UNIVERSITY of MARYLAND
THE FOUNDING CAMPUS

RESEARCH CONSENT FORM

Virtual Reality electronic form – Home trial

Protocol Title: Pain Perception in the Brain

Study No.: HP-00069094

Principal Investigator:
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(cell)

Sponsor: MPowering the State grant

CONCISE SUMMARY:

- This is a research study and your participation is voluntary.
- The purpose of this study is to investigate the effect of virtual reality educational modules on pain experiences at home, as compared to an audio intervention and no-intervention.
- This study will be completed over one month. During week one, the study team will educate you on how to daily record your pain via an online link. From week 2-4, we will assign you several different interventions: virtual reality, audio, or no-intervention. You will take part in the study in the comfort of your home. Through the mail, you will receive a virtual reality headset and audio player. Upon receiving the devices, we will set up a zoom meeting to explain what will happen in the upcoming weeks and how to use the tools. The research team will also be in close communication with you throughout the process via phone calls, text reminders, emails, and zoom to monitor your progress during this time.
- The greatest risks of this study are a sense of being in a closed environment and a transitory nausea while using the virtual reality device. Each device will be disinfected before being mailed to you using the appropriate protocol for COVID-19 virus.
- You will benefit by participating in this study. You will receive the VR that has been shown to reduce chronic pain. Your participation will also result in gaining knowledge that can improve pain management.
- You can receive up to a total value of $220 in the form of an electronic gift card when you return the device.
- Your alternative to participation is to not take part in this study.

PURPOSE OF STUDY

The purpose of this research study is to better understand the pain perception and how it can be influenced by using virtual reality tool in a home setting. In this study, we will investigate the effect of pain-specific virtual reality (VR) modules on the physical and psychological responses to pain, as compared to an audio intervention and no-intervention. This study can provide valuable information for a long-term study in the future. You may be eligible to participate in the future studies. If you agree to be re-contacted to take part in other studies, we will contact you via email and/or by phone. Also, if you are interested in checking on the status of the study, you are welcome to contact us for any updates.

We are enrolling 54 participants diagnosed with Temporal Mandibular Disorder or TMD in this study, which will take place at your home with help from the Colloca Lab staff, University of Maryland School of Nursing (UMSON).

PROCEDURES

The study procedures will be completed over one month, during which you will be in constant communication with a member of the research team. You will be assigned to the three different interventions each week: virtual reality, audio, or no-intervention. The intervention each should take approximately 20 mins each day. You will engage in your assigned intervention for that week using the provided device at home. A daily link will be sent via phone or email to document your pain diary. Following the intervention, you will return the devices through the mail using the return label provided.

<u>At home</u>

1. *Assigned intervention of the week (~15 minutes)* –During the month, you will be assigned to one intervention among virtual reality module, audio content, and no intervention at each virtual visit. Virtual calls will be set to provide you all the instructions to follow the protocol requirements. You will receive instructions about the intervention, and get the hands-on experience by going through each module of the intervention that you are assigned to for that week. After working with the device, both the experimenter and you will *electronically* sign the form indicating that the device is functioning properly.

- ✓ *Virtual Reality intervention*: you will complete the scheduled modules five times a week. This VR is assisting users in using immersive reality to reduce pain, learning cognitive and behavior self-coping skills and retraining the pain pathways. There are several sessions, which will be delivered using an all-in-one head-mounted display. Each session varies in duration approximately from 3 to 15 minutes.
- ✓ *Audio intervention:* you will complete the scheduled modules 5 times a week during the study. Each session varies in duration approximately from 3 to 15 minutes.

- ✓ *No-intervention*: you will continue with your normal daily activity without any added interventions.

You will receive all three interventions above through the mail. The intervention will be assigned to you in a random order generated by computer.

2. *Pain-related Questionnaires (~10 minutes)* – After the intervention, you will virtually answer pain-related questions via a computer or phone. You will also receive via email a link to complete a series of questionnaires that measure various aspects of pain including your psychological traits. The experimenter will assist you via a virtual meeting if you have any questions about these questionnaires.

3. We may need to re-contact you for additional data collection related to this project (e.g. completion of additional questionnaires) and we may email / mail you the required data collection tools.

_____ I consent to be re-contacted for additional data collection
_____ I do not consent to be re-contacted for additional data collection

VR Device Agreement

Given that we may need to return the VR device to the company from which we rented it, we request you to return the device at the end of the one-month session as instructed. Please read and sign the part below.
I acknowledge that while I am participating in this study, I will take proper care of the VR device that I am entrusted with. I further understand that upon completion of the intervention, I will return the device.

_____
Participant name (Please print)

_____
Participant signature and Date

VR Device Maintenance

We have confirmed that our research team members checked the VR device for its function prior to your use. The device is functioning properly and it is in a good shape.

_____

Participant signature and Date

In Case of Malfunctioning of VR Device

If the device does not work as intended, please inform us immediately. We will assist you with troubleshooting the source of problem referencing the manual over the phone or through zoom. Each participant will also have access to the same manual along with the device. If the problem persist, the research team will contact the representative of applied VR to further explore the issue. If the malfunction of the device is unresolvable, we will invite you to bring the device back to us, and provide you with a replacement. We will ensure the replacement is functioning properly by going through the intervention with you.

- ✓ Contact information:

Dr. Luana Colloca, the principal investigator at 301-364-8089 (cell).

Also, you can email the staff at the Colloca Lab: nrscollocalab@umaryland.edu

You can also contact Dr. Yang Wang at 410-706-5975 (office) or 571-508-9487 (cell).

VR Device Replacement

If your VR device were to be accidently damaged and subsequently not working correctly, we will ask you to mail the device back to us at the Colloca Lab. We will hopefully, provide you with a replacement device depending on availability. We ask that you mail the device back to the lab for a replacement within 3-5 business days to ensure seamless continuation in the study. The goal is to have you use the VR device continually over the full course of one week, so missing one day of use lessens your ability to truly benefit from the VR intervention. We may be forced to exclude you from the study if you are not able to comply with this timeline. We are only able to replace a malfunctioning device once.

POTENTIAL RISKS/DISCOMFORTS

1. *Loss of Confidentiality:* There is always a risk for a loss of confidentiality when participating in a research study. However, every step to ensure the confidentiality and anonymity of your

results and identity will be taken. Steps will include using only an assigned code number for your personally identifiable information, including your contact information and name, on any documentation from this study. Moreover, electronic data will be password-protected and all paper copies of data will be stored in a locked cabinet. You will not be given the results of your questionnaires, because this information is used for experimental and not clinical purposes. You have the right to access and disclose your records

2. *Breach of Privacy:* There is a minimal risk for a breach of privacy. However, to minimize this, you will be accommodated in a secured room to be screened and to give you a private space to read the consent and HIPAA forms, and complete the questionnaires. Only designated research personnel will have access to the rooms for where you will be participating in research activities. We will make every effort to minimize you interacting with those who are not a part of this research study while you are participating.

3. *Risks Associated with Heat Stimulations:* The heat stimulations delivered on your forearm last less than 15 seconds, and they may produce an uncomfortable and unpleasant sensation. Your skin may become red as result of repetitive stimulations. You will actively contribute to choosing a level of painful stimulation acceptable and tolerable for you. We will never use a higher intensity than the one selected. Please remember that you can stop the experiment at any time and withdraw from the study.

4. *Risks Associated with Psychological Questionnaires:* You may experience some discomfort while answering questions on the psychological questionnaires. However, you are not required to answer any questions that make you feel uncomfortable.

5. *Risks Associated with the immersive VR*. Immersion in the VR may cause of a sense of being in a closed environment and very rarely nausea. These effects are uncommon, only transitory, and they disappear once the VR is removed. At home, consider removing the VR goggles if you experience any nausea and inform the Principal Investigator and research team quickly in case you experience any discomfort.

6. *Unknown Risks:* There may be unknown risks or discomforts involved with participating in this study that are not yet known. Research study staff will update you in a timely manner if any information that may affect your health, welfare, and decision to remain in the study surfaces.

POTENTIAL BENEFITS

You will benefit by participating in this study. You all will receive the VR that has been shown to reduce chronic pain.

ALTERNATIVES TO PARTICIPATION
Your alternative is to not take part. If you choose not to take part, your healthcare at the University of Maryland, Baltimore will not be affected.

COSTS TO PARTICIPANTS
Research-related injuries are seen as unforeseen and unlikely. However, if medical issues arise as a result of this study, we will provide you with assistance in finding medical care but costs incurred will be yours and/or your insurance company's responsibility.

PAYMENT TO PARTICIPANTS
Participants will receive a total value of $220, which will be processed at the end of the study participation. Participants who will complete part of the study will receive $100 for completion of three out of the four visits; $50 for completion of two out of the four visits; and $25 for completion of only one visit. At each visit, a participant will receive a payment checklist. The payment will be in a form of electronic gift card (e.g. Walmart, Amazon). Gift cards will be emailed to them. We will ask you to provide your name, address and social security number to process the payment. If you do not have a social security number because of your current visa status, your compensation will be provided in another form. At the end of the study following the intervention, we will provide the return label to mail the device back to us and submit the completed pain diary to receive the payment. The payment is contingent upon the completion of the intervention as indicated and the return of the device.

CONFIDENTIALITY AND ACCESS TO RECORDS
Only Dr. Luana Colloca and her trained and designated research personnel will have access to confidential information. All confidential information that includes personally identifiable information will be coded with a code number. The principle investigator will be the only individual with access to the key of the assigned code numbers. All confidential information will be locked in a cabinet in a secured location at the University of Maryland, School of Nursing. Your personally identifiable information will not be used for this study's analyses but it will be kept on file if federal agencies, such as the Intuitional Review Board (IRB), are mandated to review any information.
The data from the study may be published. However, all study records will be considered confidential, and all participants' names and personally identifiable information will not be used in reports or publications. People designated from the institutions where the study is being conducted and people from the sponsor will be allowed to inspect sections of your medical and research records related to the study. Everyone using study information will work to keep your personal information confidential. Your personal information will not be given out unless required by law. Efforts will be made to limit access to your personal information, including research study 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.

Those designated from the University of Maryland will be allowed examine certain research records of this study; however, anyone inspecting this information will do their best to keep this personal information confidential. Your personal information will not be released unless mandated by law.

RIGHT TO WITHDRAW

Your participation in this study is voluntary. You do not have to take part in this research study. You are free to withdraw your consent at any time. Refusal to take part or to stop taking part in the study will involve no penalty or loss of benefits to which you are otherwise entitled. If you decide to stop taking part, you have questions, concerns, or complaints, or if you need to report a medical injury related to the research, please contact the investigator Dr. Luana Colloca at 410706-8244 (office) or 301-364-8089 (cell). You can also contact Rachel Massalee (4438544103), Dr. Yang Wang at 410-706-5975 (office) or 571-508-9487 (cell). There are no adverse consequences (physical, social, economic, legal, or psychological) for deciding to withdraw from this research study. If you withdraw from this study, already collected data may not be removed from the study database. If you wish to withdraw from this study at any time, a written withdrawal request is required and should be sent to Dr. Luana Colloca at *colloca@umaryland.edu or* University of Maryland Baltimore School of Nursing, 655 W Lombard Street, Baltimore, MD, 21201. You will be informed of any findings in this study that may affect your willingness to continue participating. If you are an employee or student, your employment status or academic standing at UMB will not be affected by your participation or non-participation in this study.

CAN I BE REMOVED FROM THE RESEARCH?

The investigator, Dr. Luana Colloca, can remove you from the research study without your approval. Possible reasons for removal include incomplete data, and non-compliance with completing tasks. The entire study can be stopped at any time by the university, investigator, Institutional Review Board (IRB), or the facility where the study is conducted.

UNIVERSITY STATEMENT CONCERNING RESEARCH RISKS

The University is committed to providing participants in its research all rights due them under State and federal law. You give up none of your legal rights by signing this consent form or by participating in the research project. This research has been reviewed and approved by the Institutional Review Board (IRB). Please call the IRB if you have questions about your rights as a research participant.

The research described in this consent form has been classified as minimal risk by the IRB of the University of Maryland, Baltimore (UMB). The IRB is a group of scientists, physicians, experts, and other persons. The IRB's membership includes persons who are not affiliated with UMB and persons who do not conduct research projects. The IRB's decision that the research is minimal

risk does not mean that the research is risk-free. You are assuming risks of injury as a result of research participation, as discussed in the consent form.

If you are harmed as a result of the negligence of a researcher, you can make a claim for compensation. If you have questions, concerns, complaints, or believe you have been harmed through participation in this research study as a result of researcher negligence, you can contact members of the IRB or the staff of the Human Research Protections Office (HRPO) to ask questions, discuss problems or concerns, obtain information, or offer input about your rights as a research participant.

The contact information for the IRB and the HRPO is:

University of Maryland Baltimore
Human Research Protections Office
620 W. Lexington Street, Second Floor
Baltimore, MD 21201410-706-5037

Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a virtual copy of this signed consent form.

☐☐If you agree to participate in this study, please type your name and last name below.

_____
Participant's Signature

Date:_____

_____
Signature of Investigator or Designee Obtaining Consent

Date:_____

☐If we can contact you for future research studies, please type your name and last name below:

_____
Participant's Signature