A Novel Telehealth Intervention using Nutrition and Exercise to Extend Intervention Benefits: Enhancing Physical Function in the Long-term for Obese Older Adults

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Study Summary

Title	A Novel Telehealth Intervention using Nutrition and Exercise to Extend Intervention Benefits: Enhancing Physical Function in the Long-term for Obese Older Adults
Short Title	Enhancing Physical Function in the Long-term for Obese Older Adults
Protocol Number	Pro00105630
Phase	N/A
Methodology	Qualitative individual interviews and/or focus groups will be conducted in-person or via the phone with: obese older adults who previously (within the last 20 months) participated in a weight loss intervention Single-arm pilot intervention investigating the feasibility, fidelity, and acceptability of a tele-nutrition and tele-exercise 3 month weight maintenance intervention
Study Duration	1 year
Study Center(s)	Single-center
Objectives	This study seeks to develop and test the feasibility, acceptability, and fidelity of a tele-nutrition and tele-physical activity weight-maintenance intervention tailored towards obese older adults who recently lost weight.
Number of Subjects	Up to 60 (Aim 1: up to 30; Aim 2: up to 20)
Diagnosis and Main Inclusion Criteria	Past participants of weight loss intervention for obese, older adults
Study Product, Dose, Route, Regimen	N/A
Duration of administration	N/A
Reference therapy	N/A
Statistical Methodology	We plan to use applied thematic analysis for the semi-structured interviews and focus groups. Descriptive statistics, proportions for feasibility, adherence and retention will be calculated, and student's t-test will be conducted to compare weight change over time in the pilot study.

1 Introduction

This document is a protocol for a human research study. This study is to be conducted according to US and international standards of Good Clinical Practice (FDA Title 21 part 312 and International Conference on Harmonization guidelines), applicable government regulations and Institutional research policies and procedures.

1.1 Background

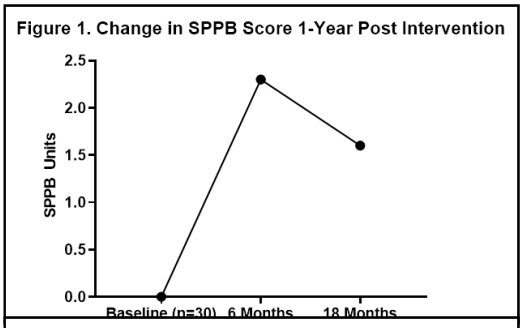
The obesity pandemic, in combination with population aging, has created an urgent demand for effective treatments for geriatric obesity. Almost 40% of older (>60 years) adults in the U.S. are obese (BMI >30 kg/m2) (1) and similar trends are being recorded globally (2). Older adults with excessive body weights experience dramatic losses of mobility, independence, and performance of activities of daily living, as well as a host of metabolic and quality of life concerns (3-5). Yet, just as with other adult cohorts, obesity reduction presents a formidable challenge for older adults. In addition to their lower calorie requirements (due to decreased metabolic rate) and more sedentary lifestyles, older adults are prone to sarcopenia (loss of muscle mass and strength), which may be exacerbated by weight reduction. It is because of this concern that the advisability of obesity reduction in older adults has been called into question (6). However, there is increasing evidence that short-term weight loss can be safely achieved in this population (7), including our recent work showing improved function with enhanced protein intake during weight reduction (8).

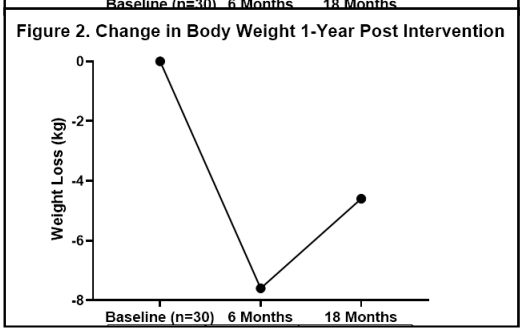
The next step in evaluating the advisability of geriatric obesity treatment is to determine whether such benefits achieved during a period of relatively intense obesity treatment are retained over time, a so called “legacy effect”. A legacy effect has happened when the benefits from a treatment or intervention are shown to persist when the intervention is no longer being administered (put both references here instead of after next sentence). “Metabolic memory,” a related term, has been used to describe the long-term impact of intensive diabetes treatment (9, 10). The potential that a short-term treatment could yield long-term benefits could be especially promising for obese older adults, who often face a number of obesity-related comorbidities and may not be able to sustain the extra burden of an ongoing weight control regimen. Unfortunately, only two studies, to our knowledge, have explored the legacy effect of obesity reduction in older adults (11, 12), and only the study by Waters et al. (12) reported physical function outcomes. These investigators conducted an 18-month follow-up assessment in 16 frail, obese older subjects who had participated in a one year, single-armed weight loss plus exercise trial; they confirmed maintenance of benefits to body weight, physical function, insulin sensitivity, and other metabolic markers. Chmelo et al. (13), conducted an 18-month follow-up to a 5-month trial of resistance training (RT) versus resistance training plus caloric restriction (RT +CR), assessing body weight and composition as well as thigh composition but not physical function. They reported loss of thigh muscle mass in both groups and found weight regain and increased total fat mass in the RT +CR group.

While obesity interventions have been shown to provide dramatic functional benefits, the sustainability of these results over time and the net long-term impact on function is unknown.

Very recently (Figures 1 and 2 below; manuscript in preparation), we have shown a "legacy effect" of obesity treatment in this population; finding that the functional benefits of an intense period of intervention persist for a year or more, even if there has been weight regain. Given this exciting finding, we hypothesize that a practical, sustainable

telehealth intervention can be developed and implemented to magnify and extend these important legacy benefits. In the proposed research, we will 1) utilize experiences from the target population and experts in the field to develop a program of novel telehealth technologies to maintain and extend the legacy benefits of obesity treatment, and 2) evaluate the feasibility of this treatment in a pilot study of obese, functionally frail older adults.





2 Study Objectives

AIM 1a: In a series of semi-structured interviews with obese, functionally frail older adults who recently completed an intensive obesity intervention, we will collect key qualitative information on determinants (facilitators and barriers) of success in maintaining the functional benefits of obesity treatment over time. In ≥24 past weight loss intervention study completers (within 6 to 24months), we will conduct semi-structured interviews with 1) past participants who have maintained their weight loss and functional improvements, to identify personal beliefs, behaviors, and environmental factors that facilitated their success, and 2) past participants who have regained their weight, to identify personal beliefs, behaviors, and environmental factors leading to their treatment relapse.

AIM 1b: **Utilizing results of Aim 1a, along with elements of our previously established evidence-based obesity intervention, we will develop a tele-nutrition and tele-exercise program intended to maintain and extend the benefits of a recent obesity intervention.** Utilizing the information obtained from the semi-structured interviews and in consultation with experts in the area of telehealth, we will create a novel program of tele-nutrition and tele-exercise guided by the Social Cognitive Theory.[3] The goal will be to maintain and extend the functional and quality of life benefits achieved in an intensive obesity intervention for older adults.

AIM 2: We will conduct a 3-month program of tele-nutrition and tele-exercise in 10 obese, functionally frail older adults who have successfully completed an obesity intervention (lost 5% of their body weight and increased SPPB by 1 point) and determine its feasibility, acceptability, and fidelity. Specifically, we will evaluate the feasibility (recruitment/retention)

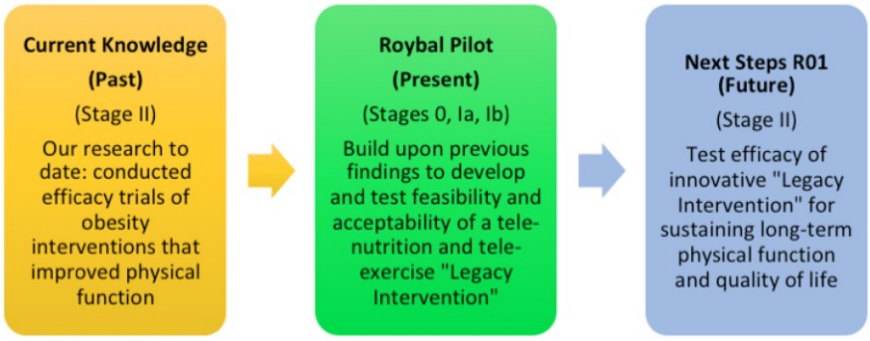
of an intervention designed to extend legacy benefits, its acceptability (as assessed by attrition and participant satisfaction), and its fidelity (as assessed by adherence). Additionally, we will access physical function (SPPB) at 0 and 3 months.

3 Study Design

3.1 General Design

We have used the NIH Stage Model to illustrate our past, present and future vision for an implementable and effective intervention that preserves the benefits of obesity treatment in overweight and obese older adult populations. As illustrated in **Figure 3**, we will build upon our previous research findings and engage participants who have or have not successfully maintained their function and weight loss to identify determinants of success/failure and develop a patient-centered tele-nutrition and tele-exercise program ("Legacy Intervention") (Stage 0). Feasibility and acceptability of the "Legacy Intervention" will be tested among obese, older adults who have successfully completed an intensive obesity intervention (Stages 1a/1b). Qualitative feedback via semi-structured interviews (Aim 1a) and focus group (Aim 2) will be utilized throughout this project to allow for refinement and modification to maximize implementation.

Figure 3. NIH Stage Model



3.2 Primary Study Endpoints

Individual interview group feedback (transcripts) to identify personal beliefs, behaviors, and environmental factors that facilitated their success or treatment relapse.
Determine the feasibility, acceptability, fidelity of a tele-nutrition and tele-physical intervention.

4 Subject Selection and Withdrawal

4.1 Inclusion and Exclusion Criteria

From Aim 1a and Aim 2: All potential participants will have previously participated in a weight loss intervention conducted by the Bales Starr Nutrition Lab and checked the box on their consent form that states, "Yes, I agree to be contacted about potential future follow-up and future research studies."

Study staff will contact potential subjects to request their participation in the study. If potential subjects express interest, they will go through a phone screening process to determine initial eligibility. If potential subjects pass the screening process, they will be sent a consent form through REDcap and a virtual consent appointment will be scheduled.

Aim 1a:
We will contact our past participants, who previously agreed to be contacted for future research study, and successfully completed a lifestyle intervention (lost at least 3% body weight and increased short physical performance battery (SPPB) score by 1 point or 6-minute walk test (6MWT) by 50 meters) within the last 6 to 24 months. Inclusion/Exclusion criteria is below:

Table 1. Inclusion/Exclusion Criteria Aim 1a

Inclusion Criteria	Exclusion Criteria
• Participated in a weight loss intervention in the last 6 to 18 months and lost ≥ 3% body weight and improved SPPB score by ≥ 1 point or 6MWT by ≥ 50 metes (Perera et al. J Am Geriatr Soc. 2006;54(5):743-9) • Age ≥ 60 • Able to speak and understand spoken and written English.	• Presence of unstable or symptomatic life-threatening illness • Neurological conditions causing functional impairment, including Parkinson's disease, multiple sclerosis, and permanent disability due to stroke • Inability to complete physical function assessment • Unwilling to have their individual interview audio recorded • History of cognitive impairment

Aim 2: Participants who agreed to be contacted for future research studies will be recruited from our on-going weight loss interventions and inclusion and exclusion criteria is below:

Table 3. Inclusion/Exclusion Criteria Aim 2

Inclusion Criteria	Exclusion Criteria

• Participated in a weight loss intervention in the last 3 months and lost ≥ 3% body weight and improved SPPB score by ≥ 1 point or 6MWT by ≥ 50 metes (Perera et al. J Am Geriatr Soc. 2006;54(5):743-9) • Age ≥ 60 • Able to speak and understand spoken and written English. • Able to record dietary intake and weight	• Presence of unstable or symptomatic life-threatening illness • Neurological conditions causing functional impairment, including Parkinson's disease, multiple sclerosis, and permanent disability due to stroke • Inability to complete physical function assessment • No access to internet connection to participate in the tele-intervention • Unable or unwilling to use provided tablet to participant in tele-intervention • History of cognitive impairment

4.2 Subject Recruitment and Screening

1. All potential participants will have successfully participated and completed (lost at least 3% body weight and improved function (SBBP score by 1 point or 6MWT by 50 meters) a weight loss intervention conducted by the Bales Starr Nutrition Lab and checked the box on their consent form that states, "Yes, I agree to be contacted about potential future follow-up and future research studies." For Aim 1a, participants will have successfully completed a weight loss intervention in the past 6 to 18 months. For Aim 2, potential participants will have successfully completed a weight loss intervention in the past 3 months. Participants in Aim 1a will be completely different from participants in Aim 2.
2. Potential participants identified will be contacted by study to determine interest. If participants are interested a telephone screen will be conducted to determine eligibility.

4.3 Early Withdrawal of Subjects

4.3.1 When and How to Withdraw Subjects

Participants may be withdrawn from the study if they are disruptive during the group discussions or cannot be contacted by the study staff after initial contact.

5 Study Procedures

AIM 1a: Collect key qualitative data on determinants (facilitators and barriers) of success in maintaining the functional benefits of obesity treatment over time.

Interview Participants: The Bales Starr Nutrition Lab at Duke University currently have two ongoing weight loss interventions in obese, older adults. We will contact our past participants, who previously agreed to be contacted for future research study, and successfully completed a lifestyle intervention (lost at least 3% body weight and increased short physical performance battery (SPPB) score by 1 point or 6-minute walk test (6MWT) by 50 meters) within the last 6 to 18 months. Participants who pass the telephone screen are willing to participate will be consented (Tabe 1), weighed, and complete the SPPB and 6MWT to determine their current functional status. Participants will then be separated into one of two groups, **Maintainers** or **Non-maintainers**, based on their current functional status (Table 2; n=12 to 15 per group or until thematic saturation is reached in each group). Next, semi-structured interviews will be conducted to identify personal beliefs, behaviors, and environmental factors that facilitated their success or treatment relapse.

Table 1. Inclusion/Exclusion Criteria Aim 1a

Inclusion Criteria	Exclusion Criteria
• Participated in a weight loss intervention in the last 6 to 18 months and lost ≥ 3% body weight and improved SPPB score by ≥ 1 point or 6MWT by ≥ 50 meters (Perera et al. J Am Geriatr Soc. 2006;54(5):743-9) • Age ≥ 60 • Able to speak and understand spoken and written English.	• Presence of unstable or symptomatic life-threatening illness • Neurological conditions causing functional impairment, including Parkinson's disease, multiple sclerosis, and permanent disability due to stroke • Inability to complete physical function assessment • Unwilling to have their individual interview audio recorded • History of cognitive impairment

Setting: Screening will be conducted by telephone. Consents will be sent electronically and a consent presentation will be conducted virtually using Duke Zoom. Consented participants will come to the Duke Center for Living Stedman Center and will complete SPPB and 6-minute walk to determine their group assignment based on functional outcomes (Table 2). Next, using telephone or Duke Zoom, participants will undergo a guided semi-structured interview (sample interview guide for both groups below).

Table 2. Aim 1a Participants

Groups	**Criteria**	**Social Cognitive Theory**
Maintainers	Physical function improvements were maintained	Personal, environmental, and behavioral facilitators
Non-maintainers	Physical function improvements were regressed	Personal, environmental, and behavioral barriers

Note to IRB: This is an interview guide for semi-structured qualitative interviews of participants as laid out in the study protocol. The interviewer will use this guide to organize the interview. Because it is a guide, exact questions may vary during the course of the interview or order may vary somewhat depending on answers given by participants. However, the guide provides a general structure and order for questions and ensures that all domains are covered in the interview as appropriate, based on the answers of the participant being interviewed. The interviewer will adhere to the guide, but will also follow the conversation, which may stray from the guide as he/she feels is appropriate.

Sample semi-structured interview guide for the Maintainers

1. **Personal**
    1. Do you see yourself differently than you did before or during the study?
    2. How does it feel to have maintained your weight loss/function status?
    3. What is your definition of success, as it relates to your weight or health?
    4. What's one thing that is contributing to your success of maintaining weight loss/continuing to eat healthy?
    5. When you think of other goals you have achieved, what about you do you believe helped you to achieve them?
        1. Can you describe a personal attribute that helped you maintain your weight loss?
    6. How do you feel about your body? About your health?
2. **Behavioral**
    1. What activities reinforce your motivation to eat healthy meals and/or move your body?
    2. What behaviors have helped you be successful?
    3. How have your behaviors changed since completing the study?
    4. Describe the process of changing your behavior long term.
    5. What were your expectations of losing weight? Were those expectations met?
    6. Has COVID-19 impacted your ability to maintain your nutrition and physical activity habits? If so, how? If not, why?
3. **Environmental**
    1. What outside yourself helps you to maintain your weight loss or achieve other goals?
    2. What outside yourself is crucial to your success?
    3. Describe the support outside of yourself that helps you maintain activities/choices that support your health?
    4. Did you experience an event, idea, or person that reinforced your commitment to maintaining weight loss?
    5. How does your culture/community affect your eating/exercise habits?
    6. How does your family/friends influence your behavior?
    7. How did your social support network (friends, family, colleagues) react to your weight loss?

Sample semi-structured interview guide for the Non-maintainers

Personal

1. What thoughts do you have about your weight journey since you completed the study?
2. How do you feel about your body? About your health? About your current weight?
3. What about your personality or experiences affects your health/nutrition choices?
4. What has worked for you in the past regarding _____(exercise, weight loss, diet)?
5. Has there been a time when you were successful and how did that make you feel?
6. If you could change one thing today regarding your health, what would that be?
7. Is there anything about your health or your weight that concerns you?
8. Describe your approach to other goals you have
   a) Why do you think you were able to achieve those goals?
   b) Why do you think you were not able to achieve those goals?

Behavioral

1. Have you maintained any habits that you acquired during the study? Why or why not?
2. Do you cook and if so, do you enjoy it?
   a) If so, how would you describe your cooking skills?

Beginner/intermediate/advanced/expert

3. What about diet is important to you?
   a) What health habits are important to you?
4. What concerns, if any, do you have about your current level of physical activity?
5. What concerns, if any, do you have about your current eating habits?
6. When you tried ____(dieting, Eggspdite) in the past, what got in the way?
   a) If it was a person - what would it take to get them on board with your habit changes?
   b) If it was finances/access to food - have you ever used community resources to help improve your access to food?
7. Describe your personal process of trying to adopt long lasting behavior change.
8. What were your expectations of losing weight?
   a) What were you hoping to change, achieve?
   b) Were those expectations met? Not met?
9. Has COVID-19 impacted your nutrition and/or physical activity? If so, how? If not, why?

Environment

1. How does your family/friends influence your eating/exercise habits?
2. What do you feel are your main barriers to healthy eating/exercise?
3. How does your culture/community affect your eating/exercise habits?
4. While you were participating in the _____ study, where did your support come from?
5. When you were in the study how did your social support network (friends, family, colleagues) react?

AIM 1b: Develop novel, customizable tele-programs of nutrition and exercise to maintain and extend legacy benefits of a recent obesity intervention: Creation of tele-intervention protocols for testing

The information gained from the individual interventions, combined with our expertise in nutrition and exercise interventions in obese, frail older adults and our established experts in tele-health and behavior science will inform the content of Tele-nutrition and Tele-exercise Legacy Intervention. Furthemore, protocol development for the Legacy Intervention will employ Social Cognitive Theory[3] components that are key to maintaining behavior change. Expected Findings: we anticipate the "Legacy Intervention" will include cognitive behavioral strategies (e.g., goal setting, self-monitoring, and social support) and draw upon a toolbox of e-approaches, including daily and weekly text reminders, virtual exercise classes, virtual individual and group nutrition classes, and step tracking device.

AIM 2: Determine the feasibility, acceptability, and fidelity of a 3-month lifestyle enhancing tele-intervention: Pilot intervention trial

The 3-month tele-nutrition and tele-physical activity intervention developed in Aim 1b will be pilot-tested in older adults who, within the last 3 months, successfully completed a lifestyle intervention and meet the inclusion criteria in Table 3.

Successful completion of a lifestyle intervention: lost at least 3% body weight and increased SPPB score by 1 point or increased their 6MWT by 50 meters from their baseline.

We will enroll participants until we reach a total of 10 study completers. We anticipate enrolling approximately 15, allowing for a 30% dropout rate.

Table 3. Inclusion/Exclusion Criteria Aim 2

Inclusion Criteria	Exclusion Criteria
• Participated in a weight loss intervention in the last 3 months and lost ≥ 3% body weight and improved SPPB score by ≥ 1 point or 6MWT by ≥ 50 metes (Perera et al. J Am Geriatr Soc. 2006;54(5):743-9) • Age ≥ 60 • Able to speak and understand spoken and written English. • Able to record dietary intake and weight	• Presence of unstable or symptomatic life-threatening illness • Neurological conditions causing functional impairment, including Parkinson's disease, multiple sclerosis, and permanent disability due to stroke • Inability to complete physical function assessment • No access to internet connection to participate in the tele-intervention • Unable or unwilling to use provided tablet to participant in tele-intervention • History of cognitive impairment

Setting: Screening will be conducted by telephone. Consents will be sent electronically and a consent presentation will be conducted virtually using Duke Zoom. Consented participants will come to the Duke Center for Living Stedman Center to receive their tablet and Garmin watch and will be provided an overview of how to login to the tele-intervention. All additional interaction will occur virtually.

Measurements:

Baseline: Baseline outcomes will be assessed after participant picks up tablet and Garmin watch. Using Duke Zoom, participants will be guided through their functional assessment and will be asked to complete their questionnaires using a REDcap link that was sent to them. Midpoint (6 weeks) and Endpoint (12 weeks): outcomes will be collected virtually as they were at baseline

Outcome Measures

Table 4: Aim 2 Outcome Measures and Collection Points		
Measurement/Procedure	**Time Points**	**Method**
Function and Activity		
SPPB	0, 6, 12 weeks	Balance (side-by-side, semi-tandem, tandem), gait speed (3-meter timed walk), strength (chair stands).
6-minute walk test (aerobic endurance)	0, 6, 12 weeks	Farthest distance walked as possible in 6 minutes (measured using Garmin watch)
Average Step Count	Weekly	Average weekly step count will be determined using Garmin VivoSmart3 watch
Body Weight and Diet		
Body weight	Weekly	Same scale, light clothing and no shoes, measured to nearest 0.1 kg
3-day diet record; Daily food journal (Adherence)	0,6, 12 weeks	3-day diet record by multiple pass; analyzed Food Processor (Version 10.13, 2013; ESHA Research); Daily food journal assessed by registered dietitian
Function, body composition		
SPPB (6, 64, 66)	0, 6, 12 weeks	Balance (side-by-side, semi-tandem, tandem), gait speed (4-meter timed walk), strength (chair stands).
6-minute walk test (aerobic endurance)	0, 6, 12 weeks	As many walking laps as possible in six minutes between cones placed 40 meters apart
Questionnaires		
Quality of Life; Mood; Depression; Stress; Sleep; Life Satisfaction	0, 6, 12 weeks	SF-36; CES-D; Perceived stress; Pittsburgh sleep
Acceptability		
Participant Satisfaction Questionnaire	12 weeks	Participants will asked to rate their satisfaction using a five point Likert scale (very dissatisfied; dissatisfied; neutral; satisfied; very satisfied) on a) satisfaction with the delivery of the tele-nutrition intervention, b) satisfaction with the delivery of the tele-exercise intervention c) satisfaction with their ability to maintain their physical function d) satisfaction with their ability to maintain their weight loss e) satisfaction with interactions with the registered dietitian.
Feedback Session	12 weeks	Using an interview guide we will examine aspects of the program in-depth from participants' perspectives.
Attrition Rate	12 weeks	Attrition Rate (%) = (Number of dropouts ÷ number of total participants) x 100
Feasibility		
Feasibility	12 weeks	Proportion of participants recruited will be calculated as the number of patients deemed potentially eligible and contacted for enrollment divided by the total number of patients enrolled.
Fidelity		
Adherence to tele-nutrition intervention	12 weeks	Proportion adherent to the tele-nutrition intervention will be computed by dividing the number of participants who maintained their weight by the total number of participants
Adherence to the tele-exercise intervention	12 weeks	Proportion adherent to the tele-exercise intervention will be computed by dividing the number of participants who maintained their functional status by the total number of participants
Retention	12 weeks	Proportion retention will be computed by dividing the number of retained subjects at the end of the intervention by the total number of participants

Risk/Benefit Assessment
The risk to human subjects for participation in this study is minimal compared to the potential health benefits they will receive from participating in the interventions and receiving detailed nutrition and exercise information.

Physical Risks:
Low-Intensity Chair Tele-Exercise: All physical activity and exercise involves some risk; however, the low-intensity chair exercises will be lead by trained certified group exercise instructors and carefully designed to ensure maximum safety. Participants will be instructed to only do the activities they feel comfortable doing and will asked to provide their rate of perceived exertion multiple times throughout the exercise class to allow for close monitoring. Furthermore, the exercise prescription described in the present study approximate the standard physical activity recommendations for older adults. The most common adverse consequences associated with participation in physical activity are fatigue, muscle soreness.
Participants will be provided contact information for Dr. Starr and all study team members and encouraged to communicate with them about any concerns regarding any aspects of the study. All reported events will be recorded in the adverse event log (including the subject's name, date, and event description) and the PI and study team will be notified. All health occurrences will be recorded and regularly reviewed by the study staff and reported to the IRB according to IRB guidelines**.**

Psychological Risks
Semi-Structured Interviews: Participants may feel uncomfortable by questions asked during interview. We will inform all participants that they can refuse any of the questions at any time during the study and they will be allowed to take a break during the interview if needed.

Legal Risks
The present study poses no legal risks to participants.

Economic Risks
The present study poses no economic risks to participants.

Social Risks
Loss of confidentiality is always a potential risk and every effort will be made to keep participant information confidential. To reduce loss of confidentiality, participants will be instructed to not use the provided tablet for personal use. Furthermore, the tablet will be cleaned to remove any personal information.

Vulnerable Populations
Vulnerable populations will not be eligible for participation in this study.

Alternatives to Participation
The only alternative is non-participation. Participants may choose not to participate in the study, or, if they agree to participate in the study, they may withdraw from the study at any

time. Their decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which they are entitled, and will not affect their access to health care at Duke. If they withdraw from the study, no new data will be collected for study purposes other than data needed to keep track of their withdrawal. If they withdraw from the study all data and samples that have already been collected for study purposes will be used unless a written request for all data to be destroyed is received. Participants who withdraw from the study will discontinue all study procedures.

Benefits

A number of potential health benefits that may accrue to participants and important scientific knowledge will likely result from this work. We expect that participants will achieve lifestyle modifications that could be sustained as a part of their personal health regimen in the setting of their community environment. Additionally, information collected from this study will benefit others through a greater understanding of how to best maintain physical function following an intensive weight loss intervention.

6 Statistical Plan

This is a pilot study that will be used to generate preliminary data for a larger clinical trial. The data analysis for both Aims are outlined below:

Aim1a: A qualitative analytical approach is well suited to exploring concepts related to a complex process (long-term adherence to weight loss and physical activity). We plan to use applied thematic analysis, organizing the data in response to the a priori questions contained in the semi-structured interviews and interview guides. Interview guide questions will be developed utilizing input from the Interventionist and socio-behavioral researchers. We will use applied thematic analysis to analyze the data. Audio recordings will be transcribed verbatim following a transcription protocol. Two analysts will use NVivo 12 software to develop and apply structural (a priori) codes to segment participants' narratives into conceptual categories (e.g., all text describing a similar concept, such as psychosocial factors). Next, analysts will identify and apply content-driven (emergent) codes to the text for each of the conceptual categories (e.g., potential themes related to psychosocial factors). Inter-coder reliability assessments will be conducted on approximately 25% of transcripts during both structural and content coding. Discrepancies in coding will be resolved through analyst discussions; transcripts will be re-coded and the codebook revised accordingly. Once coding is complete, we will examine code frequencies across transcripts to identify salient factors for each interview group, followed by comparing and contrasting factors between groups. To conclude analyses, analytical memos and reports will be written, describing the factors influencing success in maintaining the functional benefits of obesity treatment over time, together with illustrative quotes.

Aim 2. Feasibility: Proportion of participants recruited will be calculated as the number of participants deemed potentially eligible and contacted for enrollment divided by the total number of participants enrolled. Proportion retention will be computed by dividing the number

of retained participants at the end of the intervention by the total number randomized into the study. Fidelity: Proportion adherent to the tele-nutrition diet and tele-exercise intervention. Acceptability: Levels of attrition will be calculated and satisfaction will be assessed with survey items on a Likert-scale and focus group.
We will calculate these rates of retention, adherence, and attrition and their respective confidence intervals overall. While non-powerful, in a series of sensitivity tests, we will assess if adherence overall was impacted by demographic/socioeconomic variables.
We will employ a simplified applied thematic analysis for the feedback session recording and transcript following a similar approach to 1a above, less the NVivo interface and group comparison given the single group. Assessment of our measures used with screening/recruitment, adherence/retention, attrition/participant satisfaction, physical function, and self-efficacy will inform our feedback session interview guide where we will examine aspects of the program in-depth from participants' perspectives. This will allow us to examine individual level success through our objective intervention documentation in tandem with rich data from participants during the feedback session.
For physical function outcome measures a repeated measures analysis of variance will be employed to determine differences between timepoints, followed by pairwise comparison of each time point to the baseline time point.

7 Safety and Adverse Events

Oversight and Reporting: Dr. Starr will be responsible for the operation of this research study according to the study's protocol and IRB policies. Any serious adverse event, study-related or not study related will be reported via email to the Duke University IRB within 24 hours of learning about the event. Within 5 business days following the initial report, a Notification of a Problem or Event Requiring Prompt Reporting Form will be sent to the Duke IRB. This study is not an intervention and thus will not have a safety monitoring board, however the investigator will submit the number of adverse events, complaints, withdrawals, and protocol violations to the Duke University IRB. In addition, the PIs will review quarterly adverse event reports and make adjustments to the protocol if needed.

We expect adverse events to be limited to loss of protected health information. The study team has outlined procedures for data management to protect against loss of data (detailed below). Breaches in data security will be reported within 24 hours of detection, and a plan for management of the breach and modification of data security procedures will be developed within 3 business days, if applicable.

8 Data Handling and Record Keeping

8.1 Confidentiality

Information about study subjects will be kept confidential and managed according to the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

Data Storage: In order to assure each subject's confidentiality, data collected under this protocol will be coded and stored in a secure locked file cabinet located in the Center for Aging Nutrition Lab in the sub-basement of the Busse Building, Duke South. Access to subject files will be limited to those directly related to the conduct of this study. Electronic versions of these data will be stored on a limited access, password protected, secure server with coded patient identifiers. Study participants will be assigned a code number that will be linked to their name. Only authorized study personnel will have access to the linked name-code key. Data will be marked solely with the participant's code number.

Protected health information (PHI) collected from this study includes name, dates, email, medical record number, and phone numbers. PHI obtained from interviews and subjects' medical records will be recorded directly into the study's database (e.g., REDCap, Excel, MS Access).

We will develop Standard Operating Procedures for data management to protect against data loss and maintain patient confidentiality. Patient involvement in the study and information collected in the context of this research study will be considered confidential. This confidentiality will be assured through several mechanisms: Each participant will be assigned a de-identified study ID that will be used on study forms. All study forms and paper records that contain participant information will be kept in PI's office in a locked file cabinet which is secured and locked when not in use. Materials that need to be discarded will be destroyed. Specifically, compensation will be provided by check or gift card. Subjects will have to complete the IRB personal data disclosure form to receive compensation. The form will include social security number so it will be stored securely in the PI's office until it is submitted to employee travel and reimbursement (ET&R) via secure drop box. Upon receiving of payment, the social security number will be redacted from the form immediately. Forms will be submitted to ET&R every 2 to 4 weeks.

Access to all participant data and information will be restricted to authorized study personnel and covered entities identified protocol. Access to computerized data will be password protected and staff members will be assigned passwords that allow them access to only those elements of the data management system to which they are authorized. Data will be managed by Duke Medicine Department supported IT service. Study personnel will maintain certification with the Duke IRB that they have completed training in research ethics, which includes training on confidentiality. Participants will not be identified by name in any reports or publications, nor will data be presented in such a way that the identity of individual participants can be inferred. For data storage and collection, we will utilize Microsoft Access 2010 or Excel, or a REDcap database. Identifiers will be removed from analytic data sets after data merging, with personal identifiers kept in a separate location from the analytic data. No individual subject will be identified in any reports from the study. Data storage computer will be password protected. Files containing names and addresses will have a separate password and will be accessible only to personnel who need to contact subjects. All data files will be organized by study ID number and have no names or other identification attached. This ID number links all computerized study records.

Audio files will be recorded using a DigiTalks USB Recorder and saved to the project's secure folder behind the Duke server. Only IRB-approved key personnel will have access to the recorder, the audio recordings and transcribed data. Audio files will be transcribed by GMR Transcription Services, Inc. and directly uploaded to their secure website. GMR's transcription system uses 256 bit SSL and data are automatically encrypted. Duke staff will have a secure individual account that allows audio files and completed transcripts to be uploaded and ensures complete confidentiality and security at all times. GMR's transcriptionists only have access to the files assigned to them.

8.1 Records Retention

All study forms, paper records, and transcription files will be retained for at least 6 years and safely destroyed thereafter to protect confidentiality.

9 Study Monitoring, Auditing, and Inspecting

9.1 Study Monitoring Plan

The PI, with the assistance of study staff, will be responsible for overall monitoring of the data. Any unanticipated problems, deviations or protocol changes will be reported by the PI to the IRB within 24 hours.

10 Ethical Considerations

This study is to be conducted according to US and international standards of Good Clinical Practice (FDA Title 21 part 312 and International Conference on Harmonization guidelines), applicable government regulations and Institutional research policies and procedures.

This protocol and any amendments will be submitted to a properly constituted independent Ethics Committee (EC) or Institutional Review Board (IRB), in agreement with local legal prescriptions, for formal approval of the study conduct. The decision of the EC/IRB concerning the conduct of the study will be made in writing to the investigator and a copy of this decision will be provided to the sponsor before commencement of this study. The investigator should provide a list of EC/IRB members and their affiliate to the sponsor.

All subjects for this study will be provided a copy of the consent form and written consent will be obtained from each participant.

11 Study Finances

11.1 Funding Source

This study is financed through a grant from the US National Institutes of Health.

11.2 Conflict of Interest

The investigators have no conflict of interest to report.

11.3 Subject Stipends or Payments

Aim 1a: Participants will be compensated $40.00 for completing functional assessment and semi-structured interview.
Aim 2: Participants will be compensated up to $100 for completing Aim 2
$25.00 following baseline testing
$25.00 following midpoint (6weeks) testing
$50.00 following endpoint (12 weeks) testing
Participants will also be able to keep their Gramin watch

12 Publication Plan

Dr. Starr holds the primary responsibility for publishing manuscripts from this study.

13 References

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