Effects of blood flow restriction training on muscle strength for elders

Submission date	Recruitment status	Prospectively registered
05/09/2024	No longer recruiting	<pre>Protocol</pre>
Registration date	Overall study status	Statistical analysis plan
19/09/2024	Completed	Results
Last Edited	Condition category	Individual participant data
06/09/2024	Other	[X] Record updated in last year

Plain English summary of protocol

Background and study aims

Recently, the blood flow restriction training method has become popular. The common blood flow restriction training method uses voodoo tape, but the extent of blood flow restriction cannot be quantified using such an approach. Currently, there is a blood flow restriction system, which can measure limb occlusion pressure (LOP). However, the effects of different levels of blood flow restriction combined with resistance training on muscle strength and functional performance remain unclear. Hence the purpose of this study is to investigate the effects of different extents of blood flow restriction on muscle strength and functional movement performance.

Who can participate?

People who live in Taiwan and aged 65-85 years old who are without significant injuries within 6 months (such as fractures)

What does the study involve?

Participants are randomly allocated to one of three groups:

- 1. High blood flow restriction: participants will perform knee extension exercises under high blood flow restriction with low resistance training
- 2. Low blood flow restriction: participants will perform knee extension exercises under low blood flow restriction with low resistance training
- 3. Control group: participants will perform knee extension exercises under high resistance training without blood flow restriction.

Sessions are three times a week for 8 weeks and last about 1 hour each, including warm-up, resistance training, resting between sets, and cool-down. Leg muscle strength, muscle mass and functional performance, such as walking and balance, are measured before the intervention, after a 4-week intervention and after an 8-week intervention.

What are the possible benefits and risks of participating

The possible benefits include gaining muscular strength in the lower extremity and further improvement in functional performance. Risks include possible muscle soreness after the intervention.

Where is the study run from? China Medical University, Taiwan (R.O.C)

When is the study starting and how long is it expected to run for? May 2023 to July 2024

Who is funding the study? China Medical University, Taiwan (R.O.C)

Who is the main contact?

Dr Yu-Lin You, oilfish@mail.cmu.edu.tw

Contact information

Type(s)

Public, Scientific, Principal Investigator

Contact name

Dr Yu-Lin You

Contact details

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Nil known

Study information

Scientific Title

Effects of an 8-week resistance training with different level of blood flow restriction on muscular strength, dynamic balance for elders

Study objectives

Greater blood flow restriction may induce greater improvement on muscular strength and functional performance

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 30/05/2023, China Medical University Hospital Research Ethics Committee (2 Yude Road, Taichung, 40047, Taiwan; +886-4-22052121; irb@mail.cmuh.org.tw), ref: CMUH112-REC3-072

Study design

Randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Other

Participant information sheet

Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Healthy elders

Interventions

Participants will be randomly allocated into three groups using sealed envelopes, namely high blood flow restriction, low blood flow restriction, and a control group. All participants will undergo isokinetic muscular strength of the lower extremity measurements, timed up-and-go test, and skeletal muscle mass measurement before the intervention, after a 4-week intervention.

The interventions for those groups:

- 1. High blood flow restriction: participants will perform knee extension exercises under high blood flow restriction with low resistance training
- 2. Low blood flow restriction: participants will perform knee extension exercises under low blood flow restriction with low resistance training
- 3. Control group: participants will perform knee extension exercises under high resistance training without blood flow restriction.

The level of blood flow restriction is determined by the limb occlusion pressure (LOP).

For the high blood flow restriction group, the level of blood flow restriction is set at 60% LOP, while for the low blood flow restriction group, the level of blood flow restriction is set at 30% LOP.

Intervention frequency: three times a week for 8 weeks

Duration: approximately 1 hour for a session including warm-up, resistance training, resting between sets, and cool-down.

Intervention Type

Other

Primary outcome measure

Muscular strength of the lower extremity measured using a Biodex isokinetic dynamometer before the intervention, after a 4-week intervention and after an 8-week intervention

Secondary outcome measures

- 1. Dynamic balance measured using the timed up-and-go test before the intervention, after a 4-week intervention and after an 8-week intervention
- 2. Walking ability measured using the 6-meter walk test before the intervention, after a 4-week intervention and after an 8-week intervention
- 3. Skeletal muscle mass measured by Inbody 270 before the intervention, after a 4-week intervention and after an 8-week intervention

Overall study start date

30/05/2023

Completion date

15/07/2024

Eligibility

Key inclusion criteria

- 1. Adults aged 65-85 years old
- 2. Live in Taiwan
- 3. Without significant injuries in the last 3 months (such as fractures), open wounds on the lower extremity

Participant type(s)

Healthy volunteer

Age group

Senior

Lower age limit

65 Years

Upper age limit

85 Years

Sex

Both

Target number of participants

30

Total final enrolment

30

Key exclusion criteria

- 1. Musculosekeletal injuries of the lower extremity within 6 months
- 2. High blood pressure
- 3. Neural diseases, such as Parkinson's disease

Date of first enrolment

30/05/2023

Date of final enrolment

29/05/2024

Locations

Countries of recruitment

Taiwan

Study participating centre China Medical University, Taiwan

Department of Sports Medicine No. 100, Section 1 Jingmao Road Beitun District Taichung City Taiwan 406040

Sponsor information

Organisation

China Medical University

Sponsor details

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Sponsor type

University/education

Website

https://www.cmu.edu.tw/

ROR

https://ror.org/00v408z34

Funder(s)

Funder type

University/education

Funder Name

China Medical University, Taiwan

Alternative Name(s)

CMU

Funding Body Type

Private sector organisation

Funding Body Subtype

Universities (academic only)

Location

Taiwan

Results and Publications

Publication and dissemination plan

Plnned publication in a high-impact-peer-reviewed journal

Intention to publish date

31/12/2025

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Dr Yu-Lin You (oilfish@mail.cmu.edu.tw) until 04/10/2025. The personal information of all participants will be anonymized by code name.

IPD sharing plan summary

Available on request