Effect of Physical Exercise in Bariatric Surgery Patients: Protocol of a Randomized Controlled Clinical Trial

Andrea Herrera (✉ Andrea.herrera.s@gmail.com )
Universidad Católica del Maule  https://orcid.org/0000-0002-9691-1874

Andrea Tabach
Hospital San Juan De Dios, Curicó

Karen Andaur
Hospital San Juan de Dios, Curicó

Antonio Zamunér
Universidad Católica del Maule

Study protocol

Keywords: Physical Exercise, Bariatric Surgery, Morbid Obesity

Posted Date: June 11th, 2020

DOI: https://doi.org/10.21203/rs.3.rs-21324/v1

License: ☕️ This work is licensed under a Creative Commons Attribution 4.0 International License. Read Full License

Version of Record: A version of this preprint was published on February 1st, 2021. See the published version at https://doi.org/10.1186/s13063-021-05056-4.
Abstract

**Background:** Bariatric surgery is an effective approach to weight loss and long-term comorbidity resolution. Although recommended in several guidelines, supervised exercise has not been systematically prescribed after bariatric surgery. The aim of this study is to determine the effects of two types of exercise, moderate-intensity continuous training (MICT) and high-intensity interval training (HIIT), on body composition, cardiopulmonary function and perceived quality of life in bariatric surgery patients.

**Methods:** This randomized controlled clinical trial will include 75 adults of both sexes scheduled for bariatric surgery. They will be randomly assigned to one of three groups: 1) MICT, 2) HIIT, or 3) a control group. The intervention will occur 2 days a week for 4 months. Outcomes will be assessed at four points: 1) one week before surgery; 2) 21 days after surgery (baseline before the exercise program); 3) 8 weeks after beginning the exercise program; and 4) one week after the end of intervention. Primary outcomes will include body composition, heart rate variability, and six-minute walk test and quality of life scores. Secondary outcomes will be maximal respiratory pressure, flowmeter, hand dynamometry, and 30-second sit-to-stand test results.

**Discussion:** Both exercise protocols in this study were developed according to evidence-based practice. It is expected that, after 16 weeks of intervention, body composition (measured by electrical bioimpedance), cardiopulmonary function (measured by heart rate variability, maximal inspiratory pressure, maximal expiratory pressure, peak expiratory flow, handgrip strength, and the six-minute walk test) and perceived quality of life (measured by the Moorehead-Ardelt quality of life questionnaire II and bariatric analysis and reporting outcome system scores) will improve, especially in the HIIT group.

**Trial registration:** ClinicalTrials.gov, NCT04235842, registered 22 January 2020.

Introduction

**Background and rationale (6a)**

Obesity is an anomalous state of health characterized by excess body fat due mainly to caloric intake and expenditure imbalance (1). The daily energy consumption of this population is estimated at approximately 3000 Kcal/day, far above the requirements of sedentary individuals (2).

In its latest National Health Survey (2017), Chile was found to have a high risk of non-communicable diseases and few protective factors. A total of 10,301,529 Chileans (58.6% of the population) have some degree of excess weight, of whom 39.8% are overweight, 31.2% are obese and 3.2% are morbidly obese.

Studies have shown (3–5) that obesity leads to a state of chronic inflammation and oxidative stress, which is related to numerous chronic diseases such as cardiovascular and respiratory diseases (6, 7). Obese people also suffer from social pressure, leading to impaired social interaction, body image
rejection and low self-esteem, which compromises their psychological health, well-being and, thus, negatively impacts their quality of life (8, 9).

When morbidly obese patients do not respond to the usual obesity treatments, such as exercise, dieting and pharmacological treatment, they become candidates for restrictive and/or malabsorptive bariatric surgery (10, 11). Currently, four procedure types exist: adjustable gastric band, Roux-en-Y gastric bypass, vertical sleeve gastrectomy and bilio-pancreatic bypass (12, 13).

Patients usually experience significant weight loss the first postoperative year (56–85% of their excess weight), of which 70% is fat mass and 30% lean mass (14).

Some studies have shown that bariatric surgery results not only in weight loss and comorbidity changes, but also in complications such as severe anemia, osteopenia, dehydration, constipation, intestinal obstruction, vitamin and mineral deficiency, fatigue, posture changes, etc. (15, 16). Preventing such complications is crucial for bariatric surgery patients, especially through non-pharmacological means.

Thus, exercise could be a relevant solution since it maintains muscle mass, generates tension and load on the bones, activates the metabolism, red blood cell production and intestinal peristalsis, improves cardiopulmonary function and general functionality, contributes to bone mineralization, and helps maintain independence (17). Indeed, several studies have shown the benefits of regular exercise before and after bariatric surgery (18–20).

Among bariatric surgery patients, moderate-intensity continuous training (MICT) effectively decreases postoperative lean mass loss and increases fat mass loss, controls glucose homeostasis and improves cardiovascular capacity (20–22). High-intensity interval training (HIIT) has recently been proposed as an alternative to MICT and is well tolerated by overweight and insulin-resistant individuals (23, 24). The HIIT method has proven effective in improving cardiorespiratory fitness, VO2 max, and insulin sensitivity in healthy subjects (25–27). In addition, it has been described as more motivating than MICT due to a greater feeling of fatigue and its shorter sessions (28). However, to our knowledge, no studies have compared the effectiveness of MICT and HIIT in postoperative bariatric surgery patients.

Although participation in regular physical activity programs is a standard recommendation after bariatric surgery in Chile, supervised exercise is not currently recommended or prescribed.

**Objectives {7}**

The aim of this study will be to determine the effect of MICT and HIIT programs on body composition, cardiopulmonary function and perceived quality of life in bariatric surgery patients. We will also compare the effects of supervised exercise programs with those of standard follow-up. We hypothesized that both exercise programs will lead to greater improvement in the assessed outcomes than standard recommendations. Moreover, we expect the HIIT protocol to result in greater gains than MICT.
**Trial Design {8}**

This protocol is a randomized, single-blind, three-arm, parallel-group study. Participants will be randomly assigned to one of the three groups: 1) a control group (CG); 2) a moderate-intensity continuous exercise training group (MICT-G); or 3) a high-intensity interval exercise training group (HIIT-G).

**Methods: Participants, Interventions And Outcomes**

**Study setting {9}**

The study will be carried out in a public hospital in Curicó, Maule, Chile. All procedures will be performed in the Physical Medicine and Rehabilitation Service.

**Eligibility criteria {10}**

**Inclusion criteria**

Participants of either sex will be considered eligible if they are between 18 and 65 years old, have undergone bariatric surgery at the above-mentioned hospital, have been cleared for exercise, are in the final phase of operative wound healing, have been administered antithrombotics after surgery and have no plans to change their residence in the year after surgery.

**Exclusion criteria**

Participants with immediate postoperative complications (anastomosis or wound dehiscence) or decompensated comorbidities, who are on dialysis, or who suffer from a neuromotor disease will be excluded.

**Who will take informed consent? {26a}**

After receiving a list of patients scheduled for bariatric surgery from a staff member of Bariatric Surgery Service of the hospital, AHS will telephone each, invite them to participate, and make an individual appointment. In this, the objective of study, inclusion and exclusion criteria, participation, risks, benefits and ethical implications will be explained. In the case that the potential participant wants to participate in the research, the informed consent will be signed in 3 copies. One for the participants, one for the researcher and one for the clinical record from the hospital.

**Additional consent provisions for collection and use of participant data and biological specimens {26b}**

Not applicable, this trial does not have biological specimens.

**Interventions**
Explanation for the choice of comparators {6b}

Participants will be randomly assigned to one of the three groups: 1) a control group (CG) that will receive standardized recommendations; 2) a moderate-intensity continuous exercise training group (MICT-G); or 3) a high-intensity interval exercise training group (HIIT-G).

Intervention description {11a}

Participants allocated to the MICT and HIIT groups will perform two weekly sessions of supervised exercise for 16 weeks. Sessions will be divided into a 3-week adaptation period and 13 weeks of formal training. All sessions will consist of:

1. a) Join Mobility (3 minutes): head and neck, shoulder, elbow, wrist, hip, knee, ankle and trunk.
2. b) Warm-up (7 minutes): treadmill walking at 1–2 km/h.
3. c) Aerobic Component:

   MICT group: 15 minutes on a cycle ergometer at moderate intensity (40–60% of Heart Rate Reserve) or at a perceived exertion rating of 5–6 out of 10.

   HIIT group: 8 minutes on a cycle ergometer, including a 60-second sprint at 90% maximal heart rate followed by a 60-second rest until four sets are completed.

4. d) Strength training: 15 minutes of exercise in the large muscle groups with weight machines or dumbbells, including 1–2 sets of 8–10 repetitions at 50–60% of one-repetition maximum strength (1RM).
5. e) Cool-down (5 minutes): proprioceptive neuromuscular facilitation exercises for abdominal muscles and the pelvic floor will be performed on a mat. Stretching exercises for arm, leg, and trunk muscles will be performed in three 30-second sets. Hemodynamic variables will be checked to ensure that blood pressure and heart rate values return to baseline.

Exercise Progression

Beginning with the fourth week, the aerobic load in the MICT group will be adjusted to 60% of the heart rate reserve and the duration will be adjusted to 30 min. In the HIIT group, the number of sets will be increased to 1 by week until 10 sprints. Strengthening exercises will be performed in 3 sets of 10–12 repetitions, with intensities between 60–70% 1RM. The 1RM value will be assessed at baseline and week 8.

During both training programs, heart rate, blood pressure, oxygen saturation and perceived exertion will be evaluated with the Borg CR-10 scale.

Participants allocated to the CG will be follow the indications of regular physical activity practice according to WHO (at least 150 minutes per week of moderate physical activity or at least 75 minutes of...
intense physical activity), will be explained by ATA. The protocol followed by all patients operated of bariatric surgery at the San Juan de Dios hospital is to receive these indications.

**Criteria for discontinuing or modifying allocated interventions {11b}**

Will be criteria for discontinuing: participant request, severe alteration of hemodynamic parameters during the training, participants who attend less than 85% of the training sessions, participants who were absent on evaluation days and participants from the training group who engage other regular physical exercise.

**Strategies to improve adherence to interventions {11c}**

Not applicable, this trial does not have strategies to improve adherence.

**Relevant concomitant care permitted or prohibited during the trial {11d}**

Not applicable, this trial does not have concomitant care permitted or prohibited.

**Provisions for post-trial care {30}**

Once the study is completed, the CG and group with less effect of the study, will be invited to carry out the training that has obtained the best effect.

**Outcomes {12}**

Outcomes will be assessed at four time points: 1) one week before surgery; 2) 21 days after surgery (baseline before starting the exercise program); 3) 8 weeks after the beginning of the exercise program; and 4) one week after the end of intervention.

Primary outcomes will be: 1) body composition; 2) heart rate variability; 3) six-minute walk test results and 4) perceived quality of life. Secondary outcomes include the results for: 1) maximal respiratory pressure, 2) flowmeter, 3) hand dynamometry, and 4) the 30- second sit-to-stand test.

Data collection will include sex, age, place of residence, marital status, education level, and physical activity level according to the International Physical Activity Questionnaire (29).

**Body Composition**

Body composition will be measured with tetrapolar bioelectrical impedance, (INBODY 270, Inbody Co. Ltd, Korea). The body fat percentage, muscle and bone mass will be evaluated.

**Heart rate variability**

R-R intervals will be recorded with a Polar V800 heart rate monitor (Polar, Oi, Finland); a sensor will be placed on the chest at the fifth intercostal space. The participant will then rest in the supine position for
10 minutes to stabilize heart rate and blood pressure. R-R intervals will be recorded under the following conditions: 1) after resting in the supine position for 10 minutes; 2) after resting in the orthostatic position for 10 minutes (active standing). The participants’ respiratory rate will be recorded throughout the test.

Heart rate variability will be analysed through spectral analysis in an autoregressive model. The spectral components will be obtained at low frequency (LF, 0.04–0.15 Hz) and high frequency (HF, 0.15–0.4 Hz) bands in absolute units (ms$^2$). Standardized units are calculated as the ratio between LF or HF (absolute units) and the power spectral density, minus the very low frequency component (VLF, 0.003–0.04 Hz) and multiplied by 100. The LF band is modulated by the sympathetic and parasympathetic autonomic nervous system (with sympathetic predominance), the HF band is associated with cardiac vagal control, and the LF/HF ratio is calculated to assess sympathovagal balance (30).

**Maximal respiratory pressures**

Maximal inspiratory (MIP) and expiratory (MEP) pressure will be assessed with a respiratory pressure meter (MicroRPM, MicroMedical Ltd., Kent, UK). All measurements will be performed with the participant seated, using a 2 mm aperture mouthpiece and a nose clip to prevent air leakage. MIP will be measured from residual volume, whereas MEP will be measured from total lung capacity. Clear instructions about performing the test will be provided (31).

**Flowmeter**

While the patient is seated, a mini-Wright flowmeter (Clement Clarke, Mason, OH, USA), nosepiece, and disposable nozzle will be used to measure peak expiratory flow. Peak expiratory flow measurement will be based on maximum inspiration. After being instructed the use of the flowmeter, the patients will be asked to blow as hard and as long as possible (32).

**Hand dynamometry**

To evaluate handgrip strength, a digital dynamometer will be used (CAMRY EH101, Guangdong, China). After being instructed about the test and use of the dynamometer, the participants will perform a maximal isometric contraction for 5 seconds with each hand while standing (33).

**Six-minute walk test**

The six-minute walk test will be used to evaluate functional capacity. It will take place in a flat corridor with a 15-meter track. A cone will be placed at each meter to determine the beginning and ending distance. Participants will be instructed to walk back and forth as quickly as possible for 6 minutes, and the total distance covered during will be recorded. Before and after the test, blood pressure, heart rate and oxygen saturation values will be measured. Verbal encouragement will be given every minute, according to Mexican National Institute of Respiratory Disease guidelines (34).

**Perceived quality of life**
The Moorehead-Ardelt quality of life questionnaire II will be applied at each evaluation, and the Bariatric Analysis and Reporting Outcomes System (BAROS), which has been validated for bariatric surgery patients, will be applied at the final evaluation (35, 36).

Moorehead-Ardelt quality of life questionnaire II

This test measures quality of life in 6 dimensions: self-esteem, physical activity, social activity, work activity and sexual activity. Each dimension has 10 response options that are accompanied by images for clarification. Each answer is scored through a visual scale ranging from −0.5 (most unfavourable situation) to +0.5 (most favourable situation). The sum of all dimensions produces a global score: very good (2.1 to 3), good (1.1 to 2), fair (-1 to 1), poor (-2 to -1.1) and very poor (-3 to -2.1).

Bariatric Analysis and Reporting Outcomes System

This test measures quality of life and the benefits of bariatric surgery by incorporating the weight loss or gain percentage after surgery into the Moorehead-Ardelt questionnaire, including comorbidity resolution, reoperation and complications. While the Moorehead-Ardelt scoring is identical to that described above, the other items are scored according to dimension. Scores for the weight loss dimension (as percent of excess weight lost) were: -1 (0–24%), 0 (25–49%), 1 (50–74%), 2 (75–100%). Scores for the comorbidities dimension were: -1 (aggravated), 0 (no changes), 1 (some improvement), 2 (one major comorbidity resolved and improvement in others), 3 (all major comorbidities resolved and all others improved). Scores for the complications dimension were: deduct 0.2 points for a minor complication, deduct 1 point for a major complication, deduct 1 point for reoperation. Global scores for the instrument are the sum of all dimensions, categorized as failure (≤1), fair (>1 to 3), good (>3 to 5), very good (>5 to 7) and excellent (>7 to 9).

Thirty-second sit-to-stand test

Participants will be instructed to cross their arms over their chest and stand in front of a reinforced 44-cm-high chair that is positioned against a wall. They will then sit and stand as many times as possible in 30 seconds, and the number of repetitions will be recorded.

Participant timeline {13}

Sample size {14}

GPower 3.1 was used to determine the sample size, assuming a power of 80% and a significance level of 5%. Calculations were based on Herring et al. (2017), considering BMI and heart rate. A total of 17 participants per group were required to detect an effect size of 1.01. However, due to possible dropouts, 25 participants will be included in each group, totaling 75 volunteers.

Recruitment {15}

Participants recruitment will occur weekly. A list of patients who are scheduled to have bariatric surgery will be provided by a staff member of the San Juan de Dios, Curicó’s Hospital, Chile. Participants who are
interested and meet inclusion criteria will be invited to participate in the study after signing the informed consent.

**Assignment Of Interventions: Allocation**

**Sequence generation {16a}**

**Concealment mechanism {16b}**

**Implementation {16c}**

After baseline assessment, randomization will be performed in blocks of 5 using sealed opaque envelopes. A colleague not involved in the study belonging to the Physical Medicine and Rehabilitation Service will manage the randomization procedure and will inform the lead researcher about the group assignments. The Fig. 2 shows the study design flow chart describing all the steps of the study (Fig. 2).

**Assignment Of Interventions: Blinding**

**Who will be blinded {17a}**

This will be a single-blinded study. The outcome assessor will have no information about the participants study group.

**Procedure for unblinding if needed {17b}**

Not applicable, unblinding is not permissible in this trial.

**Data Collection And Management**

**Plans for assessment and collection of outcomes {18a}**

The assessments will be carried out at the institution's Physical Medicine and Rehabilitation Service, and the intervention program will be carried out in the Service's Adult Physical Therapy Gym. All the assessments will be conducted by a trained and experienced physical therapist. Prior the start of the study, was trained and familiarized with the evaluation protocol.

**Plans to promote participant retention and complete follow-up {18b}**

A weekly phone call will be made to CG participants, asking about their health status and the indications for this group will be reinforced, in turn a text message will be sent to remind the evaluation date and
Participants who are in the training groups, in each session will be asked for feedback on their health status and will be sent a text message to remind them the training schedule.

In the event that any participant misses their training or evaluation, they will immediately proceed to call to ask about the reasons for not showing up.

**Data management {19}**

All the information collected from this trial will always be protected and in the care of the lead research, who will assign a secure locker in his office where all documents of the investigation will be kept.

All electronic material will be duly stored and backed up in the researcher’s computer equipment with a safe password.

**Confidentiality {27}**

In order to keep confidentiality after the assessments, the outcomes assessor will store the participants’ data separately from any identifying information and coded with a unique study ID. This ID will be linked to participant identity only within an encrypted, password-protected local database running on a secure host device maintained by outcome assessor and the study supervisor.

**Plans for collection, laboratory evaluation and storage of biological specimens for genetic or molecular analysis in this trial/future use {33}**

Not applicable, this trial does not have biological specimens.

**Statistical Methods**

**Statistical methods for primary and secondary outcomes {20a}**

Data normality will be assessed with the Shapiro-Wilk test. Variance homogeneity and sphericity will be assessed with the Levene and Mauchly tests, respectively. For variables that meet the assumptions of ANOVA, a mixed model ANOVA with Bonferroni correction will be used to assess the group-by-time interaction. Other data will be analyzed with the Wilcoxon test for comparisons within groups and the Mann-Whitney test with Bonferroni correction for comparisons between groups. The significance level will be set at 5%. Cohen’s d will be calculated to determine the effect size. All analysis will be performed in SPSS 24.

**Interim analyses {21b}**

Not Applicable. Interim analyses will not be performed in the present study.
Methods for additional analyses (e.g. subgroup analyses) {20b}

Not Applicable. Additional analyses are not planned in the present study.

Methods in analysis to handle protocol non-adherence and any statistical methods to handle missing data {20c}

Per-protocol and intention-to-treat analysis will be performed in order to account for the possible dropouts during the study. In the per-protocol analysis, we will include only the participants who attended at least 85% of the sessions and underwent the baseline and post intervention outcome assessments. For the intention-to-treat analysis, we will consider all the participants who underwent the baseline assessments and after being assigned to one of the study groups, took part in at least one session. Missing data will be handled by multiple imputation method. Five imputed data sets will be obtained by multiple linear regression models for each variable. The final imputed value will be the arithmetic mean of the 5 data values created.

Plans to give access to the full protocol, participant level-data and statistical code {31c}

Not Applicable. Public access to the full protocol, data sets and statistical code are not planned for this trial. However, this information might be available upon a reasonable request to the corresponding author keeping participants anonymity.

Oversight And Monitoring

Composition of the coordinating centre and trial steering committee {5d}

Not Applicable. This trial was approved by the board review committee from the Research and Teaching Department of the San Juan de Dios Hospital (Curicó, Chile) and does not require monitoring by a steering committee.

Composition of the data monitoring committee, its role and reporting structure {21a}

Not applicable. Since this is study will be performed at the Physical Medicine and Rehabilitation Service of the San Juan de Dios, Curicó’s Hospital, monthly reports will be routinely elaborated and provided to the Research and Teaching Department. Therefore, this trial does not require a data monitoring committee.

Adverse event reporting and harms {22}
In the end of each training session and evaluations participants will be asked to report any complaints and symptoms produced by the proposed activity. Outcome assessor and the lead researcher will be in charge to collect and record this information throughout the study. All complications and dropouts will be reported in the final manuscript.

**Frequency and plans for auditing trial conduct {23}**

Not Applicable. Auditing trial conduct are not planned for this study.

**Plans for communicating important protocol amendments to relevant parties (e.g. trial participants, ethical committees) {25}**

In case of any change to the current protocol, the lead research will be responsible to inform and send the new version the ethical committee for their approval. After the approval the clinical register will be updated and all the amendments will be informed.

**Dissemination Plans {31a}**

Each participant will receive a full report with the results of their assessments. By the end of the study, the lead research will be contact all the participants to provide the final results of the trial. Also, preliminary results will be reported in international conferences and final results in a manuscript that will be submitted to an indexed scientific journal.

**Discussion**

The objective of this study will be to investigate the effects of 16 weeks of MICT or HIIT on body composition, cardiopulmonary function and perceived quality of life in bariatric surgery patients.

MICT has been proven effective for increasing fat mass loss and decreasing lean mass loss after bariatric surgery, as well as for improving control of glucose homeostasis and cardiovascular capacity (21, 22). On the other hand, HITT improves cardiorespiratory fitness and insulin sensitivity in the obese and is well tolerated by overweight and insulin-resistant people (25–27).

However, to the best of our knowledge, no studies have compared MICT and HITT protocols in bariatric surgery patients. Determining which exercise strategy better suits this population is relevant for bariatric surgery management and formulating recommendations. Another strength of our study is the presence of a control group that follows current Chilean recommendations after bariatric surgery. If our hypothesis is confirmed, this study could lead to new recommendations about supervised exercise after bariatric surgery.
It should be also pointed out assessing cardiac autonomic control with heart rate variability will provide important information about the effectiveness of both methods in a cardiovascular marker related to the risk of cardiovascular events and mortality (37, 38).

**Trial Status**

Recruiting.

Version 2. January 21, 2020.

Date recruitment began: December 2, 2019.

Approximate date when recruitment will be completed: December 31, 2022.

**Declarations**

**Acknowledgements**

The authors would like to acknowledge the following individuals for their invaluable contributions to this study: Mr. Mauro Salinas Cortés (San Juan de Dios, Curicó’s Hospital director), Dr. Sergio Ballesteros Montoya (Research and Teaching Department Chief of San Juan de Dios, Curicó’s Hospital), Dr. Francisco Zúñiga Reyes (Bariatric Surgery Service Chief of San Juan de Dios, Curicó’s Hospital), PT. Ignacio Bravo Silva (Physical Medicine and Rehabilitation Service), Mrs. Elizabeth Valdivia Muñoz (Physical Medicine and Rehabilitation Service).

**Authors’ contributions (31b)**

(AHR):

**References**

1. Muñoz M, Botella-Romero F, Gomez-Ramirez S, Campos A, Garcia-Erce JA. Iron deficiency and anaemia in bariatric surgical patients: causes, diagnosis and proper management. Nutr Hosp. 2009;24(6):640–54.

2. Atalah E. Epidemiología de la obesidad en Chile. Rev Med Clin Condes. 2012;23(2):117–23.

3. Bluher M. Adipose tissue inflammation: a cause or consequence of obesity-related insulin resistance? Clin Sci (Lond). 2016;130(18):1603–14.

4. De Tursi Rispoli L, Vazquez Tarragon A, Vazquez Prado A, Saez Tormo G, Mahmoud Ismail A. Gumbau Puchol V. [Oxidative stress; a comparative study between normal and morbid obesity group population]. Nutr Hosp. 2013;28(3):671–5.
5. Esser N, Legrand-Poels S, Piette J, Scheen AJ, Paquot N. Inflammation as a link between obesity, metabolic syndrome and type 2 diabetes. Diabetes Res Clin Pract. 2014;105(2):141–50.

6. Papapietro K, Massardo T, Riffo A, Diaz E, Araya AV, Adjemian D, et al. [Bone mineral density disminution post Roux-Y bypass surgery]. Nutr Hosp. 2013;28(3):631-.

7. Gutiérrez F, Avendaño J, González J, Marín M, Aceves A, Campos E, et al. Alteraciones hepáticas en el paciente con obesidad mórbida sometido a cirugía bariátrica. Med Int Mex. 2013;29(1):20–5.

8. Folope V, Chapelle C, Grigioni S, Coeffier M, Dechelotte P. Impact of eating disorders and psychological distress on the quality of life of obese people. Nutrition. 2012;28(7–8):e7–13.

9. Juvanhol L, Correira G, Aranjo E, Mara M, Gómez M. Quality of life and its relation with corporal mass and satisfaction with the weight in school-children. Journal of Nursinf UFPE on line. 2012;6(8):1774–80.

10. Diez I, Martínez C, Sanchez-Santos R, Ruiz J, Frutos M, De la Cruz FT, et al. Recomendaciones de la SECO para la práctica de la cirugía bariátrica y metabólica (Declaración de Victoria-Gasteiz, 2015). Bariátrica & Metabólica Iberoamericana. 2015;5(3.3):842-5.

11. Hewitt S, Sovik TT, Aasheim ET, Kristinsson J, Jahnson J, Birketvedt GS, et al. Secondary hyperparathyroidism, vitamin D sufficiency, and serum calcium 5 years after gastric bypass and duodenal switch. Obes Surg. 2013;23(3):384–90.

12. Basfi-Fer K, Rojas P, Carrasco F, Valencia A, Inostroza J, Codoceo J, et al. [Evolution of the intake and nutritional status of zinc, iron and copper in women undergoing bariatric surgery until the second year after surgery]. Nutr Hosp. 2012;27(5):1527–35.

13. Brzozowska M, Sainsbury A, Eisman J, Baldock P, Center J. Bariatric Surgery and Bone Loss: Do We Need to Be Concerned? Clinic Rev Bone Miner Metab. 2014;12:2017–227.

14. Carrasco F, Klaassen J, Papapietro K, Reyes E, Rodriguez L, Csendes A, et al. [A proposal of guidelines for surgical management of obesity]. Rev Med Chil. 2005;133(6):699–706.

15. Carrasco F, Papapietro K, Csendes A, Salazar G, Echenique C, Lisboa C, et al. Changes in resting energy expenditure and body composition after weight loss following Roux-en-Y gastric bypass. Obes Surg. 2007;17(5):608–16.

16. Savino P, Carvajal C, Nassar R, Zundel N. Specific nutritional requirements following bariatric surgery. rev colomb cir. 2013;28(2):161–71.

17. Sanchez Ortega L, Sanchez Juan C, Garcia AA. [Evaluation of a structured program of physical exercise in morbidly obese patients awaiting bariatric surgery]. Nutr Hosp. 2014;29(1):64–72.

18. Coleman KJ, Caparosa SL, Nichols JF, Fujioka K, Koebnick C, McCloskey KN, et al. Understanding the Capacity for Exercise in Post-Bariatric Patients. Obes Surg. 2017;27(1):51–8.

19. Lund MT, Hansen M, Wimmelmann CL, Taudorf LR, Helge JW, Mortensen EL, et al. Increased post-operative cardiopulmonary fitness in gastric bypass patients is explained by weight loss. Scand J Med Sci Sports. 2016;26(12):1428–34.
20. Muñoz R, Hernández J, Palacio A, Maiz C, Pérez G. El ejercicio físico disminuye la pérdida de masa magra en pacientes obesos sometidos a cirugía bariátrica. Revista Chilena de Cirugía. 2016;68(6):411–6.

21. Mundbjerg LH, Stolberg CR, Bladbjerg EM, Funch-Jensen P, Juhl CB, Gram B. Effects of 6 months supervised physical training on muscle strength and aerobic capacity in patients undergoing Roux-en-Y gastric bypass surgery: a randomized controlled trial. Clin Obes. 2018;8(4):227–35.

22. Proulx E, Auclair A, Piche ME, Harvey J, Pettigrew M, Biertho L, et al. Safety of Blood Glucose Response Following Exercise Training After Bariatric Surgery. Obes Surg. 2018;28(12):3976–83.

23. Jung ME, Bourne JE, Beauchamp MR, Robinson E, Little JP. High-intensity interval training as an efficacious alternative to moderate-intensity continuous training for adults with prediabetes. J Diabetes Res. 2015:191595.

24. Sim AY, Wallman KE, Fairchild TJ, Guelfi KJ. High-intensity intermittent exercise attenuates ad-libitum energy intake. Int J Obes (Lond). 2014;38(3):417–22.

25. Cocks M, Shaw CS, Shepherd SO, Fisher JP, Ranasinghe A, Barker TA, et al. Sprint interval and moderate-intensity continuous training have equal benefits on aerobic capacity, insulin sensitivity, muscle capillarisation and endothelial eNOS/NAD(P)H oxidase protein ratio in obese men. J Physiol. 2016;594(8):2307–21.

26. Kessler HS, Sisson SB, Short KR. The potential for high-intensity interval training to reduce cardiometabolic disease risk. Sports Med. 2012;42(6):489–509.

27. Matsuo T, Saotome K, Seino S, Shimojo N, Matsushita A, Iemitsu M, et al. Effects of a low-volume aerobic-type interval exercise on VO2max and cardiac mass. Med Sci Sports Exerc. 2014;46(1):42–50.

28. Guiraud T, Nigam A, Gremeaux V, Meyer P, Juneau M, Bosquet L. High-intensity interval training in cardiac rehabilitation. Sports Med. 2012;42(7):587–605.

29. Mantilla A, Gómez A. International Physical Activity Questionnaire. An adequate instrument in population physical activity monitoring. Revista Iberoamericana de Fisioterapia y Kinesiología. 2007;10(1):48–52.

30. Heart rate variability. : standards of measurement, physiological interpretation and clinical use. Task Force of the European Society of Cardiology and the North American Society of Pacing and Electrophysiology. Circulation. 1996;93(5):1043–65.

31. Forti M, Zamuner AR, Andrade CP, Silva E. Lung Function, Respiratory Muscle Strength, and Thoracoabdominal Mobility in Women With Fibromyalgia Syndrome. Respir Care. 2016;61(10):1384–90.

32. Gomara M, Rodriguez M. Peak-flow meter: technique and utilities in Primary Health Care. Medifam. 2002;12(3):76–91.

33. Díaz G, Callejas P, Cuesta V, Calvera S. Concordance-conformity within Camry and Jamar hand dynamometers in adults. Revista De Nutrición Clínica Y Metabolismo. 2018;1(1):35–41.
34. Gochicoa L, Mori U, Guerrero S, Silva M, Cid S, Velázquez M, et al. Six-Minute Walk Test: Recommendations and procedure. Neumología y cirugía de tórax. 2015;74(2):127–36.

35. Moorehead MK, Ardelt-Gattinger E, Lechner H, Oria HE. The validation of the Moorehead-Ardelt Quality of Life Questionnaire II. Obes Surg. 2003;13(5):684–92.

36. González J, Gómez G, Arriagada G. Evaluation of gastric bypass surgery using the Baros score. Revista Chilena de Cirugía. 2006;58(5):365–70.

37. Hillebrand S, Gast KB, de Mutsert R, Swenne CA, Jukema JW, Middeldorp S, et al. Heart rate variability and first cardiovascular event in populations without known cardiovascular disease: meta-analysis and dose-response meta-regression. Europace. 2013;15(5):742–9.

38. Wulsin LR, Horn PS, Perry JL, Massaro JM, D'Agostino RB. Autonomic Imbalance as a Predictor of Metabolic Risks, Cardiovascular Disease, Diabetes, and Mortality. J Clin Endocrinol Metab. 2015;100(6):2443–8.

Figures
| TIMEPOINT | ENROLLMENT | Randomization | Post-randomization |
|-----------|------------|---------------|-------------------|
| Enrollment | -t₀ (1 week before surgery) | t₀ (21 days after surgery) | t₁ (Post 8-week intervention) | t₂ (Post 16-week intervention) |
| Eligibility screen | X | X | X | X |
| Informed consent | X | X | X | X |
| Randomization | O | O | O | O |
| INTERVENTIONS: | | | | |
| MICT-G | | | | |
| HIIT-G | | | | |
| CG | | | | |
| ASSESSMENTS: | | | | |
| Body composition | X | X | X | X |
| HRV | X | X | X | X |
| 6MWT | X | X | X | X |
| MAQ II | X | X | X | X |
| BAROS SCORE | X | X | X | X |
| MIP/MEP | X | X | X | X |
| PEF | X | X | X | X |
| Handgrip strength | X | X | X | X |
| Squat test | X | X | X | X |
Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- supplement1.doc
- supplement2.docx
- supplement3.pdf
- FundingDocumentation.pdf