (score between 26 and 50) was associated with a recommendation to talk about symptoms with a close relative; grade 2 (score between 51 and 65) recommended that they quickly discuss their symptoms with a family doctor; and grade 3 (score higher than 65) recommended that they meet a family doctor as soon as possible (Multimedia Appendices 1-4).

The main outcome was the median age of possible NDD notification of infants. The secondary outcomes were (1) the median time of the mothers' PND notifications after childbirth; (2) the rates of adoption (assessed by the percentage of users who filled in at least 1 questionnaire); (3) user satisfaction regarding app functionality, the relevance of advice received, and the level of support in child follow-up; and (4) the relevance of the NDD notifications assessed by physicians, using a specific optional survey asking parents the following questions:

- In the past month, did your doctor detect a developmental disorder in your child during a follow-up consultation? YES/NO
- If you had a notification by Malo, did you follow the recommendation of the app to visit a physician? YES/NO
- If YES, which health professional did you contact? GP or pediatrician?
- Which of the following reflects the physicians' reply? (1) The notification is not relevant, (2) the notification is relevant and a medical surveillance of the evolution of the symptom is needed, (3) the advice of an expert is needed, or (4) a treatment is indicated.

### Analysis

The analysis was performed when at least 4000 users downloaded the app and filled in at least 1 infant's questionnaire of neurodevelopment screening.

Sensitivity, specificity, predictive positive and negative values, and the Youden index of the algorithms triggering notifications of suspected NDDs were calculated according to the physician's feedback. A notification was considered relevant if a physician suggested a specific medical surveillance of the disorder or the consultation of an expert or a therapist.

Chi-square test was used in 2×2 tables to assess the statistical association between the medical relevance of the notification (relevant or not) and the notification results (notification or no notification of a possible NDD). We also assessed the rate of probable PND of mothers having a score >50 in the survey.

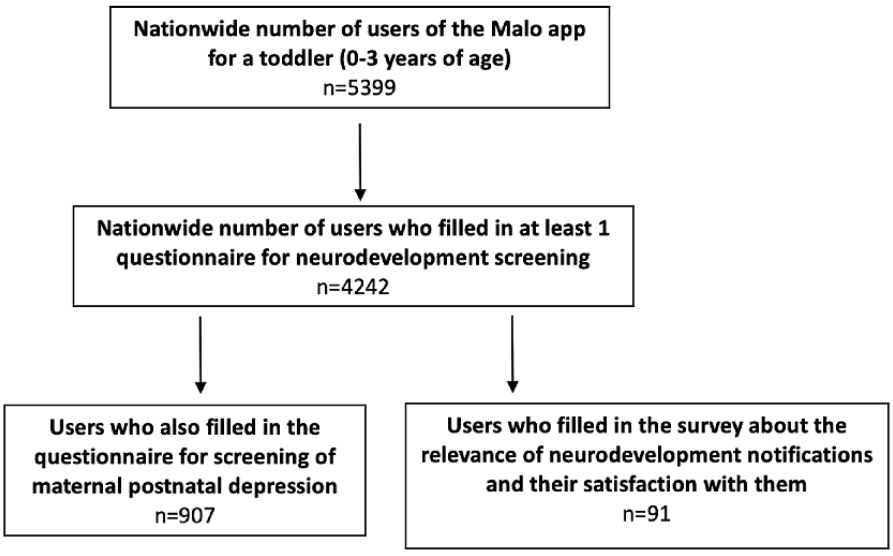
The level of statistical significance was 5% for all statistical tests (exploratory tests).

## Results

### Overview

Between November 11, 2021, and January 14, 2022, 6426 users downloaded the app, and at least 1 questionnaire was filled in for 4242 children (fill rate=66.0%), leading to the analysis of 5309 questionnaires and 126,539 questions for pediatric neurodevelopment assessment. Data analysis was performed at the end of January 2022 (Figure 1).

**Figure 1.** Flowchart of users of the Malo app. Among 91 respondents, 54 received notification of a possible neurodevelopmental disorder requiring a physician visit and reported the physician's assessment of the relevance of the notification.



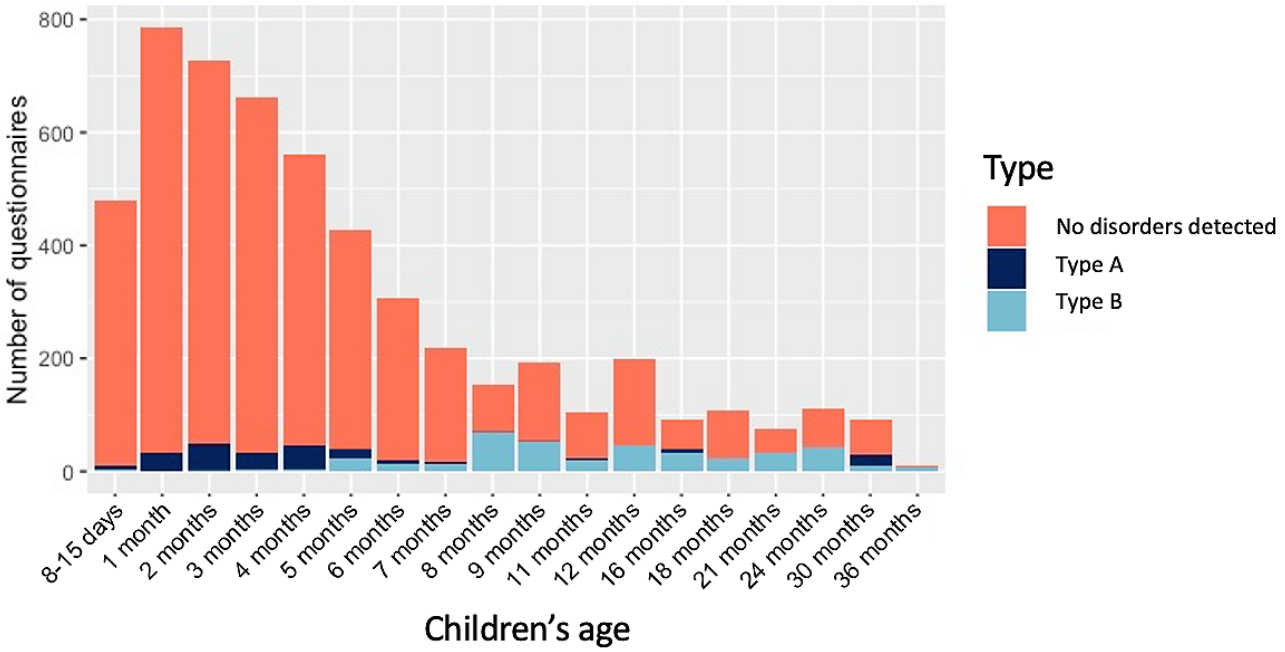

The median age of the toddlers assessed by the questionnaires was 3.9 months, and 2202 (51.9%) were boys.

During the 8 weeks of recruitment, among the 4242 children, 216 (5.1%) had a type A notification of a possible disorder (recommended a GP visit), and 397 (9.4%) had a type B notification (recommended a pediatrician visit) (Figure 2).



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**Figure 2.** Distribution of the notifications of possible neurodevelopmental disorders and their type according to the toddler's age. There were 2 types of notifications: type A recommended talking about the symptoms with a general practitioner and type B suggested meeting with a pediatrician.



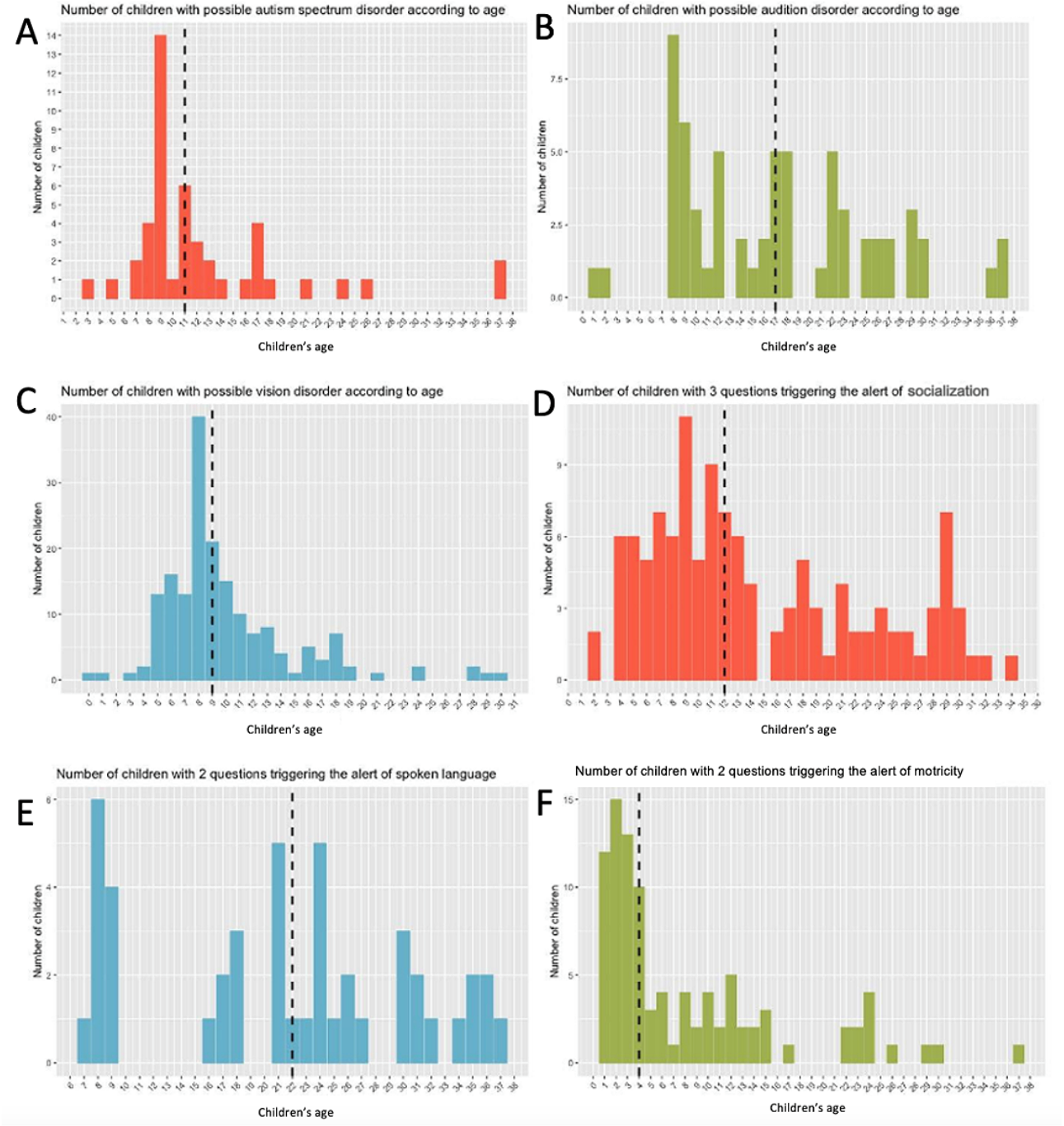

There were 0.9% (39/4242) toddlers with notifications for possible ASD, and the median age of alert was 11 months.

The rates of possible vision and auditory disorders were 11.3% (481/4242) and 1.8% (78/4242), respectively, and the median age of children at the time of such alerts was 9 and 17 months, respectively. The rate of possible socialization disorders was 2.8% (120/4242), and the median age of alerts was 12 months. The rate of possible language disorders was 1.1% (45/4242), and the median age of alerts was 22 months. The rate of possible motricity disorder was 2.2% (95/4242), and the median age of alerts was 4 months (Figure 3).



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**Figure 3.** Number of children with possible neurodevelopmental disorders according to age (months): (A) autism spectrum disorder, (B) auditory, (C) visual, (D) socialization, (E) language, and (F) motricity. The dashed line is the median time of detection by the app.




## Analysis of the Assessment of the Relevance of the Alerts by the Physician

Among the 91 users who agreed to answer the survey concerning the physician consultation, 27 had no alert, and 64 had received an alert of a possible NDD, which suggested a visit to their physician.

Among users who received a notification suggesting a visit to their physician for a neurodevelopmental issue, 84.4% (54/64) answered "YES" to the question "If you had a notification, did you follow the recommendation of the app to visit a physician?" Among users who visited a physician, 51.9% (28/54) met with a family doctor and 48.1 % (26/54) met with a pediatrician (48.1%, 26/54).

The analysis of the clinical relevance of the alerts, as assessed by the physician, showed a sensitivity of 100%, a specificity of 73.5%, a positive predictive value of 70.4%, a negative predictive value of 100%, and a Youden index of 72% ($P$<.001). Among the 38 children with true positive notifications of a possible NDD suggested by the app, medical surveillance of the evolution of the symptoms was proposed in 31 cases (81.6% of relevant notifications), the advice of an expert was needed in 2 cases (5.3%), treatment was immediately initiated in 4 cases (10.5%), and another medical act was executed in 1 case (2.6%).



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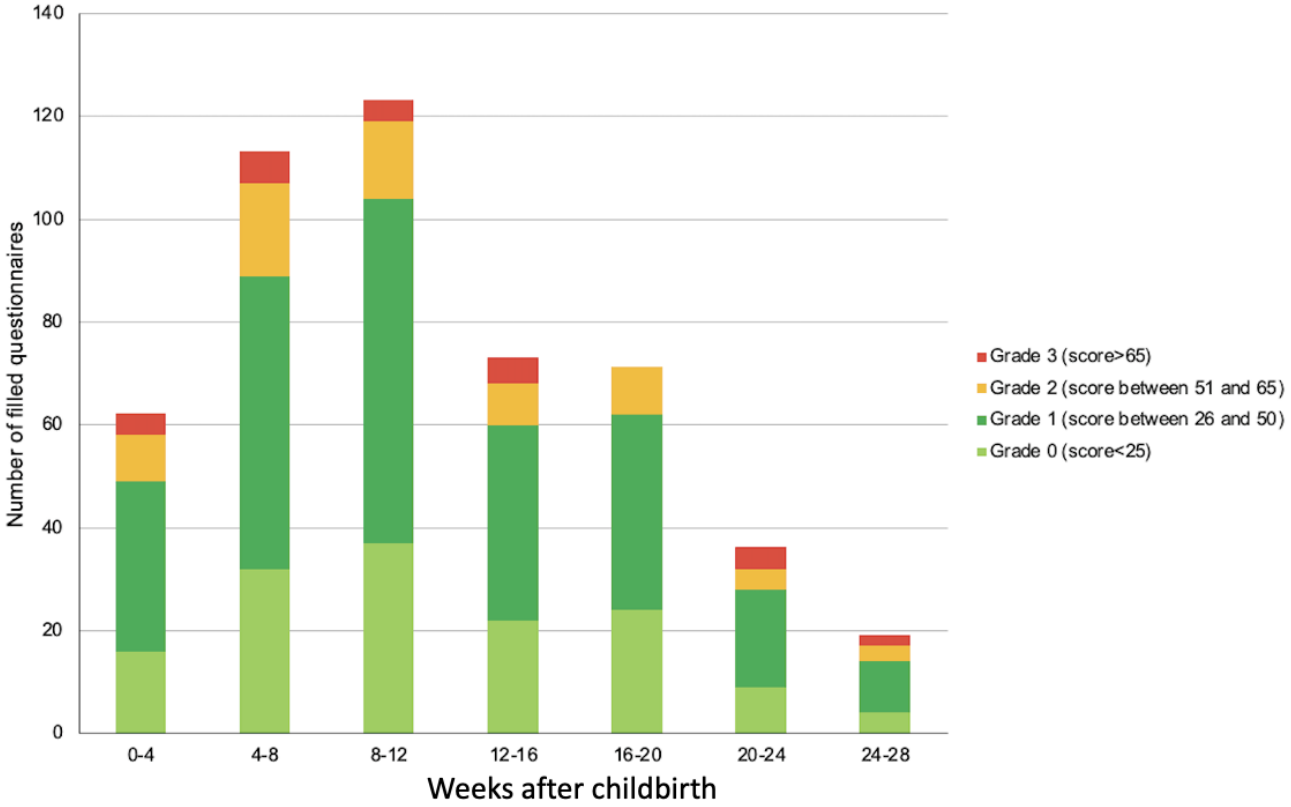
### Satisfaction Analysis

Among users who filled in the satisfaction survey, 77.4% (82/106) reported that the app improved the follow-up of their child, 95.3% (101/106) found the app easy to use, and 98.1% (104/106) reported that the advice was adapted to the follow-up of the development of their child.

### Screening of PND

Among 907 mothers who completed PND questionnaires, 151 (16.6%) were suspected to have PND. The median time of detection was between 8 and 12 weeks after childbirth, and 370 (40.8%) of the detections occurred before the eighth week after childbirth (Figure 4).

**Figure 4.** The distribution of the results of the maternal postnatal depression screening according to the number of weeks after childbirth. Only grade 2 or 3 triggered a notification to visit a physician.




## Discussion

### Principal Findings

Our study is the first to prospectively assess, in a "real-world" manner, the benefit of mother-child dyad follow-up by a dedicated multidomain familial mobile health (mHealth) smartphone app providing early detection of NDDs and maternal PND.

The main result is that 0.9% (39/4242) of toddlers were identified as potentially having ASD, and the median age of the alert was 11 months. This is very close to the 0.6% ASD rate in the general population [4]. Our detection age is at least 3 years earlier than what is usually observed, as the mean age of disease detection is usually late (4-6.8 years for ASD) [10].

EPROs enable users and patients to have relevant clinical effects on many outcomes such as quality of life, early detection of events, and best orientation to specific care even for new diseases such as COVID-19 [1-3,19-21].

In our study, we show that ePROs may help parents to optimize the neurodevelopment follow-up of their children. In a recent survey from France, the identification of the first symptoms of NDDs was done by parents (without a dedicated ePRO) in 61% of cases and by a health professional in only 14% of cases [10]. That is why we have chosen to provide parents with a smartphone app that allows for a relevant and scalable screening of NDDs based on validated questionnaires. The instruments allowed parents to screen for autism spectrum, language, socialization, hearing, vision, and motricity disorders and triggered alerts when the app recommended a consultation. Since early detection of ASD proved to be achievable and stable by 12-18 months of age in a recent study of 1269 infants, we found it worthwhile to provide parents with an instrument for neurodevelopmental skills assessment as early as possible [5-9]. The median ages of notification for possible autism spectrum, vision, and audition disorders were 11, 6, and 18 months, respectively. The median ages of notification for possible socialization, language, and motor disorders were 12, 22, and 4 months, respectively. These results are very encouraging and confirm the feasibility and relevance of familial multidomain screening of NDDs via a smartphone app. Early screening allows for early diagnosis and interventions as reported by works on the efficacy of early treatments of cases among very young children and recent promising studies on early interventions [22-24]. Moreover, the early detection of visual, audition,



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language, and motor skill disorders is also associated with better prognosis, especially when they are diagnosed before 3 years of age [25-27].

We also performed an analysis of physician feedback after an alert about a possible NDD. Most users (54/64, 84.4%) followed the recommendation of the app to visit their family doctor or pediatrician after an alert. The physician agreed with the relevance of the alert in 70.4% of cases (predictive positive value). Among this 70.4%, the physician triggered a specific medical surveillance in 81.6% of notifications or initiated a treatment or referred parents to an expert. The sensitivity and the negative predictive value of notifications were 100%, and the specificity was 73.5%. Although these data are declarative by users and ASD diagnosis was not directly confirmed by physicians, we can suppose that the specificity of the ASD notifications is close to Pierce et al's [9] results, showing an overall stability or specificity of an autism spectrum diagnosis of 84% at earlier than 18 months of age through a universal screening program in primary care. In a recent diagnostic accuracy study including 13,511 children aged 11-42 months, Barbaro et al [28] showed an 83% positive predictive value and 99% estimated negative predictive value of the Social Attention and Communication Surveillance-Revised tool for autism identification when it was used by nurses for 12-month-old children. Our results seem to be similar when parents perform a screening using our app.

To improve the neurodevelopment of the child, we added an early PND screening tool to the ePRO instrument because PND is well known to disrupt the crucial mother-infant relationship on which optimal child development depends. It is the most common complication associated with childbirth, and it may exert harmful effects on children such as increased risk of ASD [29]. It is usually underdetected or detected after many months. The early treatment of PND is effective and does not necessarily require drugs to improve symptoms in the earliest stages [30]. Its prevalence in France is 18% and we found that 151 (16.6%) of users had probable PND in our cohort. Interestingly, 40.8% of the detections occurred before the eighth week after childbirth, which is within the recommended time frame to begin treatment for this underdetected disorder [15,16]. As the app sent notifications to the user recommending a visit to a family doctor if depression was suspected, we think that this early screening may contribute to an improvement in care and may reduce the negative impact of PND on pediatric neurodevelopment.

The rate of users who filled in at least 1 questionnaire regarding toddler neurodevelopment was high (66.0%) and the rate of parents who followed recommendations for an early visit to the physician was 84.4% (54/64). This underscores parents' interest and confidence in this instrument, as the average response rate reported in the literature for general eHealth apps is 49% [31]. We made the choice to incorporate 2 domains of health assessment in a single smartphone to avoid requiring families to use 2 separate apps.

The levels of satisfaction were also high (between 77.4% and 98.1% according to the assessed domains) and contributed to the high rate of adoption. A high level of satisfaction for eHealth solutions is defined as rates higher than 75% [32,33].

## Study Limitations

Limitations of our study are the following. First, sample selection bias is always possible in the absence of randomization, due to social media recruitment modalities and because using the mobile app requires possession of a smartphone. We could have asked users questions about their educational level, practice classification (rural or urban), technical experience, and marital status, but we designed the app to collect as little personal data as possible. However, the very high rate of smartphone penetration in France (92% in a 2018 survey) among people aged 25-39 years led us to believe that the risk of a selection bias associated with smartphone use was low. Nonetheless, we do note that parents without smartphones cannot benefit from the app [34].

Because the social media recruitment strategy could have selected for more employed people in urban areas, we complemented the recruitment with national and regional press campaigns and the support of health insurance companies who also phoned and sent postal mail to members in the required age group. In France, everyone aged 25-45 years has basic and complementary health insurance; therefore, we think we reached as many potential users as possible, regardless of their socioeconomic status. However, the women who agreed to participate in the PND study may more likely have been first-time mothers with a higher level of education compared to the general population. This was recently observed in a longitudinal study from Italy on predictors of PND [35]. The impact of this potential selection on the PND screening rate is probably low, as the observed incidence result in our study (n=151, 16.6%) is close to the rate in the general population (17.7%) [16]. The second limitation was that the data were declarative by users with a comparative arm, and ASD diagnoses were not directly confirmed by physicians. Third, the attrition rate (ie, the discontinuation of eHealth app use) was not assessed, but it could be interesting to study whether the benefit of early detection of NDD is maintained over time by prolonged use [36].

## Conclusions

To our knowledge, this multidomain mHealth app dedicated to both the early detection of NDDs in toddlers and the early detection of maternal PND is the first app with real-life data of clinical relevance on this topic. Results suggest that a multidomain familial mHealth app is suitable and effective for regular use in the mother-child dyad follow-up.

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analyzed, and interpreted the data; prepared, reviewed, and approved the manuscript; and made the decision to submit the manuscript for publication.

## Authors' Contributions

FD had full access to all data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. FD and OB conceptualized and designed the study. All authors contributed to the acquisition, analysis, and interpretation of the data and drafting the manuscript. Critical revision of the manuscript for important intellectual content was done by FD, FLG, AG, and OB. FD, ALS, and BD were in charge of statistical analysis as well as administrative, technical, and material support.

## Conflicts of Interest

FD reports receiving personal fees from AstraZeneca, Ipsen, Kelindi, Pfizer, Chugai, and Roche and has stocks in Kelindi. FLG, AG, and MD have stocks in Kelindi. JDZ is an investor in the company derived from the technological product analyzed in the article. The other authors declare no conflicts of interest.

Multimedia Appendix 1
Screenshot of the Malo app showing questions about motricity.
[PNG File , 187 KB - mhealth_v10i5e38181_app1.png ]

Multimedia Appendix 2
Screenshot of the Malo app showing that everything is ok.
[PNG File , 115 KB - mhealth_v10i5e38181_app2.png ]

Multimedia Appendix 3
Screenshot of the Malo app showing questions about postnatal depression.
[PNG File , 444 KB - mhealth_v10i5e38181_app3.png ]

Multimedia Appendix 4
Screenshot of the Malo app showing notification to visit a physician for potential postnatal depression.
[PNG File , 614 KB - mhealth_v10i5e38181_app4.png ]

## References

1. Denis F, Basch E, Septans A, Bennouna J, Urban T, Dueck AC, et al. Two-year survival comparing web-based symptom monitoring vs routine surveillance following treatment for lung cancer. JAMA 2019 Jan 22;321(3):306-307 [FREE Full text] [doi: 10.1001/jama.2018.18085] [Medline: 30667494]
2. Galmiche S, Rahbe E, Fontanet A, Dinh A, Bénézit F, Lescure F, et al. Implementation of a self-triage web application for suspected COVID-19 and its impact on emergency call centers: observational study. J Med Internet Res 2020 Nov 23;22(11):e22924 [FREE Full text] [doi: 10.2196/22924] [Medline: 33147165]
3. Basch E, Deal AM, Dueck AC, Scher HI, Kris MG, Hudis C, et al. Overall survival results of a trial assessing patient-reported outcomes for symptom monitoring during routine cancer treatment. JAMA 2017 Jul 11;318(2):197-198 [FREE Full text] [doi: 10.1001/jama.2017.7156] [Medline: 28586821]
4. GBD 2019 Mental Disorders Collaborators. Global, regional, and national burden of 12 mental disorders in 204 countries and territories, 1990-2019: a systematic analysis for the global burden of disease study 2019. Lancet Psychiatry 2022 Feb;9(2):137-150 [FREE Full text] [doi: 10.1016/S2215-0366(21)00395-3] [Medline: 35026139]
5. Wetherby AM, Brosnan-Maddox S, Peace V, Newton L. Validation of the infant-toddler checklist as a broadband screener for autism spectrum disorders from 9 to 24 months of age. Autism 2008 Sep 01;12(5):487-511 [FREE Full text] [doi: 10.1177/1362361308094501] [Medline: 18805944]
6. Turner-Brown LM, Baranek GT, Reznick JS, Watson LR, Crais ER. The first year inventory: a longitudinal follow-up of 12-month-old to 3-year-old children. Autism 2013 Sep;17(5):527-540 [FREE Full text] [doi: 10.1177/1362361312439633] [Medline: 22781058]
7. Chlebowski C, Robins DL, Barton ML, Fein D. Large-scale use of the modified checklist for autism in low-risk toddlers. Pediatrics 2013 Apr;131(4):e1121-e1127 [FREE Full text] [doi: 10.1542/peds.2012-1525] [Medline: 23530174]
8. Robins DL, Casagrande K, Barton M, Chen CA, Dumont-Mathieu T, Fein D. Validation of the modified checklist for Autism in toddlers, revised with follow-up (M-CHAT-R/F). Pediatrics 2014 Jan 23;133(1):37-45 [FREE Full text] [doi: 10.1542/peds.2013-1813] [Medline: 24366990]
9. Pierce K, Gazestani VH, Bacon E, Barnes CC, Cha D, Nalabolu S, et al. Evaluation of the diagnostic stability of the early autism spectrum disorder phenotype in the general population starting at 12 months. JAMA Pediatr 2019 Jun 01;173(6):578-587 [FREE Full text] [doi: 10.1001/jamapediatrics.2019.0624] [Medline: 31034004]



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10. Ce que nous disent les personnes et les familles sur leur parcours de vie. French Government. 2020 Jun. URL: https://www.ipsos.com/sites/default/files/ct/news/documents/2020-06/etude_ipsos_tnd_2020_def.pdf [accessed 2022-04-26]
11. Dépistage des troubles de l'audition chez l'enfant: guide pratique. Ministère des Solidarités et de la Santé. 2009 Jun. URL: https://solidarites-sante.gouv.fr/IMG/pdf/Depistage_des_troubles_de_l_audition_chez_l_enfant.pdf [accessed 2022-04-26]
12. Dépistage des Troubles Visuels chez l'Enfant: Guide Pratique. 2009 Jun. URL: https://solidarites-sante.gouv.fr/IMG/pdf/Depistage_des_troubles_visuels_chez_l_enfant.pdf [accessed 2022-04-26]
13. van Beeck Calkoen EA, Engel MSD, van de Kamp JM, Yntema HG, Goverts S, Mulder M, et al. The etiological evaluation of sensorineural hearing loss in children. Eur J Pediatr 2019 Aug 31;178(8):1195-1205 [FREE Full text] [doi: 10.1007/s00431-019-03379-8] [Medline: 31152317]
14. McConaghy JR, McGuirk R. Amblyopia: detection and treatment. Am Fam Physician 2019 Dec 15;100(12):745-750 [FREE Full text] [Medline: 31845774]
15. Hahn-Holbrook J, Cornwell-Hinrichs T, Anaya I. Economic and health predictors of national postpartum depression prevalence: a systematic review, meta-analysis, and meta-regression of 291 studies from 56 countries. Front Psychiatry 2017 Feb 1;8:248 [FREE Full text] [doi: 10.3389/fpsyt.2017.00248] [Medline: 29449816]
16. O'Connor E, Rossom RC, Henninger M, Groom HC, Burda BU. Primary care screening for and treatment of depression in pregnant and postpartum women: evidence report and systematic review for the us preventive services task force. JAMA 2016 Jan 26;315(4):388-406. [doi: 10.1001/jama.2015.18948] [Medline: 26813212]
17. Troubles du neurodéveloppement Repérage et orientation des enfants à risque synthèse. Haute Autorité de Santé. 2020 Feb. URL: https://www.has-sante.fr/upload/docs/application/pdf/2020-03/fs_tnd_synthese_v2.pdf [accessed 2022-04-26]
18. Jullien S. Screening for autistic spectrum disorder in early childhood. BMC Pediatr 2021 Sep 08;21(Suppl 1):349 [FREE Full text] [doi: 10.1186/s12887-021-02700-5] [Medline: 34496788]
19. Denis F, Fontanet A, Le Douarin Y, Le Goff F, Jeanneau S, Lescure F. A self-assessment web-based app to assess trends of the COVID-19 pandemic in France: observational study. J Med Internet Res 2021 Mar 12;23(3):e26182 [FREE Full text] [doi: 10.2196/26182] [Medline: 33709945]
20. Denis F, Septans A, Periers L, Maillard J, Legoff F, Gurden H, et al. Olfactory training and visual stimulation assisted by a web application for patients with persistent olfactory dysfunction after SARS-CoV-2 infection: observational study. J Med Internet Res 2021 May 27;23(5):e29583. [doi: 10.2196/29583]
21. Denis F, Galmiche S, Dinh A, Fontanet A, Scherpereel A, Benezit F, et al. Epidemiological observations on the association between anosmia and COVID-19 infection: analysis of data from a self-assessment web application. J Med Internet Res 2020 Jun 11;22(6):e19855 [FREE Full text] [doi: 10.2196/19855] [Medline: 32496206]
22. Siu AL, Bibbins-Domingo K, Grossman DC, Baumann LC, Davidson KW, Ebell M, et al. Screening for autism spectrum disorder in young children. JAMA 2016 Feb 16;315(7):691. [doi: 10.1001/jama.2016.0018]
23. Landa RJ. Efficacy of early interventions for infants and young children with, and at risk for, autism spectrum disorders. Int Rev Psychiatry 2018 Feb 14;30(1):25-39 [FREE Full text] [doi: 10.1080/09540261.2018.1432574] [Medline: 29537331]
24. Stahmer AC, Dababnah S, Rieth SR. Considerations in implementing evidence-based early autism spectrum disorder interventions in community settings. Pediatr Med 2019 May;2:18 [FREE Full text] [doi: 10.21037/pm.2019.05.01] [Medline: 31565699]
25. Dépistage des troubles visuels chez l'enfant. Ministère des Solidarités et de la Santé. 2016 Apr 13. URL: https://tinyurl.com/mr48znau [accessed 2022-04-26]
26. Dépistage des troubles de l'audition chez l'enfant. Ministère des Solidarités et de la Santé. 2016 Apr 13. URL: https://solidarites-sante.gouv.fr/prevention-en-sante/sante-des-populations/enfants/article/depistage-des-troubles-de-l-audition-chez-l-enfant [accessed 2022-04-26]
27. Patterson JW, Armstrong V, Duku E, Richard A, Franchini M, Brian J, et al. Early trajectories of motor skills in infant siblings of children with autism spectrum disorder. Autism Res 2022 Mar 26;15(3):481-492. [doi: 10.1002/aur.2641] [Medline: 34826349]
28. Barbaro J, Sadka N, Gilbert M, Beattie E, Li X, Ridgway L, et al. Diagnostic accuracy of the social attention and communication surveillance-revised with preschool tool for early autism detection in very young children. JAMA Netw Open 2022 Mar 01;5(3):e2146415 [FREE Full text] [doi: 10.1001/jamanetworkopen.2021.46415] [Medline: 35275169]
29. Pham C, Symeonides C, O'Hely M, Sly PD, Knibbs LD, Thomson S, Barwon Infant Study Investigator Group. Early life environmental factors associated with autism spectrum disorder symptoms in children at age 2 years: a birth cohort study. Autism 2022 Jan 11:13623613211068223. [doi: 10.1177/13623613211068223] [Medline: 35012378]
30. Holt C, Gentilleau C, Gemmill AW, Milgrom J. Improving the mother-infant relationship following postnatal depression: a randomised controlled trial of a brief intervention (HUGS). Arch Womens Ment Health 2021 Dec 19;24(6):913-923. [doi: 10.1007/s00737-021-01116-5] [Medline: 33742282]
31. Patient Adoption of mHealth. IMS Institute for Healthcare Informatics. 2015 Sep. URL: https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/patient-adoption-of-mhealth.pdf [accessed 2022-04-30]
32. Denis F, Viger L, Charron A, Voog E, Dupuis O, Pointreau Y, et al. Detection of lung cancer relapse using self-reported symptoms transmitted via an internet web-application: pilot study of the sentinel follow-up. Support Care Cancer 2014 Jun 12;22(6):1467-1473. [doi: 10.1007/s00520-013-2111-1] [Medline: 24414998]




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33. Morgenstern-Kaplan D, Rocha-Haro A, Canales-Albarrán SJ, Núñez-García E, León-Mayorga Y. An app-based telemedicine program for primary care and specialist video consultations during the COVID-19 pandemic in Mexico. Telemed J E Health 2022 Jan 01;28(1):60-65. [doi: 10.1089/tmj.2021.0055] [Medline: 33733868]
34. Baromètre du numérique 2018. 2018 Dec 03. URL: https://www.credoc.fr/download/pdf/Sou/Sou2018-4439.pdf [accessed 2022-04-26]
35. Molgora S, Saita E, Barbieri Carones M, Ferrazzi E, Facchin F. Predictors of postpartum depression among Italian women: a longitudinal study. IJERPH 2022 Jan 29;19(3):1553. [doi: 10.3390/ijerph19031553]
36. Eysenbach G. The law of attrition. J Med Internet Res 2005 Mar 31;7(1):e11 [FREE Full text] [doi: 10.2196/jmir.7.1.e11] [Medline: 15829473]

## Abbreviations

**ePRO:** electronic patient-reported outcome
**GP:** general practitioner
**mHealth:** mobile health
**NDD:** neurodevelopmental disorder
**PND:** postnatal depression

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Original Paper

# Review and Analysis of German Mobile Apps for Inflammatory Bowel Disease Management Using the Mobile Application Rating Scale: Systematic Search in App Stores and Content Analysis

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## Abstract

**Background:** Patients suffering from inflammatory bowel disease (IBD) frequently need long-term medical treatment. Mobile apps promise to complement and improve IBD management, but so far there has been no scientific analysis of their quality.

**Objective:** This study evaluated the quality of German mobile apps targeting IBD patients and physicians treating IBD patients using the Mobile Application Rating Scale (MARS).

**Methods:** The German Apple App Store and Google Play Store were systematically searched to identify German IBD mobile apps for patient and physician use. MARS was used by 6 physicians (3 using Android smartphones and 3 using iPhones) to independently assess app quality. Apps were randomly assigned so that the 4 apps with the most downloads were rated by all raters and the remaining apps were rated by 1 Android and 1 iOS user.

**Results:** In total, we identified 1764 apps in the Apple App Store and Google Play Store. After removing apps that were not related to IBD (n=1386) or not available in German (n=317), 61 apps remained. After removing duplicates (n=3) and apps for congresses (n=7), journals (n=4), and clinical studies (n=6), as well as excluding apps that were available in only 1 of the 2 app stores (n=20) and apps that could only be used with an additional device (n=7), we included a total of 14 apps. The app “CED Dokumentation und Tipps” had the highest overall median MARS score at 4.11/5. On the whole, the median MARS scores of the 14 apps ranged between 2.38/5 and 4.11/5. As there was no significant difference between iPhone and Android raters, we used the Wilcoxon comparison test to calculate *P* values.

**Conclusions:** The MARS ratings showed that the quality of German IBD apps varied. We also discovered a discrepancy between app store ratings and MARS ratings, highlighting the difficulty of assessing perceived app quality. Despite promising results from international studies, there is little evidence for the clinical benefits of German IBD apps. Clinical studies and patient inclusion in the app development process are needed to effectively implement mobile apps in routine care.



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**KEYWORDS**

mHealth; IBD; ulcerative colitis; Crohn disease; inflammatory bowel disease; telemedicine; mobile apps; rating; rating scale; quality; usability; chronic disease; IBS; app store

## Introduction

In the era of COVID-19, telemedicine has become an indispensable cornerstone in the effort to maintain care of patients with chronic diseases [1-5]. Immunosuppressed patients are a fragile population, prone to infections in general, especially if they use corticosteroids [6-9]. Avoiding unnecessary face-to-face hospital visits is essential to lower the risk of infection. Remote monitoring tools, such as mobile apps [10] and video consultations [3,11] enable patient-physician communication even during the pandemic.

As inflammatory bowel disease (IBD) often affects younger people [12] who grew up interacting with mobile apps (ie, digital natives), IBD apps represent a great opportunity to improve the management of IBD patients [13]. In most cases, IBD requires life-long treatment and monitoring. One of the main goals of therapy is the prevention of disease relapses once remission has been achieved. Tight monitoring of clinical symptoms is key to ensure an adequate level of immunosuppression, control of disease activity, and quality of life. Hence, it is essential to monitor symptoms such as stool frequency, stool consistency, urgency, rectal bleeding, abdominal pain, and extraintestinal symptoms to identify disease relapses as early as possible [14]. Telemonitoring via mobile apps allows more patient-related data to be collected continuously and on demand to individually adapt therapy to each patient. Furthermore, this data can be used to generate insights into treatment efficiency, side effects, and the detailed progression of the disease.

An increasing body of evidence supports the use of mobile apps in IBD, as in other chronic diseases [15,16], to increase quality of life and medication adherence, to improve patient outcomes, and to decrease health care costs in chronic diseases such as type 2 diabetes [17], chronic obstructive pulmonary disease [18,19], and chronic heart failure [20,21]. In IBD, mobile health (mHealth) interventions to monitor patients have been shown to reduce health care visits by 33% and reduce hospital admissions without increasing disease activity or decreasing patient satisfaction [22]. In November 2019, the German government passed a law, the "Digitale-Versorgung-Gesetz DVG," that allows a consulting physician to prescribe apps, similar to prescriptions for medical devices and drugs [23]. In order for an app to become permanently eligible for prescription via the law, a company needs to provide supporting scientific evidence. This evidence has not been provided for IBD apps that are freely available in app stores. We therefore believe it is crucial to assess the quality of these freely available IBD-related apps to adequately inform potential users.

Accordingly, the aim of this study was to review current publicly available German IBD apps for patients and physicians and rate their quality using the Mobile Application Rating Scale (MARS). MARS was developed in 2015 to objectively assess mHealth apps. It has 5 main sections (with subitems), including engagement, functionality, aesthetics, information quality, and a subjective section [24]. MARS has been used to evaluate several types of eHealth apps, such as apps for rheumatology [25], food allergies and intolerances [26], management of low back pain [27], depression self-management [28], and pain management [29].

## Methods

### Selection of Mobile Apps

We identified available apps with an extensive search in the German Apple App Store and Google Play Store in April 2020. The search included the following keywords: "Morbus Crohn," "Colitis ulcerosa," "CED," "Chronisch entzündliche Darmerkankungen," "IBD," "Crohn's disease," "ulcerative colitis," "UC," "inflammatory bowel disease," "Crohn," and "colitis." The search was carried out semiautomatically, initially using a web crawler to retrieve available apps. The app store descriptions for the available apps were read by 2 raters (JK and MG), who then manually screened them for the inclusion and exclusion criteria. The screened apps did not have to be IBD specific, but had to at least be health specific. For example, they had to include functions such as medication reminders, toilet finders, or symptom diaries. Disease-specific apps that targeted other diseases were not considered to fit the inclusion criteria. Apps were included if they were (1) in the German language, (2) available in both app stores, (3) targeted patients or physicians, and (4) were clearly designed for IBD treatment, were relevant to IBD, or were at least relevant to health in general. Apps were excluded if they were (1) only usable with an additional device, (2) congress apps, (3) journal apps, (4) apps only available to study participants or physicians, or (5) inactive apps.

### App Evaluation

All 6 raters were physicians completing their internal medicine fellowships. Half the raters (n=3) used iPhones and the other half (n=3) used Android smartphones. As recommended by the developers of MARS, all participating raters viewed the training video by Stoyanov et al [24] before rating the apps, and the raters tested each app for at least 10 minutes. The different MARS rating aspects were discussed by the team in advance. The selected apps were downloaded and rated between July and October 2020. All the raters (n=6) tested 4 of the final 14 apps (with most downloaded from the app stores), and the remaining 10 apps were randomly allocated, so that each remaining app was rated by 1 iPhone and 1 Android user.

### Statistical Analysis, Additional App Functions and App Store Ratings

Statistical analysis was implemented following the same design as Knitza et al [25], who recently performed an analysis of



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German mobile apps for rheumatology. MARS section scores were calculated by taking the arithmetic mean of the score for each item in a section, with the overall score being the arithmetic mean of the section scores (excluding the subjective quality score). Overall scores and section scores were summarized as the median and range for each app, and apps were ranked based on the median overall MARS score. We analyzed item score deviations by section and rater using a random intercept–only mixed-effects linear regression model including the individual item scores as the dependent variable, a random effects term for the rater, and nested random effects terms for the MARS section and app. Using random intercepts from this model, we estimated how the item scores in each section for each app deviated from the overall mean item score to rank and plot the importance of the sections within each app. Similarly, we plotted the random effect intercepts and respective 95% CIs for the raters to rank the raters by their deviation from the overall mean item score as a measure of rater bias. Random intercept and fixed effect term CIs spanning both sides of 0 were considered insignificant. Finally, we analyzed interrater agreement at the item, section, and overall score levels for raters from a rater sample as the ICC2k (2-way random, average measures, absolute agreement). All data analysis was performed using the open-source R software package (v 3.5.3; R Foundation). Mixed-effect analysis was carried out using the lme4 R package.

Additional app functions and information are shown in Table 1. The result section was generated by manually screening the final apps, checking the home page of the developers of the apps, and reading the descriptions of the apps in the 2 different app stores. This search was performed by 1 of the 6 raters (MG). The following information was systematically assessed: target group, target disease, developer of the app, app category and technical aspects, studies available, medical product, and privacy policy. For the screening of available studies, we additionally searched PubMed and Google Scholar for the app names. MG manually collected the app store ratings and the number of ratings from both app stores on Aug 24, 2021.



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**Table 1.** Characteristics of the included IBD[a] apps.

| App name | Target group | Target disease | Developer | Category and technical aspects | Studies available | Medical product | Privacy policy available |
|---|---|---|---|---|---|---|---|
| De Diagnose | Patients | Nonspecific | Progressive Programming | Diagnostic support, video, audio files | No | No | Yes |
| Symptomate | Patients | Nonspecific | Infermedica | Diagnostic support | No[b] | Yes | Yes |
| Deutsches Gesundheitsportal | Patients | Nonspecific | HealthCom GmbH | Education, scientific articles, SmPC[c] | No | No | Yes |
| Gesina | Patients | Nonspecific | GesundHeits GmbH Deutschland | Diary, education, video call, toilet finder, video files | No | Yes | Yes |
| Foody | Patients | Nonspecific | Martin Stemmle, independent developer | Diary, report function | No | No | No |
| Carenitiy | Patients | Nonspecific | Carenitiy, Else Care SAS | Social network, education, video files, nutrition recommendation | No | No | Yes |
| Stuhlgang Protokoll | Patients | Nonspecific | digitalsirup GmbH | Diary, stool protocol, report function with statistics and charts | No | No | Yes |
| Das Schmerztagebuch-Pain Tracer | Patients | Nonspecific | Grünenthal GmbH | Education, reminder, pain diary, report function | No | No | Yes |
| Manage My Pain | Patients | Nonspecific | ManagingLife, Inc. | Diary, report function, medication reminder, password protection | Yes[d] | No | Yes |
| Alarm Medikamenten Einnahme/ Medisafe | Patients | Nonspecific | Medisafe Project Ltd., Medisafe Europe | Diary, reminder, report function | No | No | Yes |
| Mediteo | Patients | Nonspecific | Mediteo GmbH | Diary, reminder | No | Yes | Yes |
| CED Dokumentation und Tipps | Patients | IBD | Abbvie GmbH&Co KG | Diary, toilet finder, education, report function, medication reminder, stool protocol, password protection | No | No | Yes |
| CED-Forum | Patients | IBD | Cross4Channel—Gesellschaft für digitales Healthcare Marketing GmbH | Diary, education, social network, medication reminder, toilet finder | No | No | Yes |
| Cara Care | Patients | Intestinal disease[e] | HiDoc Technologies GmbH | Diary, education, reminder, audio files, report function, nutrition recommendations | Yes[f] | Yes | Yes |

[a]IBD: inflammatory bowel disease.

[e]Intestinal disease: IBD, irritable bowel/gut syndrome, or gastroesophageal reflux disease.

[b]The developer website states that clinical studies are available, but they could not be identified using Google Scholar or PubMed.

[c]SmPC: summary of product characteristics.

[d]Manage My Pain–related studies [30-32].

[f]Cara Care–related studies [33].

# Results

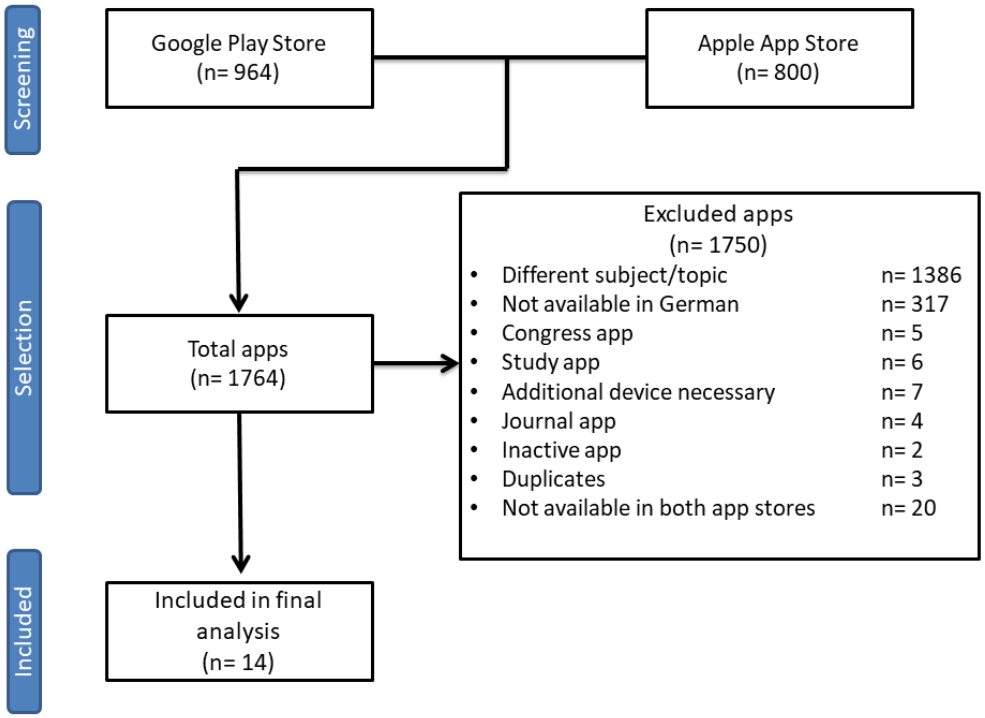
## App Screening and Inclusion

We initially retrieved 1764 apps using the web crawler. We removed 1386 apps because they were not related to IBD, 317 apps because they were not available in German, 5 apps because they were used for congresses, and 6 clinical study apps. We also excluded 7 apps because they required an additional device, most frequently a fecal calprotectin test device. Several of these device-specific apps required an invitation for user registration or required a specific calprotectin test kit (eg, the partner apps from Abbvie, CalApp/IBDoc by Bühlmann Laboratories, and the CalproSmart by Calpro AS). The QuantOn Cal app was only usable with the specific QuantOn Cal test kit. Of the remaining apps, 20 were only available in 1 of the 2 app stores and were also excluded, as were 4 journal apps, 3 duplicates, and 1 inactive app. We included a final total of 14 apps in the MARS analysis (Figure 1).



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**Figure 1.** Flowchart of the app selection process.




## Characteristics of the Mobile Apps

Only 3 of the 14 rated apps (21%) addressed IBD in general, and none of them were specific to Crohn disease or ulcerative colitis. The other 11/14 apps (77%) were not IBD-specific but were relevant to IBD in other ways, such as by including pain and medication diary functions, stool protocols, or a toilet finder (see Table 1).

Importantly, we found that all of the final 14 analyzed apps addressed patients; none of them directly targeted physicians. A diary function was included in 9 of the 14 apps (64%); depending on the app, patients could track pain, frequency of defecation, or eating habits. A public toilet finder was included in 3 of the 14 apps (21%). Most of the apps had a reminder function, whether for appointments or medication. CED Forum was the only 1 of the 14 final apps that provided IBD patients an IBD-related social media platform with features similar to conventional social media platforms. It provided chatrooms on topics such as medication, symptoms, and other personal experiences, as well as diet.

Most of the apps were developed directly or indirectly by subcompanies of pharmaceutical companies. The app Carenity enabled patients to complete surveys for scientific studies; several of these can be found on PubMed or Google Scholar [34,35]. Patients did not receive compensation for completion. The app Deutsches Gesundheitsportal was the only app to directly quote research and to include articles and chapters [36]. There were also some studies based on the app Manage My Pain [30-32]. A past study analyzed patient adherence and acceptance for this app [37]. We identified 1 German study of the app Cara Care, which is for irritable bowel syndrome [33]. We classified 3 of the apps (3/14, 21%) as medical products [38-40].

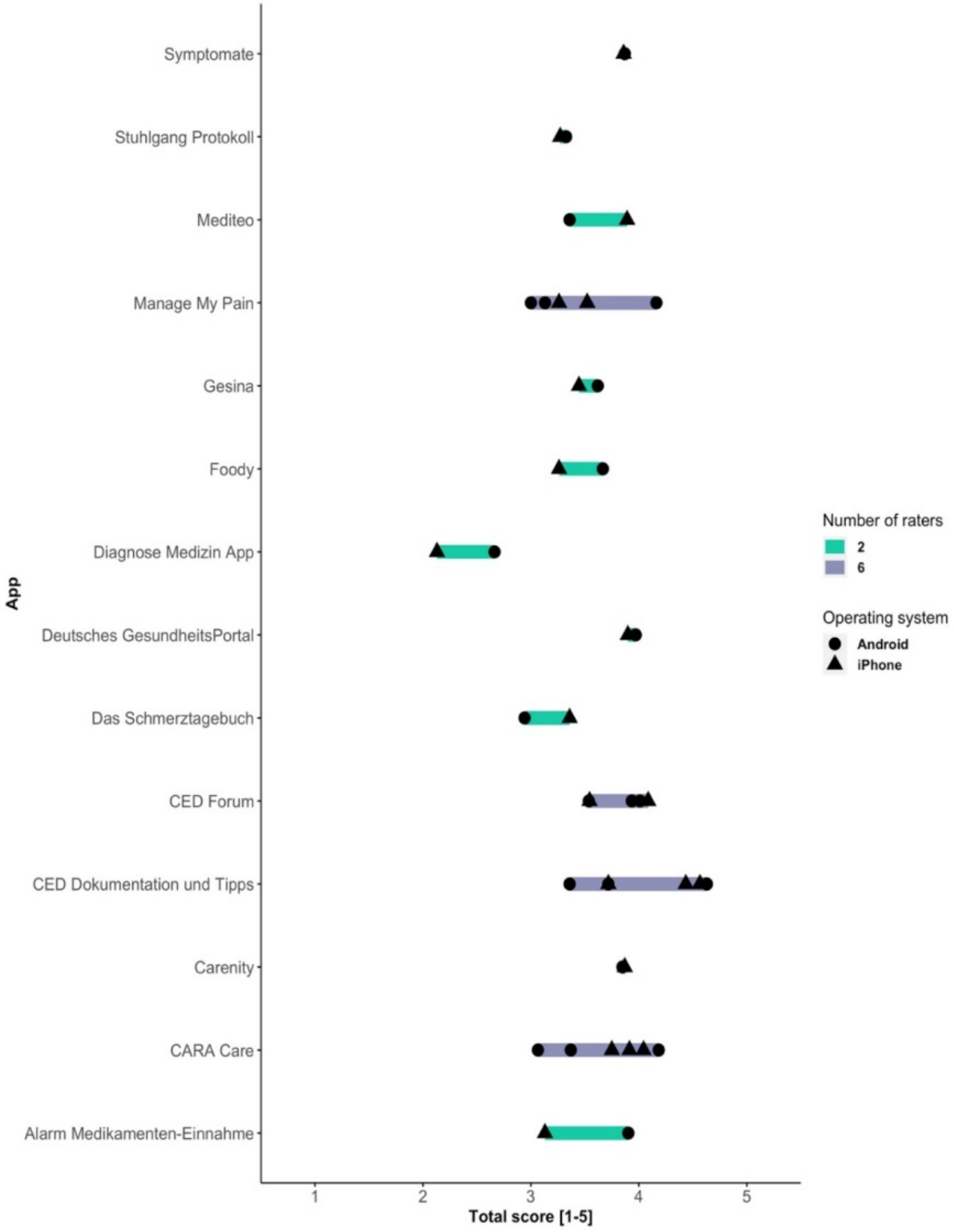
## App Ratings

Overall, app quality was varied. Median MARS scores ranged between 2.38/5 and 4.11/5. Figure 2 shows the individual MARS scores assigned by individual raters.



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**Figure 2.** Overall MARS ratings.

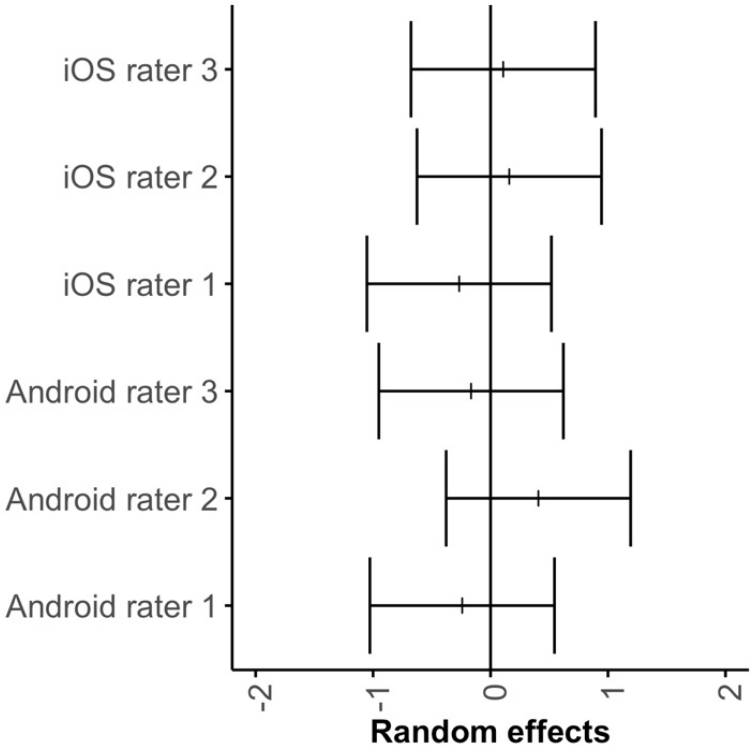



There was no significant difference between the iPhone and Android raters ($P$=.64, V=111.5). Rater agreement on the overall MARS score was good at the app level (ICC2k 0.84, 95% CI 0.68-0.93), for section score (ICC2k 0.82, 95% CI 0.76-0.88), and for individual item score (ICC2k 0.84, 95% CI 0.81-0.86). Random intercepts for observers from the mixed-effects model are presented in Figure 3.



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**Figure 3.** Rater deviations in item scores.




The median total MARS and section scores are displayed in Table 2, as are the respective app store ratings and number of ratings of the respective apps. The MARS sections with the highest scores were functionality and aesthetics, with median scores of 4.12 and 4.00, respectively. Subjective quality had the lowest section score with a median of 2.88.

Multimedia Appendix 1 shows that the subjective quality section was rated systematically lower than the random intercept for each app. Otherwise, no systematic item score deviations were observed.



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**Table 2.** Descriptive statistics for MARS[a] score depending on raters and app store ratings.

| App name | MARS score, median (range) | | | iPhone raters, n | Android raters, n | MARS section score, median (range) | | | | | Google Play Store | | Apple App Store | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Total | Android | iPhone | | | Aesthetics | Engagement | Functionality | Information | Subjective quality | Rating | Number of ratings | Rating | Number of ratings |
| Alarm Medikamenten-Einnahme | 3.56 (2.98-4.14) | 3.97 | 3.16 | 1 | 1 | 4.17 (3.46-4.88) | 3.30 (3.16-3.44) | 4.00 (3.65-4.35) | 3.48 (3.03-3.93) | 2.88 (1.64-4.12) | 4.6 | 216321 | 4.5 | 2.258 |
| Cara Care | 3.89 (3.42-4.36) | 3.32 (2.71-3.93) | 3.97 (3.82-4.12) | 3 | 3 | 4.17 (3.45-4.89) | 4.00 (3.30-4.70) | 4.25 (3.62-4.88) | 3.71 (3.44-3.98) | 3.00 (2.18-3.82) | 4.6 | 2.092 | 4.8 | 3.100 |
| Carenity | 3.93 (3.92-3.94) | 3.94 | 3.93 | 1 | 1 | 4.67 (4.67-4.67) | 3.80 (3.52-4.08) | 4.12 (3.94-4.30) | 3.69 (3.66-3.72) | 3.38 (3.20-3.56) | 4.6 | 134 | 5 | 1 |
| CED Dokumentation und Tipps | 4.11 (3.54-4.68) | 3.79 (3.07-4.51) | 4.44 (3.99-4.89) | 3 | 3 | 4.50 (3.63-5.00) | 4.10 (3.16-5.00) | 4.75 (4.46-5.00) | 4.00 (3.60-4.40) | 3.62 (2.74-4.50) | 3.5 | 118 | 4.3 | 15 |
| CED Forum | 3.97 (3.72-4.22) | 3.95 (3.74-4.16) | 4.07 (3.74-4.4) | 3 | 3 | 4.00 (3.58-4.42) | 4.40 (4.06-4.74) | 4.00 (3.71-4.29) | 3.76 (3.31-4.21) | 3.50 (2.79-4.21) | 3.8 | 209 | 3.7 | 30 |
| Das Schmerztagebuch | 3.17 (2.83-3.51) | 2.93 | 3.41 | 1 | 1 | 3.67 (3.20-4.14) | 3.10 (2.68-3.52) | 4.12 (3.94-4.3) | 3.21 (3.15-3.27) | 1.75 (1.04-2.46) | 3.7 | 86 | 3.7 | 15 |
| Deutsches GesundheitsPortal | 3.90 (3.88-3.92) | 3.92 | 3.89 | 1 | 1 | 4.00 (3.53-4.47) | 3.80 (2.67-4.93) | 4.38 (3.85-4.91) | 4.21 (3.44-4.98) | 3.12 (2.59-3.65) | 4.2 | 64 | 5 | 6 |
| Diagnose Medizin App | 2.38 (1.87-2.89) | 2.74 | 2.02 | 1 | 1 | 2.00 (0.59-3.41) | 2.40 (2.12-2.68) | 3.75 (2.34-5.00) | 2.50 (2.50-2.50) | 1.25 (1.25-1.25) | 4.5 | 7.179 | 3.8 | 23 |
| Foody | 3.48 (3.19-3.77) | 3.68 | 3.27 | 1 | 1 | 3.33 (2.86-3.8) | 3.30 (2.88-3.72) | 4.12 (3.94-4.30) | 3.50 (2.79-4.21) | 3.12 (2.59-3.65) | 4.2 | 225 | 4.5 | 268 |
| Gesina | 3.57 (3.53-3.61) | 3.60 | 3.55 | 1 | 1 | 4.67 (4.20-5.00) | 3.30 (3.16-3.44) | 3.62 (3.44-3.80) | 3.77 (3.16-4.38) | 2.50 (2.50-2.50) | 3.6 | 82 | 4.3 | 70 |
| Manage My Pain | 3.43 (2.97-3.89) | 3.08 (2.38-3.78) | 3.6 (3.4-3.8) | 3 | 3 | 3.83 (3.15-4.51) | 3.30 (2.71-3.89) | 4.00 (3.48-4.52) | 3.31 (3.05-3.57) | 2.88 (2.15-3.61) | 4.6 | 2.586 | 3.3 | 3 |
| Mediteo | 3.65 (3.29-4.01) | 3.39 | 3.91 | 1 | 1 | 4.00 (4.00-4.00) | 4.00 (3.72-4.28) | 4.12 (3.94-4.30) | 3.50 (3.03-3.97) | 2.62 (1.38-3.86) | 4.3 | 6.511 | 4.6 | 11.092 |
| Stuhlgang Protokoll | 3.35 (3.34-3.36) | 3.36 | 3.34 | 1 | 1 | 3.83 (3.59-4.07) | 3.20 (2.63-3.77) | 4.50 (3.79-5.00) | 2.97 (2.45-3.49) | 2.25 (1.90-2.60) | 4.4 | 190 | 4.6 | 31 |
| Symptomate | 3.95 (3.93-3.97) | 3.94 | 3.97 | 1 | 1 | 4.67 (4.2-5.00) | 3.60 (3.03-4.17) | 5.00 (5.00-5.00) | 3.62 (3.44-3.80) | 2.88 (2.70-3.06) | 4.5 | 3.142 | 4.4 | 8 |

[a]Mobile application rating scale



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## Discussion

### Comparison to Previous Work

To our knowledge, no high-quality analysis of German IBD apps has yet been carried out. Our work was intended to inform patients and physicians alike about IBD apps based on the results of structured and objective testing criteria in order to guide and facilitate the selection and inclusion of appropriate IBD apps in the clinical routine.

In contrast to a previous analysis in rheumatology that used a similar search strategy [25], we did not find a single app that targeted physicians as users. This reflects an untapped potential and an opportunity, as physicians are increasingly using medical apps [41,42].

Only a few (3 of 14) of the rated apps were IBD specific: CED Dokumentation und Tipps, CED Forum, and Cara Care. None were specific to Crohn disease. Considering the relatively high incidence and prevalence of IBD [43], it was surprising that we could not identify a single disease-specific IBD app, either for Crohn disease or ulcerative colitis. In contrast, a previous analysis discovered multiple disease-specific German apps for rheumatic disease [25], including such comparatively rare types as systematic lupus erythematosus [44]. Overall, the retrieved apps addressed various patient-relevant functions and topics, but a single disease-specific app with combined app features would likely be more frequently and regularly used by IBD patients. Furthermore, such an app could include more specific topics, such as the fistulas associated with Crohn disease and IBD-associated arthritis or uveitis [45,46].

### Principal Findings

In general, information quality was rated rather poorly compared to aesthetics and functionality, representing another unmet need. As information concerning medication and disease are the top 2 features requested by patients suffering from chronic inflammatory rheumatic diseases [47], we infer that IBD patients likely also need this information. Accordingly, we are currently carrying out a patient survey to validate this assumption.

CED Dokumentation und Tipps was the app with the highest MARS score. This app was IBD specific and had several extra functions, such as a medication and appointment reminder, toilet finder, and diary function, that could be used to document pain level, stool frequency, weight, and eating habits. This app also provided nutrition recommendations, password protection, and had an especially intuitive interface and design.

Most of the apps were designed by pharmaceutical companies and did not explicitly report involving patients in their design. Notably, and in line with previous findings, very few supporting studies could be identified [25]. The app Deutsches Gesundheitsportal was the only app providing evidence (by quoting studies), while the app Carenity enabled patients to complete surveys for clinical studies. There was only one app, Manage My Pain, for which studies were available on function and patient adherence [30,32,37]. Another shortcoming of the examined apps was that none offered IBD-specific scores, such as the partial Mayo score for ulcerative colitis [48] or the Harvey-Bradshaw Index for Crohn disease [49].

In order to be eligible for prescription in Germany, developers need to provide evidence for the usefulness of their app. Only 1 of the 14 included apps, Cara Care, is expected to be among the first eligible apps in Germany related to irritable bowel syndrome and IBD. The developer homepage states that Cara Care is already eligible for prescription for patients with irritable bowel syndrome and that the developer has applied for eligibility for patients with IBD [50].

### Outlook

This study excluded apps for which a device was necessary for their use, such as the PartnerApp by Abbvie and QuantOn Cal, which both require a fecal calprotectin test device [51,52]. In our web search, we observed that these were the only devices with accompanying apps that could monitor inflammation activity in the bowel. In the future, these devices might be effective complementary apps that could provide objective data about actual disease status and other objective parameters, enabling improved remote monitoring.

Fecal calprotectin can predict relapses in IBD and indicate the response to medical treatment [53]. Furthermore, normalization of fecal calprotectin has recently been recommended as a treatment target in both ulcerative colitis and Crohn disease in the STRIDE (selecting therapeutic targets in inflammatory bowel disease) statements [54].

In several countries, including the United Kingdom and United States, IBD centers have already developed models for the use of telemedicine and have reported positive outcomes, such as decreased costs, decreased travel time, and reduced overall time for medical visits for patients [55-57]. Video consultations are used in most of these models. To the best of our knowledge, mobile apps have not been included in any of these models.

Some of the apps rated in our current study had a function allowing the creation of summary reports, for example of the last 3 months. Such reports can provide the treating physician a much more detailed and regular overview of the patient's status, including treatment response and disease progression. The use of an additional app developed by a patient organization could be a useful supplement for improving telemedicine in IBD. Based on our study results, we suggest including the following disease-specific information in such apps: current therapy options (including evidence from major relevant clinical studies) and disease-specific scores, such as the Harvey-Bradshaw Index for Crohn disease [49] and the partial Mayo score for ulcerative colitis [48]. All major stakeholders, including patients, gastroenterologists, and scientists should be part of the app development process. In addition, studies of individual apps should be conducted to investigate their clinical and economic benefits and safety. Furthermore, the apps should be available in both app stores so that a recommendation can be made that is independent of the operating system. The developers of the apps should also be clearly identifiable. Finally, easy and secure data transmission to health care professionals should be ensured.

In the future, it may make sense to integrate the MARS score into the respective app stores in order to provide a standardized evaluation unit as an orientation aid for users. The



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implementation of MARS scores has been useful for the re-evaluation, optimization, and development of apps by revealing possible weaknesses of the apps and ways to improve them in a targeted manner. Evaluation with MARS should be carried out by patients and physicians as well as researchers, since future apps should ideally include 2-way communication and data exchange.

### Limitations

This study has several limitations. Importantly, the apps were all rated by physicians; no patients were included. There was a clear discrepancy between the physician MARS ratings and user ratings in the app stores, suggesting that there would also be significant differences in MARS scores if the same app was rated by a doctor and by a patient. To address this in a follow-up study, the results of this study will be discussed in a patient focus group and a reduced number of apps will be evaluated by patients. The IBD-specific apps had a significantly lower number of ratings compared to the non–disease-specific apps, which we consider was most likely due to the smaller target group. Using the web crawler, we performed an objective and automatic initial app search, similar to previous studies [58,59]. Nevertheless, some IBD apps may not have been recognized by our search strategy and might have been overlooked. Similarly, only apps available in both app stores were included. No detailed data safety analysis was performed, and we only assessed the availability of privacy policy information. Some apps also offered password protection. We excluded apps from our study that required additional devices, such as calprotectin test devices, because most of them were only accessible within specific clinical study programs and no funding was available to buy the devices. As some studies have already shown, the use of additional devices to provide objective and predictive laboratory data, such as from fecal calprotectin tests, is very useful for disease management and improves treatment [15-17,22,53,54]. The immense speed of mHealth development is also a general limitation on research in this area.

### Conclusion

Our current study shows that at the moment, only a limited number of IBD-related apps are available to patients, and none are available to physicians. We found that app quality was varied, and we observed a general absence of clinical evidence and patient involvement.

### Acknowledgments

The present work was performed in fulfillment of the requirements for obtaining the degree Dr. med. for MG.

### Authors' Contributions

MG drafted the initial manuscript. MG, JK, VH, IG, HS, and TO rated the apps. MG, NV, TA, and JK performed the statistical analysis. All authors reviewed the draft and suggested changes. All authors approved the final manuscript.

### Conflicts of Interest

None declared.

Multimedia Appendix 1
MARS section item scores by each section and app.
[PNG File , 64 KB - mhealth_v10i5e31102_app1.png ]

### References

1. Alonso S, Marques G, Barrachina I, Garcia-Zapirain B, Arambarri J, Salvador J, et al. Telemedicine and e-Health research solutions in literature for combatting COVID-19: a systematic review. Health Technol (Berl) 2021;11(2):257-266 [FREE Full text] [doi: 10.1007/s12553-021-00529-7] [Medline: 33558838]
2. Petersen W, Karpinski K, Backhaus L, Bierke S, Häner M. A systematic review about telemedicine in orthopedics. Arch Orthop Trauma Surg 2021 Oct;141(10):1731-1739 [FREE Full text] [doi: 10.1007/s00402-021-03788-1] [Medline: 33635399]
3. Elsner P. Teledermatology in the times of COVID-19 ? a systematic review Internet. JDDG-J Ger Soc Dermatology 2020 Jul 27;18(8):841-845 [FREE Full text] [doi: 10.1111/ddg.14180]
4. Dodoo J, Al-Samarraie H, Alzahrani A. Telemedicine use in Sub-Saharan Africa: Barriers and policy recommendations for Covid-19 and beyond. Int J Med Inform 2021 Jul;151:104467. [doi: 10.1016/j.ijmedinf.2021.104467] [Medline: 33915421]
5. Kernder A, Morf H, Klemm P, Vossen D, Haase I, Mucke J, et al. Digital rheumatology in the era of COVID-19: results of a national patient and physician survey. RMD Open 2021 Feb;7(1):1548 [FREE Full text] [doi: 10.1136/rmdopen-2020-001548] [Medline: 33622673]
6. Brenner E, Ungaro R, Gearry R, Kaplan G, Kissous-Hunt M, Lewis J, et al. Corticosteroids, But Not TNF Antagonists, Are Associated With Adverse COVID-19 Outcomes in Patients With Inflammatory Bowel Diseases: Results From an International Registry. Gastroenterology 2020 Aug;159(2):481-491.e3 [FREE Full text] [doi: 10.1053/j.gastro.2020.05.032] [Medline: 32425234]



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7. Waljee AK, Wiitala WL, Govani S, Stidham R, Saini S, Hou J, et al. Corticosteroid Use and Complications in a US Inflammatory Bowel Disease Cohort. PLoS One 2016;11(6):e0158017 [FREE Full text] [doi: 10.1371/journal.pone.0158017] [Medline: 27336296]
8. Toruner M, Loftus EV, Harmsen WS, Zinsmeister AR, Orenstein R, Sandborn WJ, et al. Risk factors for opportunistic infections in patients with inflammatory bowel disease. Gastroenterology 2008 Apr;134(4):929-936. [doi: 10.1053/j.gastro.2008.01.012] [Medline: 18294633]
9. Govani S, Wiitala WL, Stidham R, Saini S, Hou JK, Feagins LA, et al. Age Disparities in the Use of Steroid-sparing Therapy for Inflammatory Bowel Disease. Inflamm Bowel Dis 2016 Aug;22(8):1923-1928 [FREE Full text] [doi: 10.1097/MIB.0000000000000817] [Medline: 27416039]
10. Kondylakis H, Katehakis D, Kouroubali A, Logothetidis F, Triantafyllidis A, Kalamaras I, et al. COVID-19 Mobile Apps: A Systematic Review of the Literature. J Med Internet Res 2020 Dec 09;22(12):e23170 [FREE Full text] [doi: 10.2196/23170] [Medline: 33197234]
11. James H, Papoutsi C, Wherton J, Greenhalgh T, Shaw S. Spread, Scale-up, and Sustainability of Video Consulting in Health Care: Systematic Review and Synthesis Guided by the NASSS Framework. J Med Internet Res 2021 Jan 26;23(1):e23775 [FREE Full text] [doi: 10.2196/23775] [Medline: 33434141]
12. Day AS, Ledder O, Leach ST, Lemberg DA. Crohn's and colitis in children and adolescents. World J Gastroenterol 2012 Nov 07;18(41):5862-5869 [FREE Full text] [doi: 10.3748/wjg.v18.i41.5862] [Medline: 23139601]
13. Goodhand J, Dawson R, Hefferon M, Tshuma N, Swanson G, Wahed M, et al. Inflammatory bowel disease in young people: the case for transitional clinics. Inflamm Bowel Dis 2010 Jun;16(6):947-952. [doi: 10.1002/ibd.21145] [Medline: 19834978]
14. Guan Q. A Comprehensive Review and Update on the Pathogenesis of Inflammatory Bowel Disease. J Immunol Res 2019;2019:7247238 [FREE Full text] [doi: 10.1155/2019/7247238] [Medline: 31886308]
15. Farias FD, Dagostini C, Bicca YDA, Falavigna V, Falavigna A. Remote Patient Monitoring: A Systematic Review. Telemed J E Health 2020 May;26(5):576-583. [doi: 10.1089/tmj.2019.0066] [Medline: 31314689]
16. Khan F, Granville N, Malkani R, Chathampally Y. Health-Related Quality of Life Improvements in Systemic Lupus Erythematosus Derived from a Digital Therapeutic Plus Tele-Health Coaching Intervention: Randomized Controlled Pilot Trial. J Med Internet Res 2020 Oct 20;22(10):e23868 [FREE Full text] [doi: 10.2196/23868] [Medline: 33079070]
17. Liu K, Xie Z, Or C. Effectiveness of Mobile App-Assisted Self-Care Interventions for Improving Patient Outcomes in Type 2 Diabetes and/or Hypertension: Systematic Review and Meta-Analysis of Randomized Controlled Trials. JMIR Mhealth Uhealth 2020 Aug 04;8(8):e15779 [FREE Full text] [doi: 10.2196/15779] [Medline: 32459654]
18. Achelrod D, Schreyögg J, Stargardt T. Health-economic evaluation of home telemonitoring for COPD in Germany: evidence from a large population-based cohort. Eur J Health Econ 2017 Sep;18(7):869-882 [FREE Full text] [doi: 10.1007/s10198-016-0834-x] [Medline: 27699567]
19. Cruz J, Brooks D, Marques A. Home telemonitoring effectiveness in COPD: a systematic review. Int J Clin Pract 2014 Mar;68(3):369-378. [doi: 10.1111/ijcp.12345] [Medline: 24472009]
20. Seto E, Leonard KJ, Cafazzo JA, Barnsley J, Masino C, Ross HJ. Perceptions and experiences of heart failure patients and clinicians on the use of mobile phone-based telemonitoring. J Med Internet Res 2012 Feb 10;14(1):e25 [FREE Full text] [doi: 10.2196/jmir.1912] [Medline: 22328237]
21. Ware P, Ross H, Cafazzo J, Boodoo C, Munnery M, Seto E. Outcomes of a Heart Failure Telemonitoring Program Implemented as the Standard of Care in an Outpatient Heart Function Clinic: Pretest-Posttest Pragmatic Study. J Med Internet Res 2020 Feb 08;22(2):e16538 [FREE Full text] [doi: 10.2196/16538] [Medline: 32027309]
22. de Jong MJ, van der Meulen-de Jong AE, Romberg-Camps M, Becx M, Maljaars J, Cilissen M, et al. Telemedicine for management of inflammatory bowel disease (myIBDcoach): a pragmatic, multicentre, randomised controlled trial. Lancet 2017 Sep 02;390(10098):959-968. [doi: 10.1016/S0140-6736(17)31327-2] [Medline: 28716313]
23. Ärzte sollen Apps verschreiben können. Bundesministerium für Gesundheit (BMG). 2020 Apr. URL: https://www.bundesgesundheitsministerium.de/digitale-versorgung-gesetz.html [accessed 2020-11-11]
24. Stoyanov S, Hides L, Kavanagh D, Zelenko O, Tjondronegoro D, Mani M. Mobile app rating scale: a new tool for assessing the quality of health mobile apps. JMIR Mhealth Uhealth 2015 Mar 11;3(1):e27 [FREE Full text] [doi: 10.2196/mhealth.3422] [Medline: 25760773]
25. Knitza J, Tascilar K, Messner E, Meyer M, Vossen D, Pulla A, et al. German Mobile Apps in Rheumatology: Review and Analysis Using the Mobile Application Rating Scale (MARS). JMIR Mhealth Uhealth 2019 Aug 05;7(8):e14991 [FREE Full text] [doi: 10.2196/14991] [Medline: 31381501]
26. Mandracchia F, Llauradó E, Tarro L, Valls R, Solà R. Mobile Phone Apps for Food Allergies or Intolerances in App Stores: Systematic Search and Quality Assessment Using the Mobile App Rating Scale (MARS). JMIR Mhealth Uhealth 2020 Sep 16;8(9):e18339 [FREE Full text] [doi: 10.2196/18339] [Medline: 32936078]
27. Escriche-Escuder A, De-Torres I, Roldán-Jiménez C, Martín-Martín J, Muro-Culebras A, González-Sánchez M, et al. Assessment of the Quality of Mobile Applications (Apps) for Management of Low Back Pain Using the Mobile App Rating Scale (MARS). Int J Environ Res Public Health 2020 Dec 09;17(24):1-16 [FREE Full text] [doi: 10.3390/ijerph17249209] [Medline: 33317134]




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28. Myers A, Chesebrough L, Hu R, Turchioe M, Pathak J, Creber R. Evaluating Commercially Available Mobile Apps for Depression Self-Management. AMIA Annu Symp Proc 2020;2020:906-914 [FREE Full text] [Medline: 33936466]
29. Salazar A, de Sola H, Failde I, Moral-Munoz J. Measuring the Quality of Mobile Apps for the Management of Pain: Systematic Search and Evaluation Using the Mobile App Rating Scale. JMIR Mhealth Uhealth 2018 Oct 25;6(10):e10718 [FREE Full text] [doi: 10.2196/10718] [Medline: 30361196]
30. Rahman Q, Janmohamed T, Pirbaglou M, Clarke H, Ritvo P, Heffernan J, et al. Defining and Predicting Pain Volatility in Users of the Manage My Pain App: Analysis Using Data Mining and Machine Learning Methods. J Med Internet Res 2018 Nov 15;20(11):e12001 [FREE Full text] [doi: 10.2196/12001] [Medline: 30442636]
31. Rahman Q, Janmohamed T, Clarke H, Ritvo P, Heffernan J, Katz J. Interpretability and Class Imbalance in Prediction Models for Pain Volatility in Manage My Pain App Users: Analysis Using Feature Selection and Majority Voting Methods. JMIR Med Inform 2019 Nov 20;7(4):e15601 [FREE Full text] [doi: 10.2196/15601] [Medline: 31746764]
32. Bhatia A, Kara J, Janmohamed T, Prabhu A, Lebovic G, Katz J, et al. User Engagement and Clinical Impact of the Manage My Pain App in Patients With Chronic Pain: A Real-World, Multi-site Trial. JMIR Mhealth Uhealth 2021 Mar 04;9(3):e26528 [FREE Full text] [doi: 10.2196/26528] [Medline: 33661130]
33. Brinkmann J, Geigis L. Cara Careinfluss einer E-Health-basierten low-FODMAP-Diät auf die Symptomschwere und Lebensqualität beim Reizdarmsyndrom. Z Gastroenterol Internet Georg Thieme Verlag KG Aug 2019:13. [doi: 10.1055/s-0039-1695463]
34. Gauchoux R, Boisbouvier A, Santos RD, Radoszycki L. Rheumatoid arthritis and ankylosing spondylitis clinical trials: how to encourage patient participation? Results from a real-world study conducted via Carenity, a worldwide online patient community. Ann Rheum Dis 2019:78-308. [doi: 10.1136/annrheumdis-2019-eular.6922]
35. Hui CY, Walton R, Mckinstry B, Vasileiou E, Pinnock H. What do people with asthma want to see in an asthma self-management app? What do people with asthma want to see in an asthma self-management app? A review of views expressed in online social discussion forums. 2017 Presented at: Health Informatics Conference; Oct 3-4, 2017; Edinburgh, Scotland URL: https://www.research.ed.ac.uk/en/publications/what-do-people-with-asthma-want-to-see-in-an-asthma-self-manageme
36. Günter B. Deutsches Gesundheitsportal-Über uns. Germany, Köln: Deutsches Gesundheitsportal; 2021. URL: https://www.deutschesgesundheitsportal.de/ueber-uns/ [accessed 2021-06-04]
37. Slepian PM, Peng M, Janmohamed T, Kotteeswaran Y, Manoo V, Blades AM, et al. Engagement with Manage My Pain mobile health application among patients at the Transitional Pain Service. Digit Health 2020;6:2055207620962297 [FREE Full text] [doi: 10.1177/2055207620962297] [Medline: 33117557]
38. Symptom Checker. Infermedica. URL: https://infermedica.com/de/product/symptom-checker [accessed 2021-06-04]
39. Über uns. CARACARE. URL: https://cara.care/de/about/ [accessed 2021-06-04]
40. Mediteo + Mediteo app. URL: https://www.mediteo.com/de/mediteo-m/ [accessed 2021-06-07]
41. Ventola CL. Mobile devices and apps for health care professionals: uses and benefits. P T 2014 May;39(5):356-364 [FREE Full text] [Medline: 24883008]
42. Knitza J, Vossen D, Geffken I, Krusche M, Meyer M, Sewerin P, Arbeitskreis Junge Rheumatologen. [Use of medical apps and online platforms among German rheumatologists : Results of the 2016 and 2018 DGRh conference surveys and research conducted by rheumadocs]. Z Rheumatol 2019 Nov;78(9):839-846. [doi: 10.1007/s00393-018-0578-3] [Medline: 30542914]
43. Ng S, Shi H, Hamidi N, Underwood F, Tang W, Benchimol E, et al. Worldwide incidence and prevalence of inflammatory bowel disease in the 21st century: a systematic review of population-based studies. Lancet 2017 Dec 23;390(10114):2769-2778. [doi: 10.1016/S0140-6736(17)32448-0] [Medline: 29050646]
44. LupusLog. Google Play Store. URL: https://play.google.com/store/apps/details?id=de.monks.lupuslog&hl=en_US&gl=US [accessed 2021-06-04]
45. Marzo M, Felice C, Pugliese D, Andrisani G, Mocci G, Armuzzi A, et al. Management of perianal fistulas in Crohn's disease: an up-to-date review. World J Gastroenterol 2015 Feb 07;21(5):1394-1403 [FREE Full text] [doi: 10.3748/wjg.v21.i5.1394] [Medline: 25663759]
46. Levine JS, Burakoff R. Extraintestinal manifestations of inflammatory bowel disease. Gastroenterol Hepatol (N Y) 2011 Apr;7(4):235-241 [FREE Full text] [Medline: 21857821]
47. Knitza J, Simon D, Lambrecht A, Raab C, Tascilar K, Hagen M, et al. Mobile Health Usage, Preferences, Barriers, and eHealth Literacy in Rheumatology: Patient Survey Study. JMIR Mhealth Uhealth 2020 Aug 12;8(8):e19661 [FREE Full text] [doi: 10.2196/19661] [Medline: 32678796]
48. Lewis JD, Chuai S, Nessel L, Lichtenstein GR, Aberra FN, Ellenberg JH. Use of the noninvasive components of the Mayo score to assess clinical response in ulcerative colitis. Inflamm Bowel Dis 2008 Dec;14(12):1660-1666 [FREE Full text] [doi: 10.1002/ibd.20520] [Medline: 18623174]
49. Best WR. Predicting the Crohn's disease activity index from the Harvey-Bradshaw Index. Oxford Academic 2006 Apr 01;12(4):304-310 [FREE Full text] [doi: 10.1097/01.MIB.0000215091.77492.2a] [Medline: 16633052]
50. Sommer A, Brinkmann J. Cara Care für Ärzt*innen. CARA CARE. URL: https://cara.care/de/doctors/ [accessed 2021-05-13]
51. PartnerApp. App Store. URL: https://apps.apple.com/de/app/partnerapp/id1449719677 [accessed 2021-05-13]




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52. QuantOn Cal. Google Play Store. URL: https://play.google.com/store/apps/details?id=de.preventis.gmbh.quantoncal&hl=en_US&gl=US [accessed 2021-05-13]
53. Pedersen N, Thielsen P, Martinsen L, Bennedsen M, Haaber A, Langholz E, et al. eHealth: individualization of mesalazine treatment through a self-managed web-based solution in mild-to-moderate ulcerative colitis. Inflamm Bowel Dis 2014 Dec;20(12):2276-2285. [doi: 10.1097/MIB.0000000000000199] [Medline: 25248002]
54. Turner D, Ricciuto A, Lewis A, D'Amico F, Dhaliwal J, Griffiths AM, International Organization for the Study of IBD. STRIDE-II: An Update on the Selecting Therapeutic Targets in Inflammatory Bowel Disease (STRIDE) Initiative of the International Organization for the Study of IBD (IOIBD): Determining Therapeutic Goals for Treat-to-Target strategies in IBD. Gastroenterology 2021 Apr;160(5):1570-1583. [doi: 10.1053/j.gastro.2020.12.031] [Medline: 33359090]
55. Li SX, Thompson KD, Peterson T, Huneven S, Carmichael J, Glazer FJ, et al. Delivering High Value Inflammatory Bowel Disease Care Through Telemedicine Visits. Inflamm Bowel Dis 2017 Oct;23(10):1678-1681. [doi: 10.1097/MIB.0000000000001210] [Medline: 28817463]
56. Ruf B, Jenkinson P, Armour D, Fraser M, Watson AJM. Videoconference clinics improve efficiency of inflammatory bowel disease care in a remote and rural setting. J Telemed Telecare 2020 Oct;26(9):545-551. [doi: 10.1177/1357633X19849280] [Medline: 31167590]
57. George L, Cross R. Remote Monitoring and Telemedicine in IBD: Are We There Yet? Curr Gastroenterol Rep 2020 Feb 10;22(3):12. [doi: 10.1007/s11894-020-0751-0] [Medline: 32040650]
58. Schultchen D, Terhorst Y, Holderied T, Stach M, Messner E, Baumeister H, et al. Stay Present with Your Phone: A Systematic Review and Standardized Rating of Mindfulness Apps in European App Stores. Int J Behav Med 2021 Oct;28(5):552-560 [FREE Full text] [doi: 10.1007/s12529-020-09944-y] [Medline: 33215348]
59. Terhorst Y, Messner EM, Schultchen D, Paganini S, Portenhauser A, Eder AS, et al. Systematic evaluation of content and quality of English and German pain apps in European app stores. Internet Interv 2021 Feb 24;24(April 2021):100376 [FREE Full text] [doi: 10.1016/j.invent.2021.100376] [Medline: 33718002]


## Abbreviations

**IBD:** Inflammatory bowel disease
**MARS:** mobile application rating scale
**mHealth:** mobile health


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Original Paper

# Privacy, Data Sharing, and Data Security Policies of Women's mHealth Apps: Scoping Review and Content Analysis

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## Abstract

**Background:** Women's mobile health (mHealth) is a growing phenomenon in the mobile app global market. An increasing number of women worldwide use apps geared to female audiences (female technology). Given the often private and sensitive nature of the data collected by such apps, an ethical assessment from the perspective of data privacy, sharing, and security policies is warranted.

**Objective:** The purpose of this scoping review and content analysis was to assess the privacy policies, data sharing, and security policies of women's mHealth apps on the current international market (the App Store on the Apple operating system [iOS] and Google Play on the Android system).

**Methods:** We reviewed the 23 most popular women's mHealth apps on the market by focusing on publicly available apps on the App Store and Google Play. The 23 downloaded apps were assessed manually by 2 independent reviewers against a variety of user data privacy, data sharing, and security assessment criteria.

**Results:** All 23 apps collected personal health-related data. All apps allowed behavioral tracking, and 61% (14/23) of the apps allowed location tracking. Of the 23 apps, only 16 (70%) displayed a privacy policy, 12 (52%) requested consent from users, and 1 (4%) had a pseudoconsent. In addition, 13% (3/23) of the apps collected data before obtaining consent. Most apps (20/23, 87%) shared user data with third parties, and data sharing information could not be obtained for the 13% (3/23) remaining apps. Of the 23 apps, only 13 (57%) provided users with information on data security.

**Conclusions:** Many of the most popular women's mHealth apps on the market have poor data privacy, sharing, and security standards. Although regulations exist, such as the European Union General Data Protection Regulation, current practices do not follow them. The failure of the assessed women's mHealth apps to meet basic data privacy, sharing, and security standards is not ethically or legally acceptable.

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**KEYWORDS**

mHealth; women's health; ethics; privacy policy; data sharing; privacy; data security; data transparency; femtech; mobile apps; mobile health

## Introduction

### Background

Mobile health (mHealth) is defined by the World Health Organization (WHO) as mobile apps and wearable devices used for health care. Software programs that provide health-related services used by mobile phones and tablets are called mHealth apps [1]. Mobile apps were first introduced by Apple and then by Google Play in 2010. Since then, apps have been frequently used by mobile device users [2]. According to Statista, which reports on data related to the number of apps available on the leading app stores, 3.48 million apps were available on Google Play in the first quarter of 2021, and 2.22 million were available



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on the Apple App Store. Among the most popular apps are those in the category of health and fitness [3]. The growing number of mobile apps, including mHealth apps, has produced a demand for health services and increased access to health information by mobile app users [1].

Women's health is a field that focuses on the effect of gender on disease and health and encompasses a range of biological and psychosocial issues [4]. Women's health is broad and consists of several dimensions: sexual and reproductive health (including pregnancy, sexually transmitted diseases, and menopause), physical health and life expectancy (including nutrition, exercise, and weight management), and mental health. The aforementioned dimensions of women's health are those that are commonly characterized on the mHealth market [5]. In our study, we explored what is available on the market under the topic of women's health.

Hundreds of thousands of apps provide services for women on the Apple App Store and Google Play. These apps monitor women's health and bodily functions, including ovulation, pregnancy, breastfeeding, menstrual cycles, physical activities, mental health, mood levels, stress, and sleep [2]. Millions of people worldwide use women's health apps [6]. The topics covered by women's health apps include fitness, lifestyle management, nutrition, diet, reproductive health, medication adherence, and disease management. However, fewer apps are directly related to women's sexual health and fertility than to diet and exercise [7]. A WHO report recognized that reproductive, maternal, newborn, and children's health have been a priority for mHealth services in alignment with WHO initiatives, such as the Millennium Development Goals and Every Woman Every Child [1]. In the same report, the WHO recommended the use of women's mHealth apps in rural areas and low-income countries. Notably, low-cost women's mHealth apps tend to increase their popularity, especially among rural and low-income countries [8].

In the market, *femtech* (*female technology*; ie, technology geared to female audiences) is an industrial term. Femtech refers to technology related to women's health, such as software, services, diagnostics, or products [9]. The term *femtech* was coined by the cofounder of Clue, one of the most famous fertility-tracking companies. In her blog, Tin [10] stated that "what female health needs through technology is femtech." Because half of the global population is female, investment in femtech is growing according to demand [9]. Femtech firms have received significant investment funding. In 2012 alone, they attracted US $57 million; this number increased to US $392 million in 2018 and reached US $2.3 billion in 2020 [11]. This has led to the design of a business model that focuses on individual empowerment involving self-designated women's health technologies. Women-centered technology is a new concept that has been gaining popularity in the market and has been related to the increased observability of women's health issues [12]. This huge growth and expansion in the femtech market comes with the price that some of these apps use the data they collect to generate profit. This occurred, for example, in the case of Bounty UK, a pregnancy and parenthood website and app; the UK Information and Commissioner's Office found that the company supplied and sold data related to pregnant women, new mothers, and infants to a third party "without being fully clear with people that it might do so" [13].

In the sociocultural context, women's bodies have always been characterized as fluctuating and requiring a high amount of self-regulation. Technology has become a tool for women to oversee their bodies and health [2]. In addition, women are considered to carry the most responsibility in the reproductive health process, from preventing pregnancy to monitoring it until delivery [14]. Motherhood, as in the sociocultural structure, can still affect women in terms of shaming and blaming, including domestic violence, which is strongly associated with unwanted pregnancy and abortion [6]. Furthermore, a lack of knowledge about fertility and the cultural reservation around it encourages women to use mHealth apps to obtain more clarity and awareness in this domain without needing to ask publicly [15]. Sociocultural norms make women more vulnerable in the new tech era [12]. Issues related to women's bodies that are taboo in some cultures influence the demand for and use of women's mHealth apps. In most reserved, family-oriented societies, women are expected to conceive a child. Women use these apps as an alternative method to protect themselves from cultural shame [16]. However, stigma about abortion and pregnancy leads some ideological campaigns to use these data to prevent women from obtaining help [6]. Women are under surveillance in some political structures; some states keep track of women's periods to become aware of any acts of abortion that could be indicated from this information [17]. For example, the Missouri government kept records of women's periods in clinics to flag any abortion attempts [18]. Moreover, the *ideal* body image of women—an image that is thin but robust, sporty, and sexualized—has been commercialized, influencing the femtech industry to design apps for women that encourage women to strive toward this body image. This has provoked the need and increased the demand for such apps [2]. Women dealing with all these issues are placed in a vulnerable position because they are considered responsible for infertility, are pressured to conceive a child at a certain age or prevent pregnancy, and feel the need to maintain a certain body image [6]. In summary, the need and responsibility of women to conceive a child, prevent pregnancy, or obtain an abortion generates a high demand for women to use these apps. Cultural shame of women's infertility or weight management leads them to use these apps as a safe zone. Therefore, the following question is raised: Are these apps valid and secure, and are they a safe zone for women? This question was addressed through our study.

In general, personal and health-related data that could be collected in mHealth apps raise ethical concerns, particularly in terms of data privacy, sharing, and security. However, the type of data collected in femtech is typically sensitive, intimate data [17]. Furthermore, women's mHealth apps are accessible and used on a global level. The practices are set in different cultures and backgrounds [12]. Modern technology has been affected by commercialism and masculinist ideologies [16]. Women's mHealth apps are mainly commercial, and the data they collect are circulated among different agencies, generating profit for these apps [6]. User consent, especially about sharing data in general or with a third party, is a concern for women's privacy. Women, as end users of these apps, typically share



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their personal, health, and intimate data. Research indicates that end users do not have full awareness of what their consent entails [17]. In femtech, the concerns about data privacy and sharing with the commercial agendas of these apps, who accesses the data, and how it is used are complicated and unclear. In addition, in the sociocultural context, women's vulnerability related to privacy risk by mismanagement and misuse of these data is highly alarming [6]. In this study, we assessed the current practices of the most popular apps in terms of privacy and data sharing.

The concept of women's health and the case of mHealth is our focus in this report. The spectrum of women's health encompasses more than just reproductive health and pregnancy. However, most previous studies have focused on reproductive health, pregnancy, and ovulation rather than on women's health in general. As a result of the increasing number of women using health apps, as well as the increased number of women's health apps available, we directed our focus to women's health for this study. As women's health has become digitalized in the form of femtech mHealth apps, the primary concern has been privacy and data protection [13].

### Privacy, Data Sharing, and Data Security Policies

In total, 3 main concerns arise when considering the ethical implications of mHealth apps: data privacy, data security, and data sharing.

#### *Data Privacy*

Data privacy is the right of users to control how their information is collected, managed, and used. Data privacy is widely recognized as an essential freedom [19], and respect of data privacy is increasingly regulated at national and international levels, such as by the General Data Protection Regulation (GDPR) in Europe and the Health Insurance Portability and Accountability Act in the United States [20]. Kotz [21] pointed out 25 subcategories of threats to data privacy in mHealth apps, which fall into three main categories: misuse of users' identities, unauthorized access to data, and unauthorized disclosure of data. A recent scoping review by Nurgalieva et al [22] delineated further criteria for assessing privacy and privacy-related measures, including data ownership, confidentiality, permission systems, auditability, consent, notice of use, disclosure, authenticity, anonymization, data retention, and data access mechanisms.

#### *Data Sharing and Data Security*

The concepts of privacy and data security partially overlap. Data security is a means to ensure the privacy of users' data; however, as pointed out by Nurgalieva et al [22], "while security relates to protection against unauthorized access to data, privacy is an individual's right to maintain control over and be free from intrusion into their private data and communications, and relates to trust in mHealth services." Data security can thus be defined as the set of procedures and safeguards established to ensure that only authorized users can access a set of data. Assessing data security practices allows for an understanding of how strictly data privacy rights are enforced.

Unauthorized access and data security are not the only issues at stake when considering data privacy. Health-related data gathered from a user can be shared with third parties in various ways. For example, the user may share information with their physician, insurance company, family, and friends, similar to how other information is shared in social networks. This is already happening—many companies offering direct-to-consumer genetic analyses for discovering ancestry or health-related information, such as the presence of genetic markers associated with specific diseases, already offer different degrees of data sharing functions, including the option to share personal data with third parties. Personal health-related data can also be shared in aggregated and anonymized forms for research purposes. This was the case in the Genographic Project [23], a genetic anthropological population study launched in 2005 by the National Geographic Society.

In summary, mHealth apps enable the widespread collection of a wealth of health-related information. Assuming that data privacy and data protection are fundamental human rights, including the right to understand and control which personal data are collected, who collects them, and how and by whom they are used, it is imperative to understand what privacy rights are recognized in practice and how they are enforced.

## Methods

### Overview

The following sections describe the methodology by which women's mHealth apps were screened, selected, and analyzed regarding their privacy, data sharing, and data security policies. The scoping review followed the methodology introduced by Arksey and O'Malley [24] and was adapted for this app review.

The scoping review protocol was developed by the first author (NF) in cooperation with the second author (MC) in November 2020. The protocol determined the procedure for the initial app search, screening, selection, and analysis. First, the database search and app selection guided by the protocol are described. Second, the screening and selection procedure, which yielded a total of 23 apps that were subject to a refined analysis, is outlined. Third, the analysis schema applied to the selected apps is explained.

### Initial Search for Women's mHealth Apps

The purpose of this scoping review and content analysis was to evaluate and assess the privacy, data sharing, and data security policies of popular, publicly available women's mHealth apps on the Apple App Store and Google Play markets, which are considered the largest app markets. As outlined in the *Introduction* section, a considerable number of available apps focused on women's health and functions (ie, femtech apps).

Therefore, as a first step, appropriate keywords that characterize femtech apps were identified. The keywords were based on our literature search, which described the topic of our scoping review, as explained in the *Introduction* section. Search syntaxes were developed that aligned with a general understanding of women's mHealth. Different combinations of search terms were tested, starting with a more extensive keyword set to identify a search string that yielded a broad set of results while remaining



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adequately specific. The primary database search aimed to minimize the number of false-negative results (ie, missing important apps) at the expense of considerable false-positive results (ie, apps that would later be screened out because they did not satisfy the purpose of the analysis). Textbox 1 presents the resulting search string; the 2 components were combined using the OR function.

The search focused on apps available in either the Apple App Store or Google Play. The search procedure made use of the mobile app database 42matters, a private company that provides app intelligence and mobile audience data. In the database, the search strings were categorized to be more specific. In the database search interface, we applied our search terms as detailed in Textbox 1. The database provided more specific filters for searching. The first filter was applied in the search field for *description*, *developer name*, and *title*. For the second filter, the Interactive Advertising Bureau (Interactive Advertising Bureau categories are an industry-standard taxonomy for content categorization that was used by the database), *medical health* was chosen. The third filter was the genre, for which *medical* and *health and fitness* were selected. The fourth filter was the match style of words, for which *exact match* was chosen.

The search performed by the first author (NF) in January 2021 yielded a total of 136 apps from which various pieces of information were collected to allow further screening of the apps (Table 1).

**Textbox 1.** Search strings used in the database search.

**Central notion and search string**

- Focus on females
  - woman OR women OR feminine OR female
- Focus on health
  - health OR medical OR medicine

**Table 1.** Information collected from identified apps.

| Information type | Description |
|---|---|
| App name | Name of the app on the market |
| Description | Description of the app provided by the developers |
| Downloads | Download frequency; orders of magnitude: 500, 1000, 5000, 10,000, 50,000, 100,000, 500,000, 1,000,000, 5,000,000, 10,000,000, 50,000,000, and 100,000,000. For screening and selection, the logarithm to the base 10 of the download numbers was used because most download information was available only in orders of magnitude, as explained in the *Methods* (*Screening and Selection* section) |
| Rating | User rating. Mean rating (between 1 and 5; 1: lowest, 5: highest) |
| Title | Title of the app |
| Specific search terms | All keywords that categorize the app |
| Developer | Developer's name |
| Rating count | Number of ratings the app has received from users. For screening and selection, the logarithm to the base 10 of the rating frequency was used |
| Language (default) | Languages that have been provided by the app |
| Market status | Whether the app has been published on the market |
| Website | The app's website |
| Interactive Advertising Bureau category | Interactive Advertising Bureau categories are an industry-standard taxonomy for content categorization used by the database |

## Screening and Selection

The scoping review focused on apps with certain characteristics such as an adequate number of downloads and a sufficiently large number of ratings by app users. To determine statistically plausible cutoff values for the selection of apps to include in a detailed analysis, a statistical analysis was performed on the connection among download frequency, rating frequency, and actual rating values.

The primary search indicated that the identified apps fell into 2 categories defined by the app providers, Apple App Store and Google Play. *Health and fitness* was the more general category, and *medical* was the more specific category. Of the 163 apps identified in the search, 43 (26.4%) were characterized as *health and fitness* and 93 (57.1%) were characterized as *medical*. The categories did not have sharp boundaries regarding the actual use of the apps; for example, some menstrual cycle tracker apps fell into the *health and fitness* category, whereas others were in the *medical* category. This was because some apps had



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additional functionalities, making them more health-oriented than others. The analysis relied on the categorization provided by the app providers.

From a statistical point of view, the 2 categories differed substantially concerning download frequency. The mean logarithm of *health and fitness* apps was 4.2 (ie, approximately 15,000 downloads; SD 1.8), whereas the mean logarithm of *medical* apps was 2.9 (ie, approximately 800 downloads; SD 1.5), which presented a significant difference ($P<.001$). The rating frequency distribution displayed a typical long-tail behavior in that many apps yielded only a few ratings and few apps yielded many ratings. Overall, *health and fitness* apps yielded more ratings than *medical* apps; 40% (37/93) of the *medical* apps and 16% (7/43) of the *health and fitness* apps did not produce any ratings. When excluding the apps without ratings and focusing on the mean ratings the apps received, a weak correlation was observed [25] between download quantity and the app ratings ($r=0.29$; $P=.005$) and between the number of ratings and the app ratings ($r=0.32$; $P=.002$). In other words, apps that were downloaded and rated more often had higher ratings. This is crucial, given that apps related to general health were downloaded much more often than medical apps; thus, conducting a direct comparison of both groups regarding quality would not make sense. On the basis of this analysis, we concluded that the 2 categories needed separate cutoff values for choosing the apps for the qualitative analysis.

The main reasons for choosing the cutoff values were that (1) a low download frequency indicated less popular apps, (2) a low rating frequency led to a higher variance in ratings, and (3) download and rating frequencies were strongly correlated. Therefore, rating variances independent of rating frequencies were examined to identify cutoff values separately for the 2 app categories.

For each app, the pair (logarithm of the rating frequency and rating value) was evaluated. These number pairs were ordered in terms of rating frequency (lowest to highest), the rating value variance per bin was calculated for each bin size (starting with 5, ending with 25, sliding window approach), and the distributions were verified visually. For the *health and fitness* apps, a distinct decrease in the rating value variance was observed at bin size 21. This meant that upon reaching the 21st item of the list, the variance dropped. The logarithm of the rating frequency of this bin size was 2.86; thus, the rating frequency should be approximately ≥720. Of the 43 *health and fitness* apps, 16 (37%) fulfilled this criterion. A sensitivity analysis revealed that the apps not chosen in the sequence had 540 and 227 ratings, making it plausible to assume that the result was not strongly affected by a different criterion.

For the *medical* apps, we used the same rating variance value as that used for the *health and fitness* apps. The same reasoning identified bin size 39 as the cutoff value, for which the logarithm of the rating frequency was ≥2, resulting in the selection of 18 apps that had at least 100 ratings. In total, of 163 apps, 34 (20.9%) were selected for further analysis. A sensitivity analysis revealed that the apps had 82, 78, and 45 ratings, supporting the plausibility of the cutoff criterion.

In summary, 34 apps were chosen on the basis of the statistical criterion and were further analyzed using the exclusion criteria in Table 2.

Using these criteria, 4 medical consulting apps were excluded because users were required to be associated with a specific hospital in a certain region or country. In addition, 4 other apps were excluded because they were not available in English, although the store page showed that they were available in English. Then, 1 app was not available in the Apple App Store at the time of our analysis because there was no update for the iPhone 11 (software version 14.4; Apple Inc). The same app downloaded from Google Play crashed after opening. In addition, 1 app did not provide a service related to women's health. Lastly, 1 app was no longer available in the store. In summary, of the 34 apps, 11 (32%) were excluded, and 23 (68%) remained for the final analysis. Figure 1 provides an overview of the search and selection process including the number of apps identified.

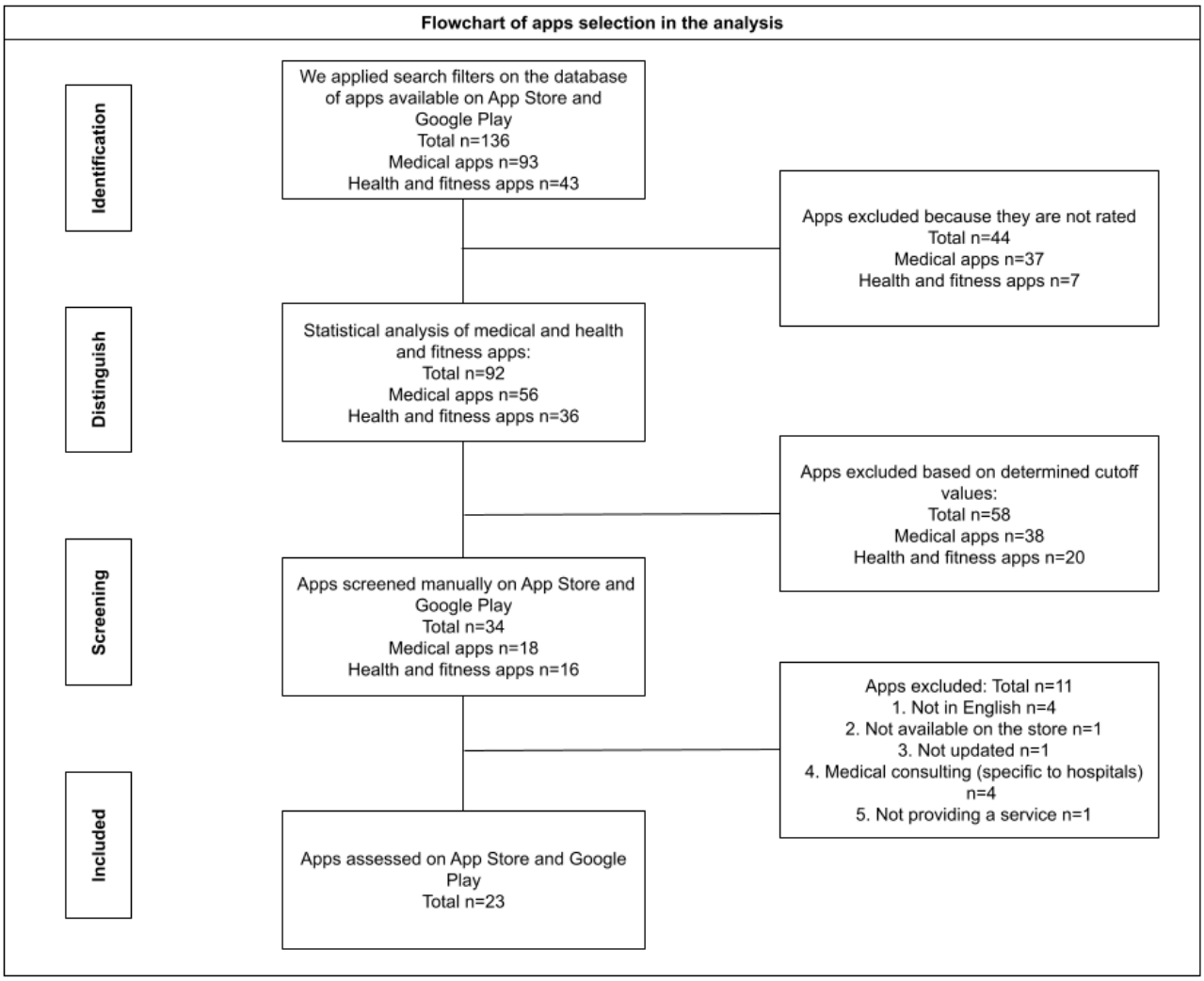
**Table 2.** Exclusion criteria.

| | Description |
|---|---|
| Language | The app must be available in English. |
| Time Frame | The app must be functional in the search period (January to March 2021). |
| Service | The app must provide a service related to women's health, not only access to information (such as articles or magazines) or a game related to one of the topics described by the search string. |



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**Figure 1.** PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flowchart outlining the search and selection procedure.




## App Analysis

In the last step, the 23 identified apps were downloaded and assessed independently by 2 reviewers (the first [NF] and third author [GS]). Apps on Google Play were assessed in LDPlayer 4 (Xuanxi International Co), a PC framework software that allows Android apps to run on a computer. LDPlayer 4 emulates a Samsung A908N tablet and uses Android 7.1.2 (security patch October 5, 2017, kernel 3.18.48). Apple App Store apps were analyzed on an iPhone 11 (software version 14.4). All apps were downloaded and tested between February and March 2021.

One of the main differences between the Apple App Store and Google Play is that the Apple App Store has the option to review an app's privacy policy before downloading the app. This option is not available in Google Play. However, Google Play includes a Pan European Game Information (PEGI) score, which is a rating system developed and intended to assess the appropriateness of video games, considering the presence of bad language, discrimination, drugs, fear, gambling, sex, violence, and in-game purchases [26]. Nevertheless, the PEGI score does not always provide useful information on the appropriateness of apps for certain age groups. PEGI scores can be inconsistent; for example, apps for lung cancer screening and abortion are both rated as PEGI 3. In addition, the PEGI age limit often contradicts age limits specified within privacy policies or terms and conditions.

The downloaded apps were assessed manually by 2 independent reviewers against a variety of user data privacy, data sharing, and security assessment criteria. These criteria, presented in Table 3, were selected from 2 studies that focused on app security and privacy assessments [27,28]. The selected assessment criteria were developed in compliance with the European Union (EU) GDPR. The assessment questions were categorized into several domains: privacy policy, data gathering, data sharing, security, and transparency. Our assessment was based on *yes* and *no* answers. In some cases, it was not clear if the criteria applied, so *not applicable* was used as a response for vague statements or if the question was not answered. In addition, a qualitative portion of the assessment was included for each question, which allowed the reviewers to add comments detailing their observations. These comments are not included in Table 3 but are included in the *Results* section. This review assessed each app's privacy policy, if it existed, by screening each app manually after downloading. In this analysis step, the apps were evaluated using the assessment questions listed in Table 3.



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**Table 3.** Data privacy, sharing, and security assessment results (N=23).

| | Value, n (%) |
|---|---|
| **Privacy policy** | |
| **Is the privacy policy available within the app?** | |
| Yes | 16 (70) |
| No | 7 (30) |
| **Is the privacy policy available before downloading the app?** | |
| Yes | 19 (83) |
| No | 4 (17) |
| **Is there a short-form notice (in plain English) highlighting key data practices that are disclosed in detail in the full privacy policy?** | |
| Yes | 0 (0) |
| No | 23 (100) |
| **Is the privacy policy available in any other languages?** | |
| Yes | 3 (13) |
| No | 20 (87) |
| **Are there specifications of the privacy policy for users in certain regions or countries?** | |
| Yes | 11 (48) |
| No | 12 (52) |
| **Is contact information provided for the users' questions regarding the privacy policy?** | |
| Yes | 19 (832.6) |
| No | 4 (17) |
| **Does the app request explicit consent to start storing all user health and sensitive data when an account is created?** | |
| Yes | 12 (52) |
| No | 11 (48) |
| **Data gathering** | |
| **Is there an age restriction for data collection and account creation for adult services?** | |
| Yes | 21 (91) |
| No | 2 (9) |
| **Does required sensitive data include personal data that directly identifies the person (eg, first name, surname, email, date of birth, and mobile phone number)?** | |
| Yes | 21 (91) |
| No | 2 (9) |
| **Does required sensitive data include health-related personal information?** | |
| Yes | 23 (100) |
| No | 0 (0) |
| **Is an account required to use the app (ie, does the app require a login and password)?** | |
| Yes | 14 (61) |
| No | 9 (39) |
| **Are data collected when a user registers through a web-based account?** | |
| Yes | 15 (65) |
| No | 8 (35) |
| **Are data collected when the app is used?** | |
| Yes | 11 (48) |
| No | 12 (52) |



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| | Value, n (%) |
|---|---|
| **Data sharing** | |
| **Can the user opt out or withdraw by deleting the app?** | |
| Yes | 17 (74) |
| No | 3 (13) |
| N/A[a] | 3 (13) |
| **Can the user delete past data by request?** | |
| Yes | 14 (61) |
| No | 7 (30) |
| N/A | 2 (9) |
| **Does the app allow behavior tracking?** | |
| Yes | 23 (100) |
| No | 0 (0) |
| N/A | 0 (0) |
| **Does the app allow location tracking?** | |
| Yes | 14 (61) |
| No | 7 (30) |
| N/A | 2 (9) |
| **Does the app share users' data with a third party?** | |
| Yes | 20 (87) |
| No | 0 (0) |
| N/A | 3 (13) |
| **Can the user change the sharing settings?** | |
| Yes | 12 (52) |
| No | 9 (39) |
| N/A | 2 (9) |
| **Does the app share personal data for research purposes with a third party?** | |
| Yes | 18 (78) |
| No | 4 (17) |
| N/A | 2 (9) |
| **Does the app share data with third parties for tracking and analysis?** | |
| Yes | 15 (65) |
| No | 4 (17) |
| N/A | 4 (17) |
| **Are personal data shared if required by law?** | |
| Yes | 20 (87) |
| No | 1 (4) |
| N/A | 3 (13) |
| **Data security and transparency** | |
| **Does the app explain how the users' data security is ensured (eg, encryption, authentication, or firewall system)?** | |
| Yes | 13 (57) |
| No | 8 (35) |
| N/A | 2 (9) |



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| | Value, n (%) |
|---|---|
| **Is the app transparent about how it processes data?** | |
| Yes | 16 (70) |
| No | 6 (26) |
| N/A | 1 (4) |

[a]N/A: not applicable

# Results

## Overview

Our assessment included 23 women's mHealth apps. Among the 23 women's mHealth apps that we analyzed, 16 (70%) were related to fertility health, ovulation or menstrual cycle tracking, and pregnancy; 1 (4%) was related to abortion; 2 (9%) were related to breast and lung cancers; 1 (4%) was related to women's mental health and self-care; and 3 (13%) were related to women's health exercises (eg, pelvic floor exercises and weight tracking; Table 4). These categories matched those defined as the dimensions of women's health in the Introduction section

Figure 2 displays the general characteristics of the 23 apps analyzed in this study. We plotted download frequency against rating frequency ($\log_{10}$ scale) of *health and fitness* apps (black) and *medical* apps (blue); point size is scaled with the rating value of each app. The figure demonstrates the (expected) strong correlation between download and rating frequency and reproduces the initial finding that *health and fitness* apps are generally more popular than *medical* apps (see the *Screening and Selection* section). The results of the evaluation of data privacy, data sharing, and security assessment are summarized in Table 3.

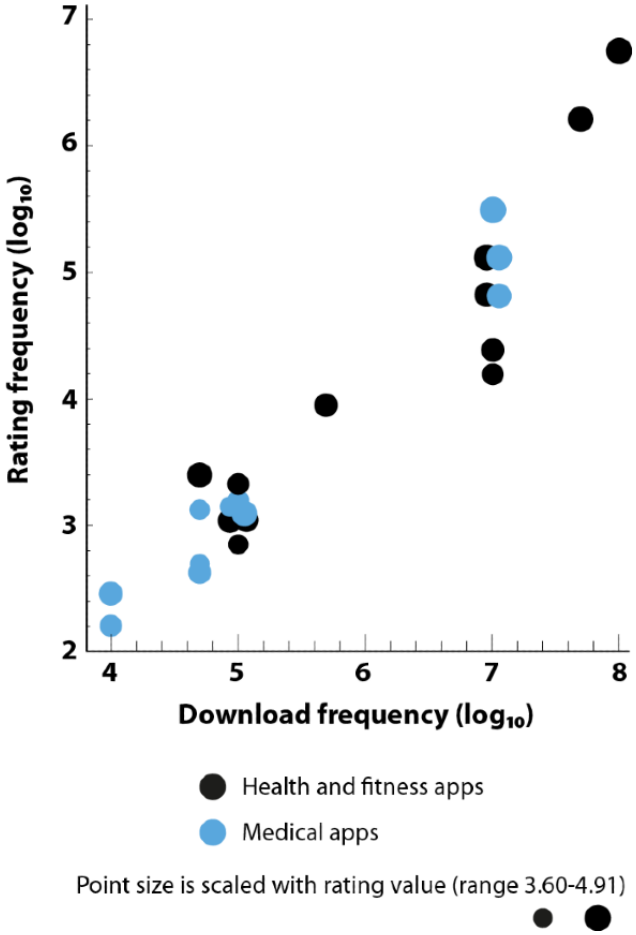
**Table 4.** Women's health app taxonomy (N=23).

| Category | Apps, n (%) |
|---|---|
| Fertility health, ovulation or menstrual cycle, and pregnancy | 16 (70) |
| Abortion | 1 (4) |
| Breast cancer and lung screen | 2 (9) |
| Women mental health (self-care) | 1 (4) |
| Exercise (eg, pelvic floor exercises and weight tracking) | 3 (13) |



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**Figure 2.** Scatterplot demonstrating the statistical relationship between download frequency and rating frequency of the 23 analyzed apps.




## Privacy Policy

In 4% (1/23) of the apps, we found that the privacy policy was available on the store page but not inside the app itself; we assessed the app using only the information available in the Apple App Store. Of the 23 apps, 1 (4%) was available in English only on Google Play but not on the Apple App Store. Therefore, we analyzed the app only on Google Play.

Of the 23 apps reviewed, 7 (30%) did not have a privacy policy available within the app, whereas 4 (17%) had a privacy policy available on the Apple App Store page before downloading the app. As Google Play does not require the privacy policy to be included on the page displayed before downloading the app, Google Play users cannot read the privacy policy beforehand. The other 13% (3/23) of the apps did not have privacy policies either within the app or before downloading the app. In addition, of the 23 apps, 1 (4%) had a privacy policy after creating an account, but the privacy policy was not accessible anywhere else in the app. In 4% (1/23) of the apps, the link led to the privacy policy on the app website. However, on the website, the privacy policy was available on another page. Thus, reaching the privacy policy requires a long process; the user must go through the main website and search for it, and at least four clicks were required to find it. Therefore, users who want to read the privacy policy cannot reach it directly from the app page on the store or in the app itself.

Of the 23 apps analyzed, 11 (48%) provided their services in more than one language, including English, yet their privacy policies were only available in English. Only 13% (3/23) of the apps provided their privacy policies in languages other than English. None of the apps reviewed had a short-form notice (in plain English) highlighting key data practices that were disclosed in detail in the full privacy policy. Only 9% (2/23) of the apps provided options for viewing the privacy policy (summary view or full view) but not in a short-form notice. In addition, of the 23 apps, 1 (4%) included the privacy policy with illustrated pictures, but the privacy policies of the remaining apps were in plain text.

Of the 23 apps, 11 (48%) had specifications in their privacy policies related to certain laws and regulations, such as the California Consumer Privacy Act, the EU GDPR, and the UK Data Protection Act 2018). Of the 23 apps, 4 (17%) did not provide any contact information to address users' questions regarding the privacy policy, whereas 3 (13%) did not have a privacy policy at all.

A total of 48% (11/23) of the apps did not require explicit consent to the privacy policy. The welcome page of 4% (1/23) of the apps provided an option to read the privacy policy; however, clicking or consenting was not required before entering the app. Among the 52% (12/23) of the apps that required consent, only 8% (1/12) displayed the consent requirement at the welcome page with transparent options (the welcome page provided 4 options for consent, and they had to be accepted to



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enter and use the app). Another app prompted the user to accept the privacy policy; however, the privacy policy did not exist—it was not available in the app, store, or website. We considered this to be a pseudoconsent. The welcome pages of 3 other apps asked personal and health questions and would not allow the user to move to the next page without filling in all fields, but consent was not required until the second page. One app's privacy policy had an option to "expressly agree," but the form was accessible only after registration, whereas another app's welcome page had a large button to "get started," under which was written in smaller font that by tapping "get started," the user was stating "I consent to the privacy policy."

### Data Gathering

We found that 17% (4/23) of the apps provided different age restrictions on the Apple App Store compared with those on Google Play; of the 23 apps, 3 (13%) showed different ages on the app store pages and in their privacy policies, and 2 (9%) did not provide any age restrictions. Only 35% (8/23) of the apps had privacy policies that stated that users under a certain age should have parental consent.

All apps in the study required the entry of sensitive health-related data and personal information. Of the 23 apps, 1 (4%) also asked for information about the children, such as the child's age and overall health-related questions. Only 9% (2/23) of the apps did not collect sensitive data, such as personal data that directly identified the user (eg, name, surname, email address, date of birth, and mobile phone number). Of the 23 apps, 11 (48%) collected personal data once the user started using the app without any registration, whereas 9 (39%) required no consent before using the app.

### Data Sharing, Security, and Transparency

Of the 23 apps, 7 (30%) did not provide the user an option to delete past data by request, such as by sending an email, and 3 (13%) did not allow the user to opt out or withdraw by deleting the app. Of the 23 apps, 3 (13%) others did not provide any information on requesting to opt out or withdraw by deleting the app. All apps allowed behavioral tracking, whereas only 4% (1/23) of the apps gave the user the ability to opt out. Of the 23 apps, 7 (30%) did not allow location tracking, and 2 (9%) other apps did not provide any information about location tracking. Of the 23 apps, 20 (87%) shared user data with third parties, 9 (39%) did not require explicit consent to share user data with third parties, and 3 (13%) did not provide any information in their privacy policies and did not require consent related to the sharing of user data with third parties. We found that 78% (18/23) of the apps shared personal data for research purposes, 33% (6/18) of which did not require user consent, and 65% (15/23) of the apps shared data with a third party for tracking and analysis.

In total, of the 23 apps, 20 (87%) shared user information if required by law. Of these 20 apps, 9 (45%) did not require user consent; 2 (10%) did not require user consent and did not provide a clear statement in their privacy policies disclosing whether they share user information; and 1 (5%) did not have a privacy policy. Among the 23 apps reviewed, 16 (70%) were transparent about how they processed the data, and 6 (26%) did not share any information regarding how the data were processed. Of the 23 apps, 8 (35%) did not provide information regarding how users' data would be secured.

## Discussion

### Principal Findings

The goal of this review and content analysis was to assess the privacy, data sharing, and security policies of women's mHealth apps on the market. This scoping review was important because of the growing presence and use of such apps in the women's health domain, as identified by both health sciences and the mHealth app market (ie, femtech).

This review revealed important shortcomings associated with privacy policies and consent practices, especially in the case of women's mHealth apps. The apps that we analyzed were the most frequently downloaded from the market and had the highest ratings. Through our review and analysis, we found that women's mHealth apps collected and tracked personal and health data. However, their standard practices did not follow regulations, such as the EU GDPR. Data privacy and protection have been suggested as fundamental human rights. In this review and analysis, we sought to understand the practices of select women's mHealth apps. Our results revealed poor data privacy protection practices. It is ethically unacceptable that, despite the existence of regulations such as EU GDPR, there are still gaps in data privacy and security practices.

All apps included in our analysis collected personal and health data; however, the option for the user to give consent and read the privacy policy was not always available. The involvement of end users is essential, especially when personal and health data are collected. Not requiring the consent of the end user when collecting sensitive information is an ethical violation. Moreover, the use of a range of women's mHealth apps is increasing worldwide [7]. Many available apps provide services in multiple languages, which allows them to be used by people who cannot speak English. However, we found that most apps provided their privacy policies only in English. Users who cannot read English are unable to review and understand these privacy policies. Therefore, users may give their consent without reading or understanding the privacy policies of these apps. The right of the end user to access and understand what they provide consent for is a basic right that must be upheld.

The type of data collected by women's mHealth apps is considered sensitive in general. In some cultures, women's bodies and health are taboo subjects. Therefore, the collection of women's personal and health data could have negative consequences in certain areas of the world [12]. Given the sensitive nature of women's health, women's mHealth apps should practice increased privacy rather than the poor practices uncovered in this study. Moreover, some women's mHealth apps collected not only women's sensitive data but also information on children and infants. These observations demonstrate the complexity of the standard practices of data privacy and consent. Finally, also the age of the users is a factor to consider, as younger women are—because of a generally higher affinity of younger people to health apps—likely to be



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a big audience for these apps [2]. Adolescence and early adulthood are important phases in the human life span, and the experience of potential violation of privacy on sensitive data can have a considerable impact. Our study was not designed to consider those aspects, but future studies should include the role of age and culture on femtech use.

### Recommendations

It is evident that poor data privacy practices do not deter users, as demonstrated by the high number of users of apps with unsatisfactory privacy policies. This generates the following 2 questions. First, are women as end users aware of the privacy practices of the mHealth apps to which they provide their personal and health data? Second, do they know how their data will be used? Future studies should focus on measuring women's awareness of mHealth apps' data privacy and sharing practices. It is critical to understand what data women share with mHealth apps, whether they understand the apps' privacy policies in their current forms and whether alternative forms of the apps' privacy policies should be made available.

Consumers are typically unable to assess privacy, data sharing, and data security policies. More stringent regulations would require apps to adhere to defined standards for their policy descriptions and how they may or may not prompt users to accept their policies. Although not an ideal solution, privacy checkups should be easily accessible so that users can better understand policies in the absence of stricter regulations. Despite current regulations, such as the GDPR, protocols should be improved to enable users to examine and understand policies. An educational study on the relevance of data protection, particularly with artificial intelligence, was conducted on pooled personal data. Further studies could be conducted for cases in which clear and transparent privacy policies do not exist. We recommended surveying women with a short-form privacy policy to illustrate the main points while providing access to the full form. Privacy policies should be improved to include illustrated figures and photos in a shorter form to aid in the end user's awareness and understanding. This is imperative for understanding the future design of women mHealth apps.

The Apple App Store and Google Play, which are considered the largest app providers, should require that apps follow the regulations. It was observed that the Apple App Store requires privacy policies to be displayed on the apps' store pages; however, this is not the case for Google Play. The Apple App Store and Google Play should be responsible for such regulations, rather than only reaping the benefits associated with mHealth apps. For instance, an app that provides services in multiple languages should be required to also provide its privacy policy in those languages.

### Conclusions

This review and content analysis examined the most popular women's mHealth apps on the market. The market for women's mHealth apps is large, with millions of users worldwide; the mHealth app industry is growing, and the number of available apps is increasing. Women's health is a complicated topic in many ways. In our analysis, we found that the most popular women's mHealth apps on the market have poor data privacy, sharing, and security practices. Although regulations exist, such as the EU GDPR, current practices do not follow them. Moreover, other studies conducted on various dimensions of women's mHealth apps, such as on reproductive health, pregnancy, and ovulation, have concluded that those apps have poor practices in terms of privacy, data sharing, and data security [6,17]. These poor data privacy and sharing practices generate concern regarding health and personal data. The studied mHealth apps lack basic data privacy and security practices, which is unacceptable, both ethically and legally.

### Authors' Contributions

NF was the main author, designed the study, collected the data, reviewed the data, performed the analysis, drafted the manuscript, and wrote the paper. MC was involved in the study design, performed the quantitative data analysis, and was involved in writing the paper. GS was involved in collecting the data, reviewed the data, and was involved in writing the paper. NBA contributed to the discussion. All authors critically revised the paper.

### Conflicts of Interest

None declared.

### References

1. World Health Organization. A practical guide for engaging with mobile network operators in mHealth for reproductive, maternal, newborn and child health. Geneva, Switzerland: World Health Organization; 2014.
2. Lupton D. Australian women's use of health and fitness apps and wearable devices: a feminist new materialism analysis. Fem Media Stud 2019 Jul 05;20(7):983-998. [doi: 10.1080/14680777.2019.1637916]
3. Ceci L. Number of apps available in leading app stores 2021. Statista. 2022 Jan 27. URL: https://www.statista.com/statistics/276623/number-of-apps-available-in-leading-app-stores/ [accessed 2021-05-07]
4. Women's health. Gale Encyclopedia of Medicine. 2008. URL: https://medical-dictionary.thefreedictionary.com/women%27s+health [accessed 2021-02-02]
5. Alexander LL, LaRosa JH, Bader H, Garfield S, Alexander JW. New Dimensions in Women's Health. 8th edition. Burlington, MA, USA: Jones & Bartlett Learning; 2021.



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6. Mehrnezhad M, Almeida T. Caring for intimate data in fertility technologies. In: Proceedings of the 2021 CHI Conference on Human Factors in Computing Systems. 2021 May Presented at: CHI '21; May 8 - 13, 2021; Yokohama, Japan p. 1-11. [doi: 10.1145/3411764.3445132]
7. Hughson JP, Daly JO, Woodward-Kron R, Hajek J, Story D. The rise of pregnancy apps and the implications for culturally and linguistically diverse women: narrative review. JMIR Mhealth Uhealth 2018 Nov 16;6(11):e189 [FREE Full text] [doi: 10.2196/mhealth.9119] [Medline: 30446483]
8. Hatt T, Gardner C, Wills A, Harris M. Scaling mobile for development: harness the opportunity in the developing world. Global System for Mobile Communications. 2013 Aug. URL: https://www.gsma.com/mobilefordevelopment/resources/scaling-mobile-for-development-harness-the-opportunity-in-the-developing-world/ [accessed 2021-04-09]
9. Rosas C. The future is Femtech: privacy and data security issues surrounding Femtech applications. Hastings Bus Law J 2019;15:319.
10. Tin I. The rise of a new category: Femtech. Clue. 2016 Sep 15. URL: https://helloclue.com/articles/culture/rise-new-category-femtech [accessed 2021-05-20]
11. Grand View Research. 2021 Jun. URL: https://www.grandviewresearch.com/industry-analysis/womens-health-app-market [accessed 2022-04-21]
12. Almeida T, Balaam M, Comber R. Woman-centered design through humanity, activism, and inclusion. ACM Trans Comput Hum Interact 2020 Aug 31;27(4):1-30 [FREE Full text] [doi: 10.1145/3397176]
13. Lu D. The femtech gold rush. New Sci 2019 Jun;242(3232):20-21 [FREE Full text] [doi: 10.1016/s0262-4079(19)30973-x]
14. Lupton D. Quantified sex: a critical analysis of sexual and reproductive self-tracking using apps. Cult Health Sex 2015;17(4):440-453. [doi: 10.1080/13691058.2014.920528] [Medline: 24917459]
15. Hamper J. 'Catching ovulation': exploring women's use of fertility tracking apps as a reproductive technology. Body Soc 2020 Mar 31;26(3):3-30. [doi: 10.1177/1357034x19898259]
16. Almeida T, Comber R, Balaam M. HCI and intimate care as an agenda for change in women's health. In: Proceedings of the 34th CHI Conference on Human Factors in Computing Systems. 2016 May Presented at: CHI '16; May 7-12, 2016; San Jose, CA, USA p. 2599-2611. [doi: 10.1145/2858036.2858187]
17. Shipp L, Blasco J. How private is your period?: a systematic analysis of menstrual app privacy policies. Proc Priv Enh Technol 2020;2020(4):491-510. [doi: 10.2478/popets-2020-0083]
18. Mahdawi A. If the government tracks women's periods, why not track male ejaculation, too? The Guardian. 2019 Nov 2. URL: https://www.theguardian.com/world/commentisfree/2019/nov/02/if-the-government-tracks-womens-periods-why-not-track-male-ejaculation-too [accessed 2019-11-02]
19. Arora S, Yttri J, Nilse W. Privacy and security in mobile health (mHealth) research. Alcohol Res 2014;36(1):143-151 [FREE Full text] [Medline: 26259009]
20. Health Insurance Portability and Accountability Act of 1996. Office of the Assistant Secretary for Planning and Evaluation. 1996 Aug 20. URL: https://aspe.hhs.gov/reports/health-insurance-portability-accountability-act-1996 [accessed 2021-06-07]
21. Kotz D. A threat taxonomy for mHealth privacy. In: Proceedings of the 3rd International Conference on Communication Systems and Networks. 2011 Presented at: COMSNETS '11; January 4-8, 2011; Bangalore, India p. 1-6. [doi: 10.1109/comsnets.2011.5716518]
22. Nurgalieva L, O'Callaghan D, Doherty G. Security and privacy of mHealth applications: a scoping review. IEEE Access 2020 Jun 4;8:104247-104268. [doi: 10.1109/access.2020.2999934]
23. Behar DM, Rosset S, Blue-Smith J, Balanovsky O, Tzur S, Comas D, Genographic Consortium. The Genographic Project public participation mitochondrial DNA database. PLoS Genet 2007 Jun;3(6):e104 [FREE Full text] [doi: 10.1371/journal.pgen.0030104] [Medline: 17604454]
24. Arksey H, O'Malley L. Scoping studies: towards a methodological framework. Int J Soc Res Methodol 2005 Feb;8(1):19-32. [doi: 10.1080/1364557032000119616]
25. Evans JD. Straightforward Statistics for the Behavioral Sciences. Pacific Grove, CA, USA: Thomson Brooks/Cole Publishing; 1996.
26. The Pan-European Game Information (PEGI). URL: https://pegi.info/ [accessed 2021-03-10]
27. Bondaronek P, Alkhaldi G, Slee A, Hamilton FL, Murray E. Quality of publicly available physical activity apps: review and content analysis. JMIR Mhealth Uhealth 2018 Mar 21;6(3):e53 [FREE Full text] [doi: 10.2196/mhealth.9069] [Medline: 29563080]
28. Grindrod K, Boersema J, Waked K, Smith V, Yang J, Gebotys C. Locking it down: the privacy and security of mobile medication apps. Can Pharm J (Ott) 2016 Dec 6;150(1):60-66 [FREE Full text] [doi: 10.1177/1715163516680226] [Medline: 28286594]


## Abbreviations

**EU:** European Union
**femtech:** female technology
**GDPR:** General Data Protection Regulation



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**mHealth:** mobile health
**WHO:** World Health Organization

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Original Paper

# The Quality of Indian Obesity-Related mHealth Apps: PRECEDE-PROCEED Model–Based Content Analysis

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## Abstract

**Background:** The prevalence of obesity in India is increasing at an alarming rate. Obesity-related mHealth apps have proffered an exciting opportunity to remotely deliver obesity-related information. This opportunity raises the question of whether such apps are truly effective.

**Objective:** The aim of this study was to identify existing obesity-related mHealth apps in India and evaluate the potential of the apps' contents to promote health behavior change. This study also aimed to discover the general quality of obesity-related mHealth apps.

**Methods:** A systematic search for obesity-related mHealth apps was conducted in both the Google Play Store and the Apple App Store. The features and quality of the sample apps were assessed using the Mobile Application Rating Scale (MARS) and the potential of the sample apps' contents to promote health behavior change was assessed using the PRECEDE-PROCEED Model (PPM).

**Results:** A total of 13 apps (11 from the Google Play Store and 2 from the Apple App Store) were considered eligible for the study. The general quality of the 13 apps assessed using MARS resulted in mean scores ranging from 1.8 to 3.7. The bivariate Pearson correlation between the MARS rating and app user rating failed to establish statistically significant results. The multivariate regression analysis result indicated that the PPM factors are significant determinants of health behavior change ($F_{3,9}$=63.186; $P$<.001) and 95.5% of the variance ($R^2$=0.955; $P$<.001) in the dependent variable (health behavior change) can be explained by the independent variables (PPM factors).

**Conclusions:** In general, mHealth apps are found to be more effective when they are based on theory. The presence of PPM factors in an mHealth app can greatly influence the likelihood of health behavior change among users. So, we suggest mHealth app developers consider this to develop efficient apps. Also, mHealth app developers should consider providing health information from credible sources and indicating the sources of the information, which will increase the perceived credibility of the apps among the users. We strongly recommend health professionals and health organizations be involved in the development of mHealth apps. Future research should include mHealth app users to understand better the apps' effectiveness in bringing about health behavior change.

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**KEYWORDS**

obesity; mHealth apps; PRECEDE-PROCEED Model; Mobile App Rating Scale; health communication; health behavior change techniques; health information



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## Introduction

### Background

Obesity is an alarming health issue that leads to significant health and social difficulties for people globally. Generally, obesity is defined by the measurement of the BMI [1]. Per clinical guidelines, a BMI of 25 kg/m$^2$ to 29.9 kg/m$^2$ indicates overweight or preobesity and a BMI of 30 kg/m$^2$ or greater indicates obesity [2]. Obesity is associated with all-cause mortality. The health consequences of obesity are vast, including cardiovascular diseases, diabetes, musculoskeletal disorders, and some cancers, such as endometrial, breast, and colon cancer. The next generations are in a more dangerous position since the health consequences of childhood obesity are extensive, including premature death and disability in adulthood [3].

### Obesity in India

An increase in the consumption of junk food and the adoption of sedentary lifestyles are the major reasons for the increase in the prevalence of obesity in India. According to the India National Family Health Survey-4, the number of people with obesity in India doubled between 2006 and 2016. The prevalence of obesity among women ages 5 to 49 years in India is 20.7%, which is a 60% increase from 2005 to 2006. The prevalence of obesity among men ages 5 to 49 years in India doubled to 18.6% from 9.3% in the year 2005 to 2006 [4,5]. A study involving 14.4 million children in India revealed that the country has the second-highest prevalence of childhood obesity in the world after China [3]. The prevalence of obesity in India is increasing at an alarming rate.

### Obesity and Media

Obesity is the fastest-growing global public health issue and media campaigns can increase public awareness of obesity [6]. Media campaigns are found to be more effective in raising awareness about the causes of obesity, health problems associated with obesity, and healthy habits to prevent and manage obesity [7,8]. Public attention to a particular issue correlates with the degree of salience of the issues covered in the media. Media can be used to provide information as simply as possible and to update the information constantly [9]. Though media can have an impact on knowledge and attitudes about obesity among the public, evidence is still limited as to whether media can influence health behavior change [10].

### mHealth Apps for Obesity

Television was the dominant form of media for increasing obesity awareness, but with the rapid advance of digital media, the evaluation of other media, such as internet-based media, is increasingly important [10]. The most recent and fastest evolving internet-based media is mobile media [11]. Substantially, mobile media are used for the delivery of health information [12]. The World Health Organization defined mHealth as medical and public health practices supported by mobile devices [13]. Smartphones have gained popularity and are being adopted for mHealth practices. There are different types of mHealth apps developed and available for general use in obesity management [14]. The benefits of mHealth apps include cost-effectiveness, the potential for real-time data collection, feedback capability, minimized participant burden, relevance to multiple populations, and increased dissemination capability [15]. Obesity-related mHealth apps have proffered an exciting opportunity to remotely deliver obesity-related information. This opportunity raises the question of whether such apps are truly effective. Therefore, the purpose of this study was to identify existing obesity-related mHealth apps in India and evaluate the potential of the app contents in promoting health behavior change.

### The PRECEDE-PROCEED Model

The PRECEDE-PROCEED Model (PPM) is a widely accepted health education framework for planning and evaluating health behavior change programs [16,17]. The anticipated influence on health behavior change can be evaluated by the presence of 3 factors in health interventions, predisposing factors, enabling factors, and reinforcing factors. Predisposing factors include the following variables, which act as antecedents to health behavior change: knowledge, attitudes, beliefs, values, and motivation. Enabling factors include the following variables, which act as antecedents that facilitate health behavior change: teaching skills, providing resources, providing a service, and tracking progress. Reinforcing factors include the following variables, which provide rewards or feedback for health behavior change: interacting with health professionals to obtain support and interfacing with social media sites for encouragement [18]. This study attempts to identify the presence of PPM variables in Indian obesity-related mHealth apps for promoting health behavior change. This study also aimed to examine the overall quality of obesity-related mHealth apps.

## Methods

This study involved a qualitative content analysis of the available obesity-related mHealth apps in the Google Play Store and Apple App Store.

### Study Sample

There are studies showing that mHealth app users are more likely to use free apps, which is why most previous studies on mHealth apps focused only on free apps [19] (R Subramanian, PhD, unpublished data, August 2015). Likewise, this study will focus only on free obesity-related mHealth apps. Free obesity-related apps were identified using the following search terms in the Google Play Store and Apple App Store during June 2021: “obesity”, “obese”, “obesity calculator”, “obesity diet”, and “obesity exercise”. An app was considered for inclusion if the app content had obesity related-information and the app was rated above 3 out of 5 stars.

### Measurement

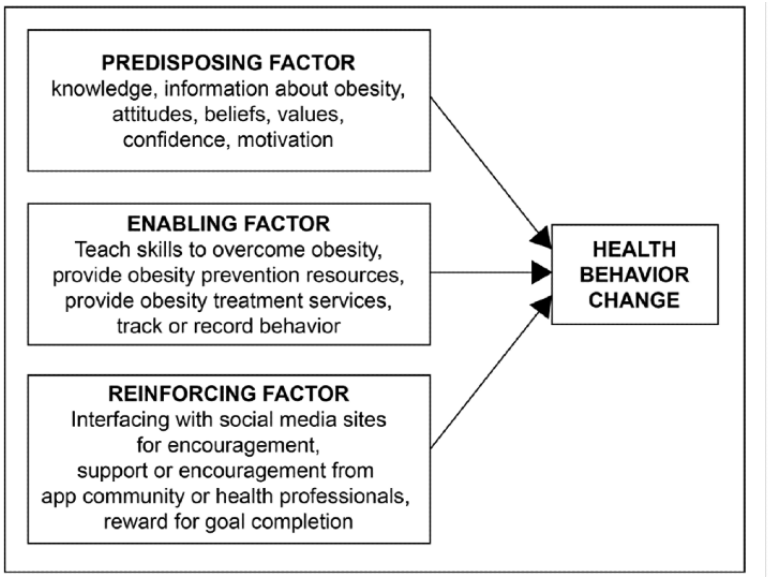
Each sample app was coded for basic descriptive information, such as the app name, user rating, and the number of downloads. The features and quality of the sample apps were assessed using the Mobile Application Rating Scale (MARS) [20-22] and the potential of the app contents to promote health behavior change was assessed using the PPM [18]. MARS is a measure for classifying and assessing the quality of mHealth apps. The MARS uses a Likert scale ranging from 1 (inadequate) to 5 (excellent) to score apps on the following criteria: engagement,



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functionality, aesthetics, information quality, and subjective quality [22]. The PPM (Figure 1) was used to measure each app according to its level of anticipated influence on health behavior change.

**Figure 1.** Framework of PRECEDE-PROCEED Model factors influencing health behaviour change [23].




### Data Collection

The MARS and PPM were explained to 2 coders, who were researchers studying mHealth apps with several years of experience and a good knowledge of mHealth apps [24,25]. The coding sheet is presented in Multimedia Appendix 1. The coders were instructed on each measure and its definition to ensure clear differentiation between the items used to assess the sample apps [20]. Both coders assessed the content of the sample apps independently. Finally, the researchers and the coders discussed disagreements until a consensus was reached [18].

### Data Analysis

Descriptive statistics were calculated for all items under the MARS and PPM. The Cronbach α was used to evaluate the reliability between each item under the 5 criteria of the MARS, engagement, functionality, aesthetics, information quality, and subjective quality. The Pearson correlation coefficient was then calculated to determine the relationship between the MARS rating and app user rating. The Cronbach α was used to evaluate the reliability between each measure item under the 3 factors of the PPM (predisposing factors, enabling factors, and reinforcing factors) and items used by reviewers to assess the app's ability to promote health behavior change. Multivariate regression analysis was then performed to test the influence of PPM factors on the app's ability to promote health behavior change, as assessed by reviewers.

## Results

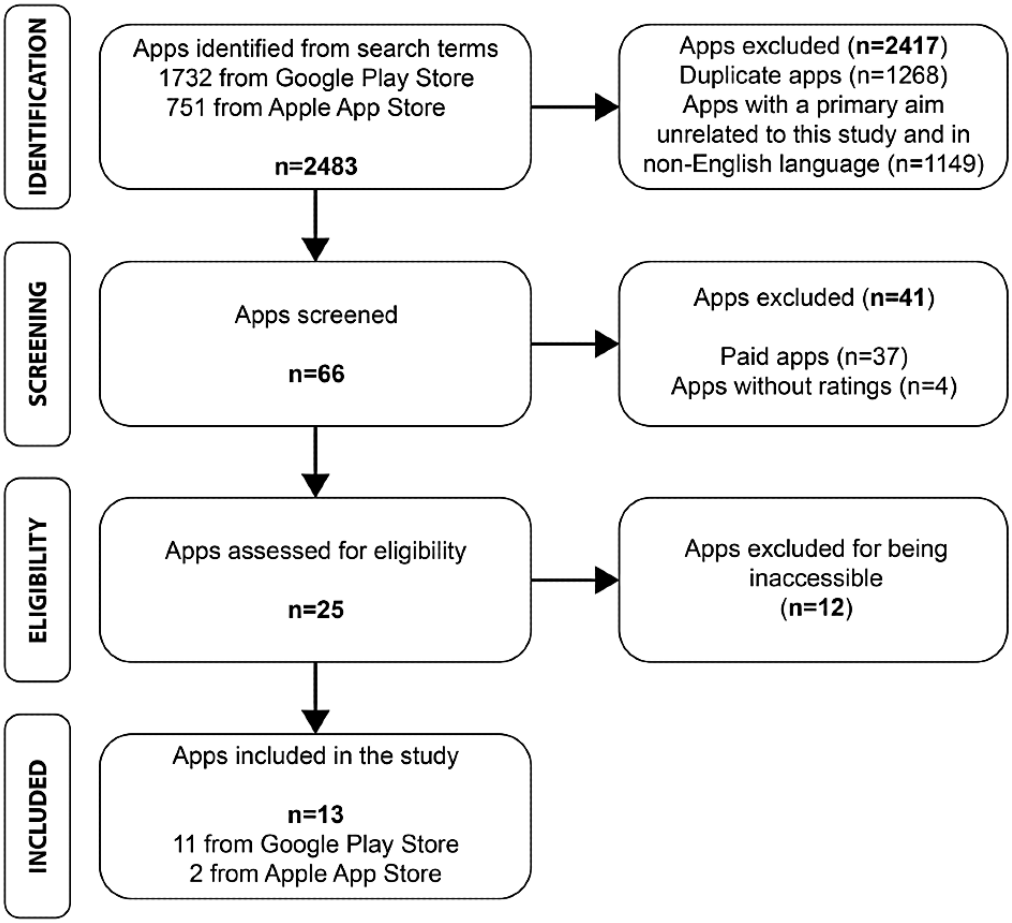
### mHealth App Sample Selection

The initial search with the following search terms resulted in 2483 apps from the Google Play Store (n=1732) and the Apple App Store (n=751): "obesity", "obese", "obesity calculator", "obesity diet", and "obesity exercise". Figure 2 shows a flowchart of the obesity-related mHealth app selection process. Descriptive information on the sample apps is presented in Multimedia Appendix 2.



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**Figure 2.** PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-analyses) flowchart of the obesity related mHealth apps selection process.




## General Quality: MARS

Among the Google Play Store apps chosen for the study (Table 1), Fitpaa- Your Fitness Dad received the highest score in the engagement (4.6) and information (4.2) categories. The app Fat to Fit – lose weight at home female workout received the highest score in the functionality domain (4.5); Weight Loss Diet 7 Day Detox Cleanse received the highest score in the aesthetics domain (4.3) and Indian Diet Plans received the highest score in the subjective quality (4.0) domain. Among the Apple App Store apps chosen for the study, Jeewith received the highest score in the functionality (3.2), and aesthetics (4.0) domains and IFSO received the highest score in the engagement (2.6), information (3.1), and subjective quality (2.0) domains. Fitpaa – Your fitness dad and Obesity Treatment received the highest overall mean scores based on each dimension of the MARS (3.7).



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**Table 1.** The quality of obesity-related mHealth apps based on the Mobile Application Rating Scale.

| App Name | Engagement | Functionality | Aesthetics | Information | Subjective quality | Overall score |
|---|---|---|---|---|---|---|
| **Google Play Store apps** | | | | | | |
| Weight Loss Protocols | 3.2 | 4.2 | 3.0 | 3.8 | 3.5 | 3.5 |
| Fat to Fit – lose weight at home female workout | 4.4 | 4.5 | 3.0 | 3.2 | 2.5 | 3.5 |
| Fitpaa – Your fitness dad | 4.6 | 3.7 | 3.0 | 4.2 | 3.25 | 3.7 |
| Lose Belly Fat Guide | 2.0 | 3.5 | 2.0 | 1.5 | 1.0 | 2.0 |
| Help for Kids Health and Diet | 3.2 | 3.7 | 3.0 | 2.7 | 3.0 | 3.1 |
| Obesity Treatment | 3.4 | 4.0 | 4.0 | 4.0 | 3.2 | 3.7 |
| Obesity Guide | 1.6 | 3.7 | 1.6 | 1.4 | 1.0 | 1.8 |
| Indian Diet Plans | 3.6 | 4.0 | 3.6 | 2.8 | 4.0 | 3.6 |
| Obesity Treatments | 2.8 | 3.0 | 2.0 | 2.0 | 1.5 | 2.2 |
| Weight Loss Diet 7 Day Detox Cleanse | 3.0 | 4.2 | 4.3 | 2.1 | 1.7 | 3.1 |
| Child Diet Guide | 2.6 | 4.0 | 2.6 | 1.8 | 1.0 | 2.4 |
| **Apple App Store apps** | | | | | | |
| Jeewith | 2.4 | 3.2 | 4.0 | 2.1 | 1.0 | 2.5 |
| IFSO | 2.6 | 3.0 | 3.6 | 3.1 | 2.0 | 2.8 |

## MARS Rating Versus User App Rating

The reliability of the dimensions of the MARS scores for the sample apps was found to be strongly consistent (Cronbach α=.938). Internal reliability was found to be strong for the subjective quality domain (α=.947), good for the aesthetics (α=.820) and information (α=.888) domains, and fair for the engagement (α=.791) domain. Internal reliability was found to be poor for the functionality (α=.645) domain, so the performance measure item was removed and after doing so, the internal reliability was found to be good (α=.826).

The bivariate Pearson correlation was computed to test the relationship between the MARS rating and user app rating. The results (Table 2) show that the MARS rating and user app rating are not statistically significantly correlated ($R$=0.258; $P$=.39).

**Table 2.** The correlation between the Mobile Application Rating Scale (MARS) rating and user app rating (n=13).

| Rating | User app rating | MARS rating |
|---|---|---|
| **User app rating** | | |
| *r* | 1 | 0.258 |
| *P* value[a] | —[b] | .39 |
| **MARS rating** | | |
| *r* | 0.258 | 1 |
| *P* value[a] | .39 | — |

[a]*P* values are derived from a 2-tailed *t* test.

[b]Not applicable.

## The Presence of PPM Factors

Apart from the causes for obesity listed in the coding sheet (Table 3), there were a few other causes mentioned in the sample apps, which include sleep deprivation, certain medications, a diet with high amounts of simple carbohydrates, biological causes, hormonal causes, and the frequency of eating. Apart from the effects of obesity listed in the coding sheet, there were a few more effects mentioned in the study sample apps, including gall stone formations, gout and gouty arthritis, insulin resistance, Alzheimer disease, social stigmatization, depression among youth, sleep apnea, joint problems, liver disease, infertility, and effects on sperm quality.



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**Table 3.** The presence of PRECEDE-PROCEED Model factors within the reviewed (n=13) obesity-related mHealth apps.

| Factors, variables, and items | Apps, n (%) |
|---|---|
| **Predisposing factors** | |
| **Knowledge and information** | |
| About obesity | 6 (46) |
| Genetics[a] | 5 (38) |
| Overeating[a] | 6 (46) |
| Physical inactivity[a] | 5 (38) |
| Social issues[a] | 2 (15) |
| Psychological factors[a] | 3 (23) |
| Hypothyroidism[a] | 2 (15) |
| Type 2 diabetes[b] | 6 (46) |
| High blood pressure[b] | 5 (38) |
| High cholesterol[b] | 3 (23) |
| Stroke[b] | 5 (38) |
| Heart attack[b] | 5 (38) |
| Cancer[b] | 6 (46) |
| What is BMI? | 4 (31) |
| Classification of BMI | 6 (46) |
| BMI calculator | 5 (38) |
| **Attitudes, beliefs, and values** | |
| Requires log-in | 3 (23) |
| Mentions the sources of information | 2 (15) |
| Exercise tips from a physiotherapist | 2 (15) |
| Food recommendations from a nutritionist | 3 (23) |
| **Confidence and motivation** | |
| Color indication to create fear | 1 (8) |
| Testimonial | 0 (0) |
| **Enabling factors** | |
| **Teach skills** | |
| Walking[c] | 3 (23) |
| Swimming[c] | 1 (8) |
| Cycling[c] | 0 (0) |
| Exercise precaution | 1 (8) |
| Diet plan | 9 (69) |
| **Provide resources** | |
| Food calorie chart | 2 (15) |
| Healthy recipes | 4 (31) |
| Nutritional breakdown of specific food items | 1 (8) |
| Representations of food with images | 1 (8) |
| In app[d] | 3 (23) |



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| Factors, variables, and items | Apps, n (%) |
|---|---|
| External link[d] | 0 (0) |
| Image demonstration for exercise | 2 (15) |
| **Provide services** | |
| Treatment for obesity (surgery) | 4 (31) |
| **Track or record behavior** | |
| Calorie or food tracker | 0 (0) |
| Exercise tracker | 3 (23) |
| BMI tracker | 3 (23) |
| Weekly or monthly report of calories consumed | 0 (0) |
| Weekly or monthly report of exercise progress | 0 (0) |
| Goal setting | 3 (23) |
| Reminders | 1 (8) |
| **Reinforcing factors** | |
| **Interfacing with social media sites for encouragement** | |
| Sharing completion of exercises or weight reduction on social media | 2 (15) |
| **Support and encouragement** | |
| Community | 2 (15) |
| Interaction with health professionals | 2 (15) |
| Interaction with a trainer or coach | 2 (15) |
| Games | 0 (0) |
| **Rewards** | |
| Rewards for goal completion | 2 (15) |

[a]These items are classified as causes of obesity.

[b]These are effects of obesity.

[c]These are general exercise recommendations.

[d]These are video demonstrations for exercises.

## The Relationship Between PPM Factors and Health Behavior Change

Table 4 presents the internal consistency (Cronbach α) of PPM variables and the internal consistency of the measure items under the reviewer's assessment of the app's ability to promote health behavior change. All the measure items of PPM factors and the app's ability to promote health behavior change were found to be internally consistent.

A multivariate regression analysis was performed to test the influence of PPM factors on the app's ability to promote health behavior change, as assessed by the reviewers. The results from Table 5, Table 6, and Table 7 show that the PPM factors are significant determinants of health behavior change ($F_{3,9}$=63.186; $P$=.001). The value of $R$=0.977 indicates a strong positive correlation and $R^2$=0.955 indicates that 95.5% of the variance in the dependent variable (health behavior change) can be explained by the independent variables (PPM factors).



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**Table 4.** The internal consistency of PRECEDE-PROCEED Model (PPM) variables.

| PPM factors and variables | Excluded items[a] | Internal consistency of items | Internal consistency of variables |
|---|---|---|---|
| **Predisposing factors** | | | |
| Knowledge and information | None | .938 | .911 |
| Attitudes, beliefs, and values | None | .855 | |
| Confidence and motivation | Testimonial | Not performed as there is only one item | |
| **Enabling factors** | | | |
| Teaching skills | Cycling and exercise precaution | .710 | .845 |
| Providing resources | None | .830 | |
| Providing services | None | Not performed as there is only one item | |
| Tracking or recording Behavior | | .756 | |
| **Reinforcing factors** | | | |
| Interfacing with social media | None | Not performed as there is only one item | .960 |
| Support and encouragement | None | .899 | |
| Rewards | None | Not performed as there is only one item | |
| **App's ability to promote health behavior change** | | | |
| Enough information to bring about health behavior change (predisposing factors) | N/A[b] | N/A | .827 |
| Enough resources to bring about health behavior change (enabling factors) | N/A | N/A | |
| Enough support to bring about health behavior change (reinforcing factors) | N/A | N/A | |

[a]These items were excluded from analysis as there is no variance in scores between the apps, or the items were deleted.

[b]N/A: not applicable. There are no items associated with these variables.

**Table 5.** Model summary for the regression analysis[a] between PRECEDE-PROCEED Model factors and the reviewer's assessment of the app's ability to promote health behavior change.

| Model | *R* | $R^2$ | Adjusted $R^2$ | Standard error of the estimate |
|---|---|---|---|---|
| 1 | 0.977 | 0.955 | 0.940 | 0.50642 |

[a]Predictors: constant and reinforcing, predisposing, and enabling factors.

**Table 6.** ANOVA results for the regression analysis[a] between PRECEDE-PROCEED Model factors and the reviewer's assessment of the app's ability to promote health behavior change. All data are based on model 1 from the regression analysis.

| | Sum of squares | Degrees of freedom | Mean square | *F* test (*df*) | *P* value |
|---|---|---|---|---|---|
| Regression | 48.615 | 3 | 16.205 | 63.186 (3) | .001[b] |
| Residual | 2.308 | 9 | .256 | N/A[c] | N/A |
| Total | 50.923 | 12 | N/A | N/A | N/A |

[a]Dependent variable: reviewer's assessment of the app's ability to promote health behavior change.

[b]Predictors: constant and reinforcing, predisposing, and enabling factors.

[c]N/A: not applicable.



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**Table 7.** Coefficients from the regression analysis[a] between PRECEDE-PROCEED Model factors and the reviewer's assessment of the app's ability to promote health behavior change. All data are based on model 1 from the regression analysis.

| Predictors | Unstandardized coefficients | | Standardized coefficients | | |
|---|---|---|---|---|---|
| | β | Standard error | β | *t* test (*df*) | *P* value |
| (Constant) | 3.922 | 0.259 | | 15.165 (12) | .001 |
| Predisposing factors | 0.112 | 0.024 | .339 | 4.649 (12) | .001 |
| Enabling factors | 0.257 | 0.065 | .440 | 3.930 (12) | .003 |
| Reinforcing factors | 0.581 | 0.123 | .530 | 4.746 (12) | .001 |

[a]Dependent variable: reviewer's assessment of the app's ability to promote health behavior change.

# Discussion

## Principal Findings

This study aimed to examine the features and quality of obesity-related mHealth apps using the MARS and assess the presence of factors that promote health behavior change using the PPM. We analyzed a total of 13 obesity-related mHealth apps, 11 from the Google Play Store and 2 from the Apple App Store. The Apple App Store had a much lower number of obesity-related mHealth apps compared to the Google Play Store. Regarding the overall quality of the 13 apps assessed using the MARS, the mean scores ranged from 1.8 to 3.7. This study supports the findings of previous studies that suggest when mHealth apps focus heavily on the functionality domain of the MARS, the performance, ease of use, navigation, and gestural design are compromised [20]. The subjective quality domain of the MARS depends on all 4 domains, engagement, functionality, aesthetics, and information. Among all 4 domains, the apps in this study scored the lowest in information. The information domain comprises accuracy, goals, quality of information, quantity of information, visual information, credibility, and evidence-based information. The absence of sources of information in most of the apps studied affected the credibility score and the evidence-based information score. These findings support the findings of previous studies which established that mHealth apps containing evidence-based information and information from credible sources receive high scores in the information domain of the MARS [26] and mHealth apps that do not include sources of information receive the lowest scores [27]. Among the studied apps, all received moderate mean scores for each of the 4 domains of the MARS, engagement, functionality, aesthetics, and information; this affected the mean score for the subjective quality domain of the study sample apps since the subjective quality domain depends on the other 4 domains of the MARS.

There are many mHealth apps currently available for various health issues; finding an appropriate app among the wide selection for a particular health issue is challenging for users [9,28]. Normally, users select an mHealth app based on ratings and reviews; thus, ratings become key for any app to be downloaded by new users [28,29]. We failed to establish a statistically significant Pearson correlation coefficient between MARS scores and the ratings of study sample apps in the app store. This nonsignificant result may be due to information asymmetry between coders and app users with regard to the app quality attributes. The trustworthiness of apps with few ratings may also be compromised by fake reviews from app developers; this may partly explain the nonsignificant result [30].

Most of the study sample apps were established upon predisposing factors to address obesity, including the following variables: knowledge and information about obesity; attitudes, beliefs, and values; and confidence and motivation. Commonly, mHealth app users will form judgements about apps' contents by evaluating the information using web-based platforms, especially when they come across unfamiliar information about health conditions, and they use the sources of the information to judge its credibility [31]. Therefore, mentioning the sources of information and ensuring that recommendations of exercise and diet plans are provided by health professionals is important; this was found in only a small number of study sample apps. None of the sample apps had testimonials, but previous studies strongly recommended apps add testimonials or narrative messages that focus on real experiences of users, which can lead to strong emotional arousal among users and are an important factor in promoting health behavior change [32,33].

With regard to enabling factors, the teaching skills variable was found in a number of study sample apps. One of the least common enabling factors among the apps was the ability to track or record behavior, which contradicted a previous study on diabetes management apps [34]. Previous studies found that the tracking facility in mHealth apps proved to be motivating and influenced health behavior change among app users, especially for weight loss [35,36]. Self-tracking of food and exercise helps users set goals and track their achievements [9]. The self-tracking, goal setting, and daily, weekly, or monthly reporting features in mHealth apps were found to be very helpful in bringing about health behavior change [9], but those features were also only found in a small number of study sample apps. One important finding from the study is that 69% (9/13) of the sample obesity-related mHealth apps specified diet plans as a measure to address obesity, but only 23% (n=3) of sample apps included exercise as a recommendation. This finding supports the findings of previous studies that the mHealth apps focus either on physical activity or dieting practices, but not equally on both for weight loss [37].

Reinforcing factors, which include interfacing with social media sites for encouragement, support and encouragement from a community or health professionals, and rewards for goal completion, were found to be present in only 2 apps among the study sample, 1 from the Google Play store and 1 from the



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Apple App Store. This finding is consistent with the findings of previous studies that only a few mHealth apps allow users to connect the app to external systems or communities, such as social media platforms [18]. Sharing task completion on social media is the most welcomed feature by mHealth app users because they can obtain emotional support and motivation from others [9]. Such mobile features help or guide users to undergo health behavior change by establishing interactions with health professionals, allowing them to gain support from their peer group, and providing them with access to a virtual coach. Past studies have shown that a lack of motivation and social support among mHealth app users reduces the likelihood of health behavior change [38]. This study found that most of the sample mHealth apps did not include reinforcing factors, which are considered vital in bringing about health behavior change among app users.

### Limitations

The findings of this study should be taken into consideration with some limitations. First, the obesity-related mHealth apps used in the analysis were free; analyses including paid apps may produce different results since paid apps are generally given extra care during the development of all aspects of the app. This study is not supported by any funding, which is the reason for the omission of paid versions of obesity-related mHealth apps. Similarly, we were also unable to download and study inaccessible apps, which required log-in credentials from an affiliated health care organization or clinic [39]. Second, the study did not collect data from actual users of the mHealth apps; doing so may result in a better understanding of the influence of the apps' features on health behavior change. This may also open up a new dimension to this study.

### Conclusion

There are numerous mHealth apps available in the Google Play Store and the Apple App Store to promote health behavior change. Previous studies have shown that mHealth apps are more effective when they are based on scientific theories [18]. This study found that the presence of PPM factors in an mHealth app can greatly influence users' health behavior change. So, this study suggests that mHealth app developers consider this when developing efficient apps. Also, mHealth app developers should consider providing health information from credible sources and including the sources of the information, which will increase the perceived credibility of the apps among users. Users of mHealth apps vary in gender and age group; so, mHealth app developers should concentrate on providing general health behavior tips that can be used by all gender and age groups or tips for specific gender and age groups. Though there are numerous mHealth apps available, there is a paucity in the involvement of health professionals and health organizations in the development of these apps. Most of the available mHealth apps bypass regulations and nationally recognized health guidelines (R Subramanian, PhD, unpublished data, August 2015). So, we strongly suggest health experts be directly involved in the development of mHealth apps rather than third-party developers [37]. The findings of this study make several contributions to the current literature related to mHealth apps. Future research should include actual mHealth app users to better understand the apps' effectiveness in bringing about health behavior change.

### Conflicts of Interest

None declared.

Multimedia Appendix 1
Coding sheet.
[DOCX File , 20 KB - mhealth_v10i5e15719_app1.docx ]

Multimedia Appendix 2
Descriptive information of study sample apps.
[PNG File , 2192 KB - mhealth_v10i5e15719_app2.png ]

### References

1. Measuring Obesity. Obesity Prevention Source. 2022. URL: https://www.hsph.harvard.edu/obesity-prevention-source/obesity-definition/how-to-measure-body-fatness/ [accessed 2022-05-05]
2. Obesity and overweight. World Health Organization. 2021 Jun 09. URL: https://www.who.int/news-room/fact-sheets/detail/obesity-and-overweight [accessed 2022-05-02]
3. India has 14.4 mn children with obesity. The Hindu. 2017. URL: https://www.thehindu.com/sci-tech/health/india-has-144-mn-children-with-obesity/article19030849.ece [accessed 2022-04-28]
4. National family health survey (NFHS-4). Goverment of India, Ministry of Health and Family Welfare. 2016. URL: https://dhsprogram.com/pubs/pdf/FR339/FR339.pdf [accessed 2022-04-28]
5. Zee Media Bureau. Obesity rates swell in India: One fifth of Indian women now overweight. Zee News. 2017. URL: https://zeenews.india.com/health/obesity-rates-swell-in-india-one-fifth-of-indian-women-now-overweight-1986264 [accessed 2022-04-28]



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6. Barry CL, Gollust SE, McGinty EE, Niederdeppe J. Effects of messages from a media campaign to increase public awareness of childhood obesity. Obesity (Silver Spring) 2014 Feb;22(2):466-473 [FREE Full text] [doi: 10.1002/oby.20570] [Medline: 23836508]
7. Boles M, Adams A, Gredler A, Manhas S. Ability of a mass media campaign to influence knowledge, attitudes, and behaviors about sugary drinks and obesity. Prev Med 2014 Oct;67 Suppl 1:S40-S45 [FREE Full text] [doi: 10.1016/j.ypmed.2014.07.023] [Medline: 25066020]
8. King EL, Grunseit AC, O'Hara BJ, Bauman AE. Evaluating the effectiveness of an Australian obesity mass-media campaign: how did the 'Measure-Up' campaign measure up in New South Wales? Health Educ Res 2013 Dec;28(6):1029-1039. [doi: 10.1093/her/cyt084] [Medline: 23962490]
9. Peng W, Kanthawala S, Yuan S, Hussain SA. A qualitative study of user perceptions of mobile health apps. BMC Public Health 2016 Nov 14;16(1):1158 [FREE Full text] [doi: 10.1186/s12889-016-3808-0] [Medline: 27842533]
10. Kite J, Grunseit A, Bohn-Goldbaum E, Bellew B, Carroll T, Bauman A. A systematic search and review of adult-targeted overweight and obesity prevention mass media campaigns and their evaluation: 2000-2017. J Health Commun 2018 Jan;23(2):207-232. [doi: 10.1080/10810730.2018.1423651] [Medline: 29336684]
11. Campbell SW. Mobile media and communication: a new field, or just a new journal? Mob Media Commun 2013 Jan 01;1(1):8-13. [doi: 10.1177/2050157912459495]
12. Steinhubl SR, Muse ED, Topol EJ. Can mobile health technologies transform health care? JAMA 2013 Dec 11;310(22):2395-2396. [doi: 10.1001/jama.2013.281078] [Medline: 24158428]
13. World Health Organization Global Observatory for eHealth. mHealth: New horizons for health through mobile technologies. World Health Organization: Institutional Repository for Information Sharing. 2011. URL: http://apps.who.int/iris/handle/10665/44607 [accessed 2022-04-28]
14. Bhardwaj N, Wodajo B, Gochipathala K, Paul DP, Coustasse A. Can mHealth revolutionize the way we manage adult obesity? Perspect Health Inf Manag 2017;14(Spring):1a [FREE Full text] [Medline: 28566984]
15. Tate EB, Spruijt-Metz D, O'Reilly G, Jordan-Marsh M, Gotsis M, Pentz MA, et al. mHealth approaches to child obesity prevention: successes, unique challenges, and next directions. Transl Behav Med 2013 Dec;3(4):406-415 [FREE Full text] [doi: 10.1007/s13142-013-0222-3] [Medline: 24294329]
16. Montano DE, Kasprzyk D. Theory of reasoned action, theory of planned behavior, and the integrated behavioral model. In: Glanz K, Rimer BK, Viswanath K, editors. Health Behavior and Health Education: Theory, Research, and Practice, 4th Edition. San Francisco, CA: Jossey-Bass; 2008.
17. Jeihooni AK, Heidari MS, Harsini PA, Azizinia S. Application of PRECEDE model in education of nutrition and physical activities in obesity and overweight female high school students. Obesity Medicine 2019 Jun;14:100092. [doi: 10.1016/j.obmed.2019.100092]
18. West JH, Hall PC, Hanson CL, Barnes MD, Giraud-Carrier C, Barrett J. There's an app for that: content analysis of paid health and fitness apps. J Med Internet Res 2012 May;14(3):e72 [FREE Full text] [doi: 10.2196/jmir.1977] [Medline: 22584372]
19. Krebs P, Duncan DT. Health app use among US mobile phone owners: a national survey. JMIR Mhealth Uhealth 2015 Nov 04;3(4):e101 [FREE Full text] [doi: 10.2196/mhealth.4924] [Medline: 26537656]
20. Bustamante LA, Gill Ménard C, Julien S, Romo L. Behavior change techniques in popular mobile apps for smoking cessation in France: content analysis. JMIR Mhealth Uhealth 2021 May 13;9(5):e26082 [FREE Full text] [doi: 10.2196/26082] [Medline: 33983130]
21. Hayman M, Alfrey K, Cannon S, Alley S, Rebar AL, Williams S, et al. Quality, features, and presence of behavior change techniques in mobile apps designed to improve physical activity in pregnant women: systematic search and content analysis. JMIR Mhealth Uhealth 2021 Apr 07;9(4):e23649 [FREE Full text] [doi: 10.2196/23649] [Medline: 33825693]
22. Stoyanov SR, Hides L, Kavanagh DJ, Zelenko O, Tjondronegoro D, Mani M. Mobile app rating scale: a new tool for assessing the quality of health mobile apps. JMIR Mhealth Uhealth 2015 Mar;3(1):e27 [FREE Full text] [doi: 10.2196/mhealth.3422] [Medline: 25760773]
23. Green LW, Kreuter MW. Patient education and counseling. In: Health Promotion Planning: An Educational and Environmental Approach, 2nd Edition. Mountain View, CA: Mayfield Publishing Company; 1992.
24. Glanz K, Rimer BK, Viswanth K, editors. Health Behaviour and Health Education: Research and Practice, 4th Edition. San Francisco, CA: Jossey-Bass; 2008.
25. Hall PC, West JH, McIntyre E. Female self-sexualization in MySpace.com personal profile photographs. Sex Cult 2012;16(1):1-16. [doi: 10.1007/s12119-011-9095-0]
26. Salehinejad S, Niakan Kalhori SR, Hajesmaeel Gohari S, Bahaadinbeigy K, Fatehi F. A review and content analysis of national apps for COVID-19 management using Mobile Application Rating Scale (MARS). Inform Health Soc Care 2021 Mar 02;46(1):42-55. [doi: 10.1080/17538157.2020.1837838] [Medline: 33164594]
27. Mani M, Kavanagh DJ, Hides L, Stoyanov SR. Review and evaluation of mindfulness-based iPhone apps. JMIR Mhealth Uhealth 2015 Aug 19;3(3):e82 [FREE Full text] [doi: 10.2196/mhealth.4328] [Medline: 26290327]




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28. Shen N, Levitan M, Johnson A, Bender JL, Hamilton-Page M, Jadad AR, et al. Finding a depression app: a review and content analysis of the depression app marketplace. JMIR Mhealth Uhealth 2015 Feb 16;3(1):e16 [FREE Full text] [doi: 10.2196/mhealth.3713] [Medline: 25689790]
29. Mendiola MF, Kalnicki M, Lindenauer S. Valuable features in mobile health apps for patients and consumers: content analysis of apps and user ratings. JMIR Mhealth Uhealth 2015 May 13;3(2):e40 [FREE Full text] [doi: 10.2196/mhealth.4283] [Medline: 25972309]
30. Domnich A, Arata L, Amicizia D, Signori A, Patrick B, Stoyanov S, et al. Development and validation of the Italian version of the Mobile Application Rating Scale and its generalisability to apps targeting primary prevention. BMC Med Inform Decis Mak 2016 Jul 07;16:83 [FREE Full text] [doi: 10.1186/s12911-016-0323-2] [Medline: 27387434]
31. Eastin MS. Credibility assessments of online health information: the effects of source expertise and knowledge of content. J Comput-Mediat Commun 2001;6(4):JCMC643. [doi: 10.1111/j.1083-6101.2001.tb00126.x]
32. Durkin SJ, Biener L, Wakefield MA. Effects of different types of antismoking ads on reducing disparities in smoking cessation among socioeconomic subgroups. Am J Public Health 2009 Dec;99(12):2217-2223 [FREE Full text] [doi: 10.2105/AJPH.2009.161638] [Medline: 19833980]
33. Kreuter MW, Green MC, Cappella JN, Slater MD, Wise ME, Storey D, et al. Narrative communication in cancer prevention and control: a framework to guide research and application. Ann Behav Med 2007 Jun;33(3):221-235. [doi: 10.1007/BF02879904] [Medline: 17600449]
34. Chomutare T, Fernandez-Luque L, Arsand E, Hartvigsen G. Features of mobile diabetes applications: review of the literature and analysis of current applications compared against evidence-based guidelines. J Med Internet Res 2011 Sep 22;13(3):e65 [FREE Full text] [doi: 10.2196/jmir.1874] [Medline: 21979293]
35. Goldstein CM, Thomas JG, Wing RR, Bond DS. Successful weight loss maintainers use health-tracking smartphone applications more than a nationally representative sample: comparison of the National Weight Control Registry to Pew Tracking for Health. Obes Sci Pract 2017 Jun;3(2):117-126 [FREE Full text] [doi: 10.1002/osp4.102] [Medline: 28702210]
36. Birkhoff SD, Smeltzer SC. Perceptions of smartphone user-centered mobile health tracking apps across various chronic illness populations: an integrative review. J Nurs Scholarsh 2017 Jul;49(4):371-378. [doi: 10.1111/jnu.12298] [Medline: 28605151]
37. Rivera J, McPherson A, Hamilton J, Birken C, Coons M, Iyer S, et al. Mobile apps for weight management: a scoping review. JMIR Mhealth Uhealth 2016 Jul 26;4(3):e87 [FREE Full text] [doi: 10.2196/mhealth.5115] [Medline: 27460502]
38. Alnasser AA, Alkhalifa AS, Sathiaseelan A, Marais D. What overweight women want from a weight loss app: a qualitative study on arabic women. JMIR Mhealth Uhealth 2015 May 20;3(2):e41 [FREE Full text] [doi: 10.2196/mhealth.4409] [Medline: 25993907]
39. Ahmed I, Ahmad NS, Ali S, Ali S, George A, Saleem Danish H, et al. Medication adherence apps: review and content analysis. JMIR Mhealth Uhealth 2018 Mar 16;6(3):e62 [FREE Full text] [doi: 10.2196/mhealth.6432] [Medline: 29549075]


## Abbreviations

**MARS:** Mobile Application Rating Scale
**PPM:** PRECEDE-PROCEED Model


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Original Paper

# German Mobile Apps for Patients With Psoriasis: Systematic Search and Evaluation

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## Abstract

**Background:** Psoriasis is a chronic inflammatory skin disease. The visibility of erythematous plaques on the skin as well as the pain and itchiness caused by the skin lesions frequently leads to psychological distress in patients. Smartphone apps are widespread and easily accessible. Earlier studies have shown that apps can effectively complement current management strategies for patients with psoriasis. However, no analysis of such apps has been published to date.

**Objective:** The aim of this study is to systematically identify and objectively assess the quality of current publicly available German apps for patients with psoriasis using the Mobile Application Rating Scale (MARS) and compile brief ready-to-use app descriptions.

**Methods:** We conducted a systematic search and assessment of German apps for patients with psoriasis available in the Google Play Store and Apple App Store. The identified apps were randomly assigned to 1 of 3 reviewers, who independently rated them using the German MARS (MARS-G). The MARS-G includes 15 items from 4 different sections (engagement, functionality, aesthetics, and information) to create an overall mean score for every app. Scores can range from 1 for the lowest-quality apps to 5 for the highest-quality apps. Apps were ranked according to their mean MARS-G rating, and the highest-ranked app was evaluated independently by 2 patients with psoriasis using the user version of the MARS-G (uMARS-G). Furthermore, app information, including origin, main function, and technical aspects, was compiled into a brief overview.

**Results:** In total, we were able to identify 95 unique apps for psoriasis, of which 15 were available in both app stores. Of these apps, 5 were not specifically intended for patients with psoriasis, 1 was designed for clinical trials only, and 1 was no longer available at the time the evaluation process began. Consequently, the remaining 8 apps were included in the final evaluation. The mean MARS-G scores ranged from 3.51 to 4.18. The app with the highest mean MARS-G score was Psoriasis Helferin (4.18/5.00). When rated by patients, however, the app was rated lower in all subcategories, resulting in a mean uMARS-G score of 3.48. Most apps had a commercial background and a focus on symptom tracking. However, only a fraction of the apps assessed used validated instruments to measure the user's disease activity.

**Conclusions:** App quality was heterogeneous, and only a minority of the identified apps were available in both app stores. When evaluated by patients, app ratings were lower than when evaluated by health care professionals. This discrepancy highlights the importance of involving patients when developing and evaluating health-related apps as the factors that make an app appealing to users may differ between these 2 groups.



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**Trial Registration:** Deutsches Register Klinischer Studien DRKS00020963; https://tinyurl.com/ye98an5b

***(JMIR Mhealth Uhealth 2022;10(5):e34017)*** doi:10.2196/34017

**KEYWORDS**

psoriasis; eHealth; mHealth; telemedicine; teledermatology; disease management; smartphone application; mental health; mobile health; health app; dermatology; skin

## Introduction

Psoriasis is a chronic inflammatory skin disease affecting about 1.5 million people in Germany [1]. Erythematosquamous plaques, mostly on extensor surfaces of the extremities, are characteristic of this illness, but the disease can involve every part of the skin and can also affect the joints.

The chronicity of psoriasis and the pain, itchiness, and stigma associated with it put an immense physical and mental burden on patients. In addition, psoriasis is associated with several comorbidities, including diabetes [2], cardiovascular disease [3], inflammatory bowel disease [4], anxiety, and depression [5].

Although there is currently no known cure for the disease, a wide variety of treatment options, ranging from phototherapy to topical and systemic agents, are available and highly effective in alleviating signs and symptoms in most patients [6]. However, adherence to treatment as well as knowledge of the disease and its optimal management are often low [7], potentially diminishing treatment efficacy [8].

The rise of smartphone use in the general population in recent years opens new possibilities for the care of patients with dermatological conditions. mHealth provides unprecedented and personalized tools to complement and boost existing therapies [9], as highlighted in a study by Svendson et al [10]. The authors demonstrated that smartphone apps targeted specifically at patients with psoriasis led to a significant improvement in adherence to treatment and outcomes [10]. Another study on patients with rheumatic diseases by Knitza et al [11] showed that most participants saw medical apps as beneficial and would use such apps if available. It is plausible to assume that such a survey among patients with psoriasis would yield similar results given that both conditions are chronic, difficult to treat, and associated with low adherence to existing treatments [7]. In 2019, Germany established the digital health applications (DiGA) directory, where scientifically validated digital health apps licensed as medical devices are listed systematically. Similar to medications, physicians can now prescribe DiGAs, and costs are reimbursed by insurance companies. However, at the moment, no DiGAs exist for patients with psoriasis. Therefore, these patients and their treating dermatologists are still confronted with a confusingly large number of apps, offering different functions and modalities; these apps are often not evidence-based and ineligible for cost reimbursement by insurance companies [12,13].

The goal of this study was therefore to identify and assess publicly available smartphone apps for patients with psoriasis and create brief app descriptions, including objective quality ratings. To our knowledge, a systematic review and assessment of smartphone apps for patients with psoriasis has not been conducted to date.

## Methods

### App Screening

We conducted a systematic search of the German Apple App Store as well as the Google Play Store on January 7, 2021. The search terms used were as follows: “Psoriasis” OR “Schuppenflechte” (the German nonmedical term for psoriasis). A total of 2 independent reviewers searched each app store. The inclusion criteria are as follows: apps that were (1) available in both app stores, (2) available in the German or English language, and (3) specifically designed for patients with psoriasis. The exclusion criteria are as follows: apps that (1) were designed for conferences or clinical trials, (2) were not free to use, and (3) included advertisements.

### App Characteristics

We collected the following information available in the app stores and on app homepages:

- App name
- Rating
- Number of ratings
- Developer
- Version
- Date of last update
- Cost
- Platform and affiliations

We collected the following information on the apps from the app stores or the developer’s website:

- Affiliation (commercial, government, nongovernmental organization [NGO], university, or not known)
- Focus (increase happiness or well-being; mindfulness, meditation, or relaxation; reduce negative emotions; depression; anxiety or stress; anger; behavior change; alcohol or substance use; goal setting; entertainment; relationships; physical health; or other)
- Theoretical background (assessment; feedback; information or education; monitoring or tracking; goal setting; advice, tips, strategies, or skills training; cognitive behavioral therapy (positive events and thought challenging); acceptance commitment therapy; mindfulness or meditation; relaxation; gratitude; strengths-based; or other)
- Technical aspects (allows sharing, has an app community, allows password protection, requires login, sends reminders, and needs web access to function)



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### App Quality Ratings

The 3 reviewers used the validated German version of the Mobile Application Rating Scale (MARS-G) [14,15], and all reviewers previously underwent training on how to correctly apply the MARS to app evaluation using a training video [16], as suggested by Stoyanov et al [17].

The MARS score captures the following 4 objective aspects:

- Engagement (5 items)
- Functionality (4 items)
- Aesthetics (3 items)
- Information (7 items)

These sections contain a total of 19 items on a 5-point Likert scale, from 1 (strongly disagree) to 5 (completely agree), as well as a subjective measure of app quality with 4 additional questions. The final MARS-G score for each app is calculated as the mean of the 4 objective categories (engagement, functionality, aesthetics, and information). The score can range between 1 (worst) to 5 (best). The subjective app quality is additionally reported as the mean score of the 4 respective questions.

In addition, the MARS-G includes an app-specific subjective perceived impact score, called the psychotherapy score. The psychotherapy score includes the following 6 items: awareness, knowledge, attitudes, intention to change, help-seeking, and behavior change. These items can be used to estimate the app's impact on knowledge, attitudes, and intention to change behavior.

For training purposes, the MARS-G was used by all 3 reviewers to evaluate 1 app that was excluded from the study based on our inclusion and exclusion criteria. The results were discussed until no questions remained to achieve the same understanding across reviewers.

We randomly assigned each app to 2 reviewers. Of the reviewers, 2 used an iPhone (iPhone X and iPhone 12 Pro, both running with iOS 14.3; Apple Inc) and 1 used an Android phone (Asus ZenFone 3 running Android 8.0.0; ASUSTek Computer Inc). We rated all apps included in this study from January 9, 2021, to January 29, 2021. As required, every app was tested independently for at least 10 minutes before applying the MARS-G criteria.

All reviewers were medical students aged 22 to 25 years who were focusing on patients with psoriasis as part of their medical studies.

Additionally, the best-rated app was evaluated by 2 patients with psoriasis at the Department of Dermatology, Venereology, and Allergology at the University Medical Center Mannheim with the user version of the MARS-G (uMARS-G), a modified version, specifically for patients [18]. There are only a few differences between the uMARS-G and MARS-G. The information category contains 4 questions instead of 7, and the uMARS-G completely omits the psychotherapy score.

Patients were asked to spend at least 10 minutes exploring the app before rating it.

### Ethics Approval

The study was conducted in accordance with the Declaration of Helsinki and approved by the Medical Ethics Committee of the Medical Faculty Mannheim, Heidelberg University (2020-515N-MA). The trial is registered at Deutsches Register Klinische Studien (registration number DRKS00020963). Written informed consent was provided by each patient before participating in the study.

### Patient Characteristics

The selected patient participants were already part of other trials in which they also used a medical health app. Both seemed to be reliable and conscientious when answering questionnaires. Likewise, both could be assumed to have sufficient language comprehension and competence. One of the patients was 38 years of age and the other was 56 years. Both were asked to participate in the survey on March 8, 2021, during their appointments at the dermatology outpatient clinic.

### Statistical Analysis

After assessing the MARS-G score for all apps using the previously described methods, the results from both raters were averaged to represent the final score each app achieved in our study.

## Results

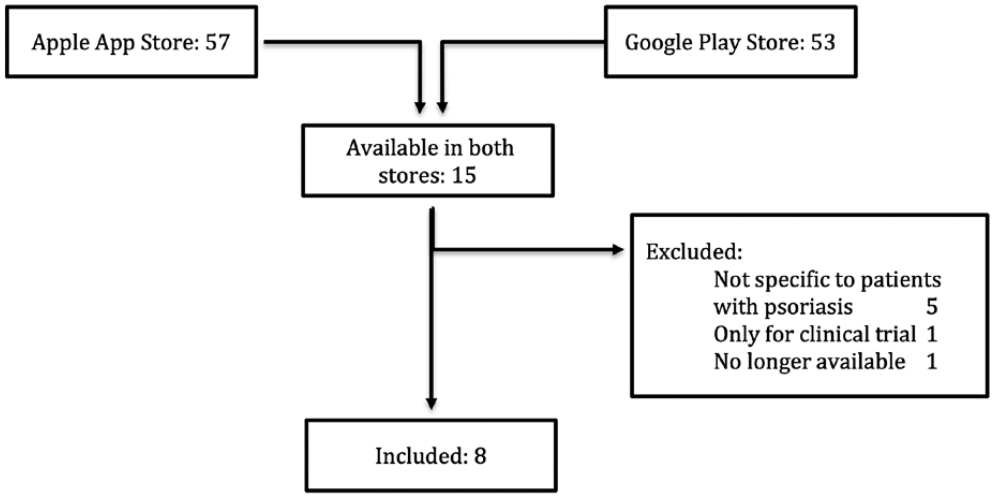
### App Screening

A total of 95 unique apps were identified in the German Apple App Store (n=57) and the Google Play Store (n=53) using the previously specified search terms. 15 of the apps were available in both stores. Of these apps, 5 were not specifically targeted at patients with psoriasis and 1 was designed for a clinical trial only. Furthermore, 1 app that was previously included in our study was no longer available in both app stores at the time of rating. Therefore, the app was excluded from further analyses. A total of 9 apps were eligible for our study (Figure 1).



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**Figure 1.** App screening process.




## App Characteristics

A majority of the apps (6/8, 75%) were commercial, password-protected (6/8, 75%), and focused on symptom tracking (ie, diaries, 5/8, 63%; Table 1). The remaining 2 apps were affiliated with an NGO (1/8, 13%) or of unknown origin (1/8, 13%). Of the 8 apps, 2 (25%), Itchy – Psoriasis & Ekzem and DLQI 4 Psoriasis, used scientifically validated scores and questionnaires to evaluate the patient's condition, such as the Psoriasis Area and Severity Index (PASI) [19] and Dermatology Life Quality Index (DLQI) [20]. The remaining apps, which offered diary functions, did not use validated instruments.

Of the 8 apps, 3 (38%) allowed users to connect with other patients with psoriasis through an app community. The Kopa for Psoriasis app additionally offers disease information and recommendations; however, the sources of the information were not indicated. The P.S.O. Psoriasis Arztfinder acts as a search engine, enabling users to find German physicians treating patients with psoriasis.

**Table 1.** Origin, focus, and specific technical aspects of the apps included in the evaluation.

| App name | Origin | Focus | Theoretical background | Technical aspects |
|---|---|---|---|---|
| DLQI 4 Psoriasis | Commercial | Symptom diary | DLQI[a] | N/A[b] |
| Imagine – Skin Tracker | Commercial | Symptom diary | N/A | N/A |
| Itchy – Psoriasis & Ekzem | Unknown | Symptom diary | DLQI, PASI[c] | Allows password-protection |
| Kopa for Psoriasis | Commercial | Web-based forum, information | N/A | Has an app community, allows password-protection |
| P.S.O. Psoriasis Arztfinder | NGO[d] | Finding physicians | N/A | Allows password-protection |
| Psoriasis Forum | Commercial | Web-based forum | N/A | Has an app community, allows password-protection |
| Psoriasis Helferin | Commercial | Symptom diary | N/A | Allows password-protection |
| Psoriasis Monitor | Commercial | Symptom diary | N/A | Allows sharing on social media, has an app community, allows password-protection |

[a]DLQI: Dermatology Life Quality Index.

[b]N/A: not applicable. These apps did not use validated instruments and therefore have no theoretical background.

[c]PASI: Psoriasis Area and Severity Index.

[d]NGO: nongovernmental organization.

## App Quality Ratings

Table 2 shows the apps' MARS-G ratings. The mean MARS-G score for all assessed apps varied between 3.00 and 4.18. The app Psoriasis Helferin received the highest MARS-G score (4.18), followed by Imagine – Skin Tracker (4.08) and Psoriasis Forum (4.01). The highest psychotherapy subscale score was achieved by Psoriasis Helferin (3.50) and Imagine – Skin Tracker (3.50), followed by Psoriasis Monitor (3.25). The highest MARS-G subjective scores were achieved by Imagine-Skin Tracker (3.88) and Psoriasis Helferin (3.25). The interrater reliability was 0.66.

When comparing the objective MARS-G score and the subjective subscale scores, all apps received a higher objective MARS-G rating (Figure 2). A detailed analysis of the mean subscale ratings across all apps revealed that the apps were rated best in aesthetics and functionality (4.31; Figure 3). In contrast, the apps achieved the lowest ratings for psychotherapy (2.792) and the subjective score (2.21).



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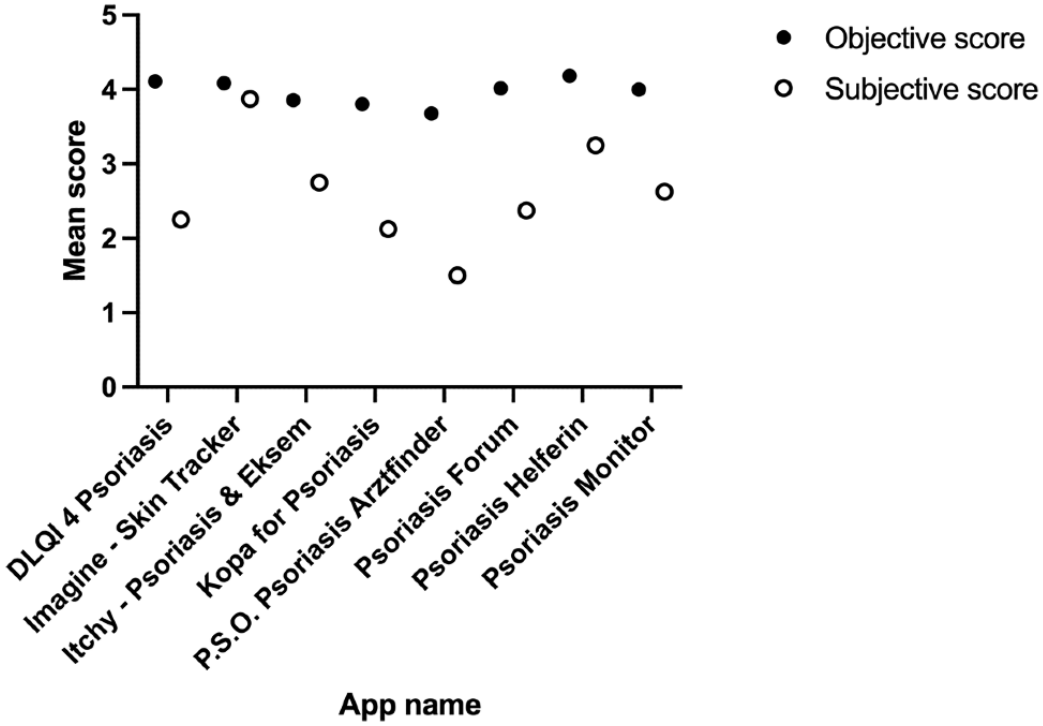
**Table 2.** App version, general function, and mean app quality calculated by professional raters using the German Mobile Application Scale (MARS-G).

| App name | Version | | General function | Engagement[a] | Functionality[a] | Aesthetic[a] | Information[a] | Mean objective score[a] | Mean subjective score[a] | Psychotherapy[a] |
|---|---|---|---|---|---|---|---|---|---|---|
| | iOS | Android | | | | | | | | |
| DLQI 4 Psoriasis | 1.0 | 1.0 | Progress documentation | 2.90 | 4.88 | 4.67 | 4.00 | 4.11 | 2.25 | 2.63 |
| Imagine – Skin Tracker | 2 | N/A[b] | Progress documentation | 3.70 | 4.75 | 4.33 | 3.55 | 4.08 | 3.88 | 3.50 |
| Itchy – Psoriasis & Ekzem | 1 | N/A | Progress documentation | 3.70 | 4.50 | 4.83 | 2.40 | 3.86 | 2.75 | 3.00 |
| Kopa for Psoriasis | 4.80 | N/A | Forum | 3.80 | 4.38 | 4.00 | 3.03 | 3.80 | 2.13 | 2.50 |
| P.S.O. Psoriasis Arztfinder | 0 | N/A | Finding physicians | 2.50 | 4.25 | 4.00 | 3.97 | 3.68 | 1.50 | 2.75 |
| Psoriasis Forum | 0 | 1.0.3 | Forum | 4.30 | 4.13 | 3.83 | 3.80 | 4.01 | 2.38 | 2.00 |
| Psoriasis Helferin | 4.7 | 1.0.1 | Progress documentation | 3.10 | 4.13 | 5.00 | 4.50 | 4.18 | 3.25 | 3.50 |
| Psoriasis Monitor | 4.4 | 2.0.12 | Progress documentation, communication with a physician | 3.90 | 4.13 | 4.33 | 3.63 | 3.00 | 2.63 | 3.25 |

[a]Each score is based on the MARS-G.

[b]N/A: not applicable. Both raters used an iOS phone to rate these apps.

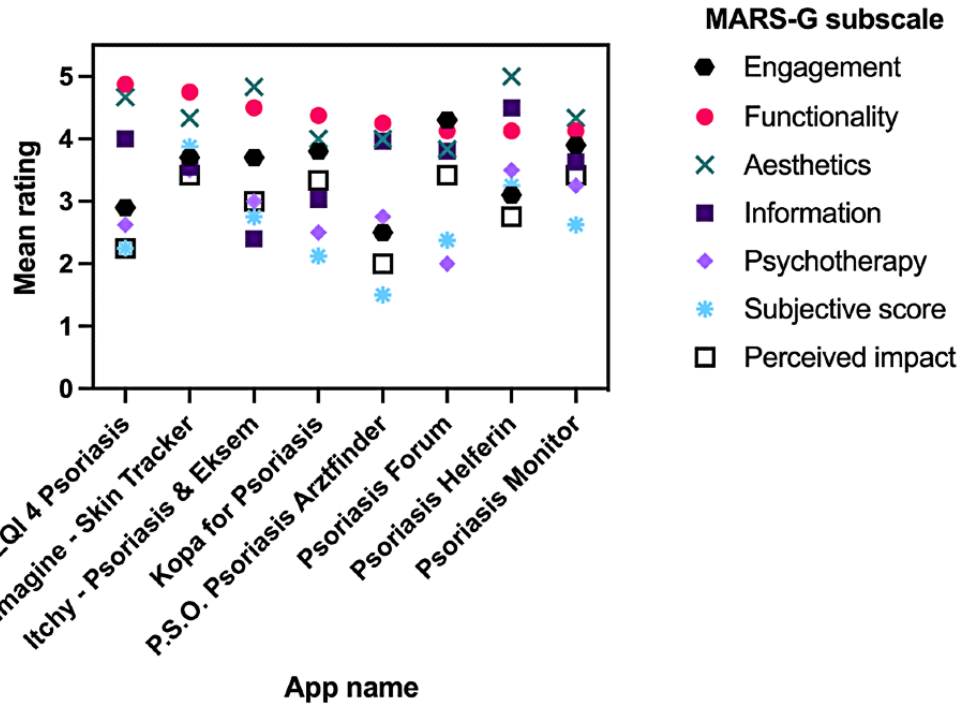
**Figure 2.** Mean objective and subjective German Mobile Application Rating Scale (MARS-G) scores.






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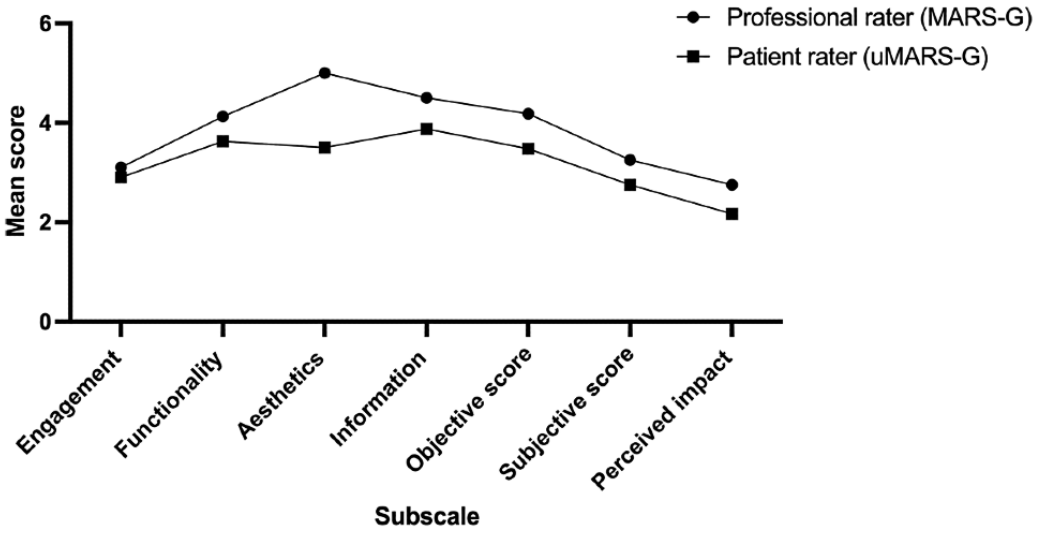
**Figure 3.** Mean scores for each German Mobile Application Rating Scale (MARS-G) subscale.




### uMARS-G Ratings

As Psoriasis Helferin received the highest MARS-G score (4.18), it was then rated by 2 patients with psoriasis, resulting in a considerably lower uMARS-G score (3.48). Patient ratings were lower for all uMARS-G subscales (Figure 4).

**Figure 4.** Mean subscale scores for the German Mobile Application Rating Scale (MARS-G) and user version of the MARS-G (uMARS-G).




## Discussion

### Principal Findings

To our knowledge this is the first study systematically identifying and rating currently available German smartphone apps specifically designed for patients with psoriasis. App quality was assessed by independent reviewers and patients using validated instruments and ready-to-use information was compiled to inform patients and health care professionals.

The overall app quality was heterogeneous. The app Psoriasis Helferin achieved the highest MARS-G score (4.18), and its main function is to track symptoms.

When 2 patients with psoriasis rated this app using the uMARS-G, the mean score decreased to 3.48. All subcategories were scored lower by patients (uMARS-G) than by professionals (MARS-G). The aesthetics subcategory revealed the largest difference.

These rating differences demonstrate the different perceptions, priorities, and preferences of patients. Therefore, health care providers should offer their patients a selection of apps or, at least, customizable apps. Patients may use medical apps less often if their preferences are not considered; this has already been demonstrated in studies analyzing treatment adherence [21]. This topic must be explored further in clinical studies.



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Psoriasis Helferin also achieved the best results in the MARS-G information subscale, with 4.50 points. Importantly, Psoriasis Helferin does not include any validated disease assessment instruments such as the PASI or DLQI [19,20]. This makes its clinical use problematic since there is no established procedure to date for comparing data collected by an app to medical records produced during routine visits. In our opinion, more apps that include scientifically validated instruments are required to increase the validity of patient-generated data.

We showed that all apps achieved passable results in the dimensions of aesthetics and functionality. By contrast, only 2 apps achieved 4 points or more for the information dimension, DLQI 4 Psoriasis and Psoriasis Helferin; no apps achieved 4 points or more for the psychotherapy dimension. This could indicate that app developers do not focus sufficiently on providing evidence-based information and psychological support to patients. It has been shown that emotional well-being is higher in well-informed patients [22]. In addition, the willingness to seek help from qualified physicians and change one's behavior are important precursors to successful treatment. Therefore, the questions addressed in the psychotherapy score determine if the app will be able to help patients improve their conditions. For the psychotherapy dimension, Psoriasis Helferin also achieves a passable score, along with the app Imagine – Skin Tracker, achieving 3.50 points.

Similar to previous app reviews [22], our results highlight the importance of including patients, clinicians, and researchers in the app development process, as stressed previously, to create appealing, validated, and truly beneficial apps. Physicians should be aware of the content and quality of the apps they recommend or even prescribe. In this regard, apps that primarily include a forum function should be approached with caution since personal experiences and incorrect advice from unqualified users may be unfavorable to the medical management of the patient's condition. Interestingly, an earlier study among patients with rheumatic conditions showed that this group was the least interested in a forum function [11]. Although they also live with a chronic disease, it remains to be seen if this conclusion can be transferred to patients with psoriasis. Thus, further surveys on the preferences of patients with psoriasis are needed to identify the most important app subjects and functions.

## Limitations

The MARS is one of the most often used and validated tools to evaluate health app quality [14]. The interrater reliability was 0.66 in our study, showing moderate agreement between raters.

The MARS helps raters evaluate the functionality, aesthetics, and information provided by apps; however, we found the equal contribution of all 4 categories to the final score is suboptimal for certain types of apps. For example, for an app focusing on information for patients, the quality of the information provided should have more weight than for an app used solely as a symptom diary. In apps designed with a narrow focus, the final score does not necessarily reflect the overall quality of these apps. Thus, we recommend using the MARS only to compare apps with a similar focus.

Further, data privacy and security are not part of the MARS, although it is an important aspect in any analysis of health care apps with sensitive information being shared by users. Although all apps but Kopa for Psoriasis included a privacy statement that the user had to agree to before use, the statements were long and difficult to understand for the average user. This makes it challenging for any patient or health care provider to grasp where and how their data is stored.

In an article from 2017, Baptista et al [23] question the utility of the uMARS as a simple adaptation of the MARS for lay users since the perceived quality of mobile apps may differ widely between health care providers and patients. This difference in perception can also be seen in our data, where the aesthetics of the apps were rated much lower by patients compared to researchers. We agree with Baptista et al [23] that further research addressing the different perspectives of patients and health care providers is needed.

Another limitation is that by focusing on apps available in app stores, we excluded web-based apps. The decision to only include apps only available in both app stores was based on our aim to analyze apps which are easily accessible and may be recommended by physicians. However, this approach excluded a significant proportion of apps available in only 1 of the app stores and makes our results less generalizable. In addition, the digital world is constantly changing; therefore, the results of this study may only be relevant for a short period of time, necessitating the frequent reanalysis of the key data.

## Conclusions

We were able to identify and compile several German apps specifically designed for patients with psoriasis that are publicly available and free of charge. Using the MARS-G, the highest mean score was achieved by Psoriasis Helferin. Importantly, patients rated the apps less positively than health care professionals. This should be considered when digital health care apps for patients with psoriasis become available on prescription as part of the DiGA directory in Germany. To be considered as DiGA, however, studies on the efficacy of specific apps are needed, which so far do not exist for all the apps we evaluated. Both professionals and patients rated the perceived impact of Psoriasis Helferin on health behavior as moderate. Other apps, which were evaluated by professionals only, performed even better in this area. Thus, we conclude that the benefit of apps as complements to traditional therapy for patients with psoriasis can not only be determined by randomized controlled trials [10] but also through subjective evaluations by patients and professionals. Additionally, a greater emphasis should be put on the evaluation of data privacy as private and often sensitive data are shared through these apps. Mobile dermatology apps represent a promising tool to complement the care of patients with psoriasis, but many critical aspects must be analyzed in more detail in an interdisciplinary manner, requiring close collaboration between dermatologists, app developers, and data protection officers.



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## Authors' Contributions

All authors had full access to the study data and approved the manuscript. We thank the patients who participated in this study.

## Conflicts of Interest

JAvA and CL received financial support from Novartis GmbH for a conference. AS has conducted clinical trials for AbbVie Inc, Boehringer Ingelheim, Celgene Corp, Eli Lilly and Company, Janssen Pharmaceuticals, LEO Pharma A/S, Merck & Co Inc, Novartis GmbH, and Pfizer Inc. AS was a member of the advisory boards of LEO Pharma A/S and UCB and obtained honoraria from Novartis GmbH, Janssen Pharmaceuticals, and UCB. Additionally, AS received financial support from Janssen Pharmaceuticals, AbbVie Inc, Pfizer Inc, and Novartis GmbH for conferences and received grant funding from Novartis GmbH. JK received financial support from Novartis GmbH, Sanofi SA, UCB, and Thermo Fisher Scientific. JK was a member of the advisory boards of and obtained honoraria from AbbVie Inc, Novartis GmbH, Eli Lilly and Company, Medac GmbH, Bristol Myers Squibb, Sanofi SA, Amgen Inc, Gilead Sciences Inc, UCB, ABATON, GlaxoSmithKline, Chugai Pharmaceutical Co Ltd, Boehringer Ingelheim, and Janssen Pharmaceuticals. VO has no conflicts of interest to report.

Multimedia Appendix 1
CONSORT-eHEALTH checklist (V 1.6.1).
[PDF File (Adobe PDF File), 348 KB - mhealth_v10i5e34017_app1.pdf ]

## References

1. Parisi R, Iskandar IYK, Kontopantelis E, Augustin M, Griffiths CEM, Ashcroft DM, Global Psoriasis Atlas. National, regional, and worldwide epidemiology of psoriasis: systematic analysis and modelling study. BMJ 2020 May 28;369:m1590 [FREE Full text] [doi: 10.1136/bmj.m1590] [Medline: 32467098]
2. Mamizadeh M, Tardeh Z, Azami M. The association between psoriasis and diabetes mellitus: a systematic review and meta-analysis. Diabetes Metab Syndr 2019;13(2):1405-1412. [doi: 10.1016/j.dsx.2019.01.009] [Medline: 31336500]
3. Masson W, Lobo M, Molinero G. Psoriasis and cardiovascular risk: a comprehensive review. Adv Ther 2020 May;37(5):2017-2033 [FREE Full text] [doi: 10.1007/s12325-020-01346-6] [Medline: 32314303]
4. Fu Y, Lee C, Chi C. Association of psoriasis with inflammatory bowel disease: a systematic review and meta-analysis. JAMA Dermatol 2018 Dec 01;154(12):1417-1423 [FREE Full text] [doi: 10.1001/jamadermatol.2018.3631] [Medline: 30422277]
5. Kurd SK, Troxel AB, Crits-Christoph P, Gelfand JM. The risk of depression, anxiety, and suicidality in patients with psoriasis: a population-based cohort study. Arch Dermatol 2010 Aug;146(8):891-895 [FREE Full text] [doi: 10.1001/archdermatol.2010.186] [Medline: 20713823]
6. Armstrong AW, Read C. Pathophysiology, clinical presentation, and treatment of psoriasis: a review. JAMA 2020 May 19;323(19):1945-1960. [doi: 10.1001/jama.2020.4006] [Medline: 32427307]
7. Murage MJ, Tongbram V, Feldman SR, Malatestinic WN, Larmore CJ, Muram TM, et al. Medication adherence and persistence in patients with rheumatoid arthritis, psoriasis, and psoriatic arthritis: a systematic literature review. Patient Prefer Adherence 2018;12:1483-1503 [FREE Full text] [doi: 10.2147/PPA.S167508] [Medline: 30174415]
8. Urquhart J. The odds of the three nons when an aptly prescribed medicine isn't working: non-compliance, non-absorption, non-response. Br J Clin Pharmacol 2002 Aug;54(2):212-220 [FREE Full text] [Medline: 12207644]
9. Becker S, Miron-Shatz T, Schumacher N, Krocza J, Diamantidis C, Albrecht U. mHealth 2.0: experiences, possibilities, and perspectives. JMIR Mhealth Uhealth 2014;2(2):e24 [FREE Full text] [doi: 10.2196/mhealth.3328] [Medline: 25099752]
10. Svendsen MT, Andersen F, Andersen KH, Pottegård A, Johannessen H, Möller S, et al. A smartphone application supporting patients with psoriasis improves adherence to topical treatment: a randomized controlled trial. Br J Dermatol 2018 Nov;179(5):1062-1071. [doi: 10.1111/bjd.16667] [Medline: 29654699]
11. Knitza J, Simon D, Lambrecht A, Raab C, Tascilar K, Hagen M, et al. Mobile health usage, preferences, barriers, and eHealth literacy in rheumatology: patient survey study. JMIR Mhealth Uhealth 2020 Aug 12;8(8):e19661 [FREE Full text] [doi: 10.2196/19661] [Medline: 32678796]
12. Kao C, Liebovitz DM. Consumer mobile health apps: current state, barriers, and future directions. PM R 2017 May;9(5S):S106-S115. [doi: 10.1016/j.pmrj.2017.02.018] [Medline: 28527495]
13. Subhi Y, Bube SH, Rolskov BS, Skou TAS, Konge L. Expert involvement and adherence to medical evidence in medical mobile phone apps: a systematic review. JMIR Mhealth Uhealth 2015 Jul 27;3(3):e79 [FREE Full text] [doi: 10.2196/mhealth.4169] [Medline: 26215371]



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14. Terhorst Y, Philippi P, Sander LB, Schultchen D, Paganini S, Bardus M, et al. Validation of the Mobile Application Rating Scale (MARS). PLoS One 2020;15(11):e0241480 [FREE Full text] [doi: 10.1371/journal.pone.0241480] [Medline: 33137123]
15. Messner E, Terhorst Y, Barke A, Baumeister H, Stoyanov S, Hides L, et al. The German version of the Mobile App Rating Scale (MARS-G): development and validation study. JMIR Mhealth Uhealth 2020 Mar 27;8(3):e14479 [FREE Full text] [doi: 10.2196/14479] [Medline: 32217504]
16. MARS-Rating Universität Ulm. MARS - mobile anwendungen rating skala. YouTube. 2017 Jun 02. URL: https://www.youtube.com/watch?v=5vwMiCWC0Sc [accessed 2022-04-22]
17. Stoyanov SR, Hides L, Kavanagh DJ, Zelenko O, Tjondronegoro D, Mani M. Mobile app rating scale: a new tool for assessing the quality of health mobile apps. JMIR Mhealth Uhealth 2015;3(1):e27 [FREE Full text] [doi: 10.2196/mhealth.3422] [Medline: 25760773]
18. Stoyanov SR, Hides L, Kavanagh DJ, Wilson H. Development and validation of the user version of the Mobile Application Rating Scale (uMARS). JMIR Mhealth Uhealth 2016;4(2):e72 [FREE Full text] [doi: 10.2196/mhealth.5849] [Medline: 27287964]
19. Ashcroft DM, Wan Po AL, Williams HC, Griffiths CE. Clinical measures of disease severity and outcome in psoriasis: a critical appraisal of their quality. Br J Dermatol 1999 Aug;141(2):185-191. [doi: 10.1046/j.1365-2133.1999.02963.x] [Medline: 10468786]
20. Finlay AY, Khan GK. Dermatology Life Quality Index (DLQI)--a simple practical measure for routine clinical use. Clin Exp Dermatol 1994 May;19(3):210-216. [Medline: 8033378]
21. Bewley A, Page B. Maximizing patient adherence for optimal outcomes in psoriasis. J Eur Acad Dermatol Venereol 2011 Jun;25 Suppl 4:9-14. [doi: 10.1111/j.1468-3083.2011.04060.x] [Medline: 21507078]
22. Knitza J, Tascilar K, Messner E, Meyer M, Vossen D, Pulla A, et al. German mobile apps in rheumatology: review and analysis using the Mobile Application Rating Scale (MARS). JMIR Mhealth Uhealth 2019 Aug 05;7(8):e14991 [FREE Full text] [doi: 10.2196/14991] [Medline: 31381501]
23. Baptista S, Oldenburg B, O'Neil A. Response to "Development and Validation of the User Version of the Mobile Application Rating Scale (uMARS)". JMIR Mhealth Uhealth 2017 Jun 09;5(6):e16 [FREE Full text] [doi: 10.2196/mhealth.6419] [Medline: 28600277]


## Abbreviations

**DiGA:** digital health applications
**DLQI:** Dermatology Life Quality Index
**MARS:** Mobile Application Rating Scale
**MARS-G:** German Mobile Application Rating Scale
**NGO:** nongovernmental organization
**PASI:** Psoriatic Area and Severity Index
**uMARS:** user version of the Mobile Application Rating Scale


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Corrigenda and Addenda

# Correction: A Mobile-Based Intervention to Increase Self-esteem in Students with Depressive Symptoms: Randomized Controlled Trial

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**Related Article:**

Correction of: http://mhealth.jmir.org/2021/7/e26498/

***(JMIR Mhealth Uhealth 2022;10(5):e39448)*** doi:10.2196/39448

In "A Mobile-Based Intervention to Increase Self-esteem in Students with Depressive Symptoms: Randomized Controlled Trial" (JMIR Mhealth Uhealth 2021;9(7):e26498), the authors noted the following errors.

In the originally published article, the effect size for self-esteem was incorrectly reported as $d$=0.77. The correct value should be $d$=0.40. Therefore, in relation to this value, the phrase "medium to large effect" should be corrected to "small to medium effect." The effect sizes of all other result parameters were converted correctly.

Furthermore, in the originally published article, commas separating degrees of freedom in the $F$ values were missing (eg, $F_{1,222}$ was erroneously presented as $F_{1222}$).

Pertaining to these two errors, the following corections were made in the article.

1. In "Abstract" (Results), the sentence "Per-protocol (PP), complete-case, and intention-to-treat analyses showed a significantly higher reduction in depressive symptoms (PP: $F_{1222}$=3.98; $P$=.047; $d$=0.26) and a significantly higher increase in self-esteem (PP: $F_{1220}$=8.79; $P$=.003; $d$=0.77) in the intervention group than in the wait-list control group" has been corrected to "Per-protocol (PP), complete-case, and intention-to-treat analyses showed a significantly higher reduction in depressive symptoms (PP: $F_{1,222}$=3.98; $P$=.047; $d$=0.26) and a significantly higher increase in self-esteem (PP: $F_{1,220}$=8.79; $P$=.003; $d$=0.40) in the intervention group than in the wait-list control group."

2. In "Results" (Between-Group Differences), the phrase "The analyses resulted in a medium to large effect size for the increase in self-esteem ($\eta_p^2$=0.038; $d$=0.77) in the PP sample across time" has been corrected to "The analyses resulted in a small to medium effect size for the increase in self-esteem ($\eta_p^2$=0.038; $d$=0.40) in the PP sample across time."

3. In "Discussion" (Principal Findings), the phrase "In addition, a medium to large effect size of $d$=0.77 (RSE; PP sample) was found for the increase in self-esteem,…" has been corrected to "In addition, a small to medium effect size of $d$=0.40 (RSE; PP sample) was found for the increase in self-esteem,…."

4. In "Discussion" (Conclusion), the sentence "The use of the app led to a significantly higher reduction in depressive symptoms ($d$=0.26) and a significantly higher increase in self-esteem ($d$=0.77)" has been corrected to "The use of the app led to a significantly higher reduction in depressive symptoms ($d$=0.26) and a significantly higher increase in self-esteem ($d$=0.40)."

5. In "Abstract" (Results), "$F_{1222}$" has been corrected to "$F_{1,222}$" and "$F_{1220}$" has been corrected to "$F_{1,220}$."

6. In "Results" (Between-Group Differences), "$F_{1398}$" has been corrected to "$F_{1,398}$," "$F_{1223}$" to "$F_{1,223}$," "$F_{1261}$" to "$F_{1,261}$," "$F_{1221}$" to "$F_{1,221}$," and "$F_{1259}$" to"$F_{1,259}$."

7. In Table 3, "(1398)" has been corrected to "(1,398)," "(1222)" to "(1,222)," "(1220)" to "(1,220)," "(1223)" to "(1,223)," "(1261)" to "(1,261)," and "(1259)" to "(1,259)."

8. In "Results" (Attitude and Expectation), "$F_{1275}$" has been corrected to "$F_{1,275}$."

The correction will appear in the online version of the paper on the JMIR Publications website on May 20, 2022, together with



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the publication of this correction notice. Because this was made after submission to PubMed, PubMed Central, and other full-text repositories, the corrected article has also been resubmitted to those repositories.

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