Title: Feasibility of Aerobic Exercise for Recovery from Work-related Concussion

NCT Number: NCT06263179

Document Date: 01/26/2024

Adult Consent to Participate in a Research Study

Title of research study: ***Feasibility of Aerobic Exercise for Recovery from Work-related Concussion***

Version Date: ***1/26/2024***

Investigator: **Jacob I. McPherson, DPT, PhD; Christopher Stavisky, OTR/L, PhD**

Key Information: The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

You are being invited to take part in a research study because you have been diagnosed with a concussion occurring within a work-related setting.

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.

Why is this research being done?

There is a lot of research on how to treat people with sport-related concussion. There has not been a lot of research on the treatment of injured workers with concussion. We have developed an exercise program for people with sport-related concussion. We believe that this program may be helpful for injured workers with concussion too. We want to learn if this program will be useful for other people with concussions.

How long will the research last and what will I need to do?

We expect that you will be in this research study for up to 6 weeks.

You will be asked to complete questionnaires, perform a supervised treadmill walking test, and complete an exercise program 4-5 days per week (20 minutes per day). Following each of your weekly clinic visits, you will check-in with our research team. After 6 weeks, or when your physician decides you have recovered from your concussion, you will complete some questionnaires and perform another treadmill walking test.

More detailed information about the study procedures can be found under ***"What happens if I say yes, I want to be in this research?"***

Is there any way being in this study could be bad for me?

Aerobic exercise has many positive health benefits. Individuals may experience some muscle soreness or fatigue which can be normal when adapting to a new exercise regimen.

More detailed information about the risks of this study can be found under ***"Is there any way being in this study could be bad for me? (Detailed Risks)"***

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include faster recovery from your concussion. Additionally, the information we gather from your participation will help us to optimize our program so that we can apply it to a larger population.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You may choose not to enroll in this study.

Your alternative to participating in this research study is to not participate.

Detailed Information: The following is more detailed information about this study in addition to the information listed above.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team (Dr. McPherson) at jim6@buffalo.edu. You may also contact the research participant advocate at 716-888-4845 or researchadvocate@buffalo.edu.

This research has been reviewed and approved by an Institutional Review Board ("IRB"). An IRB is a committee that provides ethical and regulatory oversight of research that involves human subjects. You may talk to them at (716) 888-4888 or email ub-irb@buffalo.edu if:

- You have questions about your rights as a participant in this research
- 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 want to get information or provide input about this research.

How many people will be studied?

We expect about 40 people here will be in this research study.

What happens if I say yes, I want to be in this research?

If you agree to participate in the study, you will be asked to perform questionnaires asking about your symptoms and mental health during your recovery. Then you will be asked to complete a walking test while we measure your heartrate. Based on your performance on the walking test we will provide a customized exercise program which you will perform 4-5 days per week for 20 minutes. This initial visit will take about 45-60 minutes. When exercising at home, you will measure your heartrate using a device that we provide.

Each week you will see your physician as part of your normal clinical care. After these visits, our research team will check in with you to address any questions or concerns. These visits will take 10-15 minutes or less and will occur in the same facility as your medical visits.

At the end of the study (6 weeks, or when your physician decides you have recovered from your concussion), you will perform some questionnaires about your symptoms and mental health during your recovery and repeat the treadmill exercise test. This visit will take 30-40 minutes.

Data will be kept in the office of Dr. McPherson. The limited dataset will be kept in the same office or within a secure cloud storage drive (e.g., UB Box). These will be stored for 10 years or until all related projects have been completed. Dr. McPherson and the research team highlighted in this document will have access.

If you elect not to participate within this study, your clinical management (i.e. visits with your physician) will not be impacted.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible to perform your prescribed exercise program 4-5 days per week while wearing the provided heartrate monitoring device. You will also be asked to follow-up with our team weekly after each of your physician visits.

What happens if I say yes, but I change my mind later?

You can leave the research at any time it will not be held against you.

If you decide to leave the research, contact the investigator so that the investigator can collect the heartrate device and cancel any remaining follow-up visits with the research team. If you stop being in the research, already collected data will not be removed from the study database.

Is there any way being in this study could be bad for me? (Detailed Risks)

- Physical risks – mild muscle soreness, mild and temporary increase in concussion-related symptoms
- Psychological risks- no known psychological risks
- Privacy risks- no known privacy risks
- Loss of confidentiality – There is a small chance that someone who is not authorized could see your private study information. We are taking steps so that does not happen. More information can be found in ***"What happens to the information collected for the research?"***
- Legal risks- no known legal risks
- Social risks- no known social risks
- Economic risks- no known economic risks

In addition to these risks, this research may hurt you in ways that are unknown. These may be a minor inconvenience or may be so severe as to cause death.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical or education records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization.

Your data will be retained after the study for future research. Data will be maintaining on a secure database with access provided only to our research team.

If information that identifies you is removed from your study information, it could be used for future research studies or given to other researchers without your additional consent.

Federal law provides additional protections of your medical records and related health information. These are described in the HIPAA section of this document.

A description of this clinical trial will be 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 person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include not returning for medical follow-up

appointments, lack of adherence to the exercise program, or the report of increased symptoms during exercise deemed excessive.

What else do I need to know?

Who is paying for this research?

This study is funded by The National Center for Advancing Translational Sciences of the National Institutes of Health under award number UL1TR001412 to the Clinical Translational Science Institute at the University at Buffalo

What medical costs am I responsible for paying?

The sponsor of this study will cover the tests or procedures required by the research study that would not otherwise be part of your standard care. The tests or procedures that would be provided to any patient with your condition, regardless of whether he/she was participating in the research study, are considered standard care and will be billed to you or your private or public health insurance company. You will still be responsible for the cost of your usual ongoing medical care, including deductibles and co-payments. If you have any questions about what expenses are covered by the sponsor and what expenses are the responsibility of you or your health insurance provider, please contact a member of the study staff and/or your health insurance provider.

You and your private or public health insurance company will not be charged for any of the tests or procedures done for this study.

Who will pay for my medical care if participating in this research harms me?

It is important that you tell your study doctor if you feel that taking part in this study has injured you or caused you to become ill.

You will receive medical treatment if you are injured or become ill as a result of this study. Your doctor will explain the treatment options to you and tell you where you can get treatment.

The University at Buffalo makes no commitment to provide free medical care or payment for any unfavorable outcomes that result from your participation in this research. Medical services will be billed at the usual charge and will be your responsibility or that of your third-party payer but you are not precluded from seeking to collect compensation for injury related to malpractice, fault, or blame on the part of those involved in the research including The University at Buffalo.

Will I get paid for my participation in this research?

If you agree to take part in this research study, we will pay you $30 at your initial meeting and each at subsequent meeting with the research team for your time and effort. If you complete each follow-up meeting you will be paid $100 at the conclusion of your last meeting with the research team. In total, you will be paid between $130-$250. All payments will be made using preloaded debit cards. If you receive a single gift card deposit of $100 or greater (this does not include U.S. Bank Prepaid Debit Cards), you will be asked to complete an IRS Form W-9. This form will be held confidentially by the research team and those responsible for administering research funds.

What are my alternatives to participating in this research study?

Instead of being in this research study, your choices may include not participating in this study. There are no known risks or possible benefits of not participating.

What will happen to my information and samples?

Your information (both identifiable and de-identified) may be used to create products or to deliver services, including some that may be sold and/or make money for others. If this happens, there are no plans to tell you, or to pay you, or to give any compensation to you or your family.

HIPAA: Authorization for the Use and Disclosure of Identifiable Health Information for Research Purposes

This section describes information about you and about your health that will be obtained by the researchers when you participate in the research study. By signing this form you are agreeing to permit the researchers and/or other parties (described in detail below) to have access to this information and to use or disclose it for the purposes of the research described in this document. If there are any parts of this form that you do not understand, please be sure to ask us for further clarification.

A. What individually identifiable health information will be collected about you as part of this research study?

___x__ Information from your full medical records: clinical history, exam findings, and if you've recovered from your concussion documented by your managing physician at the concussion center.

B. Who is authorized to create or provide this information for research use?

__X___ UBMD Clinical Practice Plan(s) (identify): Orthopaedics and Sports Medicine
__X___ Principal Investigator or designee

C. Who is authorized to receive the information from the information providers identified in (B)?

__√__ Principal Investigator or designee

D. With whom may your protected health information be shared?

Your health information may be shared with others outside of the research group for purposes directly related to the conduct of this research study or as required by law, including but not limited to:

___X__ Clinical staff not involved in this research study who may become involved in your care if it is potentially relevant to your treatment

Your information may also be shared with individuals or entities responsible for general administration, oversight and compliance of research activities. Examples of this include the institution's Privacy and Security Officers or other internal oversight staff, Safety Monitoring Boards, an Institutional Review Board, The Research Foundation of the State University of New York, University at Buffalo Foundation Services, and accrediting bodies, or with certain government oversight agencies that have authority over the research including the Department of Health and Human Services (HHS), the Food and Drug Administration (FDA), the National Institutes of Health (NIH), and the Office of Human Research Protections (OHRP). Your information may also be shared with other entities as permitted or required by law. All reasonable efforts will be used to protect the confidentiality of your individually identifiable health information that may be shared with others as described above.

Although safeguards are in place to prevent accidental disclosure of your information beyond the purposes described above, the information disclosed through this authorization is no longer protected by HIPAA. There is the potential for this information to be re-disclosed by the recipient(s). After such a disclosure, the information may no longer be protected by the terms of this authorization against further re-disclosure.

E. How long are the information providers listed in (B) authorized to provide your information for this research project?

__X___ b. This authorization will expire at the end of the research study. After that time, this authorization may not be used to acquire additional information about you.

__X___ d. Your protected health information will go into a database that will be maintained indefinitely. Any future study using this information that falls outside the scope of this current study will be required to follow guidelines designed to govern access to that information and to protect the privacy of that information.

F. What are your rights after signing this authorization?

You have the right to revoke this authorization at any time. If you withdraw your authorization, no additional efforts to collect individually identifiable health information about you will be made. You should know, however, that protected health information acquired using this authorization prior to its withdrawal may continue to be used to the extent that the investigator(s) have already relied on your permission to conduct the research. If you chose to withdraw this authorization, you must do so in writing to the following individual(s):

Jacob I McPherson DPT, PhD
534 Kimball Tower
Buffalo, NY 14214

If you send us a request to withdraw your authorization, we will forward that request to the institutions we have shared it with in order to collect your individually identifiable health information.

G. What will happen if you decide not to sign this authorization?

Refusing to sign this authorization will not affect the present or future care you receive at this institution and will not cause any penalty or loss of benefits to which you are otherwise entitled. If you decide not to sign this authorization, you will not be able to participate in the research study.

Signature Block for Capable Adult

Your signature documents your permission to take part in this research. By signing this form you are not waiving any of your legal rights, including the right to seek compensation for injury related to negligence or misconduct of those involved in the research.

Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	