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Effects of exercise training and diet restriction on cardiovascular function in obese population

Submission date
27/04/2017

Recruitment status
No longer recruiting

Registration date
28/04/2017

Overall study status
Completed

Last Edited
08/06/2023

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Obesity causes atherosclerosis, where the blood vessels (arteries) become clogged, harden and narrow, which can lead to heart disease. Obesity is also linked to endothelial dysfunction, arterial stiffness and autonomic dysfunction. Endothelial dysfunction, where the endothelium (inner lining) of blood vessels fails to function normally, can be measured using a method called brachial artery flow-mediated dilation (FMD). Pulse wave velocity (PWV), the rate at which the arterial pulse moves down the vessel, is a way to measure arterial stiffness. Autonomic dysfunction is assessed by measuring heart rate variability (HRV), the variation in the time interval between heartbeats. The aim of this study is to investigate the effects of an 8-week combined exercise and diet intervention on endothelial function, autonomic nervous system and arterial stiffness in obese adults.

Who can participate?
Obese adults, aged 18 and over

What does the study involve?
Participants complete an eight-week exercise training and diet intervention. Body measurements and blood samples are taken, and FMD, PWV and HRV are measured before and after the 8-week combined exercise and diet intervention, to find out whether the exercise and diet intervention improves endothelial function, autonomic function and arterial stiffness.

What are the possible benefits and risks of participating?
Exercise training and diet may improve the participants' health and heart function. The risks of the study are minor, as the physical examinations and procedures are performed by experienced doctors in the appropriate clinical setting and exercise training is individually tailored and supervised by professional trainers. The blood sampling is associated with a small risk of bruise and inflammation of the veins. Vigorous exercise can result in injuries. This risk is minimized by tailoring exercise to the participant's individual needs, based on the assessment of his or her physical fitness.

Where is the study run from?
Sunstarasia Weight Loss Camp (China)

When is the study starting and how long is it expected to run for?
March 2016 to September 2016

Who is funding the study?
1. National Natural Science Foundation of China
2. Natural Science Foundation of Guangdong Province
3. Foundation of Youth Talents in Higher Education of Guangdong Province of China
4. Pearl River Scholar Program in Guangdong Province of China

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
SAHPL02

Study information

Scientific Title
Effects of an 8-week combined exercise and diet intervention on endothelial function, autonomic function and arterial stiffness in obese adults

Study objectives
Exercise and diet intervention improves endothelial function arterial stiffness and autonomic function in obese adults.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of Guangzhou Sport University, 17/03/2016, ref: GSU20160012

Study design
Obese subjects (BMI ≥ 30 kg/m2) were recruited from the weight loss camp (single-centre) and various parameters were measured before and after 8-week combined exercise and diet intervention.

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet

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

Health condition(s) or problem(s) studied
Obesity

Interventions
Obese subjects (BMI ≥ 30 kg/m2) were recruited from the weight loss camp after physical examination. The weight loss camp was totally closed with uniformly managed accommodation, diet and training during the 8-week intervention period. The campers lived in the same building, where they could not move in and out freely. Subjects were provided with energy-restricted diets of 1300-2200 kcal/day based on weight. The energy percentages provided by protein, fat and carbohydrate were 20%, 20% and 60%, respectively, while energy distributions at breakfast, lunch and dinner were 30%, 40% and 30%, respectively. All meals were prepared and supervised by registered professional dietitians during the diet intervention. Subjects performed a series of endurance exercise such as bicycling, walking, running, dancing and ball games for 5 hour/day, supplemented with resistance exercise. Training interventions were performed 6 day/week for 8 weeks. The exercise program was designed to result in an energy expenditure of 1500-2500 kcal /day. Qualified trainers supervised the subjects during the training program. Measurements were performed before and after the 8-week combined exercise training and diet intervention.

Intervention Type
Other

Primary outcome measure
1. Endothelial function, assessed by flow-mediated dilation (FMD)
2. Circulating endothelial progenitor cells levels, evaluated by flow cytometry
3. Heart rate variability (HRV), aortic pressure, augmentation pressure, augmentation index, measured using the SphygmoCor device (AtCor Medical, Sydney, Australia)
4. Pulse wave velocity (PWV), measured using both the SphygmoCor device and an oscillometric device (boso ABI-system 100; BOSCH & SOHN, Germany)

Measurements performed before and after the 8-week combined exercise training and diet intervention.

Secondary outcome measures
1. Body composition determined using a body composition analyzer (Inbody 370, Biospace, Seoul, Korea)
2. Resting heart rate (HR) and brachial systolic/diastolic blood pressure (bSBP/bDBP), measured using a sphygmomanometer
3. Aerobic fitness, assessed using the Physical Working Capacity at a heart rate of 150 beats per minute (PWC150) or a heart rate of 170 beats per minute (PWC170) cycle ergometer test (Ergoselect 100, Ergoline, Bitz, Germany)
4. Circulating irisin levels, measured using irisin ELISA kit (Phoenix Pharmaceuticals, CA, USA) following the manufacturer’s instructions
5. Concentrations of vascular endothelial growth factor (VEGF), endothelial nitric oxide synthase (eNOS), adiponectin, tumor necrosis factor-alpha (TNF-α), high-sensitivity C-reactive protein (hsCRP) and superoxide dismutase (SOD) in serum, analyzed using ELISA Kits respectively (Cusabio, Biotech. Co., LTD, Wuhan, China) according to the manufacturer’s instructions

Measurements performed before and after the 8-week combined exercise training and diet intervention.

Overall study start date
18/03/2016

Completion date
02/09/2016

Eligibility

Key inclusion criteria
1. Obese adults who had a body mass index (BMI) ≥ 30 kg/m2)
2. Aged 18 and over

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
22

Key exclusion criteria
1. Unstable angina pectoris
2. Myocardial infarction within the last 12 months
3. Decompensated heart failure
4. Cardiomyopathy
5. Severe valvular heart disease
6. Considerable pulmonary disease
7. Uncontrolled hypertension
8. Kidney failure
9. Orthopaedic and/or neurological limitations to exercise
10. Surgery during the intervention period
11. Drug or alcohol abuse

Date of first enrolment
01/04/2016

Date of final enrolment
31/07/2016

Locations

Countries of recruitment
China

Study participating centre
Sunstarasia Weight Loss Camp
Huizhou
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Sponsor information

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Sponsor type
University/education

ROR
https://ror.org/046r6pk12

Funder(s)

Funder type
Government

Funder Name
National Natural Science Foundation of China

Alternative Name(s)
Chinese National Science Foundation, Natural Science Foundation of China, National Science Foundation of China, NNSF of China, NSF of China, , National Nature Science Foundation of China, Guójiā Zìrán Kēxué Jījīn Wěiyuánhuì, NSFC, NNSF, NNSFC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
China

Funder Name
Natural Science Foundation of Guangdong Province

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

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
China

Funder Name
Foundation of Youth Talents in Higher Education of Guangdong Province of China

Funder Name
Pearl River Scholar Program in Guangdong Province of China

Results and Publications

Publication and dissemination plan
The trialists plan to publish the results of this study to academic journals this year.

Intention to publish date
15/07/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Min Hu (whoomin@hotmail.com).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Dataset	sub study	14/08/2017	08/06/2023	No	No
Other publications		05/10/2017	08/06/2023	Yes	No
Results article		14/08/2017	08/06/2023	Yes	No