

Balance Recovery Training for Fall Prevention in Retirement Communities

NCT02551666

October 13, 2015

CONSENT FORM

Project Title: Balance recovery training for fall prevention in retirement communities

You are invited to take part in a research study led by Dr. Michael Madigan, a researcher from Texas A&M University and funded by the National Institutes of Health. The information in this form is provided to help you decide whether or not to take part. If you decide to take part in the study, you will be asked to sign this consent form. If you decide you do not want to participate, there will be no penalty to you, and you will not lose any benefits you normally would have.

Why Is This Study Being Done?

The purpose of this study is to evaluate how two different exercises help improve your balance and keep you from falling.

Why Am I Being Asked To Be In This Study?

You are being asked to be in this study because your age is 60 or above, and you live in a retirement community.

How Many People Will Be Asked To Be In This Study?

60 people (participants) will be invited to participate in this study.

What Are the Alternatives to being in this study?

The alternative to being in the study is not to participate.

What Will I Be Asked To Do In This Study?

You will be asked to attend two screening sessions to confirm your eligibility, 5 sessions during which we will measure your balance, and 12 exercise classes (3 times a week for 4 weeks). Your participation in this study will last up to 6 months and includes 19 visits in all. The investigators will come to your location for these visits, so you will not have to travel to visit them.

Visit 1 (Week 1): 30 minutes – initial screening to determine eligibility

Visit 2 (Week 1): 30 minutes – medical screening to determine eligibility

Visit 3 (Week 1): 60 minutes – balance measurements will be collected

Visits 4-6 (Week 2): 30 minutes – exercise class

Visits 7-9 (Week 3): 30 minutes – exercise class

Visits 10-12 (Week 4): 30 minutes – exercise class

Visits 13-15 (Week 5): 30 minutes – exercise class

Visit 16 (Week 6): 60 minutes – balance measurements will be collected

Visit 17 (Week 10): 60 minutes – balance measurements will be collected

Visit 18 (Week 18): 60 minutes – balance measurements will be collected

Visit 19 (Week 30): 60 minutes – balance measurements will be collected

If you leave the study early, you may be asked to complete one additional session during which we will measure your balance.

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Will Photos, Video or Audio Recordings Be Made Of Me during the Study?

The researchers will take photographs and/or videos during the study so that we can learn as much as possible about the study. But we will only take these photographs and/or videos if you give your permission to do so. Indicate your decision below by initialing in the space provided.

_____ I give my permission for photographs/videos to be made of me during my participation in this research study.

_____ I do not give my permission for photographs/videos to be made of me during my participation in this research study.

Are There Any Risks To Me?

As with any physical exercise, there is a risk of soreness, injury, or falling. Injuries could include a muscle strain, joint sprain, broken bone, or other unexpected injury. However, we will protect you as best we can using our detailed screening process, trained personnel, safe and controlled exercises, and a fall prevention harness during balance testing and training.

You will also be asked to complete a low-dosage x-ray of your full-body and spine to ensure you do not have severe osteoporosis. This procedure is used to estimate the amount of fat mass and lean mass in your whole body and in your arms and legs and to measure bone mineral density in your spine and hip. For this DXA scan you will be asked to lie flat on a table for approximately 10 minutes while this test is being performed. The DXA scans expose you to minimal radiation (2.5 mRem), equal to the natural atmospheric background radiation during two days in College Station. It is not harmful to you. All radiation doses carry a finite risk of inducing cancer or genetic disorders in a fetus. The DXA doses are such that these risks are small by comparison with the natural incidence of these conditions.

Are There Any Benefits To Me?

The direct benefit to you by being in this study is that you will be able to participant in free exercise classes, and as a result you will improve your balance and overall health.

Will There Be Any Costs To Me?

Aside from your time, there are no costs for taking part in the study.

Will I Have To Pay Anything If I Get Hurt In This Study?

If you suffer any injury as a result of taking part in this research study, please understand that the investigators do not have any funds to help pay for your injury. However, all needed facilities, emergency treatment, and professional services will be available to you, just as they are to the community in general. You will not give up any of your legal rights by signing this consent form.

Will I Be Paid To Be In This Study?

You will receive \$200 for completing the study. You will be paid \$50 after the 6th exercise class, \$50 after the 12th exercise class, \$50 after the balance measurements during week 10, and \$50 after the balance measurements during week 30.

CONSENT FORM

Will Information From This Study Be Kept Private?

The records of this study will be kept private. No identifiers linking you to this study will be included in any sort of report that might be published. Research records will be stored securely and only Michael Madigan and the other personnel on this project will have access to the records.

Information about you will be stored in locked file cabinet. This consent form will be filed securely in an official area. People who have access to your information include the Principal Investigator and research study personnel. Representatives of regulatory agencies such as the Office of Human Research Protections (OHRP) and entities such as the Texas A&M University Human Subjects Protection Program may access your records to make sure the study is being run correctly and that information is collected properly.

The agency that funds this study (National Institutes of Health) and retirement communities where study procedures are being performed may also see your information. However, any information that is sent to them will be coded with a number so that they cannot tell who you are. Representatives from these entities can see information that has your name on it if they come to the study site to view records. If there are any reports about this study, your name will not be in them.

Information about you and related to this study will be kept confidential to the extent permitted or required by law.

Make available medical files:

The medical team on this project may elect to review your medical files during the screening process in case additional information is needed to determine your eligibility. If needed, this information will be kept private and only be used to determine your eligibility.

If you agree to allow the medical team to have access to your medical files, please initial here:

Who may I Contact for More Information?

You may contact the Principal Investigator, Michael Madigan, PhD, to tell him about a concern or complaint about this research at 979-862-1214 or mlm@tamu.edu.

For questions about your rights as a research participant; or if you have questions, complaints, or concerns about the research, you may call the Texas A&M University Human Subjects Protection Program office at (979) 458-4067 or irb@tamu.edu.

What if I Change My Mind About Participating?

This research is voluntary and you have the choice whether or not to participate in this study. You may decide to not begin or to stop participating at any time. If you choose not to be in this study or stop being in the study, there will be no penalty or effect on any aspect of your life.

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STATEMENT OF CONSENT

I agree to be in this study and know that I am not giving up any legal rights by signing this form. The procedures, risks, and benefits have been explained to me, and my questions have been answered. I know that new information about this research study will be provided to me as it becomes available and that the researcher will tell me if I must be removed from the study. I can ask more questions if I want. A copy of this entire consent form will be given to me.

Participant's Signature

Date

Printed Name

Date

INVESTIGATOR'S AFFIDAVIT:

Either I have or my agent has carefully explained to the participant the nature of the above project. I hereby certify that to the best of my knowledge the person who signed this consent form was informed of the nature, demands, benefits, and risks involved in his/her participation.

Signature of Presenter

Date

Printed Name

Date