Informed Consent Form (ICF)

Project Title:

A Multicenter, Randomized Controlled Study on the Evaluation of Functional Impairment and the Promotion of Exercise Rehabilitation Standards in Maintenance Hemodialysis (MHD) Patients

Protocol Version and Date:

Version 2.0, February 12, 2025

Informed Consent Form Version and Date:

Version 2.0, February 12, 2025

Dear Patient,

You are cordially invited to participate in a multicenter, randomized controlled clinical study entitled *"Evaluation of Functional Impairment and Promotion of Exercise Rehabilitation Standards in Maintenance Hemodialysis (MHD) Patients"*, which has been approved and initiated by The First People's Hospital of Yunnan Province. This study will be conducted at our hospital, with a planned enrollment of 40 voluntary participants. The protocol has been reviewed and approved by the Ethics Committee of The First People's Hospital of Yunnan Province.

This consent form provides information to help you decide whether to participate. Your participation is entirely voluntary. Your decision will not affect your routine medical care or rights in this hospital. If you choose to participate, the research team will make every effort to safeguard your safety and rights during the study.

Please read this document carefully. If you have any questions, please ask the investigator who explains this consent form to you.

I. Background

Maintenance hemodialysis (MHD) is the primary treatment for patients with end-stage renal disease (ESRD). The focus of therapy has shifted from prolonging life to improving quality of life. However, MHD patients frequently suffer from reduced physical function, lower quality of life, and higher rates of hospitalization and mortality. Lack of physical activity leads to muscle weakness and functional impairment, creating a burden on families and healthcare resources. Therefore, improving physical function and quality of life in MHD patients has become a research priority in nephrology.

Rehabilitation medicine has gained increasing attention in nephrology. The "Standards for Rehabilitation Services in Chronic Kidney Disease Patients" provide guidance for exercise rehabilitation. Based on these Standards, this study adopts a multicenter, randomized controlled design to evaluate the effects of introducing exercise rehabilitation techniques (ERT) during dialysis. ERT includes warm-up, core exercise, and relaxation phases, aiming to improve muscle strength, endurance, and overall health through individualized interventions. The study will assess the impact of ERT on physical function, psychological health, and quality of life in MHD patients, as well as hospitalization and mortality outcomes, thereby providing evidence for the promotion of safe and cost-effective rehabilitation programs.

II. Objectives

The purpose of this study is to evaluate the clinical effectiveness of ERT in MHD patients through the implementation of the Rehabilitation Standards. The main objectives are to determine whether ERT can improve physical function (e.g., muscle strength, 6-minute walk distance), psychological condition (e.g., anxiety, depression), nutritional status, and cognitive function, while reducing hospitalization and mortality, thus optimizing quality of life and long-term prognosis. The study also aims to explore the feasibility, safety, and compliance of ERT and analyze outcome differences across dialysis centers, contributing to standardized and generalizable rehabilitation strategies.

III. Participants

This study will recruit 800 MHD patients across 15 dialysis centers nationwide, with 40 participants expected at The First People's Hospital of Yunnan Province.

Inclusion Criteria:

1. On maintenance hemodialysis for >3 months;
2. Frequency: three sessions/week;
3. Kt/V ≥ 1.2;
4. Clinically stable;
5. Age 18–74 years;
6. Able and willing to provide written informed consent.

Exclusion Criteria:

1. NYHA class IV heart failure;
2. Recent unstable angina;
3. Severe peripheral arterial disease or musculoskeletal disorders;
4. Walking distance <200 m;
5. Resting SpO_2 <90%;
6. Amputation or conditions precluding exercise.

IV. Study Procedures

If you agree to participate, you will be assigned a unique study ID and research file.

1. **Intervention Group:** Routine dialysis + structured ERT (20–60 minutes/session, 3 times per week, for 2 years). ERT includes: warm-up (stretching, limb lifts), core exercises (upper-limb resistance, bedside cycling), and relaxation (stretching). All sessions will be supervised by trained staff, and prescriptions will be adjusted individually for safety.
2. **Control Group:** Routine dialysis without additional exercise.

Assessments:

1. Baseline: functional, psychological, cognitive, fall risk, sleep quality, self-management, and self-efficacy assessments.
2. Follow-up: every 6 months × 5 visits. At each visit, an additional 5 mL blood sample will be collected for proteomics and metabolomics.

Samples will be stored in the Biobank, 15th floor, Building 2, The First People's Hospital of Yunnan Province. After study completion, remaining samples will be disposed of as medical waste per regulations.

V. Alternative Treatments

Participation in this study will not interfere with your routine diagnosis and treatment. You may continue all standard care regardless of participation.

VI. Risks and Discomforts

ERT may cause mild discomfort such as muscle soreness, fatigue, or swelling. Improper design or performance could risk musculoskeletal strain or cardiovascular stress. However, the program consists of moderate-intensity aerobic and resistance training, proven safe and well tolerated in MHD patients.

VII. Expected Benefits

ERT may enhance physical function, flexibility, muscle strength, and endurance, improve movement patterns, reduce pain, and restore daily activities. It may also help prevent secondary injuries and improve quality of life.

VIII. Costs

No additional costs will be charged to participants.

IX. Compensation

At each follow-up, an additional 5 mL blood sample will be collected. Participants will receive 50 RMB per collection, paid in a lump sum at study completion.

X. Indemnity

All interventions are voluntary under informed consent. The study team will provide supervision and guidance. In case of injury or adverse effects, medical assistance will be provided, and compensation will follow applicable laws.

XI. Participant Responsibilities During the Study

You must:

1. Provide accurate medical history and health status;
2. Report any discomfort to investigators;
3. Avoid restricted medications;
4. Inform investigators of participation in other studies.

XII. Confidentiality

Your information will be strictly confidential and anonymized. Published reports will not reveal personal identity. Regulatory authorities and ethics committees may access your records under confidentiality agreements.

XIII. Re-consent

Re-consent will be required if:

1. The study protocol changes;
2. Identifiable samples are used for new research;
3. Stored identifiable samples are reused;
4. Other major changes occur.

XIV. Voluntariness

Participation is voluntary. You may withdraw at any time without affecting your medical care. Investigators may also withdraw you if necessary for safety or protocol reasons.

XV. Contact Information

For questions or study-related concerns, please contact:
Dr. Ying Shen – Tel: 13888279940

For rights-related concerns or complaints, please contact:
Ethics Committee, The First People's Hospital of Yunnan Province – Tel: 0871-63648772

Signature Page for Study Participants

Participant Consent Statement：

☐ I have read the above information regarding this study, and the study physician has explained the details of the study to me. Before signing this consent form, I have had all my questions about the study answered to my satisfaction. Based on this understanding, I voluntarily agree to participate in this clinical study. My decision is made with full knowledge of the potential risks and benefits of participation. I confirm that no deception, coercion, or undue inducement has been used by the investigators to obtain my consent. I also understand that I may withdraw from the study at any time without penalty or loss of medical benefits.

☐If the participant is a person without legal capacity or with limited legal capacity, this informed consent form must also be signed by his/her legal guardian.

Participant Signature：_____ Guardian Signature (if applicable)：_____

Date：_____ Date：_____

Participant Contact Information：_____ Guardian Contact Information：_____

Investigator Statement：

I confirm that I have explained the details of this study to the participant, especially the potential risks and benefits of participation.

Investigator Signature：_____

Date：_____

Investigator Contact Information：_____