Official Title: Effectiveness of Progressive Elastic Band Resistance Training in Older Adults With Sarcopenia in Long-Term Care Facilities: A Randomized Controlled Trial

Document Type: ICF

Protocol ID: CHIS11403

IRB approved number: B-ER-114-074 (by IRB, National Cheng Kung University Hospital, Tainan, Taiwan)

Document Date: March 14, 2025

Sponsor / Responsible Organization: Cishan Hospital, Ministry of Health and Welfare, Taiwan

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Brief Description of Document: This document provides the informed consent form for a randomized controlled trial evaluating the effectiveness of a 12-week elastic band progressive resistance training program in preventing and treating sarcopenia among older adults in long-term care facilities. It outlines the study objectives, procedures, eligibility criteria, potential risks and benefits, data confidentiality, and participant rights, and ensures that all participants or their legally authorized representatives provide informed and voluntary consent prior to participation.

Informed Consent Form (English Version)

This form applies to human subject research not governed under Article 8 of the Medical Care Act, including questionnaire-based studies, interviews, and specimen collection.

(This informed consent form must be explained in detail to the participant by the principal investigator. The participant should carefully consider the information before signing.)

You are invited to participate in this research study. This information and consent form provides important details about the study. The principal investigator will explain the study procedures to you and answer any questions you may have.

Study Title: Effectiveness of Progressive Resistance Training Using Elastic Bands for the Prevention and Treatment of Sarcopenia in Older Adults in Rural Long-Term Care Facilities

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Funding Source: Ministry of Health and Welfare Research Grant Program (Year 114)

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◆ 1. Introduction

Sarcopenia is a condition characterized by the loss of muscle mass and muscle strength. It may lead to physical weakness, impaired function, and increased risk of adverse health outcomes, including disability and mortality. In addition to aging, factors such as poor nutrition, reduced physical activity, and certain medical conditions may contribute to sarcopenia.

Previous studies have demonstrated that elastic band exercise can effectively prevent or improve sarcopenia in older adults. This study adopts a progressive resistance training program using elastic bands based on prior research and exercise prescriptions. The aim is to provide an effective and safe rehabilitation approach that requires less manpower and minimizes the risk of exercise-related injuries.

All medical interventions carry potential risks, and participation in clinical research is no exception. You are encouraged to carefully consider whether to participate in this study.

◆ 2. Purpose of the Study

The purpose of this study is to evaluate whether a progressive resistance training program using elastic bands can help prevent and improve sarcopenia in older adults residing in rural long-term care facilities.

Elastic bands are considered a safe and practical exercise tool for older adults and can be implemented in group-based programs. This training program is designed based on rehabilitation principles, including repetitive practice, high training volume, progressive overload, and task-oriented training, with the goal of improving muscle mass, handgrip strength, functional ability, and quality of life.

◆ 3. Study Duration and Number of Participants

The study will be conducted from the date of IRB approval until November 30, 2025.

A total of 60 participants will be enrolled and randomly assigned into two groups: 30 participants in the intervention group and 30 participants in the control group.

◆ 4. Inclusion and Exclusion Criteria

You may be eligible to participate if you meet the following criteria:

- Aged 60 years or older
- Currently residing in or receiving care from a long-term care facility affiliated with or contracted by Cishan Hospital
- Have sufficient cognitive function and physical ability to participate in exercise training

You will not be eligible if you have any of the following conditions:

- Unable to maintain a sitting position for more than one hour
- Uncontrolled hypertension, recent infection, or major cardiovascular disease
- Conditions contraindicated for exercise according to American College of Sports Medicine (ACSM) guidelines
- Bedridden status
- Respiratory conditions requiring continuous oxygen support

◆ 5. Study Procedures

This is a prospective pilot study. Participants will undergo assessments at three time points: before the intervention, at week 6, and at week 12.

Participants will be randomly assigned to either the intervention group or the control group.

If you are assigned to the intervention group, you will participate in a 12-week elastic band progressive resistance training program, conducted twice per week, with each session lasting at least 30 minutes.

If you are assigned to the control group, you will continue your usual daily activities without participating in the training program.

All assessments will be conducted by trained healthcare professionals and include measurements such as body composition, muscle strength, ultrasound muscle thickness, calf circumference, handgrip strength, walking speed, questionnaires (SARC-F, EQ-5D), nutritional assessment (MNA), and upper limb functional tests.

During all assessments and training sessions, trained personnel will be present to ensure your safety.

◆ 6. Data Confidentiality

All personal information collected in this study will be kept strictly confidential. Your data will be de-identified using a study code instead of your name or personal identifiers.

Paper records will be stored in locked cabinets, and electronic data will be encrypted and stored on secure devices. All data will be retained for five years after study completion and then destroyed.

◆ 7. Use of Data and Materials

No biological specimens will be collected in this study.

Your data will not be reused for other research without additional ethical approval. If future research exceeds the scope of your consent, your permission will be requested again.

◆ 8. Risks and Discomforts

This study does not involve invasive procedures. However, the following potential risks may occur:

- **Risk of falls:** During walking tests, there is a risk of falling similar to daily activities. Staff will be present to ensure safety.
- **Fatigue:** Exercise sessions may cause fatigue, especially in less active individuals. Exercise will be stopped immediately if discomfort occurs.

A physical therapist will be present during all sessions. If any adverse symptoms occur, you should inform the staff immediately.

Emergency contact (24-hour):
Dr. Sheng-Hui Tuan
Tel: +886-905-484-121

◆ 9. Benefits

Participation in this study may help improve muscle strength, physical function, and quality of life. However, improvement cannot be guaranteed.

The findings of this study may contribute to better rehabilitation strategies for older adults and may benefit future patients with similar conditions.

◆ 10. Compensation and Insurance

If any injury occurs as a result of participation in this study, Cishan Hospital will provide necessary medical assistance and compensation in accordance with regulations.

No additional financial compensation will be provided for participation.

◆ 11. Participant Rights

Participation in this study is voluntary. You may withdraw at any time without providing a reason, and your decision will not affect your medical care.

Your personal data will be protected and kept confidential. Research results may be published, but your identity will not be disclosed.

If you have any questions about your rights, you may contact the Institutional Review Board.

◆ 12. Withdrawal from the Study

You may withdraw from the study at any time. Data collected before withdrawal may still be used for analysis, but no further data will be collected after withdrawal.

The investigator may also terminate the study if necessary.

◆ 13. Signature

I have read and understood the information provided above. I have had the opportunity to ask questions and have received satisfactory answers. I voluntarily agree to participate in this study.

Participant Name: _____
Signature: _____
Date: _____

Legal Representative (if applicable): _____
Relationship: _____
Date: _____

Witness (if applicable): _____
Date: _____

Principal Investigator / Research Staff: _____
Date: _____