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Preventing weight gain in African American breast cancer survivors using smart scales and activity trackers: A randomized controlled pilot study

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Abstract

Purpose—This study evaluated the feasibility and preliminary efficacy of two 6-month, self-regulation interventions that focused on daily self-weighing (DSW), and used objective monitoring and tailored feedback about weight (±activity), to prevent weight gain among African American breast cancer survivors.

Methods—Participants (n=35) were randomized to an intervention + activity monitoring (INT+), intervention (INT), or control (CON) group. Interventions included a wireless scale (±activity tracker) that transmitted objective data to a mobile app/website, emailed lessons, and tailored feedback based on objective weight (±activity data). Participants completed in-person and online assessments at baseline, 3 and 6 months.

Results—Ninety-four percent of participants completed assessments at 3 months, and 97% at 6 months. Median (IQR) weight change after 6 months was −0.9% (−4.4−0.1) in the INT+ (p=0.075; p=0.067 vs. CON) and −0.2% (−4.2−1.3) in the INT groups (p=0.463; p=0.357 vs. CON), versus a 0.2% (−0.7−1.7) gain in the CON group. The proportion of INT+, INT and CON participants that were at or below baseline weight was 72.7%, 53.8% and 45.5% respectively (effect sizes d=.64, d=.18). Most INT+ participants weighed and wore trackers ≥5 days/week (INT +, 81.9% vs. INT, 38.5% vs. CON, 0%; p< 0.0005; INT+, 72.7%). Both intervention groups perceived DSW as positive, and 100% would recommend the program to other breast cancer survivors.

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COMPLIANCE WITH ETHICAL STANDARDS

Ethical Approval: All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Informed Consent: Informed consent was obtained from all individual participants included in the study.

Conflict of Interest Statement: The authors declare that they have no conflict of interest.

Conclusion—An intervention focused on DSW as a self-monitoring strategy shows promise for preventing weight gain in breast cancer survivors.

Implications for Cancer Survivors—Daily self-monitoring of weight and activity may be a feasible and accessible approach to promote weight gain prevention in breast cancer survivors.

Keywords

breast cancer survivors; African American; randomized trial; weight gain prevention; intervention; technology

INTRODUCTION

Breast cancer is the most commonly diagnosed cancer among women worldwide [1]. There are an estimated 3.1 million female breast cancer survivors in the United States [2]. Women often experience weight gain after breast cancer diagnosis, which increases risks for comorbidities, fatigue, functional decline and poorer quality of life [3–4]. Observational studies have demonstrated that breast cancer survivors who gain 5–10% or more above prediagnosis weight have poorer survival [5,6], and weight gain over time is associated with increased cardiovascular disease and diabetes risk factors [7,8], which are already prevalent comorbidities among cancer survivors [3,9]. In contrast, weight maintenance in the first 2–3 years after breast cancer diagnosis is associated with improved survival [5,6]. Thus, preventing weight gain in breast cancer survivors is an important public health goal that can have considerable impact by decreasing risk for comorbidities and enhancing survival outcomes [3,5,6].

African American breast cancer survivors are more likely to experience obesity and cancer-related comorbidities relative to other women [10,11] and may be at higher risk for weight gain after diagnosis [12]. Only a handful of weight control interventions have focused specifically on African American breast cancer survivors [13]. Although these small studies have shown promise, they have targeted weight loss after treatment [14–16], dietary change [17] or weight loss maintenance [18], and only two were randomized trials. The few studies that have tested lifestyle interventions to prevent weight gain among women with breast cancer were during treatment and among predominantly White populations [19–23]. Self-regulation of weight through frequent self-weighing is a feasible and potentially scalable approach to supporting weight maintenance among adult populations [24–28]. Previous interventions based on a self-regulation approach that have encouraged daily self-weighing and taught individuals to make small changes in diet and exercise behaviors based on daily weight information have been effective in preventing weight gain in young adults [29–31]. Distance- and technology-based lifestyle interventions have the potential to enhance access to cost-effective weight control programs for the growing population of cancer survivors [32]. Although non face-to-face interventions have been effective for weight loss [33–36] and maintenance among cancer survivors [37], few have used web-based or mobile technologies [32,38,39] or focused on minority populations of cancer survivors [32,38].

Among overweight and obese racial/ethnic minority adults, electronic health interventions have demonstrated short-term and modest weight loss outcomes, while the efficacy of

mobile health interventions is largely unknown [40]. The emergence of smart scales and wearable activity trackers represents a unique opportunity to use distance-based objective self-monitoring tools to encourage daily self-monitoring in the context of weight management interventions. In a pilot randomized trial of a 12-week smartphone-based weight loss intervention for overweight and obese adults (n=40; 27.5% minorities) that used a wireless scale and activity tracker for self-monitoring, the intervention group achieved clinically significant weight loss compared to a health education group [41]. Among breast cancer survivors (n=29; 3% minorities), Spark et al. [39] evaluated a 6-month tailored text-messaging intervention to promote weight maintenance after completion of a 6-month telephone-delivered weight loss intervention and found that participants had lost 5.2% on average of baseline weight after 18 months. While these technology-based weight control interventions show initial promise, few racial/ethnic minority participants were included, and little is known about the acceptability of digital scales and activity trackers for facilitating weight gain prevention among African American women or breast cancer survivors. To date, no randomized weight gain prevention trials have been conducted in post-treatment breast cancer survivors; few behavioral interventions for breast cancer survivors have focused on minority populations [13,42] or used digital scales and activity trackers for objective self-monitoring.

The WELL (Weighing Every day for Love of Life and) Body study aimed to capitalize on the potential of wireless scales and activity trackers to deliver real-time guidance and individualized feedback tailored in response to objectively monitored weight and activity patterns. Therefore, the purpose of this pilot study was to evaluate the feasibility and preliminary efficacy of two 6-month, remotely-delivered, self-regulation interventions that focused on daily self-weighing and used objective monitoring and tailored feedback on weight only, or weight plus activity, to promote weight gain prevention among African American breast cancer survivors. We hypothesized that a self-regulation approach would be feasible and that participants randomly assigned to the self-regulation plus activity monitoring or self-regulation intervention groups would have a lower magnitude of weight gain at 6 months compared to those in the control group.

METHODS

Study Design

This 3-arm pilot randomized trial evaluated the feasibility of two self-regulation interventions (intervention plus activity monitoring or intervention, hereafter referred to as INT+ and INT) compared to a control group among African American breast cancer survivors. Both 6-month interventions were aimed at preventing weight gain through the self-regulation of eating and exercise behaviors. Given that weight loss interventions have had limited success in achieving clinically meaningful weight loss among African American breast cancer survivors [14–18], focusing on weight gain prevention could be a feasible alternative approach to promoting weight management in this population, as messages regarding weight maintenance may be more culturally relevant [43], and weight gain can be prevented using technology-based intervention approaches delivered at a lower intensity than needed for weight loss [24, 43]. Participants were randomly assigned to one of 3

groups: self-regulation intervention with objective activity monitoring (INT+), self-regulation intervention (INT), or delayed intervention control (CON). Follow-up assessments occurred at 3 and 6 months in a similar manner to baseline assessments, using online questionnaires and clinic measurements. Participants received $40 for completing each of the baseline, 3-month and 6-month online questionnaires and clinic assessments. All study procedures were reviewed and approved by the Protocol Review Committee of the UNC Lineberger Comprehensive Cancer Center and Institutional Review Board of the University of North Carolina at Chapel Hill.

Participants and Recruitment

Individuals were eligible to participate if they met the following inclusion criteria: female, age 18 or older; self-identify as African American or black; diagnosed with stage I–IIIA breast cancer within the last 10 years; body mass index (BMI) of 20–45 kg/m^2; completed cancer treatment (except endocrine treatment); no evidence of progressive disease or second primary cancers; able to read, write and speak English; have access to the Internet and a computer on at least a weekly basis; use an Internet e-mail address or willing to sign up for a free email account; willing to be randomized; physician approval to participate.

Participants were recruited over a 9 month period in 2014 using multiple approaches to identify and contact potentially eligible women, including: calling individuals in a hospital-based health registry/cancer survivorship cohort who had consented to be re-contacted about studies of potential interest, clinic-based in-person recruitment, and direct mailings to individuals identified through the local tumor registry. We also used community-based approaches, such as advertising at local community events with information tables and flyers and asking organizations to share recruitment information via social media and email. Recruitment advertisements directed interested individuals to a recruitment website with detailed study information and a link to a preliminary online screening questionnaire. Initial screening included questions about age, race/ethnicity, height, weight, and cancer diagnosis. Study staff contacted individuals who were initially eligible and completed screening by phone. Eligible and interested individuals were scheduled for a baseline assessment visit and received an email with a unique link to a secure online informed consent form and physician consent form for the participant to obtain medical clearance. Informed consent was obtained from all study participants via the online consent and in-person. After completion of baseline online questionnaires and clinic assessments, participants were randomly assigned to one of three groups in blocks of 6 with stratification by BMI 20–24.9 (normal weight) and BMI ≥25 (overweight or obese), since weight gain trajectories and ability to engage in regular activity may differ between these groups. The randomization sequence was generated by a research team member not involved in intervention delivery, who used a computer-based random number generator to produce the random allocation sequence and placed assignments in sealed, opaque envelopes. Data collection occurred between January 2014 and June 2015 in Chapel Hill, NC.

Procedures for both Intervention Groups

Table 1 outlines the intervention approach and study components, which are described below. The goal of the interventions was to prevent weight gain through self-regulation of

behaviors, with an emphasis on daily self-weighing as the primary self-observation activity to monitor changes in weight and promote changes in eating and exercise behaviors, and in turn prevent weight gain. Participants in both intervention groups received: 1) a face-to-face individual session, 2) a Bluetooth and Wifi-enabled wireless scale (Withings WS-30, Cambridge, MA) [44] with access to a companion mobile app and website with graphs of weight trends; 3) 24 weekly email-delivered behavioral lessons; and 4) 24 weekly emails with tailored feedback on self-weighing and weight data. The intervention was based on self-regulation theory [45] and a framework successfully used in STOP Regain, which emphasized daily self-weighing and self-regulation of eating and exercise behaviors to prevent weight regain [25] and a more recent study of weight gain prevention for young adults, SNAP (Study of Novel Approaches to Prevention) which emphasized daily self-weighing and either small changes on a daily basis or larger periodic changes [24,46].

After baseline assessment and randomization, an interventionist with PhD training in nutrition intervention conducted an initial one-hour face-to-face session. Participants received education about weight gain in breast cancer survivors, behaviors associated with body weight, and health consequences of weight gain. The session provided an overview of energy balance through diet and physical activity behaviors, the importance of self-weighing as an indicator of energy balance, and emphasized daily use of the wireless scale as a tool or indicator of progress with diet and physical activity behaviors. Participants received a wireless scale that was configured during the initial visit to automatically sync weight data with the individual's online account and/or mobile app. Prior to randomization, the interventionist initialized a scale and set up a companion website profile for each participant. Participants in both intervention groups were instructed to monitor their weight by weighing themselves daily using the wireless scale and taught how to use the scale and access the Withings website (www.withings.com) or app for viewing weight trends over time. Research assistants retrieved objective weight-related data for each participant on a weekly basis to drive content for tailored feedback messages and collect process data on adherence.

Over 24 weeks, intervention participants received weekly email lessons from the interventionist that focused on skills and cognitive behavioral strategies that are commonly taught in standard behavioral weight control programs (e.g., self-monitoring, problem solving, finding social support). The instructional lessons were adapted from previous online weight control interventions (STOP Regain, SNAP) [24,25,46] to focus on breast cancer survivors and use daily self-weighing as the primary self-monitoring strategy to guide self-regulation of eating and exercise behaviors. Lesson were 4–5 pages (standard letter size, accessed as PDF) with standardized content for all participants and a new topic each week. Intervention participants were taught to practice core self-regulation strategies, including: 1) weighing themselves daily; 2) comparing their current weight with their weight at study baseline to detect small weight changes as they occur; 3) implementing problem solving and behavioral strategies to deal with changes; 4) evaluating the success of these strategies; 5) providing self-reinforcement for successfully maintaining their weight, or making diet and physical activity changes if they were above their baseline weight. To help participants interpret daily weight data and take recommended actions based on their current weight, participants were taught to use a color zone monitoring approach adapted from the STOP Regain and SNAP interventions and outlined in Table 1 [24,25,46].

During the intervention, participants were encouraged to make two changes each day, one change in their eating behavior and one change in their activity behavior, to prevent weight gain. Women were instructed to identify one small change in diet that would reduce their intake by approximately 100 kcal per day (e.g., drink 1 less soda per day) and received a recommendation and exercise plan to gradually increase their aerobic activity each week during the intervention until they reached 150–225 minutes per week of moderate-intensity physical activity (i.e., 3–5 metabolic equivalents (METs), 30–45 minutes on 5 days/week, consistent with current guideline for cancer survivors) [47].

Based on self-weighing frequency and weight change obtained from wireless scale data, participants received weekly tailored feedback messages recommending self-regulation skills and behavioral strategies. Feedback messages were tailored using an algorithm for self-weighing frequency (weighing 6–7 days vs. <6 days) and color zone for the week (green, yellow or red; see Table 1). Participants were instructed to practice either reinforcing themselves or taking recommended actions to bring their weight back to their weight at the beginning of the program. For instance, feedback encouraged participants to keep weighing daily or provided tips to support adoption of daily self-weighing. Additionally, messages provided reinforcement for current behaviors consistent with weight regulation (green zone) or offered new tips for reducing intake or increasing activity, and other evidence-based strategies for successful weight loss (yellow or red zone).

Additional Procedures for Self-regulation Intervention with Activity Monitoring

The INT+ group received all of the above and were asked to wear an activity tracker (Withings Pulse, Cambridge, MA) [48], which interfaced with the wireless scale and synced data to a single online account. The only difference between INT+ and INT group lessons was in the weekly homework; INT+ participants were encouraged to track their activity daily in addition to weighing themselves daily. Tailored feedback to participants in this group incorporated both objective physical activity monitoring information garnered from the activity tracker and weight data from the wireless scale. In addition to feedback on weight and daily self-weighing, the message provided specific feedback on whether participants were monitoring their activity and meeting their weekly exercise recommendation. The messages reinforced the importance of monitoring activity, of regular exercise for weight management, or provided specific strategies for adopting and maintaining physical activity behaviors.

Procedures for Control Group

The control group participants received a wireless scale at baseline for evaluation purposes, which allowed us to isolate the effects of our intervention from any potential effects related to the novelty of the scale and companion website/mobile app. In the initial face-to-face individual session, participants were blinded to the intervention focus on daily weighing during the 6-month study period (so as not to alter the natural frequency of self-weighing and history of weight gain) and were advised to maintain their current weighing behaviors. After 6 months, control participants received all of the INT group lessons with modified delivery of the intervention for 3 months. Given that they had already participated for 6 months and to minimize the amount of time individuals had to wait to receive educational

materials, lessons were emailed to participants twice a week over 3 months and without weekly feedback emails.

Measures

Participants were assessed for all of the following measures at baseline, 3 and 6 months unless otherwise noted. Anthropometric and clinical data were collected by the interventionist or one other research staff member, using a standard protocol. Self-monitoring data were downloaded weekly by a research assistant and reviewed by the interventionist for accuracy. All data were double-entered into a database by two of five trained doctoral students to ensure accuracy of data entry.

Demographics and other health-related variables—At baseline, participants were asked to report their age, education level, marital status, employment status, income, medication use, smoking behaviors, weight history, comorbid conditions and cancer history. At 3 and 6 month assessments, participants reported medication use and any health events.

Anthropometric and clinical measures—*Weight* was measured in light clothing, without shoes, on a calibrated digital scale (Tanita BWB 800) at each assessment visit. Two measures were completed and averaged. *Height* was determined to the nearest 0.1 cm at the baseline assessment visit using a wall-mounted stadiometer. The average of two height measures was used. Weight and height measures were used to calculate BMI (weight in kilograms divided by height in meters squared). *Waist circumference* was measured at exhale using a Gulick II tape measure at the midpoint between the highest point of the iliac crest and lowest part of the costal margin. Two measures of waist circumference were taken to the nearest 0.1 cm; if the difference exceeded 1.0 cm, a third measure was taken. *Body composition* was measured with the BodPod (COSMED, Concord, CA) after a 2-hour fast and refraining from strenuous exercise for 8 hours. *Blood pressure* was measured using a Dinamap Monitor Pro 100, while seated after a 5-minute rest period with cuff size determined by arm circumference. Three consecutive measurements, with a 30-second wait between each reading, were averaged. *Hemoglobin A1c and blood lipids* (triglycerides, total cholesterol, HDL and LDL) were assessed by fingerstick and analyzed using the Alere Afinion analyzer and the Alere Cholestech LDX analyzer respectively.

Adherence to self-monitoring—Self-weighing habits were objectively measured via the wireless scales, which sent weight data directly to a companion app and website (www.withings.com) accessible through an online profile. Weight data were downloaded weekly from participants' online profiles and tabulated to derive total days weighed (out of a possible 168 program days), average days weighed per week (number of days weighed/24 program weeks), and a measure of average weighing frequency of 5 or more days per week. A few participants (n=2) reported experiencing technical problems syncing weight data via the companion app or Wifi network. However, these were resolved with the assistance of the interventionist (e.g., update app, changed Wifi password), and self-weighing data from these participants were ultimately synced and collected.

Objective self-monitoring of physical activity was assessed via the activity tracker, which transmitted activity data to the same companion app and website profile as the weight data. Daily activity data, including days tracked, were downloaded and recorded weekly for the INT+ group for the purpose of informing weekly tailored feedback. We calculated total days tracked, average number of days tracked per week and a measure of tracking on 5 or more days per week. Technical difficulties that arose with the trackers included getting them wet from sweat (n=1) or laundry (n=1), and a few participants lost them (n=3). Lost trackers were replaced and other issues were quickly resolved through troubleshooting with the interventionist, so that activity data were transmitted to participants' website profiles.

Adherence to weight management strategies—At 6 months, intervention participants reported how often (1 = *not at all* to 8 = *always*) they used various strategies to control their weight over the past 6 months, including making 100-calorie diet changes to reduce intake, tracking dietary intake with an app or website, increasing daily steps, exercising at least 5 days a week, and wearing a pedometer or other activity monitor [24,46].

Diet—Dietary intake was measured at each assessment time point using the Automated Self-Administered 24-Hour Dietary Recall (ASA-24) developed by the National Cancer Institute [49], an online system that guides participants through a multi-pass recall of foods eaten over the previous 24 hours. Women were asked to complete a 24-hour recall twice (one weekday and one weekend day) at each time point to provide an accurate representation of typical consumption.

Physical activity—The Paffenbarger Activity Questionnaire (PAQ) was administered to all participants by an interviewer at each assessment visit to assess physical activity at each assessment period [50]. The PAQ has been used to assess leisure time activity in many weight loss trials and was scored to provide an estimate of calories expended per week in overall leisure time activity (using metabolic equivalents from the Compendium of Physical Activities [51].

Self-weighing habits and perceptions—Participants were asked how frequently they had weighed themselves within the past 3 months on a 7-point scale, ranging from several times a day to never [46,52]. Perceptions about daily self-weighing were assessed for the intervention groups at 6 months using items included in previous weight gain prevention and self-regulation interventions [30,46]. Items comprised questions about whether they found daily self-weighing to be positive, easy to remember, easy to do, helpful and were likely to continue weighing after study completion. Questions also asked whether participants perceived daily self-weighing to be frustrating, made them self-conscious, and provoked anxiety. Responses were on an 8-point scale, with higher scores indicating more favorable perceptions.

Program acceptability and satisfaction—At 6 months, intervention participants were asked how much of the email lessons and feedback emails they read (1= *none* to 4 = *all/most*). Intervention participants also rated the eating and activity approaches (i.e., reducing intake by 100 calories per day, increasing activity each day) taught during the program using an 8-point scale, including the helpfulness, difficulty, confidence in the effectiveness of the

approaches for preventing weight gain, and confidence in continuing the approaches [53]. Higher scores indicated greater acceptability. Additional questions asked intervention group participants about the helpfulness of various program features for reaching their weight goals (e.g., smart scale, activity tracker; 1 = *not at all helpful* to 4 = *extremely helpful*), their overall satisfaction with the program (1 = *very dissatisfied* to 4 = *very satisfied*) and whether they would recommend the program to other breast cancer survivors (1 = *definitely not* to 4 = *definitely would)* [54].

Statistical analyses

The primary outcome of proportion of participants who completed the 3-month and 6-month assessments was calculated along with an exact 95% confidence interval. Given the small sample size and that data were considerably skewed, we conducted nonparametric tests. Baseline demographic characteristics were compared among groups using Kruskal-Wallis tests for continuous variables or Fisher's exact tests of independence for categorical variables. Descriptive statistics (percentages, medians, interquartile ranges) of study measures (demographics, anthropometrics, clinical measurements, and behaviors) are reported at baseline, 3 months and 6 months. Change in anthropometric, clinical and behavioral outcomes, and adherence to daily self-weighing from baseline to 6 months among the three groups were compared using Kruskal-Wallis tests. Changes scores and analyses are reported on participants with complete data at baseline and 6 months (n=33 out of 35 for weight), given the pilot nature of the study and the consistency of findings with intention-to-treat analyses (i.e., when missing data were imputed with the last observation carried forward). Within each group, change scores were tested to examine if they were significantly different from 0 using Wilcoxon signed rank tests. Pairwise contrasts between each intervention group and the control group were evaluated with Wilcoxon rank sum tests without correcting for multiple comparisons as the study purpose was to examine feasibility. Spearman rank correlations were conducted to assess the association between total days of self-monitoring and weight change. To evaluate adherence to weight management strategies, self-weighing perceptions, program acceptability and satisfaction with the interventions, we used Mann-Whitney U tests to compare responses between the two intervention groups (n=23). All analyses were conducted using SPSS 22.0 (Chicago, IL).

RESULTS

Enrollment and Baseline Characteristics

We enrolled 35 women over a nine month period of recruitment, averaging about 4 participants per month (Figure 1). Of 487 potential contacts, 162 were screened (33.3% response rate), 50 were eligible (30.9% of 162), and 35 completed baseline assessments and were randomized to the three groups (21.6% of 162, 7.2% enrollment rate). Table 2 shows baseline characteristics by study groups. Participants were on average (SD) 53.0 (9.1) years of age, obese (BMI of 33.9 (5.9) kg/m^2), with baseline weight of 88.4 (16.7) kg, and 3.1 (2.3) years post-diagnosis. Over half were employed full-time (63%) with college degrees (66%), and most had stage I–II breast cancer (77%), hypertension (57%) and were post-menopausal (80%). At baseline, the majority of women reported weighing themselves less than once a week (77.1%) over the past 3 months, with only 8.6% reporting daily weighing.

Most women reported never or hardly ever self-monitoring their diet (80.0%) or physical activity (82.9%) over the previous 3 months. There were no significant differences in baseline characteristics across the three groups.

Retention and Adherence

Table 3 shows retention rates and data regarding adherence to self-monitoring and program utilization by group. At 3 months, a total of 94.3% of participants completed both in-person and online assessments. Participant retention rates at 6 months were 97.1% for the in-person visit and 94.3% for online measurements. Retention rates at 3 months did not differ among groups for clinic visits or online assessments, and neither did completion of 6-month clinic visits or online questionnaires. No adverse events were reported during the course of the study.

Self-monitoring—Among the INT+ and INT groups, the median total days weighed was 154 (91.7%) and 106 (63.1%) out of 168 prescribed days compared with 11 total days (6.5%) in the control group ($p<0.0005$ between groups). Over 80% of INT+ participants weighed 5 or more days per week on average, and this proportion significantly differed between groups. Within the INT+ group, 72.7% of participants wore activity trackers 5 or more days per week, and median total days worn was 162 out of 168 days (96.4% of prescribed days). Both intervention groups maintained self-weighing days per week over the course of the study with no group differences and no decrease over time from week 1 to 24 (INT+, $p = 0.414$; INT, $p = 0.140$). Similarly, activity tracking remained consistent over time in the INT+ group.

Program utilization—There were no differences between intervention groups in the use of emailed intervention components. Ninety percent of INT+ and 100% of INT participants reported reading *some-all/most* of the email lessons, while 90.9% and 100% read *some-all/most* of the email feedback. INT+ participants reported significantly more frequent tracking intake using an app or website ($p=0.037$) and wearing a pedometer or activity monitor ($p = 0.001$) compared to INT participants. Both groups reported comparable use of other weight management strategies, including making 100-calorie diet changes to reduce intake, increasing daily steps, and exercising at least 5 days per week.

Effects

Weight change and clinical measures—Table 4 shows study outcomes by each group over time. Median weight change from baseline to 3 months was significant among intervention groups, but not the control group (INT+, $p=0.008$ compared to baseline; INT, $p = 0.023$; CON, $p = 0.678$) (Figure 2). At 6 months, median weight change was −0.94% in the INT+ ($p = 0.075$ compared to baseline) and −0.22% in the INT group ($p = 0.463$) versus a 0.18% gain ($p = 0.327$) in the control group. In comparison with the control group, there was greater weight change over 6 months in the INT+ group ($p = 0.067$), but not the INT group ($p = 0.357$). The proportion of INT+, INT and CON participants that were at or below baseline weight was 72.7%, 53.8% and 44.4% respectively (X^2 (2), N = 33) = 1.756; $p = 0.454$, Cohen's $d = .64$, $d = .18$ vs. CON). Total days of self-weighing was significantly correlated with weight change at both 3 and 6 months (3 months: r = −.490, $p = 0.004$; 6

months, r = −.629, $p < 0.0005$), while total PA days were not (3 months: r = −.169, $p = 0.619$; 6 months, r = −.160, $p = 0.639$).

INT+ group participants decreased BMI over 6 months, which was significantly different from the control group ($p = 0.046$ between groups). At 6 months, the INT+ group had significantly decreased waist circumference ($p=0.021$ compared to baseline) and systolic blood pressure ($p=0.047$ compared to baseline). No significant differences were observed in other clinical measurements.

Diet and physical activity behaviors—There were no differences between groups over time in changes in dietary intake and energy expenditure from physical activity (Table 4). However, from baseline to 6 months, the INT+ group reported a significant 432 kcal increase in energy expenditure per week ($p = 0.028$ compared to baseline), and there was a trend toward decreased dietary intake per day in this group ($p = 0.062$ compared to baseline).

Perceptions of Daily Self-weighing

Both intervention groups had favorable perceptions of weighing themselves daily at 6 months with no differences between groups. Interventions participants reported that daily self-weighing was easy to do [Mdn(IQR): INT+, 8 (4−8) vs. INT, 6 (2−7), $p = 0.206$], easy to remember (INT+, 7 (7−8) vs. INT, 5 (2.3−7.8), $p = 0.058$), helpful (INT+, 7.5 (5−8) vs. INT, 7.5 (5.3−8), $p = 0.951$), and positive (INT+, 7 (4−8) vs. INT, 8 (3.5−8), $p = 0.680$). Both groups endorsed being very likely to continue daily weighing after the program (INT+, 8 (5−8) vs. INT, 8 (3.5−8), $p = 0.579$). With respect to negative perceptions, intervention groups had comparably low ratings for whether they perceived daily self-weighing to be anxiety provoking (INT+, 2 (1−5) vs. INT, 2 (1−4.5), $p = 0.942$), frustrating (INT+, 2 (1−4) vs. INT, 2 (1−5), $p = 0.944$), or made them feel self-conscious (INT+, 2 (1−6) vs. INT, 3 (1−4), $p = 0.925$).

Satisfaction and Acceptability of Approaches

Participant ratings of program approaches are shown in Table 3. Consistent with participants' positive perceptions about self-weighing, the program feature that women across both groups found most helpful for reaching their weight goals was the smart scale. INT+ participants also rated the activity tracker as extremely helpful. Other most highly rated program components were the email feedback and working to change the way they thought about making healthy changes. Participants in both intervention groups highly ranked the helpfulness of information received in the program for controlling their weight and the approach of making 100-calorie dietary changes. Although both intervention groups reported that it was somewhat difficult to make the recommended changes in eating and, participants in both groups felt highly confident that they would continue to follow the approaches taught in the program. Furthermore, women reported that the approach they were taught would help them prevent weight gain. Most INT+ (100%) and INT (91.7%) participants were somewhat satisfied or very satisfied with the program ($p = 1.00$ between groups), and 100% of both groups reported they would recommend the program to other breast cancer survivors.

DISCUSSION

This study demonstrates the feasibility of recruiting and retaining African American breast cancer survivors to safely participate in a weight gain prevention intervention using a self-regulation framework with objective monitoring and tailored feedback on weight only or weight plus activity. Our innovative technology-delivered approach, which capitalized on the use of newer technology without requiring regular face-to-face contact, focused on daily self-weighing and small behavior changes, included emailed behavioral skills training and tailored feedback, and achieved high rates of retention and adherence after 6 months. Among the INT+ group that self-monitored both weight and activity, the improvements in weight, energy expenditure, and dietary intake over time were encouraging and show initial promise for a self-regulation approach to preventing weight gain in this population of cancer survivors compared to controls. Further, participants in both intervention groups were satisfied with the program, had favorable perceptions of both daily self-weighing and small behavior changes, and were likely to continue using these key approaches taught in the self-regulation intervention. To our knowledge, this is one of the few randomized trials of lifestyle interventions focused on weight gain prevention in African American breast cancer survivors and the first to report their experiences using a technology-delivered intervention with objective measures of self-weighing and activity tracking. As such, our findings are encouraging for future studies and the development of accessible and scalable interventions for underserved cancer survivors in need of lifestyle interventions.

A third of breast cancer survivors contacted were screened for the study, with 70% of eligible participants (7.2% of potential contacts approached) enrolling in the trial. Although our recruitment rate was low, it was comparable to the 5.7% recruitment rate in pooled analyses of distance-based diet and exercise intervention trials among predominantly White cancer survivors that also used recruitment mailings [55]. Among our recruitment strategies used, mass mailings yielded the largest number of enrolled participants (16 out of 35, 48%). The WELL Body study achieved high retention rates of 94% at 3 months and 97% at 6 months. Previous distance-based lifestyle intervention studies among cancer survivors have reported similar rates of study completion over 90% [32,55]. It is noteworthy that our retention rates were higher than the 71.0−90.5% range among randomized controlled trials in a systematic review of weight loss interventions for women with breast cancer [38], almost all of which were delivered face-to-face, and higher than the 71.0−91.7% completion rates in previous trials among African American breast cancer survivors [14–18]. That attrition rates in this study were lower than other web-based lifestyle interventions among cancer survivors is also encouraging [32]. The women who enrolled may have had higher motivation to adopt behavior changes and thus to remain in the study [55]. High retention rates also may have been a function of the technology-delivered intervention approach, which obviated the need for participants to travel for face-to-face sessions or spend time on telephone counseling, adherence and satisfaction with different intervention components, or rapport built with the interventionist. Together, these findings demonstrate the feasibility of recruiting and retaining African American breast cancer survivors to participate in a distance-based lifestyle intervention program and suggest that a technology-delivered intervention may lead to improved retention and engagement.

Previous studies have shown that regular self-weighing is associated with better weight gain prevention [26]. Similarly, we found that more frequent self-weighing was strongly correlated to weight loss at 6 months. Mean (SD) weight loss after 6 months in both intervention groups combined was −1.9 (4.3) kg on average or −2.2 (5.0)% (range: 20% loss to 3.4% gain) of initial body weight, and 63% of intervention participants were at or below their baseline weight. Although the focus of our intervention was on weight gain prevention, these weight losses are similar to those found in previous weight loss interventions among African American breast cancer survivors which have ranged from 0.8 to 3.3% and were all delivered in face-to-face individual or group sessions, some including telephone counseling [14–18,56]. Similar to these interventions, we found improvements in the INT+ group over time in BMI [14–16,56], waist circumference [15,56], systolic blood pressure [15], energy expenditure [14,16] and a trend toward reduced caloric intake [14,16]. The lack of changes in lipids and metabolic measures is consistent with other six-month behavioral weight loss interventions in breast cancer survivors [56,57].

This is the first study to encourage daily-self weighing as a self-regulation approach for weight gain prevention among breast cancer survivors. Of the few other weight gain prevention trials that have encouraged daily weighing within lifestyle interventions [26,30,31] most have relied on self-reported measures of weighing behaviors. An intervention among first-year college students that included an introductory video lecture, encouraged daily self-weighing, provided Wi-Fi enabled scales without access to an app or online profile, and emailed daily feedback with a graph of weight data produced mean (SD) weight losses of −0.19 (2.89) kg at 6 months and −0.47 (3.66) kg at 1 year, one-tenth of the weight loss achieved in this study at 6 months [31]. The median frequency of self-weighing in the first 6 months was 5.0 days per week compared to 6.4 (INT+) and 4.4 (INT) days per week in our study. Although our intervention had similar components, WELL Body participants were able to view weight (and activity) graphs and trends via their individual profile on the commercial website and app, received weekly lessons on behavioral skills, instructions to make small diet changes and gradually increase activity, and weekly emailed feedback encouraging adherence to daily weighing (and activity tracking). Given the multiple intervention strategies used and different study populations, we are unable to isolate the specific effects of daily self-monitoring and other components delivered on weight outcomes. However, adherence to and acceptability of daily weighing were high among intervention participants, especially those in the INT+ group, in the context of a technology-delivered weight gain prevention. Further evaluation of this self-regulation intervention approach among breast cancer survivors is necessary.

While both intervention groups demonstrated small, but significant within group weight losses at 3 months, only the INT+ group (i.e., used wireless scale and activity tracker) showed a trend toward maintaining weight losses at 6 months relative to weight gain in the control group. In general, the magnitude of changes in eating and exercise behaviors appeared to be greater in this group compared with the INT group that only received the scale. Both intervention groups reported comparable use of email lessons, feedback and weight management strategies, found the smart scale and tailored feedback to be helpful for reaching their weight goals, and indicated highly positive perceptions about daily self-weighing and satisfaction with the program approach. Thus, the improvements in the INT+

group may be explained in part by the significantly higher levels of adherence to self-monitoring and use of the activity tracker. Over 81% of INT+ group participants, more than twice the amount of INT group participants, weighed themselves 5 days or more on average over the course of the study, and 73% wore trackers on 5 or more days. Furthermore, INT+ participants found the activity tracker to be extremely helpful and reported more frequent use of an app or website to track dietary intake and use of an activity monitor. While the activity tracker may have contributed to improved engagement, better adherence and subsequent changes in diet and activity, it is unclear whether the improvements among INT+ participants were attributable to the tracker alone, to receiving tailored feedback about adherence and behaviors based on tracker data, or some synergistic effects of these components with use of the scale. Recent studies have shown that people stop using trackers after only a few weeks of wear [58,59], and a systematic review on the effectiveness of accelerometer use on weight outcomes found that these devices have small effects, and the body of research is relatively small and limited by poorly designed comparison groups [60]. Thus, future studies to isolate the effects of activity trackers and feedback on weight control and to sustain longer-term engagement and adherence are warranted. Altogether, our findings suggest that implementation of a self-regulation approach that employs both a wireless scale and activity tracker may be useful for promoting weight gain prevention in breast cancer survivors.

This is one of the few lifestyle intervention studies specifically for African American breast cancer survivors and the first study to evaluate a distance-based technology-delivered approach. Although the small sample size limited our statistical power to detect significant group differences and conduct multivariate analyses, the achievement of modest weight losses within the INT+ group using a less intensive intervention approach is notable. Our study sample included only women that had regular access to the Internet and thus may not be generalizable to breast cancer survivors with more limited technology resources. The lack of blinded outcome assessors was a study limitation; as the interventionist was also responsible for data collection, this may have influenced participants' adherence and completion of follow-up assessments. Other sources of potential bias included incomplete outcome data from a few participants and self-report measures that may have resulted in over- or underestimates of dietary intake, energy expenditure and other outcomes. As both intervention groups received a multicomponent intervention, another study limitation is our inability to determine the independent effects of components on weight outcomes. Thus, it is unknown whether daily self-weighing, the tracker, email lessons or tailored feedback based on objective weight, with or without activity, or some combination of these impacted weight. Future studies using alternate study designs (e.g., fractional factorial) could be conducted to identify the most efficacious components for intervention optimization and further evaluation.

In summary, this study indicates that a distance- and technology-based intervention focused on daily self-weighing and small behavior changes was feasible and acceptable among African American breast cancer survivors. Given that breast cancer survivors are at risk for weight gain and associated comorbid conditions, and few weight loss interventions have resulted in clinically meaningful weight loss outcomes among African American breast cancer survivors, there is a need for more effective weight management interventions for this

population. Our intervention, which focused on weight gain prevention using technology-enabled daily self-monitoring of weight and activity, demonstrated weight change comparable to previous weight loss interventions in African American breast cancer survivors. Weight gain prevention may be a useful and potentially sustainable approach to reducing disease risks and mortality related to weight gain and obesity after breast cancer. Future evaluation of this self-regulation intervention approach in a larger trial over a longer period of time is warranted to determine the most effective strategies for preventing weight gain among breast cancer survivors.

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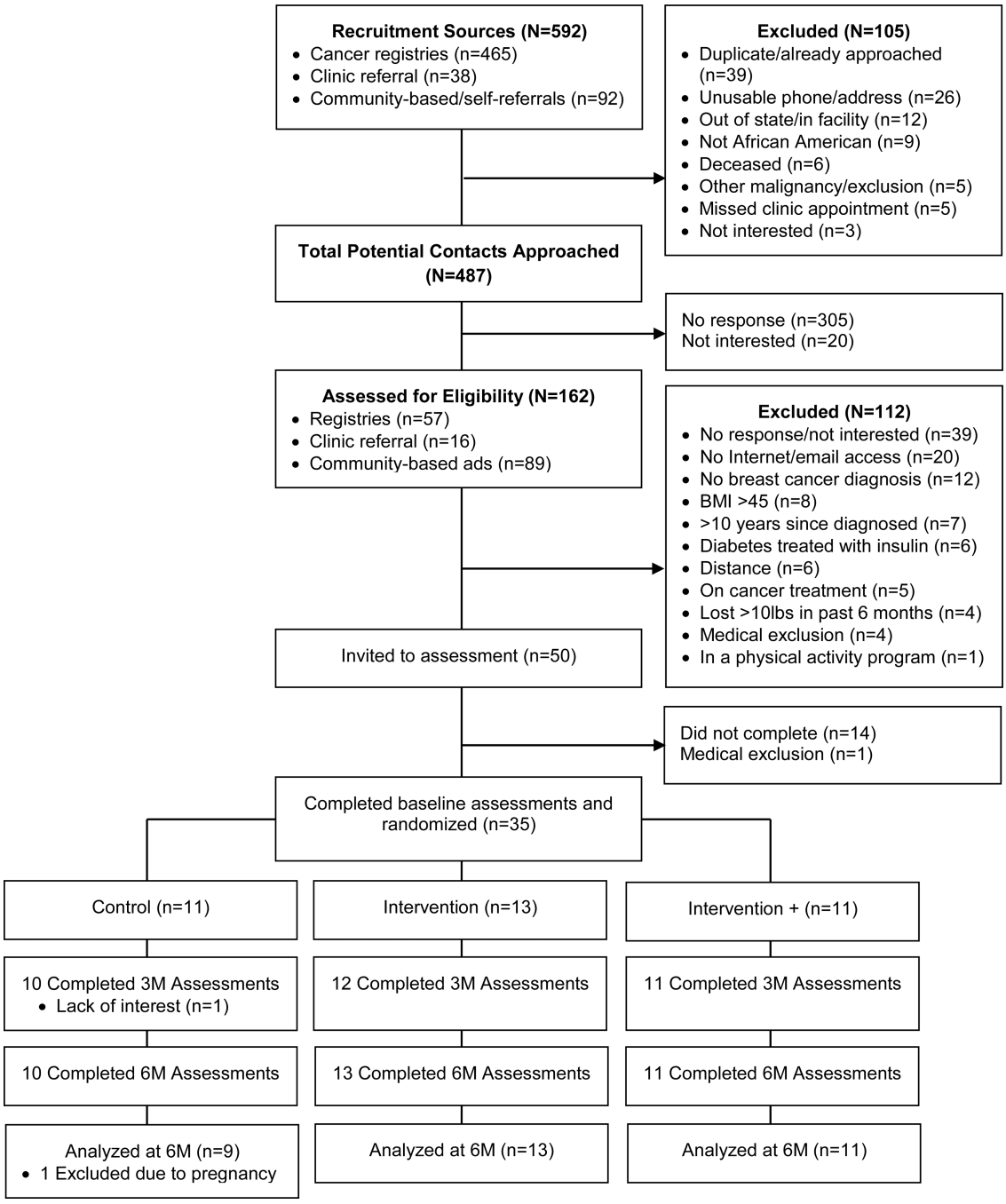

Figure 1. CONSORT diagram of study enrollment and retention in WELL Body 6-month randomized controlled trial

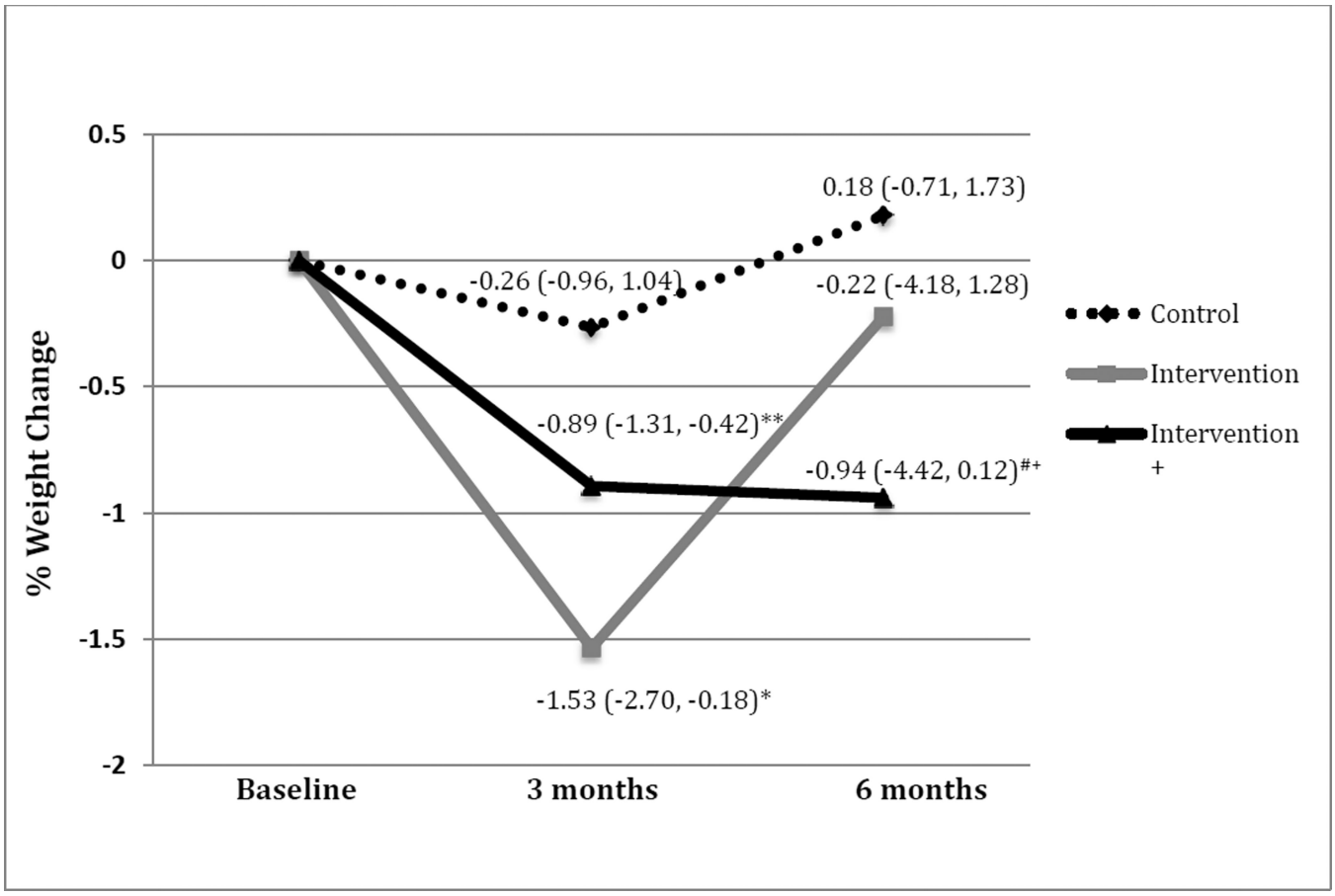

Figure 2. Median percent weight change (IQR) during WELL Body trial by group

*p = 0.023 within group compared to baseline. **p = 0.008 within group compared to baseline.

#p = 0.075 within group compared to baseline. +p = 0.067 vs. control group.

Table 1

Overview of WELL Body self-regulation intervention

Key Intervention Concept	Intervention Approach	Components Used
Self-monitoring weight	Self monitor weight daily using wireless scale. Use weight as indicator of whether diet and activity changes are working.	Smart scale to monitor weight Email lessons Tailored feedback email
Dietary changes recommended for maintaining weight (green zone)	Make one small change in diet every day (roughly equivalent to 100 calories).	Email lessons
Physical activity changes recommended for maintaining weight (green zone)	Gradually increase moderate-intensity exercise to 150–225 min/week (30–45 min/day on 5 days/week) over 6 months. (INT+ only: Monitor activity daily using activity tracker).	Email lessons Tracker to monitor activity Tailored feedback email
Actions to take in yellow zone (weight is 3–4 pounds above baseline weight)	Make additional small changes in eating (e.g., make at least 1 small change at every meal), weigh daily and meet weekly exercise goal. Use problem-solving skills, with focus on changing surrounding environment to support small changes.	Smart scale to monitor weight Email lessons Tailored feedback email
Actions to take in red zone (weight is ≥5 pounds above baseline weight)	Make additional small changes in eating (e.g., make at least 1 small change at every meal and snack), weigh daily and meet weekly exercise goal.	Smart scale to monitor weight Email lessons Tailored feedback email

INT+ Self-regulation intervention plus activity monitoring

Table 2

Baseline characteristics of participants in the WELL Body trial

Variable	Control (n=11)	Intervention (n=13)	Intervention+ (n=11)	*P* value
Age, y				
M(SD)	54.4 (11.1)	52.6 (9.4)	52.2 (6.9)	.843
Range	35–71	36–67	45–65	
Education level, n (%)				.246
HS degree/less	3 (27.3)	2 (15.4)	0 (0.0)	
Some college	3 (27.3)	3 (23.1)	1 (9.1)	
College degree+	5 (45.5)	8 (61.5)	10 (90.9)	
Marital Status, n (%)				1.000
Married	5 (45.5)	7 (53.8)	5 (45.5)	
Other	6 (54.5)	6 (46.2)	6 (54.5)	
Employed Full-time, n (%)	6 (54.5)	7 (53.8)	9 (81.1)	.351
Income, n (% <$60,000/year)	6 (54.5)	5 (50.0)	5 (50.0)	1.000
Current/former smoker, n (%)	2 (18.2)	3 (23.1)	1 (9.1)	.855
Mean Weight (SD), kg	93.8 (20.8)	85.5 (15.3)	86.3 (13.9)	.438
Mean BMI (SD), kg/m^2	35.3 (6.5)	32.7 (6.1)	34.0 (5.3)	.570
Months since diagnosis, Med (IQR)	50 (38)	50 (50)	30 (9)	.074
Cancer stage, n (%)				.154
Stage I	5 (45.5)	1 (7.7)	5 (45.5)	
Stage II	5 (36.4)	7 (53.8)	5 (45.5)	
Stage III	2 (18.2)	5 (38.5)	1 (9.1)	
Anti-hormone therapy, n (% current)	0 (0)	3 (23.1)	1 (9.1)	.355
Breast Cancer surgery, n (%)	11 (100)	12 (92.3)	11 (100)	1.00
Chemotherapy, n (%)	9 (81.8)	10 (76.9)	9 (81.8)	.855
Radiation, n (%)	8 (72.7)	11 (84.6)	9 (81.8)	.871
Co-morbid conditions, n(%)				
Hypertension	6 (54.5)	7 (53.8)	7 (63.6)	.915
High cholesterol	3 (27.3)	3 (23.1)	0 (0.0)	.268
Type 2 diabetes	3 (27.3)	2 (15.4)	2 (18.2)	.871
Medications, n (%)				
Hypertension	6 (54.5)	8 (61.5)	7 (63.6)	1.000
High cholesterol	3 (27.3)	2 (15.4)	0 (0)	.239
Diabetes	2 (18.2)	2 (15.4)	2 (18.2)	1.000
Menopausal status, n (%)				1.000
Premenopausal	2(18.2)	3 (23.1)	2 (18.2)	
Postmenopausal	9 (81.8)	10 (76.9)	9 (81.8)	
Energy intake, kcal/d (SD)	1698 (561)	1695 (669)	1864 (460)	.731
% Calories from Fat	40.4 (8.5)	37.6 (9.3)	41.9 (6.3)	.433
Mean energy expenditure (SD), kcal/day	441 (462)	616 (522)	701 (948)	.653
Self-monitoring frequency, n (%)				

Variable	Control (n=11)	Intervention (n=13)	Intervention+ (n=11)	*P* value
Weighing, Less than 1×/week	8 (72.7)	12 (63.6)	7 (63.6)	.467
Diet, Never/ hardly ever	8 (72.7)	10 (76.9)	10 (90.0)	.661
PA, Never/ hardly ever	9 (81.8)	11 (84.6)	9 (81.8)	1.000

SD standard deviation, *IQR* interquartile range

Table 3

Adherence to assessments, self-monitoring, program utilization, and acceptability of approaches by participants in the WELL Body trial

Variable	Control (n=11)	Intervention (n=13)	Intervention+ (n=11)	*P* value
Clinic visit completion, % (95% CI)				
3 months	90.9 (58.7, 99.8)	92.3 (64.0, 99.8)	100 (71.5, 100)	1.000
6 months	90.9 (58.7, 99.8)	100 (75.3, 100)	100 (71.5, 100)	1.000
Online survey completion, % (95% CI)				
3 months	90.9 (58.7, 99.8)	92.3 (64.0, 99.8)	100 (71.5, 100)	1.000
6 months	90.9 (58.7, 99.8)	92.3 (64.0, 99.8)	100 (71.5, 100)	.629
Self-monitoring				
Self-weighing frequency over 6 months				
Days per week, Mdn (IQR)	0.5 (0, 1.8)	4.4 (3.2, 5.9)	6.4 (5.4, 6.7)	**<.0005**
≥5 days per week, n(%)	0 (0)	5 (38.5)	9 (81.9)	**<.0005**
Activity tracking frequency over 6 months				
Days per week, Mdn (IQR)	-	-	6.8 (3.5)	-
≥5 days per week, n(%)	-	-	8 (72.7)	-
Self-weighing frequency by week				
Week 1, Mdn (IQR)	1 (0, 2)	6 (4, 7)	7 (4, 7)	**<.0005**[a]
Week 13, Mdn (IQR)	0 (0, 1)	5 (2.5, 7)	7 (5, 7)	**<.0005**[a]
Week 24, Mdn (IQR)	0 (0, 0)	4 (0, 7)	7 (5, 7)	**<.001**[a]
Activity tracking frequency by week				
Week 1, Mdn (IQR)	-	-	7 (5, 7)	
Week 13, Mdn (IQR)	-	-	7 (7, 7)	.715[b]
Week 24, Mdn (IQR)	-	-	5 (0, 7)	.172[b]
Program utilization				
Read some-all/most email lessons, n (%)[c]	-	12 (100)	9 (90)	.455
Read some-all/most email feedback, n (%)[d]	-	12 (100)	10 (90.9)	.478
Weight management strategies, M(SD)[d,e]				
Reduced dietary intake w/100-calorie changes	-	4.8 (2.0)	5 (1.8)	.797
Tracked intake using app/website	-	1.9 (1.6)	4.3 (3.1)	**.037**
Increased daily steps	-	5.3 (1.8)	6.0 (2.1)	.348
Active at least 5 days per week	-	4.8 (1.8)	6 (2.0)	.124
Wore a monitor to track activity	-	3.3 (2.5)	7.0 (1.5)	**.001**
Acceptability of approaches, Mdn (IQR)[d]				
Smart scale[f]	-	2.5 (2, 4)	4 (3, 4)	.197
Activity tracker[f]	-	-	4 (3, 4)	
Email feedback[f]	-	3 (2, 3)	3 (2.8, 4)	.521
Changing thoughts about making healthy changes[f]	-	3 (2, 4)	3 (2.5, 4)	.420

Variable	Control (n=11)	Intervention (n=13)	Intervention+ (n=11)	*P* value
Information on weight control[g]	-	8 (6.3, 8)	8 (5, 8)	1.000
Focus on making100-calorie diet changes[g]	-	7.5 (4.8, 8)	7 (5, 8)	.584
Difficult making recommended diet changes[h]	-	4 (2, 5.75)	6 (4, 6)	.082
Difficult making recommended activity changes[h]	-	5 (2.25, 6)	4 (3, 6)	.995
Confidence in continuing eating approach[i]	-	8 (5.3, 8)	7 (5, 8)	.447
Confidence in continuing exercise approach[i]	-	7.5 (5.3, 8)	7 (5, 8)	.792
Confident that approach helps prevents weight gain[i]	-	8 (5, 8)	7 (6, 8)	.716

[a] *p*=value comparing Intervention vs. Intervention+: *p*=.248 at 1 week, *p*=.272 at 13 weeks, *p*=.175 at 24 weeks.

[b] *p*-value comparing to week 1.

[c] Results based on participants with response at 24 weeks (i.e., n=12 for Intervention, n=10 for Intervention+).

[d] Results based on participants with response at 24 weeks (i.e., n=12 Intervention, n= 11 Intervention+).

[e] 1 = *not at all* to 8 = *always*

[f] 1 = *not at all helpful* to 4 = *extremely helpful*

[g] 1 = *not at all helpful* to 8 = *extremely helpful*

[h] 1 = *very easy* to 8 = *very difficult*

[i] 1 = *not confident* to 8 = *very confident*

Table 4

Median (IQR) values for WELL Body trial outcomes across groups at baseline, 3 months, and 6 months

Outcome variable and group	Baseline Median (IQR) (n = 35)	3 months Median (IQR) (n = 33)	6 months Median (IQR) (n = 33)	Change from Baseline to 6 Months		
				Median (IQR)	*P* within group[a]	*P* for Intervention vs. Control[b]
% Weight change						
Intervention +	Ref	−0.89 (−1.31, −0.42)	−0.94 (−4.42, 0.12)	–	.075	.067
Intervention	Ref	−1.53 (−2.70, −0.18)	−0.22 (−4.18, 1.28)	–	.463	.357
Control	Ref	−0.26 (−0.96, 1.04)	0.18 (−0.71, 1.73)	–	.327	
Weight (kg)						
Intervention +	85.0 (82.5, 100.0)	84.6 (81.9, 98.8)	84.3 (77.5, 96.9)	−1.0 (−4.0. 0.1)	.062	.058
Intervention	85.6 (77.4, 91.4)	82.0 (75.0, 90.0)	82.9 (71.3, 91.7)	−0.2 (−3.4, 1.1)	.552	.751
Control	94.2 (79.7, 110.9)	92.8 (75.5, 112.6)	93.7 (75.3, 102.7)	.2 (−0.7, 1.3)	.441	
BMI (kg/m^2)						
Intervention +	34.0 (32.3, 39.2)	34.0 (32.1, 38.4)	32.5 (30.6, 37.5)	−0.4 (−1.7, −0.1)	.050	**.046**
Intervention	32.4 (30.4, 35.0)	31.7 (29.4, 32.9)	32.2 (28.0, 34.1)	−0.1 (−1.3, 0.3)	.345	.357
Control	34.1 (32.3, 42.1)	33.6 (30.9, 42.5)	34.0 (30.1, 39.8)	0.1 (−0.2, 0.5)	.374	
Waist circ (cm)						
Intervention +	107.7 (96.1, 112.6)	107.2 (91.3, 110.1)	103.3 (91.8, 110.6)	−2.70 (−5.2, −0.4)	**.021**	1.00
Intervention	104.5 (96.1, 106.3)	99.1 (90.2, 102.7)	99.9 (89.1, 104.9)	−2.50 (−4.8, 0.1)	.055	.909
Control	109.4 (103.5, 113.8)	103.1 (97.2, 116.1)	102.1 (95.6, 110.6)	−3.05 (−5.4, 0.1)	.066	
% Body fat						
Intervention +	46.9 (42.1, 52.9)	45.6 (42.0, 51.8)	47.0 (42.7, 52.8)	0.0 (−1.2, 0.5)	.221	.840
Intervention	48.0 (42.5, 51.5)	46.0 (41.1, 49.6)	44.6 (41.7, 52.1)	−0.6 (−2.4, 1.3)	.442	.916
Control	46.8 (44.2, 51.4)	45.8 (42.4, 52,9)	47.0 (42.6, 53.4)	0.10 (−2.5, 1.7)	.889	
SBP (mmHG)						
Intervention +	122.3 (112.3, 137.7)	118.3 (103.7, 135.7)	109.7 (104.7, 127.7)	−8.7 (−14.3, 2.3)	**.047**	.454
Intervention	116.0 (111.7, 143.2)	117.3 (109.0, 126.8)	130.3 (111.3, 141.3)	6.0 (−4.7, 12.72	.279	.310
Control	124.3 (118.3, 127.3)	122.0 (113.6, 131.7)	121.7 (117.6, 127.3)	−4.0 (−10.4, 8.3)	.440	
DBP (mmHG)						

Outcome variable and group	Baseline Median (IQR) (n = 35)	3 months Median (IQR) (n = 33)	6 months Median (IQR) (n = 33)	Change from Baseline to 6 Months		
				Median (IQR)	*P* within group[a]	*P* for Intervention vs. Control[b]
Intervention +	81.0 (66.7, 85.7)	76.7 (69.3, 83.0)	77.7 (67.7, 80.7)	−1.3 (−6.7, 2.3)	.266	.823
Intervention	78.7 (72.5, 89.7)	79.0 (71.1, 86.7)	79.0 (77.2, 90.7)	3.3 (−3.5, 6.7)	.279	.109
Control	80.3 (72.0, 90.0)	79.5 (71.7, 85.2)	86.3 (73.1, 87.0)	−3.8 (−5.8, 1.2)	.327	
Hemoglobin A1c						
Intervention +	5.7 (5.4, 6.1)	5.7 (5.6, 6.1)	5.9 (5.5, 6.1)	0.10 (−0.1, 0.2)	.465	.165
Intervention	5.7 (5.5, 5.9)	5.7 (5.5, 6.0)	5.6 (5.5, 6.0)	0.0 (−0.1, 0.1)	.491	**.021**
Control	5.6 (5.3, 5.9)	5.7 (5.2, 5.9)	5.8 (5.4, 6.1)	0.15 (.03, 0.3)	**.041**	
Total Cholesterol (mg/dl)						
Intervention +	182.0 (144.0, 190.0)	180.0 (154.0, 192.0)	173.0 (152.0, 207.0)	−6.0 (−16.0, 16.0)	.838	.383
Intervention	201.0 (172,0, 218.5)	187.5 (164.5, 227.5)	202.0 (175.0, 230.0)	7.0 (−10.5, 17.5)	.196	.108
Control	191.0 (170.0, 221.0)	183.5 (152.5, 204.5)	196.0 (160.3, 236.5)	−8.0 (−18.5, 1.3)	.233	
LDL (mg/dl)						
Intervention +	103.4 (78.5, 126.8)	99.0 (84.0, 116.0)	98.5 (83.8, 120.8)	−2.5 (−11.3, 7.0)	.759	.420
Intervention	112.0 (92.0, 144.0)	110.0 (88.0, 161.0)	117.5 (86.5, 147.0)	−9.5 (−16.5, 22.5)	.906	.879
Control	119.0 (94.0, 123.4)	103.0 (83.5, 121.3)	108.5 (83.0, 125.8)	−8.0 (−17.0, 4.0)	.345	
HDL (mg/dl)						
Intervention +	45.0 (39.0, 65.0)	52.0 (41.0, 73.0)	56.0 (44.0, 94.3)	2.0 (−3.0, 4.0)	.476	.430
Intervention	54.0 (44.0, 72.0)	53.0 (44.8, 73.5)	57.0 (52.0, 78.5)	6.0 (0.0, 16.0)	**.030**	.710
Control	43.0 (38.0, 85.0)	53.0 (36.8, 83.5)	56.0 (43.0, 66.0)	7.0 (−3.0, 11.5)	.310	
Triglycerides (mg/dl)						
Intervention +	71.0 (64, 134)	94.0 (63, 214)	102.0 (68, 126)	4.0 (−15, 25)	.476	.585
Intervention	104.0 (87.5, 137)	91.5 (66.5, 125.8)	86.0 (73, 155.5)	−8.0 (−26.5, 28.5)	.701	.764
Control	111.0 (63, 188)	89.0 (50.8, 130.3)	103.5 (68.3, 170)	−3.5 (−13, 3)	.398	
Energy intake (kcal/day)[c]						
Intervention +	1848 (1497, 2141)	1715 (1389, 2117)	1519 (1146, 1796)	−154 (−657, 2)	.062	.456
Intervention	1778 (1032, 2322)	1320 (1012, 1940)	1529 (1152, 2253)	0 (−315, 307)	.861	.845
Control	1587 (1198, 2173)	2084 (1494, 2198)	1701 (1248, 2426)	−124 (−566, 552)	.859	
Energy expenditure (kcal/week)						

Outcome variable and group	Baseline Median (IQR) (n = 35)	3 months Median (IQR) (n = 33)	6 months Median (IQR) (n = 33)	Change from Baseline to 6 Months		
				Median (IQR)	*P* within group[a]	*P* for Intervention vs. Control[b]
Intervention +	432 (48, 720)	504 (288, 2016)	864 (96, 1481)	432 (0, 706)	**.028**	.207
Intervention	607 (144, 1075)	744 (528, 1014)	384 (120, 1191)	72 (−504, 461)	.937	.844
Control	144 (48, 720)	504 (72, 1367)	144 (0, 1006)	0 (−573, 358)	.866	

Median (IQR) displayed for participants completing measurement at each visit: Baseline (n = 11 for Intervention+, n=13 for Intervention, n=11 for Control); 3 months (n=11 for Intervention+, n=12 for Intervention, n=10 for Control); 6 months (n=11 for Intervention+, n = 13 for Intervention, n = 9 for Control).
At 6 months, n=8 for Control measures of % body fat, blood pressure, hemoglobin A1c, total cholesterol, HDL, and triglycerides.
Sample sizes for valid LDL measures: Baseline (n=10 for Intervention+, n=13 for Intervention, n= 9 for Control); 3 months (n=11 for Intervention+, n=11 for Intervention, n=8 for Control); 6 months (n=10 for Intervention+, n=12 for Intervention, n=6 for Control).

BMI body mass index, *SBP* systolic blood pressure, *DBP* diastolic blood pressure, *LDL* low-density lipoprotein cholesterol, *HDL* high-density lipoprotein cholesterol.

[a] *p* values within group estimated using Wilcoxon signed rank test.

[b] *p* values between Intervention group vs. Control estimated using Kruskal-Wallis tests.

[c] Dietary recalls below probable cutpoint (600 kcal) for daily intake by an adult woman were recoded to 600 kcal (n=1 at baseline, 3 months and 6 months).