Title: A Study to Test the Effectiveness of Different Interventions to Improve Physical Activity in Adults.
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ADULT PARTICIPANT INFORMED CONSENT

Department of Health and Exercise Science

Study Title: A Study to Test the Effectiveness of Different Interventions to Improve Physical Activity in Adults.

STUDY INVESTIGATORS:

Primary Investigator: Kaigang Li, PhD, Assistant Professor

Co-Primary Investigator; Kayla Nuss, MA, MS

WHAT IF I HAVE QUESTIONS?
For questions or concerns about the study, you may contact **Kaigang Li** at **(970) 491-7253.** For questions regarding the rights of research subjects, any complaints or comments regarding the manner in which the study is being conducted, contact the CSU Institutional Review Board at: RICRO_IRB@mail.colostate.edu; 970-491-1553.

WHAT IS THE PURPOSE OF THIS STUDY?
The purpose of this study is to assess the impact of a physical activity promotion program. The program is designed to provide different approaches to motivate participants to enact healthy lifestyle changes such as becoming more physically active. The approaches include wearing a wearable fitness tracker (WFT), participating in motivational interviewing (MI), wearing a WFT + participating in MI, or being provided with physical activity guidelines and education.

WHY AM I BEING INVITED TO TAKE PART IN THIS RESEARCH?
You are being asked to participate in the study because you fit these criteria: You are an adult female, age 30-49 or 60-69 or an adult male, age 40-49 who does not currently engage in 150 minutes of moderate to vigorous PA per week, owns an Android, or iPhone smartphone device, is willing to download a mobile app to be used on the smartphone device, is willing to wear a small, wrist worn fitness tracker for the duration of the study, and is be willing to attend 6 biweekly MI sessions over 12 weeks. You do not have a history of myocardial infarction, angina, coronary artery bypass surgery, congestive heart failure, or diabetes, limiting conditions such as concurrent cancer treatment, peripheral artery disease, orthopedic injury, or pain limiting arthritis, are not seeking to participate in other structured PA programs during the duration of the study, are not pregnant at the initiation of the study or plans to become pregnant during the study, and do not have a history of alcohol or other substance abuse within the previous 12 months.

WHERE IS THE STUDY GOING TO TAKE PLACE AND HOW LONG WILL IT LAST?

Study procedures will take place at Colorado State University (Fort Collins main campus) in the Human Performance Clinical Research Laboratory (HPCRL) in the Department of Health & Exercise Science (Moby Complex). You will be asked to be involved for twelve weeks. You may be asked to attend six (6) bi-weekly motivational interviewing sessions, each lasting 30 to 45 minutes each. **If necessary, based on the COVID-19 pandemic, these MI sessions, as well as all education and informed consent meetings will be conducted remotely using Skype or Facetime.**

WHAT WILL I BE ASKED TO DO?

This study uses a randomized assignment plan. This means that you have an equal chance of being assigned to one of four study groups. The assignment to groups is done randomly (like flipping a coin) by a computer program. If you volunteer to participate in this study, **you will be assigned to one of the following groups. You cannot choose which group you will be in:**

Wearable Fitness Tracker (WFT): Individuals assigned to this group will be given a Fitbit wrist-worn wearable fitness tracker and will be instructed to wear it for the duration of the study. You will download the corresponding mobile application on your smartphone to be used for the duration of the study. You will be trained by a member of our team on how to utilize the Fitbit and mobile application. The Fitbit tracks daily steps, miles traveled, kcals expended, and daily activity time. This device provides these data to the wearer via a small screen. You will aim to complete at least 150 minutes of moderate physical activity (like brisk walking) per week. Researchers will have the capability to track your physical activity using a Fitbase database. You will be asked to set biweekly physical activity goals, which will be emailed to the study coordinator. We will also give you some information on the benefits of physical activity and some strategies on how to meet the general physical activity guidelines. You will be asked to ONLY wear the WFT provided to you by our research team, and not one that you may own.

Motivational Interviewing (MI): You will participate in six biweekly motivational interviewing sessions in person or by Skype/Facetime. These sessions will take place in the HPCRL at CSU or remotely. The sessions will be conducted by a PhD student who was be trained by a motivational interviewing practitioner. You will aim to complete at least 150 minutes of moderate physical activity (like brisk walking) per week. You be will asked to set bi-weekly physical activity goals, which will be discussed during the MI sessions. You will be provided a log book and will be asked to log your physical activity with the goal. We will also give you some information on the benefits of physical activity and some strategies on how to meet the general physical activity guidelines. You will be asked to NOT wear a WFT if you happen to own your own for the duration of the study.

WFT+MI: You will be given the Fitbit wrist-worn wearable fitness tracker, and will participate in six (6) biweekly motivational interviewing sessions in person or by

Skype/Facetime. You will also be trained by a member of our team on how to utilize the Fitbit and the associated mobile application. You will aim to complete 150 minutes of moderate physical activity (like brisk walking) per week. You will be asked to set bi-weekly physical activity goals, which will be discussed during MI sessions. Researchers will have the capability to track your daily physical activity from the Fitbit application. We will also give you some information on the benefits of physical activity and some strategies on how to meet the general physical activity guidelines. You will be asked to ONLY wear the WFT provided to you by our research team, and not one that you may own.

Physical Activity Education: We will give you some information on the benefits of physical activity and some strategies on how to meet the general physical activity guidelines. This meeting may be conducted via Skype or Facetime. At the conclusion of the study, you will be offered the chance to participate in one motivational interviewing session with a trained facilitator. You will be asked to NOT wear a WFT if you happen to own your own for the duration of the study.

Pre- and Post-Assessments
All participants will complete two weeks of physical activity monitoring using a waist-worn ActiGraph clinical grade accelerometer. An accelerometer records information about body movement during everyday activities such as walking. The monitors are safe and use a battery similar to a watch battery for power. They are not GPS tracking devices, nor do they record heart rate. We will ask that you wear the monitor for 24 hours for 7 days, for two weeks during your study participation. The first week will be before the program beings and the second week will be at the conclusion of the program. All participants will also complete a survey about their exercise habits and motivation for exercise at the beginning of the program, and then again at the conclusion on the program.

ARE THERE ANY BENEFITS FROM TAKING PART IN THIS STUDY?

There are no direct benefits from taking part in this study. However, during your participation in either group you will have the opportunity to learn new things about how people can be engaged in more physical activity. Therefore, we hope that you will learn new information and approaches that will help you to incorporate healthier lifestyles into your daily life.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

It is not possible to identify all potential risks in research procedures, but the researcher(s) have taken reasonable safeguards to minimize any known and potential, but unknown, risks. Some of the procedures for which you are being asked to volunteer have a number of associated risks:

Physical well-being
There are minimal risks to an exercise intervention. You may experience fatigue, muscle soreness, or acute shortness of breath due to beginning a new exercise

program. Despite this, research indicates that the benefits of moderate intensity exercise outweigh the risks and include improvements in cardiometabolic health and reduced disease risk.

Psychological well-being
This study has no risk or very small risk on subjects' psychological well-being; actually a number of studies have indicated that exercise improves psychological well-being.

Economic well-being
This study should have minimal impact on participants' economic well-being. A subset of them will need to travel to the HPCRL once every two weeks for twelve weeks, which may be a slight economic burden.

Social well-being
This study has no risk or very small risk on participants' social well-being as a subset of subjects will experience four short visits with the lab staff without any other social interaction. Another subset will experience motivational interviewing which is participant centered, with its primary focus on the social and emotional wellbeing of the participant.

WILL I RECEIVE ANY COMPENSATION FOR TAKING PART IN THIS STUDY?
Upon completion the twelve (12) week program, you will keep the Fitbit (if assigned to a Fitbit group) or receive $50.00 (for those assigned to MI only or control group).

WHO WILL SEE THE INFORMATION THAT I GIVE?
All information gathered in this study will be kept as confidential as possible. Your privacy is very important to us and the researchers will take every measure to protect it. Your information may be given out if required by law; however, the researchers will do their best to make sure that any information that is released will not identify you. No reference will be made in written or oral materials that could link you to this study. For this study, we will assign a code to your data so that the only place your name will appear in our records is on the consent and in our data spreadsheet which links you to your code. Only the research team will have access to the link between you, your code, and your data. All records will be stored in a restricted access folder and in a locked drawer in a restricted-access office at CSU for at least three years after completion of the study. After the storage time, the information gathered will be destroyed. We may be asked to share the research files with the sponsor or the CSU Institutional Review Board ethics committee for auditing purposes. Your identity/record of receiving compensation (NOT your data) may be made available to CSU officials for financial audits.

If you choose to take part in this study, your private information will be collected. Any identifiers linking you to your private information will be removed. After we remove those identifiers, the information could be used for future studies or distributed to another research for future research studies without your permission.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at anytime.

DO I HAVE TO TAKE PART IN THE STUDY?

Your participation in this study is voluntary. You may refuse to participate in this study or in any part of this study. You may withdraw at any time without prejudice to your relations with CSU. You are encouraged to ask questions about this study at the beginning or any time during the research study.

Participant Consent:

Your signature acknowledges that you have read the information stated and voluntarily wish to participate in this research. Your signature also acknowledges that you have received, on the date signed, a copy of this document containing 5 pages.

_____ _____

Signature of person agreeing to take part in the study Date

_____

Printed name of person agreeing to take part in the study

_____ _____

Name of person providing information to participant Date

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Signature of Research Staff