Enhancing Function in Later Life: Exercise and Functional Network Connectivity (FORCE)

NCT02068612

Older Adult Consent Form

12/22/2017

University of Colorado Boulder

Permission to Take Part in a Human Research Study

Enhancing function in later life: Exercise and functional network connectivity (FORCE)
Principal Investigator: Angela D. Bryan, PhD

Why am I being invited to take part in a research study?

We invite you to take part in a research study because you are a healthy adult who is 60 years or older and do not currently exercise regularly.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.
- You will be offered a copy of this document

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at the CUChange Lab. You can reach the lab at force.researchstudy@gmail.com or at (303) 492-9549 or you can call Dr. Bryan directly at (303) 492-8264.

This research has been reviewed and approved by an Institutional Review Board ("IRB"). You may talk to them at (303) 735-3702 or irbadmin@colorado.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

Why is this research being done?

As people age, there are changes that happen to their bodies and to their minds, and these changes affect how people function socially, emotionally, and even economically. However, we do not know exactly how or why these changes take place. Some studies have shown that physical exercise may protect against the changes in cognitive function that happen as people age. But it is not clear how

much exercise might be necessary or what intensity of exercise is best. This research is designed to compare the effects of two forms of exercise, higher intensity versus lower intensity, on cardiovascular health, brain functioning, and cognitive functioning. We will compare the effectiveness of these exercise programs by looking at their effects on 1) physiological tests on a treadmill, 2) questionnaires and surveys that ask about social, emotional, and financial functioning, and 3) assessing brain structure and function using magnetic resonance imaging (MRI). It is our hope that learning more about how exercise results in positive changes across multiple domains of function will help in the development of treatment and prevention programs for the improvement of health and quality of life for older adults.

How long will the research last?

We expect that you will be in this research study for approximately 6 months.

How many people will be studied?

We expect that about 320 adults ages 60 years or older will be in this research study.

What happens if I say yes, I want to be in this research?

If you join the study, you will be asked to come to the Clinical Translational Research Center (CTRC) at the Wardenburg Health Center on the CU Boulder main campus in Boulder, CO a total of 3 times over the course of 6 months. You will also be asked to come to the Intermountain Neuroimaging Consortium at the Center for Innovation and Creativity (CINC), which is very near the CU Boulder main campus, a total of 2 times over the course of 6 months. We will ask you to take part in a 16-week supervised exercise-training program at the CUChange Exercise lab, also located at the CINC. Finally, we will ask that you provide contact information for someone who knows you well (a spouse, child, family member or close friend). Please note that this individual must be 18 years or older. We will call them to ask for their views on your current social, emotional, and financial functioning. It is up to you to decide who we should call to get this information. They will not be asked any personal questions about themselves except their relationship to you.

The first study appointment is an orientation session that will take place at the CTRC. If you are comfortable with the study procedures and agree to participate, you will receive a physical exam from a physician to ensure that it is safe for you to begin an exercise program. Following the physical exam you will also be asked to participate in a 12 lead ECG monitored Graded Exercise Test (GXT). During the GXT you will walk on a treadmill for approximately 12 – 15 minutes. During this test your heart activity and blood pressure will be monitored by a physician with a 12 lead ECG. The treadmill test will start off easy and will gradually increase in speed and incline every 2 minutes until you reach your maximum heart rate. If the doctor says it is safe for you to continue, you will complete study measures on a computer and some additional tests of your physical function, like how quickly you rise from a chair and walk across the room. You will also provide a blood sample at this session. A total of 53 ml (3.58 tablespoons) of your blood will be drawn by a trained phlebotomist. A portion of the blood sample will be used to obtain DNA. We will use the DNA to measure some of your genes. We will also look at gene activity by measuring a process called DNA methylation. The purpose of these tests is to determine whether the effects of exercise are different for people with different DNA profiles, and whether exercising at different levels of intensity has an effect on DNA methylation. The Research Associate who reviews this Consent Form with you will answer any questions about genetic testing.

The second study session will take place at the CTRC. During this visit you will have an exercise test to find out how hard you can exercise on a treadmill before you are exhausted. We would like to find out what your maximal exercise intensity level is before you start your exercise training program. This

exercise test will involve walking on a treadmill for about 10 -15 minutes while you breathe through a special mouthpiece. The exercise will be easy at first, but will gradually become more difficult until you can no longer continue. We will monitor your heart activity (ECG) during the test to make sure it is normal. After your treadmill test, you will complete some measures that ask how you are doing emotionally, socially and financially. When you are done, you will find out which exercise program you have been assigned to complete.

In addition, at the study session you will be given the option of taking home a kit that you can use to collect a small fecal sample that you will bring back to us. It basically involves touching a q-tip to some toilet paper after you go to the bathroom, and then bringing the q-tip back to us in a sterile container at the next session. We would provide you with everything you need to do this collection procedure, as well as instructions. You can choose not to participate in this aspect of the study. You won't earn any extra money for doing the fecal sample collection portion of the study.

For the third study session you will come to the CINC to complete some paper and pencil and computerized tests of your cognitive function and to have an MRI scan. The MRI machine uses a magnetic field to take pictures of your brain, both while you rest and while you complete some simple tasks while you are in the scanner.

This study will have 2 different exercise training groups of research subjects like you. To decide which group you will be in, we will use a method of chance. This method is like flipping a coin or rolling dice. The two groups will get slightly different exercise training.

After this third session, you will be ready to start the 16-week exercise-training program. Three times per week for 16-weeks, you will be asked to come to the CUChange Exercise Lab at the CINC so that one of our research team members can meet with you while you exercise. Each session will last approximately 1 hour. The actual exercise will last approximately 40 minutes.

Two months (8 weeks) after you start your exercise program, you will again complete measures of your social, emotional, and financial functioning. You can complete these measures before or after one of your regularly scheduled exercise sessions at the CINC.

When your 16-week exercise training program is over, you will be asked to come back to the MRI facility at the CINC to complete a second set of cognitive function measures and get a second MRI scan. If you choose, you will also receive another fecal sample collection kit, which you can bring back to us at the next session.

As the final part of the study, you will come back to the CTRC to complete a second fitness assessment, and provide another 53ml (3.58 tablespoons) blood sample, a portion of which will be used to collect DNA, You will also complete a final set of measures of your social, emotional, and financial functioning.

In total, we expect that you will be in this research study for a total of 6-months.

What happens if I do not want to be in this research?

You can leave the research at any time and it will not be held against you.

What happens if I say yes, but I change my mind later?

You can leave the research at any time and it will not be held against you. If you leave the study early,

it is up to you to decide whether researchers can use the information that has been collected on you, or whether you would prefer all of your information to be removed from our study database.

Is there any way being in this study could be bad for me?

Risks associated with blood draws. In this study we will need to get 53 ml (3.58 tablespoons) of blood from you at your first visit, and another 53 ml (3.58 tablespoons) of blood 4 months later. We will get blood by putting a needle into one of your veins and letting the blood flow into a glass tube.

- You may feel some pain when the needle goes into your vein.
- A day or two later, you may have a small bruise where the needle went under the skin.
- There is also the risk of fainting. Trained personnel will be present during the blood draw procedures to assist you if you feel light headed or faint.

Risks associated with an MRI scan. There are no known harmful effects from the MRI, as long as some safety measures are taken. Before the scan, you will be asked to fill out a screening form asking about things that might be a health risk or interfere with the image. Other risks you might experience include:

- Some people feel nervous or claustrophobic from the scanner's small space. If you become nervous in small, tight spaces, you should tell the study staff.
- You may be sore or uncomfortable from lying in one position for a long time. The scanner can be noisy. We will give you earphones to block most of the noise. The noise can be annoying, but it is not loud enough to damage your hearing. You will be asked to do some tasks while you are in the scanner. Sometimes these tasks can be tiring or frustrating; however, these tasks last only 5-10 minutes at most.
- Some people have reported feelings during the MRI scan, such as "tingling" or "twitching". This is caused by changes in the magnetic field that can stimulate nerves in your body. The feelings will usually stop soon after the scan is completed. If you have these feelings and are uncomfortable, you can tell the MRI staff, and we will stop the scan.

Risks associated with the collection of genetic data. There are risks that come with genetic (DNA) tests. Because in some cases the results of these genetic tests may allow us to predict the risk of getting an illness, we will keep the results confidential (only known to scientists working on this research project). With regard to the collection of genetic information, this study does not involve any diagnostic testing and will not provide any information that would determine your immediate risk for disease.

Risks associated with the treadmill tests. About 1 in 100 people will have an irregular heartbeat during the exercise test. If you have an irregular heartbeat, then we will ask that you see your doctor for follow-up before continuing with the study. About 4 in 10,000 people have chest pain or a heart attack and 1 in 10,000 people die during an exercise test. About 1 in 100 people will have an irregular heartbeat during the exercise test. Based upon protocols performed at the CTRC, the incidence for an irregular heartbeat increases to 1 in 7 when the exercise testing is performed as a screening measure for individuals older than 40 years of age.

Other possible discomforts associated with the treadmill test include:

- Skin irritation associated with electrodes used for the maximal exercise test
- Dry mouth
- Fatigue and minor muscle and joint discomfort
- Soreness or injury

Risks associated with exercise training. Any time that you engage in physical activity there are risks of:

- Injury
- Muscle soreness
- Physical discomfort
- Potential life threatening cardiovascular events

While attending the exercise training sessions for this study you will be under the supervision of trained personnel in the CUChange Exercise Lab. The CUChange lab is equipped according to American College of Sports Medicine (ASCM) guidelines for an exercise facility and the personnel will be trained in basic life support.

Risks associated with breach of confidentiality. Every effort will be made to protect the information you give us. Any personal identifying information and any record linking that information to study ID numbers will be destroyed when the study is completed. Information resulting from this study will be used for research purposes and may be published in summary form; however, you will not be identified by name in any publications.

In general, it is possible that the screening may reveal a medical/psychological abnormality. In this case, you will be provided with information about the abnormality and if needed a referral will be made to a doctor from whom you may choose to seek treatment.

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include learning more about your physical fitness and learning how to increase your exercise behavior from a trained exercise scientist.

What happens to the information collected for the research?

The University of Colorado Boulder has rules to protect information about you. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy.

This part of the consent form tells you what information about you may be collected in this study and who might see or use it.

We cannot do this study without your permission to see, use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will do everything we can to keep your records a secret. It cannot be guaranteed.

You can cancel your permission to use and disclose your information at any time until the end of the study by writing to the study's Primary Investigator, at the name and address listed below. After that time, we will destroy your identifying information and the list linking your identifying information to your data, and we will have no way to know which data and samples were yours. If you do cancel your permission to use your data and specimens before the end of the study, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

Principal Investigator:
Angela Bryan, PhD
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Dept. of Psychology and Neuroscience
345 UCB, Muenzinger Hall,
Boulder, CO, 80309

Both the research records that identify you and the consent form signed by you may be looked at by others who have a legal right to see that information, including:

- Federal offices such as the Food and Drug Administration (FDA) that protect research subjects like you.
- People at the CU Boulder Institutional Review Board (CU IRB)
- The principal investigator and the rest of the study team.
- The National Institute on Aging (NIA), which is the organization paying for this research study.
- Officials at the institution where the research is being conducted and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research

This study has been issued a Certificate of Confidentiality from the federal government to help protect your privacy. This certification means that the researchers cannot be forced to tell people who are not connected with the study, such as the court system, about your participation in this study. But, if you request that we do so, we will release information that is unique to you.
There are three exceptions to this promise of confidentiality:

1. If we see or are told information that makes us reasonably suspect that a child or at-risk adult is being or has been abused, mistreated, or neglected, we will immediately report that information to the county department of social services or a local law enforcement agency.
2. If we learn of a serious threat of imminent physical violence against a person, we will report that information to the appropriate legal authorities and make reasonable and timely efforts to notify the potential victim.
3. This promise of confidentiality does not include information we may learn about future criminal conduct.

We might talk about this research study at meetings. We might also print the results of this research study in relevant journals. But we will always keep the names of the research subjects, like you, private.

You have the right to request access to your personal health information from the Investigator. To ensure proper evaluation of test results, your access to these study results may not be allowed until after the study has been completed.

The investigator (or staff acting on behalf of the investigator) will use your information for the research outlined in this consent form. A description of this clinical trial is 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.

Can I be removed from the research without my OK?

The study doctor may decide to stop your participation without your permission if the study doctor thinks that being in the study may cause you harm, or for any other reason. Also, the sponsor may stop the study at any time.

What else do I need to know?

This research is being funded by the National Institute on Aging, a division of the National Institutes for Health (NIH).

If you need medical care because of taking part in this research study, contact the investigator and medical care will be made available. Generally, this care will be billed to you, your insurance, or other third party. The University of Colorado has no program to pay for medical care for research-related injury.

You will be paid up to $300 if you complete all aspects of this study. For completing the first study session at the CTRC, you will be paid $20. For completing the fitness test and assessments at the CTRC, you will be paid $30. For completing the first study session at CINC, you will be paid $30. For completing the 16 week exercise prescription, you will be paid $80. If you complete all 48 possible exercise training sessions (3 sessions per week for 16 weeks) you will be paid an additional $20. For completing the 2-month assessments during one of your exercise sessions, you will be paid $20. For competing the post-16-week training MRI session at the CINC you will be paid $50. Finally, for completing the final follow-up study session, which includes another fitness test at the CTRC, you will be paid $50. In addition, the study doctor may ask you to see your doctor before continuing to participate in the study. If you see your doctor at the request of the study doctor to be able to continue participating in the study, you will be paid an additional $100. If your doctor does not allow you to participate in the study, you will be paid the $100 at one time. If your doctor allows you to participate in the study, you will be paid the $100 across the remainder of your study visits. If you leave the study early, or if we have to take you out of the study, you will be paid only for the visits you have completed.

Signature Block for Capable Adult

Your signature documents your permission to take part in this research.

Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	12.22.2017 IRB Approval Date