ISRCTN92716243 https://doi.org/10.1186/ISRCTN92716243

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

Submission date
09/12/2023

Recruitment status
No longer recruiting

Registration date
29/12/2023

Overall study status
Completed

Last Edited
28/12/2023

Condition category
Other

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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

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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 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

Secondary study design
Randomised controlled trial

Study setting(s)
University/medical school/dental school

Study type(s)
Other

Participant information sheet
No participant information sheet available

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

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

Overall study start date
01/08/2022

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

Age group
Adult

Lower age limit
20 Years

Upper age limit
40 Years

Sex
Both

Target number of participants
30

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
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406040

Sponsor information

Organisation
China Medical University

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Sponsor type
University/education

Website
http://www.cmu.edu.cn/eng/

ROR
https://ror.org/00v408z34

Funder(s)

Funder type
University/education

Funder Name
Chinese Medical University

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 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