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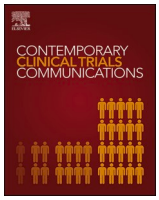

The impact of exercise on prevention of sarcopenia after bariatric surgery: The study protocol of the EXPOBAR randomized controlled trial

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ABSTRACT

Introduction: Bariatric surgery is one of the treatments for severe obesity, with proven efficacy in reducing weight and diseases associated with obesity. Weight loss associated with bariatric surgery is greatly associated with a significant reduction of skeletal muscle and bone mineral mass, which leads us to induce that after bariatric surgery, patients incur an increased risk of sarcopenia. The need for prophylactic programs that prevent sarcopenia in bariatric surgery patients seems to be one of the crucial points for the long-term surgical success of bariatric and metabolic surgery. The aim of this randomized clinical trial will be to study the effects of a 16-week supervised exercise intervention program on the prevention of sarcopenia, in patients undergoing bariatric surgery. As a secondary purpose, it is also intended to characterize metabolic risk factors, physical fitness, and quality of life in post-bariatric surgery patients.

Method: A total of 45 patients on the waiting list for bariatric surgery and who have subsequently perfurgery, will be include on EXPOBAR (*EXercise POst BARiatric*) and randomized into 2 groups, experimental and control. The intervention starts one month after surgery, for a total of 16 weeks. Parameters of body composition, metabolic risk, quality of life, physical activity, physical fitness, and sedentary behavior will be determined. For each participant, outcomes are measured at five different time points: before the surgery, before the exercise program, after the exercise program, six and twelve months after de exercise program.

Results: This study will provide the effects of a physical exercise on sarcopenia, in patients after bariatric surgery.

Trial registration: The trial was registered at Clinicaltrials.gov NCT03497546.

1. Introduction

The high prevalence of obesity leads to it being considered as a public health problem, with high mortality [1]. Severe obesity, categorized as a chronic disease, has associated pathological conditions, leading to other chronic diseases such as diabetes, and cardiovascular diseases, in addition to psychological disorders and social repercussions [2].

Bariatric surgery is one of the most effective treatments for severe obesity, with proven efficacy in reducing weight and diseases associated with obesity, resulting in a short time, weight loss that can reach 60% of excess weight, as well as an improvement in comorbidities [3–5].

Weight loss associated with bariatric surgery is greatly associated with a significant reduction of skeletal muscle and bone mineral mass, which leads to induce that after bariatric surgery, patients are at an increased risk of sarcopenia [6]. Sarcopenia is a pathological disorder characterized by generalized loss of skeletal muscle mass and function, with implications for quality of life. Sarcopenia is also associated with diabetes, metabolic syndrome, and cardiovascular diseases [7].

In fact, sarcopenia is associated whit severe obesity whit a prevalence of 2% in adults' patients in age group of 60–70 years [8] then increases to 8% when the patients are woman [9] and to 10% in older

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patients [8]. Although, obesity and sarcopenia increase health risk when they co-exist [10].

In this context, several authors suggested that reduced levels of physical activity are a predictor in the development of sarcopenia and that the combination of aerobic and strength exercises in bariatric patients can be effective, preventively and in the treatment, of sarcopenia [11]. This mechanism is important also because in the first years after bariatric surgery, de muscle mass significantly decrease and continued to drop out at two years, with a muscle mass loss represented more than 20% [12].

The repercussions of large weight loss after bariatric surgery and the onset of sarcopenia or modification of pre-existing sarcopenia remain little documented or studied, however, the existed studies show different results. One year after surgery, the early establishment of adequate nutritional support in combination with physical activity is an important anabolic stimulus for muscle protein synthesis and prevention of muscle mass loss and the occurrence of sarcopenia [13], but two years after surgery, the loss of muscle mass may not relate to the parameters of protein metabolism or surgical technique [12]. However, physical exercise could positively influence skeletal muscle mass in many clinical populations [13–16], where we can include bariatric patients. 26. In this point, bariatric surgery predisposes patients to sarcopenia and consequently osteoporosis, because the relationship is relevant [11].

The guidelines recommended combined moderate-intensity exercise to maintain muscle mass. The American College of Sports Medicine (ACSM) states that from the moment the patient is surgically discharged, a program of progressive exercises for all individuals, should follow the FITT-VP principle (frequency, intensity, time, type, volume, progression) [14]. Also, The American Society for Metabolic and Bariatric Surgery (ASMBS) recommends, in addition to preoperative exercises, a progressive walking program, starting on the first postoperative day, which includes aerobic exercises and strength training $\geq$30 min/day [15]. Regarding the type of training, we have evidence that in the obese population, strength training and aerobic training can increase muscle strength and metabolic improvements [17].

The need for prophylactic programs that prevent sarcopenia in bariatric surgery patients seems to be one of the crucial points for the long-term surgical success of bariatric and metabolic surgery. However, sarcopenia prevalence in the long-term after surgery remains unclear and the lack of evidence of short and long-term programs highlights the need to address their development.

2. Objectives

2.1. First objectives

To analyze the effects of a 16-week supervised exercise intervention program on the prevention of sarcopenia, in patients undergoing bariatric surgery. As a secondary purpose, it is also intended to characterize metabolic risk factors, physical activity, physical fitness, and quality of life in post-bariatric surgery patients.

2.2. Secondary objectives

1. Identify, evaluate, and synthesize evidence on the effects of physical activity and exercise on the body composition of patients undergoing bariatric surgery.
2. Synthesize evidence on the effects of physical exercise on a level of sarcopenia in patients undergoing bariatric surgery.
3. Characterize the cardiometabolic profile of patients undergoing bariatric surgery.
4. Study the validity and reliability of physical fitness tests for patients undergoing bariatric surgery.
5. Characterize inflammatory markers in obesity after bariatric surgery.

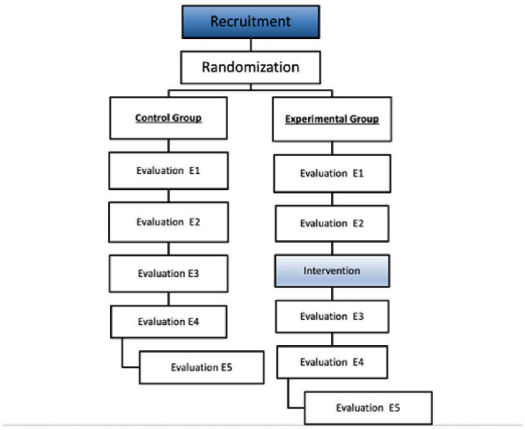

Fig. 1. Study design flow diagram.

6. Understand the barriers and facilitators for physical activity practice in patients undergoing bariatric surgery.
7. Understand and characterize the hormonal profile after bariatric surgery.
8. Evaluate noninvasive biomarkers in the mechanism of obesity after bariatric surgery.
9. Understand the impact of physical exercise on the quality of life of patients undergoing bariatric surgery.
10. Evaluate the effects of the exercise program applied to patients undergoing bariatric surgery, in body composition, comorbidities, sedentary behavior, life quality, hormonal and inflammatory profile, and physical fitness.
11. Check the evaluations and changes produced before the surgery, before and after the exercise program, and 6 and 12 months after the end of the structured and monitored exercise program.

3. Material and methods

3.1. Study design

A randomized clinical trial, registered as EXPOBAR whit de number NCT05289219.

The study will be conducted by the University and the Hospital Center for Integrated Responsibility of Bariatric Surgery and Metabolic Diseases (CRI.COM). All procedures will be management by a team member, common to the two intuitions.

Participants will be selected from the list for surgical intervention in the hospital, with criteria for performing bariatric surgery, and will be randomized into Control Group (CG) and Intervention Group (IG). Exercise training will begin one month after surgery, with a three times per week frequency, up to a maximum of 55 min per session [16]. The present study protocol complies with the SPIRIT 2013 recommenda-tions (Standard Protocol Items: Recommendations for International Trials) (additional file 1).

The invitation to participate will be made in the context of consultation and participants who agree to participate in the study will be delivered the free and informed consent form, previously approved by the University and Hospital Ethics Committee.

3.2. Sample

The sample size was calculated by the Gpower, assuming an alpha error of 0.05 and a power of 95%, a total of 46 patients (n = 23 patients per group) will be needed to detect an effect (between group difference) of at least 0,7 standard deviations in the outcome risk of sarcopenia [18]. Anticipating a potential 20% lost to follow-up and based on the number of follows in our center, a total of 55 patients will be recruited.

3.3. Randomization

Each participant will be randomly assigned to each group after signing the informed consent and conducting the initial assessments (Fig. 1). All laboratory samples and data collected will be identified with identification ID, safeguarding the confidentiality of the collected data.

At the end of this study, all participants of the control group will be offered the same intervention as the exercise group.

3.4. Inclusion and exclusion criteria

As inclusion criteria, patients should be enrolled for bariatric surgery at the hospital, aged between 18 years and 60 years, body mass index between 30 and 50 kg/m^2, men and woman, without contraindication to the practice of exercise and agree to participate in the study.

Will be exclude patients with problems in locomotion, with previous bariatric surgery, with bariatric surgery complications and, psychiatric diseases or disorders.

3.5. Outcomes

3.5.1. Anthropometry

Weight evaluation will be done using a scale and height of a stadiometer. Based on these values, the body mass index will be calculated. The international society for the advancement of kinanthropometry (ISAK) protocol was used to assess waist circumference.

3.5.2. Metabolic risk factors

Metabolic risk factors will be determined by clinical analyses (fasting blood sample) performed in the context of routine surgical evaluation, with the determination of inflammatory markers, like C-reactive protein, that is a relevant indicator of inflammation, likely decrease with exercise [19]. The mean blood pressure will be evaluated by a digital sphygmomanometer. Through the analytical profile will be determined the hormonal profile, since leptin concentrations seem to decrease after bariatric surgery and ghrelin levels decrease after gastric sleeve and increase after gastric bypass, which assumes that the contribution of ghrelin to weight loss or metabolic benefits after bariatric surgery is not direct but influenced by several factors [20].

3.5.3. Harvest saliva

The study of the physiological mechanisms involved in obesity can be enriched by the evaluation of noninvasive biomarkers, such as saliva amylase. This fluid has several functions, including the perception and ingestion of food, which makes it particularly suitable for the study of obesity. In a study to assess changes in salivary amylase in morbidly obese women, to provide information on mechanisms potentially related to the development of obesity, and to evaluate whether these changes persist after weight loss, it was observed that the enzymatic activity of amylase was increased in the group not submitted to bariatric surgery and decreases in the group that performed the surgery [21]. In this way, a saliva collection will be made at the moments of evaluation with a saliva collection assay kit, which will be analyzed by the biochemistry department.

3.5.4. Glycemia variation

This evaluation will be done through an implantable 24-h monitoring device for 5 days as a way of evaluating the glycemic response to exercise and food intake [22].

3.5.5. Physical fitness

Body composition: To evaluate body composition, the Dual-energy X-ray absorptiometry - DEXA (DXA, Hologic QDR, Hologic, Inc., Bedford, MA, USA) device will be used to measure the % fat mass, muscle mass and bone mass [23].

Muscle strength: The muscle strength of the upper limbs will be evaluated by manual pressure dynamometry (Handgrip) in both hands, with a maximum contraction of 5 s. The muscle strength of the lower limbs will be evaluated by the sit to stand test, in which participants will be instructed to stand and sit for 30 s, as many times as possible [24]. The strength of lower limbs, as well as muscle fatigue, will be evaluated with an isokinetic dynamometer (Biodex®, System 3 Pro, Biodex Corp., Shirley, NY, USA) using a protocol with two series, the first of which is 6 repetitions at 60°/sec. And the second with 25 repetitions at 180°/sec.

Cardiorespiratory fitness: Cardiorespiratory fitness will be assessed using the 6-min walk test (TC6) [24].

3.5.6. Sedentary behavior and physical activity

Accelerometer, through the feature of the application of accelerometers (ActiGraph GT3X model, Fort Walton Beach, Florida, *USA*) for 5 days before the surgery and after the exercise program [25].

3.5.7. Quality of life

Questionnaire "Bariatric Analysis and Reporting Outcome System (BAROS) as a self-report measure, validated for Portuguese, specific for bariatric surgery. This evaluation instrument was developed by the members of the NIH Consensus Conference panel in 1998 to respond to the need for a standardized method to analyze and report the results of bariatric surgery [26].

3.6. Variables

For the assessment of clinical, biochemical, and inflammatory markers, anthropometric parameters and surgical data, a health data questionnaire will be used. Other variables to consider in this study are:

3.6.1. Demographics

Gender, Age, Educational level.

3.6.2. Anthropometry

Weight (scale), height (stadimeter), body mass index, abdominal circumference (measuring tape).

3.6.3. Body composition

DEXA (DXA, Hologic QDR, Hologic, Inc., Bedford, MA, USA).

3.6.4. Clinical data

Comorbidity and metabolic risk factors (total cholesterol, HDL, LDL, triglycerides, glucose, insulin, glycated hemoglobin, mean blood pressure, vitamin D, total proteins, PTH, iron, ferritin, hemoglobin, albumin, prealbumin, lymphocytes, alcohol intake - hepatic steatoses).

3.6.5. Hormonal profile

Blood ghrelin and leptin measurement.

3.6.6. Inflammatory markers

C-reactive protein glucose, insulin, and mean blood pressure;

3.6.7. Saliva harvest

Salivary amylase.

3.6.8. Glycemia variation

Evaluation continues through an implantable device for 5 days;

3.6.9. Physical fitness

Dynamometer, isokinetic evaluation, muscle strength performance. The muscle strength of the upper limbs will be evaluated by manual pressure dynamometry (Handgrip) and lower limbs muscle strength will be evaluated with Biodex.

3.6.10. Cardiorespiratory fitness

6-min walk test (TC6) and sit-to-stand test for 30 s.

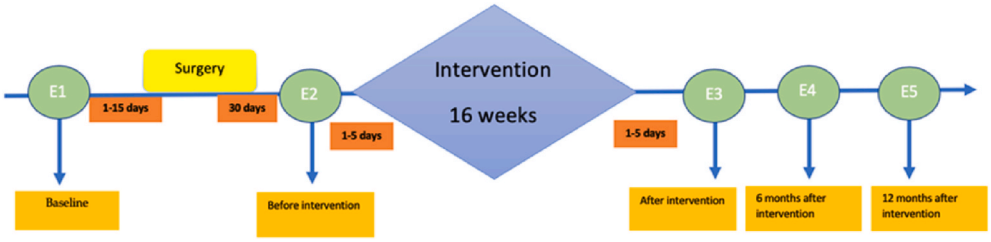

Fig. 2. Evaluation schedule.

3.6.11. *Sedentary behavior*

Accelerometers for 5 days.

3.6.12. *Quality of life*

Questionary "BAROS" as a self-report measure.

3.7. *Intervention*

The exercise program will cover a combination of aerobic and strength training, based on other experimental studies [24] already developed with morbidly obese patients, but also following the *Consensus on Exercise Reporting Template* (CERT) [24].

Exercise prescription includes the type, intensity, duration, frequency, and progression of physical activity. The duration of the program is 16-weeks, 3-times a week, for up to 50 min per session, starting 1 month after surgery, based on the recommendations of the World Health Organization (WHO) and the American College of Sports Medicine (ACSM), because the guidelines for morbidly obese patients undergoing bariatric surgery are not defined. Each session will start with 5 min of warm-up and finalization with 10 min of a cool-down, with work of flexibility and proprioception. And the warm-up and the cool-down will be developed as the component of training with the evolution by phases, both in time and in intensity. The first phase will include 20 min of interval training, encompassing circuit strength training. Each phase will have an increment of 10 min in the central block, always with a prior evaluation of the patient's response. The intensity of the exercise will be evaluated and what has been used and suggested is the Borg scale, with values in a continuous progression of the evaluation of the perceived effort of the exercise performed. And this scale allows an assessment on a scale from 0 to 20 of how rating of perceived exertion, being an evaluation of the perceived effort [27].

Those responsible for the training program will be two personal training with training in sports sciences, whose scheduling will be carried out considering the development of the program. Once de study is completed, the CG will be invited to carry out the exercise program.

3.8. *Evaluation*

We have five evaluations, baseline (before surgery), before the program (1 month after surgery), after the program (5 months after surgery), 6 months after the program (11 months after surgery) and 12 months after the program (17 months after surgery), as show in Fig. 2 and Table 2. De CG will be evaluated at the same time that the IG.

3.9. *Results*

1. Before surgery.
2. Before the intervention.
3. After the intervention.
4. Six months after the intervention.
5. Twelve months after the intervention.

Table 1
Training periodization.

	F	I	T	T			V	P
	Frequency	Intensity	Time	Type			Volume	Progression
	Warm-up: 5min on the treadmill - 50–60% FC reserve							
Phase 1 - **Week 1–4** Resistance Training	3x/week	- 40–59% reserve heart rate - 10–12 Borg	Time: 35/ 39/43 min	Strength training Aerobic training Strength training Aerobic training	3/4/5 min 7/8/9 min 3/4/5 min 7/8/9 min	Major muscle groups Aerobic Major muscle groups Aerobic	1 set-15-20 repetitions (1^a + 2^a week) 2 sets-12-15 repetitions (3^a + 4^a week)	Intensity Time (ITT)
Phase 2 - **Week 5–10** Hypertrophy Training	3x/week	- 60–80% reserve heart rate - 12–14 Borg	Time: 45 min	Strength training Aerobic training Strength training Aerobic training	5 min 10 min 5 min 10 min	Major muscle groups Aerobic Major muscle groups Aerobic	2 sets 12-15 repetitions	Intensity Time (ITT)
Phase 3 - **Week 11–16** Strength Training	3x/week	- 70–89% reserve heart rate - > 14 Borg	Time: 55 min	Strength training Aerobic training Strength training Aerobic training	8 min 12 min 8 min 12 min	Major muscle groups Aerobic Major muscle groups Aerobic	3 sets 12-15 repetitions	Intensity Time (ITT)
	Cool-down: up to 10 min - flexibility (myofascial release, mobility, static and dynamic stretching)							

Table 2
Evaluation schedule.

	Group intervention	Group control
1st Evaluation Before Surgery	Baseline	Baseline
2nd Evaluation Before the Program	1 month	1 month
3rd Evaluation After the Program	5 months	5 months
4th Evaluation	11 months (post-surgery) 6 months (post program)	11 months (post-surgery) 6 months (post program)
5th Evaluation	17 months (post-surgery) 12 months (post program)	17 months (post-surgery) 12 months (post program)

3.9.1. Statistical methods

Statistical software will be used to determine the parameters to be evaluated. Data normality will be assessed with the *Shapiro-Wilk* test and will be used an independent *t*-test or the cui-squared test, to examine differences between groups. To compare dependent variables, a two-way ANOVA will be used considering group (intervention group and control group) and five time points (pre and post-intervention).

4. Discussion

In recent recommendations, those who have chronic diseases, or some type of disability should start by doing small amounts of physical activity with a gradual increase in frequency, intensity, and duration. In addition, for additional benefits should do strengthening activity involving all major muscle groups and moderate or high intensities, at least 2 days a week. As general recommendations, a combination of intensities throughout the week, 150–300 min of moderate-intensity physical activity or 75–150 min of vigorous-intensity physical activity [28].

High-intensity interval training programs typically involve short periods of high-intensity exercise followed by a short period of rest or active recovery. Interval training is a type of training, which consists of alternating between periods of moderate to high-intensity exertion and rest, with variable duration, according to the exercise performed and the objective of the person. This type of training has been shown to be more beneficial to improve abdominal fat and body weight while maintaining muscle mass., in increasing weight loss, as well as a positive effect on bone mineral density, aerobic capacity and muscle strength [29].

Exercise prescription includes the type, intensity, duration, frequency, and progression of physical activity. These five components are applicable to the development of exercise programs for persons regardless of age, functional capacity, and presence or absence of coronary heart disease risk factors. These five components of exercise prescription are reported as Frequency, Intensity, Time, and Type (FITT) with the Volume of exercise added along with the Progression component to produce the acronym FITT-VP. The training sessions will follow an evolution subdivided by progressive phases in training (Table 1). As carried out in previous studies, this strategy carried out through phases of increment of training variables allows better adaptability for this type of patients [30,31].

Each session will start with 5 min of warm-up and finalization with 10 min of a cool-down, with work of flexibility and proprioception. The maintenance of balance and postural stability may be compromised in obese individuals, depending on the degree of obesity, although the support base provided by the position of the foot is proportional to the structural morphology of each subject. Flexibility is also gradually impaired in obese individuals and of course, these changes may be related to postural changes aggravated by a sedentary lifestyle and biological aging itself alongside all metabolic alterations inherent to the pathology of obesity [32].

EXPOBAR aims to be the first RCT in Portugal to evaluate the effects of supervised and structured physical exercise on possible sarcopenia induced by bariatric surgery. Previous studies suggest that there is a decrease in sarcopenia in the immediate period after bariatric surgery when patients have a record of physical exercise.

Interval training has proven to be the most effective in fat mass loss and in preventing muscle mass loss after bariatric surgery. Also infers an improvement in the cardiometabolic condition, with decreased risk factors.

In addition, we intend to contribute to the recommendations of the practice of exercise after bariatric surgery.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.conctc.2022.101048.

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