Safety and Efficacy of Multisensory Stimulation Virtual Reality for Stroke Patients

Informed Consent Form

NCT06275516

Sponsor: Department of Rehabilitation Medicine, The First Affiliated Hospital of Chongqing Medical University

2024.3.10

Informed Consent Form

Dear Patient (Participant),

Hello!

Stroke is a cardiovascular and cerebrovascular disease characterized by high rates of incidence, mortality, disability, and recurrence. In recent years, the incidence of stroke in China has increased significantly, with approximately 2.4 million new cases reported annually, showing a trend toward younger populations and a growing disease burden. Post-stroke survivors experience substantial cognitive and motor impairments that can disrupt daily activities, work, education, and social interactions, thereby placing considerable strain on families and society.

Virtual reality (VR) has increasingly been utilized in stroke rehabilitation to facilitate recovery of cognitive and motor functions. Thus, investigating the mechanisms and effectiveness of VR interventions is critical for improving therapeutic outcomes in stroke rehabilitation.

You are invited to participate in this study conducted by the Department of Rehabilitation Medicine at The First Affiliated Hospital of Chongqing Medical University, based on your diagnosis of stroke.

This informed consent form provides essential details to help you decide whether to participate. Please note that your participation is entirely voluntary, and you may withdraw at any time without penalty. This research has been reviewed and approved by Ethics Committee of this institution.

Please read the following information carefully and feel free to ask the principal investigator any questions you may have before deciding whether to participate.

Research Objectives

This study aims to evaluate the effects of multisensory VR rehabilitation on cognitive and motor functions in stroke patients, and to investigate the neural mechanisms underlying VR rehabilitation.

Research Procedures

Intervention: Participants will be randomly assigned to either VR rehabilitation training or conventional treadmill rehabilitation training.

Data Collection: Clinical records and functional assessments will be gathered throughout the study. Upon providing consent, you will be assigned a unique identification number, and a secure medical record file will be established exclusively for this research. All data collected will be used solely for research purposes.

Potential Benefits

Participation may contribute to improved recovery following stroke, offering valuable insights for enhancing future treatment strategies and functional outcomes.

The study outcomes will help advance the application of VR in rehabilitation therapy.

Potential Risks and Discomfort

The equipment involved in this study are not associated with any known risks.

You might experience mild fatigue during the sessions. Rest intervals will be provided, and you are free to request additional breaks as needed.

Concurrent Therapies

In addition to the research intervention, you will continue to receive conventional rehabilitation therapy.

Privacy and Confidentiality

All personal information and data collected during the study will remain strictly confidential.

Research staff will secure your data in files accessible only to authorized personnel.

You have the right to request access to your personal data for medical reasons. Regulatory authorities or ethics committee members may review your records to ensure adherence to research regulations.

Any published data or presentations will not reveal your identity or personal information.

Costs and Compensation

There is no financial compensation for participation.

However, you will receive complimentary brain function assessments (including functional evaluations and fNIRs tests) as well as professional rehabilitation evaluations and rehabilitation prescription.

In the event of any injury directly attributable to this study, you will receive free treatment and appropriate compensation, with all treatment costs covered by the research project.

Voluntary Participation and Withdrawal

Your participation is entirely voluntary, and you may withdraw from the study at any time without any negative impact on your medical care or legal rights.

Should you decide to withdraw, your data will be excluded from the final study results.

The research team reserves the right to terminate your participation if continued involvement poses significant risks or if study protocols are not followed.

Participant Responsibilities

Please provide accurate medical history and current health status.

Report any discomfort or adverse events promptly.

Inform the research team if you are involved in any other ongoing or recent studies.

Contact Information

For any questions, concerns, discomfort, injuries, or inquiries during this study, please contact Professor Dingqun Bai at ***13808380876***.

Benefit Sharing Post-Trial

Upon completion of the study, if the investigational intervention is proven safe and effective, a complimentary oral presentation will be provided to inform you about the treatment efficacy.

Consent Statement

I have carefully reviewed this informed consent form. My doctor_____ has thoroughly explained the purpose, procedures, risks, and benefits of this clinical trial and all my questions have been answered to my satisfaction. I fully understand the contents of this document and voluntarily agree to participate in the study.

Participant Signature: _____ Date: _____

Investigator Signature: _____ Date: _____

(*Note: Witness signature required for illiterate participants; proxy consent required for participants unable to provide consent.*)