Study Title: A Mobile Intervention to Reduce Pain and Improve Health (MORPH) in Obese Older Adults

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Co-Principle Investigators: Amber Brooks, MD, and Jason Fanning, PhD

Co-Investigators: Barbara Nicklas, PhD, Edward Ip, PhD, Jack Rejeski, PhD

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Background, Rationale, and Context

Chronic pain is a pervasive[1] and costly health condition among older adults that is associated with wide-ranging adverse health outcomes including falls[2], declining mobility[1], and increasing functional disability[3]. Obesity exacerbates many of these health issues, contributing to a higher frequency of intractable pain episodes, increased pain severity, multi-site pain[4], and the use of stronger opioid medications compared to normal weight individuals with chronic pain[5]. In addition, older adults who suffer from chronic pain are significantly more sedentary than those without chronic pain[6]. Despite evidence relating increased sedentary behavior to pain[7,8], non-pharmacological treatments have largely focused on moderate-to-vigorous physical activity[9] (MVPA).

Recent evidence from an intervention designed to decreased SB demonstrated the approach is effective in preventing weight regain following weight loss[10]. This technology-driven intervention—a mobile intervention to reduce pain and improve health (MORPH)—combines telecoaching and an mHealth application (app) that integrates data from multiple sources—i.e., activity monitors, food logs, scales, and daily psychosocial assessments—to extend the reach of our intervention while better tailoring the content to be patient-centered. Importantly, intervening on SB by promoting postural shifts (i.e., breaks in sitting) and light physical activities across the day can result in a larger total volume of physical activity than MVPA[11], can be incorporated into daily life[12] and is associated with fewer aversive physical sensations than MVPA[13]. Light activities are likely to be more tolerable to older adults, especially those suffering from chronic pain. An intervention combining telecoaching with individually-adaptive mHealth tools can be delivered remotely, enabling lifestyle change among older adults with chronic pain, for whom transportation is a common barrier to the receipt of healthcare[14].

This study consists of two phases: (1) an intervention development phase wherein feedback from members of the target population will be used to iteratively refine the mHealth app and to convert the weight loss and sedentary behavior components of the intervention to a telecoaching model, and (2) a two group randomized controlled pilot trial (RCT) in 30 obese (BMI=30-45 kg/m^2), low-active, older (55-85 years) adults with chronic pain randomized to either 12-weeks of active intervention or a wait-list control.

Objectives

The aim of this study is to develop and test the feasibility and acceptability of a novel, patient-centered intervention to reduce chronic pain in older adults, leveraging the combination of telecoaching and individually-adaptive mHealth tools to decrease both body mass and sedentary behavior. MORPH addresses the NIH's 2016 National Pain Strategy's call to: 1) expand non-pharmacological treatment options in older adults, who are particularly susceptible to the side effects of opioid and other pain medications; 2) develop accessible treatments that are individually-tailored; and 3) increase the development of self-management programs[15].

Aims and Hypotheses

Specific Aim 1: To use an iterative user-centered design process to develop a mHealth application, to adapt the weight loss and sedentary behavior components of the intervention to a telecoaching model, and to evaluate the usability and feasibility of the intervention for obese, older adults with chronic pain.

Hypothesis 1: As a result of the iterative, person-centered design process, we expect scores on the system usability scale[16] to improve across the development period. We expect fewer alterations to be required as the development process proceeds, and we expect fewer use and usability issues to present during the in-home trial. Note that data collected during this period will largely be qualitative in nature.

Specific Aim 2: To conduct a pilot RCT to provide initial evidence for the effect size associated with the proposed intervention on pain and physical function and to estimate the sample size needed for a RCT that is designed to compare the effects of the intervention versus usual care on pain ratings and physical function.

Hypothesis 2: We expect the provision of the in-home application to contribute to significant improvements in pain ratings and physical function compared to the usual care condition.

Methods and Measures

Study Overview: For both phases of the study, eligible participants will own an Android or iPhone smartphone, have pain in at least 2 of 5 areas (i.e., back, neck, shoulders, hips, knees) on most days during the previous 3 months, no contraindication for participation in exercise, and will be aged 55-85 years, obese (BMI=30-45 kg/m^2, weight-stable (i.e., no weight loss or gain > 5% in the past 6 months), and low-active (i.e., engaging in less than 2 days/wk of structured physical activity for at least 20 minutes). Excluded individuals will be unable to walk without assistive devices for short distances, or will have cognitive impairment as indicated by a Montreal Cognitive Assessment[57] score less than 22. During *Phase I*, participants will engage in a structured 1:1 development session wherein they will be exposed to isolated interface elements (A/B testing), will interact with the mHealth app with minimal guidance, will narrate thought processes while engaging with the app (Think Aloud) and will complete a brief structured interview. They will then use the app in-home for one week, and will finalize their participation in the study by completing the System Usability Scale[16]. During *Phase II*, individuals will be recruited to participate in a 2-group randomized controlled trial wherein they will be assigned to either a 12-week mHealth + telecoaching intervention or a wait-list control group. The primary outcomes for this pilot study will be pain ratings on two PROMIS measures[17] and performance on the Short Physical Performance Battery[18]. Additionally, those who participated in Phase I testing will be offered participation in the 12-week program. Those who express interest will complete the program as a standalone wave to avoid contaminating other Phase II participants.

Recruitment of Study Participants

Our recruitment goals include: 50% women and 30% minority. We will recruit these individuals using community-based recruitment strategies, including newspaper and radio advertisements, e-mail, direct in-clinic recruitment approach as well as, portal messages, and mass mailings. Specific inclusion/exclusion criteria (see table) are in place to eliminate those that may be adversely affected by the interventions or that are not able to comply with the interventions. To reduce adverse effects of dietary weight loss, we exclude individuals that are non-obese, those with recent weight loss, those who have osteoporosis, and/or anyone on medications that may affect bone density. To reduce fall risk, we set an upper age limit on recruitment of 85 years and will exclude anyone who cannot walk unassisted over a short distance or who has had >1 fall in the past year (see Table below).

Participant Screening and Randomization

All individuals who respond to our recruitment strategies will call a toll-free phone number and a recruiter will describe the study and perform a brief screen for general eligibility. They will be asked about their

Criteria	**Inclusion**	**Exclusion**	**Assessment**
Age	55-85 years		Self-report
Obesity status	BMI=30-45 kg/m^2		Measured on scale
Functional status		-Dependent on cane or walker to walk a short distance; >1 fall (injurious or non-injurious) in past year (does not include falls where participant was pushed/pulled by another object and was not injured) -Vision insufficient to read a smartphone screen, unable to read	Self-report
Weight stability	Weight stable—no loss or gain (±5%) in past 6 months;		Self-report
Physical activity status		-Participation in regular resistance training and/or > 20 mins on 2+ d/w of aerobic exercise in past 6 months -No contraindication to exercise	Self-report
Cognitive status		Montreal Cognitive Assessment <22	Questionnaire
Co-morbidity/health status		--Uncontrolled hypertension (>160/90 mmHg); --Current or recent past (within 1 year) severe symptomatic heart disease, uncontrolled angina, stroke, chronic respiratory disease requiring oxygen, neurological or hematological disease; cancer requiring treatment in past yr, except non-melanoma skin cancers	BP measurement Self-report on Medical History form
Medication use		Regular use of: growth hormones, oral steroids, or prescription osteoporosis medications	Self-report and medication inventory
Research participation	Willing to provide informed consent; Agree to all study procedures and assessments; Able to provide own transportation to study visits; owns an Android or Apple smartphone.	Current participation in other research study targeting pain, physical activity, or weight loss	Self-report
Pain Status	Pain in 2 or more of the following sites on most days for the previous 3 months: back, neck, shoulders, hips		

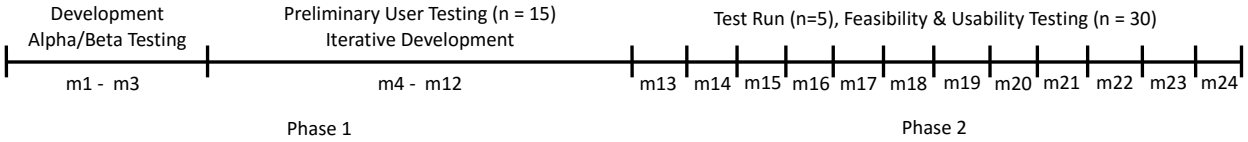
	and/or knees		
Surgery		Joint replacement or orthopedic surgery within previous 6 months or planning to have orthopedic surgery in the next 6 months	

age, weight, height, current physical activity habits, body weight in the past year, medical history, current medications, and eligibility to participate. All participants must conform to the study's inclusion/exclusion criteria. All participants, with questions regarding medical history will be cleared by a study physician (AB) and then will be approved for participation by study PI

Those who pass phone screening will be scheduled for a 1:1 development session (Phase I) or screening-visit (Phase II) at a WFBMC-affiliated facility. The screening visit will allow participants to complete self-reported questionnaires and tests of physical function. During both phases, participants provide written informed consent and complete a HIPAA authorization form in accordance with our IRB policy prior to collection of any data. For both phases, the first visit begins with measurement of weight and height to calculate BMI. Individuals who meet the BMI criteria will undergo a medical history and a cognitive test (MoCA[19]). The medical history (including blood pressure) will exclude those not meeting inclusion criteria with regard to medication use, health status, or cognitive status. Eligible participants will be randomized to treatment using a web-based randomization scheme, stratified by sex with random block sizes.

Study Procedures

A timeline for phases I and II is provided below.



Phase I – Person-Centered Design and Development

Phase I of the study will occur during the first year of the study period. During months 1 – 3, the web-based mobile application will be finalized to include novel data streams (i.e., connected scale, activity monitor, digital food log, ecological momentary assessment), initial user interface and interaction elements (to be provided by the study graphic designer), and animated educational content. Then, a select team of study investigators (lead by JF) will conduct preliminary testing of the study procedures, including the use of the application and attached peripherals, and the use of the conference calling system to be used in the study. During months 4-12, participants will be recruited to attend 1:1 sessions. After signing informed consent documents and completing baseline assessments, participants complete a series of A/B tests. In brief, a focused set of features are isolated and small variations made by the team's graphic designer (e.g., button shape or color, positioning of a feedback bar). These are presented to the participant who is asked to select their preference. This process will allow the team to identify the preferences and needs of the older adult smartphone user. Next, the participant will receive a brief introduction to the purpose of MORPH. The participant will receive minimal guidance to facilitate movement within the app, but will otherwise be asked to explore at will. Participants will be asked to narrate their thought process (i.e., to "think aloud") as they utilize the app. They will be asked to continuously narrate their internal dialogue as they were interacting with the interface. Audio recordings and detailed notes will be obtained during this process. This Think Aloud protocol provides insight into the subjective experience of the individual as they utilized the interface. Audio content will be transcribed, and key findings from the session brought to the core intervention team. Necessary iterations will be decided upon, the study graphic designer will provide updates in an A/B fashion, and

improvements made to the interface following each small grouping of interviews (n=1-3 interviews). Finally, after the interview session, the participant will bring all study peripherals to their home (i.e., Fitbit device, connected scale), and engage with the app for one week. During this period, the participant will also complete one burst of ecological momentary assessment. Following this one-week period, the participant will return to the research site to return equipment, complete the System Usability Scale[16], and receive remuneration for their time. This process is to be completed iteratively until the investigative team is confident that no further iterations are needed, and participants no longer provide meaningful interface critiques.

Phase II – MORPH Pilot Study

Whereas Phase I is concerned with ensuring the usability and desirability of the application for the target population, Phase II is meant to establish the efficacy of the program when delivered in the home. Accordingly, Phase II is a randomized controlled pilot study in which participants (N=30) will enter the study in up to three small waves. We will begin with a trial run of ~5 individuals who will all be assigned to the intervention condition to pilot all facets of the intervention. For the duration of each wave, intervention staff will keep detailed notation of software and usability challenges, and iterations will be made in between waves. Notably, these iterations will not affect the overarching structure of the intervention, but will ensure all components of the program are maximally usability for the older adult with chronic pain. The participants that are not randomized to active intervention after screening will receive monthly phone calls to keep them engaged in the study until they return for the follow up visit.

Content of Weight Loss (WL) & Sedentary Behavior (SB) Intervention. In sum, the MORPH pilot study is a 12-week randomized controlled trial. The MORPH app is embedded in a 9-week telecoaching intervention that is prefaced by 3 weeks of 1.5-hour group sessions for a total intervention spanning 12 weeks, plus 2 pre-study orientation appointments. The 3 weeks of initial face-to-face contacts are used to (a) establish the group-mediated nature of the telephone coaching contacts, (b) create connection between group members that will be built upon via the app, (c) teach basic skills needed for successful weight loss and reduced SB (e.g., mindfulness, food tracking, use of the app), and (d) develop competence in use of the mHealth app. The WL component targets a 3-5% reduction in body weight. The SB component targets: (a) increasing the number of postural shifts across the day, and (b) increasing the performance of valued activities related to independent living, including balance, strength, and mobility activates that will augment caloric restriction to promote WL and increase functional capacities as assessed by the short physical performance battery (SPPB). The distal goal of the activity component is to increase steps across the day in the range of 5,000 to 10,000 steps based on individual abilities. Individual goals for caloric intake will be prescribed to achieve an energy deficit of ~400 kcal/d from daily weight maintenance energy requirements (resting energy expenditure x activity factor of 1.3 for sedentary adults). The lowest caloric goal prescribed will be 1100 kcal/d for women and 1200 kcal/d for men. The content for the dietary weight loss intervention is based on our extensive experience in community-based trials and our most recent materials from CLIP-II, whereas the SB intervention builds upon the protocol we are using in EMPOWER (R01 AG051624-01) and has efficacy in preventing weight regain as evident from our published work with older adults[10]. Adaptation of these materials to the telecoaching + mHealth model will occur in Phase I.

Each participant will receive the Fitbit activity monitor at least 2 weeks prior to the start of the intervention and will be asked to continue their typical level of daily activity. These data will be used to establish a baseline for the SB intervention that can be tailored to each individual. Week 1 will be used as an accommodation period[20] with data from week 2 being used to assess average daily postural shifts and volume of activity. Baseline activity and weight will be built upon via weekly proximal goals, which will be set in collaboration with the study interventionist via email each week.

The intervention incorporates principles from social cognitive theory[21] and the group dynamics literature[22] into 12 weekly sessions that include nutritional education and ongoing assistance in integrating physical activities into daily life, teaching and reinforcement of self-regulatory skills, exposure to mindfulness-based stress reduction and pain management, and strategies that optimize social connection. An additional innovation is a series of highly engaging animated cartoon videos to reinforce and summarize session content. All session content will also be incorporated into bi-weekly tailored feedback. Finally, the participant's daily affective and pain experiences are used in the app to cue the participant to practice mindfulness and self-regulatory strategies at key moments throughout the day[23].

Ecological Momentary Assessment

Ecological momentary assessment (EMA; assessments collected in near real time and in the real world[24]) will be utilized to (a) gain insight into the relationships between key daily health behaviors (sleep, diet, activity) and pain and fatigue; (b) provide highly personalized feedback following the first week of each month on the relationships between an individual's health behaviors and their pain and fatigue responses across the day; and (c) guide the delivery of just-in-time mindful movement prompts. To minimize participant burden, we will use 1-week EMA bursts during weeks 1, 5, and 9. During each burst, participants will receive approximately 6 brief (i.e., <60 seconds) daily assessments delivered via smartphone within 2-hour intervals throughout waking hours, and will report current level of pain (on an 11-point Likert scale) and affect (the Feelings Scale[26]), as well as whether any medications had been taken since the previous survey. These variables can be expected to influence SB and eating patterns, along with previous night's sleep duration and quality, which will be reported on the first assessment of each day (assessed via items from the Pittsburgh sleep quality index[27]). These assessments will be used to identify daily risk periods: "pain peaks" and "affect troughs". We expect these two variables in particular to contribute to higher levels of SB and unhealthy eating[14,28]. These daily risk periods will be identified in feedback to the participant, and will also be used to craft "awareness alerts". Specifically, these data will be utilized by the program staff to create up to two daily Fitbit silent alarms. These prompts aim to cue the participant to both be mindful of their current state, and to engage in brief mindful-based exercises—which are practiced in weekly telecoaching sessions—to improve affect, reduce pain, and prevent overeating or extended sitting. The aim is to set prompts prior to daily pain periods and/or sitting period to encourage movement to suppress sitting-related stiffness and pain. These prompt schedules will be updated automatically with each EMA burst, and participants will have the opportunity to manually alter the timing of daily prompts. Those in the wait listed control condition will also complete EMA bursts on the same schedule as those in the intervention arm, and these will provide insight into the effect of the intervention on daily behaviors and trajectories of pain and fatigue.

Device Use

Because device ownership is a requirement for this study, those who lose access to the device during the intervention will be noted, but will be asked to return for post-study assessments. We are not, however, able to provide a device. All participants will be provided a Fitbit and connected scale for the purposes of the study. If the Fitbit is lost, stolen, or damaged, participants will be provided with a replacement. If a participant withdraws from the study, they will be asked to return the Fitbit. After completion of the last study visit, participants will be allowed to keep the Fitbit, as the devices become worn with time. The connected scales and ActivPal will be returned to the research center upon completion of the study.

Study Assessments

During Phase I, study assessments occur during the primary study visit (P1V1), and again after completion of the one-week trial (P1V2)

During Phase II, study assessments occur during a baseline physical function and questionnaire appointment (P2V1), and a technological orientation (P2V2). Note that no measures are collected during

the P2V3 nutrition appointment. Final assessments are collected during the final week of the intervention or following the intervention (P2V4). A table of assessments collected during Phase II is provided below.

MORPH Measures	Outcome	P1V1	P1V2	P2V1	P2V2	P2V3	P2 Inter-vention	P2 Weeks 1,5,9, 12	P2V4	P2V5 *Control only	P2V6 *Control only	P2 Control Inter-vention
Week		0	1	0	0		1-12	1,5,9,12	12-14	15	16	17-29
A/B Preferences	Primary Non-RCT*	X										
Retrospective Think Aloud Coding	Primary Non-RCT*	X										
System Usability Scale	Primary Non-RCT*		X									
Issue Logs	Other		X				X					X
Demographics & Medical History	Other	X		X								
MOCA	Other	X		X								
Adverse Events	Other		X				X		X			X
CES-D	Other	X		X					X			
FACIT	Other	X		X					X			
Pittsburgh Fatigability	Other	X		X					X			
Pittsburgh Sleep Quality Index	Other	X		X					X			
SF-36	Other	X		X					X			
Satisfaction with Physical Function	Other	X		X					X			
Self-Efficacy for Walking	Other	X		X					X			
Movement Self-Efficacy	Other	X		X					X			
Self-Efficacy for Managing Eating	Other	X		X					X			
MAAS	Other	X		X					X			
Power of Food	Other			X					X			
Food Cravings	Other			X					X			
Perceived Stress	Other	X		X					X			
Body Weight	Secondary	X		X					X			

Height, BP, Pulse	Other	X		X					X			
PROMIS Pain Intensity Scale (3 item)	Primary *RCT Phase	X		X					X			
PROMIS Pain Interference Scale (8 item)	Primary *RCT Phase	X		X					X			
Short Physical Performance Battery (SPPB)	Primary *RCT Phase			X					X			
Mobility Assessment Tool Short Form (MAT-SF)	Other			X					X			
In-Home Weight (Connected Scale)	Other						X				X	
Sedentary Activity & Transitions (ActivPal)	Secondary			X					X			
Steps, Light and Vigorous Activity (ActivPal)	Secondary				X			X *only week 12				
Sedentary Activity & Transitions (Fitbit)	Other	X					X				X	
Steps, Light and Vigorous Activity (Fitbit)	Other	X					X				X	
Daily Pain (EMA)	Other	X			X		X	X			X	
Daily Affect (EMA)	Other				X			X				
Medication used? (EMA)	Other				X			X				
App Use (count)	Secondary						X					
Retention	Secondary								X			

Study Measure(s)

1. Baseline demographic data will be recorded based on participant self-report. Medical information on prior and existing co-morbidities and hospitalizations will be ascertained by self-report and confirmed by direct query of the participant at the screening visit. We will also record medication use by asking participants to bring in all medications (including nutritional supplements).

2. Adverse events will be assessed by asking participants at each assessment visit, and during weekly telecoaching calls. Participants will be asked to report any health changes, injuries, etc. and these will be recorded using the Adverse Event Form.

3. Physical function (a primary outcome of this study) will be assessed using the Short Physical Performance Battery (SPPB[18]), which is a measure of lower-extremity function consisting of walking speed, balance, and repeated chair stands. Perceptions of physical functioning will be assessed using the Mobility Assessment Tool Short Form (MAT-SF[29]).

4. Pain (the second primary outcome of this study) will be assessed using the PROMIS[17] pain intensity (3 item) and pain interference (8 item) scales.

5. Body weight: Body weight will be measured in-clinic on the same scale. As a process measure, we will also obtain body weights weekly from individuals in-home using a connected scale.

6. Sedentary behavior, minutes of light and moderate-vigorous physical activity, and energy expenditure: We will use the ActivPAL™ monitor to assess treatment effects on daily SB and physical activity.[79-84] Participants will be asked to wear the devices continuously (they are water resistant) for 7 consecutive days at each time point. Data will be downloaded at the end of each 7-day period and cleaned and summarized for statistical analyses. We will also obtain daily Fitbit data, which will provide ongoing assessments of physical activity and sitting behavior.

7. Psychosocial Assessments: Since attachment-related behavior is an important facet of group-mediated interventions and known to be associated with responsiveness to behavior change, we will assess anxiety and avoidance experienced in close relationships.[91] As social cognitive measures, we will assess self-efficacy expectations related to physical activity[30,31] and eating behavior[32], and outcome expectations for physical function and appearance[33]. Perceived stress will be evaluated with a short-form of the perceived stress scale[34], trait mindfulness with the MAAS[35], and control in resisting food using the power of food scale[36]. Depression will be assessed using the CES-D[37], and health-related quality of life using the SF-36[38].

8. Sleep: Sleep can be expected to influence both daily pain and daily sitting behavior, so sleep will be assessed in two ways. First, the Pittsburgh Sleep Quality Index[27] will be used to assess sleep at each assessment visit. Additionally, sleep quality will be assessed on a 4-point scale upon waking during the first EMA of each day during EMA burst periods.

9. Craving Assessment: (Phase II only)At baseline and follow-up visits, and following an overnight fast, we will administer a multidimensional state measure of craving[39]. The measure of craving provides subscales that assess the desire to consume highly valued foods, the positive reinforcement resulting from their consumption, the relief from negative feeling states that these foods provide, lack of control related to food consumption, and hunger.

10. Fatigue measures: The following fatigue questionnaires will be administered: 1) FACIT Fatigue Scale[40]; and 2) Pittsburgh Fatigability Scale[41].

11. Cognitive function will be assessed during screening using the Montreal Cognitive Assessment (MoCA)[19]; participants must score ≥22 to be eligible.

12. Ecological Momentary Assessment: EMA will be used to study within-person and within-day interactions between sleep quality and duration (assessed via items from the Pittsburgh Sleep Quality Index[27]), affect (assessed via the feelings scale), and level of pain.

During weeks 1, 5, and 9, participants will complete week-long daily assessments. Participants will be instructed to complete assessments upon waking up in the morning and immediately prior to going to bed at night. Additionally, each participant will receive up to five daily text message prompts with links to secure web-based questionnaires. Each assessment will take the average user less than one minute to complete, and will contain all items with the exception of sleep items, which will be assessed only during the first assessment of the day.

13. App Use: We will note how many times the app is opened from the home screen throughout the study.

14. Retention: We will record retention as the number of consented participants who complete baseline and follow-up testing.

Statistical Analyses

For Specific Aim 1 (development of mHealth application), we will use simple descriptive statistics and qualitative data to evaluate usability and feasibility of the intervention. For Specific Aim 2 (pilot RCT), the goal of the analysis is to (1) estimate the effect size of the intervention such that the results can be used to power a future larger RCT, and (2) explore appropriate methods and models for analyzing EMA/EMI data. We plan to estimate the effect size using the following generalized linear model: $Y_{FU} = \beta_0 + \beta_1 Y_{BL} + \beta_2 Int + \text{covariates} + \varepsilon$, where Y represents the primary outcomes (SPPB score, PROMIS pain scales), subscripts FU and BL denote measurement at week 12 follow up and baseline respectively, Int represents intervention status, □ represents regression coefficient, and ε represents random error. Because of the small sample size, we may include important covariates (e.g., gender, age) into the model if the two arms happen to be highly imbalanced. In case covariates are used, effect sizes will be estimated using the adjusted values from the above equation. We also plan to conduct similar analyses of secondary outcomes of the RCT (e.g., WL & sedentary behavior) using the aforementioned model and apply the appropriate model link function if the secondary outcome is not continuous. Although our primary goal is to determine feasibility and effect size using data collected from baseline and week 12, we do recognize the potential value of the intensively collected EMA data. Exploratory analyses, including visualization will be used to study the utility of EMA data, which include both pain and psychosocial variables. For example, we will determine if preliminary evidence supports the cross-lagged reciprocal relationship between pain and self-efficacy. Another example is the examination of intra-person vs inter-person variation in the EMA variables. The exploratory analysis is expected to inform the analytic plan for a future larger study.

Database management: All data except those generated from the activity monitors, connected scales, and EMA (these will be coded automatically) will be entered into the web-based study database as collected. Our data entry system will protect confidentiality and data security and the use of text containing identifying information will be avoided. Activity monitor data will be downloaded to a server and the summary data merged with other study data. Final analysis datasets will be stored in SPSS and SAS. All data will undergo range checks at the time of data entry and will be examined periodically by histograms and bivariate scatterplots to check for inconsistencies, unusual data needing further verification, and outliers. Plots of longitudinal observations will be used to inspect for unusual changes that need to be verified against source documents.

Human Subjects Protection

Subject Recruitment Methods:

Subject Recruitment Methods: We will recruit these individuals using community-based recruitment strategies, including newspaper and radio advertisements, e-mail, direct in-clinic recruitment approach as well as, portal messages, and mass mailings. We will also advertise in the Aging Center's VITAL newsletter and participate in community outreach events.

Informed Consent: The informed consent process will follow the procedures of the WFSM Institutional Review Board. The potential participant is mailed the informed consent form and asked to read it before their initial visit. The form is written in simple, easy-to-understand language. At first contact with the prospective participant during the initial visit, the study staff member will explain the purpose, methods and extent of the study. We require study staff to review all of the key aspects of the study verbally with the potential participants and to question potential participants to ascertain whether s/he has understood the information. Potential participants are encouraged to ask questions regarding the consent form and the study. A copy of the signed and dated consent form will be given to participants, and the original document will be placed in their individual study file, which will be stored in a secure location. In compliance with the Health Insurance Portability and Accountability Act (HIPAA) and the Standards for Privacy of Individually Identifiable Health Information of the Department of Health and Human Services, we will access personal health information only after obtaining informed consent.

Potential Study Risks: There are inherent potential risks to human subjects who participate in any research study and the potential risks to study participants in this study are listed below. Any injuries or illnesses (adverse events) during the course of a participant's enrollment in the study are monitored regularly.

- Physical function tests: There is a small risk of injury during the physical function tests, such as muscle strains or pulls, falls, or joint injury. Risks will be minimized by having experienced/trained staff conducting these assessments. A warm-up and range of motion practice will be conducted before testing. If a participant reports pain, dizziness, or other medical problem, the test will be terminated.

- Weight loss at any age include the concomitant loss of lean (muscle and bone) tissue along with fat mass loss. However, the clinical impact of this muscle and bone loss is not known. Since most adults with obesity have a higher muscle mass and bone density, this risk is mitigated by excluding individuals who are non-obese and less likely to benefit from weight loss.

    - During the behavioral weight loss classes, we will also provide nutrition education regarding adequate intake of calcium and Vitamin D, including encouraging use of dietary supplements. Participants will be counseled to consume, either using food or dietary supplements, at least 1300 mg of calcium and 1000 IU of Vitamin D daily.

- Risks of the movement intervention are minimal, but also may include an enhanced fall risk. This will be minimized by reviewing environmental factors that are known to increase fall risk.

- Risks associated with wearing the activity monitors are minimal, but may include minor skin irritations. Participants will be instructed to note these on their log and if it becomes bothersome to remove the device and call staff for further instructions.

Confidentiality and Privacy

Confidentiality will be protected by collecting only information needed to assess study outcomes, minimizing to the fullest extent possible the collection of any information that could directly identify study participants, and maintaining all study information in a secure manner. To help ensure subject privacy and confidentiality, only a unique study identifier will appear on the data collection form. Any collected patient identifying information corresponding to the unique study identifier will be maintained

on a separate master log. The master log will be kept secure, with access limited to designated study personnel. Following data collection, subject identifying information will be destroyed at the earliest opportunity, consistent with data validation and study design, producing an anonymous analytical data set. An entirely separate identifier number will be used for any data collected via the web, and the key stored offline in a secure location. Data access will be limited to study staff. Data and records will be kept locked and secured, with any computer data password protected. No reference to any individual participant will appear in reports, presentations, or publications that may arise from the study.

Data and Safety Monitoring

The co-PIs, along with the study physician, will be responsible for the overall monitoring of the data and safety of study participants. In addition, we will use the WFU Pepper Center's appointed Data Safety Monitoring Board. This board meets twice a year and reviews all studies that are supported by the WFU Pepper Center. A copy of the report will be reported to the IRB after each meeting.

Reporting of Unanticipated Problems, Adverse Events or Deviations

Any major AE (i.e., any serious injury, including all SAEs) will be recorded and reported to the co-PIs immediately after completing any and all actions that are necessary to protect the subject's health and safety. Minor AEs will be recorded and reported within seven days. A description of the event, and the date and location of the event will be recorded on the AE Reporting Form. The PIs and the Medical Director will meet quarterly, or as needed, to review all reported events and these will be compiled and reported in aggregate to the data safety officer. Within 24 hours of notification of any SAE, the PIs will report the event to the WFSM Institutional Review Board (IRB), if required.

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