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High-intensity interval training counteracts the adverse effects of a short-term low-carbohydrate diet on anxiety but is less effective than moderate-intensity continuous training

Submission date
02/04/2023

Recruitment status
No longer recruiting

Registration date
06/04/2023

Overall study status
Completed

Last Edited
04/04/2023

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Although low-carbohydrate (LC) diets have been adopted as a treatment for neurological and mental health conditions, the effects on mental and physical health in nonclinical individuals living with overweight/obesity are unclear. Combining LC diets with high-intensity interval training (HIIT) or moderate-intensity continuous training (MICT) may bring added benefits to physical fitness and mental health, but questions remain regarding which exercise prescription practised alongside LC diets could induce the best results. Therefore, the present study aimed to investigate a 4-week LC diet intervention combined with HIIT or MICT on mental health and physical health in overweight females.

Who can participate?
Healthy volunteers living with overweight or obesity

What does the study involve?
The study aims to investigate a four-week diet and exercise program for anxiety symptoms in overweight individuals. The effect of the dietary and exercise intervention on aerobic fitness and eating behaviours are also examined. The dietary intervention involves an LC diet, which requires daily carbohydrate intake of less than 50 g or less than 10 % of the total daily energy intake. Exercise programs include HIIT or MICT sessions five times a week for four weeks.

What are the possible benefits and risks of participating?
The benefits of participating include improvements in body composition and cardiorespiratory fitness through the intervention. The risks of participation include that an LC diet may result in side effects such as constipation, fatigue, weakness and skin inflammation (i.e. keto rash or Prurigo pigmentosa) due to ketosis. Normal human physiological responses including high ventilatory demand induced-sensation of breathlessness, locomotor muscle fatigue and

soreness may be elicited during exercise. The sensation of breathlessness and perceived fatigue will be disappeared around 30 min after the termination of the exercise while the muscle soreness may remain for a few hours after the exercise.

Where is the study run from?
The University of Macao (China)

When is the study starting and how long is it expected to run for?
April 2021 to September 2023

Who is funding the study?
The University of Macao (China)

Who is the main contact?
Zhaowei Kong, zwkong @um.edu.mo (China)

Contact information

Type(s)
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
MYRG2020-00266-FED

Study information

Scientific Title
High-intensity interval training counteracts the adverse effects of a short-term low-carbohydrate diet on anxiety but is less effective than moderate-intensity continuous training

Study objectives
Low-carbohydrate dietary intervention alone would increase the frequency of anxiety symptoms, while adding high-intensity interval training (HIIT) and moderate-intensity continuous training (MICT) programs would alleviate the effects on anxiety, with more significant benefits of MICT compared to HIIT.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 06/11/2022, Research Ethics Panel of the University of Macau (Room 5011, Administration Building, University of Macau, N6, Avenida da Universidade, Taipa, Macau, 999078, China; +853 8822 4399; rskto@um.edu.mo), ref: BSERE22-APP011-FED

Study design
Single-centre interventional single-blind randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Effects of low-carbohydrate diet combing with HIIT or MICT on eating behaviour and cardiorespiratory fitness in individuals with overweight and obesity

Interventions
Participants were randomly assigned to one of the following four groups to receive a four-week intervention:
1. No intervention control (CON)
2. Low-carbohydrate diet (LC-CON)
3. Low-carbohydrate diet and moderate-intensity continuous training (MICT) (LC-MICT)
4. Low-carbohydrate diet and high-intensity interval training (HIIT) (LC-HIIT)
Generation of a random sequence allocation was performed by independent personnel who were not involved in the intervention after the enrollment of the participants, and access to the sequence was restricted to this personnel only. Allocations were concealed from the participants and the research group until they started their first training or non-training session.

The LC diet intervention is a four-week low-carbohydrate diet plan that restricts daily intake of carbohydrates to < 50 g or <10% of the total energy intake, with 65% of the energy from fats, and 25% of the energy from proteins approximately. There are no restrictions regarding the sources of the macronutrients (e.g., saturated fat or unsaturated fat) or the amount of daily energy intake.
The exercise interventions include 20 sessions of HIIT or MICT performed five times a week for four weeks.
HIIT involves 10 repetitions of 6-s ‘all-out’ cycling with an initial 1 kg workload interspersed with 9-s passive recoveries. The workload is increased by 0.5 kg once the participants can maintain a cycling speed of more than 100 rpm for all sprint bouts in two consecutive training sessions until the workload reaches 5% of their body weight.
MICT is performed as 30 min of continuous cycling with a speed of 50 ± 5 rpm at 50% of VO2 peak for the first 10 training sessions, and 60% of VO2 peak for the last 10 training sessions.

The intervention provider, Dr Zhaowei Kong, majored in physical education and sports science and has been researching low-carbohydrate diets combined with exercise training for six years at the kinesiology laboratory of the University of Macao.

The exercise interventions will occur at the kinesiology laboratory (at a strictly controlled room temperature (22 °C) and humidity (50%–60%)) of the University of Macao. In the laboratory, there are cycle ergometers (Monark 894E, Varberg, Sweden) for the exercise intervention, and a Cortex gas analyzer for measuring cardiorespiratory fitness (VO2 max).

The main mode of intervention delivery is face-to-face communication individually, but the Internet is also used for online communication.

Intervention Type
Behavioural

Primary outcome(s)
Effects of a low-carbohydrate diet combined with HIIT or MICT on anxiety levels in individuals with overweight and obesity measured using the General Anxiety Disorder Scale (GAD-7) at baseline and after the last training session at each week (i.e., at week 1, 2, 3, 4)

Key secondary outcome(s))
The following secondary outcome measures evaluating the effects of a low-carbohydrate diet combined with HIIT or MICT in individuals with overweight and obesity are assessed at baseline and three days after the intervention:
1. Eating behaviour measured using The Dutch Eating Behavior Questionnaire (DEBQ)
2. Cardiorespiratory fitness measured using the maximal oxygen uptake (VO2 max)

Completion date
09/01/2023

Eligibility

Key inclusion criteria
1. Suitable to engage in exercise (as assessed by the physical activity readiness questionnaire; PAR-Q, and a medical history check)
2. Living with overweight or obesity, defined as body mass index ≥ 23 kg·m-2 as the cut-off point for the Asian population
3. Inactive as determined by self-reporting less than one hour of regular structured exercise per week for at least six months before enrolment.

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Total final enrolment
96

Key exclusion criteria
1. Diagnosed with cardiometabolic diseases or any other conditions that could affect the ability to perform physical activity, or any mental illness (e.g., anxiety disorder)
2. Regular use of tobacco (daily use) or alcohol (>3 times per week) in the past six months
3. Body weight fluctuations (≥ 2 kg in previous six months?)
4. Followed any strict or restrictive dietary regimen over the past six months

Date of first enrolment
10/11/2022

Date of final enrolment
20/11/2022

Locations

Countries of recruitment
Macao

Study participating centre
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Sponsor information

Organisation
University of Macau

ROR
https://ror.org/01r4q9n85

Funder(s)

Funder type
University/education

Funder Name
Universidade de Macau

Alternative Name(s)
, University of Macau, UM

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Macao

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository (the University of Macao; https://www.um.edu.mo/).

Data from all measures taken during the intervention will be stored on a hard disk in a computer of the kinesiology laboratory of the University of Macao. The IPD will not be publicly available at any time. Written informed consent was obtained from all participants before the intervention. Please refer to the attachment.

IPD sharing plan summary
Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Informed consent		04/04/2023	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes