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ORIGINAL

# Randomized controlled trial protocol: A quanti-quali approach for analyzing the results of an intervention on the waiting list for bariatric surgery

# *Protocolo de estudo controlado randomizado: abordagem quanti-quali para análise de resultados de uma intervenção em fila de espera para cirurgia bariátrica*

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## ABSTRACT

**Objective**

This article aims to describe the protocol of a randomized clinical trial and the baseline results of the study of a one-year interdisciplinary intervention in users of the public health system in the bariatric surgery waiting list.

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**Methods**

A randomized, single-blind clinical trial will be conducted including 88 participants recruited on an outpatient clinic of the public health system. Participants were randomized into the control group (n=44), receiving the usual treatment; and into the intervention group (n=44), participating in the educational intervention. Participants had their food intake, negative affectivity and physical inactivity/sedentary behavior assessed, as well as anthropometric and body composition measurements; their blood samples were collected; and also had different physical capacity tests.

**Results**

Of the 157 participants invited, 27 had severe functional limitations, one was under-age, and four declined the study due to associated diseases. Eighty-eight participants were randomized: 44 for the Control Group and 44 for the Intervention Group. When comparing the demographic and biochemical characteristics, there were no differences between groups except for serum glucose (GC=110.4±46.8mg/dL and GI93.1±16.9mg/dL, *p*=0.039).

**Conclusion**

This study protocol describes the methodology used in the study of educational intervention for the promotion of health care of patients on the waiting list for bariatric surgery. It shows that there is similarity between the baseline comparison groups. *Registro Brasileiro de Ensaios Clínicos* (Brazilian Clinical Trials Registry), RBR-775y3d.

**Keywords**: Bariatric surgery. Clinical trial. Obesity. Public Health System.

## RESUMO

***Objetivo***

*Descrever protocolo de ensaio clínico randomizado e resultados de linha de base dos efeitos de intervenção interdisciplinar de um ano, com usuários do sistema público de saúde na fila de espera para cirurgia bariátrica.*

***Métodos***

*Será conduzido um ensaio clínico randomizado, uni-cego, com 88 participantes recrutados em ambulatório do sistema público de saúde e randomizados entre o grupo controle (n=44) que recebe o tratamento habitual e entre o grupo de intervenção (n=44) que participa da intervenção educativa. Os participantes tiveram o consumo alimentar, afetividade negativa e inatividade física/comportamento sedentário avaliados, bem como medidas antropométricas e de composição corporal, amostras de sangue e testes de capacidade física.*

***Resultados***

*Dos 157 participantes convidados, 27 apresentaram limitações funcionais graves, 1 era menor de 18 anos e 4 declinaram devido a doenças associadas. Oitenta e oito participantes foram randomizados: 44 para o Grupo Controle e 44 para o Grupo Intervenção. Quando comparados quanto as características demográficas e bioquímicas, não houve diferença entre os grupos, exceto para glicose sérica (GC=110,4±46,8mg/dL e GI93,1±16,9mg/dL; p=0,039).*

***Conclusão***

*Este protocolo de estudo descreve a metodologia utilizada no estudo de intervenção educativa para a promoção do cuidado integral com pacientes em espera para cirurgia bariátrica. Mostra que há semelhança entre os grupos de comparação na linha de base. Registro Brasileiro de Ensaios Clínicos RBR- 775y3d.*

***Palavras-chave***: *Cirurgia bariátrica. Ensaio Clínico. Obesidade. Sistema Público de Saúde.*

## INTRODUCTION

Obesity has biological and psychological components in its genesis and maintenance, being considered one of the most prevalent health problems in the world, still on the rise, and one that significantly reduces people's expectations and quality of life [1-3]. The challenges to its containment and treatment are clear. In the case of severe obesity, bariatric surgery has been the best alternative

treatment. Brazil's *Sistema Único de Saúde* (SUS, Brazilian Unified Health System) provides this surgical procedure, but the number of surgeries performed is still insufficient [4,5], resulting in a long waiting period, which can last from three to seven years [5,6]. The reduction of 5 to 10% of body weight before bariatric surgery decreases the surgical complications and comorbidities associated with obesity, and in some cases may prevent surgery through the adoption of new habits [4,7,8].

Health education interventions aim to promote changes to the person's eating behavior, physical activity level and self-care. The approach based on integral care consists of interdisciplinary teamwork, within a framework of full health care, encouraging popular participation and social control, as well as bonding and accountability relationships [9-11]. It is still a challenge in the public health care system to create effective strategies to promote the necessary care for associated chronic diseases, to improve or avoid the aggravation of physical capacity reduction, and to assist in the control of behavioral disorders such as binge eating, depression, anxiety and stress [12-15]. Few randomized controlled studies have investigated the effects of behavioral interventions on body weight loss in obese patients who are candidates for surgery, with controversial results on effectiveness versus usual treatment [7,16,17]. Therefore, evaluative and controlled studies have been insufficient in this area, resulting in the lack of evidence capable of supporting the implementation of educational interventions as strategies of improving the health conditions of patients with severe obesity, waiting for bariatric surgery.

Thus, the objective of this study will be to describe the protocol of a randomized clinical trial and the baseline results of the anthropometric variables, body composition, biochemical composition, physical ability, eating behavior and psychic aspects as indicators of the results of an interdisciplinary intervention with patients in the SUS waiting list for bariatric surgery.

## METHODS

The present study protocol follows the recommendations of the SPIRIT (Standard Protocol Items for Clinical Trials) report, which defines the standard items for the elaboration of clinical trial protocols [18].

A randomized, controlled, single-blind, two-arm intervention study will be conducted with patients with severe obesity who are on the waiting list for bariatric surgery in the general surgery outpatient clinic of the *Base Hospital of São José do Rio Preto*. The duration of the study will be one year. The study was approved by the university's Research Ethics Committee of *Faculdade de Ciências Farmacêuticas - Universidade Estadual de São Paulo* (FCF - UNESP, Faculty of Pharmaceutical Sciencies, *São Paulo* State University, No.2289208).

### Participants and Recruitment

Inclusion criteria were: (a) individuals who have a Body Mass Index [BMI]≥40kg/m$^2$ or a BMI≥35kg/m$^2$, with comorbidities; (b) individuals between 18 and 65 years-old; (c) and individuals who had been in the waiting list for bariatric surgery for at least a year. The criteria for non-inclusion were: (a) individuals with chronic kidney disease; (b) who have any type of cancer under treatment; (c) individuals with severe cardiovascular disease; (d) with chronic obstructive pulmonary disease; (e) with uncontrolled systemic arterial hypertension; (f) with untreated thyroid disorders; (g) with severe functional limitations that limit body movement; (h) and a history of drug and alcohol abuse.

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A total of 88 patients with severe obesity were randomized using a computer software and blinded to the evaluators, with n=44 for the intervention group and n=44 for the control group. Details of patient recruitment are shown in Figure 1. Patient allocation was performed with a distribution of 1:1.

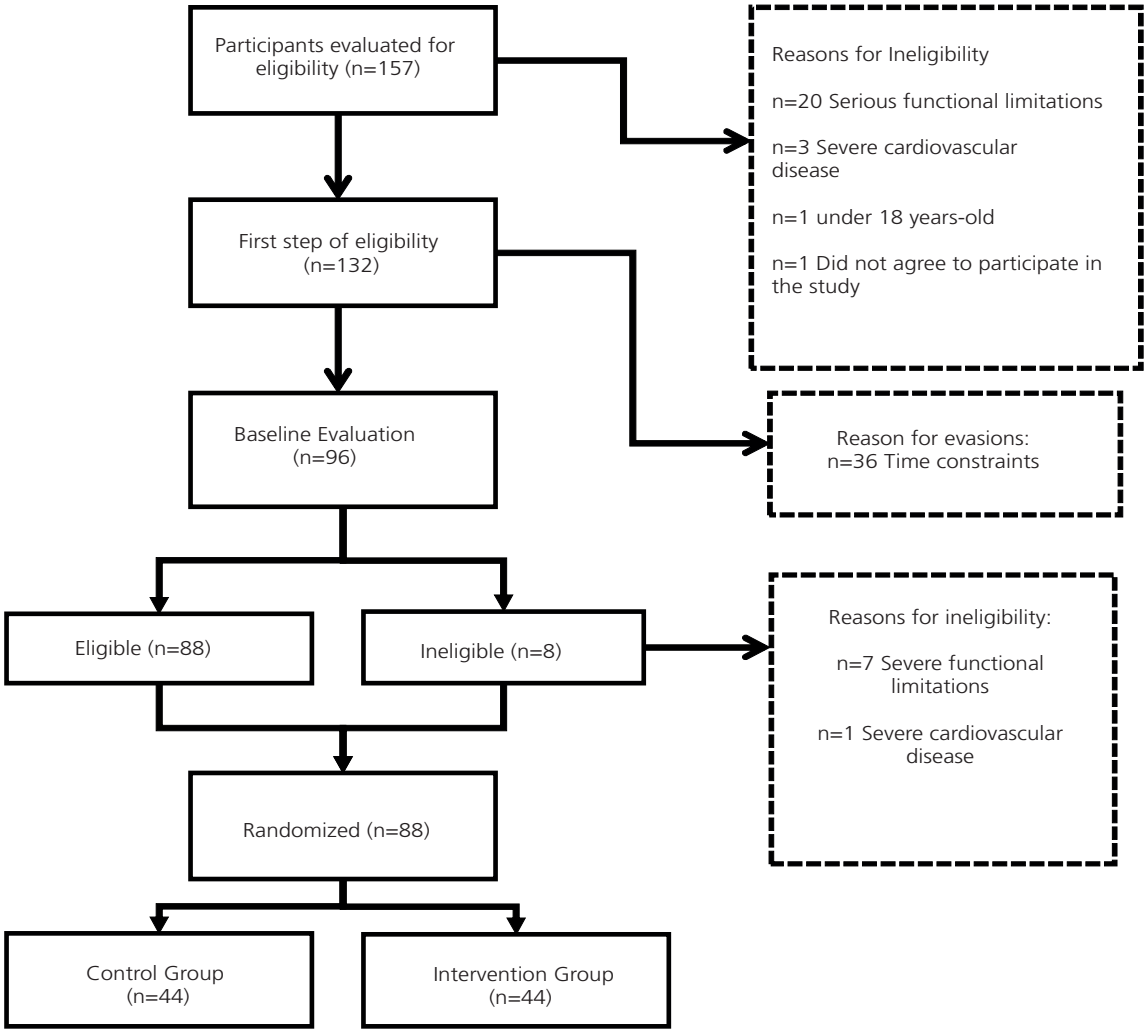


**Figure 1**. Recruitment and flow of study participants. *São José do Rio Preto* (SP), Brazil, 2017.

The patients were divided into four educational groups (10 to 15 people) with biweekly meetings in the first semester and monthly meetings in the following semester, in a total of 18 meetings, lasting one hour each.

The intervention project contemplates a process of formation of the health team, along the lines of Permanent Education [19] with active methodologies [20] for the improvement of the profile of competence in the management of obesity and for group conduction. The educational process is coordinated by a pair of educators, being performed in 10 face-to-face meetings, in association with virtual meetings, having the participation of specialists to discuss and deepen into emerging issues.

The proposals developed by health professionals in their specific fields of knowledge are detailed as follows:

Approach to the human movement: It is recommended that the participants perform at least 150 minutes of moderate physical activity per week for the development and maintenance of physical fitness and health, and decrease their sedentary behavior [21]. Face-to-face meetings are held with physical education professionals and physiotherapists to encourage regular physical activities with moderate intensity, to decrease the amount of time spent in long-term sedentary activities (sitting and/or lying) and to solve doubts and problems related to the barriers reported by participants during the practice of physical activities. In addition to face-to-face meetings, motivational strategies are developed in the social networks.

Psycho-sociocultural approach: The Psychology professional applies Cognitive Behavioral Therapy with the purpose of restructuring non-functional thoughts and behaviors, covering psycho-sociocultural aspects, as well as those aspects shared in the care process so that strategies for coping with the problem are identified, strategies that must be elaborated bearing in mind the proposal of co-responsibility in the care process, established between the team and the patients, focusing on the individual and with possibilities of collective support, aiming at the development of the patients' autonomy [22].

Food and nutrition education: The activities developed are based on the presuppositions of popular education, critical participatory education, and emancipating education [23]. Nutritionists promote patient autonomy and the identification of motivational elements to potentiate resources from territories and social contexts in order to facilitate the management of obesity. The eating habits are discussed considering the complexity of the food phenomenon and commensality [24], in a way that favors the control of risk factors and the adaptation to the surgical intervention process.

Patients in the control group are referred to the original treatment offered by the outpatient clinic, which consists of: the care given by the social service professional, who receives patients who have been referred for bariatric surgery, verifies the indication criteria and registers the patient in the waiting list for the procedure. The waiting period can last for up to two years in the general surgery outpatient clinic of the Base Hospital of *São José do Rio Preto*, and the individual is not assisted by the outpatient staff during this period.

## Outcome measurements

All outcome measurements described below were assessed at the baseline, and will be assessed 6 and 12 months after the procedure.

Sociodemographic Data and Medical History: The socio-demographic data and medical history were self-reported by the participants, and filled-out by the evaluation team. Data referring to age, sex, ethnicity, educational level, marital status, income level, medications used, alcohol consumption, smoking habits, occupational status and pre-existing illnesses were collected at this point.

Anthropometric and Body Composition Measurements: The individual's height (with a high precision stadiometer) and neck circumference (Sanny tape measure – circumference measured at the midpoint of the neck) were measured; and fat mass and lean mass (InBody 230 bioimpedance scale, Biospace, South Korea) following the procedures described by Beato *et al*. [25].

Food Ingestion: Food intake was assessed using the food diary methodology [26]. Patients fill out a specific form with all food and drink they consumed over the last three non-consecutive

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days, being two days of the week and one day of the weekend. To improve the accuracy of this form, the patients received a training coordinated by nutritionists, where they discussed the aspects related to the identification and quantity of food and drink consumed in the day. In order to calculate the Reported Energy Intake, the DietSys data processing system [27] will be used as the database for converting food intake into energy and nutrients, which uses the Food Consumption Table of the Brazilian Population (4th edition), and for the remaining food, the USDA Nutrient Database for Standard Reference will be used.

Food Behavior: The food behavior will be evaluated using the Three-factor Food Questionnaire (TFEQ-18) translated and adapted for Brazil [28]. The TFEQ-18 was validated by Karlsson *et al*. [29]. The 18-item version of the TFEQ-18 will be used, with a three-factor structure that assess inherent aspects of eating behavior such as: cognitive restriction, emotional eating and lack of control [29].

Negative Affectivity: The scale of Depression, Anxiety and Stress (DASS 21), will be used to assess the presence of depression, anxiety and stress symptoms in the participants [30]. For this study, the Brazilian version as proposed by Vignola & Tucci [31] was used.

Physical Inactivity and Sedentary Behavior: The International Physical Activity Questionnaire (IPAQ) in its short version [32] was used to estimate the amount of time spent by the individual on moderate to vigorous physical activities, performed for at least ten continuous minutes, in the previous week. Sedentary behavior was determined by asking about the total time spent sitting. The energy expenditure in walking activities (3.3 Metabolic Equivalent [MET]), of moderate (4.0MET) and vigorous (8.0MET) intensity were quantified in MET-min/week. Patients who perform <600MET-min/week in the total score by the questionnaire will be considered as physically inactive [33].

Determination of Serum Levels of Biochemical Markers: Blood samples are obtained by venipuncture in vacuum-dried tubes, and were allowed to coagulate at room temperature. The serum is separated by centrifugation, at 2000rpm for 20 minutes and stored in a freezer at -70°C for further analysis.

Serum concentrations of glucose, total cholesterol, HDL-cholesterol, triglycerides, alanine aminotransferase, aspartate aminotransferase, C-reactive protein, urea, and creatinine were determined using an automated equipment (Unicel DXL 800, Beckman Coulter, California, United States) and using commercial kits. Low-density lipoprotein levels were estimated through the Friedwald *et al*. [34] formula, for triglyceride levels lower than 400mg/dL.

Systemic Arterial Pressure: Resting systolic and diastolic blood pressure was measured using an oscillometric device (BP3AC1-1 PC; Microlife AG, Clearwater, Florida, Unites States), positioned in the left arm of the individual. Three measurements were checked and the mean value was then calculated [35].

## Physical Tests

Sit-to-stand test: Subjects are instructed to stand up from the sitting position of an armless chair (43cm high chair) as fast as possible for five times with their arms crossed over the chest. Two trials are performed with a one-minute interval, the shortest time for the performance of the test will be considered for analysis [36].

Handgrip Strength test: It was performed using a grip strength dynamometer (TKK, Grip Strength Dynamometer 0-100kg, Takei, Japan). The subjects are instructed to remain seated, with

their elbows flexed at 90° and the forearm in a neutral position. After a verbal command, three repetitions are performed for each hand, with as much strength as possible with a 30-second-interval between each attempt for the same hand. For the analysis, it is considered the highest value obtained from the dominant hand, normalized by body weight [37].

6-Minute Walk Test: The participants' aerobic functional capacity is measured indirectly by the submaximal six-minute walk test, which is performed on a 30-meter flat course. For analysis, the total distance traveled in meters [38] is considered.

Toe-touch Test: The thoraco-lumbar and hip flexibility is assessed by the toe-touch test [39]. Three attempts are made with an interval of 20 seconds, with the smallest value in centimeters of the distance between the middle finger to the ground being considered.

Physical Fitness Score: For each measure of physical performance (sit-to-stand; handgrip strength; 6-minute walk; toe-touch test), a categorical score was assigned in order to allow patients unable to safely perform the physical tests to be analyzed. In order to do so, those who failed to take the test received a score of 0. The subjects who completed the test received a score between 1 and 4 (worse and better in the test), determined by the performance quartile values obtained in each physical test. The total physical fitness score was calculated by the sum of all physical tests.

### Sample Calculation

For the calculation of the sample size, an estimation was performed from the study of Camolas *et al*. [7], a large effect size (Cohen's d=0.90) for body weight loss over a six-month period (behavioral *vs*. control intervention) of individuals who are candidates for bariatric surgery. Thus, considering a power of 95% and an alpha value of 0.05; the minimum sample size estimated was of 34 patients per group. Considering a 20% follow-up loss, this value was corrected for 44 patients per group.

The baseline characteristics between groups presented in this study protocol were performed through an independent *t*-test or a Mann-Whitney test for the continuous variables, and an $\chi^2$ test for the categorical variables.

## RESULTS

A total of 157 patients in the waiting list for bariatric surgery were invited to participate in the study. Of these, 69 were not selected for the study: 27 due to severe functional limitations, 1 for being under 18 years-old, 37 declined the invitation, and 4 declined claiming associated diseases. Eighty-eight participants were randomized into control (n=44) and intervention (n=44) groups. The total sample consisted of women (n=76; 86.4%) and men (n=12; 13.6%). Among the participants, 69.3% were in stable union relationships, and 13.6% were single.

Table 1 describes the baseline characteristics of the intervention and control groups. The mean age of the participants was 37.9(SD±9.3) years-old, the intervention group being: 38.3(SD±9.1), and in the control group being: 37.6(SD±9.6). Mean body weight was 123.2(SD±21.9)kg, with 125.5(SD±23.8)kg in the intervention group and 120.9(SD±19.8)kg in the control group. Mean BMI was 46.0(SD±6.3)kg/m$^2$, 46.2(SD±6.7) in the intervention group, and 45.8(SD±6.0) in the control

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group. The data on cardio-metabolic risk factors and physical capacity are shown in Table 2. All variables used to assess cardio-metabolic risk presented similar means between groups, except for fasting glucose, for which it was observed a mean value of 110.4(SD±46.8)mg/dL in the control group, and 93.1(SD±16.9) in the intervention group; *p*=0.039.

**Table 1**. Clinical and demographic characteristics of the patients who are candidates for bariatric surgery in the SUS. *São José do Rio Preto* (SP), Brazil. 2017.

| Characteristics | Control (n=44) | | Intervention (n=44) | | *p*-value |
|---|---|---|---|---|---|
| | n | % | n | % | |
| *Sex* | | | | | 0.293 |
| Male | 4 | 9.1 | 8 | 18.2 | |
| Female | 40 | 90.9 | 36 | 81.8 | |
| *Marital status* | | | | | 0.770 |
| Not married | 12 | 27.3 | 15 | 34.1 | |
| Married/Stable union | 32 | 72.7 | 29 | 65.9 | |
| *Skin Color* | | | | | 0.326 |
| White | 29 | 65.9 | 31 | 70.5 | |
| Black | 1 | 2.3 | 6 | 13.6 | |
| Brown | 14 | 31.8 | 7 | 15.9 | |
| *Social class* | | | | | 0.971 |
| A (BRL20,888.00) | 0 | 0.0 | 1 | 2.3 | |
| B1 (BRL9,254.00) | 1 | 2.3 | 6 | 13.6 | |
| B2 (BRL4,852.00) | 11 | 25.0 | 0 | 0.0 | |
| C1 (BRL2,705.00) | 12 | 27.3 | 10 | 22.7 | |
| C2 (BRL1,625.00) | 18 | 40.9 | 20 | 45.5 | |
| D/E (BRL768.00) | 2 | 4.5 | 7 | 15.9 | |
| *Has a job* | | | | | 0.933 |
| Yes | 25 | 56.8 | 24 | 54.5 | |
| No | 19 | 43.2 | 20 | 45.5 | |
| *Smokes* | | | | | 0.945 |
| Yes | 4 | 9.1 | 6 | 13.6 | |
| No | 40 | 90.9 | 38 | 86.4 | |
| *Alcoholic individual* | | | | | 0.144 |
| Yes | 15 | 34.1 | 8 | 18.2 | |
| No | 29 | 65.9 | 36 | 81.8 | |
| *Pre-existing disease* | | | | | 0.696 |
| Yes | 33 | 75.0 | 32 | 72.7 | |
| No | 11 | 25.0 | 12 | 27.3 | |
| *Medication* | | | | | 0.407 |
| Yes | 34 | 77.3 | 29 | 65.9 | |
| No | 10 | 22.7 | 15 | 34.1 | |
| *Physical activity* | Mean | SD | Mean | SD | |
| MET-minutes/week | 387.7 | 345.9 | 477.4 | 454.6 | 0.528 |
| Sitting time/week (min) | 268.5 | 177.3 | 306.4 | 221.6 | 0.545 |
| Sitting time/weekend (min) | 348.4 | 227.2 | 281.6 | 183.8 | 0.214 |

Note: MET: Metabolic Equivalent; SD: Standard Deviation.

**Table 2**. Anthropometric characteristics, body composition, cardio-metabolic risk markers, and baseline physical abilities of patients candidates for SUS bariatric surgery. *São José do Rio Preto* (SP), Brazil. 2017.

| Characteristics | Control (n=44) | | Intervention (n=44) | | *p*-value |
|---|---|---|---|---|---|
| | Mean | SD | Mean | SD | |
| Age (years) | 37.6 | 9.6 | 38.3 | 9.1 | 0.724 |
| Height (cm) | 162.2 | 7.1 | 164.4 | 9.1 | 0.214 |
| Weight (kg) | 120.9 | 19.8 | 125.5 | 23.8 | 0.355 |
| BMI (kg/m$^2$) | 45.8 | 6.0 | 46.2 | 6.7 | 0.997 |
| Fat mass (kg) | 62.7 | 12.4 | 63.2 | 13.4 | 0.917 |
| Lean mass (kg) | 58.2 | 9.2 | 62.2 | 13.8 | 0.113 |
| Fat (%) | 51.7 | 3.8 | 50.4 | 4.6 | 0.203 |
| Neck Circumference (cm) | 40.6 | 3.6 | 42.3 | 5.1 | 0.222 |
| | | | | | |
| Systolic Blood Pressure (mmHg) | 136.2 | 19.4 | 134.5 | 16.7 | 0.899 |
| Diastolic Blood Pressure (mmHg) | 86.4 | 10.9 | 84.7 | 14.8 | 0.922 |
| Glucose (mg/dL) | 110.4 | 46.8 | 93.1 | 16.9 | 0.039 |
| AST (mg/dL) | 16.4 | 9.0 | 16.9 | 8.9 | 0.690 |
| ALT (mg/dL) | 13.5 | 11.9 | 10.7 | 6.4 | 0.510 |
| Total Cholesterol (mg/dL) | 201.3 | 42.2 | 185.8 | 30.7 | 0.055 |
| LDL Cholesterol (mg/dL) | 115.0 | 34.1 | 106.8 | 23.9 | 0.468 |
| HDL Cholesterol (mg/dL) | 49.4 | 11.3 | 48.2 | 11.1 | 0.511 |
| Triglycerides (mg/dL) | 184.7 | 90.5 | 154.6 | 61.8 | 0.201 |
| C-Reactive Protein (mg/dL) | 15.4 | 9.2 | 17.5 | 12.8 | 0.802 |
| Urea (mg/dL) | 28.0 | 9.0 | 28.0 | 6.4 | 0.486 |
| Creatinine (mg/dL) | 0.62 | 0.13 | 0.63 | 0.16 | 0.996 |
| | | | | | |
| MGS relative to the dominant side (score) | 2.3 | 1.1 | 2.7 | 1.1 | 0.116 |
| Sit and lift test (score) | 1.9 | 1.3 | 2.4 | 1.3 | 0.101 |
| Flexibility (score) | 2.2 | 1.2 | 2.5 | 1.3 | 0.268 |
| 6-min walk (score) | 2.4 | 1.1 | 2.5 | 1.1 | 0.695 |
| Total physical fitness score | 8.8 | 2.9 | 10.1 | 3.2 | 0.068 |

Note: BMI: Body Mass Index; AST: Aspartate Aminotransferase; ALT: Alanine Aminotransferase; MGS: Manual dominant Grip Strength; LDL: Low Density Lipoprotein; HDL: High Density Lipoprotein.

## DISCUSSION

The current randomized controlled trial will test the effectiveness of an intervention performed by an interdisciplinary team about obese patients who are candidates for bariatric surgery, on their health and wellness indicators in a one-year period. The intervention is being carried out in a specialized outpatient clinic, developed as a health education group focused on full health care, and the project contemplated permanent education benefits based on an active methodology for professionals [19,20].

To the best of our knowledge, only three prospective, randomized, controlled studies have evaluated the effect of interventions that seek lifestyle changes in obese individuals who are on the waiting list for bariatric surgery [7,16,17]. However, it is important to point out that there is a great heterogeneity between the studies in relation to the characteristics of the intervention (*e.g.*, time,

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duration, content, health professionals involved) and none investigated the effects of an intervention similar to the one in this study, taking into account the outcomes considered here. The results of interdisciplinary educational interventions, given the wealth of meanings, have been documented by qualitative approaches, as opposed to linear models of research. Thus, the present study seeks to break this duality by associating both approaches, qualitative and quantitative, in the perspective of integrating a series of variables for the understanding of a complex process.

In order to meet the assumptions of a quantitative research, methodological rigor was sought in this study and, at this point, homogenization between the control and intervention groups could be emphasized for all studied variables, except for fasting glucose, which could be adjusted according to the statistical resources. It is also important to evaluate the physical capacity and the use of instruments to investigate inherent aspects of eating behavior and negative affectivity as indicators of qualitative results.

The behavioral and physical capacity assessment of patients who sought bariatric surgery may help in a better therapeutic response based on preoperative variables. In the study by Wadden & Sarwer [40], it was revealed that behavioral predictors may guide the choice of the most appropriate surgical procedure to be taken, and allow health professionals to make better choices in pre and post-operative counseling to optimize long-term outcomes. In addition, Hansen *et al*. [38] indicated that improvement in the walking capacity before the surgery is strongly correlated with weight loss after bariatric surgery. Evidence indicates the importance of multidisciplinary work in the preoperative period in different health parameters, and not only regarding weight loss.

This clinical trial protocol is not free from limitations, which need to be highlighted. In particular, it was observed a relatively large proportion of participants who refused to participate in the survey or who were considered ineligible according to the non-inclusion criteria. Thus, patients who presented major health problems due to the severity of their obesity were not included, representing a possible selection bias.

Cases of participants abandoning clinical trials are frequently observed in the literature [41], since in the screening process it is observed a considerable evasion of possible participants due to time constraints for personal reasons (n=6). Knowing this information beforehand enabled us to be prudent in performing sample calculation, assuming a power of 95%.

## CONCLUSION

This protocol contributes with information on the educational approach applied with patients in the waiting list for a surgical procedure with the objective of improving the health indicators of individuals with severe or morbid obesity, and better prepare them for the surgery, supporting the decision making process regarding the chosen treatment and/or the best form of caring for the patient.

## CONTRIBUTORS

MM EVANGELISTA, AH CRISP, MRM OLIVEIRA, SL ROSSATO, R BOSSA and CM VIEIRA contributed with the conception and design, and analysis and interpretation of data. AH CRISP collaborated with interpretation of data. MRM OLIVEIRA contributed with the conception and design. MM EVANGELISTA, AH CRISP, MRM OLIVEIRA, SL ROSSATO, R BOSSA and CM VIEIRA review and approve the article.

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