Informed Consent Form - Information Disclosure Page

(Version: V2.0 Release Date: 2025.5.5)

Dear Participant,

You are invited to participate in a single-center, prospective, randomized controlled clinical study titled "Virtual Reality-Based Mindfulness Intervention for Anxiety and Pain During Local Anesthesia Vascular Minimally Invasive Surgery." The principal investigator of this study is_____ from Tongji Hospital, Tongji Medical College, Huazhong University of Science and Technology. This study is funded by the Tongji Hospital, Tongji Medical College, Huazhong University of Science and Technology Hospital Fund. The study protocol has been reviewed and approved by the Medical Ethics Committee of Tongji Hospital, Tongji Medical College, Huazhong University of Science and Technology for clinical research.

Before deciding whether to participate, please read the following information as carefully as possible. It will help you understand the study, its purpose, procedures, duration, as well as the potential benefits, risks, and discomforts associated with participation. If you wish, you may discuss this with your relatives or friends or ask the study doctor to explain further to assist your decision-making.

If you are currently participating in other clinical studies, please inform your study doctor or researcher. Thank you for your support of this research.

1. Why is this study being conducted?

The 2023 World Heart Report released by the World Heart Federation (WHF) revealed that 20.5 million people worldwide died from cardiovascular diseases (CVD) in 2021, making CVD one of the leading causes of death globally, accounting for nearly one-third of all deaths. For coronary artery disease and peripheral vascular disease, minimally invasive vascular interventions under local anesthesia—such as percutaneous stent implantation, percutaneous balloon angioplasty, coronary angiography, and inferior vena cava filter placement—as well as minimally invasive great saphenous vein surgery have become the clinical treatments of choice due to their minimally invasive nature. However, studies indicate that approximately 60%-80% of patients undergoing local anesthesia experience varying degrees of anxiety due to being awake during the procedure. Additionally, patients with vascular diseases often have chronic, complex conditions, with over 50% exhibiting symptoms of anxiety or depression, making their psychological state more fragile. Furthermore, although local anesthetics block pain transmission, patients may still perceive mechanical stimuli from surgical manipulations (e.g., vessel stripping, catheter insertion, or stent deployment). Existing research shows that intraoperative anxiety and pain can lead to reduced patient compliance, involuntary movements, increased demand for anesthetic drugs, higher postoperative pain incidence, and even unplanned surgery cancellation or interruption. Therefore, exploring effective psychological interventions is crucial for improving the perioperative experience of patients undergoing minimally invasive vascular surgery under local anesthesia.

This study aims to explore the effectiveness, feasibility, and safety of combining VR with mindfulness interventions to alleviate anxiety and pain in patients undergoing minimally invasive vascular surgery under local anesthesia through a prospective, single-center, simple randomized controlled trial. The study will compare the combined VR and mindfulness intervention with conventional psychological care in terms of intraoperative anxiety levels, postoperative pain intensity, intraoperative vital signs, and BIS values, while also assessing

intervention safety by monitoring VR-related motion sickness, psychological, and somatic symptoms. This project seeks to preliminarily investigate the combined application of VR and mindfulness interventions for patients undergoing minimally invasive vascular surgery under local anesthesia, evaluating its effectiveness, feasibility, and safety in reducing anxiety and pain. Optimizing anxiety and pain management for such procedures holds significant importance for enhancing operating room nursing quality and patient experience.

2. Who will be invited to participate in this study?

This study intends to enroll approximately 160 eligible patients voluntarily undergoing minimally invasive vascular surgery under local anesthesia at the Zhongfa Campus of Tongji Hospital, Tongji Medical College, Huazhong University of Science and Technology. The study has been reviewed and approved by the Medical Ethics Committee of Tongji Medical College. This informed consent form provides information to help you decide whether to participate. Your participation is entirely voluntary. Please read carefully and direct any questions to the responsible investigator.

Inclusion criteria: ① Age ⩾18 years; ② ASA class I–III; ③ Diagnosis of arterial diseases (e.g., coronary, iliac, renal, or mesenteric artery stenosis/occlusion ⩾70%) or venous diseases (e.g., C3–C5 lower extremity varicose veins, DVT, CVI) confirmed by clinical and imaging (Doppler ultrasound, venography, DSA, CTA, MRA, CTPA, etc.); ④ Scheduled for minimally invasive varicose vein surgery, percutaneous (arterial/venous) stent placement, balloon angioplasty, or IVC filter implantation under local anesthesia; ⑤ Voluntary participation with signed informed consent; ⑥ Ability to comply with study examinations and follow-ups; ⑦ No severe systemic diseases or surgical contraindications (e.g., cardiopulmonary dysfunction, coagulation disorders) affecting safety or results.

3. Participating Institutions and Estimated Enrollment

The participating institution is Tongji Hospital, Tongji Medical College, Huazhong University of Science and Technology, with an estimated enrollment of 160 subjects.

4. What Will Be Required If You Participate?

4.1 Before enrollment, doctors will record your medical history and perform vascular Doppler ultrasound, DSA, and physical examinations.

If eligible, you may voluntarily join the study and sign the informed consent.

If you decline, treatment will proceed per your preference.

4.2 If you volunteer, the study will follow these steps:

(1) If you are eligible and agree to participate in this study, you will be assigned to a corresponding surgical group based on the type of planned surgery: ① minimally invasive great saphenous vein surgery group; ② peripheral vascular interventional surgery group; ③ coronary interventional surgery group. You will then be randomly assigned to either the VR mindfulness intervention group or the control group.

(2) During the preoperative visit, we will explain the surgical procedure, inform you of precautions, and require you to sign an informed consent form.

(3) During the study, you will be invited to complete a Mini-Mental State Examination, general demographic information form, anxiety scale, pain scale, Brief Fatigue Inventory, Pittsburgh Sleep Quality Index, and satisfaction survey. We will also monitor your blood pressure, heart rate, and bispectral index during the surgery.

(4) On the day of surgery, after arriving at the waiting area, the nurse will provide the

corresponding intervention based on your group assignment. After the surgery begins, the research nurse in the operating room will provide the intervention again according to your group. ① VR mindfulness intervention group: In addition to routine psychological care, you will receive one VR mindfulness intervention before and during the surgery. The VR scenes feature relaxing natural environments like forests, ocean waves, or starry skies, with mindfulness audio recommended by Peking University's School of Psychological and Cognitive Sciences. The two interventions last approximately 15min and 25min <60min>②min. ② Control group: Routine psychological care measures.

(5) We will closely monitor any adverse reactions during and after the intervention. If severe side effects occur, we will immediately stop the intervention and provide appropriate symptomatic treatment.

3. Other tasks requiring your cooperation

You will need to truthfully complete the general demographic form, Mini-Mental State Examination, Five Facet Mindfulness Questionnaire, Brief Fatigue Inventory, and Pittsburgh Sleep Quality Index one day before surgery. On the day of surgery, you will complete the anxiety and pain scales before and after the intervention. One day after surgery, you will fill out the Brief Fatigue Inventory, Pittsburgh Sleep Quality Index, and satisfaction survey based on your actual experience. Your responses are crucial for researchers to evaluate the intervention's effectiveness. If you cannot comply with the intervention or form completion during the study, please inform us promptly.

5. Potential benefits of participation

We expect VR mindfulness intervention may alleviate anxiety and pain in patients undergoing minimally invasive vascular surgery under local anesthesia and improve their medical experience, though no guarantees can be made. This study may provide guidance for future care in reducing anxiety and pain for such patients.

6. Possible adverse reactions, risks, discomforts, and inconveniences

Possible side effects (1) VR-related motion sickness, dizziness, nausea, etc.; (2) Psychological reactions, as some patients may experience anxiety, stress, or other negative emotional responses during VR-based mindfulness interventions; (3) Cognitive overload, where immersive VR experiences may lead to symptoms like distractibility or mental confusion.

If you experience any discomfort, new changes in your condition, or unexpected circumstances during the study—whether related to the research or not—please promptly notify your doctor or nurse. They will assess the situation and provide appropriate medical care. During the study, you will need to truthfully complete forms, participate in training and monitoring, which may take some of your time and could cause inconvenience.

7. Regarding Costs

Apart from treatment and examination fees, no additional charges will be incurred for participating in this study. Researchers will make every effort to prevent and address any harm potentially caused by the study. If adverse events occur during the trial, a medical expert committee will determine whether they are related to the research. The project team will cover treatment costs and provide compensation for trial-related injuries. Treatment and examinations for other pre-existing conditions will not be covered.

8. Confidentiality of Personal Information

Your medical records (study files/CRFs, lab reports, etc.) will be securely stored at the hospital

where you are treated. Doctors will record test and examination results in your medical file. Researchers, ethics committees, and regulatory authorities may access your records. Any published results of this study will not disclose your identity. We will protect the privacy of your medical data to the fullest extent permitted by law.

In accordance with medical research ethics, trial data—excluding private personal information—will be available for public inquiry and sharing via web-based electronic databases, ensuring no leakage of private details.

9. How to Obtain More Information?

You may ask questions about the study at any time and receive answers accordingly.

If any significant new information arises during the study that may affect your willingness to continue participation, your doctor will promptly inform you.

10. Voluntary Participation and Withdrawal

Participation is entirely voluntary. You may decline to join or withdraw at any time without affecting your relationship with your doctor or compromising your medical care or other interests.

For your utmost benefit, the doctor or researcher may discontinue your participation in this study at any time during the research process.

If you withdraw from the study midway, for the sake of your health, you may be asked about your use of the trial medication. If the doctor deems it necessary, you may also be required to undergo physical and laboratory examinations, which will benefit your well-being.

If your condition changes and you need any additional treatment, you may pursue it at any time. Please inform your doctor truthfully afterward.

11. What should you do now?

Participation in this study is entirely your (and your family's) decision. Before making your decision, please ask your doctor any questions you may have.

Thank you for reading the above materials. If you decide to participate, please inform your doctor, who will arrange all research-related matters for you. Please keep this document.

Informed Consent Form. Consent Signature Page

- Project Title:____A Single-Center, Prospective, Randomized Controlled Clinical Study on Virtual Reality-Based Mindfulness Intervention for Anxiety and Pain in Local Anesthesia Vascular Minimally Invasive Surgery____

Institution:____Tongji Hospital, Tongji Medical College, Huazhong University of Science and Technology____

Declaration of Consent

I have read the above information about this study and had the opportunity to discuss it with the doctor and ask questions. All my questions have been answered satisfactorily.

I understand the potential risks and benefits of participating in this study. I know participation is voluntary, and I confirm having sufficient time to consider it. I also understand:

- I may consult the doctor for more information at any time.

+ I may withdraw from this study at any time without discrimination or retaliation, and my medical treatment and rights will not be affected. I agree to allow the ethics committee or management to review my research data.

I will receive a signed and dated copy of this informed consent form.

Finally, I voluntarily agree to participate in this study and will strive to follow the doctor's

instructions.
Subject Signature:_____ Year_____ Month_____ Day
Contact Phone:_____
I confirm that I have explained the trial details to the patient, including their rights, potential benefits, and risks, and provided them with a signed copy of the informed consent form.
Investigator Signature:_____Year_____Month_____Day
Contact Phone:_____