Study title: Effects of Virtual Reality on Pain and Anxiety Using Validated Survey and Biodata Analyses

Study support provided by: Cedars-Sinai Medical Center

Cedars-Sinai Principal Investigator: Omer Liran, MD

Study contact phone number at Cedars-Sinai: (310) 423-3754

1. Key Information

We are asking for your consent to take part in this research study. This section provides key information about the study. The rest of this form has more detailed information.

- **Voluntary:** Taking part in this research study is your choice. You can also stop taking part at any time. You will not lose any services, benefits or rights you would normally have if you choose not to take part or stop taking part.

- **Purpose:** The purpose of this study is to assess the impact of virtual reality (VR) therapy on pain and anxiety in patients who are admitted in the hospital. We want to see if using VR therapy will improve pain management, offer additional pain relief, or be an effective alternative to traditional pain medication. We will also measure real-time clinical data during VR therapy, such as heart rate and pupil size.

- **Procedures:** The main things that will happen in this study are: 1-time use of a virtual reality headset. Using the headset will take about 15 minutes. You will also complete pre-use and post-use surveys. The surveys will be conducted using the study tablet.

- **Duration:** Taking part in this study will last about 0.5 hour.

- **Risks:** All research studies involve some risks. Risks or discomforts from this study may be: minor psychological distress from questionnaires regarding health and ~5% risk of “cybersickness,” presenting as short-term symptoms related to entering VR environments (vertigo, nausea, headache).

- **Benefits:** You are not likely to be helped from taking part in this research study. But the information learned from this study may help others in the future.

- **Alternatives:** You can choose not to take part. There may be other choices for you.

Please take time to read this entire form. You should ask questions before deciding whether to take part in this study. You can talk with family, friends and/or healthcare providers before you decide.

During the study, we may find out new information about this research study. We will tell you about any important changes or new findings that may impact whether you want to continue taking part in the study.

2. Purpose of the Study

We are doing this study to see if using an audiovisual headset helps to manage or improve pain and anxiety during your hospital stay. We want to know if the use of this tool can limit the extent to which pain and anxiety interferes with your daily life and if your psychological and physical distresses improve.

You are being asked to take part in this research study because you are admitted at Cedars-Sinai Medical Center (CSMC) and currently experiencing pain and/or anxiety.

The study will include up to 34 people in total.

3. Study Procedures

This section talks about what will happen in this study.

When you read this section, also read the flowchart of procedures. The flowchart is given with this consent form. The flowchart of procedures shows a timeline of the study. It shows which study procedures are research-related and which are standard of care (routine).

Research-related procedures are procedures done only for the research study. They would not be performed for your routine care outside of the study. **Standard of care (routine) procedures** would be performed as part of your routine care even if you did not take part in this study.

The procedures in this study are often part of routine care for a person with your condition. They are not experimental procedures. The procedures and their risks are research-related. This means they are being done only for research purposes. These common procedures and their risks should be the same as when performed outside this study.

Description of research procedures:

This is a research study that will require only a 1-time visit for VR therapy. Standard (routine) care will involve treatment as prescribed by your provider for your pain and/or anxiety condition. Your study participation will not dictate your standard treatment or care. This study will allow the researchers to learn whether the software programs are better, the same, or worse than the current standard of care. Audiovisual therapy has been used in several studies at Cedars-Sinai. The results of these studies have demonstrated the device to

be safe; less than 25% of patients who use the VR headset have minor, short-term side effects from the device.

You will be asked to use the VR unit 1-time for about 15 minutes, as well as to complete two surveys, before and after the dedicated VR therapy. The surveys will ask questions about your pain and anxiety levels, and other VR related questions including system usability, simulator sickness, and immersive tendencies. The VR headset will also collect information of your heart rate and pupil size throughout the therapy session. The biodata will be collected using sensors and will not cause any harm or pain during the process.

In the event that any of the study equipment are lost or damaged, you will not be held responsible for the lost or damaged study equipment. However, all study equipment, whether damaged or intact, must be returned at the end of the session.

As part of this study, we will be collecting prescription data from the Cedars-Sinai Medical Center. Our study will request permission to obtain prescription data to assess the pain and/or anxiety medication use during your stay at CSMC. The data will be collected from 90 days before enrollment until 90 days after completion of the study. The data will be requested from CURES between 8/1/2022 to 7/1/2023. As with all study data, this information will only be used for research purposes and will comply with all requirements of the California Confidentiality of Medical Information Act and the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

- **Questionnaires:** You will be asked to complete a questionnaire. We will ask you questions to find out your pain and anxiety level pre- and post-VR session. We will also ask you questions about system usability, simulator sickness, and immersive tendencies post-VR session. We think it should take about 15 minutes to complete the questionnaire. Questionnaires will ask you to respond to sensitive questions about your current pain and anxiety level.

- **Medication Review:** We will ask you about your past and current medications. Talk with the study team about any non-study medications. Non-study medications include over-the-counter drugs, supplements or vitamins.

- **Demographic Information:** We will ask you about demographics, which may include your age, gender identity, sexual orientation, race and ethnicity.

- **Medical History Review:** We will ask you about your medical and surgical history.

How long will you be in the study?
We think you will be in this study for/until about 30 minutes. This includes the 15-minute VR session and 15-minute questionnaire.

4. Possible Risks and Discomforts of the Research Procedures

This section talks about the possible risks and/or discomforts of the study procedures.

- **VR Intervention:** While using the VR headset, you may experience discomfort with the virtual environment, including temporary headache, vertigo, or nausea. These should be short-term and should stop soon after the headset is removed.

- **Questionnaires:** Some questions may make you feel uncomfortable or embarrassed. The questionnaire will be labeled with a unique study number. This will link your identity so that only the research team can recognize you.

- **Medication Review:** This does not have any physical risks.

- **Demographic Information:** This does not have any physical risks.

- **Medical History Review:** This does not have any physical risks.

- **Other risks**: Even though we will protect your privacy as much as possible, there is a very small chance that the data could be identified as yours. The risk of this happening is very small, but may increase in the future as technology changes. Research using data from this study may lead to new tests, drugs, or devices with commercial value. You will not receive any payment for any product developed from research using your samples and data. If you do not want your data and samples used for other research, you should not participate in this study.

5. Benefits From Taking Part in the Study

Taking part in this research study may or may not have direct medical benefit to you. The possible benefits of taking part in the research study are pain and/or anxiety relief, greater satisfaction with care, and overall improvements in physical and mental health. No benefit is guaranteed. It is possible that your condition may stay the same or even get worse.

We hope the information learned from this research study will benefit other individuals with acute or semi-acute pain and anxiety in the future by helping us to learn how we can reduce pain and anxiety, while minimizing the use of opioids and anxiolytics.

6. Reasons Participation May Be Stopped

Your participation in this study may be stopped at any time. The researcher or the sponsor can stop your participation without your consent for any reason. Some reasons for stopping your participation include:

- The study is stopped or suspended.
- Funding for the study is reduced, stopped or withdrawn.
- It is in your best interest.
- You do not follow the study procedures.
- You do not consent to continue in the study after being told of changes in the research that may affect you.

7. Choosing to Take Part and Other Options

Taking part in research is voluntary. You have the right to choose not to take part. You can stop taking part in this research study at any time. You can do this without any penalty or loss of benefits to which you would be entitled outside of the study. Your choice not to take part or to stop taking part will not affect the care you get at Cedars-Sinai.

If you decide to stop taking part, we will keep any data collected on you up to the time you choose to stop. Also, if you stop taking part, the study team may ask you whether you want to give further data from your routine medical care.

8. Confidentiality Protections

We will do our best to keep your personal information collected as part of this study private. But we cannot guarantee total privacy. We may put a copy of your research consent and authorization forms in your electronic medical record at Cedars-Sinai. Your personal information may be given out if required by law. Publications or presentations about this study at scientific meetings will not use your name and other identifiable personal information.

Organizations that may look at and/or copy your medical records for research oversight, quality assurance and data analysis include:

- Accrediting agencies (agencies that grant official certifications to educational institutions)
- Government and regulatory groups, such as the Food and Drug Administration (FDA) and Office for Human Research Protections (OHRP)
- The Institutional Review Board (IRB), which reviews research to protect people taking part in studies
- Safety monitors, which monitor the safety of individual participants and the overall safety of the study
- Companies that sponsor the study and authorized representatives of the sponsor

Attached to this consent form is an Authorization Form. It outlines with whom your information may be shared for this research and under what circumstances.

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

We might share your information and/or research samples collected in this study. It might be shared with other researchers at Cedars-Sinai, other academic institutions or third-party commercial entities for future research without additional informed consent from you.

Information that identifies you will be removed and will not be shared with other researchers or anyone outside of Cedars-Sinai.

9. Research-Related Illness or Injury

We do not expect you will have any illness or injury from this research study. If you believe that you are ill or have been injured from this study, please contact the study team at the phone number listed on page 1 of this consent form.

10. Financial Considerations

Costs of Participation
You will not be billed or charged. The sponsor/study will cover the cost of all items, drugs and services, including standard of care procedures and the study drug/device. You and your insurance company will not be charged for your participation in this research study.

Compensation for Participating
You will not be financially compensated for participating in this study.

Financial Interest in the Research
The principal investigator and institution have no potential financial conflict of interest with this study.

11. Contact for Questions or Problems

Please contact the investigator for questions, problems or concerns about the research. Their contact information is on page 1 of this form.

You might have feedback, questions, problems, concerns or want to obtain more information about this study. If so, you can talk with someone who is not part of this study by contacting:

Cedars-Sinai Human Research Protection Program (HRPP)
Phone: 310-423-3783
Email: ResearchConcerns@cshs.org
Website: cedars-sinai.org/research/administration/office-of-research-compliance/review-board.html

The Cedars-Sinai HRPP protects the rights and welfare of research participants.

Experimental Subject's Bill of Rights

In accordance with California Health and Safety Code 24172, any person who is required to consent to participate as a subject in a research study involving a medical experiment or who is requested to consent on behalf of another has the right to:

1. Be informed of the nature and purpose of the experiment.

2. Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized.

3. Be given a description of any attendant discomforts and risks to the subject reasonably to be expected from the experiment.

4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.

5. Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.

6. Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.

7. Be given an opportunity to ask any questions concerning the experiment or the procedure involved.

8. Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation in the medical experiment without prejudice.

9. Be given a copy of any signed and dated written consent form used in relation to the experiment.

10. Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.

AUTHORIZATION FOR USE AND DISCLOSURE OF IDENTIFIABLE HEALTH INFORMATION FOR RESEARCH

1. USE AND DISCLOSURE OF HEALTH INFORMATION

If you agree to this Authorization, you give permission to the Sponsor, Principal Investigator, other investigators and their research team described in the Consent Form for Research ("Research Team") to use or disclose your identifiable health information ("private information") for the research study titled "Effects of Virtual Reality on Pain and Anxiety Using Validated Survey and Biodata Analyses" which is described in the Consent Form for Research ("Consent Form") to which this Authorization is attached. In particular, you authorize the research team acting under the direction of the Principal Investigator to review your medical records and collect your private information from the following sources:

☐ Laboratory tests
☐ Pathology reports
☐ Imaging reports (e.g., x-rays or scans)
☐ Photographs or videos of your image
☒ Doctor/clinic records
☒ Hospital/medical records
☐ Mental health records
☐ Billing records

☐ Demographics, which may include age, gender identity, race, ethnicity, and/or sexual orientation

☒ Other tests or other types of medical information: survey responses.

2. WHO WILL HAVE ACCESS TO YOUR PRIVATE INFORMATION?

Your private information will be used by and/or shared with the Research Team.

In addition to the research team, if applicable, the following parties may receive your private information and inspect your records:

- The reviewing Institutional Review Boards and Cedars-Sinai offices with authority to oversee research compliance.
- U.S. government agencies, such as the Food and Drug Administration and the Department of Health and Human Services.
- Researchers at other organizations who are participating in this research study.
- The Study Sponsor, its business partners, and Cedars-Sinai's business partners for matters related to research study oversight, conduct of the research, data analysis, use of research results in product development, and payment or reimbursement.

- Representatives from regulatory agencies in other countries may join in the review of your research records, including research-related medical reports and information, with the Sponsor and/or the FDA.

Cedars-Sinai takes steps to protect your private information when sharing it with the recipients described above. Though these steps and applicable law are meant to protect your private information, there is a risk that a recipient could share your private information without your permission.

3. WHEN WILL MY AUTHORIZATION EXPIRE?

By signing this document, you authorize the use and sharing of your private information until the end of the research study and any related optional sub-study you choose to participate in.

4. REVOKING AUTHORIZATION

You may change your mind and revoke (take back) this Authorization at any time. Even if you revoke this Authorization, the research team may still use or disclose private information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. To revoke this Authorization, you must write to the Principal Investigator of the research study by writing to the Office of Research Compliance and Quality Improvement, 6500 Wilshire Blvd, Suite 1800, Los Angeles, Calif. 90048 and/or emailing to ResearchConcerns@cshs.org.

5. NOTICE OF RIGHTS AND OTHER INFORMATION

You do not have to agree to this Authorization, but if you do not agree, you may not participate in the research study. Cedars-Sinai may not condition (withhold or refuse) the provision of standard of care treatment for you on whether you agree to this Authorization.

If you agree to this Authorization, please sign on the appropriate signature line on the Signature Page. You will receive a copy of this Authorization.

Signature Page

Consent Form for Research and Authorization for Use and Disclosure of Identifiable Health Information (Research)

If you agree to take part in this study, you should sign and date on the signature lines below. You will be given a signed and dated copy of this form. This includes the "Experimental Subject's Bill of Rights," "Authorization for Use and Disclosure of Identifiable Health Information (Research)" and any optional sub-study descriptions, when applicable.

Signature by the Participant
Main Research Study: *I agree to take part in the research study described to me during the informed consent process and described in this informed consent form. My questions have been answered to my satisfaction.*

You will be given a signed and dated copy of this form.

Participant name (please print)	Signature	Date

Authorization for Use and Disclosure of Identifiable Health Information (Research): *I hereby agree that my identifiable health information may be used and/or disclosed in accordance with the "Authorization for Use and Disclosure of Identifiable Health Information (Research)."*

Participant name (please print)	Signature	Date

Signature by the Investigator
I attest that all the elements of informed consent described in this form have been discussed fully in non-technical terms with the participant. I further attest that all questions asked by the participant were answered to the best of my knowledge.

Investigator name (please print)	Signature	Date