

Effects of blood flow restriction training on muscle strength for elders

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| Submission date 05/09/2024 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 19/09/2024 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results |
| Last Edited 06/09/2024 | Condition category Other | <input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

Study type(s)

Other

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 and after an 8-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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Senior

Lower age limit

65 years

Upper age limit

85 years

Sex

All

Total final enrolment

30

Key exclusion criteria

1. Musculoskeletal 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

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

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