# Study Protocol with Statistical Analysis Plan

## Effects of Elastic-Band Resistance Training With or Without Breathing Exercise on Pulmonary Function and Functional Performance in Community-Dwelling Older Adults With Pulmonary Function Impairment: A Randomized Controlled Trial

| | |
|---|---|
| **Brief Title** | Elastic-Band Resistance and Breathing Training for Older Adults With Pulmonary Function Impairment |
| **Acronym** | EBBT-PFI |
| **NCT Number** | Not yet assigned |
| **Document Type** | Study Protocol with Statistical Analysis Plan |
| **Document Version** | Version 1.0 |
| **Document Date** | November 4, 2025 |
| **Sponsor/Responsible Institution** | Beijing Sport University |
| **Ethics Review Board** | Ethics Committee for Sports Science Experiments of Beijing Sport University |
| **Study Site** | Huayuan Road Community Health Service Center, Haidian District, Beijing, China |

*Confidentiality and use: This document is prepared for clinical trial registration and study documentation. Personally identifiable information may be redacted before public submission, where applicable.*

# 1. Protocol Synopsis

| Item | Description |
|---|---|
| **Study Design** | Single-center, three-arm, parallel-group randomized controlled trial. |
| **Population** | Community-dwelling adults aged 60 years or older with pulmonary function impairment identified by spirometry screening. |
| **Allocation** | Eligible participants are randomly assigned in a 1:1:1 ratio to EB+BT, EB, or CON. |
| **Intervention Duration** | 12 weeks. |
| **Assessment Time Points** | Baseline (Week 0), Week 6, and Week 12. |
| **Study Arms** | Elastic-band resistance training plus breathing training (EB+BT), elastic-band resistance training alone (EB), and usual health education (CON). |
| **Primary Objectives** | To evaluate whether elastic-band resistance training, with or without structured breathing training, improves pulmonary function and functional performance. |
| **Safety Monitoring** | Attendance, training logs, symptoms, blood pressure, heart rate when needed, and adverse events are monitored during the study. |

# 2. Background and Rationale

Pulmonary function impairment is common among older adults and may be associated with reduced physical activity, lower exercise tolerance, impaired mobility, and poorer respiratory-related health status. Community-dwelling older adults with early or mild pulmonary function decline may not receive formal pulmonary rehabilitation, but they may still benefit from simple, low-cost, and feasible exercise-based interventions.

Exercise training is a core non-pharmacological strategy for respiratory-related functional limitation. Resistance training may improve peripheral muscle strength, muscular endurance, and movement efficiency, while breathing training may improve breathing pattern, symptom perception, and respiratory-related health status. However, most evidence comes from patients with diagnosed chronic respiratory disease or structured pulmonary rehabilitation settings. Evidence is more limited for community-screened older adults with pulmonary function impairment.

Elastic bands are inexpensive, portable, and easy to adjust for different ability levels. A community-based elastic-band resistance training program, with or without structured breathing training, may therefore provide a practical early intervention model for older adults with pulmonary function impairment.

# 3. Objectives and Hypotheses

## 3.1 Primary Objectives

- To evaluate the effects of a 12-week elastic-band resistance training program on pulmonary function and functional performance in community-dwelling older adults with pulmonary function impairment.
- To determine whether adding structured breathing training to elastic-band resistance training provides additional benefits for pulmonary function and respiratory-related health status.

### 3.2 Hypotheses

- Compared with usual health education, elastic-band resistance training will improve pulmonary function, lower-limb muscle strength, walking ability, and short-duration exercise tolerance.
- Compared with elastic-band resistance training alone, elastic-band resistance training plus structured breathing training will produce additional improvement in selected pulmonary function indicators and respiratory-related health status.

## 4. Study Design and Setting

This is a single-center, three-arm, parallel-group randomized controlled trial. Participants are randomly assigned in a 1:1:1 ratio to elastic-band resistance training plus breathing training (EB+BT), elastic-band resistance training alone (EB), or usual health education (CON). The intervention period lasts 12 weeks. Outcomes are assessed at baseline, Week 6, and Week 12.

The study is conducted at Huayuan Road Community Health Service Center, Haidian District, Beijing, China. The site provides support for recruitment, screening, intervention delivery, follow-up assessments, and participant safety monitoring.

## 5. Participants

### 5.1 Recruitment

Participants are recruited through posters in the community health service center and surrounding community areas, online community platforms, and referral from relevant departments during physical examination, chronic disease follow-up, or outpatient services. Interested individuals undergo basic information registration, preliminary health inquiry, eligibility screening, and spirometry assessment.

### 5.2 Inclusion Criteria

- Age 60 years or older.
- Community-dwelling older adult.
- Able to communicate and walk independently.
- Willing to participate in the 12-week intervention and all study assessments.
- Pulmonary function impairment identified by community-based spirometry screening.
- Provided written informed consent.

### 5.3 Exclusion Criteria

- Acute or unstable cardiovascular, respiratory, or severe musculoskeletal disease that makes exercise training unsafe.
- Recent acute exacerbation, surgery, severe infection, or other health event that may affect safe participation.
- Significant cognitive impairment, communication disorder, or inability to cooperate with training or assessments.
- Currently receiving systematic pulmonary rehabilitation or regular structured exercise training that may affect estimation of the intervention effect.
- Unable to meet spirometry quality-control requirements.
- Unable to complete key baseline outcome assessments.

### 5.4 Definition of Pulmonary Function Impairment

Pulmonary function impairment is defined using a reference-distribution framework. Forced expiratory volume in 1 second (FEV1), forced vital capacity (FVC), or FEV1/FVC below the lower limit of normal (LLN) is considered abnormal. LLN is defined as the fifth percentile of the reference distribution, approximately corresponding to a z-

score less than -1.645. FEV1 or FVC below LLN indicates impaired ventilatory volume, while FEV1/FVC below LLN indicates airflow limitation. Raw values and z-scores are recorded. Predicted values and z-scores are calculated using the Global Lung Function Initiative 2012 spirometry reference equations with the Northeast Asian ethnic module.

## 6. Sample Size

Sample size was estimated using G*Power 3.1. Based on a three-group comparison, one-way analysis of variance was used as an approximate model. With a two-sided alpha level of 0.05, power of 0.80, and medium effect size of f = 0.25, at least approximately 17 participants per group were required, corresponding to a minimum total sample size of approximately 60 participants. Considering potential attrition, withdrawal, and insufficient adherence in a community-based exercise intervention, the study planned to over-recruit participants. A total of 90 eligible participants were randomized.

## 7. Randomization, Allocation Concealment, and Masking

Eligible participants are randomized in a 1:1:1 ratio. The random allocation sequence is generated independently by a third-party researcher who is not involved in recruitment, outcome assessment, or intervention delivery. Group assignments are placed in opaque, sealed, sequentially numbered envelopes and kept by an independent researcher. After baseline assessment and confirmation of eligibility, the corresponding envelope is opened according to enrollment order to determine the assigned group.

Because of the nature of the exercise interventions, participants and intervention providers are not masked to group allocation. Outcome assessors are masked to group assignment during follow-up assessments whenever possible. Participants are instructed not to disclose their group assignment during assessments. Data analysts use coded group labels during the main statistical analysis whenever possible.

## 8. Interventions

All interventions are delivered in a unified setting at the community health service center. The intervention period lasts 12 weeks. Participants in the EB+BT and EB groups receive supervised exercise sessions three times per week. Attendance records and training logs are used to monitor adherence. Blood pressure, heart rate, and self-reported symptoms are recorded when needed to support safety monitoring.

### 8.1 Elastic-Band Resistance Training Plus Breathing Training Group

Participants in the EB+BT group receive elastic-band resistance training combined with structured breathing training and usual health education.

#### Elastic-band resistance training

Elastic-band resistance training is the core exercise intervention. Each session lasts approximately 60 minutes and includes a warm-up of approximately 10 minutes, a main training phase of approximately 40 minutes, and a cool-down of approximately 10 minutes. The warm-up includes joint mobility, low-intensity dynamic activity, and movement preparation. The cool-down includes low-intensity relaxation and stretching.

The main training phase uses progressive elastic-band resistance exercises with 10 lb, 15 lb, and 20 lb resistance levels selected and progressed according to individual capacity and movement quality. Exercises target shoulder girdle, upper-limb pushing and pulling, hip and knee flexion and extension, ankle dorsiflexion and plantarflexion, and trunk stability. Each session includes 8 to 10 exercises, including 4 to 5 upper-limb and 4 to 5 lower-limb exercises, with optional core-stability exercises when appropriate. Exercises are performed in an order that prioritizes large muscle groups and multi-joint movements before smaller muscle groups and single-joint movements.

During the initial phase, the focus is movement learning and adaptation. Participants perform 2 sets of 10 to 12 repetitions for each exercise. From Week 3 onward, most exercises progress to 3 sets of 12 to 15 repetitions. Training may be modified for participants with lower fitness levels or joint discomfort, while maintaining movement quality as the prerequisite for progression.

Training intensity is prescribed and monitored using the OMNI-RES perceived exertion scale from 0 to 10. The target intensity is 4 to 6 during the early phase and is gradually progressed to 6 to 7 after adaptation. If a participant can complete the target repetitions with OMNI-RES persistently at or below 3 and without compensation or discomfort, resistance level or movement difficulty may be increased. If marked fatigue, compensation, or discomfort occurs, the current load is maintained or reduced.

#### Structured breathing training

Structured breathing training mainly uses a three-ball breathing trainer, supplemented by diaphragmatic breathing, pursed-lip breathing, rhythmic breathing, and breathing control exercises. Breathing training is arranged before or after resistance training or as a separate module. Participants receive supervised breathing training three times per week and are encouraged to perform home practice.

The breathing trainer component emphasizes slow inspiration, maintenance, and slow expiration, while avoiding shoulder elevation, rapid inhalation, or upper-chest compensation. Diaphragmatic and pursed-lip breathing are used to promote diaphragmatic participation, extend expiration, and improve respiratory rhythm and relaxation. Rhythmic breathing and breathing control practice are used to help participants establish a more stable and economical breathing pattern during activity.

Breathing training is quantified by training level, maintenance time, repetitions, and Borg perceived breathing effort. Training begins at a low level with shorter maintenance time and fewer repetitions, targeting light to moderate perceived breathing effort, and progresses according to tolerance and skill acquisition.

### 8.2 Elastic-Band Resistance Training Group

Participants in the EB group receive the same elastic-band resistance training prescription, frequency, and duration as the resistance training component in the EB+BT group, along with usual health education. No structured breathing training is provided. This arm is used to evaluate the effect of elastic-band resistance training alone and to serve as the comparator for the incremental effect of structured breathing training.

### 8.3 Usual Health Education Group

Participants in the CON group do not receive systematic exercise training. They receive usual health education and daily activity guidance, including general lifestyle advice, basic physical activity recommendations, and safety instructions. They complete the same assessments at baseline, Week 6, and Week 12 and maintain follow-up contact by telephone or online communication.

## 9. Outcome Measures

All outcomes are measured at baseline, Week 6, and Week 12 by trained assessors using standardized procedures.

### 9.1 Primary Outcome Measures

The primary outcomes include pulmonary function outcomes and selected functional performance outcomes.

- Forced expiratory volume in 1 second (FEV1), measured by standardized spirometry.
- Forced vital capacity (FVC), measured by standardized spirometry.
- FEV1/FVC ratio, calculated from spirometry results.
- FEV1 z-score, calculated using reference equations to standardize pulmonary function according to age, sex, height, and ethnicity.
- FVC z-score, calculated using reference equations.
- FEV1/FVC z-score, calculated using reference equations.

- 30-second chair stand test, recorded as the number of complete sit-to-stand repetitions in 30 seconds.
- 4-meter gait speed, calculated from walking time at usual comfortable speed.
- 2-minute step test, recorded as the number of valid steps reaching the required knee height in 2 minutes.

### 9.2 Secondary Outcome Measures

- Dominant-side and non-dominant-side quadriceps strength, measured using a standardized muscle strength testing device.
- Dominant-side and non-dominant-side triceps surae strength, measured using a standardized muscle strength testing device.
- Timed Up and Go test, recorded as the time required to stand up from a chair, walk a fixed distance, turn, return, and sit down.
- Dominant-side and non-dominant-side handgrip strength, measured using a standardized handgrip dynamometer.
- St. George's Respiratory Questionnaire total score, used to assess respiratory-related health status; lower scores indicate better status.
- Pittsburgh Sleep Quality Index total score, used to assess subjective sleep quality; lower scores indicate better sleep quality.

### 9.3 Measurement Procedures

Spirometry is performed using a standardized device and standardized forced-expiratory maneuver procedures. Participants are seated, wear a nose clip, use a disposable mouthpiece, and complete maximal inspiration followed by rapid, sustained, forced expiration. At least three acceptable maneuvers are required, with additional attempts performed within participant tolerance if reproducibility criteria are not met.

Muscle strength tests are performed in standardized positions with standardized instructions. Each muscle group is tested twice with at least 60 seconds of rest between trials. The maximum value is used for analysis; a third trial may be added if the first two values differ substantially. Functional performance tests and questionnaires are administered using standardized instructions. Whenever possible, the same assessor measures the same participant at different time points under similar environmental conditions.

## 10. Adherence and Safety Monitoring

Training attendance, total training time, weekly target completion, and training logs are recorded to monitor adherence. During training sessions, research staff monitor symptoms and record blood pressure and heart rate when needed. Any adverse events, serious adverse events, or exercise-related discomfort are documented, including the time, description, severity, relationship to the intervention, management, and outcome. Participants are advised to report any discomfort or health changes during the study period.

## 11. Quality Control and Data Management

All assessors and intervention providers receive standardized training before study implementation. Outcome measurements and interventions follow standardized operating procedures. Spirometry quality control includes at least three acceptable maneuvers and additional attempts within participant tolerance when needed. Outcome measurements are performed by trained assessors under similar conditions across time points when possible.

Original data are recorded using participant identification codes and stored securely. Data entry is checked by two researchers to reduce recording and entry errors. Study data are anonymized or coded for analysis, and access to identifiable information is restricted to authorized study personnel.

## 12. Statistical Analysis Plan

This section describes the planned statistical analysis for the randomized controlled trial. The main statistical objective is to compare changes in pulmonary function, functional performance, muscle strength, respiratory-related health status, and sleep quality among the three study groups over the 12-week intervention period.

### 12.1 Analysis Sets

The primary analysis set is the per-protocol set, defined as participants who complete baseline and Week 12 primary outcome assessments and have sufficient participation to allow evaluation of the assigned intervention. This choice is used because missing data are expected to arise mainly from loss to follow-up or failure to complete post-intervention testing.

The randomized set includes all participants who were randomized. The safety set includes participants who attended at least one intervention or follow-up contact after randomization and is used for summaries of adverse events and safety monitoring. If data availability allows, sensitivity analyses may be performed using all randomized participants with available repeated measurements.

### 12.2 General Principles

All statistical tests are two-sided. Statistical significance is set at $P < 0.05$. Continuous variables are summarized as mean and standard deviation when approximately normally distributed, and as median and interquartile range when clearly non-normally distributed. Categorical variables are summarized as frequencies and percentages. No interim efficacy analysis is planned.

Outcome analyses focus on the prespecified assessment time points: baseline, Week 6, and Week 12. The primary contrast of interest is change from baseline to Week 12 among the three groups. Week 6 results are used to describe the trajectory of change during the intervention period.

### 12.3 Baseline Comparisons

Baseline demographic and clinical characteristics are compared among groups to describe comparability after randomization. For normally distributed continuous variables, one-way analysis of variance is used. For non-normally distributed continuous variables, the Kruskal-Wallis test is used. For categorical variables, the chi-square test or Fisher exact test is used as appropriate. Baseline comparisons are descriptive and are not used as the sole basis for covariate selection.

### 12.4 Primary Outcome Analyses

Primary outcomes include FEV1, FVC, FEV1/FVC, FEV1 z-score, FVC z-score, FEV1/FVC z-score, 30-second chair stand test, 4-meter gait speed, and 2-minute step test. Each primary outcome is analyzed using a linear mixed-effects model with group, time, and group-by-time interaction as fixed effects and participant identifier as a random intercept. The group-by-time interaction is the main term of interest and is used to evaluate whether changes over time differ among groups.

For each primary outcome, estimated marginal means are obtained from the model. Prespecified pairwise comparisons include EB+BT versus CON, EB versus CON, and EB+BT versus EB at Week 12 and, when relevant, for change from baseline to Week 12. Multiplicity adjustment for post hoc pairwise comparisons is performed using the Bonferroni method. Results are reported as means and standard deviations by group and time point, change from baseline to Week 12, estimated between-group differences, 95% confidence intervals, and P values.

### 12.5 Secondary Outcome Analyses

Secondary outcomes include dominant-side and non-dominant-side quadriceps strength, dominant-side and non-dominant-side triceps surae strength, Timed Up and Go test, dominant-side and non-dominant-side handgrip strength, St. George's Respiratory Questionnaire total score, and Pittsburgh Sleep Quality Index total score. These outcomes are analyzed using the same linear mixed-effects model framework as the primary outcomes, with group, time, and group-by-time interaction as fixed effects and participant identifier as a random intercept.

For outcomes in which lower values indicate better performance or status, including Timed Up and Go, St. George's Respiratory Questionnaire, and Pittsburgh Sleep Quality Index, negative change values are interpreted as improvement. For outcomes in which higher values indicate better performance, positive change values are interpreted as improvement.

### 12.6 Model Checking and Assumptions

Model assumptions are assessed by visual inspection of residual distributions and residual-versus-fitted plots. If marked non-normality, extreme outliers, or heteroscedasticity is observed, the analysis may be supplemented by appropriate sensitivity analyses, such as non-parametric comparisons of change scores or transformed outcome analyses. Any deviations from the planned model are documented and justified.

### 12.7 Missing Data Handling

For the primary per-protocol analysis, participants without baseline and Week 12 primary outcome assessments are not included in the main analysis. Missing data are not imputed when missingness is primarily due to loss to follow-up or failure to complete post-intervention testing. The number of participants included in each analysis is reported. If repeated-measure data are available at some but not all time points, linear mixed-effects models use all available observations under the model assumptions.

### 12.8 Adherence and Safety Analyses

Adherence variables include attendance sessions, weeks meeting the training target, total training time, target completion rate, and high adherence rate. Continuous adherence variables are summarized as mean and standard deviation or median and interquartile range, and categorical adherence variables are summarized as counts and percentages. Between-group comparisons for adherence are performed between the two exercise groups using independent-samples t tests, Mann-Whitney U tests, chi-square tests, or Fisher exact tests as appropriate.

Safety outcomes include adverse events and serious adverse events, especially events considered related to the exercise intervention. Events are summarized by group using counts, percentages, event description, severity, relatedness, management, and outcome. No formal hypothesis test is required for rare safety events unless the number of events permits meaningful comparison.

### 12.9 Exploratory Analyses

Exploratory analyses may include dose-response analyses and correlation analyses. Dose-response analyses examine associations between total training time and changes in selected outcomes while controlling for group, primarily among participants in the exercise groups. Correlation analyses may evaluate associations between changes in pulmonary function and changes in functional or symptom-related outcomes using Spearman correlation coefficients when distributional assumptions are not met. These analyses are considered exploratory and hypothesis-generating.

### 12.10 Statistical Software

Statistical analyses are performed using SPSS version 26.0 and/or R software. Linear mixed-effects models may be fitted using appropriate R packages such as lme4 and lmerTest, and estimated marginal means may be obtained using emmeans. The final software and package versions used for analysis should be documented in the study report.

## 13. Ethical Considerations

The study is conducted in accordance with the principles of the Declaration of Helsinki and was reviewed by a human subjects protection review board. Written informed consent is obtained from all participants before participation. Participants may withdraw from the study at any time. Study data are coded or anonymized and used only for scientific research purposes.

## 14. Dissemination and Data Sharing

Study findings may be disseminated through academic publication, conference presentation, or clinical trial registry reporting. Individual participant data will not be publicly shared because the study involves health-related data from older adults, and public sharing was not specified in the informed consent or ethics approval. De-identified data may be considered only upon reasonable request and with appropriate ethical approval.

## 15. Protocol Amendments

Any protocol amendments that affect participant safety, study procedures, outcomes, or analysis plans should be documented, dated, and submitted for ethics review when required. Updated versions should be maintained in the study record and uploaded to ClinicalTrials.gov if applicable.