Pilot and Feasibility Test of a Mobile Health-Supported Behavioral Counseling Intervention for Weight Management Among Breast Cancer Survivors

Lisa M Quintiliani1, PhD.; Devin M Mann2, MD, MS; Marissa Puputti1, B.S.; Emily Quinn3, M.A.; Deborah J Bowen4, PhD

1Boston University, Department of Medicine, Section of General Internal Medicine, Boston, MA, United States
2Boston University, Department of Medicine, Section of Preventive Medicine and Epidemiology, Boston, MA, United States
3Boston University, School of Public Health, Data Coordinating Center, Boston, MA, United States
4University of Washington, School of Medicine, Department of Bioethics & Humanities, Seattle, WA, United States

Corresponding Author:
Lisa M Quintiliani, PhD.
Boston University
Department of Medicine
Section of General Internal Medicine
801 Massachusetts Ave
Crosstown Center
Boston, MA, 02118
United States
Phone: 1 617 638 2777
Fax: 1 617 638 5580
Email: lmquinti@bu.edu

Abstract

Background: Health behavior and weight management interventions for cancer survivors have the potential to prevent future cancer recurrence and improve long-term health; however, their translation can be limited if the intervention is complex and involves high participant burden. Mobile health (mHealth) offers a delivery modality to integrate interventions into daily life routines.

Objective: The objective of this study was to evaluate the effects of a one-group trial with a pre-post evaluation design on engagement (use and acceptability), physiological (weight), behavioral (diet and physical activity), and other secondary outcomes.

Methods: The 10-week intervention consisted of mHealth components (self-monitoring of selected diet behaviors via daily text messages, wireless devices to automatically track weight and steps) and 4 motivational interviewing–based technology-assisted phone sessions with a nonprofessionally trained counselor. Participants were overweight breast cancer survivors who had completed treatment and owned a smartphone. Weight was measured objectively; diet and physical activity were measured with brief self-reported questionnaires.

Results: Ten women participated; they had a mean age of 59 years (SD 6), 50% belonged to a racial or ethnic minority group, 50% had some college or less, and 40% reported using Medicaid health insurance. Engagement was high: out of 70 days in total, the mean number of days recording steps via the wristband pedometer was 64 (SD 7), recording a weight via the scale was 45 (SD 24), and responding to text messages was 60 (SD 13); 100% of participants completed all 4 calls with the counselor. Most (90%) were very likely to participate again and recommend the program to others. Mean weight in pounds decreased (182.5 to 179.1, mean change \(-3.38 \text{ [SD 7.67]}\)), fruit and vegetable daily servings increased (2.89 to 4.42, mean change 1.53 \text{ [SD 2.82]}), and self-reported moderate physical activity increased in metabolic equivalent of task (MET) minutes per week (2791 to 3336, mean change 545 \text{ [SD 1694]})

Conclusions: Findings support the conduct of a fully powered trial to evaluate the efficacy of mHealth as a feasible intervention modality for breast cancer survivors. Future research should employ accelerometer-based physical activity assessment and consider development of an all-in-one app to integrate devices, messaging, and educational content and other mHealth approaches to support behavioral counselors conducting weight management interventions.
Introduction

Owing to multiple factors including improved treatment, the 5-year survival rate in the United States for women with breast cancer for 2003-2009 is 90%, up from 75% in 1975-1977 [1]. There are >3.1 million female breast cancer survivors in the United States [1]. Increasing attention is now being focused on how to increase quality of life, prevent future cancer recurrence, and reduce risk of chronic diseases, such as cardiovascular disease and diabetes [2].

For people who have already completed treatment and are either disease free or whose cancer is stable, the 2012 Nutrition and Physical Activity Guidelines for Cancer Survivors from the American Cancer Society recommend the following: (1) achieving a healthy weight; (2) moderate-vigorous physical activity of 150 minutes per week and strength training 2 times per week; and (3) eating a diet that is high in vegetables, fruits, and whole grains [2]. However, translation of these findings into population-wide, inexpensive, sustainable programs has to date proven largely unrealized. Key questions remain in terms of how interventions should be optimally designed for maximum effectiveness and reach to the entire cancer survivor population. This is particularly true for populations that face health disparities, those who belong to low-income or racial/ethnic minority groups, as these populations often experience less favorable cancer outcomes and higher rates of obesity compared with other populations [3,4].

Mobile health (mHealth) involves the use of any mobile technology, such as mobile phones and wireless sensors, to deliver and share personalized health information [5]. Mobile health holds immense promise to deliver behavioral interventions that are embedded into individuals’ daily routines, that are highly personalized to individuals’ behaviors, health conditions, and daily routines, and have the potential to reach diverse populations. Smartphone ownership is now higher among black, non-Hispanic (70%) and Hispanic (71%), populations compared with white (61%) populations [6]. In concordance with the promise of mHealth intervention modalities, an increasingly large body of literature now exists that has been examined in multiple systematic reviews covering particular mHealth strategies [7,8] (eg, apps, text messaging) and health topics [9,10] (eg, weight, physical activity, nutrition). A systematic scoping review focusing on weight management published in late 2015 revealed that half of the 457 articles reviewed were published within the past 2 years [10]. Bennett and colleagues [11] also reviewed the use of electronic health (eHealth) interventions for weight management among racial/ethnic minority populations and found that interventions featuring more advanced features of eHealth technology and the use of mHealth technologies are needed. Although more research is needed to summarize and recommend best practices, intervention designers can use information from these reviews to help inform the design of future interventions, including which mHealth strategies to select, how to implement them, and how to combine human behavioral counselors with mHealth components.

Although there is much that can be learned from this body of literature that can be applied to the optimal design and development of interventions, there are very few published studies using technology (mobile or Web-based) to deliver interventions to cancer survivors. This is important because cancer treatment can result in a range of circumstances that affect diet and physical activity behaviors of cancer survivors, including changes in taste and smell, physical discomfort such as lymphedema, and changes in social support structures [2].

A systematic review conducted by Goode et al [12] analyzed print, telephone, and Web-based interventions for diet, physical activity, or weight management among cancer survivors. Of 27 studies, 3 were delivered using the Web (1 of which was via the social media platform Facebook) and none were delivered via text message. In addition, none of the studies specifically targeted minority race or ethnic groups. The review concluded with support for broad-reach methods, specifically telephone based, and the need to integrate newer technologies, such as texting and mobile technologies, to deliver interventions with potential for broad reach to diverse populations of cancer survivors. Although some studies have since been published [12] or are in development [13] that have some mHealth components such as texting or use commercial weight loss applications [14], published studies evaluating interventions with multiple mHealth components for weight management and related behaviors among cancer survivors are limited.

Given the body of evidence for the importance of lifestyle behaviors for cancer survivors and the increasingly large literature on mHealth interventions, the time is ripe to deliver mHealth interventions to adult cancer survivors. Our approach is to use multiple mHealth strategies to augment a human counselor-delivered behavioral intervention to address weight management-related behaviors. The purpose of this study was to evaluate a weight management mHealth intervention for breast cancer survivors on the following feasibility and preliminary efficacy outcomes: engagement (use and acceptability); physiological (weight); behavioral (diet and physical activity); and psychological and other outcomes (self-efficacy, perceived stress, social support, sleep, loss of control over eating, fatigue). The selection of these outcomes served to provide a detailed picture of the effects of the intervention directly both on weight and weight-related behaviors and factors that influence these behaviors. The feasibility data served to help the research team decide if this...
intervention approach is suitable for further testing and refinement in future studies [15].

**Methods**

**Study Design**

We conducted a one-group pilot study with a pre-post evaluation design to evaluate the feasibility and preliminary efficacy of a human counselor–delivered behavioral intervention incorporating multiple mHealth strategies targeting weight management behaviors among breast cancer survivors (ClinicalTrials.gov NCT02387671). The protocol was approved by the Boston University Medical Center Institutional Review Board.

**Formative Feedback**

Before the start of the pilot study, we conducted individual interviews with 4 women from our target population to obtain feedback on mHealth intervention design features. Informed consent was obtained from participants at the start of the interview. Interview participants had a mean age of 62.3 years (SD 7.5) and body mass index (BMI) of 33.5 kg/m² (SD 5.0); 1 (25%) reported being Hispanic, 2 (50%) black or African American, and 1 (25%) white. Suggestions for features of an mHealth intervention included providing educational/culturally relevant resources, offering information on opportunities for social support (ie, recommending local support groups), and encouraging the use of mobile phone apps and programs to search the Internet for more information. Concerns included participants believing recalls of food intake could be inaccurate and maintaining an appropriate number of interactions between the counselor and participants. Additionally, the need for a thorough orientation to any mHealth strategies (devices, apps, the agenda for counseling sessions) was noted. We refined our intervention approach in response to the findings.

**Recruitment and Participants**

Recruitment methods included contacting individuals on a university-maintained registry of people interested in research, postings on a university website for those looking for research studies, postings on university-wide emails, recontacting individuals from the interviews described above, announcements at the hospital-based breast cancer survivor support group, posting paper flyers, and posting notices on Craigslist and in a local newspaper. Through all methods, individuals were asked to call or email the study team to request further information. When the individual contacted the study team, she was screened for eligibility. Eligibility criteria were 18 years of age or older, able to speak and read English, female, 2 years or more since breast cancer diagnosis (self-reported) and 6 months or more since end of cancer treatment (surgery, radiation, or chemotherapy), self-reported overweight or obese (BMI greater than 25 kg/m², as assessed by self-reported height and weight), be an owner of an Android or iOS-platform smartphone, and have WiFi at home. Exclusion criteria included contraindications for physical activity, pregnancy, presence of a pacemaker or other internal medical device, and medical conditions (dementia, active cancer, anorexia) or any other condition in the opinion of the study team deemed to make the participant unsuitable for inclusion in the study. For eligible individuals, a staff member then scheduled an in-person baseline study visit at our research office space at an academic medical center. At this visit, a staff member measured their height and weight, asked whether they would be willing to share Fitbit account information (log-in/password) with the study team, and observed their ability to navigate programs on a smartphone to verify eligibility. Individuals who had a BMI of 25.0 kg/m² or greater according to measured height and weight, were willing to share Fitbit account information, and appeared able to navigate programs on their smartphone (from the research staff members' perspective) were eligible to participate. We chose these eligibility criteria in order to compose a sample that would be similar to a sample targeted in a future, larger-scale, randomized controlled efficacy trial, yet also be feasible to obtain within the parameters of a small-scale pilot study (for example, it was determined that it would not be feasible to provide smartphones to individuals who did not already own one). This sample also served to target breast cancer in early survivorship phases or later such that cancer treatment-related physical effects have decreased for most women [16].

Eligible participants were asked to provide their informed consent to participate and were enrolled into the intervention and asked to complete a paper-and-pencil baseline questionnaire. Participants were recontacted 10 weeks after baseline to complete a follow-up paper-and-pencil questionnaire. Participants received US $20 for completing each questionnaire and received the wristband pedometer and scale devices to keep.

**Intervention**

After enrollment, participants engaged in a counselor-delivered intervention with multiple mHealth components [17] over 10 weeks (Textbox 1). Participants engaged in self-monitoring nutrition behaviors; automatic (ie, passive) weight and behavioral monitoring via a scale and wristband pedometer; and received technology-assisted phone counseling from a behavioral health counselor.
Textbox 1. Description of intervention components.

| Intervention component | Description |
|------------------------|-------------|
| **1. Self-monitoring** | Daily text messages sent to ascertain participants' dietary intake immediately after enrollment and for the next 10 weeks. Each message was the same and contained 5 questions that prompted a yes or no response or a numerical value. Responses from the messages were recorded and conveyed to the health counselor to assist in the counseling sessions. Messages corresponded to content in the telephone counseling sessions. |
| **Questions:** | |
| • Did you eat more than one high-calorie snack? | |
| • Did you eat food from a restaurant or fast-food place? | |
| • Did you drink more than one sugary drink? | |
| • Did you eat until you were uncomfortably full? | |
| • How many servings of fruits & vegetables did you eat? | |
| **2. Automatic weight and behavioral monitoring** | Weight scale Participants were asked to record their body weight daily using Fitbit Aria [18,19]. Wristband pedometer Participants were asked to wear the wristband daily to track their steps and hours of sleep by wearing the Fitbit Flex wristband. Weight, steps, and sleep recordings were synchronized through WiFi (weight) or via cellular Bluetooth (steps & sleep) connections to the participants' Fitbit app installed on their mobile phone. |
| **3. Technology-assisted counseling** | Counselor training A behavioral health counselor conducted telephone sessions with participants. The counselor underwent training in study-specific protocols (eg, recording phone calls) and motivational interviewing techniques, such as viewing and discussing a series of 4 training videos, practicing and receiving feedback on counseling with a structured call guide. Before interacting with participants, the study director rated a recorded telephone session between the counselor and a volunteer for attaining a sufficient level of motivational interviewing spirit and empathy (eg, asking permission, supporting the participant and not confronting or giving advice). The coach had a bachelor’s degree in nutrition. Counseling session topics and ordering Participants engaged in 4 phone calls with the study counselor, one every other week. The first and second calls focused on physical activity, sleep, and fatigue. The third and fourth calls focused on 2 out of 4 possible nutrition topics chosen by the participant. The 4 nutrition topics were sugary beverages, fruits and vegetables, snacking, and cooking/preparing meals/eating out. This approach was intended to bring about small decreases in daily energy intake by making small daily behavioral changes, such as substituting no-calorie beverages for sugary beverages. This “small changes” approach has demonstrated efficacy in multiple populations, including overweight or obese adults [20] and multicultural socioeconomically disadvantaged adults [21,22]. Counseling session content The counselor used a structured, yet flexible, guide to conduct the sessions that followed principles of motivational interviewing [23], the Social Contextual Model [24], and was adapted from a guide used in a previous study [25]. The guide was built in Excel and used embedded logic to flow from section to section. The calls included 6 sections: introduction (introduce the topic of the call, review privacy information); provide feedback on current behavior compared with recommendations, obtain information on participant’s behavior (eg, what type of physical activity she enjoys); assess importance & confidence in changing the behavior; assess influences on their behavior (eg, finances, stress, family/friends/neighborhood); assess motivation to change behavior; if motivated, conduct collaborative goal setting, and if not, prompt discussion of what it would be like to change). In each subsequent call, the counselor checked in about what was discussed in the previous call. Participants’ data collected during self-monitoring were used to guide the counseling sessions. All calls were recorded. Resources The counselor had a list of weblinks for resources around each topic area (such as sleep, fatigue, fruits and vegetables, and so on) The resources were compiled from sources that were both reputable and user-friendly. Examples included choosemyplate.gov, mayoclinic.org, and cdc.gov. Resources were sent to the participants if the participant requested them. Asynchronous messages During interim weeks between calls, the counselor maintained contact with the participants through 3 asynchronous text messages per week to monitor their progress in the study. The messages served several purposes: |
| • The counselor would monitor whether participants were tracking behaviors (self-monitoring and automatic weight and behavioral monitoring). If participants were not tracking all behaviors at least 5 days per week, the counselor would try to resolve any issues with tracking (eg, device difficulties, confusion on how or what to track). If they were meeting the 5-day-per-week target, the counselor encouraged them to keep up the good work. |
• The counselor would check in on any goals the participant had set during the counseling calls (e.g., “Hi, it looks like you have not yet reached your goal of walking 10,000 steps 7 days per week. Do you have any questions about this goal? Have you been experiencing any difficulties?” or “Just checking in on the goal you set to plan out your meals every Sunday evening. How has that been going? Have you experienced any successes? Any difficulties?”).
• The counselor would send a message to the participant 2 days before each counseling call as a reminder of the upcoming call.
• The participants and counselor also used asynchronous messages as needed to ask/answer questions, comments, or requests for information.

Measures

Our measures comprised both feasibility (engagement and acceptability) and outcomes (physiological, behavioral, and secondary variables), because it is important to both demonstrate the feasibility of the intervention approach and emulate the evaluation approach of a future larger-scale efficacy trial.

Engagement and Acceptability

We collected data on number of calls completed, duration of calls, number of responses received to text messages, and valid days of wearing the wristband pedometer and recording a weight on the scale. Daily step counts of <100 and >50,000 were considered invalid. We also asked open- and closed-ended questions on the appeal of the intervention, perception of the number of calls received, perceptions of setting and meeting health goals, how likely they would be to participate again, and suggestions for improving the intervention.

Evaluation Outcomes

Physiological

Weight and height were measured using a protocol in which participants removed shoes or footwear, outer garments, and so on and stood with their back against a wall [26]. The same procedure was used at 10 weeks. Height measurements were recorded to the nearest ¼ inch, rounding down [27]. Height was measured at baseline only.

Behavioral

Diet was measured by an 18-item food frequency questionnaire, the PrimeScreen, which has been compared for reliability and validity against a full-length food frequency questionnaire and biomarkers [28]. Correlation coefficients for comparability between dietary components of the PrimeScreen and a full-length food frequency questionnaire range from .36 for other vegetables to .82 for eggs and for nutrient estimates range from .48 for folate, .58 for fiber, to .59 for saturated fat. Correlation coefficients for comparability between PrimeScreen and biomarkers were .33 for vitamin E and .43 for both beta-carotene and lutein/xanthin. Participants indicate the frequency with which they eat each food, with 5 response category options, ranging from less than once a week to twice or more per day. Foods were then grouped into categories: fruits and vegetables, 6 items; whole grains, 1 item; red and processed meats, 2 items; whole fat dairy foods, 1 item; and high calorie, 3 items. A composite diet score was calculated, with a score from 0 (worst) to 100 (best) assigned for intake from each of the 5 food categories and then averaged [29].

Sugary beverage intake was evaluated via the 15-item Beverage Questionnaire (BEVQ-15) [30], which assesses frequency of past-month consumption of common sugary drinks including sweetened juice drinks, soda, and energy drinks. Of note, 100% fruit juice is not included as a sugary drink. The BEVQ-15 has shown adequate reliability and validity with 4-day food intake records (Spearman r value = .673 for grams of total sugar-sweetened beverages).

Fast-food intake was assessed via a 1-item question: “In the past 7 days, how many times did you eat fast food? Include meals eaten at work, at home, or at fast food restaurants, carryout or drive-through, such as food you get from Dunkin Donuts, McDonald’s, Panda Express, or Taco Bell,” which was based on a question derived from a large population-based survey [31]. Response options were as follows: less than once per week, once per week, 2-4 times per week, nearly daily, and twice or more per day.

Physical activity was measured using the International Physical Activity Questionnaire (IPAQ) [32,33]. This tool provides an internationally relevant measure of physical activity, which has undergone extensive validity and reliability testing. The IPAQ covers all areas of moderate and vigorous physical activity in everyday life, with questions in regard to job-related physical activity; transportation physical activity; housework and family care physical activity; recreation, sport, and leisure time physical activity; and time spent sitting.

Psychological and Other Secondary Variables

Self-efficacy was assessed separately for fruit and vegetable intake and physical activity, asking the participants to rate their confidence that they can perform these behaviors under a variety of circumstances [34]. We used the 4-item Perceived Stress Scale [35] (sample question: “In the last month, how often have you felt that you were unable to control the important things in your life?”), with response options ranging from 0 (never) to 4 (very often). Social support was assessed using the question “How much can you rely on family or friends for support and encouragement?” with answer options a lot, somewhat, and not at all [36]. Sleep was evaluated using the question “How often during the past 4 weeks did you get enough sleep to feel rested upon waking up?” with response options never, rarely, sometimes, often, and very often [37]. Perceived loss of control over eating was evaluated using the validated 7-item Loss of Control over Eating Scale-Brief, with 5 response options ranging from 1 (never) to 5 (very often) [38]. Fatigue was evaluated using a scale of 0-10 with 0 being “no fatigue” ranging up to 10 as fatigue “as bad as you can imagine” [39,40].

Statistical Analysis

All surveys and measurements for outcomes were conducted in person and collected on paper. Surveys were then entered in duplicate into REDCap [41] by two individuals and compared for accuracy. Data were examined descriptively using...
frequencies, means, and medians. Analysis was conducted using SAS version 9.3 (Cary, NC).

Results

Participant Flow Through the Study

In response to our recruiting efforts, 27 individuals were screened for eligibility. Fourteen were excluded for not meeting the eligibility criteria; the most frequent reasons for being ineligible were not having home WiFi and/or a smartphone (n=9) and not being overweight/obese (n=3). Three individuals were eligible but declined to participate, because of perceived need for more assistance with using the devices, perceptions that the intervention would offer a prescribed diet and exercise program, and not being able to enroll until a later date. Therefore, 10 participants were enrolled. Recruitment methods for enrolled participants were hospital-based breast cancer support groups (n=4), the patient registry (n=3, of whom 2 gave formative feedback), hospital-wide email (n=2), and the newspaper advertisement (n=1). All participants completed both the baseline and follow-up surveys.

Participant Characteristics

Characteristics of participants are listed in Table 1. Approximately half reported belonging to a minority race/ethnic group and 40% reported financial limitations as reflected by being covered by Medicaid insurance or receiving food assistance benefits within the past 2 years. The majority accessed the Internet on their mobile phone but less frequently used their mobile phone for health-related purposes. Self-reported breast cancer stage was early or 0-I (60%) and stage II or above (40%). Mean self-reported years since diagnosis was 7.1 (SD 4.0).
## Table 1. Participant characteristics.

| Characteristic                                                                 | N=10 |
|-------------------------------------------------------------------------------|------|
| **Age in years, mean (SD)**                                                   | 58.6 (6.1) |
| **Ethnicity/race, n (%)**                                                     |      |
| Hispanic white                                                                | 1 (10) |
| Non-Hispanic black                                                            | 3 (30) |
| Non-Hispanic white                                                            | 5 (50) |
| Other                                                                         | 1 (10) |
| **Highest level of education, n (%)**                                         |      |
| High school graduate/GED\(^a\) or lower                                      | 2 (20) |
| Some college/university                                                       | 3 (30) |
| College/university graduate or higher                                         | 5 (50) |
| **Work for pay, n (%)**                                                       |      |
| Yes                                                                           | 6 (66.7) |
| No                                                                            | 3 (33.3) |
| **Type of insurance, n (%)**                                                  |      |
| Medicaid (ie, public insurance) only or in combination                        | 4 (40) |
| Private insurance                                                             | 5 (50) |
| Medicare (ie, public insurance for older adults) & private                    | 1 (10) |
| **Delayed taking medication due to cost, n (%)**                              |      |
| Yes                                                                           | 2 (20) |
| **Household receives food stamps, n (%)**                                     |      |
| Yes                                                                           | 4 (40) |
| **Always had enough money to buy food, n (%)**                                |      |
| Yes                                                                           | 9 (90) |
| **Use the Internet at least occasionally, n (%)**                             |      |
| Yes                                                                           | 10 (100) |
| **Send or receive email at least occasionally, n (%)**                        |      |
| Yes                                                                           | 10 (100) |
| **Access the Internet on a mobile handheld device, n (%)**                   |      |
| Yes                                                                           | 9 (90) |
| **Use mobile phone to download apps, n (%)**                                  |      |
| Yes                                                                           | 9 (90) |
| **Have apps to track health, n (%)**                                          |      |
| Yes                                                                           | 4 (40) |
| **Receive text updates or alerts about health or medical issues, n (%)**      |      |
| Yes                                                                           | 0 (0) |
| **Social support**                                                            |      |
| A lot                                                                         | 5 (50) |
| Somewhat                                                                     | 5 (50) |
| Not at all                                                                    | 0 (0) |

\(^a\)GED=General Education Diploma
Engagement and Acceptability

Out of 70 opportunities (7 days a week × 10 weeks) to record self-monitoring and automatic behavioral monitoring data, mean number of responses was 60 (SD 13), median 64 (range 24-68) for responding to text messages; 64 (SD 7) for recording a step measurement, median 52 (range 3-67); 45 (SD 24) for recording a weight measurement, median 67 (range 52-70); and 43 (SD 19) for recording a sleep measurement, median 47 (range 9-63).

All participants completed all 4 counseling calls. Mean duration of calls 1 to 4 was 29 (SD 9), 22 (SD 11), 28 (SD 14), and 24 (SD 13) minutes, respectively. Of 20 nutrition-related calls completed (2 per participant), there were 8 calls about fruits and vegetables, 6 about cooking, 5 about snacking, and 1 call about sugary drinks. To illustrate the data collected during the intervention, median number of recorded steps and mean weight are presented in Figure 1.

For acceptability, 9 participants reported setting health goals during the last 3 months and all participants reported meeting some (n=8) or all (n=2) of their personal goals. All participants rated the calls as very helpful in setting personal goals to change their health habits and felt the number of calls was “just right.” Whereas 2 participants responded that the number of text messages/emails from their counselor was “too many,” the other 8 felt the number was “just right.” Nine of 10 participants responded that it is “very likely” that they would participate again or recommend the program to others. However, 7 of 10 participants responded that it is “somewhat unlikely” or “not at all likely” that they would participate again if they had to pay for the program.

Written feedback included participants’ difficulty with using the devices (including seemingly erratic weight and sleep readings) and desire for self-monitoring diet behaviors in a more streamlined fashion. Participants noted the calls and the wristband pedometer and scale devices were helpful in setting and achieving goals.

Evaluation Outcomes

As listed in Table 2, there were beneficial changes in physiological and behavioral outcomes, including weight, nutrition behaviors (daily servings of fruits and vegetables and the composite diet score), and physical activity. Those reporting “often” or “very often” to feeling rested upon waking in the past 4 weeks increased from 5 at baseline to 7 at follow-up. Other variables showed minimal changes (such as self-efficacy) or nonbeneficial changes (such as intake of sugar-sweetened beverages). For fast-food consumption, 6 stayed at the same response, 2 increased from < 1 time per week to 1 time per week, 1 decreased from once per week to < 1 time per week, and 1 skipped this question at baseline. Beneficial changes were also reported for perceived fatigue, loss of control eating, and perceived stress.
Table 2. Change in behavioral, psychological, and other outcomes from baseline to 10-week follow-up.

| Outcome                          | Baseline mean (SD) | Baseline median (range) | Change mean (SD) | Change median (range) |
|---------------------------------|--------------------|-------------------------|-----------------|----------------------|
| Weight, pounds                  | 182.5 (24.9)       | 179.1 (23.4)            | −3.38 (7.67)    | 6.76 (13.31)         |
| Diet behaviors, servings/day    |                    |                         |                 |                      |
| Fruits & vegetables             | 2.89 (1.79)        | 4.42 (1.91)             | 1.53 (2.82)     |                      |
| Whole grains                    | 0.30 (0.31)        | 0.32 (0.30)             | 0.03 (0.33)     |                      |
| Whole fat dairy                 | 0.34 (0)           | 0.31 (0)                | −0.03 (0.28)    |                      |
| Red meat                        | 0.51 (0.42)        | 0.62 (0.76)             | 0.11 (0.92)     |                      |
| High calorie                    | 0.36 (0.31)        | 0.51 (1.07)             | 0.15 (0.86)     |                      |
| Diet composite score            | 60.16 (9.19)       | 66.91 (8.80)            | 6.76 (13.31)    |                      |
| Sugar-sweetened beverages, fluid ounces | 8 (7)          | 13 (15)               | 5 (13)          |                      |
| Low physical activity, MET-minutes/week\(^a\) | 1967 (3189)       | 3076 (2685)            | 1108 (3636)     |                      |
| Moderate physical activity, MET-minutes/week\(^a\) | 830 (0-10,584)   | 2473 (0-8262)          | 1029 (−6552 to 8064) |                      |
| Vigorous physical activity, MET-minutes/week\(^a\) | 2792 (4475)       | 3336 (4422)            | 545 (1694)      |                      |
| Vigorous physical activity, MET-minutes/week\(^a\) | 660 (0-14,175)    | 1755 (0-14,160)        | 345 (−3090 to 3360) |                      |
| Vigorous physical activity, MET-minutes/week\(^a\) | 1776 (4103)       | 2568 (3751)            | 792 (5565)      |                      |
| Vigorous physical activity, MET-minutes/week\(^a\) | 0 (0-13,200)      | 1080 (0-11,040)        | 0 (−10,320 to 10,560) |                      |
| Self-efficacy                   |                    |                         |                 |                      |
| Fruits & vegetables             | 3.1 (0.6)          | 2.9 (0.6)               | −0.3 (0.6)      |                      |
| Physical activity               | 3.0 (1.1)          | 2.9 (1.0)               | −0.1 (0.8)      |                      |
| Fatigue                         | 4.4 (2.1)          | 2.6 (1.6)               | −1.8 (0.8)      |                      |
| Loss of control eating          | 1.9 (0.8)          | 1.4 (0.5)               | −0.5 (0.7)      |                      |
| Perceived stress                | 5.1 (3.3)          | 4.7 (3.2)               | −0.4 (3.3)      |                      |

\(^a\)MET=Metabolic Equivalent of Task

Discussion

This mHealth-supported behavioral counseling intervention for weight management was feasible to implement, as demonstrated by high levels of engagement with the intervention components (self-monitoring, automatic behavioral monitoring, and counseling phone sessions) and high levels of acceptability with intervention components. In our study, out of 70 opportunities to answer self-monitoring text messages, the mean number of responses was 60, or 86%. Our findings compare favorably with other reported engagement outcomes in the literature. For example, in a study among overweight or obese women from racial/ethnic minority groups, one intervention component included daily text messages prompting self-monitoring with an accompanying feedback message. Among 26 intervention group participants, the adherence rate for responding to the message was 49% (SD 28) [18]. In another intervention using a wearable pedometer (the clip-on Fitbit) among women, mean number of days of wear-time was 106 out of 112 days (94%) [42], which is comparable with our data in which out of 70 opportunities to log a step count via Fitbit wristband pedometer, the mean number of times that participants recorded their steps was 64, or 91%. Taken together, our study has comparable outcomes with other research using mHealth strategies for weight or weight-related behaviors, such as physical activity. It is possible that high levels of engagement with intervention components are the result of the integration of mHealth into participants’ daily lives, allowing for simpler and more frequent self-monitoring.

In addition, there were several beneficial physiological, behavioral, and other variables. Notably, weight change decreased by a mean of 3.38 pounds, which reflects a 2% loss of baseline weight. Although this is lower than the generally accepted clinically meaningful weight loss level of 5%, our intervention was of a shorter duration (10 weeks) and of a moderate intensity level that may be able to be sustained over the long term. Combined with changes in diet and physical activity as well as changes in other variables such as fatigue and sleep, participation in the intervention led to multiple beneficial changes that could be further examined in a larger trial.

About half of our participants were reflective of a population facing health disparities (ie, low income or belonging to a racial/ethnic minority group). Others have examined the use of mHealth strategies among health disparity populations. For example, Smith and colleagues [43] examined the preferences of African American breast cancer survivors for lifestyle modification and found that peer-led sessions and incorporation...
of support groups would be important components of intervention strategies. The integration of human-based intervention components such as counselor-delivered phone calls with technology-related approaches was also supported by the weight management study conducted among breast cancer survivors by Spark and colleagues [44]. We ultimately decided to involve human coaching because it is not yet established that fully automated eHealth/mHealth interventions have comparable efficacy with interventions that utilize human counselors [11]. Thus, future directions for mHealth interventions for breast cancer survivors from health disparity-facing groups could investigate optimal ways of integrating human-based components, such as behavioral counseling, into mHealth-based interventions. The scalability of this approach can be broadened as community health workers/patient navigators are increasingly integrated into health care systems [45] and can support telephone-based delivery of behavioral interventions. This approach can become even more widely implemented as devices become more available across population groups (eg, among low-, medium-, and high-resourced groups) and data from these devices become better integrated with electronic medical records.

Limitations to our pilot study design include a lack of a control group and a small sample size. Although it is appropriate for sample sizes for pilot studies to be based on practical considerations based on recruitment and budgetary limitations [46], a larger sample size may have expanded our capacity to generate feasibility data. In addition, our eligibility criteria requiring ownership of a smartphone and home WiFi is also a limitation in that it may have led to bias in our sampling design [47]; our criteria may have excluded members of our target population (for example, women from low-income groups without access to home WiFi). These design decisions were made to enable the functionality of the weight scale (which relied on a WiFi connection) and because providing smartphones was beyond the financial resources of the study. However, in future work, we will select newer devices that do not rely on WiFi connectivity, and examine the option of providing lower-cost smartphones to those who do not own one. Another limitation is the lack of objective assessment of physical activity at baseline and follow-up time points via accelerometry. Our self-reported data on physical activity likely reflect an overestimation of physical activity, yet may still be useful in exploring the direction of change from baseline to follow-up time points. Similarly, the data on steps/day as measured by the wristband pedometer during the intervention period also reflected moderately high levels of physical activity. Moreover, other research has shown that the Fitbit Flex wristband pedometer can underestimate step count in treadmill walking and running [48]. Taken together, future studies may consider eligibility criteria in which participants have lower levels of physical activity upon entry to the study. Future research will also systematically capture cancer stage and treatment details from the medical record.

In conclusion, our findings demonstrate that a pilot test of an mHealth-supported behavioral counseling intervention conducted among breast cancer survivors was feasible and demonstrated some positive physiological and behavioral changes. Future work could examine this intervention approach in a larger study, powered to detect significant changes in weight, and further investigate optimal ways to integrate behavioral counseling with mHealth strategies.

Acknowledgments
This study was funded by a pilot grant award from the Boston University Center for Future Technologies in Cancer Care (NIH grant #: 5 U54 EB015403). We declare no financial disclosures or role of the sponsor in the review or approval of this manuscript. We would like to acknowledge assistance provided in research and data management by Ryan Manganelli, BS, and Danielle Sundermier.

Authors’ Contributions
LMQ and DMM contributed to the study design and LMQ, DMM, and MP contributed to the implementation, interpretation of results, and writing of the manuscript. EQ conducted data analyses and contributed to the writing of the manuscript.

Conflicts of Interest
None declared.

References
1. American Cancer Society. Cancer Treatment & Survivorship Facts & Figures. Atlanta: American Cancer Society; 2014. URL: http://www.cancer.org/acs/groups/content/@research/documents/document/acspc-042801.pdf [accessed 2016-02-18] [WebCite Cache ID 6fNQDwn1F]
2. Rock CL, Doyle C, Demark-Wahnefried W, Meyerhardt J, Courneya KS, Schwartz AL, et al. Nutrition and physical activity guidelines for cancer survivors. CA Cancer J Clin 2012;62(4):243-274 [FREE Full text] [doi: 10.3322/caac.21142] [Medline: 22539238]
3. American Cancer Society, Cancer Facts & Figures for African Americans 2011-2012. Atlanta: American Cancer Society; 2011. URL: http://www.cancer.org/acs/groups/content/@epidemiologysurveillance/documents/document/acspc-027765.pdf [accessed 2016-02-18] [WebCite Cache ID 6fNQID5ck]
4. Flegal KM, Carroll MD, Kit BK, Ogden CL. Prevalence of obesity and trends in the distribution of body mass index among US adults, 1999-2010. JAMA 2012 Feb 1;307(5):491-497. [doi: 10.1001/jama.2012.39] [Medline: 22253363]
5. Panayi ND, Mars MM, Burd R. The promise of digital (mobile) health in cancer prevention and treatment. Future Oncol 2013 May;9(5):613-617. [doi: 10.2217/fon.13.42] [Medline: 23647287]

6. Pew Research Center. The Smartphone Difference. 2015. URL: http://www.pewinternet.org/files/2015/03/PI_Smartphones_0401151.pdf [accessed 2016-02-18] [WebCite Cache ID 6fNOKdEnN]

7. Head KJ, Noar SM, Iannarino NT, Grant HN. Efficacy of text messaging-based interventions for health promotion: a meta-analysis. Soc Sci Med 2013 Nov;97:41-48. [doi: 10.1016/j.socscimed.2013.08.003] [Medline: 24161087]

8. Payne HE, Lister C, West JH, Bernhardt JM. Behavioral functionality of mobile apps in health interventions: a systematic review of the literature. JMIR Mhealth Uhealth 2015;3(1):e20 [FREE Full text] [doi: 10.2196/mhealth.3335] [Medline: 25803705]

9. Blackman KC, Zoellner J, Berrey LM, Alexander R, Fanning J, Hill JL, et al. Assessing the internal and external validity of mobile health physical activity promotion interventions: a systematic literature review using the RE-AIM framework. J Med Internet Res 2013;15(10):e224 [FREE Full text] [doi: 10.2196/jmir.2745] [Medline: 24095951]

10. Bardus M, Smith JR, Samaha L, Abraham C. Mobile Phone and Web 2.0 Technologies for Weight Management: A Systematic Scoping Review. J Med Internet Res 2015;17(11):e259 [FREE Full text] [doi: 10.2196/jmir.5129] [Medline: 26573984]

11. Bennett GG, Steinberg DM, Strout C, Lanphere M, Lane I, Askew S, et al. Electronic health (eHealth) interventions for weight management among racial/ethnic minority children: a systematic review. Obes Rev 2014 Oct;15 Suppl 4:146-158. [doi: 10.1111/obr.12218] [Medline: 25196411]

12. Goode AD, Lawler SP, Brakenridge CL, Reeves MM, Eakin EG. Telephone, print, and Web-based interventions for physical activity, diet, and weight control among cancer survivors: a systematic review. J Cancer Surviv 2015 Mar 11. [doi: 10.1007/s11764-015-0442-2] [Medline: 25757733]

13. Lee MK, Park H, Yun YH, Chang YJ. Development and formative evaluation of a web-based self-management exercise and diet intervention program with tailored motivation and action planning for cancer survivors. JMIR Res Protoc 2013;2(1):e11 [FREE Full text] [doi: 10.2196/resprot.2331] [Medline: 23612029]

14. McCarroll ML, Armbruster S, Pohle-Krauza RJ, Lyzen AM, Min S, Nash DW, von Gruenigen Vivian E. Feasibility of a lifestyle intervention for overweight/obese endometrial and breast cancer survivors using an interactive mobile application. Gynecol Oncol 2015 Jun;137(3):508-515. [doi: 10.1016/j.ygyno.2014.12.025] [Medline: 25681782]

15. Bowen DJ, Kreuter M, Spring B, Conroy DE, Spring B, Weinner D, et al. How we design feasibility studies. Am J Prev Med 2003 Sep;24(5):188-197. [Medline: 12918242]

16. Bennett GG, Steinberg DM, Stoute C, Lanpher M, Lane I, Askew S, et al. Electronic health (eHealth) interventions for health behavior interventions: applications for cancer prevention for working-class, multiethnic populations. Prev Med 2009 May;36(5):452-457 [FREE Full text] [Medline: 19696764]

17. Lutes LD, Daiss SR, Barger SD, Read M, Steinbaugh E, Winnett RA. Small changes approach promotes initial and continued weight loss with a phone-based follow-up: nine-month outcomes from ASPIRES II. Am J Health Promot 2012;26(4):235-238. [doi: 10.4278/ajhp.090706-Q216] [Medline: 22375574]

18. Bennett GG, Herring SJ, Pulco E, Stein EK, Emmons KM, Gillman MW. Web-based weight loss in primary care: a randomized controlled trial. Obesity (Silver Spring) 2010 Feb;18(2):308-313 [FREE Full text] [doi: 10.1093/oby/2009.242] [Medline: 19696764]

19. Bennett GG, Warner ET, Glasgow RE, Askew S, Goldman J, Ritzwoller DP, Be Fit, Be Well Study Investigators. Obesity treatment for socioeconomically disadvantaged patients in primary care practice. Arch Intern Med 2012 Apr 9;172(7):565-574 [FREE Full text] [doi: 10.1001/archinternmed.2012.1] [Medline: 22412073]

20. Bennett GG, Warner ET, Glasgow RE, Askew S, Goldman J, Ritzwoller DP, Be Fit, Be Well Study Investigators. Obesity treatment for socioeconomically disadvantaged patients in primary care practice. Arch Intern Med 2012 Apr 9;172(7):565-574 [FREE Full text] [doi: 10.1001/archinternmed.2012.1] [Medline: 22412073]

21. Rollnick S, Miller W, Butler C. Motivational Interviewing in Health Care: Helping Patients Change Behavior. New York: The GuilfordPress; 2008.

22. Sorensen G, Emmons K, Hunt MK, Barbeau E, Goldman R, Peterson K, et al. Model for incorporating social context in health behavior interventions: applications for cancer prevention for working-class, multiethnic populations. Prev Med 2003 Sep;37(3):188-197. [Medline: 12918242]

23. Quintiliani LM, Whiteley JA. Results of a Nutrition and Physical Activity Peer Counseling Intervention among Nontraditional College Students. J Cancer Educ 2016 Jun;31(2):366-374. [doi: 10.1007/s13187-015-0588-4] [Medline: 25994357]

24. Madden AM, Smith S. Body composition and morphological assessment of nutritional status in adults: a review of anthropometric variables. J Hum Nutr Diet 2016 Feb;29(1):7-25. [doi: 10.1111/jhn.12278] [Medline: 25420774]

25. Davis N, Murabito J, Rich S, Wartofsky MJ. Clinical Protocol Manual: Framingham Heart Study. 1994. URL: http://www.framinghamheartstudy.org/share/protocols/offspring_exam_5.pdf [accessed 2016-02-18] [WebCite Cache ID 6fNQR69IA]
28. Rifas-Shiman SL, Willett WC, Lobb R, Kotch J, Dart C, Gillman MW. PrimeScreen, a brief dietary screening tool: reproducibility and comparability with both a longer food frequency questionnaire and biomarkers. Public Health Nutr 2001 Apr;4(2):249-254. [Medline: 11299098]

29. Delichatsios HK, Friedman RH, Glanz K, Tennstedt S, Smigelski C, Pinto BM, et al. Randomized trial of a "talking computer" to improve adults' eating habits. Am J Health Promot 2001;15(4):215-224. [Medline: 11349340]

30. Hedrick VE, Savla J, Comber DL, Flack KD, Estabrooks PA, Nsiah-Kumi PA, et al. Development of a brief questionnaire to assess habitual beverage intake (BEVQ-15): sugar-sweetened beverages and total beverage energy intake. J Acad Nutr Diet 2012 Jun;112(6):840-849 [FREE Full text] [doi: 10.1016/j.jand.2012.01.023] [Medline: 22709811]

31. California Health Interview Survey. UCLA Center for Health Policy Research; California Department of Public Health; California Department of Health Care Services; 2009. URL: http://healthpolicy.ucla.edu/chiis/design/Documents/CHIS2009adultquestionnaire.pdf [WebCite Cache ID 6hG4iQ0xy]

32. Craig CL, Marshall AL, Sjöstöm M, Bauman AE, Booth ML, Ainsworth BE, et al. International physical activity questionnaire: 12-country reliability and validity. Med Sci Sports Exerc 2003 Aug;35(8):1381-1395. [doi: 10.1249/01.MSS.0000078924.61453.FB] [Medline: 12900694]

33. Yore MM, Ham SA, Ainsworth BE, Kruger J, Reis JP, Kohl HW, et al. Reliability and validity of the instrument used in BRFSS to assess physical activity. Med Sci Sports Exerc 2007 Aug;39(8):1267-1274. [doi: 10.1249/mss.0b101e3180618bb] [Medline: 17762359]

34. Sallis JF, Pinski RB, Grossman TL, Patterson TL, Nader PR. The development of self-efficacy scales for health related diet and exercise behaviors. Health Educ Res 1988;3(3):283-292. [doi: 10.1093/her/3.3.283]

35. Cohen S, Kamarck T, Mermelstein R. A global measure of perceived stress. J Health Soc Behav 1983 Dec;24(4):385-396. [Medline: 66681417]

36. Barrera M, Sandler I, Ramsay T. Preliminary development of a scale of social support - Studies on college-students. Am J Community Psychol 1981;9(4):435-447. [doi: 10.1007/BF00991874]

37. Buxton OM, Quintiliani LM, Yang MH, Ebbeling CB, Stoddard AM, Pereira LK, et al. Association of sleep adequacy with the maintenance of weight loss, physical activity, and dietary behavior change. JMIR Mhealth Uhealth 2015;3(3):e88 [2015, 10.2196/mhealth.4114]

38. Latner JD, Mond JM, Kelly MC, Haynes SN, Hay PJ. The Loss of Control Over Eating Scale: development and psychometric evaluation. Int J Eat Disord 2014 Sep;47(6):647-659. [doi: 10.1002/eat.22296] [Medline: 24862351]

39. Neuberger G. Measures of fatigue: The Fatigue Questionnaire, Fatigue Severity Scale, Multidimensional Assessment of Fatigue Scale, and Short Form-36 Vitality (Energy/Fatigue) Subscale of the Short Form Health Survey. Arthritis Care Res 2003;49(S5):S175-S183. [doi: 10.1002/art.11405]

40. The University of Texas MD Anderson Cancer Center. Brief Fatigue Inventory. 1997. URL: http://www3.mdanderson.org/depts/symptomresearch/pdf/BFI-English%20SAMPLE.pdf [accessed 2016-02-18] [WebCite Cache ID 6fNR5c20L]

41. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap)--a metadata-driven methodology and workflow process for providing translational research informatics support. J Biomed Inform 2009 Apr;42(2):377-381 [FREE Full text] [Medline: 19890169]

42. Cadmus-Bertram LA, Marcus BH, Patterson RE, Parker BA, Morey BL. Randomized Trial of a Fitbit-Based Physical Activity Intervention for Women. Am J Prev Med 2015 Sep;49(3):414-418. [doi: 10.1016/j.amepre.2015.01.020] [Medline: 26071863]

43. Smith SA, Claridy MD, Whitehead MS, Sheats JQ, Yoo W, Alema-Mensah EA, et al. Lifestyle Modification Experiences of African American Breast Cancer Survivors: A Needs Assessment. JMIR Cancer 2015;1(2) [FREE Full text] [Medline: 26380378]

44. Spark LC, Fjeldsoe BS, Eakin EG, Reeves MM. Efficacy of a Text Message-Delivered Extended Contact Intervention on Physical Activity Intervention for Women. Am J Prev Med 2015 Sep;49(3):414-418. [doi: 10.1016/j.amepre.2015.01.020] [Medline: 26380378]

45. Krok-Schoen JL, Oliveri JM, Paskett ED. Cancer Care Delivery and Women's Health: The Role of Patient Navigation. J Oncol Pract 2016 Jun;12(5):e88 [FREE Full text] [doi: 10.1200/jop.2015.00433] [Medline: 26373696]

46. Leon AC, Davis LL, Kraemer HC. The role and interpretation of pilot studies in clinical research. J Psychiatr Res 2011 May;45(5):626-629 [FREE Full text] [doi: 10.1016/j.jpsychires.2010.10.008] [Medline: 21035130]

47. Henry GT. Practical Sampling. In: Bickman L, Rog DJ, editors. Sage Handbook of Applied Social Research Methods 2nd Edition. Thousand Oaks, CA: Sage Publications, Inc; 2009.

48. Evenson KR, Goto MM, Furberg RD. Systematic review of the validity and reliability of consumer-wearable activity trackers. Int J Behav Nutr Phys Act 2015;12(1):159 [FREE Full text] [doi: 10.1186/s12966-015-0314-1] [Medline: 26684758]

Abbreviations

BEVQ: Beverage Questionnaire
BMI: body mass index
IPAQ: International Physical Activity Questionnaire
mHealth: mobile health

Edited by G Eysenbach; submitted 29.10.15; peer-reviewed by S Smith, B Fjeldsoe, L Cadmus-Bertram; comments to author 24.01.16; revised version received 17.02.16; accepted 18.03.16; published 09.05.16

Please cite as:
M Quintiliani L, Mann DM, Puputti M, Quinn E, Bowen DJ
Pilot and Feasibility Test of a Mobile Health-Supported Behavioral Counseling Intervention for Weight Management Among Breast Cancer Survivors
JMIR Cancer 2016;2(1):e4
URL: http://cancer.jmir.org/2016/1/e4/
doi: 10.2196/cancer.5305
PMID: 28410174

©Lisa Quintiliani, Devin M Mann, Marissa Puputti, Emily Quinn, Deborah J Bowen. Originally published in JMIR Cancer (http://cancer.jmir.org), 09.05.2016. This is an open-access article distributed under the terms of the Creative Commons Attribution License (http://creativecommons.org/licenses/by/2.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Cancer, is properly cited. The complete bibliographic information, a link to the original publication on http://cancer.jmir.org/, as well as this copyright and license information must be included.