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

NCT04994938

January 5, 2024

Department of Veterans Affairs

Research Consent Form

Participant Name: _____ Date:_____

Title of Study:_The Development and Implementation of a Peer-Led Diet and Exercise Intervention in Older Urban Dwelling Veterans with Dysmobility

Principal Investigator: __Odessa Addison, DPT, PhD_____ Facility: VA Maryland Health Care System

IRB Study Number: HP-100748
Sponsor: Veterans Health Administration
Title: Participant

INTRODUCTION: You are being asked to participate in a research study that is being done at the VA Maryland Health Care System (VAMHCS) and the South Texas Veteran Health Care System (STVHCS; in San Antonio, Texas). If you agree to participate by signing this consent form, your research activities will all take place at the VAMHCS. Before you decide to take part, it is important for you to know why the research is being done and what it will involve. This includes any potential risks to you, as well as any potential benefits you might receive.

Read the information below closely and discuss it with family and friends if you wish. Ask one of the study staff if there is anything that is not clear or if you would like more details. Take your time to decide. If you do decide to take part in this study, your signature on this consent form will show that you received all of the information below, and that you were able to discuss any questions and concerns you had with a member of the study team.

CONCISE SUMMARY

The majority of older Veterans do not meet the minimum healthy diet or physical activity recommendations. Identifying ways to increase participation in programs that improve dietary quality and physical activity may reduce the risk of disability (movement declines). Interventions led by a peer may be one way to help make lasting behavioral changes. A Peer is someone who is part of the same societal group such as a similar age or shared experience. The purpose of this study is to develop and test a diet and exercise intervention that is led by a peer. We are asking you to participate in this study because you have expressed an interest in improving your diet and exercise habits and are at risk for movement declines in the future. During this study you will be asked to participate in weekly classes lead by a peer that focus on diet and exercise education for 12 weeks. You will also be asked to participate in group exercise classes two times per week for 12 weeks. During this study you will be asked to undergo a number of tests including: body composition testing, tests to determine how well you walk and move, and tests to examine your eating patterns. These tests are conducted before and after the 12 week peer led intervention. There are risks to participating in this study including the risk of falls, muscle soreness, fatigue, or chest pain or injury during the exercise. You may be paid up to $100 for participation, depending upon

how much of the study you complete. If you are interested in learning more about this study, please continue reading below.

RESEARCH DETAILS

PURPOSE OF THE STUDY

The majority of older Veterans do not meet the minimum recommendations for exercise and diet despite known benefits. It is important to identifying ways to increase the ability of individuals to participate in programs that try to improve diet and exercise. Programs led by peers may be one method to improve adherence to these programs. This study will pilot and evaluate a 12-week peer-led diet and exercise intervention that targets older Veterans and assess its feasibility in two separate urban areas, Baltimore, Maryland and San Antonio, Texas. We invite you to participate in this research study under the direction of Odessa Addison, PT, DPT, PhD. This is a collaborative study with the STVHCS. If you decide to participate in this study, you will be one of about 20 patients asked to participate in this study in the VAMHCS, and one of 35 participants in the total study. This collaborative study will combine VA research activities and data from the VAMHCS with research activities and data from the STVHCS.

STUDY PROCEDURES:

You will undergo 4 phases of study participation: 1) Consent and Screening (phase 1); Baseline testing (phase 2); 12-weeks of peer led diet and exercise intervention (phase 3); and post-testing (phase 4). Your participation in this study is expected to last approximately 4 months. All tests and exercise training procedures will be completed at VAMHCS facilities including the Baltimore VA Medical Center, Baltimore VA Annex, and the VA Loch Raven Outpatient Center. In order to participate, you must agree to participate in peer led diet and exercise classes.

Phase 1: Consent and Screening (Total of 1.5-2 hours in one visit)

Informed Consent (approximately 30 min): During the consent, we will review all details of the research program in private. You will be provided with adequate time to have your questions answered, concerns addressed or clarified, and for you to consider whether or not you wish to participate. You will be given a copy of the informed consent. You also will be asked to complete a test to determine your ability to understand and think clearly. If you are eligible, you will complete screening tests.

Screening (approximately 1 hour): After you sign this consent to participate, exams, tests, and/or procedures may be done as described below to find out if you can continue in the study; this is called screening. If you receive your health care at the VA, we will access your medical file to obtain additional information on your medical history and medications. If you receive your care from a non-VA doctor, you might be asked to complete a form asking for permission for your non-VA doctor to send us additional information on your medical history. If abnormalities are detected, we will tell you, and with your permission, results will be forwarded to your private doctor. You may be asked to repeat one or more of the tests if there is an unforeseen problem with data collection. If medical concerns can be addressed to correct the cause of ineligibility, you may contact us for re-screening. These procedures are for research only.Your medical history will be reviewed, and a physical examination will be performed to determine if you are eligible for the study. If you have recently had a physical examination as part of another research study by our group, we might not repeat some of these assessments.

Phase 2: Baseline Research Testing (Total of 4-5 hours over 1-2 weeks)

If you pass the screening and choose to continue with the study, you will complete baseline testing. The order of the tests will depend on your schedule and the availability of appointments. Some of the tests can be performed during the same visit. All of these tests will require a total of 2-3 visits during a 2-3 week period. The testing period may take longer than 2-3 weeks if tests need to be repeated or rescheduled.

Vital signs (15 min): We will measure your vital signs (blood pressure, heart rate), and ask you about your medications. You may eat, drink, and take medications as usual before these measurements.

Physical Performance Tests (1-2 hours): You will have some physical tests of function. These tests will be done by the staff and each test will be explained to you. These include tests of balance, getting up from a chair, walking different distances and measuring your grip strength. In one of these tests you will walk for 6 minutes. We may take your blood pressure before or after any of these tests.

Body Composition (30 minutes): You will lie comfortably on a large machine (DXA) while your body is scanned to measure body fat and muscle mass. The DXA scans are painless, but do involve

exposure to low doses of x-rays. The scan will take less than 30 minutes to complete. In addition, the size of several parts of your body (example: waist and hip) will be measured with a measuring tape. We will also measure your height and weight in order to calculate your body mass index.

Questionnaires (20-30 minutes): You will be asked to complete, in private, forms about your feelings, about your ability to complete different activities during your day ("activities of daily living"), your levels of physical activity, your feelings of function and disability, and some general questions about your mental and physical health (for example, how do you sleep at night?). These questionnaires will take about 20-30 minutes. If you prefer to complete these tests at home, we can provide you a link to complete these tests on your phone or computer on your own time.

Food questionnaires (30 min-1 hour): You will also complete a 24-hour food recall that will be reviewed by the study dietitian and analyzed for nutritional content.

Phase 3: 12-weeks of peer led diet and exercise classes (2 hours per week))
After Phase 2, you will enter the diet and exercise intervention that is led by a Veteran Peer. This phase includes two parts: 1) Exercising twice per week in our facilities and 2) attending one healthy behavior class per week that is led by a peer leader. The exercise sessions will include 45-50 min of group exercise. The healthy behavior classes will be focused on guidance to make behavior change including nutrition basics, portion control, recipe modification, safe exercising, including exercising at home, managing common health concerns, and available community resources.

Phase 4: Post Testing (Total of 4-5 hours over 1-2 weeks)
12-weeks after beginning the intervention you will have all tests that were described in the baseline research testing section (Phase 2) performed again. You will be asked to continue with your group exercise and diet classes during this phase. Additionally, we will ask you about your experience in the program, and your likelihood to continue with what you have learned in the program.

WILL I BE TOLD NEW INFORMATION ABOUT THIS STUDY?

If abnormalities are detected from the history and physical, or the DXA we will tell you, and with your permission, the results will be forwarded to your private doctor. You will also be informed of any new findings that develop during the course of the research that may affect your willingness to continue participation.

Participant Name: _____ Date:_____

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Principal Investigator: __Odessa Addison, DPT, PhD_____ Facility: VA Maryland Health Care System

FUTURE USE OF DATA INCLUDING FOR PARTICIPANT RE-CONTACT

In the future, researchers may need more information about you, or may ask you if you are willing to participate in a new study. Please initial below your preference for being re-contacted. You may change your mind about providing information in the future by informing Dr. Addison at 410-605-7000 ext. 55393. I can___ cannot____ be re-contacted for information.

WHAT ARE MY RESPONSIBILITIES IF I TAKE PART IN THIS RESEARCH?
If you take part in the screening procedures for this research, you will be responsible to come to your screening visits, follow the instructions of the research team, and notify staff in advance if you need to cancel or reschedule appointments.

POTENTIAL RISKS/DISCOMFORTS:
1) Physical Performance Tests: There is a small risk you will fall, experience chest pain, or become short of breath or dizzy during these tests. The person doing the test will stop if you have any symptoms such as chest pain. We have performed more than 1000 functional tests without complications. We have taken care to reduce risks and the exercise technician doing these tests is trained in CPR.

2) Body composition: The radiation dose which you will receive as a result of taking part in this study includes radiation from DXA scans. Using the standard way of describing radiation dose, you will receive 2 mrem to your total body in one year. Please be aware that this radiation exposure is necessary for research purposes only and is not essential for your medical care. The University of Maryland Baltimore (UMB)/ VA Radiation Safety Committee, a group of experts on radiation matters, has reviewed the use of radiation in this research study and has approved this use as being within the UMB/VA Radiation Safety Guidelines for research subjects of 3000 mrem to any tissue in a 13-week period and 5000 mrem in one year. The radiation dose you will receive to your whole body is in the range of 11-22 mrem, which is equivalent to the exposure limit of 5000 mrem per year that is established for radiation workers such as physicians and X-ray technologists who work with radiation and this level of exposure has never been associated with any definite adverse effects.

Please advise your doctor if you have taken part in research studies at UMB or other institutions that involved the use of radiation so that it may be determined that the total radiation dose from all studies is not excessive. Examples of such studies include x-ray studies conducted in radiology departments, cardiac catheterization, and fluoroscopy as well as nuclear medicine studies, e.g. thallium scan of your heart, and scans of your brain.

3) Questionnaires/Food Questionnaires: There is no physical risk to completing our questionnaires. However, you potentially might experience psychological stress filling out these questionnaires.

4) Privacy and Confidentiality: The risk of providing your health information is that a breach of confidentiality may occur. Results from the body composition testing (CT/DEXA) will be available in your electronic medical record stored at the VA. It is possible that VA medical Center Staff may access this record. This risk will be reduced as your health information will only be used by Dr. Addison, her research team, and VA Medical Center Staff. Additionally, Dr. Addison and her research team undergo training on the Health Insurance Portability and Accountability Act (HIPAA) and the Veterans Health Administration Privacy Policy in order to protect your privacy to the best of their abilities within state and federal law. Loss of confidentiality will be minimized by storing data in a secure location such as locked office and locked cabinet. Electronic data will be stored in secure databases. During the group intervention visits for the group diet and exercise 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 your identity or recognize you from other clinics or locations within the VA. Group participants will be reminded to respect the privacy of you and all other participants and to not disclose any information from the group to anyone outside the group. You should also protect your own privacy by only sharing what you feel comfortable sharing. In addition to the risk described in this form, there may be unknown risks/discomforts involved in participating in the study. Study staff will update you in a timely way on any new information that may affect your health, welfare, or decision to stay in this study.

POTENTIAL BENEFITS

You may or may not benefit by taking part in this study. There is no guarantee that you will receive direct benefit from your participation in this study. The benefits of participating in this study may be: You will receive information about your general health, your physical performance, and your diet. These tests will help you to know how your physical performance and diet compares to others.

Your participation in an exercise and diet program may also result in general heart and muscle strength benefits.

ALTERNATIVES TO PARTICIPATION

The following alternative procedures or treatments are available if you choose not to participate in this study: You may choose not to participate in this study without any risk of penalty or loss of benefits to which you are entitled. Your healthcare at the VAMHCS will not be affected. You could pursue an exercise or diet program outside of this program.

COSTS TO PARTICIPANTS

Transportation to VAMHCS facilities is the only cost to you. Parking at the medical center, and all research tests are free to research participants.

You will not be charged for any treatments or procedures that are performed for research purposes in this study. If you usually pay co-payments for VA care and medications, you will still pay these co-payments for VA care and medications that are not part of this study.

PAYMENT/REIMBURSEMENT TO PARTICIPANTS

You will receive the following:

- o $50 after you complete Phase 2 - Baseline testing
- o $ 50 after you complete Phase 4- Post-exercise testing

You will be reimbursed by a voucher cash from the VAMHCS that may be redeemed for cash at the VAMHCS cashier.

MEDICAL TREATMENT AND COMPENSATION FOR INJURY

The VA will provide treatment for research related injury in accordance with applicable federal regulations (38 CFR 17.85). Every reasonable safety measure will be used to protect your wellbeing. If you are injured as a result of taking part in this study, the VAMHCS will provide necessary medical treatment at no cost to you unless the injury was due to your not following the study procedures. This care may be limited by local or federal law.

If you should have a medical concern or get hurt or sick as a result of taking part in this study, call: Dr. Brock Beamer at 410-605-7000 ext. 54870 during the day, or 301-996-1065 after hours.

The VA does not normally provide any other form of compensation for injury. However, by signing this form, you have not waived any legal rights or released the VAMHCS or its agents from liability for negligence.

CONFIDENTIALITY AND ACCESS TO RECORDS

This study will involve confidential information. We have several procedures in place to help protect your confidentiality. Your name will not be included on the collected data. Instead, a code number will be placed on the data, and through an identification key, the researchers will be able to link your survey to your identity. Only the researchers will have access to the identification key. The information we collect from you will be stored at the VAMHCS and the STVHCS . Electronic data for this study will remain securely behind the VA firewall and will only be accessible through secure VA computer accounts. The networks and computer files are only accessible by authorized study team members. All paper records will be securely stored in locked file cabinets behind locked doors at the VAMHCS

Efforts will be made to limit your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB, the VAMHCS Office of Research Compliance and other representatives of this organization. Study records can be reviewed by federal agencies, can be reviewed by federal agencies, VA Office of Research & Development (ORD) (if VA-funded, VA Office of Research Oversight (ORO), VA Office of Inspector General (OIG), and the Office of Human Research Protections (OHRP). The monitors, auditors, the IRB, the Food and Drug Administration will be granted direct access to your medical records for verification of the research procedures and date. By signing this document, you are authorizing this access.

Your research records and/or identifiers will be retained in accordance with the VA records control schedule. The “records control schedule” is a set of rules set by the federal government that states when federal agencies are allowed to dispose of records. The VA and VHA must follow these rules.

The data from the study may be published. However, you will not be identified by name. People designated from the institutions where the study is being conducted and people from the sponsor will be allowed to inspect sections of your medical and research records related to the study. Everyone using study information at the VAMHCS will work to keep your personal information

confidential. Your personal information will not be given out unless required by law or authorized by you in the VAMHCS "HIPAA Authorization to Obtain, Use and Disclose Protected Health Information for Research". However, if your information is disclosed to other entities, the VAMHCS no longer has control of that information. Please see the HIPAA Authorization for this study for further details.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

If you are a patient in the VAMHCS, the results of your medical tests for this study may be included in your medical record. Your medical and research records will be kept strictly confidential to the fullest extent permitted by law.

Health Information Portability and Accountability Act (HIPAA)

There are rules to protect your private health information. Federal and state laws and the federal medical law, known as the HIPAA Privacy Rule, also protect your privacy. By signing this form, you provide your permission called your 'authorization,' for the use and disclosure of information protected by the HIPAA Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information from your medical records such as medical history, allergies, lab results, research tests and diet and exercise records.

The research team may also need to disclose your health information and the information it collects to others as part of the study progress. Others may include the Institutional Review Board, Food and Drug Administration, Office (FDA), Office of Human Research Protections (OHRP), the VA Office of Research Oversight (ORO), and the Government Accountability Office (GAO).

Your health information disclosed pursuant to this authorization may no longer be protected by Federal laws or regulations and may be subject to re-disclosure by the recipient.

You can revoke this authorization, in writing, at any time. To revoke your authorization, you must write to the Release of Information Office at this facility or you can ask a member of the research team to give you a form to revoke the authorization. Your request will be valid when the Release of Information Office receives it. If you revoke this authorization, you will not be able to continue to participate in the study. This will not affect your rights as a VHA patient to treatment or benefit outside of the study.

If you revoke this authorization, Dr. Addison and her research team can continue to use information about you that was collected before receipt of the revocation. The research team will not collect information about you after you revoke the authorization.

Treatment, payment or enrollment/eligibility for benefits cannot be conditioned on you signing this authorization. This authorization will expire at the end of the research study unless revoked prior to that time.

WILL MY INFORMATION BE USED FOR RESEARCH IN THE FUTURE?

Information collected from you for this research may be used for future research studies or shared with other researchers for future research. If this happens, information which could identify you will be removed before any information are shared. Since identifying information will be removed, we cannot ask for your additional consent.

RIGHT TO WITHDRAW

Your participation in this study is voluntary. You do not have to take part in this research. You are free to withdraw your consent at any time. Refusal to take part or to stop taking part in the study will involve no penalty or loss of benefits to which you are otherwise entitled. Your participation will not affect the way you now pay for medical care at the VAMHCS.

If you decide to stop taking part, if you have questions, concerns, or complaints, or if you need to report a medical injury related to the research, please contact the investigator Odessa Addison, PT, DPT, PhD at 410-605-7000 extension 55393.

There are no adverse consequences (physical, social, economic, legal, or psychological) if you decide to withdraw from this research study.

If you withdraw from this study, already collected data may not be removed from the study database. You will be asked whether the investigator can collect data from your routine medical care. If you agree, this data will be handled the same as research data. You will be told of any significant new findings which develop during the study which may affect your willingness to participate in the study.

CAN I BE REMOVED FROM THE RESEARCH?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include missing study appointments, failure to follow instructions of the research staff, if the person in charge decides that the research study is no longer in your best interest. The sponsor can also end the research study early. The study doctor will tell you about this and you will have the chance to ask questions if this were to happen.

The VA Maryland Health Care System (VAMHCS) has designated the University of Maryland Baltimore (UMB) Institutional Review Board (IRB) to review this research study.

If you wish to confirm that this study is in fact IRB approved and is being conducted at the VAMHCS, or if you have any questions, concerns, complaints, you may contact:

University of Maryland Baltimore
Human Research Protections Office
620 W. Lexington Street, Second Floor
Baltimore, MD 21201
410-706-5037

You may also contact the VAMHCS Research Protections Officer (RPO)**.**

VAMHCS Research Protections Officer
Baltimore VA Medical Center
10 North Greene Street, Mail Stop 151
Baltimore, MD 21201
443-421-5602

The VAMHCS Research Protections Officer may contact you in the future to ask you about your experiences with this research study.

Department of Veterans Affairs

Research Consent Form

Participant Name: _____ Date:_____

Title of Study:_The Development and Implementation of a Peer-Led Diet and Exercise Intervention in Older Urban Dwelling Veterans with Dysmobility

Principal Investigator: __Odessa Addison, DPT, PhD_____ Facility: VA Maryland Health Care System

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

Your signature indicates that the research team member obtaining consent has explained the research study to you. You have been told of the risks or discomforts and possible benefits of the study. You have been told of other choices of treatment available to you. You have been given the chance to ask questions and obtain answers.

Furthermore, by signing this document below, you voluntarily consent to participate in this study and authorize the use and disclosure of your health information for this study. You also confirm that you have read this consent, or it has been read to you. You will receive a copy of this consent after you sign it.

I agree to participate in this research study as has been explained in this document.		
_____ Participant's Name (Print)	_____ Participant's Signature	_____ Date

_____ Person Obtaining Consent (Print)	_____ Consenter's Signature	_____ Date