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Effects of walking with blood flow restriction on intraocular pressure and ocular perfusion pressure

Submission date	Recruitment status	[ ] Prospectively registered
08/11/2022	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
16/11/2022	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
14/11/2022	Other	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Increased intraocular pressure (IOP) and decreased ocular perfusion pressure (OPP) are the main risk factors for the occurrence and development of glaucoma, a common eye condition in which the optic nerve, which connects the eye to the brain, becomes damaged. This study aimed to compare the effects of low-intensity walking with blood flow restriction and moderate-intensity continuous running on IOP and OPP.

Who can participate?
Healthy adult volunteers

What does the study involve?
Participants will be randomly assigned to perform 3 exercise tests:
1. 40% heart rate reserve (HRR) intensity walking (LOW group)
2. 40% HRR intensity walking with blood flow restriction belt of 60% maximum limb occlusive pressure (LOP) (L-BFR group)
3. 60% HRR intensity running (MCE group).
Blood pressure and IOP will be measured before exercise, immediately after exercise, and 5 and 10 minutes after exercise.

What are the possible benefits and risks of participating?
The study could provide potential exercise benefits for healthy people and has limited risks.

Where is the study run from?
Qingdao Haici Hospital (China)

When is the study starting and how long is it expected to run for?
June 2020 to December 2020

Who is funding the study?
1. Natural Science Foundation of Shandong Province (China)
2. Shandong Provincial Natural Science Foundation (China)

Who is the main contact?
Yinghao Li, zhengzhouliyinghao@163.com (China)

Contact information

Type(s)
Principal Investigator

Contact name
Dr Yinghao Li

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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 low-intensity walking with blood flow restriction and moderate-intensity running on intraocular pressure and ocular perfusion pressure among healthy adults

Acronym
WALKING+BFR

Study objectives
Low-intensity walking with blood flow restriction was more conducive to improving the ocular perfusion pressure (OPP) level than moderate-intensity continuous running. This may be due to an increase in mean arterial pressure.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 07/06/2020, Qingdao Haici Hospital Ethics Committee (No. 4, Renmin Road, Qingdao, China; +86 0532-83777800; qdhaiciwenhua@163.com), ref: 2022-HYJ-475

Study design
Single-centre cross-sectional cohort study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Healthy adults

Interventions
First, we measured baseline height, weight, resting heart rate, resting blood pressure, and maximum limb occlusive pressure (LOP), and then performed an incremental load test on the same day. The treadmill speed was set at 40% and 60% of the heart rate reserve (HRR) using the recorded incremental load test data. Then, subjects were randomly assigned to perform three exercises through a randomization lottery: 1) 40% HRR intensity walking (LOW group); 2) 40% HRR intensity walking with a 60% LOP blood flow restriction belt (L-BFR group); and, 3) moderate-intensity continuous running with 60% HRR intensity (MCE group). Exercises were carried out from 13:00-16:00 h after lunch. Stimulating drinks containing caffeine or alcohol were prohibited. There must be 72 h between the exercise tests. HR and Rating of Perceived Exertion (RPE) were recorded every 5 minutes from before exercise to 10 minutes after exercise; blood pressure and intraocular pressure (IOP) were tested before exercise, immediately, and 5 min and 10 min after exercise. All exercises and tests were performed at the Xinzheng Second People's Hospital. This study adopts a double-blind design, and neither the experimenter nor the participants know the purpose of the experiment in advance.
Each test required 5 min of warm-up activity. The LOW group performed 30 min of walking exercise on a treadmill with 40% HRR intensity. In the L-BFR group, based on the LOW group, a blood flow restriction cuff with 60% LOP pressure should be worn on the proximal end of the thigh, inflated before the exercise, and deflated immediately after the end of the 30-minute exercise. The MCE group performed 30 min of running exercise on a treadmill with 60% HRR intensity.

Intervention Type
Behavioural

Primary outcome measure
Intraocular pressure and ocular perfusion pressure measured using a non-contact jet tonometer at baseline (T0), immediately after exercise (30 min), and 5 and 10 minutes after exercise

Secondary outcome measures
1. Heart rate measured using polar band at baseline (T0) and every 5 minutes until 40 minutes
2. Blood pressure measured using a non-contact jet tonometer at baseline (T0), immediately after exercise (30 min), and 5 and 10 minutes after exercise

Overall study start date
01/06/2020

Completion date
01/12/2020

Eligibility

Key inclusion criteria
1. Aged ≥ 18 years old
2. BMI <24kg/m2
3. No systematic training experience except for daily physical education
4. No bone, cardiovascular disease or other sports-related discomforts
5. A degree of myopia < 200 degrees

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
16

Total final enrolment
16

Key exclusion criteria
Bone, cardiovascular disease or other sports-related discomforts

Date of first enrolment
01/08/2020

Date of final enrolment
20/08/2020

Locations

Countries of recruitment
China

Study participating centre
Qingdao Haici Hospital
No. 4 Renmin Road
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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
Government

Funder Name
Natural Science Foundation of Shandong Province

Alternative Name(s)
Shandong Provincial Natural Science Foundation, Shandong Natural Science Foundation, Natural Science Foundation of Shandong, Shandong Province Natural Science Foundation,

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
China

Funder Name
Natural Science Foundation of Shandong Province

Alternative Name(s)
Shandong Provincial Natural Science Foundation, Shandong Natural Science Foundation, Natural Science Foundation of Shandong, Shandong Province Natural Science Foundation,

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
China

Results and Publications

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

Intention to publish date
01/01/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Yinghao Li, zhengzhouliyinghao@163.com. Anonymized intraocular pressure and ocular perfusion pressure data will be shared. Consent was required and obtained from participants.

IPD sharing plan summary

Available on request