Multimodel Exercise and Weight Loss in Older Obese Veterans with Dysmobility

NCT02806336

March 16, 2021

UNIVERSITY of MARYLAND BALTIMORE

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HP-00069566 Introduction Page_V2

Introduction Page

1 * Abbreviated Title:
Multimodal Exercise and Weight Loss in Older Veterans with Dysmobility

2 * Full Title:
Multimodal Exercise and Weight Loss in Older Veterans with Dysmobility

3

* Select Type of Submission:

- (●) **IRB Application**
- ( ) Humanitarian Use Device (for FDA approved Indication & non-research purposes ONLY)
- ( ) Single Patient Expanded Access (pre-use)
- ( ) Single Patient Emergency Use (post-use)
- ( ) Unsure if this proposal requires IRB review (Not Human Subject Research)

Note: The Type of Submission cannot be changed after this application has been submitted for review.

4 Original Version #:
8

ID: VIEW4DF8709A33C00
Name: v2_Introduction Page

Research Team Information

1 * Principal Investigator - Who is the PI for this study (person must have faculty status)? ***Faculty status is defined as being a full-time (>51% effort) faculty member holding one of the following titles at UM: Professor; Associate Professor; Assistant Professor.***
Leslie Katzel

CITI Training: ID00008791

1.1 * Does the Principal Investigator have a potential conflict of interest, financial or otherwise, related to this research?
◯ Yes ● **No**

2 Point of Contact - Who is the alternative point of contact for the PI? This person can be a study coordinator or any other study team member. In case the IRB cannot contact the PI, this person is a secondary person to contact:
Jeffrey Beans

CITI Training: ID00006931

2.1 Does the Point of Contact have a potential conflict of interest, financial or otherwise, related to this research?
◯ Yes ● **No**

3 Other Team Members - list all additional members of the research team for this study. DO NOT include the PI or POC in this list:

	Name	Edit Submission	cc on Email	Research Role	Has SFI?	CITI Training
View	William Perez	no	no	Research Team Member	no	
View	Steven Prior	no	no	Sub-Investigator	no	ID00008139
View	Brian Phipps	no	no	Research Team Member	no	
View	Elizabeth Dennis	no	no	Research Team Member	no	ID00008066
View	Odessa Addison	yes	yes	Sub-Investigator	no	ID00000097
View	John Sorkin	no	no	Statistician	no	ID00011932
View	Brock Beamer	no	no	Sub-Investigator	no	ID00000006
View	Steven Yoo	no	no	Research Team Member	no	
View	Lynda Robey	yes	yes	Research Team Member	no	ID00005538

IMPORTANT NOTE: All research team members (including PI) must have current CITI and HIPAA training completed.

ID: VIEW4DF85C16F2800
Name: v2_Research Team Information

Resources

If this study is a collaborative UM/VA study, please clarify which resources are being used at each institution.

1 * Describe the time that the Principal Investigator will devote to conducting and completing the research:
He will spend 25% of his time on conducting and completing the research.

2 * Describe the facilities where research procedures are conducted:
Clinical Research Facilities. The research-specified study visits for the current proposal will occur at Geriatric Research Education and Clinical Center (GRECC) of the Baltimore VA Medical Center. The Baltimore VA Medical Center GRECC is located on the 4th floor of the Baltimore VA Medical Center. There are 15,000 sq ft of clinical research space in the GRECC available for the conduct of research into aging and physical function. There is a 400 sq ft room with 2 beds, the requisite computers, glucose analyzers, metabolic carts and 3 nurses/2 LPNs staff for the performance phlebotomy and vital signs monitoring. For cardiovascular exercise testing, there is a dedicated 500 sq ft room equipped with 2 automated treadmills with ECG monitoring with validated systems for measurement of aerobic capacity (COSMED Quark Ergo metabolic cart, Quinton Q4500 ECG with Treadmill (ST65) and Marquette Max-1 with Treadmill (Sensormedics 2000)). The room is equipped with a crash cart and defibrillator.

Exercise Training Facilities. There is a Senior Exercise Rehabilitation Center (SERC) in the BVAMC Annex with wheelchair access, shower facilities and an indoor walking track. The room is equipped with treadmills, aerodyne bicycle ergometers, upright and recumbent Lifecycles, Lifefitness cross-trainers, pneumatic weight training stations for the major muscle groups, free weights. An Automotic External Defibrillator (AED) is present on-site, and all staff are trained in CPR. There is a Robotics and Rehab Center at the Loch Raven Community Based Outpatient Center with wheelchair access and shower facilities. The room is equipped with treadmills, pneumatic weight training stations for the major muscle groups, and free weights. An Automatic External Defibrillator (AED) is present on-site, and all staff are trained in CPR.

3 * Describe the availability of medical and/or psychological resources that subjects might need as a result of anticipated consequences of the human research:
For unexpected or newly discovered medical problems, patients will be referred to appropriate medical care at the BVAMC or UMMS medical providers, as appropriate. Patients will also be provided with copies of laboratory results upon request after providing authorization for release of this information. For urgent medical problems that occur during exercise, a physician or nurse practitioner will be available on an as-needed basis to assist with urgent medical care, they will be available on-call at all times participants are exercising in either facility.

4 * Describe the process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions:
All persons assisting with the research are encouraged to read the approved protocol and current copy of research consent form before beginning to assist with the research procedures. They are also encouraged to meet with the study PI and research team members to discuss their involvement in the protocol and how best to protect participant safety during their involvement. The PI is also available by phone or in-person for questions any study team member may have regarding their duties with this research study. If a team member is removed from the research team, their access to sensitive data will be immediately revoked.

ID: VIEW4DF83CB976400
Name: v2_Resources

Sites Where Research Activities Will Be Conducted

1 * Is this study a:

- ○ Multi-Site
- ● **Single Site**

2 * Are you relying on an external IRB (not UM) to be the IRB of Record for this study?

○ Yes ● **No**

3 * Are any other institutions/organizations relying on UM to be the IRB of Record for this study?

○ Yes ● **No**

3.1 Attach the applicable regulatory documents here (i.e., IRB Authorization Agreement (IAA), FWA, local ethics approval, other IRB approvals, etc.). Final UM approval will be contingent upon final execution of all required regulatory approvals:

Name	Created	Modified Date

There are no items to display

4 * Is UM the Coordinating Center for this study? (Applicable for multi-site studies. A Coordinating Center is responsible for overall data management, monitoring and communication among all sites, and general oversight of conduct of the project.)

○ Yes ● **No**

5 Is VA the Coordinating Center for this study? (Applicable for Collaborative studies between the VA, UM and other sites. A Coordinating Center is responsible for overall data management, monitoring and communication among all sites, and general oversight of conduct of the project)

○ Yes ● **No**

6 * Institution(s) where the research activities will be performed:

- ☐ University of Maryland, Baltimore
- ☐ University of Maryland, Upper Chesapeake Kaufman Cancer Center
- ☑ **VAMHCS**
- ☐ UMB School of Medicine
- ☐ Marlene and Stewart Greenebaum Cancer Center
- ☐ University Physicians Inc.
- ☐ Shock Trauma Center
- ☐ General Clinical Research Center (GCRC)
- ☐ Maryland Psychiatric Research Center (MPRC)
- ☐ Johns Hopkins
- ☐ International Sites
- ☐ UMB Dental Clinics
- ☐ Center for Vaccine Development
- ☐ Community Mental Health Centers
- ☐ Private Practice in the State of Maryland
- ☐ Institute of Human Virology (IHV) Clinical Research Unit
- ☐ Joslin Center
- ☐ UMB Student Classrooms
- ☐ National Institute of Drug Abuse (NIDA)
- ☐ National Study Center for Trauma and EMS
- ☐ Univ of MD Cardiology Physicians at Westminster
- ☐ Nursing Homes in Maryland
- ☐ University of Maryland Biotechnology Institute
- ☐ Maryland Department of Health

- [ ] Maryland Proton Treatment Center
- [ ] Mount Washington Pediatric Hospital
- [ ] Institute of Marine and Environmental Technology (IMET)
- [ ] Other Sites
- [ ] University of Maryland Medical System (Select below)

ID: VIEW4DF870DF2C000
Name: v2_Sites Where Research Activities Will Be Conducted

Funding Information

1 * Indicate who is funding the study:

- [x] **Federal**
- [ ] Industry
- [ ] Department / Division / Internal
- [ ] Foundation
- [ ] Private
- [ ] State Agency

2 * What portion of the research is being funded? (Choose all that apply)

- [ ] Drug
- [ ] Device
- [x] **Staff**
- [x] **Participant Compensation**
- [x] **Procedures**
- [ ] Other

3 Please discuss any additional information regarding funding below:
VA Merit award grant. Study is also supported by the Baltimore GRECC

ID: VIEW4DF85DF452400
Name: v2_Funding Information

DHHS Funded Study

You indicated that this is a Federally funded study.

1 * Is this study sponsored by a Department of Health and Human Services (DHHS) agency?

○ Yes ● **No**

2 You may upload any grant documents here:

Name	Created	Modified Date
There are no items to display		

ID: VIEW4DF87B9560800
Name: v2_DHHS Funded Study

Federal Agency Sponsor Contact Information

You indicated that this is a Federally funded study.

1

* Agency Name:
Veterans Health Administration

* Address 1:
810 Vermont Avenue, NW (10P9R)

Address 2:

* City:
Washington

* State:
DC

* Zip Code:
20420

* Contact Person:
Tshaka Cunningham

* Phone Number:
202-443-5758

* Federal Agency Email:

Grant Number 1 (if applicable):
1I01RX001813-01A1 - OR - Check here if Grant 1 is not assigned a number. ☐

If Grant 1 has no number, please provide the following information:
Title of Grant 1:
Multimodal Exercise and Weight Loss in Older Veterans with Dysmobility
PI of Grant 1:
Leslie Katzel

Grant Number 2 (if applicable):
- OR - Check here if Grant 2 is not assigned a number. ☐

If Grant 2 has no number, please provide the following information:
Title of Grant 2:

PI of Grant 2:

Grant Number 3 (if applicable):
- OR - Check here if Grant 3 is not assigned a number ☐

If Grant 3 has no number, please provide the following information:
Title of Grant 3:

PI of Grant 3:

Grant Number 4 (if applicable):
- OR - Check here if Grant 4 is not assigned a number. ☐

If Grant 4 has no number, please provide the following information:
Title of Grant 4:

PI of Grant 4:

ID: VIEW4DF8584874400
Name: v2_Federal Agency Sponsor Information

Research Protocol

1 * Do you have a research protocol to upload?

- ○ Yes
- ● **No, I do not have a research protocol and will use the CICERO application to enter my study information**

2 If Yes, upload the research protocol:

Name	Created	Modified Date
There are no items to display		

ID: VIEW4E00563F8D000
Name: v2_Research Protocol

HP-00069566 Risk Level_V2

Risk Level

What is the risk level of your study? (Ultimately, the IRB will determine the appropriate risk level and your designation is subject to change.)

* Choose One:

- ○ Minimal - The probability & magnitude of harm/discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations/tests.
- ● **Greater Than Minimal - Does not meet the definition of Minimal Risk.**

ID: VIEW4E02805225800
Name: v2_Risk Level

Type of Research

1 * Indicate **ALL** of the types of research procedures involved in this study (Choose all that apply):

- [ ] Use of unapproved drug(s)/biologic(s) or approved drug(s)/biologic(s) whose use is specified in the protocol.
- [ ] Evaluation of food(s) or dietary supplement(s) to diagnose, cure, treat, or mitigate a disease or condition.
- [ ] Use of device(s) whose use is specified in the protocol
- [x] **Psychological/Behavioral/Educational Method or Procedure (i.e., survey, questionnaires, interviews, focus groups, educational tests).**
- [x] **Sample (Specimen) Collection and/or Analysis (including genetic analysis).**
- [x] **Data Collection or Record Review (i.e., chart review, datasets, secondary data analysis).**
- [ ] None of the above.

2 * Is this study a clinical trial OR will this study be registered at ClinicalTrials.gov?
A clinical trial is a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

● **Yes** ○ No

ID: VIEW4E0280569E000
Name: v2_Type of Research

Lay Summary

1 * Provide a summary of the background and purpose of the study in language that can be understood by a person without a medical degree.

Older obese adults suffer disproportionately from walking mobility limitations. Sedentary, obese older adults are at an increased risk for having or developing difficulties with mobility. These individuals are often excluded from studies due to their advanced mobility limitations. A number of studies have compared the effects of weight loss alone, exercise alone, or weight loss in combination with exercise on functional performance in older adults, but none of the studies have specifically targeted subjects who use walking assistive devices. The purpose of this study is to test the effects of a 3 month multi-modal balance intervention (MMBI) with a nutrition program with optional retention till 24 months on fitness, functional performance, mobility, and muscle mass. The results of this study will lead to new and more effective interventions that could reduce disability, fall risk, injury-related hospitalization and death in older Veterans.

ID: VIEW4E02805CF7000
Name: v2_Lay Summary

Justification, Objective, & Research Design

If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer boxes below.

1 * Describe the purpose, specific aims, or objectives of this research. State the hypothesis to be tested:

Specific aim 1: Examine the effects nutrition + multimodal balance intervention (MMBI) on mobility and functional performance in the following outcomes:
a. 6 minute walk (primary outcome)
b. Other physical performance outcomes: 6MW with economy of gait, gait rite, four square step test, 8 foot up and go, short physical performance battery, grip strength, lower extremity strength

Specific aim 2: Examine the relationship between muscle mass, strength, and functional performance using DXA and CT scans to quantify body composition.

Specific aim 3: Examine the impact of the intervention on patient reported measures of function and disability using the Late Life Function and Disability Instrument (LLFDI).

2 * Discuss the research design including but not limited to such issues as: probability of group assignment, potential for subject to be randomized to placebo group, use of control subjects, etc.:

All subjects will now receive MMBI and nutrition (combined intervention. Weight loss will be a covariate in the analyses.

3 * Describe the relevant prior experience and gaps in current knowledge. Describe any relevant preliminary data:

Sedentary, obese older adults are at increased risk for having or developing difficulties with mobility. Cross-sectional and longitudinal studies demonstrate that a variety of indices of body composition including BMI, waist circumference, total body fat on DXA, appendicular and leg fat free mass on DXA, appendicular skeletal muscle index (ASMI), leg muscle cross sectional area on CT scan predict the development of walking disability in obese older adults. 21-23 Each measure of body composition has limitations and there is no consensus as to which is the best predictor of mobility disability. 21,24 Mobility impairments associated with obesity develop over time. Obesity in young adult and middle age increases the risk for subsequent walking limitations (walking speed < 1.2 m/s or difficulty walking 0.5 km in older adults.25 In the Stenholm study, obesity at age 50 quadruples the risk for walking limitations in older age. In the Health ABC study, obesity and lower physical activity both increased risk for mobility limitations. 17 Muscle mass, muscle structure and muscle fat infiltration, which are often present in sedentary obese older adults, are also predictors of incident mobility limitations in well-functioning older persons in Health ABCs. 26 A subset of older obese individuals had low muscle mass relative to their body weight along with excess body fat resulting in sarcopenic obesity. 5-7 Obesity and sarcopenia have synergistic adverse effects on disability and morbidity. It is thought that inflammation and insulin resistance are key factors underlying the loss of muscle quantity and quality (force normalized for the amount of lean tissue), decreased number and size of muscle fibers, reduced mitochondrial function and decreased synthesis of muscle protein (Bianchi & Volpato 2016; Drummond et al., 2012; Marcus et al., 2012; Addison et al., 2012).
Seventeen older (age >70 years) adults with a history of falls were recruited for a preliminary study of our MMBI. Subjects exercised 3 times/week for 16 weeks in our gymnasium followed by a four-month long home exercise regimen (adapted from the VISN 8 program) after completion of the center-based portion of the intervention. Sixteen out of 17 individuals completed all portions of the study with > 90% adherence in the 16 who completed the study. Six of the 16 fell at least once during the 4 months of the home-based phase of the study, and an additional six subjects reported at least 1 near fall. These falls and near falls did not occur during the exercise, but rather during normal daily activities. Four-square times in those who fell were significantly slower (12.7 +6.5 seconds) than in those who did not fall (6.0 + 2.1 seconds, $p < 0.01$). Notably, however, the slower individuals also had the greatest improvement with the intervention. After 16 weeks of center-based exercise, MMBI scores on the functional gait assessment increased by 12% and the time to complete the four-square test decreased by 24%, with even greater improvements of 40-50% for individuals whose function was most impaired at baseline. Distance covered during the six minute walk increased by 5% ($p < 0.04$). Maximum weight lifted during a leg press increased demonstrating significant improvements in lower extremity strength. Importantly these improvements were maintained after the four-month home-based exercise program. The subjects in this study differ from those we propose to study as the primary enrollment criteria was a history of falls, not obesity. In addition, there was no requirement that they use walking assistive devices. Nevertheless, these findings demonstrate that our multimodal intervention can be performed safely in an at risk population and improves multiple physical performance domains.
GEROFIT cross-sectional data
We performed assessments of physical functioning in 24 older (> 65 years) Veterans at risk of functional and mobility decline based on their use of walking assistive devices enrolled in the GEROFIT clinical demonstration project. All of the subjects had performance-based evidence of impaired mobility. Overall the subjects had slow gait speed, poor lateral mobility and balance on the four square step test (FSST), poor endurance on the 6 minute walk test and reduced lower extremity proximal strength on the chair stands. Many of the Veterans scored below the 5th percentile on many of these measures and >50% had SPPPB scores < 9. Impact of 3 months of Gerofit on functional performance in older obese Veterans: In this revised grant we provide preliminary data in 16 obese (BMI 35.8 + 5.7) older (71 + 4 years) Veterans with SPPB scores <10 (8.5 + 1.7, mean+ SD) indicative of lower extremity functional impairment who completed 3 months of Gerofit. On average these subjects had 10 medical problems and were taking 15 medications per day. After 3 months their SPPB improved from 8.5 + 1.7 to 9.56 + 2.1, the number of chair stands performed in 30 seconds increased from 7.5+ 3.7 to 8.9 + 5.4, four square step test (FSST) time an index of fall risk and lateral mobility decreased (improved) from 14.0+ 5.0 to 13.0 + 4.2 seconds and 6 minute walk distance increased from 363 + 118 yards to 418 +122 yards. On average weight did not change in these Veterans. The exercise intervention proposed in this study will be of longer duration, with greater individualized attention with a more customized exercise progression than that employed in Gerofit.

4 * Provide the scientific or scholarly background, rationale, and significance of the research and how it will add to existing knowledge:

Depending upon the criteria employed, it is estimated that >11 million older adults, or approximately one-third of non-institutionalized older adults have imparied mobility and >4 million older adults use walking assistive devices (1,2). It is well established that performance-based indices of impaired mobility such as slow gait speed, inability to perform the 400 m walking test and poor distance covered during the 6 minute walk test are predictive of increased mobility limitation, mobility disability, cardiovascular mortality and death. 11-14
It is important to distinguish between impaired mobility and disability. In the EPESE studies, a 3 level hierarchical approach was used to classify the subjects' mobility status: 1) no disability, 2) having mobility-related disability only (the inability to walk a half mile or climb stairs without help),or 3) having a disability in the activities of daily living (the inability to perform one or more of the following basic activities without the help of another person: moving from a bed to a chair, using the toilet, bathing, and walking across a small room) and mobility-related disability. 15 Other criteria have also been employed for disability such as inability to perform a 400 meter long-distance corridor walk or complete it within a certain time frame, inability to walk 300 meters during a 6 minute walk, slow gait speed during a variety of timed walks, or difficulty with other tasks such as stair climbing and chair rise ability. 16-19 The progression from functional limitation to disability is impacted by many factors (see discussion of disablement by Verbrugge and Jette). 20 There is limited data on whether interventions can reduce or reverse the course of progression once difficulties with ambulation have occurred, particularly in subjects who use walking assistive devices. To provide insight into this question, we will test whether obese older adults using assistive devices for ambulation can improve their mobility with dynamic balance, aerobic and strength exercises combined with medically supervised weight loss.

ID: VIEW4E02805EA0C00
Name: v2_Justification, Objective, & Research Design

Supporting Literature

1 * Provide a summary of current literature related to the research: ***If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer box below.***

INTERVENTION STUDIES: Few studies have examined the effect of weight loss combined with exercise rehabilitation on functional status in older obese individuals who use walking assistive devices; these individuals are often excluded from studies due to their advanced mobility limitations. There is limited evidence from intervention studies that weight loss alone increases mobility and lower extremity function. Beaver et al pooled the results from 3 weight loss interventions in middle-aged and older adults (27,28) and found an adjusted weight loss of 7.8 kg was associated with significant improvements in self-reported mobility disability and walking. Conversely, some have urged caution regarding weight loss interventions in older adults because both unintentional and intentional weight loss were associated with higher risk for mobility limitations in the Health ABC study. 29 Recent findings from the longitudinal Invecchiare in Chianti Study also raise intriguing questions about whether weight loss is beneficial in obese older adults (23). Surprisingly obese participants who lost weight over follow-up had a significantly greater increase in multimorbidity than other subjects, including obese participants who maintained or gained weight over time (P = .005). By contrast in longitudinal follow-up of nonobese participants, changes in weight had no effect on changes in multimorbidity over time. A number of studies have compared the effects of weight loss alone, exercise alone or weight loss in combination with exercise on functional performance in older adults, but none of the studies have specifically targeted subjects who use walking assistive devices. In a study of obese older adults by Rejeski, both weight loss and weight loss in combination with physical activity increased gait speed during a 400 meter walk, 13 and 18 seconds respectively, but there were no significant differences between the two interventions. 30

Importantly in that study, neither of the two interventions decreased the time to complete the 400 meter walk by more than the 20 seconds proposed for a clinically meaningful change by Kwon et al. 31 A 12 month study in frail obese elderly by Villareal et al32 compared four groups, a control group, a diet group with a 500–750 kcal deficit diet with 1 g protein/kg/day, a multicomponent exercise group and a combined diet plus exercise group. All subjects received calcium and vitamin D supplementation. The main outcome was the change in the modified Physical Performance Test. 33 Compared to the control group, diet and exercise was more effective than either individual intervention alone in performing the modified Physical Performance Test. This study did not specifically target older adults who use walking assistive devices, and the study population was predominantly white women limiting the applicability of their findings to other populations. We anticipate that our population will be predominantly obese African American men all of whom will use an assistive device.

Several prominent studies have examined the role of exercise as an intervention to prevent or retard the onset of mobility disability. In the Lifestyle Interventions and Independence for Elders Pilot Study (LIFE-P), 19,34-36 a total of 424 sedentary persons, ages 70-89 years at risk for disability, were randomized to a moderate-intensity physical activity(PA) intervention or a successful aging (SA) health education intervention and were followed for an average of 1.2 years. It is important to note that subjects who used a cane or other walking assistive device to complete the 400 meter walk test were excluded from the study. The baseline SPPB scores of 7.5 were similar in both groups. With intervention, PA had higher SPPB scores at 6 and 12 months versus SA of 8.7 + 0.1 versus 8.0 + 0.1, and 8.5 + versus 7.9 + 0.2, respectively ($p < .001$). The 400-meter walking speed was essentially unchanged in PA compared to a slight decline in SA. The PA group had a lower incidence of major mobility disability (inability to complete a 400-meter walk). In the LIFE-P obesity blunted the beneficial response to the physical activity intervention such that the non-obese individuals had a 5 times greater improvement in long-distance walking speed than obese individuals in the intervention group. 36 Our subjects will differ substantially from those in LIFE-P due to our selection criteria for obesity and requirement that subjects use walking assistive devices. In LIFE-P, the average BMI was 30.2. In addition, 42% were obese with BMI > 30. 31 Unlike the proposed study, there was no nutrition component in LIFE-P. Lifestyle Interventions and Independence for Elders (LIFE) Study was a randomized control trial of lifestyle interventions designed to preserve the ability to walk in older adults. The study compared a moderate-intensity physical activity program to a successful aging health education program in 1,600 sedentary older adults who are followed for an average of 2.7 years. 18,37 The primary aim was to assess the long-term effects of the interventions on the primary outcome of major mobility disability, defined as inability to walk 400 m. The study demonstrated that the physical activity intervention decreased subsequent major mobility disability by 18%>.38 The LIFE study excluded those who used a walker to complete the 400 m walk and/or those who were unable to complete the 400 m walk without sitting down or with the help of another person.

PATIENT REPORTED MEASURES OF FUNCTION AND DISABILITY: Performance-based measures of walking conducted in the research setting or as part of clinical care provide objective, quantified indices of mobility that can be compared versus population norms. These performance-based measures may not fully capture the challenges that mobility limited individuals experience during their normal activities. In performing exercise rehabilitation trials, it is important to assess whether the measured ambulatory benefits during maximal and submaximal exercise translate into improved patient self-perceived ambulatory function. One widely employed instrument to assess outcomes in community-dwelling older adults is the Late-Life function and Disability Instrument (LLFDI) (8-10). It is designed to assess and be responsive to meaningful change in two distinct outcomes: function and disability. The LLFDI defines functional limitations as limitations in ones' ability to do discrete actions or activities, and disability as limitations in a person's performance of socially defined life tasks expected of an individual within their sociocultural and physical environment. The function component's 3 function subscales (basic lower extremity, advanced lower extremity and upper extremity) and the disability component's subcomponents [limitation (instrumental and management roles) and frequency (social and personal roles) dimensions of the disability component are scored on a 0-100 scale. The LLFDI has excellent construct validity and is sensitive to change (39).

Collectively there is a general consensus that lifestyle interventions to treat obesity in older adults must include hypocaloric diets with sufficient quantity of high quality protein with a combination of aerobic and resistive exercise (40,41) to promote the preservation of muscle mass as subjects lose weight. Despite numerous studies, the optimal intervention to improve physical functioning and reduce risk for future mobility disability is not known, particularly in older adults who use walking assistive devices and there is limited information on whether older obese adults can sustain the improvements over time.

APPENDICULAR SKELETAL MUSCLE MASS INDEX AND VO2peak: Some older obesity sedentary individuals have low muscle mass relative to body weight (relative sarcopenia).5-7 We determined the Appendicular Skeletal Muscle Mass (ASM) as the sum of the lean soft tissue mass in the arms and legs, and the appendicular skeletal muscle index (ASMI) defined as the ASM divided by height squared (ASM/Ht2 in kg/m2) from DXA scans in 108 middle-aged and older subjects enrolled in GRECC studies. The prevalence of sarcopenic obesity using the proposed ASMI criteria of < 7.26 kg/m2 in men was 5%. There was a strong relationship between ASMI and VO2peak ($r = 0.49$, $p < 0.01$).

2 If available, upload your applicable literature search:

Name	Created	Modified Date
There are no items to display		

ID: VIEW4E02805A7E400
Name: v2_Supporting Literature

Study Procedures

If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer boxes below. (If this study is a collaborative UM/VA study please list each procedure that is being conducted and the locations where it is being conducted.)

1 * Describe all procedures being performed for research purposes only (these procedures would not be done if individuals were not in the study) and when they are performed, including procedures being performed to monitor subjects for safety or to minimize risks:

PHASE 1 SCREENING will occur following written informed consent and will include medical history and physical examination will be performed at the Baltimore VA Medical Center Geriatrics Research Education and Clinical Center (GRECC). Individuals who have a history of symptomatic angina or claudication, or who are otherwise unable to complete the 6 minute walk test will not be eligible and will exit from the study. Gait speed (to determine study eligibility) will be assessed during a 10 meter walk. Subjects will be assessed for the appropriateness, fit, and use of walking mobility aids. Disability will be assessed through administration of the 6 item activities of daily living (ADL) and 6 item instrumental activities of daily living (IADL) questionnaire. A blood draw will be completed to assess their ability to safely participate in the study. Participants who meet inclusion/exclusion criteria will proceed to baseline testing. We anticipate that 20-30% of the individuals brought in for screening evaluations will not qualify for this study. Participants who meet inclusion/exclusion criteria will proceed to Phase 2. If new medical abnormalities are detected during research procedures we will tell the participants of the results and with their permission, we will forward the results to their primary care physician for appropriate follow up. For VAMHCS patients, lab results will be listed in their electronic medical record (CPRS). For those Veterans who do not receive care at the VAMHCS, they will be provided copies of their results, and with their permission, we can share with their non-VA provider. For subjects enrolled in this study before the COVID-19 pandemic that we are inviting back into the study we will review their medical history and medications before they resume participation in the study.

Phase 2 BASELINE TESTING includes:
Body composition assessment (see below for description)
Anthropometric measurements (see below for description)
Lateral mobility and balance assessments (see below for description)
Patient reported perceptions of function and disability (Late-Life Function and Disability Instrument questionnaire)
Physical Function test battery (see below for description)
Self reported physical activity levels (CHAMPS questionnaire)
Assessment of cognitive function (Montreal Cognitive Assessment, MoCA)
3 x 24 hour food records
The order of the tests will vary from subject to subject depending upon their schedule and the availability of the equipment.

After completion of baseline testing, participants will enter the intervention phase
Phases 3-5. Interventions and Outcome Assessments will be performed at 3 months and at 6, 12 months and a final assessment at the end of 24 months for subjects who are in the optional retention exercise program.

INTERVENTIONS
MULTIMODAL BALANCE INTERNVETION (MMBI): The MMBI has been designed to specifically address the proximal strength, balance, and mobility deficits of these severely deconditioned older obese Veterans who use assistive devices. The MMBI intervention will be conducted in the VA hospital or the VA Annex in downtown Baltimore and at the more suburban Loch Raven Community Based Outpatient Clinic. The two sites are 6 miles apart and there is routine shuttle service between them. Our MMBI will be held once a week or once every other week for an hour and will consist of a dynamic balance class (30 minutes), a supervised obstacle course (10 minutes), and lower extremity and core strengthening (20 minutes). The exercises will focus on dynamic weight shifts with an emphasis on the lateral and diagnoal directions. Over time the exercises will gradually increase in difficulty. An instructor will lead each class and 1-2 assistants will be present to assist in mitigating the risk of falls. The supervised obstacle course will focus on obstacle negotiation, walking over challenging surfaces, and moving in the lateral, diagonal, and backward directions. Strength training of the lower extermities and core will focus on strengthening the major muscles of the lower extremity and core (hip flexors/extensors, hip abductors/adductors, knee flexor/extensors, ankle plantar fexor/dorsiflexors, ankle invertors/evertors, and core abdominal/back extensor muscles) utlizing commonly standard gymnasium equipment, ankle weights, and body weight. If group exercise is unavailable due to COVID-19, individuals will be provided with a written home exercise program to perform or sessions via telehealth twice a week. The intervention is 3 months long with optional extension out to two years.

We anticipate that some participants will have acute medical events during the study and may need to curtail or temporarily suspend the exercise intervention. When this occurs, the participant's status will be changed to 'suspended'. When medically cleared, we will perform a modified re-initiation of the training phase until the participant can re-establish exercise intensity previously performed, at which time they will resume the study at the week at which they were assigned suspended status. If an acute medical event occurs in the 2 weeks prior to the planned interim or final month outcome assessment, we will postpone the assessment until at least 6 thrice-weekly in-center training sessions can be completed at target exercise intensity. Participants who are on medical hold for more than 4 concurrent weeks will be evaluated on an individualized basis by the site PI to assess their appropriateness to return to intervention activities.

HYPOCALORIC NUTRITION INTERVENTION: Subjects will attend nutrition sessions once a week for the first 3 months. The nutrition classes will be lead by registered dietitians, either in person, via phone or via telehealth. During phase 2, subjects will complete three 24 hour food records that will be reviewed by the study dietitian and analyzed using Nutritionist Pro software. If necessary the study dietitians will communicate via phone with participants to collect this information. This will provide an assessment of nutritional adequacy at baseline to rule out the risk of nutritional deficiencies. One on one counseling will be provided. Three 24 hour food records is considered the gold standard and is necessary to provide the study dietician with the information necessary to make a thorough dietary assessment. The ASA24 system (https://asa24.nci.nih.gov/)will be used to collect 3 24 hour food recalls during baseline for both groups, and then at 3 months. Extensive evidence has shown that 24-hour dietary recalls provide the best quality, least biased dietary data as compared to paper-based food diaries. National Cancer Institute (NCI) investigators created the free, web-based Automated Self-Administered 24 hour Recall (ASA24) system to administered 24-hour recalls. The ASA24 system was developed with Westat®, and builds on the Food Intake Recording Software System (FIRSSt) developed by Dr. Tom Baranowski of the Baylor College of Medicine. The ASA24 system consists of a Respondent Website, used to collect data from participants, and a Researcher Website for managing study logistics and access nutrient and food group data files. The coordinator or study dietician will log into the VA computer and access the website and subject specific food logs. The computer will be logged on just prior to the subject coming into the room, coordinator will navigate to the website, place subject in front of the screen, and provide the subject with instructions. Coordinator will remain with subject at all times, and then will close out the computer. At no time will the subject have access to navigate elsewhere on the computer of be left alone. There is no identifying data for participants on the ASA24 website as they are specified a unique numeric identifier for each Respondent and download system-generated usernames and encrypted passwords that they provide to Respondents so that they may access the application. Only the study's investigator(s) and the ASA24 operations team can access response data. Access is gained through usernames and strong passwords. Data output is in SAS files, which will be stored on the VA computer study folder in the GRECC file I:\shared\all\MMBI and Weight Loss Merit\ and behind password lock. Response data are secured at the hosting site using industry standard security controls, including firewalls and encryption. All data entered into the ASA24 system at the Respondent's computer is encrypted by the internet browser (e.g., Internet Explorer, Firefox) before they are transmitted to our servers using Secure Socket Layer (SSL) Technology. SSL allows for the authentication of the sending and receiving computers.
We have developed a nutrition class curriculum, based on the principles and techniques of the VA MOVE! Program which focuses on nutrition education, portion control, and other weight management skills. The classes include behavior modification and cooking demonstrations. Spouses, caregivers, and significant others who are involved in shopping and meal preparation will be encouraged to attend along with the research subject. Sample menus using the exchange meal planning principles from the ADA will be provided. We have found it valuable to have a "lunch bunch" food session where the dietitians can observe dentition, social interaction among subjects while they eat, as well as whether they have any difficult feeding themselves. Participants will receive a course outline, a weight table, and weekly food suggestions, emphasizing easy to assemble meals and snacks. They will be asked to keep weight and food diaries to monitor their progress and adherence. Individual dietary recommendations, i.e. personalized food plans, will be developed based on the participant's preferences. Each subject's daily caloric intake will be designed to produce a 10% weight loss over the first 6 months of the study. Subjects with, or at risk of having, sarcopenic obesity, the energy deficit will be more moderate than usual (range of 200-500 kcal/day) with emphasis on a higher intake of proteins of high biological quality (up to 1.5 g/kg). Based on current recommendations of the American Geriatrics Society, all subjects will be advised to take over the counter supplements of at least 1000 units of vitamin D per day and 1200 mg of calcium. We have successfully employed this nutritional intervention in GRECC studies for >25 years.

STUDY OUTCOME MEASURES will be performed at baseline and after 3 months, and at 6, and 12 months of intervention for subjects who into the longer intervention. .

Physical Function tests include include the primary outcome of distance walked on the 6-minute walk test
a) Six-minute walk test: Participants are instructed to "cover as much distance as they can" over a flat 100 foot walking surface demarcated by traffic cones.
b) 6 minute walk test with measurement of economy of gait: participants complete the 6 minute walk wearing a portable metabolic monitoring equipment (Cosmed K4b2, Cosmed, Rome, Italy) worn on the chest to assess energy expenditure during overground walking.
c) The Short Physical Performance Battery (SPPB) includes the following components: 1) Timed 4-meter walk; 2) Repeated chair stand; and 3) Balance tests. For each

component, a score of 0 to 4 is assigned, with the sum of components comprising a final score
d) Grip strength: Participants will grip and hand dynamometer as hard as they can to assess handgrip strength.
The participants may be asked to wear a small triaxial accelerometer during these tests. The QTug is a small device the size of a deck of cards that is placed above each knee during the test and provides data on standing, sitting walking, and turning and allows us to better quantify fall risk and frailty in participants.

Lower extremity strength: a Biodex System 4 Pro dynamometer will be utilized to assess peak isometric hip abductor, knee extensor, and ankle plantar/dorsiflexion strength. We will use standardized protocols as described by Biodex.

Gait Biomechanics: using an instrumented walkway (GAITrite, CIR systems INC, Clifton, NJ), spatial and temporal parameters of gait and gait variability will be assessed. The GAITrite is a 25 foot portable walkway mat embedded with pressure sensors that detect steps while the subjects walks over the mat.

Lateral mobility and balance:
a) Four square step test: Participants will timed as they step over four canes set up in a cross on the floor as a test of dynamic balance.
b) 8 Foot up and Go: Participants will be timed as they stand up from a chair, walk around a cone placed 8 feet away, and come back and sit down.
c) Functional Gait Assessment: Participants will be timed as they walk at different speeds, look in differing directions and step over objects
Participants may also be asked to wear the QTug for these tests.

Anthropometrics: height, weight, and body circumference measurements

Body composition assessment:
Body Composition: Total and regional % body fat, fat mass, lean tissue mass, and bone mineral content will be determined by dual-energy x-ray absorptiometry (DXA). Bone density of the total body, including the hips will be measured using DXA. Computed tomography (CT) scans of the abdomen and thigh will quantify abdominal fat, and thigh fat and muscle. A urine pregnancy test will be completed in women of child- bearing age prior to having the CT and DXA scans. The DXA and CT scans will be performed by radiology technicians. *Body composition assessment will not be conducted at 9 months*

2 * Describe all procedures already being performed for diagnostic or treatment purposes (if not applicable to the study, enter "N/A"):
N/A - All study procedures will be performed for research purposes only.

3 * Describe the duration of an individual participant's participation in the study:
We anticipate that each volunteer's participation, if they complete all study related activities, will be approximately 24 months. However, the duration could be more or less depending on the timeframe for each phase of testing and when the group intevention classes begin and end.

4 * Describe the amount of time it will take to complete the entire study:
4 years

5 * Describe any additional participant requirements:
None

ID: VIEW4E0280585B400
Name: v2_Study Procedures

Sample Size and Data Analysis

If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer boxes below.

1 * Provide the rationale and sample size calculations for the proposed target population:

SAMPLE SIZE CALCULATIONS were determined for the physical outcomes. Perera and colleagues proposed that an improvement of 19-22 meters on the 6 minute walk test (6MWD) would be clinically meaningful and an increase of 47-49 meters would be considered substantial (72). In our prior studies in subjects with impaired mobility, exercise increased 6MWD 10 to 30%. In our preliminary studies in obese mobility limited Veterans enrolled in Gerofit, the 6MWD increased by 15% (57 +/- 60 m) and the number of chair stands performed by 19%. We anticipate greater improvements with weight loss + MMBI on the order of 30 to 50 M greater improvement in MMBI + weight loss versus MMBI only. Using lower estimates, if the true difference in mean response of matched pairs is 30 +/- 50 meters, we will need to study 45 subjects in each group to be able to reject the null hypothesis with two-sided power of 0.8 and Type I error probability of 0.05. We previously reported that an exercise intervention in middle aged and older overweight and obese men increased VO2peak (L/min) by 17% with no change with weight loss (50). The study by Villareal et al. reported a 17% improvement in VO2peak in the combined group versus about 6% in the diet group. To detect a 15% difference in VO2peak between groups with a power of 0.80 and a p-value <0.05, we would need to enroll 41 subjects per group, which is close to the sample size required for the 6MWD. On a percentage basis we anticipate that there will be even more substantial improvements in lateral mobility and balance as assessed by the four square step test (FSST) than that observed for the change in usual gait speed or 6MWD. In our preliminary data, the MMBI decreased the time to complete the FSST by 24%, with the greatest improvement in the frailest subjects. Therefore, fewer subjects might be required to demonstrate a difference in the improvement in balance between groups.

We will enroll 60 subjects. Typical attrition rates are 20-25%, primarily due to the development of non-study related medical problems. This will result in 45 completers. If a greater than anticipated number of subjects fail to complete the study, we will enroll additional subjects.

2 * Provide the plan for data analysis. Include in the description the types of comparisons that are planned (e.g., comparison of means, comparison of proportions, regressions, analysis of variance, etc.), which is the primary comparison/analysis, and how the analyses proposed will relate to the primary purposes of the study:

All comparisons of primary and secondary outcomes will be performed in accordance with intention-to-treat principles. As with all clinical trials, it is anticipated that there may be missing data elements. Multiple imputation will be used to account for missing values. Our first analyses will be exploratory designed to identify extreme values. Extreme values will be checked to make sure they are not the result of data entry errors. Statistical significant will be a two-sided alpha of 0.05.

Specific aim 1. Our study will compare the effects of MMBI+nutrition on mobility and functional performance in older obese Veterans with walking impairment requiring a walking assistive device. We will use repeated measures ANOVA to model the time-course of our outcome measures. We will use AICC (a modification of Akaike's Information Criterion) to choose between three covariance structures that can account for the serial auto-correlation of our subject's data.

Specific aim 2. Using DXA and CT scans, we will quantify total muscle mass and cross-sectional muscle area at numerous levels at baseline,3 6, 12, and 24 months. At baseline there should be a direct correlation between total muscle, ASMI, cross-sectional muscle mass and the indices of functional performance. With the exercise intervention, we expect that there will be small, but significant increases in lean muscle mass and ASMI (ANOVA). This change may be beyond the limits of detection of the DXA. Assessment of cross-sectional muscle area by CT scan may provide a more sensitive measurement of muscle mass than DXA. The relationship between muscle mass, strength, and functional performance at baseline and after the intervention will be examined. Body composition (% fat, fat-free mass, regional distribution of body fat) may change with intervention. Regression analyses will be used to determine whether the change in 6MWD, and other mobility parameters are related to the change in muscle mass (DXA, CT scan) or muscle strength (Biodex) with intervention. We will also perform multivariate modeling. It is important to dissect how much of the improvement in mobility after intervention is attributable to changes in fitness, economy of gait, and other factors such as balance, and strength. The functional measures in combination with the assessments of muscle mass by DXA will also allow us to determine the prevalence of sarcopenia using recently published NIH guidelines.

Specific Aim 3. We will examine the impact of the intervention on patient reported measures of function and disability using the LLFDI. We will compare LLFDI total scores and subscale scores using an analysis plan similar to that for aim 1. We will also examine the correlations between the self-reported measures and performance measures to provide further evidence of validity and reliability.

ID: VIEW4E02806052800
Name: v2_Sample Size and Data Analysis

Sharing of Results

1 * Describe whether results (study results or individual subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings) will be shared with subjects or others (e.g., the subject's primary care physicians) and if so, describe how it will be shared:

Results which have clinical relevance will be shared with participants, and with their permission, their primary care providers.

ID: VIEW4E02B08CBD800
Name: v2_Sharing of Results

Psychological/Behavioral/Educational Methods & Procedures

You indicated on the "Type of Research" page that your study involves a psychological/behavioral/educational method or procedure such as a survey, questionnaire, interview, or focus group.

1 * Select all behavioral methods and procedures which apply to this study:

- [x] **Surveys/questionnaires**
- [ ] Key informant or semi-structured individual interviews
- [ ] Focus groups or semi-structured group discussions
- [ ] Audio or video recording/photographing
- [ ] Educational tests or normal educational practices (education instructional strategies, techniques, curricula, or classroom management methods)
- [ ] Individual or group behavioral observations
- [ ] Psychosocial or behavioral interventions
- [ ] Neuropsychological or psychophysiological testing
- [ ] Deception
- [ ] Other psychosocial or behavioral procedures

ID: VIEW4E09416F57800
Name: v2_Psychological/Behavioral/Educational Methods and Procedures

Surveys/Questionnaires

You indicated that this study involves surveys and/or questionnaires.

If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer boxes below.

1 * List all questionnaires/surveys to be used in the study, including both standardized and non-standardized assessments:

The CHAMPS Questionnaire
ADL/IADL
Late Life Function and Disability Instrument
Mini-Mental State Examination (MMSE)
Montreal Cognitive Assessment (MoCA)
Mini Nutritional Assessment (MNA)
Screen II
Beverage Questionnaire (BEV-Q 15)
Newest Vital Sign
Pittsburg Sleep Quality Index (PSQI)
MOVE 11
Weight Loss and Barriers Questionairre

2 * Upload a copy of all questionnaires/surveys:

Name	Created	Modified Date
BEV-Q 15(0.02)	12/9/2016 3:02 PM	9/21/2017 8:48 AM
Weight Loss and Barriers Questionairre(0.01)	7/7/2017 8:22 AM	7/7/2017 8:22 AM
MOVE11(0.01)	12/9/2016 3:14 PM	12/9/2016 3:14 PM
Pittsburgh Sleep Quality Index(0.01)	12/9/2016 3:03 PM	12/9/2016 3:03 PM
Newest Vital Sign(0.01)	12/9/2016 3:02 PM	12/9/2016 3:02 PM
MNA(0.01)	12/9/2016 3:01 PM	12/9/2016 3:01 PM
SCREEN II(0.01)	12/9/2016 3:01 PM	12/9/2016 3:01 PM
MoCA Test.pdf(0.01)	5/27/2016 1:01 PM	5/27/2016 1:01 PM
LLFDI disability questionnaire(0.01)	5/27/2016 1:00 PM	5/27/2016 1:00 PM
LLDFI Function Questionnaire(0.01)	5/27/2016 12:59 PM	5/27/2016 12:59 PM
MMSE.pdf(0.01)	4/26/2016 3:24 PM	4/26/2016 3:24 PM
CHAMPS Questionnaire.pdf(0.01)	4/26/2016 3:23 PM	4/26/2016 3:23 PM
ADLs_IADLs questionnaire.pdf(0.01)	4/26/2016 3:23 PM	4/26/2016 3:23 PM

3 * What is the total length of time that each survey is expected to take?

MMSE will only be performed at screening. MNA, SCREEN II, and Weight Loss and Barriers and MOVE 11 will only be given at baseline will take approximately 20 minutes in total. It will take approximately 5 -10 minutes per survey at each time point. The surveys are a tertiary aim of this protocol. To reduce subject burden some surveys may not be completed at all research testing time points.

4 * Are any of the questions likely to cause discomfort in participants or cause harm if their confidentiality were breached? (i.e., Illegal activities)

○ Yes ● **No**

5 * Do any questions elicit information related to the potential for harm to self or others?

○ Yes ● **No**

5.1 If Yes, what procedures are in place to assure safety?

ID: VIEW4E09460F5EC00
Name: v2_Surveys/Questionnaires

Sample Collection/Analysis

You indicated on the "Type of Research" page that your study involves a sample (specimen) collection and/or analysis.

1 * What type of samples will be involved in this study? (Check all that apply)

- [x] **Prospective (will be collected)**
- [ ] Existing (previously collected at the time of initial IRB submission)

2 * Will genetic analysis/testing be done on any of the samples?

○ Yes ● **No**

3 * Will this study involve banking of samples (storing for future research use)?

● **Yes** ○ No

4 * What is the purpose of the sample collection and/or analysis?

At screening - for eligibility purposes and to characterize the health status of this subject population. At baseline, 6 months, and 12 months to assess for inflammation and stored samples for a biorespository for future use.

5 * Is there the possibility that cell lines will be developed with any of the samples?

○ Yes ● **No**

6 * Will the samples be released to anyone not listed as an investigator on the protocol?

○ Yes ● **No**

6.1 If Yes, give name(s) and affiliation(s):

7 * Will the sample material be sold or given to any third parties?

○ Yes ● **No**

7.1 If Yes, give name(s) and address(es):

ID: VIEW4E0E1A4B80000
Name: v2_Sample Collection/Analysis

Prospective Samples

You indicated that the study involves collection of prospective samples (specimens).

1 * What type of sample will be collected? (Check all that apply)

- [x] **Blood**
- [ ] Bone Marrow Aspirate/Biopsy
- [ ] Cerebrospinal Fluid
- [ ] Saliva
- [ ] Skin
- [ ] Sputum
- [ ] Stool
- [ ] Tissue
- [ ] Tumor
- [ ] Urine
- [ ] Other

1.1 If Other, specify:

2 For blood draws, specify the amount drawn, in teaspoons, at each visit and across the course of the subject's entire participation time:
Approximately 60 cc at screening
Approximately 40 cc at 3 months
Approximately 30 cc at 12 moths
Total = approximately 130 cc

3 * What type of samples will be collected? (Check all that apply)

- [x] **Samples obtained specifically for research purposes-obtained via a separate collection procedure done solely for the purposes of the study**
- [ ] Samples obtained specifically for research purposes-additional taken during a clinical procedure
- [ ] Leftover samples that were obtained for clinical purposes (no additional research procedures required)
- [ ] Commercial (for profit) samples
- [ ] Other

3.1 If Other, specify:

4 * How are these samples labeled? For example, do they contain name, initials, dates, Social Security number, medical record number, or other unique code?
Samples are stored with a unique code and the date the sample was obtained.

5 * Will sample(s) be made available to the research subject (or his/her medical doctor) for other testing?
○ Yes ● **No**

6 * If a participant withdraws from the study, will that participant have the option to get the remaining portion of their sample(s) back?
○ Yes ● **No**

7 * If the participant withdraws, explain how their sample(s) will be handled (For example, will sample(s) be destroyed, anonymized, etc.):
Samples will be banked at the GRECC and the Division of Gerontology and Geriatric Medicine at the Baltimore VAMC indefinitely unless the subject requests any remaining samples be destroyed.

8 * Will the samples be destroyed after the study is over?
○ Yes ● **No**

8.1 If No, describe how the samples will be stored, where they will be stored, and for how long.
Samples will be banked at the GRECC and the Division of Gerontology and Geriatric Medicine at the Baltimore VAMC indefinitely unless the subject requests any remaining samples be destroyed.

ID: VIEW4E0E257D60C00
Name: v2_Prospective Samples

Sample Banking

You indicated that the study involves banking of samples (storing for future research use).

1 * Where will the sample(s) be banked? (If this study involves the VA, please state the name of the registry/repository and the CICERO protocol number is was approved under.)
Metabolic Core Lab, UMB-Pepper Center, Baltimore VAMC

2 * Does the banking institution have an approved policy for the distribution of samples?
● **Yes** ○ No

3 How long will the sample(s) be kept?
Samples in biorepository will be retained indefinitely.

4 * Will sample(s) be made available to the research subject (or his/her medical doctor) for other testing?
○ Yes ● **No**

5 * If a participant withdraws from the study, will that participant have the option to get the remaining portion of their sample(s) back?
○ Yes ● **No**

6 * If the participant withdraws, explain how their sample(s) will be handled (For example, will sample(s) be destroyed, anonymized, etc.):
Samples will be retained unless a participants requests they be destroyed.

7 * If the participant withdraws, explain how the data obtained from their sample(s) will be handled (e.g., will it be deleted?) ***(Please note that data for FDA regulated research cannot be deleted):***
Results of all testing on samples will be retained in the study database

ID: VIEW4E0E7E82B5800
Name: v2_Sample Banking

Data Collection/Record Review

You indicated on the "Type of Research" page that your study involves data collection or record review (i.e., chart review, not self-report).

1 * What type of data will be collected/analyzed in this study? (Check all that apply)

- ☐ Retrospective/Secondary Analysis (data has already been collected at the time of initial IRB submission)
- ☑ **Prospective (data is not yet in existence and/or collected)**

2 * Will this study involve adding data to a registry or database for future use?

● **Yes** ○ No

3 * Will the data be released to anyone not listed as an investigator on the protocol?

○ Yes ● **No**

3.1 If Yes, give name(s) & affiliation(s):

ID: VIEW4E0E25A8CA400
Name: v2_Data Collection / Record Review

Prospective Data

You indicated that the study involves the collection of prospective data.

1 * Where is the data being collected from? (Check all that apply)

- [x] **Medical records**
- [ ] Medical images
- [ ] Commercial (for profit) entity
- [ ] Publicly available records
- [ ] Schools
- [x] **Other**

1.1 If Other, please specify:
Physical exams and research testing

2 * What data fields will you have access to/collect for the study? For example, name, initials, date of birth, Social Security number, income, demographic information, family units, housing, etc.
Enrollment into CPRS requires full name, date of birth, social security number, address, and gender. On our general information sheet, we collect income, ethnicity, race, marital status, work status, health insurance, and previous occupation among others. In additional we will measure variables related to health status, physical functional, strength, fitness, body composition, quality of life, fatigue, disability, balance, gait, and fall risk.
We will be sharing data with HP-00060757 in order compare different participant populations doing similar testing and measurements.

You can also upload a copy of the data fields/variables to be collected for the study:

Name	Created	Modified Date
There are no items to display		

ID: VIEW4E0E25B643800
Name: v2_Prospective Data

Data Registry

You indicated that the study involves adding data to a registry or database for future use.

1 * What is the name of the registry/database to which data will be added? (If this study involves the VA, please state the name of the registry/repository and the CICERO protocol number it was approved under.)
Data will be stored in the Baltimore GRECC database GERI

2 * What is the purpose of the registry/database?
GERI is a secure password protected database behind the VA firewall for GRECC data.

3 * Who has oversight and controls access to the registry/database?
The GERI biostatistics core provides oversight and control over access to the database.

4 * Who will have access to the registry/database?
Study team members. If a team member leaves the study their access will be revoked immediately.

5 * How long will the data be stored in the registry/database?
Indefinitely as VA research data can not be destroyed. We wil follow the VA RCS10.1 data retention/destruction policy.

6 * Are participants in the study allowed to request that their data be removed?
○ Yes ● **No**

6.1 If No, explain why subjects will not be able to request that their data be removed:
VA research data can not be destroyed

ID: VIEW4E0E25BCFA400
Name: v2_Data Registry

Clinical Trial Registration

You indicated on the "Type of Research" page that your study is a clinical trial.

1 * Does the UM Clinical Trials Registry policy require registration of this trial?

● Yes ○ No

2 * Has this trial been registered?

● Yes ○ No

ID: VIEW4E093BF078C00
Name: v2_Clinical Trial Registration

HP-00069566 Clinical Trial Registration Info_V2

Clinical Trial Registration Information

You indicated that this clinical trial has been registered.

1 * Was this trial registered at www.clinicaltrials.gov?
(●) Yes ( ) No

2 If no, was this trial registered on a site other than clinicaltrials.gov?
( ) Yes ( ) No

2.1 If Yes, specify the name of the other site:

2.2 Provide justification for registering this trial on this site:

3 * Registration Number
NCT02806336

ID: VIEW4E093BF1D0800
Name: v2_Clinical Trial Registration Information

Participant Selection

1 * How many local potential participants (or specimens/charts) do you anticipate will be screened for this study? ***Screening includes determining potential participants' initial eligibility for and/or interest in a study.***
240

2 * How many participants (or specimens, or charts) will be enrolled/used for this study? ***A local prospective participant is considered enrolled in the study when a UM-approved Informed Consent Document (not including separate screening consent forms) is signed.***

Local - the number being enrolled at this site:
240

Worldwide - the number being enrolled total at all sites (including local enrollment):
240

3 * Gender:

- [x] **Male**
- [x] **Female**

4 * Age(s):

- [ ] 0 to 27 days (newborn infants)
- [ ] 28 days to 12 months (Infant)
- [ ] 13 months to 23 months (Toddler)
- [ ] 2 to 5 years (Preschool)
- [ ] 6 to 11 years (Child)
- [ ] 12 to 17 (Adolescents)
- [x] **18 to 88 years (Adult)**
- [ ] 89 years and older

5 * Race/Ethnicity:

- [x] **All Races Included**
- [ ] American Indian or Alaskan Native
- [ ] Asian/Other Asian
- [ ] Asian/Vietnamese
- [ ] Black or African American
- [ ] Hispanic or Latino
- [ ] Mixed Race or Ethnicity
- [ ] Native Hawaiian or Pacific Islander
- [ ] White or Caucasian

6

* Language(s):

- [x] **English**
- [ ] Chinese
- [ ] French
- [ ] Italian
- [ ] Japanese
- [ ] Korean
- [ ] Local Dialect
- [ ] Spanish
- [ ] Vietnamese
- [ ] Other

6.1 Specify Other:

7

* Are you excluding a specific population, sub-group, or class?

○ Yes ● No

7.1

If Yes, indicate your justification for excluding a specific population, sub-group, class, etc.:

ID: VIEW4E0E519C1D000
Name: v2_Participant Selection

Vulnerable Populations

1 * Will you be targeting ANY of the following Vulnerable Populations for enrollment? (Select all that apply)

- [ ] Employees or Lab Personnel
- [ ] Children (Minors)
- [ ] Cognitively Impaired/ Impaired Decision Making Capacity
- [ ] Pregnant Women/Fetuses
- [ ] Wards of the State
- [ ] Students
- [ ] Prisoners
- [ ] Nonviable Neonates or Neonates of Uncertain Viability
- [ ] Economically/Educationally Disadvantaged
- [x] **None of the above**

Only select populations which you will be targeting for enrollment. Do not include populations that may be enrolled incidentally. Enrollment of a vulnerable population is considered to be "targeted" if the study team will be aware that a subject is from a vulnerable group as a result of interaction with the subject or collection of specific information about the subject, and the research team does not wish to exclude them. "Incidental" enrollment is limited to situations where a study team is unaware that a subject is from a vulnerable group.

ID: VIEW4E0E519917800
Name: v2_Vulnerable Populations

Eligibility

1 * Do you have an existing Eligibility checklist(s) for this study?

● Yes ○ No

1.1 If Yes, upload here. If you need a template, you can download it by clicking **HERE**. The checklists you upload will also be available under the Documents tab of this application.

Name	Created	Modified Date
Eligibility Checklist(0.01)	1/11/2017 3:25 PM	1/11/2017 3:25 PM

1.2 If No, create an eligibility checklist below:

List inclusion criteria (List each Inclusion Criteria individually, using the ADD button):

	Number	Criteria
View	1	BMI ≥30 kg/m2
View	2	Age ≥60
View	3	Dysmobility as define by 1 or more of the following: Use of or prescribed an assistive walking device, measured gait speed < 1.0 m/s, Four Square Step Test >/= 12 secs OR inability to complete the Four Square Step Test, and/or self-reported difficulty walking 1 km.
View	4	Community dwelling
View	5	Are a Veteran

List exclusion criteria (List each Exclusion Criteria individually, using the ADD button):

	Number	Criteria
View	1	Wheelchair or scooter dependent
View	2	Poorly controlled hypertension >180 systolic or >100 diastolic
View	3	Episode(s) of acute coronary syndrome, coronary revascularization, or major cardiac/vascular procedures within the prior 6 months
View	4	NYHA Class 3 or 4 heart failure
View	5	Symptomatic angina at rest or during exercise
View	6	Syncope within the past 12 months without known resolution or cause
View	7	Chronic lung disease requiring oxygen dependency
View	9	Severe spinal stenosis limiting ambulation
View	10	Known dementia
View	11	Mini Mental State Exam score < 24
View	12	Transtibial or above the knee amputation
View	14	Poorly controlled diabetes as defined by HbA1C >10% or frequent hypoglycemic episodes
View	15	Currently undergoing chemotherapy and/or radiation therapy for cancer treatment
View	16	Other medical conditions or contraindications precluding patient participation in this study as per medical judgment of study team

After entering the inclusion and exclusion criteria above, click the Save link. CICERO will automatically generate a printable Eligibility Checklist for you to use in your research. To review the checklist, click on the resulting link below. This checklist is also available under the Documents tab of this application.

Eligibility Checklist for HP-00069566_6 v3-21-2018-1521646040912(0.01)

ID: VIEW4E0E5185F9000
Name: v2_Eligibility

Recruitment

1 * Describe plans for recruitment, including the identification of potential participants (or acquisition of charts/records/samples) and initial interactions with them: (If this study involves the VA please list all sites at which recruitment will take place.):

Community dwelling obese Veterans (age >= 60) with mobility limitations will be recruited utilizing a variety of methods including the Baltimore GRECC subject recruitment registry, advertisements, referrals from VA providers in outpatient clinics, participants of MOVE and Gerofit, physical therapists, and community outreach. As the Covid-19 restrictions on face-to-face visit are lifted we anticipate that the number of Gerofit Veterans will return to the previous >100 subjects actively interacting with our staff, many of whom will qualify for this research program. There is a new GRECC falls and balance clinic and many of the older Veterans seen in this clinic would qualify for this study. Four to eight older Veterans are typically seen per week in this clinic. The providers in this clinic have agreed to refer potential subjects for this study.

The use of multiple recruitment strategies will allow us to maximize our outreach to a diverse pool of Veterans and to include those who do not routinely seek care at the VA. Interested individuals will initially undergo a telephone screen by the project coordinator or qualified research team member to assess eligibility for the study using our inclusion/exclusion criteria. Potential participants who pass the phone screen will be invited to our facility for further in-person screening to ensure that individuals are appropriate or safe to participate. The IRB and VA privacy officer grant a partial HIPAA waiver for the collection of protected health information during the recruitment and telephone screening phase of this study.

We would like to perform a computer-based screening using the VISN 5 Corporate Database Warehouse to screen for individuals who have had a previous fall, or use an assistive device and are at risk for falls. Also, we will use data pull with real Social Security Numbers (SSNs) from VA's Information and Computing Infrastructure (VINCI) to enhance recruitment goals within the VISN. This study already has an approved HIPAA Waiver and Consent Waiver for recruitment purposes. Potential subjects from the VISN will be mailed an IRB approved recruitment letter (uploaded in recruitment section), as well as an opt in/opt out post-card (uploaded in recruitment section). Postage will be provided on the opt in/out post-card, which will allow for potential subjects to indicate whether they would like to be contacted in the future related to the study. The opt in/out post-card will not list the subject's name, but rather will only provide a letter number that we will generate and store in a password protected file on the VA server prior to mailing the letter. If no response is received within two weeks, we will follow up with a phone call to gauge subject interest.

2 * Describe measures that will be implemented to avoid participant coercion or undue influence (if not applicable to the study, enter "N/A"):

Participants will be instructed to contact the research staff through a phone number listed on a brochure if they are interested in participation in this study. If the participant is a Veteran who receives care through the VAMHCS, they will be assured that their participation will not affect their medical care. To ensure continued consent and understanding of the study procedures, participants may, at any time point, ask to review individual specific study procedures and any pre-procedure preparation they will need to do. The participants will also be encouraged to take as much time as needed to decide whether they want to participate and will be encouraged to discuss the study with family and friends before signing the consent form.

3 * Who will recruit participants (or acquire charts/records/samples) for this study? (Check all that apply)

- [x] **PI**
- [x] **Study Staff**
- [ ] Third Party

3.1 If you are using a third party, specify Third Party Recruiters:

4 Upload any recruitment tools such as screening/telephone scripts and introductory letters (do not upload advertisements here):

Name	Created	Modified Date
Opt In Out PostCard RISE 09242019.pub(0.02)	9/16/2019 3:48 PM	9/24/2019 10:32 AM
VINCI RISE Recruitment Letter 09242019.doc(0.02)	9/16/2019 3:48 PM	9/24/2019 10:32 AM
Invitation letter(0.04)	4/27/2016 9:31 AM	11/8/2018 12:58 PM
Phone screen(0.01)	4/27/2016 9:16 AM	4/27/2016 9:16 AM

ID: VIEW4E0BCAA0A6C00
Name: v2_Recruitment

HP-00069566 Advertising_V2

Advertising

1 * Will you be using advertisements to recruit potential participants?

(●) Yes ( ) No

ID: VIEW4E0BCCF811000
Name: v2_Advertising

Advertising Detail

You indicated that you will be using advertisements to recruit potential participants.

1.1 * Select the mode(s) of advertising (check all that apply):

- [ ] Radio
- [ ] Internet
- [x] **Print**
- [ ] Television
- [ ] Other

1.1.1 If Other, specify:

1.2 * Provide exact text of all proposed advertisement(s):

TEAR OFF NUMBER FLYER
DO YOU HAVE A SLOW WALKING SPEED?
DO YOU USE AN ASSISTIVE DEVICE TO WALK?

Participants are needed for a study to determine the impact of 3 months of exercise versus exercise and weight loss on fitness and body composition in patients who are overweight.

WHO MAY BE ELIGIBLE?
Men and women 60 years and older
Walk with a walking aid (cane or walker) OR have problems walking
Are a Veteran
Need to lose weight

For more information about this research study please contact: 410-605-7000 ext 55417

BROCHURE
MULTI-MODAL EXERCISE & WEIGHT LOSS IN OLDER VETERANS WITH LIMITED MOBILITY
An information guide for providers and potential study participants about this VA funded, IRB-approved study
University of Maryland School of Medicine
VA Maryland Health Care System
Geriatric Research, Education & Clinical Center

ABOUT THE STUDY
• About 1/3 of older Veterans are obese and obesity is a risk factor for mobility problems in older adults
• Using a walking aid can alter normal walking patterns and cause walking to be harder and more tiring, leading to mobility limitations
• Exercise training and weight loss may lead to improvements in mobility
• This study evaluates the impact of 3months of exercise training & weight loss on fitness, functional performance, and body composition

WHO IS ELIGIBLE
• Are a Veteran
• Age 60 and older
• Walk with a walking aid (cane, walker) OR have difficulty walking around
• Need to lose weight (BMI ≥ 30 kg/m2)
• Do not have a lower limb amputation

WHAT DO YOU HAVE TO DO?

• Medical history and physical exam
• Aerobic fitness assessments
• Strength and balance tests
• 24 hour food record
• Walking assessments
• Body composition scans (DEXA and CT scans)
• Questionnaires
* Follow up testing
RISKS
There are some risks of chest pain and musculoskeletal pain with exercise. You will be assessed at the start of the study to make sure it is safe for you to begin an exercise training program

If you think you might be interested in this study, please contact the Geriatric Research, Education & Clinical Center at

410-605-7000 ext 55417

Providers can call the same number above with the name(s) of persons who may be interested in enrolling in the study.

RECRUITING POSTER
Do you have a slow walking speed?
Do you use an assistive device to walk?

If so, you may be eligible for a 3 month research study investigating the effect of exercise training & weight loss on fitness and body composition in older adults

You may qualify if you:
• Are a Veteran
• Use a cane or walker OR have problems walking
• Are 60 years or older
• Need to lose weight (BMI ≥ 30 kg/m2)

If you are interested in more information, please call 410-605-7000 ext 55417

1.3 * Upload advertisement(s) here:

Name	Created	Modified Date
Tear off number flyer 2.27.21(0.07)	4/27/2016 9:38 AM	3/10/2021 10:49 AM
Recruiting Poster 2.27.21(0.07)	4/27/2016 9:57 AM	3/10/2021 10:34 AM
Brochure 2.27.21(0.08)	4/27/2016 9:52 AM	3/10/2021 10:31 AM

ID: VIEW4E0BCE82B8C00
Name: v2_Advertising Detail

Research Related Risks

If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer box below.

1 * Individually list each research-related risk, using a separate line for each. Next to each risk, delineate the likelihood/seriousness of the risk, and the provisions for minimizing the risk:

There are potential risks associated with some of the procedures included in this study. However, the procedures have been planned by the investigators to minimize the danger of any major complication. All subjects will undergo a thorough medical and history examination at entry into the study to assure that it is safe for them to participate in the study. All study procedures will be supervised by qualified personnel who will carefully monitor the participants.

Performance-based tests: 6MWD, 6MWD with economy of gait measurement, SPPB, handgrip strength, FSST, and FGA test: the FSST and the FGA test are timed tests that assess the dynamic ability to change directions while walking or stepping. The ability to negotiate stepping over obstacles (in the FSST and FGA) allows for the examination of real life walking and stepping skills. The SPPB involves tests of balance, gait and proximal lower body strength. All of these tests are found to be valid are reliable measures in older adults. No tests will be performed before the subject is examined by a physician and following verification of the absence of exclusion criteria (which would potentially preclude safe administration of physical function testing). These tests will be performed at the Baltimore VA Medical Center and/or at the BVAMC Annex located at 209 W Fayette Street, 4 blocks from the BVAMC and/or the Loch Raven Robotics and Rehab building at 3901 the Alameda. The testing location will be dependent upon the patient's schedule and schedule of the research staff. These tests involve a variety of timed walks, getting up from a chair, and tests of balance. There is a small risk that patients will fall, get chest pain, short of breath or become dizzy during these tests. Patients will stop the test if there are any untoward symptoms such as chest pain. There is a small risk of muscle strain or pulled muscles in the measurement of strength and fatigue. We have performed >1000 tests of functional performance without complication. To minimize risk to patients an exercise technician who is trained in CPR will be administering these tests. A crash cart and emergency medications are available in the area where these tests are performed at the BVAMC. For tests performed at the Annex, a clinical provider is present to supervise these sessions and available for consult in case of any problems. If there is a medical emergency, an AED is available on site and the 911 emergency medical system would be activated by the research team. We believe that it is highly unlikely that a subject will develop a medical emergency that would require the 911 system to be activated because in more than 25 years of training more than 1000 research subjects we have never had a subject who needed emergency treatment during tests of physical performance. The use of the QTug during these tests does not add any known risk.

Lower extremity isometric strength testing (Biodex): maximal isometric strength (MVIC) will be assessed in a variety of muscle groups including the hip abductors, knee extensors and ankle plantar and dorsiflexors. Each muscle group will be tested three times with a one minute rest between trials. Participants will be seated for all knee and ankle tests and standing for all hip tests. An external
stabilization frame will be used to minimize extraneous body movements while standing. We have used the Biodex System 4 Pro and MVIC to quantify muscle strength in numerous studies and this test is considered to be valid and reliable. Ratings of perceived effort and discomfort will be recorded periodically throughout the test. Musculoskeletal risks of strength testing include muscle soreness, joint
pains, strains/sprains, tendon rupture. These are listed in order of expected frequency. The test will be immediately terminated if a high discomfort rating is reached during the test, which is unrelated to normal exertion-induced muscle fatigue. In order to minimize risks participants will be given frequent rest breaks and the participant will be made aware that they can halt the test at any time. Additionally, for each MVIC test, the Biodex will be adjusted to minimize shear forces on the joint. There is a small risk of skin irritation or bruising from the Biodex. To minimize this risk, padding will be applied for comfort to the lower limb prior to all strength or central activation tests. We have performed Biodex strength assessments in multiple studies with minimal risk to the participants.

Body Composition: There is a small risk involved in performing the DXA and CT scans due to the radiation exposure. The radiation risk for the measurement of body composition is well within the established dosimetry of radiation guidelines for normal subjects. EHS approval for use of radiation in human subjects will be obtained for this protocol.

Exercise Training (MMBI Intervention). Exercise training 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 patients who have heart disease, poor circulation to the legs, or stroke. The risk of heart attack in these patients is one in 300,000 hrs of exercise, and risk of death is one in 800,000 hrs of exercise. In over 1,000,000 miles of walking or jogging there has been only one fatal event at the Cooper Exercise Clinic in Dallas, Texas. To minimize this risk, subjects will first undergo a medical evaluation and screening exercise treadmill tests. The risk is lower in subjects with no evidence of heart disease. Exercise sessions will take place either at the Baltimore VAMC offsite Annex at 209 W. Fayette Street or at the Loch Raven CBOC Robotics and Rehab Center at 3901 The Alameda and will be supervised by a exercise physiologists who are certified in exercise training and CPR. To minimize risk to patients, heart rate will be assessed before, during and after each session and blood pressure before and after each session. If blood pressure or heart rate go too high or subjects develop an irregular heart rate, chest pain or leg cramps, the training is stopped immediately. A clinical provider is on call and can be reached by phone for consult in case of any problems. An AED is available on-site and, should there be any unanticipated medical emergencies, staff can initiate emergency care by calling 911. We believe that it is highly unlikely that a subject will develop a medical emergency that would require the 911 system to be activated as in more than 25 years of training more than 1000 research subjects we have only had 1 subject who had a heart attack during aerobic training.

Laboratory testing: Phlebotomy will be performed once during the screening medial assessment for collection of blood samples for laboratory testing. Bruising, brief pain, and (rarely) infection are potential risks of this procedure.

Questionnaires: there may be some stress when subjects complete the LLFDI questionnaire

Confidentiality of data: Protected healthcare information will be obtained during the course of this study. The collection of data will be HIPAA compliant. To enhance data security and confidentiality, subjects will be assigned a research number. Study data will be stored in a double password protected relational database stored on a server behind the VA firewall with access restricted to VA study staff only. Biomedical data and study files will be stripped of identifiable private information and protected health information (PHI). Paper copies of the research medical charts are kept in file cabinets in locked rooms at the BVAMC. Despite the extensive protection in place, there is the remote possibility that the confidentiality of the data will be breached. If data should become lost/stolen, the PI will alert the VAMHCS Information Security Officer and Privacy Officer immediately.

Privacy: Subjects will be examined in individual examination rooms. Extensive steps will be taken to protect the privacy of research subjects. There is the remote possibility that the privacy of the subjects will be encroached upon.

COVID-19: In this COVID-19 pandemic, there is a small chance that subjects will become infected with COVID-19 due to their participation in the in-person visits to the facility. We have taken extensive steps in accordance with CDC guidance and local VA policies to minimize this risk. We will follow VAMHCS guidelines as they pertain to patient screening and access to VA facilities. All participants will be called the day before their appointments and pre-screened over the phone using the standard COVID-19 Screening Tool. Subects will be pre-scheduled for exercise and may only attend during their scheduled appointment slot. Any positive phone screens or in person screens will result in cancellation of the appointment, and subjects will be referred back to their health care provider for further instructions and follow-up. Subjects must wear a face mask at all times when they are in the facilities, including during the exercise session. Staff will extensively clean the equipment as per VA policies. You will be provided with an information sheet detailing all of the COVID-19 procedures. Subjects who do not follow the COVID-19 infection guidelines, you will be withdrawn from the study.

ID: VIEW4E1B52509F000
Name: v2_Research Related Risks

Potential Benefits and Alternatives

If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer boxes below.

1 * Describe the potential direct benefit(s) to participants:

All participants are expected to benefit from this study. At minimum, they will have assessments of their health and physical functioning. Clinically relevant results of these assessments will be provided to the subjects, and with their permission, to their health care providers. The MMBI & weight loss intervention should improve their balance, physical functioning, and decrease their risk for falling. Some participants may also no longer need to use their assistive devices. We also expect to see improvements in cardiovascular risk factors. Some participants may also benefit in psychological measures such as increased self-efficacy and decreased fear of falling. All of these factors are expected to help these participants decrease their risk of being seriously injured due to a fall.

2 * Describe the importance of the knowledge expected to result from the study:

Obesity, low cardiovascular fitness and slow gate speed is associated with increased morbidity and mortality. Few studies have examined the effect of weight loss and exercise rehabilitation on functional status in older obese individuals with mobility limitations who use walking assistive devices as these individuals often excluded from studies. There is limited evidence from intervention studies that weight loss alone or weight loss in combination with exercise rehabilitation can increase mobility and lower extremity function in older obese subjects. Preliminary studies in our group demonstrate that a novel progressive group multimodality balance intervention (MMBI) that focuses on lateral and diagonal movements, lower extremity and core muscle strengthening and dynamic obstacle negotiation can improve fitness, balance, gait and strength in older adults at high risk for functional decline. While we believe that both MMBI only and nutrition + MMBI training will improve gait and balance, we hypothesize that nutrition + MMBI will result in larger improvements in fitness, gait, balance and lower extremity strength. This intervention will potentially reduce the risk for institutionalization, reduce the cost of fall associated morbidity and mortality in older veterans by improving gait
and balance. This research directly benefits Veterans as it may lead to new and effective interventions that could improve walking mobility, reduce fall risk, reduce injury-related hospitalization and death in older Veterans. The nutrition + MMBI is readily exportable to the community and with minimal resources could be widely implemented at other VAs as part of standard of care.

3 * Describe how the potential risks to participants are reasonable in relationship to the potential benefits:

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.

4 * Describe the alternatives to participation in this study. If there are no alternatives, state that participation is voluntary and the alternative is not to participate. For intervention studies, describe appropriate alternative clinical procedures or courses of treatment available to subjects.

Participants may choose not to participate in this study or withdraw at any time without penalty or health risk. If participants choose not to take part, their healthcare at the University of Maryland, Baltimore and/or the VA Maryland Healthcare System will not be affected. Participants will not lose any VA or other benefit to which they are entitled. As an alternative to the intervention, participants could pursue exercise programs outside of this program. Other physical activity programs may be available in their area and may include non-VA hospital, physician, or private physical activity for a fee. Physical activity programs without a fee may also be available. If circumstances develop which cause participants to be removed from the study, efforts will be made to offer alternatives.

ID: VIEW4E1B5251B0400
Name: v2_Potential Benefits and Alternatives

Withdrawal of Participants

If the questions below are not applicable to the research (i.e., chart review), enter "N/A".

1 * Describe anticipated circumstances under which subjects will be withdrawn from the research without their agreement:
The principal investigator or the sponsor can remove subjects from the research study without their approval. Possible reasons for removal include failure to follow the instructions of the research staff, failure to follow COVID-19 precautions, or if the PI decides that the research study is no longer in their best interest. Subjects who do not follow the covid guidelines will be withdrawn.The sponsor can also end the research study early. The PI will tell subjects about this and they will have the chance to ask questions if the sponsor were to end the study early.

2 * Describe procedures for orderly termination:
Subjects can withdraw from the study at any time. Since this is a not a pharmacological trial there are no specific close-out or titration visits required.

3 * Describe procedures that will be followed when subjects withdraw from the research, including partial withdrawal from procedures with continued data collection:
If subjects withdraw completely from the research, this will be documented in the subject's research chart and their study status will be changed to withdrawn. Every effort to obtain a reason for withdrawl will be made, in hopes of improving the research process for this study and it's staff in the future. Withdrawn subjects' charts will be kept in a locked filing cabinet at the BVAMC. For subjects who partially withdraw from certain procedures in this study, the reasons for discontinuation for certain procedures will be documented. If subjects withdraw from this study, already collected data may not be removed from the study database in compliance with VA regulations.

ID: VIEW4E1B52531F800
Name: v2_Withdrawal of Participants

Privacy of Participants

If the study does not involve interaction with participants, answer "N/A" to the questions below.

1 * Describe how you will ensure the privacy of potential participants throughout the study ***(privacy refers to persons and their interest in controlling access to themselves):***

Participants are provided privacy during consenting as well as during all study measurements encounters related to the study. Private rooms are provided during consenting. During the group intervention visits (MMBI or nutrition classes), small groups of participants will be together under the supervision of the research staff, and it is possible that the other study participants in these groups will learn the identity of the other participants or recognize them from clinic, etc.

The initial screening information we obtain from participants will be entered - after obtaining informed consent from participants - into the IRB approved Pepper Center Registry HP-00040461. This registry is designed to collect and store information across research studies undertaken by investigators in the VA and University of Maryland. Information in the registry will be used to screen participants for entry in to this research project, as well as serve as a source of participants for future recruitment into new IRB approved studies carried out by UMB and VA researchers. As described in the Pepper Center Registry, the only data that will be stored in the registry will be data that has previously been approved for collection by the IRB under this IRB application. Thus, we are not requesting permission to collect new data. Only those subjects who approve having their data entered into the registry and agree to be re-contacted in the future for new studies will be entered in the registry. If at some time in the future participants wish to have their data removed from the registry, the data will be removed. The design and procedures related to the entry of data into the registry and their protection are detailed in HP-00040461, including the protection of PHI data by encryption and limiting access to the registry (i.e. by requiring a user name and password as well as access to the secured VA local network).

Participants may refuse to have their information entered into this Pepper Center Registry and still participate in this research protocol. The informed consent document will provide a description of the registry and will request that participants indicate their willingness to permit screening information to be stored into this registry.

2 * Describe the location where potential participants will receive research information and detail the specific actions the study team will take to ensure adequate privacy areas:

At the first visit, the PI and/or research staff will review the study with the participant and answer their questions. Informed consent will be obtained, HIPPA regulations reviewed, and all forms signed. The visit will take place at either the BVAMC, Annex, or Loch Raven Robotics and Rehab Building in a private room.

3 * Describe potential environmental stressors that may be associated with the research:

Participants are not selected on the basis of an acute illness or hospitalization; participants in this study will be attending research visits on an outpatient basis. The surveys and functional testing may induce emotional stress in some participants. All participants will be informed of the voluntary nature of the research, and will be able to terminate the testing at any time.

4 * Will this study have a site based in the European Union?

○ Yes ● **No**

5 * Will the study have planned recruitment or data collection from participants while they are located in the European Union?

○ Yes ● **No**

Access link below for information about the EU General Data Protection Regulations to assist in answering these questions.
https://www.umaryland.edu/oac/general-data-protection-regulation/

ID: VIEW4E1B525B87C00
Name: v2_Privacy of Participants

Confidentiality of Data

1 * Will stored research data contain identifiers or be able to be linked to and identify individual participants (either directly or through a code/research ID)?

- (●) **Yes**
- ( ) No, the data will be stored de-identified/anonymous (stripped of all identifiers, no way to identify individual participants)

2 * Where will research data be kept (address electronic and paper data as applicable)? (If this is a VA study please list specific sites that data will be kept.)

All research data will be stored by the PI and his research staff in locked file cabinets and on the GRECC research database GERI located on a Baltimore VA Medical Center research server at the Baltimore VA Medical Center behind the VA firewall. No data will be stored on mobile devices. Data is backed up on the server. None of the data will be leaving the VA protected environment. None of the data will be transmitted. No data will be returned to the VA.

3 * How will such data be secured?

Locked cabinets; password-protected computers/research servers within the VHA firewall and in compliance with VHA information security regulations. It data is lost or stolen, the VAMHCS ISO/PO , PI and research service will be notified immediately as per VA regulations.

4 * Who will have access to research data?

Only the primary investigator, co-investigators, and study staff will have access to research data with identifiers. If a researach team members leaves the study their access will be revoked immediately.

5 * Will study data or test results be recorded in the participant's medical records?

(●) **Yes** ( ) No

6 * Will any data be destroyed? ***(Please note that data for FDA regulated research cannot be deleted however, VA data must be destroyed according to the VHA Records Control Schedule (RCS) 10-1)***

( ) Yes (●) **No**

6.1 If Yes, what data (e.g., all data, some recordings, interview notes), when and how?

7 Do you plan to obtain a Certificate of Confidentiality?

( ) Yes (●) **No**

7.1 If Yes, upload your Certificate of Confidentiality. If you have not yet obtained the Certificate, please note that once it is obtained, you will need to submit an amendment to attach the document, make any needed changes to the submission and make needed changes to the Informed Consent Document.

Name	Created	Modified Date
There are no items to display		

8 * Discuss any other potential confidentiality issues related to this study:

Participants are provided with privacy during consenting as well as during all encounters related to the study. Private rooms are provided during consenting. With regards to how participants other confidentiality requirements are met, specifically: 1) social security numbers of participants are not solicited over the phone, 2) research staff restricts telephone and other contacts with veterans to the procedures and data elements outlined in the IRB approved protocol, 3) initial contact with participants is made in person or by letter prior to telephone contact, 4) verification of the study is provided following the guidelines set forth in HRPP/IRB policies and procedures 10G. Section S. (examples of sources of verification include the clinicaltrials.gov website and phone numbers of the principal investigator included on the consent form of which the study participant receives a copy). Enrollment notes documenting date of consent will be placed in patients' CPRS medical record charts.
In accordance with VA RC 10.1 data will be kept indefinitely and not destroyed.

ID: VIEW4E1B5265E0400
Name: v2_Confidentiality of Data

Monitoring Plan Selection

1 * Type of data safety monitoring plan for the study:

- ○ Will use/defer to the external sponsor's Data Safety Monitoring Plan
- ● **Data Safety Monitoring by a Committee**
- ○ Data Safety Monitoring by an Individual
- ○ There is no data safety monitoring plan in place

ID: VIEW4E1B00E30D400
Name: v2_Monitoring Plan Selection

Monitoring Plan - Committee

You indicated that the monitoring will be done by a Committee.

1 * Will the Committee be Internal or External?

- (●) **Internal DSMB**
- ( ) External DSMB

2 * What data will be reviewed?

- [x] **Adverse Events**
- [x] **Enrollment Numbers**
- [ ] Patient Charts/Clinical Summaries
- [ ] Laboratory Tests
- [ ] Medical Compliance
- [ ] Procedure Reports
- [ ] Raw Data
- [x] **Outcomes (Primary, Secondary)**
- [ ] Preliminary Analyses
- [ ] Other

2.1 If Other, specify:

3 * What will be the frequency of the review?

- ( ) Annually
- (●) **Bi-Annually**
- ( ) Other

3.1 If Other, specify:

4 * Safety monitoring results will be reported to:

- [x] **IRB**
- [ ] GCRC
- [ ] Sponsor
- [x] **Other**

4.1 If Other, specify:
The VA Research Service

ID: VIEW4E1B025761800
Name: v2_Monitoring Plan - Committee

Monitoring Plan - Internal DSMB

You indicated that the monitoring committee will be an internal DSMB.

1 * List Internal DSMB Members:

Name
View Jamie Giffuni, MA
View Odessa Addison, PhD
View Kathleen Michael, RN, PhD (chair)
View Stephen Seliger, MD
View Lynda Robey, MS
View Jacob Blumenthal, MD
View Gretchen Zietowski, MS, RN
View John Sorkin, MD, PhD

2 * Confirm that no financial or other conflicts of interest exists for the above individuals.

○ Yes ● **No**

3 * Will there be an interim efficacy analysis?

○ Yes ● **No**

3.1 If Yes, when?

4 * Briefly describe the DSM review process itself. Will it be an open or closed review to the investigator? Blinded/unblinded data? How will confidentiality of individual participant data be maintained?

The DSMB is just one part of the administrative oversight of research in the Division of Gerontology.
1. All procedures are reviewed by the research testing staff and signed off by the GRECC Director.
2. The PI presents the protocols at the weekly Geriatric Assessment Clinic conference to their fellow GRECC investigator, nursing and metabolic staff prior to implementation.
3. Quality management plans will be reviewed with the GRECC quality management nurse specialist.

The DSMB reviews will be open to the investigator.

The reviews will be HIPAA compliant. In reviewing the adverse events, the board will have access to patient identifiers and PHI. All specific patient identifiers will be removed in the DSMB report.

5 * What are the criteria defined in the protocol to be used for decision making regarding continuation, modification, or termination of study?

Consistent with other exercise intervention trials, there are no formal interim stopping criteria for this study. However, the OAIC (Pepper) SMB will have the authority to stop this trial at any time, temporarily or permanently, e.g. due to futility/poor enrollment or due to concerns about participant safety.

ID: VIEW4E1B0261D9400
Name: v2_Monitoring Plan - Internal DSMB

HP-00069566 Research Related Costs_V2

Research-Related Costs

1 * Is the study's financial supporter (e.g., commercial sponsor, federal or state grant or contract, private foundation, physician-sponsor) covering any research-related costs?

- ○ No
- ● **Yes**

1.1 If Yes, check all that apply:

- ☑ **Research-Related Services (personnel costs, tests, supplies, exams, x-rays, or consultations required in the study)**
- ☐ Investigational or Study Device
- ☐ Investigational or Study Drug
- ☐ Investigational Procedure(s)

1.2 If No, who is responsible for payment?

2 * Who is responsible for the uncovered research-related costs?

- ☐ Participant
- ☐ Sponsor
- ☐ UM
- ☐ Other
- ☑ **There will be no uncovered research-related costs**

2.1 If Other, specify:

3 If the participant is responsible for any research-related costs, identify and estimate the dollar amount:

ID: VIEW4E1B5D9641800
Name: v2_Research Related Costs

Compensation for Research-Related Injury

1 *Is this study under a master agreement that includes a provision requiring the sponsor to provide compensation to participants for research-related injury?

◯ Yes ● **No**

1.1 If Yes, please provide the date and title of the agreement and upload the portion of the contract language relevant to compensation for research-related injury:

Name	Created	Modified Date
There are no items to display		

1.2 If No (the study is not under a master agreement), is there proposed contract language concerning payment to participants for treatment in the event of a research-related injury?

◯ Yes ● **No**

1.2.1 If Yes, indicate the status of the contract review/approval with the ORD and upload the proposed language relevant to compensation for research-related injury:

1.2.2

Name	Created	Modified Date
There are no items to display		

ID: VIEW4E1B629EEC000
Name: v2_Compensation for Research-Related Injury

Payment/Reimbursement to Participants

1 * Will participants receive payment (money, gift certificates, coupons, etc.) or reimbursement for their participation in this research?

(●) Yes ( ) No

ID: VIEW4E1C52A5D7800
Name: v2_Payment to Participants

HP-00069566 Payment Detail_V2

Payment/Reimbursement Detail

You indicated that participants will receive payment (money, gift certificates, coupons, etc.) or reimbursement for their participation in this research.

1 * Payment/reimbursement to participants will be for: (check all that apply)

- [x] **Travel**
- [ ] Parking
- [ ] Meals
- [ ] Lodging
- [x] **Time and effort**
- [ ] Other

1.1 If Other, specify:

2 * What is the total dollar value of the payments/reimbursements over the duration of the study? ***Total payment(s) for participation in research of $600 or more in a calendar year is required to be reported on an IRS Form 1099.***
$250

3 * Describe the timing and distribution plan for the payment/reimbursement (schedule, means, etc.)?
The payment schedule is:
Completed Baseline testing - $50
Completed 3 month testing - $50
Completed 6 month testing - $50
Completed 12 month testing - $50
Completed 24 month testing - $50

This payment amount is consistent with what has been applied across the board with other GRECC protocols. There is a balance between the average distance traveled by the subjects across the Baltimore metro region (which is minimal) and the medically supervised exercise offered to them at no cost.

4 * Method(s) of payment/reimbursement to be Used:

- [x] **Cash**
- [ ] Check
- [ ] Money Order
- [ ] Gift Certificate/Gift Card
- [ ] Other

4.1 If Other, specify:

ID: VIEW4E1C54A6ACC00
Name: v2_Payment Detail

HP-00069566 HIPAA_V2

HIPAA (Health Insurance Portability and Accountability Act)

1 * Are you affiliated with, or will you be accessing data from a HIPAA-covered entity? A covered entity might be a hospital, a physician practice, or any other provider who transmits health information in electronic form.

• At UMB, this includes UMB schools designated as covered entities (School of Medicine and School of Dentistry) and entities under the University of Maryland Medical System (UMMS). The Baltimore VA Medical Center is also a covered entity.

• If you are a researcher from any school that is not a covered entity but is accessing electronic medical records from a covered entity (such as UMMC), HIPAA would be applicable. Please see a list of covered entities included under UMMS here: *executed-ace-designation-042018.pdf*

● Yes ○ No

2 * If Yes, will the study view, access, share, collect, use, or analyze health information that is individually identifiable under HIPAA?

● Yes ○ No

ID: VIEW4E1B0A2114400
Name: v2_HIPAA

HP-00069566 Protected Health Information_V2

Protected Health Information (PHI)

You indicated that HIPAA applies and the study will view, access, share, collect, use, or analyze health information that is individually identifiable.

1 * Which PHI elements will be used or disclosed in this study? (Check all that apply)

- [x] **Name**
- [x] **Address (if more specific than Zip Code)**
- [x] **Dates**
- [x] **Ages over age 89**
- [x] **Telephone numbers**
- [ ] Fax numbers
- [ ] Email addresses
- [x] **Social Security numbers**
- [x] **Medical record numbers**
- [ ] Health plan beneficiary numbers
- [ ] Account numbers
- [ ] Certificate/license numbers
- [ ] Vehicle identifiers and serial numbers, including license plate numbers
- [ ] Device identifiers and serial numbers
- [ ] Web universal resource locators (URLs)
- [ ] Internet protocol (IP) address numbers
- [ ] Biometric identifiers, including fingerprints and voiceprints
- [ ] Full-face photographic images and any comparable images
- [ ] Any other unique identifying number, characteristic, or code, unless otherwise permitted by the Privacy Rule for re-identification
- [ ] None

2 * Why is the PHI necessary for this research?

If SSNs are going to be used, describe the specific use and type of SSN to be used (real, scrambled, last 4 digits).

SSNs are required for this study because it is conducted in the VA and the VA uses SSN as the medical record number in their electronic health record. Participants are required to have an electronic heath record because they have blood work and radiology scans conducted by the VA. The EHR also includes, name, age, address, telephone #, and date(s) of tests.

3 * What is the source(s) of the PHI?

CPRS, is the electronic health record used in the VA. PHI will also be obtained from a general information form the subject will fill out and if applicable after obtaining HIPPA authorization.

4 * Provide written assurance that Protected Health Information will not be reused. (Note: this refers to re-use on another study or for a purpose which has not been approved, not to the re-use of screening data during the current study).

PHI will not be used by anyone who is not on the study team or listed in the HIPPA form. Protected health information obtained from subjects will only be used for this protocol.

5 * How will permission to allow the use/disclosure of the individual's protected health information (PHI) be obtained? (Choose all that apply:)

- [x] **Obtain written authorization *(upload authorization form at the end of the application under "Consent and HIPAA Authorization Forms")***
- [x] **Requesting waiver/alteration of authorization (includes waiver of authorization for recruitment only)**
- [ ] Qualifies as a limited data set (LDS)

5.1 If you are using a limited data set (LDS), please attach the Data Use Agreement (DUA):

Name	Created	Modified Date

There are no items to display

ID: VIEW4E1B0A24AA400
Name: v2_Protected Health Information

Waiver/Alteration of Authorization

You indicated that a waiver/alteration of authorization is requested.

1 * Provide rationale for how the research presents no more than minimal risk to the privacy of individuals:
A partial waiver is requested for recruitment purposes prior to enrollment. This provides some initial information to the research team about the potential participant who contacts the study for consideration of inclusion in or to decrease the burden of volunteers coming in who will not be eligible for the study. All persons who come in will perform a more detailed medical history relevant to exclusion criteria, whether subsequently actively enrolled in the interventions or not, Prior to the first study visit, the research team will review the HIPAA form, as well as the VA notice of privacy practices. The patient will be given the opportunity to ask questions, and then they will sign the form if they wish to continue participation in the study.
This request for wavier of HIPAA authorization is not for use of 38 USC 7332 information and that the purpose of the data is to conduct scientific research.

2 * Describe the plan to ensure the protection of PHI collected during this study from improper use and disclosure:
Subjects will sign HIPAA authorization at their first visit. All identifiers will be kept in participant's chart in a locked filing cabinet in a locked office. Electronic identifiers will be kept on an IRB approved Pepper Center Registry and/or GERI Gateway database which is double password protected and located on a SERVER that is behind the Baltimore VAMC firewall. Identifiers will be retained in accordance with the Dept. of Veterans Affairs Records Control Schedule (RCS 10-1).

REGISTRY INFORMATION
People who respond to our advertisements will be contacted by telephone and informed about the general aspects of the study. The information we obtain from subjects during the telephone screening will be entered into the IRB approved Pepper Center Registry (H-28418). This registry is designed to collect and store information across research studies undertaken by investigators in the VA and University of Maryland. Information in the registry will be used to screen subjects for entry into this research project, as well as serve as a source of subjects for future recruitment into new IRB approved studies carried out by UMB and VA researchers. As described in the Pepper Center Registry IRB application (H-28418), the only data that will be stored in the registry will be data that has previously been approved for collection by the IRB under this IRB application. Thus, we are not requesting permission to collect new data. Only those subjects who approve having their data entered into the registry and agree to be re-contacted in the future for new studies will be entered in the registry. If at some time in the future subjects wish to have their data removed from the registry, the data will be removed. The design and procedures related to the entry of data in the registry and their protection are detailed in section F1 of H-28418, including the protection of PHI data by encryption and limiting access to the registry (i.e. by requiring a user name and password as well as access to the secured VA local area network).

3 * Describe the plan to destroy the PHI collected during this study at the earliest opportunity consistent with the conduct of the research. If there is a need to retain PHI, provide a justification:
All PHI will be retained in accordance with the Dept. of Veterans Affairs Records Control Schedule (RCS 10-1).

4 * Why could the research not practicably be done without access to and use of this PHI?
The only PHI collected was directly for the conduct of the research, whether to facilitate contact/communication with the participant (or their PCP) or to document confounding health variables. The PHI is necessary to identify individual patients and determine their potential eligibility for this study.

5 * Why could the research not practicably be done without the waiver or alteration?
Given the extensive inclusion and exclusion criteria for this clinical trial, it is expected that only a small percentage of patients attending outpatient clinics and responding to recruitment advertisements will be potentially eligible for this study. It is not practical or feasible to recruit and screen every interested patient for eligibility after obtaining direct HIPAA authorization, to yield only a small percentage of those patients that are eligible for participation.. A process of "pre-screening" via electronic health record will identify those that appear potentially eligible, who can then be approached regarding their interest in the study.

6 * Will the subjects' PHI be disclosed to (or shared with) any individuals or entities outside of UM?
○ Yes ● **No**

6.1 If Yes, describe the individuals or entities outside of UM to whom PHI will be disclosed.

ID: VIEW4E180A2896400
Name: v2_Waiver/Alteration of Authorization

Informed Consent Process

If the study does not involve interaction with participants or a waiver of consent is being requested , answer "N/A" to the questions below.

1 * Indicate the type(s) of consent that will be involved in this study: (check all that apply)

- [ ] Not applicable (study may qualify as exempt)
- [x] **Request to Waive Consent/Parental Permission (Consent is not being obtained)**
- [ ] Request to Alter Consent (Some Elements of Consent Waived)
- [ ] Request to Waive Documentation of Consent (Verbal/Oral Consent)
- [x] **Written Consent Form**
- [ ] Electronic Consent

2 * Describe the Informed Consent process in detail:

Those interested in the study and with no apparent exclusionary criterion at the time of initial telephone screening are scheduled to come in to the GRECC's Geriatric Assessment Clinic where the PI or research team will explain the study, procedures and risks.
Ample time will be provided for questions and discussion. Informed consent will be obtained by the study coordinator or by one of the other members of the study team or the study PI.
The participants will be encouraged to take as much time as needed to decide whether they want to participate and will be encouraged to discuss the study with family and friends before signing the consent form.
Interested participants may either sign the Informed Consent /HIPAA documents after this discussion or they may choose to take the Consent /HIPAA forms home to review and sign at a subsequent study visit should they choose to participate.

A mini-mental status examination will be performed as part of the history and physical examination to screen for dementia. Patients with MMSE <24 will be excluded.
The research subject will be provided with a copy of all forms and copies of the signed forms will be placed in the patient's research chart and in the investigators files..

The informed consent process will be documented in the participant's study record and their VA clinical chart.

In order to ensure continued consent and understanding of the study procedures, participants may, at any time point, ask research staff to review individual study procedures and any pre-procedure preparation they will need to do.

Subjects enrolled in this study before the COVID-19 pandemic that we are inviting back into the study will be reconsented.

3 * Confirm that the consent process will explain the following:

- The activities involve research.
- The procedures to be performed.
- That participation is voluntary.
- The name and contact information for the investigator.

(●) **Yes** ( ) No

4 * Describe who will obtain Informed Consent:

The PI, co-investigators and/or research team.

5 * If obtaining consent from a legally authorized representative (LAR), describe how you will confirm that the individual is the LAR and can provide legally effective informed consent. *(Answer "N/A" if not obtaining consent from LARs)*

N/A

6 * Describe the setting for consent:

In private rooms free of distractions and onlookers/passers-by and to ensure privacy at the BVAMC Geriatric Research and Education Clinical Center, or at the Baltimore VA Annex, or at the Loch Raven Robotics and Rehab Building.

7 * Describe the provisions for assessing participant understanding:

A mini-mental status examination will be performed as part of the history and physical examination to screen for cognitive dysfuntion. Patients with MMSE <24 will be excluded.

8 * Describe the consideration for ongoing consent:

Subjects will need to come to the gym for ongoing participation in the study. Their voluntary arrival to the site is strong evidence of their ongoing consent.

Additionally, to ensure continued informed decision making and understanding of the study procedures, participants may at any time point discuss with the research team specific study procedures and any pre-procedure preparation they will need to do. The participants will also be encouraged to take as much time as needed to decide whether they want to participate in each specific session, and will be encouraged to ask questions or seek clarification at any time.

If at any time the consent form is amended to include new procedures or change in the risks, all participants will be re-consented in order to inform them of the changes made in the amended consent form.

ID: VIEW4E1C661D0AC00
Name: v2_Informed Consent Process

Waiver or Alteration Consent Process

You indicated that a waiver/alteration of consent is requested.

1 * Explain why the research involves no more than minimal risks to the subjects:
Based on recent guidance provided by ORO, we have been advised to also request a waiver of consent. This request for waiver of informed consent is for recruitment purposes only for studies that also obtain a waiver of HIPAA authorization for recruitment purposes. We will view information to determine eligibility but no research procedures will be conducted until such time that the participant agrees to take part in the study and signs the informed consent document. The recruitment process involves no more than minimal risk to the individual.

2 * Explain why a waiver or alteration of the consent process would not adversely affect the rights and welfare of the subjects:
This waiver request is for recruitment purposes only. If it is determined that the individual would be eligible to take part in the study, they will be approached and given the opportunity to agree and sign the informed consent document or they can decline participation.

3 * Informed consent is always required unless there is reason to grant a waiver or alteration of the consent process. Explain why you cannot carry out the research unless you are granted a waiver or alteration of the consent process:
This waiver request is for recruitment purposes only. If it is determined that the individual would be eligible to take part in the study, they will be approached and given the opportunity to agree and sign the informed consent document or they can decline participation.

4 If the research involves using identifiable private information or identifiable biospecimens, please explain why the research could not practicably be carried out without using such information or biospecimens in an identifiable format.

5 In some cases there will be additional pertinent information during the study that should be given to the participating subjects. For those subjects who have not been given informed consent because there is a waiver or alteration of the consent process, explain how the subjects will receive this additional important information. If applicable, please explain why a subject would not receive additional pertinent information.
N/A. Individuals who would be eligible to take part in the study will be given the opportunity to agree and sign the informed consent document or to decline participation.

6 If you are requesting an alteration of the consent process please explain why this request is necessary for the conduct of the research study. Please identify specifically what is being altered or changed in the consent process.
N/A

ID: VIEW4E1C73B344800
Name: v2_Waiver/Alteration of Consent Process

Consent and HIPAA Authorization Forms - Draft

1 Upload all of your Consent Forms for approval. Use only Microsoft Word.

Name	Created	Modified Date
VA Unapproved Consent Version02272021.doc(0.01)	3/11/2021 2:50 PM	3/11/2021 2:50 PM

IMPORTANT NOTE: the above list of consent forms (if any) are DRAFT versions. Under no circumstances should copies of these be distributed to patients/study subjects. If/when this research submission is approved by the IRB, approved consent forms will be available for download and use from the "Documents" tab of the Submission's workspace (click Exit and then look for the Documents tab - approved submissions only)

1A Archived Consent Forms:

Name	Created	Modified Date
VA Consent Version 6 3.12.20_clean.doc(0.02)	9/16/2019 3:59 PM	3/12/2020 11:48 AM
VA Consent Version 11.8.18(0.02)	8/23/2018 10:58 AM	11/8/2018 1:12 PM
VA Unappoved Consent Version 4- 11.15.17(0.04)	10/10/2017 11:05 AM	11/15/2017 2:06 PM
VA Unappoved Consent Version 4 tracked changes- 11.2.17.doc(0.03)	10/10/2017 11:05 AM	11/2/2017 1:47 PM
VA Unappoved Consent Version 3- 7.7.17(0.01)	7/7/2017 8:47 AM	7/7/2017 8:47 AM
VA Unappoved Consent Version 3- 7.7.17 tracked changes(0.01)	7/7/2017 8:47 AM	7/7/2017 8:47 AM
va unapproved consent from version 2 track changes(0.01)	2/1/2017 8:26 AM	2/1/2017 8:26 AM
va unapproved consent version 2(0.01)	2/1/2017 8:25 AM	2/1/2017 8:25 AM
VA Unappoved Consent Version 1.doc(0.06)	6/1/2016 1:50 PM	7/27/2016 10:16 AM
VA Unappoved Consent Version 1 Tracked Changes.doc(0.02)	7/19/2016 9:56 AM	7/27/2016 10:12 AM

2 Upload any HIPAA authorization forms here:

Unapproved HIPAA Version 1_Locked.pdf(0.01)	5/31/2016 2:02 PM	5/31/2016 2:02 PM

Please refer to HRPO's website for specific instructions for preparing informed consent documents and to access current templates:
http://hrpo.umaryland.edu/researchers/consents.html

ID: VIEW4E1C7712D3000
Name: v2_Consent Forms - Draft

Organization Review Requirements (other than IRB)

Answer the following questions to determine additional organizational review requirements:

1 **Department/Division Review** - All research submissions are required to undergo department/division/institutional review prior to IRB review. The following entity is listed as the required department/division/institutional review:

Med Gerontology

If this information is incorrect, please notify the HRPO office.

2 **RSC Review Criteria** - select 'Yes' if the answer is 'Yes' for any of the following questions. Review by the Radiation Safety Committee may be required.

* 2.1 Does the research involve the use of ionizing radiation? ● Yes ○ No

2.2 Does the research involve the sampling of radioactive human materials for subsequent use or analysis in a laboratory?

3 **IBC Review Criteria** - select 'Yes' if the answer is 'Yes' for any of the following questions. Review by the Institutional Biosafety Committee may be required.

* 3.1 Does the research involve human gene transfer? ● Yes ○ No
-OR-
Does the research specifically apply to human studies in which induction or enhancement of an immune response to a vector-encoded microbial immunogen is the major goal, and such an immune response has been demonstrated in model systems, and the persistence of the vector-encoded immunogen is not expected? This type of research is often referred to as recombinant vaccine trials.

3.2 Does the research involve the exposure of human subjects to pathogenic microorganisms, or the exposure of research staff to human subjects or samples known or reasonably expected to carry infectious disease(s)?

3.3 Does the research involve the sampling of materials from persons with no known infectious disease and where the only risk to study staff is occupational exposure to bloodborne pathogens as defined by the OSHA Bloodborne Pathogen Standard?

4 **Cancer Center Criteria** - Answer the following to determine if review by the Cancer Center (Hematology-Oncology) may be required.

* Does the protocol involve in any way studies related to the prevention, treatment, diagnosis, or imaging of neoplastic diseases? ○ Yes ● **No**

5 **General Clinical Research Center Review Criteria** - the GCRC offers free and/or cost shared resources for patient-oriented research. Click Here for more information.

Answer the following to determine if review by the GCRC may be required.

* Will the General Clinical Research Center (GCRC) facility or resources be used to conduct this activity? ○ Yes ● **No**

6 **VA Review Criteria** - Answer the following questions to determine if review by the VAMHCS R&D Committee may be required.

* 6.1 - Will the research be conducted by VA Investigators including PIs, Co-PIs, and Site Investigators on VA time (serving on compensated, WOC, or IPA appointments)? ● **Yes** ○ No
* 6.2 - Will the research utilize VA resources (e.g., equipment, funds, medical records, databases, tissues, etc.)? ● **Yes** ○ No
* 6.3 - Will the research be conducted on VA property, including space leased to and used by VA? ● **Yes** ○ No

PLEASE NOTE that the research may be funded by VA, by other sponsors, or may be unfunded.

ID: VIEW4E1AF91AB2400
Name: v2_Organization Review Requirements (other than IRB)

Radiation Safety Committee Review Required

1 **NOTE**: based on your answers to questions on previous page (see below) review by the Radiation Safety Committee (RSC) is required. This will involve extra steps on your (study team) part. Clicking the Continue button will result in the system creating a blank RSC Submission form for you. You will be required to fill out and submit this RSC form before you will be able to submit the Protocol form. The RSC Submission workspace and form can be reached by clicking the appropriate button on the left hand side of the Protocol submission's workspace (web page) after exiting the Protocol form.

2 **Question** - answered on IBC RSC review requirements page:

2.1 Does the research involve the use of ionizing radiation? **Yes**

2.2 Does the research involve the sampling of radioactive human materials for subsequent use in laboratory research?

If the answer to this question is wrong, a RSC submission is not required, use the Jump To menu and return to the Organization Review Requirements page to change your answer.

3 * **Confirm** - you have read the above information and understand that in addition to the IRB Protocol form, you will complete and submit the RSC Submission form :

● Yes ○ No

ID: VIEW4E1AF92170C00
Name: v2_Radiation Safety Committee Review Required

HP-00069566 IBC Review Required_V2

Institutional Biosafety Committee Review Required

1 **NOTE**: based on your answers to questions on a previous page (see below) review by the Institutional Biosafety Committee (IBC) is required. This will involve extra steps on your (study team) part. Clicking the Continue button will result in the system creating a blank IBC Submission form for you. You will be required to fill out and submit this IBC form before you will be able to submit the Protocol form. The IBC Submission workspace and form can be reached by clicking the appropriate button on the left hand side of the Protocol submission's workspace (web page) after exiting the Protocol form.

2 **Question** - answered on IBC RSC review requirements page:

3.1 Does the research involve human gene transfer? - OR - Does the research specifically apply to human studies in which induction or enhancement of an immune response to a vector-encoded microbial immunogen is the major goal, and such an immune response has been demonstrated in model systems, and the persistence of the vector-encoded immunogen is not expected? This type of research is often referred to as recombinant vaccine trials.
3.2 Does the research involve: a) the exposure of human subjects to pathogenic microorganisms, or b) the potential exposure of UMB research staff to infectious materials through the sampling or processing of materials from patients with known infectious disease or from environmental surfaces?
3.3 Does the research involve the sampling of materials from persons with no known infectious disease and where the only risk to study staff is occupational exposure to bloodborne pathogens as defined by the OSHA Bloodborne Pathogen Standard?

Yes

If the answer to this question is wrong, an IBC submission is not required, use the Jump To menu or your browser's <

3 * **Confirm** - you have read the above information and understand that in addition to the IRB Protocol form, you will fill out and submit the IBC Submission form :

● **Yes** ○ No

ID: VIEW4E1AF91ED4C00
Name: v2_Institutional Biosafety Committee Review Required

VA-Specific Criteria

1 * What is the relevance of this research to the mission of VA and the Veteran population that it serves*?
This study is particularly relevant to the older veterans as the prevalence of obesity continues to rise, placing older Veterans at increased risk for disability, morbidity and mortality. Even modest improvements in physical functioning in this older population with dysmobility may significantly impact on their ability to live independently in the community and reduced ADL dependence and potentially decrease institutionalization. This research directly benefits Veterans as it may lead to new and more effective interventions that could reduce disability, reduce fall risk, and reduce injury-related hospitalization and death. This nutritional and multimodal exercise intervention is readily exportable to the community and with minimal resources, could be widely implemented at other VAs as part of clinical care as an enhancement to MOVE!. Thus, the proposed interventions are likely to have real world impact on Veterans and their health.

2 * Describe who will be enrolled in this study:

- ○ Non-veterans will be enrolled in this study
- ● **Only veterans will be enrolled in this study**
- ○ Veterans and Non-veterans will be enrolled in this study

2.1 * If non-veterans will be enrolled in this study, provide a description of non-veterans who will be enrolled (For example: community members, family members/caretakers of Veterans, clinicians/caregivers to Veterans, etc.):
not applicable

2.2 If non-veterans will be enrolled in this study, provide a substantive justification** for the enrollment of non-veterans in this research:

2.3 * If this is a VA-funded study, was the use of non-veterans discussed within your merit award proposal?

- ○ Yes
- ○ No
- ● **N/A**

*
http://www.va.gov/about_va/mission.asp

VA Mission Statement
To fulfill President Lincoln's promise "To care for him who shall have borne the battle, and for his widow, and his orphan" by serving and honoring the men and women who are America's Veterans.

VA Core Values
VA's five core values underscore the obligations inherent in VA's mission: Integrity, Commitment, Advocacy, Respect, and Excellence. The core values define "who we are," our culture, and how we care for Veterans and eligible beneficiaries. Our values are more than just words – they affect outcomes in our daily interactions with Veterans and eligible beneficiaries and with each other. Taking the first letter of each word—Integrity, Commitment, Advocacy, Respect, Excellence—creates a powerful acronym, "I CARE," that reminds each VA employee of the importance of their role in this Department. These core values come together as five promises we make as individuals and as an organization to those we serve.
Integrity: Act with high moral principle. Adhere to the highest professional standards. Maintain the trust and confidence of all with whom I engage.
Commitment: Work diligently to serve Veterans and other beneficiaries. Be driven by an earnest belief in VA's mission. Fulfill my individual responsibilities and organizational responsibilities.
Advocacy: Be truly Veteran-centric by identifying, fully considering, and appropriately advancing the interests of Veterans and other beneficiaries.
Respect: Treat all those I serve and with whom I work with dignity and respect. Show respect to earn it.
Excellence: Strive for the highest quality and continuous improvement. Be thoughtful and decisive in leadership, accountable for my actions, willing to admit mistakes, and rigorous in correcting them.

**
a. Non-Veterans may be entered into a VA-approved research study that involves VA outpatient or VA hospital treatment (38 CFR 17.45, 17.92), but only when there are insufficient Veteran patients suitable for the study. The investigator must justify including non-Veterans and the IRB must review the justification and provide specific approval for recruitment of non-Veterans.
b. Non-Veterans may be recruited for studies that will generally benefit Veterans and their well-being but would not include Veterans as subjects. Examples include surveys of VA providers, studies involving Veterans' family members, or studies including active duty military personnel. Although active duty military personnel are not considered Veterans, they should be included in VA studies whenever appropriate.
---
e. Non-Veterans may not be entered into VA studies simply because a non-Veteran population is easily accessible to the investigator.

[VHA Handbook 1200.05 §24]

ID: VIEW4E1C7A737EB00
Name: v2_Use of Non-Veterans

VA Prohibited Research

1 * Is the research planned emergency research in subjects from whom consent can not be prospectively obtained?
○ Yes ● **No**

2 * Does the study involve children **AND** is greater than minimal risk?
○ Yes ● **No**

3 * Will recruitment phone calls involve asking veterans for their Social Security numbers?
○ Yes ● **No**

ID: VIEW4E1C8AF03A400
Name: v2_VA Prohibited Research

Additional VA

1 * For data that is combined, which site is the "Data Coordinating Center"?
Data is not combined

2 If VA data will be combined with non-VA data, describe when and how this will occur and where the combined data will be stored.
n/a

3 If the VAMHCS is the Local Coordinating Center holding the "combined data", how is the data collected? (This answer may overlap with Research Related Procedures. If so, please refer to that section.)
n/a

4 If the VAMHCS is the Local Coordinating Center holding the "combined data", how is the data received and combined with the data from the other non-VA institution(s)?
n/a

ID: VIEW8D5931EAC5B1E6E
Name: v2_Additional VA

VA Maryland Health Care System Review Required

1

Note: Based on the answers provided in your submission, this protocol qualifies as a VA study and therefore requires VA-specific reviews to ensure that all VA regulatory requirements are met. The VAMHCS Research & Development Committee (RDC) review is included in these VA-specific reviews and RDC approval is required prior to engaging in any research activities. **Importantly, you must submit this protocol to the VAMHCS RDC for review within 60 days of IRB approval.** Please see below for a summary of required VA-specific review steps.

****Before you initiate any of the following VA-specific review steps, please contact Kelly Lloyd (Kelly.Lloyd@va.gov), VAMHCS Research Protections Officer (RPO), to ensure full compliance with VA requirements.**

1. Ensure that you have already created a new project shell in IRBNet and that the title matches the title for this IRB application. Before drafting the IRB submission, the PI **should have completed Package 1 – ACOS New Project Review Form** found in the VAMHCS IRBNet library (log in to IRBNet first and then click on link), gotten it signed by the PI's VA Service Chief, and submitted it to the Research Service as a single document package within this project shell in IRBNet.
2. After you have received ACOS sign-off, you may submit your protocol application in CICERO. The application will be routed to designated reviewers including Kelly Lloyd, VAMHCS RPO. She will conduct a VA Administrative Pre-Review and the results will be communicated to the study team through the CICERO platform and may include suggested edits to the application and consent/HIPAA form(s). The study team will be responsible for implementing these edits in CICERO.
3. While the VA Specialty Review is being conducted in CICERO, complete the Information System Security Officer (ISSO) review form and email to Kelly so she can prepare her request for that additional, required review. You can find the form used for ISSO review in the VAMHCS IRBNet library (log in to IRBNet first and then click on link): **RDC – Information Security Officer Review Form.pdf.**
4. After all suggested edits have been made in the CICERO application and consents/HIPAA by the study team, Kelly will then send for VAMHCS ISSO and Privacy Officer (PO) review and the study team will be copied on these correspondences. (Please Note: Kelly will prepare PO review form).
5. Once you receive approval from ISSO and PO, Kelly will finalize her review and send the CICERO application on to the next UMB HRPO-required reviewing body.
6. You will then create another new package in your IRBNet project shell (i.e., the same project shell you already created for ACOS review) to submit the protocol documents for Subcommittee on Research Safety (SRS) review. You can find all applicable submission forms in the VAMHCS IRBNet library (log in to IRBNet first and then click on link). Please use this form within the library as a submission guide: **IRBNet Admin Review Checklist – Used only as a guide for submitters – Does not have to uploaded.**
7. After your protocol has been approved by the IRB, you'll create a third, new package in your IRBNet project shell (i.e., the same project shell you already created for ACOS review and used to submit documents for SRS review) to submit the protocol documents required for Research and Development Committee (RDC) review. You can find all applicable submission forms in the VAMHCS IRBNet library (log in to IRBNet first and then click on link). Please use this form within the library as a submission guide: **IRBNet Admin Review Checklist – Used only as a guide for submitters – Does not have to uploaded.**
8. Only after you have been approved by RDC, you may initiate study activities.

2 **Questions answered on 'Organizational Review Requirements' page**:

The research will be conducted by VA Investigators including PIs, Co-PIs, and Site Investigators on VA time (serving on compensated, WOC, or IPA appointments):	**Yes**
The research will utilize VA resources (e.g. equipment, funds, medical records, databases, tissues, etc.):	**Yes**
The research will be conducted on VA property, including space leased to and used by VA:	**Yes**

Questions answered on 'VA Prohibited Research' page:

The research is planned emergency research in subjects from whom consent can not be prospectively obtained:	**No**
The study involves fetuses:	**No**
The study involves in vitro fertilization:	**No**
The research involves work with embryonic stem cells:	**No**
The study involves children AND is greater than minimal risk:	**No**
Recruitment phone calls involve asking veterans for their Social Security numbers:	**No**

If the answers to these questions are wrong, use the Jump To menu to return to the 'Organization Review Requirements' page to change your answers.

3 * **Confirm** - You have read the above information and understand that in addition to this IRB application form (CICERO), you are required to send a submission to the VAMHCS R&D Committee **within 60 days of receiving IRB approval**.

● **Yes** ○ No

ID: VIEW4E1C8F0D7B000
Name: v2_VA Review Required

Summary of Required Reviews (other than IRB)

1 **Additional Committee Reviews** - Based on your responses to the previous questions, you have identified the following additional reviews. To complete or view these additional committees' forms, click on the links below or exit this application and click on the appropriate button on left side of this submission's webpage.

Name of Related Submission		
RSC: (RSC-00001163)	Workspace	SmartForm
IBC: Multimodal Exercise and Weight Loss in Older Veterans with Dysmobility (HP-00069566)	Workspace	SmartForm

2 **Required Department and Specialty Reviews** - Based on the PI's organization (department, division, etc.) affiliation and answers to previous questions (use of Cancer Center, etc.), the organizations listed below are required to review this application. These reviews are conducted online and no additional forms or steps by the study team are required.

Name of Organization	Review Status
Med Gerontology	Complete

ID: VIEW4E1C8D9AE4000
Name: v2_Summary of Required Reviews (other than IRB)

Additional Documents

1

Upload all additional documents here:

Name	Created	Modified Date
HP69566 UMB COVID Risk Statement Action.docx(0.01)	3/11/2021 2:49 PM	3/11/2021 2:49 PM
COVID 19 Preparedness and Response Plan 1.20.21 track changes version.docx(0.01)	3/10/2021 11:03 AM	3/10/2021 11:03 AM
track changes consent form 02272021.docx(0.01)	3/10/2021 10:23 AM	3/10/2021 10:23 AM
grecc infection control plan january 2021(0.01)	2/28/2021 10:24 AM	2/28/2021 10:24 AM
letter to subjects 02272021(0.01)	2/28/2021 10:18 AM	2/28/2021 10:18 AM
tracked consent form (0.01)	3/12/2020 11:49 AM	3/12/2020 11:49 AM
katzel real ssn back.pdf(0.01)	10/3/2019 2:59 PM	10/3/2019 2:59 PM
katzel real ssn front.pdf(0.01)	10/3/2019 2:59 PM	10/3/2019 2:59 PM
katzel waiver of HIPAA front (0.01)	10/3/2019 2:58 PM	10/3/2019 2:58 PM
katzel waiver of HIPAA back.pdf(0.01)	10/3/2019 2:58 PM	10/3/2019 2:58 PM
Qtug brochure(0.01)	9/24/2019 10:33 AM	9/24/2019 10:33 AM
Track changes consent form 9.16.19(0.01)	9/16/2019 4:00 PM	9/16/2019 4:00 PM
RISE update contact info letter(0.01)	11/8/2018 1:23 PM	11/8/2018 1:23 PM
Odessa Addison CITI Training(0.02)	9/21/2017 8:31 AM	9/21/2017 8:33 AM
Steven Yoo Citi Training(0.01)	7/7/2017 8:52 AM	7/7/2017 8:52 AM
response to reviewers 07202016(0.01)	7/20/2016 2:41 PM	7/20/2016 2:41 PM
ISOPO Checklist Signed by ISO and PO.pdf(0.01)	6/14/2016 12:53 PM	6/14/2016 12:53 PM
ISO PO Checklist signed.pdf(0.01)	6/1/2016 9:42 AM	6/1/2016 9:42 AM
katzel VA merit grant(0.01)	5/23/2016 10:54 AM	5/23/2016 10:54 AM

ID: VIEW4E0962513A000
Name: v2_Additional Documents

Final Page of Application

You have reached the final page of this application. It is recommended that you click on the "Hide/Show Errors" link on the upper or lower breadcrumb row of this page. The "Hide/Show Errors" will do a search of your application, and highlight areas that are required or need to be completed prior to submitting.

By submitting this application, you are electronically routing the protocol for departmental scientific review and all other necessary reviews. According to information you have provided, this application will be routed to the following Departments for review prior to being forwarded to the IRB for review. These reviews are conducted online and no additional forms or steps by the study team are required.

Name of Organization	**Review Status**
Med Gerontology	Complete

Required Safety Committee Reviews - In addition to the IRB, the following committees must review this submission. Each additional committee has a separate online form that the study team will be required to fill out. All committee applications (IRB plus those listed here) must be completed properly before the 'package' of applications can be submitted. The team may complete these additional forms in any order or at any time prior to submission of the IRB Application. To complete or view these additional committees' forms, click on the links below or exit this application and click on the appropriate button on left side of this submission's Workspace.

Name of Related Submission		
RSC: (RSC-00001163)	Workspace	SmartForm
IBC: Multimodal Exercise and Weight Loss in Older Veterans with Dysmobility (HP-00069566)	Workspace	SmartForm

You may check the progress of your application at any time by returning to the Workspace of this submission. A detailed history, including notes, dates, and times of events, is provided to you for this purpose.

If a reviewer returns the application to you, you must address their concerns and resubmit the protocol for review to all designated departments. After all departments have reviewed the application, it will automatically be sent to the IRB for review. Changes made to the submission after its approval must be submitted as modifications.

Investigator Attestation
By submitting this application, I, the Principal Investigator (PI), certify that the information provided in this application is complete and correct. Research will be conducted according to the submission as described, only by the approved principal investigator and study team members.

In addition, I agree to the responsibilities of a PI, including:

- Obtaining informed consent (if applicable) from all subjects as outlined in the submission.
- Reporting new information to the IRB per the requirements of the Investigator Manual.
- If Required, obtaining renewal of the protocol prior to the expiration of the approval period or halt all study activities upon study expiration.
- Accepting ultimate responsibility for the protection of the rights and welfare of human subjects, conduct of the study and the ethical performance of the project.
- Ensuring performance of all research activities by qualified personnel according to the IRB approved submission.
- Ensuring that research personnel have or will receive appropriate training.
- Ensuring no changes will be made in the research until approved by the IRB (except when necessary to eliminate apparent immediate hazards to subjects).

Click the "Finish" button and then click "Submit Application" in the submission Workspace.

ID: VIEW4E1B10C500000
Name: v2_Final Page of Application

Add a Team Member

1 * Select Team Member:
William Perez

2 Research Role:
Research Team Member

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
○ Yes ● **No**

4 * CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:
○ Yes ● **No**

5 * Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
○ Yes ● **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Will Perez is a masters trained exercise physiologist with experience in human performance

Add a Team Member

1 * Select Team Member:
Steven Prior

2 Research Role:
Sub-Investigator

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
○ Yes ● **No**

4 * CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:
○ Yes ● **No**

5 * Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
○ Yes ● **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Dr. Prior has experience implementing and overseeing exercise rehabilitation research, as well as protocol design and implementation of exercise interventions.

Add a Team Member

1 * Select Team Member:
Brian Phipps

2 Research Role:
Research Team Member

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
○ Yes ● No

4 * CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:
○ Yes ● No

5 * Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
○ Yes ● No

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Brian Phipps is a masters trained exercise physiologist with experience in human performance.

Add a Team Member

1 * Select Team Member:
Elizabeth Dennis

2 Research Role:
Research Team Member

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
○ Yes ● **No**

4 * CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:
○ Yes ● **No**

5 * Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
○ Yes ● **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Dr. Elizabeth Parker is a PhD level registered dietician. She has extensive experience counseling older adults to modify their eating behaviors.

Add a Team Member

1 * Select Team Member:
Odessa Addison

2 Research Role:
Sub-Investigator

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
● **Yes** ○ No

4 * CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:
● **Yes** ○ No

5 * Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
○ Yes ● **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Dr. Odessa Addison has been a Physical Therapist since 2005 and has worked at the VA and UMMC since 2012. During this time, she has worked closely on many research studies for older adults in the GRECC.

Add a Team Member

1 * Select Team Member:
John Sorkin

2 Research Role:
Statistician

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
○ Yes ● **No**

4 * CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:
○ Yes ● **No**

5 * Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
○ Yes ● **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Dr. Sorkin has extensive experience working in the Geriatrics Research Education and Clinical Center as head bio-statistician.

Add a Team Member

1 * Select Team Member:
Brock Beamer

2 Research Role:
Sub-Investigator

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
○ Yes ● **No**

4 * CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:
○ Yes ● **No**

5 * Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
○ Yes ● **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Dr. Beamer is a geriatrician with extensive experience conducting exercise rehabilitation research.

Add a Team Member

1 * Select Team Member:
Steven Yoo

2 Research Role:
Research Team Member

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
○ Yes ● No

4 * CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:
○ Yes ● No

5 * Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
○ Yes ● No

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Steven Yoo is a masters trained Exercise Physiologist who is joining the Study Team. He is a new employee to the VA.

Add a Team Member

1 * Select Team Member:
Lynda Robey

2 Research Role:
Research Team Member

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
● **Yes** ○ No

4 * CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:
● **Yes** ○ No

5 * Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
○ Yes ● **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Lynda Robey has extensive experience administered GRECC exercise rehabilitation protocols and extensive knowledge of IRB rules and regulations.