Metabolic Syndrome and Fall Risk
NCT02633891
3/7/2016

Department of Veterans Affairs

Research Consent Form

Participant Name: _____ Date:_____

Title of Study:_____Metabolic Syndrome and Fall Risk _____

Principal Investigator: _Lindsay Zilliox, MD 410-328-3100__ VA Facility: _Baltimore_512_

STUDY No: 00067539

SPONSOR: Veterans Affairs

- This is a research study, participation is voluntary, and you can ask questions at any time.
- This study will occur partially at the VA Maryland Health Care System (VAMHCS). It will also be conducted by VAMHCS researchers, and is being paid for by the VA.

PURPOSE OF STUDY

- The purpose of this project is to see if an exercise program can reduce fall risk in people with the metabolic syndrome (MetS) and autonomic neuropathy. The MetS is a set of risk factors for heart disease and diabetes that includes fat in the stomach area, high blood pressure, high cholesterol, and high blood sugar. The autonomic nervous system helps to control heart rate and blood pressure. Neuropathy is any disease of the peripheral nerves.
- You qualify for the study if you have the metabolic syndrome, signs or symptoms of autonomic neuropathy and are at risk of falling.
- There will be a total of 55 people in this study.
- This is a "collaborative" study that will combine VA research activities and VA data with University of Maryland research activities and University of Maryland data.

PROCEDURES

- The group that you will be in will be chosen by chance, like drawing a number. Neither you nor the study doctor will choose which group you are in. You will have an equal chance of being in each group. The study doctor will not know which group you are in.
- There are 2 groups. One group will meet one a week and be taught exercises to perform at home three times a week. The other group will meet once a week for a health education class but will not be taught any specific exercises.
- Before starting the study there is one visit for testing to make sure that you are right for this study. This visit will last about half a day. If you enroll in the study you will be asked to come in once a week, for about an hour, for 12 weeks (about 3 months) for a group class. There will then be a visit after 12 weeks to repeat testing that was done at the start of the study. The groups will then be switched and you will continue to come in for one a week for another 12 weeks and have final testing done at 24 weeks.
- You will be in the study for 24 weeks (about 6 months).

- A small amount of blood (less than 5 teaspoons) will be drawn at the start of the study and at the 12 and 24 week visits. For the whole study less than 15 teaspoons of blood total will be taken.
- Measurements to see if you have the metabolic syndrome (usual care, testing will take about 2-3 hours):
    - A medical history will be taken and an examination will be performed. You will have your vital signs taken which may include height and weight, you waist measured, and your feet and legs examined. You will also complete several questionnaires to assess your neuropathy, mobility and quality of life.
    - Blood pressure – this will be measured twice
    - Blood tests – you will be asked to not eat or drink anything other than water for at least 8 hours before coming in. Blood will be drawn to test your blood sugar and cholesterol levels. You will then be given a sugary drink and your blood sugar levels will be tested again with a finger prick after two hours. This test may not be performed if you have diabetes. Your blood will also be tested for cholesterol levels. Several other lab tests may be requested by the study team to determine the cause of neuropathy.
- Measurements to see if you have autonomic neuropathy (usual care, testing will take about 1-2 hours):
    - Cardiac autonomic neuropathy: You will be asked to stop caffeine and any medications that are known to affect autonomic function for at least one day prior to testing. Your heart rate will be recorded while you breathe in and out slowly for several minutes and breathe out forcefully for about 15 seconds.
    - Quantitative Sudomotor Axon Reflex Test (QSART): A small cup is placed on the skin at 4 places; forearm, upper leg, lower leg, and foot. The cup fills with a weak solution of a chemical (acetylcholine) that makes the skin sweat. The machine measures how much sweat is made by the skin under the cup. The acetylcholine may make your skin tingle, but does not hurt.

  - Tilt table testing: you will be asked to lie on a bed that will be tilted up. Your heart rate and blood pressure will be monitored for about 10 minutes. If you cannot tolerate the test, it may be stopped early or not performed.

- Measurements of fall risk (done for research purposes, testing will take about 2 hours):
  - Four Square Step Test – a cross is formed on the floor by two canes resting flat on the floor. You will stand in one of the squares formed by the canes facing forward. You will then be told to step into each square, one at a time, in a pattern. This will be done twice
  - You will be asked to walk normally and then to walk with changing speeds, walk while turning your head, walk while stepping over and around an object, change directions while walking, and climb stairs.
  - You will walk on a special treadmill that is controlled by a computer to copy a bump, slip, or stumble by changing speeds. You will wear a support vest over your clothes for safety.
- Groups:
  - 1) Balance exercise group: You will be taught how to do a set of 12 exercises for balance. You will meet with a trainer once a week and do the exercises at home three days a week. The exercises will take no more than 30 minutes to complete.
  - 2) Standard care group: You will meet in person once a week for a health education class but will not participate in an exercise program. You will be asked to keep a log of any exercise that you may do at home.
  - Both groups will get information about preventing falls and will be meet once a week with study staff. Both groups will keep a log of home activities and will be contacted by phone if they do not attend a weekly group session.
  - After finishing the first 12 week program you will be asked to switch groups and continue in the study for an additional 12 weeks.

  - Those in the balance exercise group for the first 12 weeks will not be taught any more exercises but will be asked to come in for additional testing (measurement of fall risk) at weeks 16 and 20.

- The treatment you get will be chosen by chance, like drawing a number. Neither you nor the study doctor will choose what treatment you get. You will have an equal chance of being given each treatment. The study doctor will know which treatment you are getting.
- To make sure that pregnant participants are not enrolled in the study you will be asked if you are able to become pregnant and if so you will be asked to take a urine pregnancy test before enrolling in the study and use birth control during the study.
- The chart below indicates where each study procedure will take place:

Study Activities Chart		
Activity	**VAMHCS**	**UMMS**
Exam and blood tests	X	X
Autonomic testing		X
Measurements for fall risk	X	X
Group sessions	X	

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

- If you take part in this research, you will be responsible to attend the weekly classes and/or training sessions and keep a log of your balance exercise program at home. If you cannot attend a weekly group session you will be contacted by phone. You will be asked to attend at least 75% of the weekly group sessions.

POTENTIAL RISKS/DISCOMFORTS:

- The risks of simple blood drawing commonly include discomfort and/or bruise at the site of the puncture. Less commonly there may be a small blood clot or swelling of the area or bleeding from the puncture site. Rarely, fainting or local infection may occur. A trained person will be drawing your blood.
- With the oral glucose tolerance test there is a small risk of developing low blood sugar when you drink the sugary drink for the test. If this happens you may get a headache or feel sick to your stomach or get sweaty, dizzy, weak, or get a fast heartbeat. This is

easily fixed by giving a drink containing sugar to raise the blood sugar. There is also a risk of high blood sugar that may also cause discomfort. Subjects are watched by nursing staff for symptoms during this procedure and before leaving. A meal is fed to all subjects before they leave.

- You may become tired from answering a large number of questions about you health and activities. If you have trouble understanding some of the questions or become tired while answering any of them, please let the study team know. You can get help with the questionnaires or some of the questions can be answered by interviewing you. Some of the questions might make you feel sad. Should you feel sad or if someone from the study team find that you are depressed or have other emotional symptoms you may be referred for a mental health evaluation. You will not have to answer any questions that make you feel uncomfortable.
- Exercise is generally safe and is recommended for people with the metabolic syndrome and autonomic neuropathy. You will be instructed in the exercise program and when exercising at home you should exercise only as long as you feel comfortable. The changes of having a major problem are small while exercising in this careful way. You may experience localized muscle or joint pain, muscle soreness after exercise, feelings of warmth, sweating, fatigue, loss of balance or falls, lightheadedness, irregular heartbeat, chest pain or shortness of breath. You should not continue to exercise if you have chest pain, shortness of breath, dizziness, irregular heart beat, or poorly controlled blood pressure. If any reason why you cannot do the exercise program is found, you will be made aware of it and medical follow-up with your doctor is recommended.
- There may be risks in this study that are not yet known.
- As with all research studies, there is the risk of the potential loss of confidentiality. Confidentiality will be maintained to the fullest extent possible and loss of confidentiality will be minimized by storing data in a secure location such as a locked cabinet in a locked office and electronic data will be password protected. Your data will be coded and personal identifiers will be removed.

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 that the program may lower your risk of falling. However, you many receive no benefit from participating.

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 University of Maryland, Baltimore if you are a non-Veteran or the VAMHCS if you are a Veteran 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.
- Additional costs that may result due to participation in the study may include: transportation and time away from work.
- Research related costs are paid for by the study and include exams, tests, education and counseling for research related purposes. For Veterans, eligibility for medical care at a VA Medical Center is based upon the usual VA eligibility policy and is not guaranteed by participation in a research study.

PAYMENT TO PARTICIPANTS

- For the initial screening and enrollment visits you will be given $25 for travel costs for each visit. You will also be given $25 for the 12 week and 24 week visits. For the weekly group sessions you will not have to pay for parking.

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 Dr. Lindsay Zilliox at 410-328-3100 (University) or 410-605-7000 ext. 6623 (VA) during the day and 410-328-1411 pager 5508 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.

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CONFIDENTIALITY AND ACCESS TO RECORDS

- The study will involve confidential information. On most of the forms your identifying information will be coded and a study number will be used. Study records will be considered confidential and will only be handled by the study staff and every effort will be made to make sure that your information is kept private consistent with HIPAA and VA regulations.
- The data will be stored in a locked cabinet in a locked office or on a password protected electronic database and only study staff will have access to the data.
- Collected data will be used in a multi-site study that combines data from the VA and the University of Maryland (UM). UM data will be sent to the VA where it will be stored.
- 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 including the VA Office of Research & Development (ORD), VA Office of Research Oversight (ORO), VA Office of Inspector General (OIG), and Office of Human Research Protections (OHRP).
- 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.
- 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.

- 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.

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 Lindsay Zilliox at 410-605-7000 extension 6623.
- There are no adverse consequences (physical, social, economic, legal, or psychological) of your decision to withdraw from the research.
- 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.
- If you are an employee, your employment status at the VAMHCS will not be affected by your participation or non-participation in this 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 failure to follow instructions of the research staff or 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, you may contact Dr. Lindsay Zilliox at 410-605-7000 extension 6623.

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Please read the University's statement below.

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 Baltimore
Office of Academic Affairs Regulatory Compliance
Human Research Protections Office
620 W. Lexington Street, Second 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 6512
Room 3D-158

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:_____

_____
Investigator or Designee Obtaining Consent Signature

Date:_____