UNIVERSITY OF CALIFORNIA, IRVINE
CONSENT TO ACT AS A HUMAN RESEARCH SUBJECT

The Effect of Virtual Reality on Pain and Patient Satisfaction in Adults Receiving Genicular Radiofrequency Ablation

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STUDY LOCATION: Gottschalk Medical Plaza

SUMMARY OF KEY INFORMATION:

The information provided in this box includes a brief yet complete summary of key information about the research, presented first as required by the federal regulations. Some sections that require additional information may be repeated later in this document.

Participation is Voluntary
You are being asked to participate in a research study. Participation is completely voluntary. Please read the information below and ask questions about anything that you do not understand. A researcher listed above will be available to answer your questions.

Study Purpose
The purpose of this research study is to investigate whether implementing Virtual Reality therapy during a genicular nerve radiofrequency ablation (GNRFA) procedure will provide better alleviation of pain and augmented satisfaction for patients. Virtual reality is a computer generated simulation of a life-like experience that usually serves people for entertainment and social interactive purposes in a simulated three-dimensional environment. Virtual reality therapy is when virtual reality is used in a clinical setting. Genicular nerve radiofrequency ablation is an option to treat knee pain without surgery. The genicular nerves are the nerves that feed into the knee. Radiofrequency ablation is a process by applying radiofrequency waves to the nerves that are carrying the painful impulses from the knee joint to reduce knee pain.

Study Procedures
This will be a randomized, non-blinded study comparing virtual reality use with standard of care to standard of care for genicular nerve radiofrequency ablation. GNRFA uses fluoroscopy guidance to introduce 3 needles at each of the three genicular nerves which transmit sensation from the knee joint. This is followed by testing for sensory response, followed by administration of local anesthetic (2% lidocaine) per standard-of-care, and then radiofrequency ablation. Radiofrequency ablation is a process by applying radiofrequency waves to the nerves that are carrying the painful impulses from the knee joint to reduce knee pain. We will request access to your medical record to review the following: prior knee RFA, prior virtual reality use, and demographics (age, gender). A survey will be

used to record the following before, during, and after your procedure: pain levels, duration of pain, anxiety levels, satisfaction with procedure, provider perception of pain, provider satisfaction, additional use of local anesthetic.

Expected Duration
Participation will last approximately 45 minutes and will include 1 visit. All study procedures will be completed on the day of your GNRFA procedure.

Risks of Participation
The more notable risks of participation include: unlikely adverse events associated with the application of VR technology, nausea using the VR technology. Also, should there be a breach in confidentiality of your data, there is a slight risk that your private medical information could be shared with individuals who are not members of the study team.

Benefits to Participants
If you are in the group that receives Virtual reality therapy and it proves to treat your condition more effectively with pain management and anxiety during your GNRFA procedure you may benefit from participating in the study, but this cannot be guaranteed.

Benefits to Others or Society
This study will help researchers learn more about virtual reality therapy for pain management in patients who receive GNRFAs and it is hoped that this information will help in the treatment of future patients with knee pain management.

Alternative Procedures or Treatments
If you decide not to participate, or if you withdraw from this study before it is completed, your other choices may include:
- Getting no treatment
- Getting standard treatment for your condition without being in a study.

WHY IS THIS RESEARCH STUDY BEING DONE?
The purpose of this research study is to test how well virtual reality therapy works for genicular radiofrequency ablation pain management using the investigational Soothe VR system.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
Approximately 60 participants will take part in the research at UCI.

AM I ELIGIBLE TO PARTICIPATE IN THIS STUDY?
Please note this may not be a complete list of eligibility criteria. We have included a few examples of study criteria to help you better understand how your eligibility in the study will be determined; your study team will go through the study eligibility criteria with you to verify if you qualify for participation in this study.

Inclusion Requirements
You can participate in this study if you:
- Are 18 years or older
- Are undergoing a genicular nerve radiofrequency ablation
- Patients who have previously received nerve blocks or radiofrequency ablation procedure

Exclusion Requirements
You cannot participate in this study if you:

- Requiring sedation during procedure
- Cognitive impairment or dementia
- History of recent stroke, epilepsy, psychosis, or claustrophobia
- Blindness or deafness
- Refusal to use the headset
- Isolation status for infection control
- Motion sickness or active nausea/vomit
- Are pregnant (Pregnancy testing Point of Care available for females of child bearing age)

HOW LONG WILL THE STUDY GO ON?
This study includes 1 visit and takes about 45 minutes over a period of 1 day.

WHAT PROCEDURES ARE INVOLVED WITH THIS STUDY?
Before you can participate in the main part of the study...
You will need to have "screening" exams, tests or procedures. The screening process helps the researchers decide if you meet the study requirements listed below. The screening procedures include: going through the inclusion and exclusion criteria. Checking for acceptance to use the headset, history of motion sickness, current nausea or vomit, and medical history.

During the main part of the study...
If the screening exams, tests and/or procedures show that you can continue to be in the study, and you choose to take part, then you will have the following procedures and tests done. The main study tests and procedures include…

1. Consent will be finalized on the day of procedure, and you will be enrolled in the study.
2. Medical record review will occur to determine outcomes such as: prior knee RFA, prior virtual reality use, and demographics (age, gender).
3. You will be randomized to virtual reality (VR) use or no virtual reality use using sealed envelopes. You will have an equal chance of being assigned to either group. Virtual reality is a computer generated simulation of a life-like experience that usually serves people for entertainment and social interactive purposes in a simulated three-dimensional environment. Virtual reality therapy is when virtual reality is used in a clinical setting.
4. Before the procedure, we will record your baseline pain, anxiety, prior VR use and VR opinion via survey.
5. Both the control (genicular radiofrequency ablation with no virtual reality) and intervention (genicular radiofrequency ablation with virtual reality) groups will receive the standard-of-care for genicular nerve radiofrequency ablation. The standard of care will be a uniform protocol agreed as consensus by practitioners as appropriate to perform a Genicular Nerve radiofrequency ablation (GNRFA). This standard-of-care includes the following guidelines:
    a. Genicular nerve radiofrequency ablation (GNRFA) is an option to treat knee pain without surgery. The genicular nerves are the nerves that feed into the knee. Radiofrequency ablation is a process by applying radiofrequency waves to the nerves that are carrying the painful impulses from the knee joint. GNRFA uses fluoroscopy guidance to introduce 3 needles at each of the three genicular nerves which transmit sensation from the knee joint. This is followed by testing for sensory response, followed by administration of local anesthetic (2% lidocaine) per standard-of-care, and then radiofrequency ablation. Fluoroscopy guidance provides high accuracy of localization at the procedure targets outside of the knee joint.
    b. Provider discretion is allowed to titrate additional 2% lidocaine local anesthetic in 1 mL additions to patient comfort levels. We will record if and how much additional local anesthetic is needed.
6. No changes in the genicular RFA procedure will be made from standard of care. Use of the virtual reality device will not affect the timing of the procedure. Regardless of the group the subject is

randomized in, the genicular RFA procedure will be done per standard of care. The procedure will take about 20 minutes.

7. The experimental group, however, will also be utilizing a virtual reality (VR) device during their procedure. The Soothe VR device has over 40 clinically researched modules to choose from with medically curated content. Subject may pick the environment of choice in a patient centric manner. The device is a headset with visual and audio components. The device will be fit and placed right before the procedure begins, and the subject will have time to choose their content.

***After you complete the main part of the study* and the procedure is completed…**

1. After the procedure is completed, a survey will be given to you determine the following outcomes: peak pain, duration of pain, patient anxiety, device satisfaction, and side effects.
2. The survey will also record Provider outcomes such as: perception of patient pain, device satisfaction, and the need for additional use of local anesthetic.

RETURN OF RESULTS

You will not be provided any research-related, clinically relevant information that may pertain to your health.

WHAT ARE THE POSSIBLE SIDE EFFECTS OR RISKS RELATED TO THE STUDY?

You may have side effects while on the study. Everyone taking part in the study will be watched carefully for any side effects. However, researchers don't know all the side effects that may happen. Side effects may be mild or very serious. The researchers may give you medicines to help lessen side effects. Many side effects go away soon after you stop using virtual reality therapy. In some rare cases, side effects can be serious, long lasting, or may never go away.

You should talk to the research team about any side effects you experience while taking part in the study.

Risks and side effects related to the Soothe VR include those which are:

Likely

- None reported

Less Likely

- Side effects associated with the application of VR technology, none reported thus far
- Nausea/vomiting associated with using VR technology
- Motion sickness, dizziness, eye strain, headaches, or other visual abnormalities associated with using VR technology
- Breach of confidentiality

Rare but serious

- No likely side effects known or reported to date
- Seizures or severe symptoms (eg: disorientation, nausea or drowsiness)

Randomization: You will be assigned to a study group by chance (like a coin flip) rather than by a medical decision made by the researchers. The treatment you receive may prove to be less effective or to have more side effects than the other study group, or than standard treatments available for your condition.

Unknown risks:

There may be risks related to the research that we don't know about yet. However, you will be informed of any additional risks to which you may be exposed, and any changes that are made to the study, as a result of any newly-identified risks.

WILL I BE PAID FOR TAKING PART IN THIS STUDY?

Compensation

You will not be compensated for your participation in this research study.

Reimbursement

You will not be reimbursed for any out of pocket expenses, such as parking or transportation fees.

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?

There is no cost to you or your insurer/third party payer for participation in this study. However, there may be out-of-pocket expenses such as parking and transportation fees.

WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THIS STUDY?

It is important that you promptly tell the researchers if you believe that you have been injured because of taking part in this study. You can tell the researcher in person or call him/her at the number listed at the top of this form.

If you are injured as a result of being in this study, UCI will provide necessary medical treatment. The costs of the treatment may be covered by the University of California or billed to you or your insurer just like other medical costs, depending on a number of factors. The University does not normally provide any other form of compensation for injury. For more information about this, you may call UCI Human Research Protections (949) 824-6068 or (949) 824-2125 or by e-mail at IRB@research.uci.edu

WHAT HAPPENS IF I WANT TO STOP TAKING PART IN THIS STUDY?

You are free to withdraw from this study at any time. **If you decide to withdraw from this study, you should notify the research team immediately**. The research team may also end your participation in this study if you do not follow instructions, miss scheduled visits, the study sponsor decides to stop the study or your safety and welfare are at risk.

If you experience any of the side effects listed above, if your health worsens, or if you are injured during the research, you may need to be withdrawn from the study, even if you would like to continue. The research team will make this decision and let you know if it is not possible for you to continue. The decision may be made to protect your safety and welfare, or because the research plan does not allow people who develop certain conditions to continue to participate.

If you withdraw or are removed from the study, the researcher may ask you to complete the patient survey.

If you elect to withdraw or are withdrawn from this research study, the researchers will discuss with you what they intend to do with your study data. Researchers may choose to analyze the study data already collected or they may choose to exclude your data from the analysis of study data and destroy it, as per your request

HOW WILL INFORMATION ABOUT ME AND MY PARTICIPATION BE KEPT?

Subject Identifiable Data

Identifiable information collected about you will be removed at the end of data collection.

Data Storage

Research data will be maintained in paper format in a secure location at UCI.

Research data will be stored electronically on a secure network in an encrypted file that is password protected, for research purposes only.

Data Retention
In accordance with UC Office of the President policy, information will be retained for 10 years after the end of the calendar year in which the research is completed.

WHO WILL HAVE ACCESS TO MY STUDY DATA?
The research team, authorized UCI personnel, and regulatory entities such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP), may have access to your study records to protect your safety and welfare.

While the research team will make every effort to keep your personal information confidential, it is possible that an unauthorized person might see it. We cannot guarantee total privacy.

Future Research Use
Researchers will use your information to conduct this study. Once the study is done using your information, we may share them with other researchers so they can use them for other studies in the future. We will not share your name or any other private identifiable information that would let the researchers know who you are. We will not ask you for additional permission to share this de-identified information.

WHO CAN ANSWER MY QUESTIONS ABOUT THE STUDY?
If you have any comments, concerns, or questions regarding the conduct of this research, please contact the research team listed at the top of this form.

A 24-hour number is also listed on the top of this form to report any health concerns or unanticipated problems you may experience after normal hours or on weekends.

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any suggestions, problems or concerns you may have about the study, please contact the UCI Institutional Review Board by phone, (949) 824-6068 or (949) 824-2125, by e-mail at IRB@research.uci.edu or at 160 Aldrich Hall, Irvine, CA 92697.

What is an IRB? An Institutional Review Board (IRB) is a committee made up of scientists and non-scientists. The IRB's role is to protect the rights and welfare of human subjects involved in research. The IRB also assures that the research complies with applicable regulations, laws, and institutional policies.

HOW DO I AGREE TO PARTICIPATE IN THIS STUDY?
You should not sign and date this consent form until all of your questions about this study have been answered by a member of the research team listed at the top of this form. You will be given a copy of this signed and dated consent form, and the attached "Experimental Subject's Bill of Rights" to keep.
Participation in this study is voluntary. You may refuse to answer any question or discontinue your involvement at any time without penalty or loss of benefits to which you might otherwise be entitled. Your decision will not affect your future relationship with UCI or your quality of care at the UCI Medical Center.

If, during the course of this study, significant new information becomes available that may relate to your willingness to continue to participate, this information will be provided to you by the research team listed at the top of the form.

Your signature below indicates you have read the information in this consent form and have had a chance to ask any questions you have about this study.

Note: If the research described in this form involves your protected health information (PHI), you will be asked to sign separate UC HIPAA Research Authorization form for the use of your PHI.

I agree to participate in the study.

_____ _____
Subject Signature **Date**

_____
Printed Name of Subject

_____ _____
Signature of Person Obtaining Informed Consent **Date**
(For research that is greater than minimal risk, this individual must be listed on Page 1 of this consent)

_____
Printed Name of Person Obtaining Informed Consent

A witness signature is required on this consent form only if: ***(Researchers: check which one applies)***

IMPORTANT! If no witness signature is required, this witness signature section of the consent form may be left blank.

☐ Consent is obtained from the subject via the Short Form process, as approved by the IRB.
☐ The subject has decision-making capacity, but cannot read, write, talk or is blind.
☐ The subject's guardian/legally authorized representative (LAR) cannot read, write, talk or is blind.
☐ The IRB specifically mandated a witness signature for this study (e.g., high risk and/or invasive research procedures).

For the witness:
I confirm that the information in this consent form was accurately explained to and understood by the subject or legally authorized representative and that informed consent was given freely.

_____ _____
Witness Signature **Date**
Note: The witness must be impartial (i.e. not a member of the subject's family, not a member of the study team).

_____
Printed Name of Witness

UNIVERSITY OF CALIFORNIA, IRVINE
Experimental Subject's Bill of Rights

The rights listed below are the right of every individual asked to participate in a research study. You have the right:

1. To be told about the nature and purpose of the study.

2. To be told about the procedures to be followed in the research study, and whether any of the drugs, devices, or procedures is different from what would be used in standard practice.

3. To receive a description of any side effects, discomforts, or risks that you can reasonably expect to occur during the study.

4. To be told of any benefits that you may reasonably expect from the participation in the study, if applicable.

5. To receive a description of any alternative procedures, drugs, or devices that might be helpful, and their risks and benefits compared to the proposed procedures, drugs or devices.

6. To be told of what sort of medical treatment, if any, will be available if any complications should arise.

7. To be given a chance to ask any questions concerning the research study both before agreeing to participate and at any time during the course of the study.

8. To refuse to participate in the research study. Participation is voluntary. You may refuse to answer any question or discontinue your involvement at any time without penalty or loss of benefits to which you might otherwise be entitled. Your decision will not affect your right to receive the care you would receive if you were not in the experiment.

9. To receive a copy of the signed and dated written consent form and a copy of this form.

10. To be given the opportunity to freely decide whether or not to consent to the research study without any force, coercion, or undue influence.

If you have any concerns or questions regarding the research study you should contact the research team listed at the top of the consent form.

If you are unable to reach a member of the research team and have general questions, or you have concerns or complaints about the research study, research team, or questions about your rights as a research subject, please contact the UCI's Human Research Protections unit in the Office of Research by calling (949) 824-6068 or (949) 824-2125 Monday – Friday, 8 am – 5 pm; or by e-mail at IRB@research.uci.edu; or by writing us at 160 Aldrich Hall, Irvine, CA 92697.