

DEPARTMENT OF PHYSICAL MEDICINE AND REHABILITATION
FACULTY OF MEDICINE, UNIVERSITAS AIRLANGGA

Study Protocol with Statistical Analysis Plan and Informed Consent Form

Official Study Title:

The Effect of Adding Elastic Resistance Training in Routine Physical Exercise on Walking Speed of Elderly People with Sarcopenia in Griya Wreda Jambangan, Surabaya

NCT Number: *Not yet assigned*

Document Date: April 20th 2026

Study Site:

Griya Wreda Jambangan
Surabaya, East Java, Indonesia

INFORM CONSENT FORM



UNIVERSITAS AIRLANGGA
FACULTY OF MEDICINE
DEPARTMENT OF PHYSICAL MEDICINE
AND REHABILITATION
Jl. Mayjen Prof. Dr. Moestopo 6-8, Tel. 031-5501493,
Surabaya

PARTICIPANT INFORMATION SHEET (*Information for Informed Consent*)

Study Title:

“The Effect of Adding Elastic Resistance Training to Routine Physical Exercise on Walking Speed in Older Adults with Sarcopenia at Griya Wreda Jambangan, Surabaya”

Dear Sir/Madam, we are physicians from the Department of Physical Medicine and Rehabilitation, Faculty of Medicine, Universitas Airlangga – Dr. Soetomo General Academic Hospital, and we are planning to conduct a research study.

Research Team:

1. Lydia Arfianti, MD, Sp.K.F.R., M.S. (K)
2. Abdul Jabbar Al Hayyan, MD, Sp.K.F.R., M.S. (K)
3. Trinita Diyah Permatasari, MD

Purpose of the Study:

To analyze the effect of adding elastic resistance training on walking speed in older adults with sarcopenia at Griya Wreda Jambangan, Surabaya.

Study Procedures:

1. Walking speed will be assessed in both groups 2 days before the exercise intervention begins.
2. Participants in the intervention group will receive elastic resistance training in addition to routine physical exercise for 8 weeks. Participants in the control group will continue routine physical exercise without additional elastic resistance training. Before each intervention session, participants will be reassessed to ensure that they are fit to participate in the intervention.
3. Walking speed will be assessed in both groups 2 days after the intervention period ends.
4. The research data will then be processed and analyzed.

Benefits for Participants:

Participants will receive information about their walking speed and will have the opportunity to undergo an 8-week elastic resistance training program as a strategy to maintain muscle mass and functional performance. If the intervention is proven effective, the control group will receive similar training so that they may obtain equivalent benefits.

Study Risks:

The risks of this study include the possibility of undesirable conditions related to the exercise intervention, such as dizziness, fatigue, muscle pain, shortness of breath, chest pain, palpitations, fainting, and falls. These risks will be minimized through medical history taking and physical examinations performed before, during, and after each exercise session. In addition, participants' symptoms and clinical condition will be monitored regularly throughout the study.

Data Confidentiality:

All participant data will be kept confidential, used only for research purposes, and will not include names or other personal identifiers.

Voluntary Participation:

Participation in this study is voluntary. Participants may stop participating at any time without any consequences related to the study.

Right to Refuse Participation

You may refuse to participate in this study without any coercion from any party, and your decision will not affect the quality of care provided to you.

Rights and Responsibilities as a Research Participant

As a research participant, you have the right to receive truthful information from the research team and information regarding the exercise program that will be provided, to receive closer monitoring, and to receive appropriate care or treatment according to standard services if any undesirable event occurs during the study.

As a research participant, you are required to follow the study procedures and the instructions of the research team. If you do not comply with the study procedures or instructions, you may be withdrawn from the study at any time.

Right to Withdraw

Your participation in this study is voluntary. You may withdraw from the study at any time and for any reason without penalty, fine, or loss of other benefits. Withdrawal will not affect your relationship with your physician, who will offer other treatment options as appropriate. You will continue to receive standard care according to your clinical indications.

Discontinuation of Participation

The investigator may discontinue your participation in this study, with or without your consent, based on relevant considerations. The investigator may decide to discontinue your participation if, in the investigator's judgment, continued participation may place you at risk, if your condition worsens, or if adverse effects arise that are considered to outweigh the potential benefits of the intervention.

Compensation for Participation in This Study

Although every effort will be made to minimize the risks of this study, undesirable events may still occur. If this happens, the research team will manage all study-related events according to applicable procedures and standards. The research team will provide reasonable compensation as an expression of appreciation for your participation in this study, for example reimbursement of transportation costs, refreshments, or a souvenir.

Contact Information

As a research participant, you may ask questions and obtain information at any time by contacting the research team. The contact person is: **Trinita Diah Permatasari, MD, mobile phone 081222313404** via WhatsApp or telephone.

If you have questions about your rights as a research participant, you may contact Trinita Diah Permatasari, MD, at Dr. Soetomo General Academic Hospital, Department of Physical Medicine and Rehabilitation, Jl. Prof. Dr. Moestopo No. 6-8, Surabaya, or by mobile phone at 081222313404.

Surabaya, _____ 2026

Participant Receiving the Explanation

Person Providing the Explanation

(_____)

(Trinita Diah Permatasari, MD)

Witness I

(_____)

RESEARCH PARTICIPATION INFORMED CONSENT FORM
(Informed Consent)

I, the undersigned:

Name :
Age / Sex :
National Identification Number :
Address :
Telephone / Mobile Number :

I have received an explanation regarding the purpose, benefits, procedures, potential adverse effects, and other complete and clear information, and I understand the study entitled:

The Effect of Adding Elastic Resistance Training to Routine Physical Exercise on Walking Speed in Older Adults with Sarcopenia at Griya Wreda Jambangan, Surabaya

I hereby voluntarily CONSENT to participate in this study. I understand that I may withdraw from the study at any time.

I provide this consent knowingly, without coercion and without pressure from anyone.

Surabaya, ____ / ____ / 2026

Witness 1

Witness 2

Investigator

Participant

(.....)

(.....)

(Trinita Diyah Permatasari,
MD)

(.....)

MEDICAL PROCEDURE CONSENT FORM

I, the undersigned:

Name :
Age :
Address :
Telephone / Email :

After receiving the explanation provided and having been given the opportunity to ask questions about matters I did not understand, I hereby give:

CONSENT

To undergo the following medical intervention: **Addition of Elastic Resistance Training to Routine Physical Exercise**

For the study entitled:

“The Effect of Adding Elastic Resistance Training to Routine Physical Exercise on Walking Speed in Older Adults with Sarcopenia at Griya Wreda Jambangan, Surabaya”

I have the right to withdraw at any time.

I provide this consent knowingly and without coercion.

Surabaya, _____ 2026

Person Giving Consent

Witness 1

Witness 2

(.....)

(.....)

RESEARCH PARTICIPANT WITHDRAWAL FORM

I, the undersigned:

Name :

Age :

Address :

Telephone / Email :

hereby declare that I am **WITHDRAWING** as a research participant from the study entitled “**The Effect of Adding Elastic Resistance Training to Routine Physical Exercise on Walking Speed in Older Adults with Sarcopenia at Griya Wreda Jambangan, Surabaya.**”

I make this withdrawal knowingly and without coercion.

Surabaya, _____ 2026

Person Making the Statement

(.....)

Witness 1

Witness 2

(.....)

(.....)

STUDY PROTOCOL

ELASTIC RESISTANCE TRAINING PROTOCOL

(Based on Liao et al., 2017 and Kwon et al., 2019)

A. Description

Elastic resistance training is a form of strength training that uses elastic resistance devices, such as elastic bands and elastic tubes, to provide progressive resistance during muscle contraction. Elastic resistance training is designed to improve muscle mass, muscle strength, physical function, and functional capacity in older adults, particularly those with sarcopenia or sarcopenic obesity.

B. Preparation

1. Prepare the required equipment, including elastic bands (TheraBand® in yellow, red, green, blue, and black resistance levels), a chair, and an adequately sized exercise area.
2. Participants should wear appropriate exercise clothing during the training session.
3. Blood pressure, heart rate, respiratory rate, body temperature, and oxygen saturation are measured before exercise.
4. Before beginning the exercise program, the researcher provides instructions and demonstrates the correct performance of each elastic resistance training exercise.

C. Procedure

1. Participants in the intervention group take part in an 8-week exercise program. Each session lasts approximately 30–45 minutes and consists of a warm-up, resistance exercises targeting the upper and lower extremities, and a cool-down. Exercises are performed using elastic bands with progressive resistance adjusted according to each participant's ability.
2. Participants perform a 10-minute warm-up consisting of neck, upper-extremity, back, and lower-extremity mobility exercises. These include neck rotation, shoulder elevation and depression, shoulder rotation, gentle trunk flexion and extension, light knee flexion and extension, ankle pumps, and marching in place.
3. Upper-extremity exercises consist of *seated chest press*, *seated row*, and *seated shoulder press*. Lower-extremity exercises consist of *standing hip abduction*, *standing hip adduction*, *seated leg press*, and *standing leg curl*.
4. Each exercise is performed for 3 sets of 10–20 repetitions at a moderate intensity, corresponding to an OMNI-RES Rating of Perceived Exertion (RPE) of 4–6, with 30–60 seconds of rest between sets.
5. When a participant is able to complete 20 repetitions at an RPE of 6, resistance is progressed by using the next elastic-band color with a higher resistance level.
6. Training is performed twice per week for 8 weeks on nonconsecutive days.
7. Blood pressure, heart rate, respiratory rate, body temperature, and oxygen saturation are measured after exercise.
8. Participants perform a 5-minute cool-down consisting of light stretching exercises.

D. Contraindications to Exercise

1. Systolic blood pressure >160 mmHg and/or diastolic blood pressure >100 mmHg.

- ## E. Criteria for Exercise Termination

- ### Elastic Resistance Training Progression Schedule

	Week	1	2	3	4	5	6	7	8
Elastic band color	Yellow	X	X						
	Red			X	X				
	Green					X	X		
	Blue							X	X
	Black								
	Silver								
Training load	Repetitions	10–15	15–20	10–15	15–20	10–15	15–20	10–15	15–20
	Sets	3	3	3	3	3	3	3	3
	OMNI RES	4–6	4–6	4–6	4–6	4–6	4–6	4–6	5–6

STATISTICAL ANALYSIS PLAN

Data were analyzed using SPSS version 27.0. The following statistical tests were performed:

1. The **Shapiro–Wilk/Kolmogorov–Smirnov tests** were used to assess the normality of data distribution in the intervention and control groups.
2. A **paired t-test** was used to compare walking speed before and after the intervention within the intervention and control groups. If the data were not normally distributed, the **Wilcoxon signed-rank test** was used.
3. An **independent-samples t-test** was used to compare walking speed between the intervention and control groups before and after the intervention. If the data were not normally distributed, the **Mann–Whitney U test** was used.