TUFTS GRADUATE SCHOOL OF ARTS AND SCIENCES
TUFTS UNIVERSITY
Department of Occupational Therapy

INFORMED CONSENT TO PARTICIPATE IN RESEARCH

The Feasibility of Immersive Virtual Reality as a treatment for Chronic Back Pain

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Study team telephone number: (617) 627-5562

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?
We invite you to take part in a research study because you have chronic back/neck pain.

What should I know about a research study?
- Someone will explain this research study to you.
- Please also read all of the following information carefully.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can decide 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. Do not sign unless you understand the information in it and have had your questions answered to your satisfaction.
- If you sign this form and decide to take part in this research study, keep a copy of the signed form for your records. It has information, including important names and telephone numbers, that you may wish to refer to.

Why is this research being done?
The purpose of this research study is to see if Virtual Reality can improve symptoms for people with chronic pain.

How long will the research last and what will I need to do?
We expect that you will be in this research study from 2 to 3 weeks depending upon how long it takes for you to schedule and attend the Immersive Virtual Reality (IVR) experience visits after completing the weeklong assessment.

Visit 1: Visit 1 will take place remotely. You will complete informed consent. You will complete surveys on symptoms. This visit will take about1 hour to complete.

Between Visit 1 and 2 you will complete brief surveys about your symptoms 3 times daily for one week using your cell phone or tablet. These surveys should take about 5 minutes to complete.

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Visits 2 and 3 will take place in-person at the Musculoskeletal Health & Ergonomics (MH&E) lab at 574 Boston Ave in Medford (Tufts University)

Visit 2: You will complete either a 10 minute or 20 minute IVR experience. Before and after each IVR experience you will complete surveys on symptoms and go through tests to measure your sensory responses. This visit will take about an hour to complete.

After Visit 2 you will complete brief surveys about your symptoms 3 times daily for at least 3 days using your cell phone or tablet. These surveys should take about 5 minutes to complete.

Visit 3: If you completed the 10 minute IVR in Visit 2 you will complete the 20 minute version in Visit 3 and vice versa if you completed the 20 minute version previously. Before and after the IVR experience you will complete surveys on symptoms and go through tests to measure your sensory responses. This visit will take about an hour to complete.

More detailed information about the study procedures can be found under the **"Procedures to be Followed"** section.

Is there any way being in this study could be bad for me?
Some people experience motion sickness or seizures during Virtual Reality. If you experience motion sickness or seizures, we will stop the session.

Some people may find the content of the Virtual Reality upsetting because it triggers fears (such as heights). We will have several different types of experiences for you to choose from, so that you can select content that you will enjoy.

More detailed information about the risks of this study can be found under the **"Risks"** section.

Will being in this study help me in any way?
There will be no long term benefit to taking part in this Virtual Reality (VR) study. Your symptoms during, immediately after research, and, possibly, for several hours later may be less. It is unlikely that participation in this study will get rid of your symptoms, or that the reduction in the symptoms will last more than a few hours after the intervention. If Virtual Reality turns out to be a good method to lessen symptoms associated with chronic pain, we plan to develop treatments that can be used by people with chronic pain.

What happens if I do not want to be in this research?
Participation in research is completely voluntary. You can decide to participate or not to participate.

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.

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PURPOSE OF STUDY
People with chronic back pain often find it hard to reduce their pain and other symptoms, such as tiredness and changes in their sensory perceptions, and that these symptoms make it hard for them to do things. Sometime drugs can help the symptoms, but many of these drugs are not safe or effective in the long term. Finding other, non-drug, methods to get rid of pain is a priority. We believe that Virtual Reality can help some people's symptoms become better.

If Virtual Reality helps reduce the symptoms of chronic pain in this research study, we plan to develop a Virtual Reality treatment which will benefit others with chronic pain.

This research study will take place at Tufts University Musculoskeletal Health Lab, located at 574 Boston Avenue.

This research study is being funded the 2021 Tufts Clinical and Translational Science Institute (CTSI) Pilot Studies Grant.

We expect up to 30 people will be enrolled in this study in order to have 20 complete the study.

The Virtual Reality system used in this study is used by game players to play virtual reality games. It has not been tested or approved by the FDA as a medical device.

If you want your own Virtual Reality system, you can purchase this system online or in many stores. You will not be given one to take home.

PROCEDURES TO BE FOLLOWED
All procedures will be performed by trained research personnel.

Prior to Visit 1 we will send you the informed consent forms to review.

Visit 1: The study Principal Investigator (PI) will explain the study to you and answer your questions. If you decide to take part, you will read and sign this consent form. You will then either scan and email, fax, or mail the consent forms back to the PI.

We will ask you some questions about you medical history and how you perceive pain. You will complete some surveys on your current level of symptoms (pain and tiredness) and your mood. You will also go through two tests to measure sensory response. One sensory test will involve mechanical pressure applied to your shoulder and thumb. The other will use a pin-like object to lightly prick your finger 10 times without breaking the skin. In each test you will rate the pain or other things you feel on a 0-100 rating scale.

We will help you upload an app on your phone or tablet so that you can answer daily surveys during the next week. Visit 1 will take about 1 hour to complete.

Between Visit 1 and Visit 2 you will complete the surveys on pain, tiredness and mood daily. You will receive a notification through your cell phone or tablet ("ping") at 3 random times throughout the day. We would like you to complete the surveys within 20-minutes of the "ping."

Visit 2: Approximately a week after Visit 1 you will complete Visit 2. First you will complete the same surveys and sensory testing you did in Visit 1. You will also go through two tests to measure sensory response. One sensory test will involve mechanical pressure applied to your shoulder and thumb. The other will use a pin-like object to lightly prick your finger 10 times without breaking the skin. In each test you will rate the pain or other things you feel on a 0-100 rating scale.

Then you will take part in either a 10-minute or 20-minute IVR session. During the Virtual Reality Sessions you will wear a virtual reality headset and operate controllers to interact with the environment. You will get to choose your Virtual Reality experience at each session. It can be the same or a different one:

- Ocean Rift: Exploring underwater habitats filled with a variety of sea creatures
- Catch & Release: Go rowing on a lake and catch virtual fish
- Waltz of the Wizard: Mixing potions and exploring a wizard's laboratory
- Robot Job Simulator: Performing jobs for robots who have a rather odd idea of what human jobs are like

After each session you will again complete the surveys and sensory testing. You will also report on whether you feel any motion sickness and about your experiences during the Virtual Reality. Visit 2 will take about 2 hours to complete.

After Visit 2 you will continue to answer surveys on your cell phone until you come in for Visit 3 which will be scheduled at least 3 days later.

Visit 3: If you completed the 10 minute IVR in Visit 2 you will complete the 20 minute version in Visit 3 and if you completed the 20 minute version you will take part in the 10 minute version. Before and after the IVR experience you will complete surveys on symptoms and go through tests to measure your sensory responses. This visit will take about an hour to complete.

After Visit 3 you will continue to answer surveys on your cell phone for 3 more days.

Whether you do the 10 minute session first or the 20 minute session first will be chosen by chance.

As a safety precaution, prior to each in-person visit, you will be asked to complete the Research Participant COVID-19 screening questionnaire, which will be provided to you by the research staff. When you arrive for each in-person visit, this COVID-19 screening questionnaire will be repeated as well.

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

WITHDRAWAL

If you are eligible to participate and decide to be in the study, the Principal Investigator may still choose to stop your participation in this study if she thinks it is in your best medical interest. Other reasons that your participation might be stopped is if you miss too many surveys during the week between the visits. You may also be withdrawn if motion sickness or seizures prevent you from being able to take part in the Virtual Reality Sessions. You can also leave the research at any time it will not be held against you. If you refuse to participate in the study or stop being in this study, it will not affect your care or treatment outside this study, payment for your health care, or your health care benefits.

If you withdraw or are withdrawn from the study, any data collected from you before your withdrawal will still be used for the study.

RISKS

There are several possible risks or discomforts associated with the research.

1) Simulator sickness: Some people experience symptoms of motion sickness (such as fatigue, headache, eye strain, difficulty focusing, increased saliva in mouth, sweating, or nausea) during Virtual Reality experiences. This risk is small. If you experience simulator sickness you can stop the session.

2) Seizures: Although we will not have people who have a history of epilepsy or seizures take part in the study, some people may experience severe dizziness, seizures, eye or muscle twitching or blackouts triggered by light flashes or patterns during the VR. This risk is very small. If you experience any of these symptoms we will immediately stop the virtual reality experience. We will recommend that you see a doctor and you will be discontinued from the study.

3) Tripping: The Virtual Reality headset will prevent you from seeing what is around you. You may trip or knock into items of furniture. This risk is very small. We will closely watch you during all Virtual Reality experiences to prevent you from moving into anything. If you have trouble with balance, you can do the Virtual Reality experience seated. In addition, the Virtual Reality system allows us to set up a digital safe area which will be free of hazards. If you get too close to the edges of that safe area you will see a blue grid which will let you know not to move any further in that direction.

4) Emotional response to VR experience: Virtual Reality provides very real experiences. You may come across a situation that you find upsetting. This risk is small. You will choose your own Virtual Reality experiences from a list which will provide information about the experience. Some examples of experiences include traveling under the sea, going fishing, or making potions in a wizard's castle. You can choose one that is unlikely to be upsetting. If an upsetting situation occurs, you can stop the VR experience.

5) Uncomfortable headset: Some people find the Virtual Reality headset uncomfortable. This risk is small. We will work with you to adjust the headset to fit as comfortably as possible.

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6) Contamination: The headset will be used by many people during the study. You may be exposed to pink eye or other skin diseases. This risk if very small. We will not allow any people with known contagious diseases to use the headset and we will disinfect the device after every use. We will provide disposable skin protectors during use.

7) Increased Pain: The sensory tests may cause increased pain. This risk is common. However, the pain will usually decrease and go away within minutes. We will stop testing when you report that they have reached pressure/pain tolerance.

8) Bruising: There is a chance that you will experience mild, brief bruising when we apply mechanical pressure during sensory testing. This risk is quite small. We will stop testing when you report that they have reached pressure/pain tolerance.

9) Stress: You may feel stressed if you receive the "ping" to respond to the surveys and are unable to do so because you are doing something you can't stop (such as driving). This risk is moderate. To reduce this risk we will give you a 20-minute window in which to respond to the "ping." This way you will have time to reach a natural stopping point in your task. It is also okay to miss a survey if you are unable to stop what you are doing. You can miss up to 10 surveys and still receive compensation.

10) Unintentional loss of confidentiality: While every effort will be made to make sure that your participation in this study is known only by the researchers, it is possible that people other than those on the research team may learn about your participation or see your data. This risk is small. Research activities will take place in a private area. Your data will be kept in locked files accessible only to research personnel.

In addition to these, this research may have risks or discomforts that are unknown at this time. These may be minor inconveniences or more severe. If in the future we become aware of any additional risks or discomforts that may affect you, we will tell you.

RESEARCH RELATED INJURY
Emergency medical treatment will be given to you if you are hurt or get sick as a direct result of being in this research study. You or your insurance carrier will be required to pay for any such medical care. Any needed medical care is available at the usual cost. All needed facilities, emergency treatment, and professional services are available to you, just as they are to the general public. The institution will not pay for your treatment if you become ill or injured as part of this study.

COSTS
You and/or your insurance provider will not have to pay for exams, tests, and procedures done for research purposes only or that are covered by the study. These include:

- The questionnaires,self-report information, and sensory testing provided before and after the Virtual Reality/Computer Games sessions
- Setting up and taking part in the Virtual Reality/Computer Game sessions.

PAYMENT

You will receive up to a total of $80 for participating in this study. You do not have to complete the entire study to be paid. You will receive $10 for completing Visit 1; $20 each for completing Visit 2 and 3 ($40 in total); and $15 for completing most surveys between Visits ($30 in total). The payment will be in the form of an Amazon Gift card given at the end of the study.

We will also provide up to a total of $40 in reimbursement for travel costs, such as mileage, taxi/ Uber, or public transportation. You will be asked to provide receipts to serve as documentation of these travel expenses and the reimbursement will be provided to you up to 1 month after study completion.

PRIVACY AND CONFIDENTIALITY

We will take measures to protect your privacy and confidentiality. All study procedures will take place in a private room. We will only report the results of the study as a group; we will store all data and recordings in locked files or protected electronic databases; and we will ensure that only members of the research team have access to these files. Your name and any other information that could identify you will be saved separate from the data and you will be assigned a unique ID number for all data. The results of the study may be published, but all the information will be done in aggregate (i.e., as a group not by individual name).

If you decide to take part in this research study, your personal information will not be given to anyone unless we receive your permission in writing. It will only be given if the law requires it. We will make every effort to keep your information private, but it cannot be completely guaranteed. Certain government agencies Office for Human Research Protections, Department of Health and Human Services, Food and Drug Administration, and The Institutional Review Board of Tufts Medical Center and Tufts University Health Sciences may check records that identify you. This might include your medical or research records and the informed consent form you signed. The records of this study might also be reviewed to make sure all rules and guidelines were followed.

We may publish the results of this research. However, we will keep your name and other identifying information confidential.
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.

WHOM TO CONTACT

If you have questions, concerns, or complaints, or think the research has hurt you, talk to Dr. Baker or the research team at (412) 328-8622.

If you have questions about your rights as a research study subject, call the Tufts Medical Center and Tufts University Health Sciences Institutional Review Board (IRB) at (617) 636-7512. The IRB is a group of doctors, nurses, and non-medical people who review human research studies for safety and protection of people who take part in the studies. Federal law requires the IRB to review and approve any research study involving humans. This must be done before the study can begin. The study is also reviewed on a regular basis while it is in progress. This research

study has been reviewed and approved by the IRB of Tufts Medical Center and Tufts University Health Sciences.

Documentation of Consent

I have been given a copy of this form. I have read it, or it has been read to me. I understand the information and have had my questions answered to my satisfaction. I agree to take part in this study.

I understand that I will be informed of any new findings developed during the course of this research study that may affect my willingness to stay in this research study.

_____	_____	_____
Participant's Signature	Date	Time (required for all clinical trials at Tufts Medical Center)

I have fully explained to _____ the nature and purpose of the above-described study and the risks that are involved in its performance. I have answered all questions to the best of my ability.

_____	_____
Date	Principal Investigator or Representative's Signature

- ☐ Please check this box if you consent to being video recorded during the research sessions so that we may conduct quality control checks. Only members of the research team will see these recordings.

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