Study title: Effects of virtual reality on cardiorespiratory fitness test results

IRB approval number: 2130870

Document date: 2/21/2024

Research informed Consent Document

Effects of virtual reality on cardiorespiratory fitness test results

Principal Investigator: …….	**Principal Investigator telephone number (available 24/7 and for emergencies):** (650) 477-7746
Sub Investigator(s): N/A	**Faculty Advisor:** N/A
Sponsor: N/A	**Other Study Contact Numbers**

Key Information Section
You may be eligible to take part in this research study because you are a student at AU or are a member of the local community. Taking part in this study is completely voluntary. If you are a student of the researcher or study staff, your choice to participate has no bearing on your performance in any classes (no extra credit, point deductions, etc.) and will not influence your standing as a student. This form contains information that will help you decide whether to take part. All of this information is important, but here are some key important points to keep in mind: • It is completely up to you whether you take part in this study.   ○ Even if you decide to join the study, you are free to leave at any time if you change your mind. • This is research; social behavioral researchers do research to learn about many different things. • Any data collected will be saved in a secure location only accessible to the researcher for three years after the study is finished. The purpose of this study is to see if completing a maximal exercise test of increasing intensity with a virtual reality (VR) device changes your aerobic capacity and cardiorespiratory function. The expected duration of the study is less than 2 hours total, spread out over three visits to the Exercise Physiology Laboratory at the Christenberry Fieldhouse. Some possible risks of participation in this study are the same that you would have during a vigorous exercise session. These include soreness and injury in your muscles, shortness of breath, and mild dehydration.

You are being asked to take part in this research study about how virtual reality use affects aerobic capacity and cardiorespiratory function during a maximal exercise test as a normal/healthy adult volunteer.

The purpose of this document is to:

- Explain your rights and responsibilities
- Explain the purpose of the study
- Describe what will happen if you decide to take part in this study
- Explain the potential risks and benefits of taking part in the study

Participation in research studies is voluntary. Please read this consent form carefully and take your time making your decision. As the study staff discusses this consent form with you, please ask them to explain any words or information that you do not clearly understand.
Please tell the study staff if you are taking part in another study.

Why is this study being done?

Use of VR devices has been shown to make exercise more enjoyable and tolerable, and this may improve how much exercise you can complete (your aerobic capacity) and also how efficient your body uses oxygen. However, no study has been completed to determine if this is true. The purpose of this study is to see how completing a maximal exercise test with a VR device changes your cardiorespiratory capacity and functioning. There will be up to 30 participants enrolled at Augusta University with a total of 30 at all sites.

How long will I be in this study?

Your active participation in this study is expected to take less than 2 hours spread out over three visits.
You can choose not to be in the study or stop participating at any time without penalty or loss of any rights or benefits you are entitled to. Please talk to the study staff first before you stop participating in the study.

What will happen to me in the study?

If you agree to be a part of this research study and meet all of the requirements (no health issues as identified by the Physical Activity Readiness Questionnaire (PAR-Q), aged 18 or older, and not a pregnant woman), you will be asked to visit the Exercise Physiology Laboratory at Augusta University on three occasions. You will have to abstain from alcohol and strenuous exercise for the 24 hours before each visit to the lab and get at least 6 hours of sleep in the night before each visit.

Why am I not eligible to participate if I am pregnant?

Being a part of this study while pregnant may expose the unborn child to significant risks, some of which may be currently unforeseeable. Therefore, pregnant women will be excluded from the study. If you are a woman of childbearing potential, a pregnancy test will be done and it must be negative before you can continue in this study.
If sexually active, you must agree to use appropriate contraceptive measures for the duration of the study and for (specify if applicable) months afterward. Medically acceptable contraceptives include:

1. surgical sterilization (such as a tubal ligation or hysterectomy),
2. approved hormonal contraceptives (such as birth control pills, patches, implants or injections),
3. barrier methods (such as a condom or diaphragm) used with a spermicide, or
4. an intrauterine device (IUD).

If you do become pregnant during this study, please inform the study staff immediately.

Day 1

Once you arrive at the laboratory, you will first complete the PAR-Q form, a survey asking about how you prefer to exercise (the PRETIE-Q), and also a pregnancy test if you are a woman. Your height, weight, age, body composition (percent body fat), and ethnicity will also be recorded, and you will be asked to put on a heart rate monitor belt at chest level in the nearest unoccupied bathroom.
If you are eligible to participate, then the investigator will discuss with you the tests that you will be asked to perform today to familiarize you with the procedure. The PI will explain to you the questionnaires that you will be asked to answer during and after exercise, as well as the procedure for the exercise test. You will have a demonstration of how to use the exercise and virtual reality equipment before using it yourself for a brief warm-up and practice exercise test.

Days 2 and 3

These two visits will each consist of one maximal exercise test on the stationary bike. The exercise test itself will be the same on both visits, except the virtual environment will be different. The test on one day will be completed in a VR environment and the test on the other day will be completed with no virtual environment (a control condition as would normally be completed in a gym, for example).
After arriving to the lab on each day, you will be asked to sit on the exercise bike that will be used for the exercise test. The investigator will help you adjust the seat and handlebars for maximum comfort and safety. While you are on the exercise bike, you will breathe through a device that will measure your respiratory gases (oxygen and carbon dioxide). Your heart rate and respiration rate will be monitored and you will periodically be asked to give a subjective rating of your perceived exertion (how hard you feel that you are working) and your affective valence (how you feel in general).

The exercise test will start, when you are ready, with a very light warm-up and then gradually increase in difficulty every minute. The exercise test will continue until you are unable or unwilling to continue. Then you will complete a cool-down at a low intensity. Once you complete the maximal exercise test on Visit 2, you can plan the day and time for Visit 3 which will be at least 1 week after Visit 2. Your participation will then be complete for that visit.
Once you have complete both Visits 2 and 3, you will be done with the entire study.

What are the risks of being in this study?

As a result of your participation in this study, you may have the following side effects and/or discomforts from completing the exercise test:

- There is a risk of experiencing muscle pain or discomfort during the exercise test. A gradual warm-up and proper adjustment of the exercise equipment will help reduce this risk.
- You will experience some muscle fatigue and thirst that you would expect to experience during an intense workout. Water will be provided for you to sip before and after each exercise test.
- You may experience some muscle soreness in the 24 hours following each exercise test. A gradual cool-down at the end of the test will help alleviate this.
- There is a small likelihood that you will experience lightheadedness as a result of the exercise. You will be able to decrease the intensity or cease exercise at any time. Should you feel lightheaded, the investigator will be nearby to ensure that you do not lose your balance.
- You may feel a loss of balance when first using the VR headset since you cannot see your immediate physical surroundings. Gradual familiarization with the VR headset on Day 1 and the use of spotters during exercise will lower the risk of falling off of the equipment.

There may be more risks that are not known or not expected.
The study staff will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

Will I benefit from this study?

You may benefit from this study by learning your $\dot{V}$ O2peak and ventilatory threshold values. The tests to determine these values is expensive, and the results may help you prepare a fitness program or exercise prescription for yourself. The study results may benefit others in the future.

Who will see my study information?

Study team members will be able to see your study information. Your records may also be reviewed in order to meet federal or state regulations. Reviewers may include the Augusta University Institutional Review Board (the committee who oversees safety of volunteers in research studies), institutional officials, and outside agencies.

How will you keep my study information confidential?

Study records that identify you will be kept confidential except as required by law. You will not be identified in study records or publications disclosed outside Augusta University. Identifiable information will be removed when recording and analyzing data and you will be assigned a code instead, known only to the researcher.

What will happen to my identifiable private information/biospecimens once collected?

Your information or biospecimens collected as a part of this research, even if identifiers are removed, will not be used or distributed for future research studies.

What are my costs (what will it cost me) for taking part in the study?

It will not cost you anything to take part in the study other than basic expenses like transportation.

Will I be paid for participation in this study?

You will not be paid for taking part in this study.

Who can answer my questions about this study?

You can ask questions about this study at any time. Please contact the study staff listed on page 1 of this document if you have questions about:

- Study procedures
- Reporting an illness, injury or other problem
- Leaving the study before it is finished
- Expressing a concern about the study
- Any other questions you may have about the study

Who can I contact to discuss my rights, problems, concerns, questions, or complaints I have as a study participant?

Contact the Augusta University Institutional Review Board at (706) 721-1483.

Could there be any harm to me if I decide to stop participating in the study before it's finished?

If you decide to withdraw from the study before it is finished, there will not be any harm to you.

Can I be removed from the study?

Yes, you may be removed from the study if:

- You are not eligible to take part in the study
- You do not follow the instructions of the study staff
- You are experiencing any adverse health effects during the exercise test, such as chest pain, balance issues, or breathing irregularities, which make your participation unsafe

STATEMENT OF CONSENT

I have read this form and the information in it was explained to me. My taking part in the study is voluntary. All of my questions were answered. I will receive a copy of this form for my records. I agree to take part in this study. **I am not giving up my legal rights by signing this form.**

_____

Participant's Name (print)

_____ _____

Participant's Signature Date /Time (00:00)

INVESTIGATOR STATEMENT

I acknowledge that I have discussed the above study with this participant and answered all of his/her questions. They have voluntarily agreed to participate. I have documented this action in the participant's medical record source documents or research chart source documents, as applicable. A copy of this signed document will be placed in the participant's medical record or research chart, as applicable. A copy of this document will be given to the participant or the participant's legally authorized representative.

_____

Printed name of Investigator obtaining consent

_____ _____

Signature of Investigator obtaining consent Date /Time (00:00)