Exercise From Afar: Progressing At-Risk Adults to Independent Exercise for Dementia Risk Reduction

April 1, 2024

NCT #: TBD

Informed Consent

We are asking you to participate in a research study titled *Exercise From Afar: Progressing At-Risk Rural Adults to Effective Independent Exercise for Dementia Risk Reduction.* We will describe this study to you and answer any of your questions. This study is being led by Dr. Erin Blocker and her research team from the Health & Human Performance Department at Emporia State University. This study is being funded by the Summer PUI Research Investigator Grant program (P20 GM103418).

What the study is about

The purpose of this research is to investigate the effects of online exercise training (via a commonly used exercise training smart phone app) on various health markers and body composition among underactive Rural Kansas adults. The study aims to compare the differences in health markers and body composition between participants who receive online exercise training and those who do not receive any intervention. This research is important for advancing our understanding of the benefits of exercise and its effects on various health indicators. The results of this study may contribute to the development of evidence-based exercise programs for Rural dwelling adults to improve their overall health and well-being.

What we will ask you to do

If you are randomized to the training group, we will ask you to participate in an exercise program that involves online exercise training that will last 16 weeks. The online exercise training will consist of cardiovascular (cardio), strength and flexibility exercises. Exercise training sessions will vary in duration, but will aim to help you work toward completing the recommended volume of cardiovascular and strength exercise weekly (as prescribed by national governing bodies). We will provide you with a fitness tracker to monitor your heart rate during the exercise sessions. The fitness tracker will also monitor your total daily physical activity, various HR measures and step count. We will help you download a smart phone application that will be used to deliver the exercise training program. This app will also serve as our means of communication for the duration of the study. You will receive instruction on how to use the application before the study begins and we will assist you will the application throughout the study as needed.

If you are randomized to the control group, you will only be asked to undergo the fitness assessments and complete the psychosocial subjective reporting at the beginning and end of the study, without receiving any intervention. However, you will have the option to receive a free 16-week training program once the study is over.

Before and after the exercise program, we will ask you to undergo fitness assessments to measure various health markers, including total cholesterol, HDL, LDL, triglycerides, and fasting blood glucose. We will use the CHOLESTECH LDX Lipid Profile + Glucose tests to measure these markers. We will also ask you to complete a few surveys before and after the intervention. All procedures in the study have been designed with evidence-based exercise principles and will be overseen by qualified exercise professionals.

Risks and discomforts

In this study, there are some risks or discomforts that could be reasonably expected. There are no legal risks associated with this study. The physical risks are minimal and may include muscle soreness, fatigue, or possible injury from exercise. Proper exercise selection will help ensure that the exercise will be safe and viable. If any physical injuries happen during the training sessions, Emporia State University and the research team are not responsible. The emotional risks are also low, but participants may feel some level of stress or frustration during the exercise sessions. If any discomfort or concerns arise during the study, participants will be encouraged to communicate with the research team.

Benefits
The benefit of participating in this study is the potential improvement in overall health including markers such as cholesterol levels, glucose levels, and body composition. Additionally, participants in the exercise training group may experience improvements in physical fitness and strength and exercise self-efficacy. There may also be indirect benefits to participants, such as gaining knowledge about exercise and healthy habits, or feeling a sense of accomplishment from completing the study. The expected benefits to society and scientific knowledge include a better understanding of effective delivery of online exercise training for Rural adults. In addition, the potential for developing more effective exercise programs for improving overall health in Rural adults may result. The results of this study may benefit individuals who are looking to improve their health and fitness levels.

Incentives for participation
If you are randomized to the training group, you will receive a wearable fitness tracker to track your heart rate and daily step count throughout the intervention. You will also receive a paid gym membership for the duration of the exercise intervention. If you are randomized to the control group will be also receive a fitness tracker after completion of your follow-up assessments. You will receive a paid gym membership following your follow-up assessments.

Privacy/Confidentiality/Data Security
We take the privacy and confidentiality of our participants very seriously. All data collected will be de-identified, which means that any personal identifying information such as names, addresses, or contact information will be kept separate from the research data. The data will be stored on securely and will only be accessible by authorized members of the research team. We will not collect any identifying information at all from participants, so their responses will remain anonymous.

Sharing De-identified Data Collected in this Research
De-identified data from this study may be shared with the research community at large to advance science and health. We will remove or code any personal information that could identify you before files are shared with other researchers to ensure that, by current scientific standards and known methods, no one will be able to identify you from the information we share.

Future use of Identifiable Data or Specimens Collected in this Research
Your information or biospecimens will not be used or distributed for future research studies.

Information about use of your biospecimens
Specimens collected from you for this study and/or information derived from your specimens will not be used to generate commercial profit. You *will not* receive any clinically relevant results discovered about you or the general subject population.

Taking part is voluntary
It is important to know that your participation in this study is voluntary. You have the right to refuse to participate before the study begins or to discontinue at any time during the study, even if you have already started. We highly prefer you to complete the study upon initiation; however, you can refuse to participate or withdraw at any time without being subject to reproach. We do require participants to complete a majority of the exercise training sessions. Participants will be allowed to miss no more than 8 training sessions throughout the course of 16 weeks, meaning you must complete a total of 40 exercise training sessions. You can choose not to participate if you're uncomfortable with these conditions.

If you have questions
The main researchers conducting this study are Dr. Erin Blocker, and two (2) undergraduate research assistants from Emporia State University. Please ask any questions you have now. If you have questions later, you may contact Erin Blocker at eblocker@emporia.edu.

Statement of Consent
I have read the above information and have received answers to any questions I asked. I consent to take part in the study.

Your Signature_____ Date_____

Your Name (printed)_____

Signature of person obtaining consent_____ Date_____

Printed name of person obtaining consent_____

This consent form will be kept by the researcher for five years beyond the end of the study.