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Blood flow restriction exercise therapy for people with obesity

Submission date
08/05/2025

Recruitment status
No longer recruiting

Registration date
08/05/2025

Overall study status
Completed

Last Edited
08/05/2025

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Obesity, especially increased visceral fat (around the organs), is a major health concern worldwide. Exercise is known to improve body composition and metabolic health. Traditional moderate-intensity continuous training (MICT) helps reduce visceral fat in obese youths, but its effectiveness depends on the amount of exercise. Blood flow restriction (BFR) training, which uses a compression device to restrict blood flow, may offer a more time-effective exercise option. This study aimed to explore the effects of low-intensity MICT combined with BFR on targeted and non-targeted metabolomics and proteomics in obese young people.

Who can participate?
Individuals aged 18-25 years with a body fat percentage greater than 30%, no long-term medication, smoking, or excessive drinking habits, and no exercise-related contraindications (e.g., cardiovascular, cerebrovascular, or respiratory diseases)

What does the study involve?
Participants will be randomly assigned to one of three groups: a no-intervention control group, an MICT intervention group, or an MICT combined with BFR intervention group. Fasting blood samples will be collected before and after the intervention to analyze plasma metabolomics and proteomics data. Participants' aerobic capacity, body composition, and abdominal fat areas will also be evaluated. Daily dietary intake and physical activity will be recorded for 3 weeks before the intervention and during the 12-week intervention period.

What are the possible benefits and risks of participating?
Participants may lose weight and receive a personalized exercise prescription. The main risk is delayed muscle soreness after exercise. The researchers will ensure the safety of all participants.

Where is the study run from?
Ocean University of China

When is the study starting and how long is it expected to run for?
June 2023 to September 2025

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Prof. Shiming Li, haiyanglishiming@163.com

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Prof Shiming Li

Contact details
No.238 Songling Road
Qingdao
China
266100
+86 (0)15731114483
haiyanglishiming@163.com

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
OUC-HM-2023005

Study information

Scientific Title
Effects of blood flow restriction training on metabolomics and proteomics in patients with obesity

Study objectives
The difference between aerobic exercise combined with blood flow restriction and not combined with metabolomics and proteomics.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 01/06/2023, Ocean University of China (No.238 Songling Road, Qingdao, 266100, China; +86 (0)15231509262; 21211913076@ouc.edu.cn), ref: OUC-HM-2023005

Study design
Single-blind randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Exercise and metabolic improvement in obese adolescents

Interventions
Participants were randomly assigned to two experimental groups (M and B) and one control group (C) by drawing lots. The intervention period lasted for a total of 12 weeks, with three sessions per week. Researchers monitored the heart rate (HR) and blood oxygen saturation during exercise to ensure the safety of participants. Initially, participants were required to perform a 10-minute warm-up activity at an intensity of 50 W on an aerobic power bike. Following the warm-up, participants in all exercise groups engaged in continuous exercise at 60% of their maximal oxygen uptake (VO2max) intensity, maintaining a speed of 60±5 revolutions per minute (RPM), until they overcame a mechanical work of 200kj. A 10-minute cool-down activity was required after the exercise. B group was required to apply a 60% limb occlusive pressure (LOP) using an inflatable cuff (Ariband, Australia) at the proximal inguinal region of both legs based on the exercise protocol of the M group. During exercise, the participants' subjective perceived exertion (RPE) and heart rate (HR) were recorded every 5 minutes. The C group did not receive any exercise intervention throughout the entire intervention period.

Intervention Type
Behavioural

Primary outcome(s)
Measured at baseline and after the intervention:
1. Plasma non-targeted metabolomics data is measured using liquid chromatography-mass spectrometry (LC-MS)
2. Plasma proteomics data is measured using liquid chromatography-tandem mass spectrometry (LC-MS/MS)
3. Plasma-targeted metabolomics data is measured using liquid chromatography-mass spectrometry (LC-MS)

Key secondary outcome(s))
Measured 3 weeks before the start of the intervention and during the 12-week intervention period:
1. Daily dietary intake measured using a questionnaire every weekend
2. Physical activity measured using a questionnaire every weekend
3. Aerobic capacity is measured using cardiopulmonary exercise testing (CPET), typically with a cycle ergometer, to determine VO_2 max (maximal oxygen uptake)
4. Body composition is measured using bioelectrical impedance analysis (BIA)
5. Abdominal subcutaneous fat area is measured using computed tomography (CT) scans
6. Visceral fat area is measured using computed tomography (CT) scans

Completion date
13/09/2025

Eligibility

Key inclusion criteria
1. Aged 18-25 years
2. Body fat percentage greater than 30%
3. No long-term medication, smoking, or excessive drinking habits
4. No exercise-related contraindications, such as cardiovascular and cerebrovascular diseases, respiratory system diseases, etc

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
25 years

Sex
All

Key exclusion criteria
Suffering from any illness that is not suitable for participating in sports

Date of first enrolment
15/05/2025

Date of final enrolment
30/05/2025

Locations

Countries of recruitment
China

Study participating centre
Ocean University of China
No.238 Songling Road
Qingdao

China
266100

Sponsor information

Organisation
Ocean University of China

ROR
https://ror.org/04rdtx186

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and analysed during the current study will be published as a supplement to the results publication.

IPD sharing plan summary
Published as a supplement to the results publication