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Study Protocol

Effects of physical exercise on sarcopenia after bariatric surgery: Study protocol of a randomized controlled trial

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Abstract

Introduction: Bariatric surgery is the treatment of severe obesity with associated pathologies, with proven evidence in its benefits. By treating overweight allows a better and even reversal of pathologies 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 framing of 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 after bariatric surgery

Method: This randomized controlled trial study will include 60 patients of both sexes on the waiting list for bariatric surgery and who have subsequently performed the surgery. They will be randomized into 2 groups, experimental and control. The intervention will take place 1 month after surgery, for a total of 16 weeks. Parameters of body composition, metabolic risk, quality of life, physical activity and sedentary behavior will be determined.

Results: Assessments will take place in five moments, the surgery, the intervention, the post-intervention, six months after the intervention, twelve months after the intervention.

Introduction

Obesity can be defined as a condition of the organism marked by excessive accumulation of fat that poses a health risk, whose prevalence has increased globally in recent decades. In 2014, the World Health Organization (WHO) issued a report on the prevalence of obesity, which was 20.1% in men and 30.5% in women, with more than 600 million of the population being obese. If we keep this data, by 2030, more than 3 million people will be overweight and obese [1].

Increasing levels of obesity are a major challenge for public health, and obesity is considered a priority intervention pathology, with a considerable increase in incidence. Given the high worldwide prevalence, obesity is considered by the WHO, the global epidemic of the 21st century, since its growth happens in the same way in developed and developing countries. More recently, WHO statistics show that more than 39% of adults aged 18 and over were overweight in 2016, with more than 13% of obese individuals [1].

Bariatric surgery is a treatment for severe and morbid obesity and for its associated diseases, with proven success rates [2]. It is known that weight loss, especially in the first year after surgery is significant and rapid, with consequences on body composition, particularly in muscle mass, with all the repercussions that may result, such as metabolic and hormonal changes, and consequent weight regain [3].

Physical exercise has positive repercussions on cardiorespiratory fitness, muscle strength, physical function, cardio-metabolic profile and glucose metabolism [4]. Insulin sensitivity also seems to have a significant increase after supervised exercise programs, regardless of weight loss. On the other hand, the decrease in insulin resistance is related to significant weight loss [5].

A recent meta-analysis showed maintenance of lean mass or at least did not show a loss of lean body mass proportional to weight loss, in bariatric surgery patients who performed

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physical exercise programs [6].

The evidence and recommendations of physical exercise habits in patients with bariatric surgery do not go any further than weight loss, which reduces the entire evolutionary process of the person undergoing this type of surgery, as well as the importance of exercise as a non-pharmacological therapy [7].

A healthy lifestyle after bariatric surgery is essential to optimize and maintain weight loss. Observational studies suggest that physical activity after bariatric surgery may be associated with additional weight loss and more effective weight loss over time. However, there is little experimental evidence on the effects of supervised exercise on obesity-related outcomes in this specific population [3].

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 [8].

Supervised physical exercise after bariatric surgery has been shown to significantly improve cardiorespiratory fitness, muscle strength, physical function, and glucose metabolism. In this context, high-intensity interval training (HIIT) can decrease muscle mass loss in the postoperative period and increase fat mass loss. But there is also evidence that it can promote glucose homeostasis in individuals with insulin resistance and improves cardiovascular condition [9].

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. In this context, several authors argue that reduced levels of physical activity are a factor 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 [10]. 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. In addition, sarcopenia is associated with the severity of fibrosis and steatosis, regardless of metabolic risk factors, in patients with nonalcoholic liver disease [11].

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 early establishment of adequate nutritional support in combination with physical activity is an important anabolic stimulus for muscle protein synthesis and prevention of the occurrence of sarcopenia [12].

Despite recent WHO recommendations on physical activity and sedentary behavior, the inclusion of programs for obese populations or undergoing bariatric surgery are limited, so exercise programs are adapted from recommendations for healthy adults with chronic or disabling diseases [13].

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, the lack of evidence of short and long-term programs highlights the need to address their development.

Objectives

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.

Specific 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.
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.

Material and methods

Study design

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

The protocol will work in partnership with the University of Évora and the Hospital Center for Integrated Responsibility of Bariatric Surgery and Metabolic Diseases (CRI.COM). All procedures will be coordinated by a responsible element, common to the two intuitions.

Participants will be selected from the list for surgical intervention (LIC) in the CRI.COM, 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 minutes per session [3].

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 Ethics Committee of the Évora University and the Hospital do Espírito Santo de Évora, EPE.

Sample

The sample size was calculated by the Gpower software, with a power of 95%, which corresponds to 45 patients, assuming an error of 0,05. With an estimated loss of up to 20%, 60 patients

will be recruited.

Randomization

Each participant will be randomly assigned to each group after signing the informed consent and conducting the initial assessments. 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.

Inclusion and exclusion criteria

As inclusion criteria, patients should be enrolled for bariatric surgery at the hospital, aged between 18 years and 60 years, without contraindication to the practice of exercise and agree to participate in the study.

Regarding the exclusion criteria, patients with problems in locomotion, surgical complications, psychiatric diseases, and neurological disorders.

Variables

For the assessment of clinical, biochemical and inflammatory markers, anthropometric parameters and surgical data, a health data questionnaire will be used.

The variables to consider in this study are:

Demographics: Gender, Age, Educational level.

Anthropometry: weight (scale), height (stadimeter), body mass index, abdominal circumference (measuring tape).

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).

Hormonal Profile: blood ghrelin and leptin measurement.

Inflammatory markers: C-reactive protein (a relevant indicator of inflammation, likely to decrease with exercise) glucose, insulin and mean blood pressure [14];

Glycemia Variation: Evaluation continues through an implantable device for 5 days [15];

Physical Fitness: Dynamometer, isokinetic evaluation, muscle strength performance (Biodex®, System 3 Pro, Biodex Corp., Shirley, NY, USA). 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.

Cardiorespiratory fitness: 6-minute walk test (TC6) and sit-to-stand test for 30 seconds [7].

Sedentary behavior: 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 [16].

Body composition: DEXA (DXA, Hologic QDR, Hologic, Inc., Bedford, MA, USA) to evaluate: % fat mass, % muscle mass, % bone mass and bone mineral density [17];

Saliva harvest: salivary amylase. The study of the physiological mechanisms involved in obesity can be enriched by the evaluation of noninvasive biomarkers, such as saliva.

Quality of life: Questionary "BAROS" as a self-report measure, validated for the Portuguese population specific for bariatric surgery [18].

Intervention

The exercise program will cover a combination of aerobic and strength training, based on other experimental studies [7] already developed with morbidly obese patients, but also following the Consensus on Exercise Reporting Template (CERT) [3];

The duration of the program is 16-weeks, 3-times a week, for up to 50 minutes per session, starting 1 month after surgery, based on the recommendations of the WHO and the ACSM, because the guidelines for morbidly obese patients undergoing bariatric surgery are not defined. Information on exercises for morbidly obese adults is limited, so the exercise programs will follow the guidelines for adults aged 18 to 65 years healthy, with chronic diseases or disabilities [19].

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 to 300 minutes of moderate-intensity physical activity or 75 to 150 minutes of vigorous-intensity physical activity [20].

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 [21].

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 (Table 1) will follow an evolution subdivided by progressive phases in training (Table 2). 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 [7,22, 23].

Each session will start with 5 minutes of warm-up and finalization with 10 minutes 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 [24].

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 minutes of interval training, encompassing circuit strength training. Each phase will have an increment of 10 minutes 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

Table 1. *Training schedule*

	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 Training resistance	3x/week	40-59% HRR 10-12 Borg	Time: 35/39/43 min	Strength training	3/4/5 minutes	Major muscle groups	1 set 15-20 Rep (1ª + 2ª week) 2 sets 12-15 rep (3ª + 4ª week)	Intensity Time (ITT)
				Aerobic training	7/8/9 minutes	Aerobic		
				Strength training	3/4/5 minutes	Major muscle groups		
				Aerobic training	7/8/9 minutes	Aerobic		
Phase 2 Week 5-10 Training Hypertrophy	3x/week	60-80% HRR 12-14 Borg	Time: 45 min	Strength training	5 minutes	Major muscle groups	2 sets 12-15 Repetitions	Intensity Time (ITT)
				Aerobic training	10 minutos	Aerobic		
				Strength training	5 minutes	Major muscle groups		
				Aerobic training	10 minutes	Aerobic		
Phase 3 Week 11-16 Training Strength	3x/week	70-89% HRR > 14 Borg	Time: 55 min	Strength training	8 minutes	Major muscle groups	3 sets 12-15 Repetitions	Intensity Time (ITT)
				Aerobic training	12 minutes	Aerobic		
				Strength training	8 minutes	Major muscle groups		
				Aerobic training	12 minutes	Aerobic		
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)	11 months (post-surgery)
	6 months (post program)	6 months (post program)
5th Evaluation	17 months (post-surgery)	17 months (post-surgery)
	12 months (post program)	12 months (post program)

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 [25].

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.

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 figure 1 and table 3. De CG will be evaluated at the same time that the IG.

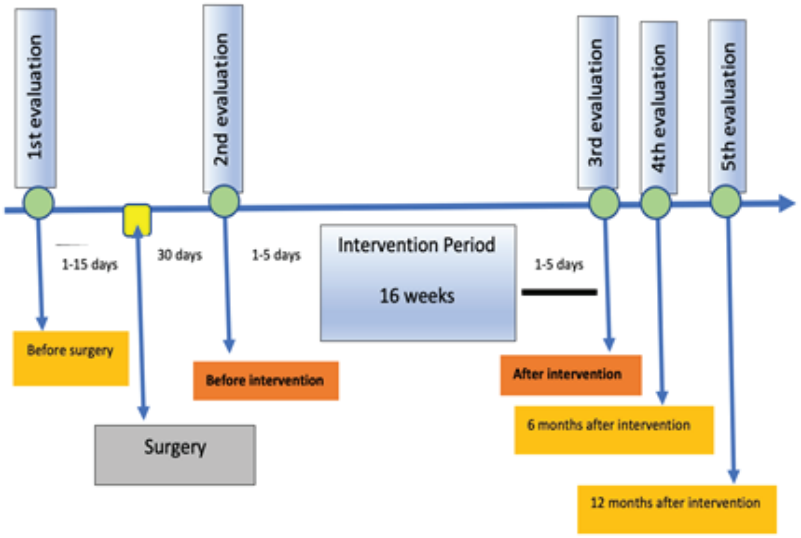

Figure 1. *Evaluation schedule*

Outcomes

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, and the abdominal circumference will be determined by a measuring tape.

Metabolic risk factors: Metabolic risk factors will be determined by clinical analyses performed in the context of routine surgical evaluation, with the determination of inflammatory markers. 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 [26].

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, in order to provide information on mechanisms potentially related to the development of obesity, and also 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 [27]. In this way, a saliva collection will be made at the moments of evaluation, which will be analyzed by the biochemistry department.

Glycemia Variation: This evaluation will be done through an implantable 24-hour monitoring device for 5 days as a way of evaluating the glycemic response to exercise and food intake.

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 [17].

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 five seconds. 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 seconds, as many times as possible [7]. The strength of lower limbs, as well as muscle fatigue, will be evaluated with an isokinetic dynamometer (Biodex) using a protocol with two series, the first of which is 6 repetitions at 60º/sec. and the second with 25 repetitions at 180º/sec.

Cardiorespiratory fitness: Cardiorespiratory fitness will be assessed using the 6-minute walk test (TC6).

Sedentary Behavior and Physical Activity: It will be with accelerometers for 5 days [16].

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 [18].

Results

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

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 qui-square test, to examine differences between groups. Pearson or Spearman correlation will be used for elucidating the relationships between variables. In addition, the effect size will be determined by Cohen's.

Discussion

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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