RESEARCH PARTICIPANT INFORMATION AND CONSENT FORM

STUDY TITLE: Virtual Immersive Gaming to Optimize Recovery in Low Back Pain (VIGOR)

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SPONSOR: The National Institute of Health

NOTE: In this consent form, "you" always refers to the research participant.

ABOUT THIS CONSENT FORM

You are being invited to participate in a research study. **It is important that you carefully think about whether being in this study is right for you and your situation.**

This consent form is meant to assist you in thinking about whether or not you want to be in this study. **Please ask the investigator or the study staff to explain any information in this consent document that is not clear to you.** You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

Your participation is voluntary. You may decide to not participate in this study. If you do participate, you may withdraw from the study at any time. Your decision not to take part or to withdraw will involve no penalty or loss of benefits to which you are otherwise entitled.

AN OVERVIEW OF THE STUDY AND KEY INFORMATION

Purpose of the research

The purpose of this study is to measure the effects of an interactive, whole-body video game on movement behaviour in people with low back pain. You will be shown a video clip of an individual playing this game to better understand the experiment. This study will consist of approximately 230 participants. Participants in this study will complete 18 sessions of video game play over 9 weeks. The game will be a little more challenging each week, but you should only perform at a level that you are comfortable with. Participation in this study is voluntary, and the refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. Over the course of the study, you may discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled. Any significant new findings developed during the course of the research, which may relate to your willingness to continue participation, will be provided to you in a timely matter.

Procedures to be followed

Each session will require approximately one hour in the laboratory. During this study, you are free to use any treatment, including medication, which you would normally take; however, you

will be asked to report any use of medication. First, we will need to determine that you qualify for our study. To be able to participate, you must be 18-60 years of age, have a history of low back pain ongoing for at least half the days in the last 6 months, have no vision impairments that restrict video game play, no history of seizures or significant motion sickness, and not have any health conditions that might restrict your movement or preclude your safe participation in the study (e.g., Osteoarthritis, Rheumatoid Arthritis, Stroke, or head injury with residual spasticity or weakness). To determine your eligibility, you will need to complete a series of surveys and a screening assessment conducted by a clinician. If you are eligible for the study, you will be given an activity monitor to wear and then be scheduled for the gameplay sessions. Prior to your first gameplay session, we will provide you with a rationale for the intervention, during which time we will explain the interaction between biological and psychological factors in pain and disability, and how our intervention is designed to improve spine motion and reduce disability. Then you will be assigned randomly to either the treatment group or the sham treatment group. The study procedures below are the same for both the treatment and the sham treatment group. The difference will be in how the virtual reality game is designed to encourage lower back movement.

Activity Monitor: You will be given an activity monitor to wear on your non-dominant hand for 1 week. We will provide a postage-paid envelope for you to return the activity monitor at the end of the week. You will be asked to wear the monitor at the following points during the study: 1) from the initial screening exam to the first gameplay session, 2) immediately following the last gameplay session until the 1 week follow up, and 3) 1 week following the 6, 12, 24, and 48 follow-up assessments.

Game: You will play a virtual reality game for 9 weeks. This will include 3 sessions/week for the first 3 weeks, 2 sessions/ week for the next 3 weeks, and 1 session/week for the last 3 weeks. After we attach sensors that track your body movements, you will play a video game for approximately 20 minutes. The sensors will be attached with Velcro straps to your back, arms, and legs.

Reaching Tasks: You will complete a reaching task at the initial session, at the beginning of every week of gameplay, and at each follow-up visit. During this task you will be asked to reach for virtual targets placed at different heights.

Questionnaires:
You will complete questionnaires about your back pain, how the back-pain limits you, and your moods. These questionnaires are completed at the baseline visit (visit 0) and the follow up visits (visits 20-24). Every visit you will be asked to rate your current level of pain, the last day you experienced pain, and how much pain you experienced in the last week. You will also be asked to report what medications you used and any changes in your health, to closely monitor how the study might be affecting you.

Follow-up assessment: After you complete the 9 weeks of virtual dodgeball, we will ask you to return to the lab after 1, 6, 12, 24, 48 weeks. During these visits, you will answer questions

about your back and perform the same reaching task described above.

Exclusion criteria
You will not be eligible to participate in the study if you have a history of spinal surgery, certain medical symptoms or impairments, are pregnant, or are involved in legal proceedings related to your back pain. You will also not be eligible if you have a history of alcohol or other substance abuse or have elevated levels of depression symptoms.

Duration of participation
Your participation in the study will consist of 23 laboratory visits over 57 weeks. Each visit will last approximately 1-hour.

If you decide not to enter this study, you can receive the usual care that you would receive even if you were not in the study. This includes therapy or medication recommended by your doctor. The study staff will discuss these options with you. You do not have to participate in this study to be treated for low back pain.

You have the option to take a paper survey instead of an electronic one. Ask the study staff if you would like a paper survey.

There are both risks and benefits of participating in research studies. We want you to know about a few key risks right now. We will give you more information in the "WHAT RISKS AND DISCOMFORTS CAN I EXPECT FROM BEING IN THE STUDY?" section.

Most Common Risks and Discomforts	Benefits to You and Others
1. There is a risk that immersive virtual reality games may not be as good as the usual approach for low back pain. 2. There is also a risk that you could have problems because of doing immersive virtual reality games. Below are some of the most common risks and discomforts: • Playing the game will require gradually increasing amounts of lower back movement, which could potentially aggravate back pain symptoms. • Similar to doing any new exercise, you may experience pain or injury to the muscles and joints in your arms and legs	There is no guarantee that you will receive any benefits from being in this study. However possible benefits include relief of low back pain. We hope the information learned from this study will provide more information about movement coordination in low back pain.

• The sensors used to measure movement may cause irritation; however, this risk is minimized using hypoallergenic foam wrap and tape to attach the sensors and we have had no prior report of irritation • It's also possible you could feel nauseated from being in the virtual reality environment, but this is minimized by having precise synchronization of motion of the headset and the graphics. • There is a risk of falling as vision of the real world is totally blocked by the virtual reality headset. Risk of falling is minimized by having you first stand in the testing area and then put on the headset. None of the virtual reality activities require steps to be taken. Additionally, the testing area is an open space with a level surface, minimizing the risk of injury if you do fall. Two research staff members will conduct every appointment which allows one to run the software and the other to monitor you and keep you safe. 3. Participation in research might involve some loss of privacy. There is a small risk that someone outside the research study could see and misuse information about you. 4. There may be some risks to you that the investigators do not know about yet, so we will let you know of any new findings.	

In general, we will not give you any individual results from the study. If we find something of medical importance to you, we will inform you, although we expect that this will be a very rare occurrence. Once the study has been completed, we will send you a summary of all of the results of the study and what they mean.

Please read, or have someone read to you, the rest of this document. If there is anything you don't understand, be sure to ask the study staff.

WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to test the safety, tolerability, and effectiveness of virtual reality games when used to treat low back pain. You are being asked to participate in this study because you have been diagnosed with low back pain and may meet the study entry requirements.

WHAT WILL HAPPEN IF I PARTICIPATE IN THE STUDY?

At your first study visit (Visit 1), you will be interviewed by the study staff and fill out questionnaires about your low back pain to see if you are eligible to be in the study. Additionally, a clinician will do a physical exam to decide whether you are fit to take part in the study.

Also, you will be given an activity monitor to wear on your non-dominant wrist for 1 week. We will provide a postage-paid envelope for you to return the activity monitor at the end of the week.

If you qualify for the study, you will be randomly assigned (like the flip of a coin) to be in/receive either immersive or neutral virtual reality games. You have an equal chance of being assigned to any one of the groups.

Neither you nor the study staff will know which group you are in. This information is available to the investigator if needed in an emergency. This is called blinding, and it is done so that a fair evaluation of results may be made.

Visit 2-19 will take place 1-2 weeks after Visit 1. At this visit you come to the motor control lab where you will be asked to play a virtual reality game for 9 weeks. This will include 3 sessions/week for the first 3 weeks, 2 sessions/ week for the next 3 weeks, and 1 session/week for the last 3 weeks. After we attach sensors that track your body movements, you will play a video game for approximately 20 minutes. The sensors will be attached with Velcro straps to your back, arms, and legs.

The first session of every week will start with a reaching task at the initial session. During this task you will be asked to reach for virtual targets placed at different heights.
You will also complete questionnaires about your low back pain at that moment and fill out medication and treatment logs.

Visits 20-24 through will be follow-up assessments, scheduled at 1, 6, 12, 24, 48 weeks after the gaming stops. At each visit, you will be asked to answer questions about your back and perform the reaching task described above. Also the activity monitor will be work following these assessments just like after the initial assessment.

WHAT ALTERNATIVES ARE AVAILABLE?

If you decide not to enter this study, you can receive the usual care that you would receive even if you were not in the study. This includes therapy or medication recommended by your doctor. The study staff will discuss these options with you. You do not have to participate in this study to be treated for low back pain.

WHAT ARE THE BENEFITS OF BEING IN THE STUDY?

There is no guarantee that you will receive any benefits from being in this study. We hope the information learned from this study will provide more information about the effect of immersive virtual reality games on low back pain.

WHAT RISKS AND DISCOMFORTS COULD I EXPERIENCE FROM BEING IN THE STUDY?

Your condition may not get better or may become worse while you are in this study.

Possible Risks Associated with immersive virtual reality training

Frequent (Between a 10-50% chance that this will happen)

- Aggravate back pain symptoms
- Fatigue
- Pain or injury to the muscles and joints in your arms and legs

Occasional (Between a 1-10% chance that this will happen)

- skin irritation by the attachment of the sensors (Velcro)
- Nausea/motion sickness

Rare (Less than a 1% chance that this will happen)

- Falls due to vision obstruction

Non-Physical Risks

Participation in research might involve some loss of privacy. There is a small risk that someone outside the research study could see and misuse information about you.

Questionnaires may contain questions that are sensitive in nature. You may refuse to answer any question that makes you feel uncomfortable.

This study will ask you questions about personal topics that might be embarrassing to talk about and that could affect your family relationships if this information were to become known outside of the study.

You may learn things about yourself that you did not know before and that could affect how you think about yourself.

Unknown or Unforeseeable Risks

The researchers will let you know about any significant new findings (such as additional risks or discomforts) that might make you change your mind about participating in the study.

Virtual Immersive Gaming to Optimize Recovery in Low Back Pain involves risks that are currently unknown or unforeseeable.

WHAT ARE THE COSTS?

The sponsor is paying for everything in this study. You will not be charged for any study visits, tests, or procedures.

WILL I BE PAID TO PARTICIPATE IN THE STUDY?

You will be paid up to $770 in cash for 23 laboratory sessions over 57 weeks. This includes a payment of up to $15 per session of virtual gameplay depending on performance. In addition, you will receive $100 for each of the follow-up visits at 1, 6, 12, 24, and 48 weeks after gameplay. This compensation is to offset the time and inconvenience that study participation imposes.

Total payments within one calendar year that exceed $600 will require the University to report these payments annually to the IRS and you. This may require you to claim the compensation you receive for participation in this study as taxable income. VCU is required by federal law to collect your social security number. Your social security number will be kept confidential and will only be used to process payment.

WHAT HAPPENS IF I AM INJURED OR BECOME SICK BECAUSE I TOOK PART IN THE STUDY?

If you are injured by, or become ill, from participating in this study, please contact your study doctor immediately. Medical treatment is available at the Virginia Commonwealth University Health System (VCU Health System). Your study doctor will arrange for short-term emergency care at the VCU Health System or for a referral if it is needed.

Fees for such treatment may be billed to you or to appropriate third party insurance. Your health insurance company may or may not pay for treatment of injuries or illness as a result of your participation in this study. To help avoid research-related injury or illness, it is very important to follow all study directions.

CAN I STOP BEING IN THE STUDY?

You can stop being in this research study at any time. Leaving the study will not affect your medical care, employment status, or academic standing at VCU or VCU Health. Tell the study staff if you are thinking about stopping or decide to stop.

If you leave the study before the final regularly scheduled visit, 48 week follow-up at appointment, payments will only be made up until the last visit you attended.

Your participation in this study may be stopped at any time by the investigator without your consent. The reasons might include:

- the investigator thinks it necessary for your health or safety
- you are found to not be eligible for the study

- the sponsor has stopped the study
- you have not followed study instructions
- administrative reasons require your withdrawal

HOW WILL INFORMATION ABOUT ME BE PROTECTED?

VCU and the VCU Health System have established secure research databases and computer systems to store information and to help with monitoring and oversight of research. Your information may be kept in these databases but are only accessible to individuals working on this study or authorized individuals who have access for specific research related tasks.

Identifiable information in these databases are not released outside VCU unless stated in this consent or required by law. Although results of this research may be presented at meetings or in publications, identifiable personal information about participants will not be disclosed.

Personal information about you might be shared with or copied by authorized representatives from the following organizations for the purposes of managing, monitoring and overseeing this study:

- The study Sponsor, representatives of the sponsor and other collaborating organizations
- Representatives of VCU and the VCU Health System
- Officials of the Department of Health and Human Services

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 Website will include a summary of the results. You can search this Web site at any time.

If you tell us that you may hurt yourself or someone else, the law says that we must let people in authority know.

STORAGE FOR FUTURE RESEARCH STUDIES

To advance science, it is helpful for researchers to share information. They do this by putting data or samples into one or more scientific databases (called registries or repositories), where it is stored along with information from other studies. Researchers can then study the information in other ways and combine information from many studies to learn even more about health and disease.

As part of this study, we would like to keep the information that you provide, along with your name, phone number, email, and mailing address in a registry to be available for other research studies in the future. Your information would be stored at VCU by Dr. James Thomas and could be used for other research studies about any topic. Your data will be protected, but there is always a possibility that information could be accessed by individuals without authorization. There is no limit on the length of time we will store your information.

In the future, if you decide that you don't want to be part of this registry, you can request that your information be removed and destroyed by contacting Dr. James Thomas. However, information that has already been shared with other researchers will continue to be used.

Future Research Studies
In the future, identifiers might be removed from the information you provide in this study, and after that removal, the information/samples could be used for other research studies by this study team or another researcher without asking you for additional consent.

Certificate of Confidentiality
To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a participant in the research project under the following circumstances: If you tell us that you may hurt yourself or someone else, the law says that we must let people in authority know.

WHO SHOULD I CONTACT IF I HAVE QUESTIONS ABOUT THE STUDY?

If you have any questions, complaints, or concerns about your participation in this research, contact:

James Thomas, DPT, Ph.D.

Physical Therapy / Occupational Therapy

College of Health Professions

James Thomas, Ph.D.

900 E. Leigh St, 4th Floor

Richmond, VA 23298

jthomas32@vcu.edu

The researcher/study staff named above is the best person(s) to call for questions about your participation in this study.

If you have general questions about your rights as a participant in this or any other research, you may contact:

Virginia Commonwealth University Office of Research
800 East Leigh Street, Suite 3000
Box 980568
Richmond, VA 23298
Telephone: (804) 827-2157

Contact this number to ask general questions, to obtain information or offer input, and to express concerns or complaints about research. You may also call this number if you cannot reach the research team or if you wish to talk to someone else. General information about participation in research studies can also be found at http://www.research.vcu.edu/irb/volunteers.htm.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

STATEMENT OF CONSENT

I have been provided with an opportunity to read this consent form carefully. All of the questions that I wish to raise concerning this study have been answered. By signing this consent form, I have not waived any of the legal rights or benefits to which I otherwise would be entitled. My signature indicates that I freely consent to participate in this research study. I will receive a copy of the consent form for my records.

Signature Block for Enrolling Adult Participants	
_____ Adult Participant Name (Printed)	
_____ Adult Participant's Signature	_____ Date
_____ Name of Person Conducting Consent Discussion (Printed)	
_____ Signature of Person Conducting Consent Discussion	_____ Date
_____ Principal Investigator Signature (if different from above)	_____ Date