Informed Consent Form · Information Disclosure Page

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Dear Subject:

We invite you to participate in a single-center, prospective, randomized controlled clinical study investigating the effects of virtual reality-based mindfulness intervention on anxiety and pain during vascular minimally invasive surgery under local anesthesia. The principal investigator is Kuang Wan from Tongji Hospital affiliated with Tongji Medical College, Huazhong University of Science and Technology. This study is funded by the hospital's research fund. The research protocol has been reviewed and approved for clinical implementation by the Medical Ethics Committee of Tongji Hospital.

Before deciding whether to participate in this study, please read the following information as carefully as possible. It will help you understand the nature of the study, its rationale, the procedures and duration involved, as well as the potential benefits, risks, and potential discomforts associated with participation. If desired, you may also discuss the details with your relatives or friends, or consult your physician for further clarification to assist in making an informed decision.

If you are currently participating in another clinical study, please务必 inform your research physician or investigator. Thank you for your support of this study.

1. Why Was This Study Conducted?

Varicose veins of the lower extremities are a common clinical manifestation of peripheral venous disorders, primarily affecting the great saphenous vein and its branches, as well as the small saphenous vein and anterior accessory saphenous vein. The "Expert Consensus on the Diagnosis and Treatment of Primary Varicose Veins of the Lower Extremities (2021 Edition)" recommends minimally invasive surgical treatment for varicose veins, which involves point-like stripping under local infiltration anesthesia combined with chemical methods (injection of sclerosing agents) and/or physical methods (e.g., radiofrequency ablation) to close the dilated vessels. However, procedures such as subcutaneous injection of local anesthetics at multiple sites and point-like vascular stripping during minimally invasive surgery for varicose veins often induce significant patient perception and pain, thereby affecting the nervous, endocrine, and circulatory systems, leading to symptoms such as elevated blood pressure and increased heart rate. Studies have demonstrated that intraoperative anxiety and pain can reduce patient compliance, cause involuntary movements, increase the demand for anesthetic agents and postoperative pain incidence, and even result in unplanned cancellation or interruption of the procedure. Therefore, psychological support and pain management during minimally invasive surgery for varicose veins under local infiltration anesthesia are crucial for ensuring therapeutic efficacy.

This study aims to investigate the efficacy, feasibility, and safety of combining virtual reality (VR) with mindfulness intervention in patients undergoing minimally invasive vascular surgery under local anesthesia for alleviating anxiety and pain through a prospective, single-center, simple randomized controlled trial. The study will compare the effects of the combined VR-mindfulness intervention versus conventional psychological care on intraoperative anxiety levels, postoperative pain intensity, and intraoperative vital signs, while evaluating intervention

safety by monitoring for VR-related motion sickness, psychological, and physical symptoms. This project seeks to preliminarily assess the effectiveness, feasibility, and safety of integrating VR and mindfulness interventions in patients undergoing minimally invasive vascular surgery under local anesthesia. Optimizing anxiety and pain management strategies for such procedures is crucial for enhancing surgical room care quality and patient experience.

II. Who Will Be Invited to Participate in This Study?

This study aims to recruit patients who have undergone minimally invasive vascular surgery under general anesthesia at the Central Hospital Campus of Tongji Hospital affiliated with Tongji Medical College of Huazhong University of Science and Technology and meet the inclusion criteria, with an estimated participation of approximately 160 volunteers. The study has been reviewed and approved by the Medical Ethics Committee of Tongji Medical College, Huazhong University of Science and Technology. This informed consent form provides you with essential information to assist in deciding whether to participate in this clinical study. Your participation is entirely voluntary. Please read it carefully; if you have any questions, please consult the investigators responsible for the study.

Inclusion criteria: ① Age ≥18 years;② ASA classification grades I–III; ③ Diagnosis of superficial venous varices confirmed by clinical examination and imaging studies (e.g., Doppler ultrasound, digital subtraction angiography), with confirmed presence of venous insufficiency and great saphenous vein varicosities, and CEAP grading levels 3–5; ④ Intended to undergo minimally invasive surgery for lower limb varicose veins under local anesthesia; ⑤ Voluntary participation in the study and signing of an informed consent form; ⑥ Ability to cooperate with all examinations and follow-up procedures during the study; ⑦ Absence of other severe systemic diseases or surgical contraindications (e.g., severe cardiopulmonary dysfunction, coagulation disorders) that may affect surgical safety or interpretation of study results.

III. Participating Institutions and Estimated Number of Participants to Be Included in the Study

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

IV. What Will Be Required to Participate in the Study?

4.1 Prior to your enrollment in the study, the physician will inquire about and document your medical history, and perform vascular color Doppler ultrasound, digital subtraction angiography (DSA), and a physical examination.

You are a qualified participant and may voluntarily enroll in the study by signing the informed consent form. If you do not wish to participate, we will proceed with treatment according to your preference.

4.2 If you voluntarily participate in the study, follow these steps:

(1) If you are eligible and agree to participate in this study, you will be randomly assigned to Group A (VR Mindfulness Group) or Group B (Control Group).

(2) During the preoperative visit, we will explain the surgical procedure, inform you of the necessary precautions, and request your signature on the informed consent form.

(3) During the study, you are requested to complete the Mini-Mental State Examination (MMSE), general demographic information form, anxiety scale, pain scale, Brief Fatigue Scale, LSEQ Sleep Scale, and satisfaction survey. Additionally, your blood pressure and heart rate will be monitored during the procedure.

(4) On the day of surgery, upon arrival at the surgical waiting area, nurses will provide appropriate interventions based on patient grouping. After surgery begins, operating room nurses will administer additional interventions according to group assignments. ① Group A (VR Mindfulness Group): In addition to standard psychological care, participants receive one VR mindfulness intervention before surgery and one during surgery. The VR scenarios depict relaxing natural environments such as forests, waves, or starry skies, utilizing mindfulness audio materials recommended by the School of Psychology and Cognitive Science at Peking University. Each intervention lasts approximately 15 minutes or 25–60 minutes respectively. ② Group B (Control Group): Receives standard psychological care measures only.

(5) We will closely monitor adverse reactions occurring during and after the intervention. In the event of severe adverse reactions, we will immediately terminate the intervention and administer appropriate symptomatic treatment.

4.3. Other matters requiring your cooperation

On the day before surgery, you are required to accurately complete general demographic information and a简易 mental status questionnaire. On the day of surgery, you must fill out an anxiety scale, a pain scale, a brief fatigue scale, and the LSEQ Sleep Questionnaire both before and after intervention. On the day of surgery, you should complete the anxiety scale and pain scale again after intervention. One day postoperatively, you must fill out the brief fatigue scale, the LSEQ Sleep Questionnaire, and a satisfaction survey based on your actual experiences. The data you provide is crucial as it will enable researchers to assess the efficacy of the intervention. If you are unable to cooperate with the implementation of the intervention or the completion of questionnaires during the study period, please inform us promptly.

V. Potential Benefits of Participating in the Study

We anticipate that VR-based mindfulness interventions may alleviate anxiety and pain in patients undergoing minimally invasive vascular surgeries under local anesthesia, thereby enhancing their healthcare experience; however, no definitive guarantees can be provided. These findings offer potential guidance for future nursing care aimed at mitigating anxiety and pain in such patients.

VI. Potential Adverse Reactions, Risks, Discomforts, and Inconveniences Associated With Participating in the Study

Possible adverse reactions: (1) VR-related motion sickness, manifested as dizziness and nausea; (2) Psychological effects: mindfulness interventions in a VR environment may induce anxiety, stress, or other negative emotional responses in certain patients; (3) Cognitive overload: immersive VR experiences may lead to cognitive overload in patients, presenting as symptoms such as attention dispersion and mental confusion.

If you experience any discomfort, notice any new changes in your condition, or encounter any unexpected situation during the study—whether or not it is related to the study—you should promptly notify your physician or nurse. They will assess the situation and provide appropriate medical intervention. During the study, you are required to provide truthful information and cooperate with certain training sessions and monitoring procedures, which may consume some of your time and potentially cause inconvenience or discomfort.

VII. Relevant Costs

No additional fees will be charged beyond treatment and examination costs for participation in this study. Researchers will make every effort to prevent and treat any potential harm arising from this study. In the event of adverse events during the clinical trial, a medical expert committee will determine their potential association with the study. The research team will cover the costs of treatment and provide corresponding financial compensation for trial-related injuries. However, treatments and examinations required for concomitant comorbid conditions are not included within the free scope.

VIII. Confidentiality of Personal Information

Your medical records (including study medical records/CRFs, laboratory reports, etc.) will be fully retained at the hospital where you received treatment. Physicians will document laboratory and other examination results in your medical records. Researchers, ethics committees, and administrative authorities will be authorized to access your medical records. Any public reports regarding the study outcomes will not disclose your personal identity. We will make every effort to protect the privacy of your personal medical information within the limits permitted by law.

In accordance with medical research ethics, except for personal privacy information, experimental data will be available for public inquiry and sharing. Such inquiries and sharing shall be limited to online electronic databases only, ensuring no leakage of any personal privacy information.

IX. How to Obtain More Information?

You may raise any questions regarding this study at any time and will receive corresponding responses.

If any significant new information emerges during the study that may affect your willingness to continue participating, your physician will promptly inform you.

10. Participants May Voluntarily Choose to Enroll in the Study or Withdraw from It at Any Time.

Participation in this study is entirely at your discretion. You may refuse to participate or withdraw from the study at any time during its conduct, which will not affect your relationship with your physician nor compromise your medical care or other benefits.

For the greatest benefit of your health, physicians or investigators may terminate your participation in this study at any time during the course of the study.

If you withdraw from the study midway, for reasons beneficial to your health, you may be asked about your use of the investigational drug. If deemed necessary by your physician, you may also be required to undergo physical and biochemical examinations, which will benefit your health.

If any additional treatment is required due to changes in your condition, you may undergo such treatment at any time and are requested to promptly inform your physician of the changes.

11. What Should We Do Now?

Your participation in this study is at your own discretion (and that of your family members). Before deciding to participate, please consult your physician regarding all relevant questions as thoroughly as possible.

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

Informed Consent Form. Consent Signature Page

- **Project Title:**The Effect of Mindfulness Intervention Based on Virtual Reality Technology on Anxiety and Pain in Vascular Minimally Invasive Surgery Under Local Anesthesia: A Single-Center, Prospective, Randomized Controlled Clinical Study

Responsible Unit: Tongji Hospital Affiliated to Tongji Medical College, Huazhong University of Science and Technology

Agreement Statement

I have reviewed the aforementioned introduction to this study and had the opportunity to discuss it with physicians and raise questions. All my inquiries were satisfactorily addressed.

I am aware of the potential risks and benefits associated with participating in this study. I understand that participation is voluntary, have had sufficient time to consider it carefully, and am fully informed of the following:

- I can always consult a physician for further information.
- I may withdraw from this study at any time without facing discrimination or retaliation, and my medical treatment and rights will not be affected. I consent to the ethics committee or administrative authorities reviewing my research materials.

I will receive a copy of the informed consent form that is signed and dated.

Finally, I have decided to consent to participate in this study and hereby pledge to adhere strictly to all medical instructions.

Subject Signature: _____ _____year_____moon_____ sun

contact number： _____

I confirm that I have explained the detailed particulars of this trial to the patient, including their rights as well as potential benefits and risks, and provided them with a signed copy of the informed consent form.

Researcher's Signature: _____ _____year_____moon_____ sun

contact number： _____