Study Protocol with Statistical Analysis Plan (SAP)

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

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Brief Description of Document: This document provides the full study protocol and statistical analysis plan for a randomized controlled trial evaluating the effectiveness of a 12-week elastic band progressive resistance training program in improving sarcopenia-related outcomes among older adults residing in long-term care facilities.

A. BACKGROUND

Sarcopenia is a progressive and generalized skeletal muscle disorder characterized by the loss of muscle mass, strength, and physical performance, and is highly prevalent among older adults. In Taiwan, the prevalence of sarcopenia in individuals aged ≥65 years exceeds 20%, posing a major public health concern due to its strong association with frailty, functional decline, falls, disability, and increased mortality .

Resistance training has been widely recognized as an effective intervention to improve muscle strength and physical function in older adults. However, in rural and long-term care facility settings, the implementation of conventional resistance training programs is often limited by insufficient rehabilitation manpower, lack of equipment, and concerns regarding safety and injury risk. These barriers highlight the need for a simple, safe, and scalable exercise model suitable for institutionalized older populations.

Elastic band-based progressive resistance training (PRT) offers several advantages, including low cost, portability, adaptability to group-based training, and reduced joint loading, making it particularly suitable for frail older adults. Previous studies have demonstrated that elastic band training can effectively improve muscle strength and functional performance while minimizing the risk of musculoskeletal injury. Furthermore, such training aligns with key rehabilitation principles, including repetitive practice, task-oriented training, and progressive overload, which are essential for neuromuscular adaptation .

Despite these advantages, evidence regarding the effectiveness of elastic band PRT in delaying the progression of sarcopenia, particularly in resource-limited long-term care settings, remains limited. Additionally, optimal training protocols and their feasibility in real-world institutional environments require further investigation.

Therefore, this study aims to evaluate the clinical effectiveness, safety, and feasibility of a structured elastic band progressive resistance training program in older adults residing in long-term care facilities, with a particular focus on rural healthcare settings. The findings are expected to provide evidence for developing scalable rehabilitation strategies that align with Taiwan's Long-Term Care 2.0 policy.

B. OBJECTIVES

B.1 Primary Objectives

The primary objective of this study is to evaluate the effectiveness of a 12-week elastic band progressive resistance training program in improving key diagnostic components of sarcopenia among older adults residing in long-term care facilities.

Specifically, the study aims to determine whether the intervention can:

- Increase appendicular skeletal muscle mass index (ASMI)
- Improve dominant handgrip strength
- Enhance gait speed
- Reduce SARC-F questionnaire scores

B.2 Secondary Objectives

The secondary objectives are to assess the broader physiological and functional effects of the intervention, including:

- Improvement in maximal voluntary isometric contraction (MVIC) of major muscle groups
- Increase in muscle thickness as assessed by ultrasonography
- Enhancement of upper limb functional performance (hand dexterity)
- Increase in calf circumference as a surrogate marker of muscle mass
- Improvement in health-related quality of life (EQ-5D)
- Improvement in nutritional status (Mini Nutritional Assessment, MNA)

B.3 Additional Implementation Objective

In addition, this study aims to evaluate the feasibility and scalability of elastic band-based progressive resistance training as a low-resource rehabilitation model in rural long-term care settings. Specifically, it seeks to determine whether such an intervention can:

- Reduce reliance on specialized rehabilitation manpower
- Be implemented as a group-based exercise program
- Serve as a standardized and reproducible intervention for sarcopenia prevention and management

C. Study Design

This study is a randomized controlled trial conducted in long-term care facilities affiliated with Cishan Hospital, Ministry of Health and Welfare, Taiwan .

Participants were randomly assigned (1:1) to:

- Intervention group (elastic band training)
- Control group (usual care)

Allocation concealment was achieved using sequentially numbered, opaque, sealed envelopes (SNOSE). Outcome assessors and data analysts were blinded.

D. Participants

Participants were recruited from long-term care facilities affiliated with or contracted by Cishan Hospital, Ministry of Health and Welfare, Taiwan. Eligible participants were older adults aged 60 years or above who resided in these facilities and possessed sufficient cognitive function to understand and follow exercise instructions. Individuals were excluded if they had severe cardiovascular disease, uncontrolled hypertension, were bedridden, or had oxygen-dependent respiratory conditions that would limit safe participation in exercise. After screening for eligibility, participants were enrolled and randomly assigned to either the intervention group or the control group. The sample size was estimated based on effect size calculations from previous studies, with a minimum of 21 participants required per group to achieve adequate statistical power.

E. Intervention

Participants in the intervention group underwent a structured 12-week PRT program using TheraBand elastic resistance bands. The training was conducted twice per week, with each

session lasting approximately 30 minutes. The exercise program targeted major muscle groups of both the upper and lower limbs and included movements such as seated chest press, seated row, and shoulder press for the upper extremities, as well as hip circumduction, seated leg press, and seated leg curl for the lower extremities. The intervention incorporated principles of proprioceptive neuromuscular facilitation (PNF) to enhance neuromuscular activation.

To ensure progressive overload, resistance intensity was increased every two weeks using a color-coded system of elastic bands, progressing from lower to higher resistance levels (yellow, red, green, blue, black, and silver). Each exercise was performed in three sets, with 10 repetitions during the first week of each stage and 20 repetitions during the second week. Exercise intensity was monitored using the Rating of Perceived Exertion (RPE), maintained between 10 and 13 to ensure a safe and moderate training intensity suitable for older adults. Participants in the control group continued their usual daily activities provided by the facility without receiving elastic band training.

F. Outcome Measures

Outcome measures were assessed at baseline and after completion of the 12-week intervention. The primary outcomes included key diagnostic components of sarcopenia, namely appendicular skeletal muscle mass index (ASMI), dominant handgrip strength, gait speed, and SARC-F questionnaire scores. Secondary outcomes included MVIC of major muscle groups, muscle thickness measured by ultrasonography (including biceps brachii, quadriceps femoris, and gastrocnemius), upper limb functional performance assessed by standardized dexterity tests, calf circumference, health-related quality of life evaluated using the EQ-5D questionnaire, and nutritional status assessed by the Mini Nutritional Assessment (MNA). All measurements were performed by trained personnel using standardized protocols to ensure reliability and validity.

G. Statistical Analysis Plan

All statistical analyses were conducted using SPSS statistical software (version 19.0, IBM Corp., Armonk, NY, USA). Continuous variables were expressed as mean ± standard deviation, and the normality of data distribution was assessed using the Shapiro–Wilk test. For within-group comparisons, paired t-tests were used for normally distributed data, while

Wilcoxon signed-rank tests were applied for non-normally distributed variables. Between-group differences were analyzed using independent t-tests or Mann–Whitney U tests, depending on data distribution. Percentage change from baseline was calculated to evaluate the magnitude of improvement, and effect sizes were estimated using Cohen's d to quantify the clinical significance of the findings. A two-tailed p-value of less than 0.05 was considered statistically significant.