

Effects of blood flow restriction of the lower extremity on functional performance

Submission date 09/12/2023	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 29/12/2023	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 28/12/2023	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 from 20-40 years old who are without significant injuries in the last three months (such as fractures)

What does the study involve?

Knee extension with or without blood flow restriction and muscular strength of the lower extremity, balance ability and functional performance, like hopping.

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?

April 2023 to April 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

No. 100, Section 1
Jingmao Road
Beitun District
Taichung City
Taiwan
406040
+886-4-22053366 ext. 7611
oilfish@mail.cmu.edu.tw

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 different level of blood flow restriction on muscular strength, balance and power

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 12/04/2023, China Medical University & Hospital (2 Yude Road, Taichung, 40047, Taiwan; +886-4-22052121; irb@mail.cmuh.org.tw), ref: CMUH112-REC2-029

Study design

Randomized controlled trial

Primary study design

Interventional

Study type(s)

Other

Health condition(s) or problem(s) studied

Healthy adults

Interventions

Participants will be randomly allocated into 3 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, Y-balance test and figure-of-eight hopping test before and after the 8-week intervention.

The interventions for those groups:

1. High blood flow restriction: participants will perform knee extension exercise under high blood flow restriction with low resistance training (30% 1repetitive maximum, RM)
2. Low blood flow restriction: participants will perform knee extension exercises under low blood flow restriction with low resistance training (30% 1RM)
3. Control group: participants will perform knee extension exercises under high resistance training (60% 1RM) 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 Type

Other

Primary outcome(s)

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

Key secondary outcome(s))

Balance measured using the Y-balance test and figure-of-eight hopping test before and after the 8-week intervention

Completion date

11/04/2024

Eligibility

Key inclusion criteria

1. Adults aged from 20-40 years old
2. Live in Taiwan

3. Without significant injuries in the last three months (such as fractures)
4. Open wounds on the lower extremity
5. Pregnancy
6. Normal resting heart rate and blood pressure

Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

20 years

Upper age limit

40 years

Sex

All

Key exclusion criteria

1. Significant injuries of the lower extremity in the last three months (such as fractures)
2. Open wounds on the lower extremity
3. Pregnant individuals
4. Resting heart rate exceeding 120 beats per minute, systolic blood pressure exceeding 120 mmHg
diastolic blood pressure exceeding 100 mmHg

Date of first enrolment

20/04/2023

Date of final enrolment

10/02/2024

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

Chinese Medical University

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Yu-Lin You (oilfish@mail.cmu.edu.tw) until 04/10/2024. Consent from participants was required and obtained. The personal information of all participants will be anonymized by code name.

IPD sharing plan summary

Available on request