INFORMED CONSENT FORM

Official Study Title

Effectiveness of Early Intervention With Virtual Reality-Based Interactive Rehabilitation on Upper Extremity Muscle Strength, Cognitive Status, and Exercise Self-Efficacy in Patients With Acute Ischemic Stroke: A Randomized Controlled Trial

Protocol Information

Protocol ID: C202405171

IRB Approval Number: C202405171

NCT Number: Not Yet Assigned

Document Type: Informed Consent Form

Document Version: Version 1.0

Document Date: August 28, 2025

Study Sponsor / Institution

Institution:

Tri-Service General Hospital, National Defense Medical Center, Taipei, Taiwan

Funding Source:

Self-funded

Principal Investigator

Yun-Qian Lin, RN, NP

Department of Neurology

Tri-Service General Hospital

Study Overview

This study is a prospective randomized controlled trial designed to evaluate the effectiveness of early virtual reality-based interactive rehabilitation in patients with acute ischemic stroke.

A total of 100 participants will be enrolled and randomly assigned to either:

Experimental Group (n = 50) ; Control Group (n = 50)

Participants in both groups will receive standard rehabilitation interventions. Participants assigned to the experimental group will additionally receive virtual reality-based interactive rehabilitation training.

The primary objective of this study is to investigate the effects of early virtual reality-based rehabilitation on upper extremity motor function, cognitive status, and exercise self-efficacy during the acute phase of ischemic stroke.

Study Contact Information

Principal Investigator

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This document is the Institutional Review Board (IRB)-approved Informed Consent Form for the above study.

IRB Case No. : C202405171

Informed Consent Form **Participant ID:**

Tri-Service General Hospital, National Defense Medical Center

Project Title: Effectiveness of Early Intervention Using a Virtual Reality Motion-Sensing Rehabilitation System on Improving Upper Limb Muscle Strength, Cognitive Status, and Self-Efficacy in Patients with Acute Ischemic Stroke

Institution: Department of Neurology, Tri-Service General Hospital (TSGH)

Funding Source: Self-funded

Principal Investigator (PI): Yun-Qian LIN (Nurse Practitioner, Dept. of Neurology)

Co-Investigator: Chia-Kuang TSAI (Attending Physician, Dept. of Neurology)

24-Hour Emergency Contact: Yun-Qian LIN; Phone: 0933-513418

I. Project Overview

This study involves two groups: an **experimental group** (using a VR rehabilitation APP) and a **control group** (traditional rehabilitation). The study aims to verify the outcomes of early VR rehabilitation intervention in acute ischemic stroke patients. A total of **100 participants** are expected to be recruited (50 per group) at the Neurology Wards and the Stroke and Neurointensive Care Unit (SNICU) of Tri-Service General Hospital. The total study duration, including data analysis, is approximately one year.

II. Research Objectives

Most existing rehabilitation studies focus on the period from the post-acute phase up to 6 months after stroke. This study investigates the effects of early virtual rehabilitation, initiated **within 24 hours of a confirmed acute ischemic stroke diagnosis**, on upper limb strength, cognitive status, and self-efficacy. The goal is to establish more effective early intervention methods and enhance patient motivation for training.

III.

Eligibility Criteria

Inclusion Criteria:

- First-time unilateral ischemic stroke confirmed by CT or MRI.
- Stroke onset within the past 10 days.
- Mild to moderate upper limb motor impairment (FMA-UE score >35 and <50).
- Age between 18 and 80 years, without severe cognitive impairment (SLUMS score >20 and <27).
- No severe visual impairment or visuospatial neglect.

Exclusion Criteria:

- Other neurological, neuromuscular, or orthopedic diseases affecting upper limb function.
- Recurrent stroke or seizures during the study.
- Severe systemic impairment or comorbid diseases.
- Refusal to participate.

IV. Procedures and Participant Responsibilities

- **Groups:** Participants are randomly assigned to either the experimental or control group.
- **Experimental Group:** Includes pre-test assessment, VR APP training, and post-test assessment. Total duration is approximately 18 hours.
- **Control Group:** Includes pre-test assessment, traditional bedside exercise, and post-test assessment. Total duration is approximately 18 hours.
- **Assessments: * FMA-UE:** Evaluates upper limb motor, sensory, and coordination (33 items, 20–30 mins).
- **SLUMS:** Cognitive status test (11 items, 10–15 mins).
- **Self-Efficacy Scale:** Measures confidence in overcoming challenges (10 items, 10–

15 mins).

- **One-on-one interview:** Conducted after the 3-week course (approx. 1 hour).
- **Rehabilitation Schedule:** Regular treatment for 3 weeks (5 days/week, once daily).

Both groups receive 60 minutes of specific intervention daily.

V. Risks and Remedial Measures

Participation is voluntary and will not affect your rights. If you feel physical or mental discomfort, you may withdraw at any time. If the assessment is too long or causes distress, contact Yun-Qian LIN at 0933-513418 for assistance.

VI. Expected Benefits

VR rehabilitation may accelerate motor recovery, provide precise training, and reduce complications from prolonged bed rest. It aims to shorten hospital stays and improve overall healthcare efficiency.

VII. Data Handling and Storage

- **Responsible Party:** Yun-Qian LIN, Dept. of Neurology, TSGH.
- **Privacy:** Data will be **coded (e.g., 001, 002)** to replace names. Your identity will remain confidential even if results are published.
- **Storage:** Physical documents are kept in a locked cabinet; electronic files are encrypted and stored on secure drives accessible only to the research team.
- **Retention:** Personal identifying data will be removed after analysis. Records will be destroyed via shredding and pulping 5 years after the study ends.

VIII. Compensation and Rights

- **Subsidies:** No fees are required; no commercial benefits are expected.
- **Damage Compensation:** TSGH will provide necessary medical assistance for any adverse reactions resulting from the study.
- **Inquiries:** Contact PI Yun-Qian LIN (0933-513418) for study questions. For rights concerns, contact the **TSGH IRB**:

Tel: 02-8792-3311 ext. 10552

Address: Room 5113, 5F, Medical Building, No. 325, Sec. 2, Chenggong Rd., Neihu Dist., Taipei City 11490

IX. Signatures

Investigator/Person Obtaining Consent:

I have explained the nature, purpose, risks, and benefits of this study and answered all questions. Signature: _____Date: _____(YYYY/MM/DD)

Participant: I have understood the study procedures and my questions have been answered. I voluntarily agree to participate.

Signature: _____Date: _____(YYYY/MM/DD)