Consent to Participate in a Research Study

TITLE: Interactive roles of cardiorespiratory fitness and adiposity on recovery of impaired glucose and vascular control after physical inactivity

PROTOCOL NO.: 1R15HL177798-01
WCG IRB Protocol #20243935

SPONSOR: NIH, National Heart, Lung, and Blood Institute (NHLBI)

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Your participation in this study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are otherwise entitled.

If you have questions, concerns, or complaints, or think this research has hurt you, talk to the research team at the phone number(s) listed in this document.

RESEARCH CONSENT SUMMARY

You are being asked for your consent to take part in a research study. This document provides a concise summary of this research. It describes the key information that we believe most people need to decide whether to take part in this research. Later sections of this document will provide all relevant details.

How long will I be in this research?

The research will take place at 1) the Exercise Science Lab in Phillips Hall and 2) the person's home, workplace, and community. Your total study participation will be 3 weeks, not including a screening day visit. There will be seven visits to the lab.

Why is this research being done?

The purpose of this research is to investigate how the overall health status affects a person's ability to restore reduced blood sugar control following a week of reduced physical activity. The study also examines the role of the vascular (circulatory) function on the recovery of blood sugar control following a return to normal physical activity.

What happens to me if I agree to take part in this research?
You will be screened on your general health and medical history. If qualified to enroll into the study, you will be monitored with a week of baseline normal activity, a second week of reduced physical activity and a third week of resumed normal activity. You will be asked to wear an activity monitor on your thigh for 3 weeks, wear a glucose monitor inserted on your arm with an insert just below the skin for 3 weeks and fill out a dietary log six times with each log takes about 30 minutes to complete.

When you come to the lab, you will have 1) a treadmill-graded exercise test to assess your fitness, 2) a test to measure your blood flow, 3) a glucose test where we draw blood to measure your glucose response after a sugary beverage 4) a few tests (BIA and DXA scans) to examine your body composition (bone, lean body mass and fat mass) 5) you will answer some questions about your physical activity habits.

You will be given an e-scooter and helmet to use during week 2 of the study as well as discuss ways to reduce your activity and increase your time spent sitting. You will be asked to record your daily physical activity and to record your meals for 2 days per week of each of the 3 weeks.

Could being in this research hurt me?

Risk of having an accident while using the e-scooter is like to that of having an accident while using a bike.

Questionnaires: There may be a risk of loss of confidentiality.

Body composition assessment utilizing BIA or bioelectrical impedance is considered to be minimal.

Body composition: assessment with the DXA scan involves low levels of radiation.

Treadmill test: The treadmill test may cause discomfort, or some muscle fatigue toward the end of the test.

Risks of Continuous blood glucose monitoring: Inserting the sensor under the skin (subcutaneously) and wearing the adhesive patch might cause infection, bleeding, pain, or skin irritations.

Risks associated with blood collection are: 1) possible discomfort during the blood draw; 2) lightheadedness or fainting; 3) bruising; and 4) infection.

Risks of the sugary beverage are the rise in your blood glucose level which may make you feel uncomfortable or agitated.

Dietary assessment: There is also a small risk of experiencing psychological discomfort with dietary assessment for individuals predisposed toward developing an eating disorder.

Will being in this research benefit me?
It is not expected that you will personally benefit from this research other than knowing how your health and level of activity may affect your blood sugar control.

Knowledge gained from this study will pave the way for future research.

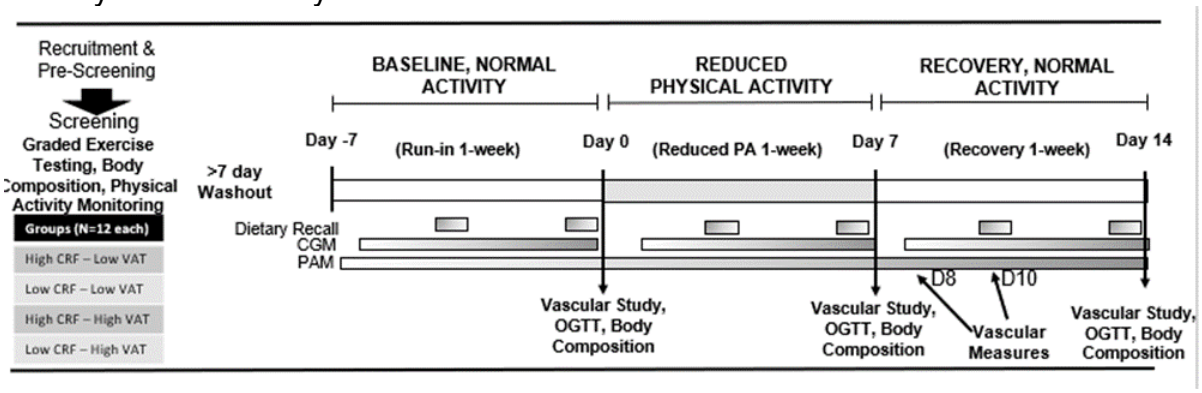
What other choices do I have besides taking part in this research?
This is an information gathering study only. Your alternative to study participation is not to participate.

What else should I know about this research?
There is a possibility that identifiers might be removed from the identifiable private information, and after such removal, the information may be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject.

DETAILED RESEARCH INFORMATION

What Is The Research About?
If you are between the ages of 18 and 40 and have a certain fitness level and amount of body fat, you are being invited to take part in a research study to monitor metabolic (blood glucose levels) and cardiovascular (blood flow) responses during a week of normal physical activity, a week when you reduce your physical activity most days of the week, and another week when you return to your normal physical activity levels.

The layout of the study is shown below



Who Is Doing The Study?
Drs. Kevin Ballard and Kyle Timmerman of Miami University are in charge of this study. **They will be assisted by masters and undergraduate students TBA.**

Do Any Researchers Stand To Gain Financially Or Personally From This Research?
None of the researchers participating in this study stand to gain financially or personally.

What Is The Purpose Of This Study?
The primary objective of this study is to monitor glucose levels and blood vessel function before and during a period of reduced physical activity and after a week of returning to regular physical activity.

Where Is The Study Going To Take Place and How Long Will It Last?
The research procedures will be conducted at two different locations at Miami University:

1) the Exercise Science Lab in Phillips Hall and 2) the person's home, workplace, and community.

The total time commitment is about 12 hours, including seven visits to the lab.

What Will I Be Asked To Do?
You will be asked to attend the Exercise Science Lab in Phillips Hall for approximately 1 hour on a screening day. If you meet the criteria decided at the screening you will be enrolled in the study and have the following time commitments. This includes about 20-30 min on Day -7, ~3 hours each on Days 0, 7 and 14. Day 8 and Day 10 will require about a 30-minute visit. You will wear a glucose monitor inserted on your arm with an insert just below the skin for 3 weeks. You will wear a physical activity monitor on your thigh for 3 weeks. You will fill out a dietary log six times, and each log will take about 30 minutes to complete. Thus the total time commitment is about 12 hours.

When you come to the lab we have you do 1) an exercise test to assess your fitness, 2) a test where we use a machine to measure your blood flow, 3) a glucose test where we give you a sugary beverage and draw blood to measure your glucose response as well as a few tests to examine your body composition. The body composition scans (one is called BIA and the other is called a DXA scan) will be done to measure the amount of bone, lean body mass and fat mass in your body. You will have to lie down on the DXA table for 15 minutes and then after that the scan will take a few minutes, while a technician will take pictures of your bones, lean mass, and fat. Before taking the scan you will be asked to stop taking calcium supplements, multivitamins and antacids 24 hours before your test, wear loose-fitting clothing with no metal and to tell the DXA technician if you might be pregnant. Before the continuous glucose monitor is placed on your arm you will be asked to stop taking vitamin C supplements and any medication with acetaminophen (such as Tylenol and some cold medicines) or aspirin or skin care products with salicylic acid (used in some pain relievers such as aspirin and some skin care products).

As we conduct the health/fitness measurements, we will explain the procedures and answer any questions you might have. You will then be given an assistive transportation device and helmet to use during week 2 of the study as well as discuss strategies to reduce your activity and increase your time spent sitting. You will be asked to record your daily physical activity and to record your meals for 2 days per week of each of the 3 weeks.

Are There Reasons Why I Should Not Take Part In This Study?
If you are in good health and can ride a bicycle/scooter safely and have no objections to the testing protocol, there are no safety-related reasons why you should not take part in this study.

What Are The Possible Risks And Discomforts?
The risks associated with participating in this study are not much more than what people experience in everyday life.

Risk of having an accident while using the e-scooter is similar to that of having an accident while using a bike. Participation in any athletic, physical, or recreational activity carries the unavoidable risk of injury regardless of the aptitude and abilities of the participants. Efforts can be made to reduce these inherent risks, but no matter how careful the participants and facilitators are, such risks are possible, but reduced. These inherent risks include, without limitation, collisions and impacts with other people or objects; slips, trips, and falls; falling or landing on uneven, worn, or hard landing surfaces; environmental exposure (e.g. insect stings, sunburn, frostbite, poison ivy, dehydration, etc.); equipment failures (even if the equipment is properly used); the actions, inactions, or negligence of others; the aggravation of pre-existing conditions; and medical emergencies and incidents (e.g. sudden cardiac arrest, etc.). These risks may result in: minor injuries (e.g. bruises, abrasions, cuts, sprains, etc.); serious injuries (e.g. broken bones, dislocations, muscle pulls, concussions, cardiac arrest, large lacerations/avulsions, etc.); and catastrophic injuries (e.g. brain injury, paralysis, death, etc.). To minimize risk of accidents and injury while using the assistive transportation devices, you will receive safety training from members of the research team who are experienced assistive transportation device riders. You will also practice riding an assistive transportation device under the supervision of research assistants and will have to demonstrate that you can safely ride an assistive transportation device on campus before being enrolled in the study. Every effort will be made to ensure that the assistive transportation device is in excellent working order, and that you understand how to ride it at safe speeds and on safe and permissible pathways, bike lanes and trails. Following training, if the study personnel feel that your proficiency is inadequate (i.e. difficulty controlling speed and/or maintaining control of the assistive transportation device) you will not be enrolled in the study. You will also receive instruction in basic e-scooter safety such as:

1) Only ride the e-scooter during daylight hours;
2) Always wear an approved helmet, provided by Miami University, while riding the e-scooter;
3) Only ride the e-scooter on legal bike-paths and streets with bike lanes, and take care to follow all applicable traffic laws and avoid narrow rural roads with speed limits in excess of 25 mph;
4) Follow all e-scooter safety procedures and instructions provided by Miami University and use proper hand turning signals while operating the e-scooter;
5) Refrain from operating the e-scooter, at any time, while under the influence of alcohol or a drug of abuse;
6) Refrain from performing any “tricks” or other dangerous stunts or maneuvers while operating the e-scooter;
7) Secure the e-scooter with a bike lock, provided by Miami University, when the e-scooter is not in use, and store the e-scooter inside a garage, home, or sheltered area;
8) While off-campus, follow and obey all local rules and traffic laws regarding the use of electronic e-scooters;

9) While on Miami University's campus, follow all safety rules outlined in Miami University's Electronic e-scooters policy, which can be found at: https://miamioh.edu/policy-library/administration-operations/university-property/electronic-scooters.html.

You will be required to sign a waiver indicating you agree with the use of the e-scooter in accordance with the above conditions.

General Risks: The only obvious risk associated with completing health questionnaires is that sensitive health-related data may be misplaced and/or viewed by unauthorized personnel. Procedures are put in place to protect your confidentiality of information. Body composition assessment utilizing bioelectrical impedance is considered to have minimal, but possible risk of those with pacemakers or implantable cardio-defibrillators.

*Body composition: a*ssessment with the DXA scan involves extremely low levels of radiation Each DXA procedure will expose you to a very small amount of radiation, much less than most routine X-ray procedures, and less than the amount of radiation you would be exposed to in a 2-hour airplane flight. Exposure to radiation can increase the risk of getting cancer and birth defects in pregnant women. The amount of radiation to which you will be exposed during the DXA scan is so small that the exact risk is unknown.' There are no risks to the BIA procedure unless you have a device implanted in your body to regulate your heart rate (a pacemaker). In that case you would not have the BIA test done.

Balke Treadmill test: The treadmill test should not cause any undue discomfort, except for some muscle fatigue toward the end of the test. Other risks, such as muscle-joint injuries and sudden death, are also possible, but are considered highly unlikely. To reduce risk, we exclude subjects with or signs/symptoms of cardiovascular disease. Finally, the test will be terminated if a subject experiences any of the general indications for stopping an exercise test as outlined by the American College of Sports Medicine.

Risks of *Continuous blood glucose monitoring*: Inserting the sensor under the skin (subcutaneously) and wearing the adhesive patch might cause infection, bleeding, pain, or skin irritations (for example, redness, swelling, bruising, itching, scarring, or skin discoloration). The chance of this happening is very low. The risk is minimized by cleaning the skin prior to application with an alcohol wipe. Metabolic patients routinely apply these to their own arms unassisted.

The risk of an overnight fast for the oral glucose test may lead to light-headedness or fainting.

Risks of blood sampling and the sugary beverage: At each visit (days 0, 7, and 14), you will have blood drawn from an antecubital vein by a member of the research team experienced in phlebotomy. Risks associated with blood collection are a small initial pain attributed to inserting the needle and a slight risk of infection. To minimize pain, a small gauge needle (21 gauge) will be used. To minimize the risk of infection, sterile procedures will be followed, including cleaning the site with an antiseptic prior to blood collection and utilizing single-use sterile needles and blood collection tubes. In addition, bruising may occasionally occur after the procedures are completed and individuals may experience lightheadedness or faint which is

common when individuals provide blood samples. A light snack (i.e., granola bar) will be provided to participants following the blood draw which will help with this and the very low chance of nausea that could occur in smaller participants who sugary beverage.

The primary risks associated with blood collection are: 1) possible discomfort during the blood draw; 2) lightheadedness or fainting; 3) bruising; and 4) infection. To minimize pain and discomfort, a small gauge needle (21 gauge) will be used. To minimize the risk of lightheadedness or fainting, you will remain supine during all blood draws. To minimize the risk of bruising, pressure will be held on the site for 2-3 minutes once the needle is removed. The risk of infection will be minimized by using sterile, single-use supplies and strict adherence to sterile procedures that include cleaning the site prior to insertion. We have significant phlebotomy experience which reduces the above risks.

Dietary assessment: There is also a small risk of experiencing psychological discomfort with dietary assessment for individuals predisposed toward developing an eating disorder. That risk is mitigated by conducting recalls instead of logs and by withholding the results of the dietary analysis from the participants if they ask.

Please let the study doctor if you think you may be pregnant. It is unknown if the study procedure is harmful to you or your unborn fetus.

Will I Benefit From Taking Part In This Study?
You will benefit from this study by receiving information related to your physical fitness (i.e. body composition, blood glucose levels, and cardiorespiratory fitness). You will also have an opportunity to ride an assistive transportation device (e-scooter) for a week.

Do I Have To Take Part In This Study?
If you decide to take part in the study, it should be because you want to volunteer. There will be no penalty or loss of benefits if you choose not to volunteer or withdraw from the study.

What Will It Cost Me To Participate?
There are no costs associated with taking part in this study.

What if the assistive transportation device (e-scooter) is lost or stolen while in my possession?
If stolen, the subject is responsible for replacing the assistive transportation device (e-scooter). You will be required to sign a paper indicating you are aware of this. The risk of this happening is extremely low if you use the U-lock provided to secure the e-scooter when not in use.

Are there identifiable benefits for the subjects?
The subject will benefit from this study by receiving information regarding their body composition, blood glucose, and other health-related markers.

Will I Receive Any Incentive For Taking Part In This Study?
At the end of the study, you will receive $200 for your time pro-rated on the amount completed ($25 for the screening, $10 for Day -7, $50 for Day 0, $50 for Day 7, and $75 for Day 14).

Who Will See The Information I Give?
Your information will be combined with information from other people taking part in the study. You will not be identified in any published or presented materials. Additionally, the researchers will make every effort to prevent anyone who is not on the research team from knowing that you gave us information or what that information is. More specifically, to maintain privacy and confidentiality, Drs. Ballard and Timmerman will code results by number rather than by name and all data will be kept on a password-protected computer. The only individuals who are able to gain access to your results are Drs. Ballard and Timmerman. However, there are some circumstances in which we may have to show your information to the other staff and health professionals associated with this project. We may be required to show information that identifies you to people who need to be sure that we have done the research correctly, such as the Miami University Institutional Review Board and WCG IRB.

Can My Taking Part In The Study End Early?
If you decide to take part in the study, you still have the right to decide at any time that you no longer want to continue. If you decide to no longer take part in this study, please email Kevin Ballard at ballarkd@miamioh.edu stating that you wish to withdraw from the study. There will be no penalty and no loss of benefits if you stop participating in the study. Drs. Ballard and Timmerman will not behave any differently to you if you decide to stop participating in the study.

What Happens If I Get Hurt Or Sick During The Study?
If you believe you are injured because of something that is done during the study, you should contact Drs. Ballard and Timmerman immediately. You can contact Dr. Ballard at ballarkd@miamioh.edu or 860-595-9356. Dr. Timmerman at timmerkl@miamioh.edu or 937-423-3516. We will make sure you receive any needed care or treatment. However, it is important for you to understand that Miami University have no plans to pay for the cost of any care or treatment that might be necessary because you get hurt or sick while taking part in this study. That cost will be billed to you or your insurance company. By signing this consent form, you do not waive your right to file a claim through the legal system.

What If I Have Questions?
Before you decide whether or not to participate in the study, please ask any questions that come to mind now. Later, if you have questions about the study, you can contact Dr. Ballard at ballarkd@miamioh.edu or 860-595-9356 or 513-529-9247 (24 hours). Dr. Timmerman at timmerkl@miamioh.edu or 937-423-3516. If you have any questions about your rights as a research participant, contact the office for the advancement of research and scholarship at OARS; by phone: 513-529-3600 or email: humansubjects@miamioh.edu.

This research is being overseen by WCG IRB. An IRB is a group of people who perform independent review of research studies. You may talk to them at 855-818-2289 or clientcare@wcgclinical.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

What Else Do I Need To Know?
I am required by federal law to provide you with a copy of this informed consent form.

You have the right to withdraw from the study at any time.

This research study has received a Certificate of Confidentiality from the government which will help protect the privacy of research subjects. The certificate protects against the involuntary release of information about you collected during the course of this research. The researchers involved in this study cannot be forced to disclose any information collected in this study in any legal proceedings.

However, you may choose to voluntarily disclose the protected information, and this certificate does not prohibit such voluntary disclosure. Furthermore, the parties listed in the Confidentiality / Authorization section of this consent form may review our records under limited circumstances and this certificate does not prohibit such disclosure.

Research Participant Statement and Signature
I understand that my participation in this research study is entirely voluntary. I may refuse to participate without penalty or loss of benefits. I may also stop participating at any time without penalty or loss of benefits.

_____ Date_____
Signature of person consenting to take part in the study

_____ Date_____
Printed name of person consenting to take part in the study

_____ Date_____
Signature of person consenting to take part in the study

_____ Date_____
Name of person providing information to the participant

_____
I have received a copy of this consent form to take home with me.