LINEBERGER COMPREHENSIVE CANCER CENTER
CLINICAL ONCOLOGY RESEARCH PROGRAM
UNIVERSITY OF NORTH CAROLINA AT CHAPEL HILL

PROTOCOL AMENDMENT #3

LCCC 1614: The MOVES Trial: MOtiVating Endometrial Cancer Survivors with Activity Monitors and Tailored Feedback

AMENDMENT INCORPORATES (check all that apply):

_x_ Editorial, administrative changes
___ Scientific changes (IRB approval)
___ Therapy changes (IRB approval)
___ Eligibility Changes (IRB approval)

AMENDMENT RATIONALE AND SUMMARY:

This amendment increases the accrual from 36 to 39 participants to account for participants who did not complete the study and ensure enough evaluable data is collected to meet the aims of the study.

1. We updated Section 1.1 to justify accrual from 36 to 39 patients.
2. Section 4.0 graphics was updated to show new accrual goal.
3. Section 5.0 was also updated to justify new accrual goal
4. We are changing the PI from Leslie H. Clark MD to Victoria Bae-Jump MD

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PROTOCOL AMENDMENT #2

LCCC 1614: The MOVES Trial: MOtiVating Endometrial Cancer Survivors with Activity Monitors and Tailored Feedback

AMENDMENT INCORPORATES (check all that apply):

_x_ Editorial, administrative changes
___ Scientific changes (IRB approval)
___ Therapy changes (IRB approval)
___ Eligibility Changes (IRB approval)

AMENDMENT RATIONALE AND SUMMARY:

This amendment adjusts timing of consent and enrollment visits to minimize the time lapse in between these two occurrences (~3 months). After careful review, waiting about three months between consent and enrollment can askew data and cause patient behavioral changes.

1. Edited exclusion criteria in section 3.2.2 to exclude patients with no computers or Bluetooth capabilities as those are required for the study.
2. Edited schema in section 4.1 and changed "Day on enrollment" to "Baseline Visit"
3. Edited section 4.2 to include:
    a. The possibility of contacting physician-identified patient's via telephone to assess interest and obtain verbal consent.
    b. In-person interactions will now allow coordinator to approach possible subjects to introduce the study prior to consent
    c. A third phone call to remind patient of fasting prior to the post-intervention visit
    d. Clarification that all subjects will now receive reminder emails to sync Fitbit and log into UNC CHART
4. Edited section 4.3 to reflect re-adjustment of timing of consent & enrollment visits so these can occur on the same day.
5. Removed mentions of GPAQ show cards and Appendix 2 and 3 in the protocol (section 4.3 and section 5.1)

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PROTOCOL AMENDMENT #1

LCCC 1614: The MOVES Trial: MOtiVating Endometrial Cancer Survivors with Activity Monitors and Tailored Feedback

AMENDMENT INCORPORATES (check all that apply):

_x_ Editorial, administrative changes
___ Scientific changes (IRB approval)
___ Therapy changes (IRB approval)
_x__ Eligibility Changes (IRB approval)

AMENDMENT RATIONALE AND SUMMARY:

This amendment adjusts timing of consent and enrollment visits to ensure study coordinators can approach subjects at standard of care visits and call subjects prior to day of eligibility and enrollment to the study. This amendment also alters eligibility criteria to exclude those with documented medical conditions, which would limit a subject's physical activity. The six-minute walk test is excluded, as it is not practical to conduct in the gynecology oncology clinic.

1. Edited exploratory objective 2.2.1 for clarity
2. Deleted previous inclusion criteria 3.1.5 describing the 6-minute walk test.
3. Added inclusion criteria 3.1.5 requesting approval from treating physician to engage in physical activity
4. Added inclusion criteria 3.1.6 and 3.1.7 to include patients having smart phones with Bluetooth capabilities and access to email
5. Edited exclusion criteria 3.2.4 and 3.2.5
6. Added exclusion criteria 3.2.6
7. Edited schema in section 4.1
8. Edited timeline of events in section 4.1
9. Edited section 4.2 Duration of Study to reflect adjusted timing of consent.
10. Added email reminders in section 4.2
11. Edited 4.3 Study Details to reflect new timing of consent
12. Edited 4.4.4 to include language about UNC CHART
13. Edited section 5.1 time and events table to reflect new timing of consent
14. Deleted erroneous randomization details in 7.1 Study Design
15. Edited sections 8.3 and 8.4.2 to reflect new Lineberger Comprehensive Cancer Center policies
16. Removed appendices 2-6 on section 10.0

LINEBERGER COMPREHENSIVE CANCER CENTER
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LCCC 1614: The MOVES Trial: MOtiVating Endometrial Cancer Survivors with Activity Monitors and Tailored Feedback

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Sponsor: Lineberger Comprehensive Cancer Center

Funding Source: Lineberger Comprehensive Cancer Center

Version Date: September 13, 2019

LCCC 1614: The MOVES Trial: MOtiVating Endometrial Cancer Survivors with Activity Monitors and Tailored Feedback

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Signature Page

The signature below constitutes the approval of this protocol and the attachments, and provides the necessary assurances that this trial will be conducted according to all stipulations of the protocol, including all statements regarding confidentiality, and according to local legal and regulatory requirements and applicable U.S. federal regulations and ICH guidelines.

Principal Investigator (PI) Name: Victoria Bae-Jump

PI Signature: _____

Date:_____

Version Date:_____

TABLE OF CONTENTS

1.0 BACKGROUND AND RATIONALE

1.1 Study Synopsis

Overweight and obese endometrial cancer (EC) survivors at UNC-CH will be approached for tailored feedback fitness intervention. We aim to enroll 36 evaluable women (18 in each arm) to evaluate if receipt of weekly tailored feedback messages can improve physical activity in EC survivors. We anticipate enrolling 39 participants to be able to evaluate 36. We hypothesize women receiving the feedback message intervention will increase step counts from baseline more than 2,000 steps compared to women in the non-intervention arm.

1.2 Background

In 2016, approximately 60,050 new cases of EC will be diagnosed with 10,470 women dying from EC (1). EC incidence in the United States has been increasing largely due to a combination of an aging population and increasing adolescent and adult obesity. In our recent multi-institutional analysis of 1400 EC patients treated over 5 years, 66% of our EC patients were obese, and 85% were overweight/obese (2). Obesity, diabetes, and insulin resistance contribute to the development of EC through hormonal alterations resulting in an estrogen dominant state, as well as through hyperinsulinemia and elevated serum glucose levels causing increased cellular proliferation and tumor growth (3-5). In addition to driving cancer development, obesity is associated with an increased risk of death in EC patients (6-9). Morbidly obese women with EC have a 6.25-fold increased risk of death from EC as compared to their non-obese counterparts (7). Fortunately, many ECs are diagnosed at an early stage and able to be fully treated via hysterectomy +/- radiation. As a result, three years following their diagnosis, EC patients are more likely to die from cardiovascular causes due to significant medical co-morbidities than from EC (10).

EC Survivor Knowledge and Readiness. Given the strong relationship between EC and obesity, we recently conducted a survey study of EC survivors to assess their knowledge of the relationship between EC and obesity (11). We found that only 46% of responders knew of the link between obesity and EC. There is evidence to suggest that the time of cancer diagnosis represents a "teachable moment" where patients are more motivated to make behavioral change (12, 13). Indeed, we found that majority (70%) of women desired to live a healthier lifestyle after their EC diagnosis (11). Despite this reported desire, only 52% of patients attempted weight loss and only 48% of patients attempted to increase physical activity. Survivors who did not attempt weight loss cited a lack of time, money or knowledge of how to lose weight. Survivors were most likely to attempt behavioral change 3 to 6 months following their diagnosis.

Physical Activity and Weight Loss. Weight loss is attained through a combination of physical activity and diet. Specifically, an individual must increase one's metabolic expenditure and reduce caloric intake in order to maintain weight loss. Modest sustained weight loss of approximately 10 kg has been shown to result in improved health outcomes (14). While both diet and physical activity are critical to sustained weight loss, physical activity appears to be particularly important to improving cardiovascular health. In fact, increasing levels of physical activity and fitness have been shown to have health benefits, even in the absence of weight loss in obese patients (15, 16). Further, increasing physical activity by 2000 steps per day (or a 20 minute walk at moderate pace) is associated with a 10% reduction in long-term cardiovascular events (defined as cardiovascular mortality, stroke, or myocardial infarction) (17). Thus, in EC survivors with significant risk of cardiovascular mortality, we will focus on increasing physical activity as the primary intervention of our study.

Activity Trackers and Physical Activity. It has been well reported that step-based physical activity programs can effectively and safely increase physical activity in sedentary individuals (18-20). Activity trackers represent the ideal accelerometer as they can track steps, calories, heart rate, and other parameters overtime that can be used by researchers or providers to monitor activity through web-based interfaces. Further, activity trackers have the added advantage of allowing women to perform self-monitoring of their behavior change, which has been shown to be more effective in similar populations (21-23).

CHART and Tailored Feedback. The Carolina Health Assessment and Resource Tool or CHART has been successfully utilized in a variety of settings to facilitate behavior change. CHART has available modules for wearable activity trackers, physical activity and weight. The modules provide users with individual assessment and tailored feedback to promote behavior change. Further, the CHART wearables module has been applied effectively to provide weekly tailored feedback in both AA men (iMOVEIt) and childcare providers (CARE2bFit). Both studies showed improved self-monitoring compliance and modest changes in physical activity. Men using wearables had about 600 more steps per day, while women in the CARE2bfit program increased their MVPA by 60% (12 to 20 minutes per day) through the middle three weeks of the study, but decreased back to week 1 levels as the program concluded. This tool has not been previously evaluated in EC patients, who appear highly motivated following their cancer diagnosis. Thus, *we propose a physical activity intervention in the EC survivor population, using weekly tailored feedback to increase steps per day using a wearable activity tracker*.

1.3 Purpose and Rationale

Given that overweight and obese women diagnosed with EC are more likely to die from cardiovascular causes of death than from EC, weight loss and physical activity in the EC survivor population is critical. We have previously shown that EC survivors are motivated to make behavioral change following their cancer diagnosis, but have a low success rate of increasing physical activity and losing weight without intervention. Tailored feedback interventions have been shown to be helpful in motivating behavioral change in other populations. Thus, *we propose a tailored feedback and activity tracker intervention to increase physical activity in EC survivors.*

2.0 STUDY OBJECTIVES AND ENDPOINTS

2.1 Primary Objective: To assess if a tailored feedback fitness intervention can increase physical activity in EC survivors from baseline to 12 weeks post-baseline.

2.2 Exploratory Objective(s):

2.2.1 To determine the acceptability of the fitness intervention in EC survivors through completion survey.

2.2.2 To assess if a tailored feedback message fitness intervention can (1) decrease BMI, (2) reduce waist to hip (W/H) ratios, (3) improve quality of life (QOL) and (4) improve serum metabolic markers (insulin, glucose, and low-density lipoprotein (LDL) levels) in EC survivors.

3.0 PATIENT ELIGIBILITY

3.1 Inclusion Criteria

To participate in this study, all subjects will:

3.1.1 Be over the age of 18 years

3.1.2 Have a confirmed diagnosis of endometrial cancer and have completed therapy (surgery, chemotherapy or radiation) within the past 6 months

3.1.3 Have no current evidence of endometrial cancer

3.1.4 Have a BMI 25 kg/m2 or greater

3.1.5 Have approval from their treating physician to engage in moderate-intensity physical activity.

3.1.6 Have a smart phone with Bluetooth capabilities turned on

3.1.7 Have access to email

3.2 Exclusion Criteria

Individuals will be excluded from this study if they:

3.2.1 Are currently undergoing treatment for their cancer

3.2.2 Are unable to read a sample message aloud

3.2.3 Do not have a computer or smart phone with Bluetooth capabilities

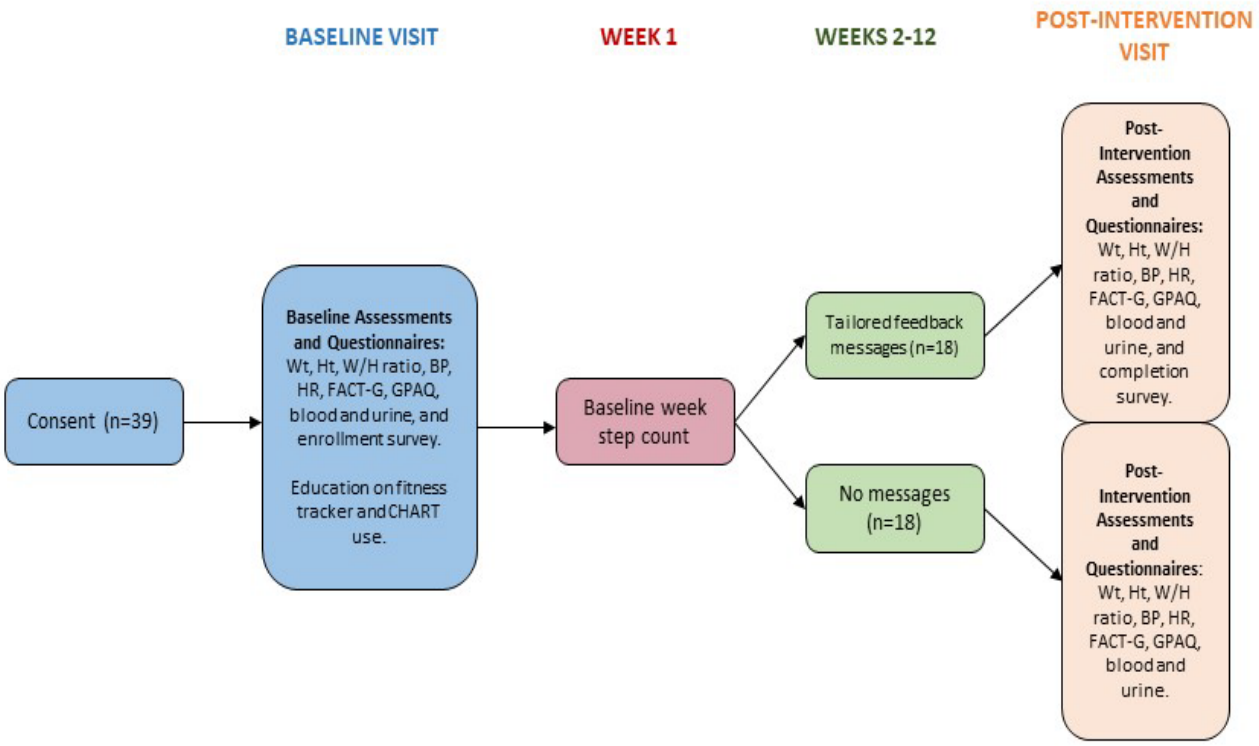
3.2.4 Are pregnant

3.2.5 Have a history of angina or palpitations with exertion

3.2.6 Have a history of uncontrolled pulmonary disease (COPD or asthma)

3.2.6 Have one or more significant medical conditions that in the physician's judgment preclude participation in the walking intervention.

4.0 STUDY PLAN



5.0 Schema

This is a randomized controlled pilot study of 39 total participants to ensure 36 evaluable datasets (n=18 per arm) of overweight or obese patients with endometrial cancer. The primary purpose of this study is to evaluate the change from baseline of daily steps in women randomized to the tailored feedback message fitness intervention. We anticipate a patient's active participation will last approximately12 weeks.

5.1 Duration of Study

Patients enrolled in this study will participate for approximately 12 weeks. The participants will be consented at the end of their cancer treatment. The participant will remain on study until their next clinic visit (~3 months).

There will be up to three in-person interactions with the patients in this study: during a clinic visit where the study is introduced, on the day of the baseline visit, and at the time of their 3-month follow up or post-intervention visit. Patients will be approached by the study coordinator for participation in this study during routine clinic visits. If a provider identifies eligible patients in advance of their scheduled visit and notifies the study coordinator, the study coordinator will contact the patient via telephone prior to their clinic visit to introduce the study and assess interest. If the patient is interested, the study coordinator will obtain a telephone consent. At the next scheduled visit, the study coordinator will obtain the patient's signed consent and provide a physical hardcopy of their signed consent form to the patient prior to initiating any study activities.

There will also be three phone calls from the study team: prior to the baseline visit to remind the patient to fast for blood collection, at the end of week 1 to ensure successful use of the fitness tracker, and prior to the post-intervention visit to remind the patient to fast again. For all subjects, study staff plans to send out email reminders so they can sync their Fitbits in time and log into UNC CHART to ensure data quality.

5.2 Study Details

Women with endometrial cancer, at the end of cancer treatment, will be recruited from the Gynecologic Oncology clinic at UNC-CH (see inclusion/exclusion criteria above). The standard care of a woman diagnosed with endometrial cancer is to undergo treatment with hysterectomy followed by possible adjuvant radiation or chemotherapy in high risk or advanced stage cancer. Following completion of therapy, a patient is seen by her oncologist every 3 months in the first 2 years following treatment for cancer surveillance. We aim to identify women within 6 months of treatment completion, generally at the initial surveillance visit. Women meeting enrollment criteria will be approached for consent. Enrolled women will receive a Fitbit fitness tracker and be instructed in how to use UNC CHART. Study staff will spend time with each participant to help them access CHART, learn to see messages, and set-up and use of the fitness tracker. All participants will keep the fitness tracker after completion of the study as token of appreciation for their participation.

At the baseline visit, patient's baseline height and weight will be obtained. Blood pressure and baseline heart rate will also be documented. Baseline BMI will be calculated. In addition to BMI, the W/H ratio will be evaluated. The W/H ratio is defined as the waist circumference in centimeters divided by the hip circumference in centimeters. W/H may be a better predictor of cardiovascular morbidity than BMI as it takes into account abdominal adiposity (25). The proper technique for measurement of the waist and hip circumference is to have the subject stand with both feet together and arms at the side without bulky clothing. Measurements should be taken at the end of expiration and be repeated twice using stretch-resistant measuring tape. Both measurements should be within 1cm of each other and the average value used. The waist measurement is taken midway between the last palpable rib and the top of the iliac crest. The hip measurement is taken at the widest portion of the buttock with the tape parallel to the floor (26). W/H ratio at baseline will be calculated.

After the above measurements and vitals are taken, patients will complete an enrollment survey including the GPAQ survey to measure baseline activity and baseline FACT-G assessment (27, 28). Pre-intervention FACT-G total score and sub-scale scores (physical well-being, social well-being, emotional well-being and functional well-being) will be compared to post-intervention scores. Finally, baseline fasting glucose, insulin and LDL will be obtained at the time of study baseline activities. Blood and urine will be collected and stored for potential future metabolomic profiling. Patients will then be randomized to either receive or not receive tailored feedback messages through UNC CHART. Participants randomized to the message arm will begin receiving encouragement and reminder UNC CHART messages to increase physical activity weekly based on the CHART algorithm (Appendix 1). Participants on the feedback arm will receive 1 message per week during the 3-month study period.

For the first week after initiating the study, each patient's baseline step count will be obtained from the fitness tracker. The mean step count over these 7 days will represent the patient's baseline step count. After the baseline week is completed, the study team will contact patients to ensure successful use of technology.

At the time of next follow up visit, the patient will undergo repeat weight, height, waist circumference, and hip circumference assessment. Heart rate and blood pressure will also be recorded at the follow up visit. The patient will complete a post-intervention acceptability survey and complete a post-intervention FACT-G assessment. Post-intervention fasting glucose, insulin, and LDL will be performed. Urine and blood will also be banked via the Tissue Procurement Facility (TPF) at the Lineberger Comprehensive Cancer Center (LCCC) for future metabolomic profiling.

5.3 Expected Risks

5.3.1 Physical Harm: The risk of physical injury related to increasing physical activity in sedentary individuals is low. Similar trials have been conducted in high-risk coronary artery disease patients without adverse events. Patients with untreated cardiac symptoms (angina, palpitations) or poorly controlled pulmonary comorbidities (such as COPD or asthma) will be excluded. There is a potential for musculoskeletal or joint injury with increased physical activity. However, there are no reported injuries in multiple large randomized trials (29-31).

5.3.2 Blood Drawing: Patients will need to undergo blood draws at baseline and post-intervention. Risks to blood draws are minimal and include pain and discomfort, infection and hematoma/bruising. Thus, women have little increased risk secondary to blood collection. Blood work will be obtained by trained staff trained hospital staff at the time of clinic visits.

5.3.3 Urine Collection: Patients will need to undergo urine collection at baseline and post-intervention. Risks to urine collection are minimal and include a small risk of infection. Thus, women have little increased risk secondary to urine collection.

5.3.4 Breach of Confidentiality: The major risk to participants included in this study is data security and confidentiality. Data will be stored in a secure, password-protected server accessible solely to trained study staff. The Study Coordinator will be trained and certified in research ethics and HIPAA tenets. All data and specimens will be given a unique research ID that will be blinded to investigators with the exception of the Study Coordinator, who will function as an honest broker. UNC CHART does not contain any identifying information, subjects are identified through study ID. Subjects must log on to UNC CHART to receive message, UNC CHART will not have email or smart phone contact information.

5.4 Removal of Patients from Protocol

Patients will be removed from the protocol if musculoskeletal injury is incurred. Patient will also be removed from the protocol at patient request. The patients will receive a phone call following week 1 to assess for adverse events, but will not be contacted in weeks 2-12 to minimize bias from the Hawthorne effect of repetitive phone calls while on trial. Patients will be instructed to contact study personnel if any concern for injury or adverse event related to trial enrollment and be removed from study.

6.0 TIME AND EVENTS TABLE

6.1 Time and Events Table

	Baseline visit	Week 1	Week 2-12	Follow up visit (Week 13)
Inclusion/Exclusion Criteria	X			
Informed Consent	X			
Education on fitness tracker and CHART	X			
Blood draw for fasting glucose, insulin, LDL	X			X
Blood and urine for banking	X			X
Fitness tracker daily step count monitoring		X (Baseline)	X	X
Weekly messages			X[1]	
AE Assessment		X (Phone call)		X (in person)
FACT-G[2]	X			X
Baseline survey including GPAQ[3]	X			
Measurements: Weight, Height, Waist/Hip Ratio	X			X
Completion survey				X[1]

[1]Only patients in the tailored feedback message arm will receive weekly messages in weeks 2-12 and complete the completion survey.
[2]Functional Assessment of Cancer Therapy, version 4 scale will be used to evaluate quality of life.
[3]Global Physical Activity Questionnaire, version 2 will be used to assess baseline physical activity.

7.0 UNANTICIPATED PROBLEMS

7.1 Definition

As defined by UNC's IRB, unanticipated problems involving risks to study subjects or others (UPIRSO) refers to any incident, experience, or outcome that:

- Is unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;
- Is related or possibly related to a subject's participation in the research; and
- Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) related to the research than was previously known or recognized.

7.2 Reporting

Any UPIRSO that occurs during the conduct of this study and that meets all three criteria listed in 6.1 must be reported to the UNC IRB using the IRB's web-based reporting system.

8.0 STATISTICAL CONSIDERATIONS

8.1 Study Design

This is a randomized, single-center, tailored feedback message intervention trial. The project will use fitness trackers to measure increase in physical activity from baseline in women randomized to receive weekly motivational feedback messages. A control group will receive a fitness tracker but no feedback message reinforcement. The primary objective of the study is to detect a 2,000 mean daily step increase from baseline in patients undergoing the feedback message intervention. Therefore, patients will be randomized, 1:1 using a 6-block scheme.

Exploratory objectives include gathering data on the acceptability of the intervention, as well as desired frequency, timing, and content of messages for use in a larger trial. Additionally, outcomes that will be the goal of a larger trial will be explored. These endpoints include: BMI, waist/hip ratio, QOL as measured by FACT-G, and serum metabolic markers (fasting insulin, glucose, and LDL).

8.2 Sample Size and Accrual

Prior studies and systematic reviews have shown participant standard deviations in daily steps of approximately 1300-1800 steps/day (20, 30, 32). Furthermore, previous studies measuring the impact of similar interventions on patient fitness levels have observed a patient step count change score standard deviation of approximately 1700 steps/day (29), where change score is defined as the change in step count from baseline to a particular week post-baseline. To determine whether there is a significant increase in physical activity among patients receiving the feedback messaging intervention versus those that do not receive the intervention, we will compare participant change scores between the each arm in our study. Assuming a participant change score standard deviation of 1800 steps/day, we estimate that 15 women will provide 80% power to detect a 2000-step difference in change score between arms (30), utilizing a two-sided Wilcoxon Two-Sample test with an alpha of 0.05. Within each arm, we will have sufficient power with n = 15 subjects to determine whether change scores within an arm are significantly different from zero, and we estimate that we will have >95% power to detect a change score of at least 2000 steps/day using a two-sided Wilcoxon Signed Rank test, assuming an alpha of 0.05 and a patient change score standard deviation of 1800 steps/day. We will also perform similar tests utilizing change scores computed at 4 weeks and 8 weeks post-baseline to determine whether these effects appear earlier on during the intervention period. We will also directly examine linear trends in daily step count with respect to time in days, as well as the overall three month average change in step count from baseline, via linear mixed models. Prior similar fitness intervention noted a 5% attrition rate in a large trial over 6 months time (29). To make a conservative estimate we will allow for 20% attrition and thus aim to enroll 39 total patients to obtain 36 evaluable datasets (18 patients in each arm). All power calculations were computing using G*Power software version 3.1.9.2 (33).

8.3 Data Analysis Plans

Our primary objective will be measured by comparing patients baseline step counts (defined as the mean step count recorded by the fitness tracker for each participant in the first 7 days following enrollment) to week 12 (final week of study participation) step counts. The week 12 step counts will also be the mean step count recorded by the fitness tracker over 7 days in a participant's final week on the study. The

mean change in steps in the intervention group will be compared to the no-intervention group using a Wilcoxon Two-sample test.

For our exploratory objectives:
Acceptability of the intervention will be measured, as previously reported, using the results of a post-intervention Likert scale survey (29). At study conclusion, patients randomized to the feedback messaging arm will complete a post-intervention survey regarding the acceptability of the invention. Question #1 of the post-intervention survey will ask patients about the acceptability of the intervention using a 5-point Likert scale. The completion survey will also include information about desired frequency of messages, desired content of messages, and timing of messages. The information obtained in this portion of the study will allow improvements to be made in our intervention prior to implementation of a larger randomized trial. The acceptability of the intervention will be defined as the proportion of patients answering favorably (very helpful or somewhat helpful) to question #1 on the completion survey. We aim to have 80% acceptability. Previous surveys of adults have shown 81% to find mobile health interventions acceptable (34). We will report the proportion of subjects reporting favorable responses to question #1 on the completion survey and the corresponding 95% CI.

Finally, we will look for decrease in BMI, improved W/H ratio, improved QOL, and improved serum metabolic markers. These data will be preliminarily evaluated in this pilot study, but will represent the primary endpoints of interest in the randomized trial to be conducted following completion of this pilot. Basic descriptive and comparative statistics will be performed to evaluate BMI, QOL, W/H ratio and insulin/glucose/LDL levels as exploratory endpoints at each time point, in addition to the change in each exploratory endpoint between time points. All computed descriptive statistics would be stratified by study arm.

8.4 Data Management/Audit

Data will be collected and stored in an Excel spreadsheet and stored on the departmental J drive in a password-protected document for security.

As an investigator initiated study, this trial will also be audited by the Lineberger Cancer Center audit committee every six or twelve months, depending on the participation of affiliate sites.

9.0 STUDY MANAGEMENT

9.1 Institutional Review Board (IRB) Approval and Consent

It is expected that the IRB will have the proper representation and function in accordance with federally mandated regulations. The IRB should approve the consent form and protocol.

In obtaining and documenting informed consent, the investigator should comply with the applicable regulatory requirement(s), and should adhere to Good Clinical Practice (GCP) and to ethical principles that have their origin in the Declaration of Helsinki.

Before enrollment onto this study, the patient will be given a full explanation of the study and will be given the opportunity to review the consent form. Each consent form must include all the relevant elements currently required by the FDA Regulations and local or state regulations. Once this essential information has been provided to the patient and the investigator is assured that the patient understands the implications of participating in the study, the patient will be asked to give consent to participate in the study by signing an IRB-approved consent form.

Prior to a patient's participation in the trial, the written informed consent form should be signed and personally dated by the patient and by the person who conducted the informed consent discussion.

9.2 Required Documentation

Before the study can be initiated at any site, the following documentation must be provided to the Office of Clinical & Translational Research (OCTR) at the University of North Carolina.

- A copy of the official IRB approval letter for the protocol
- A copy of the IRB-approved consent form

9.3 Registration Procedures

All subjects must be registered with the Lineberger Comprehensive Cancer Center, and entered into the web based clinical research platform, Oncore®.

9.4 Adherence to the Protocol

Except for an emergency situation in which proper care for the protection, safety, and well-being of the study patient requires alternative treatment, the study shall be conducted exactly as described in the approved protocol.

9.4.1 Emergency Modifications

UNC investigators may implement a deviation from, or a change of, the protocol to eliminate an immediate hazard(s) to trial subjects without prior UNC IRB approval.

For any such emergency modification implemented, a UNC IRB modification form must be completed by UNC Research Personnel within five (5) business days of making the change.

9.4.2 Single Patient/Subject Exceptions

Eligibility single subject exceptions are not permitted for Lineberger Comprehensive Cancer Center Investigator Initiated Trials under any circumstances. Other types of single subject exceptions may be allowed if proper regulatory review has been completed in accordance with Lineberger Comprehensive Cancer Center's Single Subject Exceptions Policy.

9.4.3 Other Protocol Deviations/Violations

According to UNC's IRB, a protocol deviation is any unplanned variance from an IRB approved protocol that:

- Is generally noted or recognized after it occurs
- Has no substantive effect on the risks to research participants
- Has no substantive effect on the scientific integrity of the research plan or the value of the data collected
- Did not result from willful or knowing misconduct on the part of the investigator(s).

An unplanned protocol variance is considered a violation if the variance meets any of the following criteria:

- Has harmed or increased the risk of harm to one or more research participants.
- Has damaged the scientific integrity of the data collected for the study.
- Results from willful or knowing misconduct on the part of the investigator(s).
- Demonstrates serious or continuing noncompliance with federal regulations, State laws, or University policies.

If a deviation or violation occurs please follow the guidelines below:

Protocol Deviations: UNC personnel will record the deviation in OnCore® (or other appropriate database set up for the study), and report to any sponsor or data and safety monitoring committee in accordance with their policies. Deviations should be summarized and reported to the IRB at the time of continuing review.

Protocol Violations: Violations should be reported by UNC personnel within one (1) week of the investigator becoming aware of the event using the same IRB online mechanism used to report UPIRSO.

Unanticipated Problems Involving Risks to Subjects or Others (UPIRSO:
Any events that meet the criteria for "Unanticipated Problems" as defined by UNC's IRB (see section 6.1) must be reported by the Study Coordinator using the IRB's web-based reporting system.

9.5 Amendments to the Protocol

Should amendments to the protocol be required, the amendments will be originated and documented by the Principal Investigator at UNC. It should also be noted that when an amendment to the protocol substantially alters the study design or the potential risk to the patient, a revised consent form might be required.

The written amendment, and if required the amended consent form, must be sent to UNC's IRB for approval prior to implementation.

9.6 Record Retention

Study documentation includes all Case Report Forms, data correction forms or queries, source documents, Sponsor-Investigator correspondence, monitoring logs/letters, and regulatory documents (e.g., protocol and amendments, IRB correspondence and approval, signed patient consent forms).

Source documents include all recordings of observations or notations of clinical activities and all reports and records necessary for the evaluation and reconstruction of the clinical research study.

Government agency regulations and directives require that all study documentation pertaining to the conduct of a clinical trial must be retained by the study investigator. In the case of a study with a drug seeking regulatory approval and marketing, these documents shall be retained for at least two years after the last approval of marketing application in an International Conference on Harmonization (ICH) region. In all other cases, study documents should be kept on file until three years after the completion and final study report of this investigational study.

9.7 Obligations of Investigators

The Principal Investigator is responsible for the conduct of the clinical trial at the site in accordance with Title 21 of the Code of Federal Regulations and/or the Declaration of Helsinki. The Principal Investigator is responsible for personally overseeing the treatment of all study patients. The Principal Investigator must assure that all study site personnel, including sub-investigators and other study staff members, adhere to the study protocol and all FDA/GCP/NCI regulations and guidelines regarding clinical trials both during and after study completion.

The Principal Investigator at each institution or site will be responsible for assuring that all the required data will be collected and entered onto the Case Report Forms. Periodically, monitoring visits will be

conducted and the Principal Investigator will provide access to his/her original records to permit verification of proper entry of data. At the completion of the study, all case report forms will be reviewed by the Principal Investigator and will require his/her final signature to verify the accuracy of the data.

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11.0 **APPENDICES**

Appendix 1: UNC CHART Feedback Message Library

PROJECT: MOVES
SUBJECT: FEEDBACK INFORMATION

Data input

- Data will be input into the feedback systems in two ways from FitBIT through Validic
- One physical activity variable will be used for feedback for each participant.
    - Steps per day
        - Used to compute: Average steps per day (average over days provided for that week)
- Data structure
    - The raw data will include steps and MVPA minutes for each day of the week.
    - Each weekly report will be updated based on the data retrieved for the previous 7 days.
        - Example: data below would be used to create report opened to participant on Monday MAR 14th.
    - Data will be used to compute weekly summary variables that will be used to control the CHART feedback.

Daily data for 1 participant over first 2 weeks of intervention

PID	Date	Day of week	Steps	NOTE
1562	3/07/2016	MON	0	Sync, but no Wear Steps < 2000, **not used**
1562	3/08/2016	TUE	6000	OK
1562	3/09/2016	WED	6000	OK
1562	3/10/2016	THU	8000	OK
1562	3/11/2016	FRI	4000	OK
1562	3/12/2016	SAT	.	No Sync, not 0
1562	3/13/2016	SUN	.	No Sync, not 0
1562	3/14/2016	MON	5000	OK

1562	3/15/2016	TUE	7000	OK
1562	3/16/2016	WED	8000	OK
1562	3/17/2016	THU	1000	Sync, but no wear steps <2000, **not used**
1562	3/18/2016	FRI	9000	OK
1562	3/19/2016	SAT	4000	OK
1562	3/20/2016	SUN	6000	OK

Weekly summary variables computed from daily data.

intWEEK	WKStartdate	nDaysMonitor	nDaysSync	StepPERday	goalSTEP	NOTmeetSTEP	NEWgoalstep
1	3/07/16	4	5	6000	5000	0	6500
2	3/14/16	6	7	6500	6500	0	7000

Computed Variables and Criteria

Weekly summary variables computed from daily data.

intWEEK	WKStartdate	nDaysMonitor	nDaysSync	StepPERday	goalSTEP	NOTmeetSTEP	NEWgoalstep
1	3/07/16	4	5	6000	5000	0	6500
2	3/14/16	6	7	6500	6500	0	7000

Variables for Feedback

Variable name	Limit	Compute	Description
intWEEK	1 to 6		Week of intervention
nDayMonitor	0 to 7	number of days with more than 2000 steps	Number of Days monitored
nDaySync	0 to 7	FITBIT only: number of non-missing days	Number of Days synced
StepPERday	Only computed if: nDAYSmonitored > 2	Average steps for days with more than 2000 steps	STEPS per Day
goalSTEP	5000 to 12000	Based on previous weeks step average and goal achievement.	Weekly Goal for Steps Step Goal for Current intervention WEEK

NotmeetSTEP	0 to 6	This value is carried forward from previous intweek
		If (STEPperday/goalSTEP) >= 0.90 then NOTmeetSTEP = 0
		If (STEPperday/goalSTEP) < 0.90 then NOTmeetSTEP = NOTmeetstep+1
			Number of consecutive weeks not meeting step goal.

NEWgoalSTEP	5000 to 12000	see “New Goal” section	New step goal

FEEDBACK for WEEKLY Report

SECTION: No title: bar graphs showing progress

VARIABLES:
used to control and provide Feedback

- INTweek
- nDayMonitor
- STEPperDAY
- goalSTEP

FEEDBACK and CONTROLS: INTweek

- 1-6

nDayMonitor

- 0-2
- 3+

FOR STEPS (per day):

Figure:

See PDF from Regina

Criteria 1	FEEDBACK
nDayMonitor	
IF nDaymonitor < 3	Your Week [intweek] goal was [goalstep] steps each day. You did not sync or wear your Fitbit enough last week to give you good feedback.
IF nDaymonitor >= 3	Your Week [intweek] goal was [goalstep] steps each day. You took about [stepPERday] steps each day.

SECTION: My NEW Goals (feedback)

VARIABLES:
used to Control Feedback

intWEEK
nDaymonitor
StepPERday
goalSTEP

FEEDBACK and CONTROLS:

NOTE:

- IF nDaymonitor < 3 then…
  - [Blank bar with only intweek label at bottom]
  - Other weeks and goal line stay same

Criteria 1	Criteria 2	Criteria 3	Criteria 4		
intWEEK	**nDayMonitor**	**Meeting GOAL (Steps 90%+ of Goal)**	**NOTmeetSTEP**	**Description**	**FEEDBACK**
1	IF nDaymonitor < 3			Not enough days monitored	Make your health a priority after getting your cancer diagnosis. We need to know where you're starting in order to help you reach 10,000 steps each day. You did not wear your fitbit enough, or sync, last week to give you a personal goal and meaningful feedback. Please be sure to wear your Fitbit each day, keep it charged, and sync using the app or your home computer.
1	IF nDaymonitor >= 3	ALL	ALL	Wore monitored	Let's get on track to take 10,000 steps each day to improve your health! Now that you have finished all your cancer treatment, it is an important time to focus on your health! Start with a small change. You can meet your goal by making every little move count! You will get about 1000 steps by taking a brisk 10-minute walk. Fit in 10 minutes of activity when you can. Walk on your work breaks. Make other small changes to your daily routine like parking farther from the store or your work, or taking the stairs.

2	IF nDaymonitor < 3	-	-	Not enough days monitored	You did not wear, or sync, your Fitbit enough last week to give you a personal goal and meaningful feedback. Please be sure to wear your Fitbit each day, keep it charged, and sync using the app or your home computer.
2	IF nDaymonitor >= 3	(STEPperday/goalSTEP) >= 0.90		Wore monitor Meeting Goal	Congratulations on your success last week! Every little move you make helps to strengthen your heart and gives you more energy. Getting healthy after a diagnosis of endometrial cancer is so important. What did you do last week that helped you fit more steps into your day? Use what you learned last week to help you meet your goal next week.
2	IF nDaymonitor >= 3	(STEPperday/goalSTEP) < 0.90	NOTmeetSTEP <= 2	Wore monitor NOT meeting goal NOT stuck	Some weeks it can be hard to fit in all of the activity that you'd like. Plan out your week in advance to find time to be active. Mark your calendar and stick with it. On very busy days, a few brisk 10-minute walks, can really help refresh and de-stress. Focusing on your health after your cancer diagnosis is so important.
3	IF nDaymonitor < 3			Not enough days monitored	You did not wear, or sync, your Fitbit enough last week to give you a personal goal and meaningful feedback. Please be sure to wear your Fitbit each day, keep it charged, and sync using the app or your home computer.
3	IF nDaymonitor >= 3	(STEPperday/goalSTEP) >= 0.90	NA	Wore monitor Meeting Goal	Great job! You are making excellent progress toward 10,000 steps and a healthier life! Find an exercise buddy to make your physical activity more fun. Ask a coworker, friend, or family member to go for a walk or bike ride with you. See if you can make it a weekly date.
3	IF nDaymonitor >= 3	(STEPperday/goalSTEP) < 0.90	NOTmeetSTEP <= 2	Wore monitor NOT meeting goal NOT stuck	Having an exercise buddy can help you meet your steps goal. Ask a coworker, friend, or family member to go for a walk with you. Exercise is more fun with a buddy, and you will be less likely to skip if you know someone's counting on you.
3	IF nDaymonitor >= 3	(STEPperday/goalSTEP) < 0.90	NOTmeetSTEP > 2	Wore monitor NOT meeting goal Stuck	Think about what has been getting in the way of your walking. What can you do to get moving in the right direction? If time is an issue, think about how you can you fit three, 10-minute walks into your day. Every step you take will add up to a healthier, happier you!
4	IF nDaymonitor < 3			Not enough days monitored	You did not wear, or sync, your Fitbit enough last week to give you a personal goal and meaningful feedback. Please be sure to wear your Fitbit each day, keep it charged, and sync using the app or your home computer.

4	IF nDaymonitor >= 3	(STEPperday/goalSTEP) >= 0.90	NA	Wore monitor Meeting Goal	Way to go! You met your steps target last week! Keep your activity interesting by trying something new next week. Dust off that bicycle or find a Zumba class or video.
4	IF nDaymonitor >= 3	(STEPperday/goalSTEP) < 0.90	NOTmeetSTEP <= 2	Wore monitor NOT meeting goal NOT stuck	Finding fun exercise options will help you stay on track and feel great! Try a Zumba video, dance to your favorite music, or take a hike with friends.
4	IF nDaymonitor >= 3	(STEPperday/goalSTEP) < 0.90	NOTmeetSTEP > 2	Wore monitor NOT meeting goal Stuck	Imagine yourself feeling, looking, and being your absolute best! Being more physically active can help you get there! People who are active are happier and energized. How will physical activity help you be your best? Use this as motivation to get stepping.
5	IF nDaymonitor < 3			Not enough days monitored	You did not wear, or sync, your Fitbit enough last week to give you a personal goal and meaningful feedback.
5	IF nDaymonitor >= 3	(STEPperday/goalSTEP) >= 0.90	NA	Wore monitor Meeting Goal	Great job meeting your steps goal last week. Make the most out of your walks this week by making them "brisk!" Brisk walking has been shown to lower people's risk of high blood pressure and diabetes and help them keep from gaining weight. Even if it's a 10-minute walk, really try to get your heart and lungs working.
5	IF nDaymonitor >= 3	(STEPperday/goalSTEP) < 0.90	NOTmeetSTEP <= 2	Wore monitor NOT meeting goal NOT stuck	Make the most out of your walks this week by making them "brisk!" Brisk walking has been shown to lower people's risk of high blood pressure and diabetes and help them keep from gaining weight. Even if it's a 10-minute walk, really try to get your heart and lungs working.
5	IF nDaymonitor >= 3	(STEPperday/goalSTEP) < 0.90	NOTmeetSTEP > 2	Wore monitor NOT meeting goal Stuck	Taking care of yourself helps you be your best and take good care of others. Getting active is an important way you can take care of yourself. Exercise will leave you feeling strong and refreshed. Give yourself time each day to get moving – you deserve it!
6	IF nDaymonitor < 3			Not enough days monitored	You did not wear, or sync, your Fitbit enough last week to give you a personal goal and meaningful feedback. Please be sure to wear your Fitbit each day, keep it charged, and sync using the app or your home computer.
6	IF nDaymonitor >= 3	(STEPperday/goalSTEP) >= 0.90	NA	Wore monitor Meeting Goal	Great job! You are making excellent progress toward 10,000 steps and a healthier life! Find an exercise buddy to make your physical activity more fun. Ask a coworker, friend, or family member to go for a walk or bike ride with you. See if you can make it a weekly date.
6	IF nDaymonitor >= 3	(STEPperday/goalSTEP) < 0.90	NOTmeetSTEP <= 2	Wore monitor	Having an exercise buddy can help you meet your steps goal. Ask a coworker, friend, or family member to go for a walk with you. Exercise is more fun with a buddy, and you will be less likely to skip if you know someone's counting on you.

				NOT meeting goal NOT stuck	
6	IF nDaymonitor >= 3	(STEPperday/goalSTEP) < 0.90	NOTmeetSTEP > 2	Wore monitor NOT meeting goal Stuck	Think about what has been getting in the way of your walking. What can you do to get moving in the right direction? If time is an issue, think about how you can you fit three, 10-minute walks into your day. Every step you take will add up to a healthier, happier you!

7	IF nDaymonitor < 3			Not enough days monitored	You did not wear, or sync, your Fitbit enough last week to give you a personal goal and meaningful feedback. Please be sure to wear your Fitbit each day, keep it charged, and sync using the app or your home computer.
7	IF nDaymonitor >= 3	(STEPperday/goalSTEP) >= 0.90	NA	Wore monitor Meeting Goal	Way to go! You met your steps target last week! Keep your activity interesting by trying something new next week. Dust off that bicycle or find a Zumba class or video.
7	IF nDaymonitor >= 3	(STEPperday/goalSTEP) < 0.90	NOTmeetSTEP <= 2	Wore monitor NOT meeting goal NOT stuck	Finding fun exercise options will help you stay on track and feel great! Try a Zumba video, dance to your favorite music, or take a hike with friends.
7	IF nDaymonitor >= 3	(STEPperday/goalSTEP) < 0.90	NOTmeetSTEP > 2	Wore monitor NOT meeting goal Stuck	Imagine yourself feeling, looking, and being your absolute best! Being more physically active can help you get there! People who are active are happier and energized. How will physical activity help you be your best? Use this as motivation to get stepping.
8	IF nDaymonitor < 3			Not enough days monitored	You did not wear, or sync, your Fitbit enough last week to give you a personal goal and meaningful feedback.
8	IF nDaymonitor >= 3	(STEPperday/goalSTEP) >= 0.90	NA	Wore monitor Meeting Goal	Great job meeting your steps goal last week. Make the most out of your walks this week by making them “brisk!” Brisk walking has been shown to lower people’s risk of high blood pressure and diabetes and help them keep from gaining weight. Even if it’s a 10-minute walk, really try to get your heart and lungs working.
8	IF nDaymonitor >= 3	(STEPperday/goalSTEP) < 0.90	NOTmeetSTEP <= 2	Wore monitor NOT meeting goal NOT stuck	Make the most out of your walks this week by making them “brisk!” Brisk walking has been shown to lower people’s risk of high blood pressure and diabetes and help them keep from gaining weight. Even if it’s a 10-minute walk, really try to get your heart and lungs working.

8	IF nDaymonitor >= 3	(STEPperday/goalSTEP) < 0.90	NOTmeetSTEP > 2	Wore monitor NOT meeting goal Stuck	Taking care of yourself helps you be your best and take good care of others. Getting active is an important way you can take care of yourself. Exercise will leave you feeling strong and refreshed. Give yourself time each day to get moving – you deserve it!
9	IF nDaymonitor < 3			Not enough days monitored	You did not wear, or sync, your Fitbit enough last week to give you a personal goal and meaningful feedback. Please be sure to wear your Fitbit each day, keep it charged, and sync using the app or your home computer.
9	IF nDaymonitor >= 3	(STEPperday/goalSTEP) >= 0.90	NA	Wore monitor Meeting Goal	Way to go! You met your steps target last week! Keep your activity interesting by trying something new next week. Dust off that bicycle or find a Zumba class or video.
9	IF nDaymonitor >= 3	(STEPperday/goalSTEP) < 0.90	NOTmeetSTEP <= 2	Wore monitor NOT meeting goal NOT stuck	Finding fun exercise options will help you stay on track and feel great! Try a Zumba video, dance to your favorite music, or take a hike with friends.
9	IF nDaymonitor >= 3	(STEPperday/goalSTEP) < 0.90	NOTmeetSTEP > 2	Wore monitor NOT meeting goal Stuck	Imagine yourself feeling, looking, and being your absolute best! Being more physically active can help you get there! People who are active are happier and energized. How will physical activity help you be your best? Use this as motivation to get stepping.
10	IF nDaymonitor < 3			Not enough days monitored	You did not wear, or sync, your Fitbit enough last week to give you a personal goal and meaningful feedback.
10	IF nDaymonitor >= 3	(STEPperday/goalSTEP) >= 0.90	NA	Wore monitor Meeting Goal	Great job meeting your steps goal last week. Make the most out of your walks this week by making them “brisk!” Brisk walking has been shown to lower people’s risk of high blood pressure and diabetes and help them keep from gaining weight. Even if it’s a 10-minute walk, really try to get your heart and lungs working.
10	IF nDaymonitor >= 3	(STEPperday/goalSTEP) < 0.90	NOTmeetSTEP <= 2	Wore monitor NOT meeting goal NOT stuck	Make the most out of your walks this week by making them “brisk!” Brisk walking has been shown to lower people’s risk of high blood pressure and diabetes and help them keep from gaining weight. Even if it’s a 10-minute walk, really try to get your heart and lungs working.
10	IF nDaymonitor >= 3	(STEPperday/goalSTEP) < 0.90	NOTmeetSTEP > 2	Wore monitor NOT meeting goal Stuck	Taking care of yourself helps you be your best and take good care of others. Getting active is an important way you can take care of yourself. Exercise will leave you feeling strong and refreshed. Give yourself time each day to get moving – you deserve it!

11	IF nDaymonitor < 3			Not enough days monitored	Congratulations on finishing this study! You have made some great progress over the last few weeks. Remember, small steps are important. Being active will help you be healthier and look and feel your best.
11	IF nDaymonitor >= 3	(STEPperday/goalSTEP) >= 0.90	NA	Wore monitor Meeting Goal	You met your steps goal this week. Congratulations on finishing this study strong! You should be proud of all of your hard work and how it will improve your health. Take a moment to think about how moving more is changing your life for the better. Use this as motivation to stay active.
11	IF nDaymonitor >= 3	(STEPperday/goalSTEP) < 0.90	NOTmeetSTEP <= 2	Wore monitor NOT meeting goal NOT stuck	Congratulations on finishing this study strong! You should be proud of all of your hard work and it will improve your health. Take a moment to think about how moving more is changing your life for the better. Use this as motivation to stay active.
11	IF nDaymonitor >= 3	(STEPperday/goalSTEP) < 0.90	NOTmeetSTEP > 2	Wore monitor NOT meeting goal Stuck	Congratulations on finishing this study! You have made some great progress over the last few weeks that will help make you healthier. Remember, small steps are important. Being active will help you look and feel your best.

SECTION: # My NEW Goals: (continued)

VARIABLES:
used to Control Feedback

1. ndaysMonitor
2. StepPERday
3. goalSTEP

Weeks	Feedback
1 – 6	Next Week's Goal: Take [NEWgoalSTEP] steps each day You Can Do it !

Computing new Goal For STEPS [NEWgoalstep]:

Criteria 1	Criteria 2	COMPUTE
[nDayMonitor]	**[stepPERday] AND [goalSTEP]**	**[NEWgoalSTEP]=**
IF nDaymonitor < 3		NEWgoalSTEP = goalSTEP
IF nDaymonitor >= 3	IF (STEPperday/goalSTEP) < 0.90	NEWgoalSTEP = goalSTEP
IF nDaymonitor >= 3	IF (STEPperday/goalSTEP) >= 0.90	NEWgoalSTEP = stepperday +500
IF nDaymonitor >= 3	IF stepperday >= 12,000	NEWgoalSTEP = 12,000