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Effects of exercise on physical and metabolic function of candidates before undergoing bariatric surgery

Submission date
11/04/2023

Recruitment status
No longer recruiting

Registration date
21/04/2023

Overall study status
Completed

Last Edited
07/05/2025

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Obesity is a global health problem that is progressively increasing its prevalence worldwide. Because of this, bariatric surgery is increasing in its popularity among clinicians because of its high impact on body weight reduction and body composition normalization. However, the fast rate of weight loss has several consequences, such as loss of muscle and strength, and functional capacity. Therefore, preoperative interventions are needed for surgical success from a physical and metabolic perspective. Physical exercise has been described as an effective intervention, given its effects on physical and metabolic function in the context of obesity. However, the most effective preoperative exercise prescription, along with its potential post-surgical carry-over effects, is unclear. Discrepancies in the previously published exercise programs, along with the scarce number of studies in the field, hinder the possibility to determine an optimal exercise prescription during the preoperative period of bariatric surgery. Both moderate-intensity constant training (MICT) and high-intensity interval training (HIIT) exercise programs have been shown to promote specific benefits on metabolically active tissues (e.g. skeletal muscle, white adipose tissue, and liver) in obesity. From these findings, it is possible to hypothesize that exercise, at different intensities, promotes metabolic benefits in a tissue-specific manner during obesity, which could improve the impact of this intervention in subjects with obesity by prescribing it in a subject-specific manner. This is the first known study to explore this hypothesis in candidates planning bariatric surgery who present a clear obese phenotype. The study will also assess these effects in obese patients post-surgery.

Who can participate?
Adult patients who are planning to undergo bariatric surgery

What does the study involve?
Subjects will be randomized into two different groups: MICT and HIIT. MICT will be defined as treadmill running at an intensity of 50% of the heart rate reserve (%HRR) for 30 min, whereas HIIT: will consist of six bouts of high-intensity exercise at 80% HRR intercalated by six active rest periods at 20% HRR; this to keep the average intensity between programs similar. Both training programs will consist of 10 sessions delivered in a timeframe of 4 weeks before the bariatric

surgery (preoperative period). As recommended by the Bariatric and Metabolic Surgery Chilean Society, similar nutritional support, along with the same strengthening exercise program will be delivered for MICT and HIIT groups during the preoperative period.

At baseline, post-training (2-3 days after the last training session), 1-, and 6-months post-surgery, venous blood collection along with measurements of physical (e.g. cardiorespiratory fitness) and systemic metabolic function (e.g. oral glucose tolerance test) will be measured. Moreover, during surgery as a post-training timepoint, samples of plasma, skeletal muscle from the abdominal wall, white adipose tissue, and liver, will be collected and stored for further analysis.

What are the possible benefits and risks of participating?
As potential results, it is expected that preoperative HIIT will induce higher physical and tissue-specific metabolic benefits in skeletal muscle, white adipose tissue, and liver, compared to MICT, of candidates to undergo bariatric surgery, and those benefits will be retained 6 months after the surgical procedure. Specifically, MICT will focus its benefits on the liver whereas HIIT will specifically improve the metabolic function of skeletal muscle and white adipose tissue. If the hypothesis is corroborated, the results from this project will help to determine the optimal exercise prescription in subjects with obesity, particularly in candidates to undergo bariatric surgery and in the population with similar obesity severity.

The main risks in participating are temporal physical discomfort associated with exercises, such as muscle soreness, mild muscle inflammation and feeling of tiredness. Since this study also considers venous blood drawing, there might be mild and temporary pain in the punctured zone and possible hematomas, risks that will be reduced since an experienced person will conduct these procedures.

Where is the study run from?
Southern University of Chile (Universidad Austral de Chile) (Chile)

When is the study starting and how long is it expected to run for?
October 2022 to August 2023

Who is funding the study?
Chilean National Agency for Research and Development (Agencia Nacional de Investigación y Desarrollo de Chile) (Chile) through its Early Career Researcher Fund (code 11200391) (Chile)

Who is the main contact?
Sergio Martinez-Huenchullan (Principal Investigator), sergio.martinez@uach.cl (Chile)

Contact information

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Fondecyt 11200391

Study information

Scientific Title
Effects of exercise intensity on physical and metabolic function of candidates before undergoing bariatric surgery

Study objectives
Preoperative high-intensity interval training (HIIT) will induce higher physical and tissue-specific metabolic benefits in the skeletal muscle, white adipose tissue, and liver, compared to moderate-intensity constant training (MICT), of candidates before undergoing bariatric surgery, and those benefits will be retained 6 months after the surgical procedure.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 19/11/2020, Valdivia Health Service Research Ethics Committee (560 Vicente Perez Rosales Street, Of. 307, 3rd floor, Chile; +56632281784; comiteeticasecretaria@gmail.com), ref: 350/2020

Study design
Single-centre randomized controlled study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Treatment of cardiometabolic dysfunctions in people with obesity

Interventions
Randomised control trial, where two different pre-surgical exercise programs will be compared (HIIT versus MICT). Each group will have 15 participants randomly allocated, and both training programs will last for 4 weeks. Participants will be measured at baseline, post-training and in both follow-up periods (1 and 6 months post-surgery). This is a single-centre study.

MICT and HIIT sessions will be as follows: MICT: will be defined as treadmill-running at an intensity of 50% of the heart rate reserve (% HRR) for 30 min. HIIT: will consist of six bouts of high-intensity exercise at 80% HRR of 2.5 min each, intercalated by six active rest periods at 20% HRR of 2.5 min each. The time of these intervals was set following the recommendations from the literature in terms of HIIT usage in an obesity context. % HRR will be obtained with the Karvonen formula maximum heart rate (HR max)– resting heart rate (HRrest), where the theoretical maximal heart rate will be obtained by the equation 200-(Age*0.5).

At baseline, post-training (2-3 days after the last training session), 1-, and 6-months post-surgery, venous blood collection along with measurements of physical (e.g. cardiorespiratory fitness) and systemic metabolic function (e.g. oral glucose tolerance test) will be measured. Moreover, during surgery as a post-training timepoint, samples of plasma, skeletal muscle from the

abdominal wall, white adipose tissue, and liver, will be collected and stored for further analysis. To determine if MICT and HIIT induce tissue-specific effects, metabolism-related markers (e.g. adiponectin, pAMPK/AMPKα, GLUT4, and PGC-1α) will be measured in three tissues: skeletal muscle, white adipose tissue, and liver. Afterwards, to identify potential markers/mediators behind the expected metabolic effects of MICT and HIIT, plasma samples will be shipped overseas for proteomic analysis, to characterize the different protein signatures of both interventions. Once a list of potential markers/mediators is identified, this dataset will be used to design mechanistic studies. These will be aimed to determine the metabolic relevance of those potential mediators/markers on insulin signaling and glucose transport, by knocking down the genes associated with those candidates in adipocytes and myocytes.

As potential results, we expect that preoperative HIIT will induce higher physical and tissue-specific metabolic benefits in skeletal muscle, white adipose tissue, and liver, compared to MICT, of candidates to undergo bariatric surgery, and those benefits will be kept 6 months after the surgical procedure. Specifically, MICT will focus its benefits in the liver whereas HIIT will specifically improve the metabolic function of skeletal muscle and white adipose tissue. If our hypothesis is corroborated, the results from this project will help to determine the optimal exercise prescription in subjects with obesity, particularly in candidates to undergo bariatric surgery and in the population with similar obesity severity.

Intervention Type
Behavioural

Primary outcome(s)
Insulin resistance measured using blood glucose, insulinaemia, and HOMA-IR during fasting and after an oral glucose tolerance test at baseline (pre-training), post-training, 1 month after bariatric surgery, and 6 months after bariatric surgery.

Key secondary outcome(s))
The secondary outcome measures are measured at baseline (pre-training), post-training, 1 month after bariatric surgery, and 6 months after bariatric surgery:
1. Muscle strength measured using a hand dynamometer and isokinetic chair
2. Cardiorespiratory fitness measured using a Modified Bruce protocol
3. Static balance measured using posturography
4. Anthropometric measurements including weight, height, waist and hip circumference, and body composition measured using bioimpedance
5. Spontaneous physical activity measured using the IPAQ questionnaire
6. Metabolic function including circulating levels of thyroid hormones (TSH), transaminases (ALT and AST), lipid profile, hemogram, electrolytes (Na, Cl, P), albumin, bilirubin, creatinine, and urea nitrogen measured using standard laboratory procedures

Completion date
10/08/2023

Eligibility

Key inclusion criteria
1. Aged between 18 and 60 years old
2. Planned to undergo sleeve gastrectomy

Participant type(s)

Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
60 years

Sex
All

Total final enrolment
25

Key exclusion criteria
1. Attending supervised exercise sessions
2. Medical contraindications to performing physical activity
3. Declaring functional limitations which disallow them to complete a progressive cardiorespiratory fitness test
4. Uncontrolled neuropsychiatric illnesses

Date of first enrolment
01/07/2021

Date of final enrolment
17/10/2022

Locations

Countries of recruitment
Chile

Study participating centre
Universidad Austral de Chile
Rudloff 1650
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Study participating centre

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Sponsor information

Organisation
Agencia Nacional de Investigación y Desarrollo

ROR
https://ror.org/02ap3w078

Funder(s)

Funder type
Government

Funder Name
Fondo Nacional de Desarrollo Científico y Tecnológico

Alternative Name(s)
National Fund for Scientific and Technological Development, El Fondo Nacional de Desarrollo Científico y Tecnológico, FONDECYT

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Chile

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Sergio Martinez-Huenchullan, sergio.martinez@uach.cl

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		05/03/2024	18/03/2024	Yes	No
Results article		31/05/2024	07/05/2025	Yes	No
Protocol file		31/12/2020	21/04/2023	No	No