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Original Paper

Electronic Dietary Intake Assessment (e-DIA): Comparison of a Mobile Phone Digital Entry App for Dietary Data Collection With 24-Hour Dietary Recalls

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Abstract

Background: The electronic Dietary Intake Assessment (e-DIA), a digital entry food record mobile phone app, was developed to measure energy and nutrient intake prospectively. This can be used in monitoring population intakes or intervention studies in young adults.

Objective: The objective was to assess the relative validity of e-DIA as a dietary assessment tool for energy and nutrient intakes using the 24-hour dietary recall as a reference method.

Methods: University students aged 19 to 24 years recorded their food and drink intake on the e-DIA for five days consecutively and completed 24-hour dietary recalls on three random days during this 5-day study period. Mean differences in energy, macro-, and micronutrient intakes were evaluated between the methods using paired t tests or Wilcoxon signed-rank tests, and correlation coefficients were calculated on unadjusted, energy-adjusted, and deattenuated values. Bland-Altman plots and cross-classification into quartiles were used to assess agreement between the two methods.

Results: Eighty participants completed the study (38% male). No significant differences were found between the two methods for mean intakes of energy or nutrients. Deattenuated correlation coefficients ranged from 0.55 to 0.79 (mean 0.68). Bland-Altman plots showed wide limits of agreement between the methods but without obvious bias. Cross-classification into same or adjacent quartiles ranged from 75% to 93% (mean 85%).

Conclusions: The e-DIA shows potential as a dietary intake assessment tool at a group level with good ranking agreement for energy and all nutrients.

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KEYWORDS

validity; dietary assessment; mobile phone app; young adult

Introduction

The collection of accurate dietary consumption data is important in the field of nutritional epidemiology in order to establish true relationships between nutrition and health status. The food record (weighed or estimated portions) is a traditional method used to record amounts and types of foods and beverages consumed prospectively, thus limiting recall bias [1,2]. However, one of the main limitations of food records is the high burden placed upon respondents to record this detailed dietary information [1,2]. For researchers, food record entries must be manually entered for analysis with food and nutrient software programs which takes significant time. Thus, improvements to methods for prospective dietary recording would be beneficial for research participants and researchers alike.

With 81% of Australians regularly using a mobile phone [3], the collection of dietary intake records using a mobile phone app has the potential to be more convenient for recording entries than conventional paper-based food records [4,5]. Mobile phone apps that use image-based food records rather than digital entry of foods are also increasingly available [6-9]. A recent review by our group concluded that mobile phone use to record dietary intake was preferred by users over conventional methods and offers the potential to reduce research costs through automated coding [6].

A number of commercial mobile phone apps such as MyFitnessPal and Lose It provide a platform for users to digitally record foods and beverages consumed and have these records integrated with food composition databases to calculate nutrients [10]. Only one, Easy Diet Diary, uses an Australian database of foods. However, the feedback display of nutrient intakes by these apps might elicit unintended behavior changes. We aimed to purposely design a mobile phone app (the electronic Dietary Intake Assessment, e-DIA) that would allow digital recording of all foods and beverages consumed, either weighed or estimated, but provide no nutrient content feedback. The aim of this study was to compare the energy and nutrient intakes collected with e-DIA against 24-hour dietary recalls and evaluate e-DIA's potential as a dietary assessment tool in research.

Methods

Study Sample

Students enrolled in a study aimed at assessing university students' dietary intakes were invited to participate in this validation study. Recruitment methods for the larger study included email and poster advertisements on the university campus, which included a weblink to an online screening survey. Out of 313 students who completed the survey, 170 were eligible and 113 students were enrolled at an interview during which the study protocol was explained and written informed consent was obtained. From the enrolled students, 66 agreed to participate in the validation study and 57 completed both e-DIA and 24-hour dietary recalls from March to April 2014. To boost sample size, an additional 23 students were recruited in August 2014 by the same methods. This resulted in a final sample of 80 students (Figure 1). Inclusion criteria included being a full-time student aged 19 to 24 years, being enrolled in the second, third, or fourth year of study within the Science or Engineering departments, and owning a mobile phone. Nutrition and health science students were excluded. As an incentive to participate, all students were entered in a drawing to win an Apple iPad Mini after completion of the study. The study was conducted in agreement with the National Statement on Ethical Conduct in Human Research [11], and ethical approval was obtained from the university's Human Research Ethics Committee (2014/136).

e-DIA Mobile Phone App

Students downloaded the e-DIA app using an Android or iOS platform on their own mobile phone. To record intake, the user selects the meal occasion during which the food or beverage is consumed (breakfast, lunch, dinner, or other) which opens the Edit/Delete screen (Figure 2). On this screen the user selects the Food/Drink field to search for and choose the food or drink they consumed. A search-as-you-type function which begins to show a string of options once three letters are typed was built into the app, as was a favorites function for entry of foods commonly consumed by the participant. These additional navigation functions were added after usability testing of a previous prototype of e-DIA (results unpublished). The list of foods for this search function was based on the 2007 Australian Food, Supplement, and Nutrient Database (AUSNUT 2007)—the most recent food composition database at the time this research was conducted [12]. To log foods that were not listed or could not be found in the AUSNUT 2007 database, participants were asked to enter these manually into e-DIA. The amounts of foods and beverages consumed and location of consumption were also recorded (Figure 2). Data were uploaded to the research administrator's website each day at midnight, after which the user could no longer access or view the record.

Figure 1. Flow chart of participant recruitment.

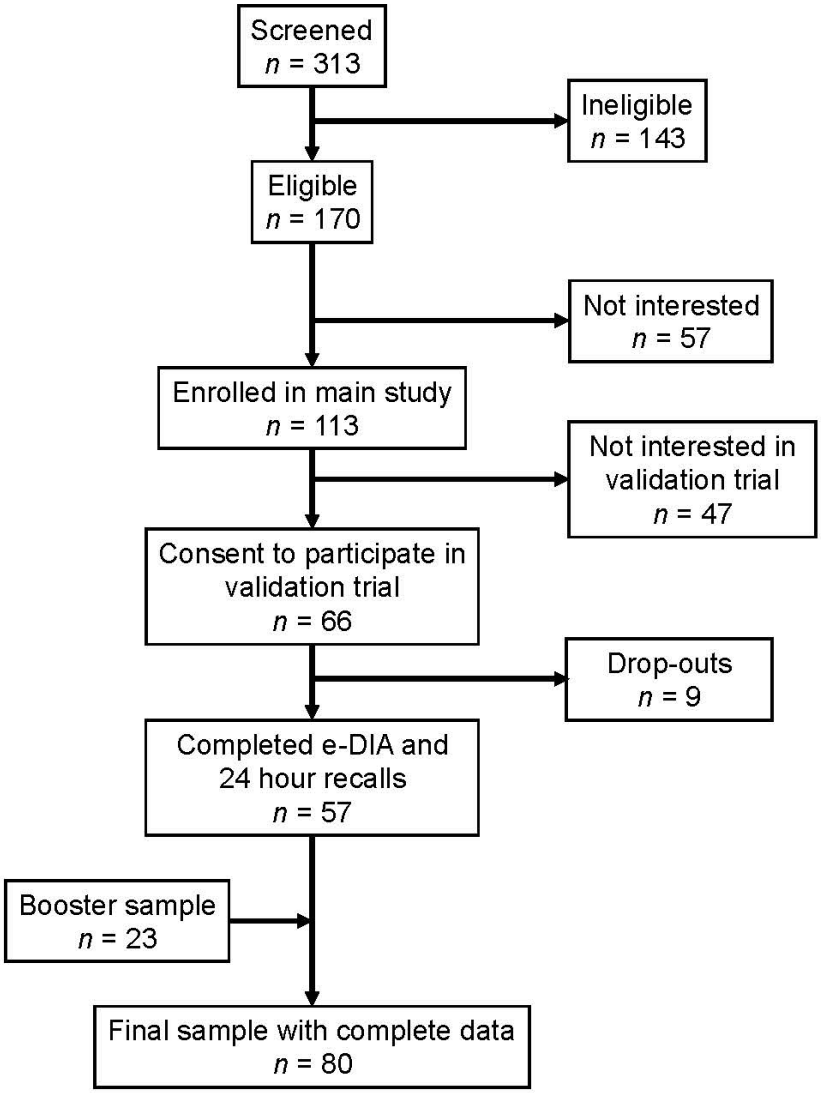
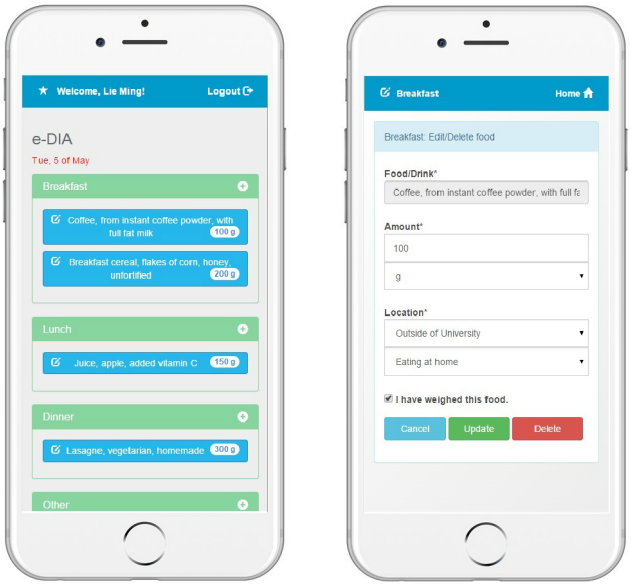


Figure 2. Screenshots of the electronic Dietary Intake Assessment (e-DIA) app.



Procedure

At an initial clinic appointment on the university campus, anthropometric data were collected by the study investigators. Height was measured to the nearest 0.5 cm, weight to the nearest 0.1 kg (without heavy clothing or shoes), and waist circumference to the nearest 0.5 cm, according to the Anthropometry Procedures Manual from the National Health and Nutrition Examination Survey (National Center for Health Statistics, US Department of Health and Human Services) [13].

Participants were instructed to complete five consecutive days of food records including three weekdays and two weekend days using e-DIA. Participants practiced selecting and entering food items and weights, and written instructions were included on how to choose foods from the database, how to enter mixed recipes, and how to estimate portion sizes when eating away from home. Participants were asked to weigh foods using the scales supplied (Salter 1066WHDR); an instruction booklet was provided. If participants were unable to weigh the foods, they were instructed to estimate portion sizes using metric cups and spoons supplied. Starting days were staggered so that all days of the week were represented across the sample. Participants were sent a text message reminder prior to each collection day which encouraged them to maintain their usual diet.

As a reference measure, three 24-hour dietary recalls were collected on three random days (including weekend days) during the five-day study period. Appropriate calling times were established at the convenience of the participants. The standard 24-hour dietary recall interview multi-pass script adapted from the Five-Step Multiple-Pass Method by the US Department of Agriculture [14] was used for the 30-minute telephone interviews, and participant responses were recorded on a standardized 24-hour dietary recall form. In addition to the metric cups and spoons, a food model booklet [15] was provided to aid in the estimation of food and beverage portion sizes for the 24-hour dietary recalls.

Data Coding and Cleaning

All entries were checked the following day by study investigators, and participants were contacted to clarify manually entered food items and obvious inconsistencies such as gross data entry errors and skipped meals.

Data collected using the e-DIA mobile web app were stored in a cloud-based database, and records were linked to food items in the AUSNUT 2007. If the nutrient composition of manually entered food items was known, study investigators added the information to the database; if unknown, investigators coded to the closest match. Food intake data from the 24-hour dietary recalls were manually entered by trained study investigators into FoodWorks 7 Premium [16], a nutrient analysis software system using the AUSNUT 2007 database [12].

Energy and nutrient intakes from the 24-hour dietary recalls and e-DIA were examined for outliers and checked against the original 24-hour dietary recall for obvious errors in data entry. Errors made by the participant in the e-DIA were left unaltered, and no outliers were removed to provide a more accurate indication of the relative validity of the e-DIA method. Vitamin and mineral supplements were excluded from analysis.

Statistical Analysis

Mean or median intakes of energy and nutrients from three days of 24-hour dietary recalls and five days of e-DIA were calculated and differences determined using paired *t* tests (normally distributed data including energy and macronutrients) or Wilcoxon signed-rank test (skewed data for alcohol and micronutrients). Correlations between the two methods were measured using Pearson product-moment correlation coefficients (or Spearman rank correlation coefficients for skewed data) for unadjusted, energy-adjusted and deattenuated data. Energy-adjusted nutrients were obtained by applying the residual method [2]. Deattenuated nutrient intakes corrected for within-person variation in both 24-hour dietary recalls and e-DIA were estimated using the Multiple Source Method [17]. Cross-classification and Bland-Altman plots [18] were used to assess the agreement between the 24-hour dietary recalls and e-DIA for energy and nutrients. Cross-classification examined the proportions of participants classified into the same, same or adjacent, or extreme quartiles of energy-adjusted intakes. Bland-Altman plots were presented to assess bias within the intake range. All data were analysed using SPSS Statistics version 22.0 (IBM Corp) [19] and a P value <.05 was considered statistically significant.

Results

A sample of 80 students (30 male) completed five days of e-DIA and three days of 24-hour dietary recalls (Figure 1). The main reason given for not participating or dropping out of the study was due to time restraints and heavy workloads. Mean body mass index (BMI) was 22.6 kg/m^2 (SD 3.8) with 63 participants (79%) in the healthy weight range (BMI 18.5-24.9), nine overweight (BMI 25.0-29.9), four obese (BMI>30.0), and three underweight (BMI<18.5). Mean waist circumference was 70 cm (SD 6.6) for females and 81 cm (SD 10.5) for males. One participant did not consent to disclosing her anthropometric data. The majority of participants lived at home with family (70%), with English being the most commonly spoken language at home (75%).

Mean and median intakes of energy and nutrients reported by 24-hour dietary recall and e-DIA are shown in Table 1. Differences between energy and nutrient intakes were mostly small, and none were statistically significant.

Table 1. Mean and median daily intakes of energy and nutrients measured by three days of 24-hour dietary recall (24HR) and five days of electronic Dietary Intake Assessment (e-DIA).

Energy and nutrients	e-DIA		24HR		Difference
	Mean (SD)	Median	Mean (SD)	Median	Mean (SD)
Energy, kJ	8148.2 (2495.2)	7699.1	8182.2 (2575.1)	7625.4	−34.3 (2090.3)
Protein, g	88.7 (33.5)	86.7	91.3 (35.0)	85.2	−2.5 (22.5)
Total fat, g	74.6 (25.6)	70.3	76.0 (31.4)	68.6	−1.4 (23.5)
SFA[a], g	28.8 (11.8)	26.4	30.1 (16.4)	26.8	−1.3 (10.8)
MUFA[b], g	28.4 (10.9)	26.5	28.7 (11.7)	25.8	−0.3 (9.8)
PUFA[c], g	11.6 (4.4)	11.2	11.4 (4.6)	10.5	0.3 (4.5)
Carbohydrate, g	213.3 (82.6)	204.8	209.0 (67.5)	197.4	4.3 (70.1)
Sugars, g	80.1 (41.8)	72.9	88.1 (50.4)	78.3	−8.0 (43.7)
Starch, g	130.5 (57.1)	122.6	120.9 (46.9)	114.7	9.6 (44.6)
Fiber, g	22.0 (8.0)	21.5	21.5 (8.5)	20.0	0.5 (7.9)
Alcohol, g	4.8 (10.7)	0.1	3.9 (10.0)	0.0	0.9 (4.7)
Vitamin A RE[d], µg	812.2 (961.5)	634.4	866.0 (1403.3)	653.1	−53.8 (574.1)
Thiamin, mg	1.5 (1.0)	1.3	1.5 (0.8)	1.3	0.1 (0.9)
Riboflavin, mg	1.9 (0.9)	1.9	2.1 (0.9)	1.9	−0.2 (0.6)
Niacin, mg	43.5 (18.5)	42.3	45.8 (21.6)	41.3	−2.3 (16.5)
Folate DFE[e], µg	343.2 (212.4)	295.2	365.1 (232.8)	313.9	−21.9 (143.4)
Vitamin C, mg	90.7 (57.5)	76.9	106.8 (89.7)	88.4	−16.1 (78.1)
Vitamin E, mg	8.6 (4.5)	7.7	8.5 (3.9)	7.9	0.1 (3.8)
Calcium, mg	705.4 (318.0)	686.2	725.6 (317.7)	658.4	−22.0 (230.3)
Iron, mg	12.7 (9.3)	11.4	12.1 (5.6)	10.8	0.6 (7.5)
Zinc, mg	11.3 (7.1)	10.0	11.2 (4.6)	10.5	0.2 (6.7)
Magnesium, mg	333.1 (133.7)	311.4	323.4 (106.8)	312.4	10.0 (100.2)
Phosphorus, mg	1403.0 (511.6)	1388.1	1383.9 (470.8)	1324.2	18.6 (321.9)
Sodium, mg	2712.3 (1480.0)	2375.5	2561.5 (952.4)	2433.3	151.0 (1234.7)
Potassium, mg	2701.1 (1003.9)	2679.2	2732.1 (801.3)	2632.6	−31.3 (768.5)

[a]SFA: saturated fatty acids

[b]MUFA: monounsaturated fatty acids

[c]PUFA: polyunsaturated fatty acids

[d]RE: retinol equivalents

[e]DFE: dietary folate equivalents

Table 2 shows the correlation coefficients between the 24-hour dietary recalls and e-DIA. All correlation coefficients were statistically significant (P<.001). Correlations for unadjusted intakes were in the range 0.50 to 0.79 (mean correlation of 0.66 for all nutrients), energy-adjusted correlations were in the range 0.40 to 0.78 (mean 0.63), and deattenuated correlations were in the range 0.55 to 0.79 (mean 0.68). The highest correlations were found for protein and saturated fats while the lowest correlation was found for polyunsaturated fats. Deattenuated correlation coefficients were generally higher than unadjusted or energy-adjusted coefficients but differences were small.

Quartile cross-classification of nutrients with the 24-hour dietary recalls and e-DIA placed 75% to 93% (mean 85%) of the participants into the same or adjacent quartile, with the highest ranking agreement for fiber and the lowest for iron. Cross-classification into extreme quartiles ranged from 0% to 9% (mean 1%) with monounsaturated fatty acids (MUFA), thiamine, and iron having the greatest proportion of extreme misclassification.

Table 2. Correlation coefficients and cross-classification of energy and nutrients between three days of 24-hour dietary recall and five days of electronic Dietary Intake Assessment.

Energy and nutrients	Correlation coefficients[a,b]			Cross-classification into quartiles[c]		
	Unadjusted	Energy-adjusted	De-attenuated	Same	Same or adjacent	Extreme
Energy, kJ	0.66	—	0.68	38	81	0
Protein, g	0.79	0.77	0.79	58	87	1
Total fat, g	0.68	0.71	0.69	41	81	5
SFA[d], g	0.75	0.78	0.76	46	91	0
MUFA[e], g	0.62	0.62	0.64	45	79	6
PUFA[f], g	0.50	0.43	0.55	46	82	2
Carbohydrate, g	0.64	0.75	0.67	49	87	2
Sugars, g	0.56	0.57	0.62	48	84	0
Starch, g	0.65	0.65	0.72	46	89	2
Fiber, g	0.54	0.63	0.64	59	93	1
Alcohol, g	0.77	0.69	0.62	44	88	1
Vitamin A RE[g], µg	0.61	0.66	0.61	49	88	4
Thiamin, mg	0.61	0.40	0.66	35	79	9
Riboflavin, mg	0.77	0.70	0.76	45	90	0
Niacin, mg	0.69	0.58	0.71	53	83	2
Folate DFE[h], µg	0.69	0.72	0.71	58	89	2
Vitamin C, mg	0.68	0.71	0.75	56	89	0
Vitamin E, mg	0.53	0.60	0.56	40	85	1
Calcium, mg	0.75	0.57	0.72	40	80	2
Iron, mg	0.57	0.42	0.61	34	75	6
Zinc, mg	0.69	0.54	0.70	49	82	2
Magnesium, mg	0.71	0.69	0.72	48	88	0
Phosphorus, mg	0.76	0.69	0.78	53	87	1
Sodium, mg	0.60	0.59	0.60	48	88	5
Potassium, mg	0.64	0.68	0.68	59	92	2

[a]Pearson correlation coefficients used for energy and macronutrients; Spearman rank correlation coefficients used for alcohol and micronutrients.

[b]All correlations were significant ($P<.001$).

[c]Based on energy-adjusted data.

[d]SFA: saturated fatty acids

[e]MUFA: monounsaturated fatty acids

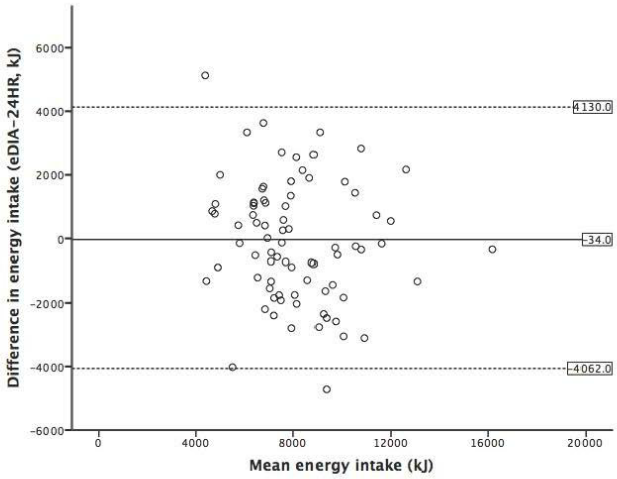
[f]PUFA: polyunsaturated fatty acids

[g]RE: retinol equivalents

[h]DFE: dietary folate equivalents

Bland-Altman plots illustrating the agreement between the 24-hour dietary recalls and e-DIA for energy and selected nutrient intakes are shown in Figures 3-7. For energy intake, the mean difference between e-DIA and 24-hour dietary recall was minimal (−34 kJ) but the 95% limits of agreement were wide (−4062 kJ to 4130 kJ). No systematic bias was detected with random scatter of data points. Similar results were found with other nutrients with small mean differences, with no obvious systematic bias but wide limits of agreement between the two methods.

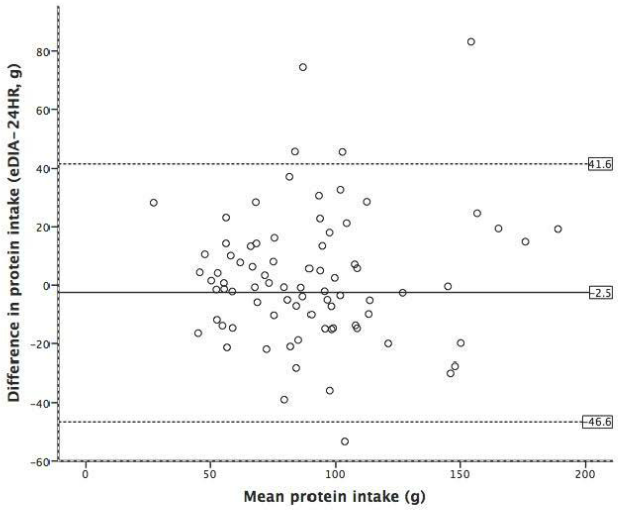
Figure 3. Bland-Altman plot of 24-hour dietary recalls (24HR) and electronic Dietary Intake Assessment (e-DIA) for energy intake.



Differences in intake between the methods are plotted against the mean of the two methods. The solid line indicates the mean difference, the dashed lines indicate the 95% limits of agreement (SD 1.96).

Mean difference −34 kJ; limits of agreement −4062 kJ, 4130 kJ.

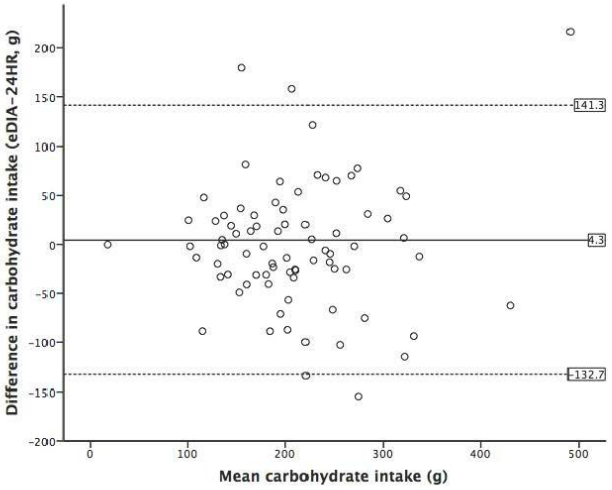
Figure 4. Bland-Altman plot of 24-hour dietary recalls (24HR) and electronic Dietary Intake Assessment (e-DIA) for protein intake.



Differences in intake between the methods are plotted against the mean of the two methods. The solid line indicates the mean difference, the dashed lines indicate the 95% limits of agreement (SD 1.96).

Mean difference −2.5 g; limits of agreement −46.6 g, 41.6 g.

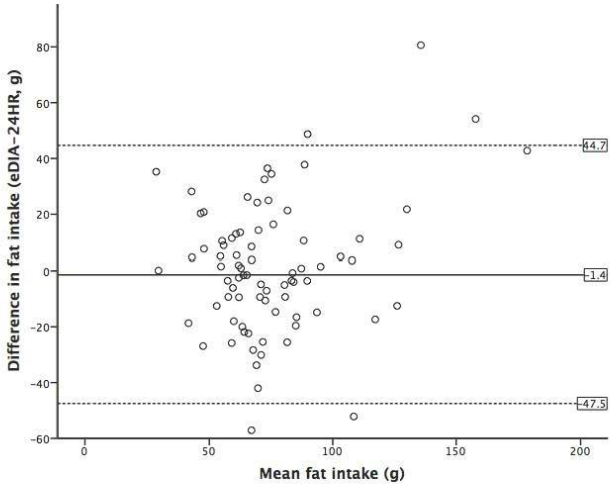
Figure 5. Bland-Altman plot of 24-hour dietary recalls (24HR) and electronic Dietary Intake Assessment (e-DIA) for carbohydrate intake.



Differences in intake between the methods are plotted against the mean of the two methods. The solid line indicates the mean difference, the dashed lines indicate the 95% limits of agreement (SD 1.96).

Mean difference 4.3 g; limits of agreement −132.7 g, 141.3 g.

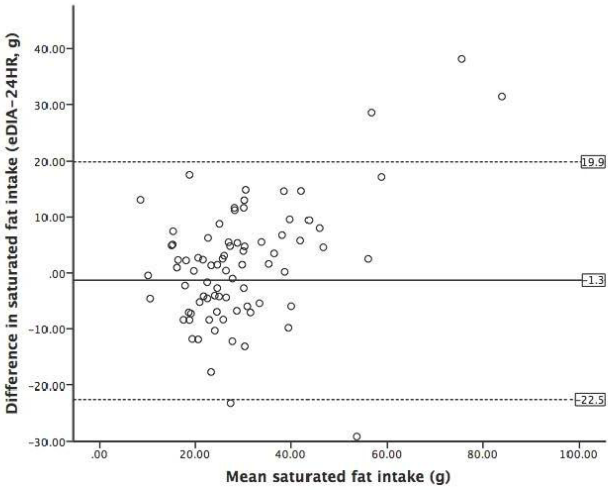
Figure 6. Bland-Altman plot of 24-hour dietary recalls (24HR) and electronic Dietary Intake Assessment (e-DIA) for fat intake.



Differences in intake between the methods are plotted against the mean of the two methods. The solid line indicates the mean difference, the dashed lines indicate the 95% limits of agreement (SD 1.96).

Mean difference −1.4 g; limits of agreement −47.5 g, 44.7 g.

Figure 7. Bland-Altman plot of 24-hour dietary recalls (24HR) and electronic Dietary Intake Assessment (e-DIA) for saturated fat intake.



Differences in intake between the methods are plotted against the mean of the two methods. The solid line indicates the mean difference, the dashed lines indicate the 95% limits of agreement (SD 1.96).

Mean difference −1.3 g; limits of agreement −22.5, 19.9 g.

Discussion

Principal Findings

This study is the first to compare the energy and nutrient intakes using a mobile phone food diary app with 24-hour dietary recall as reference measure using an Australian food composition database. Mean intakes of energy and all nutrients were similar in both methods, with no consistently higher or lower values for either method. Correlation coefficients were moderate to strong ranging from 0.55 to 0.78. Cross-classification into quartiles revealed good agreement for energy and all nutrients. In addition Bland-Altman plots showed robust agreement between the e-DIA and 24-hour dietary recalls for energy and all nutrients, without bias and with most data points located within two standard deviations of the mean. The wide limits of agreement suggest that e-DIA is unsuitable to accurately estimate intake at an individual level. However, collectively the results suggest the potential of e-DIA as an assessment tool for dietary analysis at the population level.

These findings are consistent with those of other researchers. Carter et al recently validated a mobile phone app (My Meal Mate) designed to support weight loss [20]. Mean intakes of energy, protein, carbohydrate, and fat were similar using 2-day 24-hour dietary recalls and 7-day electronic food records. Pearson correlations of 0.69 to 0.86 were found for energy and macronutrients, and Bland-Altman analysis of energy intake showed minimal bias but wide limits of agreement between the methods. Comparisons between 24-hour dietary recalls and food records collected using personal digital assistants (PDAs) also produced consistent results with no significant differences between mean intakes of energy, protein, carbohydrate, or fat [21,22]; moderate to strong Pearson correlations (1-day PDA vs 24-hour dietary recalls r=0.51-0.80, 7-day PDA vs 24-hour dietary recall r=0.72-0.85) [21]; and minimal bias as demonstrated using Bland-Altman plots [21,22].

Mobile phones are also being used for digital imaging to record food and beverage intake [8,9,23-30]. The advantage of these over the digital entry food record is that the respondent burden is considerably reduced with only images recorded and no searching and selection of foods from display lists. With a fiducial marker or reference card, the researcher uses manual or automated methods to assign the food identity and portion size to the image before automatic nutrient analysis. Examples of the use of images with human input into the assignment of foods and quantities include the remote food photography method and the Nutricam dietary assessment method [8,23-26]. Both have been shown to have validity in a free living situation using doubly labelled water to measure energy intake [8,24]. These methods are semiautomated and still require humans to correctly identify foods and amounts. The mobile device food record is an automated system for food identification and volume estimation and offers the recorder the opportunity to see the classifications and correct mislabelled food [9,27-30]. Further development of the process includes increasing correct food recognition and decreasing errors in volume estimation with the automated method. Completely automated systems using digital images provide obvious advantages over digital recording by easing both respondent and researcher burden.

Limitations and Strengths

Although the use of 24-hour dietary recall was the preferred choice of reference method, it introduces several limitations to the study design. Reliance on memory is a well-documented limitation with participants likely to forget foods consumed the previous day, although the use of the multiple pass method and portion size aids are designed to minimize the impact of errors related to memory. As the 24-hour dietary recall was

administered on days that the participants digitally recorded their food records into the e-DIA, there was potential for the recording process to have improved their recall of food and beverages. However, it should be noted that records were deleted from the app at midnight and recalls were conducted up to 22 hours after their deletion. As both methods relied on self-report, more objective measures of dietary intake such as biomarkers are needed to further validate the e-DIA.

Compared with the 2011-2012 Australian Health Survey [31], energy intakes were 8% and 11% lower for males and females, respectively, indicating some degree of under-reporting. This was primarily due to lower reported intakes of carbohydrates (especially sugar) and alcohol in the validation study. University students are a unique population group and are not representative of all young adults, as they are skewed towards higher socioeconomic backgrounds and may have higher digital and computer literacy [32].

The use of the e-DIA also has limitations, including the burden of recording foods prospectively for a prolonged period of time and trouble navigating within the e-DIA tool itself. When entering a food into the e-DIA, participants were presented with a long list of food options that was challenging to navigate. However, the presence of the favorites function relieves some of this burden by prioritizing the food options according to individual preferences. Commercial apps may have shorter lists but this is likely to result in less accurate food records and resulting nutrient intakes.

One of the main strengths of the study is the ability of e-DIA to collect dietary intake data without alerting the participants to their ongoing caloric intake. The app is linked to the Australian national food composition database compiled by Food Standards Australia New Zealand which consists of over 4500 foods [12]. This greatly reduced the need for coding although careful checking of all foods and beverages recorded each day may be useful to obtain reliable nutrient outputs. Another advantage of using the national food composition database is the inclusion of a large range of macronutrients, micronutrients, and other food components. The app is used to record food and beverages consumed in real time and therefore does not rely on memory.

Conclusions

This validation study demonstrated good agreement between the e-DIA and 24-hour dietary recalls at a group level, and no evidence of bias for energy, macro-, and micronutrients was noted. With the growing popularity of mobile phones among young adults this method of collecting dietary intake is highly acceptable in this population group. Future studies should explore the validity of the e-DIA in larger, more representative samples and employ external biomarkers to reflect usual intakes. Studies assessing the e-DIA's sensitivity to changes in dietary intake are also required. This would confirm its value as a tool to monitor dietary intake in intervention studies in public health and clinical trials.

Acknowledgments

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Authors' Contributions

MAF, JK, LMT, JL, and RR developed the app; SOC, VG, MY, RR, JL, LH, and AR were involved in data collection; AR analyzed the data and drafted the manuscript; and all authors were involved in editing the final draft and approving the manuscript.

Conflicts of Interest

None declared.

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Abbreviations

24HR: 24-hour dietary recall
AUSNUT: Australian Food, Supplement, and Nutrient Database
BMI: body mass index
e-DIA: electronic Dietary Intake Assessment
MUFA: monounsaturated fatty acids
PDA: personal digital assistant

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Original Paper

A Mobile Phone App for Dietary Intake Assessment in Adolescents: An Evaluation Study

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Abstract

Background: There is a great need for dietary assessment methods that suit the adolescent lifestyle and give valid intake data.

Objective: To develop a mobile phone app and evaluate its ability to assess energy intake (EI) and total energy expenditure (TEE) compared with objectively measured TEE. Furthermore, to investigate the impact of factors on reporting accuracy of EI, and to compare dietary intake with a Web-based method.

Methods: Participants 14 to 16 years of age were recruited from year nine in schools in Gothenburg, Sweden. In total, 81 adolescents used the mobile phone app over 1 to 6 days. TEE was measured with the SenseWear Armband (SWA) during the same or proximate days. Individual factors were assessed with a questionnaire. A total of 15 participants also recorded dietary intake using a Web-based method.

Results: The mobile phone app underestimated EI by 29% on a group level (P<.001) compared to TEE measured with the SWA, and there was no significant correlation between EI and TEE. Accuracy of EI relative to TEE increased with a weekend day in the record (P=.007) and lower BMI z-score (P=.001). TEE assessed with the mobile phone app was 1.19 times the value of TEE measured by the SWA on a group level (P<.001), and the correlation between the methods was .75 (P<.001). Analysis of physical activity levels (PAL) from the mobile phone app stratified by gender showed that accuracy of the mobile phone app was higher among boys. EI, nutrients, and food groups assessed with the mobile phone app and Web-based method among 15 participants were not significantly different and several were significantly correlated, but strong conclusions cannot be drawn due to the low number of participants.

Conclusions: By using a mobile phone dietary assessment app, on average 71% of adolescents' EI was captured. The accuracy of reported dietary intake was higher with lower BMI z-score and if a weekend day was included in the record. The daily question in the mobile phone app about physical activity could accurately rank the participants' TEE.

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KEYWORDS

adolescents; dietary assessment; mobile phone app; energy; SenseWear Armband

Introduction

Limitations with traditional dietary assessment methods, such as 24-hour recall and estimated or weighed food records, are well known. Using food records to assess individual dietary intake is both time consuming and burdensome for study participants and may lead to deviations from their habitual intake [1]. Misreporting energy intake (EI), especially underestimation, is a common problem in studies where food records or other traditional dietary assessment methods are used [2]. Other problems with food records are low compliance and participation rates in dietary studies. In Sweden, a Web-based food record

method was developed for use in a national dietary survey in the adult population (ie, 18 to 80 years of age) [3]. The participation rate was less than 40% and the proportion classified as underestimating EI was 16% among women and 21% among men. The highest proportion of participants underestimating EI was found in the youngest age group, 18 to 30 year olds. This proportion could have possibly been even larger if the survey had been conducted among adolescents, who may have less structured dietary habits than adults and who may be less motivated to participate in dietary surveys [4,5]. Even though assessing dietary intake among adolescents can be especially challenging, knowledge of their dietary intake is important for the study of the etiology of overweight and obesity and the outcome of interventions that are implemented to promote healthy dietary habits.

Since it is important to obtain high-quality dietary intake data, improving assessment methods is essential. Methods using technology have been developed and used in several studies [6-9]. Among these are methods using digital cameras, personal digital assistants, and mobile phones to keep food records. Methods utilizing technology for dietary assessment seem promising [10], but need to be developed for local conditions and evaluated with objective measurements. As yet there is no evaluated method which uses mobile phones to collect dietary data among adolescents in Sweden. However, the use of mobile phones is widespread among young people in Sweden; 99% of 13 to 16 year olds own a mobile phone and of these 89% have an advanced-feature mobile phone [11]. This makes it possible to introduce a dietary assessment method based on mobile phone technology. Integrating the traditional food record with technology may make the assessment of dietary intake more feasible and attractive for Swedish adolescents and thus lead to more compliance and a higher quality of data. Furthermore, using mobile phones in dietary studies also allows for additional data to be collected, for example, by querying the level of physical activity and other lifestyle habits.

Dietary assessment methods are evaluated by comparison with reference methods and one way to evaluate the accuracy of assessed EI is by comparison with total energy expenditure (TEE) [1]. The "gold standard" method of measuring TEE is the doubly labeled water (DLW) method, but since it is very expensive, less resource-consuming methods to assess TEE are needed [12]. TEE can be measured by, for example, accelerometry or by calculation of TEE from basal metabolic rate (BMR) and physical activity level (PAL). It has been shown that a mobile phone questionnaire consisting of two questions on physical activity can be used to accurately assess PAL in adult women [13]. However, a similar study has not been found conducted among adolescents. Integrating questions about PAL into a dietary assessment method may be a feasible way to evaluate reported EI without the need for additional assessment methods.

Some individuals misreport EI regardless of the dietary assessment method used [14]. When investigating groups with regard to dietary habits it is important to be aware of factors influencing the validity of collected data. Factors that could possibly affect reporting accuracy in dietary assessment are gender, age, socioeconomic position, weight, health-related behaviors, and psychological factors [14,15]. The most consistent finding is a greater underestimation among participants classified as overweight/obese compared to normal-weight individuals [14], and this has also been found to be consistent for adolescents [4].

In this study, the aim was to develop, implement, and evaluate a new mobile phone dietary assessment method regarding EI and TEE compared with objectively measured TEE with the SenseWear Armband (SWA) (TEE_{SWA}). Furthermore, the aim was to investigate which individual factors among adolescents affected the reporting accuracy of EI and to compare reported EI, nutrients, and food groups against the reported intake when using a Web-based method.

Methods

Mobile Phone App

From 2011 to 2012, a mobile phone app was developed in collaboration with an engineering student, with the aim of obtaining a method that could be used for the assessment of dietary intake—EI (EI_{app}), intake of nutrients, foods, and food groups—and TEE (TEE_{app}). During the development phase, five colleagues at the Department of Food and Nutrition, and Sport Science at the University of Gothenburg, Sweden, and other departments tested the mobile phone app and gave constructive feedback. Further changes were made after the method had been used by 6 adolescents and their teacher who participated in a pilot test.

The mobile phone dietary assessment method comprises the app, which is developed for Android mobile phones, a Web project (Microsoft server), and a database (Microsoft SQL server 2008R2). The Web project is used for communication between the app and the database and to enable downloading of the app to a mobile phone. The database is used for receiving, computing, and storing participant data. The app communicates with the Web project via Wi-Fi or 3G. Participant data and results from registrations are obtained from the database using the computer software FileMaker Pro 12.0 version 3 (FileMaker, Inc, Santa Clara, CA).

To ensure that the mobile phone app used the most complete Swedish food database and that the results from the mobile phone method would be comparable to a Web-based method used in a national survey [3], information about energy and nutrient content of foods, dishes, and products—as well as portion amounts that had been used in the most recent Swedish national dietary survey—was obtained from the National Food Agency. The Swedish national food database version 2010-05-05 that is used in the mobile phone app includes over 1900 foods and dishes. Prior to use in the national survey, recipes were created for common dishes in order to facilitate the recording of these dishes. The consumed amounts are estimated with well-suited units (eg, gram, deciliter, tablespoon, teaspoon, and piece) that are given as alternatives in order to estimate portion size of each food/dish. For several items, there are also pictures of foods of known weight and increasing portion sizes to aid in the estimation of consumed amounts.

The first time the mobile phone app was used by a participant he/she was asked to register an account by entering the study ID as username and a password of their own choice. The participant also entered his/her name, date of birth, gender, weight, height, email address, and phone number. Furthermore, information was entered regarding the highest completed educational level of the mother and father (no formal education; nine-year compulsory school; two-year upper secondary school, folk high school, or vocational training; at least three-year upper secondary school; or college or university); whether the participant, mother, or father were born outside of Sweden; and whether the participant has a special diet (gluten- or lactose-free, vegetarian, or other with the opportunity to specify). Female participants were also asked to enter whether they were pregnant or breast-feeding. We regarded this information to be of interest when conducting dietary assessments and in our evaluation study. The personal settings could be edited later if necessary.

To record dietary intake, the participant first entered the date and time of a meal, with the current date and time as the default setting, and type of meal—breakfast, lunch, dinner, or snack. The participant thereafter searched for the consumed food in the food database by using a free-text search, choosing from a category or type of dish. The correct amount was entered and the next food item could be searched. After all foods in the meal had been entered, the meal needed to be saved and was automatically sent to the SQL database where energy and nutrient contents were computed and stored. The saved meals could be accessed in the mobile phone app through an archive of registered days. In the archive, foods could be deleted or added and amounts could be changed. Additional functions in the mobile phone app included receiving reminders to record meals (ie, status bar notifications) at a chosen time interval and saving a meal as a template to be loaded the next time an identical meal is consumed. The app was connected to the mobile phone camera and the user could take a picture of their meal as a memory aid if the consumed foods could not be entered until later. The additional functions were included to support the participant in recording dietary intake.

In addition to recording dietary intake during a specific day, the participant was asked to answer a few questions in the mobile phone app every evening. We included questions that were considered useful when evaluating the participant's recorded dietary intake. The questions were about the use of nutritional supplements with some alternatives given and the option to enter other supplements. The intake of supplements was not included in the analysis in this study since supplement intake was not recorded with the Web-based method. Furthermore, the participant was asked to approximate how much of their dietary intake on the specific day was recorded in the mobile phone app, and if he/she had tried to gain or lose weight during that day. The participant was also asked to approximate his/her physical activity level for that specific day out of five predefined levels (very light, light, moderate, heavy, or very heavy), as well as if his/her dietary intake and physical activity had been higher or lower than usual. Some examples of activities were given for the different activity levels. Finally, the participant was asked whether he/she had felt stressed or anxious during registration day.

Participant feedback could be viewed per day or for a selected period of days, and some detailed feedback could be viewed for each meal. In the archive, the user could see details regarding his/her body mass index (BMI); estimated TEE; EI; and intake of macronutrients, fruits and vegetables, dietary fiber, calcium, iron, vitamin C, vitamin D, and folic acid in relation to recommended daily intakes [16]. Energy percentages of each meal in relation to recommended intakes was also given. The feedback could be viewed after sending the recorded meal to the server.

All data registered by the participant when creating an account, recording foods, or answering questions in the mobile phone app could be viewed by the researcher. Information that was saved included time stamps for the different activities in the mobile phone app and whether registered information was updated by the participant. Food groups for each recorded food were given and the amount of food was calculated in grams. Energy and nutrient content in the records could be viewed per food, meal, or day. In addition to EI, the database calculated the intake of 49 nutrients. Furthermore, PAL values and estimated TEE were calculated from the daily physical activity of the participant together with the participant's age, gender, and weight. Basal metabolic rate was calculated using equations by Shofield [17]. PALs for adolescents were adapted from the paper by Torun, separately for girls and boys [18]. Since we wanted a wider dispersion of estimated TEE, five levels were chosen instead of three. The specific PAL values used in the mobile phone app were as follows for girls and boys, respectively: very light (1.3 and 1.4), light (1.5 and 1.6), moderate (1.7 and 1.8), heavy (1.9 and 2.0), and very heavy (2.1 and 2.2). The text describing the different activity levels were as follows: very light = sedentary most of the day; light = sedentary, standing, or walking short distances; moderate = standing or walking most of the day, *or* sedentary but with 30 to 60 minutes of walking or bicycling at moderate speed; heavy = sedentary, standing, and walking short distances, *and* 60 minutes of strenuous physical activity/sport; very heavy = standing and walking most of the day, *and* 60 minutes of strenuous physical activity/sport.

Web-Based Method

The National Food Agency in Sweden has developed a Web-based method for dietary recording that has been used in a national survey of dietary intake [3]. The method uses the national food database version 2010-05-05 (the same as for the mobile phone method). Food intake was entered by the participant on the Internet in the evening of each day. A username and password was used by the participant to log in to a webpage, and the correct day, meal type (ie, breakfast, lunch, dinner, or other), time, and place were selected. The consumed foods/dishes were searched and entered using free-text search, choosing from a category and type of dish. The consumed amount was thereafter entered using well-suited units (eg, gram, deciliter, tablespoon, teaspoon, piece, and portion-size pictures) that were given as alternatives for each food. The participants were given a booklet with pictures of different portion sizes of known weight and a notebook in which the meal type, time and place of the meal, food, and portion size could be entered during the day in order to facilitate recording it onto

the computer in the evening. The participants were thereafter able to see results for the recorded days in the form of EI (EI_{Web}); nutrients; proportions of fat, protein, and carbohydrates; and amount of consumed fruit and vegetables in relation to recommendations. In this study, the participants conducted the Web-based method for 3 days.

Energy Expenditure

The SWA Pro 2 or 3 (BodyMedia, Inc, Pittsburgh, PA, USA) was worn by the participants on the days they recorded dietary intake. The SWA is a multisensory device that estimates energy expenditure (EE) using a two-axis accelerometer set at 1-minute intervals. It also has different sensors that measure heat flux, near-body and skin temperature, and galvanic skin response. The participants were instructed to wear the SWA on the back of the upper right arm over the triceps muscle—in accordance with the manufacturer's recommendations—on 3 full consecutive days and nights, and to remove it only when getting wet, such as when showering or swimming. When removed from the body, the SWA estimates EE as equal to the basal metabolic rate, which was calculated automatically based on the participant's age, gender, weight, and height. The computer software SenseWear Professional version 6.1 (BodyMedia, Inc, Pittsburgh, PA, USA) was used to estimate TEE from the armband's registrations together with information about the participant's age, gender, weight, and height.

Questionnaire

To obtain information about factors that could possibly influence the accuracy of the reported dietary intake, a selection of questions and questionnaire instruments were put together in a questionnaire containing 53 items that was used in this study. The questionnaire included questions about factors that have previously been found to be associated with reporting accuracy [15,19] and questions about other factors that we thought may be important (ie, conscientiousness; whether they thought what they ate was important; and whether they found the study to be comprehensible, manageable, and meaningful). The included instruments were the Three-Factor Eating Questionnaire (Revised 18-item [R-18] version) [20] and the Figure Rating Scale [21]. Furthermore, five items selected from the Brief Fear of Negative Evaluation Scale [22], and seven items selected from the Marlowe-Crowne Social Desirability Scale [23] were included, as well as 15 items assessing conscientiousness selected from the International Personality Item Pool [24]. Additional questions included those concerned with how often the participant ate lunch in the school canteen and had breakfast during a normal week; if they thought what they ate was important; and whether they perceived the study presented to them as being comprehensible, manageable, and meaningful. Indices were created from the Brief Fear of Negative Evaluation Scale, the Marlowe-Crowne Social Desirability Scale, the items assessing conscientiousness, and the three subscales in the Three-Factor Eating Questionnaire. Current and ideal body size was measured with the Figure Rating Scale and the discrepancy was categorized into no discrepancy, preferring to be smaller, or preferring to be larger.

Anthropometric Measurements

The participants' weight and height were measured with a portable scale and stadiometer using standardized procedures. The measurements were conducted in a separate room in the school by the first author (ÅS) or an assistant. The participants were asked to take off their shoes and any heavy garment, such as a sweater, and to empty their pockets before being measured. Weight was measured to the nearest 0.1 kg and height to the nearest 0.1 cm. BMI (kg/m^2) was calculated and BMI z-score and weight status were determined using tables and cutoffs from the International Obesity Task Force [25].

Participants and Setting

Data collection took place in Southwest Sweden during 2013. Prior to the main study, a pilot test was conducted in November 2012 in order to test the methods and design and to practice the presentation and implementation of the study. The pilot test took place in a school outside Gothenburg, Sweden; 5 girls and 1 boy from one classroom were recruited. The participants in the pilot test used the same methods as the participants in the main study, however, they used the mobile phone app and Web-based dietary registration method on the same 3 days instead of in separate weeks. Based on the experiences from the pilot test, the methods were revised prior to the evaluation study regarding design of the mobile phone app and presentation of the study to the participants.

A sample-size analysis was performed when designing the study in order to estimate the number of participants needed to detect an 837 kJ (200 kcal) difference between EI and TEE at alpha .05 and 80% power. A 100 kcal difference between the methods could also be considered meaningful, however, this corresponds to a small amount of food such as a glass of milk or a banana, and it is not likely that a dietary assessment method will be this exact. The equation used was as follows:

$$n=2 \times (2.8 \times \text{Standard deviation/Difference})^2$$

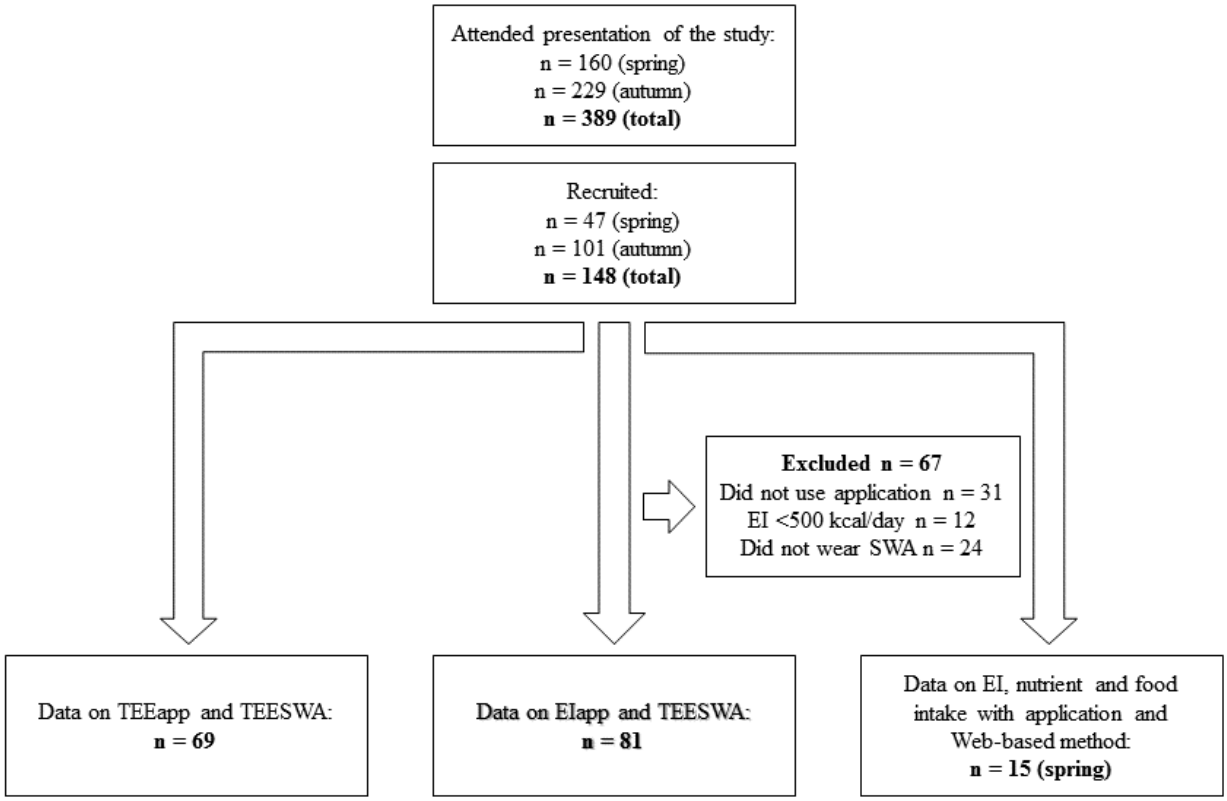
The standard deviation was derived from a previous study among 15 year olds (n=35) in Gothenburg, Sweden, which was different between girls and boys [26]. According to the sample-size calculation, the number of girls needed was 50 and the number of boys needed was 64.

Adolescents in year nine (14 to 16 year olds) were recruited to the study by visits to schools. Head teachers of 136 schools in Gothenburg, Sweden, and neighboring municipalities were contacted by post, email, or telephone with a short description of the study and its aims. Head teachers were asked if they would pass on email addresses or phone numbers of teachers to contact regarding the study. Teachers of physical education and health, and home and consumer studies were suggested since the study was relevant to these subjects. In some cases, contact with teachers was established through colleagues at the department, or through teachers who had been visited previously during the study year. The study was presented to teachers by email or telephone and they were asked if they were willing to assign class time to present the study and to recruit participants. Recruitment to the study was done continually throughout the year and at least two reminders were sent to all head teachers

and teachers who did not respond to the first email. In total, 17 presentations of the study were held in 12 schools: five presentations in four schools during spring term and 12 presentations in eight schools during autumn term. In some cases, the study was presented only to those adolescents who had said they were interested in the study when asked by their teacher. Out of 389 adolescents from 28 school classes who were given information about the study, 148 adolescents (38.0%) were recruited, including 85 girls (57.4%) and 63 boys (42.6%) (see Figure 1).

This study was conducted according to the guidelines laid down in the Declaration of Helsinki and all procedures involving human subjects were approved by the Regional Ethical Review Board in Umeå, Sweden. Written informed consent was obtained from all participants.

Figure 1. Flowchart of participants included in the different analyses.



Data Collection Procedures

From January 2013 to December 2013, the first author (ÅS), together with an assistant, visited the school classes and presented the study and methods to the adolescents. They were told about the aim of the study, that participation was voluntary, and that all collected data would be treated with confidentiality. Those who chose to participate filled out an informed consent form and a questionnaire, were measured for weight and height, and were given the material needed to participate in the study. If the participant had not yet turned 15 years of age, both the adolescent and their parent or guardian signed the informed consent form. Those who did not have an Android mobile phone were given the opportunity to borrow a mobile phone with a data traffic subscription and a charger from the university, and were given an instruction manual on how to use the mobile phone (72/148, 48.6%). Those who had their own Android mobile phone were given instructions and help on how to download and install the app on their mobile phones (9/148, 6.1%). The remaining 67 adolescents were excluded. All participants were provided with an SWA and were instructed on how to use it. During spring term, participants were also given instructions and log-in details for the Web-based dietary registration method and were provided with the booklet on portion sizes and a notebook needed for using the method.

The participants were asked to complete 3 days of dietary recording using the mobile phone app. Participants recruited during the spring term were also asked to complete an additional 3 days of dietary recording using the Web-based method. Because of difficulties in recruiting adolescents and perceived high participant burden among the participants recruited during the spring term, the participants recruited during the autumn term were not asked to complete the additional 3 days of dietary recording using the Web-based method. The days for registration were decided beforehand with the aim to have Mondays to Thursdays, Fridays, and weekends equally represented in the final data. Participants who recorded dietary intake using both mobile phones and computers were asked to complete the records on the same days of week, meaning that if they recorded with the mobile phone app on Thursday to Saturday during the first week they would record using the Web-based method on Thursday to Saturday of the following week. Half of the participants were asked to start with the mobile phone app and half with the Web-based method.

All participants were asked to record everything they ate or drank during the days of registration, including snacks and condiments, and to give the consumed amounts. They were asked to eat as usual and not change their dietary intake during the study. If the participant could not find the correct food or dish in the mobile phone app then they were asked to choose a similar food or record each part of a dish one at a time, respectively. On the same days that they recorded dietary intake, the participants were instructed to wear the SWA from 00:00 (or before going to bed the night before the measurement period) to 24:00 (or until waking up in the morning after the measurement period) and to only take it off when they were going to get wet.

Group interviews were conducted with participants approximately 1 to 2 weeks after they had participated in the study in order to identify strengths and problems with the mobile phone app method. Results of the group interviews will be used in future work to improve dietary assessment methods and are not presented here.

Data Analysis and Statistics

Statistical analyses were performed with IBM SPSS version 21, and *P* values ≤.05 were considered significant. The variables were checked for normality using the Shapiro-Wilk test. Some of the variables had a skewed distribution and, consequently, nonparametric tests were principally used.

Days with reported EI below 2092 kJ (500 kcal) were excluded, and to be included in analyses the SWA had to be worn for at least 19 hours (80%) of the day. These cutoffs were chosen in order to include a realistic completion of the methods. Implausible values of recorded food intake were found in the records of 8 participants with the mobile phone app and for 1 participant with the Web-based method. The participants in question were contacted and more realistic values were obtained.

Data are presented as median (interquartile range [IQR]), mean (SD), and percentage proportion. The Mann-Whitney U test was used to compare continuous variables between girls and boys and between participants with different weight status. Since participants classified for thinness and obesity were too few to be analyzed separately, thinness was combined with normal weight and obesity was combined with overweight in the analysis. The Wilcoxon signed rank sum test and paired-samples *t* test were used to analyze the difference between EI and TEE, as well as TEE being estimated with the mobile phone app and measured with the SWA. Bland-Altman plots and Spearman correlation coefficients were used to evaluate the reporting accuracy of EI and TEE assessed with the mobile phone app in comparison with TEE from the SWA.

In total, 15 of the 81 participants (19%) included in the main analysis had missing data on one or more questions in the questionnaire. For 2 of the participants with missing data on the Figure Rating Scale, data were imputed as *No discrepancy* between perceived and ideal body size. One participant did not reply to the question about frequency of eating breakfast and lunch in the school canteen, and for this participant the missing values were imputed with *7 days/week* and *5 days/week*, respectively. For 7 of the participants with missing data on the scale measuring conscientiousness (1-3 items each), data were imputed as the middle alternative, *Neither inaccurate nor accurate*, for the respective items. Furthermore, data were missing for the scales measuring *social desirability* (n=3, one item each), *uncontrolled eating* (n=2, one item each), and *cognitive restraint* (n=3, one, two, or three items each). These values were imputed with the median response to the items by the other participants. Results did not differ when using imputed values compared with only including data from the 66 participants with complete questionnaires.

The effect of questionnaire variables, as well as gender and BMI z-score, on reporting accuracy of EI (EI-TEE) was investigated by stepwise linear regression analysis, after having tested the variables one by one in linear regression models. The variable for eating breakfast was categorized as *7* or *less than 7 days/week*, and having lunch in the school canteen was categorized as *5* or *less than 5 days/week*. The variables regarding whether the participants found the study comprehensible, manageable, and meaningful, and whether they thought that what they ate was important were categorized as *yes* or *somewhat/no*, since few answered *no* to these questions. Additional variables in the model were school, parental education level reported by the participants (highest of both parents categorized as low, medium, or high), whether the participants and/or parent(s) were born outside of Sweden, and the presence of a weekend day in the EI record. Since there was a dependency of reporting accuracy on TEE, a second analysis was performed with the outcome variable ([EI-TEE]/TEE). Variables selected in the stepwise models were tested in a mixed linear model together with school as a random factor to take into account the dependent observations, although this did not affect the results. Factors that could possibly influence reporting accuracy were additionally investigated by calculating the mean difference between EI and TEE from the SWA, 95% CI, and Spearman correlations in subsamples based on responses to the questionnaire and questions in the mobile phone app. In these analyses, median was used as a cutoff for continuous variables.

An additional analysis was performed comparing the mobile phone app and the Web-based method of dietary assessment. Differences in EI, nutrient intakes, and food groups between the two methods were analyzed using the Wilcoxon signed rank sum test and Spearman correlations. Results from this analysis should be interpreted with caution due to the small sample size (n=15).

Results

Use of the Methods

The number of participants that completed the different methods are presented in Figure 1. The participants were asked to record their diet for 3 days, however, several participants recorded for up to 6 days. In total, 81 participants had assessments of both EI with the mobile phone app and TEE with the SWA. Furthermore, 58 of the participants who answered the questions in the evening in the mobile phone app also had diet data for the specific days (Figure 1). Of the 92 participants answering the questions in the mobile phone app, 69 (75%) had SWA data on the same or proximate days. Of the 47 participants expected

to record their diets using the mobile phone app and the Web-based method during spring, 15 (32%) completed both methods. Because of the difficulties in recruiting participants and the low number of participants that completed all methods, we consider this to be an evaluation study rather than a validation study of the mobile phone app method.

Participant Characteristics

Participant characteristics are presented in Table 1. The majority (69/81, 85%) of the 81 participants were classified as being of normal weight, however, 6% (5/81) were classified as thin, 14% (11/81) as overweight, and 1% (1/81) as obese. The most common response to the question about parents' highest completed education was university or college. A majority of the participants were born in Sweden and had parents born in Sweden, but participants with parents born outside of Sweden (20/81, 25%) were also common (see Table 1). Parental education level and origin of participants did not differ between the participants and the general population from which they were recruited. A total of 4 girls and 1 boy (all normal weight) reported eating a special diet. A total of 2 girls reported a lactose-free diet, 1 girl reported a gluten-free diet, and 1 girl reported excluding red meat from her diet. The boy reported excluding pork from his diet. Data regarding factors that may influence the accuracy of reported dietary intake are presented in Table 2. In total, 12 participants out of 81 (15%) reported taking dietary supplements—multivitamins, vitamin D, vitamin C, iron, calcium, and creatine—during registration days with the mobile phone app.

Table 1. Characteristics of Swedish adolescent study participants.

Characteristics	All (n=81)	Girls (n=50)	Boys (n=31)	Thinness/ normal weight[a](n=69)	Overweight/ obese[a] (n=12)
Age in years, median (IQR[b])	15.5 (0.5)	15.5 (0.6)	15.5 (0.4)	15.5 (0.5)	15.6 (0.5)
Weight (kg), median (IQR)	59.9 (12.5)	57.4 (9.6)[c]	66.1 (15.7)[c]	58.0 (9.8)[c]	77.2 (17.0)[c]
Height (cm), median (IQR)	170.6 (12.9)	164.9 (13.5)[c]	176.5 (12.0)[c]	170.0 (12.8)	172.8 (13.8)
BMI[d](kg/m^2), median (IQR)	21.1 (3.1)	21.1 (2.5)	20.9 (4.1)	20.7 (2.4)[c]	25.8 (1.4)[c]
BMI z-score[a], median (IQR)	0.44 (0.84)	0.38 (0.71)	0.53 (1.02)	0.33 (0.76)[c]	1.73 (0.37)[c]
Gender, n (%)					
Female	50 (62)	50 (100)	31 (100)	44 (64)	6 (50)
Male	31 (38)	0 (0)	0 (0)	25 (36)	6 (50)
Weight status [a] , n (%)					
Thinness grade 2	1 (1)	0 (0)	1 (3)	1 (1)	0 (0)
Thinness grade 1	4 (5)	3 (6)	1 (3)	4 (6)	0 (0)
Normal weight	64 (79)	41 (82)	23 (74)	64 (93)	0 (0)
Overweight	11 (14)	6 (12)	5 (16)	0 (0)	11 (92)
Obese	1 (1)	0 (0)	1 (3)	0 (0)	1 (8)
Parents' highest education [e] , n (%)					
No formal education	1 (1)	0 (0)	1 (3)	0 (0)	1 (8)
Nine-year compulsory school	14 (17)	5 (10)	9 (29)	11 (16)	3 (25)
Two-year upper secondary school/folk high school/ vocational training	8 (10)	5 (10)	3 (10)	6 (9)	2 (17)
At least three-year upper secondary school	18 (22)	13 (26)	5 (16)	16 (23)	2 (17)
College/university	40 (49)	27 (54)	13 (42)	36 (52)	4 (33)
Born outside Sweden [e] , n (%)					
None	58 (72)	38 (76)	20 (65)	51 (74)	7 (58)
Only parent(s)	20 (25)	11 (22)	9 (29)	16 (23)	4 (33)
Only participant	1 (1)	0 (0)	1 (3)	1 (1)	0 (0)
Participant and parent(s)	2 (2)	1 (2)	1 (3)	1 (1)	1 (8)

[a]Using cutoff values according to Cole and Lobstein [25].

[b]Interquartile range (IQR).

[c]*P*<.001, derived from the Mann-Whitney U test of difference between girls and boys or between thinness/normal weight and overweight/obese.

[d]Body mass index (BMI).

[e]Question answered by the participant when registering as a user in the mobile phone app.

Table 2. Factors that may influence accuracy of reported dietary intake of Swedish 15 year olds (scale ranges for all indices are 0 to 100).

Factors		All (n=81)	Girls (n=50)	Boys (n=31)	Thinness/ normal weight[a] (n=69)	Overweight/ obese[a] (n=12)
Conscientiousness[b], median (IQR[c])		72 (23), alpha[d]=.91	70 (23)	75 (23)	68 (24)	73 (19)
Fear of negative evaluation[e], median (IQR)		25 (25), alpha=.79	30 (25)[f]	15 (25)[f]	25 (28)	25 (24)
Social desirability[g], median (IQR)		62 (140), alpha=.63	62 (14)	62 (19)	62 (14)	62 (22)
Three-Factor Eating Questionnaire R-18 [h], median (IQR)						
	Cognitive restraint	32 (30), alpha=.82	34 (36)[f]	18 (23)[f]	27 (32)	39 (28)
	Uncontrolled eating	33 (28), alpha=.84	33 (27)	37 (30)	33 (28)	30 (33)
	Emotional eating	11 (33), alpha=.86	22 (33)[i]	11 (22)[i]	11 (33)	11 (19)
Figure Rating Scale, n (%)						
	No discrepancy	25 (31)	13 (26)	12 (39)	23 (33)	2 (17)
	Prefer to be smaller	40 (49)	33 (66)	7 (22)	30 (44)	10 (83)
	Prefer to be larger	16 (20)	4 (8)	12 (39)	16 (23)	0 (0)
Eating breakfast, n (%)						
	7 days/week	54 (67)	32 (64)	22 (71)	47 (68)	7 (58)
	<7 days/week	27 (33)	18 (36)	9 (29)	22 (32)	5 (42)
Lunch in school canteen, n (%)						
	5 days/week	56 (69)	35 (70)	21 (68)	46 (67)	10 (83)
	<5 days/week	25 (31)	15 (30)	10 (32)	23 (33)	2 (7)
Is what you eat important to you?, n (%)						
	Yes	41 (51)	28 (56)	13 (42)	36 (52)	5 (42)
	Somewhat	34 (42)	21 (42)	13 (42)	27 (39)	7 (58)
	No	6 (7)	1 (2)	5 (16)	6 (9)	0 (0)
Study is comprehensible, n (%)						
	Yes	62 (77)	39 (78)	23 (74)	54 (78)	8 (67)
	Somewhat	18 (22)	10 (20)	8 (26)	14 (21)	4 (33)
	No	1 (1)	1 (2)	0 (0)	1 (1)	0 (0)
Study is manageable, n (%)						
	Yes	64 (79)	41 (82)	23 (74)	56 (81)	8 (67)
	Somewhat	16 (20)	8 (16)	8 (26)	12 (18)	4 (33)
	No	1 (1)	1 (2)	0 (0)	1 (1)	0 (0)
Study is meaningful, n (%)						
	Yes	50 (62)	32 (64)	18 (58)	42 (61)	8 (67)
	Somewhat	26 (32)	16 (32)	10 (32)	22 (32)	4 (33)
	No	5 (6)	2 (4)	3 (10)	5 (7)	0 (0)

[a]Using cutoff values according to Cole and Lobstein [25].

[b]Fifteen items selected from the International Personality Item Pool [24].

[c]Interquartile range (IQR).

[d]Cronbach alpha.

[e]Five items selected from the Brief Fear of Negative Evaluation Scale [22].

[f]*P*<.05, derived from the Mann-Whitney U test of difference between girls and boys or between thinness/normal weight and overweight/obese.

[g]Seven items selected from the Marlowe-Crowne Social Desirability Scale [23].

[h]Revised 18-item (R-18) Three-Factor Eating Questionnaire.

[i]*P*<.01, derived from the Mann-Whitney U test of difference between girls and boys or between thinness/normal weight and overweight/obese.

Evaluation of Reported Energy Intake

Of the 81 participants, 10 (12%) had 1 day of assessed EI, 11 (14%) had 2 days, 54 (67%) had 3 days, and 6 (7%) had 4 to 6 days. Of the 81 participants, 13 (16%) had 1 day of measured TEE with the SWA, 17 (21%) had 2 days, 40 (49%) had 3 days, and 11 (14%) had 4 to 6 days. Of the 222 days of assessed EI, 134 (60.4%) were weekdays and 88 (39.6%) were weekend days. The number of participants out of 81 with a weekend day in their EI record was 55 (68%). Of the 222 measured days of TEE_{SWA}, the number of weekdays was 145 (65.3%) and the number of weekend days was 77 (34.7%). The SWA was worn an average of 23 (SD 1) hours per day.

The median difference between EI and TEE was -2837 (IQR 3452) kJ/day, and assessed EI was 71% of measured TEE by SWA (*P*<.001) (see Table 3). The corresponding result expressed as a mean difference was -2586 (SD 2908) kJ/day (95% CI -3231 to -1945), or an EI of 75% of TEE_{SWA} (*P*<.001). There was no significant correlation between EI and TEE. A total of 5 individuals out of 81 (6%)—all boys of which 1 was overweight and 1 obese—were outside the limits of agreement (see Figures 2-4). In total, out of 81 participants, 7 (9%) individuals (1 girl and 6 boys) were within ±5% of their TEE_{SWA}, 63 (78%) underestimated EI, and 11 (14%) overestimated EI. Of those underestimating EI, 68% (43/63) were girls. Reporting accuracy of EI did not differ between girls and boys (Table 3).

When testing each variable, there was a positive association between reporting accuracy (EI-TEE_{SWA}) and TEE (*P*<.001), and between reporting accuracy and emotional eating (*P*=.04). Reporting accuracy was higher with a weekend day in the record (*P*<.001) (Table 4). Furthermore, a negative association was found for reporting accuracy and BMI z-score (*P*<.001). In a stepwise model, TEE (*P*<.001) and a weekend day in the record (*P*=.01) were significantly associated with reporting accuracy (EI-TEE). Reporting accuracy of EI relative to TEE_{SWA}, ([EI-TEE_{SWA}]/TEE_{SWA}), was higher with a weekend day in the record of EI (*P*=.002, *P*=.007), and lower with higher BMI z-score (*P*<.001, *P*=.001) when tested separately and in a stepwise model, respectively (Table 4). The correlation between EI and TEE was still not significant, and underestimation of EI was still significant in the analysis that included the participants (n=55) with a weekend day in the record.

Of the 58 participants who answered the daily questions in the mobile phone app, 44 (76%) stated that they had recorded 95 to 100% of their dietary intake in the mobile phone app on 87 days in total. In this sample, the median difference between EI and TEE_{SWA} was -1347 (IQR 4372) kJ/day, or EI was 88% of TEE_{SWA}. When only including the 47 participants who answered that they had not felt anxious during registration day (90 days in total), the median difference between EI and TEE_{SWA} was -1753 (IQR 5134) kJ/day, or EI was 82% of TEE_{SWA}. When only the 56 participants who had not tried to change their weight during registration day were included (127 days in total), the median difference between EI and TEE_{SWA} was -2004 (IQR 4263) kJ/day, or EI was 80% of TEE_{SWA}. When only the 46 participants who replied that they had not felt stressed during registration day were included (91 days in total), the median difference between EI and TEE_{SWA} was -2322 (IQR 4682) kJ/day, or EI was 76% of TEE_{SWA}. The correlation between EI and TEE_{SWA} was not significant in any of these subsamples and underreporting of EI was significant in all samples.

Table 3. Assessed energy intake and total energy expenditure using a mobile phone app, as well as total energy expenditure measured with the SenseWear Armband among Swedish 15 year olds.

Measures	All (n=81)[a]	Girls (n=50)[a]	Boys (n=31)[a]	Thinness/ normal weight[b] (n=69)[a]	Overweight/ obese[b] (n=12)[a]
BMR[c](kJ/day), median (IQR[d])	6473 (1270)	6112 (537)[e]	7641 (1161)[e]	6305 (1121)[e]	7483 (2270)[e]
EI[f](kJ/day), median (IQR)	6904 (3427)	6527 (2410)[g]	7845 (4268)[g]	6924 (2975)	5309 (4749)
TEE_{SWA}[h](kJ/day), median (IQR)	9680 (1866)	9217 (1607)[e]	10,816 (2870)[e]	9637 (1750)[g]	10,573 (3577)[g]
TEE_{app}[i](kJ/day), median (IQR)	11,172 (2945)	10,452 (1319)[e]	13,143 (1899)[e]	10,733 (2526)[e]	13,675 (3892)[e]
EI/BMR, median (IQR)	1.08 (0.47)	1.10 (0.42)	1.06 (0.58)	1.11 (0.42)[g]	0.71 (0.56)[g]
TEE_{SWA}/BMR, median (IQR)	1.48 (0.29)	1.49 (0.20)	1.36 (0.33)	1.49 (0.25)	1.36 (0.35)
EI-TEE_{SWA} (kJ/day), median (IQR)	-2837 (3452)	-2799 (2602)	-3368 (4954)	-2782 (3454)	-3787 (4937)
EI/TEE_{SWA}, median (IQR)	0.71 (0.36)	0.70 (0.28)	0.74 (0.49)	0.72 (0.36)	0.58 (0.41)
TEE_{app}-TEE_{SWA} (kJ/day), median (IQR)	1683 (1696)	1524 (944)[j]	2516 (1897)[j]	1575 (1480)[g]	2358 (2307)[g]
TEE_{app}/TEE_{SWA}, median (IQR)	1.19 (0.17)	1.17 (0.13)	1.23 (0.26)	1.18 (0.18)	1.21 (0.30)
Correlation of EI and TEE_{SWA}, ρ (*P*)	.13 (.24)	.27 (.06)	-.16 (.39)	.14 (.27)	.27 (.40)
Correlation of TEE_{app} and TEE_{SWA}, ρ (*P*)	.75 (<.001)	.59 (<.001)	.69 (<.001)	.74 (<.001)	.59 (.04)

[a]In the analysis comparing total energy expenditure assessed with mobile phone app and total energy expenditure from the SenseWear Armband, n=69: 41 girls and 28 boys, 57 thinness/normal weight and 12 overweight/obese.

[b]Using cutoff values according to Cole and Lobstein [25].

[c]Basal metabolic rate (BMR) calculated according to Shofield [17].

[d]Interquartile range (IQR).

[e]*P*<.001, derived from the Mann-Whitney U test of difference between girls and boys or between thinness/normal weight and overweight/obese.

[f]Energy intake (EI).

[g]*P*<.05, derived from the Mann-Whitney U test of difference between girls and boys or between thinness/normal weight and overweight/obese.

[h]Total energy expenditure measured by the SenseWear Armband (TEE_{SWA}).

[i]Total energy expenditure reported via the mobile phone app (TEE_{app}).

[j]*P*<.01, derived from the Mann-Whitney U test of difference between girls and boys or between thinness/normal weight and overweight/obese.

Table 4. Factors influencing reporting accuracy of energy intake.

Factors	Univariable model (EI[a]-TEE[b,c]), *b* (95% CI)	Stepwise multivariable model (EI-TEE[c]), *b* (95% CI)	Univariable model (EI-TEE)/TEE[c], *b* (95% CI)	Stepwise multivariable model (EI-TEE)/TEE[c], *b* (95% CI)
Gender				
Girl	N/A[d]		N/A	
Boy	-367 (-1696, 962)		0.04 (-0.09, 0.16)	
Body mass index z-score[e]	-1509 (-2206, -812)[f]		-0.13 (-0.20, -0.07)[f]	-0.12 (-0.18, -0.05)[g]
TEE[c](kJ)	-0.82 (-1.13, -0.51)[f]	-0.70 (-1.01, -0.39)[f]	N/A	N/A
Parents' education [h]				
Low	462 (-2357, 1433)		-0.02 (-0.20, 0.16)	
Medium	N/A		N/A	
High	195 (-1277, 1668)		-0.001 (-0.140, 0.140)	
Born outside Sweden [h]				
No	N/A		N/A	
Participant and/or parent(s)	-1020 (-2438, 397)		-0.11 (-0.25, 0.03)	
Weekend day in record				
No	N/A	N/A	N/A	N/A
Yes	2380 (1099, 3660)[f]	1557 (351, 2763)[g]	0.20 (0.08, 0.33)[g]	0.16 (0.05, 0.28)[g]
School				
School 1	N/A		N/A	
School 2	755 (-2375, 3884)		0.08 (-0.22, 0.38)	
School 3	-683 (-3930, 2564)		-0.05 (-0.36, 0.26)	
School 4	-1165 (-4412, 2082)		-0.11 (-0.43, 0.20)	
School 5	-2108 (-5238, 1021)		-0.12 (-0.42, 0.18)	
School 6	-1323 (-4571, 1924)		-0.13 (-0.45, 0.18)	
School 7	-403 (-3180, 2372)		0.02 (-0.25, 0.29)	
School 8	2337 (-911, 5584)		0.26 (-0.05, 0.58)	
School 9	106 (-3300, 3512)		0.005 (-0.32, 0.33)	
School 10	2164 (-965, 5293)		0.23 (-0.08, 0.53)	
School 11	242 (-2887, 3371)		0.03 (-0.27, 0.33)	
School 12	-942 (-4348, 2464)		-0.09 (-0.42, 0.24)	
Fear of negative evaluation	15 (-23, 53)		0.001 (-0.002, 0.005)	
Conscientiousness	27 (-14, 67)		0.002 (-0.002, 0.006)	
Social desirability	6 (-46, 57)		-0.001 (-0.005, 0.005)	
Cognitive restraint	-9 (-40, 23)		-0.002 (-0.005, 0.001)	
Uncontrolled eating	7 (-26, 41)		0.001 (-0.002, 0.004)	
Emotional eating	28 (2, 55)[i]		0.002 (-0.001, 0.005)	
Prefer to be				
Smaller	425 (-1047, 1897)		0.04 (-0.11, 0.17)	
No discrepancy	N/A		N/A	
Larger	1445 (-403, 3294)		0.170 (-0.002, 0.350)	

Factors	Univariable model (EI[a]-TEE[b,c]), *b* (95% CI)	Stepwise multivariable model (EI-TEE[c]), *b* (95% CI)	Univariable model (EI-TEE)/TEE[c], *b* (95% CI)	Stepwise multivariable model (EI-TEE)/TEE[c], *b* (95% CI)
Breakfast				
<7 days/week	N/A		N/A	
7 days/week	141 (-1232, 1515)		0.006 (-0.130, 0.140)	
Lunch in school canteen				
<5 days/week	N/A		N/A	
5 days/week	-974 (-2358, 411)		-0.11 (-0.24, 0.02)	
What I eat is important				
Somewhat/no	N/A		N/A	
Yes	350 (-942, 1643)		0.02 (-0.10, 0.15)	
Study is comprehensible				
Somewhat/no	N/A		N/A	
Yes	468 (-1056, 1993)		0.01 (-0.14, 0.16)	
Study is manageable				
Somewhat/no	N/A		N/A	
Yes	1363 (-198, 2923)		0.10 (-0.05, 0.25)	
Study is meaningful				
Somewhat/no	N/A		N/A	
Yes	1030 (-282, 2341)		0.07 (-0.06, 0.20)	

[a]Energy intake (EI).

[b]Total energy expenditure (TEE).

[c]Total energy expenditure measured by SenseWear Armband (TEE_{SWA}).

[d]Not applicable (N/A).

[e]According to Cole and Lobstein [25].

[f]*P*<.001.

[g]*P*<.01.

[h]Question answered by the participant when registering as a user in the mobile phone app.

[i]*P*<.05.

Figure 2. Bland-Altman plot comparing energy intake (EI) assessed with a newly developed mobile phone app and total energy expenditure measured with the SenseWear Armband (TEESWA) in 81 adolescents. The sample is displayed by gender: girls (closed circles; solid regression line) and boys (open circles; dashed regression line).

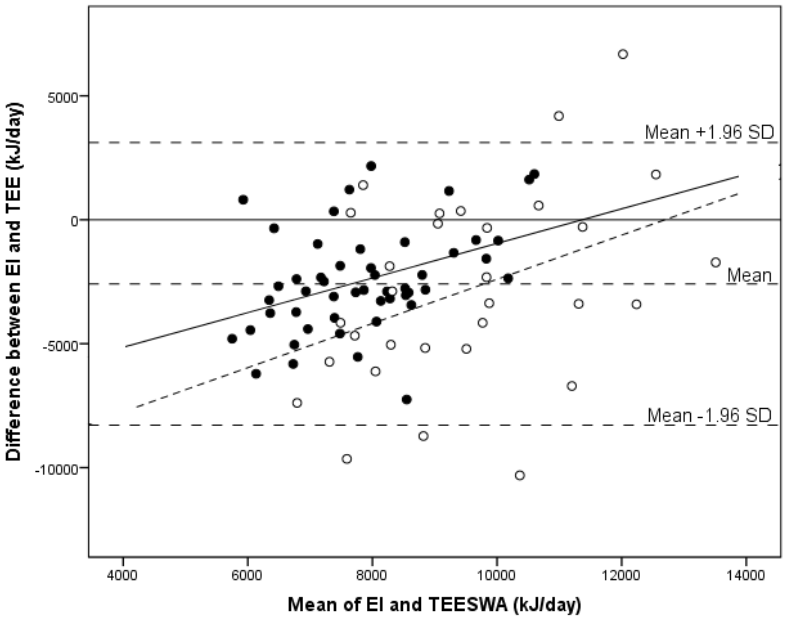


Figure 3. Bland-Altman plot comparing energy intake (EI) assessed with a newly developed mobile phone app and total energy expenditure measured with the SenseWear Armband (TEESWA) in 81 adolescents. The sample is displayed by weight status: thinness/normal weight (closed circles; solid regression line) and overweight/obese (open circles; dashed regression line).

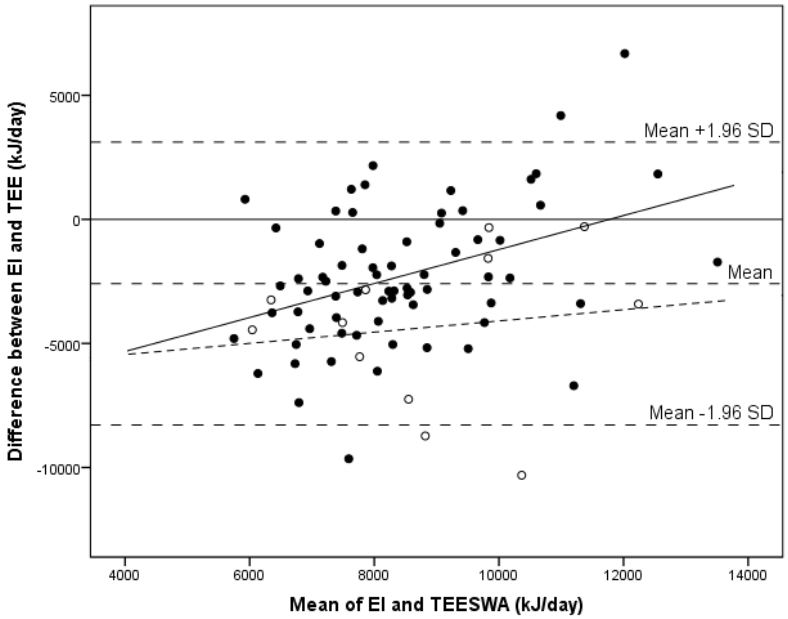
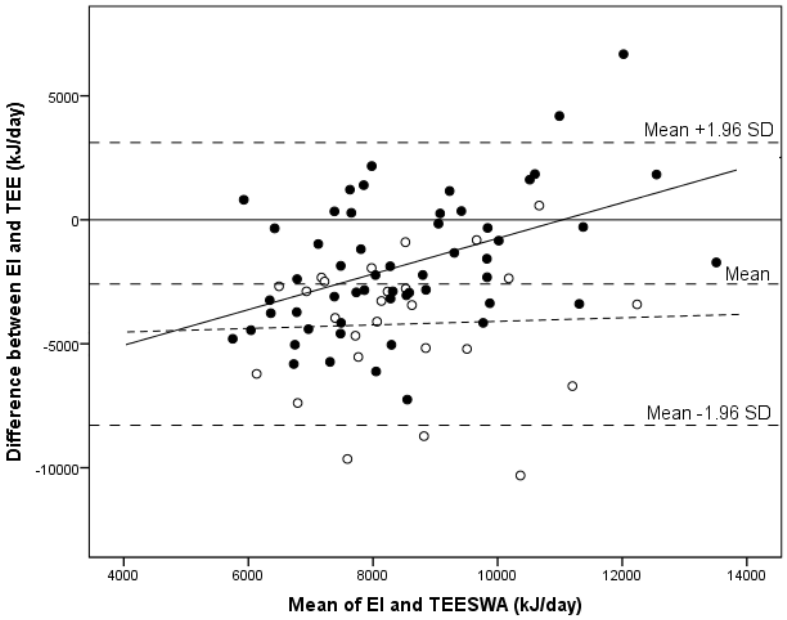


Figure 4. Bland-Altman plot comparing energy intake (EI) assessed with a newly developed mobile phone app and total energy expenditure measured with the SenseWear Armband (TEESWA) in 81 adolescents. The sample is displayed by records with and without a weekend day: records with a weekend day (closed circles; solid regression line) and records without a weekend day (open circles; dashed regression line).



Evaluation of Reported Total Energy Expenditure

Of the 69 participants included in this analysis, 17 (25%) had 1 day of TEE estimated with the mobile phone app, 18 (26%) had 2 days, 26 (38%) had 3 days, and 8 (12%) had 4 to 5 days. Of the 69 participants, 11 (16%) had 1 day of TEE measured with the SWA, 16 (23%) had 2 days, 34 (49%) had 3 days, and 8 (12%) had 4 to 6 days.

The median difference between TEE_{app} and TEE_{SWA} was 1683 (IQR 1696) kJ/day, or TEE_{app} was 1.19 times the value of TEE_{SWA} (P<.001) (see Table 3). The corresponding result expressed as mean difference was 1858 (SD 1230) kJ/day (95% CI 1563-2153), or TEE_{app} was 1.20 times the value of TEE_{SWA} (P<.001). A total of 4 individuals out of 69 (6%) were outside the limits of agreement: 2 boys and 2 girls, of which 1 was normal weight (see Figures 5 and 6). In total, 8 individuals out of 69 (12%)—5 girls and 3 boys—were within ±5% of measured TEE_{SWA}. Underestimation of TEE_{app} was seen in 1 (1%) participant out of 69, and overestimation was seen in 60 (87%) participants. The correlation between TEE from the mobile phone app and the SWA was .75 (P<.001). A correlation coefficient of .63 (P<.001) was seen when comparing participants' weight with TEE_{SWA}. However, PAL values derived from the mobile phone app were also significantly correlated with TEE_{SWA} (.37, P=.002) and with average metabolic equivalents from the SWA (.31, P=.009). Analysis by gender showed that correlations of PAL values from the mobile phone app with TEE (.49, P=.008) and average metabolic equivalents (.54, P=.003) from the SWA were statistically significant only for boys.

Figure 5. Bland-Altman plot comparing total energy expenditure estimated with a newly developed mobile phone app (TEEapp) and with the SenseWear Armband (TEESWA) in 69 adolescents. The sample is displayed by gender: girls (closed circles; solid regression line) and boys (open circles; dashed regression line).

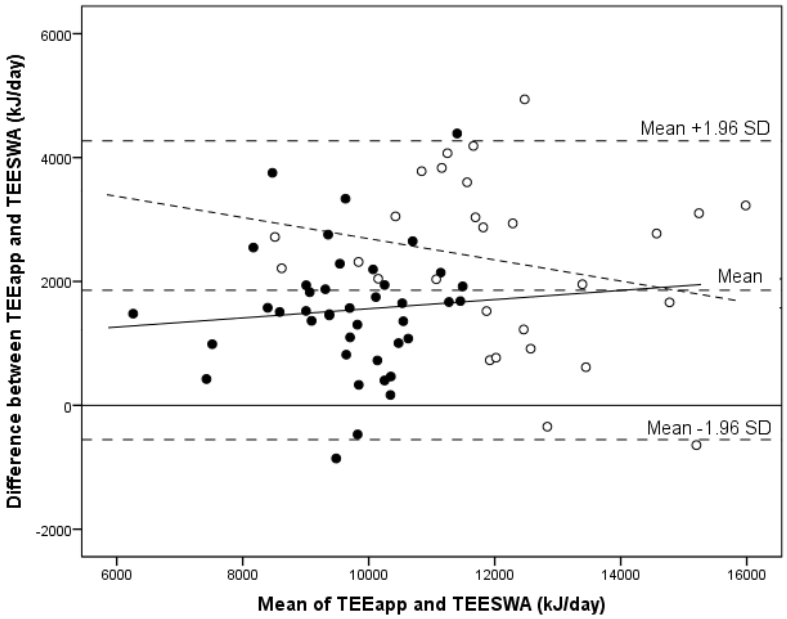
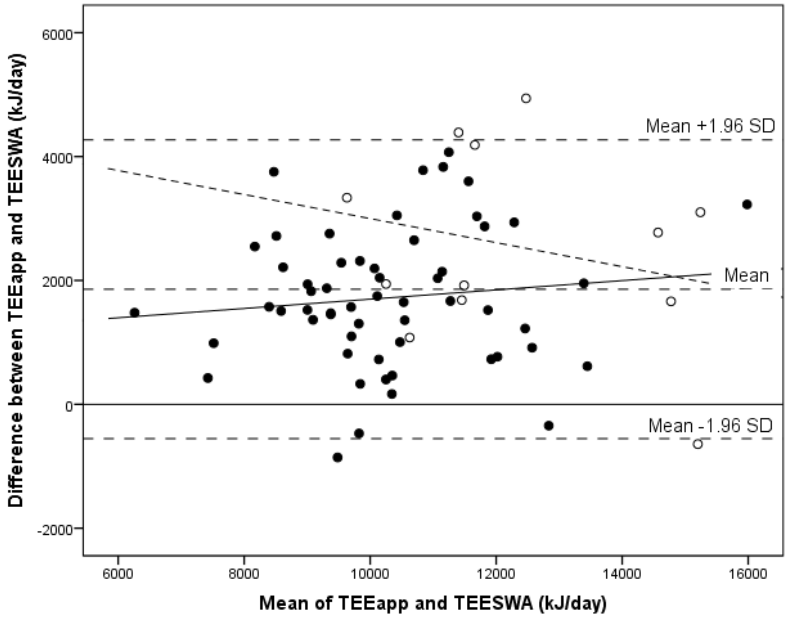


Figure 6. Bland-Altman plot comparing total energy expenditure estimated with a newly developed mobile phone app (TEEapp) and with the SenseWear Armband (TEESWA) in 69 adolescents. The sample is displayed by weight status: thinness/normal weight (closed circles; solid regression line) and overweight/obese (open circles; dashed regression line).



Comparison Between Mobile Phone App and Web-Based Method

Of the 15 participants included in this analysis, 1 individual (7%) used the mobile phone app to register diet on 1 day, 3 (20%) used it on 2 days, and 11 (73%) used it on 3 days. The Web-based method was used by 3 participants (20%) on 2 days and by 12 participants (80%) on 3 days. Of the 40 days with dietary data from the mobile phone app, 29 (73%) were weekdays and 11 (28%) were weekend days. Of the 42 days with dietary data from the Web-based method, 30 (71%) were weekdays and 12 (29%) weekend days.

The median EI assessed with the mobile phone app was 6011 (IQR 4072) kJ/day and with the Web-based method was 6899 (IQR 2579) kJ/day (*P*=.36). The correlation between EI assessed with the mobile phone app and the Web-based method was .53 (*P*=.04). Of the macronutrients, fat (.54, *P*=.04), fiber (.60, *P*=.02), and monosaccharides (.67, *P*=.007) were significantly correlated between the mobile phone app and the Web-based method. Of the 18 investigated micronutrients, folate (.59, *P*=.02), iron (.66, *P*=.008), vitamin A (.55, *P*=.04), and vitamin E (.75, *P*=.001) were significantly correlated between the methods. Furthermore, six of the 34 investigated food groups were significantly correlated: beer, wine, and spirits; breakfast

cereals; milk, fermented milk, and yogurt; nuts and savory snacks; soft drinks, sport drinks, and energy drinks; and sugar, syrup, honey, and artificial sweeteners (results not shown). Intake of protein, juice, and pasta were significantly different when the two methods were compared. The correlation between EI_{app}-TEE and EI_{Web}-TEE was .74 (P=.002), indicating a similar reporting accuracy of participants with the two methods. Reporting accuracy of EI compared with TEE from the SWA did not differ significantly between the methods.

Discussion

Principal Findings

The results showed that a mobile phone app for the recording of dietary intake captured a median EI that was 71% of TEE from the SWA in adolescents, and that there was no correlation between EI and TEE. Furthermore, BMI z-score and the presence of a weekend day in the EI record were the only investigated variables associated with reporting accuracy relative to TEE. Reported EI was almost 90% of TEE when only including the participants who said that they had recorded almost all of their dietary intake. EI, nutrients, and food groups assessed with the mobile phone app and Web-based method were generally not significantly correlated and not significantly different. TEE assessed with the mobile phone app was 1.19 times the value of TEE from the SWA on a group level, and there was a significant correlation between the two methods for TEE, and for physical activity among boys.

In a systematic review from 2010, the authors concluded that adolescents underestimate EI with food records by 18 to 42% [27], which is in line with the results of this study. A mobile phone food record method has been developed for use among adolescents, in which food images taken with the mobile phone camera are automatically identified and quantified, and nutrients are calculated [28]. To our knowledge, there are as yet no studies among adolescents evaluating assessed intakes from mobile phone food records with reference methods in free-living conditions. A previous study in 1998 among Swedish adolescents showed a mean reported EI for boys and girls of 82% and 78% of TEE, respectively, using a traditional pencil-and-paper food record over 7 days [29]. A study on US adolescents showed that the mean reported EI with a traditional food record over 2 weeks was 81% and 59% of TEE in nonobese and obese participants, respectively [30].

Factors influencing the accuracy of reported EI among adolescents have previously been described as belonging to the categories anthropometric, sociodemographic, psychosocial, behavioral, and parental characteristics [31]. In a sample of 11- to 17-year-old French adolescents, variables positively associated with underestimating EI included being overweight, having a wish to weigh less, having a restrictive diet, eating breakfast less than 7 days per week, and irregular school canteen attendance when tested individually in logistic regression models [15]. In a stepwise model, for example, being overweight and having a wish to weigh less were significantly associated with underestimation in the same study. In this study, wishing to weigh less, having a restrictive diet, eating breakfast less than 7 days per week, and irregular school canteen attendance were not associated with an underestimation of EI. Since reporting accuracy showed a dependence on the average energy values, the analysis was performed with the outcome variable, (EI-TEE)/TEE. BMI z-score and having a weekend day in the record of EI were the only investigated variables significantly associated with reporting accuracy relative to TEE. Including a weekend day in the record of EI has previously been shown to increase reporting accuracy in a sample of overweight and obese Swedish children who kept food records with the help of digital cameras [7]. One explanation could be that the participants have more time during the weekend to complete a food record. Another possible explanation is that participants could have a higher EI during the weekends and that this is reflected in the diet records. However, previous studies in Swedish children have shown that EI was not significantly different between days of the week [32-34]. The negative association between BMI and reporting accuracy has been shown previously in Swedish 15 year olds [29].

Bexelius et al constructed a mobile phone-distributed questionnaire consisting of only two questions about physical activity which adult women replied to every day for 2 weeks [13]. Aggregated PAL values were in good agreement with PAL from the DLW method, although within-subject variation in PAL between different days was high. Further evaluating the daily PAL compared with PAL from accelerometry showed that there was a true high within-subject variability in activity levels [35]. In this study, using only one question about the activity level at the end of each day gave TEE that correlated well with TEE from the SWA, even with only a few days use of each method. Since both the SWA and the mobile phone app use the participant's weight to calculate TEE, a strong correlation between the methods can be expected. A statistically significant correlation was obtained when comparing TEE from the SWA with participants' weight. Statistically significant correlations were, however, also found when comparing PAL values from the mobile phone app with TEE and the average metabolic equivalents from the SWA, but only for boys. Furthermore, TEE from the mobile phone app was overestimated compared with the SWA, indicating that the PAL values were set too high and should be moderately adjusted.

The analysis comparing EI, nutrients, and foods between the mobile phone app and the Web-based method included only 15 individuals and the two methods were used during separate weeks. Since dietary intake varies from day to day, it cannot be expected that the same foods are captured with the two methods. We considered the option of having both methods conducted on the same days. However, this involves drawbacks such as increased respondent burden and the methods influencing each other. It was therefore decided to conduct the methods on separate weeks but on the same days of the week. When investigating the relative validity of a method it is desirable to use a reference method with independent errors, for example, comparing food records with 24-hour recall. This study compared two different food records which, since they have the same embedded errors, could lead to an overestimation of the correlation between the methods. Monosaccharides, folate, iron, vitamin A, and vitamin E were the only nutrients significantly correlated between the two methods. Furthermore, six of the

34 food groups were significantly correlated, and one nutrient and two food groups were significantly different between the methods. These results are most likely attributable to the small sample size in this analysis. It should also be kept in mind that the many statistical tests increase the risk of chance findings.

It proved to be difficult to recruit participants to this study. Of the 389 invited adolescents, 38.0% (148/389) decided to participate. Of these, 54.7% (81/148) completed the mobile phone food record and the SWA and were included in the main analysis (81/389, 20.8% of those invited). The poor participation rate reduces the power to detect differences. Furthermore, this study includes a selection process for participants which was done in several steps. It can be assumed that a certain category of teachers agreed to assign class time for the study, and that the adolescents who decided to participate differed in motivation from those who did not.

Previous research has shown that practice with the equipment makes the participants more skilled in using it [36]. It is, however, not always possible to give the participants training prior to a dietary study. We aimed to make a mobile phone app that was self-explanatory, and handed out instructions to the participants. Despite this, giving the participants more training with the mobile phone app might have made the recording of dietary intake easier for them. Furthermore, most participants borrowed an Android mobile phone from the university to use in the study. Being unaccustomed to the type of mobile phone used could have also affected the reporting of dietary intake by making it more difficult for the participants. The participants received feedback about their registered dietary intake. They were asked not to change their intake based on the feedback; however, they might have done so.

Limitations

Limitations of this study include the few days of registration, since EI varies over time. Some of the participants had only 1 day of recorded EI, however, 60% had 3 days or more. The proportion of weekends in the data from the mobile phone app and the SWA were approximately the same. The SWA may not have accurately measured the TEE of the participants. We have not been able to find validation studies of the SWA in measuring TEE among adolescents, and studies conducted in other groups show varying results [37]. In a validation study of the SWA against DLW in overweight children aged 8 to 11 years where the software programs Innerview Professional 5.1 and SenseWear Professional 6.0 were evaluated, valid results on a group level were shown for Innerview Professional 5.1 but not for SenseWear Professional 6.0 in this age group [38]. Furthermore, the SWA was not valid on an individual level. Although we do not know whether the same results apply to our age group, the fact that EI from the mobile phone app and TEE from the SWA did not significantly correlate in this study may be due to the SWA not being valid to measure TEE on an individual level.

Conclusions

In conclusion, the mobile phone food record app did not accurately assess EI of adolescents when compared with TEE from the SWA in this evaluation study. Having a weekend day in the record of EI improved reporting accuracy, and BMI z-score was negatively associated with reporting accuracy. Furthermore, the mobile phone app was able to accurately rank adolescents' TEE, as well as the physical activity level among boys by using only one question about physical activity at the end of the day.

Further development of the mobile phone app method should focus on improved functions to search and record consumed foods, for example, by automatizing these steps as much as possible. Users could, for example, have the option of sending food photographs to the researcher. The app should also be developed for iPhone so that more participants will be able to use their own mobile phones.

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Authors' Contributions

Both authors contributed to the conception and design of the study, the development of the method, as well as analysis and interpretation of the data. ÅS drafted the paper and CL contributed to its content and approved the final version submitted.

Conflicts of Interest

None declared.

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Abbreviations

BMI: body mass index
BMR: basal metabolic rate
DLW: doubly labeled water
EE: energy expenditure
EI: energy intake
EI_{app}: energy intake reported via the mobile phone app
EI_{Web}: energy intake recorded using the Web-based method
IQR: interquartile range
N/A: not applicable
PAL: physical activity level
R-18: Revised 18-item (Three-Factor Eating Questionnaire)
SWA: SenseWear Armband
TEE: total energy expenditure
TEE_{app}: total energy expenditure reported via the mobile phone app
TEE_{SWA}: total energy expenditure measured by the SenseWear Armband

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Original Paper

Smartphone Apps for Schizophrenia: A Systematic Review

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Abstract

Background: There is increasing interest in using mobile technologies such as smartphones for improving the care of patients with schizophrenia. However, less is known about the current clinical evidence for the feasibility and effectiveness of smartphone apps in this population.

Objective: To review the published literature of smartphone apps applied for the care of patients with schizophrenia and other psychotic disorders.

Methods: An electronic database search of Ovid MEDLINE, the Cochrane Central Register of Controlled Trials, Health Technology Assessment Database, Allied and Complementary Medicine, Health and Psychosocial Instruments, PsycINFO, and Embase was conducted on May 24, 2015. All eligible studies were systematically reviewed, and proportional meta-analyses were applied to pooled data on recruitment, retention, and adherence to examine the overall feasibility of smartphone interventions for schizophrenia.

Results: Our search produced 226 results from which 7 eligible articles were identified, reporting on 5 studies of smartphone apps for patients with schizophrenia. All examined feasibility, and one assessed the preliminary efficacy of a smartphone intervention for schizophrenia. Study lengths varied between 6 and 130 days. Overall retention was 92% (95% CI 82-98%). Participants consistently used the smartphone apps on more than 85% of days during the study period, averaging 3.95 interactions per person per day. Furthermore, participants responded to 71.9% of automated prompts (95% CI 65.7-77.8%). Participants reported a range of potential benefits from the various interventions, and user experience was largely positive.

Conclusions: Although small, the current published literature demonstrates strong evidence for the feasibility of using smartphones to enhance the care of people with schizophrenia. High rates of engagement and satisfaction with a broad range of apps suggest the nascent potential of this mobile technology. However, there remains limited data on the efficacy of such interventions.

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KEYWORDS

eHealth; fitness; mHealth; psychosis; schizophrenia; smartphones; technology; wearables

Introduction

The growing prevalence of smartphone technology has created increasing interest in mHealth across all areas of medicine. With global smartphone ownership already at 25% [1], and nearly 65% in countries like the United States [2], these advanced mobile phones offer a novel platform to expand the impact and reach of traditional health care services. One area that stands to potentially benefit from mHealth is the behavioral health sciences, such as psychiatry, given that smartphones could serve

as proxies for capturing digital phenotypes of behaviors [3], and providing real-time psychological support.

Despite recent advances in research and practice, schizophrenia (and other psychotic illnesses) is still associated with high chronicity, disability, and global burden of disease [4]. Nonetheless, smartphone technologies may be able to assist with the diagnosis, monitoring, and treatment of psychotic illnesses, providing novel and cost-effective interventions with potentially global reach. However, little is actually known about the clinical realities of smartphones in the care of patients with psychotic illnesses.

Psychiatric diagnoses, especially psychosis and schizophrenia, already carry tremendous stigma [5,6], which exists even on digital platforms like Twitter [7]. Although there are limited data on smartphone usage among individuals with schizophrenia, it has been suggested that symptoms such as paranoia, disorganization, and cognitive impairment may limit the feasibility of technology-based interventions for this patient group. Patients with schizophrenia may therefore face a double stigma when approaching smartphones, from not only the nature of their illness, but also attitudes regarding their capacities to engage with such technologies [8]. However, preliminary evidence indicates that patients with schizophrenia likely may own and use technology in ways similar to the general population [9,10].

Along with the global population, evidence suggests that patients with schizophrenia increasingly own mobile phone and smartphones. A recent meta-analysis suggests that the overall mobile phone ownership among patients with psychosis is high at 81.4% for those surveyed in the last 2 years, although the study does not report specifically on smartphones [11]. A 2014 survey study of patients at a state-run mental health clinic in Boston, Massachusetts, found that over one-third of patients already have their own smartphones [12]. An earlier study of 1592 patients with severe mental illnesses, conducted in 2013, noted that 81% of those who owned a mobile phone were amenable toward receiving technology-enabled mental health services via their mobile phone [13]. Ownership appears to be particularly high among younger people in the earlier stages of illness, with around 69% of first-episode psychosis patients owning Internet-enabled mobile devices [9]. Global predictions of smartphone ownership suggest that these devices will become increasingly prevalent as barriers to ownership continue to diminish, and will soon replace most traditional mobile phones [14]. Thus, it is logical to assume that with time, smartphone ownership and use will become even more common in patients with schizophrenia. From the ability to identify at-risk individuals, track symptoms in outpatients, prevent relapse, encourage medication adherence, offer on-the-go support, and increase access to services, much has already been speculated about the potential of smartphone technologies to support various aspects of care for patients with schizophrenia [15,16]. In addition, patients with schizophrenia are increasingly being offered apps for self-monitoring and self-management purposes. For instance, the National Alliance of Mental Illness recently released its own app, “AIR,” [17] and there are numerous other apps for managing schizophrenia already available for download on iTunes and Android marketplaces.

Despite the increased interest and opportunities for using smartphone apps to improve outcomes in individuals with schizophrenia, there is currently limited empirical evidence to support their implementation into clinical practice. Studies that have trialed the utility of smartphones in the treatment of other mental illnesses have had mixed success, with some appearing beneficial [16], others failing to have significant impact [18], and some even indicating potential harm in certain patient groups [19]. Although academic research started examining the utility of smartphone apps in the care of schizophrenia many years ago [20], the literature has yet to be systematically examined.

Understanding the existing literature on the role of smartphones in schizophrenia will increase our understanding of what has been learnt so far, where the potential of this technology may be best realized in future, and where the speculations may actually be more theoretical rather than practical at this point. Thus, in this paper we aim to systematically review all existing studies of smartphone app trials in people with psychotic disorders and schizophrenia, and explore the current evidence base for their potential to impact on clinical care.

Methods

Eligibility Criteria and Study Selection

Only original, peer-reviewed, English research articles were included in the review. We aimed to include all published studies of smartphone apps used for improving care in schizophrenia. Thus, we included any studies that reported on any quantitative outcomes of a smartphone-based intervention among patients with schizophrenia. We defined a smartphone as a mobile phone with Internet connectivity and the ability to download and run third-party software apps available from a commercial marketplace. Studies that included patients with unspecified psychotic disorders, “severe mental illness,” or “serious mental disorders” were also eligible for review, provided that it could be confirmed that a portion of the sample studied did have a diagnosis of schizophrenia.

An electronic database search of Ovid MEDLINE, the Cochrane Central Register of Controlled Trials, Health Technology Assessment Database, Allied and Complementary Medicine (AMED), Health and Psychosocial Instruments, PsycINFO, and Embase was conducted on May 24, 2015, using the following keyword search algorithm: (“smartphone*” or “mobile phone*” or “cell phone” or “iPhone” or “mobile app*” or “phone app*”) AND (“psychiatric disorder*” or “severe mental” or “serious mental” or “psychosis” “psychotic” or “schizo*”).

Titles and abstracts of search results were screened by both authors using the aforementioned criteria. For any articles that were not excluded at this stage, the full text was retrieved and assessed for eligibility. The reference and citation lists of eligible articles were also searched to identify further studies. For any disagreements arising between the authors, discussion on that study was conducted by the authors until a consensus was reached. All articles matching our criteria were reviewed in full.

Data Extraction and Analysis

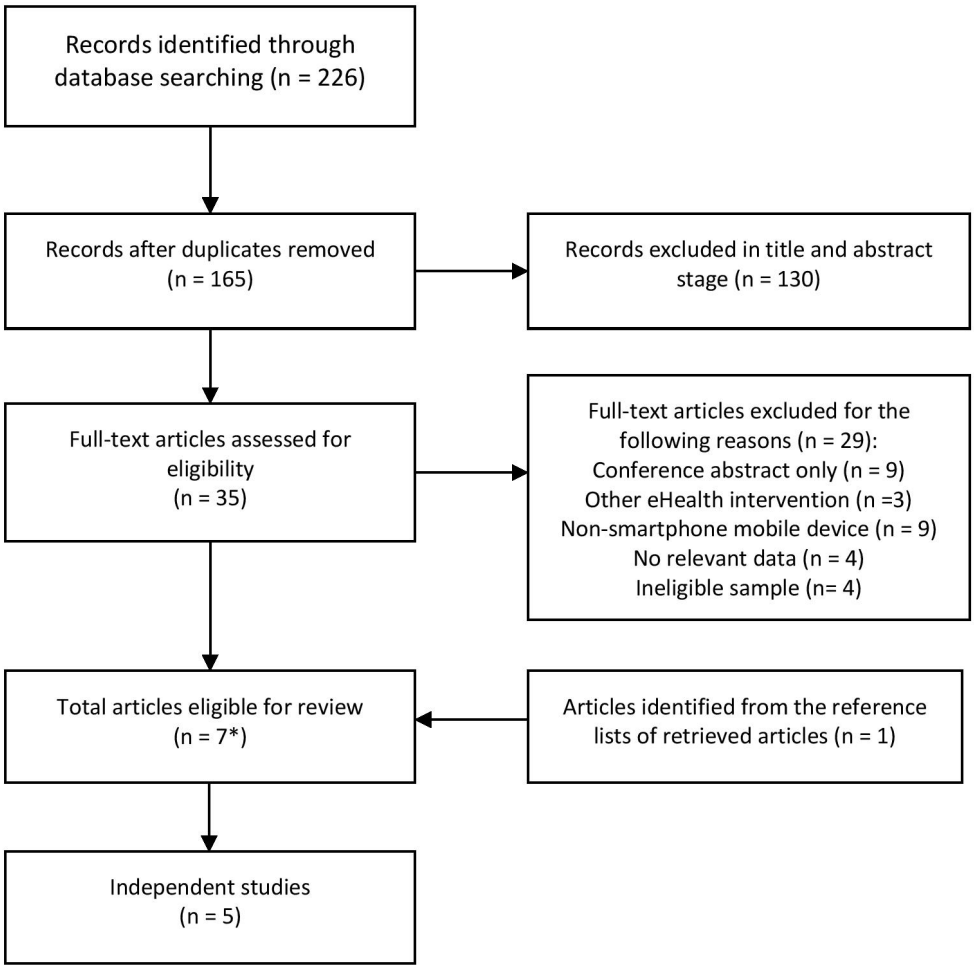
To examine the overall feasibility of smartphone apps for schizophrenia, rates of recruitment, retention, and adherence were extracted from each study. "Recruitment rates" were calculated as number of patients referred divided by number consenting to take part. "Retention" was defined as the proportion of participants who remained in the study for the entire duration and completed follow-up assessments (where applicable). "Adherence" was examined in regards to the number of days using the smartphone app, number of uses-per-day, and also the response rate to automated prompts. These feasibility data from each individual study were pooled using proportional meta-analysis in StatsDirect 2.7 [21]. A DerSimonian-Laird random-effects model was applied to all analyses to account for heterogeneity between studies [22]. Between-study variance was assessed with Cochran's Q and indexed as I^2, which estimates the amount of variance caused by interstudy heterogeneity rather than by chance. Given that only 1 study reported efficacy data, it was not possible to examine the effectiveness of smartphone interventions for schizophrenia with meta-analytic methods.

Results

Search Findings

The study selection process is detailed in Figure 1. The search strategy returned 226 results, providing 165 unique citations after duplicates were removed. Of these, 6 studies met eligibility criteria. A further study was identified from reviewing the references of the retrieved papers. The 7 eligible studies identified reported data from 5 independent trials, which were reviewed in full. Table 1 provides summary information from all included studies. However, there was substantial heterogeneity across studies, due to the fact that each app was unique. Thus, individual results are presented in the context of each individual study below (see Multimedia Appendix for a complete description of the intervention presented in Table 1).

Figure 1. Study selection process.



Systematic Review of Studies

Palmier-Claus et al [23] was one of the first to examine the role of smartphones for schizophrenia. The authors assessed the ability to use smartphones as a platform to collect clinical metrics in real time [23]. The study piloted a smartphone app to deliver 12 items from the Positive and Negative Syndrome

Scale (PANSS) and 2 from the Calgary Depression Scale (CDS) up to 6 times per day over 1 week in 36 patients: 12 with remitted schizophrenia/schizoaffective disorder, 12 with acute schizophrenia, and 12 who were identified as "at-risk" for schizophrenia. Across all patients, mean adherence with the app's survey sessions was 72%, with 82% completing at least 33% of survey sessions. Of the 8 patients who failed to complete at least 33% of the surveys, 6 were from the acute schizophrenia group.

Furthermore, the study found that smartphone apps can be used to obtain clinically meaningful self-assessments of psychiatric symptoms. Comparing app-based psychiatric ratings with those obtained from traditional paper-and-pencil ratings for the PANSS and CDS, positive symptom scales and affective symptom scales showed moderate to strong correlations, whereas questions about social withdrawal, excitement, hostility, and cognitive disorganization showed nonsignificant correlations [23]. A later analysis of results from this study suggested that the relationship between hallucinations and self-injurious thoughts may be mediated by the degree of paranoia and that paranoia predicted greater levels of self-injurious thoughts on subsequent days [24].

Ainsworth et al [25] compared how patients with schizophrenia reported their symptoms with a smartphone app versus text-message reporting of symptoms. Twenty-four patients with schizophrenia partook in this randomized repeated-measures crossover study, with all participants using both the smartphone app and text-messaging systems for 6 days each, receiving 4 short surveys about their symptoms per day. Results showed that smartphone-based symptom monitoring was preferable to text-message symptom monitoring: participants completed app-based symptom assessments on average nearly 5 times faster than on the text-messaging platform. Furthermore, participants completed a significantly greater number of entries when using the native smartphone app than using the text-message interface (69% vs. 56%) [25]. Qualitative results noted that participants were most comfortable using their own personal devices to complete surveys and felt that reporting symptoms via mobile phone was not stigmatizing, regardless of whether it was text messaging based or app based [26].

The FOCUS trial [27] investigated the feasibility and preliminary efficacy of a smartphone app to support the self-management of mental health for patients with schizophrenia. Thirty-three patients with schizophrenia/schizoaffective disorder in community treatment programs were recruited for this 1-month study. The smartphone app, "FOCUS," deployed real-time interventions to target medication adherence, social functioning, mood problems, auditory hallucinations, and sleep difficulties. Participants were asked to complete automatically prompted surveys 3 times per day. In response to participants' input, the app would also offer a self-management intervention. Participants could also use the intervention content on demand, whenever they wanted. Across all participants, 87% felt the app helped them manage symptoms. Mean adherence was 86.5%. Interestingly, the majority of app usage (62.5%) was self-initiated by participants, rather than on demand to daily prompts.

Two further studies examined the utility of smartphones to increase physical activity in patients with serious mental illnesses, including schizophrenia along with other disorders such as bipolar and major depressive disorder. The first of these included 10 patients with serious mental illness (3 of whom had schizophrenia). The study assessed the feasibility and acceptability of a wearable fitness tracker (Fitbit), paired with a smartphone app, to facilitate participant engagement in a weight loss program over a study duration of 80-113 days. Participants were highly adherent to the Fitbit, with a mean rate of daily usage of 89% during the study period. The study presented qualitative feedback about participant's experience with the Fitbit and iPhone app, which was positive overall. However, because data were not linked to individual participants' diagnosis, it is difficult to make any generalizations about the study's results for patients with schizophrenia [28].

Nevertheless, a secondary report of the same study [28] presented additional findings, showing that patients were satisfied with the program, and found that it helped them to reach their goals. Because this response was obtained from all participants, we can be certain that these particular findings do apply to those with schizophrenia. In addition, the study noted that none of the participants reported privacy concerns about using these mobile technologies [29].

Another small study investigated a smartphone app, WellWave, to promote physical activity, specifically walking, among patients with schizophrenia, bipolar disorder, and/or major depression [30]. The app encouraged users to be more active, and offered mobile surveys related to overall health. It also allowed them to text message study staff and to access reading and watch videos about recovery. Ten patients were recruited, 4 with schizophrenia. Over the 4-week study period, mean adherence to daily app usage was 94%, and engagement with automated prompts was 73%. However, only 39% were complaint with daily walks, which the app prompted. Nonetheless, 3/10 patients reported significant improvements in self-ratings of physical health after just 4 weeks of usage [30].

Table 1. Studies of smartphone apps for people with schizophrenia.[a]

Studies	Intervention	Duration (days)	Total (n)	Attrition	Adherence	User experience	Reported benefits
Ainsworth et al (2013) [25]	Android app "ClinTouch"	6	24 (24 with schizophrenia)	0/24	69% of all possible entries were completed 2.8 uses per day (mean average)	The app was rated as "pleasing" overall (scoring 3.7 on a 7-point scale). The app was not rated as "stressful" or "challenging" (scoring only 1.8 and 2.2 on 7-point scales)	Participants felt the app could help them or other service users (5.3 on a 7-point scale)
Ben Zeev et al (2014) [27]	Android app "FOCUS"	28	33 (33 with schizophrenia)	1/33 due to losing phone	Participants used FOCUS on 86.5% of days in the study 5.2 uses per day (mean average)	93.7% of participants satisfied with overall ease of use. Less than 20% found the app to be "awkward," "complicated," or "inconsistent."	87.5% of participants felt that the app helped to manage symptoms. Paired samples *t* tests showed significant reductions in positive and negative symptoms and depression.
Macias et al (2015) [30]	iPhone and Android app 'WellWave'	28	11 (4 with schizophrenia)	1/11 withdrew of own accord	Used on 94% of days 73 % response rate to prompts (3.54 per day) 70% of participants achieved ≥2 walks per week	100% of participants were satisfied with the app overall. Only criticisms were made, pertaining to color/sound preferences, and the study coming to an end.	Participants experienced both improved well-being (eg, put my head in a good place) and practical benefits (eg, Motivated me to get up and walk around the block).
Naslund et al (2015) [28] Aschbrenner et al (2015) [29]	iPhone app "PeerFIT"	80-133	10 (3 with schizophrenia)	1/10 withdrew due to medical reasons	Participants used activity monitors on 89% of days in the study	100% were "very satisfied" or "somewhat satisfied" with PeerFIT overall; 60% would recommend to a friend. Participants felt the devices were expensive for low-income individuals.	100% found the program helped them to reach their goals. Mean weight loss of 2.7 kg across all participants (P>.05).
Palmier-Claus et al (2012, 2014) [23,24]	Android app "ClinTouch"	7	44 (36 with schizophrenia)	8/44 due to noncompliance	72% of all possible entries were completed 4.4 uses per day (mean)	Not reported	Smartphone app provided clinically valid real-time measures of psychotic symptoms and affective state

[a]This is an abridged version of the table. Additional details about the intervention are presented in Multimedia Appendix 1.

Feasibility Data Analysis

To determine the feasibility of smartphone apps among individuals with schizophrenia, we pooled data from all of the individual studies reviewed [23,25,27,28,30] using proportion meta-analysis with a random-effects model. All 5 studies reported on retention over the study period. The study periods ranged from 6 to 130 days and the total retention rate was 92% (95% CI 82-98%, n=122), with moderate heterogeneity between studies (Cochran's Q=9.52, P=.05, I^2=58.8% [95% CI =0-82.3%]). For the 4 studies [23,25,27,28] that reported recruitment (n=208), the overall rate of referral to enrollment was 57% (95% CI 31-82%, Cochran's Q=43.43, P<.01, I^2=93.1%), with only 26% of referred patients uninterested in participating (as the rest were either ineligible or not contacted).

Automated prompts were used in 4 studies, although only 3 of these reported the response rate [23,25,30]. Studies used 4-6 alerts per day, and the average response rate across 70 participants was 71.9% (95% CI 65.7-77.8%), with moderate heterogeneity between studies (Cochran Q=5.83, P=.054, I^2 =65.7 [95% CI 0-88.1%]). Further summary statistics were calculated for adherence variables that could not be analyzed using proportional meta-analytic methods. Four studies reported number of uses per day [23,25,27,30]. Weighted mean averages show that apps were interacted with, on average, 3.94 times per

day during the study periods, ranging from 2.8 to 5.2 uses per day. Participants used the apps on 86.5-94% of days during the studies [27,28,30].

Discussion

Findings From Reviewed Studies

Although only a small number of studies have assessed smartphone apps for schizophrenia, with only 5 trials identified by our review, early results are encouraging. The existing literature shows that people with schizophrenia are willing and able to use smartphones to monitor their symptoms, engage in self-directed therapeutic interventions and increase their physical exercise. Rates of retention and adherence during the trials proved to be high, with 92% of participants remaining in the trials until the end, and interacting with the apps on approximately 86.5-94% of days in the study. These rates of adherence and engagement appear similar, and actually slightly higher, compared with mHealth interventions for other chronic conditions such as diabetes, cardiovascular diseases, and lung diseases [31].

Furthermore, no paper reported any adverse outcomes or cases of app use increasing paranoia or exacerbating the symptoms of schizophrenia. However, 1 participant in Ainsworth et al's study [25] did withdrew from reporting her symptoms as she found that this was making her ruminative; however, it has to be noted at that time, this patient was in the text messaging arm and not in the smartphone arm of the study. Overall, the existing literature indicates high feasibility of smartphone apps for patients with schizophrenia and other psychotic disorders. Despite been typically regarded as a difficult population to engage with health services, our results suggest that these patients are as engaged, active, and adherent with smartphone apps as other patient populations, such as those with diabetes [32-34]. However, the results of our review also raise several important discussions points and questions regarding which smartphone interventions might be better for patients, the validity of smartphone data, clinical role of smartphones, and issues related to next steps for research and clinical psychiatry.

Just as schizophrenia is a complex disorder with diverse manifestations, smartphone app use among patients with schizophrenia is also complex. Results reported by Palmier-Claus et al [23] suggest that patients in the acute stages of illness may have more difficulty with app adherence than those in partial or full remission. In addition, the highest rates of app adherence were observed among the group of participants who were classified as "at-risk" for schizophrenia, due to showing early warning signs, but did not yet have the full diagnosis. Cross-sectional studies have also found that younger psychiatric patients, in the earlier stages of illness, have the highest rates of smartphone ownership and usage [8,9,12]. Considered together, this evidence suggests that "at-risk" or "first episode" populations may ultimately be the most willing and able to use smartphones for monitoring their symptoms and engaging in mental health self-management, to prevent further (or first) psychotic episodes. Nonetheless, even older patients may benefit from smartphone-based interventions. Macias et al [30] reported that the greatest improvements in self-reported physical health from the "WellWave" app were reported by participants over the age of 50.

Although smartphones have proven feasible for real-time symptom monitoring, there is now a need to assess the validity of these measures, comparing traditional clinical metrics of psychiatric symptoms with those obtained via smartphone apps. Palmier-Claus et al [23] noted that positive symptom and affective symptoms assessed via smartphone prompts held significant correlations with traditional measures. However, weaker, nonsignificant correlations were observed for questions about social withdrawal, excitement, hostility, and cognitive disorganization. Potential reasons why smartphone self-assessments of these particular areas may differ from clinical metrics include recall bias, fear of judgment or consequences (eg, involuntary hospitalization), or even a genuine alteration in patients' state when interacting with technology, rather than a human being. However, further research is needed to better understand this important issue. Furthermore, the capacity of smartphones to collect "passive data" (from location, general phone usage, or even wearables) may eventually eclipse the utility of smartphone-aided self-report. In any case, it is important to keep in mind that smartphone-collected data is a new metric in itself, which will require clinical validation and reliability evaluation for further novel apps.

The immediate clinical role of smartphone apps appears promising. Results reported by Ben-Zeev et al [27] suggested that patients with schizophrenia were not only compliant with an app that assisted mental health self-management, but actually found the app so useful that they used it at a much higher rate than required by the study. Results of two further studies that used smartphones apps to support exercise programs for people with serious mental illnesses (including schizophrenia) also had positive feedback, high levels of engagement and appeared to effectively increase physical activity [28-30]. Given that the prevalence of obesity and cardiometabolic disorders is double among people with psychotic disorders [35], smartphone apps may offer a new tool for engaging patients in regular exercise to attenuate cardiometabolic risk. This may also confer additional psychological benefits, as moderate-to-vigorous exercise can significantly reduce psychiatric symptoms among people with schizophrenia [36]. Thus, the clinical potential for smartphone apps in psychotic illnesses appears broad, and likely will continue to expand.

Implications for Future Research

Considering the goal of this review was to explore the current evidence base for the potential of apps to impact clinical care, it must be acknowledged that there is currently much still unknown. While this review was able to identify and summarize information on acceptability, feasibility, satisfaction, and engagement, data on efficacy and clinical utility are still lacking. Examining these outcomes of smartphone apps for schizophrenia is an important target for future studies.

The result that participants feel more comfortable using their own personal devices, instead of study phones [26], makes intuitive sense, and suggests a means to lower costs and increase adherence in future research studies. While text messaging

remains an important means of communication in this digital age, smartphone-based interventions are quicker, and result in higher rates of adherence than the equivalent text-messaging interventions and thus a better platform for research studies [25]. The ability of smartphones to collect real-time symptom data creates the opportunity to answer questions about the complex temporal dynamics of psychotic symptoms and opens a window for new lines of clinical investigation [24]. Our results suggest that future researchers can reasonably expect participants to respond to two-thirds of responses, and interact around 4 times per day.

The majority of studies reviewed focused more on symptom monitoring rather than treatment interventions. Although Ben-Zeev et al's study [27] did present promising efficacy data, there remains an overall lack of evidence regarding the efficacy of these smartphone interventions. Smartphone apps for psychiatry present many unique opportunities, because therapeutic treatments for schizophrenia such as peer support, cognitive behavioral therapy, skills development could potentially be delivered via a smartphone device. However, whether such therapies would remain efficacious after been translated onto smartphone platforms is largely unknown at this time and will be an important area of future research.

Limitations

Our study presents several limitations that must be taken into account. First, despite our comprehensive search strategy and broad inclusion criteria, it is possible that other studies of smartphone apps for patients with schizophrenia are still in progress, unpublished, or even being conducted by private sector companies outside of academia, and thus are unavailable for review. Second, there was substantial heterogeneity between studies in terms of the types of apps used and their aims, thus making it difficult to draw overarching conclusions. However, because our review found high feasibility across all studies (despite these differences in design), the overall findings do indicate that smartphone apps can be feasible for use in schizophrenia across a wide variety of contexts. For example, high user engagement was observed in both apps that used automated prompts [23,30] and those which relied mostly on self-initiated usage [27,28]. Similarly, the apps proved feasible for a broad spectrum of uses, including monitoring symptoms [23,25], promoting recovery [27,30] and even improving physical health [25,27]. A final challenge of this data is extrapolating results regarding adherence and retention over longer durations than the study periods. It is possible that participants were more adherent during the study, and would have used the apps less over time. Conversely, participants equally may have built stronger habits of regular usage over time, after finding the apps engaging and beneficial from the outset. Understanding if and how patients will use smartphone apps for months or even years to monitor and manage their own condition is a clinically important question, which future research must aim to address.

Conclusion

Although the current literature on the role of smartphones in psychotic disorders such as schizophrenia is small, results suggest high feasibility and acceptability. However, there is currently limited data on the efficacy of smartphone apps. Furthermore, the literature supports many diverse use cases. With further research and clinical innovation, smartphones have the potential to become an important tool that psychiatrists can employ in the clinical care and management of psychotic disorders.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Studies of smartphone apps for people with schizophrenia.

[PDF File (Adobe PDF File), 195KB - mhealth_v3i4e102_app1.pdf]

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Abbreviations

CDS: Calgary Depression Scale
PANSS: Positive and Negative Syndrome Scale

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Original Paper

Basal Temperature Measurement Using a Multi-Sensor Armband in Australian Young Women: A Comparative Observational Study

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Abstract

Background: The menstrual cycle is a key marker of health in women of reproductive age. Monitoring ovulation is useful in health studies involving young women. The upward shift in basal body temperature, which occurs shortly after ovulation and continues until the next menses, is a potentially useful marker of ovulation, which has been exploited in clinical and research settings.

Objective: We investigated the utility of BodyMedia SenseWear (BMSW) in monitoring ovulation in young women by analyzing the correlation and agreement of basal temperatures measured using BMSW and a digital oral thermometer.

Methods: Kappa statistics were used to determine the agreement in ovulation detection between the two devices, for each participant, under each form of analysis. Participants also completed an online questionnaire assessing the acceptability of both devices.

Results: We recruited 16 participants with 15 of them providing analyzable data (11 OCP non-users, 4 OCP users). Weak to moderate correlations were observed between thermometer and BMSW temperature measurements averaged over 5 different time intervals. However, no agreement between methods was observed using Bland-Altman plots. There was a significant difference in the range of temperatures that each device recorded (thermometer: 35.3-37.2°C, BMSW: 29.7-36.7°C) with BMSW temperatures significantly lower than thermometer temperatures: mean 34.6°C (SD 1.2) versus 36.4°C (SD 0.3) respectively, $P<.001$. Poor agreement was observed between devices under quantitative analysis of ovulation while fair agreement was observed under visual analysis. Under both quantitative and visual analysis, there was 0% agreement for evidence of ovulation.

Conclusions: This study demonstrated the importance of evaluating biomeasures collected using mobile monitoring devices by comparison with standard methods. It revealed a relatively poor correlation between BMSW and oral thermometer temperature readings and suggested that BMSW is unlikely to detect an upward shift in basal body temperature. Participant behavior suggested poor compliance in the use of BMSW for basal temperature measurement and that the basal body temperature method may not be suitable for use in unselected samples of young women. There is a need for research tools for monitoring ovulation that are simple, self-administered, and inexpensive, yet appealing to young women.

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KEYWORDS

basal body temperature; young female health initiative; BodyMedia SenseWear; ovulation; menstrual cycle, young women

Introduction

The menstrual cycle is one of the key and characteristic physiological processes of women and is an important indicator of overall health in women of reproductive age [1]. Continuous fluctuations in hormone levels result in observable physiological changes throughout the menstrual cycle. These include alterations in urine luteinizing hormone (LH levels) [2,3], cervical mucus [2,4] and basal body temperature (BBT) [2,5,6]. The cyclic nature of the menstrual cycle allows for the observed presence or absence of these physiological alterations to be used as indicators of ovarian function [2]. BBT is defined as "the waking temperature of the body before any activity" [5]. Generally in women with ovulatory cycles, an increase in BBT within the range of 0.2-0.5°C occurs shortly after ovulation and persists until the following menses [5,7-9]. Thus, BBT is considered biphasic with the temperature shift generally regarded as confirmation of ovulation [5,7,8]. The relationship between the menstrual cycle and fluctuations in body temperature was first observed in 1867 [6,8]. It was not until 1926, however, that a direct association between this temperature shift and ovulation was determined [6]. Since then, this biphasic shift in BBT has been used clinically, in research, and by individuals, in various contexts including achieving pregnancy, contraception, investigation of infertility, and as a general indicator of ovarian function.

Despite modern technological advancements, the most frequently used method for monitoring BBT in both research and self-assessment settings is via a thermometer, as it has been for decades [5]. Originally this involved oral, rectal, or vaginal application of a mercury thermometer. However, due to health concerns associated with mercury and the invention of digital thermometers, the currently recommended procedure is for women to take their temperature immediately after waking using an oral digital thermometer [5].

Although the BBT method has significant limitations, it is simple, non-invasive, and cheap. It therefore continues to be useful for some clinical and research applications. Self-plotted and visually assessed temperature has been reported to be inaccurate [10]. However, interpretation using the quantitative mean temperature method (MTM) of Vollman appears to appreciably improve the method's reliability in detecting ovulation [8]. Nevertheless, it is also important that any such method achieves a high level of acceptability and compliance among users, and it would also be advantageous if other physiological data could be conveniently collected concurrently for various clinical and research purposes.

The BodyMedia Inc. armbands combine four sensors, all of which can monitor a variety of physiological parameters over time. BodyMedia SenseWear (BMSW; Figure 1) is a research model, and BodyMedia FIT is a consumer model. The sensors include a thermistor-based sensor to measure skin temperature. It has been proposed that continuously measured skin temperature is linearly reflective of core body temperature [11]. Thus, we hypothesized that, when worn under basal conditions, BMSW would be indicative of BBT and BMSW would be able to detect the upward shift in BBT that occurs shortly after ovulation. Should that be so, the BMSW and similar devices could be an accurate and reliable alternative to the current standard BBT monitoring device (a digital oral thermometer), also enabling a range of physiological data to be collected simultaneously.

Our first aim was to compare concurrent basal temperature measurements taken using an oral digital thermometer (the criterion method) with skin temperature recorded using the BMSW. For this purpose, we chose to study a sample of healthy young women aged 18-25 years who had been recruited for a wide-ranging study of young women's health, the Young Female Health Initiative (YFHI) [12].

Figure 1. The BodyMedia SenseWear armband as worn.

Methods

The BBT study was designed as a substudy of the YFHI Launch Study. The YFHI Launch study is a multidisciplinary investigation of young women's health, utilizing modern information and communication technology, a self-administered online questionnaire, and a health check carried out at the study site.

Preliminary Study

A preliminary study was conducted to determine an effective and acceptable methodology for collecting basal skin temperatures using BMSW. Two methodologies were proposed. The first involved participants wearing BMSW for 20 minutes each morning immediately after waking and before undertaking any form of activity. At the commencement of the 20-minute interval, participants were also asked to take their temperature using a digital oral thermometer. The second methodology involved participants wearing BMSW overnight and removing it immediately on waking. Participants were also requested to complete an online feedback questionnaire reflecting on acceptability of the different methodologies. This preliminary study was conducted on a convenience sample of 9 female volunteers aged 20-24 years, who were not included in the main BBT study. It was found that wearing BMSW for 20 minutes immediately after waking showed a continuous increase in temperature from start to end of the 20-minute period, for all participants on all days (data not shown). Hence, 20 minutes was deemed an insufficient period of time for BMSW to register a stable temperature reading. As anticipated, the BMSW recorded relatively stable skin temperatures on waking when the device was worn all night. Therefore, the overnight method was chosen for use in this study.

Participants

Young women aged 18-25 years, living in the State of Victoria, Australia, and not using any hormonal form of contraception were eligible to participate in the BBT study. Exclusion criteria included (1) known diagnosis of disorders causing amenorrhea/anovulation and (2) current use of hormonal contraceptives. Age-matched subjects taking combined oral contraceptive pills (OCP) were also recruited and formed a control group. Participants were recruited from three sources: (1) expressions of interest submitted through the YFHI website, (2) participants who had completed the Vaccine Against Cervical Cancer Impact and Effectiveness Study (VACCINE) [13], a study measuring the Australian human papillomavirus (HPV) vaccine program effectiveness in vaccine eligible participants, and (3) current YFHI Launch Study participants who were recruited prior to the introduction of the BBT study. All participants sourced via their expression of interest through the YFHI website were notified via email by YFHI staff. Participants sourced through either VACCINE or the YFHI Launch Study were recruited using participant lists generated from the respective studies' databases. All potential participants contacted from VACCINE and the YFHI Launch Study had given consent to be contacted in the future about other studies for which they may be eligible.

Telephone Screening

Telephone screening was performed to provide participants with an overview of the study and to assess participant eligibility. Age, current address, and use of hormonal contraception were assessed and verbal informed consent obtained. Participants were also asked about their height, weight, handedness, and approximate nightly bedtime hours to set up BMSW.

Study Procedures

Eligible participants were sent a study package containing a welcome letter thanking the participant for their participation and explaining the contents of the package, an instruction booklet, the BMSW armband and charging cable (Temple Healthcare), an Omron model MC-246 digital oral thermometer (Chemist Warehouse), reply-paid and registered postal labels, a paper log for those who chose this method of recording their temperatures taken using the thermometer, and a participant information and consent document to be completed by participants. Delivery was timed so that participants would receive their study package approximately 1 week before their next menstrual period was due, to ensure they were able to commence the temperature measuring on the first day of their period. Participants were requested to return the BMSW armband and charger and, for those applicable, the paper log at the completion of the study.

Participants were asked to commence measuring their temperature on the first day of their menstrual period and to do so every day until the first day of their following period. Participants were instructed to put the armband on immediately before going to bed and to sleep wearing it every night for the duration of the chosen menstrual cycle. They were asked to remove it immediately after waking up and before getting out of bed the following morning. Correct use of BMSW involved wearing the armband with the monitor placed on the back of the left upper arm, with the armband automatically turning itself on upon making contact with one's skin.

Participants were given standard instructions for obtaining BBT: to use the thermometer orally every morning according to the manufacturer's instructions immediately after waking and before performing any form of activity, including getting out of bed or consuming any food or drink. Participants were instructed to refrain from removing the BMSW armband until after they had used the thermometer, in order to ensure that the temperatures obtained from the two devices were comparable.

Participants who owned a smartphone were asked to download the WomanLog Pro app to record temperatures taken using the thermometer. This app is a menstrual cycle calendar, with a BBT recording and charting function. Participants were asked to submit their recorded temperatures by email at the conclusion of data collection. All temperatures recorded using the WomanLog Pro app were exported by a researcher (LH) directly from their cycle overview into Microsoft Excel in order to allow the researcher to graph data. Similarly, results recorded into paper logs were entered by the researcher into a Microsoft Excel spreadsheet before being plotted on graphs. Participants were given the option to use the app or a paper log. If participants noticed anything irregular with their menstrual cycle or forgot to wear BMSW one night or take their temperature one morning using the thermometer, they were asked to record this using either the paper log or WomanLog Pro. Participants were also asked to record whether they experienced any intercurrent illness or fever and any irregular wakening times. At the completion of their menstrual cycle, participants were asked to complete a brief, online, self-administered feedback questionnaire, generated using SurveyMonkey. This questionnaire asked

participants a series of questions encouraging them to reflect on the use of BMSW, the thermometer, and their most recent menstrual cycle. Responses were elicited using a 5-point Likert scale with answers ranging from "completely false" to "completely true".

Statistical Analysis

Upon return of the study package, all data were exported from BMSW into Microsoft Excel using SenseWear Professional Software 7.0 (BodyMedia Inc.). Daily wakening time for each participant was identified by BMSW and the mean temperatures for 10-, 30-, 60-, 90-, and 120-minute intervals prior to this wakening time were calculated.

Correlation between BMSW and thermometer temperatures was analyzed using Spearman's rank correlation test, while the level of agreement between the temperatures obtained via the two methods was further investigated using a Bland-Altman (BA) plot [14].

Temperature charts were analyzed for evidence of ovulation according to standard BBT criteria. This was achieved through charting and analyzing temperatures taken using the thermometer and BMSW, which was performed both visually as well as quantitatively using MTM [15]. Visual analysis was performed independently by 2 or 3 observers, blinded to group allocation, following the criteria outlined in Table 1 [16]. The level of agreement between two methods in detecting possible ovulation and interrater reliability were determined using Kappa statistics.

All analyses were performed using STATA version 12 (StataCorp), and $P<.05$ was considered statistically significant.

The study protocol was reviewed scientifically and approved by the Royal Women's Hospital Human Research and Ethics Committees.

Table 1. Outline of criteria used for evidence of ovulation when visually analyzing temperature charts of temperature recorded using the digital oral thermometer and BMSW.

	Criteria for evidence of ovulation for visual analysis of BBT charts
1. Biphasic[a] by >0.2°C	Indicated by a 3-day sustained shift compared with 6 previous temperatures around expected time of ovulation, calculated 2 weeks prior to following menses
2. Adequate thermal shift[a]	Sustained for at least 11 days; fast enough rise (<2 days); absence of deep falls in the luteal phase
3. Presence of a nadir	Fall in temperature immediately prior to sustained temperature rise

[a]The presence of biphasic and thermal shift are necessary to say there is evidence of ovulation, while presence of a nadir is supportive.

Results

Recruitment and Participation

We recruited 24 young women. Of these, 16 participants returned their study package. Their mean age was 22.1 years (SD 1.7). Twelve of these were not currently using hormonal contraception, while 4 were currently using an OCP.

Varying levels of completeness of the study protocol were observed in the 16 participants. Four participants completed the study in full, while 11 completed at least 17 days of temperature measurements. One participant returned their study package after only 4 days, and her data were excluded from analysis. Hence, interpretable data allowing comparison of the temperature measurement methods were available in 15 participants (12 non-OCP users, 3 OCP user controls). All available data from these participants were used to compare the BMSW and the digital thermometer methods of temperature measurement.

Comparison of Temperatures Recorded Using BodyMedia SenseWear and the Thermometer

Weak-to-moderate correlations were observed between the thermometer and BMSW at the five time intervals (range of rho values .28-.4; Figure 2). However, strong intra-participant correlations were observed between the different time intervals (rho ranged from .76-.97, $P<.001$; Figure 2).

BA plots for all five time intervals showed no agreement with the thermometer, with a substantial level of variability and systematic bias (representative data for the 60-minute interval shown in Figure 3). The poor agreement between the thermometer and BMSW was similar for all five BMSW time intervals, indicated by the range of the mean difference between the thermometer at each of the time intervals (range 1.772-1.810). However, the negative slope of points on all these BA plots indicated a higher level of agreement between BMSW and the thermometer at higher temperatures. Thus, there was evidence of bias between recordings (temperature – BMSW) with a greater temperature differential being seen at lower mean temperatures.

A significant difference in the range of temperatures recorded by each device was also apparent. The range of temperatures measured using the thermometer was small (35.3-37.2°C), with all temperatures lying within the boundaries considered normal for core temperature [17]. The range of temperatures recorded using BMSW was much wider (29.7-36.7°C). Furthermore, the absolute values of temperatures recorded using BMSW were significantly lower than those recorded using the thermometer: mean 34.6°C (SD 1.2) versus 36.4°C (SD 0.3) respectively, $P<.001$.

Figure 2. Correlations between thermometer and different time points performed to determine correlation between temperatures recorded by BMSW 10, 30, 60, 90, and 120 minutes before waking and the digital oral thermometer, as well as correlation between temperatures recorded at each of the 5 time intervals.

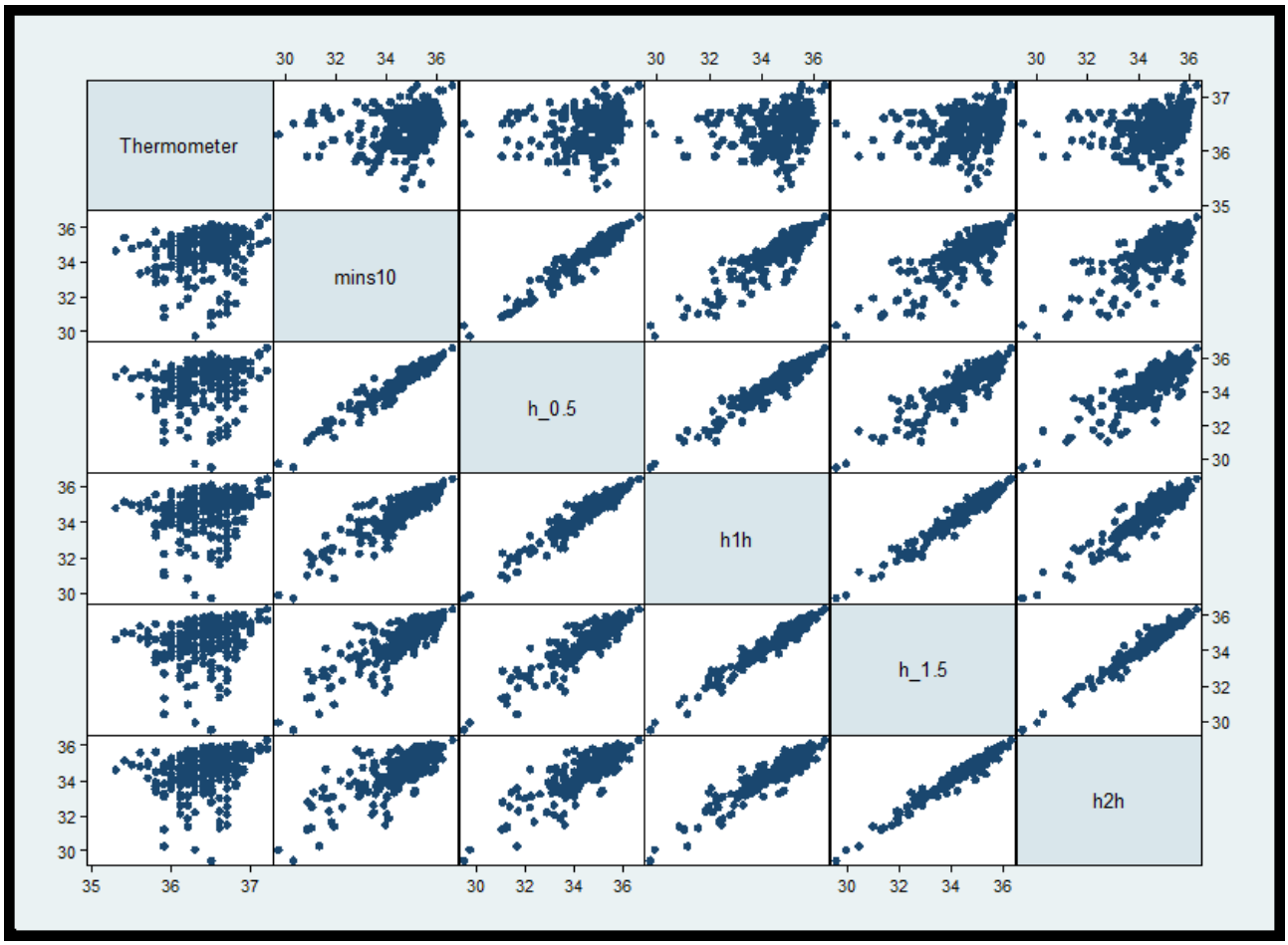
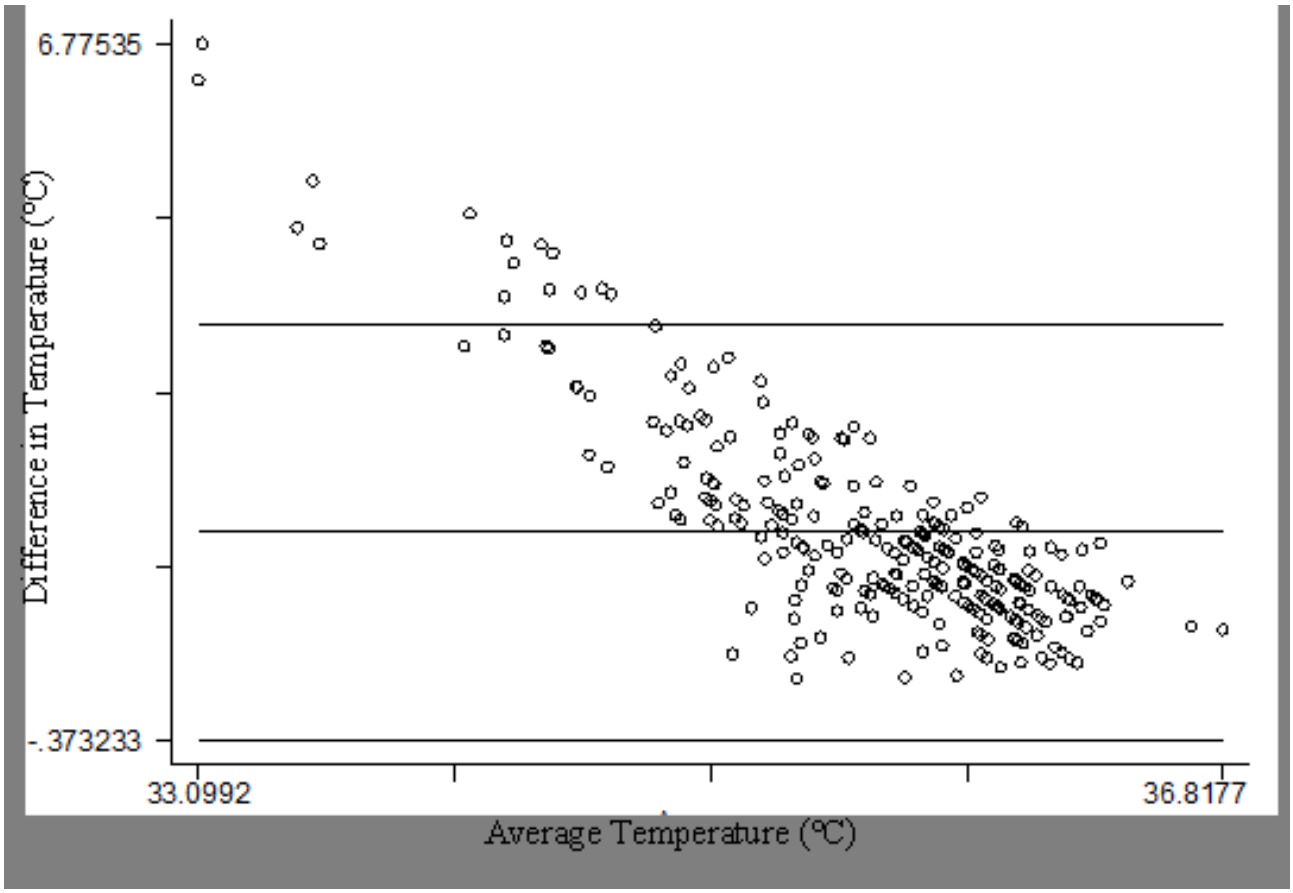


Figure 3. Bland-Altman comparison of thermometer and average temperature, for the 60-minute interval before waking recorded by BMSW (each dot represents one participant's temperature readings using the thermometer and BMSW).



Evidence of Ovulation

The results of the analysis for evidence of ovulation for all four methods performed (visual thermometer, visual BMSW, quantitative thermometer, and quantitative BMSW) are outlined in Table 2. Table 3 contains the Kappa analysis, indicating the agreement between methods overall, as well as for detection of ovulation, anovulation, and inconclusive cases.

Table 2. Number of ovulatory, anovulatory, and inconclusive menstrual cycles detected by BMSW and the thermometer under visual[a] and quantitative[b] analysis.

Method	Ovulatory	Anovulatory	Inconclusive
Visual thermometer	1	11	3
Visual BMSW	1	8	5
Quantitative (MTM) thermometer	5	9	1
Quantitative (MTM) BMSW	0	14	1

[a]Mathematical analysis was performed using the quantitative MTM method on Microsoft Excel.

[b]Visual analysis was performed by LH and YJ using the criteria for ovulation in Table 1. When these observers disagreed, JDW also made a visual determination and the majority decision was accepted. Temperature charts for visual analysis were constructed using Microsoft Excel.

Table 3. Kappa analysis of agreements between BMSW and the thermometer under quantitative[a] and visual analysis.

Methods	Kappa[b]	Agreement, %	Agreement for ovulation, %	Agreement for anovulation, %	Agreement for inconclusive cases, %
Quantitative BMSW vs quantitative thermometer	.0816	60.00	0.00	60.00	0.00
Visual BMSW vs visual thermometer	.4915	73.33	0.00	53.33	20.00
Quantitative BMSW vs visual BMSW	.1589	60.00	0.00	53.33	6.67
Quantitative thermometer vs visual thermometer	.3023	73.33	6.67	53.33	0.00

[a]Mathematical analysis was performed using the quantitative MTM method on Microsoft Excel.

[b]Kappa >.75 indicates excellent agreement, .4≤ kappa ≤.75 indicates fair to good agreement, and <.4 indicates moderate to poor agreement.

Visual Analysis of Ovulation

Visual analysis of temperatures taken using the thermometer deemed 1 participant ovulatory, 11 anovulatory, and 3 inconclusive (Table 2). Visual analysis of BMSW found 1 to be ovulatory, 8 anovulatory, and 5 inconclusive. The kappa statistic for these two methods was indicative of fair agreement, with agreement of 73%, which was the highest level of agreement observed between two methods assessing for evidence of ovulation. However, the single participant found to be ovulatory for each of these two methods was not the same, and thus the agreement for determination of ovulation was 0%.

Quantitative Analysis of Ovulation

Quantitative MTM analysis of temperatures taken using the thermometer found 5 participants to be ovulatory , 9 anovulatory, and 1 inconclusive, while quantitative MTM analysis of temperatures recorded using BMSW found 0 ovulatory, 14 anovulatory, and 1 inconclusive. The kappa statistic indicated poor agreement, with an agreement of 60% for these two methods. This was the lowest level of agreement observed. There was 0% agreement for determination of ovulation.

Twelve of 16 participants completed the online post-study feedback questionnaire (Table 4). Responses are described qualitatively below because of the small sample size. Responses clearly indicated that neither discomfort nor self-consciousness were concerns associated with BMSW use. Responses to questions in regards to convenience, however, were relatively inconclusive. When asked whether they found the device a convenient method for monitoring the menstrual cycle, the majority of participants gave neutral responses. Responses regarding the appeal of BMSW as a tool for monitoring ovulation were similarly inconclusive. However, there was a slight preference for the thermometer over BMSW. Interest in monitoring the menstrual cycle daily with devices such as BMSW or a thermometer was equivocal. However, participants expressed a strong interest in learning more about their menstrual cycle from BBT temperature monitoring.

Table 4. Summary of participant responses[a] to questions asked on their experience using both the BMSW and the thermometer in the post data collection feedback questionnaire.

Statement	Scale of agreement: 1="completely false" to 5="completely true"					Median
	1	2	3	4	5	
1. "I often found the activity monitor painful to wear"	41.7% (5)	50.0%[b] (6)	8.3% (1)	0.0% (0)	0.0% (0)	2
2. "I often found the activity monitor uncomfortable to wear"	8.3% (1)	50.0%[b] (6)	25.0% (3)	16.7% (2)	0.0% (0)	2
3. "I often found the oral thermometer uncomfortable to use"	75.0%[b] (9)	0.0% (0)	8.3% (1)	8.3% (1)	8.3% (1)	1
4. "I often found the oral thermometer painful to use"	91.7%[b] (11)	8.3% (1)	0.0% (0)	0.0% (0)	0.0% (0)	1
5. "I often did not wear the activity monitor because it was uncomfortable or painful"	75.0%[b] (9)	16.7% (2)	8.3% (1)	0.0% (0)	0.0% (0)	1
6. "I often did not use the thermometer because it was uncomfortable or painful"	100%[b] (12)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	1
7. "I found wearing the activity monitor overnight a hassle and interfered with my sleep"	33.3% (4)	58.3%[b] (7)	8.3% (1)	0.0% (0)	0.0% (0)	2
8. "I found using the oral thermometer a hassle and interfered with my day"	75.0%[b] (9)	8.3% (1)	8.3% (1)	8.3% (1)	0.0% (0)	1
9. "I often forgot to put the activity monitor on before going to sleep"	50.0%[b] (6)	25.0% (3)	8.3% (1)	16.7% (2)	0.0% (0)	1.5
10. "I often forgot to use the oral thermometer first thing upon waking every morning"	58.3%[b] (7)	33.3% (4)	8.3% (1)	0.0% (0)	0.0% (0)	1
11. "I found the activity monitor a convenient way to measure basal body temperature"	8.3% (1)	0.0% (0)	50.0%[b] (6)	8.3% (1)	33.3% (4)	3
12. "I found the oral thermometer a convenient way to measure basal body temperature"	0.0% (0)	8.3% (1)	33.3%[b] (4)	25% (3)	33.3%[b] (4)	4
13. "I often felt self-conscious or embarrassed wearing the activity monitor every night to measure basal body temperature"	83.3%[b] (10)	8.3% (1)	8.3% (1)	0.0% (0)	0.0% (0)	1
14. "I often felt self-conscious or embarrassed using the oral thermometer every morning to measure basal body temperature"	91.7%[b] (11)	8.3% (1)	0.0% (0)	0.0% (0)	0.0% (0)	1
15. "I found the oral thermometer more convenient than the activity monitor to measure basal body temperature"	33.3%[b] (4)	16.7% (2)	0.0% (0)	33.3%[b] (4)	16.7% (2)	3
16. "I preferred using the activity monitor over the oral thermometer"	16.7% (2)	33.3%[b] (4)	8.3% (1)	25% (3)	16.7% (2)	2.5
17. "I would like to use a device such as an oral thermometer or activity monitor every day in order to observe and keep track of my menstrual cycle"	33.3% (4)	8.3% (1)	41.7%[b] (5)	8.3% (1)	8.3% (1)	3
18. "I would prefer to record my menstrual cycle observations by completing a survey rather than wearing an activity monitor every night"	0.0% (0)	33.3% (4)	58.3%[b] (7)	8.3% (1)	0.0% (0)	3
19. "I would prefer to record my menstrual cycle observations by completing a survey rather than using an oral thermometer every morning"	0.0% (0)	33.3%[b] (4)	33.3%[b] (4)	33.3%[b] (4)	0.0% (0)	3
20. "I am interested in learning more about my menstrual cycle based on the basal body temperature tracking I have just completed"	16.7% (2)	0.0% (0)	8.3% (1)	16.7% (2)	58.3%[b] (7)	5

[a]Responses were elicited using a 5-point Likert Scale. The number of responses in each category is given in parentheses. The median response score for all questions is also included.

[b]The most common response scores for each statement.

Discussion

Principal Findings

This study illustrated the importance of evaluating biomeasures derived from mobile monitoring devices by comparison with standard measuring methods. In particular, there were only modest correlations and poor agreement between basal temperatures measured using the criterion method (digital oral thermometer) and the BMSW device. Results from the Spearman's correlation test and BA plots refuted the main hypothesis, demonstrating very modest correlation and agreement between temperatures taken using the thermometer and BMSW over any time interval. Although generally weak correlations were found between the thermometer and BMSW, there was a strong correlation of BMSW temperature averages between each of the five time intervals. This demonstrates consistent temperature measurement by BMSW's skin temperature sensor, which suggests the potential for high precision and reproducibility from the device. As data from the preliminary study indicated, however, this performance can be achieved only after BMSW has had sufficient time to stabilize, which is a wearing interval of greater than 20 minutes. We chose to test a wearing period of 20 minutes because we reasoned that participants were unlikely to comply with longer wearing periods first thing each morning before rising, for a whole menstrual cycle.

Despite the apparent potential for high temperature-measuring precision and consistent data, the wide range of temperatures measured by BMSW both within and between participants suggests, as with any external measurement, that it can be affected by environmental and perhaps individual physiological factors. Study participation occurred from June-September, correlating with the Australian winter. It is possible that different levels and mechanisms of heating were used by different participants or on different occasions. The wide range is also likely to have been caused by confounding factors such as not wearing the device correctly on some nights, variation in bedding and sleepwear used, alcohol consumption, variability in the time when the temperature was taken, or variability in sleep duration. Participants were asked to record whether they fell ill throughout the course of the study or had abnormal waking times, which are two potential effectors of skin temperature. However, information was not available relating to other possible confounding factors, such as whether they slept in the same room or whether they slept alone or with a partner during the study. This demonstrates the difficulty in controlling studies involving body temperature, which is an issue not only presenting itself now with BMSW or skin temperature but is repeatedly observed when using the BBT method [5].

This study aimed to evaluate the potential of mobile monitoring devices such as BMSW to obtain evidence of ovulation by detecting the upward shift in BBT that accompanies this important physiological event. Given suggestions that continuously measured skin temperature, a function BMSW can perform, is linearly reflective of core body temperature [11], it was hypothesized that, under basal conditions, BMSW would be comparable to the traditional method of a thermometer in detecting the upward shift in BBT.

However, given the modest correlation that we found between the benchmark clinical method of digital oral basal temperature measurement and BMSW-determined basal skin temperature measurement, it seems unlikely that the BMSW is a suitable device for clinical monitoring of ovulation in a population of young women such as we studied. We cannot draw more definitive conclusions on this point for several reasons. First, only a minority of participants (25%) completed data collection for a full menstrual cycle. Second, standard quantitative clinical criteria for ovulation (quantitative mean temperature method [15]) were met in only one third of participants, which is appreciably lower than would have been predicted in such a population [18]. Quantitative and visual analysis of charts of the temperatures recorded by the thermometer and BMSW over the course of each participant's menstrual cycle provided little support for the main hypothesis. When analyzed quantitatively, BMSW showed very poor agreement with the thermometer (kappa=.0816, agreement=60%). A notable observation from the quantitative analysis was BMSW's inability to detect evidence for ovulation in any participant, while thermometer temperatures deemed 5 participants ovulatory.

Patterns of participant behavior suggest low compliance with the BBT method. For instance, a high number of participants frequently omitted taking their temperature throughout the study or did not commence the study. Thus, it is possible that the apparently small number of ovulatory participants is the result of low participant compliance and the subsequent incorrect and ineffective use of the BBT method. Hence, our findings suggest that the methods evaluated may not be suitable for the monitoring of menstrual cycles or documenting ovulation in the demographic studied. It may be that outcomes would be better in a sample of young women more motivated to document their menstrual cycles, for example, due to a desire to achieve pregnancy.

Strengths and Limitations

Strengths of this study include its novelty: limited research has been carried out on the use of continuously measured skin temperature in monitoring ovulation. Moreover, although validated in many other areas of health, at the time of this study no research had been published on the use of BMSW in detecting ovulation or investigating reproductive health in general. The data comparing oral digital thermometer measurement of basal temperature with the use of BMSW temperature readings provided strong if not conclusive evidence that BMSW data were unlikely to be useful for basal temperature monitoring across the menstrual cycle. Limitations of the study included the volunteer nature of the sample studied, so that findings could not be generalized to the entire population of young Australian women, the inability to monitor independently that participants followed all aspects of the study protocol, and that the number of participants completing data collection did not allow an adequate evaluation of the ability of the methods tested to detect ovulation. Another limitation of the study was the lack of more sensitive measures to verify ovulation.

Due to the apparent lack of compliance with the methodology by this particular demographic of young women and the small number of participants, it is possible that the results are not entirely reflective of the BMSW device's performance. Hence, piloting the methodology on a demographic more likely to follow the methodology correctly could be of value. For instance, studies could involve groups who are highly motivated to monitor ovulation, such as women attempting to conceive or who have presented with infertility. Moreover, when considering BMSW's potential as a research tool in reproductive health and menstrual cycle research, the device's galvanic skin receptor sensor could be applicable in menopause research related to vasomotor symptoms.

Conclusions

This study demonstrated the importance of evaluating bio-measures collected using mobile monitoring devices by comparison with standard methods. It revealed a relatively poor correlation between BMSW and oral thermometer temperature readings and suggested that BMSW is unlikely to detect an upward shift in basal body temperature. Participant behavior suggested poor compliance in the use of BMSW for basal temperature measurement and that the basal body temperature method may not be suitable for use in unselected samples of young women. Our findings point to the need for simple, low-cost, self-administered methods for monitoring the menstrual cycle that are appealing to and accepted by young women.

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Conflicts of Interest

None declared.

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Abbreviations

BA: Bland-Altman
BBT: basal body temperature
BMSW: BodyMedia SenseWear
HPV: human papillomavirus
MTM: mean temperature method
OCP: oral contraceptive pill
VACCINE: Vaccine Against Cervical Cancer Impact and Effectiveness Study
YFHI: Young Female Health Initiative

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Original Paper

Views of Women and Health Professionals on mHealth Lifestyle Interventions in Pregnancy: A Qualitative Investigation

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Abstract

Background: Evidence suggests that women are failing to meet guidelines for nutrition, physical activity, and weight gain during pregnancy. Interventions to promote a healthy lifestyle in pregnancy demonstrate mixed results and many are time and resource intensive. mHealth-delivered interventions offer an opportunity to provide trusted source information in a timely and cost-effective manner. Studies regarding women's and health professionals' views of mHealth in antenatal care are limited.

Objective: This study aimed to explore women's and health professionals' views regarding mHealth information sources and interventions to assist women to eat well, be physically active, and gain healthy amounts of weight in pregnancy.

Methods: A descriptive qualitative research approach employed focus groups and in-depth interviews with 15 pregnant or postpartum women and 12 in-depth interviews with health professionals including two from each category: obstetricians, general practitioners, midwives, dietitians, physiotherapists, and community pharmacists. All interviews were transcribed verbatim and thematically analyzed.

Results: Women uniformly embraced the concept of mHealth information sources and interventions in antenatal care and saw them as central to information acquisition and ideally incorporated into future antenatal care processes. Health professionals exhibited varied views perceiving mHealth as an inevitable, often parallel, service rather than one integrated into the care model. Four key themes emerged: engagement, risk perception, responsibility, and functionality. Women saw their ability to access mHealth elements as a way to self-manage or control information acquisition that was unavailable in traditional care models and information sources. The emergence of technology was perceived by some health professionals to have shifted control of information from trusted sources, such as health professionals and health organizations, to nontrusted sources. Some health professionals were concerned about the medicolegal risks of mHealth (incorrect or harmful information and privacy concerns), while others acknowledged that mHealth was feasible if inherent risks were addressed. Across both groups, there was uncertainty as to who should be responsible for ensuring high-quality mHealth. The absence of a key pregnancy or women's advocacy group, lack of health funds for technologies, and the perceived inability of maternity hospitals to embrace technology were seen to be key barriers to provision. Women consistently identified the functionality of mHealth as adding value to antenatal care models. For some health professionals, lack of familiarity with and fear of mHealth limited their engagement with and comprehension of the capacity of new technologies to support antenatal care.

Conclusions: Women exhibited positive views regarding mHealth for the promotion of a healthy lifestyle in antenatal care. Conversely, health professionals expressed a much wider variation in attitudes and were more able to identify potential risks and barriers to development and implementation. This study contributes to the understanding of the opportunities and challenges in developing mHealth lifestyle interventions in antenatal care.

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KEYWORDS

pregnancy; attitude; qualitative research; mHealth

Introduction

Nutrition, physical activity and gestational weight gain (GWG) during pregnancy can impact both a woman's and offspring's short and long-term health [1-4]. Pregnant women typically value lifestyle advice [5] and are receptive to opportunistic health promotion interventions during the antenatal period [6]. Despite this, suboptimal physical activity, diet, and GWG are commonly reported [7,8]. Hospital and community-based resources to assist pregnant women achieve better nutrition and physical activity and optimize GWG may be limited [9]. In research settings, there is a growing body of evidence to support the use of interventions promoting diet and exercise, or both, to reduce excessive GWG in pregnancy [10,11], but given many are time and resource intensive, scalability is limited. Novel and sustainable ways to extend the reach to all women are required.

The methods by which women acquire lifestyle information in pregnancy are changing with increasingly accessible health information in digital format [12], while increasing documentation requirements are leading to shorter patient-provider interactions [13]. Lagan and colleagues surveyed 613 pregnant women from 24 countries to explore Internet use and its effect on their health decision-making [12]. Nearly 94% (575/613) of women used the Internet in addition to health professionals to get pregnancy information, and 83% used it to influence their pregnancy decision-making. Arguably, health services have been slow to develop information technology to satisfy the requirements of consumers.

Mobile phones have been widely adopted among all demographic groups and are increasingly used as a platform for delivering programs to support the achievement of health objectives, commonly referred to as mHealth [14]. mHealth offers an opportunity to provide trusted source information and interventions incorporating behavioral change practices through a low-cost, easy access method [14,15]. mHealth utilities used in health interventions have included text message or short message service, apps, video messaging, handheld computers, voice calls, and audio packages [15]. Systematic reviews of interventions using mHealth have found increased adherence to antiretroviral therapy, smoking cessation, engagement in physical activity, and weight loss [15-17].

A recent systematic review of technology supporting dietary and lifestyle interventions in pregnant women found four protocols and three completed studies using telephone, text messaging, video, Internet, and apps [18]. The authors concluded that mHealth interventions hold promise for interactive, practical, accessible, and instantaneous support but that there was a paucity of data on mHealth effectiveness for pregnant women. They recommended further randomized controlled trials supporting health behavior change in real-life clinical settings.

Understanding women's and health professionals' views and attitudes regarding the promotion of healthy nutrition, physical activity, and GWG with mHealth is crucial to assist in the development of practical, time-efficient, and cost-effective ways to promote healthy lifestyles in pregnancy and plan mHealth evaluations [17-19]. A number of papers have emphasized the importance of understanding and incorporating stakeholders' views into design and evaluation [19-22]. In Heron and Smyth's review of mobile technology in psychosocial and health behavior treatments, for example, the authors suggest that interventions need to be more sensitive to the individual characteristics and needs of stakeholders [17]. They argue that incorporating end user and provider feedback into design, implementation, and evaluation will facilitate feasibility and acceptability of interventions.

A small number of recent studies have examined pregnant women's and midwives' views of websites and apps or text messaging to promote healthy nutrition, physical activity, and GWG in pregnancy [20-22]. These studies demonstrated an interest among women [20-22] and midwives [20] for text messages [20,21], apps, and websites [22]. Soltani and colleagues used focus groups of women and midwives to understand their perspectives on the design of text messaging support for maternal obesity services [20]. Three main constructs emerged: benefits, risks and limitations, and service delivery of a text message program. Further, participants suggested the use of technology platforms such as Web-based services in addition to text messaging for weight management in pregnancy. The authors used these results to construct a small pilot text messaging intervention [23]. We are unaware of studies exploring other health professional stakeholder views, for example, those of dietitians, physiotherapists, general practitioners, pharmacists, and obstetricians in addition to midwives. Opportunity exists to broaden understanding of views on how mHealth and its range of technology platforms could be used to promote healthy lifestyles in antenatal care.

This study aimed to explore women's and health professionals' views regarding mHealth information sources and interventions to assist women to eat well, be physically active, and gain healthy amounts of weight in pregnancy.

Methods

Design and Ethics

A qualitative, descriptive research methodology [24,25] using face-to-face semistructured interviews and focus groups was employed to obtain in-depth data from consenting participants. Ethics approval was obtained from Deakin University (2013-213) and Mercy Hospital for Women (R13/27) Human Research Ethics Committees.

Study Participants

The study recruited pregnant or postpartum women from antenatal clinics in a tertiary level maternity hospital in Victoria, Australia, and proceeded to increase the number of participants using snowball sampling [26]. To ensure that views from a broad range of health professionals were included, two each of the following categories were purposively sampled [27] from both Victoria and Queensland: obstetricians, general practitioners, midwives, dietitians, physiotherapists, and community pharmacists. The sample size was limited by budget and informed by similar studies with midwives [20]. Women and health professionals were invited to participate in interviews or focus groups via written or face-to-face invitation.

Data Collection

Focus groups and face-to-face interviews with women and face-to-face interviews with health professionals were conducted by JW and PvdP using standardized interview guides (see Multimedia Appendix 1). The interview only methodology with health professionals was chosen for pragmatic time-related reasons. The lack of focus group interaction among health professionals, potentially yielding less in-depth interactive information, is acknowledged as a potential limitation.

The content of the interview guides was informed by the literature, including correlates of healthy pregnancy lifestyles [28], predictors of health behaviors [29], successful elements of pregnancy lifestyle interventions [10], and mHealth interventions [15] and the uses and gratification theory, a theory of media usage [30]. Semistructured and structured questions to elicit women's and health professionals' views, attitudes, and practices around mobile phones and mHealth, as well as their thoughts on optimal interventions, were investigated during the interviews and focus groups. A visual diagram including text messaging, social networking, video messaging, websites, print media, and health professional interaction was used to provide a guide to direct the discussion (Multimedia Appendix 1).

Common themes explored included mHealth's suitability and viability to provide healthy lifestyle advice and support to pregnant women, mHealth inclusion in antenatal care, use and suitability of mHealth elements, barriers and facilitators to mHealth development and implementation, and inclusions and exclusions in a program to support healthy lifestyle advice. In addition, sociodemographic characteristics of all participants were collected, as well as data on women's parity and the health professional's role and length of employment in their profession. The interviews were digitally recorded with the consent of the participants and transcribed verbatim.

Data Analysis

Data immersion, coding, category creation, and thematic analysis were used to find patterns of meaning across data sets [31,32]. The researchers JW and PvdP used an inductive approach to derive themes through interpretations of the raw data [33]. Coding categories and subcategories were allocated by the two independent researchers, and the congruence was assessed and found to be good. Discrepancies were discussed and resolved to reduce researcher bias during the thematic development phase. Both researchers agreed on the final category system and accepted it as being representative of the data.

Results

Participants

Fifteen women participated in either one of two focus groups (n=7) or an interview (n=8). Three additional women declined participation. Eleven of the women were pregnant and four postpartum (5-18 months). The mean age of the women in the study was 31.5 years, two were born outside Australia, nine were first-time mothers, and all but one owned a mobile phone. Two health professionals from each group—obstetricians, general practitioners, midwives, dietitians, physiotherapists, and community pharmacists—participated and averaged 8.3 years (range 4-27 years) practice in their current professions; all owned mobile phones. All health professionals approached participated in the study. Construct saturation, representation of content area, was reached with the women at 13 participants but interviews continued to confirm saturation. Similar saturation was reached for health professionals at 12 participants. The health professional quotes have not been differentiated due to the possibility of interviewee identification and thus breach of anonymity.

Emergent Themes

Overall

Women uniformly embraced the concept of mHealth-based interventions in antenatal care and saw them as central to information acquisition and in future antenatal care processes. The health professionals exhibited a wider variation in views towards mHealth in antenatal care. They saw it as an inevitable but often parallel service rather than integrated into the care model. Four key themes (Textbox 1) emerged from both women's and health professionals' data: engagement, risk perception, responsibility, and functionality.

Textbox 1. Themes and subthemes from interviews and focus groups regarding antenatal mHealth programs.

Engagement:

- Good access point
- Women engaged and technically proficient
- Health professionals less engaged and less technically proficient
- Allows wide reach

Perceived risk:

- Familiarity with technology reduced fear of risk for women
- Potential for causing harm and stress for women
- Potential for harm to professional integrity of health professionals and organizations
- Shifting control of information

Responsibility:

- Responsibility of government, health services, and health professionals
- Barriers included lack of advocacy, funds, information technology know-how, and commercial application

Functionality:

- Role in antenatal care
- Multiple technology elements
- Optimize user engagement and experience
- Evidence-based, practical content and delivery

Theme 1: Engagement and Access

Mobile phones were uniformly seen by both groups (health professionals [HP] and women [W]) to be a good access point for intervention programs with pregnant women, including at-risk women who may not attend antenatal visits.

> *I like to receive things on my phone, I like regular updates.* [W8, focus group]
>
> *Every person that comes in here has either a smart phone or an iPhone. It doesn't matter what nationality or how poor they are, they've all got (one) and the most up-to-date one.… It's capturing the people that miss out…the marginalized people that always slip through the system, you can catch them.* [HP6]

All women and some health professionals acknowledged that women were already engaged with health-related technology and wanted mHealth products to use. Some women considered their ability to access mHealth and related technology as providing an important adjunct to their traditional medical care. Future development of mHealth programs was seen to augment this. There was an acknowledgement from four health professionals that women were potentially more technically savvy than health professionals.

> *An [mHealth] concept would fill a gap since no one mentioned nutrition or anything barely to me in the medical profession. They seem to think it's not their domain…so it would be good to fill the gap.* [W9, interview]
>
> *Women are incredibly technical…they will be keen or interested because I see it all the time. They say to me, "Where shall I go, what should I eat, what websites or apps?"* [HP1]

While phones or mobile devices were acknowledged to be good methods to communicate with women, some health professionals' dislike of or unfamiliarity with technology limited engagement and understanding of the capacity of new technologies to support care.

> *a lot of my [health professional] cohorts wouldn't be as engaged with all of that.* [HP4]

There was concern expressed by some health professionals for the minority of women who may not have mobile or Internet access and the need to provide alternatives.

> *I think most people nowadays have access. There'll always be a small group of people that are disadvantaged and so you need a print back-up but I do think it's the way of the world now.* [HP12]

The scalability of an mHealth product was seen to be important for the wide engagement of women. Mobile phones or tablets functions were seen to reach a wider audience than traditional methods.

> *It should be able to be rolled out to the whole country.* [W12, interview]
>
> *Where does that go in the long term, and how can [mHealth] be scaled and controlled to be a beneficial way of providing support to women?* [HP4]

Theme 2: Perceived Risk

Many women appreciated the risks involved in accessing technology and in the development of an mHealth model. Many saw themselves as having the capacity to evaluate and select information to suit their situation and the ability to sift out noncredible information.

> *I make sure I know it's a trusted source. I know the trusted [sources] so I just kind of go off them if there is something I need to know.* [W8, focus group]

Many health professionals and two women were concerned about the medicolegal risks of technology. These risks were divided into two categories: harm to women (incorrect or harmful information, privacy concerns) and harm to the personal or professional integrity of health professionals and health organizations (intellectual property, privacy, and legitimacy concerns). This group was also worried that an intervention program may cause harm or stress to women. Two health professionals expressed unease about messages being shared out of context and misinterpreted by other pregnant women.

> *As a health care professional, I'm just mindful that if there was a video of me up there talking, if that was taken out of context or shared with another person where that information was not appropriate, that's a concern to me.* [HP9]

> *This is a new era…we can't tell them which technologies [websites, apps] are bad [and good]…because we'll get sued.* [HP1]

A small number of health professionals and women were concerned that not meeting an mHealth program's expectations may be stressful for women. One health professional commented on the changing needs of women during pregnancy, where advice may change depending on a medical situation or potential for harm.

> *Some women might find it [an mHealth program promoting a healthy lifestyle] anxiety provoking.* [W9, interview]

> *If you get someone that's early in their pregnancy, but then they develop a medical problem or say pelvic girdle pain, I'm thinking it wouldn't be appropriate to tell them to take the stairs, because that'll actually make their pain worse. So do you have the ability to pull them out or change it?* [HP9]

Four health professionals discussed the perceived detrimental effects to the health professional–patient relationship with the advent of health-related technology and the shifting of control of information from trusted to nontrusted, including commercial, sources. Future mHealth programs were seen by some to potentially continue the trend of information contradiction and control. Three health professionals questioned mHealth programs taking control or legitimacy away from on the ground health professionals, but others saw future evidence-based mHealth programs being able to wrest this control back. Further, two health professionals expressed concerns about the risk of losing control of information provision with commercialization of lifestyle education mHealth programs and questioned who would ultimately benefit.

> *The Internet [and other technologies] have more legitimacy than [HPs] or written info.* [HP6]

> *You're encroaching on dietitians' territory here…a dietitian might get upset if somebody else was doing it.* [HP3]

Theme 3: Responsibility for mHealth

Across both groups there was uncertainty as to who should be responsible for ensuring high-quality interventions via mHealth. Many women and health professionals suggested that maternity hospitals, general practitioners, or government health departments should take responsibility for mHealth in pregnancy to ensure legitimacy of the information provided and accessed.

> *I think hospitals need to get the right information out there so that they're not having all these women find bits and pieces everywhere else.* [HP10]

> *I think it should be introduced at the first antenatal visit [by maternity hospitals], with health professionals recommending and advising on it.* [W13, interview]

The absence of a key pregnancy or women's advocacy group, lack of health funds for technologies, and the perceived inability of maternity hospitals and governments to embrace technology were seen to be key barriers to provision. The lack of commercial apps for such a program was seen to also be an obstacle to gain funding.

> *Health in Australia has been slow to pick up the [technologies] and partly because they're a little bit scared.…All the [technologies] that the public knows have accessibility in the public realm and are visible, say the National Heart Foundation. Pregnancy doesn't have that.* [HP11]

> *I totally agree with [mHealth], but I think it comes down to the concept of funding—who's going to fund it? …I have a lack of confidence in government doing it based on past experience with IT.* [HP5]

Theme 4: Functionality

Women consistently identified the functionality of technology as adding value to antenatal care models. All women were able to comment on different elements and interactions they desired in a mHealth program. While some health professionals were able to discuss elements of mHealth and service delivery concepts, for others unfamiliarity with technology and fear of loss of control of the information provision limited their engagement with and comprehension of the capacity of new technologies.

Role in Antenatal Care

There was a distinct difference between the two groups as to whether mHealth could be integrated into or should augment traditional antenatal care. Women's use of current technologies allowed them to envisage mHealth inclusion in traditional care.

> *[mHealth] should be included in your first visit to the midwife at the hospital. Just take a consent…and sign her up.* [W2, focus group]

> *being supported by the technology helps, because you've got that personal interaction to start explaining it and getting people kind of aware and engaged and know what's going on before [using] technology.* [W12, interview]

Some health professionals viewed mHealth as adding value to the consult with some suggesting that it could help direct women away from the nontrusted sources of information. Two health professionals expressed views about mHealth not having anything to offer antenatal care in comparison to face-to-face interactions

> *I could see myself saying that there's this brilliant thing that will help you coordinate your diet and exercise for the pregnancy.… I don't have the time and resources to go into that and most people are savvy enough.* [HP11]

> *They want to be listened to, they want to know that they have been heard. And we can't do that from a text message or an app. And that's what they like about coming in and getting that face to face.* [HP1]

Many health professionals commented that an mHealth program needed to be introduced by health professionals and adjunct to health professional care. Health professionals viewed a program to be optimized by personal connection and written information to guide the user. Some women perceived a benefit in this type of combined approach but many were concerned by the time that this would take and viewed their technological abilities as adequate to adopt a program without instruction.

> *You have to create a connection with them before they start using it.* [HP1]

> *The face-to-face midwife, I don't know, it would depend on…how much it's taking out of our time.* [W8, focus group]

Multiple Technology Elements

Integration of Technology Elements

Both groups articulated that the individual requirements of women would be best served by programs or interventions that integrated multiple technology elements. This was also seen to serve the needs of different learning styles.

> *I like the concept of a one-stop shop [with different platforms]…across different mediums. So it's for every woman—every pregnant woman can gain something from this.* [W15, interview]

> *People respond to different things. You want to maintain that amount of professionalism so they see that it is a good service but this whole social media friendship, community thing, people relate to that now too, more than they used to.* [HP12]

Websites

Websites were seen to have greater depth of information than other platforms such as apps or text messages. The website concept was the most familiar mHealth element to most health professionals, whereas the majority of women saw the website as a back-up for alternate platforms including texting, apps, and social media.

> *It needs to be easy to access…but there's so many websites and you have to login so much yeah passwords…whereas if it came up in your Facebook feed it's just there. Or even just link to the website in a text, like it just took you straight there rather than, oh I need to remember to check that website once every week.* [W8, focus group]

Video Messages

Video messages were seen by both groups to aid visual learning, but there were concerns from two women that there may be an incurred cost. Two women commented that they would prefer reading to video messages.

> *I like the ideas of video messages.… Video messages can be so much more engaging. As long as they are not too long [to view on my phone].* [W15, interview]

Apps

No health professionals were aware of health promotion apps focused on pregnancy. Some women familiar with apps saw benefits with ease of access and provision of food, exercise, and weight tracking features. Two women commented that they had many apps that they never used.

> *I'd probably use an app. It would be good as a journal.* [W8, focus group]

> *I have so many apps on my phone, I never use them.* [W5, focus group]

Texts

Text messages were seen by all to be an avenue to communicate with women directly. Texting attributes noted included the ability to remind, motivate, and engage.

> *Using texts to reiterate that kind of information that you might have been told or might have actually read about but it will have gone out of your mind already.* [W15, interview]

One woman expressed concern that text messages intruded into other areas of life including paid work.

Social Networking or Forums

While social networks or forums were seen as a convenient way to create communities where common interests could be explored, some women were apprehensive that other women may be unsupportive or may make them feel anxious. The many opinions expressed on current social networks were seen to be overwhelming for some. The need for health professional moderation of social networks or forums was articulated by many. Some health professionals verbalized their fears of privacy breaches with social networks while others understood that if women were engaged in social networks, they had already accepted the privacy issues.

> *Forums are a good way to get the information across, and then people can make their own decision. You can check any time of the day. You can be involved as you want as well…* [W2, focus group]

> *I think there's a lot of assumption that women are really supportive of other women. But I'm not sure that that's actually the case when it comes to pregnancy and babies. There's a lot of competitiveness and guilt.* [W9, interview]

Optimizing User Engagement and Experience

Optimizing the user experience was seen to be crucial for an effective mHealth program. Both groups appealed for ease of access and use. Ideas to maximize engagement and motivation of women centered around tailoring and personalizing the intervention with messages concerning the baby's development, content related to women's interests, and presentation tailored to the technology platform. There appeared to be no ideal frequency of contact, with some women suggesting a preference of less than weekly contact and others preferring daily contact.

> *It might be, okay I'm not doing this for myself, I need to do this for someone else as well maybe.… It might just be a little bit extra of an influence, motivation to get out and do something.* [W8, focus group]

> *It's good if you are tailoring it.… Because I would think that generic messages would be quite annoying if they're not specific to you.* [HP9]

Evidence-Based, Practical Content and Delivery

The need for continually updated, evidence-based information was voiced by both health professionals and women as fundamental to earn trust of women and health professionals. Some women and one health professional saw the "drip feeding" of information and engagement available with technology platforms as desirable in comparison to the chunking of information in print or oral forms. The suggestions for content were focused on the practical, including recipes, menus, and exercise plans.

> *[mHealth] should be shown to be based on up-to-date research…that you don't have to question and think that they're trying to sell me something or they're anti-abortionists.* [W9, interview]

> *You hit all the key messages in the beginning…and they're repeated at spaced-out intervals.* [W7, focus group]

There were differing views about who would be the best people to deliver information to women. Health professionals remarked that they had the credibility to deliver the information, which most women agreed with. Women reported mixed feelings about hearing from peers and their experiences. Listening to other women on social media was viewed by many to have created negative peer experiences for some, while others were happy to hear from peers if they were in a similar situation.

> *I think that the women want it from health professionals as opposed to peers because…otherwise she feels that she'd be judged.… I'm here as a health professional to help support them…and not judge them.* [HP6]

> *It's nice to hear about other people's experience, to put your mind at ease, but when you are taking advice, that's a little bit different.* [W8, focus group]

Discussion

Principal Findings

This qualitative descriptive study aimed to explore women's and health professionals' views regarding a wide range of mHealth-based information sources and interventions promoting a healthy lifestyle in pregnancy. The study found that women held, in general, positive views of mHealth in promoting healthy nutrition, physical activity, and GWG in pregnancy. Health professionals' views appeared more mixed and less positive overall, although some saw benefits of mHealth in antenatal care. The current study adds to the literature by highlighting stakeholder issues related to development, implementation, and evaluation of mHealth interventions and affirms the use of formative research as highlighted by others [19].

Variations in levels of interest for mHealth between health professionals and women were demonstrated in this study. Women consistently voiced enthusiasm for information technology integration in antenatal care and were able to describe development and implementation issues and information useful for inclusion. While some health professionals were positive regarding the potential for use of mHealth in antenatal care, others quickly identified perceived risks and barriers for implementation and were more likely to see mHealth as a service that would be used in parallel to face-to-face care. The diversity of health professionals' attitudes in this study is consistent with other work considering professional views of mHealth in pregnancy [20] and primary health care interactions [34]. Although some health professionals regard technology as having the potential to improve patient knowledge and outcomes and enhance the patient-health professional relationship [34], Soltani and colleagues suggested that midwives were quick to identify limitations and risks due to these concerns being in line with their professional code of conduct of doing no harm [20]. In our study, lack of familiarity with technology, negative past interactions with women using technology, and fear of loss of information control also appeared to be associated with the concerns raised by health professionals. However, these are at odds with the finding that technology has the potential to improve patient knowledge and outcomes and enhance the patient-health professional relationship [34]. Further research is required to address health professionals' concerns and teach the benefits of technology integration in antenatal care when developing models.

Women and health professionals in this study expressed the desire for multiple technology elements within an intervention as a way to broaden engagement and reach across various modes of technology and different learning styles. Further, it is likely that more than one element will be required to address the multiple components that together facilitate behavior change [29]. For example, websites may display large quantities of information most clearly, but social media or forums may provide a better avenue for peer support [35]. With mHealth still in its infancy, interventions have relied on using stand-alone technology platforms like text messaging and apps rather than using these features in combination with other opportunities afforded by mHealth. There has been a call for increasing the

complexity of elements employed in mHealth interventions to fully exploit the functionality of portable devices and create more potent interventions [36,37]. Evidence suggests that greater engagement and improved health behavior outcomes may be facilitated by the utilization of more than one technology element [38]. It is acknowledged that increasing the complexity of mHealth interventions often increases financial, time, and resource costs. Over the last decade, new models for building and evaluating behavior change interventions have been proposed, with multiphase optimization strategy and sequential multiple assignment randomized trial designs offering promise [37]. Further research is required to understand the best combinations of technology elements to most efficiently elicit behavior change in different populations.

In this study, women expressed wide variability on acceptable rate of contact from an intervention, ranging from once per week to every day. For intervention developers, tension exists between communicating sufficiently to effect behavior change but not excessively to result in disengagement or adverse health outcomes such as stress. While more intensive interventions are associated with greater effect [39], this study and others [40] have found participants questioning the intrusiveness of intense interventions. This study supports the notion that tailoring interventions is crucial to suit women's needs. It remains unclear as to how mHealth interventions can provide accurate and timely information and feedback without adverse effects on engagement [40]. Process and engagement evaluation from mHealth antenatal interventions will offer more insights in the future. A forerunner to this research is a (yet unpublished) process evaluation from the eMoms roc study [41]. The authors found differing engagement patterns by demographic and weight status subgroups. Future engagement evaluation coupled with outcome results has the potential to offer sophisticated insights for intervention targeting and development.

Peer or social support has been identified in weight-related interventions as central to successful health behavior change [29,42]. In the study, some women expressed concerns and cynicism about the helpfulness of peer support through groups, social media, or chat rooms and the role-modeling of behaviors by other women. The concerns appeared to be associated with negative social media experiences. Mixed findings have been reported in other research [43]. In a qualitative study with 35 overweight adults in the United States, real-time social or peer support through a virtual community was identified as a key benefit to mHealth interventions [43]. Conversely, a qualitative study with 19 students and staff at Southampton University in the United Kingdom demonstrated negative attitudes towards peer support in health promotion programs [40]. The authors of the UK study highlighted the need to investigate how to foster engaging and enjoyable social support environments in interventions.

Strengths and Limitations

A strength of this study was the innovative approach including women and a wide range of health professionals to investigate opinions on mHealth in antenatal care. The broad range of those interviewed was unique and covered the range of health professionals who would see women from early pregnancy (community pharmacists) to birth (midwives and obstetricians). Conversely, having only two representatives for each health professional role may be viewed as a limitation. While construct saturation was reached, mHealth issues specifically related to their professions were not explored. Future research expanding and contrasting specific health professional views may be warranted.

The inclusion of focus group discussions and individual interviews with women utilized the positive aspects of each qualitative method. The interview-only methodology with health professionals was chosen for pragmatic reasons, and the lack of focus group interaction may have provided less in-depth, interactive, or rich information than was observed with the cohort of women [44]. The regional nature of sampling may place some limits on the generalizability of the outcomes. However, the similarity of findings overseas with midwives [20] suggests that many of the issues discussed may be commonplace.

Conclusions

This study found generally positive perceptions concerning mHealth for the promotion of healthy nutrition, physical activity, and GWG in antenatal care among women. Conversely, health professionals expressed a much wider variation in views and attitudes and were more able to identify potential risks and barriers to development and implementation. While most women could picture mHealth as an integral element in antenatal care and were able to identify variables required, health professionals were more likely to see mHealth as a parallel entity. These are unique data in the Australian context. In addition to improving the knowledge base, this research contributes to our understanding of the opportunities and challenges of developing mHealth interventions in antenatal care. Further, this study provides a foundation to inform the development of mHealth approaches that might be trialed in future studies.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Questions and diagram used in focus groups and interviews.

[PDF File (Adobe PDF File), 45KB - mhealth_v3i4e99_app1.pdf]

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Abbreviations

GWG: gestational weight gain

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Original Paper

Dutch Young Adults Ratings of Behavior Change Techniques Applied in Mobile Phone Apps to Promote Physical Activity: A Cross-Sectional Survey

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Abstract

Background: Interventions delivered through new device technology, including mobile phone apps, appear to be an effective method to reach young adults. Previous research indicates that self-efficacy and social support for physical activity and self-regulation behavior change techniques (BCT), such as goal setting, feedback, and self-monitoring, are important for promoting physical activity; however, little is known about evaluations by the target population of BCTs applied to physical activity apps and whether these preferences are associated with individual personality characteristics.

Objective: This study aimed to explore young adults' opinions regarding BCTs (including self-regulation techniques) applied in mobile phone physical activity apps, and to examine associations between personality characteristics and ratings of BCTs applied in physical activity apps.

Methods: We conducted a cross-sectional online survey among healthy 18 to 30-year-old adults (N=179). Data on participants' gender, age, height, weight, current education level, living situation, mobile phone use, personality traits, exercise self-efficacy, exercise self-identity, total physical activity level, and whether participants met Dutch physical activity guidelines were collected. Items for rating BCTs applied in physical activity apps were selected from a hierarchical taxonomy for BCTs, and were clustered into three BCT categories according to factor analysis: "goal setting and goal reviewing," "feedback and self-monitoring," and "social support and social comparison."

Results: Most participants were female (n=146), highly educated (n=169), physically active, and had high levels of self-efficacy. In general, we observed high ratings of BCTs aimed to increase "goal setting and goal reviewing" and "feedback and self-monitoring," but not for BCTs addressing "social support and social comparison." Only 3 (out of 16 tested) significant associations between personality characteristics and BCTs were observed: "agreeableness" was related to more positive ratings of BCTs addressing "goal setting and goal reviewing" (OR 1.61, 95% CI 1.06-2.41), "neuroticism" was related to BCTs addressing "feedback and self-monitoring" (OR 0.76, 95% CI 0.58-1.00), and "exercise self-efficacy" was related to a high rating of BCTs addressing "feedback and self-monitoring" (OR 1.06, 95% CI 1.02-1.11). No associations were observed between personality characteristics (ie, personality, exercise self-efficacy, exercise self-identity) and participants' ratings of BCTs addressing "social support and social comparison."

Conclusions: Young Dutch physically active adults rate self-regulation techniques as most positive and techniques addressing social support as less positive among mobile phone apps that aim to promote physical activity. Such ratings of BCTs differ according to personality traits and exercise self-efficacy. Future research should focus on which behavior change techniques in app-based interventions are most effective to increase physical activity.

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KEYWORDS

motor activity; self efficacy; exercise; behavior therapy; cell phones

Introduction

Despite its well-known benefits, 31% of adults worldwide and 40% of Dutch adults do not engage in sufficient physical activity [1-3]. In early adulthood (18-30 years of age), levels of physical activity often decline from childhood levels [4-6]. Therefore, widely available, effective, and affordable public health interventions are needed to promote physical activity in this age group.

In 2013, 59% of Dutch young adults owned a mobile phone [7]. As ownership and utilization of mobile phones increase, more people are accepting the use of mobile health apps and the popularity of physical activity apps is increasing [8,9]. In January 2015, the iTunes and Google Play stores contained 40,868 and 43,092 health and fitness apps, respectively [10,11]; such apps may be useful for promoting physical activity.

There is, however, limited evidence on the effectiveness of app-based interventions; previous research shows that Web-based interventions grounded in behavior change theory are more likely to be effective [12], but most presently available apps aiming to promote physical activity are not theory-based and do not address the most important behavioral determinants [9,13,14]. Previous research also indicates that self-efficacy and social support are both associated with physical activity and should be addressed when aiming to increase physical activity behavior [15]. Furthermore, previous research suggests that individually tailored health messages may be more effective than nontailored generic messages [16-19].

Behavior change techniques (BCTs) are systematic procedures included as an active component of an intervention designed to change behavior [20,21]. BCTs aim to address behavioral determinants such as self-efficacy. Michie et al [22] developed the Behavior Change Technique Taxonomy (v1) of 93 Hierarchically Clustered Techniques; they reported that self-regulation techniques (eg, self-monitoring, action planning, providing instruction, reinforcing effort toward behavior, goal setting, goal reviewing, and providing feedback on behavior) and planning social support or social change [23-26] appear to be mainly important to increase self-efficacy and social support for physical activity in individual, group, or community-based interventions. Middelweerd and colleagues [14] observed that the BCTs most frequently used in apps were self-regulation techniques (eg, goal setting, self-monitoring, and feedback on performance); furthermore, Direito et al [13] reported similar results.

To design tailored and targeted app-based interventions, insight into the preferences of the target population for certain BCTs applied in physical activity apps is of importance. Dennison et al [27] conducted focus group discussions with young adults and found that mobile phone features to track behavior, set goals, review progress, and receive feedback were positively evaluated. Moreover, Middelweerd et al [28] found that students prefer apps that motivate them and provide tailored feedback to achieve their personal exercise goals. Rabin et al [29] combined a quantitative survey with qualitative interviews among adults and found that adults preferred automatic tracking of physical activity and receiving feedback on exercise achievements. However, these three studies were mainly qualitative and conducted with small samples. Ehlers and Huberty [30] took a more quantitative approach and also identified self-regulation techniques as valued features, but in a sample of middle-aged women; thus, quantitative information on BCT ratings in young adults is lacking.

Thus far, studies have mainly focused on general preferences for BCTs. Because BCTs are targeting determinants of behavior, it is interesting to examine whether preferences for specific BCTs are associated with these determinants, such as self-efficacy. Furthermore, Verkooijen and De Bruijn reported [31] that the association between social comparison and physical activity is partly mediated by exercise self-identity in young adult women. Because social comparison is a BCT, the preference for this specific BCT and for other techniques might be associated with exercise self-identity. Moreover, Middelweerd et al [28] reported differences in preferences for goal setting and coaching features among participants meeting physical activity guidelines and those who did not meet guidelines. These results suggest that these preferences are associated with levels of physical activity. Lastly, personality traits are associated with physical activity [32,33], and this relationship may be mediated by behavioral determinants proposed in social cognitive models (eg, self-efficacy). As BCTs are techniques aimed at effectively changing behavioral determinants and subsequent behavior, it may be that personality influences the effectiveness of BCTs, probably due to differences in preferences and use of BCTs. Therefore, we explored the hypothesis that preferences for specific BCTs are associated with personality traits.

The aim of this paper is to explore young adults' ratings of BCTs applied in a mobile phone physical activity app targeting self-efficacy and social support as important correlates of physical activity, and to explore whether these ratings are associated with personality characteristics (ie, personality, exercise self-efficacy, and exercise self-identity) and levels of physical activity.

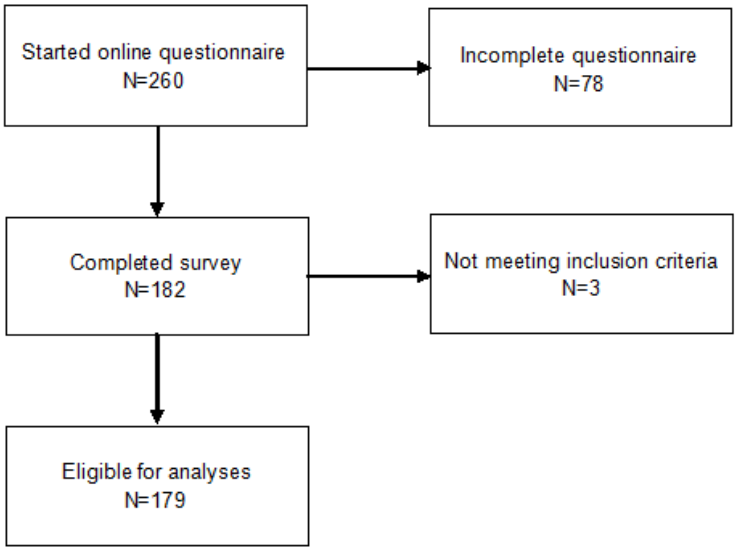
Methods

Design and Recruitment

Apparently healthy (in this case, narrowly defined as the absence of physical impairments) young adults, aged 18-30 years, were recruited to voluntarily complete an open online cross-sectional survey via email, Web-based advertising (eg, websites, social media, notification via the Vrije Universiteit Amsterdam [VU University] online communication platform), printed flyers with a link to the questionnaire (eg, universities, fitness centers,

cafes), and personal approaches (eg, asking participants personally to complete the questionnaire) at both VU University and several secondary vocational education schools. Participants were informed that they would receive an incentive for their participation (ie, an activity tracker worth 90 Euros). Participants were eligible for inclusion if they met the age criteria (18-30 years) and if they did not report physical impairments that limited their physical activity (eg, a doctor's order to not participate in any sports or physical activities); incomplete surveys (n=78) were excluded (Figure 1). A total of 260 individuals agreed to participate, but only 182 completed the survey in April 2014 (a completion rate of 70%). Data for 3 participants who had physical impairments were removed as this most likely influenced their amount of physical activity, leaving data for 179 eligible participants for analyses. The Medical Ethical Committee of VU University Medical Center approved the study. All participants gave informed consent. Seventy-eight participants did not complete the questionnaire, probably due to time constraints or technical issues.

Figure 1. Data selection process for analyses.



Procedures

The questionnaire was primarily based on existing validated instruments [34-37]. When no Dutch version of a questionnaire existed, it was translated into Dutch and back-translated into English by different translators to ensure correct interpretation of questions. The survey was pilot tested among 10 master's students at VU University who met the inclusion criteria of the study. The online survey was administered through Survey Monkey [38] and data were downloaded to SPSS 20.0 (IBM) and filtered for survey completion and eligibility criteria, according to the protocol for online questionnaires (Checklist for Reporting Results of Internet E-Surveys, CHERRIES) [39]. Personal data were deleted to prevent unauthorized access and to ensure privacy.

Measures

The 108-item questionnaire assessed demographics, personality traits [34], exercise self-efficacy [36], social support for physical activity [40], exercise self-identity [41-43], and physical activity levels [37]. Questions were included to indicate participants' ratings of BCTs applied in a mobile phone physical activity app according to the 93-item taxonomy [22].

Behavior Change Techniques

Potentially effective BCTs to enhance self-efficacy and social support for physical activity were selected from the BCT taxonomy of Michie et al [22] and recent literature on potential effective BCTs [23-26,44-46].

First, participants were asked to indicate their general preference for functionalities of an app: a personal coach, self-monitoring of physical activity, both, or neither. Second, ratings of specific BCTs were measured on a 5-point Likert scale (Table 1), for which stronger agreement meant a more positive rating of the BCT. Exploratory factor analysis—principal components analysis with orthogonal rotation—confirmed that the 16 BCTs could be grouped into 3 categories: "goal setting and goal reviewing" (goal setting for behavior, problem solving, goal setting for the outcome of behavior, action planning, reviewing behavior goals, discrepancies between current behaviors and goals, reviewing outcomes of goals, and graded tasks, with factor loadings ranging from .510 to .786), "feedback and self-monitoring" (feedback on behavior and the outcome of behavior, self-monitoring of behavior, and the outcome of behavior, with factor loadings ranging from .635 to .811), and "social support and social comparison" (unspecified practical and emotional social support and social comparison, with factor loadings ranging from .508 to .921). The Cronbach alphas of the newly created scales showed good internal consistency (.86, .81, and .83 for "goal setting and goal reviewing," "feedback and self-monitoring," and "social support and social comparison," respectively). Furthermore, Harman's single-factor test showed that a single factor did not account for the majority of the covariance, indicating that it was not necessary to adjust

for bias due to common method variance. Multimedia Appendix 1 shows details of the factor analysis and Harman's single-factor test. Because of a skewed distribution, the variables "goal setting and goal reviewing" and "feedback and self-monitoring" were dichotomized at the second tertile.

Table 1. Selected behavior change techniques (BCTs) included in the online survey.

Selected BCT[a]	Question included in the survey
Goal setting (behavior)	It is important to me that I can set short-term goals in a PA app
Problem solving	It is important to me that I can solve a problem that holds me back from exercising in a PA app
Goal setting (outcome)	It is important to me that I can set long-term goals in a PA app
Action planning	It is important to me that I can plan my exercise activities in a PA app
Reviewing behavior goal(s)	It is important to me that I have an overview of my exercise goals to improve my PA in the short-term and can review my progress in a PA app
Discrepancies between current behaviors and goal(s)	It is important to me that I can see the difference between my current exercise behavior and my goals in a PA app
Reviewing outcome goal(s)	It is important to me that I have an overview of my long-term PA goal and can review my long-term goal progress in a PA app
Graded tasks	It is important to me that I can start with easy tasks and gradually make the exercise tasks more difficult in a PA app
Feedback on behavior	It is important to me that I get feedback on my level of PA in a PA app
Self-monitoring of behavior	It is important to me that I can monitor my exercise activities in a PA app
Self-monitoring of the outcome(s) of behavior	It is important to me that I can monitor my long-term results in a PA app
Feedback on the outcome(s) of behavior	It is important to me that I get feedback on my long-term results in a PA app
Social support (unspecified)	It is important to me that I can receive advice or support from friends, family, or colleagues in a PA app to exercise more
Social support (practical)	It is important to me that I can receive practical advice from friends, family, or colleagues in a PA app to exercise more
Social support (emotional)	It is important to me that I can be encouraged by friends, family, or colleagues in a PA app to exercise more
Social comparison	It is important to me that I can compare my exercise activities with that of others in a PA app

[a]Behavior change techniques (BCTs) based on the 93-taxonomy of Michie et al [22].

Personality

Personality traits were measured with the Dutch version of the 10-item short form of the Big Five Inventory (BFI) and the Ten-Item Personality Inventory (TIPI). The original TIPI [47] was translated from the English language, back-translated to confirm the translation, and validated among Dutch university students by Hofmans et al [34]. We measured the five tendencies of personality traits: extraversion (E), agreeableness (A), conscientiousness (C), neuroticism (N), and openness (O) [35] using a 7-point Likert scale (1= totally disagree, 7= totally agree) [34,35]. Each TIPI subscale includes 2 items representing opposite poles of each Big Five personality trait and each has a subscale score ranging from 1 to 7 [34].

Exercise Self-Efficacy

Exercise self-efficacy was measured with 12 questions on a 5-point Likert scale (1=I know I cannot, 5=I know I can) based on the Self-efficacy for Exercise Scale [36]. Test-retest reliability for this scale was reported as .68 [36]. Moreover, this study also showed good internal consistency (Cronbach alpha of .90).

Exercise Self-Identity

Exercise self-identity was measured with 4 questions on a 7-point Likert scale (1=totally disagree, 7=totally agree): "Engaging in sufficient exercise is something that fits the way I want to live," "Engaging in sufficient exercise is something that fits who I am," "I see myself as someone who engages in sufficient exercise," and "I am a typical person who engages in sufficient exercise" [34,42,43]. A sum score of these constructs was constructed (ie, range 4-28) and showed good internal consistency (Cronbach alpha of .88).

Physical Activity

Physical activity was assessed with the SQUASH (ie, Short QUestionnaire to ASsess Health-enhancing physical activity), a validated Dutch questionnaire that measures different types and intensity of physical activity [37]. A test-retest analysis (5-week period) showed reproducibility of .58 (95% CI 0.36-0.74), with better reproducibility for high-intensity activities, such as active commuting and leisure time sports, than low-intensity activities, indicating that the SQUASH is a fairly reliable measure [37]. Moreover, the validity of the SQUASH was fair to good, as indicated by a correlation of .45 (95% CI 0.17-0.66) between the SQUASH and activity counts

derived from activity monitors [38]. Physical activity at work or school was assessed in hours/day instead of hours/week and subsequently transformed to scores per week. The scores that were used from the SQUASH questionnaire were total physical activity (min/week) and meeting the Dutch physical activity recommendation (yes or no).

Mobile Phone and App Use

Items were included to measure mobile phone use ("Do you use a mobile phone?" [yes or no]), past mobile phone app use ("Did you use mobile phone apps in the past?" [yes or no]), current mobile phone app use ("Do you use mobile phone apps at the moment?" [yes or no]), and physical activity app use ("Do you use mobile phone apps focused on sports and exercise?" [yes, often; yes, sometimes; yes, seldom; or no]).

Demographics

Age, gender, nationality (ie, Dutch or non-Dutch), current level of education (ie, secondary vocational education, higher education, university, other), current residence, study city, living situation (ie, own place or with parents/family), ability to exercise (ie, yes, yes despite physical activity impairments, no), height (m), and weight (kg) were collected.

Statistical Analyses

Multiple binary logistic regression analyses were used to estimate the association between the different personality characteristics (personality traits, exercise self-efficacy, exercise self-identity, and meeting the Dutch physical activity guidelines) and positive ratings (no, yes) of BCTs addressing "goal setting and goal reviewing" and "feedback and self-monitoring." Multiple linear regression analyses were used to explore the association between personality characteristics and the preference for the BCTs addressing "social support and social comparison." Potential effect moderation was evaluated for meeting the Dutch physical activity guidelines. The models were evaluated for potential confounds of total physical activity (min/week) and body mass index (BMI, kg/m^2). For all associations, $P \leq .05$ indicated a statistically significant association, except for the interaction terms, which were considered significant at $P \leq .10$.

Results

Participant Characteristics

Sample characteristics and mean scores of the independent and dependent variables for the total study population are presented in Table 2. Overall, most participants were female, highly educated, and physically active. Table 3 describes preferences for BCTs in physical activity apps, and Figure 2 describes the physical activity app functionalities desired by participants.

Figure 2. Physical activity app functionalities desired by participants.

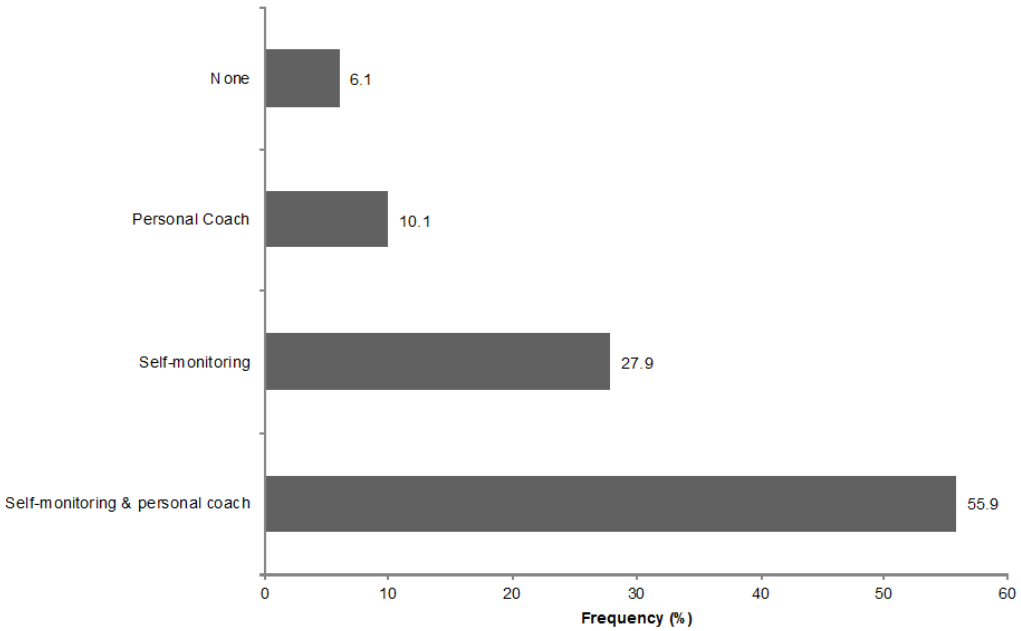


Table 2. Characteristics of participants.

Demographic characteristics		N=179
Gender, male, n (%)		33 (18.4%)
Age (years), mean (SD)		24.33 (±2.76)
Body mass index (kg/m^2), mean (SD)		22.05 (±2.62)
Dutch nationality, n (%)		152 (84.9%)
Current level of education, n (%)		
	Secondary vocational education	5 (2.8%)
	Higher education	33 (18.4%)
	University	136 (76.0%)
	Other	5 (2.8%)
Student, n (%)		118 (65.9%)
	Living situation, on their own, n (%)	150 (83.8%)
	Mobile phone use, yes, n (%)	173 (96.6%)
	Past mobile phone app use, yes, n (%)	171 (95.5%)
	Current mobile phone app use, yes, n (%)	168 (93.9%)
Physical activity app use, n (%)		
	Yes, often	35 (19.6%)
	Yes, sometimes	56 (31.3%)
	Yes, seldom	25 (14.0%)
	No	63 (35.2%)
Preference for BCTs [a]		
	Goal setting, goal reviewing (range 8-40), mean (SD)	31.12 (±6.18)
	Feedback, self-monitoring (range 4-20), mean (SD)	16.60 (±2.75)
	Social support, social comparison (range 4-20), mean (SD)	10.65 (±3.95)
Meet the Dutch physical activity recommendation of at least 30 minutes of moderate physical activity 5 days/week, n (%)		144 (80.4%)
Physical activity hours/week, mean (SD)		
	Total	48.03 (±21.57)
	Moderate to vigorous	16.60 (±17.64)
Exercise self-efficacy (range 12-60), mean (SD)		44.74 (±8.79)
Exercise self-identity (range 4-28), mean (SD)		21.64 (±5.00)
Personality (range 1-7), mean (SD)		
	Extraversion (E)	4.74 (±1.47)
	Agreeableness (A)	5.49 (±0.84)
	Conscientiousness (C)	4.86 (±1.40)
	Neuroticism (N)	3.05 (±1.24)
	Openness (O)	4.88 (±1.24)

[a]Behavior Change Technique.

Table 3. Mean preferences for behavior change techniques (BCTs) in a physical activity app[a].

BCT		Mean (±SD)
Goal setting and goal reviewing		
	Goal setting for behavior	3.84 (±1.13)
	Problem solving	3.46 (±1.31)
	Goal setting for the outcome of behavior	4.18 (±0.93)
	Action planning	3.55 (±1.20)
	Review of behavior goals	3.85 (±1.01)
	Discrepancy between current behavior/goal	4.12 (±1.02)
	Review of the outcome of behavior goals	4.04 (±1.01)
	Graded tasks	4.07 (±0.98)
Feedback and self-monitoring		
	Feedback on behavior	3.93 (±0.95)
	Self-monitoring of behavior	4.41 (±0.75)
	Self-monitoring of the outcome of behavior	4.22 (±0.83)
	Feedback on the outcome of behavior	4.03 (±0.90)
Social support and social comparison		
	Social support unspecified	2.37 (±1.11)
	Social support practical	2.52 (±1.18)
	Social support emotional	2.63 (±1.30)
	Social comparison	3.13 (±1.26)

[a]Rated on a scale from 1 (strongly disagree) to 5 (strongly agree).

Associations With Ratings of BCTs Addressing Goal Setting and Goal Reviewing

Table 4 shows that few personality characteristics were significantly associated with high ratings of the BCTs addressing goal setting and goal reviewing. Meeting the Dutch physical activity guidelines did not significantly moderate the association. "Agreeableness" was significantly positively associated with high ratings of the BCTs addressing goal setting and goal reviewing (OR 1.60, 95% CI 1.06-2.41), indicating that respondents who scored 1 point higher on agreeableness (range 1-7) were 1.60 times more likely to rate this BCT category as important.

Table 4. Association between personality traits and a high preference for behavior change techniques addressing goal setting and goal reviewing[a].

Characteristic		Unadjusted odds ratio (95% CI)	*P*	Nagelkerke R^2	Adjusted odds ratio (95% CI)	*P*	Nagelkerke R^2
Personality traits							
	Extraversion (E)	1.08 (0.86-1.36)	.519	.066	1.06 (0.84-1.34)[b]	.636	.066
	Agreeableness (A)	1.61 (1.07-2.43)	.022		1.60 (1.06-2.41)[b]	.026	
	Conscientiousness (C)	0.86 (0.68-1.08)	.183		0.86 (0.68-1.10)[b]	.237	
	Neuroticism (N)	1.07 (0.82-1.39)	.626		1.04 (0.80-1.37)[b]	.755	
	Openness (O)	1.09 (0.84-1.42)	.513		1.09 (0.84-1.43)[b]	.514	
Exercise self-efficacy		1.00 (0.96-1.03)	.827	<.001	1.00 (0.96-1.03)[b]	.823	.007
Exercise self-identity		0.99 (0.93-1.05)	.649	.002	0.99 (0.93-1.06)[b]	.773	.007
Meeting the Dutch physical activity guidelines		0.83 (0.39-1.78)	.636	.002	0.88 (0.40-1.92)[c]	.747	.006

[a]Categorized on the 2nd tertile (sum score of 8 questions on a 5-point Likert scale; 8-33 considered low and 34-40 considered high preference).

[b]Adjusted for total physical activity (min/week) and body mass index (kg/m^2)

[c]Adjusted for body mass index (kg/m^2)

Associations With Ratings of BCTs Addressing Feedback and Self-Monitoring

Table 5 shows that no significant associations were found between BCT feedback and self-monitoring and exercise self-identity and meeting Dutch physical activity guidelines. A significant negative association was found with "neuroticism" (OR 0.76, 95% CI 0.58-1.00) and a significant positive association was found with exercise self-efficacy (OR 1.06, 95% CI 1.02-1.11), indicating that respondents who scored 1 point higher on neuroticism (range 1-7) were 1.32 times less likely to rate this BCT category as important, and respondents who scored 1 point higher on the 60-point exercise self-efficacy scale were 1.06 times more likely to rate "feedback and self-monitoring" as important BCTs. Meeting the Dutch physical activity guidelines did not moderate the associations.

Table 5. Association between personality traits and a high preference for behavior change techniques addressing feedback and self-monitoring[a].

Characteristic		Unadjusted Odds Ratio (95% CI)	*P*	Nagelkerke R^2	Adjusted Odds Ratio (95% CI)	*P*	Nagelkerke R^2
Personality traits							
	Extraversion (E)	1.10 (0.88-1.39)	.407	.061	1.07 (0.84-1.35)[b]	.585	.073
	Agreeableness (A)	1.10 (0.74-1.61)	.645		1.08 (0.73-1.60)[b]	.705	
	Conscientiousness (C)	0.86 (0.69-1.08)	.188		0.84 (0.70-1.06)[b]	.141	
	Neuroticism (N)	0.80 (0.61-1.04)	.101		0.76 (0.58-1.00)[b]	.054	
	Openness (O)	1.12 (0.86-1.46)	.382		1.12 (0.87-1.46)[b]	.414	
Exercise self-efficacy		1.06 (1.02-1.10)	.003	.071	1.06 (1.02-1.11)[c]	.003	.088
Exercise self-identity		1.04 (0.98-1.10)	.241	.010	1.05 (0.98-1.12)[c]	.157	.029
Meeting the Dutch PA guidelines		0.99 (0.46-2.12)	.983	<.001	1.07 (0.49-2.32)[d]	.867	.007

[a]Categorized on the 2nd tertile (sum score of 4 questions on a 5-point Likert scale, 4-17 low and 18-20 high preference).

[b]Adjusted for total physical activity (min/week)

[c]Adjusted for total physical activity (min/week) and body mass index (kg/m^2)

[d]Adjusted for body mass index (kg/m^2)

Associations With Ratings of BCTs Addressing Social Support and Social Comparison

Data obtained from the linear regression analysis between personal characteristics and ratings of BCTs addressing social support and social comparison (range 4-20) are presented in Table 6. No significant associations were found and meeting the Dutch physical activity guidelines was not a significant moderator.

Table 6. Association between personality characteristics and preference for behavior change techniques addressing social support and social comparison.

Characteristic		Standardized B (95% CI)	*P*	Nagelkerke R^2	Adjusted standardized B (95% CI)	*P*	Nagelkerke R^2
Personality traits							
	Extraversion (E)	0.08 (-0.08 to 0.23)	.329	.046	0.07 (-0.10 to 0.23)[a]	.430	.049
	Agreeableness (A)	0.10 (-0.06 to 0.25)	.217		0.09 (-0.06 to 0.24)[a]	.254	
	Conscientiousness (C)	-0.13 (-0.28 to 0.02)	.087		-0.14 (-0.30 to 0.03)[a]	.103	
	Neuroticism (N)	-0.01 (-0.16 to 0.15)	.907		-0.02 (-0.18 to 0.14)[a]	.821	
	Openness (O)	0.09 (-0.07 to 0.24)	.280		0.08 (-0.07 to 0.24)[a]	.299	
Exercise self-efficacy		0.08 (-0.07 to 0.23)	.308	.006	0.09 (-0.06 to 0.24)[a]	.266	.015
Exercise self-identity		-0.04 (-0.19 to 0.11)	.605	.002	-0.03 (-0.18 to 0.12)[b]	.696	.005
Meeting the Dutch physical activity guidelines		0.08 (-0.07 to 0.22)	.310	.006	0.09 (-0.06 to 0.24)[b]	.229	.013

[a]Adjusted for total physical activity (min/week) and body mass index (kg/m^2).

[b]Adjusted for body mass index (kg/m^2).

Discussion

Principal Findings

This study examined young adults' ratings of BCTs applied in a mobile phone physical activity app aimed at improving self-efficacy and social support for physical activity. Furthermore, a number of possible correlates of such ratings were explored. It should be noted that participants were asked to rate BCTs based on their experiences and wishes or requirements of a hypothetical mobile phone physical activity app and not of an existing app. In this study, the ratings of all BCTs addressing self-efficacy were relatively high, but the BCTs addressing social support were not. Respondents who scored higher on agreeableness were more likely to rate BCTs addressing "goal setting and goal reviewing" positively. Furthermore, respondents who scored higher on neuroticism were less likely to rate BCTs addressing "feedback and self-monitoring" positively, while higher scores on self-efficacy were associated with more positive ratings of "feedback and self-monitoring."

Ratings of Behavior Change Techniques

This study's finding that BCTs addressing "goal setting and goal reviewing" and "feedback and self-monitoring" were positively rated is in line with previous research, in which app features for (automatic) tracking of behavior, setting goals, monitoring behavior, and receiving feedback were evaluated positively in different studies [27,29]. In this study, the most preferred BCTs by young adults were "goal setting on the outcome of behavior," "self-monitoring of behavior," and "self-monitoring of the outcome of behavior." The study of Ehlers and Huberty [30] supports this finding, by indicating that self-regulation techniques (eg, tracking physical activity, goal setting, and receiving feedback) are valuable features of health behavior apps. Middelweerd et al [28] pointed out that participants, overall, preferred a combination of a (virtual) coach with goal setting and that participants would like to receive personal feedback. This study provides further support for positive ratings of BCTs, including goal setting and receiving personal feedback. Earlier findings that social support features were less appreciated among middle-aged women were replicated for young adults, based on the lower preference for social support techniques in apps found in this study [30]. It may be that the high physical activity and exercise self-efficacy levels of the participants in this study caused them to perceive social support as unnecessary. By contrast, about half of the participants preferred a personal coach, which could be seen as another form of social support. Additional analyses (not shown) indicated that those preferring a personal coach did not significantly differ with respect to their preferences for social support from those who did not prefer a personal coach.

Personal Characteristics and Ratings of Behavior Change Techniques

The association between personality traits and BCT categories has not been previously reported or investigated. This study found a significant positive association for agreeableness and BCTs addressing "goal setting and reviewing." Agreeableness is characterized by having the tendency to be kind, cooperative, and trustworthy [37]; thus, participants who were categorized as being cooperative and trustworthy were more likely to be open to app features like goal setting and goal reviewing. This study found an inverse association between neuroticism and BCTs addressing "feedback and self-monitoring." Neuroticism

is characterized by negative affect and emotional instability [48]. Rhodes and Smith [32] noted that avoidance of physical activity or cancelling physical activity plans may be a logical extension of this personality trait, which can also make them less likely to use app features like goal setting, goal reviewing, receiving feedback, and self-monitoring of physical activity behavior. These preliminary results indicate that personality traits could be considered when designing app-based interventions. Previous research showed that tailoring advertising messages to respondents' personality traits increased their motivation to use a product. Thus, tailoring BCTs to participants may increase the effectiveness of an app-based intervention. However, future research is needed to examine how BCTs should be tailored.

Furthermore, this study found an association between exercise self-efficacy and BCTs addressing "feedback and self-monitoring." It may be that when a person perceives that one can successfully engage in physical activity, monitoring physical activity and receiving feedback on physical activities affirm and ratify a positive feeling toward physical activity behavior. Moreover, when participants' exercise self-efficacy is low, monitoring their physical activity behavior may elicit unpleasant feelings and, therefore, generate less appreciation for self-monitoring app features. This suggests that app developers should consider designing app-based interventions tailored to personality and exercise self-efficacy.

Although this study did not find any associations between participants meeting the Dutch physical activity guidelines and ratings of potential effective BCTs, Middelweerd and colleagues [28] found some differences in ratings of app features between young adults who met and who did not meet these guidelines. For example, the latter preferred a goal setting feature and a personal coach, whereas participants meeting the physical activity guidelines reported goal setting as unnecessary and preferred highly detailed training information [28]. Furthermore, differences may also exist between men and women, as men appear to have a preference for team-based, competitive activities, while women do not [49]. The lack of association with participants' physical activity level could also be explained in terms of a high overall level of physical activity in this study, as more than 80% of participants met the guidelines; thus, this study may not have had sufficient power to detect differences in preferences for BCTs between those meeting and not meeting the Dutch guidelines.

Strengths and Limitations

This is the first study to explore associations between personality characteristics and ratings of BCTs applied in mobile phone physical activity apps. Given the current lack of adequate physical activity and preference for apps to support and monitor physical activity, scientific evidence to inform app-based interventions is needed.

Several limitations need to be considered in the interpretation of the findings of this study. The first important limitation is the cross-sectional design, so no causal inferences can be made. Second, the sample was rather homogeneous in gender, physical activity level, and education level; therefore, the results cannot be generalized to more heterogeneous samples. The fact that participants were highly active and had high levels of self-efficacy may have influenced their preferences for certain BCTs. Reasons for the homogenous sample in this study could be that the participants comprised a convenience sample, and the study's topic (physical activity and apps) and the activity tracker incentive may have attracted more physically active participants. An additional incentive to participate in the study was a prize draw in which one activity tracker could be won. Such an incentive was probably more attractive to participants who already were physically active and who may already have had a preference for tracking their behavior. This may have influenced their preferences for certain BCTs. Consequently, the high levels of preferences for self-monitoring BCTs might be somewhat biased. The time and effort needed to complete the survey may have led to lower participation of less educated participants [50], despite efforts to actively recruit participants at secondary vocational education schools to reach participants with lower education. However, it is well-known that those with lower education and who are physically inactive are hard to reach. Furthermore, men are less likely to participate in lifestyle-related research [51-55]. The fact that our sample was mainly female, with higher education, and more likely to be physically active than the general population of Dutch young adults may have biased the results, and the BCTs identified may not be reflective of the population at large. Furthermore, this study examined a relatively large number of correlations, but only 3 associations were found to be significant, resulting in increased risk of Type 1 error. These associations should, thus, be interpreted with caution and regarded as exploratory findings. Finally, the participants were asked to rate BCTs based on a one-sentence description, and not on actual experience. Consequently, for some participants, past experiences might have positively or negatively influenced their ratings, whereas for others the ratings remained hypothetical.

Future Research

Future research should focus further on indicating potential differences in the ratings of BCTs between active and inactive participants and using more representative samples. Self-regulation BCTs are potentially effective and were highly appreciated among the young adults in this study. Therefore, these techniques may be considered by physical activity app developers, who should implement these BCTs correctly; the apps should be subsequently tested for their effectiveness in improving physical activity motivation, self-efficacy, and behavior [56]. Although the literature indicates social support as an important correlate of physical activity, young adults in this study did not appreciate this in a mobile phone app. This may indicate that social support should be provided through different or traditional interventions. In addition, this study suggests the value of studying in detail the tailoring of BCTs to participants' personality characteristics.

Future research should examine the effectiveness of BCTs applied in apps. In previous research, it has been shown that the BCTs included in this study can effectively change behavior; however, because of lack of evaluation research, little is known about their effectiveness in apps [14]. Even if BCTs have been found to be effective in other intervention methods, effectiveness

in app operationalization should be tested, as effectiveness of BCTs may be dependent on the actual intervention.

Conclusion

To conclude, ratings of various self-regulation BCTs in a mobile phone app were high in a selected group of highly educated and physically active young adults. BCTs addressing social support were less appreciated. Differences in ratings of BCTs due to differences in personality and exercise self-efficacy between young adults should be taken into account.

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Authors' Contributions

LSB designed the survey, collected data, performed the analyses, drafted the manuscript, and incorporated all feedback. AM designed the survey, provided intellectual input and feedback, and approved the final version of the manuscript. StV designed the survey, provided intellectual input and feedback, and approved the final version of the manuscript. JB provided intellectual input to the design and execution of the review and to the manuscript, provided feedback, and approved the final version of the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Summary of exploratory factor analysis results for the behavior change techniques (N=179).

[PDF File (Adobe PDF File), 352KB - mhealth_v3i4e103_app1.pdf]

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Abbreviations

BCT: behavior change technique
BFI: big five inventory

TIPI: ten-item personality inventory

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Original Paper

Use of the Fitbit to Measure Adherence to a Physical Activity Intervention Among Overweight or Obese, Postmenopausal Women: Self-Monitoring Trajectory During 16 Weeks

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Abstract

Background: Direct-to-consumer trackers and devices have potential to enhance theory-based physical activity interventions by offering a simple and pleasant way to help participants self-monitor their behavior. A secondary benefit of these devices is the opportunity for investigators to objectively track adherence to physical activity goals across weeks or even months, rather than relying on self-report or a small number of accelerometry wear periods. The use of consumer trackers for continuous monitoring of adherence has considerable potential to enhance physical activity research, but few studies have been published in this rapidly developing area.

Objective: The objective of the study was to assess the trajectory of physical activity adherence across a 16-week self-monitoring intervention, as measured by the Fitbit tracker.

Methods: Participants were 25 overweight or obese, postmenopausal women enrolled in the intervention arm of a randomized controlled physical activity intervention trial. Each participant received a 16-week technology-based intervention that used the Fitbit physical activity tracker and website. The overall study goal was 150 minutes/week of moderate to vigorous intensity physical activity (MVPA) and 10,000 steps/day; however, goals were set individually for each participant and updated at Week 4 based on progress. Adherence data were collected by the Fitbit and aggregated by Fitabase. Participants also wore an ActiGraph GT3X+ accelerometer for 7 days prior to the intervention and again during Week 16.

Results: The median participant logged 10 hours or more/day of Fitbit wear on 95% of the 112 intervention days, with no significant decline in wear over the study period. Participants averaged 7540 (SD 2373) steps/day and 82 minutes/week (SD 43) of accumulated “fairly active” and “very active” minutes during the intervention. At Week 4, 80% (20/25) of women chose to maintain/increase their individual MVPA goal and 72% (18/25) of participants chose to maintain/increase their step goal. Physical activity levels were relatively stable after peaking at 3 weeks, with only small declines of 8% for steps (P=.06) and 14% for MVPA (P=.05) by 16 weeks.

Conclusions: These data indicate that a sophisticated, direct-to-consumer activity tracker encouraged high levels of self-monitoring that were sustained over 16 weeks. Further study is needed to determine how to motivate additional gains in physical activity and evaluate the long-term utility of the Fitbit tracker as part of a strategy for chronic disease prevention.

Trial Registration: Clinicaltrials.gov NCT01837147; http://clinicaltrials.gov/ct2/show/NCT01837147 (Archived by WebCite at http://www.webcitation.org/6d0VeQpvB)

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KEYWORDS

exercise; health behavior; health promotion; Internet; mHealth; motor activity; physical activity; technology; women

Introduction

Physical inactivity is related to increased risk of several chronic diseases, including cardiovascular disease, stroke, Type 2 diabetes, and cancer [1-4]. Yet when assessed using objective measures, only 2-3% of middle aged and older US women are achieving physical activity levels consistent with the national recommendations [5]. Web-based technologies, including body-worn sensors and smartphone apps that utilize the phone's onboard accelerometer, are among the most promising approaches to create scalable interventions for this serious public health problem. Analyses of theory-driven diet and physical activity interventions have shown that the component most strongly associated with successful behavior change is self-monitoring when used in combination with at least one additional self-regulatory technique (eg, goal setting, review of previously set goals, frequent behavioral feedback) [6-8]. Numerous off-the-shelf trackers are now available, many of which align well with these proven behavioral change techniques. These devices, when used within a theory-driven intervention, may therefore provide an efficient way to enable participants to improve self-regulation and adopt healthy behaviors. These trackers and apps have the added benefit of allowing investigators to obtain detailed, real-time feedback on participants' activity level and adherence to specific physical activity goals.

Few published studies have examined the use of accelerometer-based trackers as intervention tools, particularly with regard to the aggregation and analysis of tracker data as a measure of adherence. One such device, the Fitbit, has been shown to be usable and valid for physical activity monitoring [9,10]. Published studies using the Fitbit as an intervention tool include 3 single-arm studies [11-13] and 1 randomized trial among older adults [14]. This study reports in detail the adherence of women assigned to use a clip-on Fitbit tracker as part of a low-touch physical activity intervention. Main study outcomes have been reported previously [15].

Methods

Participants

Participants were 25 postmenopausal, overweight or obese women assigned to a 16-week low-touch, Fitbit-based intervention as part of a randomized controlled trial. All had a body mass index (BMI) over 25.0 kg/m^2, were regular Internet users, owned a computer or tablet with Internet access, and were able to exercise safely as determined by the Physical Activity Readiness Questionniare (PAR-Q) [16]. Procedures were approved by the University of California, San Diego (UCSD) Human Research Protections Program and written informed consent was obtained from each participant (trial registration number NCT01837147).

Study Visits

Each participant attended 3 study visits; 2 prior to randomization and 1 at the end of the 16-week study.

Measures

Baseline Physical Activity

The ActiGraph GT3X+, worn for 7 days prior to randomization and again at the end of the study, was used to measure baseline physical activity. This lightweight triaxial accelerometer is worn around the waist and has been validated and calibrated for use in controlled and field conditions. Standard calibration thresholds were used to aggregate data into intensity categories [17].

Baseline Demographics and Technology Use

Web-based questionnaires were used to collect demographics and technology use (items from the Pew Internet and American Life Project as well as a small number of study-specific items).

Body Mass Index

BMI (kg/m^2) was calculated from height and weight, which were measured using standard procedures.

Physical Activity Adherence

The primary adherence measure during the 16-week intervention was data collected and uploaded to the Web by the Fitbit One tracker. Each participant's Fitbit was linked to the Fitabase analytics system (Small Steps Labs, San Diego, CA, USA), which enabled the investigators to remotely monitor physical activity. Fitabase daily totals for steps and intensity-specific minutes of physical activity (PA) were downloaded at the end of the study.

Intervention

Participants received a Fitbit One physical activity tracker, which clips to the waistband or bra or can be placed in a front pants pocket. An internal accelerometer measures motion which is then aggregated into physical activity data. Summary information (eg, steps) is available on the tracker itself and data are wirelessly uploaded to a personalized website that displays daily steps, minutes/day of activity, and a graph showing the temporal pattern of physical activity during the day and over time (eg, weeks or months).

To minimize potential barriers to navigating the technology, the project coordinator (1) set up the Fitbit account and tracker for each participant, (2) demonstrated how to download and install the Fitbit software, (3) trained the participant on the website's self-monitoring and self-regulation features, and (4) provided the participant with an intervention handbook with study goals, information on building self-regulation skills, and detailed instructions (including screenshots) on how to install the Fitbit software. The study coordinator guided the participant through an initial goal setting process for moderate-to-vigorous intensity physical activity (MVPA) and steps and helped her

develop a specific plan to achieve those goals. Study goals were 150 minute/week of MVPA and 10,000 steps/day; however, individual goals could be higher or lower. At Week 4, participants received a telephone call to evaluate progress, provide feedback, and update their personalized goals to establish targets for the remaining 12 weeks of the study. The study coordinator was logged into the participant's Fitbit account during the call, enabling her to view an objective assessment of the participant's progress to facilitate the goal setting process.

Data Analysis

Analyses were completed using SAS 9.4. Baseline characteristics were compared using chi-square and *t* tests. Physical activity data (both ActiGraph and Fitbit) were adjusted for number of valid wear days and repeated measures analysis was used to assess (1) changes in physical activity and (2) revision of goals at baseline versus 4 weeks.

Results

The intervention group consisted of 25 women (mean age 58.6 years [SD 6.5]) with a BMI of 29.2 kg/m^2 (SD 3.8; Table 1). On the baseline ActiGraph assessment, participants were performing 24 (SD 39) minutes/week of MVPA in bouts of at least 10 minutes (the type of activity prescribed by the physical activity guidelines). None of the participants was meeting the recommended amount of 150 min/week of MVPA in bouts [18]. Eighty-four percent of participants (21/25) were daily Internet users (Table 2).

Table 1. Baseline characteristics of study participants (n=25).

Baseline characteristics		Mean (SD)
Age, years		58.6 (6.5)
Body mass index (kg/m^2)		29.2 (3.8)
Non-Hispanic white, n (%)		23 (92)
College degree or higher, n (%)		14 (56)
Moderate to vigorous physical activity [a]		
	Average MVPA performed in Freedson bouts (minutes/week)	24 (39)
	Total accumulated moderate to vigorous activity (minutes/week)	172 (83)
Steps [a]		
	Average steps per day	5906 (1964)
	% walking ≥10,000 steps/day	4

[a]As measured by ActiGraph GT3X+ accelerometer.

Adherence to Tracker Usage

During the 16-week intervention, participants adhered well to wearing the tracker, with the median participant logging 10 hours/day or more of wear time on 94.6% of intervention days (106/112). Mean valid wear was 90 days (SD 22) with a range from 14 to 111 days. Adherence to tracker usage peaked at Week 3 and was maintained throughout the study period, with no significant decline in the mean number of valid wear days per week during the 16 weeks (Figure 1).

Individualized Goal Setting

The objective feedback provided by continuous monitoring enabled the refinement of individualized goals midway through the intervention, allowing the acceleration of goals for participants who are doing well and the downward revision of goals for participants for whom the initial goal proved unrealistic. At baseline, participants set goals of 124 minute/week of MVPA (SD 34) and 8140 steps/day (SD 2224). At the 4-week goal setting call, participants slightly increased their overall MPVA goal to 143 + 70 min/week (P=.15) by lengthening bout duration to 32 + 13 min/bout (P=.01) while decreasing the bouts to 4.6 + 1.3 bouts/week (P=.11). Step goals marginally increased to 8660 + 2560 steps/day (P=.06).

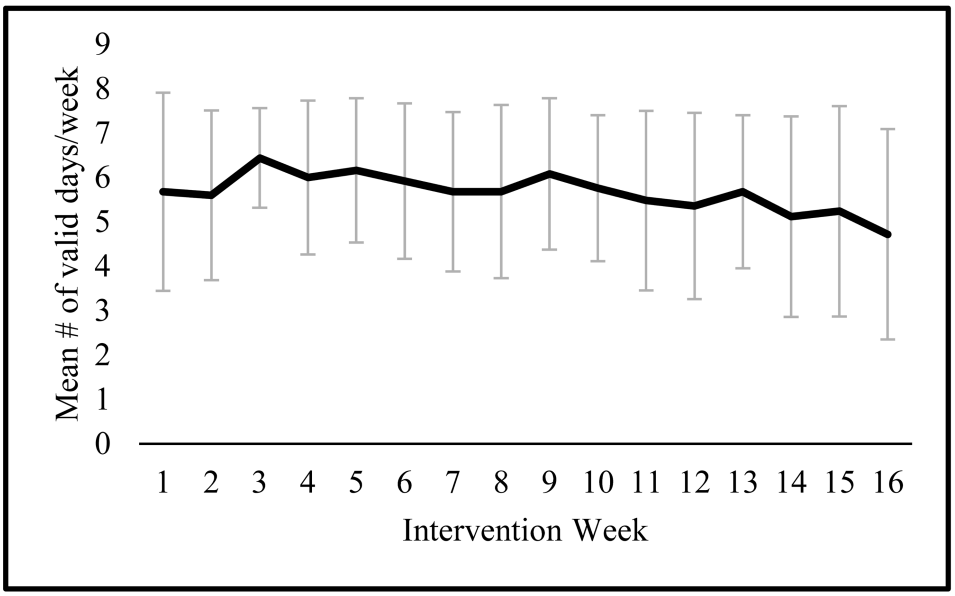
Table 2. Technology use of study participants (n=25).

Technology use		Percentage
Daily Internet user		84
Comfortable using computers and the Internet [a]		
	Neutral	4
	Somewhat or very comfortable	12
	Very comfortable	84
Enjoys using computers and the Internet [b]		
	Neutral	17
	Somewhat enjoy	21
	Very much enjoy	62
Type of primary computer		
	Desktop	32
	Laptop	64
	Tablet	4
Operating system of primary computer		
	Windows	64
	Mac	36

[a]Women who responded "Very uncomfortable" or "Somewhat uncomfortable" were ineligible for this study.

[b]Women who responded "Very much do not enjoy" or "Somewhat do not enjoy" were ineligible for this study.

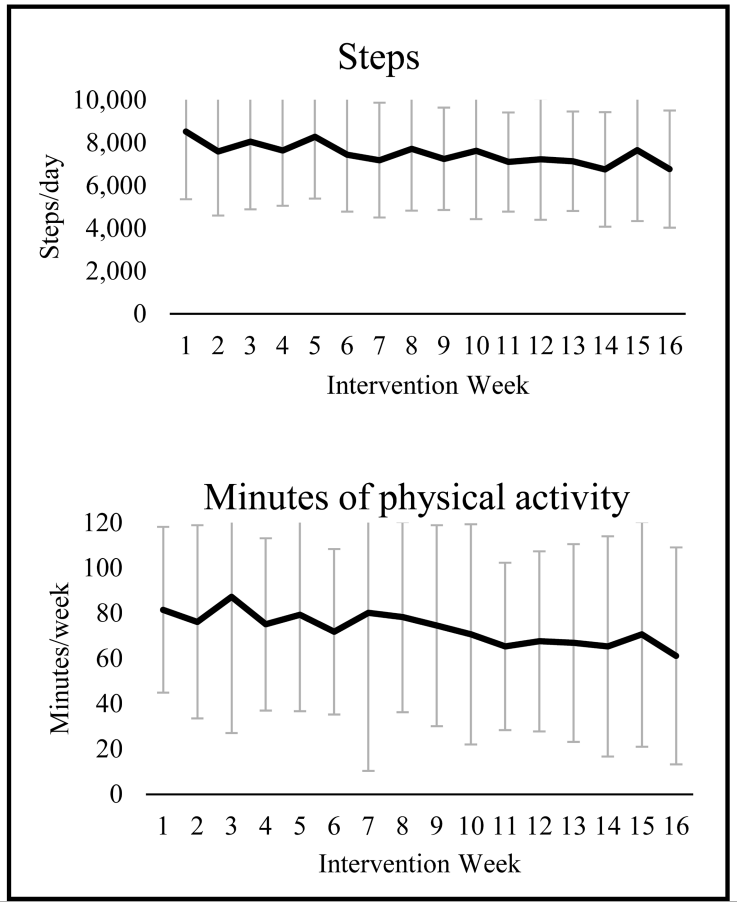
Figure 1. Adherence to wearing the Fitbit tracker during the 16-week intervention period among postmenopausal, overweight/obese women (N=25). Valid days are defined as those with 10 hours or more of wear time.



Adherence to Study and Individual PA Goals

As reported elsewhere [15], significant pre/post increases were observed on ActiGraph-measured physical activity outcomes. Physical activity adherence during the intervening 16 weeks was assessed using Fitbit data. Based on this measure, participants averaged 7540 steps/day (SD 2373) and 82 minutes/week (SD 43) of accumulated "fairly active" and "very active" minutes during the intervention period (Figure 2). Physical activity levels peaked at Week 3, but no statistically significant decline was observed through the intervention period. During Weeks 1-4 participants averaged 7922 (SD 2671) daily steps, or 98.3% of their personalized goal (mean goal: 8140 steps/day; SD 2224) and 91 minutes/week of "fairly" or "very active" minutes (SD 50), or 79.4% of their personalized goal (mean goal: 124 minutes/week; SD 34). During Weeks 5-16 participants accumulated 7395 steps/day, or 85.2% of their updated personal goal (mean goal: 8660 steps/day; SD 2561), and performed 79 minutes/week of activity (SD 45), or 59.7% of their updated goal (mean goal: 142 minutes/week; SD 70).

Figure 2. Fitbit-measured steps and minutes of "fairly or very active" physical activity during a 16-week intervention among postmenopausal, overweight/obese women (N=25).



Discussion

Principal Findings

This study provides initial evidence that middle aged and older women adhere very well to wearing and using the Fitbit tracker and that it is a promising tool for continuous monitoring of physical activity adherence in this population. Unlike research accelerometers (eg, the ActiGraph), the Fitbit is suited for continuous long-term use by participants and is designed for use as a behavior change tool.

Limitations

Limitations of this study include a specialized, nongeneralizable sample, small sample size, short study duration of 16 weeks, and inclusion of only overweight or obese individuals, who may be more likely to change in the short term. While a few studies have been published using the Fitbit as an intervention tool to provide behavioral feedback to participants [11-14], this is, to our knowledge, the first study to demonstrate the feasibility of the Fitbit for continuous monitoring of physical activity adherence by investigators.

Future Work

More data are needed regarding the integration of consumer-based electronic sensors for physical activity promotion and monitoring within the context of behavioral medicine research. Two additional areas where research is needed are (a) studies testing the use of physical activity sensors for promotion and/or monitoring of physical activity within the health care setting and (b) additional validation studies examining the accuracy of consumer-based sensors compared with standard research measures (eg, ActiGraph) across population subgroups and for different intensities and types of physical activity. Furthermore, new models of the Fitbit and other trackers now include features such as heart rate and global positioning systems (GPS) sensors, which provide additional opportunities for assessing objective, intensity-related data on physical activity adherence. The fast pace of product development and evolution will continue to present new opportunities and challenges for behavioral mHealth research and intervention science.

Acknowledgments

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Conflicts of Interest

None declared.

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Abbreviations

BMI: body mass index
GPS: global positioning systems
MVPA: moderate-to-vigorous physical activity
PA: physical activity

UCSD: University of California, San Diego

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Original Paper

Web-Based and Mobile Delivery of an Episodic Future Thinking Intervention for Overweight and Obese Families: A Feasibility Study

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Abstract

Background: The bias toward immediate gratification is associated with maladaptive eating behaviors and has been cross-sectionally and prospectively related to obesity. Engaging in episodic future thinking, which involves mental self-projection to pre-experience future events, reduces this bias and energy intake in overweight/obese adults and children. To examine how episodic future thinking can be incorporated into clinical interventions, a Web-based system was created to provide training for adults and children in their everyday lives.

Objective: Our study examined the technical feasibility, usability, and acceptability of a Web-based system that is accessible by mobile devices and adapts episodic future thinking for delivery in family-based obesity interventions.

Methods: We recruited 20 parent-child dyads (N=40) from the surrounding community and randomized to episodic future thinking versus a nutritional information thinking control to test the feasibility of a 4-week Web-based intervention. Parents were 44.1 (SD 7.8) years of age with BMI of 34.2 (SD 6.8) kg/m^2. Children were 11.0 (SD 1.3) years of age with BMI percentile of 96.0 (SD 1.8). Families met weekly with a case manager for 4 weeks and used the system daily. Adherence was collected through the Web-based system, and perceived acceptance of the Web-based system was assessed postintervention. Measurements of body composition and dietary intake were collected at baseline and after the 4 weeks of intervention.

Results: All 20 families completed the intervention and attended all sessions. Results showed parents and children had high adherence to the Web-based system and perceived it to be easy to use, useful, and helpful. No differences between conditions were found in adherence for parents (P=.65) or children (P=.27). In addition, results suggest that basic nutrition information along with episodic future thinking delivered through our Web-based system may reduce energy intake and weight.

Conclusions: We showed that our Web-based system is an accepted technology and a feasible utility. Furthermore, results provide initial evidence that our system can be incorporated into family-based treatments targeting behaviors related to weight control. These results show promising utility in using our Web-based system in interventions.

(JMIR mHealth uHealth 2015;3(4):e97) doi:10.2196/mhealth.4603

KEYWORDS

obesity; ecological momentary intervention; episodic future thinking; Web-based; health behavior

Introduction

The development of obesity is contributed in part by a series of choices that influence positive energy balance. Although it is well publicized that obesity results from energy intake in excess of energy expenditure [1,2], many individuals choose the immediate gratification of overindulging in unhealthy and high-energy-dense foods over the more rational decision of consuming healthier foods for the long-term goal of healthy weight. This choice may reflect the bias toward immediate gratification that has been cross-sectionally and prospectively associated with obesity [3-5]. Moreover, this bias may be compounded for children, who have more difficulty resisting immediate gratification than adults [6], and may be even worse for obese children, who find it more difficult to delay gratification for food rewards [7]. Furthermore, a bias toward immediate gratification predicts diminished success with weight loss in family-based obesity treatment [8].

Skills for reducing the bias toward immediate gratification in adults and children are emerging, and one such skill is episodic future thinking (EFT). EFT, a type of prospective thinking, is mental self-projection into the future to pre-experience events [9]. EFT is thought to reduce impulsive decision making by increasing the value of delayed outcomes [10] and guiding individuals toward choices with long-term benefits [11]. During eating episodes, EFT can reduce the impulsive desire to engage in excess energy intake and reframe time perspective to focus more on healthy weight benefits. Studies show that engaging in EFT reduces the bias toward immediate gratification during decision making [12] and reduces energy intake in tempting food situations in adults [13] and children [14]. However, little is known about EFT's training effects on eating behaviors outside the context of the laboratory.

A feasible method for delivering EFT was needed to provide daily training in the everyday lives of adults and children. Electronic media offer opportunities to extend current approaches [15,16]. Our Web-based system, the Mobile Audio Manager and Response Tracker (MAMRT), was developed to provide daily training for adults and children during real-world eating episodes in an ecological momentary intervention (EMI). Based on the Technology Acceptance Model [17,18], our Web-based system was designed to be responsive and mobile to increase ease of use, a component necessary for a technology to be accepted.

EMI has become more widely accepted as the use of technology has become ubiquitous in the lives of adults and children [15]. In contrast to controlled laboratory settings, EMI provides treatments to people in their natural settings during their everyday lives, which enhances validity [15]. Furthermore, research shows that interventions incorporating technology can elicit behavioral changes and be effective for changing a variety of health behaviors [19-21]. Previous research has also supported the use of Web-based dietary intervention [22,23].

We incorporated EFT into a Web-based EMI involving 20 parent-child dyads interested in changing their eating behaviors and losing weight. All families were provided 4 weeks of nutrition education and randomized to EFT or a control nutrition information thinking (NIT) condition. NIT was only provided with nutritional education, but no EFT training. Families in both conditions were asked to use the system in the same fashion. We expected no between-group differences in the feasibility, usability, and acceptability of MAMRT. However, because EFT could be helpful in regulating eating, we also explored EFT's effects in weight change and eating habits compared to the control condition.

Methods

Participants and Procedures

Families were recruited from the surrounding community through an existing database and advertisements via flyers and postcards. Parents of interested families were screened by telephone to assess initial eligibility. Families were initially eligible if the parent was overweight and the child was overweight and between the ages of 8 and 12 years. In addition, both had to have access to a mobile electronic device (eg, mobile phone, tablet, laptop) and be interested in weight loss, willing to participate in a 4-week intervention, and not currently involved in other weight loss programs. Initially eligible families were invited to an orientation and a formal screening appointment where both parent and child received a detailed presentation on study procedures, signed consent forms, completed measures, participated in individual interviews, and verified that their electronic devices were compatible with our study purposes. Parents and children were required to have regular access to a mobile electronic device (specifically around eating episodes); however, it was not required that parents and children had their own individual devices. Families were excluded from participation if either the parent and child or both were not considered overweight (body mass index [BMI] less than 25 kg/m^2 and BMI percentile less than 85), were not interested in changing their eating habits through the use of this technology, were not comfortable using or did not have access to a mobile electronic device with Wi-Fi and/or reliable Internet access, were unable to read at the 3rd grade reading level, or could not follow study protocol (ie, attend all sessions, access electronic device daily, and complete all assessments).

A total of 54 parents were initially screened by telephone, and 25 families were excluded. Of the 25 families excluded, 5 families did not meet inclusionary criteria, 4 families declined to participate, and 16 families did not attend orientation. Of the 29 families that attended orientation, 5 families did not meet weight inclusionary criteria and did not continue onto final screening. After final screening, 4 families were excluded. Of the 4 families excluded, 2 families declined to participate and 2 families did not meet final screening inclusionary criteria (Figure 1).

A total of 40 eligible and interested participants (20 overweight/obese parent-child dyads) were invited to participate in the 4-week intervention and were randomly assigned to either the EFT condition (n=11) or the NIT control condition (n=9). Families were randomly assigned to conditions in blocks of 4 families stratified by child sex. Stratification was accomplished based on a sequence set up by the project statistician. The project statistician was not involved in the data collection, and study

personnel had no input in the randomization sequence. Participants were not told which group was the experimental group.

Due to the behavioral nature of the manipulations, it was not possible to blind study participants or study personnel to randomization assignment. Outcome assessors who collected weight, dietary intake, and system ratings were not blinded to the intervention; however, outcomes collected electronically such as adherence, dietary restraint, demographics, adherence, and device usage did not require blinding. Parents and children in both conditions completed the same measures, were given the same dietary information, and were instructed to use MAMRT in the same fashion. The difference between the two conditions was families in the NIT control condition received only nutritional information while families in the EFT condition received both nutritional information and EFT training.

Families in both conditions completed 3 days of 24-hour dietary recalls together (parent and child) over the phone before and after the 4-week intervention. Families attended a 90-minute preintervention appointment, 4 weekly 60- to 90-minute intervention sessions, and a 90-minute postintervention appointment. All procedures were conducted in accordance with guidelines for the ethical conduct of human research outlined by the National Institutes of Health and with the approval of the University at Buffalo Social and Behavioral Sciences Institutional Review Board.

At preintervention, parents and children were taught the Traffic Light diet [24]. The Traffic Light diet is an eating plan that categorizes food based on nutrient composition into green, yellow, or red foods. Green foods are low in calories, fat, and sugar and are also rich in nutrients. Yellow foods are higher in calories than green foods but are still a good source of nutrients and include the dietary staples needed for a balanced diet. Red foods are high in calories, fat, and/or sugar and are not a good source of nutrients. All families were taught to eat fewer calories than they normally eat, maintain nutrient balance by eating the recommended servings based on the Dietary Guidelines for Americans [25] issued jointly by the US Department of Agriculture and the US Department of Health and Human Services, limit their consumption of red foods, and increase their consumption of green foods. Parents and children in both conditions were given a workbook to record their daily dietary intake before their first intervention session. All materials were presented at a 3rd grade reading level for adequate comprehension.

At the first intervention session, all families received an introduction on how to use the study website. Parents and children learned how to use their own devices to access the website. The website was developed to be personally tailored and interactive. The opening page was the participant's log-in page. Each participant (parent and child) was given an individual account that required a unique log-in to access the study website. Upon logging in, participants were directed to an audio page which displayed their cues and their first name (Figure 2).

Cues were participant-generated personal audio recordings created in their own words and recorded in their own voice. During their intervention sessions, families in both conditions generated nutritional cues based on behavioral and dietary strategies known to positively influence weight control such as portion control, energy density, stimulus control, eating out, food shopping strategies, and social support. Participants were told the audio recordings were to be used as cues to help them think about healthy eating behaviors. All families were given the same behavioral and nutritional dietary strategies.

In addition to the behavioral and dietary strategies, parents and children in the EFT condition generated audio recordings of positive events they were looking forward to and could vividly imagine. EFT participants generated cues similar to those used in previous EFT study procedures [12-14]. To help participants think about autobiographical details of their events, they rated the valence, salience, arousal, frequency, and vividness of each event on scales of 1-5 (1 for very low and 5 for very high). Because vividness of episodic imagery in EFT predicts the amount of reduction in bias toward immediate gratification [26], only specific events with the highest scores were recorded. Only EFT participants generated recordings of positive future events.

In both conditions, parents and children generated cues together with a case manager; however, participants generated their own individual recordings. Audio recordings were generated using standard laptop microphones and Audacity, a free, open source, cross-platform software program for recording and editing sounds. Families in both conditions generated 4 audio recordings per session. These recordings generally lasted no more than 60 seconds.

In addition to generating cues at their intervention sessions, individual families in both conditions met together (parent and child) with a case manager to obtain weight measurements and discuss eating habits and use of the Web-based system. Case managers elicited participants' understanding of the system and emphasized the importance of listening and thinking about their cues during eating episodes. Families in both conditions were directed to use their cues at least twice a day, at any point where decisions were made regarding food (eg, foods that they may eat, are planning to eat, or are actually eating).

To remind participants to use their cues, they received prompts at 6:00 AM and 3:00 PM daily. These prompt schedules were set at those times so that participants would receive them before their first and last meal consumptions. Prompts were delivered automatically through the system and were sent directly to the participant's electronic device in a text message or email (based on preference). Each reminder included the study website's URL and a brief message to complete prompt exercises by the end of the day.

Prompt exercises included participants listening to their cues and completing a short survey about their cues. After listening to their audio, participants had the option to listen to more recordings or be directed to a short survey. When participants decided to continue to the survey, they would answer 5 questions that were short responses or multiple choice. There were 2 fixed questions, "What meal did you use your audio for?" and "How are you keeping in mind the cue during the day?" The other 3 questions displayed would change each time the participant accessed the survey to keep the questions novel and nonrepetitive. Examples of other questions were "Thinking

about your cue, what's most interesting about it?" and "How can the cue help you make healthy food choices?" and "How much do you think about your audio cue throughout the day?" These questions were asked to help participants think about their cues and keep their cues in mind during eating episodes.

For example, a participant in the EFT condition may have used an upcoming party as the basis for one EFT cue. In the cue, the participant described the party in detail to help vividly imagine pre-experiencing the event. Before dinner, the participant would listen to that recording, answer questions about the event, and imagine being at that event. The participant would imagine looking good in a specific outfit at the event and how reducing the intake of high-energy-dense foods would help achieve this.

After the 4-week intervention, families attended a 90-minute postintervention appointment where feasibility of MAMRT was evaluated. Parents and children completed evaluations separately. Families were compensated US $30 for completing all 6 dietary recalls, US $96 for complete adherence to study protocol (US $0.50 for each completed exercise with the system plus an opportunity to earn a US $5.00 bonus per week if all exercises were completed by their next appointment), and US $24 for completing measures at their postintervention appointment.

Figure 1. Consort participant recruitment and retention diagram.

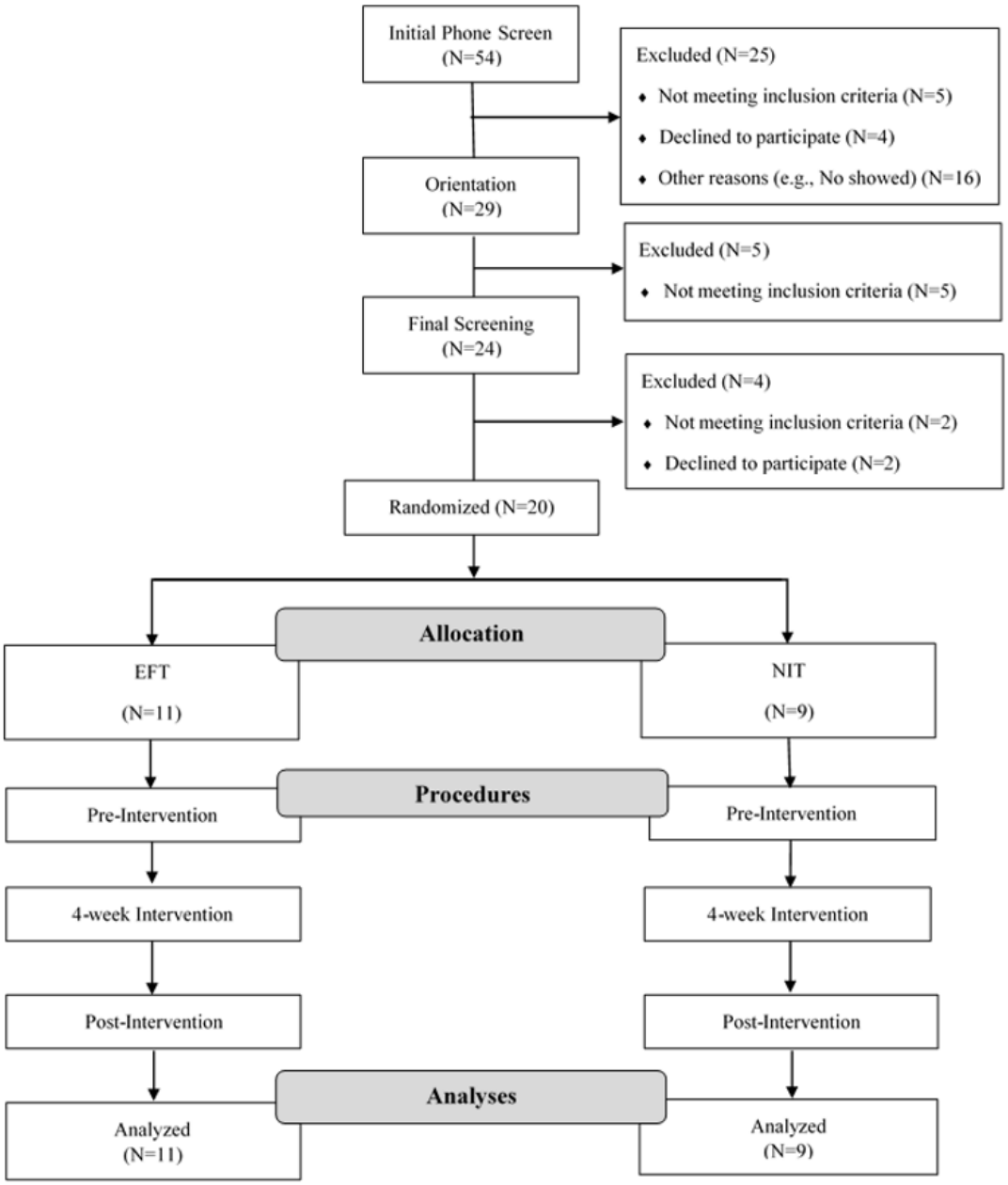
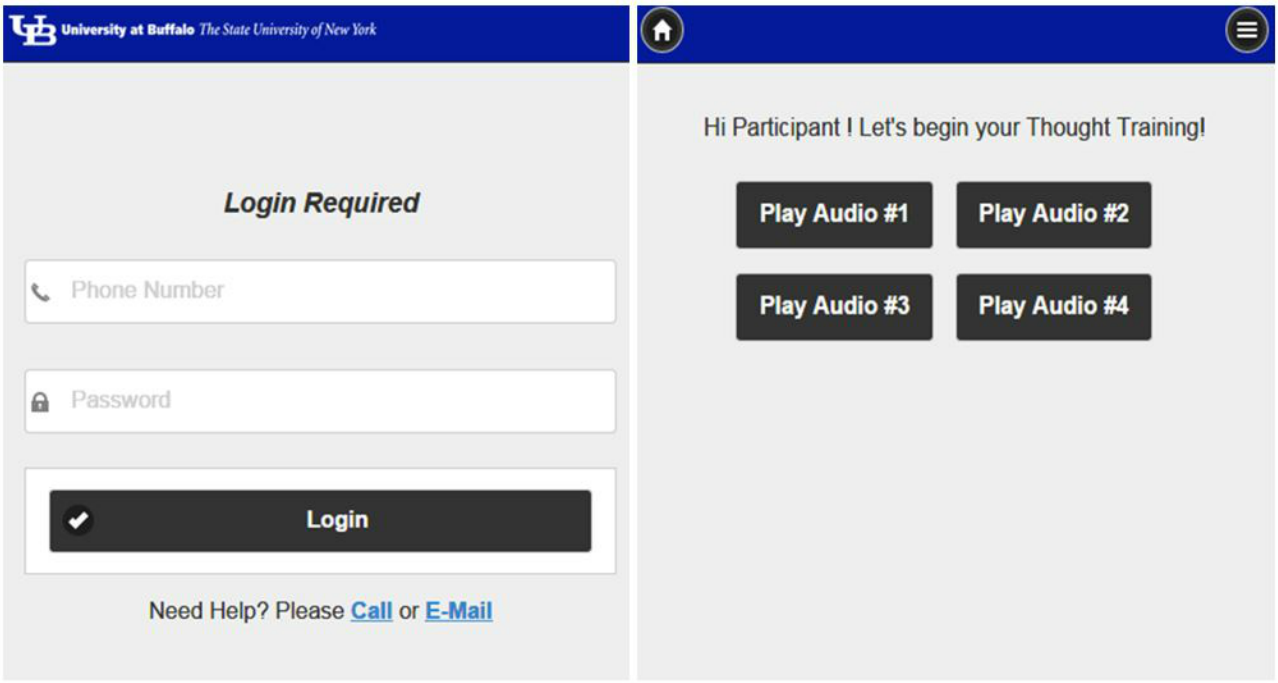


Figure 2. Participant log-in and default landing page (audio page).



The Mobile Audio Manager and Response Tracker

The participant interface and investigator page were created using JavaScript, HTML, and CSS. In addition to the audio page, participants could access other features on the study website through the menu tabs (Figure 3). Participants could view their appointment dates and times and the prompt delivery schedule via the Calendar tab, receive instructions and tips on how to use the system through the Manual tab, and contact the experimenters directly with problems through the Contact Us tab. These features allowed study information to be easily accessible for all participants in both conditions.

An administrator page linked to the participant's study website was created as a platform for investigators. To restrict access to investigators only, log-in was required. The administrator page consisted of multiple managers for the various components of the EMI (Figure 4). Investigators added participants and assigned personalized identification numbers, passcodes, condition, and access through the Participant Manager. Through the Audio Manager, investigators could upload specific audio recordings from each session, determine the number of audio files accessible to participants, and view all the audio files that were uploaded. The Event Manager allowed investigators to set up the prompt delivery schedules and participant appointment dates and times that could also be viewed through the participant user interface. In addition, investigators could upload manuals for participants through the Manual Manager, restrict or grant investigator access through the Experimenter Manager, add or remove survey questions in the Question Manager, and enter and view data through the Data Manager. All information added through the administration page would first go to the Quality Check page to ensure that all manually entered information was correct. The administrator page was accessible from a desktop or mobile device allowing investigators to easily monitor the system remotely at any time.

Data collected from the website were stored and managed in a secure MySQL database only accessible to members of the lab. MySQL is a free, open source, relational database management system based on structured query language. MySQL was used because it is free, stores large amounts of information, and organizes data in a way that can be accessed quickly and easily. The study website collected participant log-in dates and times, device used (eg, mobile phone, tablet, desktop), names of audio file accessed as well as the duration of time it was accessed, and survey responses and the time the responses were submitted. The user interface displayed data in a simple, user-friendly manner. Data could also be downloaded in standard Microsoft Excel format. The system allowed for flexible retrieval of data to address specific questions based on the researcher's needs (Figure 5).

The system was designed to streamline data collection and analyses for investigators while also being personally tailored and interactive for participants. The system was responsive and compatible with a variety of electronic devices (eg, desktops, laptops, tablets, mobile phones) and operating systems (Windows and OS X).

Figure 3. Participant menu page.

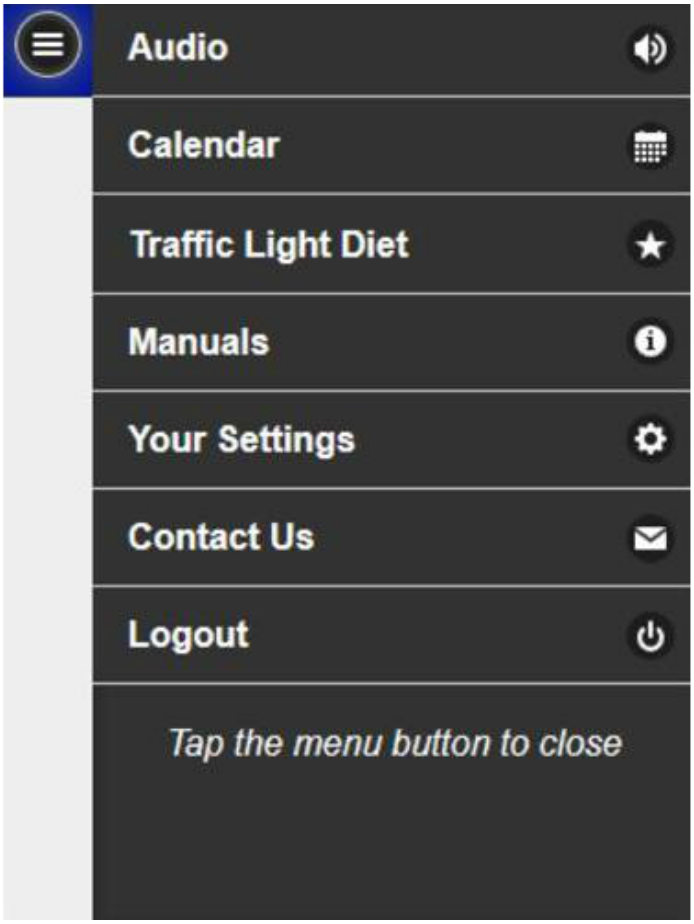


Figure 4. Administrator menu page.

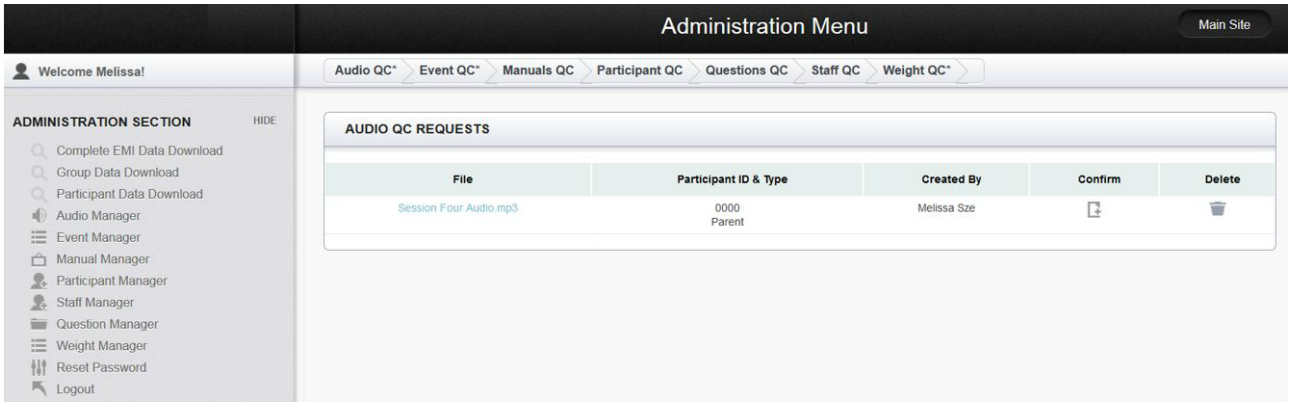
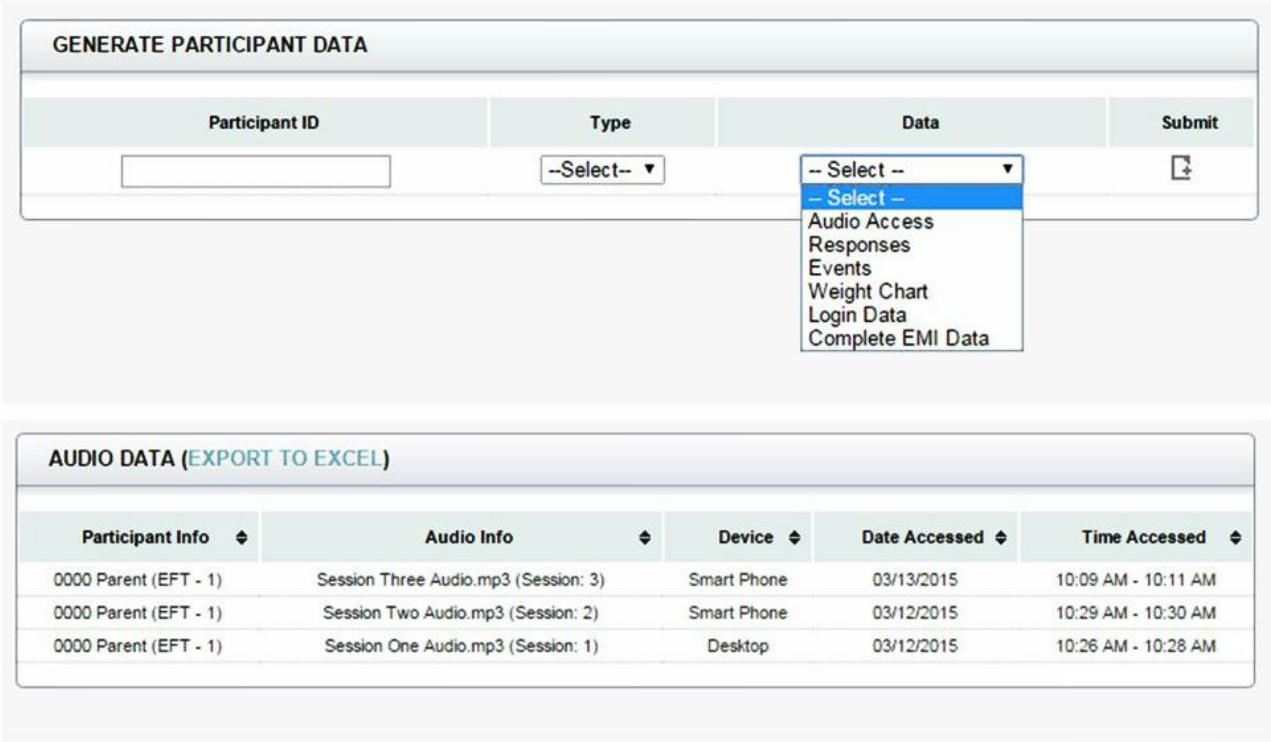


Figure 5. Administrator data manager page.



Measures

Demographics

Race/ethnicity, income, and educational level were obtained using a standardized questionnaire adapted from the MacArthur Research Network on Socioeconomic Status and Health [27] at screening.

Anthropometrics

Weight was measured to the nearest 0.2 lb using a digital scale (Tanita BWB-800P), and height was measured in centimeters to the nearest millimeter using a Digi-Kit digital stadiometer. Measurements were taken at each visit. BMI (kg/m^2), BMI percentile, and percent overweight were established by comparing BMI population standards [28,29]. Overweight/obese children had a BMI at or above the 85th percentile, and parents had a BMI at or above 25.

Dietary Restraint

The Dutch Eating Behavior Questionnaire (DEBQ) was completed during screening and used to assess eating behaviors in adults [30]; an adapted version was used for children [31]. The DEBQ is a validated measure to detect 3 different psychologically based eating behaviors: (1) restrained, (2) emotional, and (3) external eating [30,32].

Adherence to Using the Mobile Audio Manager and Response Tracker System

Participants were instructed to use the system at two separate periods during the day for 4 consecutive weeks, for a total of 14 responses per week and 56 responses across the 4 weeks. Adherence was collected through the MAMRT system and calculated as the percentage of completed responses daily each week for 4 weeks.

Frequency of Device Type Used

The frequency of which device (eg, desktop, tablet, mobile phone) participants used to access the system was collected through the MAMRT system and calculated as the percentage of overall use.

Ratings of the Mobile Audio Manager and Response Tracker System

Perceived usefulness, ease of use, and helpfulness were obtained using a self-report survey at postintervention. Parents and children provided ratings on 5-point Likert scales on the usefulness (1 for not at all and 5 extremely) of each component of the study website: (1) listening to nutritional audio cues, (2) completing the survey responses, (3) timing of the prompt reminders, (4) receiving the prompts twice daily, and (5) having 1 Web link to access the audio cue and survey questions. Parents and children provided ratings on how frequently (1 for never and 5 for always) they (1) listened to their audio cues before eating episodes, (2) thought about their audio cue during eating, and (3) used their audio cue in difficult food situations. Rated frequency was used as an index to calculate perceived ease of use. Parents and children provided ratings on how helpful the program was in making healthy changes to their eating habits (1 for not at all and 5 extremely). The program consisted of using the system daily during any eating episode (eg, breakfast, lunch, dinner, snack) and tempting food situations.

Dietary Measures

Usual energy intake and servings of green and red foods were accessed through phone-based 24-hour dietary recalls (1 weekend day and 2 weekdays) for parents and children

preintervention and postintervention. Parents and children completed their recalls together. Children completed their recalls first with the assistance of their parents, and parents completed their recalls after. The experimenter guided the participants through the dietary recall process using a multipass interview style [33]. First, participants made a quick list of all foods and beverages consumed throughout that day and the time of consumption. For the second pass, the experimenter returned to the beginning of the list and asked for portion sizes, brand names, and the type of foods and beverages that were consumed (regular/diet, white/wheat, etc). The final pass was to prompt the participant to recall other foods they may have forgotten, such as foods that were eaten in small amounts. Participants were asked to have measuring cups, measuring spoons, and a ruler in front of them during the interview. This methodology has been validated in other studies [33,34]. The total number of calories consumed was calculated for the recall based on manufacturer labels and analyzed through Nutritionist Pro software (Axxya Systems LLC) [35]. The reliability of coding red and green foods was determined by 2 independent analysts; the reliability between observers was 94.6% agreement.

Analytical Plan

Separate one-way analyses of variance (ANOVAs) were conducted to determine group differences in participant characteristics for parent and child. Analyses of device frequency, ease of use, usefulness, helpfulness, and adherence to the system were assessed using a two-way ANCOVA, with group as the between variable and parent education as the covariate. Changes in weight and eating behavior were assessed using three-way ANCOVA, with group as a between variable, pre to post as within variables, and parent education as the covariate. In both analyses, contrasts were used to assess changes by group for parent or child. Data analyses were completed using SYSTAT version 11 (Systat Software).

Results

All 20 parent-child dyads (N=40) completed the 4 weeks of intervention and attended all sessions (including pre- and postintervention); all were included in the analyses. Parents were 44.1 (SD 7.8) years of age and 90% (18/20) female with a 34.2 (SD 6.8) kg/m^2 BMI, 15.7 (SD 2.3) years of education, and US $89,705.88 (SD US $58,429.19) household income. Children were 11.0 (SD 1.3) years of age and 45% (9/20) female with a 96.0 (SD 1.8) BMI percentile. There were no significant differences in participant baseline characteristics between the two conditions as shown in Table 1.

Analyses showed a significant overall difference in helpfulness for parents ($F_{1,17}$=5.12, P=.04), as parents in EFT reported higher helpfulness. There were no significant differences between conditions for parents' and children's mean ratings of ease of use ($F_{1,17}$=1.45, P=.25; $F_{1,17}$=1.03, P=.32), usefulness ($F_{1,17}$=0.21, P=.66; $F_{1,17}$=0.24, P=.63), and mean ratings of children's helpfulness ($F_{1,17}$=1.39, P=.25). No significant differences in any of the other variables to assess utility of the system were observed for parents or children as shown in Table 2.

Exploratory analyses for energy intake, red and green food intake, BMI, and percent overweight by parent-child and group are shown in Table 3. Results showed significantly greater reductions in BMI ($F_{1,17}$=8.83, P=.01) and percent overweight ($F_{1,17}$=8.99, P=.01) for parents in EFT versus control conditions. In addition, there were trends in larger reductions in energy intake for EFT versus control for both parents ($F_{1,17}$=3.05, P=.10) and children ($F_{1,17}$=3.93, P=.06). No other variables showed trends toward significance between group differences.

Table 1. Participant baseline characteristics.

		Child			Parent		
		EFT (n=11)	NIT (n=9)	*P* value	EFT (n=11)	NIT (n=9)	*P* value
Age (years), mean (SD)		11.1 (1.4)	11.0 (1.3)	.91	45.0 (7.1)	43.0 (8.8)	.57
Weight (lbs), mean (SD)		139.5 (28.7)	140.6 (38.8)	.94	203.6 (39.7)	205.3 (47.0)	.93
BMI (kg/m^2), mean (SD)		26.6 (3.7)	27.3 (4.5)	.70	33.5 (6.6)	35.0 (7.4)	.62
BMI percentile, mean (SD)		95.7 (2.1)	96.4 (1.4)	.37	93.2 (4.5)	93.6 (5.8)	.86
Percent overweight, mean (SD)		52.3 (18.7)	57.3 (22.0)	.59	52.5 (30.5)	61.4 (34.0)	.55
Usual calorie intake, mean (SD)[a]		2308.6 (719.5)	1923.7 (463.6)	.18	2153.3 (455.6)	1878.8 (382.4)	.17
Red food servings, mean (SD)[a,b]		22.3 (8.0)	21.7 (5.1)	.85	24.2 (8.8)	23.9 (4.0)	.93
Green food servings, mean (SD)[a,b]		0.7 (1.2)	0.7 (0.9)	.90	0.6 (0.8)	0.2 (0.4)	.30
DEBQ, mean (SD) [c]							
	Restraint	1.8 (0.5)	1.7 (0.5)	.40	3.0 (0.6)	2.8 (0.6)	.59
	Emotional	1.3 (0.5)	1.1 (0.1)	.19	3.1 (0.5)	3.0 (1.0)	.93
	External	2.1 (0.4)	1.8 (0.5)	.10	3.7 (0.4)	3.4 (0.4)	.10
Sex				.37			.20
	Male	5	6		2	0	
	Female	6	3		9	9	
Race/ethnicity				.78			.89
	Non-minority, non-Hispanic	8	6		10	8	
	Other race/ethnicity	3	3		1	1	
Education							.09
	Some high school				0	1	
	High school				0	1	
	Some college or vocational training				1	0	
	Completed 2-year college degree				2	2	
	Completed 4-year college degree				4	4	
	Compete graduate degree				6	1	
Income [d]							.17
	US $49,999 or less				1	2	
	US $50,000-89,999				4	3	
	US $90,000-139,999				2	3	
	US $140,000 or more				2	0	

[a]Assessed by 24-hour dietary recalls.

[b]Servings are based on the USDA Dietary Guidelines for Americans.

[c]Dutch Eating Behavior Questionnaire.

[d]A total of 3 participants chose not to answer this item.

Table 2. Adherence, device frequency, and ratings of the MAMRT system.

		Child			Parent		
		EFT (n=11)	NIT (n=9)	*P* value	EFT (n=11)	NIT (n=9)	*P* value
Adherence, n % (SD)							
	4-week average response	78.7 (15.1)	81.0 (15.5)	.65	87.0 (13.3)	92.9 (8.5)	.27
Device frequency, n % (SD) [a]							
	Desktop	27.0 (30.9)	16.1 (33.0)	.34	34.2 (38.9)	21.3 (33.7)	.33
	Tablet	21.4 (28.7)	31.2 (37.0)	.24	2.7 (5.9)	16.5 (31.3)	.15
	Mobile phone	51.7 (39.2)	52.8 (44.4)	.87	63.1 (38.5)	62.2 (45.1)	.92
Ease of use, mean (SD) [b]							
	Listening to audio cue before eating	3.5 (0.7)	3.6 (1.5)	.97	3.4 (0.7)	3.9 (0.8)	.41
	Thinking about events from audio cue during eating episodes	3.6 (0.9)	3.1 (1.6)	.37	3.8 (1.2)	3.6 (0.9)	.26
	Using audio cue in tempting situations	3.6 (1.0)	2.8 (1.5)	.18	3.5 (1.1)	2.7 (0.9)	.08
Usefulness, mean (SD) [b]							
	Nutrition audio cue	3.4 (0.9)	3.4 (1.5)	.79	4.0 (1.0)	4.0 (1.0)	.62
	Completing survey responses after listening to the audio cue	3.7 (1.2)	3.6 (1.6)	.67	2.5 (1.2)	3.1 (1.5)	.76
	Timing of the scheduled prompts and reminder messages	2.8 (1.1)	3.0 (1.7)	.87	3.7 (0.9)	3.3 (0.7)	.32
	Receiving prompts twice daily	3.8 (0.9)	3.2 (1.8)	.39	4.1 (1.1)	3.9 (0.6)	.80
	One web link to access audio cue and survey questions	3.8 (1.3)	3.3 (1.2)	.54	4.0 (1.4)	4.0 (1.3)	.75
Helpfulness, mean (SD) [b]							
	Changing eating habits	4.2 (0.9)	3.9 (1.1)	.25	4.3 (0.8)	3.9 (0.9)	.04

[a]Overall frequency of which device was used to access the system.

[b]Ratings of the system are on a 5-point Likert scale (values closer to 1=not at all; 5=extremely).

Table 3. Changes in dietary intake and body composition.

	Children			Parents		
	EFT (n=11)	NIT (n=9)	*P* value	EFT (n=11)	NIT (n=9)	*P* value
Usual calorie intake, mean (SD)[a]	−839.6 (650.7)	−443.2 (423.4)	.06	−791.2 (348.3)	−482.4 (237.3)	.10
Red food servings, mean (SD)[a,b]	−8.6 (7.2)	−6.8 (3.3)	.31	−7.5 (6.0)	−6.4 (3.0)	.88
Green food servings, mean (SD)[a,b]	0.8 (1.3)	0.8 (1.2)	.33	0.5 (0.8)	0.1 (0.3)	.19
BMI (kg/m^2), mean (SD)	−0.6 (0.5)	−0.4 (0.6)	.61	−1.0 (0.5)	−0.2 (0.5)	.01
Percent overweight, mean (SD)	−3.8 (3.1)	−2.7 (3.5)	.67	−4.6 (2.0)	−1.1 (2.2)	.01

[a]Assessed by 24-hour dietary recalls.

[b]Servings are based on the USDA Dietary Guidelines for Americans.

Discussion

Principal Findings

This study examined the feasibility, usability, and acceptability of our Web-based system, MAMRT, for dietary interventions. According to the Technology Acceptance Model, perceived usefulness and ease of use are determinants of acceptance and use of a certain technology [17]. Parents' and children's high ratings of ease of use and usefulness in both conditions suggest that the system was an accepted technology. Moreover, high ratings of helpfulness and high adherence suggest that our Web-based system is a feasible utility for interventions in both adults and children. No differences found between groups in ratings of ease of use and usefulness of the system and participant adherence suggest that our system is highly usable and may be adapted to serve a variety of EMI purposes (not limited to EFT or nutritional guidance).

To our knowledge, this is the first technology with a responsive design for users and investigators that collects detailed time-stamped usage of audio files including the duration accessed and the device type used (eg, mobile phone, tablet, desktop) to access those files, includes an automated messaging delivery service, and organizes and displays data based on investigator needs. These specifications were necessary in determining participant usability and acceptability and streamlining data collection for the investigators.

While the MAMRT system had several components (prompts, audio files, and database), the cost of execution was relatively low. The supporting software used (MySQL and Audacity) is free, and the creation of additional users (participants/investigators) required no cost. Furthermore, the portability and compatibility with various platforms and ability to modify survey questions suggest translation to other research topics and settings (eg, multisite).

Although our study was not powered to detect meaningful difference in changes in weight and energy intake, results favored the EFT participants in reduction of parent weight and trends toward significant differences in energy intake. These results support research demonstrating the effect of EFT in reducing the bias toward immediate gratification [10,12-14,26] that can be related to obesogenic behaviors [36,37]. While this feasibility study was only implemented for 4 weeks, these exploratory analyses supports future research in investigating MAMRT's use in interventions for changing unhealthy eating behaviors.

Strengths and Limitations

There are potential limitations in this pilot feasibility study. We excluded families without access to mobile electronic devices, which could potentially bias our sample. For example, adherence rates to the system could decrease for families with lower socioeconomic status (SES). Although our sample size was small, predominately white, and well-educated, electronic technologies have become more available, affordable, and widely adopted across all SES and age groups in the United States [38,39]. Furthermore, a strength to MAMRT is the flexibility for participants. Whereas some EMIs require mobile phones, short message service, and/or the use of certain operating systems, our system is not limited to any specific device, permitting participants to use the system at no additional cost. The flexibility of the system allows it to be available for all user demographics and diverse groups of participants. Moreover, delivery of the prompts (email or text) did not influence responses (eg, adherence, speed).

The 4-week use of the MAMRT is short, and its use was restricted by environmental limitations. Unlike parents, who generally had access to their electronic devices throughout the day, children were limited due to school and other obligations. Considering that some children consumed 2 of the 3 main meals during school, this restriction limited children's opportunity to use the system during those eating episodes. We also did not exclude individuals who did not have their own electronic devices. In the future, it would be interesting to see if requiring both parents and children to have their own mobile devices would increase EFT exposure and produce greater behavioral changes because results showed both parents and children used mobile phones more frequently than other devices to access the system.

Regardless of the small sample size and short duration of the intervention, we did find significant changes in parental weight and trends in energy intake favoring EFT for parents and children from pre- to postintervention. It is interesting that parents but not children reported the EFT system to be more helpful than control. Understanding the basis for these generational differences in perception of helpfulness may be important to design more powerful EFT interventions as complements to obesity treatment in the future.

It is plausible that children in the EFT condition were unable to master all the new dietary information introduced in that short amount of time in conjunction with learning EFT. Perhaps EFT children were overwhelmed by having to simultaneously learn nutritional information and the use of EFT. In a longer program, it may be beneficial to phase in EFT after the basic aspects of family-based weight control treatment have been mastered. Further research is needed to investigate if increased exposure to EFT and MAMRT would produce greater behavioral changes.

Other studies have demonstrated the feasibility of using technology in weight control [40,41] and even suggested that EMI enhances standard treatments [42,43]. As family-based treatments last for considerably longer than 4 weeks, it is important to investigate if increased exposure to MAMRT and greater exposure to elements of traditional family-based treatments (eg, dietary information, exercise program, positive parenting) would produce greater and more sustained weight loss and changes in eating behavior. One advantage of the use of technology to implement EFT is that EMI can reduce the burden that may accompany traditional in-person treatment meetings. These advantages include daily support, reduced expenses (eg, travel) and participation in interventions, and personally tailored programs for participants. Tailoring programs may increase effectiveness of health behavioral interventions [44,45]. Moreover, our system could be a suitable replacement for dietary recording, which can be time consuming and challenging for participants. It is possible that the use of the MAMRT system may reduce the need for as many in-person meetings as traditional family-based treatment, making the treatment more accessible and powerful.

Conclusion

This study examined the feasibility of a Web-based intervention for children and adults that adapts EFT for delivery of family-based obesity treatment. These results demonstrated that both adults and children found MAMRT usable and acceptable; adherence to the system demonstrated its feasibility, consistent with the Technology Acceptance Model [17,18]. Future research is needed to determine its utility in behavioral change. These findings have implications for family-based interventions that attempt to improve eating behaviors in adults and children simultaneously, in the real world and in real time.

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Authors' Contributions

YYS contributed to the development of the Web-based system and the initial draft of manuscript; TOD, LHE, CKK, and RLC contributed to the study design; YYS, TOD, and CKK contributed to the data collection; and YYS, TOD, CKK, and LHE contributed to the data analysis and results interpretation. All authors provided critical revisions to the paper and approved the final manuscript. Funding was awarded to LHE.

Conflicts of Interest

LHE is a consultant and has equity in Kurbo. Others have no conflicts of interest to declare.

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Abbreviations

ANOVA: analysis of variance
BMI: body mass index
DEBQ: Dutch Eating Behavior Questionnaire
EMI: ecological momentary intervention
EFT: episodic future thinking
MAMRT: Mobile Audio Manager and Response Tracker
NIT: nutritional information thinking
SES: socioeconomic status

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Original Paper

A Community-Engaged Approach to Developing an mHealth HIV/STI and Drug Abuse Preventive Intervention for Primary Care: A Qualitative Study

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Abstract

Background: Despite ongoing prevention efforts, HIV and other sexually transmitted infections (HIV/STIs) and drug use remain public health concerns. Urban adolescents, many of whom are underserved and racial minorities, are disproportionately affected. Recent changes in policy, including the Affordable Care Act, and advances in technology provide HIV/STI and drug abuse prevention scientists with unique opportunities to deliver mobile health (mHealth) preventive interventions in primary care.

Objectives: The purpose of this community-engaged study was to develop an mHealth version of the Storytelling for Empowerment preventive intervention for primary care (hereinafter referred to as "S4E").

Methods: A total of 29 adolescents were recruited from a youth-centered primary care clinic in Southeast, Michigan, to participate in qualitative interviews. Participants were predominantly African American (n=19, 65.5%) and female (n=21, 72.4%) with a mean age of 16.23 (SD 2.09). The principles of community-based participatory research (CBPR), in conjunction with agile software development and the recommended core prevention principles of the National Institute on Drug Abuse (NIDA) were employed during S4E development. CBPR principles are aimed at improving the effectiveness of research by addressing locally relevant health problems, working with community strengths, and translating basic science into applied research. Complementing this approach, the NIDA prevention principles are derived from decades of drug abuse prevention research aimed at increasing the effectiveness and uptake of programs, through the development of culturally specific interventions and ensuring the structure, content, and delivery of the intervention fit the needs of the community. Data were analyzed using thematic analysis.

Results: A total of 5 themes emerged from the data: (1) acceptability of the mHealth app to adolescents in primary care, (2) inclusion of a risk assessment to improve clinician-adolescent HIV/STI and drug use communication, (3) incorporation of culturally specific HIV/STI and drug use content, (4) incorporation of interactive aspects in the app to engage youth, and (5) perspectives on the appearance of the app.

Conclusions: There is a dearth of mHealth HIV/STI and drug abuse preventive interventions for primary care. Incorporating the principles of CBPR in conjunction with agile software development and NIDA-recommended core prevention principles may

be helpful in developing culturally specific mHealth interventions. An important next step in this program of research is to examine the feasibility, acceptability, and efficacy of S4E on adolescent sexual risk and drug use behaviors, and HIV/STI testing. Implications for prevention research and primary care practice are discussed in the context of the Affordable Care Act and technological advances.

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KEYWORDS

adolescent; primary prevention; HIV; STI; mHealth; telemedicine; primary health care; drug users; sexually transmitted infections

Introduction

Despite ongoing prevention efforts, HIV/STI and drug use remain public health concerns in the United States. Compared with older age groups, for whom incidence has remained stable, HIV/STI incidence among youth (aged 15-19) continues to increase [1,2]. The disproportionate incidence of HIV/STI during adolescence may be attributed to increased risk taking during this developmental period [3], including the onset of sexual and drug use behaviors [4,5]. Disparities among adolescents also suggest that underserved racial/ethnic minorities, many who live within urban contexts, are more likely to engage in HIV/STI risk behaviors, including drug use [4,5], and use of alcohol and drugs prior to sexual intercourse [4]. These drug use patterns may increase youth's engagement in sexual risk behaviors (eg, inconsistent condom use) and subsequent exposure to HIV/STI infections. Given the dearth of mHealth interventions that assess and target multiple HIV/STI adolescent risk behaviors (ie, drug use and sexual risk behaviors) and increase HIV/STI testing [6-8], the purpose of this study was to develop an mHealth version of the Storytelling for Empowerment preventive intervention.

A face-to-face intervention, Storytelling for Empowerment (SFE) is registered as a best practice with the Substance Abuse and Mental Health Services Administration (SAMHSA) National Registry of Evidence-Based Programs and Practices. SFE was developed in 1995 with a grant from the SAMHSA Center for Substance Abuse Prevention High Risk Youth Program and was further evaluated through three subsequent SAMHSA grants. SFE aims to increase HIV/STI and drug use self-efficacy, including condom use skills, knowledge, HIV/STI testing, and communication. SFE has been shown to prevent and reduce HIV/STI risks, including drug use and sexual risks [9-11]. SFE consists of 6 core sections, including knowledge power (eg, effects of drug use), skill power (eg, decision making), personal power (eg, self-efficacy), character power (eg, empowerment), cultural power (eg, community protective factors), and future power (eg, clinician-adolescent HIV/STI communication). Although the original SFE intervention focused on licit and illicit drug use outcomes [9,10], additional sections on sexual risk behaviors have been developed and evaluated [11].

The ecodevelopmental framework [12-14] postulates that adolescents are embedded in integrated ecological systems and may experience heightened vulnerability to negative health outcomes if they lack developmentally appropriate skills required to navigate these different systems. Building on developmental and social interaction theories, ecodevelopmental theory further posits that these systems influence and are influenced by the adolescent over time [12]. Within this framework, researchers have proposed empowerment strategies that link youth's strengths and proactive behaviors to natural helping systems, while offsetting risk behaviors [15]. While most ecodevelopmental interventions to date have focused on the family microsystem (eg, improving family functioning and parent-adolescent communication) [14,16,17], fewer youth-driven interventions have been tested within the primary care microsystem. Thus, for the purposes of this study, we focus on the primary care microsystem. Recommendations issued by the United States Preventive Services Task Force have highlighted the need for primary care clinicians to provide screening for HIV/STI risk behaviors (eg, drug use) and HIV/STI status [18]; however, few HIV/STI and drug abuse preventive interventions for primary care exist [19,20].

Recent shifts in public health policies, including the Affordable Care Act (ACA), combined with advances in technology, provide prevention scientists and practitioners alike with innovative opportunities to implement HIV/STI and drug abuse preventive interventions. For example, mobile health (mHealth) interventions, including apps and primary care settings, offer novel approaches and contexts to deliver prevention programs [6,7,21]. Yet, few researchers have developed mHealth HIV/STI and drug abuse preventive interventions for primary care that focus on curbing risk practices (eg, drug use, condomless sex) and increasing HIV/STI testing [7,8,19]. Even fewer researchers have employed the principles of community-based participatory research (CBPR) to inform the development and adaptation of efficacious HIV/STI and drug abuse preventive interventions into an mHealth platform for primary care. A community-engaged approach may aid in the development of theory-driven, culturally specific mHealth interventions for the targeted community [22]. The purpose of this community-engaged study was to adapt face-to-face SFE [9-11], an efficacious adolescent HIV/STI and drug abuse preventive intervention, into an mHealth modality for primary care (S4E). For the purposes of this study, S4E was culturally specific such that the development was youth driven, targeted a specific health care center, and addressed the local HIV/STI and drug use community needs.

Methods

This study was guided by the principles of CBPR (eg, build on the strengths and resources of the community [23]). As part of this approach, the Youth Leadership Council (YLC) was engaged in all aspects of the study, including proposal submission, development of the interview guide, participant

recruitment, identification of content for app development, and manuscript preparation. The YLC is a diverse, youth-led group that aims to research community health issues, use media and the arts to advocate for change, and partner with universities to make the primary care clinic and surrounding community a healthier place for adolescents.

Sampling and Recruitment

Initially, we aimed to recruit younger adolescents (ie, 13-15 years of age). However, at the recommendation of the YLC, we changed our approach and targeted a study sample that was more representative of the primary care clinic population (ie, 12-21 years of age). Therefore, to be included in this study, participants had to (1) be between 13 and 18 years of age, and (2) provide assent and parental consent (if under 18 years of age). Potential participants were recruited from the waiting room of the primary care clinic via strategies found to be effective when conducting qualitative research with vulnerable populations [24]. As such, recruitment procedures included establishing relationships with the primary care clinic, face-to-face flier distribution, word of mouth, and snowballing approaches. For example, participants reached out to their peers who also received services at the clinic and informed them about the study. Data collection occurred between December 2013 and October 2014, and was approved by our University's Institutional Review Board.

A total of 29 adolescents participated in this study. Participants were primarily African American (n=19, 65.5%), followed by non-Hispanic white (n=7, 24.1%), Hispanic (n=2, 6.8%), and other (n=1, 3.4%). The majority of adolescents were female (n=21, 72.4%) with a mean age of 16.21 (SD 2.12).

Interview Guide

The interview guide consisted of 3 open-ended grand tour questions aimed at minimizing questioning bias and privileging participants' voices: "Would you please describe your thoughts about participating in an intervention delivered on a mobile device through your primary care clinic that is designed to prevent HIV/STI and drug abuse in adolescents?" "What content would you find most helpful to include and engage people your age?" "Would you please describe your thoughts regarding the design aspects and what the app should look like?" The grand tour questions were followed by probes to gather in-depth data (eg, "How long should the app last?"). Furthermore, we included probes to ensure that our questions were tethered to the SFE modules and to gather in-depth data on how they could be translated to an app-like experience. For example, our grand tour question, "What content would you find most helpful to include and engage people your age?" was followed by probes such as, "What information with respect to HIV/STI and drug use would you find helpful in an app?" Data gathered from this probe were then applied to the development of the knowledge aspects of the app, which correspond to knowledge-, skill-, personal-, character-, cultural-, and future-power aspects of SFE. To ensure that we did not overlook any design, content, or process aspects that adolescents believed to be important in the development of the app, participants were asked at the conclusion of the interview to discuss any relevant topics that were not addressed. Consistent with the iterative process, the interview guide was gradually modified after each interview to include probes that participants identified as relevant and that were not initially included in the interview guide (eg, "What are your thoughts on including a risk assessment to promote clinician-adolescent communication?").

Procedures

Focus group and individual interviews were utilized for data collection. Focus group interviews have been shown to be empowering for vulnerable populations, as the group processes allow for a shared experience among participants and may produce data that cannot be obtained solely through individual interviews [24,25]. A total of 9 focus group interviews (n=25) were conducted and ranged in size from 2 to 6 participants. A limitation to focus group interviews, however, is that not all adolescents may feel comfortable discussing topics related to sexual risk and drug use behaviors in a group setting. Therefore, we also conducted individual interviews (n=4). All interviews were conducted in a private room located in the primary care clinic. Each interview was digitally recorded, lasted between 45 and 75 minutes, and was facilitated by the lead author and trained research assistants. Prior to each interview, a meal was shared between the research team and participants, aimed at facilitating informal conversations and building rapport [24]. Participants were provided bus tokens and received a US $20 incentive.

Guided by the principles of agile software development [26], the qualitative interviews and app programming were synergistic. Agile software development aims for continuous design improvement and testing based on rapid feedback and change [26]. The development of the HIV/STI and alcohol/drug modules was informed by the qualitative interviews in conjunction with relevant National Institute on Drug Abuse (NIDA) core prevention principles. For the purposes of this study, we employed NIDA-recommended prevention principles 1, 2, 3, 4, 8, 9, 12, 13, 15, and 16 [27] (Table 1). While we conducted interviews to identify HIV/STI and drug use-specific content to include in the app, the interface was being built. Thus, the backend system and framework (eg, code, database, design) were developed as qualitative data were collected. As part of the iterative process, weekly meetings were held with the programmer to discuss all aspects of the app development, including content, framework, and UX (user experience). Once the qualitative interviews were completed and content was finalized, the messaging was incorporated into the interface.

Table 1. Incorporating the NIDA prevention principles into the app development.

NIDA prevention principles	How this was accomplished
Principle 1: Programs should enhance protective factors and prevent and reduce risk factors.	S4E aims to improve clinician-adolescent HIV/STI and drug use communication, condom use and drug use resistance self-efficacy, and increase HIV/STI testing.
Principle 2: All forms of licit and illicit drug abuse should be addressed.	The Alcohol/Drugs module includes both licit and illicit drugs, including abuse of medication without a doctor's prescription.
Principle 3: Programs should address culturally specific risk and protective factors and licit and illicit drug use in the targeted community.	In-depth qualitative data informed the development of culturally specific content, including risk and protective factors and licit and illicit drug use.
Principle 4: Prevention programs should be tailored to address risks specific to the targeted community, including age, gender, and race, to improve program effectiveness.	The community-engaged approach aimed to identify risks specific to the targeted community.
Principle 8: Programs targeting high-school students should increase social competence skills, including communication, self-efficacy, and drug-resistance skills.	S4E aims to improve clinician-adolescent HIV/STI and drug use communication, self-efficacy, and drug-resistance skills.
Principle 9: Programs aimed at key transition points, including the transition to young adulthood, may yield beneficial effects.	S4E targets those in adolescence and young adulthood, a transitional period marked by increased risk taking.
Principle 12: Adapted programs should retain the core elements of the original research-based intervention.	We retained the core elements (knowledge development, self-efficacy, and communication) of the face-to-face Storytelling for Empowerment intervention.
Principle 13: Programs should be long-term, including the use of booster sessions.	An mHealth app may provide opportunities for adolescents to engage in long-term prevention, including booster sessions.
Principle 15: Prevention programs should include interactive exercises to work toward optimally effective interventions.	S4E incorporates interactive exercises. Additionally, we plan to develop a clinician component to allow interaction and retrieval of adolescents' risk assessment data, with an aim of improving clinician-adolescent interaction, including HIV/STI and drug use communication.
Principle 16: Research-based programs can be cost effective.	mHealth apps, including S4E, have the potential to be cost effective through greater reach to populations disproportionately affected by HIV/STI and drug use, as well as by relieving some of the responsibilities and sparing resources in a clinic setting.

Analytic Approach

Trained research assistants transcribed verbatim the digital audio recordings of each interview. A different research team member then reviewed these transcripts for accuracy. Data were transferred to NVivo 10 (QSR International Pty Ltd) for storage, organization, and analysis. Data analysis followed the tenets of thematic analysis, which consisted of 6 sequential steps [28,29]. First, the research team familiarized themselves with the data by transcribing all interviews and reviewing each transcription prior to the next scheduled interview. Second, the research team met weekly and generated an initial list of codes to discuss. Third, the initial codes were collated into emerging themes. Fourth, the team generated a thematic table of the analyses and checked the extent to which the emerging themes reflected the coded extracts and data. Fifth, the team generated clear definitions and names for each theme and overall analysis. Lastly, the team identified the most compelling examples relating back to the analysis of the study [28,29].

The analytic process yielded 252 initial codes. Of these, 5 themes were identified (see Table 2 for the analytic process): (1) an mHealth app is acceptable to adolescents in primary care, (2) inclusion of a risk assessment to improve clinician-adolescent HIV/STI and drug use communication, (3) incorporation of culturally specific HIV/STI and drug use content, (4) incorporation of interactive aspects in the app to engage youth, and (5) perspectives on the appearance of the app. Following each theme, we describe the ways in which qualitative data were used to inform the development of the S4E app and, where applicable, how each aspect translates to the content of the original SFE intervention.

Table 2. Thematic analytic process.

Research question	Theme	Categories	Subcategories
"What are the facilitators and barriers to participating in an mHealth intervention in a primary care setting?"	An mHealth app is acceptable to adolescents in primary care.	Barriers to using an app	Confidentiality
		Facilitators to using an app	Informational
			Youth familiarity with technology
		Perspectives on the length and delivery of the preventive intervention	Mode of delivery
			Length
			When to deliver
			Where to deliver
"What are your thoughts about including your physician and/or parents in an mHealth preventive intervention?"	Inclusion of a risk assessment to improve clinician-adolescent HIV/STI and drug use communication	Barriers to communicating HIV/STI risk behaviors to physicians	Barriers to talking to doctors/nurses
			Methods to improve doctor/nurse communication
			Why youth do not seek help
		Facilitators to communicating HIV/STI behaviors to physicians	Why include doctors/nurses in the app
			Why it is easier to talk to doctors/nurses
			Doctors can answer questions/help you understand
"What do you believe are the most relevant drug/alcohol and sexual risk behaviors in your community that could be included in this intervention?"	Incorporation of culturally specific HIV/STI and drug use content	Specific HIV/STI to highlight	HIV/AIDS
			Gonorrhea
			Chlamydia
			Herpes
		HIV/STI risk and protective factors	Why youth are participating in risky sexual behaviors
			Why youth do not use condoms
			Relevant risky sexual behavior
			Where youth get information
			Availability of free condoms
		HIV/STI knowledge development	Birth control methods
			Signs/symptoms of STIs
			Pregnancy
			Including a doctor when talking about condoms
		Specific licit and illicit drugs to highlight	Marijuana
			Alcohol
			Prescription pills
		Drug use risk and protective factors	Relevant topics to app besides sex and drugs
			Substance use in schools
			Why youth use substances
			How to prevent substance use

Research question	Theme	Categories	Subcategories
		Drug use knowledge development	Long-term effects of drug use
			Drug effects
			How to stop using drugs
"What kinds of activities would you find most interesting to maintain your attention in an app?"	Incorporation of interactive aspects in the app to engage youth	Including activities to engage youth	Quiz
			Game
			Glossary/vocabulary words
			Number of activities
		Using videos to engage youth	Characteristics of the videos
			People in the videos
			Content of the videos
			Length of the videos
		Perspectives on including audio	Not including music in the app
			Including music in the app
			Type of music
"What are your opinions in terms of the kind of style the app should have? What colors do you find most engaging?"	Perspectives on the appearance of the app	Format	Different sections
			Interactive/user-friendly
			Ages to target
		Appearance of the app	Simple
			Bright colors
			Text
			Images

Trustworthiness of Data

Trustworthiness of data is the process by which methodological rigor is employed to minimize researcher bias and ensure study findings accurately describe the participants' perspectives [30,31]. Trustworthiness was established through credibility, transferability, dependability, and confirmability [31]. To ensure credibility, or rigor in the research process, the research team participated in prolonged engagement with participants, research reflexivity, and coanalysis. The primary author, for example, made many informal visits to the primary care clinic, including sharing meals with potential and former participants. Transferability is the extent to which study findings can be applied to other contexts. To this end, the study sample and methodological approach used to develop the app have been described in detail. Dependability is concerned with working toward explicit and repeatable study findings. This was achieved by conducting an audit trail to document research decision-making processes. Lastly, confirmability acknowledges that in qualitative research, because the researcher is the data collection instrument, there is the potential for biases. Because the data collection and app development were synergistic, this process allowed for management of subjectivity. For example, in each subsequent interview, we provided examples of design templates informed by feedback from previous interviews. This was done once participants shared their perspective and essentially served as member checks [31].

Results

An mHealth App is Acceptable to Adolescents in Primary Care

Participants (N=29) provided insight into a framework for the acceptability, logistical aspects, and potential barriers when using an app in primary care. Adolescents reflected on when and where to deliver the app, what platform to use, and the most appropriate length to maintain engagement.

Barriers and Facilitators to Using an App

Participants (N=29) were asked about the barriers and facilitators to using an app in primary care. The biggest potential barrier noted by participants was that of confidentiality. One participant expressed,

> *Just your overall level of comfort with sharing experiences with an electronic device is not really, to some people it might be a little bit risky, you know? Because they're like, "I mean, who's gonna look at this? Is this gonna be part of a statistic?" Just confidentiality.* [Male, 18]

Similarly, another participant expressed,

> *Just wondering how many people would be able to see your answers or your responses to whatever is on the app?* [Female, 15]

Adolescents also shared their perspectives with respect to the facilitators and acceptability of an app in primary care. Participants stated that an app was ideal because of the familiarity that youth have with technology. For example, one participant mentioned,

> *I think an app would be more attractive, rather than a clipboard and seven pieces of paper, you know? People our age are more gravitated towards technology and stuff like that.* [Male, 18]

Another adolescent expressed,

> *I feel like an app being used in a doctor's office, it would be something that would be more memorable than maybe looking at a piece of paper [brochure on HIV/STI and drug use information].* [Female, 16-18]

Perspectives on the Length and Delivery of the App

Participants mentioned that to effectively deliver information, the app would have to be relatively short to maintain adolescents' attention. One participant expressed,

> *I don't think it should be extremely long, but I don't think it should be really short. I think it should maybe be just right. You don't want to make it where they get tired of it, but you want to have different options in that they don't do the same one over and over again.* [Female, 13-15]

Similarly, another participant mentioned,

> *It should maybe be, like, 10 minutes, 15 minutes.* [Female, 13-15]

Participants also expressed their views on when and where the app would be most effectively delivered. Many adolescents mentioned the app should be delivered before seeing their doctor. One individual stated,

> *Deliver the app at check-in because that can also, especially if you are there for the doctor, you were to be like, say the behavior (drug use, sexual risk) to talk about today. It kind of can link in with the doctor's appointment.* [Female, 16-18]

With respect to where to deliver the app, participants noted a preference for either the waiting or exam rooms while waiting for the clinician. One participant stated,

> *I think an exam room would be best.* [Male, 16-18]

Another adolescent expressed a preference to complete the app in the waiting room, as long as the mobile device had a privacy screen protector:

> *There are also like screen protectors that you can put on the screen so that if you look from the side, it just appears black but like if you're looking at it straight on looks, like you can see it normal. So that might be a good idea.* [Female, 17-18]

App Development

Data provided insight into the acceptability of delivering a preventive intervention via an mHealth app in primary care. Based on adolescents' feedback, we developed an app that aims to ensure participants' confidentiality such that only their clinician will have access to their responses. Specifically, adolescents are assigned unique username and password information aimed at maintaining their confidentiality, including risk assessment responses. A next important step will be the production of a clinician interface to communicate and retrieve adolescent risk assessment data while maintaining compliance with Health Insurance Portability and Accountability Act standards. Furthermore, we developed an app that is relatively short in duration and can be completed during their health care visit. Specifically, the S4E app can be completed in less than 60 minutes and delivered in the clinic waiting/exam rooms.

Inclusion of a Risk Assessment to Improve Clinician-Adolescent HIV/STI and Drug Use Communication

Participants (N=29) expressed their opinions on barriers to clinician-adolescent HIV/STI and drug use communication, and the role that an app may play in facilitating these difficult conversations.

Barriers to Clinician-Adolescent HIV/STI and Drug Use Communication

Participants (N=29) discussed barriers to communication and engagement in clinician-adolescent HIV/STI and drug use communication. Adolescents expressed concerns with regard to being judged by their clinician. For example, one participant stated,

> *Who likes to just go to somebody and say, "I'm on drugs?" That's, like, something that you don't really talk about a lot. So, it's, like, why would I tell a doctor if they are going to look down on me or something, like, make you feel worse about doing it?* [Female, 16-18]

Another participant reflected,

> *Kids aren't always honest with their doctors. They might have a reason. They might be afraid they're going to tell their parents. They might feel like they're gonna be judged.* [Female, 16-18]

Role of an App in Facilitating Clinician-Adolescent HIV/STI and Drug Use Communication

Participants (N=29) described the role that an app may have in facilitating clinician-adolescent HIV/STI and drug use communication. Specifically, adolescents suggested that, as part of the app, a risk assessment would help to facilitate difficult conversations, including sexual risk and drug use behaviors. For example, one participant mentioned,

> *A lot of people don't say things to doctors that they're thinking or feeling. So, if you could just do it through the app, it would be easy.* [Female, 17-18]

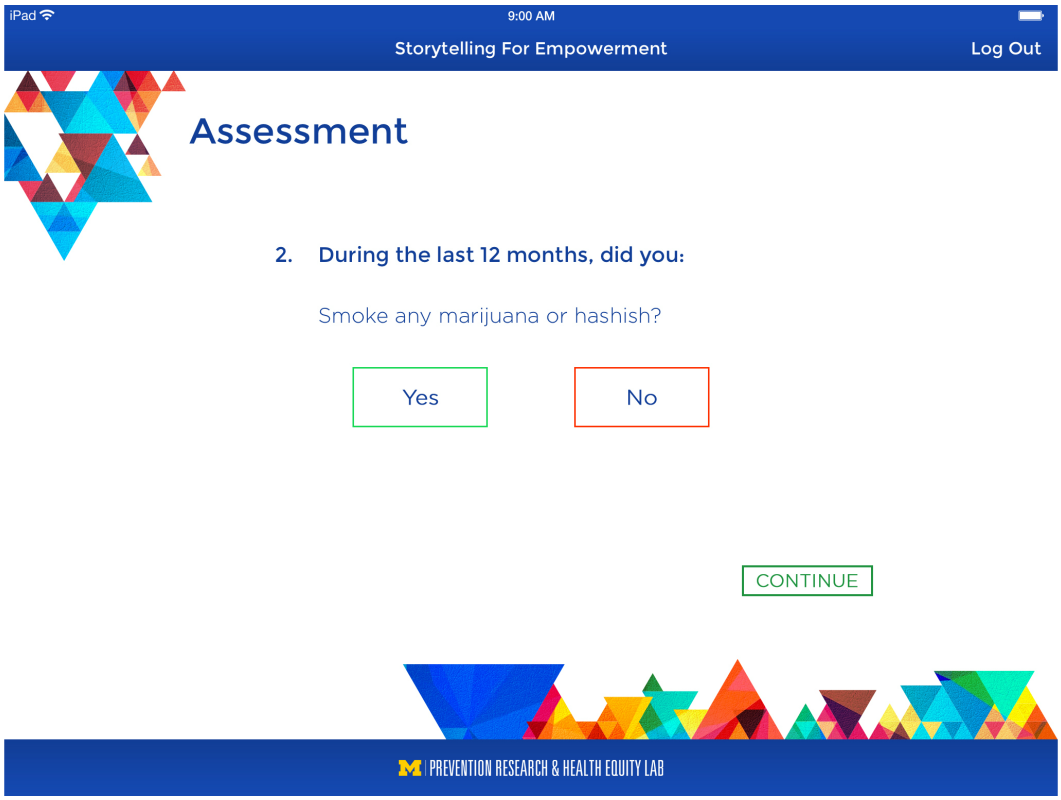
Similarly, another adolescent expressed,

> *I think that would be a lot better (having an assessment shared with a clinician), because some teens are kind of scared to say it face-to-face about substance use or sexual things. So, I feel like the app would be a lot better.* [Female, 15]

App Development

Data informed the development of a brief risk assessment as part of the S4E intervention. The risk assessment is completed prior to participating in the HIV/STI and Alcohol/Drug Use modules, assesses past 12-month sexual risk and alcohol and drug use behaviors, takes approximately 1 minute to complete, and will be provided to the clinician to initiate and engage the adolescent in HIV/STI and drug use communication (Figure 1).

Figure 1. S4E risk assessment.



Incorporating Culturally Specific HIV/STI and Drug Use Content

Participants (N=29) shared the importance of culturally specific HIV/STI and drug use content that is prevalent in their community.

Specific HIV/STI to Highlight

Participants (N=29) suggested specific HIV/STI to highlight and areas in which they believe knowledge could be increased. For example, one adolescent stated,

> *I know a lot of people who are concerned about herpes, gonorrhea, chlamydia, and AIDS.* [Female, 15]

Similarly, another participant mentioned,

> *The ones (HIV/STI) that are not typically talked about, like, syphilis isn't typically talked about. Like, chlamydia and gonorrhea is mentioned, but it's not always talked about.* [Female, 16-18]

Another adolescent expressed,

> *With STDs, it's not a matter of which STD to teach about, it's a matter of how to teach about all of them. Because they are all really important.* [Male, 16-18]

HIV/STI Sexual Risk and Protective Factors

Participants (N=29) described specific HIV/STI sexual risk and protective factors that should be highlighted in the app. By far, the most frequently reported risk factor was condomless sex. One participant shared an experience of having engaged in condomless sex and stated,

> *I don't know man, I wasn't thinkin'. I wanted to see how it feels.* [Male, 13-15]

Another participant described peer pressure and not having condoms,

> *The only thing I can really think of is like peer pressure. I know like a lot of people have older friends and they might not be doing safe sex because I know I have old friends. I have friends that are having sex, so it could be peer pressure or they just don't have a condom, and they want to have sex so bad.* [Female, 13-15]

Youth also shared their views with regard to HIV/STI protective factors, with a focus on self-efficacy. One participant stated,

> *I think it's really important for people to understand that they are in charge of their bodies, not their doctor, not their mom, not their dad, them.* [Female, 16-18]

HIV/STI Sexual Risk Knowledge Development

Participants (N=29) reflected on the importance of the app as a vehicle to disseminate HIV/STI information, including signs and symptoms of HIV/STI, and condom use. For example, one adolescent mentioned,

> *I think educating people about birth control, like knowing that there is more than just condoms (is important).* [Female, 16-18]

Adolescents also mentioned the app should include a section on symptoms. One participant shared,

> *Include symptoms that you could be having and you could confuse with something more simple, like the common cold. And actually learning that the most common symptom is no symptoms at all.* [Female, 17-18]

Specific Licit and Illicit Drugs to Highlight

Adolescents (N=29) identified licit and illicit drugs that were relevant to their community. Not surprisingly, participants focused on alcohol and marijuana. One adolescent stated,

> *Everybody is using all different types of drugs, but marijuana is the one I see a lot.* [Female, 17-18]

Additionally, youth discussed prescription pills as problematic in their community. For example, one participant stated,

> *It's not even sometimes specific pills. It's just whatever you find in the cabinets of some people.* [Female, 13-15]

Similarly, another participant shared the following:

> *I think it's a lot easier to take a pill than to smoke a blunt I guess. Because you take pills, a lot of people take pills on a daily basis. Like, it's normal. I grew up with pills or whatever. I think it's a lot easier to kind of deal with yourself.* [Male, 16-18]

Licit and Illicit Drug Use Risk and Protective Factors

Participants (N=29) explored potential risk and protective factors for adolescent drug use. The majority of youth identified risk and protective factors within family and peer contexts. One participant stated,

> *A lot of kids have problems that are going on at home and they don't know like another way to deal with it than drugs.* [Female, 18]

Another adolescent noted that peer pressure has a salient influence on drug use,

> *I think kids our age are using drugs because, at our school, there's a whole bunch of popular kids. And, you know, they do all that stuff. So, the kids that haven't done it yet, they do it just to get attention from them so they can hang out with them.* [Female, 13-15]

With regard to protective factors, youth identified the importance of having a trusted adult in their lives. One participant mentioned,

> *Honestly, somebody that knows me a while that I can get to know too. Someone, like, an adult who I've known them my whole life. I can talk to them about personal things and all that so he can tell me what to do, give me some stuff, ideas I can do and go to.* [Male, 13-15]

Licit and Illicit Drug Use Knowledge Development

Adolescents (N=29) mentioned various myths and questions many adolescents have with respect to drug use. Participants were particularly interested in creating app content that addressed facts and effects of drugs relevant to their community. In addition, participants expressed the importance of content that aims to educate, as opposed to create fear in adolescents, as well as harm reduction approaches:

> *So, if you drink a lot, don't say, "Don't drink because of this or that." Say, "If you are drinking, here are some steps that you can take to no longer drink or to at least not excessively drink." Not saying, "Stop drinking completely."* [Female, 16-18]

App Development

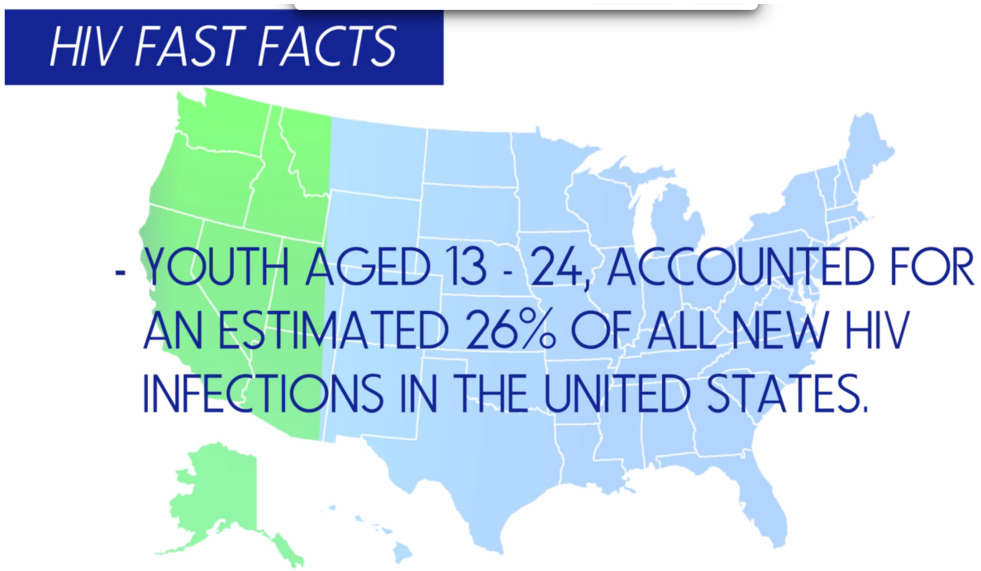
Data were combined to develop characters and scripts for videos as part of the S4E preventive intervention. In addition, with an aim of developing culturally specific content for the targeted community, content development was informed by local HIV/STI and drug use epidemiologic data. Working closely with the Youth Leadership Council, in conjunction with the NIDA-recommended prevention principles, we developed and included videos highlighting community-specific sexual risk (eg, condomless sex) and drug use (eg, marijuana) behaviors, HIV/STI and drug use risk (eg, peer pressure) and protective (eg, self-efficacy) factors, and HIV/STI and drug use knowledge development (eg, condom demonstration, refusal skills). Draft models of characters and storylines were shown to adolescents to gather feedback, and necessary revisions were made before finalizing the stories (Figures 2 and 3). As an illustration, one video focused on 3 characters, 2 of whom engaged in unprotected sex while the third demonstrated condom use self-efficacy and refusal skills. The video highlighted HIV/STI sexual risk (ie, peer pressure) and protective (ie, self-efficacy) factors, HIV/STI sexual risk (ie, condomless sex) and protective (ie, condom use) behaviors, and unintended health consequences of HIV/STI risk behaviors (ie, acquisition and transmission of HIV/STI). Furthermore, throughout the development process, we ensured that the videos aligned with core concepts of the face-to-face version of SFE intervention (ie, knowledge-, skill-, personal-, character-, cultural-, and future-power). In this video, for example, the messaging incorporates knowledge power (ie, effects of condomless sex), skill power (ie, decision making strategies), character power (ie, positive character traits), cultural power (ie, community-specific protective factors identified in the qualitative interviews), and future power (ie, clinician-adolescent HIV/STI and drug use communication).

Beyond the development of the storytelling videos, we utilized the data to develop videos aimed at increasing HIV/STI and drug use knowledge and self-efficacy. The videos focused on HIV/STI and drug use epidemiological data (eg, prevalence, etiology, effects, and symptoms) that youth identified as important to them (Figure 4).

Figure 2. Draft model of storytelling character and video.

Figure 3. Finalized storytelling character and video.

Figure 4. HIV/STI knowledge development.



Incorporating Interactive Aspects in the App to Engage Youth

Participants (N=29) elaborated on interactive activities the app could include to engage youth. Familiar media sources, such as videos, audio, and creative interactive activities, were discussed as important elements to incorporate to engage youth and increase participation in the app.

Including Interactive Activities to Engage Youth

Youth (N=29) discussed the importance of interactive information delivery. Participants expressed that drag and drop modalities, games, and quizzes might be helpful to reinforce information provided in the app. For example, one adolescent expressed,

> *Just not something you would read in school. Like, long paragraphs and stuff. I think kind of more quotes and stuff would kind of make you more interested instead of paragraphs and stuff.* [Female, 15]

Another participant emphasized activities to keep adolescents' interested and shared,

> *I don't know if you could turn it into games, but if you could turn it into a game, do it. It will keep the interest there. I'll play, continue to play it because it keeps me interested.* [Female, 16-18]

Other participants suggested using the app to evaluate the learning process:

> *Like, for activities, just make it more interactive. Maybe you could have a rate of test your knowledge kind of thing. You could have it where they would maybe take a pretest and they see how they get what they know, and then like at the end of looking at what you're looking at, you could have something where it's like a posttest.* [Female, 13-15]

Adolescents commented on the importance of keeping the activities youth-friendly, fun, and interactive, while also presenting important information. One participant mentioned,

> *I don't think it should be serious the whole time, but it should be serious, not just all humor, so they understand it's a topic that's serious.* [Male, 13-15]

Another adolescent mentioned,

> *It's a serious topic, but at the same time, it could be fun.* [Male, 18]

Using Videos to Engage Youth

Youth shared the importance of including videos to "hook" the adolescents' interest in the app. For example, one youth stated,

> *I think that to make the app better, we should like put videos of people who have those problems and so we can see what people actually have to go through.* [Female, 13-15]

Another participant expanded,

> *Maybe a more literal approach to the effects and the experiences…Why you don't want it [HIV/STI], how to get it, what you should do to prevent it…somebody that's not afraid to open up. You need experience right there live in your face, to be like, "wow."* [Male, 18]

Participants also mentioned the utility of animated videos and the ways in which these videos would help engage youth. One participant expressed,

> *We could try, you could have a comic strip with the characters and you could talk about drugs and stuff.* [Male, 13-15]

Perspectives on Including Audio

Youth expressed the importance of including both video and audio as part of the app processes. One participant noted,

> *Probably have like captions and then read to you. You can follow along with it.* [Male, 13-15]

Another adolescent mentioned,

> *I think I would learn more by hearing it.* [Female, 13-15]

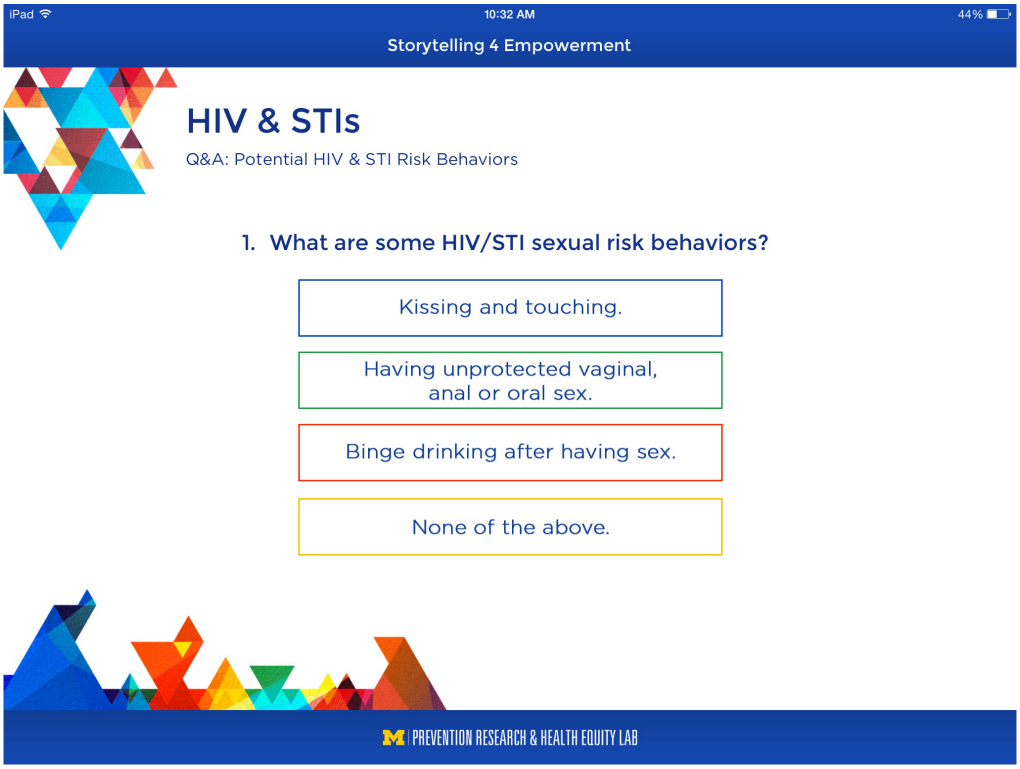
Participants also expressed the importance of including headphones if audio were to be included as part of the app. One youth shared,

> *And then, because if it's audio, then you would wanna keep it to yourself probably. Not have it out loud.* [Female, 13-15]

App Development

Data were used to inform the development of interactive activities, including quizzes, to maintain the adolescent's attention and engagement in the app (Figure 5). The participants' feedback was also used to inform the development of the storytelling videos (described earlier). Additionally, we developed an app that incorporated audio throughout the entire intervention. Therefore, in addition to the text displayed on the screen, all presented data were read aloud.

Figure 5. Interactive activity.



Perspectives on the Appearance of the App

Participants (N=29) described their preferences with regard to the app appearance and format. Youth discussed the importance of an app being aesthetically engaging, including bright colors, and bold, bubble, and graffiti style text, while also being user-friendly and simple.

App Format

Adolescents highlighted the importance of having different sections in the app in an effort to maintain an interactive element. For example, one youth expressed,

> *I think it should be separate modules because it could be easier to find something.* [Female, 13-15]

One participant stated the importance of language when discussing how to format the app to engage youth:

> *Break things down in my language, and things I do. I mean, don't say things like in my street talk, but break it down into where I can understand it would definitely be helpful.* [Female, 17-18]

Appearance of the App

Participants (N=29) expressed the need to develop an app that is aesthetically appealing to youth. Adolescents described an app that is simple with respect to user experience and bright visuals and text. One youth mentioned,

> *It should be colorful.* [Female, 18]

Similarly, another participant said,

> *I think bright and bold is, like, catchy.* [Female, 17-18]

One youth discussed the effectiveness of visuals, as compared to text-heavy sections,

> *If there was a lot of colors and visual, a lot of visual things that you can see in the app instead of just a lot of words with questions. Like, if there was actual images of certain things, that would draw me in.* [Female, 15]

App Development

Through an iterative process, we developed the framework used throughout the app. Specifically, we developed draft models of the app's format and appearance (Figure 6), shared these models

with the Youth Leadership Council and participants, and made necessary revisions based on their feedback, which ultimately led to our final model (Figure 7). In the S4E app, we minimized text and provided more visuals to enhance the user experience (Figure 8). Finally, in consultation with the Youth Leadership Council, the S4E logo was developed for branding the mHealth preventive intervention (Figure 9).

Figure 6. Draft model of app appearance.

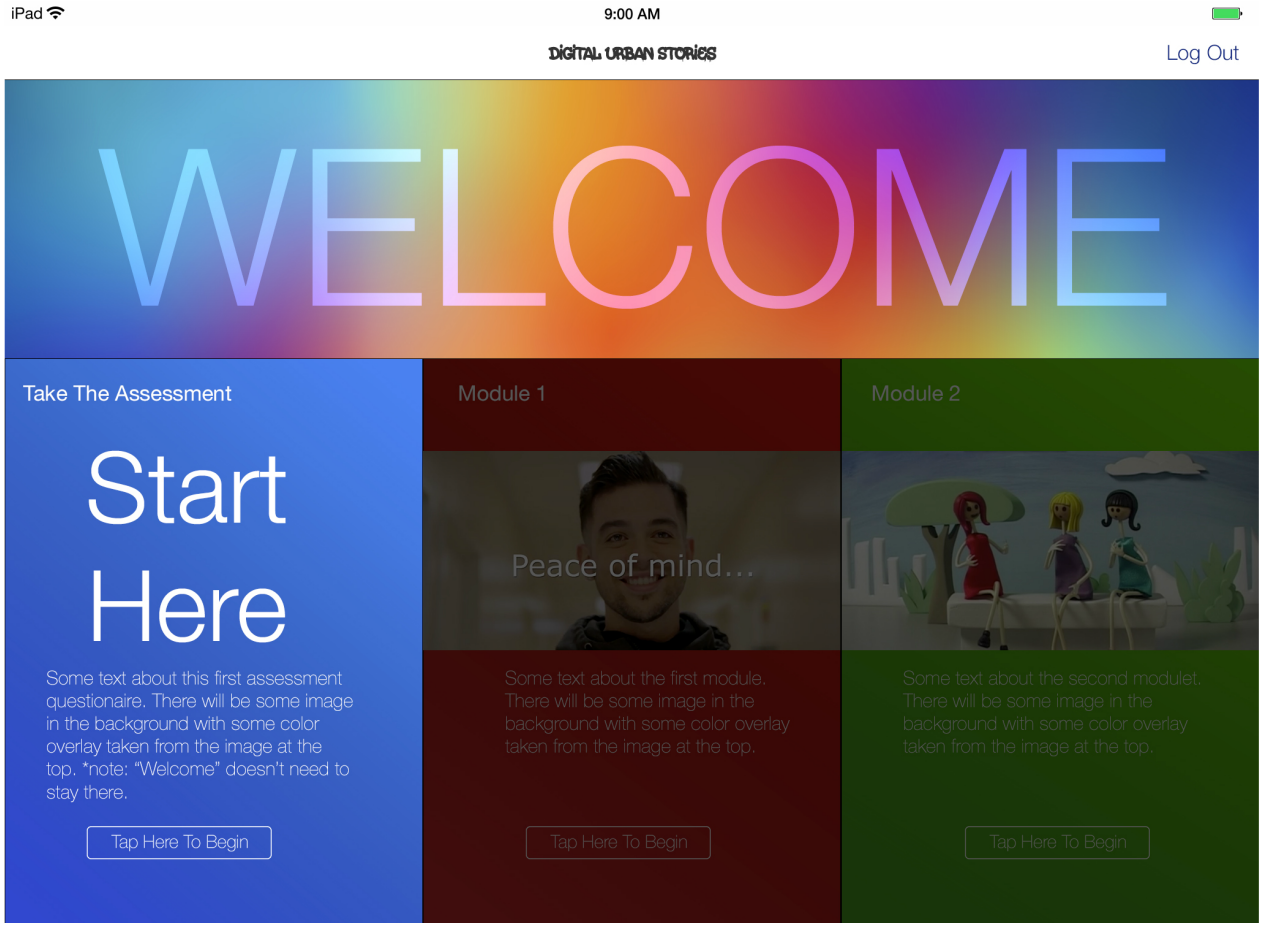


Figure 7. Final model of app appearance.

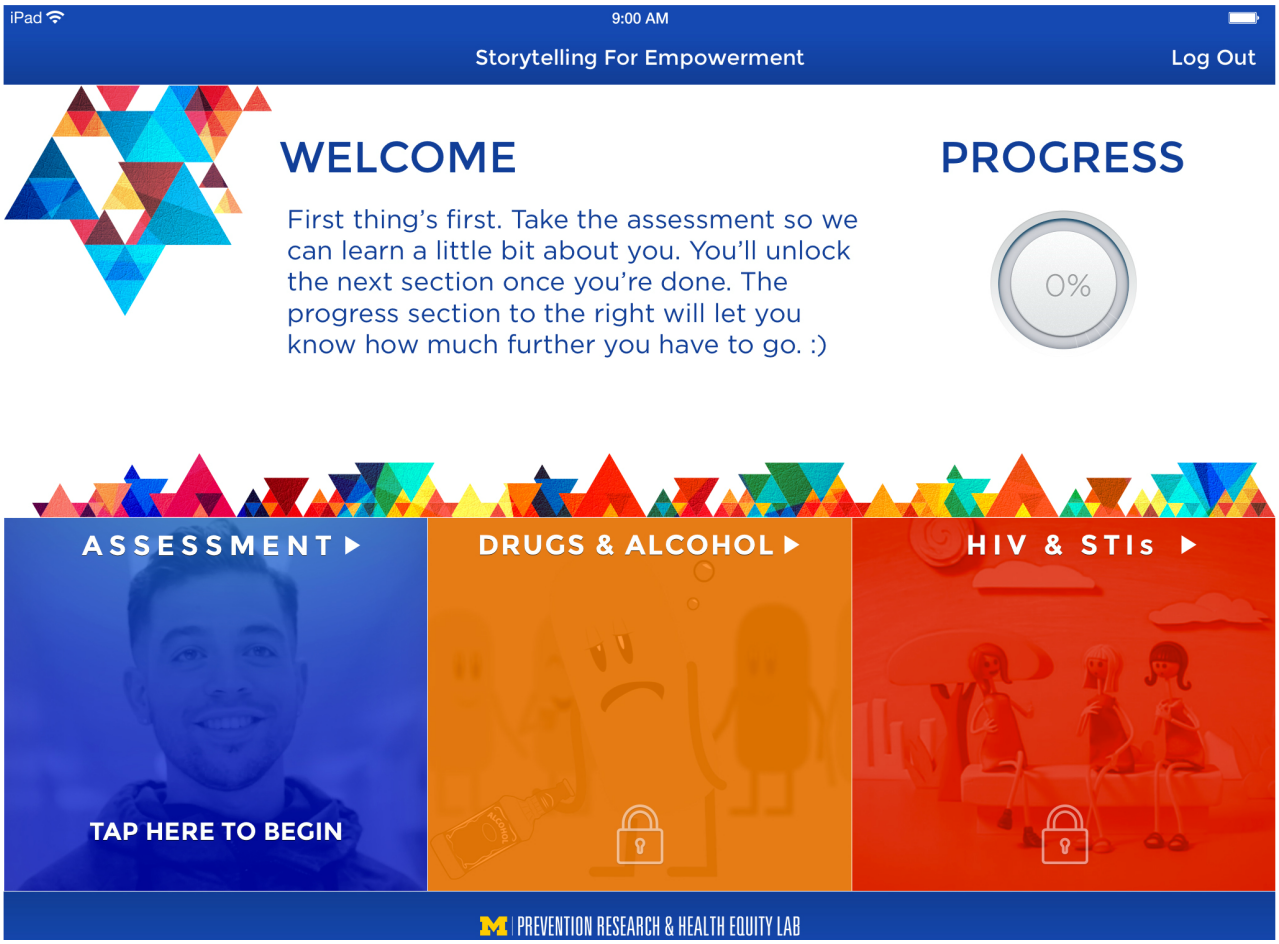


Figure 8. Visuals to enhance the user experience.

Figure 9. S4E logo.

Discussion

Principal Findings

The purpose of this study was to develop an mHealth version of the Storytelling for Empowerment preventive intervention for primary care. Perhaps now more than ever, apps have become ubiquitous in prevention science. Yet, few apps have been developed specifically for primary care contexts. This study works to fill this gap through a community-engaged approach to gather data on the barriers and facilitators to participation in an intervention delivered via an app in primary care, as well as content, format, and processes that should be incorporated in the app design.

Findings of this study highlight important barriers and facilitators to the uptake of S4E in primary care. Specifically, adolescents expressed concern with sharing personal information, including HIV/STI risk behaviors, and the security of such information in an app platform. This finding expands on a recent report issued by the IMS Institute for Healthcare Informatics (2013) [32] by providing an adolescent consumer perspective. In that report, clinicians identified a lack of confidence in the security and privacy of patient data collected by apps as a significant concern when implementing mHealth interventions in primary care. Therefore, prior to scaling up mHealth preventive interventions, it is essential for prevention researchers to demonstrate that apps are secure and maintain the privacy of patient data. Doing so may optimize the uptake of apps by both clinicians and adolescents. With respect to facilitators, mHealth platforms have the potential to advance the delivery of HIV/STI and drug abuse preventive interventions in disproportionately affected populations, including urban youth [33]. Participants in this study expressed having access to and familiarity with technology as important facilitators for the uptake of apps in primary care. In fact, a recent report by the Pew Research Center (2015) suggested that approximately 66% of Americans are mobile phone owners, which may provide an entry point for the delivery of mHealth interventions. Furthermore, younger, ethnic and racial minority populations with relatively low income and educational attainment are more likely to be mobile phone-dependent, as compared with their counterparts [34]. Thus, mHealth approaches to HIV/STI and drug abuse prevention, including the use of mobile phones may have greater reach to those who disproportionately carry the burden of HIV/STI.

Demonstrating the utility of incorporating the principles of CBPR [35,36], agile software development [26], and NIDA-recommended core prevention principles [27] has important implications in the development of mHealth preventive interventions. Our study demonstrates that these approaches complement one another and may be helpful in developing culturally specific apps, which, in turn, have the potential to be more effectively integrated and implemented in primary care. Primary care interventions will be most efficacious/effective to the extent that they are acceptable to their target population. Our community-engaged approach aimed to give a voice to youth, who are key stakeholders in the development of the app. As such, the community provided vital information with respect to the design, content, and process of the app. These data (eg, community risk and protective factors,

specific behaviors) were used to develop stories of cultural relevance to the targeted community who happened to be predominantly African American females residing in an urban area. The agile software development [26] approach allowed for a feedback loop, which was essential to ensuring cultural relevance. Specifically, because data were collected while the interface and preliminary models were built, this provided the research team with opportunities to share concept models with participants early on in the design process, and gather feedback with respect to necessary modifications. Equally important, incorporating the NIDA prevention principles ensured that the content of the app was grounded in decades of prevention research. For example, NIDA Principle 1 is concerned with enhancing protective factors and reducing risk factors [27]. Participants' feedback informed the development of modules aimed at improving clinician-adolescent sexual risk and drug use communication (protective factor), and the potential effects of unprotected sex (risk factor).

Future Research

This study has important research implications. For example, the development of apps has far outpaced the vetting process yet a dearth of mHealth HIV/STI and drug abuse preventive interventions have been found to be efficacious in preventing and reducing HIV/STI risk behaviors [19,37]. Therefore, an important next step is to examine the effects of S4E on HIV risk behaviors in a randomized clinical design. In addition, this study focused on adolescent perspectives, yet it may be equally important to understand clinician perspectives. Therefore, future research should examine clinician perspectives on the utility of an mHealth intervention in primary care practice. Furthermore, although we did not present the data in our results, participants' expressed the need to include parents in prevention programs and for improved parent-adolescent HIV/STI communication. Based on participants' feedback, it would be important to obtain parent perspectives on mHealth interventions in primary care. This research could focus on the ways in which parents could be involved, including further developing their skill set to communicate with youth about HIV/STI [6].

In light of the recent implementation of the ACA and technological advances, several important practice implications have emerged. Consistent with the American Academy of Pediatrics (AAP) recommendations of strengths-based approaches with adolescents in clinical care, mHealth modalities have the potential to facilitate clinician-adolescent HIV/STI and drug use communication, whereby clinicians can focus on adolescent strengths and protective skills aimed at preventing and reducing HIV/STI risk behaviors, and increasing HIV/STI testing [20,38]. For example, participants of this study recommended the inclusion of a risk assessment, to enable clinician-initiated conversations with adolescents with respect to their risk behaviors. Beyond the potential prevention benefits apps may have for adolescent consumers, primary care centers can also benefit. For example, mHealth modalities have the potential to relieve some of the responsibility and resource utilization in primary health care clinics, while still delivering a patient-centered intervention [39]. Furthermore, with expected increases in primary care visits as a result of the ACA, mHealth apps have the potential to engage adolescents in interventions who may not participate in prevention programs otherwise. Many barriers to integrating mHealth interventions in primary care practice remain, including the myriad of apps available on the market. As of June 2013, there were approximately 23,682 apps related to health care readily available in the Apple Store [32]. However, from a research perspective, availability may not guarantee efficacy/effectiveness. Furthermore, from a practice perspective, the number of apps may be overwhelming; it may not be feasible for clinicians to utilize multiple apps for various health risk behaviors, nor to remain informed as to which apps have undergone rigorous testing. As such, the development of apps targeting multiple health risk behaviors may prove more practical in primary care settings.

Limitations

Findings should be interpreted in light of study limitations. First, a purposive sample was used in this study and thus is not representative of the US urban primary care adolescent population. Therefore, the transferability or generalizability of the data collected to inform the development of the app may be limited. Although the purpose of this study was to obtain adolescent perspectives on app development, a second limitation is that data on clinician perspectives were not collected. Future research should work to include the perspectives of clinicians, to develop a fuller understanding of barriers and facilitators to implementing an mHealth preventive intervention in primary care.

Conclusions

Notwithstanding these limitations, this study represents an important step in working toward the development and testing of an mHealth version of the Storytelling for Empowerment preventive intervention for primary care. The long-term goal of research on this intervention program is to take S4E from efficacy, to effectiveness, to scaling up, in an effort to narrow and ultimately eliminate HIV/STI and drug use health disparities experienced by adolescents.

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Authors' Contributions

The Youth Leadership Council consisted of Ian Stewart, Erika Riano-Mojica, Bishop Warford, Franco Machado, Kiristen Hubbard, Max Abuelsamid, Sakinah Rahman, Zaki Rahman, Ziara Chestang, and Katheryne Messer.

Conflicts of Interest

None declared.

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Abbreviations

CBPR: community-based participatory research
S4E: Storytelling for Empowerment
STI: sexually transmitted infections

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Original Paper

Crafting Appealing Text Messages to Encourage Colorectal Cancer Screening Test Completion: A Qualitative Study

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Abstract

Background: mHealth interventions that incorporate text messages have great potential to increase receipt of preventive health services such as colorectal cancer screening. However, little is known about older adult perspectives regarding the receipt of text messages from their health care providers.

Objective: To assess whether older adults would value and access text messages from their physician's practice regarding colorectal cancer screening.

Methods: We conducted four focus groups with 26 adults, aged 50 to 75 years, who had either recently completed or were overdue for colorectal cancer screening. A trained moderator followed a semistructured interview guide covering participant knowledge and attitudes regarding colorectal cancer screening, potential barriers to colorectal cancer screening, attitudes about receiving electronic communications from a doctor's office, and reactions to sample text messages.

Results: Participant responses to three primary research questions were examined: (1) facilitators and barriers to colorectal cancer screening, (2) attitudes toward receiving text messages from providers, and (3) characteristics of appealing text messages. Two themes related to facilitators of colorectal cancer screening were perceived benefits/need and family experiences and encouragement. Themes related to barriers included unpleasantness, discomfort, knowledge gaps, fear of complications, and system factors. Four themes emerged regarding receipt of text messages from health care providers: (1) comfort and familiarity with technology, (2) privacy concerns/potential for errors, (3) impact on patient-provider relationship, and (4) perceived helpfulness. Many participants expressed initial reluctance to receiving text messages but responded favorably when shown sample messages. Participants preferred messages that contained content that was important to them and were positive and reassuring, personalized, and friendly to novice texters (eg, avoided the use of texting shorthand phrases and complicated replies); they did not want messages that contain bad news or test results. They wanted the ability to choose alternative options such as email or phone calls.

Conclusions: Older adults are receptive to receiving cancer screening text messages from health care providers. Sharing sample messages with patients may increase acceptance of this tool in the clinic setting. Supportive tailored text messaging reminders could enhance uptake of colorectal cancer screening by enhancing patient self-efficacy and providing cues to action to complete colonoscopy or fecal occult blood testing.

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KEYWORDS

colorectal cancer; screening; mhealth; text messages; qualitative; older adults

Introduction

Over the last decade, mobile phone ownership has increased dramatically in the United States. Approximately 90% of US adults now own a mobile phone, and 58% own a smartphone with access to the Internet [1]. This high prevalence of mobile phone ownership is similar across racial and rural/urban categories [1]. Even among individuals with low incomes and little education, mobile phone ownership exceeds 84% [1]. In contrast, a significant digital divide exists for home broadband Internet access where large differences are seen along racial, economic, educational, and geographic lines [2].

The popularity of mobile phones affords an opportunity to reach broadly across populations, including members of medically underserved communities. Over 80% of mobile phone owners use their devices to send or receive text messages, representing a low-cost method of communication [3]. Several studies have demonstrated that text messaging interventions can have positive effects on weight loss, physical activity, disease self-management, smoking cessation, medication adherence, and appointment attendance [4-8]. However, the majority of these studies have targeted younger populations.

Many diseases disproportionally affect older adults. As an example, colorectal cancer, which is the second leading cause of cancer deaths in the United States, predominately occurs in adults over age 50 [9,10]. Routine screening can prevent colorectal cancer and decrease mortality, yet approximately one-third of Americans fail to receive regular screening [11].

Text messaging interventions could encourage screening and support patients throughout the screening process. However, it is unclear how agreeable older patients would be to receiving colorectal cancer screening-related text messages. In studies conducted in older patients with heart disease in New Zealand, most participants were interested in receiving cardiac rehabilitation text messages and when sent messages, 82% read some or all of them [12,13]. In contrast, two other studies found that less than half of older patients opted for text messages [14,15]. In addition, recent systematic reviews conclude that more research is needed to define the optimal content and structure of text messaging interventions [7].

To assess whether older adults would value and access text messages from their physician's practice, we conducted a qualitative study examining the potential utility of text messages to support colorectal cancer screening. We particularly wanted to explore older adults' thoughts about receiving health-related text messages and their opinions regarding the characteristics of desirable messages. This new information is needed to guide the development of text messages that are acceptable and useful to an older population.

Methods

Participants

We recruited participants from three community-based primary care practices affiliated with a large academic medical center in Winston-Salem, North Carolina, selected to represent a diverse patient population in urban, suburban, and rural locations. The urban practice serves a primarily socioeconomically disadvantaged patient population; the other two practices serve mostly insured patients. The Wake Forest Baptist Health Institutional Review Board approved the study protocol. All participants provided written informed consent and received a $25 gift card for participating in a focus group (held November-December 2013).

To identify potential participants, we queried electronic medical records to identify patients aged 50 to 74 years who had completed a primary care visit within the last 6 months. We mailed recruitment letters to 300 patients with no documented history of colonoscopy within the last 10 years and 161 patients with a documented colonoscopy within the last 3 years. Patients were invited to call to enroll in the study, and a study staff member also made follow-up calls to invite participation. We formed four focus groups of 6 to 10 participants each (2 focus groups from the urban practice and 1 focus group each from the suburban and rural practices). As groups were formed, we selectively called patients to ensure a balance of gender, age (50-64 years vs 65-74 years), screening status, and use of technology (experience with text messaging vs no experience).

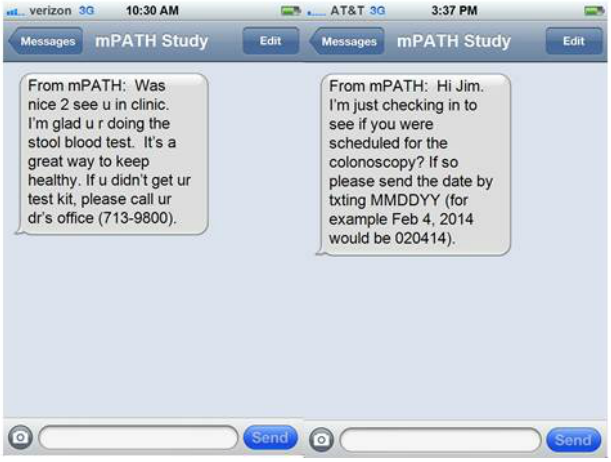
Baseline Data Collection

All participants completed a telephone survey assessing mobile phone ownership, text messaging frequency, health literacy level, and history of colorectal cancer screening. Health literacy was measured with the screening item, "How confident are you filling out medical forms by yourself?" [16]. Participants were categorized as adequate (quite a bit or extremely) or low (somewhat, a little bit, or not at all) literacy. To contextualize the analysis, we used information from the initial telephone survey questionnaire combined with demographic information (education, health insurance coverage) collected in a brief on-site questionnaire.

Focus Group Structure

A trained moderator led each focus group using a semistructured moderator guide, which was revised as needed after each focus group to validate concepts and subsequent investigator interpretations emerging from previous groups. Each focus group explored participant knowledge, attitudes, and beliefs about colorectal cancer screening; potential barriers to colorectal cancer screening; attitudes about receiving electronic communications from a doctor's office; and reactions to a sample of text messages about colorectal cancer screening designed to vary by use of language, formality, and requests for a reply. To prime the discussion, each group watched a 6-minute video colorectal cancer screening decision aid during the focus group encounter. During the course of the focus groups, participants were sent sample text messages regarding colorectal cancer screening on their personal mobile phones or were shown sample text messages on a large screen (see Figure 1). The messages varied in the formality (eg, use of first names vs last names), length, use of shorthand text phrases, and interactivity (ie, instruction to text back a date or a "1" to confirm receipt). All focus groups were audio-recorded, transcribed, and de-identified to protect participant confidentiality.

Figure 1. Examples of text messages that participants viewed regarding colon cancer screening.



Analysis

We conducted a descriptive thematic content analysis [17]. Interim analysis revealed that saturation had been reached, with no new themes arising from the data [18]. To ensure consistency in coding, we created a preliminary coding dictionary based on themes explored in the moderator guide [17-19]. After coding a sample of the transcripts, we added codes based on group consensus of themes not captured by the preliminary coding scheme. Using this final coding dictionary, each focus group transcript was then coded by one investigator and reviewed by a second investigator for agreement. Disagreements were resolved by group consensus. Four investigators (KW, ND, SE, and DM) each served as a primary coder and secondary coder for one transcript.

Results

Overview

We conducted four focus groups (26 participants), each lasting 90 minutes. Characteristics of participants are shown in Table 1. In accordance with our purposive sampling strategy, 27% of our participants reported not being up to date on colorectal cancer screening, and 42% reported being regular users of text messaging. We analyzed emergent themes guided by three primary research questions: (1) facilitators and barriers to colorectal cancer screening, (2) attitudes toward receiving text messages from providers, and (3) characteristics of appealing text messages.

Table 1. Characteristics of focus group participants.

Demographic characteristics		N=26
Age, years, mean (range)		60 (50-73)
Female, n (%)		16 (62)
Race/ethnicity, n (%)		
	White, non-Hispanic	10 (38)
	African-American	16 (62)
Educational attainment, n (%)		
	Less than high school	3 (12)
	High school graduate	10 (38)
	More than high school	13 (50)
Covered by health insurance, n (%)		19 (73)
Up-to-date on colorectal cancer screening, n (%)		19 (73)
Low health literacy, n (%)		8 (31)
Uses text messaging regularly, n (%)		11 (42)

Facilitators to Colorectal Cancer Screening

Quotations illustrating the seven themes regarding facilitators and barriers of colorectal cancer screening are shown in Textbox 1. Participants perceived benefits associated with early detection and the need to be checked.

> *When you have cancer or any other kind of illness, that's a lotta times there's nothing that you, yourself, can do about it. But if you go…and get some help, then it's a good chance that everything will be all right.* [adequate literacy, screened female]

Many participants described screening as a very matter of fact decision. Patients often mentioned that their doctor had recommended screening when they turned 50. Others mentioned prompting by media sources such as a physician television personality. Finally, some participants reported that symptoms, most commonly blood in the stool, motivated them to be tested.

Textbox 1. Representative quotes for primary barriers and facilitators of colorectal cancer screening by emergent theme.

Facilitators:

- Perceived benefit/need: benefit of early detection of colorectal cancer and need to be checked for cancer.

  I reckon for health, I didn't want anything to go wrong there, and I just went in and took care of it. [adequate literacy male]

- Family experiences and encouragement: diagnosis or screening of a family member or direct prompting or encouragement by a family member.

  She (my wife) got me to go down and do it and I'm glad I did now. [adequate literacy male]

Barriers:

- Unpleasantness: concern about the bowel preparation process or handling stool sample.

  I hate the prep. I just can't, there's gotta be an easier way than drinking all that liquid, and just feeling like you're blown up. [low literacy male]

- Discomfort: actual or anticipated discomfort associated with colorectal cancer screening, typically colonoscopy.

  I won't go back unless I'm guaranteed to be knocked out. …I said, 'I may actually end up with colon cancer because I am terrified of the screening.' It was horrible. [adequate literacy female]

- Knowledge gaps: lack of knowledge or misinformation about colorectal cancer and screening guidelines.

  Well, I just told him no, I didn't wanna do it, you know? I didn't see any—there was nothing wrong with me. [adequate literacy female]

- Fear of complications: concern regarding actual or anticipated complications.

  I know one of my members, they had it, and they was sick for days. [low literacy female]

- System factors: difficulties with appointments, referrals, or insurance or use of reminder letters or calls.

  Sometimes at the doctor's office, for you to get…a referral from a doctor's office, that's pulling teeth. [low literacy female]

Family experiences with colorectal cancer diagnosis and treatment were described by several screened participants. Others mentioned direct prompting by family members as an important factor in their decision to be screened or described encouraging other family members to be tested.

Barriers to Colorectal Cancer Screening

Barriers associated with unpleasantness and discomfort were commonly mentioned by participants, especially with regards to colonoscopy. The bowel cleaning preparation was frequently described as unpleasant (eg, taste, volume of beverage required, nausea, need to be in close proximity to bathroom), but for most screened participants it did not appear to be an actual barrier to a repeat procedure. Anticipation of unpleasantness was perceived as a barrier for others.

> *I think that's the biggest hang-up about having a colonoscopy. People are so afraid of the prep. It truly is not so bad anymore.* [adequate literacy female]

Concerns about discomfort during the colonoscopy were also mentioned, but most people reported that it was painless. Multiple participants reported a desire to be sedated or "knocked out." However, for two screened women, a prior painful colonoscopy was a significant barrier to repeat screening. Adequate literacy participants appeared more likely to mention unpleasantness, but there were no demographic differences for concerns about discomfort.

Knowledge gaps were a barrier to screening for at least some participants, particularly those without health insurance. These gaps manifested as misperceptions (only men need it, screening is only needed if you have symptoms) and questions that arose during the focus group regarding correct screening interval, accuracy of different tests, difference between sigmoidoscopy and colonoscopy, and desire for more information about polyps. Knowledge-related barriers did not appear to differ by health literacy, education, or clinic location.

Some participants also mentioned fear of complications (ie, anesthesia or the endoscopy damaging something). A few participants mentioned experiencing complications or suspected complications (eg, hemorrhoids); others mentioned friends or family members with more serious complications following the procedure (eg, hospitalization or infection). This appeared more common among adequate literacy participants.

Finally, a few participants, most but not all of whom were adequate literacy and insured, noted that efficient office systems could increase colorectal cancer adherence. Others reported

problems associated with obtaining a referral and scheduling the appointment (system factors). For some it was like "pulling teeth" [low literacy female].

Attitudes Toward Receiving Text Messages From a Health Care Provider

Four key themes emerged regarding text messages from health care providers: (1) comfort and familiarity with technology, (2) privacy concerns and potential for errors, (3) impact on patient-provider relationship, and (4) perceived helpfulness. The overall positive or negative valence of expressed attitudes did not appear to vary by setting (urban, underserved practice vs suburban/rural practice). Quotations illustrating each theme are shown in Textbox 2.

Textbox 2. Representative quotes regarding text messages from a health care provider by emergent theme.

- Comfort and familiarity: comfort with use of text messaging and other new communication strategies (mixed valence).

  It seem like now, since I'm over 50 now, I notice, they kinda pushing me into this technology and it's like this is not me. [adequate literacy female]

  Well, I get texts from my doctor, from my dentist, especially, send texts all the time.… I've been doing it now for a couple of years, and it's fine with me. [adequate literacy female]

- Privacy concerns/potential for errors: concern about others accessing personal information or mix-ups (negative valence).

  If it was a doctor doing it—which I know it can't be him—he would have my files right there in front of him.… But if you get other people doing it, I think that's where the problem will come in that could be errors, and that would make me a little bit scared. [low literacy female]

- Impact on patient-provider relationship: positive ability to enhance communication and sense of caring or negative perception of technology as impersonal (mixed valence.

  Doctors especially in a clinic like this see so many people—and you don't have a really tight relationship with your doctor anymore it seems. And a text just makes it that much more impersonal. [adequate literacy male]

  I just feel that it would be nice of him if he told me to get it and I didn't get it, to remind me that I didn't get it, and he hasn't got the results back yet. So I think that's caring on his part if you receive texts. [low literacy female]

- Perceived helpfulness: sense that information would be helpful or redundant with current communication (mixed valence).

  People say, 'I didn't get no paper in the mail,' saying something happened with the mail or you forget. It's good to get reminders. [adequate literacy female]

  I just don't see how it could possibly be feasible for doctors to be sending out this kind of stuff. And if they have done their job while you were there, this shouldn't be necessary. All of that should have been covered. [adequate literacy female]

Participants varied in their comfort and familiarity with text messaging, with some expressing positive attitudes regarding its ease and convenience or prior experiences with text reminders from other providers such as dentists or patient portals. Convenience was discussed slightly more among those with adequate health literacy and those who had health insurance compared to those with low health literacy and those with no insurance. More commonly, participants expressed concern regarding lack of familiarity with text messaging or perceptions that it was impersonal, intrusive, or for a younger generation.

> *Now if you call my house and leave a message on my answering machine, I will reply to you, I will do it. And I think that's a little bit more personal, you know. I've always said text is for people that don't want to talk to you. And this is the generation we're in now. They don't have time to sit down and talk on the phone.* [adequate literacy female]

A number of participants with adequate health literacy were not regular text message users, and general concerns about technology were more commonly expressed by non-texters. Expressed texting familiarity did not seem to be associated with health insurance status.

Several participants also expressed concerns about privacy or the potential for errors when text messaging with providers. There was a perception that text messages might not be secure; about half of participants expressed concerns about other people accessing personal information, either by accessing a phone or through more generalized security breaches. Participants with adequate health literacy and those with health insurance were more likely to discuss these concerns than those with low health literacy and those with no health insurance. Other participants expressed concerns about mix-ups or errors (wrong patient or wrong test results) or intentional deception from someone "playing a joke." These types of concerns appeared more common among participants with adequate health literacy and those with health insurance. Participants who were not regular texters also raised concerns about errors more often than those who were regular texters.

Participants expressed diverse opinions about the impact of text messaging on their relationship with their provider. Some participants felt texts were impersonal and a poor substitute for face-to-face communication, but others perceived them as caring or supportive. Concerns about the impact on patient-provider relationship were expressed slightly more often among those

who were not habitual texters than those who did text as a means of communication.

Participants also expressed divergent opinions about the perceived helpfulness of text messages from health care providers. Some participants viewed reminders as indicative that a medical office failed to properly inform the patient at the time of the initial appointment or that a patient was not taking sufficient responsibility. These participants believed there was no need for such messages.

> *I know what I need to do. I appreciate you reminding me of my appointment, but I'm a grown man. If I'm gonna make this appointment, I'm gonna make it. If I'm not, nothing you say is gonna make me make it….just call and remind me of—if need be—of my appointment. That's that.* [low literacy male]

Others acknowledged that reminders are helpful and that the information contained in text messages might be helpful for later reference. There were no apparent differences in attitudes regarding helpfulness by participant characteristics.

Characteristics of Appealing Text Messages

Participants responded much more positively when viewing sample text messages (see Figure 1) than when asked about general opinions regarding text messages. Feedback about the specific text messages or text messaging in general did not differ by health literacy, health insurance coverage, education, or regular use of text messaging. Characteristics of appealing text messages are summarized in Textbox 3.

Textbox 3. Suggestions for crafting appealing text messages from medical providers.

- Message should have a positive, reassuring tone (eg, “Hang in there, Bob”); informal messages are commonly perceived as more positive.
- Text messages should be personalized to provide reassurance that it is going to the right person; individuals vary in their preference for use of first or last names.
- The message should be tailored so that it contains content that is important to the person, recognizing that individuals disagree about what type of content is important (eg, appointment reminders).
- Texts should be friendly to novice texters:
  - Avoid use of texting shorthand phrases such as “nice 2 see u.”
  - Messages should not require participants to text back dates or other information; participants were more comfortable with short numerical replies to confirm dates or receipt (eg, “Text 1 to confirm”).
- Content should not contain bad news or test results.
- Patients should have alternatives (opt out of text messages and/or receive letters or phone calls if they prefer).

Participants generally found the messages easy to comprehend and potentially helpful or encouraging.

> *Yeah, it's kind of encouraging—the prep may be a little challenging, but it'll be okay* [adequate literacy female]

Participants wanted a positive, reassuring tone. Less formal language was perceived as somewhat more supportive and caring. For example, several participants responded very positively to this text message: “Hang in there, Jim. I know the prep and clear diet can be challenging, but it is well worth it. Remember you will need to have someone to take you to the test tomorrow.”

Although many responded positively to the overall content, some disliked the use of the first name. Personalization was deemed very important because it confirmed the message was going to the intended recipient.

The content of the messages was perceived as very important, but participants differed in their opinions about what content was necessary. There was a desire for messages to be brief but informative. Some participants viewed the doctor’s phone number or reminders about tests as unnecessary, but others thought it was helpful or caring. Other participants expressed a preference for only getting a brief text message to call their doctor or did not want the word “colonoscopy” to be used in the message.

Participants wanted text messages that were friendly to novice texters. Participants did not like use of shorthand text abbreviations (eg, nice 2 see u) and felt it could be confusing. Many participants had limited comfort with interactivity, preferring simple instructions like “Text 1 to confirm that you received this message” over instructions to text back numerical dates.

With regards to general thoughts regarding the use of the text messages in the health care setting, there was strong consensus that the content of text messages should not contain bad news or test results.

Many participants also wanted alternative options like phone, letter, or email or the choice to opt out of all messages.

> *So now instead of automatically sending you a message like that, also, ask, ‘Do you want a reminder?’ …I don't need that reminder* [adequate literacy female]
>
> *It's a personal thing, and you have to approach people in the way they feel most comfortable* [adequate literacy female]

Preferred mode of communication did not appear to differ based on health literacy, education, health insurance, or use of texting. Cost of text messaging was a concern expressed by only one participant.

Discussion

Principal Findings

In four focus groups of diverse individuals with varying colorectal cancer screening histories, we explored barriers and facilitators to colorectal cancer screening and identified several suggestions for developing text messaging interventions targeting older individuals. Our results confirmed many of the previously reported colorectal cancer screening facilitators (perceived benefits, family history, and encouragement) and barriers (disdain for the bowel prep and fear of procedural complications) [20-23]. We identified several themes relating to positive and negative attitudes about receiving text messages from a health care provider that may be important to consider when designing text messaging interventions and systems. Although many participants in our study had limited familiarity with text messaging and initially expressed some concerns, they were generally positive when shown sample text messages pertaining to screening. From their feedback about our sample text messages, we derived several recommendations about crafting appealing health-related text messages. Carefully designed text messages have the potential to overcome some of the identified barriers to colorectal cancer screening by providing encouragement and reassurance and enhancing self-efficacy to complete colorectal cancer screening tests.

Comparison With Prior Work

This qualitative study is one of the first to explore older adult attitudes about receiving cancer screening text messages. A few studies have examined the use of text messages for care along the cancer continuum [24]. Two survey studies found that 37% to 45% of women were agreeable to receiving mammogram reminders by text message [25,26], and a pilot study of cervical cancer screening text messages reported high satisfaction with the intervention [27]. We are unaware of prior studies investigating willingness to receive text messages encouraging colorectal cancer screening, a topic many adults find distasteful [28]. Other researchers have reported variability in older adults' willingness to receive health-related text messages [13-15]. The increased receptivity we observed after participants viewed sample messages suggests that sharing some potential messages with participants may increase program uptake. In addition, studies of text message reminders have generally found high levels of patient satisfaction [8].

Implications for Design of Text Messages

A major goal of our study was to determine what content and characteristics would make a text message appealing or objectionable to older adults. Systematic reviews of text message interventions have specifically called for more research in this area [7]. We derived several key recommendations for crafting appealing health-related text messages (summarized in Textbox 3). Focus group participants wanted messages that were positive, tailored so that content was relevant, and personalized (with name) and did not contain bad news or test results. In addition, the messages should not use texting shorthand phrases or require participants to text back anything more than a simple, single character reply. Supporting these recommendations, a meta-analysis of text message interventions for health promotion found that personalized and tailored messages were associated with greater efficacy [29]. While we are not aware of prior studies specifically examining older adults' attitudes about the specific content and format of text messages, qualitative studies in adolescents and young adults reinforces the importance of texts using casual, supportive language and containing helpful information [30-33].

Participants in our study also wanted the choice to opt out of text messages and receive the health information by email or some other means. This finding is consistent with studies finding varied preferences for receiving automatic reminders [14,15,34-37]. Younger age has been associated with an increased preference for text messages over phone calls or emails [15,36]; however, individuals' familiarity with sending or receiving text messages is a greater predictor of patient acceptance [15,37]. Given that adult use of text messaging has increased dramatically over the last decade [38,39], more and more people will likely choose texting as their preferred communication modality in the future.

A distinct advantage of text messages is the ability to easily tailor them to the individual. Our results reveal some tailoring may be required to craft text messages that are broadly appealing, but this should be achievable with relatively simple algorithms (eg, patient preference for first or last name). With tailoring, potential differences in preferences based on literacy, gender, and mode of screening can be accommodated. Appealing clinic reminder systems will allow participants to choose greeting (first or last name), level of detail, and modality (text, email, or phone).

Implications for Colon Cancer Screening Practice and Research

Discussions about colonoscopy dominated all the focus groups, with few people expressing knowledge of other screening tests. Others have similarly reported that patients are more knowledgeable about colonoscopy than fecal screening tests [22,40]. However, when patients are informed of their screening options, almost as many will chose fecal occult blood testing as will chose colonoscopy [41-43]. Given the colonoscopy-specific barriers we and others have observed, offering fecal testing as an alternative has the potential to increase screening rates.

Future research should investigate which colorectal cancer screening messages are most effective and whether offering a variety of delivery modalities (such as email vs text messaging) increases efficacy. Based on our findings, our research team has created a series of messages to support fecal occult blood testing and colonoscopy for colorectal cancer screening. We are currently testing these messages in a multisite randomized controlled trial, and we let participants choose between email and text message delivery.

Limitations

This study adds substantially to the literature on mHealth interventions by including the perspectives of patients who are not regular users of text messaging and patients with low health literacy. Limitations of our study relevant to the generalization of results include the predominant focus on colorectal cancer

screening and the exclusion of younger and older adults who would not be eligible for colorectal cancer screening. In addition, although we broached concepts derived from earlier groups with subsequent groups to assess their salience and our interpretation of these findings, we did not provide full results of our findings back to the participants for validation [19].

Conclusions

Our results have several implications for encouraging colorectal cancer screening and the use of text messages more broadly in clinical practice. Participants were generally more positive when they viewed sample text messages. It may be important to show patients examples of the messages they will receive to increase buy-in; tailoring and personalization are also key. In summary, we believe texting can be a powerful tool to address health disparities through its ability to connect with hard to reach populations to encourage completion of preventive health services such as colorectal cancer screening.

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Conflicts of Interest

None declared.

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Original Paper

A Text-Messaging and Pedometer Program to Promote Physical Activity in People at High Risk of Type 2 Diabetes: The Development of the PROPELS Follow-On Support Program

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Abstract

Background: Mobile technologies for health (mHealth) represent a promising strategy for reducing type 2 diabetes (T2DM) risk. The PROPELS trial investigates whether structured group-based education alone or supplemented with a follow-on support program combining self-monitoring with pedometers and tailored text-messaging is effective in promoting and maintaining physical activity among people at high risk of T2DM.

Objective: This paper describes the iterative development of the PROPELS follow-on support program and presents evidence on its acceptability and feasibility.

Methods: We used a modified mHealth development framework with four phases: (1) conceptualization of the follow-on support program using theory and evidence, (2) formative research including focus groups (n=15, ages 39-79 years), (3) pre-testing focus groups using a think aloud protocol (n=20, ages 52-78 years), and (4) piloting (n=11). Analysis was informed by the constant comparative approach, with findings from each phase informing subsequent phases.

Results: The first three phases informed the structure, nature, and content of the follow-on support program, including the frequency of text messages, the need for tailored content and two-way interaction, the importance of motivational messages based on encouragement and reinforcement of affective benefits (eg, enjoyment) with minimal messages about weight and T2DM risk, and the need for appropriate language. The refined program is personalized and tailored to the individual's perceived confidence, previous activity levels, and physical activity goals. The pilot phase indicated that the program appeared to fit well with everyday routines and was easy to use by older adults.

Conclusions: We developed a feasible and innovative text messaging and pedometer program based on evidence and behavior change theory and grounded in the experiences, views, and needs of people at high diabetes risk. A large scale trial is testing the effectiveness of this 4-year program over and above structured group education alone.

Trial Registration: International Standard Randomized Controlled Trial Number (ISRCTN): 83465245; http://www.controlled-trials.com/ISRCTN83465245/83465245 (Archived by WebCite at http://www.webcitation.org/6dfSmrVAe)

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KEYWORDS

physical activity; mHealth; text messaging; pedometer; tailoring; type 2 diabetes; intervention development

Introduction

Background

Like most developed countries, the United Kingdom is facing a growing prevalence of type 2 diabetes (T2DM) [1]. Furthermore, in England there has been a marked increase in the number of people identified with impaired glucose regulation (IGR): blood glucose levels higher than normal but below the threshold for T2DM and associated with increased risk of developing T2DM and further complications [2]. Given the significant economic burden of treating T2DM [3], prevention of the condition is a public health priority.

The main targets for T2DM prevention are weight loss and physical activity promotion [4,5]. Physical activity slows the progression of T2DM and its cardiovascular consequences [6] and thus is often argued to be a cornerstone of T2DM prevention initiatives [5]. Indeed, several large, high-quality clinical trials have shown that relatively modest changes in lifestyle (eg, increased physical activity) can reduce its incidence [7,8].

Structured self-management education is recommended for facilitating lifestyle change (including physical activity) among people with T2DM and those identified as being at high risk of developing T2DM [9]. The Pre-diabetes Risk Education and Physical Activity Recommendation and Encouragement (PREPARE) study, which combined group-based structured education and pedometer use, reported improvements in glucose regulation in people at high risk of T2DM [10]. Notably, only the group that received a pedometer in addition to structured education demonstrated better clinical outcomes. Indeed, meta-analyses have shown that interventions that prompt self-monitoring by pedometers resulted in increased physical activity [11,12]; among individuals with T2DM, walking programs that do this have shown that they are feasible and effective at increasing moderate intensity bouts of physical activity [13,14].

T2DM prevention guidelines recommend the provision of ongoing support for people identified as being at risk, particularly when barriers for behavior change are encountered [9,15]. Although primary care offers a system for identifying individuals at high risk of T2DM (eg, through the National Health Service [NHS] Health Checks in England), it lacks the capacity and resources to offer ongoing support to the patient through regular face-to-face contact with health care professionals. As such, there is a need to develop and evaluate scalable and cost-effective T2DM prevention programs that provide ongoing behavior change support beyond structured education and pedometers and are suitable for implementation in routine care [16]. Tailored, computer-generated feedback on pedometer-measured step counts may be a cost-effective way to provide ongoing support for physical activity among people at high risk for T2DM. One way of achieving this is through the use of mHealth (ie, mobile phone technology [17]), specifically via short message service, hereafter referred to as "text messaging."

mHealth Approaches

While smartphone ownership is increasing (estimated at 55% in the UK adult population), it is less than 20% in people aged 65 years and older who are more likely to be at risk of T2DM [18]. Nonsmart mobile phone ownership, estimated at 77% in those aged 65-74 years [19], is commonplace; hence, text messaging has a potentially wider reach in this group. Furthermore, text messaging can be automated and individually tailored, and it allows frequent delivery with asynchronous receipt (ie, people can choose when to read the messages). Thus, it is potentially an efficient delivery channel for providing participants with information, feedback, and a choice of when to access messages.

Text-messaging interventions are increasingly used in T2DM prevention. A recent randomized controlled trial (RCT) [20] evaluated a text-messaging T2DM prevention intervention delivering randomly generated lifestyle advice messages to men aged 35-55 years in India. It reported significantly lowered incidence of T2DM at 24-month follow-up. However, no between-group differences in self-reported physical activity were observed. A T2DM prevention intervention in a general population (mean age of 42 years) [21,22] that sent very frequent (5-7 per week) tailored messages (including general educational messages, diet and exercise tips, and health reminders) and prompt messages to encourage goal setting increased participant risk awareness and knowledge of T2DM. However, the majority of text-messaging interventions for T2DM self-management and prevention have targeted clinical outcomes only, in younger and middle-aged adults (55 years and younger), and have not measured behavioral outcomes (eg, physical activity) [23].

It is widely accepted that the development of complex behavior change interventions, including mHealth approaches, should be informed by behavior change theory, evidence, and formative research [24,25] and that sufficient details of the final intervention are reported [26,27]. Yet, many published mHealth studies of physical activity promotion do not describe the structure, content, or evidence base for the intervention in enough detail to allow replication. Taken together, there is

uncertainty about the active ingredients, effectiveness, feasibility, and acceptability of evidence-based mHealth to increase physical activity in a population of people at risk of T2DM which includes older adults.

Context: Walking Away From Diabetes and the PROPELS Trial

Walking Away from Type 2 Diabetes [28,29] is an annual group-based, structured education session (hereafter referred to as "Walking Away"). It is typically delivered to groups of 4-10 individuals by 2 trained educators over 3 hours. It is designed to promote walking by targeting perceptions and knowledge about IGR and physical activity self-efficacy as well as promoting self-regulatory skills such as goal setting, self-monitoring, and problem solving for relapse prevention. Participants receive a pedometer, but there is no additional contact with educators beyond the session and hence no feedback on individual progress.

PROPELS (Promotion Of Physical activity through structured Education with differing Levels of ongoing Support for those at high risk of type 2 diabetes) [ISRCTN83465245] is a multisite RCT that aims to examine the long-term effectiveness of the Walking Away education with different levels of ongoing support (over 4 years) [30]. The RCT includes 3 arms: Group 1 receives an informational advice leaflet; Group 2 receives the leaflet, annual Walking Away sessions, and a pedometer; and Group 3 receives the leaflet, annual Walking away sessions, and pedometer plus a comprehensive follow-on support program using pedometer self-monitoring, tailored text messaging, and telephone calls.

Purpose

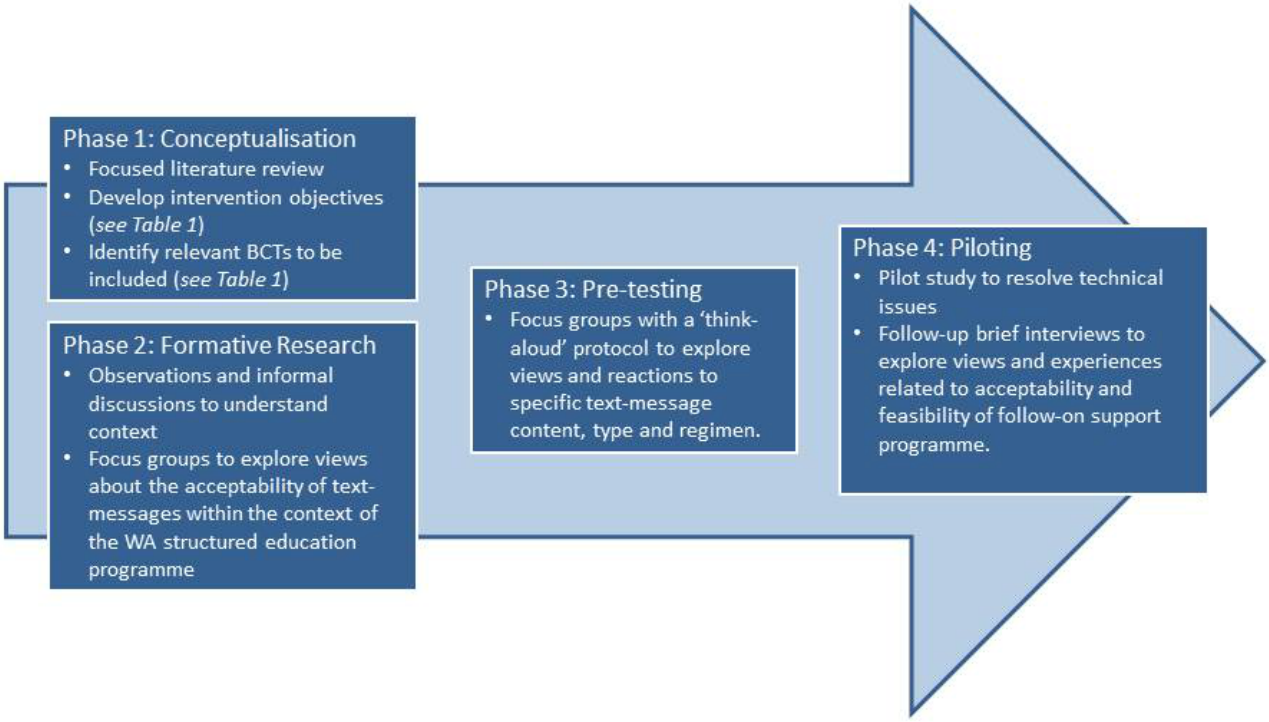
This paper describes the iterative development of the PROPELS follow-on support program and presents evidence about its feasibility and acceptability. The protocol for the PROPELS RCT is published elsewhere [30].

Methods

Design and Framework

To develop the PROPELS follow-on support program, we used a structured, iterative process involving concurrent and sequential research with the target population while maintaining a strong focus on integration of theory and evidence. Our framework for intervention development and piloting was informed by the model by Dijkstra and De Vries [31] for developing computer-generated tailored interventions (to conceptualize the program) and the mHealth development and evaluation framework by Whittaker et al (2012) [32] and Fjeldsoe et al (2012) [33]. An outline of our framework is shown in Figure 1. This development study was approved by National Research Ethics Service Committee East Midlands-Leicester (12/EM/0151) as part of the PROPELS RCT.

Figure 1. Design and framework of the PROPELS follow-on support program.



Phase 1: Conceptualization

We conducted a focused literature review to identify the key psychosocial determinants of increasing and/or maintaining physical activity levels among adults at risk of developing T2DM (see Phase 1 results for the key findings from this review). In line with Dijkstra and De Vries' [31] model of developing computer-generated tailored interventions, we then translated these determinants of physical activity into the key objectives (see Multimedia Appendix 1) of the PROPELS follow-on support program.

Phase 2: Formative Research

In parallel with Phase 1, we (KM and HE) conducted informal observations of Walking Away sessions in diverse regions where it has been commissioned into routine care pathways for the prevention of T2DM. In addition, we (KM, HE, and WH) engaged in discussions with Walking Away educators involved in an ongoing evaluation of Walking Away taking place within primary care [29]. In this phase, we aimed to become familiar with the delivery of Walking Away, develop initial ideas about the PROPELS follow-on support structure and content, understand the cultural and ethnic diversity of our target population, explore educators' views about supplementing Walking Away with text messaging and pedometer support, and inform the development of topic guides for subsequent focus groups.

Following this, we conducted 3 formative focus groups with our target population. Eligibility criteria included having attended the Walking Away session within the last 3 years as part of an ongoing evaluation in primary care [29], having provided consent to be contacted with regard to other research within the department, and having ability to speak and understand spoken English. Potential participants were sent an information leaflet and opt-in reply slip. A researcher telephoned those who had expressed an interest in taking part to check willingness and arrange attendance at a focus group. Written informed consent was taken immediately before the focus groups. A total of 15 participants (5 women and 10 men) aged between 39 and 76 years participated. A flexible topic guide was used that covered experiences of Walking Away (eg, what was most and least helpful for increasing physical activity and what could be improved to facilitate sustained changes), use of mobile phones in everyday life, and integration of a text-messaging follow-on support program into Walking Away.

Focus groups were audio recorded and transcribed verbatim. Our analytical approach was based on the constant comparative method [34]. Specifically, KM familiarized herself with the data and identified initial codes. This involved organizing the data into meaningful groups and identifying interesting aspects in the data that formed the basis of repeated patterns (themes) across the dataset. Codes were assembled into an initial coding framework (KM and HE); this was used to code the complete dataset. NVivo qualitative data indexing software (QSR International) was used to facilitate the analysis.

Phase 3: Pretesting

We created exemplar text messages based on the findings of Phases 1 and 2 (see the "Phase 1 and 2 Results" sections) and conducted 4 further focus groups (n=20; ages 52-77). Eligibility was the same as in Phase 2, but we also invited participants from the Walking Away study control group who had not previously attended the program [29]; recruitment and consent procedures were identical to Phase 2. Prior to attending a focus group, participants received a pedometer and activity diary via postal mail and were encouraged to record the number of steps per day for 1 week. Participants were asked to bring along a mobile phone to the focus group.

As in Phase 2, a topic guide covered experiences of Walking Away. Additionally, it explored experiences of wearing the pedometer and recording steps. During the focus group, participants were sent example text messages (Figure 2) to provoke reactions in situ and generate think-aloud [35] reactions and discussions about different types of messages. Data analyses followed the approach used in Phase 2. The coding framework was further developed from the Phase 2 coding framework to reflect the current phase of development.

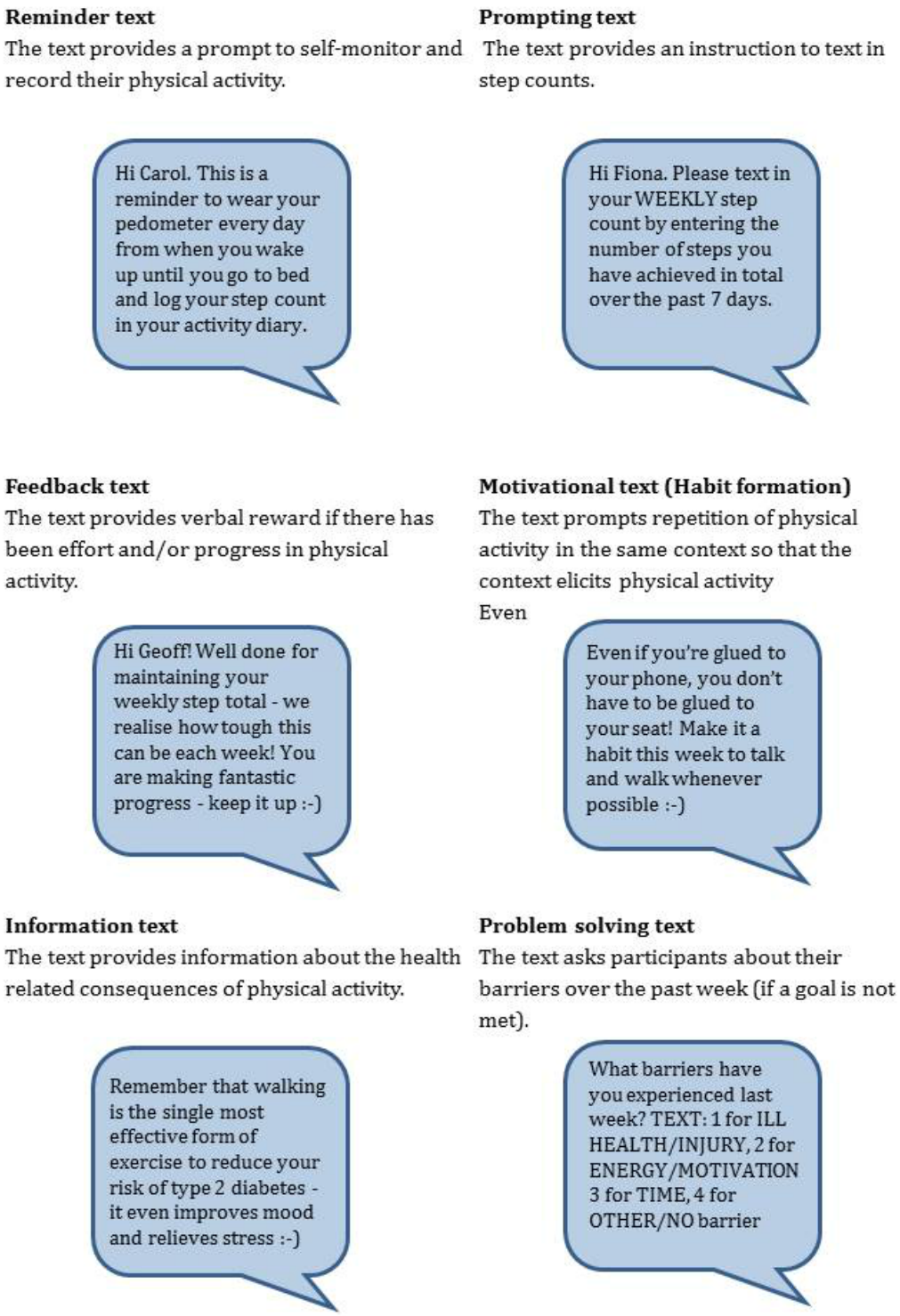
Phase 4: Piloting

Using the findings of Phases 1 through 3, KM drafted an initial set of text messages and tailoring matrices. The tailoring matrices (for each week of the program) specify the individual characteristics to which each message will be adapted. SS developed a computer program to automatically generate and send text messages (in line with the tailoring matrices) and to handle incoming messages. We subsequently tested the content and schedule of the text-messaging and pedometer program and the delivery processes required (eg, registering with the text message system, gathering information for tailoring, and receiving and replying to the messages). We also aimed to identify and resolve potential technical issues with the automated system.

Participants were 11 people (6 men and 5 women) from the Phase 2 and 3 focus groups who had indicated interest, including participants who were less keen on the use of text messages. This 8-week pilot study mimicked the proposed initial 8 weeks of the PROPELS follow-on support program. Participants were mailed an instruction booklet with details on how to register and what to expect from the text-messaging system, a pedometer, and an activity diary. They were instructed to wear the pedometer and self-monitor steps using the activity diary for 1 week to determine a baseline number of steps that would inform their step goals for the next 8 weeks. KM administered the brief telephone assessment to elicit each participant's short- and long-term step goals, an action plan for increasing physical activity, and information for the tailoring variables. Then, each week, participants received a reminder message to prompt them to submit their weekly step count via text message. This triggered an automated, tailored feedback message with the content depending on goal progress. Participants also received tailored motivational messages if they did not make progress with step counts or text in a step count.

After the 8-week period, KM conducted brief, semistructured telephone interviews with all available participants (n=10) to gain their feedback on the program. Interviews were recorded, transcribed, and analyzed as in Phases 2 and 3.

Figure 2. Example text messages used in Phase 3.



Results

Phase 1: Conceptualization

We focused our literature review on text-messaging interventions to promote physical activity but also reviewed physical activity behavior change interventions within our target population more broadly to identify a number of salient behavior change techniques (BCTs) [36] to incorporate within the PROPELS follow-on support program. The main findings from our focused literature review are as follows.

Text Messaging for Physical Activity Promotion

The evidence base for text-messaging interventions to promote health is growing, as demonstrated by two comprehensive meta-analyses. In one meta-analysis that focused on physical activity promotion using mobile devices [37], most of the included interventions delivered through text messaging were passive, sending participants relay messages (eg, goal intentions) or generic, nontailored information about health benefits, and participants were mostly younger adults. There were two exceptions: a pilot study with older people with chronic

obstructive pulmonary disease [38] provided the control (self-monitoring) group with a pedometer and mobile phone, prompted them to text in details about their symptoms and exercise, and responded with a standard message to thank them and encourage continued submission of data. Intervention (coaching) group participants received additional ongoing reinforcement coaching messages. Objectively measured step count increased in the self-monitoring group only. The intervention was feasible to deliver; however, delivery was not automated as a nurse manually adjusted text responses, and scalability was limited due to all participants being provided with a phone. The second study, an RCT of a fully automated intervention consisting of a wrist-worn device, an interactive website to provide feedback on physical activity, and text-messaging reminders of activity plans in middle-aged healthy adults reported significant increases in objectively measured activity compared to no support [39].

A second meta-analysis investigated the efficacy of different formats of text-messaging-based interventions for various health behaviors and outcomes. Message tailoring and personalization were significantly associated with greater intervention efficacy [40]. Furthermore, interventions that involved decreasing frequency of messages over the course of the intervention were more effective than interventions that used a fixed message frequency [40]. Text message-only physical activity interventions without tailored feedback did not increase physical activity [41]. Hence, tailored feedback appears to be a promising component of mHealth physical activity interventions.

Taken together, physical activity interventions using text messages may be more effective if they incorporate active components such as self-monitoring, provide tailored feedback and personalized messages, and decrease the frequency of text messages over time.

Theory and Behavior Change Techniques Informing the PROPELS Follow-On Support Program

Health behavior change interventions (ie, not just text-messaging interventions) that combine self-monitoring with at least one other self-regulatory BCT (eg, goal setting) have been shown to be significantly more effective at increasing physical activity than those that did not include these specific BCTs [42]. These BCTs are congruent with the process of self-regulation or more specifically, control theory [43], which proposes that setting goals, self-monitoring behavior, receiving feedback, and reviewing goals following feedback are central to behavioral self-management. The PROPELS follow-on support program was thus structured around behavioral self-regulation (Figure 3). This facilitated the selection and sequencing of the primary BCTs that are prevalent in the program's components [36]. Specifically, during the Week 1 educator telephone call, physical activity goals and an action plan were established (Figure 4). The subsequent text-messaging component drew upon a selection of BCTs to (1) encourage self-monitoring of physical activity behavior, (2) provide tailored feedback regarding physical activity progress (to highlight the discrepancy between goals and current behavior), and (3) review behavioral goals. A more detailed description of all BCTs employed within the PROPELS follow-on support program is shown in Multimedia Appendix 1.

Interventions among people with or at risk of T2DM that included a higher number of BCTs [44] or a higher number of BCTs and specific BCTs such as goal setting [45] have been associated with more weight loss. Furthermore, there is consistent evidence demonstrating the importance of several other key determinants of physical activity behavior change across general populations as well as in high-risk groups. These include attitudes toward physical activity [46], intrinsic motivation [47], and (maintenance) self-efficacy [48], especially when this is targeted in conjunction with self-regulation [49]. With this in mind, the PROPELS follow-on support program also targeted other determinants of physical activity behavior change via the text message component and employed additional BCTs to achieve the overall intervention objectives (see Multimedia Appendix 1). Given that uncertainty remains about the acceptability of the aforementioned BCTs when delivered by text message, one aim of Phases 2-4 was to explore the acceptability and feasibility of this approach with our target population.

Figure 3. Modified self-regulation control theory which informed the PROPELS follow-on support program.

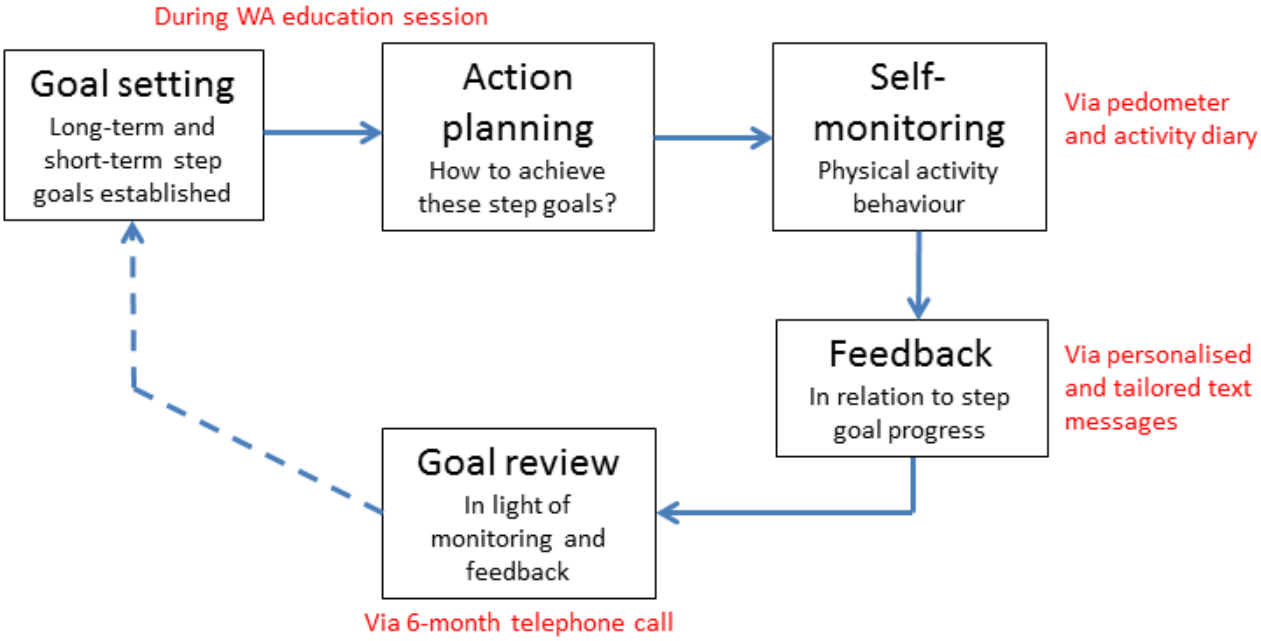
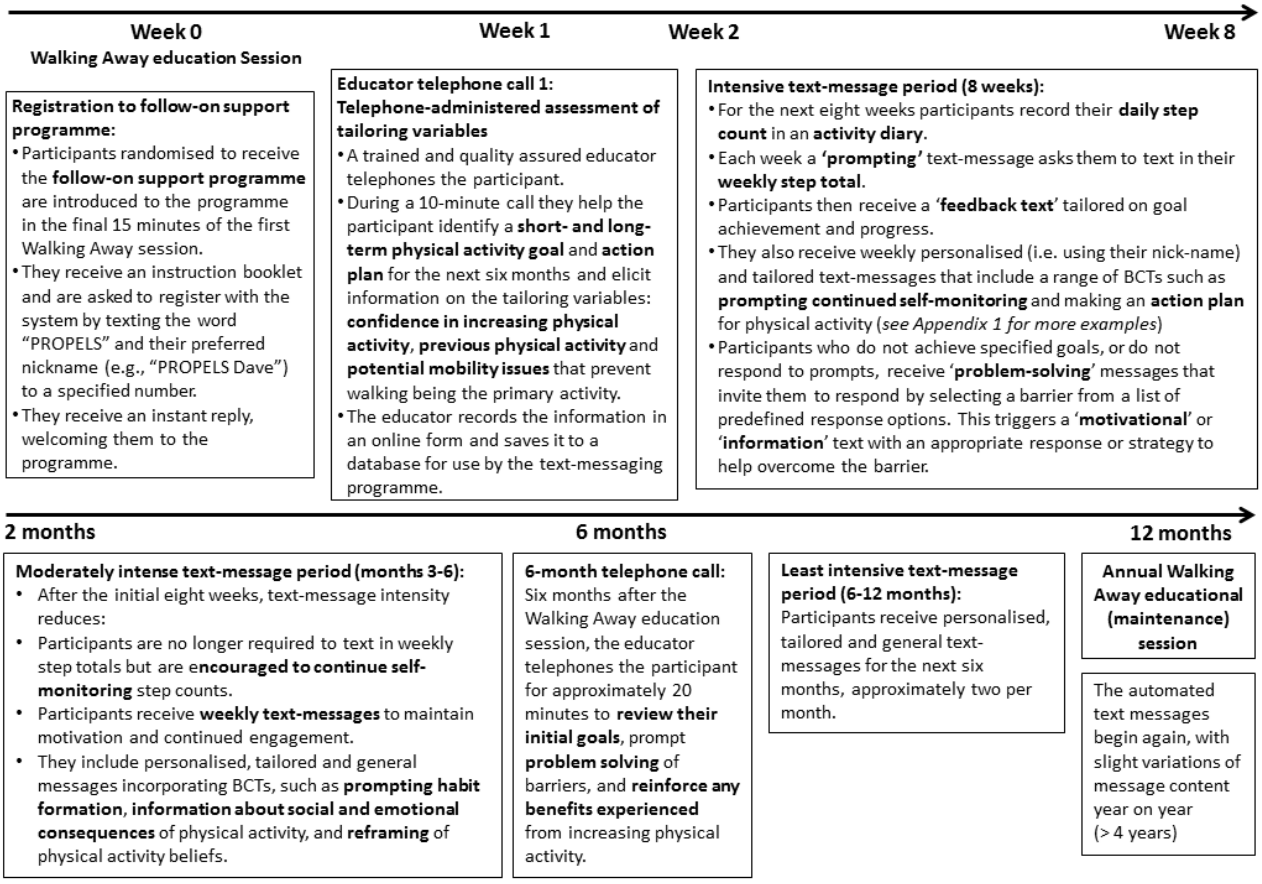


Figure 4. The final PROPELS follow-on support program overview.



Phase 2: Formative Research

The key findings from Phase 2 that influenced intervention development and subsequent phases are presented under two interlinked themes: acceptability of text messaging for physical activity promotion and requirements for the structure of the follow-on program that includes text message content.

Acceptability of Text Messaging for Physical Activity Promotion

The majority of participants reported using mobile phones in daily life and being able and willing to use text messages, even if they were not in the habit of doing so as a primary means of communication. Most agreed that text messages could serve as

a useful reminder to aid habit formation and provide additional support following an education session.

> *I think if texting had been in it [Walking Away trial] before it would have helped my motivation a lot.* [FG3]

The potential ease of integrating a text-messaging program into daily life was highlighted; participants reported that a positive feature was the freedom to choose when to read a message and whether to act on the information provided within it.

> *...whereas texting is ideal. You can carry on with your normal day-to-day living but still get the motivation.* [FG1-A]

> *You don't have to listen to it, but it's an idea. You can read all these and just take from it what you want to, don't you? That's what we do, gather the information and decide what you want to do from there.* [FG3]

Another perceived benefit was the opportunity to receive immediate feedback. Many participants reported that a two-way interaction, especially the process of reporting weekly step counts and receiving subsequent feedback, would facilitate motivation and maintenance and could foster a sense of accountability (ie, someone to report to).

> *It would be good knowing that we'd put the figures in at the end of the week, that you have received them and that you've looked at them and that you're interested in what we're doing.* [FG2-A]

Positive views were not unanimous. Some participants felt that texting was "not for [their] generation," although this did not necessarily mean they were against it.

> *Well, you know, I think it's just that I don't use it, you know, it's not that I don't like it.* [FG1-B]

A small number of participants expressed a strong dislike of text messages, reporting that they are intrusive and/or impersonal.

> *No, I wouldn't [want to receive text messages], I would find that intrusive. It's bad enough 'have you been missold PPI,' 'have you done this'...so you don't even look at your text messages. If it's not from family I block the lot so no, I wouldn't want text messages.* [FG1-C]

Requirements for the PROPELS Follow-On Support Program

Monitoring and feedback were salient themes. When reflecting on experiences of Walking Away, participants generally reported that the pedometer was a useful monitoring tool that promoted awareness of activity levels.

> *And it does encourage you because you think, I've hardly moved! I think it keeps it in your mind.* [FG2]

Some participants reported that they were still using it to monitor their physical activity 2-3 years after Walking Away, but the majority reported a lack of continued engagement with the pedometer or activity diary following an initial period of active engagement.

> *You get up at half six in the morning, you think I'll go and get a wash and you get changed, and then you go off to work and, "Oh, I didn't put it on"...you start to forget about it.* [FG2-C]

> *Once I've got home I think, oh, I don't think I'll do any more, I sit on the computer or watch the telly, I need someone to push me out, get out the chair and go and do a walk.* [FG3-C]

Closely tied to the notion of self-monitoring was the importance of feedback for facilitating behavior change and maintenance. Participants commonly reflected that a lack of contact between the annual Walking Away group education sessions had decreased their motivation to continue with the strategies discussed in the session (eg, setting goals, wearing a pedometer). Several participants described how feedback on their goal setting and progress with increasing physical activity levels would have been useful.

> *It would have been nice to have the results of that [physical activity measures] because we never knew about that.* [FG1-D]

The preferred content of the text messages differed greatly according to individual preferences and characteristics. Some participants, especially those who described themselves as self-motivated and the sporty-type (ie, someone who has been fairly active in the past) wanted very different messages from those who described themselves as sedentary and needing more of a push. Furthermore, several participants reported prominent mobility issues, such as osteoarthritis, which meant that content focusing solely on walking was not relevant to them. Hence, the idea of the follow-on support content being tailored to individual characteristics (see Phase 3 for more detail) was appealing to participants.

Participants were adamant that text messaging should supplement, rather than replace, face-to-face contact, especially in relation to strengthening motivation. Some suggested that telephone support, in addition to text messages, could foster rapport between PROPELS educators and participants and provide additional support that cannot be communicated via a text message, thus overcoming the perception that text messages are impersonal.

> *But, [if] you've got somebody there you can speak to...say, 'right I'm having a problem, I've done such and such and I can't register me steps' or whatever, it's just about [the educator] saying 'right, you should do this' or 'I'll get somebody to ring you back and tell you what to do,' you can't do that on text can you?* [FG1-E]

Taken together, the Phase 2 findings indicate the need for (1) two-way interaction (ie, inputting of step counts and providing immediate feedback about physical activity progress), (2) timely reminders for self-monitoring of physical activity, (3) further consideration of how to overcome perceived barriers to using text messaging (ie, by providing participants with an overview of the benefits of text messaging for follow-on support at the initial Walking Away session), (4) tailored and personalized text message content (explored further in Phase 3), and (5) additional telephone support to enhance rapport between

educator and participant and provide support beyond text messages only (ie, problem solving and in-depth social support).

Phase 3: Pretesting

During the pretesting focus groups, participants were sent a variety of text-messages developed as a result of Phases 1 and 2. Messages included "reminder texts," reminders to wear the pedometer and log daily steps and instructions to text in step counts; "feedback texts," feedback about behavior including social reward and positive reinforcement; "motivational texts," messages using BCTs to strengthen motivation for physical activity (eg, habit formation, commitment, reframing physical activity beliefs); "information texts," information about health consequences; and "problem-solving texts," which contained response options to a list of predefined barriers when a goal was not met (Figure 2). Depending on a participant's response to the latter, they were sent a tailored motivational or information text.

We present key themes emerging from the Phase 3 pretesting focus groups that informed the final content of the PROPELS follow-on support program. We categorize the data into views about self-monitoring of physical activity and text message type, language, and frequency.

Self-Monitoring of Physical Activity

The majority of participants reported that self-monitoring their daily steps with the pedometer increased their motivation to be more active due to increased awareness of their own activity.

> *I found the pedometer really, really useful. I didn't wear it all the time, but once I wear it I make sure I do 10,000 steps. If I looked at it half way through the day and think I've only done 5,000 then I went out for a walk purposely just to get the figures up.* [FG4]

Some participants found the pedometer demotivating or disheartening, especially those with mobility problems who felt that because they could not engage in walking as their primary activity, the step count was always low.

> *I wish that it was not just dependent on the steps. Because we do all sorts of other things rather than just steps.* [FG7]

For these individuals, the self-monitoring process should allow for other activities to be counted (eg, swimming, gardening).

Text Message Type, Language, and Frequency

Reminder Texts

Several participants commented that establishing appropriate frequency of reminder texts was key to avoiding the intervention becoming off-putting and Big Brother-like or "checking up on you," especially when people had developed a habit of wearing the pedometer. This suggested a reduction in reminders as the intervention progresses.

> *If you've got something constantly...well, not constantly, but weekly reminding you to do something then you're still there doing it. And possibly if you're doing it for several weeks then you'll get actually used to wearing it and putting it on. It's like putting your clothes on. You put your socks on, put your pants on, "oh I'll put my thing [pedometer] on." It's all getting used to what you're doing, like with your lifestyle.* [FG5]

Prompting Texts

Participants were generally happy with the idea that a text message would prompt them to input their weekly step count; this was considered a useful motivational tool.

> *I suppose the very fact that we would be doing it [texting in step counts] we are creating a certain level of discipline which we didn't have before.* [FG4]

Feedback Texts

The exemplar feedback messages for having achieved one's step goal (ie, positive reinforcement) were well received, again fostering a sense of accountability.

> *We are all school kids in a sense, in our heads, so if someone says you did well it's really encouraging* [FG5]

We tested a variety of feedback messages for the event of not achieving one's step goal. The consensus was that these should be fairly light-hearted, positive, and encouraging. Messages that emphasized a discrepancy between the person's current behavior and goal were well received, as long as the texts also offered encouragement and support, for example, by including positive elements along with more negative feedback.

> *...you've got to put in, you know, the positive that eliminates some of the negativity out of the messages. So this one was 'thanks for the text, keep wearing your monitor and logging your steps, try to increase your activity to ensure'...it's not quite positive enough.* [FG4]

Indeed, several participants commented that humor could be used to provide feedback when not achieving a step goal.

> *You can't castigate somebody but you can try and get some laugh out of it from some point of view, saying 'get off your bottom and go for a walk!'* [FG6]

However, participants also recognized that messages could be interpreted differently and the use of humor was risky, especially when participants were low in confidence.

> *...if I read that and I was in the wrong mood I'd take that as you're telling me what to do, and I'd say 'b*****r off.'* [FG4]

Motivational Texts

The feedback on motivational messages varied greatly. Overall, participants reported that the language and content of the motivational messages were acceptable due to the gentle, suggestive nature rather than "being told you've got to do it." Some exemplar messages were perceived as a bit dated (eg, recommendations to not use a remote control to change the TV channel) or irrelevant (eg, tips about using stairs at home; "...but I live in a bungalow!"). Participants preferred practical tips and suggestions for increasing activity over more motivational suggestions (eg, "try writing down your barriers to activity this week"). In one focus group, participants suggested general

supportive messages not necessarily linked to physical activity or health.

> *I know why I'm doing it [to reduce the chances of T2DM] so we don't need reminding of it all the time.* [FG7]

Information Texts

The consensus was that messages focusing on health consequences of inactivity were too prominent and that a focus on benefits other than weight and reduced risk of T2DM would be preferred.

> *You could just say 'good morning, this is PROPELS, hope you have a nice day' or whatever...just simple—it doesn't need to really say anything.* [FG6]
>
> *...when you've got a weight problem like I've got, I don't need to be reminded—I'm doing my best!* [FG4]

Problem-Solving Texts

Some participants felt that the predefined response format was not appropriate for problem solving.

> *It's like one of those PPI messages [spam text messages about reclaiming missold insurance]—I hate those!* [FG4]

However, others liked the idea that they could easily text in the reason why they had not achieved their goal. Participants generally liked the tailored and personalized texts that were triggered by responding to the problem-solving texts (eg, the message, "Take it easy this week. We hope that you feel better soon" as a response to selecting the illness or injury response option).

Tailoring

The concept of individually tailored text messages was very well received, especially in relation to individual goal progress and/or achievement.

> *You should get the one [text message] that's relevant to you. If you're doing more [steps], if you're achieving your target or doing more, you still get one, but it should be different.* [FG4]

Participants advised that different people need different support, especially in terms of confidence and self-discipline in adhering to an activity plan. They suggested that messages should be less direct or less pushy if people are struggling to meet their goal and/or have mobility problems limiting the amount of walking that they could achieve.

Language and Frequency

We tested language variations within the messages. The general feedback was that the language needed to be formal, friendly, and polite with use of the participant's name but limited use of emoticons.

> *I'm just warning you that it might be interpreted that you are shouting at us because in text language, capitals [letters] is shouting* [FG5]
>
> *It makes it sound as though you're talking at us, rather than a computer.* [FG6]

Regarding the frequency of messages, participants responded that less is more. Overall, they perceived daily messages as too heavy-handed and potentially demotivating.

> *...otherwise if you are going to get this [text message] daily you're going 'oh another one' and you get fed up with it.* [FG6]

In sum, the Phase 3 findings expanded the findings from the previous phases by (1) further emphasizing the importance of personalizing and tailoring messages according to key variables (eg, previous levels of physical activity, mobility issues that limit physical activity, individuals' confidence in increasing physical activity, goal achievement/progress), (2) shaping the content of the messages (ie, the type of benefits to focus on within the motivational messages), (3) informing the frequency of messages and sequencing of the follow-on support program, and (4) highlighting the importance of including other activities (eg, cycling, swimming) to maintain engagement of participants who did other activities than walking alone.

As a result of the findings from Phases 2 and 3, we added a Week 1 educator telephone call (Figure 4): a brief telephone-administered assessment including key information required to tailor subsequent text messages. We also added a conversion chart to the activity diary, which would enable participants to convert other activities (for which they might not be wearing their pedometer or for which they perceive a pedometer to not accurately assess) into steps for texting in. For example, this chart includes descriptions of other activities (such as swimming breaststroke, moderate effort, and cycling 10 mph) and provides a conversion into a step count, based on MET equivalents [50], that can be added to the participant's total.

Phase 4: Piloting

In the final piloting phase, we developed a full set of text messages and tailoring matrices for the initial 8 weeks of the follow-on support program. Examples of the tailoring matrices for Weeks 1 and 4 are shown in Multimedia Appendix 2. In this section, we present findings on the participant feedback on the content and structure of the program followed by technical issues.

Program Content and Structure

Most participants found that the follow-on support motivated them to be physically active due to increased awareness of their own activity. Participants found the telephone call, in which the brief assessment was administered, helpful in providing additional support, especially with overcoming any technical barriers.

> *But, you've got somebody there you can speak to then say, "right I'm having a problem, I've done such and such and I can't register me steps" or whatever, it's just saying, "right, you should do this or I'll get somebody to ring you back and tell you what to do," you can't do that on text can you?* [R5]

Participants reported that the system provided continued support and encouragement. For example, the reminder texts were helpful prompts to continue self-monitoring; continued goal

setting and immediate feedback provided further motivation to be active.

> *It's quite nice. It keeps me sort of in the zone in the fact that I enjoy using the pedometer because it keeps my mind on exercise. I'm conscious of it, and, you know, if I haven't done too much moving about, I go and walk some more.* [R5]

> *I usually do remember to put me pedometer on...but as I say it's nice to know there's a reminder there and when I send off my figures I get an immediate response. I think it's all been quite encouraging actually.* [R4]

They reported that the frequency of messages (at most 2 per week) to be sufficient for the 8-week period but commented that over time the messages could decrease in frequency as they would not need as much reminding.

> *As I say I think at the beginning you need more frequent reminders, you know I think you've got that right, and then as it goes on you don't need so many.* [R6]

Overall, participants were positive about the text message content, readability, and clarity and struggled to recall examples of discouraging messages. Several participants picked out the feedback texts and motivational texts, which provided instructions (tips) for increasing physical activity, as particularly useful.

> *Do you know I've even started...this is what you have got me doing...when I'm on the kitchen chair, making a cup of coffee or something, I start running on the spot for a hundred! I count up to a hundred, running on the spot. So that's another hundred steps!* [R10]

Those who did not consistently increase their step counts reported receiving slightly more negative messages but none they perceived as chastising.

> *I found that very encouraging. It was good. When I'd done a good week, it's very...I only missed one week, and although you didn't down me, you didn't say anything nasty, you just said try a little harder, I know it's hard to get the exercise in, so I found it very encouraging.* [R1]

Technical Issues

A total of 9 of the 11 participants received the full regimen of text messages as intended. Minor technical glitches impeded the full delivery to 2 participants. Most participants had no difficulty registering with the text system, and more than 90% of all incoming messages from the participants were correctly formatted. Almost all participants responded to at least two prompting texts and received tailored feedback on at least two occasions. Three-quarters responded to all prompting texts and received tailored feedback texts every week.

Several participants were unclear about the type of messages they could respond to. Some sent thank you messages in response to the feedback texts and then received a text message about unrecognized format.

> *I was just replying to your request or your advice, when I didn't do the correct steps one week, you gave me a couple of bits of helpful advice and I text back thanking you for that, and obviously it wouldn't let me send.* [R7]

Related to this, participants wanted a greater degree of flexibility in the format for texting in step counts. They were asked to enter the word "steps" followed by their weekly step total but some submitted only numbers or the word "step" or "step-count for week," which triggered an unrecognized response text.

Finally, participants with limited experience in texting reported receiving and reading texts without problem but utilized help from relatives (usually grandchildren) when prompted to text in their weekly step counts.

> *Oh, yes, I could [read all the messages]...it's just getting them sent off. Because again I think this week I was late, I thought I'd sent them in twice and then I had to check with [granddaughter], and I think I had pressed some other button. I think I've got a handle on it now. It sounds stupid but they didn't have all these phones back then.* [R2]

In sum, the piloting phase indicated that (1) the structure of the follow-on support (including the brief telephone call) was acceptable, (2) the frequency of text messages over the 8-week pilot phase was acceptable but should be reduced over time, (3) the content and language used in the text messages were acceptable, (4) minor technical issues needed to be resolved, and (5) participant instructions in both the Walking Away session and the follow-on support booklet required refinement.

The Final PROPELS Follow-On Support Program

The findings from each phase were consolidated into a finalized set of text messages and underpinning schedule with integrated tailoring. This involved the development of tailoring matrices for each week of the program with additional messages for Years 2 through 4 (to ensure that there was sufficient variation in message content for the 4-year study). We briefly describe each component of the resulting PROPELS RCT follow-on support program in Figure 4.

Discussion

Principal Findings

Using a systematic approach to the development and piloting of the PROPELS text-messaging and pedometer follow-on support program, we identified the following key components: differing frequency of text messages according to period and year of program, tailored text message content according to key variables, personalized text messages using the participant's nickname, facility for two-way interaction, use of motivational texts emphasizing affective benefits rather than health benefits, and inclusion of general encouragement messages. Participant need for social support from and rapport with the educator and the need for a way of eliciting information for tailoring resulted in the addition of supplemental telephone calls. Furthermore, we identified and addressed potential barriers such as impersonal messages or unfamiliar technology.

A key task was to assess the acceptability of a text-messaging intervention for our target group: older adults at risk of T2DM. Their active involvement in the intervention development phases resulted in specific components to meet their needs. For example, an instruction booklet about the text-messaging program and telephone calls to supplement the text messages were added to the follow-on support program to facilitate user engagement. We acknowledge that some initial training or help with text messaging (at the initial Walking Away education session) may be required to ensure that all participants are able to engage with this type of text-messaging support. Automated tailored text messaging following structured group education enables initial one-to-one help with getting started and reduces the time commitment for health care professionals and participants. It is scalable and fits into participants' everyday lives while maintaining ongoing support following the initial education session. This is particularly important in primary care, where many people are identified as being at risk through health checks (eg, NHS Health Check, in England [51]) but where there is limited capacity for providing ongoing support for behavior change. In England, a key objective of the NHS Five-Year Forward View [52] is to implement scalable diabetes prevention programs; if successful, the PROPELS intervention may be an ideal candidate for this. Future research could explore variations of follow-on support: providing the follow-on support as a standalone intervention or pairing the follow-on support with a one-off telephone call that covers the Walking Away education session content for people who are unable or unwilling to attend group-based structured education.

The PROPELS text-messaging and pedometer follow-on support could be adapted fairly easily for other target groups such as people with newly diagnosed or established T2DM attending structured education (eg, DESMOND [Diabetes Education and Self-Management for Ongoing and Newly Diagnosed] [53]) or people with or at risk of other conditions (eg, cardiovascular disease) where increasing physical activity reduces the risk of developing the condition or its consequences.

Limitations

Time constraints related to timelines of the PROPELS RCT [30] meant that we were unable to conduct a pilot of longer duration to test the acceptability of varying text-messaging frequency, participant engagement, and retention over time. These are assessed in the PROPELS RCT along with physical activity outcomes [30]. Further qualitative work embedded within the RCT may identify potential future adaptations and facilitate long-term implementation and could provide an in-depth understanding of how participants engage with the program over time, which components are most and least helpful, and how pedometer use, text messages, and telephone calls influence physical activity change over time.

We acknowledge that, especially in developed countries, text messaging may become less acceptable over time, and participants may prefer newer technologies such as smartphones that incorporate accelerometers. Although older adults have relatively low rates of smartphone ownership [18], recent research indicates that text messaging is becoming increasingly popular with that age group [54]. Taken together, this indicates that mHealth interventions through smartphones would have had limited reach in the PROPELS study, and a predominantly text message-focused program is currently more acceptable. One advantage (and direction for future work) of the PROPELS follow-on support program is that it could be easily adapted for delivery across a variety of platforms (eg, email, app) which would allow people to choose which version they use.

A final potential limitation relates to the weekly reporting of steps. Although PROPELS participants are encouraged to record their daily step count in their activity diary and text in the weekly total, there is more room for error in comparison to, for example, texting in each day's total in response to a daily prompt. However, our participants voiced aversion to the idea of daily texts as overkill and off-putting. Future qualitative work in the PROPELS trial may provide an insight into participant experiences and preferences for self-monitoring step counts.

Comparisons With Prior Work

We developed a novel, interactive program whereby participants self-monitor their physical activity using a pedometer, text in their weekly step count, and receive automated tailored feedback on goal achievement and progress. Previous mHealth interventions for T2DM prevention included untailored, passive text-messaging content such as information about T2DM risk [20].

The methods that we employed to develop the PROPELS follow-on support program combine features of published mHealth development frameworks [31,32] and multiple iterative phases of qualitative research (similar to a user-centered design process [55]). The high level of engagement with our target population enabled refinements in the design to optimize its acceptability to users.

Robust development of mHealth behavior change interventions can be time consuming [33,56] and is often allocated limited time in RCT protocols. A potential consequence of rapid development is that insufficient attention is given to the underpinning theory and evidence base or selection of active ingredients (BCTs). Given the time constraints of the PROPELS RCT protocol (12 months to conceptualize, develop, and test the follow-on support program prior to the RCT's commencement), this paper provides a detailed outline of a pragmatic framework for developing and piloting a text-messaging intervention that draws on relevant behavior change theory and uses rigorous qualitative methods incorporating user engagement. It encourages replication and application to the development of similar interventions.

Conclusions

We developed a feasible and innovative text-messaging and pedometer program based on evidence and behavior change theory and grounded in the experiences, views, and needs of people at high risk of T2DM. A large-scale RCT is testing the effectiveness of this 4-year program over and above group-based structured education alone.

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Authors' Contributions

WH, SS, and HE designed the initial protocol for the follow-on support component of the PROPELS intervention. KM and HE designed the methodological approach of the development and pilot study and collected and analyzed the data used to develop and refine the follow-on support program. SS developed the Web-based interface and the computer program to generate and send the tailored text messages. KM, JT, and WH developed the curriculum and training to support educators with the delivery of the follow-on support intervention and led on developing materials for assessing quality in delivery. KM and HE co-led writing the manuscript with extensive input from WH, JT, and SS. All authors contributed to, read, and approved the final manuscript.

Conflicts of Interest

KM, SS, JT, TY, SG, and HE declare that they have no conflicts of interest. WH has undertaken consultancy work for AbbVie Ltd. MJD has acted as consultant, advisory board member, and speaker for Novo Nordisk, Sanofi-Aventis, Lilly, Merck Sharp & Dohme, Boehringer Ingelheim, AstraZeneca, and Janssen and as a speaker for Mitsubishi Tanabe Pharma Corporation. She has received grants in support of investigator and investigator-initiated trials from Novo Nordisk, Sanofi-Aventis, and Lilly. KK has acted as a consultant and speaker for AstraZeneca, Boehringer Ingelheim, Janssen, Lilly, MSD, Novartis, Novo Nordisk, and Sanofi. He has received grants in support of investigator-initiated trials from AstraZeneca, Boehringer Ingelheim, Lilly, Novartis, Novo Nordisk, Roche, and Sanofi.

Multimedia Appendix 1

Key findings from Phase 1: Intervention objectives, determinants of physical activity targeted in the PROPELS follow-on support program, and included behavior change techniques.

[PDF File (Adobe PDF File), 10KB - mhealth_v3i4e105_app1.pdf]

Multimedia Appendix 2

Example tailoring matrices.

[XLS File (Microsoft Excel File), 127KB - mhealth_v3i4e105_app2.xls]

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Abbreviations

BCT: behavior change technique
IGR: impaired glucose regulation
NHS: National Health Service
NIHR: National Institute for Health Research
PROPELS: Promotion of Physical activity through Structured Education with differing Levels of ongoing Support for people at high risk of type 2 diabetes
RCT: randomized controlled trial
T2DM: type 2 diabetes

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Original Paper

Developing and Pretesting a Text Messaging Program for Health Behavior Change: Recommended Steps

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Abstract

Background: A growing body of evidence demonstrates that text messaging-based programs (short message service [SMS]) on mobile phones can help people modify health behaviors. Most of these programs have consisted of automated and sometimes interactive text messages that guide a person through the process of behavior change.

Objective: This paper provides guidance on how to develop text messaging programs aimed at changing health behaviors.

Methods: Based on their collective experience in designing, developing, and evaluating text messaging programs and a review of the literature, the authors drafted the guide. One author initially drafted the guide and the others provided input and review.

Results: Steps for developing a text messaging program include conducting formative research for insights into the target audience and health behavior, designing the text messaging program, pretesting the text messaging program concept and messages, and revising the text messaging program.

Conclusions: The steps outlined in this guide may help in the development of SMS-based behavior change programs.

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KEYWORDS

mHealth; telemedicine; SMS; text messaging; behavior change; behavior modification

Introduction

A growing body of evidence indicates that text messaging-based programs (short message service [SMS]) on mobile phones can help people modify health behaviors [1-3]. Text messaging programs related to health behaviors have been used in a variety of contexts including HIV prevention, medication adherence, pregnancy education, substance use/smoking cessation, weight loss, diabetes management, and depression [2,3]. Many of these programs have consisted of a series of automated and interactive text messages that guide a person through the process of behavior change.

Text messaging-based programs may be effective for several reasons [1]. Text messages are generally sent by an automated system to the user according to a preset schedule. Studies indicate that text messages are very likely to be read within minutes of being received [4,5]. In contrast to most behavior change programs, they do not require the user to seek out information and support to maintain engagement (eg, by going to a website) [5]. Thus, despite their brevity and text-based limitations, they may have a readership and engagement advantage over other communication modalities [2]. Text messages may be helpful because they provide short, timed bursts of information throughout the day, which are constant

reminders of a behavior change goal [5]. This aspect of text messages may maintain goal saliency and confer value beyond the specific content of the behavior change information they contain [3]. Also distinctive of text messaging programs is their ability to provide support and advice in-the-moment or near-the-moment of decision making. This element may be especially important for individuals who are facing strong cravings or recovering from addictions, for which real-time support may make a difference [4]. Finally, text messaging programs that are automated can be designed to mirror elements of in-person counseling, such as by offering tailored advice, behavioral monitoring, goal setting, feedback, and other important behavior change techniques [3,5].

Given the widespread use of texting and mobile phones and the evidence base to support their use, numerous text messaging programs have been developed globally. Current initiatives by the World Health Organization (WHO) such as "Be He@lthy, Be Mobile" and other governmental initiatives exist to address noncommunicable diseases and other health issues worldwide [6]. While there remain privacy concerns associated with text messaging [7], large public health and medical systems in the United States and the United Kingdom have integrated text messaging into their offerings for the public [8,9]. Given the high mobile penetration in the United Kingdom [10], the National Health Service (NHS) rolled out a text messaging program that was integrated into routine clinical services in 2014. The Veterans Health Administration (VHA), the largest health care system in the United States, is in the process of developing a similar program [9]. In addition, in 2013, almost half of US state quitlines that provide phone counseling offered their callers quit smoking text messaging in addition to regular phone counseling services [11,12]. Thus, text messaging has become an acceptable communication platform for achieving public health goals, both in large governmental health systems (ie, NHS and VHA) and in smaller, independent ones.

This paper supports the development of text messaging programs for behavior change and provides guidance on the steps to develop such a program. To date, few published resources exist that describe the process of developing a text messaging program for health behavior change [13,14], and those that do exist are mainly limited to technical aspects of development.

Methods

The authors drew from the evidence base in recommending specific steps for designing and developing text messaging programs, though this evidence was limited (exceptions include Head et al [3]). Where evidence was lacking, this guide drew on insights gleaned from the collective experience of the authors in designing, developing, and evaluating programs in the United States, United Kingdom, and New Zealand for health behavior change in the areas of smoking cessation, physical activity, healthy eating, and weight management [1,2,5,15-22]. One author (LCA) drafted the guide and the others provided input and review.

Results

Steps for Developing a Text Messaging Program

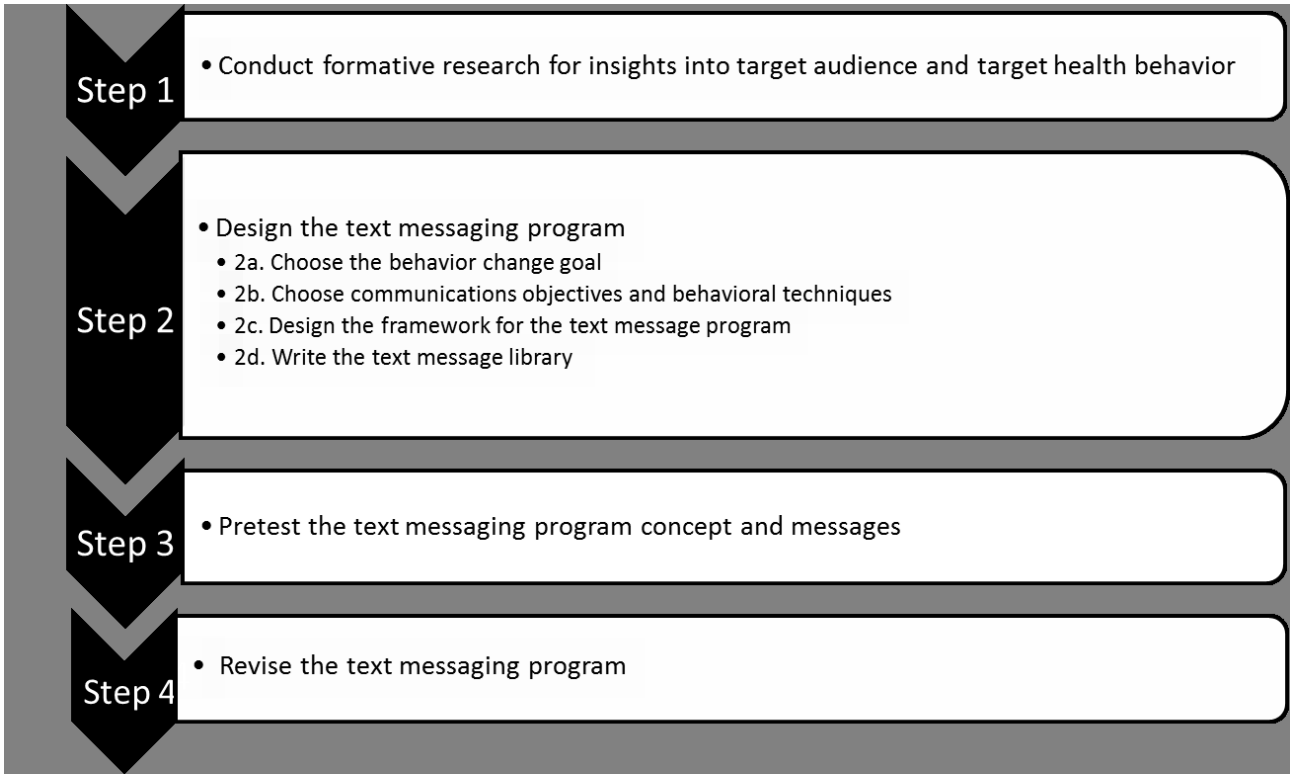
Text messaging programs should follow the same phases of development that are typical for any health communication material [23]. As with other programs, once a text messaging program has been developed and pretested, additional evaluation is recommended to determine its efficacy and, after dissemination, its effectiveness. Figure 1 displays the recommended steps for developing and pretesting a text messaging health behavior program [23]. Prior to beginning the design process, formative research should provide the basis for understanding key behavior change mechanisms for the health behavior and population of interest (Step 1). The remainder of this paper will focus on Step 2 (designing the text messaging program) and will also touch on Steps 3 and 4 (pretesting and revising the program).

Step 2: Designing the Text Messaging Program

Step 2a: Choose the Behavior Change Goal and Target Audience

Health behavior change goals should be selected based on a balance of health priorities and characteristics of the target audience, such as readiness to change. For example, the target audience may be pregnant smokers and the behavior change goal may be smoking cessation among those who are interested in quitting. For a more detailed discussion on choosing a behavior change goal and selecting a target audience, see the National Cancer Institute (NCI)'s *Making Health Communication Programs Work* [23]. One consideration that is specific to mobile phones is whether a text messaging program is a good match for the target audience. Factors may include whether the target audience owns a mobile phone, and whether they have a data plan or unlimited text messaging, so that they will not incur charges when receiving messages or responding to the program. For US populations, Pew Research Center's Internet & American Life Project provides useful information on the digital media habits of segments of the US population, including those segmented by age, gender, ethnicity, and other demographic factors [24]. In the case of pregnant smokers, the ubiquity of mobile phone ownership among women between the ages of 18 and 49 years makes the technology a good fit for the audience [25].

Figure 1. Steps for developing a text messaging program.



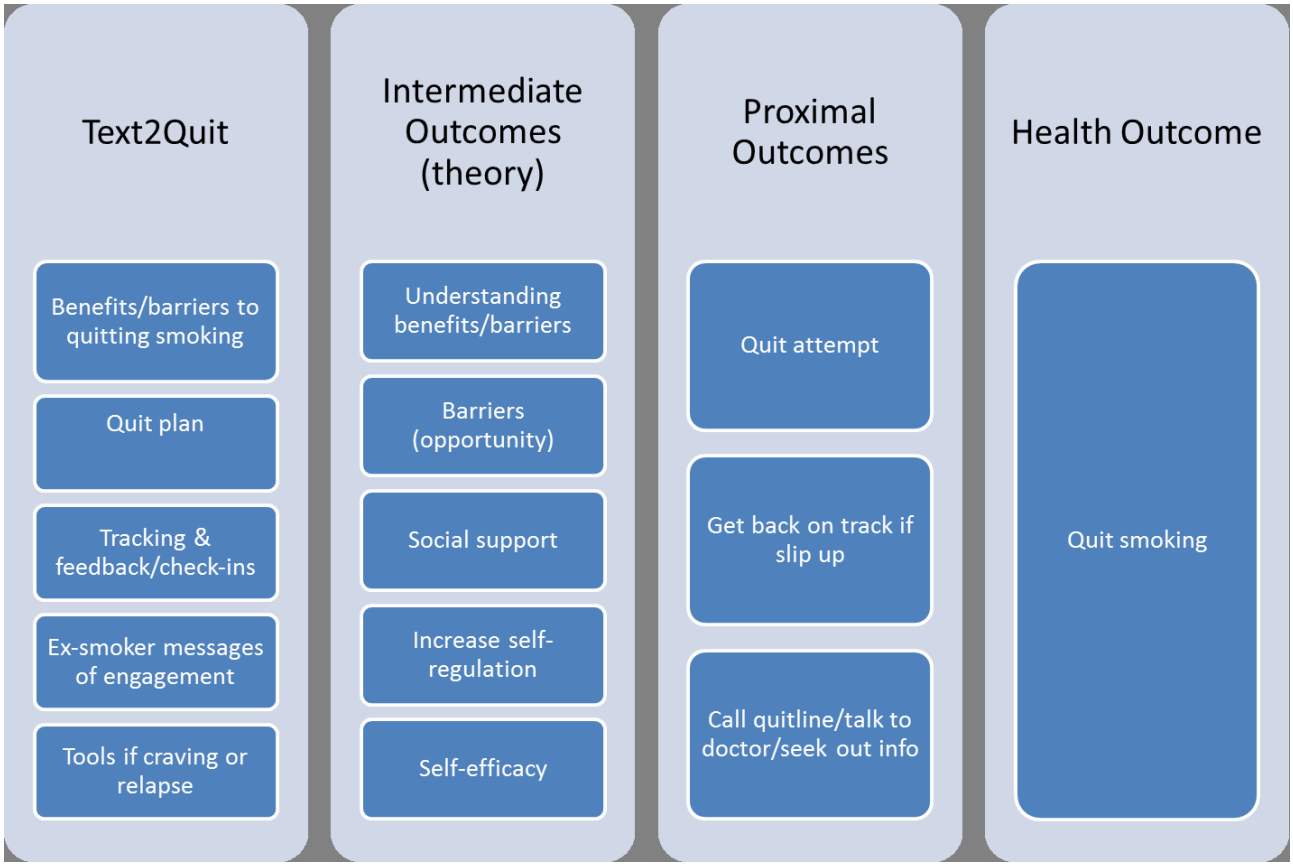
Step 2b: Choose the Communication Objectives and Behavioral Techniques

Consideration needs to be given to the communication objectives and behavioral techniques that will be used to promote change in the targeted behavior. Communication objectives generally consist of beliefs, attitudes, and knowledge that people will learn by participating in a given program [23], and behavioral techniques are the actions that people should take to make the targeted behavior change [26]. Communication objectives and behavioral techniques should be based on theory and insights from formative research or other existing research about the factors influencing behavior.

Once communication objectives and behavioral techniques are identified, consideration should be given to how they can be supported by the attributes of text messaging as a modality. Some theoretical constructs may be especially well-suited to mobile communication, such as the Health Belief Model's construct of cue to action [27] and the use of implementation intentions [28], which prompt the setting of goals around if-then statements (ie, "If I finish work, then I will head to the gym for a workout."). Likewise, some behavioral techniques, such as tracking of daily goals and receiving feedback on goals, readily lend themselves to mobile programs [26]. For example, in a study about binge drinking behaviors, Suffoletto et al [29] designed their text messages around constructs such as self-monitoring, positive feedback, perceived barriers, and behavioral intentions, drawing from the Health Belief Model, the Information Motivation Behavior Model, and the Theory of Planned Behavior.

We recommend a logic model or behavioral schematic to outline how a particular program's text message components (inputs) fit with theoretical constructs and proximal and longer-term behavioral and health outcomes. Figure 2 presents a logic model relating the program components of Text2Quit, a smoking cessation text messaging program based on social cognitive theory, to intermediate, proximal, and health outcomes (based on Abroms et al [15]). Text2Quit program components include text messages that contain information on benefits of and barriers to quitting smoking, a quit plan, and an ex-smoker story about quitting from a quitpal, or peer coach. The program also contains text message-based tools for tracking cigarettes smoked and obtaining help if craving cigarettes or smoking. These are hypothesized to affect intermediate constructs, which in turn affect quitting smoking. For example, a person's understanding of the benefits of and barriers to quitting, sense of social support, self-efficacy, and ability to self-regulate when having a craving are hypothesized to affect proximal outcomes. These may include making quit attempts or calling a quitline, and ultimately impact the person's likelihood of quitting smoking.

Figure 2. Logic model for Text2Quit, a smoking cessation SMS text messaging program based on social cognitive theory.



Step 2c: Design the Framework for the Program

The framework for the program provides an overarching plan of how messages are sent to users. The framework should include a description of the timing and frequency of messages, as well as indicate the kinds of messages that will "check-in" on users (surveys) and the keywords users will be able to use to ask for additional help in times of need. For an example of a framework and message library, see the QuitNowTxt message library [30]. In designing the framework, decisions may need to be made about the following key issues.

Frequency of Messages

The frequency of messages should address the need for the program to communicate key information without overwhelming or burdening the user. Often, text messaging programs send out at least one message/day during key behavior change periods and fewer messages (eg, 3 messages/week) in less acute phases. Depending on the health behavior being targeted, fewer or more text messages per day may be appropriate. For example, Text2Quit sends 5 messages on the quit date, daily messages in the first week after the quit date, and 3 messages per week in the weeks after that [16]. For users who are frequent texters, message frequency may need to be higher so that messages stand out from the many texts they already send and receive daily. It should be noted that some programs only send out texts when a user requests information. For example, SexInfo, a sexual health information service, is a reactive service that replies when the user initiates a question/query to the system [31].

Balance of Message Quantity and Importance

The science on message frequency and quantity has not yet identified the ideal "dose." Poorman et al [32] suggested from a systematic review of the SMS health behavior literature that participants may be better retained if message quantity is varied over time, while Head et al [3] reported that programs with decreasing message frequency were more effective than those with constant message frequencies. A common criticism of these types of programs is that the program sends out "too many messages" [15]. Another related consideration, especially among programs targeting addictive behaviors like eating or smoking, is that the messages may act as a trigger for the behavior that is to be avoided. Abroms et al [15] found that while overall the program was effective, some participants reported that the texts were a trigger for smoking.

Timing of Messages

The timing of messages may be related to both the content of the messages (eg, what the messages ask the user to do), the daily routine of the user (eg, when the user is free to consider the text message), and the nature of the behavior change (eg, what time of day is appropriate for targeting that behavior). Consideration also needs to be given to what will trigger the messages (ie, date of enrollment or behavior change, in a weekly cycle). In Papua New Guinea, a text messaging program aimed at providers treating malaria patients was found to be most acceptable in the mornings and during work hours, to help facilitate the usefulness of the reminders [33]. While 2 messages per day were found to be acceptable, providers did not like their repetitiveness over time [33]. A study of binge drinking behaviors concentrated messages in the days leading up to and

during the weekends, when binge drinking was more likely to occur [29]. Another study found that adolescent girls preferred the message timing to vary, as it was seen to be less "robotic" if the message timing was unpredictable [34].

Nature of Interaction With the Program

Interaction, or bidirectional messaging, is helpful to promote engagement in a program. Shneiderman lists "Eight Golden Rules of Interface design," of which the following may be especially relevant for SMS programs: provide consistency, offer short-cuts, offer error prevention (ie, "Did you mean this?" or "We didn't understand you.") and provide responsive feedback for user-initiated actions [35]. Opportunities for interaction in an SMS program can occur around surveys (eg, "Are you ready to quit? Reply 1 if you are ready or 2 if you are not ready"), with tracking (eg, "How many cigarettes did you smoke yesterday? Reply and see if you met your goal.") and with keywords. Keywords are words that the user can send into the system at any time for additional help (eg, a user texts the keyword "CRAVE" if having a craving and receives an immediate reply with additional help). Keywords should be limited in number, so that users can easily remember them and use them as needed. By responding to a program survey or using keywords, users can expect to receive positive feedback or an actionable reply from the program. One way to promote interaction is to "gamify" the interaction, providing the user with points that the system can track over time for key types of interaction with the system. Abroms et al used a trivia game as a means of distracting the user during smoking cravings [15]. In Bauer et al's weight management program [36], responses to check-in questions about eating and physical activity elicited an appropriate automatic response relating to encouragement, motivation, positive reinforcement, or reminders. The algorithms for an automatic text messaging program need to consider human error and include a variety of responses. For example, it might be helpful for the program to recognize common misspellings or typos, so that it will still respond appropriately rather than ignore messages. Regardless of program type, it is important to have an automated message for potential emergency texts and to have protocols in place to manage anticipated or even unanticipated events that may need to be handled by a live person. One solution is to have a real person/provider monitor messages for responses such as, "I have a headache, please help" that the program might not otherwise recognize. Another solution would be to have an automated response that says that the program does not recognize the response and to contact emergency services in the case of a medical emergency. For example, if a person replies to a computer-generated survey with a high-risk response (eg, with a high blood sugar reading or severe weight loss), the response triggers an alert to a clinician who then contacts the patient. In another example, following the release of inpatients from an eating disorders program, one study [37] had staff monitor incoming communication so that if patient responded that they were bingeing, a provider would follow-up with a personalized response rather than allow an automated reply to go through.

Source of Messages

The source of text messages is generally the program name (eg, SmokefreeTXT or CDC), so it is easily recognized by the participant as coming from the program. However, automated messages may be supplemented with messages from a real person/counselor/clinician. Even within automated program messages, the message source can vary with some messages coming from the program and others from a specific "person" who is part of the program**.** For example, in Text2Quit, some messages come from a fictitious quit pal who offers social support (eg, Erika/Text2Quit). In other programs, users are paired with an actual quit buddy to interact via text and who supports their quit attempt [38].

Degree to Which the Program Will Be Tailored

A decision has to be made as to whether the program will run as a single generic program, with all users receiving the same content, whether there will be different versions (or protocols) for different types of users, or even whether individually tailored versions of the program may be offered. In general, creating extra protocols or tailoring to individual characteristics can be more expensive and therefore should be carefully thought through ahead of time. Tailored protocols may be considered because they can result in higher readership, higher message recall, perceptions of higher personal relevance, and in some cases, greater behavior change [39]. Some evidence exists to support the use of tailored text messaging programs [3,40]. Kharbanda et al [40] found it was helpful to add a child's name to a text message about immunizations and follow-up vaccines, because it was more salient for parents. In another study, adolescent participants expressed that it would be more appealing if they were asked how they were feeling and the responses were tailored directly to them [34]. Logic can be built so that participants receive different message content based on their stage of change, readiness, and timing around key behaviors of interest (ie, quitting or birth of baby). This logic can be assigned from the outset, or can be modified based on responses to messages received by the program.

Table 1. Message examples based on approach.

Behavioral approach	Example message
1. Provide health information, advice, and tips, often tailored around user characteristics	Your baby is now 1 month old. Congrats! Remember to keep putting baby to sleep on his/her back to avoid SIDS.
2. Ask users to set goals	On what date will you quit smoking?
3. Provide opportunities for tracking progress	Track your exercise. Reply with the number of minutes you exercised yesterday.
4. Provide reinforcement for goals that are met	Congrats! You met your goal.
5. Offer reminders (eg, to take vitamins, to follow through with goals)	Your appointment is tomorrow.
6. Offer social support	Hi! My name is Mary. I've been through this and losing weight is tough. But if you stick with it, you'll make it.

Supplemental In-Person Interaction

Models of mobile programs include programs that stand alone (eg, SmokefreeTXT) [41] or programs that supplement other existing programs such as face-to-face group counseling [42], phone counseling at quitlines, or those that supplement interactive websites. In cases in which texting supplements a larger program, mobile communication can be thought of as additional touch points to reinforce messaging from counseling sessions or Internet programs. To date, most text messaging programs for behavior change that have been evaluated have been stand-alone programs [16,17], and evidence to support their use as a supplemental platform (in addition to other in-person or mobile/Web-based components) is mixed [43,44].

Privacy Concerns

Text messaging is not a secure technology and, therefore, has risks associated with it for transmitting personal health information. This is especially a sensitive issue when programs will include personal health information and originate from a Health Insurance Portability and Accountability Act (HIPAA) covered entity, within the US context [7], or meet other health care-related privacy standards internationally. One way to make risks more transparent to participants is to disclose them in clear language at the time of signing up. Privacy risks are detailed in the terms and conditions of program use and explicitly state that text messaging is not secure, and that by signing up, the subscriber agrees to the risks. One example is how the NCI describes their terms of service online for the use of SmokefreeTXT [45]. A similar disclosure will be included in the roll-out of the Veteran Administration's Annie text messaging system, which is currently being pilot tested and will perform a variety of functions including the collection of blood pressure readings [9].

Step 2d: Write the Message Library

The message library is a database of specific messages that will be sent to the user. Messages need to be written for each case supported by the program. Messages need to be 160 characters (including spaces) or less to be delivered as a single text message to a mobile phone, unless the users have smartphones. When necessary, messages may be split between 2 text messages to accommodate additional content. For an example of an existing message library, see QuitNowTxt message library [30]. Once written, a message library can be checked—by coding each message for its content—to see that it conforms to the planned communication objectives and behavioral techniques [26].

The following are some considerations when writing the message library.

Messages Can Take Many Forms

Messages can be based on many behavioral approaches including providing information or advice, asking users to track behaviors, providing feedback on goals, offering reminders, providing positive reinforcement, or providing social support (see Table 1 for examples). Chib et al [46] used texting to ask quiz questions about HIV transmission and testing. We recommend limiting each message to a single topic or actionable item.

Message Style

Assuming the source is a credible health entity, the language should fit the professional character of the organization and not be inclined to use slang, too many abbreviations (eg, "how r u doin?"), or informal punctuation (eg, "well done!!!!"). Our experience is that users find this type of language to be unprofessional coming from a credible health source. According to Ranney et al [34], even teens expressed that they did not like slang used in health messages.

Literacy Demands of Target Audience

Once the message library is drafted, check the literacy demands associated with the messages. This can be done using the Flesch-Kincaid Grade Level Test or Flesch Reading Ease test tool to determine the readability of the messages. In general, shorter words and sentences have lower literacy demands. Generally, for an adult audience, an 8th-grade reading level is considered the maximum recommended reading level [13], and in some cases, a lower reading level may be necessary. Further, with populations that may have low English literacy, but higher literacy in another language, a text messaging program can offer a translated version. For example, the program Text4Health provided parents with the option of switching the program language as follows: "To receive messages in Spanish, text ESPANOL" [40].

Mobile Phone or Social Media Integration

Given that mobile phone penetration is at 64% among adults in the United States [25], and there are up to an estimated 1.75 billion users globally [47], users are likely to be reading text

messages on mobile phones. This means that text messages can be seamlessly linked to Web content to expand their content in the form of mobile Web pages, videos, audio, games, and social media. Increasingly, text messaging programs are being built in conjunction with mobile phone apps. The large-scale texting program, text4baby, now has an app that can be downloaded to support the text platform, as well as mobile Web pages offering additional content to supplement approximately 50% of the text messages [48]. However, because this adds additional development costs, it is important to study whether the addition of apps confers benefits to the end user. Additionally, social media provides another low-cost extension for an SMS intervention. In a weight-loss intervention for college students, the enhanced group received Facebook content reinforced with SMS content [44].

Build Automated Evaluation Into the Programming

The message library can be written to include periodic check-ins about the program's success. These may take the form of surveying users about behavior change of interest (eg, "Text2Quit: Have you smoked a cigarette over the past 7 days? Reply 1 if yes or 2 if no"). These offer the opportunity to redirect program messaging for the user (eg, If reply is 1: "Sorry to hear you slipped; Here's what you can do to get back on track."), as well serve the purpose of providing valuable data on participant engagement and a program's success [15]. Reminder text messages can be effective in prompting users to reply, in order to increase response rates for key program evaluation metrics. One consideration related to response rates is that there is likely to be more missing data with the increasing frequency of check-ins. Thus, the importance of higher response rates will need to be balanced against providing multiple opportunities to check-in with users and obtain updates on their status.

Step 3. Pretesting the Text Messaging Program

Once the program is designed, we suggest building in a pretesting phase to solicit feedback on the program and the specifics of the message library. Based on feedback from this phase, revisions should be made to improve the program. Ideally, this process should be iterative and involve multiple rounds of revisions and feedback [49]. The following are ways to obtain feedback on the program.

Prior to Launch, Conduct Interviews With Target Audience Members to Test the Program and Sample Messages

In these interviews or focus groups, describe the program to potential users, show them the message library (or portions of it), and ask for feedback on specific messages (eg, see Ybarra et al [49]). Users might be asked to rate messages for tone, content, clarity, and persuasiveness. They could be asked to rewrite messages that are objectionable, unclear, or otherwise unsatisfactory. This might be done in-person, over the phone, by email, or through a message board on a website. To simulate receiving program text messages, part of the pretesting interview may include sending sample text messages to the users' phone and asking for feedback on individual messages via SMS.

Launch Program for Pilot

There are a number of easy-to-use SMS platforms that provide the opportunity to set up a program using a Web-based interface that allows for the scheduling of text messages and provision of interactive surveys, keywords, and branching logic (targeted scheduling of messages and content). Some are free or low-cost programs like TextIt and Ez Texting, and are especially well-suited for use with a small group and for a limited period; however, many others exist and can be found highlighted in available resources like the mHealth Platform Compendium [50], the Text Messaging in Healthcare Research Toolkit [13], and the Mobile Messaging Toolkit [14]. Another low-cost method for piloting is to send out program messages manually to simulate the experience of an automated program. This can be done with a program like Google Voice, so that messages can be sent from a desktop.

Pilot Test the Program

After the program is up and running, feedback from users can be obtained by running a short pilot test, such as 2-4 weeks in length and with as few as 10-30 participants, and surveying users about their experience [15,49,51,52]. Surveys may be conducted by phone, on the Internet, or by SMS. Key areas to examine in the pilot test include the following: What is the user experience of being in the program? What about the program is most and least engaging? Is there anything confusing or annoying about the program? How is the message volume and timing? Did participants unsubscribe? Did participants change behavior? These issues can be addressed with both survey questions and qualitative (long-response) feedback.

In addition to survey data, computer records of program use, if available, reveal program engagement, and in some cases, behavior change [39,53-56]. Ideally, computer records will detail every instance of user interaction with the SMS system (complete with time and date stamp) and the nature of that engagement. It is important to understand how the program you choose to utilize collects user data and what data are available to you. For example, computer records can indicate at what point users text in for additional help and/or how they are doing in the program, assuming the program contains check-ins on behavior change (eg, Did you exercise today?).

Additionally, the keyword STOP, a standard keyword across programs for unsubscribing [13], provides a marker of program disengagement. To understand disengagement, we recommend using a 1-item survey at the point of unsubscribing. When users unsubscribe with the keyword STOP, it is sometimes possible to send a 1-item survey that asks for the reason(s) for unsubscribing. This could be completed as an open-text response or using a multiple-choice approach. Such feedback can be valuable and differentiate between users who stop because they have successfully changed their behavior and, therefore, no longer need the program (eg, "already quit") and those who find the program unhelpful throughout (eg, "not helpful"). If a user complains about receiving too many messages, this may be an opportunity to offer a low-dose version of the program to keep the user engaged and subscribed.

Test Alternate Versions of the Program

If possible, consider testing 2 (or more) versions of the program to evaluate users' experiences on key decision variables (eg,

program with and without a "buddy" protocol). Another option is to change the program over time while monitoring key metrics of success (eg, unsubscribe rates, engagement rates, levels of behavior change). Once the program is launched, it is important to be aware of different dissemination processes (including public Web-based dissemination like that done for the NCI's texting programs) so as to not contaminate any randomized controlled trials in which use of the program is assigned.

Iterate

Like other health behavior interventions, these text messaging programs should be revised. Based on feedback from users collected through surveys and computer records of use, the programs should be constantly improved, and new versions deployed for use.

Discussion

Based on the authors' experiences of designing, developing, trialing, and implementing text message behavior change programs, it is important to have a good design process. Perhaps one of the most important factors is to be flexible and responsive to the input and feedback of your target audience: if they do not enjoy the program they may disengage.

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Authors' Contributions

LA drafted the manuscript and CF, RW, JMV, and JSR provided feedback. JMV assisted with editing early drafts and JSR incorporated feedback from subsequent reviews and edited the draft for final submission.

Conflicts of Interest

The George Washington University/Dr Lorien Abroms have licensed the Text2Quit and Quit4Baby programs to Voxiva Inc. Dr Lorien Abroms has stock options in Voxiva Inc.

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Abbreviations

CDC: Centers for Disease Control and Prevention
HIPAA: Health Insurance Portability and Accountability Act

mhealth: mobile health
NCI: National Cancer Institute
NHS: National Health Service
SMS: short message service
VHA: Veteran's Health Administration
WHO: World Health Organization

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Viewpoint

Mobile Phones in Research and Treatment: Ethical Guidelines and Future Directions

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Abstract

Mobile phones and other remote monitoring devices, collectively referred to as "mHealth," promise to transform the treatment of a range of conditions, including movement disorders, such as Parkinson's disease. In this viewpoint paper, we use Parkinson's disease as an example, although most considerations discussed below are valid for a wide variety of conditions. The ability to easily collect vast arrays of personal data over long periods will give clinicians and researchers unique insights into disease treatment and progression. These capabilities also pose new ethical challenges that health care professionals will need to manage if this promise is to be realized with minimal risk of harm. These challenges include privacy protection when anonymity is not always possible, minimization of third-party uses of mHealth data, informing patients of complex risks when obtaining consent, managing data in ways that maximize benefit while minimizing the potential for disclosure to third parties, careful communication of clinically relevant information gleaned via mHealth technologies, and rigorous evaluation and regulation of mHealth products before widespread use. Given the complex array of symptoms and differences in comfort and literacy with technology, it is likely that these solutions will need to be individualized. It is therefore critical that developers of mHealth apps engage with patients throughout the development process to ensure that the technology meets their needs. These challenges will be best met through early and ongoing engagement with patients and other relevant stakeholders.

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KEYWORDS

ethics; informed consent; mHealth; mobile phones; Parkinson's disease; privacy; regulation

Introduction

Mobile phones are an increasingly common form of information and communication technology that combine mobile computing capabilities with telecommunications [1]. In 2011, there were over 6 billion cell and mobile phone subscriptions reaching 87% of the world's population [2]; 1 in 3 subscriptions were for a mobile phone [3]. The ability to run third-party software apps on mobile phones has prompted their use in health settings to improve diagnosis and personalize health care [1]. This use of mobile phone technologies for this purpose has been termed "mHealth."

Mobile phone apps may support an individual's self-report of symptoms or passively record time, location, and other information using a large array of on-board instruments, such as a global positioning system (GPS), wireless local area network (WLAN; or Wi-Fi), cellular network antennae, Bluetooth, accelerometers, gyroscopes, pressure sensors,

proximity-sensing magnetometers, barometers, humidity sensors, temperature sensors, and ambient light sensors [4]. Microphones and cameras may also record images and sounds in the vicinity of the phone, including personal conversations [5]. Additional external sensors may allow recording of physiological information, such as heart rate, blood pressure, glucose levels, and even brain activity using a portable brain scanner (eg, electroencephalogram) [6]. This information can be linked to other commercially available electronic databases, including Web-based platforms (eg, Facebook, Google) or government-controlled personal medical records. Algorithms may be used to organize and decode the recorded information to provide data on disease state, response to treatment, physical activity levels, falls, and tremor. Mobile phones can then send this information to research or clinical teams, which enables timely responses that were not possible using older technologies [4].

mHealth technologies are being increasingly used to help patients manage chronic, degenerative neurological diseases, such as Parkinson's disease (PD), that produce changes in mobility, communication, mood, and independence. In the following, we use PD as an example, although most considerations discussed below are valid for a wide variety of conditions. Mobile phones and other remote sensing devices have been used with people with PD to monitor their movement at home [7-9], hand tremor [10], timing of medication and meals [7], community mobility [11], and voice patterns [12].

The ability to remotely monitor a wide range of markers of social well-being in PD is increasingly important. Medications and other treatments, such as deep brain stimulation, can improve the motor symptoms of people with PD, but these medications and treatments may not be accompanied by similar improvements in the nonmotor symptoms and quality of life outcomes [11]. Mobile phones have the potential to measure both motor and nonmotor symptoms in PD, and they can analyze large amounts of data before providing summary reports to the patient and his or her physician to guide treatment decisions [13]. The capacity of mobile phones to collect a wide range and quantity of personal information from patients raises novel and complex ethical and practical challenges that research teams and clinicians need to understand if we are to maximize the promise of the technology while minimizing any unintended harms. Analogous concerns have been examined in the context of Internet research and eHealth [14-17]. Given the additional capacity of mobile phones to collect personal information and the explosion in mHealth apps, an examination of the ethical challenges raised by the use of mobile phones in the research and treatment of persons with major neurodegenerative disorders, such as PD, is urgently needed.

Ethical Issues Raised by the Use of Mobile Phones for Research and in the Clinic

Privacy, Security, and Data Ownership

Privacy is the ability to control the recording and sharing of personal information with others. This requires knowledge of what will be recorded, how it will be used and for how long, who will have access to this information, and what the risks are of discovery and misuse by third parties.

What Can Mobile Phones Reveal About a Person?

Geolocation technologies on a mobile phone (eg, GPS, WLAN) can reveal a range of personal information. This might include where you live, where your children go to school, whether you visit a therapist and if so how often, how often you visit drinking or gambling establishments, whether you arrive early or late to work, whether you have participated in a protest or are associated with outlawed or terrorist organizations, and other habits or routines [5,18-20]. It is possible to identify a specific individual with reasonable certainty from this information. Consequently, it may be impossible to deidentify an individual's mobile phone data, the standard way of protecting personal privacy in research. This may be of particular relevance in PD where up to 1 in 6 patients will develop severe compulsive disorders (eg, pathological gambling, hypersexuality, compulsive shopping) as a result of their dopamine replacement therapy [21]. These behaviors can cause substantial harm to others and may come to the attention of relevant government authorities, which could then lead to criminal or civil suits [22]. The difficulty in anonymizing mobile phone data is particularly salient in a global research environment that increasingly requires the sharing of data in publicly available repositories.

The greatest threat to privacy is third-party use of data recorded, collected, and transmitted by a mobile phone. Data may come into the hands of a third party via hacking of information sent over the Internet or via Bluetooth (commonly referred to as "sniffing"); legal interception by government agencies (eg, subpoena); incidental discovery by someone accessing the phone; or by telecommunication companies and cloud storage providers, for example, Internet service provider (ISP), Google, Amazon, who may claim ownership of the data recorded by or transmitted through their networks [23].

Subpoena and Government Interception

Researchers and clinicians can only provide limited guarantees on privacy protection. For instance, data collected on mobile phones may be subpoenaed as part of legal proceedings in civil (eg, divorce, litigation) or criminal cases. This includes both the data collected on the phone itself or data and their analysis held by researchers or clinicians. Researchers and clinicians are obliged to hand over such private information when subpoenaed.

Mobile phones are more prominent in the public domain than in traditional office-based pen-and-paper or desktop computer research kept within the offices of researchers or clinicians. The information collected via mobile phones is more liable to be encountered by third parties who are not involved in the research or clinical care. The legal subpoena of clinical data is possible within any research setting. However, a person's participation in a research study is more likely to become known to authorities through the presence of an app on their mobile phone [20]. The simple discovery of an mHealth app on a phone may be enough to disclose personal information that users may wish to keep private, such as their having a neurodegenerative disorder or medication-induced addiction.

Hacking and Third-Party Data Ownership

The security of data collected via mobile phones cannot be guaranteed. Hacking of personal data from mHealth apps has resulted in medical identity theft and significant financial losses [23], and such data have been used in the courts [24]. mHealth apps are not required to adhere to strict privacy regulations, such as the US Health Insurance Portability and Accountability Act Privacy Rule, and therefore may be stored and transferred using methods that are less secure than those normally required of electronic medical data [23]. The data transmitted may include usernames, passwords, and other personal information that may enable forms of identity theft.

Encryption is essential for the storage and transmission of data using mobile phones; however, a recent study found that many mHealth apps do not use encryption when transferring data [23]. Even with modern encryption methods, data may be accessible to hackers and/or government authorities. The recent incidences of high-profile mobile phone hacking in the United States and United Kingdom illustrate the vulnerability of mobile phone users to privacy violations [25]. There are also potential privacy violations from computer malware and virus programs that exploit vulnerabilities in how data are stored on the device or from malevolent app developers who steal data for commercial or criminal interests [23,26]. Developers can take steps to ensure that data collected by an mHealth app are not available (eg, via data logs, SD card storage, exported, and side channels) to other apps or programs contained on the phone [23]. As He et al [23] demonstrate, most mHealth apps currently available do not take the necessary security measures to protect an individual's privacy.

It is also not clear who owns the data in research and clinical settings. Mobile phone data may be transmitted to the research team or clinician via ISP or telecommunication companies. These companies often record metadata as well as the data transferred over their networks, and may sell them to other third parties. Government agencies may also obtain access to this information, as revealed by Edward Snowden in the recent National Security Agency affair [27].

Obtaining Informed Consent

Before using mHealth technologies, clinicians and researchers need to seek and obtain the informed consent from participants. Participants need to be informed of the risks and benefits of using mHealth technologies and must have the capacity to understand these risks and make a free and uncoerced decision about whether to participate [28]. A challenge in mHealth is communicating the complex nature of the risks raised by this technology and negotiating the risks that individuals are willing to face. How much input should people have over what they wish to have recorded and shared? How will the data be used, where will it be stored and in what form, how will it be shared, and for how long? Participants must also be made aware of what will happen to their data once their study participation is complete.

Researchers and clinicians using mobile phone technologies need to develop consent processes that actively engage individuals in their own privacy decision making as much as possible. Understanding the risks posed by third-party access to their personal health data can be difficult to communicate given the complexity of mHealth technologies. Meeting these ethical challenges will require technology developers to create apps that assist participants in understanding their participation and give them as much say as possible in what is shared and with whom. This may involve trade-offs between, on the one hand, maximizing the data obtained and what may be done with it, and, on the other hand, enabling participants to control what they consent to and how their data may be used and stored.

As part of the consent process, researchers and clinicians need to inform participants about the circumstances in which they are obliged to disclose the participants' personal information. This potentially includes information that can pose an immediate and likely threat to themselves or to others (eg, suicide, homicide). Patients must also be informed of the potential for identification of "incidental findings," specifically clinically significant information related to their health, such as cognitive impairment and dementia, depression and other psychiatric disorders, or medication abuse or other compulsive behaviors that may benefit from additional treatment. Patients should be informed about the processes in place to deal with potential incidental findings and provide them with further information and access to clinical treatment should any emerge. Participants should also be given the opportunity to indicate whether they would like to be told about the presence or absence of incidental findings.

The potential for mobile phones to record conversations about third parties or bystanders raises additional ethical and legal concerns. For example, mobile phones may record conversations to examine the impact of PD on patients' speech and socialization [11,12]. Researchers may obtain consent from the research participant to have their conversations recorded but they cannot easily obtain consent from bystanders (eg, friends and family) who may also be recorded via the mobile phone. The recording and/or communicating of third-party conversations (even to a secure portal) is illegal in some jurisdictions. Researchers may therefore need to develop methods for ensuring that bystanders are able to consent to having their conversations recorded. One option would be to provide an alert on the mobile phone indicating to the participant that a recent conversation has been audio recorded so that they can ask third parties to consent to the recording. An opt-in approach could be applied where the conversation is only sent to researchers or clinicians if the third-party individuals agree. This would further burden the participant who would have to disclose their mHealth participation and, therefore, possibly their clinical condition to obtain the third party's consent. The opt-in approach also obtains consent after the fact, and therefore, may be inadequate in some jurisdictions.

Storing and Sharing Mobile Phone Data

How mobile phone data are stored and shared can have important implications for privacy risk. Developers may choose to create a secure "vault" on the device that is physically transferred to researchers or clinicians at predetermined intervals. This allows greater control of data and protection for participants, but at the cost of reduced flexibility and timeliness.

It could limit the benefits that a patient or participant may derive from the ability to self-manage their condition.

The most clinically and scientifically useful approach is to periodically upload the data electronically (eg, via 3G or wireless networks) to researchers or clinicians. This allows for instantaneous transfer of data, but provides less privacy protections as it involves transmitting data over third-party networks. Developers will need to decide where and when data are uploaded (eg, only at certain locations or times, such as from a home Wi-Fi network) as opposed to routinely uploading via public Wi-Fi or mobile networks. Developers will need to reach a balance between maximizing clinical or scientific utility while minimizing the risk to privacy. Solutions will vary depending on how the technology is being employed.

Developers will also need to consider what data to collect and transmit from the mobile phone. The ability to collect as much raw data as possible maximizes the information that a research and clinical team can extract. It also increases the potential risk to the participant. A balance needs to be struck between maximizing scientific and clinical utility and protecting privacy. It is preferable to only collect data sufficient for the purpose of the study or clinical intervention (eg, postcode or distance from home), rather than collecting all data routinely. By collecting only the minimum amount of information, app developers can help participants maintain control over their raw data [20].

Developers also need to make data comprehensible to the participant before they are sent or before consent is given to share the data. Developers should provide easily understandable visual information to participants about where their information will go, who will have access to it, and for how long. This will greatly increase participants' understanding of the risks involved with this technology and enable them to make more informed decisions. Such processes will help participants to see what their sharing policies are and what the results of these policies will be [20].

Communication of Clinical or Research Results

A critical decision in the clinical or research use of mobile phones is when and what to tell research participants or patients about their data. The communication of clinically meaningful feedback to participants about their data maximizes the benefits for participants and mitigates the harm from potential privacy violations. To be clinically meaningful, the findings must be scientifically robust. The ethical obligation to share an individual's data with them is more acute in the clinical setting where the explicit aim is to facilitate better clinical management of the disease, and there is strong evidence to support the clinical claims being made. Feedback is also provided by a qualified individual responsible for the patient's clinical management. In research, the clinical relevance of data is, by definition, less certain because the research aim is to establish an evidence base for clinical intervention. In research, providing individualized clinical feedback from the data is inappropriate, and may lead to additional harm if the clinical advice is misleading or provided by nonprofessionals.

The provision of immediate and useful information by appropriately qualified clinicians can potentially better enable individuals to manage their health and improve the clinician/patient relationship by empowering patients to take more control over their health and well-being [29,30]. However, to serve this purpose the information collected by the mobile phone needs to be presented in ways that are meaningful, accurate, and easily understood. Well-designed platforms that provide such feedback to patients will maximize the potential for individuals to self-manage their health and well-being. Participants may also be assisted to access effective clinical services for the treatment of any symptoms identified in the data collected via their mobile phone. Developers and researchers may also wish to identify opportunities in the app in which participants can receive information that will enable them to make healthier choices. Research is needed to establish what impact the provision of clinical information recorded on mobile phones may have on a person's behavior. Communication of deteriorating motor symptoms, for example, could adversely impact on well-being and health-related behaviors. See Eonta et al [31] for practical guidance on the ethical communication of clinical information to patients using mobile phones and other mHealth technologies.

Access to mHealth Technology

While there has been a rapid growth in mobile phone coverage in recent years, some segments of the population lack access. People from lower socioeconomic groups may not be able to afford a phone capable of supporting the app or connecting with mobile or Internet networks required to transmit potentially large volumes of data. There is an ethical imperative not to exclude these patients from benefiting from mHealth monitoring.

Disease-related impairments may also interfere with the effective use of these technologies. PD may impair both fine motor and speech skills, therefore creating difficulty in accessing touch screens or voice-based interaction with mobile phones. Designers of mHealth apps must consider ways of reducing the effects of these cognitive, motor, or other impairments. Having a choice on how to interact with an app is one approach (eg, voice-activated, image- or text-based interface). People with PD who experience fine motor difficulties may be assisted by reducing the sensitivity of the screen to repeated touch, appropriate spacing and sizing of buttons, use of swipe on-screen keyboard, and external devices such as a stylus. People with voice-related difficulties may be assisted by a plug-in microphone and software that can be trained to an individual's voice (eg, Dragon Dictate).

Given the complex array of symptoms and differences in comfort and literacy with technology, it is likely that these solutions will need to be individualized. It is therefore critical that developers of mHealth apps engage with patients throughout the development process to ensure that the technology meets their needs. This will assist developers, clinicians, and research teams to target the symptoms that are of greatest concern to patients. Developers should use reference groups (eg, consumer, family, industry, health care professional) to anticipate challenges in developing technology that meets these challenges [11]. As one patient reported in regard to the use of mobile phones for diabetes, "It's not just about blood glucose results and HbA1c results, it's about how people feel and, perhaps,

how their mood may affect their glucose levels" [29]. A summary of the recommendations for managing these ethical challenges is presented in Table 1.

Table 1. Ethical recommendations for the use of mobile phones in the clinic and laboratory.

Ethical issue	Recommendation
Anonymity and de-identification	In many cases, deidentification is not possible. Developers must communicate this to users when obtaining consent.
Third-party use of data	Individuals should be informed about the risk of third parties accessing data collected on mobile phones, either via hacking, legal interception (eg, subpoena), incidental discovery by someone accessing the phone, or by telecommunication companies (eg, ISP provider, Google) that may claim ownership of the data recorded by or transmitted through their networks.
Storage and transmission of data	The risk of privacy violations can be minimized by thoughtful consideration of how the data are stored locally on the phone or transmitted to the research or clinical team. Apps can be placed in secure vaults on mobile phones to minimize incidental discovery. Developers should also record and transmit the minimal amount of data necessary for the purpose of the app.
Obtaining informed consent	Participants need to be informed about the risks and benefits of using mHealth technologies and must have the capacity to understand these risks and make a free and uncoerced decision about whether to participate. Researchers and clinicians should employ visual aids that communicate the complex nature of the risks posed by mHealth. Developers should maximize opportunities for users to control what data are shared with the clinical/research team, such as through the use of pop-up messages asking whether they consent to specific information being shared.
Communication of clinically relevant results	Feedback of clinically relevant information should be provided by a qualified health care professional and when there is strong empirical evidence to support the findings. Users should be informed at the point of consent what information may be uncovered by mobile phones and whether they will be informed about these findings. Patients should also be assisted with accessing necessary clinical services as a result of the findings.
Access to mHealth technologies	Efforts should be undertaken to prevent individuals benefiting from advances in mHealth as a result of their socioeconomic status or physical or mental impairments.
Active engagement with patients	Developers should use reference groups (eg, consumer, family, industry, health care professional) throughout the development process to ensure that the technology meets participants' needs.
Regulation of mHealth products	mHealth technologies should be rigorously evaluated to demonstrate their safety and effectiveness before the widespread rolling out of mHealth apps and associated products.

Regulating and Evaluating mHealth Apps and Products

An explosion in mHealth research [32] has led to a rapid proliferation of small pilot or seed programs, many of which lack scientific evidence of efficacy on which to base clinical use. There is limited evidence on the effectiveness, or safety, of mHealth apps as a self-management tool for improving health [29]. Hence, there is an urgent need to evaluate their effectiveness via randomized controlled trials before the widespread rollout of mHealth apps and associated products (eg, brain or heart monitors) [33]. This need was recognized by the World Health Organization and other leading agencies responsible for implementing medical products in the Bellagio call to action on global eHealth evaluation that called for rigorous evaluation "to generate evidence and promote the appropriate integration and use of technologies...to improve health and reduce health inequalities" [34].

It is imperative that the use of mHealth apps by researchers, clinicians, universities, and hospitals is based on rigorous evaluations of their effectiveness and safety [29], using the CONSORT-EHEALTH checklist [35] and GRADE framework [32]. Policy makers should not be seduced by the hype and promise of mHealth technology. The prima facie simplicity and cost effectiveness of mHealth solutions may blind decision makers to the lack of robust empirical evidence that is needed to justify their routine use [29]. Premature implementation of untested mHealth interventions may result in failed projects, wasted resources, and poorer health outcomes for patients.

There is currently no regulation of mHealth devices or apps and no guarantee that they provide clinically accurate information. The Food and Drug Administration (FDA) recently released guidelines for how they intend to regulate the marketing of mHealth apps that meet the definition of medical devices (ie, those "whose functionality could pose a risk to a patient's safety if the mobile app were to not function as intended") [36], although these recommendations are currently nonbinding and do not prevent apps from being made available. The FDA has recently approved the marketing of an mHealth app to continuously monitor glucose levels [36].

However, most apps are made available to patients directly via publicly available app stores, without passing through regulatory gatekeepers to ensure their safety and effectiveness. The clinical use of these devices and apps needs to be regulated in the same way as any other medical or psychotherapeutic intervention. This is particularly important given the influence of vested commercial interests that may push for quick rollout and be more concerned with growing markets than improving global health [37]. The regulation of mHealth products would also help to minimize privacy violations through malware or other computer-based viruses. The development of a Web-based approval system for verifying the quality of mHealth apps, such as the Health on the Net Foundation Code of Conduct, or

National Health Service app stores, such as the United Kingdom Health Apps Library, may be useful for ensuring the quality of mHealth apps.

Regulators will also need to deal with the increasingly globalized nature of mHealth research. Traditional processes of institutional ethics approval and recruitment provide significant barriers to conducting mHealth research that crosses national borders and involves numerous agencies. Ethical oversight of mobile phone research will need to evolve in order to allow it to happen, and to prevent it from being done with insufficient ethical oversight by commercial entities (eg, Apple, Facebook, Google). Failure to do so may leave these companies with a vastly superior understanding of health and behavior than researchers, governments, and policy makers. Unlike publicly funded research, these findings will be protected by commercial-in-confidence and trade secrets laws.

Conclusions

Mobile phones and other remote monitoring devices have the potential to provide researchers with access to unprecedented volumes of clinically relevant data on patients' quality of life and psychosocial functioning, movement at home, in the community, and social integration. Neurologists and other treating clinicians will get real-time measures of disease progression and the impact of medication over periods not previously possible. The promise of this technology—the ability to collect, analyze, and communicate vast amounts of personal data almost immediately to research and clinical teams—also poses new and unique ethical and technical challenges that need to be managed if we are to realize the promise while minimizing potential risks of harm. While the ethical issues of privacy, consent and equity are not unique to mHealth, specific solutions are needed that address the particular ethical challenges raised my mobile phone technologies. The development of mobile phone apps that optimally address these challenges will require early and ongoing engagement with patients and other relevant stakeholders.

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Conflicts of Interest

None declared.

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Abbreviations

APCN: Asia-Pacific Centre for Neuromodulation
FDA: Food and Drug Administration
GPS: global positioning system
ISP: Internet service provider
PD: Parkinson's disease
WLAN: wireless local area network

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Original Paper

The Most Popular Smartphone Apps for Weight Loss: A Quality Assessment

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Abstract

Background: Advancements in mobile phone technology have led to the development of smartphones with the capability to run apps. The availability of a plethora of health- and fitness-related smartphone apps has the potential, both on a clinical and public health level, to facilitate healthy behavior change and weight management. However, current top-rated apps in this area have not been extensively evaluated in terms of scientific quality and behavioral theory evidence base.

Objective: The purpose of this study was to evaluate the quality of the most popular dietary weight-loss smartphone apps on the commercial market using comprehensive quality assessment criteria, and to quantify the behavior change techniques (BCTs) incorporated.

Methods: The top 200-rated Health & Fitness category apps from the free and paid sections of Google Play and iTunes App Store in Australia (n=800) were screened in August 2014. To be included in further analysis, an app had to focus on weight management, include a facility to record diet intake (self-monitoring), and be in English. One researcher downloaded and used the eligible apps thoroughly for 5 days and assessed the apps against quality assessment criteria which included the following domains: accountability, scientific coverage and content accuracy of information relevant to weight management, technology-enhanced features, usability, and incorporation of BCTs. For inter-rater reliability purposes, a second assessor provided ratings on 30% of the apps. The accuracy of app energy intake calculations was further investigated by comparison with results from a 3-day weighed food record (WFR).

Results: Across the eligible apps reviewed (n=28), only 1 app (4%) received full marks for accountability. Overall, apps included an average of 5.1 (SD 2.3) out of 14 technology-enhanced features, and received a mean score of 13.5 (SD 3.7) out of 20 for usability. The majority of apps provided estimated energy requirements (24/28, 86%) and used a food database to calculate energy intake (21/28, 75%). When compared against the WFR, the mean absolute energy difference of apps which featured energy intake calculations (23/28, 82%) was 127 kJ (95% CI -45 to 299). An average of 6.3 (SD 3.7) of 26 BCTs were included.

Conclusions: Overall, the most popular commercial apps for weight management are suboptimal in quality, given the inadequate scientific coverage and accuracy of weight-related information, and the relative absence of BCTs across the apps reviewed. With the limited regulatory oversight around the quality of these types of apps, this evaluation provides clinicians and consumers an informed view of the highest-quality apps in the current popular app pool appropriate for recommendation and uptake. Further research is necessary to assess the effectiveness of apps for weight management.

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KEYWORDS

behavior change techniques; evaluation; obesity; quality; smartphone apps; weight management

Introduction

Obesity is an accelerating global health challenge. The Global Burden of Disease Study 2013 reports 37% of adults (2.1 billion) globally are overweight or obese, with a prevalence of more than 60% in Australia, the United Kingdom, and the United States [1]. Given the magnitude of the epidemic, treatment strategies and interventions with long-term effectiveness and a wide reach are required to address this major public health concern.

Among researchers, there is growing interest into the use of smartphones to deliver behavioral interventions for health because of their cost advantages, ubiquity, and portability [2,3]. Estimates of adult smartphone ownership are 64%, 54%, and 51% in Australia [4], the United Kingdom, and the United States, respectively [5]. A total of 68% of Australian [6], 86% of British [7], and 35% of American smartphone users [8] report downloading a smartphone app. Simultaneously, a plethora of health- and fitness-related apps are now available to individuals through the commercial market (eg, the Google Play store and iTunes App Store) [3,6] and their popularity is ever increasing [9].

Smartphone apps hold promise in supporting health behavior change and weight management [2,3,10-13]. To ensure that these apps are able to influence sustained positive health outcomes, quality assessment is necessary. A range of frameworks have been used to evaluate the quality of apps in a variety of medical and health promotion areas, such as cancer [14-16], diabetes [17,18], smoking [19-21], mental health [22-24], headaches [25], cardiology [26], alcohol [27,28], HIV [29], and pain management [30,31]. These evaluation frameworks include the analysis of content source and expertise, information quality, app technology and design, user engagement and ease of use, and behavioral theories.

Yet, despite the high prevalence of overweight and obesity, there are few evaluations of the quality of weight-management apps, such that even within a review and analysis of mobile health apps for the most prevalent conditions by the World Health Organization, there was no mention of evaluating apps addressing overweight and obesity [32]. To our knowledge, only two studies have evaluated the quality of weight-loss apps. One of the first studies to conduct a systematic analysis of smartphone and iPad weight-loss apps revealed that only eight of 54 apps were of good quality and less than a third had complete scientific accuracy of measurements and nutrition content linked to recommendations from evidence-based guidelines (eg, body mass index [BMI] and estimated energy requirements) [33]. Suboptimal information quality has also been found in Korean obesity-management smartphone apps [34].

When specifically considering the potential for commercial weight-loss apps to enable behavior change, the literature is similarly limited; however, there appears to be a shortage of evidence-based content [35,36] and behavioral theory-based strategies [13,37] being applied. Abraham and Michie's [38] theory-linked taxonomy of behavior change techniques (BCTs) offers a method of assessing effective behavioral interventions by providing a systematic framework for categorizing the elements necessary for facilitating behavior change. This 26-item taxonomy has been used in a recent review, revealing that an average of 8.1 out of 26 BCTs were incorporated across 40 physical activity and dietary apps [39]. However, given that the majority were physical activity apps (n=30) and only six dietary apps were reviewed, a comprehensive analysis of the quality and evidence base of commercial dietary weight-loss apps, specifically, is warranted.

In addition to the scarcity of comparative studies assessing the quality and effectiveness of dietary weight-loss apps, the urgent and ongoing need for further evaluation of weight-loss apps is reinforced by the limited oversight and standardization around the quality of health and fitness apps by regulatory bodies, such as the US Food and Drug Administration (FDA) [40] and Australia's Therapeutic Goods Administration [41]. Therefore, the aims of this study were to extend the body of research assessing the quality of such apps by, firstly, examining the accountability, scientific coverage, accuracy, technology-enhanced features, and usability of popular dietary weight-loss smartphone apps and, secondly, by quantifying BCT incorporation in these apps.

Methods

Sample Attainment

Dietary and weight-loss smartphone apps were located in the *Health & Fitness* category of the Google Play store and iTunes App Store in Australia on August 15, 2014. Using a method from previous studies which determined popularity [35-37], the first 200 ranked apps in the *Top Selling* and *Top Apps* or *Top Paid Apps* and *Top Free Apps* sections of the respective stores above were selected.

Each app underwent initial screening based on the descriptions and associated screenshot images provided by the stores. Inclusion in this evaluation required that the app meet the following criteria: (1) was intended for weight management, (2) addressed dietary behaviors, (3) involved the tracking of energy intake, nutrients, or foods, as self-monitoring has been found to have a consistent association with weight loss, both in intervention programs [42] as well as in smartphone-based strategies [2], (4) had stand-alone functionality (ie, not requiring subscription to another program to operate) [37], and (5) was in English. Apps which were miscategorized under the *Health & Fitness* category or that addressed other health behaviors were excluded. Specific diet subcategory (eg, paleo diet) apps were also excluded because of limited generalizability [37].

Apps which fulfilled the inclusion criteria were downloaded onto a Samsung S2 smartphone running Jelly Bean 4.1.2 software (for Google Play store Android apps) and onto an iPhone 5 running iOS 7.0.1 (for Apple apps). After one day of use of the app, another screening against the inclusion criteria was undertaken, and those failing to meet the criteria were excluded. Duplicate apps which were available on both the Android and iPhone platforms were selected for use only on the Android operating system.

Evaluation Criteria

As no widely accepted standards of quality evaluation for apps existed, a pro forma evaluation based on a modified version of the instrument developed by Gan and Allman-Farinelli [33] was collaboratively developed between the University of Sydney, Australia, and the University of Leeds, the United Kingdom. The tool contained the following basic descriptive information: name of app, developer, version, number of downloads, average ratings (ie, average number of stars that the app was rated), total number of ratings, number of users who voluntarily rated it, and price. The tool also included the following quality assessment features: accountability, scientific coverage and content accuracy, technology-enhanced features, usability, and incorporation of BCTs (see Table 1). Accountability measures, based on Silberg's standards [43], evaluated an app's authorship (ie, the author's credentials and affiliations), attribution (ie, provision of information sources and references), disclosure (ie, sponsorship disclosure), and currency (ie, how up-to-date the content was kept).

Scientific coverage and content accuracy examined the range and accuracy of information related to weight management and general dietary advice provided by the apps. The practice guidelines for the treatment and management of overweight and obesity in adults released by the Dietitians Association of Australia (DAA) [44] and the National Health and Medical Research Council (NHMRC) [45] were consulted to determine the elements that would be relevant to a weight-management app based on a self-management approach. The features of healthy eating were derived from the NHMRC Australian Dietary Guidelines [46] and Nutrient Reference Values (NRVs) [46].

An additional element was included to further determine the accuracy of these dietary weight-loss apps in assessing energy intake. A weighed food record (WFR), which is considered to be the gold standard of dietary assessment [47], was kept by the first author (JC) for 3 days. The same 3-days' worth of food intake was entered into all the apps, but using household measures or the default serving sizes provided by the app so as to mimic the food tracking process which would be conducted by a normal user. To determine the accuracy of the energy intake values provided by the apps, they were compared with the WFR results that were analyzed using the nutrient analysis software package FoodWorks, version 7 (Xyris Software) [48] with the Australian Food and Nutrient Database (AUSNUT) 2007 [49].

Apps were also appraised for their inclusion of a range of 14 technology-enhanced features compiled from common features observed in previous app evaluations, as these have been reported to reduce burden or enhance engagement in behavioral strategies [35,36]. The usability of apps was measured by the validated 10-item System Usability Scale (SUS), where items are ranked using a 5-point Likert scale, giving an overall usability score of 0-100 [50,51], and matched with a 7-point adjective rating scale: *worst imaginable*, *awful*, *poor*, *ok*, *good*, *excellent*, or *best imaginable* [52].

Abraham and Michie's [38] 26-item taxonomy presented in the following three-phase categorization format was used: (1) motivational enhancing, (2) planning and preparation, and (3) goal striving and persistence [53]. This categorization format was used as a framework to quantify the incorporation of 26 BCTs into the apps, as this taxonomy provides a systematic method of identifying effective behavior change elements.

A total composite score out of 100 for their fulfilment of the different features of the quality assessment evaluation criteria was given to each app. The scoring system awarded the highest weight to scientific coverage and accuracy (32 points) and BCTs (26 points), followed by usability (SUS score out of 100 was scaled down proportionally to 20 points), technology-enhanced features (14 points), and accountability (8 points).

Table 1. Quality assessment evaluation criteria and scoring system.

Evaluation criteria	Maximum score[a]
26 behavior change techniques (out of 26)	
For each of the 26 behavior change techniques[b]	1
Accountability (out of 8)	
Authors credited	1
Author's affiliation	1
Author's credentials	2
Information sources/references given	2
Sponsorship disclosed	1
App modified in the last month	1
Scientific coverage and accuracy (out of 32)	
Anthropometric assessment	
Body mass index (BMI)	
Formula: BMI calculated and its use defined	2
Interpretation of BMI: cutoff point for risk and treatment indicated when cutoff point exceeded; indicates healthy weight range	4
Safety net on maximal weight loss which can be achieved	2
Energy requirement calculator (calculates basal metabolic rate, energy requirement, or deficit based on individual's age, gender, physical activity level, and weight-loss goal)	4
Calorie counter	
Contains food database that helps calculate energy intake	4
Energy intake calculations of apps coincide with 3-day WFR[c]	10
Features of healthy eating	
Calculates intake of macronutrients	2
Recommends servings for five main food groups as per the AGHE[d]	2
Recommends intake or limits other nutrients (ie, saturated fat, fiber, salt, and sugar) as per the AGHE and NRVs[e]	2
Technology-enhanced features (out of 14)	
Weight/energy intake progress graphs or charts	1
Recipes	1
Pictures of food	1
Barcode scanner	1
Online social support/networking components (eg, Twitter and Facebook)	1
Internet website links	1
Food databases that can be modified (ie, add new foods and remember favorite foods)	1
Educational material	1
Reminders to log meals	1
Calendar	1
Flags for lapses in dietary goal adherence	1
Physical activity tracking device (eg, accelerometer)/connection to activity apps	1
Tracking of negative thoughts/stress	1
Ability to export data/details about meals/daily summaries	1
Usability (weighted score out of 20)	

Evaluation criteria	Maximum score[a]
SUS items[f]	N/A[g]

[a]A total composite score out of a maximum of 100 is calculated from the summation of 5 individual quality criteria subscores.

[b]As per Dusseldorp et al's [53] three-phase categorization of behavior change techniques list.

[c]WFR: weighed food record.

[d]AGHE: Australian Guide to Healthy Eating.

[e]NRV: Nutrient Reference Value.

[f]SUS: System Usability Scale, as per Brooke's [51] System Usability Scale list.

[g]N/A: not applicable. Each SUS item is rated on a 5-point Likert scale from 1 (strongly disagree) to 5 (strongly agree). Note that scores for individual SUS items are not meaningful on their own. The SUS score is calculated using a formula, with a maximum of 100, but in this evaluation tool the SUS score has been weighted.

Evaluation Procedure

The evaluation process was discussed among all the other authors to develop a systematic approach for conducting the assessment. All authors were present in the discussion of the assessment criteria, and for consultation on the scoring of individual apps. One expert assessor conducted all the app quality evaluations, with the second assessor reviewing 30% of the apps for inter-rater reliability purposes. Where discrepancies arose in assessors' results, they were resolved by discussion and, when necessary, in consultation with a third assessor. Apps were used by the first author (JC) for a total of 5 days and scored against the quality assessment criteria. On the first day, the assessor familiarized herself with the menu and interface and thoroughly explored the different functions and key features of the app. Food logging was also completed by the primary assessor after each midmeal and main meal on the first, second, and third days. In order to maintain consistency across the 5 days, additional engagement with the app was based upon push notification prompts and reminders from the app in order to replicate the frequency of app engagement which is likely to be carried out by individuals in a naturalistic setting.

Data Analysis

The different components of the pro forma evaluation were analyzed using descriptive statistics. The frequency, mean, standard deviation, and relative rankings of apps were determined based on each assessment criteria and by overall score. Two-way mixed intraclass correlation coefficients (ICCs) were determined for inter-rater reliability. Absolute and percentage differences of the mean energy intake values of the 3 days were calculated for each app against the WFR. The overall mean of differences and 95% CIs of the apps from the WFR were calculated. Linear regression analysis was used to determine the relationship between the rankings of the apps as per the app stores (ie, popularity) versus the quality assessment criteria. $P<.05$ was considered significant. Statistical analyses were conducted using IBM SPSS Statistics for Windows, version 22.0 (IBM Corp) [54].

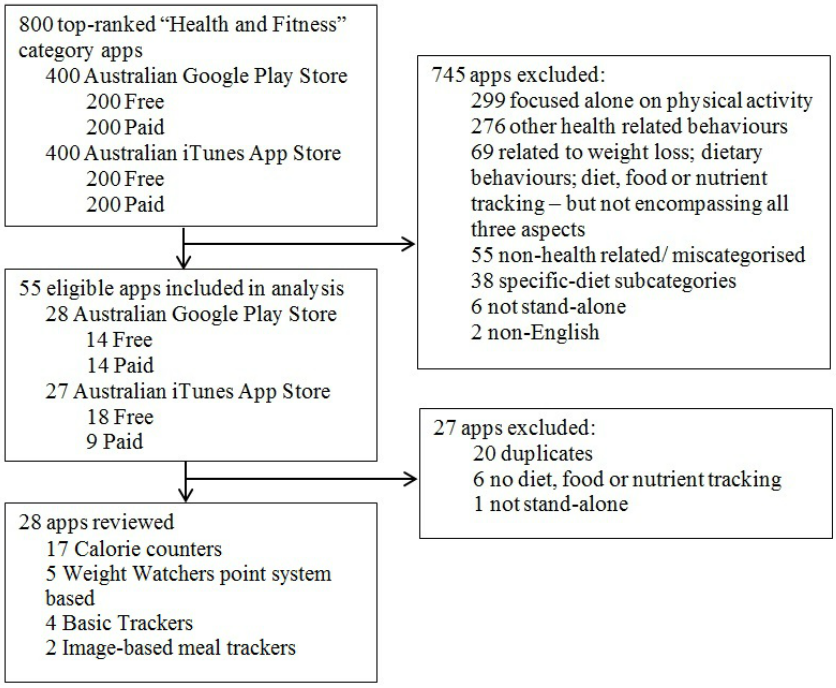
Results

Sample Characteristics

From the sample of 800 top *Health & Fitness* category apps, 55 apps met the inclusion criteria following the initial screening and were downloaded to be included in the analysis. After the first day of use, 27 apps were excluded from further detailed evaluation because of duplication, lack of tracking functions, or not being stand-alone in functionality. A total of 28 apps were reviewed in detail, with 9 apps (32%) evaluated by both assessors. An excellent level of inter-rater reliability was observed (two-way mixed ICC .94, 95% CI .75-.99). These 28 apps were characterized into the following four categories: calorie counters (17/28, 61%), Weight Watchers point system-based apps (5/28, 18%), basic trackers which logged food or nutrients but contained no energy calculations (4/28, 14%), and image-based meal trackers which used a process of taking photos of meals in order to track intake rather than a focus on calorie counting (2/28, 7%) (see Figure 1).

A total of 23 apps out of 28 (82%) provided outputs which could be compared to the WFR and were included in the accuracy analysis of energy intake. The following 5 apps out of 28 (18%) were excluded from analysis as they did not calculate energy intake: Michelle Bridges 12 Week Body Transformation (12WBT); Food Journal by Katie Wright; FoodTrackerPro by Aspyre Solutions; Argus—Pedometer, Run, Cycle; and TwoGrand.

Figure 1. Flow diagram of the sampling procedure with the number of dietary weight-loss smartphone apps included or excluded.



Quality of Apps

The scores for each of the evaluation components and the ranking of the apps based on their total quality score are summarized in Table 2. Noom Weight Loss Coach received the top ranking based on its overall score of 75. This was followed by Calorie Counter PRO by MyNetDiary and ControlMyWeight by CalorieKing (score of 65). The app receiving the lowest overall score was Food Journal by Katie Wright (score of 17). The mean overall score for the apps was 47.3 (SD 13.9).

Regression analyses determined that lower-numbered rankings in the app store (ie, greater popularity) were significantly associated with total quality assessment score (R^2= .375; *P*=.001), scientific coverage and accuracy (R^2=.377; *P*=.001), technology-enhanced features (R^2=.192; *P*=.02), and incorporation of BCTs (R^2=.166; *P*=.03), while showing no significant association with accountability and usability (see Figure 2).

Accountability

Only 1 app out of 28 (4%), Calorie Counter by SparkPeople, fulfilled all the accountability criteria. The mean score for accountability was 3.5 out of 8 (SD 2.3; see Table 2). Over half the apps were modified within the last month (17/28, 61%) and credited the authors (16/28, 57%). Around 40% of the apps disclosed sponsorship (12/28, 43%), information sources and references for the food database used by the apps (12/28, 43%), and authors' affiliations (11/28, 39%). Under a third of the apps (9/28, 32%) reported authors or app development team members with scientific or health professional credentials.

Scientific Coverage and Accuracy

The mean score for scientific coverage and accuracy was 18.8 out of 32 (SD 8.0), with ControlMyWeight by CalorieKing and Noom Weight Loss Coach both receiving the highest scores (28 out of 32) (see Table 2). The majority of apps provided estimated energy requirements (24/28, 86%) and contained a food database that helped to calculate energy intake (21/28, 75%) (see Figure 3). Less than a third of apps incorporated each of the anthropometric assessment features—calculation of BMI and defining its use (9/28, 32%), interpretation of BMI and healthy weight range (8/28, 29%), and safety net on maximal weight loss (8/28, 29%). The different features of healthy eating were incorporated to different extents, with 16 apps out of 28 (57%) calculating intake of macronutrients. However, only 11 apps out of 28 (39%) recommended guidelines for achieving healthy dietary patterns, such as limiting saturated fat, salt, and sugar, and maximizing fiber intake. Only 6 of the 28 apps (21%) recommended servings for the five main food groups. TwoGrand and Food Journal by Katie Wright did not include any of the elements for scientific coverage and accuracy.

Table 2. Relative ranking of popular dietary weight-loss smartphone apps. Ranking was determined according to their total score which was calculated from the sum of the scores for each component of the quality assessment criteria.

Rank	App	Score					
		Acc.[a]	SCA[b]	TEF[c]	Us.[d]	BCT[e]	TS[f]
1[g]	Noom Weight Loss Coach by Noom, Inc (2010, USA)	5	28	9	19	14	75
2	Calorie Counter PRO by MyNetDiary, Inc (2010, USA)	3	27	6	17	12	65
2[g]	ControlMyWeight by CalorieKing Wellness Solutions (2012, Australia)	6	28	3	20	8	65
4	Food Diary and Calorie Tracker by MyNetDiary, Inc (2010, USA)	3	27	6	16.5	11	63.5
5[g]	Easy Diet Diary by Xyris Software (2011, Australia)	7	27	5	20	4	63
6	Calorie Counter by SparkPeople (2012, USA)	8	20	8	15	10	61
7[g]	Jillian Michaels Slim-Down: Weight Loss, Diet & Exercise Solution (2010, USA)	6	22	7	13	9	57
8	MyPlate Calorie Tracker LITE by Demand Media, Inc (2013, USA)	6	21	7	17	5	56
9[g]	Calorie Counter by MyFitnessPal, Inc (2009, USA)	2	22	8	12.5	10	54.5
9	Calorie Counter & Diet Tracker by Calorie Count (2010, USA)	3	25	7	13.5	6	54.5
9[g]	My Diet Coach Pro by InspiredApps (A.L) Ltd (2012, USA)	3	18	6	12.5	15	54.5
12	Nutritionist—Dieting made easy by Outlier (2011, USA)	5	22	6	14	7	54
13	My Diet Diary Calorie Counter by MedHelp, Inc (2011, USA)	4	22	5	11.5	8	50.5
14[g]	Calorie Counter by FatSecret (2010, USA)	2	22	9	14.5	2	49.5
15	Cronometer by BigCrunch Consulting, Ltd (2011, USA)	4	22	4	14.5	3	47.5
16	Value Diary Plus by Fenlander Software Solutions, Ltd (2011, UK)	0	23	8	12	4	47
17	Diet Watchers Diary by Croc Software (2012, Israel)	0	20	3	15.5	4	42.5
18	Body Tracker—body fat tracker by Linear Software, LLC (2012, N/A[h])	3	19	4	10.5	4	40.5
19[g]	Map My (walk, run, ride, fitness) apps by MapMyFitness, Inc (2008, USA)	6	20	4	4.5	5	39.5
19	Map My + (walk, run, ride, fitness) apps by MapMyFitness, Inc (2008, USA)	6	20	4	4.5	5	39.5
21	Pts Plus Weight Diary by Frippware (2012, N/A)	0	20	4	11	4	39
22	Point Tracker Weight Watchers by PointTracker (N/A, UK)	0	18	3	13	3	37
23	Points Calculator & Weekly Weight Loss by Christian Robert Gossain (2011, N/A)	1	20	2	11	2	36
24	Argus—Pedometer, Run, Cycle by Azumio (2013, USA)	4	6	6	10.5	8	34.5
25	TwoGrand by TwoGrand, Inc (2013, USA)	2	0	5	15.5	7	29.5
26[g]	Michelle Bridges 12WBT[i](2012, Australia)	6	6	1	11.5	3	27.5
27	FoodTrackerPro by Aspyre Solutions (2010, Australia)	2	4	4	13	3	26
28	Food Journal by Katie Wright (2012, USA)	1	0	0	15	1	17
Mean (SD)		3.5 (2.3)	18.8 (8.0)	5.1 (2.3)	13.5 (3.7)	6.3 (3.7)	47.3 (13.9)

[a]Acc.: accountability (out of 8).

[b]SCA: scientific coverage and accuracy (out of 32).

[c]TEF: technology-enhanced features (out of 14).

[d]Us.: usability (out of 20).

[e]BCT: behavior change technique (out of 26).

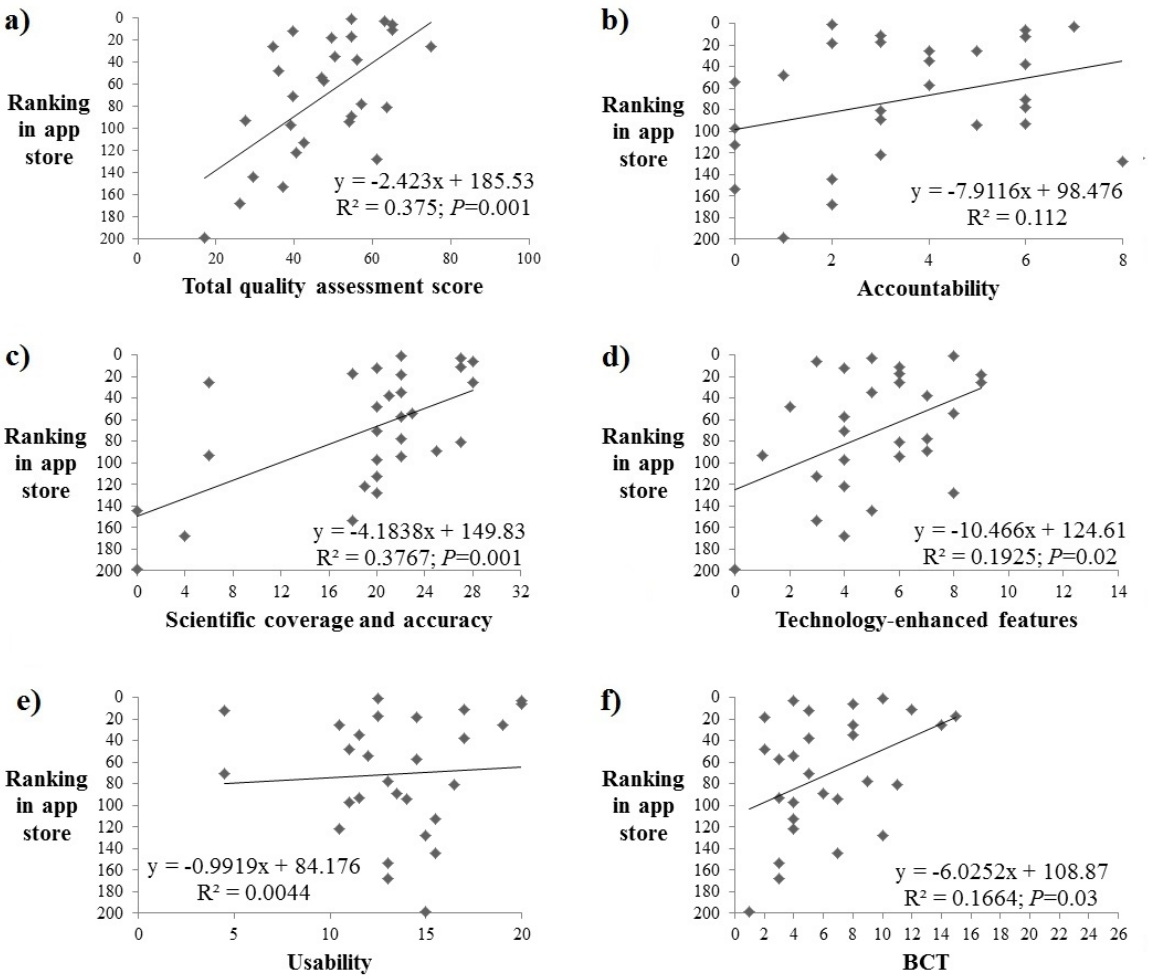
[f]TS: total score (out of 100).

[g]Evaluated by two assessors for inter-rater reliability purposes.

[h]N/A: not applicable (as country or year was unavailable).

[i]12WBT: 12 Week Body Transformation.

Figure 2. Regression analyses of the association between the rankings in the commercial app store (ie, popularity) versus quality assessment measures: (a) overall quality assessment score, (b) accountability, (c) scientific coverage and accuracy, (d) technology-enhanced features, (e) usability, and (f) behavior change technique (BCT). Note: ranking is numerical, with the rank of most popular apps starting from 1 and the least popular app ranked at 200.



Across the 23 apps which featured energy intake calculations, mean absolute energy difference when compared against the WFR was 127 kJ (95% CI -45 to 299) and mean percentage energy difference was 1.9% (95% CI -0.5 to 4.4; see Figure 4). Calorie Counter by FatSecret and Points Calculator & Weekly Weight Loss had the greatest discrepancy in reported energy intake values, with 1001 kJ (14%) greater and 700 kJ (10%) lower energy differences, respectively. In contrast, Map My (walk, run, ride, fitness) and Map My + (walk, run, ride, fitness) reported the smallest energy difference—13 kJ (0.2%) lower—when compared with the WFR.

Figure 3. Screenshot of sample smartphone app which provides estimates of energy requirements and searchable food databases (from Noom Weight Loss Coach by Noom, Inc).

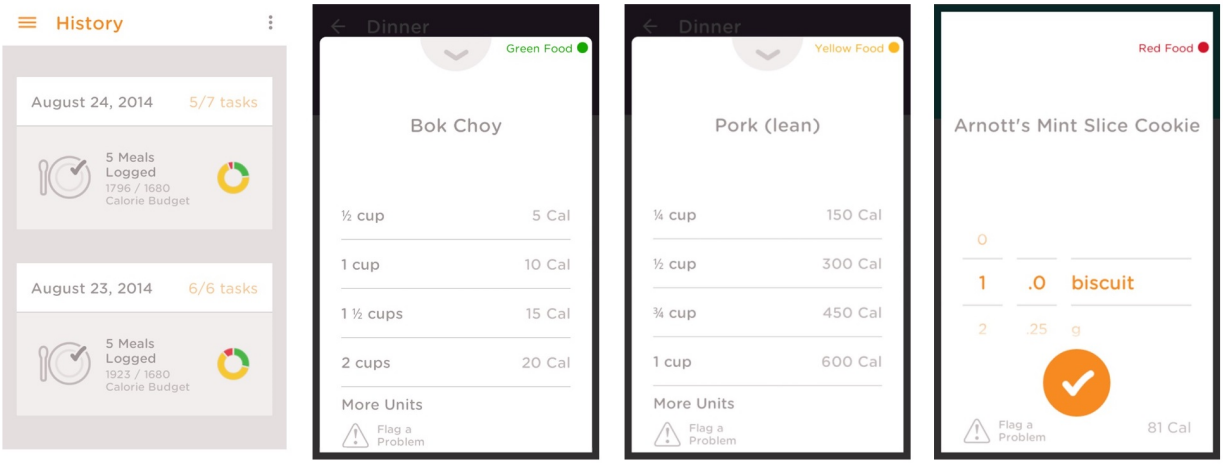
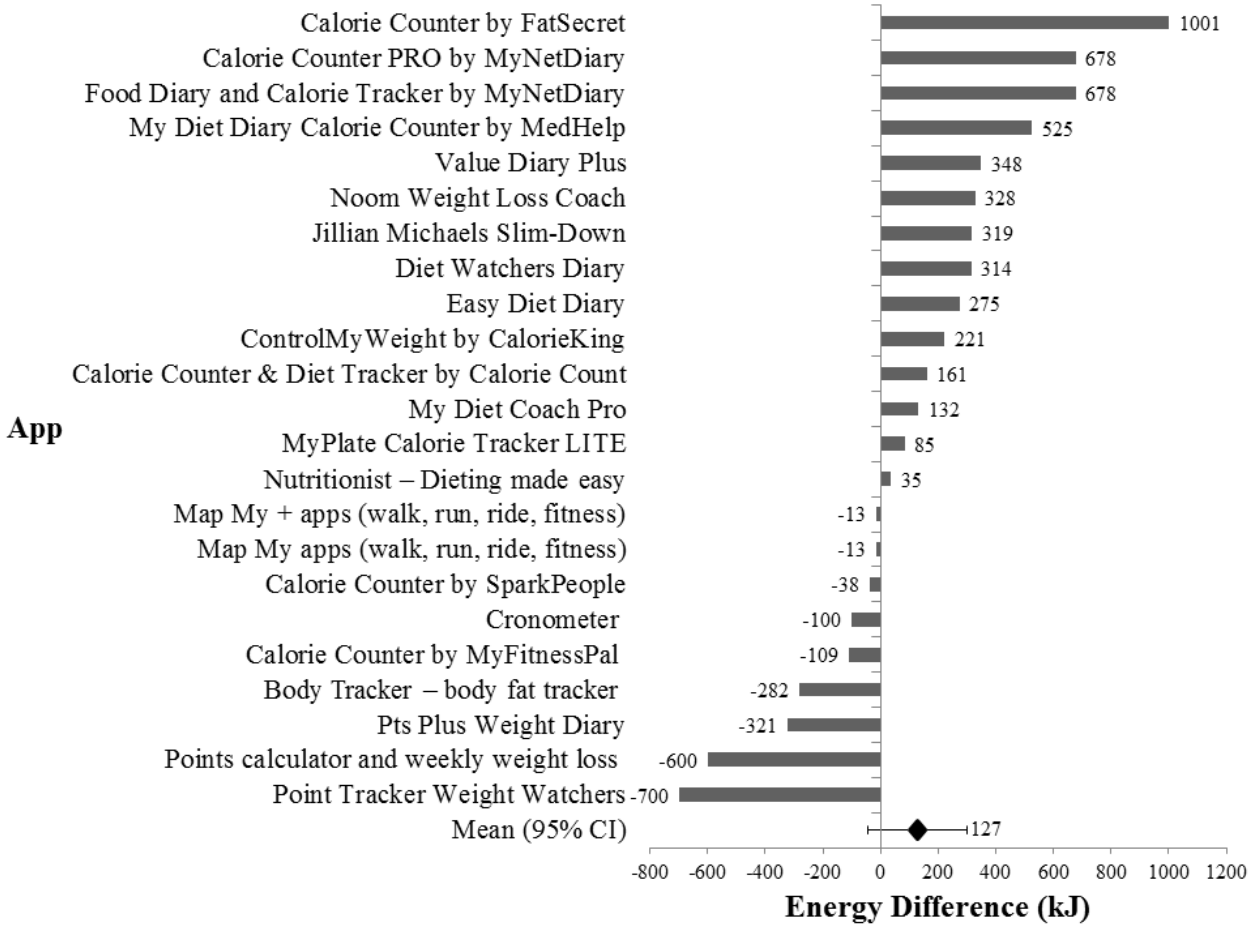


Figure 4. Accuracy of dietary apps compared to the weighed food record (WFR). Differences in mean energy intake values (kJ) over 3 days for dietary apps (n=23) were compared against the 3-day WFRs analyzed on FoodWorks. The overall mean difference of all the apps from the WFRs is denoted by the black diamond, and the 95% CI is indicated by the error bars.



Technology-Enhanced Features

Out of the 14 technology-enhanced features considered, a mean of 5.1 features (SD 2.3) were identified across the apps. The apps with the greatest inclusion of technology-enhanced features were Calorie Counter by FatSecret and Noom Weight Loss Coach (score of 9 out of 14), while Food Journal by Katie Wright contained none of the features (see Table 2).

Weight or energy intake progress charts and modifiable food database were the most common technology-enhanced features present across the apps (22/28, 79%), followed by barcode scanners and online social support or networking, which were

both included by 12 of the 28 apps (43%) (see Figure 5). A quarter of the apps (7/28, 25%) had the ability to export data, either for direct access by the individual or for a dietitian to access (eg, Easy Diet Diary), and included a built-in physical activity tracking device (eg, pedometer, accelerometer, or connection to other activity monitoring apps). Flags for lapses in dietary goal adherence was the least observed technology-enhanced feature, only appearing in 2 of the 28 apps (7%). Figure 6 illustrates examples of some of these features found in commercial apps.

Usability

The mean SUS score was 67.5 (SD 18.5) out of 100 (range 0-100), equating to an adjective rating of *ok*. The majority of apps (25/28, 89%) had a usability rating from *ok* to *best imaginable*. The 2 apps out of 28 (7%) with the greatest usability scores were ControlMyWeight by CalorieKing and Easy Diet Diary by Xyris (see Table 2). These apps had a greater adaptability within the food database, allowing favorite, recent foods to be memorized, and had a range of household and metric measures, which increased the ease of self-monitoring food and energy intake. They also included additional features which fostered an increased engagement with the app.

Incorporation of Behavior Change Techniques

An average of 6.3 (SD 3.7) of the 26 BCTs were included across the apps. The majority of the apps (26/28, 93%) integrated less than half of the BCTs. My Diet Coach Pro had the highest incorporation of BCTs (15 BCTs) followed by Noom Weight Loss Coach (14 BCTs), while Food Journal by Katie Wright had the lowest BCT inclusion (1 BCT) (see Table 2).

Figure 5. Incorporation of technology-enhanced features across apps. Number of total apps (n=28) incorporating each technology-enhanced feature.

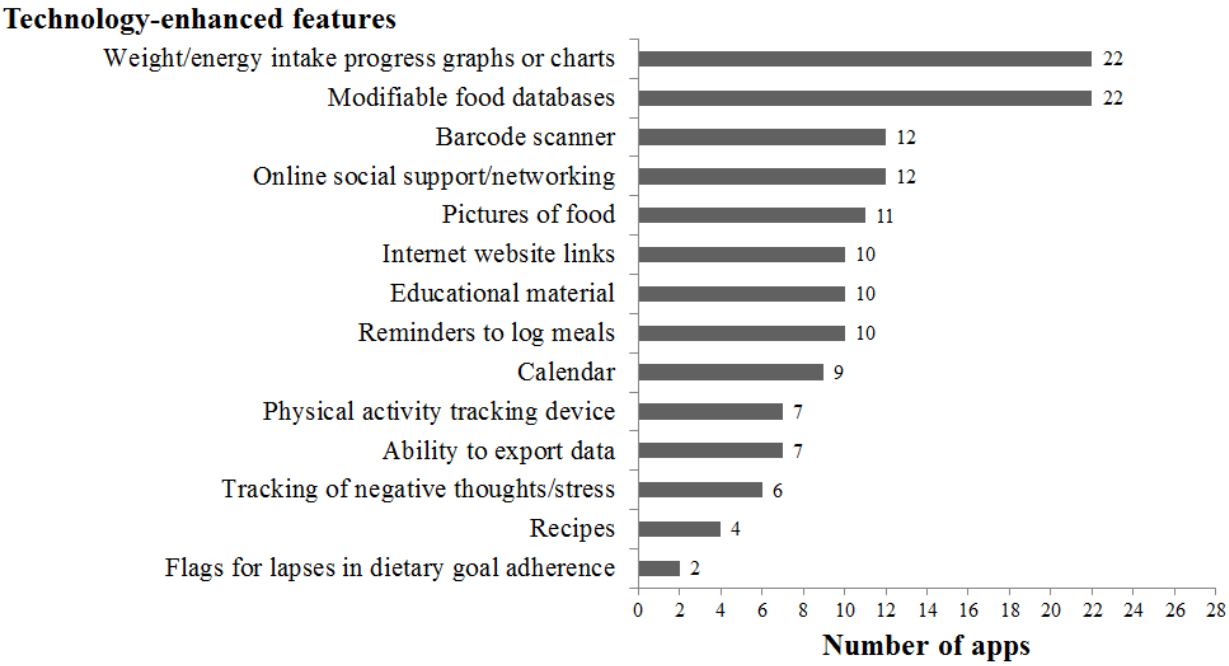


Figure 6. Screenshots of technology-enhanced features present in smartphone apps: (a) modifiable food database (from Calorie Counter by FatSecret), (b) weight progress charts (from Noom Weight Loss Coach by Noom, Inc), (c) built-in physical activity tracking device (eg, pedometer, accelerometer, or connection to other activity monitoring apps) (from Noom Weight Loss Coach by Noom, Inc), and (d) flags for lapses in dietary goal adherence (from MyFitnessPal by MyFitnessPal, Inc).

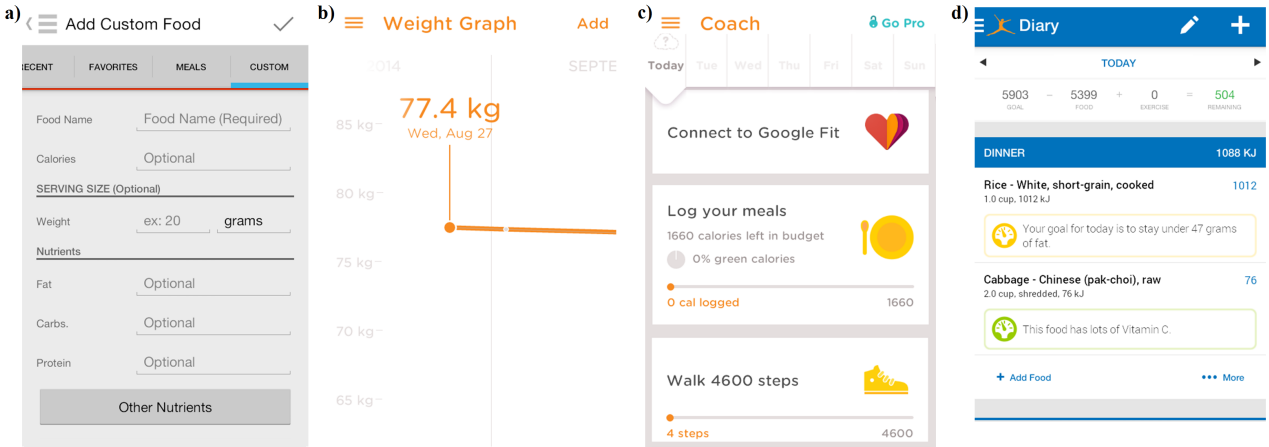
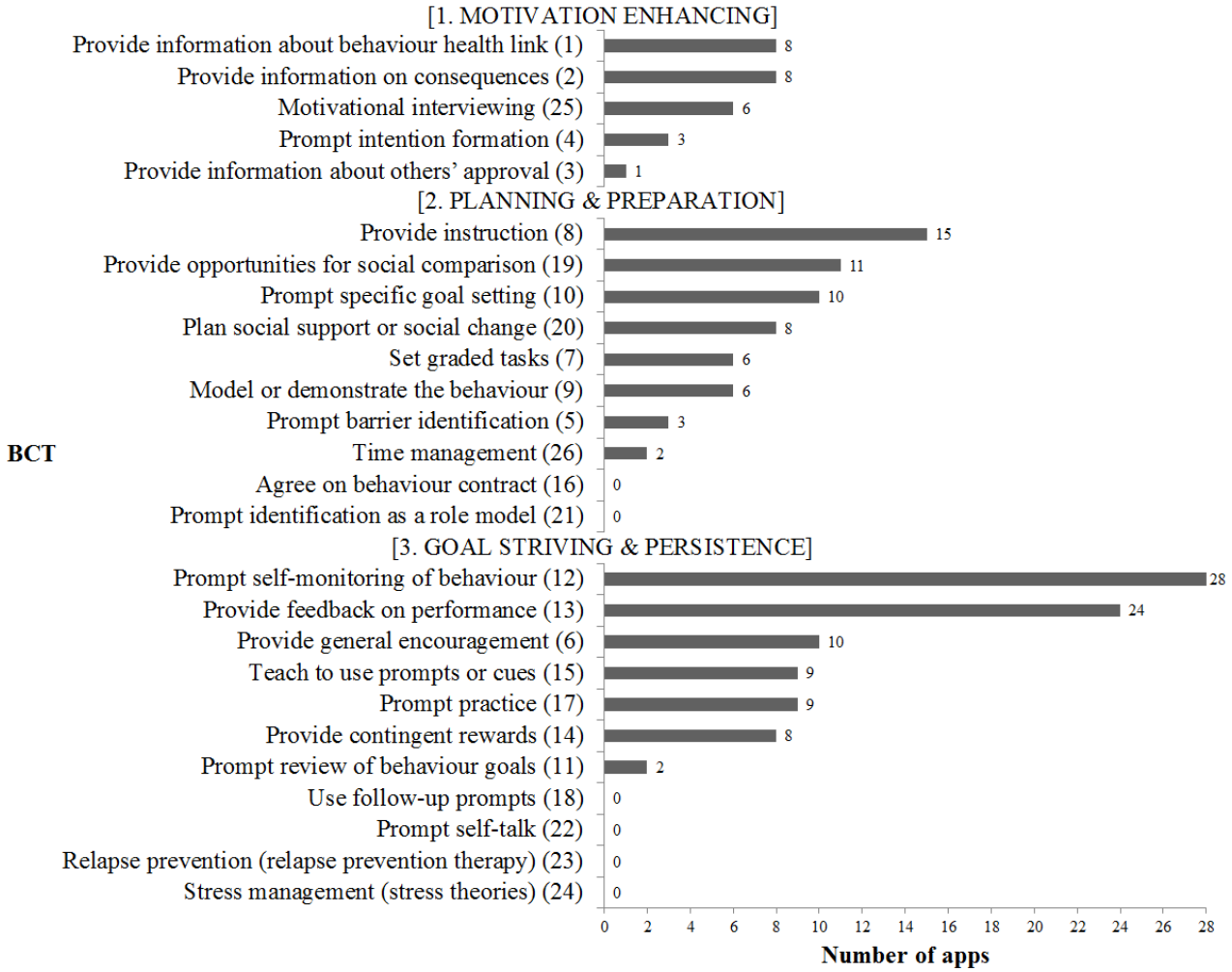


Figure 7 highlights the proportion of apps that included each individual BCT, as per the three-phase categories. BCTs associated with goal striving and persistence were the most commonly incorporated, followed by planning and preparation, and lastly motivation enhancing. All apps incorporated *self-monitoring of behavior*, which predominantly appeared in the form of tracking of food or energy intake, and also through the monitoring of physical activity and exercise. *Feedback on performance* was also present in the majority of apps (24/28, 86%). Feedback predominantly appeared in the form of instant feedback, whereby energy intake was immediately updated when foods or exercises were logged. Longer-term trends of energy intake and weight progress were represented graphically by many apps. Only 2 apps out of 28 (7%)—Food Diary and Calorie Tracker, and Calorie Counter PRO—provided individualized and tailored feedback. Absent across all the apps were the following BCTs: agreeing on behavioral contract, identification of a role model, using follow-up prompts, self-talk, relapse prevention, and stress management (stress theories).

Figure 7. Incorporation of behavior change techniques (BCTs) across apps. Number of apps (n=28) incorporating each of the 26 individual BCTs according to the three-phase categories: motivation enhancing, planning and preparation, and goal striving and persistence.



Discussion

Principal Findings

This evaluation indicates that, overall, the most popular dietary weight-loss apps available on the commercial market are suboptimal in quality. Few apps scored well for measures of accountability and while, overall, many apps scored reasonably in the domain of scientific coverage and accuracy, there was limited scientific coverage of information relevant to weight management. Although the agreement between apps and a dietitian-coded weighed food record was fair—mean difference 127 kJ, 95% CI -45 to 299—the accuracy of energy intake calculations was variable across different apps. There was restricted coverage of technology-enhanced features, and the usability of apps ranged from the *worst imaginable* to the *best imaginable*. A limited incorporation of BCTs was found across the apps reviewed.

Evaluations based on assessing the actual app content and the inclusion of evidence-based information have been determined to be better predictors of appraising the quality of apps than content-independent review methodologies [55]. Furthermore, the self-management nature of these commercial dietary weight-loss apps emphasizes the necessity of delivering robust and accurate evidence-based information through these apps to the consumer. Considering the extent of BCT incorporation also

provides an indication of the likely effectiveness of these apps to facilitate behavior change [56,57].

The accountability of apps is fundamental, both for the public and for their use as weight management tools in clinical practice or for the distribution of wide-reaching public health interventions to target obesity. Although many apps were updated regularly, less than half of the reviewed apps disclosed sponsorship, provided references and sources of information, and declared the authors' affiliations, which parallels the poor accountability found in other studies of obesity-management apps, both in Australia [33] and Korea [34]. It is also disconcerting that there was an absence of scientific and health professionals guiding the design and development of these weight-loss apps. This may offer one explanation for the predominance of calorie counting apps and limited scientific coverage of information that would support weight management, such as energy balance, and foods and beverages to meet the requirements and recommendations from dietary guidelines. Lay users and dietitians have expressed similar sentiments over the credibility, comprehensiveness, accuracy, and general quality of health and fitness apps, as well as the reputability and legitimacy of the app sources [3,58]. This indicates a need for collaborative input from researchers and qualified health professionals to guide the improvement and development of comprehensive theory-based dietary weight-loss apps with tailored and targeted nutrition advice.

Furthermore, there was variability in the accuracy of energy intake calculations, although the mean difference was small with the 95% CI indicating nonstatistically significant variation between the two methods. However, some weight-management apps display a large discrepancy in values when compared to the WFR. For example, the second most highly ranked app—Calorie Counter PRO by MyNetDiary, Inc—also had the second highest energy overestimation at 678 kJ. These results highlight the range of potential under- or overestimation by apps; however, the results are concordant with other studies which have found that dietary assessment carried out by mobile phones and nutrition apps have similar validity and reliability [59] and moderate-to-good correlations for measuring energy and nutrition intakes [60] when compared with conventional methods. In this evaluation, even when a trained dietitian entered the foods and serving sizes, there were difficulties experienced due to the lack of alternative serving sizes or household measures, and the inability to match the foods consumed as the majority of apps used a US food database. Another source of variability in accuracy may be the modifiability of food databases in some apps, which although offers the benefit of user customization of foods consumed, nevertheless presents shortcomings in the accuracy of nutrients when users enter them in themselves, and also can lead to losses to the quality of the food database from alterations by crowdsourcing. Since tracking of energy intake is an important feature of many apps, the need for accuracy is important to avoid misleading the consumer.

Evidence suggests that weight loss is supported by frequent contact with an intervention [37,61]. However, in health and fitness apps, retention has been found to rapidly decrease from 47% retention at 30 days to only 30% at 90 days [62], and with a quarter of downloaded health apps only used once, and three-quarters discontinued after the tenth use [63]. Similarly, self-monitoring and use of a weight-loss app is reported to decline over a 6-month period [10,64]. Thus, the usability (ie, the efficiency, acceptability, and appeal) of an app for its target audience is critical, particularly if the aim is to use apps repeatedly to facilitate long-term changes in behavioral outcomes and weight loss. For the dietary weight-loss apps reviewed, the mean SUS of 67.5 is equivalent to an adjective rating of *ok*. However, the weight-loss apps best rated for usability in this review, such as ControlMyWeight by CalorieKing and Easy Diet Diary by Xyris, were rated *best imaginable* (SUS 100), and out-rated other apps for recording physical activity exertion (SUS 75.4; *good*) [65] and for diabetes self-management (SUS 84; *good*) [66]. Many of the dietary weight-loss apps reviewed would still benefit from improvements in the ease of app use, as well as user engagement, particularly if they are to be the medium for delivering public health or preventative health interventions for chronic disease and obesity management.

Food logging and self-monitoring can be burdensome and time-consuming, and can result in noncompliance and underestimation as usual dietary intakes may be altered to avoid the inconvenience of recording [67]. Hence, technology-enhanced features, such as barcode scanners, can assist in reducing user burden and in maintaining motivation and compliance for ongoing use of the apps through online social networking with health professionals and others trying to lose weight [2,35,36]. In this evaluation, the restricted range of technology-enhanced features integrated within commercial apps may be another contributor to the decline in engagement with an app, especially as the primary role of these weight-loss apps is to promote self-monitoring and tracking.

In Internet-based interventions, incorporation of more BCTs were found to have a larger effect on behavior than interventions with fewer techniques [57]. Across the 28 apps reviewed, less than a quarter of the 26 BCTs were included. This gap between the theoretical framework, which has established the potential to enable behavior change and weight loss, and its subsequent inclusion in apps is consistent with the findings from other evaluations of weight loss [13,35-37] and physical activity and dietary [39] apps. The hallmarks associated with effective healthy eating and physical activity interventions have been determined to be self-monitoring accompanied by at least one of the following: feedback on performance, intention formation, specific goal setting, and a review of behavioral goals [56]. All the apps analyzed in this review included self-monitoring of behavior, as it was an inclusion criterion of this evaluation, and feedback on performance was also present in the majority of apps. However, only 2 apps—My Diet Coach Pro and Noom Weight Loss Coach—included the range of BCTs commonly associated with greater effectiveness.

These 2 apps also included gamification, which is defined as using elements of game design in nongame contexts [68], and involves the inclusion of *motivational affordances*, such as points, levels, clear goals, feedback, rewards, progress, and challenges [69]. Gamification has been found to yield positive effects among a review of empirical studies on gamification [69]. Furthermore, in physical activity and dietary health and

fitness apps, behavioral theory and, more specifically, motivational components of behavior were significantly associated with gamification [70]. This suggests that gamification not only has an apparent overlap with BCT constructs, but that it also has the potential to increase the motivation of app users in order to sustain habits and engage individuals with the behavioral strategies within apps through creation of positive, intrinsically motivating, "gameful" experiences [69,71,72]. Therefore, the gamification of weight-management apps may be a possible avenue for enhancing the delivery of behavioral theories, particularly motivational components; more in-depth study of the relationship between gamification and health behavior change is necessary.

One of the key strengths of this study was the theory-driven approach to app evaluation which allowed for a thorough examination of multiple parameters around the quality of the apps, such as accountability, scientific coverage, accuracy, technology-enhanced features, and usability, as well as behavioral theory. Particularly, as there is no industry standard or regulation of weight-management apps, this evaluation will assist health professionals in understanding which apps from among the current popular app pool are of the highest quality and appropriate for recommendation to their clients, and will assist in protecting consumers from misinformation.

Limitations

It was not feasible in this study to evaluate all the weight-loss apps available to the public. Hence, it is possible that there are other apps that incorporate all the BCTs (but are not popular) or that some country-specific popular apps were missed. The accuracy of energy intake observed among all apps may have been influenced by the researcher being trained in nutrition (ie, a dietitian) and it is possible that the lay public would have more difficulty matching foods and interpreting the serving size to enter.

Although specific components of behavior change interventions may be understood to facilitate behavior change, they still require testing in trials. Emerging evidence suggests that caution should be exercised in the recommendation of apps in weight management. In randomized controlled trials evaluating commercial weight-loss smartphone apps such as MyFitnessPal [64] or Lose It! [73], although weight loss was observed in the intervention groups, the effects were not statistically significant when compared to the controls. In contrast, a researcher-developed weight-loss app, My Meal Mate (MMM), demonstrated significant weight reduction compared with controls in a 6-month period [10].

Conclusions

With the relative absence of BCTs incorporated, along with variability in the additional measures of quality of these apps, such as the scientific coverage and accuracy, the recommendation of dietary weight-loss apps in clinical practice and in public health should proceed with caution. Ongoing evaluation of these apps and implementation of a standardized framework for quality assessment is necessary to drive the design and development of higher-quality apps on the market. Further research around efficacy trials of apps to promote weight loss is also warranted.

Authors' Contributions

This project was carried out at the University of Sydney as a partial fulfilment of the Master of Nutrition and Dietetics Degree. JC, JEC, and MAF contributed to the conception and design of the study. JC conducted the research, analyzed the data, and drafted the first version of the manuscript. JEC and MAF contributed to writing and editing the manuscript. MAF had primary responsibility for the final content of the manuscript. All authors read and approved the final manuscript. Ms Monica Nour judged the single discrepancy in the inter-rater assessment.

Conflicts of Interest

JC declares no personal or financial conflicts of interest. JEC developed the My Meal Mate app on a grant from the National Prevention Research Initiative (grant number G0802108). It is available free of charge. MAF has developed food-based apps, but not for weight management.

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Abbreviations

12WBT: 12 Week Body Transformation
Acc.: accountability
AGHE: Australian Guide to Healthy Eating
AUSNUT: Australian Food and Nutrient Database
BCT: behavior change technique
BMI: body mass index
DAA: Dietitians Association of Australia
FDA: Food and Drug Administration
ICC: intraclass correlation coefficient
N/A: not applicable
NHMRC: National Health and Medical Research Council
NRV: Nutrient Reference Value
SCA: scientific coverage and accuracy
SUS: System Usability Scale
TEF: technology-enhanced features
TS: total score
Us.: usability
WFR: weighed food record

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Original Paper

Let Visuals Tell the Story: Medication Adherence in Patients with Type II Diabetes Captured by a Novel Ingestion Sensor Platform

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Abstract

Background: Chronic diseases such as diabetes require high levels of medication adherence and patient self-management for optimal health outcomes. A novel sensing platform, Digital Health Feedback System (Proteus Digital Health, Redwood City, CA), can for the first time detect medication ingestion events and physiological measures simultaneously, using an edible sensor, personal monitor patch, and paired mobile device. The Digital Health Feedback System (DHFS) generates a large amount of data. Visual analytics of this rich dataset may provide insights into longitudinal patterns of medication adherence in the natural setting and potential relationships between medication adherence and physiological measures that were previously unknown.

Objective: Our aim was to use modern methods of visual analytics to represent continuous and discrete data from the DHFS, plotting multiple different data types simultaneously to evaluate the potential of the DHFS to capture longitudinal patterns of medication-taking behavior and self-management in individual patients with type II diabetes.

Methods: Visualizations were generated using time domain methods of oral metformin medication adherence and physiological data obtained by the DHFS use in 5 patients with type II diabetes over 37-42 days. The DHFS captured at-home metformin adherence, heart rate, activity, and sleep/rest. A mobile glucose monitor captured glucose testing and level (mg/dl). Algorithms were developed to analyze data over varying time periods: across the entire study, daily, and weekly. Following visualization analysis, correlations between sleep/rest and medication ingestion were calculated across all subjects.

Results: A total of 197 subject days, encompassing 141,840 data events were analyzed. Individual continuous patch use varied between 87-98%. On average, the cohort took 78% (SD 12) of prescribed medication and took 77% (SD 26) within the prescribed ±2-hour time window. Average activity levels per subjects ranged from 4000-12,000 steps per day. The combination of activity level and heart rate indicated different levels of cardiovascular fitness between subjects. Visualizations over the entire study captured the longitudinal pattern of missed doses (the majority of which took place in the evening), the timing of ingestions in individual subjects, and the range of medication ingestion timing, which varied from 1.5-2.4 hours (Subject 3) to 11 hours (Subject 2). Individual morning self-management patterns over the study period were obtained by combining the times of waking, metformin ingestion, and glucose measurement. Visualizations combining multiple data streams over a 24-hour period captured patterns of broad daily events: when subjects rose in the morning, tested their blood glucose, took their medications, went to bed, hours of sleep/rest, and level of activity during the day. Visualizations identified highly consistent daily patterns in Subject 3, the most adherent participant. Erratic daily patterns including sleep/rest were demonstrated in Subject 2, the least adherent subject. Correlation between sleep /rest and medication ingestion in each individual subject was evaluated. Subjects 2 and 4 showed correlation between amount of sleep/rest over a 24-hour period and medication-taking the following day (Subject 2: r=.47, P<.02; Subject 4: r=.35, P<.05). With Subject 2, sleep/rest disruptions during the night were highly correlated (r=.47, P<.009) with missing doses the following day.

Conclusions: Visualizations integrating medication ingestion and physiological data from the DHFS over varying time intervals captured detailed individual longitudinal patterns of medication adherence and self-management in the natural setting. Visualizing multiple data streams simultaneously, providing a data-rich representation, revealed information that would not have been shown by plotting data streams individually. Such analyses provided data far beyond traditional adherence summary statistics and may form the foundation of future personalized predictive interventions to drive longitudinal adherence and support optimal self-management in chronic diseases such as diabetes.

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KEYWORDS

ingestion sensor platform; data visualization; time domain methods; medication adherence; patient self-management

Introduction

Medication adherence is defined as "the extent to which patients take medications as prescribed by their health care providers" [1]. An estimated 50% of patients do not adhere to prescribed medication regimens over time [1]. In the United States, US $100 billion in unnecessary hospitalizations and a total direct and indirect estimated cost of US $290 billion occurs from non-adherence annually; while non-adherence is estimated to cost the European Union €1.25 billion annually [1-4].

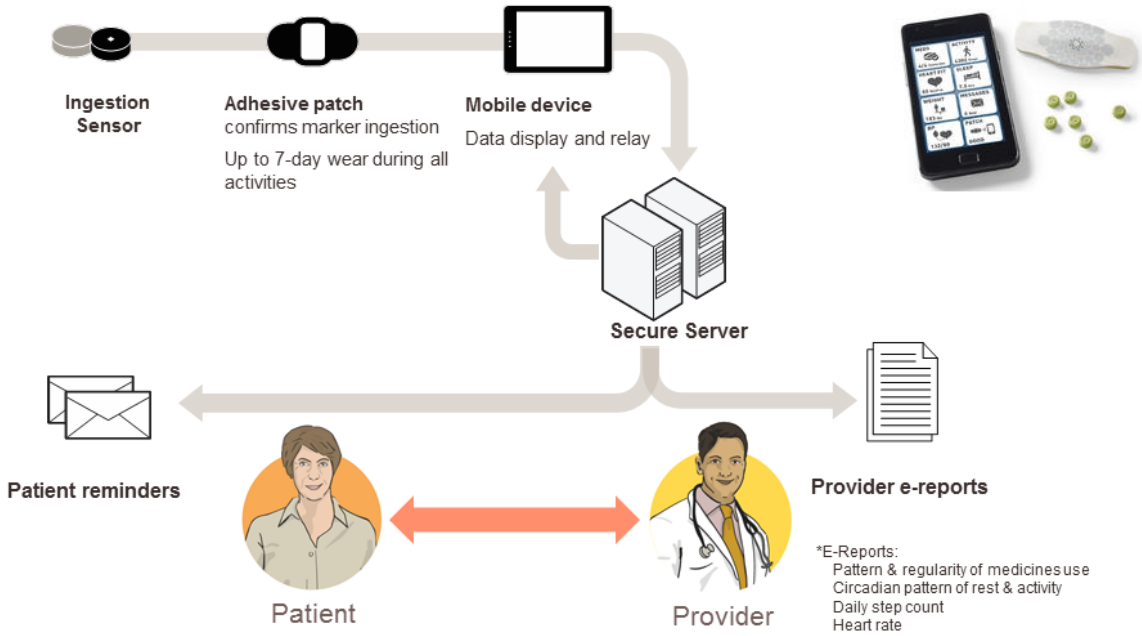
Any attempt to address this problem is complicated by the absence of reliable measurement of medication adherence, a difficulty that has plagued medicine since the days of Hippocrates [5]. The current gold standard is directly observed therapy, where a health care worker watches a patient swallow each dose of medication. This is expensive and impractical in chronic disease management. Alternatively, patient questioning, pill counts, and prescription refill rates have been used as methods for assessing adherence, but these have been shown to be inaccurate [1,6]. Electronic monitoring methods such as medication event monitoring systems, which rely on the opening of an electronic cap or patient dispensation of medication as a proxy measure of ingestion, emerged in the 1980s. The limitations of these systems, such as mismatches between electronic cap opening and actual intake, or patients obviating electronic assessment by decanting pills into a different container, have been well documented [7-10]. None of the methods of assessing medication adherence described above monitor actual medication ingestion, nor do they include any physiological measures such as activity, heart rate, or sleep/rest.

A Novel Sensor Platform to Monitor Medication Adherence and Self-Management

A novel technology, Digital Health Feedback System (DHFS), is now available that allows for the date- and time-stamping of actual ingestions of oral medications rather than surrogate measures of ingestion. The system has been shown to be safe, reliable, and highly accurate, with a positive detection accuracy of sensor-detected ingestions of approximately 99.1% (321/324 ingested under direct observation; 95% CI 97.3-99.7) [11]. In the renal transplant population, the system accurately detected the ingestion of two sensor-enabled capsules taken at the same time with a detection rate of 99.3% (n=2376) [12]. The system is approved by the US Food and Drug Administration (FDA) and CE marked (European Conformity marking) (August 2012). It is the only system ever approved by the FDA for the measurement of medication adherence (July 2015).

This system consists of a 1 mm^3 edible sensor (1 x 1 x.45 mm microchip), coated with very thin layers of commonly ingested excipients (ie, minerals and metals), and a small detector patch worn on the torso. When ingested with medication, the sensor readily separates from the carrier, is energized, and communicates with the adhesive-backed detector patch worn on the torso. The detector patch interprets the information as unique to the ingested sensor and records it along with physiological metrics including heart rate, step activity, and sleep/rest. All of the recorded data are sent wirelessly to a paired device, such as a mobile phone or a personal computer, and are subsequently uploaded to a secured, centralized data storage location (Figure 1) [12-15]. The patch can be configured to acquire various physiologic data at predetermined intervals. Individuals using the system generate dense physiological data that can be viewed in combination with the patient's medication ingestion data.

Figure 1. Overview of the Digital Health Feedback System to monitor medication adherence and self-management (figure courtesy of Proteus Digital Health).



Continuous Wearable Sensor Platforms Require Novel Modes of Analysis

As described above, the DHFS includes a continuous wearable monitor patch and generates dense individual data on adherence and physiological measures. A patch, sampling every 5 minutes, can generate over 1000 data events per patient in a 24-hour period. In order to be interpretable and useful to a health care provider and patient, these dense data require novel methods of analysis not used previously in adherence monitoring. Currently, adherence data are traditionally reported as summary statistics, that is, "taking adherence," the percentage of doses taken in relation to the total number of prescribed doses and "timing adherence," the percentage of doses taken during a prescribed time interval. Such summary statistics derived from the ingestion sensor platform, while highly accurate in comparison to any other adherence assessment, will not reflect the richness of information that the entire DHFS system is capable of providing.

For dense DHFS data, we reasoned the use of more advanced analyses incorporating visualization methods were needed. Information visualization enhances human cognition in multiple ways, including enhancement of pattern recognition, such as when information is organized in space by its time relationships, and supporting the ease of perceptual inference of relationships that are otherwise more difficult to induce [16]. Thus, visualizations could capture dense data and, if well designed, may be able to quickly inform health care workers and be easily understood by patients with minimal training. The issue of how to present large amounts of continuous dense data to a patient and health care audience, and the study of effective ways of using visualizations to support the analysis of large amounts of medical data, is currently acknowledged as an area of critical need [17]. Visual analytics, defined as the science of analytical reasoning facilitated by advanced interactive visual interfaces [16], is an emerging discipline that has shown significant promise in addressing many of these information overload challenges [18]. One of the major figures in the field of visual analytics is Edward Tufte, who encourages the use of data-rich visualizations that present all available data without editing. He emphasizes that data-rich graphics can actually reveal what the data mean [19]. Furthermore, it is unclear how physiological measures can be used to increase understanding of individual patient medication ingestion patterns and self-management beyond traditional adherence summary statistics. Exploratory analyses using data-rich visualizations may indicate how this might be done. Thus, we explored combining multiple data streams of medication ingestion and physiological data together in novel data-rich visualizations to see if we could capture longitudinal patterns of medication-taking behavior and self-management in individual patients with type II diabetes. If successful, we reasoned that visualization data may provide information for individually tailored interventions that could support medication adherence.

The visualizations in this paper were derived from the data output of a trial of the DHFS system in patients with type II diabetes. Time domain methods were used to graph signal changes over time, visualizing multiple signals simultaneously. The trial included 5 patients each taking metformin twice daily over 37-42 days [13,20] and was a user experience study designed to evaluate the use of the technology. Thus, our work focuses on visualizations capturing longitudinal patterns of medication-taking and self-management over the course of the study; it does not focus on glucose control.

As an initial approach, we investigated whether varying the time interval over which data are analyzed and visualized provides different insights into patients' medication-taking behavior. Thus separate analyses were performed looking at data for each individual over (1) the entire study period, (2) 24-hour periods, and (3) weekly time periods. Visualizations generated attempted to explore relationships that would be of

value in supporting patient medication adherence and self-management in this chronic disease state.

Methods

User Experience Trial

Data analyzed were from a user experience study, which was a prospective, single-arm, observational cohort study (conducted by Diabolo Clinical Research) that aimed to characterize the at-home adherence patterns of 5 patients with type II diabetes to oral metformin [20]. The study captured each subject's medication adherence and physiological data using the DHFS. Components of DHFS networked self-management system have been previously outlined in detail (see [20] and Figure 1). Subjects were instructed to continuously wear the personal monitor (RP2, Proteus Digital Health), co-ingest an edible sensor (IEM version DP4.2, Proteus Digital Health) whenever taking metformin, and to take one weight measurement daily (Medical Scale A&D) [13,20]. The subjects were also instructed to take at least one pre-meal fasting blood glucose measurement daily, preferably in the morning to provide a fasting glucose measurement, with a wireless glucometer (OneTouch Ultra2, Life Scan) and test strips [13,20]. Mobile phones used were Android 2 Global 2.2 operating system (Motorola). The data from the telemetered devices were then integrated into the DHFS system. Full ethical approval for the study was obtained from Ethical and Independent Review Services, Corte Madera. All participants signed an informed consent.

Data Analysis and Visualization Generation Methods

We analyzed Microsoft Excel and Matlab files exported from the DHFS database and wireless glucose monitor, containing individual subject's DHFS outputs of pulse measured every 10 minutes, activity recorded every 5 minutes, sleep/rest, and glucose.

Standard summary statistics in percentages were calculated across all subjects for (1) taking adherence, defined as the number of ingestible sensor tablet detections by the personal monitor divided by the number of metformin doses prescribed, and (2) scheduling or timing adherence, defined as the number of ingestible sensor tablets detected within a±2-hour time window around the pre-determined dosing time divided by the number of sensors detected. Descriptive statistics of daily glucose measurement, with mean, maximum, and minimum range, along with 95% confidence intervals across the study period were calculated.

Verification of System and Data Cleaning

Patch function was checked using number of individual activity events reported over a 24-hour time period, with sampling every 5 minutes, that is, 288 measurements daily. The amount of continuous patch wearing per subject was recorded. In correlation calculations, days without full patch function were removed. The total number of events per subject per day recorded by the monitoring patch including heart rate, activity, and posture were approximately 720. Thus, over the 197 days of the study, data events recorded ranged from approximately 26,640-30,240 per subject, with a total number of data events recorded of greater than 141,840 for the entire study.

Algorithms were developed using Matlab and applied to analyze data for medication-taking behavior, sleep/rest, activity, heart rate, and then integrated with glucose measurements over (1) the entire study period, (2) daily, and (3) weekly. The sleep/rest state signal is derived from an algorithm based on activity, position, and pulse. The temporal structure of this sleep/rest state signal was used to derive the waking time. Waking time derivation was based on the following assumptions: (1) there is a single daily waking event, (2) short interruptions in long rest periods are transient state changes that should be ignored, and (3) similarly short rests in long waking periods do not suggest the main daily transitions. Visualizations were plotted using Matlab.

Pearson's r correlation between sleep/rest metrics and medication-taking behavior was calculated using a single daily measure, derived from physiological features tracked by the personal monitor patch, and a daily adherence measure of either number of doses taken or timing of dose ingestion. A delay in medication ingestion of greater than 12 hours was considered to be a missed dose. The daily sleep/rest measure used were total hours of rest, and number of sleep disturbances between 10 p.m. and 8 a.m.

Results

Demographics and Traditional Summary Statistics of Medication-Taking and Timing Adherence

Subjects were 5 patients with type II diabetes (2 females and 3 males), age 43-61, prescribed twice-daily metformin. Subjects 1, 2, and 5 used insulin in addition to metformin during the study. Days of participation per subject ranged from 37-42, with a total number of subject days of 197. On average, the cohort took 78% (SD 12) of prescribed medication and took 77% (SD 26) within the prescribed ±2-hour time window. Figure 2 shows those metrics for individual subjects. Figure 3 also shows the range of daily glucose measurements for each subject with the mean, maximum, minimum, and 95% confidence interval over the period of the trial.

Figure 2. Standard representation of medication taking and scheduling adherence across study period by subject.

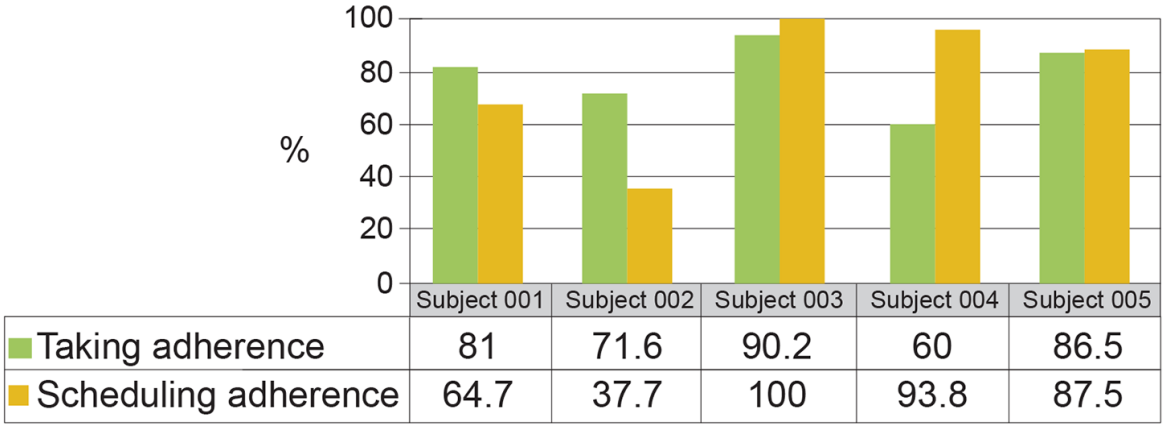
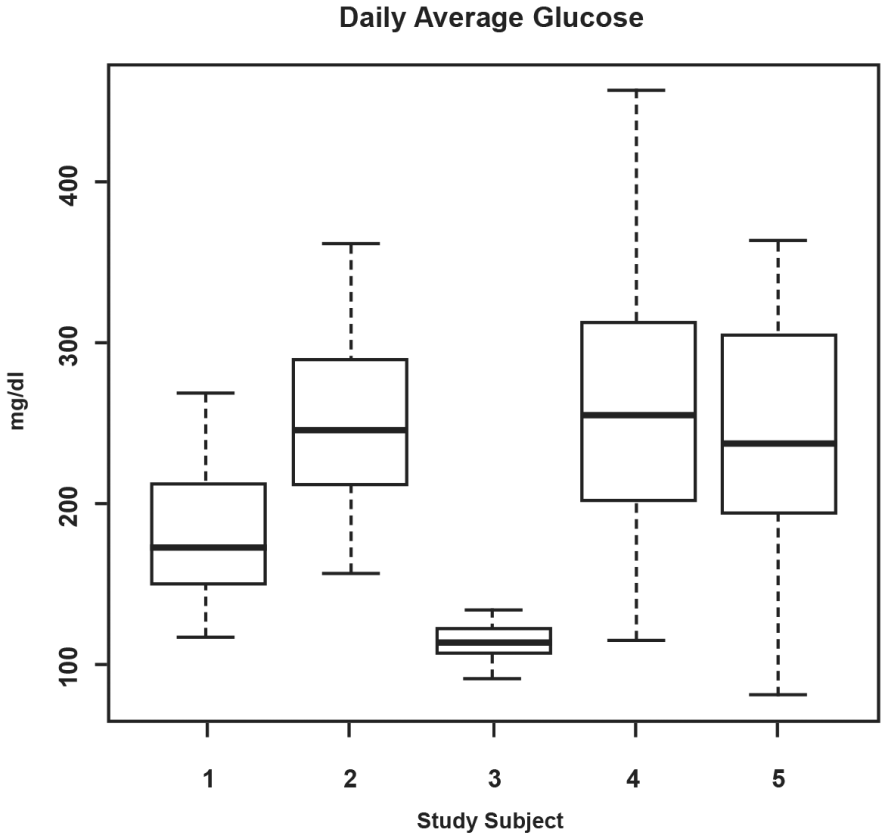


Figure 3. Daily average glucose measurements taken by subject.



Verification of System and Data Cleaning

Patch use across 197 subject days of participation in the study showed subjects wore the patch continuously between 87-98% of the time. One isolated event of greater than 288 events was observed due to patch dysfunction. Data from days of no recording were removed as described above.

Data Visualizations Incorporating the Entire Study Period

Medication-Taking Behavior, Timing of Ingestions, and Missed Doses

The DHFS system allows precise time-stamping of ingestions. The initial visualizations sort to provide a means to quickly evaluate how closely patients executed the twice daily dosing regimen prescribed and what the fraction of missed doses looked like in terms of the time of their occurrence. Figure 4 provides a summary graph of doses taken, total missed doses, and fraction of missed doses taking place in the morning or evening per subject over the period of the trial. The majority of missed doses occurred in the evening, particularly in Subjects 2 and 4 who had the lowest adherence.

In Figure 5, we plotted the fraction of medication ingested versus the time of day ingestion took place for the 5 subjects across the entire study period (Figure 5). This graphic provides information on the range of morning and evening medication ingestion timing and allows discernment of the subjects' daily timing patterns. Subject 3 took medication over the narrowest range of time (in the morning over a 1.25 hour range and in the evening over a 2.4-hour range) and had a consistent pattern of

ingestion. Subject 2 took medication over the widest range of times (over an 11-hour range in both the morning and evening) and had no consistently repeated pattern of ingestion timing in either the morning or the evening. Given that the mean half-life of metformin is approximately 5.7 hours in patients with type II diabetes [21], Subject 2 would have considerable variability in the plasma levels of metformin by timing adherence alone. Subject 4 took medication over a 4.5 and 4.8 hour time range, in the morning and evening respectively, but multiple doses were missed, mostly in the evening. Subjects 1 and 5 missed 19% and 14% respectively of their total doses. Subject 1 showed a range of ingestion times in the morning of 4.0 hours and a wide range of 11 hours for the timing of her second dose. Subject 5 ingested medication over a range of 8.5 hours in the morning and 5.8 hours in the evening. These graphs provide information on longitudinal patterns of missed doses and twice daily dose timing beyond the traditional summary graphs (Figure 2).

Figure 4. Dosage adherence summary for whole trial.

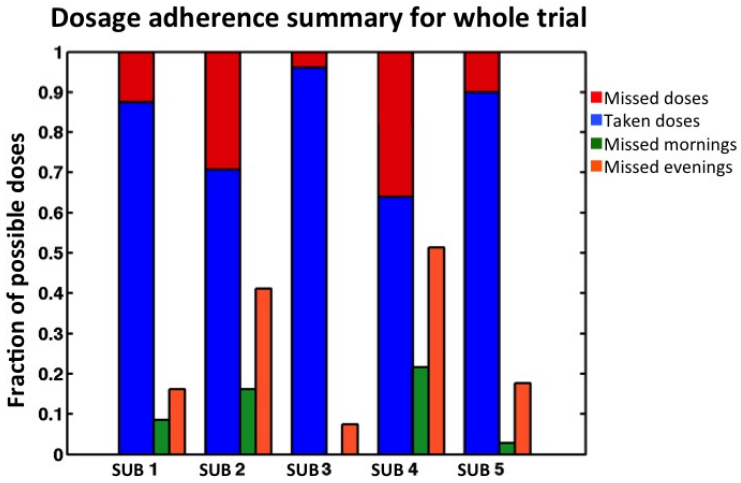
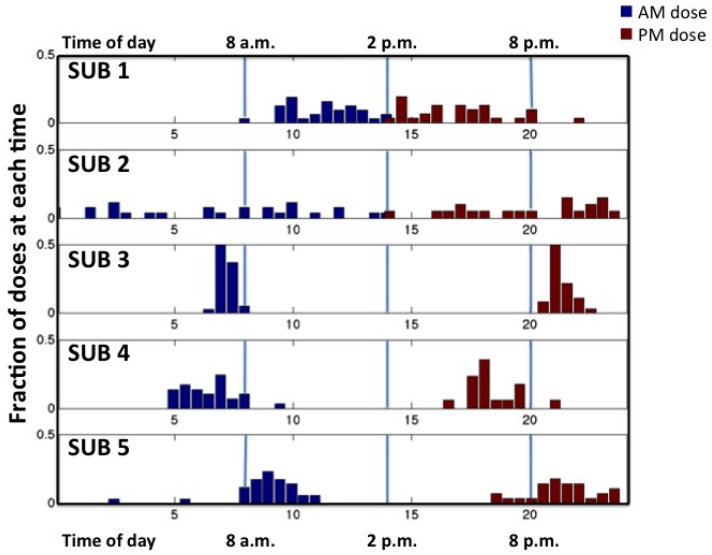


Figure 5. Frequency distribution of the time of day at which the subjects ingested medication.



Waking Times, Medication-Taking Behavior, and Glucose Self-Monitoring

The DHFS is capable of identifying sleep/rest behavior in addition to the precise timing of medication ingestion. The ability to execute consistent timing of drug ingestion twice daily may be connected to individual daily waking and bedtimes. Using DHFS data, we derived each subject's waking time and bedtime (see Methods for mathematical derivation of these). Figure 6 shows the variability of sleep and waking time for each subject across the study.

We then visualized wake time with medication ingestion time for each subject, but also incorporated time of glucose measurement over the course of the study to explore if it was possible to visualize morning self-management patterns in individual subjects. Subjects in this study were instructed to take at least 1 daily glucose measurement, preferably first thing in the morning to provide a daily fasting glucose measure.

Figure 7 shows patterns of morning self-management of medication ingestion and blood glucose measurement in relation to waking time for Subjects 2, 3, and 4 (Subjects 1 and 5 are shown in Graphs 1 and 2 in Multimedia Appendix 1). Each individual subject displayed distinct patterns. Subject 3 ingested metformin within 3.5 hours of waking and always took blood glucose measurements before medication ingestion. Over the entire period of the trial, Subject 3 missed no morning doses.

Subject 2 took medication and blood glucose measurements at widely varying times after waking but showed a very close association between timing of morning glucose measurement and medication ingestion (r=.6113, P>.001). Subject 4 took metformin within minutes of waking but missed multiple metformin doses. The proximity of waking time and medication ingestion for Subject 4 may partly account for the consistency in timing adherence of this subject, thus when the subject remembered to take the medicine, he did so on waking usually between 6-8 a.m. Subject 4 did not take blood sugar measures every morning and those taken were frequently made hours after waking and thus unlikely to represent fasting glucose values. Subjects 1 and 5 took their metformin dose within 4 hours of waking and their graphs are shown in Graphs 1 and 2 in Multimedia Appendix 1. The visualizations suggest that Subjects 2 and 4 did not have well-developed, consistent successful morning routines, in contrast to Subject 3. Subject 4 had some timing consistency that could be used to reinforce a medication ingestion routine on waking. Subject 2 showed no consistent pattern with waking. We note that these visualizations captured longitudinal patterns of waking, medication ingestion, and glucose measurement beyond traditional adherence summary graphs.

Figure 6. Frequency distribution of the estimated sleep and wake times of subjects.

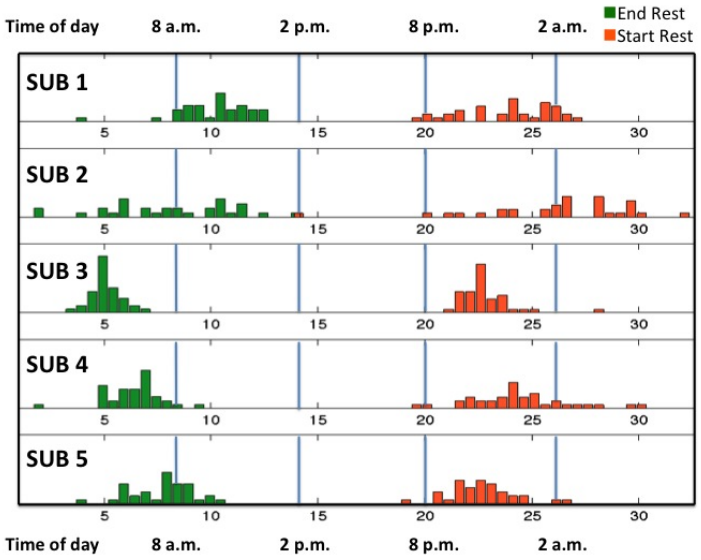
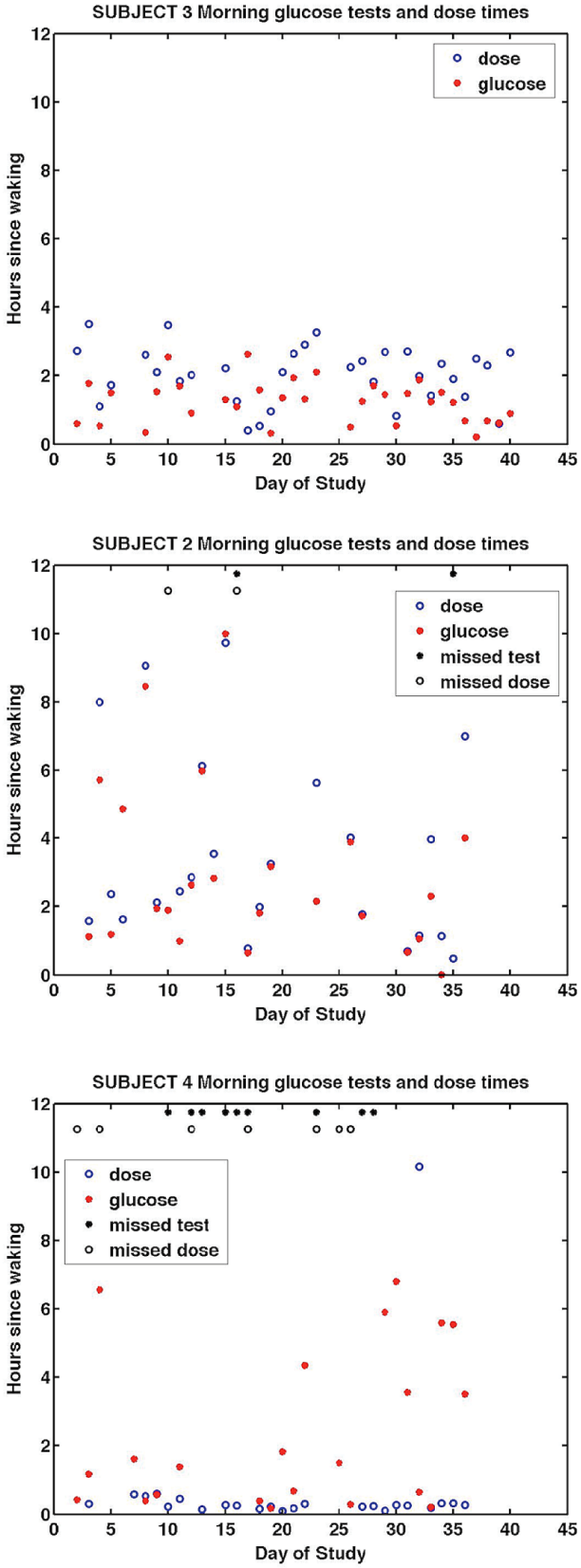


Figure 7. Morning glucose tests and metformin dose ingestion times in hours after waking for Subject 3 (top), Subject 2 (middle), and Subject 4 (bottom).



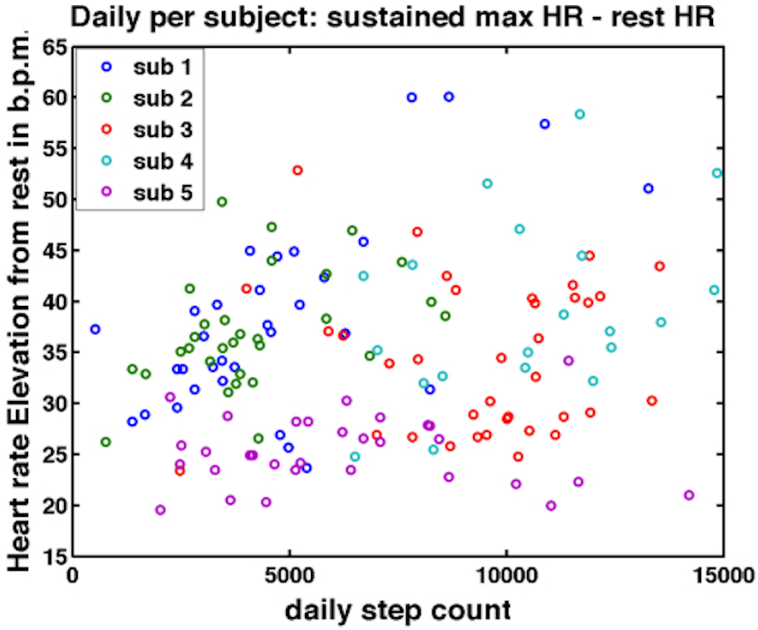
Activity Levels and Heart Rate

The DHFS also monitors heart rate and activity. An important aspect of patient self-management in chronic diseases like diabetes is maintaining healthy levels of physical activity. Subjects 3 and 4 had the most frequent and vigorous exercise levels, averaging between 8000 and 12,000 steps on most days. Subjects 1 and 2 had the lowest step counts averaging 4000-5000

steps per day. Subject 5 showed the widest range of daily step count with an average of 6000 steps per day. Step count distribution and daily average, maximum, and minimum heart rates for each patient are shown in Graphs 3 and 4 in Multimedia Appendix 1.

We then combined data on heart rate and step activity to gain potential insight into the fitness levels of the subjects. We looked at the sustained maximum heart rate in terms of the elevation of the heart rate from resting (calculated for each individual) and its relationship to daily step count in each subject (Figure 8). In Figure 8, Subjects 1 and 2 have steep slopes in heart rate at relatively low step counts in comparison to Subjects 3 and 4. This may imply lower cardiovascular fitness levels in Subjects 1 and 2. Subject 5, a known hypertensive taking the medication atenolol, showed limited elevation in heart rate with elevated step count.

Figure 8. Sustained heart rate elevation from rest associated with daily step count, by subject. The graph plots the heart rate elevations from rest in beats per minute against each subject's daily step counts.



Data Visualizations Over 24-Hour Periods

We then explored whether data analysis using visualization over a 24-hour time frame would offer different information than visualization over the entire study period. We generated graphs for each day of study participation, incorporating medication ingestion, sleep/rest, activity, and glucose measurement (both the time of day the glucose measurement took place and the actual glucose level are represented on the graph) for each subject. We found that with this combination of ingestion and physiological data, it was possible to generate visualizations that reconstructed the broad pattern of the patient's day in relation to their medication-taking. Thus we could see when patients rose, tested their blood glucose, took their medication, became physically active, and later went to bed. Samples of these daily graphs for each subject are provided; Subjects 2, 3, and 4 are shown in Figures 9-11 and Subjects 1 and 5 in the Graphs 5 and 6 in Multimedia Appendix 1. These samples were chosen either because they represent a consistent feature of the subject's longitudinal daily pattern or provided detail on how the structure of a patient's day appeared related to their medication ingestion pattern that day.

Figure 9 shows visualizations of the most adherent participant, Subject 3 on Days 1, 9, and 14 of the study. The graphs show that Subject 3 had blocks of continuous sleep/rest (sleep/rest is visualized as a state that is either awake, 0, or asleep, 100), typically rose around 5 a.m., engaged in a period of the highest activity level, possibly exercise, subsequently took a blood glucose measurement, and ingested metformin medication around 7 a.m. The subject remained fairly active throughout the day, took a blood glucose measurement in the evening, promptly ingested metformin, and went to sleep/rest prior to midnight. Subject 3 showed limited variation in the patterns. One minor variation occurred in the evening of Day 9 when blood glucose was measured at approximately 9 p.m., followed by sleep/rest. Subject 3 then got up later to take metformin and then went back into sleep/rest at around 11 p.m. The visualizations capture the daily patterns of a highly adherent subject who demonstrates consistent self-management routines longitudinally over the study.

Figure 10 shows Subject 2 on Days 4, 5, and 9. Subject 2's daily graphs showed considerable variation in behavior patterns. On Day 4, the subject's continuous sleep/rest was of short duration taking place both at night and in the middle of the day; activity in between sleep/rest was low level; six blood glucose measurements were taken; and metformin was ingested at midday and then approximately 9 hours later. On the following Day 5, Subject 2 had an almost 12-hour period of sleep/rest starting just after midnight, took her blood glucose around noon, took metformin dose around 2 p.m., and had a further period of sleep/rest. The subject had low activity levels outside sleep/rest periods and missed the evening metformin dose. On Day 9, Subject 2 had no identifiable sleep/rest period until late evening, again showed low levels of activity, measured her blood glucose twice, and took four metformin in a 24-hour

period. Two of these metformin were taken minutes apart. Subject 2's graphs showed wide daily variation, with continuous changes in sleep/rest patterns and erratic medication-taking behavior. These visualizations provide considerable data beyond traditional adherence summary statistics. It can be appreciated that poor adherence in this subject may not respond to simple medication reminders or even missed dose reminders but will require a broader approach. The visualizations suggest health care providers should talk to the subject more broadly about factors that influence medication adherence such as sleep disturbance, mood alteration associated with significant sleep disturbance, the length of time these issues have persisted and should extend the interview to try to understand whether the patient's daily patterns were the result of untreated concurrent conditions such as depression, hyperthyroidism, chronic pain, gastroesophageal reflux disease, or were a reaction to external stressors or both.

Figure 11 shows sample daily graphs from Subject 4 on Days 17 and 34. Subject 4 appeared to show some variability in medication-taking with variable sleep length. On Day 17, Subject 4 had poor sleep/rest and did not take a metformin or a blood glucose measurement. On Day 21, after a continuous period of sleep/rest, Subject 4 took a morning dose of metformin prior to measuring his blood glucose three times between noon and 3 p.m. and took an evening dose between 6 and 7 p.m. The graphs provide examples of a day when the patient is non-adherent and a day when the patient was adherent. (Samples and discussion of daily graphs for Subjects 1 and 5 are available as Graphs 5 and 6 in Multimedia Appendix 1).

This interval of analysis enabled highly individualized insight into each participant's daily behavior patterns over the period of study in relationship to medication ingestion. The data potentially provide information to support individually tailored interventions to improve adherence outcomes.

Figure 9. Daily medication taking, sleep/rest, activity, and glucose measurement for Subject 3 on Day 1 (top), Day 9 (middle), and Day 14 (bottom).

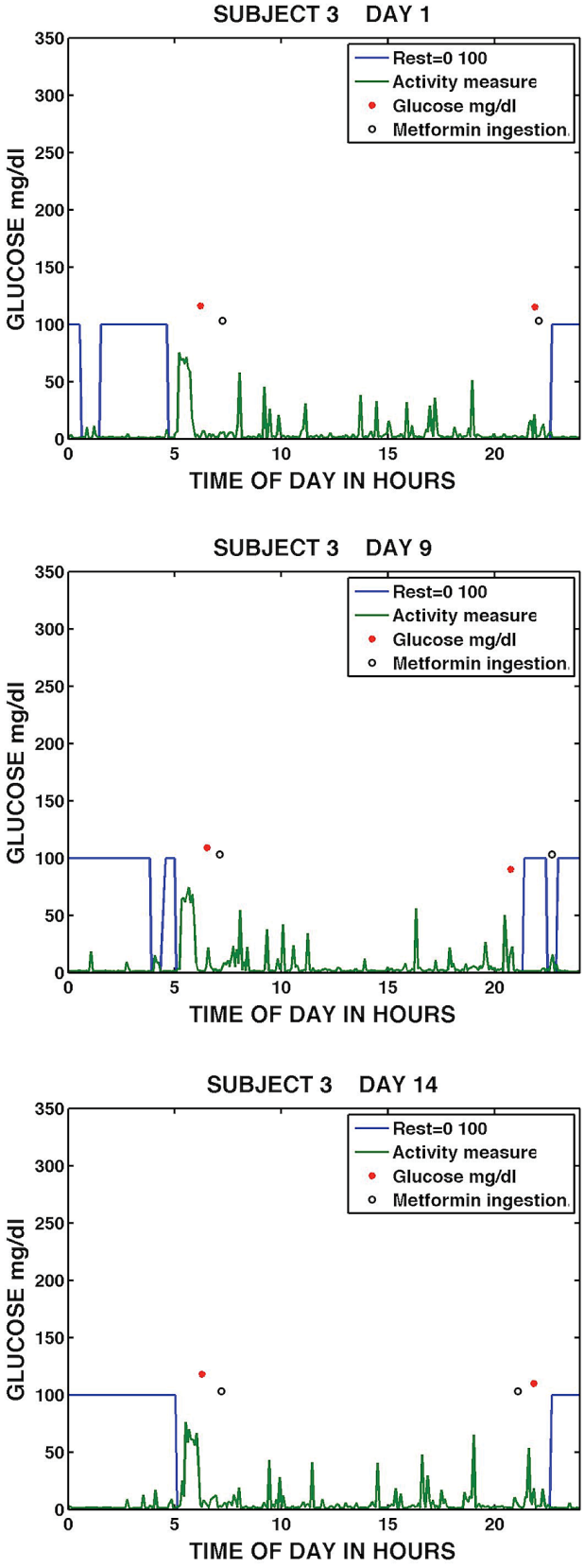


Figure 10. Daily medication taking, sleep/rest, activity, and glucose measurement for Subject 2, Day 4 (top), Day 5 (middle), and Day 9 (bottom).

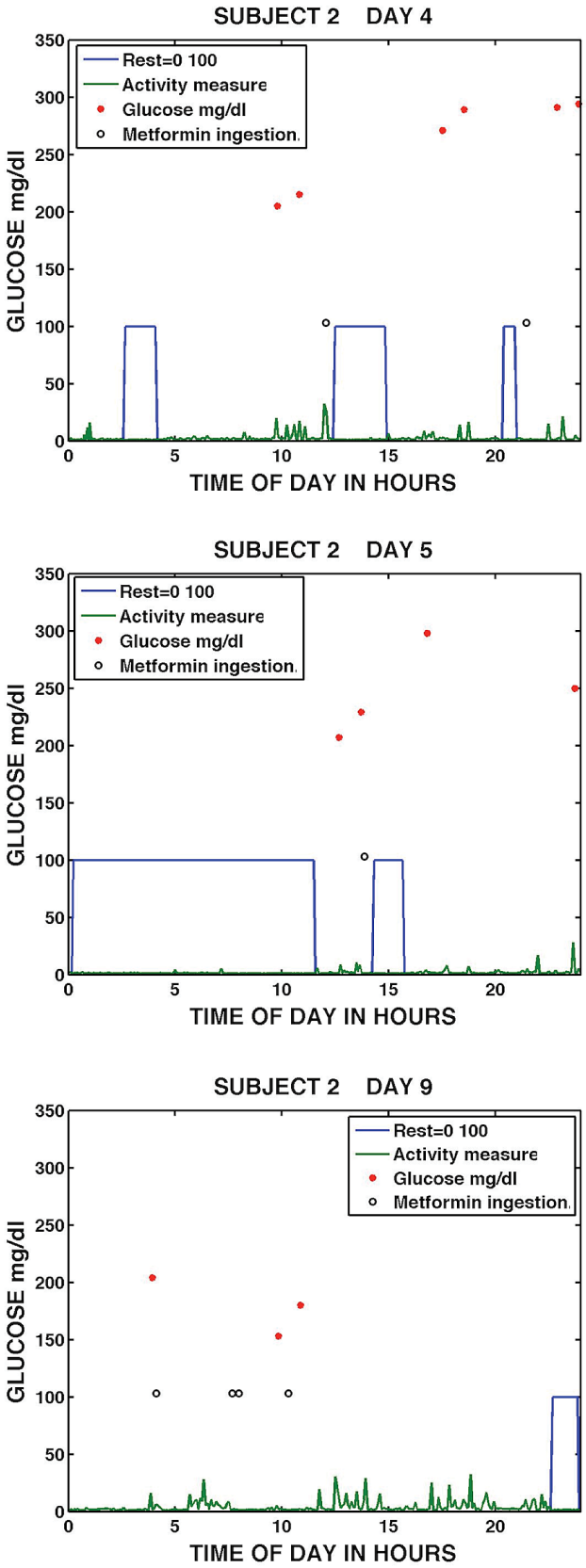
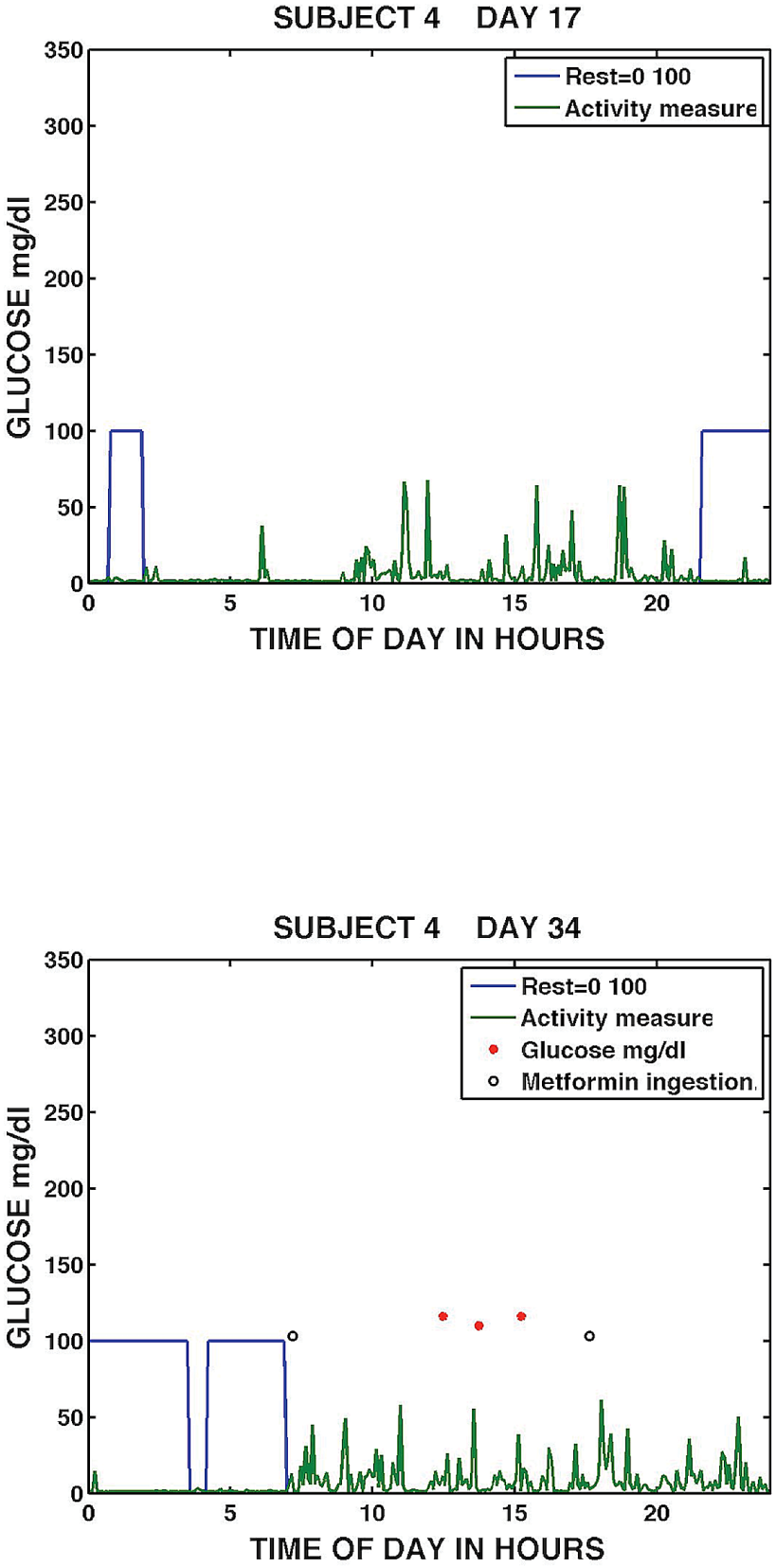


Figure 11. Daily medication taking, sleep/rest, activity, and glucose measurement for Subject 4, Day 17 (top), and Day 34 (bottom).

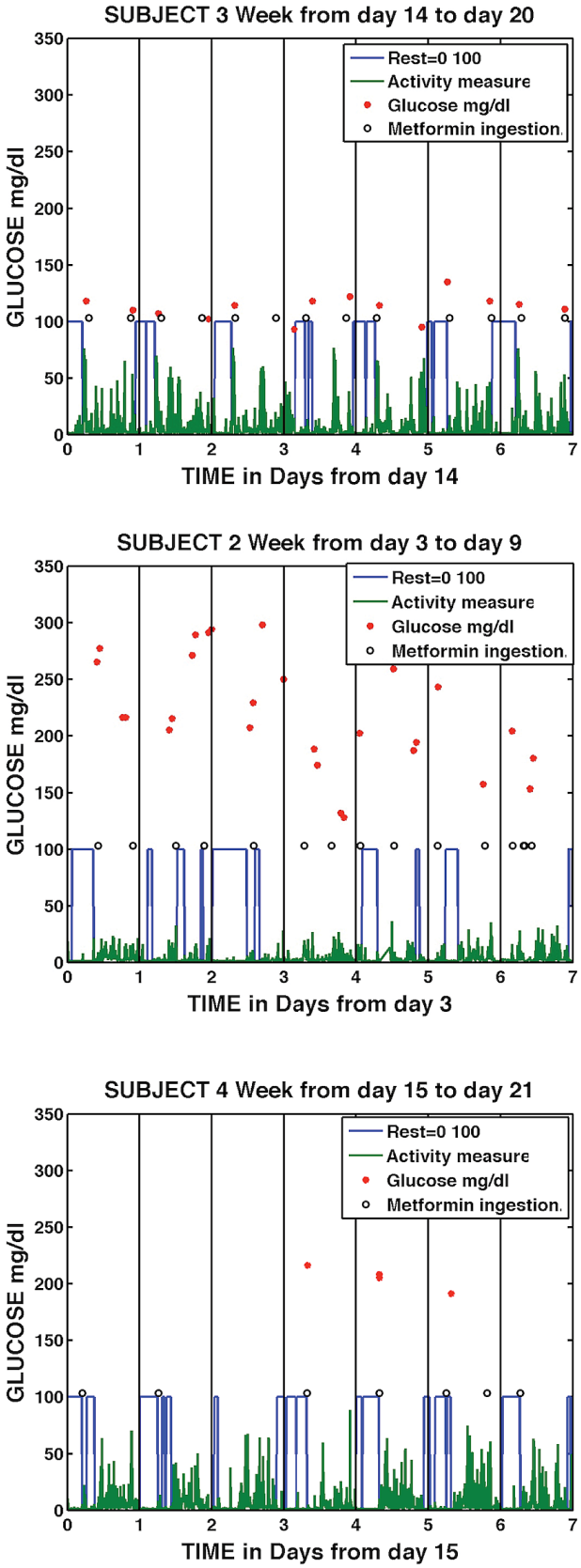


Data Visualizations Over Weekly Periods

While daily graphs demonstrated the ability of the DHFS to provide detailed insights into individual daily patterns of behavior, we wanted to capture both the detail of the daily analysis with longitudinal patterns of behavior, so we generated visualizations using the data input over weekly periods. Figure 12 show samples of graphs combining medication ingestion, sleep/rest, activity, and glucose measurement (both the time of day the glucose measurement took place and the actual glucose

level are represented) over weekly time frames. The sample graphs chosen either represent the typical longitudinal pattern of that subject over the course of the study or include patterns associated with incomplete medication-taking. Figure 12 shows examples of these, for Subjects 2, 3, and 4. (Weekly graph examples for Subjects 1 and 5 are available as Graphs 7 and 8 in Multimedia Appendix 1). Figure 12 shows Subject 3 over a 1-week period from Days 14-20, with regular periods of sleep/rest, exercise, active daytime periods, and glucose measurements taken twice daily with all readings below 150 mg/dl. Subject 2 is shown over a 1-week period from Days 3-9, with erratic and often interrupted sleep/rest patterns, four medication dose ingestions on Day 9, varying numbers of blood glucose measurements, mostly greater than 180 mg/dl, and generally low levels of activity. Subject 4 is shown on Days 15-21 of the trial, with regular activity, variable sleep/rest length, and missed multiple medication doses, particularly in the evening. Subject 4 took four blood glucose measurements during this period and had elevated glucose readings.

Figure 12. Weekly medication taking, sleep/rest, activity, and glucose measurement for Subject 3, Days 14-20 (top); Subject 2, Days 3-9 (middle); and Subject 4, Days 15-21 (bottom).



Analysis of Sleep/Rest and Medication-Taking Behavior

The daily and weekly visualizations suggested there may be some association with variation in sleep pattern and medication ingestion in some subjects, particularly Subject 2. To evaluate whether there was a relationship between sleep/rest and medication-taking behavior in the individual patients, we looked at the correlation between (1) total hours of sleep/rest the

previous night and pill taking the next day, and (2) sleep/rest disruptions (breaks in sleep between 10 p.m. and 8 a.m.) and medication-taking behavior the following day for each subject over the entire study period. Tables 1 and 2 show these correlations. The medication-taking behavior of Subjects 2 and 4 appeared to be significantly affected by the amount of sleep/rest they had the previous night. Subject 2 also appeared to have a robust relationship between the absence of breaks in sleep/rest between 10 p.m. and 8 a.m. and the likelihood of taking metformin medication the following day. Larger studies are needed to fully evaluate the relationship between amount of sleep/rest and medication adherence.

Table 1. Total hours of sleep/rest the previous night correlated with medication-taking adherence the next day.

Subject	Correlation coefficient (*r*)	*P* value
1	-.158	.433
2	.475	.022[a]
3	.206	.236
4	.350	.050[a]
5	.188	.321

[a]*P*<.05

Table 2. Number of breaks in sleep/rest between 10 p.m. and 8 a.m. correlated with medication-taking adherence the next day.

Subject	Correlation coefficient (*r*)	*P* value
1	-.143	.427
2	-.468	.009[a]
3	.136	.424
4	-.116	.506
5	.066	.722

[a]*P*<.05

Discussion

Principal Findings

The DHFS is the only system to date that can detect actual medication ingestion events. It also captures dense physiological data simultaneously. This study aimed to use modern methods of visual analytics to represent continuous and discrete data from this novel sensor system, plotting multiple different data types simultaneously to evaluate the potential of the DHFS to capture longitudinal patterns of medication adherence. The DHFS was able to provide remote monitoring of ingestion events and physiological metrics in the natural setting over the entire period of the study. High levels of continuous patch wearing with an early prototype were demonstrated in this study (current monitor patch versions are four generations from the version used).

Our study demonstrated a number of findings. Visualization of the data with simultaneous variable plotting, integrating physiologic and medication ingestion data, provided useful detailed information on longitudinal medication-taking and timing adherence patterns beyond traditional summary statistics. Varying the time interval over which the variables were visualized provides complementary data, with visualizations over a 24-hour period demonstrating the ability to reconstruct basic daily behavior patterns in relation to medication ingestion. While there was some overlap of behavior in this small sample, essentially each subject emerged as having their own distinct longitudinal pattern. Even if that pattern was one of variability, such as Subject 2, who showed widely variable patterns of medication ingestion and timing with highly variable morning and daily routines, including sleep/rest patterns. In contrast, our analyses also enabled us to look at the behavior patterns of Subject 3, a patient with type II diabetes, who was highly adherent to the prescribed regimen and whose glucose measures remained under 150 mg/dl over the period of the study. The regularity of this subject's daily routine, including sleep/rest cycles and level of exercise, was striking in comparison to some of the other subjects. As the number of these types of analyses using the DHFS over wide populations grows, it will be also be important to increase our understanding of how highly adherent and optimally self-managed patients behave. This will enable us to identify "success habits" and share those with other patients. The focus of adherence consultations can then include not just "how you are failing," but also generalized examples of "how to succeed."

One of the most significant strengths of the visualizations presented is that they encompass idiographic data analysis techniques that can focus on individual variability over time. These methods are uniquely suited to the analysis of individually tailored interventions evolving over time to promote medication adherence. The initial graphs on timing of ingestions and missed doses may allow the health care provider and patient to discuss patterns of medication-taking across a monitored time period and to focus on the time of day patients may need the most support. Addition of the 24-hour graphs provide detailed

information on patterns of activity and sleep/rest on days when doses were missed and may allow a more in-depth interaction with the patient on the types of support needed. To illustrate how this information could be used in practice, in discussion with Subject 2, the health care provider could extend the interview on factors affecting this patient's medication adherence to include sleep/rest patterns and other disorders associated with significant sleep disturbance, such as depression, hyperthyroidism, chronic pain, gastroesophageal reflux disease, to try to understand whether the patients' daily patterns are the result of untreated concurrent conditions or a reaction to stressors, or both. The visualizations provide the opportunity to extend the health care patient interview allowing broader personalized intervention to support treatment success beyond the use of medication reminders alone, which would be unlikely to successfully support medication adherence in Subject 2. However, Subject 4, who most frequently took his medication after waking, may well respond to reminders alone, particularly missed dose reminders, timed around his waking. Similarly dose reminders may work well in the evening time for Subjects 1, 4, and 5, particularly missed medication reminders around dinner time, to reduce the number of missed medications in the evening. The fully developed DHFS is capable of delivering near real-time feedback, which can be incorporated into individually tailored patient missed-dose reminder interventions. Thus the visualizations tell individual stories for each subject that can inform intervention and future management to support medication adherence and patient self-management.

A major stated aim of this paper is to provide and explore modes of data visualization that are accessible to both health care worker and patient consumer. This requires visualizations to preserve the accuracy of the data, while maintaining accessibility to the maximum number of individuals without prior training. Despite the density of the multiple different data types summarized by some of the visualizations, it was possible to develop graphs that could be easily understood and potentially suitable for use by patients and health care workers with minimal training. Health care workers in particular have very little time, and continuous data streaming of individual variables can easily overwhelm providers with data that may be largely unusable. As stated in the introduction, visual analytics is an emerging discipline that has shown significant promise in addressing many of these information overload challenges [18]. In data-rich illustrations, every data point has value, when such illustrations are examined closely [19]. Further, as Tufte emphasizes, a key take-away point is that data-rich graphics do not simply represent the data in visual form but can reveal what the data mean [19]. We contend that an example of this principle is the multiple data stream visualizations over 24 hours, where only by visualizing this data could we appreciate that we were able to reconstruct the broad structure of a person's day and see how their medication-taking behavior was related. Plotting data streams together, providing a data-rich representation, was more meaningful than plotting each data stream individually and revealed information that would not have been appreciated if each data stream had been plotted individually.

Based on visualizations showing variability in sleep/rest and medication-taking behavior in some subjects, we evaluated potential correlations between medication-taking behavior sleep/rest patterns. This analysis suggested medication-taking behavior in 2 individual subjects was significantly influenced by sleep/ rest patterns over the period monitored. Other researchers have found sleep disturbance, especially when reported with depression, is associated with poor medication adherence [22,23]. Larger studies over longer periods of time would be needed to definitively establish whether sleep disturbance is significantly correlated with non-adherence in certain individuals and in general.

As these visualizations could prove useful and relevant in clinical practice, investigation of their ease of use and utility to health care workers and patients is currently in progress. While our analyses across varying time intervals provided complementary data, using a weekly interval of analysis we were able to provide much of the detail of daily structure in combination with longitudinal patterns over a 1-week period. Thus, we estimate that the weekly visualizations will prove the most useful interval of evaluation in future studies incorporating tailored individual interventions to support medication adherence and optimal self-management. The addition of subject input such as personal event logs would further increase the impact of these visual analyses of DHFS data and enrich feedback that could be given to individuals to guide self-management.

In future, as the number of these analyses and use of the DHFS system grows, reference databases on patterns of longitudinal medication adherence and self-management patterns will accumulate and measurable estimates of comparability of longitudinal patterns to large sample populations will be available. Ultimately, we anticipate that machine-learning techniques will make predictive interventions possible to support longitudinal medication adherence and patient self-management.

Limitations

The major limitation of this work is the study size. Work is currently underway to further refine analytic algorithms within larger studies. Co-ingestion of an edible sensor whenever taking metformin, as occurred in this user experience study, is now being replaced with combined formulations of edible sensor and medication [24]. The focus of this work is analysis of medication-taking and physiological correlates. Limited comment is made here on the adequacy of glycemic control of type II diabetes in these subjects. Further, rigorously designed and larger studies will be necessary to evaluate the DHFS as a tool for monitoring and improving glycemic control within type II diabetic self-management.

Conclusions

Visualizations integrating medication ingestion and physiological data from the DHFS over varying time intervals captured detailed individual longitudinal patterns of medication adherence and self-management in the natural setting. Visualizing multiple data streams simultaneously, providing a data-rich representation, revealed information that would not have been appreciated by plotting data streams individually. Such analyses provided data far beyond traditional adherence summary statistics and may form the foundation of future personalized predictive interventions to drive longitudinal

adherence and support optimal self-management in chronic diseases such as diabetes.

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Conflicts of Interest

YB was employed by and is currently a consultant to Proteus Digital Health, which created the Digital Health Feedback System.

Multimedia Appendix 1

Supplementary graphs.

[PDF File (Adobe PDF File), 1MB - mhealth_v3i4e108_app1.pdf]

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Abbreviations

DHFS: Digital Health Feedback System
FDA: Food and Drug Administration

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Original Paper

Health App Use Among US Mobile Phone Owners: A National Survey

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Abstract

Background: Mobile phone health apps may now seem to be ubiquitous, yet much remains unknown with regard to their usage. Information is limited with regard to important metrics, including the percentage of the population that uses health apps, reasons for adoption/nonadoption, and reasons for noncontinuance of use.

Objective: The purpose of this study was to examine health app use among mobile phone owners in the United States.

Methods: We conducted a cross-sectional survey of 1604 mobile phone users throughout the United States. The 36-item survey assessed sociodemographic characteristics, history of and reasons for health app use/nonuse, perceived effectiveness of health apps, reasons for stopping use, and general health status.

Results: A little over half (934/1604, 58.23%) of mobile phone users had downloaded a health-related mobile app. Fitness and nutrition were the most common categories of health apps used, with most respondents using them at least daily. Common reasons for not having downloaded apps were lack of interest, cost, and concern about apps collecting their data. Individuals more likely to use health apps tended to be younger, have higher incomes, be more educated, be Latino/Hispanic, and have a body mass index (BMI) in the obese range (all $P<.05$). Cost was a significant concern among respondents, with a large proportion indicating that they would not pay anything for a health app. Interestingly, among those who had downloaded health apps, trust in their accuracy and data safety was quite high, and most felt that the apps had improved their health. About half of the respondents (427/934, 45.7%) had stopped using some health apps, primarily due to high data entry burden, loss of interest, and hidden costs.

Conclusions: These findings suggest that while many individuals use health apps, a substantial proportion of the population does not, and that even among those who use health apps, many stop using them. These data suggest that app developers need to better address consumer concerns, such as cost and high data entry burden, and that clinical trials are necessary to test the efficacy of health apps to broaden their appeal and adoption.

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KEYWORDS

cell phones; mobile apps; telemedicine

Introduction

As of 2015, 64% of the overall US population and 82% of persons aged 18-49 years owned an app-enabled mobile phone [1]. Additionally, 15% of the population now owns a mobile phone-connected wearable device, such as a Fitbit or smartwatch [2]. As such, it is not surprising that mobile phone apps, which focus on health, fitness, or medical care (ie, health apps), have become highly popularized. Over 40,000 health-related apps were available for download from the Apple iTunes store alone as of 2013 [3]. While many people may first associate health apps with fitness and diet-focused apps (eg, Lose It!, MapMyFitness, and MyFitnessPal), the category spans numerous domains inclusive of prevention/lifestyle, self-diagnosis, provider directories, diagnosis/education, prescription filling, and treatment compliance. For instance, health apps such as iStayHealthy and PozTracker exist to track HIV medication and personal health statistics (eg, CD4 count), and WellDoc exists for diabetes management.

The field of mobile health apps is still in a nascent stage and is characterized by a number of limitations, both in terms of sophistication of the apps themselves as well as in knowledge of consumer profiles. Most health apps have not been designed with input from health care and behavior change professionals. A detailed analysis found that among apps classified as "health and fitness" or "medical," only one-fifth offered the possibility of facilitating actual behavioral or physical changes versus nonevidence-based gimmicks or simple information provision [3]. Most apps advertised as health related have limited functionality, “do little more than provide information,” and do not offer tracking or data input options [3]. Indeed, a recent review of physical activity apps found that none provided evidence-based guidelines for aerobic activity and only 2% did so for resistance training [4].

Data is also limited with regard to consumer opinions and usage patterns of health-related apps. One survey of pediatric practices in New York found that 35% of parents and 17% of teens had used a health-related app [5], but this study primarily focused on adolescents and recruited a small sample (n=148). Others have only examined specific apps, for instance, reporting demographics of MapMyFitness users [6], or have surveyed specific populations such as those with health insurance [7].

Additionally, developers typically do not release information on the number of users and the extent to which consumers continue to use apps over time. Download statistics and feedback ratings from app stores are available, but such data lack validity and do not provide detailed information with regard to important information such as demographics of users, primary reasons people download health apps, barriers to use, consistency of use, and reasons for noncontinuance. Given this lack of population-based data on health apps, the goal of this study was to survey multiple aspects of health app use from a consumer perspective using a diverse sample of mobile phone users in the United States.

Methods

Study Design and Sample

A cross-sectional survey of 1604 mobile phone users in the United States was conducted in June 2015. Toluna, a survey management company, hosted the survey and recruited participants. Toluna identified potential participants by emailing their existing panel of respondents and by posting targeted online advertisements. Once respondents clicked on the Toluna survey link, they were screened for the following eligibility criteria: aged 18 years or older, spoke English, and owned a mobile phone. Those who were eligible completed an online informed consent document. As surveys of technology use tend to include more females and persons from higher socioeconomic backgrounds, we employed Toluna’s quota sampling capability to attempt to achieve the following demographic distribution: 50% female; 50% having completed high school or fewer years of education; 60% earning less than US $50,000 per year; and 30% Latino/Hispanic, 30% black, 30% white, and 10% Asian or other. Respondents received points for completing the survey through Toluna, which they could redeem for rewards. Respondents were required to indicate an answer before moving on to the next question, but could review and change previous answers. Each question appeared individually on a unique page. Start and stop times were assessed and only surveys completed within less than 120 minutes were analyzed. Toluna sent the authors a deidentified data file. The New York University School of Medicine Institutional Review Board approved all study procedures.

Survey Items

The survey consisted of 36 questions encompassing the following domains: (1) sociodemographic characteristics, (2) history and reasons for health app use/nonuse, (3) perceived effectiveness of health apps, (4) reasons for stopping use, and (5) standard health questions (eg, tobacco use, weight, height, medical diagnoses, physical activity, and eating behaviors). As there was no precedent for app use items, our research team developed app-related questions and field-tested them among a diverse team of colleagues with expertise in survey development. Questions were presented to each participant in the same order as there was a necessary logical order; however, the order of within-item responses was randomly assigned to reduce response-set bias. The survey took participants an average of 9 minutes to complete.

Data Analysis

Descriptive statistics were calculated for all items. Open-ended responses were examined qualitatively using thematic analysis. In particular, we used an inductive qualitative analytical approach [8]. Two coders examined the data and determined overarching categories. Representative quotes were selected for each theme. Regarding the quantitative analysis, given the high prevalence (>50%) of app users (primary outcome), we employed multivariable Poisson regression—GENMOD procedure in SAS (SAS Institute Inc)—using methods outlined by Zhao [9]. The analysis assessed the following demographic correlates of ever having downloaded a health app: age, sex, race/ethnicity, education, income, body mass index

(BMI)—underweight, overweight, or obese versus normal weight—and self-reported diagnosis of any current chronic health condition. Statistical significance was determined by *P* values less than .05. All statistical analyses were conducted using SAS version 9.3 (SAS Institute Inc).

Results

Demographic and Health Characteristics

A total of 7189 people visited the survey page, and 6871 (95.58%) agreed to participate. Of the 6871 who agreed to participate, 2089 (30.40%) completed the entire survey and 485 of these (23.22%) were removed due to overfilling of the demographic quotas. The mean age of the analytic sample was 40.1 years (SD 15.7) and ranged from 18-81 years. A total of 49.56% (795/1604) of the sample was female, and 60.38% (960/1590) had annual incomes of less than US $50,000 per year. In terms of race/ethnicity, the sample was 25.44% black (408/1604), 7.11% Asian (114/1604), 35.47% white (569/1604), 27.87% Latino/Hispanic (447/1604), and 2.87% other (46/1604) (Table 1). Figure 1 shows the spatial distribution of the sample throughout the United States by self-reported residential ZIP codes.

In terms of health, only 16.40% (263/1604) reported they never engaged in physical activity for at least 15 minutes, 34.04% (546/1604) had BMIs in the normal range, and 62.03% (995/1604) were overweight or obese. Only 50.69% (813/1604) considered themselves overweight, and 51.12% (820/1604) thought their health was very good or excellent. Almost a quarter (353/1604, 22.01%) smoked cigarettes every day and 12.16% (195/1604) on at least some days. The most prevalent medical diagnoses respondents reported having were hypertension (364/1604, 22.69%), high cholesterol (319/1604, 19.89%), depression (267/1604, 16.65%), obesity (198/1604, 12.34%), and diabetes (163/1604, 10.16%) (Table 1; see Multimedia Appendix 1 for the full list of items and responses).

Figure 1. US distribution of sample by ZIP code.

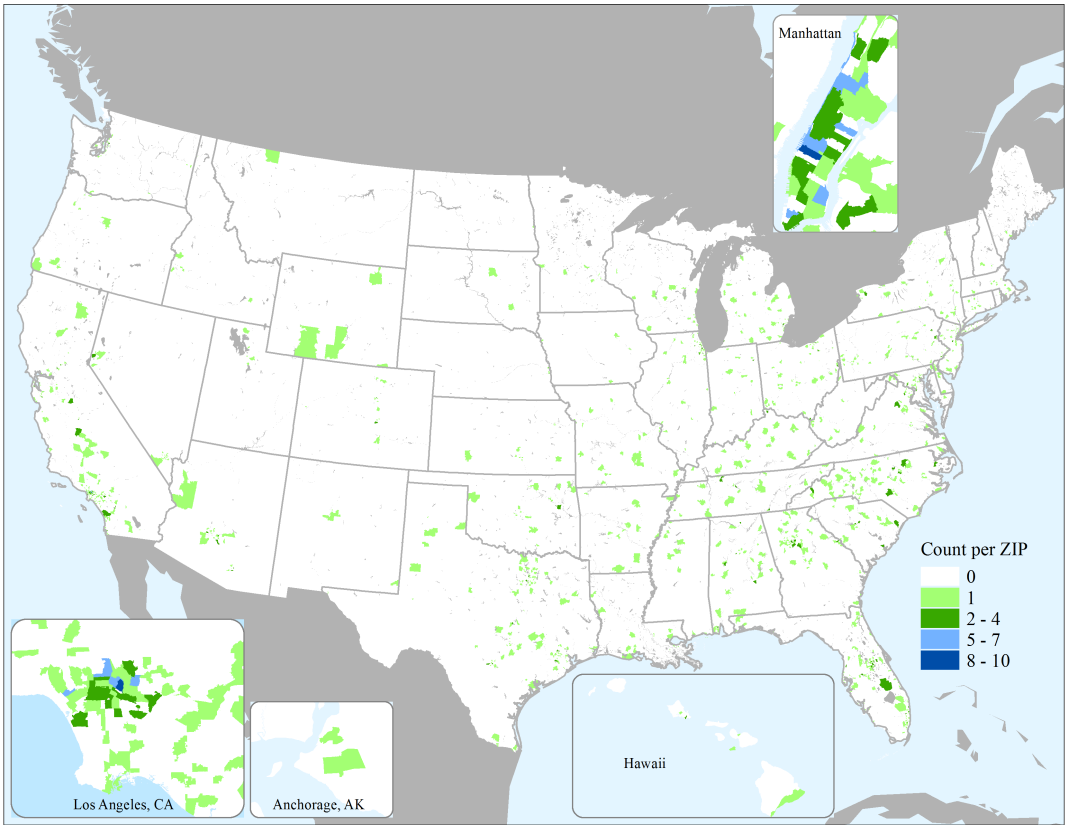

Table 1. Sociodemographic and health characteristics of the sample (abridged [a]) (n=1604).

Item	Characteristic	n (%)
Sex	Female	795 (49.56)
Race/ethnicity		
	African American or black	408 (25.44)
	Asian American or Asian	114 (7.11)
	White or Caucasian	569 (35.47)
	Native American/Pacific islander	20 (1.25)
	Latino/Hispanic	447 (27.87)
	Other	46 (2.87)
Born in the United States	Yes	1445 (90.09)
Education		
	Less than 12th grade	79 (4.93)
	High school degree or GED[b]	722 (45.01)
	Some college/vocational school/apprenticeship	399 (24.88)
	Bachelor's degree	276 (17.21)
	Graduate degree (master's, PhD, MD, etc)	128 (7.98)
Household income		
	Less than US $25,000	463 (28.87)
	US $25,000-49,999	497 (30.99)
	US $50,000-74,999	218 (13.59)
	US $75,000-99,999	195 (12.16)
	US $100,000+	231 (14.40)
Region of country (n=1594) [c]		
	Northeast	322 (20.20)
	Midwest	242 (15.18)
	South	636 (39.90)
	West	394 (24.72)
In general, would you say your health is...?		
	Poor	44 (2.74)
	Fair	204 (12.72)
	Average	536 (33.42)
	Very good	603 (37.59)
	Excellent	217(13.53)
Body mass index (kg/m^2)		
	<18.5 (underweight)	63 (3.93)
	18.5-24.9 (normal)	546 (34.04)
	25-29.9 (overweight)	438 (27.31)
	≥30 (obese)	557 (34.73)
Do you consider yourself to be...?		
	About the right weight	683 (42.58)
	Underweight	108 (6.73)
	Overweight	813 (50.69)

[a]Table 1 is an abridged version; see Multimedia Appendix 1 for the full list of items and responses.

[b]GED: General Educational Development.

[c]Not all participants provided ZIP code information.

Health App Usage

Most respondents used mobile phones sold by Apple (565/1604, 35.22%) or Samsung (567/1604, 35.35%). AT&T was the most popular service provider (420/1604, 26.18%) followed by Verizon (342/1604, 21.32%) and T-Mobile (311/1604, 19.39%). With regard to health app use, 58.23% (934/1604) had downloaded an app to track their health in the past, with 41.6% (389/934) having downloaded more than five health-related apps. The most frequent reasons people reported for downloading health apps were to track how much physical activity they were getting (493/934, 52.8%), to track what they ate (445/934, 47.6%), to lose weight (437/934, 46.8%), and to learn exercises (318/934, 34.0%).

The majority (612/934, 65.5%) of respondents opened their health apps at least once per day, and 44.4% (415/934) used their apps for 1-10 minutes. Belief that apps keep data secure was high, with 44.0% (411/934) and 34.2% (319/934) reporting they moderately or very much trusted their apps' data security. Similarly, 44.5% (416/934) and 36.8% (344/934) thought that apps recorded data with moderate or high accuracy, respectively. The three most popular methods by which respondents learned about apps was searching the app store (327/934, 35.0%), from friends/family (287/934, 30.7%), and Web searches (170/934, 18.2%). Only 20.37% (210/1031) of respondents reported that a doctor had recommended a health app to them. A large proportion noted that they would never pay anything for a health app (662/1604, 41.27%), 20.26% (325/1604) would pay up to US $1.99, and 22.76% (365/1604) would pay at most between US $2.00 and US $5.99.

Nonuse and Reasons for Discontinuing Use

Among the 41.77% (670/1604) who had never downloaded a health app, the most important reasons they had not done so were lack of interest (181/670, 27.0%), high cost (156/670, 23.3%), lack of trust in apps collecting their data (103/670, 15.4%), concern that they would use too much data (85/670, 12.7%), and belief that they did not need a health app (73/670, 10.9%). A large portion of the sample (427/934, 45.7%) reported that they downloaded health apps they no longer use. The most frequent reasons for discontinuance were the following: took too much time to enter data (190/427, 44.5%), loss of interest (173/427, 40.5%), hidden costs (154/427, 36.1%), apps were confusing to use (140/427, 32.8%), and did not like that the apps shared their data with friends (124/427, 29.0%) (Table 2; see Multimedia Appendix 2 for the full list of items and responses).

Preferences for App Features

Overview

In terms of potential features and uses for health apps, 57.36% (920/1604) would be somewhat or very interested in the ability to make appointments with, or write to, their doctors, and 62.16% (997/1604) would like to view their medical records. Less than 10% of respondents used these features at the time of the study. Three primary themes emerged from the analysis of open-ended items, as discussed below.

Weight Loss, Calorie Tracking, Nutrition, and Physical Activity

The majority of comments concerned the intersection of food intake, physical activity, and weight management. A major theme was that participants wanted apps to provide more specific and personalized recommendations, regarding exercises/activities and what to eat than are currently available. For instance, a number of respondents noted they wanted an app to assess their health history, and for the app to tell them what exercises they should do and what they should and should not eat. For instance, participants wanted an app to tell them the following: "Remind me what food I have to eat every single day," "Tell me when I am eating the wrong food," and "Suggest exercises, customize workouts to fit my goals and needs." Generally, they wanted apps that helped them reach specific exercise and nutrition goals rather than just "lose weight." Tracking was also an important theme, with participants wanting more accurate and easier-to-use methods of showing how many calories they consume and burn daily. Participants stated, "I would want it to tell me how many calories I need to consume for the day and keep track so I know when I need to stop eating," "I wish I could take a picture of my food and it would count the calories for me," and "[I would want the app to] Speak to me if I tell it what I ate and tell me how many calories I ate then tell me how many calories I have left to eat that day." A number of participants also wanted the apps to help keep them motivated, particularly using humor and encouragement. Specifically, they noted, "I would like it to have something entertaining for me to focus on should I ever get unwanted food cravings as a distraction," and they wanted it to have "...an alarm to remind me to get moving, 'it's time for your 30 min. walk, hop to it chubby'... it has to be funny !!!"

Table 2. Characteristics of health app use (abridged [a]).

Survey item	Response category	n (%)
3. Have you ever downloaded an “app” to track anything related to your health? (n=1604)	Yes	934 (58.23)
4. How many health-related smartphone apps have you used?[a] (n=934)		
	1-5 apps	545 (58.4)
	6-10 apps	104 (11.1)
	11-20 apps	160 (17.1)
	More than 20	125 (13.4)
5. Please check off all the reasons you have used health apps. (check all that apply) [a] (n=934)		
	Track how much activity/exercise I get	493 (52.8)
	Help me watch what I eat	445 (47.6)
	Weight loss	437 (46.8)
	Show/teach me exercises	318 (34.0)
	Track a health measure	266 (28.5)
6. Rank the most important reasons you have not downloaded a health app. [a] (n=670)		
	I’m just not interested in health apps	181 (27.0)
	They cost too much to buy	156 (23.3)
	I don’t trust letting apps collect my data	103 (15.4)
	My health is fine and I don’t need one	73 (10.9)
	They would use too much of my data	85 (12.7)
	They are too complicated to use	72 (10.7)
7. What would be the maximum amount you would pay for a health-related app? [a] (n=1604)		
	I wouldn't pay anything	662 (41.27)
	US $1-US $3.99	400 (24.94)
10. How much do you trust that your health apps automatically record your data accurately? [a] (n=934)		
	Moderately trust	416 (44.5)
	Very much trust	344 (36.8)
13. To what extent do you think health apps have improved your health? (n=934)		
	Made worse/didn't help at all	98 (10.5)
	Just a little bit/somewhat improved	563 (60.3)
	Very much improved	273 (29.2)
14. Which health apps do you currently have on your phone? (free text) [a] (n=934)		
	Walgreens	123 (13.2)
	Fitbit	107 (11.5)
	Weight Watchers	59 (6.3)
	Web MD	36 (3.9)
	Nike+	34 (3.6)
15. Are there any health apps you downloaded and no longer use? (n=934)	Yes	427 (45.7)

Survey item	Response category	n (%)
16. What reasons do you no longer use them? (check all that apply) [a] (n=427)		
	Takes too much time to enter data	190 (44.5)
	Lost interest	173 (40.5)
	There were hidden costs	154 (36.1)
20. Has a doctor ever recommended you use a health app? (n=1031)	Yes	210 (20.37)

[a]Table 2 is an abridged version; see Multimedia Appendix 2 for the full list of items and responses.

Communication With Medical Care Systems

The next most common theme involved improved communication with the health care system. Many participants simply wanted an app to show their medical records, while others wanted to easily make appointments and to engage in two-way communication with their doctors. Having reminders for medication taking and appointments was also commonly mentioned. Some respondents wanted an all-in-one system such that they did not have to use multiple medical-related apps. Participants described a desire for an app that would keep track of all their vital statistics (weight, diet, sleep, etc) to better communicate with their doctors during appointments (ie, linking with and inputting these data into their medical record). For instance, one participant stated, "I would want to be able to easily schedule appointments with my doctor, write to my doctor with concerns, have my doctor be able to respond to my concerns, view my medical records, be able to track my medications." Another participant noted that interaction with the electronic health record (EHR) would enable "...graphs showing my health as time passes."

Medical Monitoring

A number of participants mentioned they wanted an app to track symptoms and make possible diagnostic suggestions. They wanted to "...have full access to my health records and the doctors I have to see, to diagnose some health concerns or issues by symptoms," and to "Help me to diagnose myself by typing in my symptoms" or "...jotting down symptoms that are ailing me at the time, so I could send them to my doctor."

Correlates of Having Downloaded an App

Having downloaded a health app was significantly ($P \leq .05$) related to younger age, being Latino/Hispanic, having a higher income, having greater than high school education, and obesity. There was also a trend for African Americans to be more likely to use health apps (relative risk [RR]=1.12, $P=.07$). No significant relationship was found with sex or history of chronic disease after controlling for other variables (Table 3).

Table 3. Multivariable correlates of health app usage.

Variable	RR[a] (95% CI)	*P*
Intercept		<.001
Female (vs male)	0.98 (0.90-1.07)	.64
Age in years (each year)	0.98 (0.97-0.98)	<.001
Race/ethnicity (vs white)		
African American or black	1.12 (0.99-1.26)	.07
Asian American or Asian	0.94 (0.78-1.13)	.51
Latino/Hispanic	1.19 (1.06-1.33)	.002
Education (vs less than high school)	1.12 (1.03-1.22)	.01
Income (vs US $50,000-$74,999)		
US $100,000+	1.33 (1.16-1.51)	<.001
US $75,000-$99,999	1.32 (1.16-1.50)	<.001
US $25,000-$49,999	0.98 (0.85-1.13)	.81
Less than US $25,000	0.79 (0.67-0.93)	.004
Diagnosed with chronic disease	0.97 (0.89-1.05)	.42
BMI [b] (vs normal weight)		
Underweight	0.88 (0.75-1.05)	.15
Overweight	1.09 (0.98-1.21)	.10
Obese	1.11 (1.01-1.22)	.02

[a]RR: relative risk.

[b]BMI: body mass index.

Discussion

Principal Findings

This study examined health app usage among a socioeconomically and geographically diverse sample of US mobile phone users. A little over half (934/1604, 58.23%) of mobile phone users had downloaded a health-related mobile app. Fitness and nutrition were the most common categories of health apps used, with most respondents using them at least daily. A fairly large proportion of respondents, however, had not used health apps. Common reasons for not doing so were lack of interest, cost, and concern about apps collecting their data. Persons more likely to use health apps tended to be younger, tended to have higher income and greater education, were Latino/Hispanic, and had a BMI in the obese range. Latinos/Hispanics were 20% more likely to use a health app than those who identified as white. Individuals earning between US $25,000 and US $74,999 per year were equally likely to use health apps. Likelihood of use increased by about 30% for those earning more than US $75,000 per year, but decreased for those earning less than US $25,000. There was a trend for increased use of health apps and higher BMI, with those who were obese being about 11% more likely to use apps than persons in the normal range. Cost was a significant concern among respondents, with a large proportion indicating that they would not pay anything for a health app. Interestingly, among those who had downloaded health apps, trust in their accuracy and data safety was quite high, and most felt that the apps had improved their health. About half of the app users (427/934, 45.7%) had stopped using some health apps, primarily due to high data entry burden, loss of interest, and hidden costs.

Comparison With Prior Work

Our study provides a novel and meaningful contribution to the literature, as few prior studies have specifically examined the use of mobile health apps. While not as detailed as this survey, a 2012 Pew Research Center survey (n=3014) of mobile phone use provides some data to compare trends. The Pew survey found that 19% of mobile phone users had at least one health app, whereas the rate we found was significantly higher at 58.23% (934/1604) [10]. Similar to our findings, the Pew survey indicated that younger persons and those with higher incomes and education were more likely to use a health app. In contrast to our findings, the Pew survey found that women were more likely to use health apps. We also assessed additional variables not examined in the Pew survey, finding that health app use was higher among those identifying as Latino/Hispanic, and among those who were obese. As the prevalence of health app use has increased significantly from 19% to 58% since the Pew survey was conducted, the difference in use among men and women may have leveled out as more men adopted their use.

In terms of the most common reasons for health app use, our findings mirror those of two previous surveys indicating that exercise, nutrition, weight management, and blood pressure apps are most popular among consumers [7,10]. Interestingly, only 18% of respondents to a survey conducted by HealthMine

stated they liked to learn health and wellness information from an app [7]. While we did not ask an exactly similar question, our data indicate a much higher regard for health apps, with respondents noting they found that apps improved their health and wanted increased features. Qualitative responses from our study indicated that consumers want improved health information capacity from their apps, with more specific and tailored health suggestions. This discrepancy may indicate that consumers have problems with the interfaces available on current apps rather than the concept of getting health information from apps in general.

Strengths and Limitations

This study has number of strengths. First, the survey was conducted with a highly diverse national sample. In contrast to methods used by many online surveys, the quota sampling technique allowed us to collect data from groups that are typically under-represented in surveys of technology use: specifically, oversampling persons from racial/ethnic minority backgrounds, those with high school or less education, and those earning less than US $50,000 per year. Second, the survey assessed novel information, especially with regard to reasons for use and discontinuance of health apps, and analyzed demographic and health-related correlates of health app use. Third, the survey adhered to advanced online survey methodology, such as IP address verification, and employed a large sample size resulting in highly reliable estimates of survey responses (95% CI ± 2.5). In terms of limitations, the responses relied on self-report and included only persons who participate in panels managed by the survey company. In addition, these are cross-sectional data, and while helpful for examining health app usage at one point in time, it is likely that people vary their use patterns over time. These limitations should have minimal impact on the validity of the data, however, given the sampling and survey management techniques employed.

Future Directions

Survey data from this study provides critical insight with regard to directions for the development of health-related mobile apps. While many people use health apps, a substantial portion of the population does not, primarily due to lack of interest or perceived need. Many consumers find that the abilities of apps remain limited. It appears that people are using apps to manage health conditions related to weight, which may be attributable to the proliferation at present of apps related to activity and nutrition, as well as use of mobile phone-connected wearable devices, such as the Fitbit and Apple Watch. The primary reason respondents stopped using apps was the demanding nature of data entry. Burdensome manual recording requirements are especially prominent in calorie- and nutrition-tracking apps. Open-ended responses indicated a strong interest in apps that would simplify their use and improve the ability of apps to track data without manual entry. Mobile monitoring devices are only in their infancy, primarily consisting of watches and similar bands (eg, Jawbone). Further development of more advanced and integrated products, such as biometric smart clothing [11] and even noninvasive sensor devices that continuously monitor end points such as blood glucose [12], will further the advancement of health apps by overcoming data entry burden.

It also appears that many respondents were unaware of apps that accomplish some of the functions they wanted (eg, scanning a barcode to show nutritional information). This finding suggests that apps are generally difficult to find among the large number available, and supports the need for refereed clearinghouses that could help consumers evaluate features and make sense of available apps. Cost also appears to be a significant concern both for nonusers and users, with most people unwilling to pay anything for apps and discontinuing use when they find that in-app payments are required. Consumer aversion to cost may be due to the perception that mobile phone use and apps are primarily associated with communication and entertainment. While consumers are relying on their apps for health advice, they do not yet appear to see them as providing information that warrants payment.

App developers need to do more to promote the value and worth of their apps if they are to sustain a viable business model. This will likely necessitate increased openness to partnering with researchers to conduct well-designed trials examining the efficacy of health-directed apps. The state of the evidence for health apps is significantly lacking [4,13-15], limiting enthusiasm and perceived value among both consumers and health care professionals. Recommendations by health care providers could be influential in promoting health app adoption, but our results indicate that few health care providers currently advise health app use. This may be attributable to limited familiarity, but also to a lack of clinical trial evidence [16], which would likely be a foundational requirement for providers to feel comfortable that they are making sound recommendations to their patients [17]. Companies have attempted to create app formulary systems whereby providers can "prescribe" an app [18], but a disconnect remains between developers' goals and the level of data that health care providers need in order to feel confident in recommending an app [19]. While not as rigorous, other techniques to promote value could involve review and ratings by expert panels such as those conducted by the UK's National Health Service, which has launched a refereed library of health apps [20]. Additionally, academic/business partnerships such as those developed between Walgreens and Stanford Persuasive Technology Lab [21] could improve apps through increased integration of evidence-based principles into app design. Nevertheless, to truly be accepted within the health care infrastructure, apps will likely require clinical trial evidence in line with standard academic medical practices.

Our findings also suggest that a largely untapped market exists for apps that improve interactions with the health care system. Open-ended responses indicated a significant desire for apps that can help consumers coordinate their health care services. Consumers would like apps that can accomplish basic tasks such as making and being reminded of appointments and viewing information about their medications, as well as more complex capabilities such as syncing with their electronic health record and automatically uploading daily health status data. Consumers find that these features would allow them and their health care team to more accurately communicate and monitor their health. Integration, however, is important as consumers reported they do not want to toggle between multiple apps to accomplish these goals. Interest in syncing capabilities is also

common among health care providers, 93% of whom noted that they would find value in apps connected to an EHR [22]. Health care integration capabilities of apps are likely lagging behind development of fitness and nutrition-focused apps due to data security and regulatory concerns among health care information technology professionals [23]. We also found high rates of distrust of data security among consumers who have not used a health app and dislike of apps that shared data with friend networks. Further penetration of apps into the health care sector will clearly require resolving information security and privacy issues, which is an objective of the Precision Medicine Initiative. Privacy is a significant issue for marketing and sponsorship of health apps with other recent surveys finding that few people would use an app sponsored by their employer insurance program, likely due to privacy concerns [7]. Thus, it appears that consumers would prefer health apps developed by private companies or trusted health care sources, such as hospitals or health care systems that operate separately from insurers. Results indicate that future work by researchers and app developers should include a focus on qualitative methods and usability testing to further define the requirements of quality apps and to ensure health apps meet expectations of end users.

Conclusions

This research suggests that critical problems remain for the future of health apps. At present, apps are concentrated in the activity and weight-loss domain, which may limit perceptions of their utility for large portions of the population. Pricing and data entry problems also emerged as important concerns. App development by for-profit companies is a primary pathway for creating innovative products, but companies need to better respond to these user barriers in order for these products to reach a broader population. For health care systems, significant interest exists among users for communicating with doctors and using apps to seek health care-related services. The potential in this use of apps is great, and health care systems must embrace this technology and work through privacy and regulatory barriers to supply the services that patients are already requesting.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Sociodemographic and health characteristics of the sample.

[PDF File (Adobe PDF File), 33KB - mhealth_v3i4e101_app1.pdf]

Multimedia Appendix 2

Characteristics of health app use.

[PDF File (Adobe PDF File), 54KB - mhealth_v3i4e101_app2.pdf]

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Abbreviations

BMI: body mass index
EHR: electronic health record
GED: General Educational Development
RR: relative risk
VA: Veterans Affairs

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