The Development and Implementation of a Peer-Led Diet and Exercise Intervention in Older Urban Dwelling Veterans with Dysmobility-Part 2

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Study Summary

Title	The Development and Implementation of a Peer-Led Diet and Exercise Intervention in Older Urban Dwelling Veterans with Dysmobility-Part 2
Protocol Number	HP-00100748
Rationale	The multitude of interventions that have attempted to address diet and physical activity in older adults, have focused on either diet (most limited to weight loss), or physical activity alone, and few have focused directly on the unique needs of older Veterans who often live in underserved areas without access to professional resources. Many of these interventions have included non-minority populations and those with higher education levels, decreasing the ability to translate these interventions to other populations. Peer leaders may better understand the unique needs of other Veterans.
Study Duration	12 weeks training; With screening, baseline testing, intervention, and post testing we anticipate total participation will be ~4 months.
Study Center(s)	Baltimore VA Medical Center and the South Texas Veterans Health Care System
Objective	This project proposes to assess the feasibility, acceptance, and impact of a peer-led nutrition and exercise intervention in older Veterans.
Number of Subjects	36 Veterans (30 Veterans and 6 peer leaders) across two sites. 15 Veterans and 3 peer leaders at this site.
Inclusion Criteria	1) Veteran age 65 years and older 2) Dysmobility (defined as self-reported difficulty in at least one of the following activities: walking quickly across a street, walking one mile, ascending one flight of stairs, rising from a chair without the use of arms, or a fear of falling)
Exclusion Criteria	1) High cardiovascular risk 2) Utilizing home oxygen 3) Contraindications to an exercise intervention as determined by physical exam 4) Dementia (on medical record review or a mini-mental status exam score <25) 5) Currently regularly exercising or participating in a diet or weight loss intervention, 6) Behavior that prevents group interaction

1. Introduction

This document is a protocol for a human research study. This study will be conducted according to Good Clinical Practice guidelines as adopted by FDA, applicable government regulations, and Institutional research policies and procedures.

1.1. Background and Preliminary Studies

Veteran Health Relevance

Over the next 10 years, the share of Veterans age 65+ years old will increase to over 50% of the Veteran population.[1] The ability to safely maintain mobility with aging is critical as immobility is the leading cause of long term care admissions.[2] Older adults with mobility limitations have increased falls and increased healthcare utilization and expenditures.[3] Older adults with mobility limitations also are more likely to have decreased diet quality.[4] Further, Veterans demonstrate an increased risk for obesity and multimorbidity than non-Veterans.[5-7] Our preliminary data indicate that older Veterans (mean ± SD: age 69.5 ± 6.9 years; BMI 35.3 ± 5.1 kg/m^2; 4+ comorbidities diagnosed) with dysmobility demonstrate increased caloric intake with suboptimal diet quality including reduced fruit and vegetable intake when compared to age-matched norms (**Table 1**). Further they report that their reduced physical activity and poor dietary quality are related to a multitude of health and personally related issues, including a lack of motivation or boredom (31%), lack of access to exercise facilities (68%), self-reported poor diet and exercise habits (37%), and disabling health conditions or medications that interfere with diet and exercise (25%). There are a number of well-established factors contributing to poor nutrition in aging including physiological, social, emotional and environmental changes.[8-10] Among older Veterans with mobility limitations, these factors are further compounded by accessibility limitations and inability to complete instrumental activities of daily living such as shopping or cooking.[11]

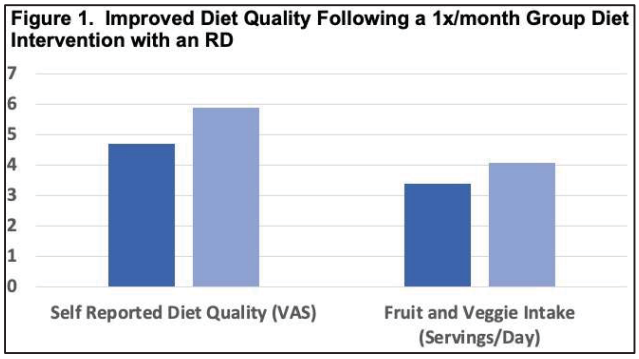
Table 1. Dietary quality in older adults with dysmobility compared to national age matched norms from NHANES 2015-2016. Data are Mean (SE)

Nutrients and Food Group Equivalents	Older Adults with Dysmobility (N=28)	NHANES Males 60-69 yrs	NHANES Males 70+ yrs
Energy, kcal/d[1]	2184 ± 122	2166 ± 56.7	2014 ± 51.0
Fat, g[1]	89.3 ± 5.2	86.5 ± 2.6	83.9 ± 2.9
Total Fruits, cup eq.[2]	0.84 ± 0.18	0.97 ± 0.11	1.06 ± 0.09
Total Vegetables, cup eq.[2]	1.3 ± 0.16	1.81 ± 0.12	1.60 ± 0.07
Sodium, mg[1]	4062 ± 259	3627 ± 107.6	3351 ± 122.4
Added sugars, tsp.[2]	17.8 ± 4.21	16.08 ± 1.25	13.22 ± 0.810

Benefits and Limitations of Group-Based Diet and Exercise Interventions in Older Adults with Dysmobility: Chronic disease and frailty are more likely to develop with age, and these outcomes are associated with increased risk for poor quality of life.[12] A recent systematic review reported there was strong and consistent observational evidence for a link between "healthier" diets and lower risk of declines in physical performance.[13] Further exercise interventions in Veterans have consistently been shown to improve physical performance. However, few studies have examined determinants of dietary intake and physical activity among older Veterans with limited physical functioning.

We recently conducted a clinical demonstration project that targeted improving diet quality in older Veterans with multiple chronic conditions (MCC) participating in Gerofit, a national exercise and health promotion program targeting older adults with dysmobility (N=50; age 69.7 ± 0.7 years; BMI 31.7 ± 0.9 kg/m^2; 72% black; average of 14.5 ± 1.0 health conditions). We found that exercise improved physical function including six-minute walk distance and ability to rise from a chair. Additionally, participation in monthly group classes with a Registered Dietitian (RD) increased self-reported dietary quality and daily fruit and vegetable intake **(Figure 1)** [14]. Sixty-two% of individuals attended at least two group classes and consumption of ≥5 fruit and vegetable servings/day increased from 21% to 33% of individuals (P<0.01) throughout the study. These data provide preliminary evidence that we can improve diet

quality among older Veterans. However, all group classes were led by RDs, reducing their ability to be scaled to accommodate the majority of older Veterans who frequently do not have access to professional resources. These data indicate the need for alternative approaches to improve the scalability of lifestyle interventions in resource poor communities.[15-17]



MOVE! is the largest weight management program in the U.S., designed to encourage healthy eating behavior and increase physical activity in Veterans who are more likely to be overweight or obese with poor diet,[5, 6] and self-report disability and high numbers of comorbid conditions.[6, 18] Participation in MOVE! is associated with successful short-term health improvements including weight loss and, as participation increases, greater improvements in weight and diet occur. [19] However, only 25% of MOVE! participants engage in sustained participation.[19] Gerofit is another popular national VA program that targets meeting American College of Sports Medicine (ACSM) physical activity guidelines in older adults dysmobility. We previously published that in Gerofit, despite clinically significant improvements in mobility and high satisfaction with the program, only 53% of older adults remain active in participation at 3-months.[20] We find that 71% of all dropouts occur within the first 3 months of Gerofit. These data demonstrate that even expert-led, well-established lifestyle interventions, targeted to older Veterans with dysmobility have a low adherence/retention rates over several months. Peer leaders may be one way to improve adherence to a lifestyle program.

Benefits of Peer Leaders: Physicians often have little time to offer support for lifestyle counseling, especially among older adults with MCC that require time consuming medical management. Further, diet and physical activity support from other trained professionals such as RDs and exercise physiologists are often not readily available in low-income urban communities. [15-17] Peer leaders offer a cost-effective opportunity to promote physical activity, healthy diet behaviors, and well-being in older adults by facilitating attention, retention, and motivation in recipients.[21] Group-based peer-led lifestyle interventions are particularly well suited for older Veterans as social interaction is a powerful motivator for this population.[22] Peer leaders can serve as relatable role models to better connect and empathize with individuals of equal status and similar age, background, and abilities[23] since they often share a common culture, language, and knowledge about the problems that their community experiences.[24] We have previously shown that using experienced, doctoral-level trainers to implement a diet modification intervention did not yield superior participant outcomes compared to training implemented by trained peer leaders.[25] Further, we found that this program could be implemented by peer leaders with high adherence to the intended intervention protocol (protocol adherence ranging from 89% to 100% of items rated as “mostly” or “fully” completed) with long term sustainability. These data provide support for the use of peer leaders to disseminate impactful education via lifestyle programs in a cost-effective and easily scalable manner.

Though previous peer-led diet and exercise interventions have been found to be successfully implemented, there are numerous limitations in their design that make them suboptimal for older Veterans with dysmobility. The majority of previously published peer-led interventions were not based upon professionally led, evidence-based interventions with available long-term follow-up data, have targeted only diet (mainly weight loss) or exercise (as opposed to both), and have emphasized walking, but not achievement of U.S. Departments of Agriculture dietary guidelines or ACSM physical activity guidelines (i.e. strength, endurance, and flexibility) for older adults. These gaps in the literature provide an opportunity for improvement in peer-led interventions.

1.2. Innovation

Our study design allows for a comprehensive assessment of complex personal and social phenomena. In doing so, the proposed research fills a critical knowledge gap in aging research by identifying and elaborating on barriers to a healthy lifestyle that may have not been captured previously in older Veterans with dysmobility. Further, the use of peer-led interventions offers a potentially low-cost, easily scalable approach. This approach will encourage dietary and physical activity change with the goal of improving energy balance and ultimately increasing mobility in this at-risk population. As both Baltimore, MD and San Antonio, TX have a large number of typically understudied minority populations, the two sites will allow us to develop a program that specifically targets a group of older Veterans typically excluded from lifestyle interventions trials (older urban males from minority populations).

2. Study Objective

The goal of this pilot project is to assess the feasibility, acceptance, and impact of a peer-led nutrition and exercise intervention in older Veterans.

3. Study Design

3.1 General Design

We will enroll 30 Veterans (and 6 additional peer leaders) at the Baltimore and South Texas VAMCs (18 subjects at each site) with a goal of 10 Veterans and at least 1 peer leader at each site completing the study. Each site will conduct the study in parallel but will rely on their local institutions for IRB and VA R&D regulatory approvals. This has been approved with a waiver from Central office (see other documents). We anticipate that the entire study will take ~18 months to complete. The sample size of 10 participants and 3 peer leaders completing the study per site was chosen to examine feasibility of the intervention.

3.2 Specific Aims

In older Veterans with dysmobility (N=10/site), we will determine the feasibility and acceptability of the peer-led intervention by assessing:

a) reach (recruitment, retention)
b) adoption (satisfaction, perceived utility attendance, engagement)
c) implementation (fidelity of intervention)
d) estimated magnitude of potential impact on select outcomes (i.e. energy balance, diet quality and mobility)

3.3. Study Endpoints

Primary outcome: To determine the feasibility and acceptability of a 12-week peer-led intervention in older Veterans with dysmobility (N=10/site).

Secondary outcomes:

a) To assess mobility and function, we will assess a standard battery of functional assessments, including strength, balance, and endurance before and after the 12-week intervention.

b) To examine cardiometabolic risk factors. We will assess BMI, body composition, and resting blood pressure before and after the 12-week intervention.

c) To examine psychological health. We will assess quality of life, fatigue, sleep quality, dietary intake and physical activity, and depression before and after the 12-week intervention.

3.4 Potential Risks to Subject Safety

We believe that the benefits associated with this study will exceed the risks, thereby resulting in a low risk:benefit ratio for any participant in the study. Specific risks for procedures can be found below.

Body Composition: The radiation risk for the measurement of body composition is well within the established dosimetry of radiation guidelines for normal subjects.

Physical Activity: Completion of physical activity is associated with the risk of cardiovascular complications such as chest pain, heart attack, or sudden death and complications related to stress and strains of muscles, twisted ankles, or falls. This risk is increased in subjects who have heart disease, poor circulation to the legs, or stroke. The AHA consensus statement on exercise standards estimates that the acute risk of sudden cardiac arrest during exercise training in subjects with known cardiac disease is approximately 1 event per 60,000 hrs of aerobic exercise. The risk of exercise training is greater at higher exercise intensities. We offset this risk by carefully pre-screening subjects with medical evaluations prior to exercise. All peer leaders will be certified in American Heart Association Basic Life Support (BLS) prior to leading any class. Additionally, all leaders will undergo a competency evaluation prior to leading any classes. Competencies will include identifying signs and symptoms of a medical emergency, how and when to call 911 in the gym setting, and who should be contacted for any adverse events that are not medical emergencies, and common injuries that occur with exercise. All exercise sessions will also have a trained staff member certified in AHA Basic Life Support (BLS) (trained exercise physiologist or other medical professional) present during all diet and exercise sessions. The staff member will only step in to assist the peer leader if 1) the peer leader requests assistance or 2) The staff member feels it is necessary to step in for the health and safety of the participant or the peer leader. All instances of the staff member assisting the peer leaders will be documented and assessed as part of the feasibility of the study. Resuscitation equipment is available for immediate use should the subjects need treatment. Depending upon the severity of the side effect, subjects will be instructed to call 911, or if less severe, referred to their primary care physician. If blood pressure or heart rate go too high or subjects develop an irregular heart rate, chest pain or leg cramps, the physical activity program is stopped immediately. Muscle and bone soreness and injury can also occur during testing and training, but subjects will be taught proper form for all physical activity techniques to minimize this.

Dietary Modification: There are minimal risks of consuming a healthy diet. Body weight will be monitored to ensure that BMI does not fall below a healthy BMI of 18.5 kg/m^2. Proper hydration guidelines also will be provided.

Mobility and Functional assessments: There is a minimal risk of falling during the walking and mobility tests. A standby aid is always present, and a gait belt is used to increase safety when necessary. Ample rest periods are provided to limit fatigue during testing. Subjects also can have musculoskeletal pain. In our collective experience in performing hundreds of these tests, we have not had any serious adverse events.

Questionnaires: The interviews and questionnaires in this study are time consuming but of minimal risk.

3.5 Potential Benefits and Alternative procedures

Participants may or may not benefit by taking part in this study. There is no guarantee they will receive direct benefit from your participation in this study. The benefits of participating in this study may be: information about their general health, physical performance, and diet. These tests will help them to know how their physical performance and diet compares to others. Their participation in an exercise and diet program may also result in general heart and muscle strength benefits

4. Subject Selection and Withdrawal

4.1. Inclusion Criteria

1) Veteran
2) Self-reported dysmobility (defined as self-reported difficulty in at least one of the following activities: walking quickly across a street, walking one mile, ascending one flight of stairs, rising from a chair without the use of arms, or a fear of falling)

4.2. Exclusion Criteria

1) A high cardiovascular risk (poorly controlled hypertension >160/100, class IV chronic heart failure, symptomatic angina at rest, or syncope in the last year without known resolution of cause)
2) Utilizing home oxygen
3) Contraindications to an exercise intervention
4) Dementia (on medical record review or a mini-mental status exam score <25)
5) Currently regularly exercising or participating in a diet or weight loss intervention,
6) Behavior that prevents group interaction

4.3 Early Withdrawal of Subjects

4.3.1 When and How to Withdraw Subjects

Subjects have the right to withdraw fully or partially from the study at any time and for any reason without prejudice to his or her future medical care by the physician or at the institution. Participation in this study is voluntary and the alternative is not to participate or to pursue an exercise intervention outside of the study.

Withdrawal of full consent for a study means that the subject does not wish to receive further investigational treatment and does not wish to or is unable to continue further study participation including any follow-up in person, by phone, through third parties including relatives or friends, via discussion with other treating physicians, and by use of medical records; subject data up to withdrawal of full consent will be included in the analysis of the study. Any subject may withdraw full consent to participate in the study at any time during the study. The Sponsor Investigator or sub-investigator will discuss with the subject appropriate procedures for withdrawal from the study during the informed consent process.

4.3.2 Data Collection and Follow-up for Withdrawn Subjects

If subjects are withdrawn prematurely from the study, appropriately designated research staff will make efforts to collect data throughout the protocol defined follow-up period for that subject. If participants decided to withdraw from the study, study staff will attempt to conduct an exit interview to request reasons for withdrawal and ways to improve the program.

If a subject withdraws consent to participate in the study, attempts will be made to obtain permission to

record data up to the protocol-described end of subject follow-up period.

Investigator and designated research staff make it a high priority to obtain data on all subjects lost to follow up. Lost to follow up will be defined as a subject missing 3 or more consecutive visits without reasonable explanation, not answering or responding to 3 follow up phone calls to subject or emergency contacts, or returned receipt of 1 certified letter.

5. Study Protocol

5.1 Peer Leader Recruitment and Training

Peer leaders will be selected based on the following eligibility:

1) Veteran
2) Prior participation in a VA-directed lifestyle program for at least 6 months,
3) Demonstrating an understanding on the importance of diet and exercise determined by a successful diet change or completing at least 85% of all exercise sessions
4) Expressing a desire for further training in the peer leader role when approached
5) Have been successful in making and maintaining positive changes to their diet and exercise habits

Once chosen, peer leaders selected from both Baltimore and San Antonio sites will be consented and sign up to attend a full day in-person training workshop delivered in-person and virtually by the PI and co-investigators at each site and with the other sites selected peer leaders. Training will be interactive, with emphasis on the provision of social support to encourage positive behavior change. They will learn about social determinants of health and discuss solutions to overcome potential physical, social/environmental, and behavioral/lifestyle barriers described among older Veterans in their communities (see **Questionnaires**). They will also be taught key safety information for working with older Veterans with multimorbid conditions (i.e., signs of low blood sugar). Additionally, they will learn key communication skills in order to convey information to their peers as an advocate of change. Training will consist of leading mock sessions and receiving supervision from the PI and co-investigators. Mock sessions will be recorded and the sessions will be rated against an adherence checklist. Three peer leaders will initially be chosen at each site.

5.2 Participant Procedures

5.2.1 Recruitment, Screening, Enrollment

With screening, baseline testing, intervention, and post testing we anticipate total participation will be ~4 months. We will approach recruitment using multiple avenues based on our experience with interventions in older Veterans. Participants will be recruited using flyers posted in VA clinics, clinician referrals and from the Baltimore metropolitan area by media advertisement. Older Veterans participating in the intervention will initially undergo a telephone screen to assess eligibility (see **phone screen form**). Those who pass the screen will be invited to the respective facility to sign informed consent and for a brief medical history and physical examination. Eligible participants will be scheduled for baseline testing.

5.2.2 Baseline Testing: Data for primary and secondary outcomes will be collected using standardized protocols and trained staff. All baseline testing will be conducted at the Baltimore VA over 1-2 visits during a one-week period. These tests are described in detail below.

5.2.3 Peer Led Exercise and Diet Intervention Procedures: Peer leaders at each site will serve as event organizers, offer guidance, and demonstrate healthy eating and exercise techniques at their

respective site. Participants will meet in groups weekly for 12 weeks with the peer leaders to learn and discuss various content dealing with diet, exercise, and managing comorbidities (~20-30 min/session) and bi-weekly they also will participate in a group exercise session (~45-50 min/session performed [after the education component]). To ensure peer leaders implement the diet and exercise intervention as developed and results reflect the true test of the program, peer leaders will complete weekly fidelity checks to document adherence to topics discussed, quality of delivery, major issues, component differentiation, participant engagement, etc. Anticipated diet themes include budget friendly nutrition for optimal aging, nutrition basics (i.e., healthy dietary patterns, hydration), recipe modification, and mindful eating. Anticipated physical activity themes include ACSM physical activity recommendations (duration, intensity, mode), as well as problem solving focused on how to safely exercise in their home environments. Other topics to be included: managing common comorbidities (i.e. sleep behaviors, preventing and managing diabetes, avoiding excessive sitting, managing stress), and available community resources. Sessions will be structured as a brief overview of the topic, followed by group discussion to allow the group to openly discuss barriers to consume a healthy diet and achieving ACSM guidelines, as well as exchange ideas to improve their diet and exercise behaviors. This group dynamic will provide an opportunity for participating older adults to build their social network and provide supportive relationships in order to facilitate behavior change through meeting self-selected goals. These themes will not be prescriptive, but rather will provide a potential foci or topics for each week of the program. Peer leaders will be compensated for their time and effort. All peer leaders will have ongoing supervision by research study staff.

5.2.4 12-Week (Post) Assessments: All tests as described below in the baseline assessment will be repeated after the 12-week intervention. Additionally, a post intervention exit interview (both quantitative and qualitative questions) will be conducted by a research team member to obtain direct feedback on participant experience (i.e., program enjoyment, lesson applicability, confidence and willingness long-term to implement the behavior changes, and identification of additional barriers not addressed). This interview is anticipated to take 20-25 minutes and will be done/recorded with the participants permission on VA Microsoft teams by study staff.

6. Study Procedures

All subjects will undergo baseline testing and test after 12 weeks of the intervention as described below. All study procedures will be performed at the Baltimore VA.

6.1. Feasibility and Acceptability. A flow chart (i.e., consort chart) will be prepared to identify and summarize issues in recruitment and retention (i.e. record total numbers screened, numbers excluded with reasons for non-participation, timing and frequency of dropout, etc.). Acceptable recruitment is defined as 100% of total targeted enrollment within two months of initiating recruitment efforts. Retention will be assessed by frequency count of drop-outs; 80% retention will be considered acceptable. We will examine attrition, and perform qualitative exit interviews whenever feasible. The Usage Rating Profile- Intervention (URPI) feasibility and feasibility subscales will be utilized to assess both peer leaders and participants response to the intervention. We will define successful adherence as participants completing at least 75% of all sessions. We also will evaluate a random sampling of 30% of peer leader sessions to evaluate whether peer leaders accurately covered all prescribed material for each topic.

6.2. Body Composition: Standing height and weight (light clothing, without shoes) will be measure using a calibrated digital scale and body mass index calculated as weight [kg] /height squared [m^2].Total and regional fat mass, lean tissue mass, % body fat, bone mineral content, and bone density will be determined by dual-energy x-ray absorptiometry (DXA).

6.3. Dietary Intake: Instruction on completing a a self-administered 24-hour recall will be provided to participants by a Registered Dietitian. Food recall will be entered and analyzed for macronutrient and

micronutrient composition using the ASA24 program. The recall will be used to calculate the Healthy Eating Index (HEI). HEI scores range from 0 to 100, with higher scores indicating better adherence to the Dietary Guidelines for Americans..

6.4. Mobility: The six-minute walk distance will be measured as the distance walked quickly during a period of six minutes. Gait Speed will used to assessment of functional mobility. Will be calculated from a four-meter walk performed at self-selected and fast walking speeds, with the average of three trials used. Timed Get Up and Go Test (TUG) will assess mobility, balance, walking ability, and fall risk. Measured by recording the time to get up from a fully seated position, walk around a cone placed three meters away, and return to a seated position, with the fastest of two trials used. 30-second chair stand number will be recorded as the number of chair stands achieved in 30-seconds. Four square step test will be used to examine balance. Participants will be timed as they step over four canes set up in a cross on the floor as a test of dynamic balance. Finally handgrip strength will be assessed and the short physical performance battery will be performed. Assistive devices will be used as needed, with the same device used at baseline and the follow up assessment.

6.5. Subjective Assessments: Participants will be asked 20-25 minutes of questionnaires administered via either VA Qualtrics, redcap, or on paper copy depending on participant preference. Questionnaires are related to demographics and medical history, TV and internet use, dietary intake and food insecurities (the short healthy eating index, the VA Binge Eating Screener, the three-factor eating questionnaire, and USDA short form food insecurity), quality of life (SF-12), depression (Center for Epidemiologic Studies Depression Scale), sleep (insomnia severity index-7), smoking and alcohol use (Alcohol Use Disorders Identification Test-3), physical activity (Physical Activity Scale for the Elderly). See **Questionnaires**.

6.6. Statistical Plan

A flow chart (i.e., consort chart) will be prepared to identify and summarize issues in recruitment and retention (i.e. record total numbers screened, numbers excluded with reasons for non-participation, timing and frequency of dropout, etc.). Acceptable recruitment is defined as 100% of total targeted enrollment within two months of initiating recruitment efforts. Retention will be assessed by frequency count of drop-outs; 80% retention will be considered acceptable. Examination of attrition, along with qualitative interviews (whenever feasible). The Usage Rating Profile- Intervention (URPI) acceptability and feasibility subscales will be utilized to assess both peer leaders and participants response to the intervention. We will define successful adherence as participants completing at least 75% of all sessions. We also will evaluate a random sampling of 30% of peer leader sessions to evaluate whether peer leaders accurately covered all prescribed material for each topic. The focus in a feasibility pilot study like this is to estimate the magnitude of potential impact. Data will be inspected for out-of-range values, missing data, and internal consistency (when relevant). Clinical outcomes of interest are changes in diet quality and mobility after the 12-week intervention. Data from this pilot will be compared to changes in Gerofit. Similar changes in mobility with higher adherence and retention will indicate that long term success is feasible for the program and warrant a longer duration trial. Summary statistics with confidence intervals will be calculated to describe average levels and trajectories of clinical outcomes over time. Baseline variables will be summarized, and frequency distributions will be examined for unusual data distributions or data points.

7. Safety and Adverse Events

7.1. Recording of Adverse Events

Throughout the study, the investigator or study staff will seek information about adverse events by specific questioning and, if appropriate, by examination. Information on all AEs will be recorded immediately in the source document, and also in the appropriate case report form (CRF). AEs will be reviewed by Site Investigator on a monthly and ad hoc basis, depending on severity and expected/unexpected nature of the event. All AEs occurring during the study period will be recorded. The clinical course of each event will be followed until resolution, stabilization, or until it has been determined that the study treatment or participation is not the cause.

7.2 Reporting of Serious Adverse Events and Unanticipated Problems

Each participant will be evaluated for any adverse events (AE). Any incidents, experiences, and outcomes either reported by the subject to the PI or designated research staff or medical staff caring for the subject, and which meet AE criteria will be documented. Any AE reported as serious (SAE) will be reported to the IRB and, if deemed appropriate by PI, SAE and or unanticipated risks to subjects or others (UPIRSO) may be reportable to the Baltimore Pepper Center Data Monitoring Committee. All AE that are not serious will be summarized annually and submitted to the IRB and R&D Committees.

SAE will be reported per IRB policy and procedure. Events that do not involve AE or SAE, and which are a result of study participation are also promptly reported to the IRB per local policy. The report will include a description of the event, when and how it was reported, as well as any official chart records or documentation to corroborate the event or the reporting of the event. All AE will be graded as mild, moderate, or severe. Any action resulting in a temporary or permanent suspension of this study (e.g. local site IRB actions) will be reported to the IRB and study sponsor.

7.3 Medical Monitoring

The Sponsor (or investigator initiating the study) will review the safety and progress of this study on a monthly basis or when needed if protocol deviations/violations or AEs occurs.

The PI and or Co-PI will review source documentation in the research record and or medical record when study coordinator provides an electronic alert or secure email to review.

8. Data Handling and Record Keeping

8.1. Confidentiality

Information learned about all subjects will be kept confidential. All data and protected health information in paper form will be kept confidential by assigned uniquely coded identifier and kept secured (password protected and/or double locked). Subjects will not be identified in any way in any publication.

8.2. *Source Documents*

Source data will be originated both electronically and on paper. No VA sensitive information will leave the VA protected environment. Sensitive VAMHCS electronic data for this study will remain securely behind the VA firewall and will only be accessible through secure VA computer accounts. The network and computer files are only accessible by authorized study team members. Electronic research files are backed up regularly. All sensitive VA paper records will be securely stored in locked file cabinets behind locked doors in the GRECC. All research related electronic data is stored coded and subject identifiers, such as names, are not stored in the same files that contain the research data.

Only de-identified electronic data are sent to and received from the San Antonio VA for further analysis. The electronic data is stored in either VA Qualtrics or VA RedCap, which is hosted by VINCI. VA Qualtrics, or paper surveys maybe used to collect questionnaires and then transferred to VA RedCAP. This will be decided by participant preference.

All entries will be printed legibly in black ink. Erasures and white-out material are prohibited. If any entry error has been made on paper, to correct such an error, draw a single straight line through the incorrect entry and enter the correct data above it. All such changes must be initialed and dated. For clarification of illegible or uncertain entries, print the clarification above the item, then initial and date it.

8.2.1 Research Electronic Data Capture (REDCap) and origination of electronic source data

De-identified medical histories, physical exams, concomitant medications, checklists of consent processing, and documentation of eligibility criteria may be originated electronically in REDCap. Then REDCap forms will be downloaded in PDF format and printed to file in the paper participant record at the research site. Other electronically originated data in REDCap include: adverse event (AE) assessments and AE logs, enrollment logs, protocol deviation logs, and other study management checklists. Other electronic medical record data (VA CPRS) including pre-existing history, exams, medication lists, and such may be accepted as source data.

All missing data will be routinely queried, corrected, and or explained. If a space on the CRF is left blank because the procedure was not done or the question was not asked, write “N/D”. If the item is not applicable to the individual case, write “N/A”.

8.2.2 Paper source data

Paper source data will be entered into the REDCap database. All missing data will be routinely queried, corrected, and or explained. If a space is left blank on paper because the procedure was not done or the question was not asked, write “N/D”, initialed and dated by the staff member. If the item is not applicable to the individual case, write “N/A”.

- Questionnaires and assessments may be originated electronically in either VA Qualtrics or VA REDCap. This will be done only after written informed consent on paper copies is completed. If surveys are done in VA Qualtrics or if it is otherwisenecessary to originate survey data on a paper source that data will be transfered to REDCap for calculation, data management and analysis. Paper sources will be filed in paper subject records.

8.2.3 Handwritten entries

All handwritten entries will be created contemporaneously to the visit or phone call, and legibly in blue or black ink. Erasures and white-out material are prohibited. If any entry error has been made on paper, to correct such an error, draw a single straight line through the incorrect entry and enter the correct data above it. All such changes must be initialed and dated. For clarification of illegible or uncertain entries, print the clarification above the item, then initial and date it.

8.3 *Data Management*

Database Management Software: All data collection for this project will be maintained using the VA REDCap or VA Qualtrics platform which is centrally managed by VIReC (VA Information Resource Center).

Data System: VA REDCap is a computing environment developed by Vanderbilt University consisting of a collection of instruments centrally managed by VIReC. Data projects are designed to be end-user oriented and constructed to optimize workflow and minimize errors.

All data will be input using a web front-end interface. All users are individually assigned authorization for access to specific components of the database application. Information that is input is checked for logical and range consistency and mandatory data fields must be entered in order to input a record.

De-identified data may be transferred between sites via VA REDCap or a sharepoint site set up for the study that will be located behind the VA firewall. In this manner all data will remain behind the VA firewall.

8.4 *Records Retention*

The regulatory binder is maintained by the study coordinator or a designated staff member.

The Principal Investigator is responsible for maintaining study essential documents for at least six years after the funding grant period ends.

These documents should be retained for a longer period if required by a funding agency or other institutional retention policy. In such an instance, it is the responsibility of the sponsor or Principal Investigator to inform the institution as to when these documents no longer need to be retained.

9 Study Monitoring, Auditing, and Inspecting

9.1 Study Monitoring Plan

The Principal Investigator (PI) will be responsible for ensuring the timely monitoring of the data and safety of study participants. The PI will communicate with other members of the study staff to review adverse events and protocol compliance on a weekly basis.

Data and safety monitoring for this study will be provided by the Baltimore GRECC data saftey monitoring Board (DSMB). The GRECC DSMB will provide an ongoing independent evaluation of this study focused on safety and feasibility, including participant accrual and retention and adverse events monitoring. . Meetings will occur at least one time per year at which time recommendations will be made for endorsement to continue. These recommendations will range from approval to continue (unconditionally or with conditions to be addressed) to probation or possibly termination, if there are problems with enrollment or safety concerns.

9.2 Auditing and Inspecting

The Principal Investigator will permit study-related monitoring, audits, and inspections by the IRB, the funding sponsor, the Baltimore GRECC DSMB, government regulatory bodies, and University compliance groups of all study related documents (e.g. source documents, regulatory documents, data collection instruments, study data etc.). The investigator will ensure the capability for inspections of applicable study-related facilities (e.g. pharmacy, diagnostic laboratory, etc.).

Participation as an investigator in this study implies acceptance of potential inspection by government regulatory authorities and applicable University compliance and quality assurance offices.

10 Ethical Considerations

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

This protocol and any amendments will be submitted to the Institutional Review Board (IRB), in

agreement with local legal prescriptions, for formal approval of the study conduct.

All subjects for this study will be provided a consent form describing this study and providing sufficient information for subjects to make an informed decision about their participation in this study. If abnormalities are detected from the history and physical, or the DXA we will inform the participant, and with their permission if they desire, the results will be forwarded to their doctor.

11 Study Finances

11.1 Funding Source

This study is financed through a grant from the U.S. Department of Veterans Affairs.

11.2 Conflict of Interest

VA Investigators are required to submit Conflict of Interest disclosures with every new study submitted for review by UTHSA IRB and VA Research and Development Committee.

11.3 Subject Stipends or Payments

This study will reimburse the peer leaders up to $500 for their time and effort. Participants will receive $50 for completing the baseline assessments and $50 for completing 12-week assessments ($100 total).

12 Publication Plan

The Institution, Sponsor or respective designees may present or publish the results of a scientific investigation involving this Study in accordance with VA policies.

13 References

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