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The effect and mechanism of blood flow restriction on improving visceral fat in obese young people

Submission date 22/01/2025	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 28/01/2025	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 28/01/2025	**Condition category** Other	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims
Obesity, especially the increase in visceral fat, 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 aims to explore the effects of combining low-intensity MICT with BFR on abdominal visceral fat in obese young adults.

Who can participate?
-Individuals aged 18-25 years
-Body fat percentage greater than 30%
-No long-term medication, smoking, or excessive drinking habits
-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, a MICT intervention group, or a 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 three 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. Researchers will ensure the safety of all participants.

Where is the study run from?
The study is conducted at Ocean University of China.

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

Who is funding the study?
The study is initiated and funded by the investigator.

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

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
OUC-HM-2023005

Study information

Scientific Title
Effect of blood flow restriction training on improving visceral fat in obese youth based on multi-omics study

Study objectives

The effect of aerobic exercise combined with blood flow restriction is better than that without combined reduction of visceral fat.

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 15231509262; 21211913076@ouc.edu.cn), ref: OUC-HM-2023005

Study design
Single-blind randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Fitness/sport facility, Laboratory, University/medical school/dental school

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Exercise and weight loss for obese youth

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 50W 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 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 measure

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. 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.

Secondary outcome measures
Measured 3 weeks before the start of the intervention and during the 12-week intervention period:
1. Daily dietary intake measured using questionnaire every weekend.
2. Physical activity measured using questionnaire every weekend.

Overall study start date
01/04/2023

Completion date
01/12/2025

Eligibility

Key inclusion criteria
1.Age: 18-25 years old
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)
Learner/student

Age group
Adult

Lower age limit
18 Years

Upper age limit
26 Years

Sex
Both

Target number of participants
36

Total final enrolment
36

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

Date of first enrolment
15/04/2023

Date of final enrolment
15/06/2023

Locations

Countries of recruitment
China

Study participating centre
Ocean university of China
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Sponsor information

Organisation
Ocean University of China

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Sponsor type
University/education

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ROR
https://ror.org/04rdtx186

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal.

Intention to publish date
25/12/2025

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