E1574-P

Improving Balance and Mobility

NCT02374463

Informed consent document

Document date June 12, 2019

Department of Veterans Affairs

Research Consent Form

Participant Name: _____ Date:_____

Title of Study: Improving Mobility and Function in Older Veterans

Principal Investigator: Leslie Katzel MD, PhD, 410-605-7248

VA Facility: Baltimore 512

STUDY No: HP-00060757

SPONSOR: Veterans Health Administration

This is a research study. Your participation is voluntary. You will be given plenty of time to review this consent form. You may ask questions at any time during the review of the consent form and at any time during the study, if you agree to participate. You will be provided with a copy of this consent form.

PURPOSE OF STUDY

Older adults are more likely to fall than young adults. Balance training has been shown to reduce the risk of falls. Tai Chi is recommended by the Center for Disease Control (CDC) to prevent falls in older adults. However, Tai Chi may not sufficiently improve walking balance. We have developed a balance program (MMBI) that may be more effective than Tai Chi at reducing fall risk. The purpose of this study is to see if our MMBI is more effective at reducing the risk of falls as compared to Tai Chi. We are asking you to participate in this study because you have either fallen in the past year or you feel as though you are at risk of falling. We will recruit 90 subjects, all in the Baltimore/Washington area.

STUDY OVERVIEW

This study is being conducted by the VA Maryland Health Care System (VAMHCS). At the start of the study, there will be several visits to determine your eligibility and a baseline assessment of your function and balance. All study testing visits will take place at either the Baltimore VA Medical Center or Baltimore VA Annex. You will then participate in our MMBI balance classes. After the study is complete you will be compared to other individuals who previously participated in tai chi classes. You are expected to come in 3 times a week to exercise in one of our two gyms which are located in the Baltimore VAMC Annex or Loch Raven Community-Based Outpatient Clinic. After three and six months of exercise training, we will retest your function and balance.

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PROCEDURES

The first 2 visits will be performed to determine whether you are eligible for the study.

Baseline Screening (approximately 2.5 to 3 hours):

Consent (Approximately 30 minutes): During the visit for the consent process, we will review all the details of the research program in a private setting. 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. A copy of the informed consent form will be given to you.

Baseline Screening (Approximately 90 minutes): We will review your medical history and a physical examination will be performed. Your blood will also be tested for evidence of disease. We will examine risk factors for heart disease including sugar (glucose) levels, and cholesterol levels. We will need to draw about 6 teaspoons of blood.

Additional Optional Blood Draw: At this time, you have the choice to have additional blood drawn. This blood work would be stored and used for future research. This blood will be tested to see if certain blood markers are in your blood at this time. We will take an additional 6 teaspoons of blood. If you agree, this will also be drawn at 6 and 12 months. This would mean that a total of ~20 teaspoons over the course of 12 months would be drawn.

_____ Yes, I agree to this additional blood draw to be stored for future data analysis.

_____ No, I would prefer that my blood not be drawn for future data analysis.

Subject Initials _____ Date_____

An EKG will be performed and we will measure your height and weight. You will also be asked to complete questionnaires that measure your mental ability. If you have recently had a physical examination as part of another research study by our group, to decrease the amount of tests that you have, we might not repeat some of these assessments. One test (Four Square Step Test) requires that you step into several boxes to measure your balance and coordination.

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 by a physician in the community, you might be asked to fill a form asking for permission for that doctor to send us additional information on your medical history. People with major health problems such as

recent heart attack, poorly controlled high blood pressure, dementia, or other major medical conditions that would interfere with the ability to exercise will be excluded from the study. 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 research tests should it be necessary due to a technical error in its performance and/or measurement, an inadequate sample is obtained for analysis, or there was an unforeseen problem with data collection.

Exercise Stress Test (approximately 1 hour):

Exercise stress test: You will perform an exercise test to help tell how likely you are to have heart disease. Electrodes will be placed on your chest to obtain an electrocardiogram (ECG or EKG). You will walk on a treadmill that will go faster and tilt more uphill every 3 minutes. During the test you will have your blood pressure, heart rate and ECG watched by a doctor and exercise physiologist trained in exercise testing. The test will be stopped if you become tired, dizzy, your ECG or blood pressure becomes abnormal or you have chest pains or other pain. If the results suggest you may have a medical problem then you will be advised to have an independent evaluation by your doctor. If your test is abnormal, you may not be able to continue participation in this research study. Including all the preparations, this test usually takes about 1 hour of your time. Depending upon your personal schedule, this stress test might be performed at visit 1.

The next 2 visits will provide the "before" measurements to be compared with the "after" measurements done after the training exercise. The order of these visits and tests may vary.

Testing (approximately 4 hours each):

The order of these visits and tests might vary depending upon your schedule and the availability of testing times in the Department of Radiology at the Baltimore VA Medical Center and the VAMHCS Human Performance Laboratory. All of these tests will also be repeated after 6 months of exercise and some of them will be repeated at 3 months as well as at the very end of the study, one year after the baseline tests

Body composition, ultrasound, functional assessment, and questionnaires visit (approximately 3.5- 4 hours):

Body Composition: We will use two x-ray tests to measure the amount of your muscle and fat:

1. Computerized tomography scan: You will have CT scans of the abdomen and thigh. CT scans are painless, but do involve exposure to low doses of x-rays. You will lie on a large machine and your lower body will pass through a large ring. Your head will not be enclosed. The CT scan takes about 20 minutes to complete. The CT scans are done so we can measure the muscle, fat and bone tissues in your legs and belly. You will have the CT scan two times, during the baseline visits and again after 6 months of exercise.
2. DXA Scan: You will lie comfortably on a large machine (DXA) while your body is scanned to determine total body fat and muscle mass. In addition, the DXA will measure bone density (how solid your bones are). This is a painless test but involves exposure to low-level radiation. This will take about 30 minutes to complete. You will have the DXA scan two times, during the baseline visits and again after 6 months of exercise.

Ultrasound: We will measure the size of your muscles with an ultrasound machine which can take pictures of your muscles. To do this, you will be asked to lie on a cushioned table and gel will be placed on the skin of your hips and thighs. You will be covered to protect modesty, so that only the skin over the muscle being studied at that moment will be exposed. An ultrasound probe will be moved over your hips and thighs to take pictures of the muscles. This test will be completed during the baseline visit and again after 6-months of exercise.

Functional Assessments: We will measure how good your balance is during a four square step test, modified physical performance test (MPPT), and a portion of the Mini-Best Test. Your endurance will be tested while you walk on an indoor course to see how far you can go in 6 minutes. You will also perform test to see how well you walk over ground, up steps, and keep your balance. This likely will make you tired. These tests will be completed during the baseline visits, 3 months, after 6 months of exercise and again at the end of the study after 6 months of home exercise. These tests will take about 60 to 70 minutes to complete.

Questionnaires: You will be asked to complete questionnaires about your balance, quality of life, level of fatigue, how well you take instructions and daily activities. Questionnaires will take approximately 30-45 minutes to complete.

Gait Assessment and Strength Testing (approximately 2 hours):

Gait Assessment: This test will be performed at the VAMHCS Human Performance lab at the Baltimore VA Annex. For this test, you will walk across a plastic mat that is attached to a computer to measure how and when your feet land. This testing will take approximately 30 minutes.

Strength Assessment: We will also measure your leg and hip strength using either a Biodex Dynamometer or Keiser equipment. We will measure the amount of weight you are able to move one time with your legs while from both standing and seated positions. You will be asked to perform movements several times per joint and leg. This testing will take approximately 60 to 90 minutes.

For 6 months, you will have 3 visits per week for exercise training (MMBI classes) at the Baltimore VA Annex SERC or Loch Raven Rehabilitation Gym.

Exercise Intervention

MMBI classes: After baseline measurements, for the next 6 months, you will participate in the MMBI group class. You will be asked to attend exercise classes, 3 times per week for an hour. A skilled instructor will lead each class with 1-2 assistants present to assist will fall risk prevention. The classes will consist of a group balance class (30 minutes), a supervised obstacle course (10 minutes), and lower body and core body strength training (20 minutes). You will start exercise at a very low level. Over the 6 months of the class, the exercises will gradually increase in difficulty to challenge your balance.

We will perform an abbreviated testing after you have completed three months of training. This will be done in conjunction with your exercise days. This brief testing will include balance and walking measurements. (FSST, FGA, Mini-best, and MPPT)

The next 2 visits will provide the "after" measurements to be compared with the "before" measurements done before exercise started. The order of these tests and visits may vary.

After-Exercise Testing (approximately 4 hours each)

After 3 months of exercise training we will repeat measures of function, walking, and questionnaires. After you complete the 6 months of exercise training, we will repeat the assessments of strength, function, walking, body composition, ultrasound and questionnaires

repeating all baseline measurements. This will require 2 more visits the order of the tests and visits may vary. You will continue exercise training until after-exercise testing is completed.

Following the after-exercise testing, you will be encouraged to continue exercising at home without coming in for any visits for 6 months.

Home Exercises: Near the end of the gym exercise program, you will get instructions for a home exercise program. We want you to continue exercising at home at least 3 times per week. Once a month for the next 6 months, we will call you to see how you are doing with your exercise at home and see if you have had any fall or changes to your health.

The last visit will provide the final measurements to be compared with the measurements done before and after the exercises in the gym.

Final Testing (approximately 2 hours)

After you complete the 6 months of home exercise, we will repeat some of the assessments performed at the baseline testing visits. This includes the fall assessments, walking tests, and functional testing. We will not repeat the strength testing, ultrasound, CT or DXA. This will take one visit of approximately 2 hours to complete.

Your Privacy: All of the people who do research with the test results have special training to keep your information private. All of your test results will be stored with only a secret code number. All of this work will be supervised carefully. There will be no way for most of the researchers to find out who you are. Dr. Katzel will lock away papers that can break the code and find out who you are. This information would be used only in order to re-contact you in the future. We may want to contact you after this study is over in order to ask additional questions, or perhaps to ask you again to volunteer for another research project.

Registry: In the future, researchers may need more information about you, or may ask you if you are willing to participate in a new research study. As we informed you during the telephone screening for this project, the information we obtained from you was entered into a secure, password protected computerized registry. Information in the registry will be used to screen subjects for entry into this research project, and also as a source from which UMB and VA researchers working with us can contact subjects for future recruitment into new IRB approved studies. Please check the box below as to whether or not you agree to have your phone screen information stored in the registry and will allow us to contact you for participation in future

research studies. Even if you agree to be re-contacted now, you may still change your mind about providing this information in the future.

_____ Yes, my information may be stored in the registry and I may be re-contacted for information

_____ No, my information may not be stored in the registry and I may not be re-contacted for information

Subject Initials _____ Date_____

POTENTIAL RISKS/DISCOMFORTS:

Screening Visit: There is no added risk beyond that experienced during a routine medical evaluation.

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

Functional and Gait Assessments: These tests involve a variety of timed walks, getting up from a chair, and tests of balance. There is a small risk that you will fall, get chest pain, get short of breath or become dizzy during these tests. The exercise technician will stop the test if you have any significant symptoms such as chest pain. We take precautions to keep this risk low by excluding patients with unstable medical conditions.

Tests of physical performance will be performed at the Baltimore VA Medical Center and at the BVAMC Annex. The testing location will be dependent upon the particular test, the subject's schedule and the schedule of the research staff. To further minimize risk to subjects an exercise technician who is trained in cardiopulmonary resuscitation (CPR) will be administering these tests. A crash cart and emergency medications are available in the area where these tests are performed at the Baltimore VAMC. For tests performed at the BVAMC Annex, a clinical provider is on call and can be reached by phone for consult in case of any problems. If there is a medical emergency at the annex, an AED (defibrillator) is available on site and the 911 emergency medical system would be activated by the research team. If 911 is activated you would be taken to the nearest available hospital for care. We believe that it is highly unlikely that you 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 never had a subject who needed emergency treatment during tests of physical performance.

Strength Testing or Training: Due to the nature of the training required to improve balance, there is a risk of stumbling or falling during the balance training portion of the exercise session. To minimize fall risk, trained exercise physiologists and medical personnel are stationed appropriately to assist you during the balance training. During the strength training, there is a risk of tenderness or swelling around the joints or muscles. You may also experience some muscle soreness. The risk of more serious injury such as a sprain is small. This is minimized by having trained exercise specialists to teach you the proper way to do the exercise, and also to watch over you while you exercise. The exercise technician will stop you if you have any significant symptoms such as chest pain, dizziness, arm or leg pain.

Exercise training and strength testing sessions will take place at the Baltimore VAMC Annex or Loch Raven Rehabilitation Gym. They will be supervised by exercise physiologists who are certified in exercise training and CPR. 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. If 911 is activated you would be taken to the nearest available hospital for care. We believe that it is highly unlikely that you 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.

Exercise Treadmill Test: The risks for exercise testing are small. Sometimes people faint or get dizzy. The exercise can make their muscles sore. Some people have irregular heartbeats or chest pain. A heart attack can happen during this test rarely. In people who did not have heart disease before, less than 1 in 10,000 would die during this test. Your blood pressure, heart rate and rhythm, and breathing are continuously monitored by a licensed clinician. Other personnel trained in CPR, exercise testing and emergency treatment will be helping. Emergency medicines and equipment will be present.

Body Composition Testing: The radiation dose which you will receive as a result of taking part in this study includes radiation from the DXA machine and the CT scan. Using the standard way of describing radiation dose, you will receive 252.0 mrem to your total body, 482.0 mrem to your bladder, 402.0 mrem to your ovaries/testes, and 322.0 mrem to your spleen in one year. During your participation in this study other organs and tissues may receive lesser radiation doses. 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 (UMB) and 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 3,000 mrem to any tissue in a 13-week period and 5,000 mrem in one year. The radiation dose you will receive to your bladder and ovaries/testes is in the range of 300-5000 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. The radiation dose to your total body, bone and all other organs and tissues is in the range of 0-300 mrem, which is equivalent to the level of natural background radiation that you would be exposed to each year living in the area of the country. Background radiation levels will vary from place to place, but this level of exposure has never been associated with any definite adverse effects. Thus, the risk to you, if any, is estimated to be small. Please be aware that this radiation exposure is necessary for this research study only and is not essential for your medical care. 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. Should any study-related problems occur, medical treatment will be provided.

Ultrasound Testing: Ultrasound imaging is a non-invasive technique that is commonly used and has no anticipated risks. The ultrasound gel used in this study is water soluble and is not likely to cause any adverse reactions.

Confidentiality of data: Protected healthcare information will be obtained during the course of this study. The collection of data will be HIPAA compliant. Despite the extensive protection in place, there is the remote possibility that the confidentiality of the data will be breached. Loss of confidentiality will be minimized by storing data in a secure location such as a locked office and locked cabinet and/or electronic data will be password-protected."

Privacy: Subjects will be examined in individual examination rooms. There is the remote possibility that the privacy of the subjects will be encroached upon.

There may also be risks in this study which are not yet known.

POTENTIAL BENEFITS

There are some aspects of this study that could be of potential benefit to you:

(1) A detailed assessment of risks for falling down will be shared with you and with your permission, your personal doctor;

(2) The balance training you will perform has helped other people improve their balance. We cannot be certain that it will benefit you also;

(3) You may get stronger. Many people who get stronger with exercise feel they have more energy and less pain from arthritis.

There are also potential benefits to society from your participation in this research. For example, someday fewer people may fall and break their hip.

You may or may not benefit from participating in this study.

There is no guarantee that you will receive direct benefit from your participation in this study.

ALTERNATIVES TO PARTICIPATION

This is not a treatment study. Your alternative is to not take part. If you choose not to take part, your healthcare at the VA Maryland Health Care System (VAMHCS) or the University of Maryland, Baltimore will not be affected.

COSTS TO 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.

The only cost to you will be transportation to the facility.

Parking is free.

CONFIDENTIALITY AND ACCESS TO RECORDS

Participant Name: _____ Date:_____

Title of Study: Improving Mobility and Function in Older Veterans

Principal Investigator: Leslie Katzel MD, PhD, 410-605-7248

VA Facility: Baltimore 512

Your research records will be kept strictly confidential to the fullest extent permitted by law. Your name will not be used in any reports or publications. Research records will not be released to your private physician without your prior consent. Dr. Katzel and the research team take 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. Everyone using study information will work to keep your personal information confidential. You have the right to expect that all communications and records about your care and participation in this research study will be treated as confidential by VA Maryland Health Care System. Monitors from the University of Maryland IRB and the VA Office of Research Compliance may need to see your research records to help ensure that the rights and welfare of the research participants are protected and that the study is carried out in an ethical manner.

The Veterans Health Administration (VHA) and its Offices may inspect your research records. Your research records will be stored at the VA Maryland Health Care System (VAMHCS) and the University of Maryland, Baltimore.

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.

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

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.

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WHAT ARE MY RESPONSIBILITIES IF I TAKE PART IN THIS RESEARCH?

If you take part in this research, you will be responsible to come for your study visits.

MEDICAL TREATMENT AND COMPENSATION FOR INJURY

Every reasonable safety measure will be used to protect your well-being. If you are injured as a result of taking part in this study, the VA Maryland Health Care System (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:

DURING THE DAY:
Dr. Katzel at 410-605-7248 and

AFTER HOURS:
Dr. Katzel at 410-908-2698.

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.

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 anytime. 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, Leslie Katzel, at 410-605-7248.

There are no adverse consequences (physical, social, economic, legal, or psychological) of a your decision to withdraw from the research, A written withdrawal is requested. It should be sent to the principal investigator, Leslie Katzel at the following address: 10 N. Greene St

(BT/18/GR), Baltimore, MD 21201. If you withdraw from this study, already collected data may not be removed from the study database.

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 not following study-related direction from the Investigator, a treatment becomes available for you which may be better for you than the care available in this study, or you have a serious reaction during the study. Also, the entire study may be stopped by the sponsor, the Investigator, the Institutional Review Board, the VAMHCS, or the University. The sponsor may also decide to stop the Investigator's participation in the study. In that case, your participation will end unless another investigator is identified and approved by the sponsor and the Institutional Review Board.

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, you may contact Leslie Katzel at 410-605-7248.

The University of Maryland Baltimore (UMB) is committed to providing participants in its research the rights due them under State and federal law. You give up none of your legal rights by signing this consent form or by participating in the research project. This research has been reviewed and approved by the Institutional Review Board (IRB). Please call the Institutional Review Board (IRB) if you have questions about your rights as a research subject.

By signing this Consent Form, you are not giving up any legal rights. If this research project is conducted in a negligent manner and you are injured as a direct result, you may be able to

recover the costs of care and other damages from the individuals or organizations responsible for your injury.

If you have questions, concerns, complaints, or believe you have been harmed through participation in this research study as a result of researcher negligence, you can contact members of the IRB or the UMB Human Research Protections Office (HRPO) to ask questions, discuss problems or concerns, obtain information, or offer input about your rights as a research participant. The contact information for the IRB and the HRPO is:

University of Maryland School of Medicine
Human Research Protections Office
620 W. Lexington Street, 2nd floor
Baltimore, MD 21201
410-706-5037

You may also contact the VAMHCS Human and Animal Research Protections Officer (HARPO). The contact information for the HARPO is:

VAMHCS Human and Animal Research Protections Officer
Baltimore VA Medical Center
10 North Greene Street, Mail Stop 151
Baltimore, MD 21201
410-605-7000, extension 56512
Room 3D-150

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

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Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

If you agree to participate in this study, please sign your name below.

_____
Participant's Signature

Date:_____

Participant Name: _____ Date:_____

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_____

Investigator or Designee Obtaining Consent Signature

Date:_____