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

NCT02068612

Young Adult Consent Form

10/25/2017

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 an adult between the ages of 25 and 35 years who does 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) 492-9549or 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. We do not know exactly how or why these changes take place, but we think that they involve changes in brain structure and function. Additionally, some studies have shown that physical exercise may protect against the changes in cognitive function that happen as people age. This research is designed to characterize how aging affects brain health and social, emotional, and economic functioning. We are also interested in looking at the effects of physical activity. We will address these questions by comparing younger and older adults in terms of 1) physical fitness, as measured by physiological tests on a treadmill, 2) questionnaires and surveys that ask about social, emotional, and financial functioning, and 3) brain structure and function, as assessed by magnetic resonance imaging (MRI). It is our hope that this research 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 about 5 hours. This study will involve three separate sessions.

How many people will be studied?

We expect that about 50 adults between 25 and 35 years of age 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 in a total of 3 times. The first session will take place at the Clinical Translational Research Center (CTRC) at Wardenburg Health Center located on the CU Boulder main campus in Boulder, CO. The second session will again be at the Clinical Translational Research Center (CTRC) at Wardenburg Health Center located on the CU Boulder main campus. The third study session will be held at the Intermountain Neuroimaging Consortium at the Center for Innovation and Creativity (CINC), which is very near the CU Boulder main campus.

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 an exercise test at the CTRC 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 they are normal. After your treadmill test, you will complete some measures that ask how you are doing emotionally, socially and financially. 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 53ml (3.58 tablespoons) of your blood will be drawn by a trained phlebotomist. In addition, we will collect a small sample of saliva from you. The saliva 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 and physical fitness are different for people with different genetic variants (DNA profiles),

and whether exercising has an effect on gene activity (DNA methylation). The Research Associate who reviews this Consent Form with you will answer any questions about genetic testing.

For the second 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.

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 53ml (3.58 tablespoons) of blood from you at your first visit. 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.
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 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 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 current level of physical fitness.

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 give us permission, 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
University of Colorado Boulder
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, for example:

- 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

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 $100 if you complete all aspects of this study. For completing the first study session at the CTRC, you will be paid $30. For completing the second study session at CINC, you will be paid $30. For completing the fitness test and assessments at the CTRC, you will be paid $30. If you complete all aspects of the study you will get a paid $10 bonus. 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	10.25.2017 IRB Approval Date