FEDERAL UNIVERSITY OF HEALTH SCIENCES OF PORTO ALEGRE
PROGRAM OF POSTGRADUATE STUDIES IN NUTRITIONAL SCIENCES

Performance of an intervention based on the Brazilian Dietary Guidelines in the treatment of overweight and obese individuals: a randomized clinical trial.

Porto Alegre- RS, Brazil

April 08, 2025

SUMMARY

1. INTRODUCTION 5
3. JUSTIFICATION 7
4. HYPOTHESIS 7
5. OBJECTIVES 7
5.1 General objectives: 7
5.2 Specific objectives: 7
6. Ethical Aspects 8
7. METHODOLOGY 8
7.1 Study design 8
7.2 Characterization of the study population and sampling 8
7.2.1 Sample size calculation 8
7.2.2 Sampling 9
7.2.3 Randomization and concealment of the allocation list 9
7.3 Outcomes 9
7.3.1 Primary outcomes 9
7.3.2 Secondary outcomes 10
7.4 Study Procedures 10
7.4.1 Control group procedures 11
7.4.2 Intervention group procedures 12
7.5 Sociodemographic 14
7.6 Anthropometric 14
7.7 Behavioral and Lifestyle 16
7.8 Assessment of food consumption 17
7.9 Evaluation of biochemical tests 17
8. STATISTICAL ANALYSIS 17
9. SCHEDULE 18
10. BUDGET 19
REFERENCES 20
APPENDIX A 23

SUMMARY

Introduction: The global increase in obesity implies the need to develop and evaluate treatment strategies aligned with national food and nutrition guidelines. The causes are multifactorial and require integrated health actions. Food and Nutrition Education aims to promote the autonomous and voluntary practice of healthy eating habits, which can directly impact diet quality and health profile. The Dietary Guidelines for the Brazilian Population are one of the main instruments guiding FNE actions in the country.

Objective: To evaluate the effect of a Dietary Guidelines for the Brazilian Population -based intervention on diet quality and clinical parameters in overweight and obese individuals.

Methodology: A Randomized clinical trial to compare the effect of a GAPB-based intervention (intervention group - IG) vs. standard individual nutritional follow-up (control group - CG). The control group (CG) will receive individual nutritional counseling, and the intervention group (IG) will receive guidance in group activities based on the recommendations of the Dietary Guidelines for the Brazilian Population. The study will include adult individuals of both sexes diagnosed with overweight and obesity, as defined by Body Mass Index. Participants will be assessed before and after the interventions using food consumption questionnaires and the eating practices scale, along with anthropometric, sociodemographic, and lifestyle data.

Keywords: Food and nutrition education; overweight; obesity; Hospital Outpatient Clinic.

LIST OF ABBREVIATIONS

CT	Total Cholesterol
GC	Control Group
GI	Intervention Group
HDL	High-density lipoproteins High-density lipoprotein
BMI	Body Mass Index
IPAQ	International Physical Activity Questionnaire
LDL	Low-density lipoproteins
CRP	C-reactive protein
SISVAN	Food and Nutritional Surveillance System
SUS	Unified Health System
TG	Triglycerides

1. INTRODUCTION

Obesity is a growing public health problem, affecting more than one billion people worldwide. In Brazil, the percentage of overweight and obese people is 57.7%, encompassing more than half of the population (1). The southern region of Brazil also shows a significant increase, with the percentage of overweight people rising from 19.83% to 27.6% from 2019 to 2023. The city of Porto Alegre, capital of Rio Grande do Sul, is the second-largest city in Brazil, with the highest percentage of overweight adults, at approximately 62.2% (2–4). Given these rising epidemiological data, it is estimated that by 2035, more than 4 billion people will be overweight and obese globally (5).

Another relevant aspect concerns the economic impact of chronic non-communicable diseases on the Brazilian Unified Health System (SUS), where approximately $ 654 million is spent annually, representing 22% of all direct health costs in Brazil. This is attributable to high Body Mass Index (BMI), demonstrating the urgent need for effective public policies to control overweight and obesity (6).

Overweight and obesity are characterized by the abnormal or excessive accumulation of adipose tissue, which poses a greater risk of health complications (7). Recognized as a multifactorial condition, obesity presents important behavioral risk factors, evidenced by inadequate habits (8). Thus, a major influence on this health condition is the modern lifestyle, which is mostly based on unfavorable behaviors such as a sedentary lifestyle, stress, inadequate eating habits, alcohol, and smoking (9).

It is also observed that dietary practices in this current lifestyle have undergone a transition from the use of unprocessed and minimally processed foods to the incorporation of ultra-processed foods, a practice common in countries with both higher and lower socioeconomic development (10). This behavior can be observed according to reports from SISVAN Web, which show that the prevalence of ultra-processed food consumption in Brazil was 70% among adults in 2024 (11). Several studies have pointed to the health risks associated with the consumption of ultra-processed foods, with a high level of evidence linking them to being overweight and obesity, in addition to evidence from experimental studies (12,13).

Primary treatments for obesity include dietary modifications, increased physical activity, behavioral changes, and, when necessary, medication and surgical interventions. (14)From a nutritional standpoint, it is evident that a diverse, balanced, and healthy diet is essential for the prevention and control of chronic non-communicable diseases. Therefore, it is essential to include food and nutrition education initiatives to promote healthy eating, support

regional habits, reduce food waste, and foster sustainability (15).

The inclusion of Nutrition Education as part of the treatment for overweight and obesity is an important tool for promoting autonomy in both the development of culinary skills and food choices. It also encourages self-care and dialogue between the individual and healthcare professionals, in a continuous and prolonged manner (Brazil, 2018), to provide an environment of mutual support, with greater exchange of knowledge, optimization of working time, and ample opportunities for use in community spaces and... better health education (16).

Based on the information presented, it is evident how important it is to develop nutrition education actions for overweight and obese individuals, aiming to promote knowledge about healthy eating and improve the quality of life of this population. Therefore, the objective of this research is to evaluate the effects of an intervention based on the Dietary Guidelines for the Brazilian Population in overweight and obese patients treated in a hospital outpatient clinic.

2. JUSTIFICATION

Evidence in the literature has indicated a growing and consistent relationship between the consumption of ultra-processed foods and overweight and obesity. In this sense, there is a perceived need to evaluate the performance of methods for treating overweight and obesity that are aligned with the Dietary Guidelines for the Brazilian Population and, consequently, with contemporary national guidelines.

Based on this, this research is justified by the need to investigate nutritional monitoring methods to deepen understanding of how effective collective actions can improve food consumption, clinical parameters, and adherence to treatment, with the aim of enhancing the nutritional treatment of overweight and obese individuals.

3. HYPOTHESIS

Overweight and obese individuals seen in outpatient settings who participate in a group-based intervention can achieve the same benefits in improved food consumption and clinical and anthropometric parameters as those in standard individual follow-up.

4. OBJECTIVES

4.1 General objectives:

To evaluate the performance of an intervention based on the Dietary Guidelines for the Brazilian Population regarding food consumption and clinical parameters in overweight and obese individuals.

4.2 Specific objectives:

- To characterize the studied population according to sociodemographic, behavioral, and lifestyle data, such as sex, gender, age group, average family income, education level, physical activity, smoking, alcohol consumption, medications used, and associated comorbidities, among other data relevant to the research, through a specific questionnaire.
- To assess and compare patients' food consumption according to the NOVA food classification before and after the interventions.
- Analyze and compare dietary practices according to the Dietary Guidelines for the Brazilian Population using the dietary practices scale before and after the interventions.

- Analyze and compare laboratory tests, such as fasting blood glucose, glycated hemoglobin, uric acid, triglycerides, total cholesterol, LDL cholesterol, HDL cholesterol, and C-reactive protein, before and after the interventions.
- To evaluate individuals' anthropometric data according to weight, BMI, and waist circumference before and after the interventions.
- To identify and evaluate participation in treatment based on participant attendance and changes in nutritional (anthropometric) parameters, and diet quality.
- To analyze the participants' level of motivation toward the outcome of weight loss using the transtheoretical model of change, before and after the interventions.

5. ETHICAL ASPECTS

The study will be submitted to the Research Ethics Committee of the Santa Casa de Misericordia de Porto Alegre (ISCMPA) and the Federal University of Health Sciences of Porto Alegre (UFCSPA) for review through the Plataforma Brazil platform and can only begin after obtaining written approval of the protocol and the Informed Consent Form (ICF).

The study will be conducted according to the recommendations of the International Good Clinical Practice guidelines (17), the updated version of the Declaration of Helsinki (WMA, 2024), and in accordance with Brazilian Resolution RDC 466/2012 and all its complementary regulations (19).

6. METHODOLOGY

6.1 Study design

This is a randomized, parallel-group, open-label clinical trial with a 1:1 allocation, designed according to the Standard Protocol Items: Recommendations for Interventional Trials (20)and will be reported in accordance with the guidelines of the Consolidated Standards of Reporting Trials (21), and will be registered in the Brazilian Registry of Clinical Trials (ReBEC), through the website http://www.ensaiosclinicos.gov.br.

6.2 Characterization of the study population and sampling.

6.2.1 Sample calculation

The sample size calculation was performed using G*Power 3.1.9.7. The sample size was calculated to estimate an effect size of f=0.2 (corresponding to Cohen's d=0.4), as suggested by Brysbaert. A significant level of 0.05 and 80% power will be adopted, requiring 52 participants (26 per group). An additional 15% will be added to account for potential loss to follow-up. Therefore, the sample will consist of 60 participants, with 30 participants per group (22).

6.2.2 Sampling

The sampling will be non-probabilistic, non-purposive, and convenience based. It will consist of adult individuals under follow-up at the Endocrinology Service of the Santa Casa de Misericordia de Porto Alegre. Individuals will be invited to participate in the study and answer the questionnaires.

6.2.3 Randomization and concealment of the allocation list

The randomization list will be generated electronically by validated software, with a 1:1 allocation ratio. The researchers responsible for including individuals will access the study website and complete a simple clinical form to generate that patient's randomization. The randomization performed by the system developed for this study will be characterized as central randomization, which ensures the confidentiality of the randomization list, so that the researchers do not know which group the patient will be allocated to.

6.3 OUTCOMES

6.3.1 Primary outcomes

6.3.1.1 Food consumption according to the NOVA food classification

Dietary intake will be assessed using the 24-hour dietary recall available on the Quest Nova platform. This instrument consists of 58 items featuring common foods in the Brazilian diet; participants indicate whether they consume each item using dichotomous (yes/no) responses. The estimated completion time for the questionnaire is 15 minutes. This tool enables the identification of both quantitative and qualitative aspects of the participants' dietary habits. To ensure a representative average intake, the assessment will be administered twice within the same week, once at baseline (pre-intervention) and once post-intervention.

6.3.1.2 Dietary practices in accordance with the GAPB.

Adherence to healthy eating practices will be measured using the Dietary Practice Scale based on the Dietary Guidelines for the Brazilian Population. This validated, self-administered instrument consists of 24 statements regarding healthy dietary habits as recommended by the guidelines. For each statement, participants indicate their level of adherence using a 4-point Likert scale ranging from "Strongly Agree" to "Strongly Disagree." The scale is a robust tool designed to quantify compliance with national dietary recommendations and to evaluate the overall quality of food-related behaviors.

6.3.2 Secondary outcomes

6.3.2.1 Anthropometric measurements:

Anthropometric measurements will be taken before and after the application of the group intervention and individualized care, to allow comparative analyses. Body weight will be measured using a standardized scale, and Body Mass Index (BMI) will be calculated by dividing weight in kilograms by height in meters squared to determine nutritional status. Waist circumference will be measured with a tape measure at established anatomical reference points and recorded in centimeters. Waist circumference will help classify metabolic risk, with cutoff points of 102 cm for men and 88 cm for women. These measurements provide essential data for assessing changes in body composition and associated health risks.

6.3.2.2 Biochemical tests:

Data on laboratory tests, including fasting blood glucose, glycated hemoglobin, total cholesterol, HDL cholesterol, LDL cholesterol, uric acid, triglycerides (TG), and C-reactive protein (CRP), will be obtained from participants' medical records.

6.3.2.3 Transtheoretical model of change:

The Transtheoretical Model, based on the Prochaska Scale, will be used, comprising five stages of individual motivation: pre-contemplation, contemplation, preparation, action, and maintenance.(23)

6.4 Study procedures

This study aims to evaluate the performance of an intervention based on the Dietary Guidelines for the Brazilian Population, in improving food consumption and clinical

parameters in overweight individuals. To this end, it will consist of two groups: a control group (CG) and an intervention group (IG). Patients will be invited to participate in the study during their scheduled appointment at the Metabolic Nutrition Clinic. They will be invited to participate after the consultation is completed. Data collection will be carried out through interviews by the principal investigator and a trained team. Patients in the control group will continue to be monitored at the clinic. The interventions for the control group will be conducted in the rooms of UFCSPA.

The GC will receive standard, individualized outpatient nutritional counseling at the Metabolic Nutrition Clinic of the Endocrinology Service of the Irmandade Santa Casa de Misericordia de Porto Alegre, comprising four individual monthly consultations. The GI group will participate in four group sessions on Food and Nutrition Education, held at the Federal University of Health Sciences of Porto Alegre (UFCSPA) campus. These sessions will be based on the Dietary Guidelines for the Brazilian Population and the first booklet of the series of Protocols for the Use of the Dietary Guidelines for the Brazilian Population. There will be no additional costs for participating in these meetings.

In addition, both groups will receive phone calls or text messages after the start of the consultations/collective actions, as well as brochures (educational material) about healthy eating. This contract aims to clarify any doubts, reinforce the guidelines, and remind participants to attend the meetings.

6.4.1 Control group

The control group will receive individualized nutritional care consisting of 4 monthly in-person consultations, held at the Metabolic Nutrition Clinic of the Endocrinology Service of the Irmandade Santa Casa de Misericordia de Porto Alegre and conducted by a qualified nutritionist. Each consultation will last 50 to 60 minutes.

Individual nutritional care provided in the outpatient clinic follows the principles of person-centered care, considering the individual's current health status, lifestyle, cultural preferences, adequacy of energy and nutrient intake, and individual circumstances. Realistic treatment goals will be defined, such as a 5% to 10% reduction in body weight, with a focus on weight-loss maintenance, preservation of lean mass, clinical improvement, and quality of life. Therefore, each appointment aims to assess food consumption, identify areas for improvement through active listening, propose gradual and realistic changes in diet through

nutritional guidance, and establish jointly constructed goals for the month leading up to the next appointment (8,24).

During the consultations, topics related to healthy eating will be addressed, as recommended by the Dietary Guidelines for the Brazilian Population, aiming to improve the quality of food through the NOVA food classification system and recommendations for healthy eating practices, respecting the reality of each participant, encouraging autonomy and empowerment through information for healthier food choices (25).

As an informative tool to reinforce the guidelines, participants will receive materials with practical recommendations based on the food guide. Furthermore, when the nutritionist determines that the dietary prescription will facilitate adherence to the dietary recommendations and ensure adequate quantities consumed for weight loss, an individualized meal plan will be prescribed, emphasizing the importance of food quality by encouraging the consumption of unprocessed and minimally processed foods, respecting the participant's socioeconomic conditions, cultural preferences, and appropriate level of readiness for change.

Therefore, a dietary plan is recommended that involves a reduction of 500 to 1000 kcal/day, combined with encouragement of higher-quality food. It is worth highlighting that care will be provided ethically and without stigmatization, with an understanding of excess weight as a multifactorial, complex condition. Therefore, the service is based on a welcoming approach through empathetic communication aimed at promoting adherence to treatment and the participant's autonomy (8,26).

6.4.2 Intervention group

Participants in the Intervention Group (GI) will attend four monthly group sessions on Food and Nutrition Education (FNE), lasting up to 1 hour for the first three sessions and 2 hours for the last. These sessions will be held in person and conducted by the research nutritionist, using educational materials and active, interactive teaching-learning methodologies with accessible, inclusive, and stigma-free language, aiming to promote participant empowerment in their own dietary care. The objective of the sessions is to promote autonomy and empowerment in decision-making about food choices, as well as to promote person-centered care by considering the participants' social, family, and cultural contexts. It also aims to strengthen the bond between professionals and users, and to provide encouragement and support in the process of changing habits (27).

The activities will be based on the guidelines of the Dietary Guidelines for the Brazilian Population, which values food as a social and cultural practice and recognizes food in its nature and degree of processing as central to healthy choices (25). Therefore, the actions will be developed as follows:

- The first session will last up to one hour and will consist of a roundtable discussion for participants to introduce themselves. The goal is to create an environment of listening, belonging, and interaction, and to foster bonding among group participants while addressing important concepts of proper and healthy eating. This will include a conversation about the meanings and importance of healthy eating, and, at the end, a dynamic activity to demystify common myths surrounding it.

- The second session will last up to one hour and will cover the NOVA classification of foods according to the Dietary Guidelines for the Brazilian Population, with emphasis on the differentiation between unprocessed, minimally processed, processed, and ultra-processed foods. The practical activity will involve examples of everyday foods and the identification of their corresponding food groups according to the NOVA classification. In addition, the recommended proportions for a healthy meal, according to the principles of the Food Guide, will be addressed.

- The third nutritional education session will address food nutritional labeling and guidelines for purchasing commercially available foods. Printed examples of food products will be used to critically analyze labels and identify the main nutrients associated with health risks, such as sodium, sugar, and saturated fat. Real examples of printed food packaging will be used for analysis. Furthermore, the discussion will include practical guidance on healthier choices in the shopping environment, reinforcing participants' active role in building healthier, more conscious eating habits.

- The fourth session will be a culinary workshop held in the UFCSPA food laboratory, lasting up to 2 hours. In this session, healthy, practical, and low-cost recipes will be prepared, prioritizing local and culturally appropriate ingredients. The culinary workshop aims to promote the development of culinary skills, the revival of homemade recipes, and the appreciation of food as a social and pleasurable act. It is expected that the intervention will contribute to expanding the dietary repertoire, reducing the consumption of ultra-processed foods, and improving the health status of overweight and obese participants. To ensure equal benefit for both subgroups, all relevant questions or comments arising from the collective actions of one subgroup will be clarified and passed on to the other.

6.5 Sociodemographic data

will be collected from participants using a questionnaire developed by the researchers containing: name, age, date of birth, full address, race (white, black, brown, yellow, and indigenous), marital status, education level, occupation, email, and telephone number. This data will then be classified according to these criteria:

Age range: The age will be calculated based on the date of birth provided by the respondent.

Sex: will be provided by the interviewee and categorized as male and female.

Gender: will be provided by the respondent and categorized as male, female, non-binary, other (with the option to specify) or with the option "prefer not to answer".

Marital status: will be provided by the interviewee and stratified into single, married/living with a partner, divorced, and widowed.

Family income: the family's financial support will be expressed in absolute terms and categorized into tertiles: low, medium, or high.

Education level: This will be determined by the level of education, such as incomplete elementary school, complete elementary school, incomplete high school, complete high school, incomplete higher education, or complete higher education.

Occupation: The interviewee will indicate whether they perform any paid productive activity, and the work activity will be classified into two categories: works / does not work/retired / unemployed / INSS beneficiary/housewife/student or other.

Health issues: you will be asked about any chronic illnesses or current health conditions.

6.6 Anthropometric data

Weight: Will be measured before and after the procedure for comparison purposes, using a Welmy Digital Scale with a capacity of 300kg and an accuracy of 100g. The person being evaluated should stand barefoot, wearing minimal clothing and accessories, with their arms at their sides and their gaze fixed on a point in front of them. The measurement will be recorded in kilograms, with two decimal places, on the data collection form. (Brazil, 2011).

Height: This will be measured using a Tonelli-brand stadiometer. Height will be quantified only once before the interventions. The stadiometer will be positioned at A wall without a baseboard, forming a right angle with the floor. The person being evaluated should be barefoot , with feet together , in an upright position , arms extended along the body, the back of the head, shoulders, buttocks, calves, and heels against the wall , and if this is not possible, at least three of these factors should be positioned, and the head should be positioned in the Frankfurt horizontal plane. The movable part of the equipment will be lowered, fixing it against the head with sufficient pressure to compress the hair. Remove the individual when you are certain that the person has not moved. The reading will be carried out. without releasing the moving part of the equipment, and the measurement will be made in centimeters (28).

BMI (Body Mass Index): Body mass index (BMI) will be calculated by dividing body weight (kg) by height (m) squared and will serve to classify nutritional status (Table 1). The BMI values found will be classified according to WHO (2000)...

BMI	Classification
<18.5	Underweight
18.5-24.9	Eutrophic
25-29.9	Overweight
30-34.9	Grade I Obesity
35-39.9	Grade II Obesity
>40	Grade III Obesity

Table 1. Classification of nutritional status (29).

Waist circumference: This will be measured using the Cescorf brand measuring tape, provided by the researchers. Waist circumference will be measured three times. The patient should stand upright, with a relaxed abdomen, arms extended along the body, and legs parallel and slightly apart. Clothing should be removed to expose the waist area. The researcher will make a small mark with a pen at the midpoint between the lower edge of the last rib and the hip bone (iliac crest), viewed from the front of the person, on the right or left side. It should be verified that the tape measure is at the same level around the waist; it should be neither loose nor tight. At the end of a normal exhalation, with an inelastic anthropometric tape measure encircling the abdominal region at the midpoint between the lower edge of the last rib and the iliac crest, the measurements will be recorded in centimeters on the data collection form. The

average will be used for metabolic risk classification, with the cutoff point for risk being 102 cm for men and 88 cm for women (NIH, 1998).

6.7 Behavioral and lifestyle data

Some lifestyle data will be collected individually before and after the interventions using a questionnaire developed by the researchers to determine whether participants' self-perceptions and lifestyle habits have changed. The questionnaires will be produced by the researchers and will contain the following topics:

Smoking: whether the participant is a smoker (smoker / ex-smoker / non-smoker);

Perception of health status: based on the following question added to the questionnaire developed by the researchers: "In general, how do you think your health is?" with answers categorized as ' excellent ', ' good ', ' fair ', ' poor '; this question is simple and widely used in research for self-assessment of current health status. (IBGE, 2020).The results will be presented as percentages.

Treatment attendance: This will be assessed through appointment registration (attendance at 75% of appointments required).

Transtheoretical model of change: To better understand how much the participant is progressing towards healthier behaviors, the transtheoretical model will be used, based on the Prochaska Scale, which is composed of five stages of individual motivation: pre-contemplation; contemplation; preparation; action; and maintenance (Prochaska; DiClemente; Norcross, 1992). At each stage, participants will be asked about the aspect of weight, characterized as follows: Pre-contemplation: does not intend to lose weight in the next 6 months; Contemplation: intends to lose weight in the next 6 months, but without concrete plans for the next month; Preparation or Decision: intends to lose weight in the next 30 days; Action: has adopted behavioral changes aimed at a healthy weight, but only recently (< 6 months); Maintenance: has already adopted behavioral changes aimed at a healthy weight for 6 months or more. The scale will be applied to both groups, before and after the study.

Physical activity: Patients will also be asked about their physical activity. For this, the International Physical Activity Questionnaire (IPAQ - short version) will be used to determine how many times a week participants walk continuously for 10 minutes, how many times a week

they do light, moderate, and vigorous exercise (stages determined by physical exertion and changes in heart rate), and how long they usually spend sitting in a day (32).

Medications used: Participants will be asked about the medications they are using.

6.8 Assessment of food consumption

To assess food consumption and eating habits, the R24-Nova and the eating habits scale will be used (33,34).

R24-Nova: The 24-hour dietary recall from the Quest Nova platform will be applied. This questionnaire presents 58 questions covering a range of foods commonly found on Brazilian tables – participants must indicate whether they consumed each food (yes or no). The estimated time to complete the questionnaire is 15 minutes. This tool will enable the identification of both quantitative and qualitative aspects of participants' eating habits. It will be applied twice in the same week, before and after the interventions, to obtain an average of the results.

Food Practices Scale of the Dietary Guidelines for the Brazilian Population: The scale will be administered. This scale presents 24 statements about healthy eating according to the GAPB. For each statement, respondents must indicate whether they incorporate that practice, using a 4-point Likert scale: "strongly agree"; "agree"; "disagree"; "strongly disagree".

The Dietary Guidelines for the Brazilian Population Practices Scale is an instrument that measures adherence to a healthy diet. This scale of dietary practices, composed of 24 statements, is a self-administered, validated, and useful tool for evaluating adherence to dietary practices according to the GAPB recommendations (35). This scale is used by the Ministry of Health to compose the brochure "How is your diet?", a material that assesses the level of adherence to healthy dietary practices (34).

6.9 Evaluation of biochemical tests

Data regarding laboratory tests, including fasting blood glucose, glycated hemoglobin, total cholesterol, HDL cholesterol, LDL cholesterol, uric acid, TG (triglycerides), and CRP (C-reactive protein), will be found in the medical records.

STATISTICAL ANALYSIS

The results for qualitative variables will be presented as frequencies and percentages, symmetrical quantitative variables as means and standard deviations, and asymmetrical quantitative variables as medians and interquartile ranges [P25-P75].

Normality will be verified using the Shapiro-Wilk test. Groups will be compared using the Chi-square test, Fisher's exact test, Mann-Whitney test, and Student's t-test, according to the nature and distribution of the data. To evaluate the effects of the interventions, a repeated measures mixed ANOVA will be applied, or, in case of absence of normality and/or losses, GEE (Generalized Estimating Equations) models will be used to evaluate the main effects of group and time point assessed, and the group*time interaction, with Sidak's test for multiple comparisons. Results will be presented as mean and confidence interval. 95%.

The analyses will be performed using SPSS (IBM SPSS Statistics for Windows, Version 25.0; Armonk, NY: IBM Corp.). The significance level adopted will be 0.05, and comparisons will be considered significant when $p < 0.05$.

For statistical calculation of treatment adherence, attendance will be considered using the following formula: number of appointments held / total number of appointments scheduled X 100.

The data collected will be stored in a database, with any information that could identify omitted participants.

7. TIMELINE

Period : January 2025 to December 2026																								
	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D
Literature Review																								
Project development	x																							
Submission to the Ethics Committee		x	x	x																				
Recruitment of participants				x	x	x																		
Data collection				x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x			
Development of actions in the GC and GI																	x	x	x	x				
Data tabulation					x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x			
Statistical analysis																						x	x	

Article Writing																						x	
Revision																							x
Presentation																							x
Announcement of results																							x

8. BUDGET

Item	**Amount**	**Justification**	**Unit Price**	**Total value**
A4 sheets	1500	Printouts of informed consent forms and questionnaires.	13.90 (500 units)	41.70
Ballpoint pen	5	Used for completing questionnaires and informed consent forms.	0.80	4.00
Black ink cartridge	2	Printouts of informed consent forms and questionnaires.	21.90	43.80
Measuring tape	1	Used for anthropometry.	52.00	52.00
Ingredients for culinary activity	1	Activity in the intervention group	500.00	500.00
Expenses for transporting participants	300	Reimbursement for the 30 patients of The intervention group attended 4 group activity sessions in UFCSPA	5.00	3000
Total: R$ 1841.50				

Note: The researcher will be responsible for the costs.

REFERENCES

1. Brasil. Cenário da obesidade no Brasil. Vol. 54. 2024. Report.
2. Pan American Health Organization. One in eight people are now living with obesity. 2024.
3. Phelps NH, Singleton RK, Zhou B, Heap RA, Mishra A, Bennett JE, et al. Worldwide trends in underweight and obesity from 1990 to 2022: a pooled analysis of 3663 population-representative studies with 222 million children, adolescents, and adults. The Lancet. 2024 Mar 16;403(10431):1027–50. doi:10.1016/S0140-6736(23)02750-2 PubMed PMID: 38432237.
4. Brasil. Ministério da Saúde. Vigitel Brasil 2021: vigilância de fatores de risco e proteção para doenças crônicas por inquérito telefônico: estimativas sobre frequência e distribuição sociodemográfica de fatores de risco e proteção para doenças crônicas nas capitais dos 26 estados brasileiros e no Distrito Federal em 2021. Brasília: Ministério da Saúde, 2021. 2022. p. 131.
5. World Obesity Federation. World Obesity Atlas 2023 [Internet]. 2023. Report. Available from: www.johnclarksondesign.co.uk
6. Giannichi B, Nilson E, Ferrari G, Rezende LFM. The projected economic burden of non-communicable diseases attributable to overweight in Brazil by 2030. Public Health. 2024 May 1;230:216–22. doi:10.1016/j.puhe.2024.02.029 PubMed PMID: 38579649.
7. World Health Organization. Obesity and overweight [Internet]. 2024 [cited 2024 Dec 6]. Available from: https://www.who.int/news-room/fact-sheets/detail/obesity-and-overweight
8. ABESO. POSICIONAMENTO SOBRE O TRATAMENTO NUTRICIONAL DO SOBREPESO E DA OBESIDADE DEPARTAMENTO DE NUTRIÇÃO DA ASSOCIAÇÃO BRASILEIRA PARA O ESTUDO DA OBESIDADE E DA SÍNDROME METABÓLICA. 2022.
9. Balwan WK, Kour S. Lifestyle Diseases: The Link between Modern Lifestyle and Threat to Public Health. Saudi Journal of Medical and Pharmaceutical Sciences. 2021 Apr 6;7(4):179–84. doi:10.36348/sjmps.2021.v07i04.003
10. Baker P, Machado P, Santos T, Sievert K, Backholer K, Hadjikakou M, et al. Ultra-processed foods and the nutrition transition: Global, regional and national trends, food systems transformations and political economy drivers. Obesity Reviews. Blackwell Publishing Ltd; 2020. doi:10.1111/obr.13126 PubMed PMID: 32761763.
11. SISVAN. Relatório do Consumo Alimentar dos indivíduos acompanhados por período, fase do ciclo da vida e índice [Internet]. 2024 [cited 2024 Dec 11]. Available from: https://sisaps.saude.gov.br/sisvan/relatoriopublico/index
12. Lane MM, Gamage E, Du S, Ashtree DN, McGuinness AJ, Gauci S, et al. Ultra-processed food exposure and adverse health outcomes: umbrella review of epidemiological meta-analyses. BMJ. 2024 Feb 28;e077310. doi:10.1136/bmj-2023-077310
13. Hall KD, Ayuketah A, Brychta R, Cai H, Cassimatis T, Chen KY, et al. Ultra-Processed Diets Cause Excess Calorie Intake and Weight Gain: An Inpatient Randomized

Controlled Trial of Ad Libitum Food Intake. Cell Metab. 2019 Jul;30(1):67-77.e3. doi:10.1016/j.cmet.2019.05.008
14. Shauna M. Levy, Michelle Nessen. 2023 [Internet]. 2023 [cited 2024 Dec 14]. Obesidade. Available from: https://www.msdmanuals.com/pt/profissional/dist%C3%BArbios-nutricionais/obesidade-e-s%C3%ADndrome-metab%C3%B3lica/obesidade
15. Brasil. MARCO DE REFERÊNCIA DE EDUCAÇÃO ALIMENTAR E NUTRICIONAL PARA AS POLÍTICAS PÚBLICAS [Internet]. Ministério do Desenvolvimento Social e Combate à Fome, Secretaria Nacional de Segurança Alimentar e Nutricional, editors. 2012 [cited 2024 Dec 12]. Available from: https://www.cfn.org.br/wp-content/uploads/2017/03/marco_EAN.pdf
16. Brasil.INSTRUTIVO DE ABORDAGEM COLETIVA PARA MANEJO DA OBESIDADE NO SUS [Internet]. 2021 [cited 2024 Dec 21]. Available from: http://189.28.128.100/dab/docs/portaldab/publicacoes/instrutivo_abordagem_coletiva.pdf
17. Organiação Mundial de Saúde. Boas Práticas Clínicas: Documento das Américas República Dominicana 2-4 de Março de 2005. 2005. Report.
18. World Medical Association. WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Participants. 2024. Report.
19. Conselho Nacional de Saúde. RESOLUÇÃO Nº 466, DE 12 DE DEZEMBRO DE 2012. 2012.
20. Chan AW, Tetzlaff JM, Gotzsche PC, Altman DG, Mann H, Berlin JA, et al. SPIRIT 2013 explanation and elaboration: guidance for protocols of clinical trials. BMJ. 2013 Jan 9;346(jan08 15):e7586–e7586. doi:10.1136/bmj.e7586
21. Schulz KF, Altman DG, Moher D. CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials. BMC Med. 2010 Dec 24;8(1):18. doi:10.1186/1741-7015-8-18
22. Brysbaert M. How Many Participants Do We Have to Include in Properly Powered Experiments? A Tutorial of Power Analysis with Reference Tables. J Cogn. 2019 Jul 19;2(1). doi:10.5334/joc.72
23. Prochaska JO, Diclemente CC, Norcross JC. In Search of How People Change Applications to Addictive Behaviors. 1992. Report.
24. Brasil. Instrutivo de Abordagem Individual para Manejo da Obesidade no SUS [Internet]. 2024. Available from: https://aps.saude.gov.br/
25. Ministério da Saúde. Guia Alimentar para a População Brasileira [Internet]. 2014. Available from: www.saude.gov.br/bvs
26. Brasil. Portaria SCTIE/MS nº 53, de 11 de novembro de 2020. Aprova o Protocolo Clínico e Diretrizes Terapêuticas de Sobrepeso e Obesidade em Adultos. [Internet]. 2020 Nov. Report. Available from: http://conitec.gov.br/.
27. Ministério da Saúde. Manual de atenção às pessoas com sobrepeso e obesidade no âmbito da atenção primária (APS) do Sistema Único de Saúde [Internet]. 2022. Available from: http://bvsms.saude.gov.br/bvs/publicacoes/manual_atencao_pessoas_
28. Brasil. Orientações para a coleta e análise de dados antropométricos em serviços de saúde [Internet]. 2011 [cited 2025 Jan 13]. Available from:

https://bvsms.saude.gov.br/bvs/publicacoes/orientacoes_coleta_analise_dados_antropometricos.pdf
29. WHO. WHO Technical Report Series OBESITY: PREVENTING AND MANAGING THE GLOBAL EPIDEMIC. 2000.
30. National Institutes of Health. Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults: Executive Summary. Am J Clin Nutr. 1998 Oct;68(4):899–917. doi:10.1093/ajcn/68.4.899
31. IBGE. Pesquisa Nacional de Saúde 2019. 2020.
32. Matsudo S, Araujo T, Matsudo V, Andrade D. QUESTIONARIO INTERNACIONAL DE ATIVI DADE FISICA (I PAQ): ESTUDO DE VAll DADE E REPRODUTIBILIDADE NO BRASIL INTERNATIONAL PHYSICAL ACTIVITY QUESTIONNAIRE (lPAQ): STUDY OF VALIDITY AND RELIABILITY IN BRAZIL. 2001. Report.
33. Louzada ML da C, Souza TN, Frade E, Gabe KT, Patricio GA. QuestNova: inovação na avaliação do consumo alimentar segundo o processamento industrial. Rev Saude Publica. 2024 Nov 21;58(1):38. doi:10.11606/s1518-8787.2024058006307
34. Brasil. COMO ESTÁ A SUA ALIMENTAÇÃO? [Internet]. 2018 [cited 2025 Jan 20]. Report. Available from: http://189.28.128.100/dab/docs/portaldab/publicacoes/guiadebolso_folder.pdf
35. Gabe KT, Jaime PC. Development and testing of a scale to evaluate diet according to the recommendations of the Dietary Guidelines for the Brazilian Population. Public Health Nutr. 2019 Apr 1;22(5):785–96. doi:10.1017/S1368980018004123 PubMed PMID: 30744711.

1. APPENDIX A

FREE AND INFORMED CONSENT FORM (TCLE)

Study title: “Performance of a dietary guide-based intervention for the Brazilian population in the treatment of overweight and obese individuals: a randomized clinical trial”

You are invited to participate in the study " Performance of an intervention based on the dietary guidelines for the Brazilian population in the treatment of overweight and obese individuals: a randomized clinical trial".

Before agreeing to participate, it is important that you understand the objectives of this research and clarify any doubts you may have. Participation in this study is entirely voluntary, and if you agree to participate, you will receive a signed copy of this document, which contains all the explanations. Please read the information carefully and feel free to ask any questions that come to mind. You may discuss this study with the rest of your family, friends, or your doctor before giving your consent. You have the full right to refuse to participate. If you choose to withdraw your consent to the study after agreeing to participate, you have the right to do so at any time. If you decide to leave the study, please inform the study team. A final consultation with the researchers may be scheduled to answer your questions and conclude your participation in the study.

In this study, we aim to evaluate the effect of a form of dietary counseling on the nutritional treatment of overweight and obese individuals. In this way, we can foster healthy eating habits, improving the health and quality of life for these people.

1) **How many participants are in the study, and how long will my participation last?** We expect to include 60 individuals in this study. Your participation will last 5 months.

2) **What are the study interventions?** You will be randomly assigned to one of the two study groups. Neither you nor the attending professional will be able to choose which group you are assigned to.

    - If you are selected for group 1: You will receive monthly individual consultations based on established guidelines and recommendations from the Dietary Guidelines for the Brazilian Population, conducted in an outpatient setting. You will then be required to follow the nutritionist's recommendations for 4 months.

    - If you are selected for group 2: You will participate in group sessions developed by a nutritionist based on the recommendations of the Dietary Guidelines for the Brazilian Population, held on the UFCSPA campus (Federal University of Health Sciences of Porto Alegre). You will then be invited to follow the proposed recommendations for 4 months.

    - During the 5 months of the study, you may receive phone calls, text messages, or emails from the research team, who will be able to answer questions, remind you to follow recommendations, and remind you to attend your scheduled appointment.

What are the study procedures? By agreeing to participate in this study, you will be asked to complete two data collection periods: one before and one after the intervention. Therefore, during the first and last consultations, we would like to ask for your authorization to collect the following data:

- Weight, height, and waist circumference.
- Two questionnaires to assess your food consumption and eating habits.
- Application of questions regarding your level of motivation for weight loss.
- A questionnaire to characterize the frequency and intensity level of physical activity performed.
- Data from your medical record regarding blood tests (fasting blood glucose, glycated hemoglobin, uric acid, triglycerides, total cholesterol, LDL cholesterol, HDL cholesterol, and C-reactive protein).

The data listed above will be collected to compile the analyses necessary for the study. Therefore, throughout these procedures, your data will be completely private. If any questions during this collection cause you any embarrassment or discomfort, you do not need to answer them.

Furthermore, throughout the study you will receive phone calls or messages after the start of the group consultations/actions. This contract aims to clarify any doubts, reinforce the guidelines, and remind you to attend the meetings.

3) **Who will have access to my information?** All information collected in this research or obtained through medical records will be confidential, and only the study team will have access. At no time will your name or any information about your health be provided to anyone who is not a member of the study team. The information will be confidential and used only for the purposes of this research. The study results will be released for academic and scientific purposes without identifying any data that could reveal the participants' identities.

4) **What are my responsibilities?** Over the next 5 months, you will attend the study site once for initial data collection, then every 30 days for 4 months for consultations/group sessions, and once at the end of the study for data collection. Each time you attend, you will need to sign the attendance list; this information will also be important for the study.

5) It is important that you attend all appointments/group sessions so that the study team can check your health and collect the data needed for this study.

6) **What are the possible risks of participating in this study?** You will be subject to minimal risks. If you do not feel comfortable answering any questions or performing the measurements, you do not need to do so.

7) At any time, you can contact the researchers of this study by telephone. The person responsible for the research is Fernanda Michielin Busnello, and she can be contacted at (51) 3303-8867.

   If you experience any symptoms, especially weakness or a feeling of faintness, you will be referred for treatment at the Porto Alegre Emergency Hospital, under the researchers' responsibility.

8) **What are the potential benefits?** Your participation in this research will help evaluate the effects of two nutritional monitoring methods. We hope that your data, collected during this study, will provide valuable insights into science and may benefit overweight and obese individuals in the future.

9) **Will I be paid or reimbursed for participating in the study?** Individuals participating in the group activities, which will be held in the classrooms of the Federal University of Health Sciences of Porto Alegre (UFCSPA), will receive a reimbursement of 10 reais for transportation expenses per meeting (5 reais for the trip there and 5 reais for the return trip). This amount will be paid on meeting days via Pix transfer, TED (Electronic Transfer Available), or in cash, at the participant's preference.

10) viduals participating in the group activities, which will be held in the classrooms of the Federal University of Health Sciences of Porto Alegre (UFCSPA), will receive a reimbursement of 10 reais for transportation expenses per meeting (5 reais for the trip there and 5 reais for the return trip). This amount will be paid on the meeting days via Pix transfer, TED (Electronic Transfer Available), or in cash, according to the participant's preference.

11) **Will I be compensated for damages related to the study?** You will be guaranteed the necessary assistance throughout your participation in the study, and all your rights will be maintained, including guarantees of compensation for any damage arising from the research, during your participation and until the conclusion of this project.

12) **Contact in case of questions or emergencies:** This study was approved by the Ethics and Research Committee of the Santa Casa de Misericórdia de Porto Alegre (ISCMPA) and the Federal University of Health Sciences of Porto Alegre (UFCSPA). The Ethics Committee is a group that conducts the ethical review of the study to maintain your safety and protect your rights. The study team is available to provide any clarifications before, during, and after the study.

    Contact information:

    - Research Ethics Committee of the Santa Casa de Misericordia de Porto Alegre (ISCMPA). Av. Osvaldo Aranha, 80, Room 17. Historic Center neighborhood. Postal Code: 90035-190 - Porto Alegre/RS. Telephone: 51 3214-8571. Email: cep@santacasa.tche.br. Public service hours: 09:00 to 12:00 hours - 13:30 to 17:00 hours.

    - Research Ethics Committee of the Federal University of Health Sciences of Porto Alegre. Rua Sarmento Leite, 245, Building 3, Room 605. Postal Code: 90050-170 - Porto Alegre/RS. Tel 51 3303-8804. Email: cep@ufcspa.edu.br. Public. Service Hours: 8:00 AM to 12:00 PM / 1:00 PM to 5:00 PM.

    Principal Investigator: Fernanda Michielin Busnello, e-mail: fernandab@ufcspa.edu.br, Telephone: (51) 33038867. Address: Rua Sarmento Leite, 245, Building 3, room 507. Postal Code: 90050-170 - Porto Alegre/RS

    You will be provided with any information that is discovered during the study that may influence your decision to continue participating.

YOUR AGREEMENT TO PARTICIPATE IN THE SURVEY

This Informed Consent Form is prepared in duplicate. All pages must be initialed and signed (at the end) by the person invited to participate in the research or by their legal representative/guardian, and by the responsible researcher or by a person delegated by them.

Based on the information in this document, I voluntarily agree to participate in this research because:

I received a full explanation of the research.

I have read and understood this document.

All my doubts have been clarified.

I grant access to my medical records, and the researcher has assured me that the information will be treated confidentially, securely, and anonymously.

I voluntarily agree to participate in this research as described and understand that I may withdraw my consent at any time during the research without prejudice.

I received a signed copy of this document.

Therefore, in agreement, I have initialized all pages and signed this document, with one copy remaining in my possession.

Porto Alegre, _____/_____/_____ (Location, day, month and year)

_____

Name of the research participant in block letters.

_____ _____/_____/_____

Participant's signature Date

Researcher

I, Fernanda Michielin Busnello (principal investigator), explained the study objectives, procedures, and potential risks and benefits to the research participant indicated above, answered all questions asked, and obtained their voluntary consent to participate. I confirm that I will comply with all requirements set forth in CNS Resolution No. 466 of 2012, items IV.3 and IV.4, during the process of obtaining the participant's voluntary consent for this research and during the conduct of the study.

Porto Alegre, _____/_____/_____ (Location, day, month and year)

_____

Researcher's name

_____ _____/_____/_____

Researcher's signature Date