

Effectiveness of a Home-base Walking Exercise Program on Depression, Frailty, and Quality of Life in Patients with Heart Failure

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Study Protocol

1. Study Design and Participants

- A. This study adopts an experimental study design. The study population consists of hospitalized patients admitted to medical and surgical wards at a tertiary medical center in northern Taiwan. Eligible participants are those diagnosed with heart failure by their attending physicians and meeting the predefined inclusion criteria.

2. Randomization and Allocation

- A. After enrollment, participants will be randomly assigned to either the intervention (home-based walking group) or control group (general health education group) using a block randomization method. A total of 17 blocks will be generated to ensure balanced allocation throughout the enrollment period. Randomization codes will be prepared in advance and placed in sequentially numbered, sealed, opaque envelopes. Upon obtaining informed consent, the envelopes will be opened in sequence, and participants will be assigned to the corresponding group based on the allocation code inside the envelope.

3. Intervention

- A. Participants in the intervention group will receive standard in-hospital health education, followed by a 12-week home-based walking exercise program after discharge.
- B. Participants in the control group will receive standard health education once prior to discharge, without additional post-discharge intervention.

4. Outcome Assessment

- A. The effectiveness of the home-based walking exercise program will be evaluated at three time points:
 - i. Baseline (T0, prior to intervention)
 - ii. One month after discharge (T1)
 - iii. Three months after discharge (T2)

5. Rationale for Randomization Method

- A. Block randomization is used to maintain balance in the number of participants between the intervention and control groups throughout the enrollment period. Compared with simple randomization, block randomization reduces the risk of group imbalance due to random variation, particularly in studies with small sample sizes. This approach improves statistical power and enhances the stability of treatment effect estimates while preserving the benefits of random allocation and reducing selection bias, thereby strengthening internal validity.

6. Data Collection and Measures

- A. Outcome assessments will be conducted using repeated measures with validated questionnaires. Data collection instruments include:

- i. Demographic questionnaire
 - ii. Patient Health Questionnaire-9 (PHQ-9)
 - iii. Clinical Frailty Scale (CFS)
 - iv. Minnesota Living with Heart Failure Questionnaire (MLWHFQ)
- B. To ensure adherence to the home-based walking exercise program, participants in the intervention group will receive weekly telephone follow-ups during the 12-week intervention period. These follow-ups will monitor exercise adherence and provide ongoing support.

Statistical Analysis Plan

1. Analysis Population

- A. All analyses will be conducted according to the intention-to-treat (ITT) principle. All randomized participants will be included in the analysis based on their originally assigned groups, regardless of adherence to the intervention.

2. Statistical Software

- A. All statistical analyses will be performed using SPSS version 29.0 (IBM Corp., Armonk, NY, USA). A two-sided p-value < 0.05 will be considered statistically significant.

3. Descriptive Statistics

- A. Descriptive statistics will be used to summarize baseline characteristics of participants in the intervention and control groups.
 - i. **Categorical variables** (e.g., sex, age group, education level, economic status, past medical history, self-reported physical activity level, and New York Heart Association [NYHA] functional class) will be presented as frequencies and percentages.
 - ii. **Continuous variables** (e.g., age, left ventricular ejection fraction [LVEF], depression scores, frailty scores, and quality of life scores) will be expressed as means and standard deviations.

4. Outcome Analysis

- A. Changes in outcome variables (depression, frailty, and quality of life) between the intervention and control groups at different time points (baseline, 1 month, and 3 months post-discharge) will be analyzed.
 - i. **Independent sample t-tests** will be used to compare between-group differences in score changes at each time point.

5. Longitudinal Analysis

- A. To evaluate the effects of the intervention over time:
 - i. **Generalized Estimating Equations (GEE)** will be applied to analyze repeated measures data, including depression, frailty, and quality of life scores.
 - ii. The model will include:
 - 1. Group effect (intervention vs. control)
 - 2. Time effect (baseline, 1 month, 3 months)
 - 3. Group \times Time interaction

Informed Consent Form

1. Study Title

Effectiveness of a Home-Based Walking Exercise Program on Depression, Frailty, and Quality of Life in Patients with Heart Failure

2. Purpose

This study aims to evaluate whether a home-based walking exercise program improves depression, frailty, and quality of life in patients with heart failure.

3. Procedures

Participants will be randomly assigned to:

A home-based walking group (12 weeks), or a general health education group. Assessments will be conducted at baseline, 1 month, and 3 months after discharge.

4. Risks

Potential risks include minor injury, fatigue, or cardiovascular symptoms during exercise. Participants are advised to stop exercise and seek medical care if symptoms occur.

5. Benefits

Participants may experience improved physical and psychological health; however, no benefit is guaranteed.

6. Voluntary Participation

Participation is voluntary. Participants may withdraw at any time without affecting their medical care.

7. Confidentiality

Personal data will be coded and kept confidential in accordance with applicable regulations.

8. Contact

Participants may contact the research team for questions or concerns.

9. Consent

By signing, the participant agrees to take part in this study.