Trials

STUDY PROTOCOL

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Effect of group-based nutritional education combined with individual standard care for outpatients with type 2 diabetes: study protocol for a randomized clinical trial {1}

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Abstract

Background Diabetes remains a significant contributor to global morbidity and mortality in the twenty-first century. Lifestyle modification strategies are widely recommended for effective diabetes management. Research suggests that a person-centered approach, implemented in either group or individual settings, offers considerable potential for improving long-term disease outcomes. Nutritional counseling using the operative group model has been tested and shown to yield positive health outcomes across diverse populations affected by diabetes.

This study aims to evaluate the impact of group-based nutritional education, combined with individual standard care, compared to individual standard care alone, on health outcomes among patients diagnosed with type 2 diabetes.

Methods This study is a 12-month, parallel-group, randomized superiority controlled trial. Individuals diagnosed with type 2 diabetes will be randomized in a 1:1 ratio into one of two treatment arms: (1) individual usual care alone or (2) usual care supplemented with group-based nutritional education. The group nutritional education will consist of three sessions addressing the following themes: "Let's Go Shopping," "Healthy Plate," and "Hunger and Satiety." The primary outcome will be the change in HbA1c levels. Secondary outcomes will include fasting glucose, lipid profile, body mass, dinapenic abdominal obesity, blood pressure, eating behavior, adherence to nutritional counseling, and diabetes-related complications. All outcomes will be assessed at baseline and at 4, 8, and 12 months, except diabetes-related complications that will be assessed at baseline and 12 months. Sample size calculations were based on an estimated mean difference of 0.59 ± 1.39% in HbA1c with the intervention (patient-centered group), using a type I error rate of 5% and a type II error rate of 20%. It was determined that 88 participants per group (1:1 randomization; $n = 176$) would provide sufficient statistical power. Accounting for an anticipated dropout rate of 30%, a total of 252 participants will be recruited to ensure the necessary sample size is maintained throughout the study period.

Discussion The American Diabetes Association recommends interventions for patients with diabetes lasting more than 10 h over a period of 6 to 12 months to optimize health outcomes. Therefore, this study hypothesizes that integrating group-based nutritional education into standard treatment within a nutrition-specialized outpatient clinic may lead to further improvements in health parameters among individuals diagnosed with type 2 diabetes mellitus.

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Trial registration {2a and 2b} Clinicaltrials.gov identifier, NCT05598203. Registered on 13 October 2022.

Keywords Type 2 diabetes mellitus, Glycated hemoglobin A, Food and nutrition education, Feeding behavior, Diabetes complications, Body mass index, Lipids, Blood pressure, Outcome assessment, Health care

Introduction

Background and rationale {6a}

Diabetes is a major contributor to global morbidity and mortality in the twenty-first century, with projections estimating that 643 million individuals will be affected by 2030. Type 2 diabetes accounts for over 90% of all diabetes cases worldwide [1]. This form of diabetes is driven by a combination of genetic and environmental factors, leading to a progressive decline in β-cell mass and/or function, which manifests clinically as hyperglycemia [2].

Persistent hyperglycemia is strongly associated with the development of chronic complications. Consequently, a comprehensive range of treatment strategies has been proposed, including diabetes self-management education and support, medical nutrition therapy, regular physical activity, smoking cessation counseling when applicable, behavioral health counseling, and psychosocial care [3].

In individuals with type 2 diabetes and overweight, even modest weight loss has been shown to improve blood glucose levels and reduce dependence on hypoglycemic medications. Adopting a person-centered communication approach—characterized by inclusive, non-judgmental language and active listening to understand individual preferences, beliefs, and potential barriers—is essential for optimizing health outcomes and enhancing quality of life in this population [3]. Moreover, nutritional education interventions have proven highly effective, not only in promoting weight loss and reducing glycated hemoglobin (HbA1c) but also in lowering the risk of both microvascular and macrovascular complications [4].

Nutritional education initiatives should prioritize fostering individual autonomy and empowerment. Educational strategies should emphasize active, problem-based learning processes to enhance both theoretical knowledge and practical application. A systematic review of 33 studies on nutritional education interventions found that programs lasting more than 4 months and incorporating continuous follow-up can reduce HbA1c levels by at least 0.4%. Moreover, the review reported that both individual and group interventions improved HbA1c, although it did not clarify whether a combination of the two approaches could yield superior results [5]. Other systematic reviews, however, have indicated that group interventions may be more effective in enhancing patient knowledge, with additional benefits observed in individuals who participate in both modalities [6]. Collective initiatives, particularly those implemented in group settings, promote active participation, foster the exchange of knowledge and experiences, and encourage the development of interpersonal connections [7].

A model proposed for nutritional education initiatives within group settings is the operative group model, as introduced by Pichon-Rivière [8]. This model, which involves a collective of individuals with similar needs working toward a specific goal, has been tested and shown to yield positive outcomes in improving health among diverse populations affected by diabetes [9–13]. Notably, a randomized, controlled, and blind clinical trial involving 109 individuals with type 2 diabetes demonstrated significant results. The study found a higher proportion of participants engaging in self-care and a reduced risk of diabetic foot complications in the operative groups compared to the control group [11]. However, to date, there is a lack of studies specifically employing the operative group approach in nutritional education for patients with diabetes.

In this context, the present study hypothesizes that integrating group-based nutritional education into standard treatment within a nutrition-specialized outpatient clinic may lead to further improvements in health parameters among patients diagnosed with type 2 diabetes. The principal motivation behind this research is the pursuit of more effective strategies to enhance glycemic control, reduce the risk of complications, and improve the overall quality of life for these patients. Our efforts are driven by a commitment to base our interventions on scientific evidence and to achieve meaningful improvements in diabetes management outcomes.

Objectives {7}

We have undertaken a randomized clinical trial to assess the impact of group-based nutritional education, when added to individual usual care, on health outcomes in patients diagnosed with type 2 diabetes. The study is guided by the following five specific aims:

(1) *Glycemic control (HbA1c)*: To examine the effect of group-based nutritional education, in addition to individual usual care (intervention), on glycemic control over a 12-month period (with assessments at 4-month intervals), compared to individual usual care alone (control).

(2) *Lipid profile and blood pressure*: To evaluate the impact of group-based nutritional education, combined with individual usual care (intervention), on lipid profile and blood pressure over 12 months (with assessments at 4-month intervals), relative to individual usual care (control).
(3) *Abdominal obesity and dynapenia*: To investigate the effect of group-based nutritional education, integrated with individual usual care (intervention), on abdominal obesity dynapenia over a 12-month period (with assessments at 4-month intervals), in contrast to individual usual care (control).
(4) *Behavior and food consumption*: To analyze the impact of group-based nutritional education, when added to individual usual care (intervention), on behavior and food consumption patterns over a 12-month period (with assessments at 4-month intervals), compared to individual usual care (control).
(5) *Presence of diabetes complications (diabetic kidney disease, diabetic retinopathy, and cardiovascular disease)*: To assess the influence of group-based nutritional education, incorporated into individual usual care (intervention), on the presence of diabetes-related complications at baseline and at the end of the 12-month period, relative to individual usual care alone (control).

Trial design {8}

This study adopts a 12-month, parallel-group, randomized superiority controlled trial design. Individuals diagnosed with type 2 diabetes will be randomly allocated in a 1:1 ratio into one of two treatment arms:

(1) *Group-based nutritional education*: Participants in this arm will receive group-based nutritional education, following the model proposed by Pichon-Rivière [8], in addition to standard care.
(2) *Usual care*: Participants in this arm will receive individual nutritional counseling within a specialized outpatient nutrition clinic, consistent with the standard care protocol.

This randomization approach ensures a balanced distribution of participants between the two treatment arms, enabling a robust evaluation of the impact of group-based nutritional education compared to the established usual care.

Methods

This study has been approved by the Research Ethics Committee at Hospital de Clínicas de Porto Alegre, Brazil, under the registration number CAAE: 60,045,422,000,005,327. The protocol was meticulously developed in accordance with the Standard Protocol Items: Recommendations for Intervention Trials 2013 (SPIRIT) guidelines [14]. Adhering to these established protocols and ethical standards ensures the rigor and integrity of the research process. Following ethical approval, this study was registered with clinicaltrials.gov (NCT05598203) on October 13, 2022, and can be accessed at https://clinicaltrials.gov/ct2/show/NCT05598203.

Study setting {9}

This study will be conducted in the outpatient department of a university hospital in Porto Alegre, the capital of Rio Grande do Sul, Brazil, specifically at the Hospital de Clínicas de Porto Alegre.

Eligibility criteria {10}

The inclusion criteria include individuals of all sexes receiving treatment at the outpatient clinic of Hospital de Clínicas de Porto Alegre, with a prior diagnosis of type 2 diabetes and HbA1c values outside the recommended targets according to age and comorbidities, as defined by the 2024 American Diabetes Association guidelines [15]. Adults and elderly individuals with one associated comorbidity and HbA1c > 7%, elderly individuals with two associated comorbidities and HbA1c > 7.5%, and elderly individuals with three or more associated comorbidities and HbA1c > 8% will be considered outside the target range. The comorbidities evaluated include diabetes complications (diabetic neuropathy, retinopathy, and nephropathy), a history of cardiovascular disease or heart attack, hypertension, obstructive sleep apnea–hypopnea syndrome, urinary incontinence, and depression [15]. These comorbidities will be identified through the patient's electronic health record, specifically from medical records documented during the appointment closest to the baseline visit.

Exclusion criteria are as follows: (1) severe neuropathy; (2) cancer; (3) stage 4 or 5 chronic kidney disease; (4) chemical dependence/alcoholism; (5) consumptive disease (6) chronic steroid use; (7) chronic obstructive pulmonary disease; (8) severe gastroparesis; (9) pregnancy and/or lactation; (10) diagnosis of eating disorders; (11) body mass index > 50 kg/m^2; (12) tube feeding; (13) acute coronary syndrome episode in the last 60 days; and (14) cognitive, neurological, or psychiatric condition that prevents understanding of the questions (as determined by the researcher).

Sample size {14}

The sample size calculation was performed using PSS Health (shinyapps.io) [16], referencing the findings from

Naik et al. [17]. To detect a mean difference of 0.59 in HbA1c between participants randomized to the intervention group (patient-centered education) and those in the control group (traditional education), with a standard deviation of 1.39%, a type I error of 5%, and a type II error of 20%, a total of 88 participants per group (1:1 ratio, $n=176$) is required. Accounting for a 30% dropout rate over the 12-month study period, the inclusion of 252 participants will be necessary to maintain statistical power.

Who will take informed consent? {26a}

Researchers A.B., V.M.M., and O.G.K. have completed prior training and will oversee obtaining informed consent from all participants during the initial baseline visit.

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

Eligible individuals will be contacted by phone and invited to participate in the study. Those who agree to participate during the call will have a face-to-face visit scheduled within 1 month. During this visit, participants will receive a printed copy of the consent form and provide their signature. The consent form outlines their agreement to participate in the research, grants access to their electronic medical records, and permits the collection of blood samples and measurements at four time points: baseline, 4 months, 8 months, and 12 months.

Interventions

Explanation for choice of comparators {6b}

The standard care provided in the outpatient setting at the Hospital de Clínicas de Porto Alegre consists of individual sessions every 4 months (three meetings per year) for nutritional counseling. During these sessions, up to five combinations of dietary and lifestyle changes are collaboratively determined with the patients. This conventional care approach will be applied to the control group. It aligns with current guidelines for diabetes management [15, 18]. Subsequent visits will reassess the combinations of lifestyle changes, addressing barriers and motivations identified during the counseling process.

Intervention description {11a}

The intervention group will participate in an additional three group meetings conducted as operative groups. These sessions are designed to encourage active engagement, with participants assigned tasks to complete at home. The intervention includes three distinct sessions, scheduled weekly, fortnightly, or monthly, depending on participant availability. Each participant will attend each session once. These 1-h sessions will be held at the Hospital de Clínicas de Porto Alegre, with approximately 20 participants invited to each group.

The topics covered in these sessions will include:

(1) "Let's Go Shopping": This session focuses on the practical aspects of food acquisition through an educational activity involving the identification of foods based on the NOVA classification [19]. Aligned with the Food Guide for the Brazilian Population [20], participants will first group foods into categories: unprocessed or minimally processed, processed, or ultra-processed. An explanation will follow to clarify distinctions between these food groups. Participants will then revisit the food classifications, engaging in an open discussion to address uncertainties. Tips on analyzing food labels will be shared, emphasizing key information and guiding participants to align their choices with the golden rule of the Food Guide: "Always prefer fresh or minimally processed foods and culinary preparations to ultra-processed foods." To conclude, participants will be tasked with substituting a processed or ultra-processed food in their daily routine with an unprocessed or minimally processed alternative.

(2) Healthy Plate": In this session, participants will be divided into two teams and tasked with assembling plates that represent their typical breakfast and lunch meals. Following this activity, a detailed explanation will categorize vegetables, carbohydrate-rich foods, and protein sources, demonstrating how to construct a balanced dish in line with the Diabetes Plate method [21]. Discussions will highlight the functions of each food group, the importance of dietary diversity, and the inclusion of fruits in daily meals. The session will emphasize preferring whole grains, lean meats, and alternative protein sources such as legumes and low-fat dairy products. Attention will also be directed toward reducing salt intake, avoiding industrially processed seasonings, and carefully selecting fats for food preparation. After the explanations, participants will critically assess their chosen meal components and propose adjustments, which will be collectively discussed. To reinforce learning, participants will be encouraged to apply the healthy plate concept at home and share photos of their meals in the WhatsApp group.

(3) "Hunger and Satiety": This session invites participants to reflect on recognizing hunger and satiety cues. It begins with participants sharing how they determine when to start or stop eating, exploring the signals or reasons that guide these decisions. The concept of hunger will be explained, covering

how to identify it and distinguishing between types of hunger: physical, social, genuine desire, and emotional. Strategies for managing each type will also be discussed. The discussion will then transition to the concept of satiety, including how to recognize it and its significance in eating behavior [22]. Mindful eating practices will be introduced, emphasizing attention to meals, slow consumption, observing food characteristics, and minimizing distractions [23]. The session aims to enhance participants' awareness of their hunger and satiety signals. To conclude, participants will be encouraged to practice mindful eating during at least one meal daily.

Participants in the intervention groups will be added to a mobile phone application group to maintain motivation for lifestyle changes throughout the duration of the meetings. This platform will also serve as a channel for participants to provide feedback on the tasks assigned during each session. Additionally, participants will be encouraged to use the application to address any questions or concerns that may arise during their engagement in the program.

Criteria for discontinuing or modifying allocated interventions {11b}

If necessary, the principal investigator will be consulted regarding the potential discontinuation of a participant in the intervention group. However, there are no plans to modify or discontinue the allocated interventions. In cases where a participant misses a group meeting, they will still be retained in the study, and their adherence rate will be evaluated.

Strategies to improve adherence to interventions {11c}

Participants will be enrolled in a mobile phone application group to help sustain motivation for lifestyle changes throughout their participation in the intervention. Inclusion in this group will begin at the start of participation in the meeting groups and will continue until the completion of three meetings or the conclusion of the 4-month period, just before Visit 2.

The mobile phone application group is designed to maintain motivation for lifestyle changes, address any questions that arise during the meetings, and facilitate interaction between participants and dietitians.

In individual appointments, the dietitian will employ person-centered collaborative care. The behavioral goals and strategies established during the consultation will be co-created with the patient to enhance engagement and adherence to the treatment plan. During follow-up visits, the dietitian will assess the patient's progress in meeting these goals, as well as identify any barriers or difficulties in maintaining lifestyle changes.

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

Participants are encouraged to continue with their regular healthcare routines throughout the trial. However, participation in other nutrition programs during the study period will not be allowed.

Provisions for post-trial care {30}

After the study, participants will return to their usual care. If the intervention proves superior, it may be adopted as the standard treatment in our institution. Any adverse events reported during the study will be promptly addressed and managed.

Outcomes {12}

Primary outcome measure

The primary outcome of the study will be the change in glycemic control, as measured by HbA1c levels.

Secondary outcome measures

The secondary outcomes will include changes in fasting glucose, lipid profile, body mass index (BMI), abdominal obesity dynapenic, blood pressure, eating behavior, adherence to nutritional counseling, and the presence of diabetes-related complications.

Patients will undergo assessments at four time points: baseline, 4 months (Visit 2), 8 months (Visit 3), and 12 months (Visit 4). At each visit, various parameters will be collected, including anthropometric measurements, behavioral and food consumption assessments, adherence to nutritional counseling, dynapenia indicators, and metabolic control markers (glycemic control, lipid profile, and blood pressure). Diabetes-related complications will be evaluated at both baseline and at the 12-month visit.

Participant timeline {13}

The participants will follow the timeline as depicted in Fig. 1.

Assignment of interventions: allocation

Sequence generation {16a}

Individuals who meet the study's inclusion criteria will be randomly assigned to one of two groups: the control group (receiving usual care) or the intervention group (participating in operative groups), with a 1:1 allocation ratio. Randomization will be performed using block

	STUDY PERIOD						
	Enrollment	Allocation	Post-allocation				Close-out
TIMEPOINT	Baseline		Intervention	Visit 2	Visit 3	Intervention	Visit 4
ENROLLMENT:							
Eligibility screen	X						
Informed consent	X						
Allocation		X					
INTERVENTIONS:							
Usual care (control group)				X	X		X
Operative groups (intervention group)			X	X	X	X	X
ASSESSMENTS:							
Metabolic Control Indicators	X			X	X		X
Anthropometric and Dynapenia Measurements	X			X	X		X
Behavior and Food Consumption Assessments	X			X	X		X
Adherence nutritional counseling				X	X		X
Diabetes complication evaluation	X						X

Fig. 1 SPIRIT diagram

randomization, with two strata: baseline HbA1c levels (7–9% or 9.1–12%) and gender (male or female). The randomization process will be conducted by a blinded researcher (AVA).

Concealment mechanism {16b}

We plan to use the Clinical Trial Randomization Tool website (https://ctrandomization.cancer.gov/tool/) for blinded treatment allocation. The investigator responsible for randomization (AVA) will not be involved in the other stages of the study to maintain the blinding process.

Implementation {16c}

Participants will be informed of their allocation to either the control or intervention group via telephone call within 1 week after the baseline visit by a trained study team member.

Recruitment {15}

Participant selection will be based on the inclusion criteria outlined in the study. An electronic database containing telephone numbers will be requested from the Information Technology Center at the Hospital de Clínicas de Porto Alegre. This database will be used to identify outpatients with HbA1c levels outside the recommended therapeutic target, considering age and comorbidities in accordance with American Diabetes Association guidelines [15]. Potentially eligible individuals, who have provided consent in compliance with the General Data Protection Law [24], will be contacted and invited to participate in the study via telephone.

Assignment of interventions: blinding

Who will be blinded {17a}

In this clinical trial, blinding of participants and dietitians is not feasible due to the inherent differences between the intervention and control groups. Participants will be notified of their group assignment via telephone following the randomization process.

Procedure for unblinding if needed {17b}

Not applicable.

Data collection and management

Plans for assessment and collection of outcomes {18a}

Patients meeting the inclusion criteria will be contacted by telephone and invited to participate in the study. Upon consent, a comprehensive assessment will be conducted by pre-trained researchers, encompassing clinical, lifestyle, anthropometric, and laboratory evaluations. Clinical data, such as diabetes duration, associated comorbidities, and medication use, will be extracted from electronic medical records, focusing on the most

recent records available prior to the in-person visit, and will be verified with the patient.

Data on smoking, skin color, and education will be collected through self-report. Social class will be assessed using the Brazilian Economic Classification Criteria, a standardized questionnaire that evaluates household assets (such as appliances and automobiles), the educational level of the household head, and access to public services [25]. Patients will be categorized as belonging to the low social class if they are classified as C1, C2, or D/E.

Physical activity levels will be assessed using the short version of the International Physical Activity Questionnaire (IPAQ), which includes six questions regarding the frequency (ranging from 0 to 7 days per week) and duration (in minutes) of walking, moderate-intensity, and vigorous-intensity activities during a typical week [26]. Individuals will be categorized as having low physical activity if they engage in up to 599 metabolic equivalent tasks/minute/week of sustained activities [27].

For laboratory assessments, patients will be instructed to fast for 12 h before a blood test at the Hospital de Clínicas de Porto Alegre Clinical Pathology Laboratory. The blood test will include measurements of HbA1c, fasting glucose, and lipid profile. Fasting plasma glucose will be measured using the glucose-peroxidase colorimetric enzymatic method with the Biodiagnostica Kit [28]. HbA1c will be determined by high-performance liquid chromatography using the Turbo variant II system [29], with a reference interval of 4.0 to 6.0%. Total cholesterol will be measured using the enzymatic colorimetric method [30], HDL (high-density lipoprotein) cholesterol through an enzymatic colorimetric reaction, following Farish and Fletcher's modified procedures [31], and serum triglycerides using a colorimetric enzymatic method with a commercial kit as described by McGowan [32]. LDL (low-density lipoprotein) cholesterol will be estimated using the Friedewald formula [33].

Anthropometric measures will include weight (measured with light clothing and no shoes), height, and waist circumference (measured at the midpoint between the last rib and the iliac crest). An anthropometric scale, fixed wall stadiometer, and inelastic fiberglass measuring tape will be used for these measurements. Body mass index (BMI) will be calculated using the formula weight (kg)/height $(m)^2$, with a target BMI of < 25 kg/m^2 for adults [34] and < 27 kg/m^2 for the elderly [35].

The SARC-F questionnaire, a simple tool for rapid sarcopenia screening [36], will be administered by phone. Calf circumference will be measured at the point of greatest horizontal circumference with the participant seated, legs in a non-contracted position, and 20 cm apart. Handgrip strength will be assessed using a Hydraulic Hand Dynamometer (dominant hand), and the walking test will involve the participant walking a pre-marked 4-m distance, timed with a stopwatch.

Blood pressure measurements will be taken in triplicate using the Omron HEM-705CP Digital Blood Pressure Monitor, with a 1-min interval between each reading. The patient will be seated after a 5-min rest period, and a cuff appropriate for the arm diameter will be used. Hypertension will be defined as an average systolic pressure of 130 mmHg or higher, or a diastolic pressure of 80 mmHg or higher, measured on at least two separate occasions. Alternatively, a history of Systemic Arterial Hypertension requiring pharmacological treatment, regardless of current blood pressure values, will also be considered indicative of hypertension [37]

Eating behavior will be assessed using the Intuitive Eating Scale-2 (IES-2) [38], adapted to Portuguese [39]. This scale, based on the principles of intuitive eating, includes questions regarding food attitudes and is designed to evaluate adherence to hunger and satiety cues. Food consumption will be estimated using the 24-h dietary recall method, specifically the Multiple-Pass Method [40]. Additionally, the study will evaluate the frequency of consumption of sweets, sugary drinks, alcoholic beverages, fried foods, cooking oil, added oils used during preparation (with type and quantity specified per capita), and sausages, canned goods, preserved foods, industrialized seasonings, meat, and eggs.

The assessment of the reduction in the risk or progression of diabetes-related complications, including diabetic kidney disease, diabetic retinopathy, and cardiovascular disease, will be conducted. Both aspects will be evaluated through the review of patient electronic medical records. Diabetic retinopathy will be classified according to the severity observed during a fundoscopic examination conducted by a specialist, with categories including mild, moderate, severe non-proliferative, and proliferative retinopathy [41]. Diabetic kidney disease will be identified by an estimated glomerular filtration rate (eGFR) < 60 mL/min/1.73 m^2 and/or persistently elevated urinary albumin excretion, defined as albuminuria ≥ 14 mg/dL in at least two measurements within a 3–6-month period [42]. Serum creatinine levels will be determined using the colorimetric method [43], and the estimated glomerular filtration rate will be calculated using the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) equation [44]. Urinary albumin will be measured using the immunoturbidimetry method [45]. A history of stroke, acute myocardial infarction, coronary artery disease, peripheral arterial obstructive disease, ischemic heart disease, or heart failure will be considered indicative of previous cardiovascular disease.

Adherence to the nutritional combinations will be assessed during each scheduled visit (at 4, 8, and

12 months), along with adherence to the Diabetes Plate Method [21]. Additionally, attendance of participants randomized to the intervention group will be monitored based on their presence at the scheduled meetings, with patients considered adherent if they attend at least two meetings. Furthermore, we will evaluate whether participants randomized to the intervention group meet the recommendation of having at least 10 h of contact with a healthcare team [15]. This assessment will be conducted using data extracted from the electronic medical records.

Plan to retention and complete follow-up {18b}

To ensure participant retention in the study, researchers will maintain regular contact through phone calls every 4 months. Additionally, individuals in the intervention group will be included in a WhatsApp group throughout their participation in the scheduled meetings. It is important to note that participants will not receive monetary incentives or food during the course of the research.

Data management {19}

Researchers will get training before starting data collected, to maintain the operational procedures shown in the protocol, with the aim of maintaining the consistency and reliability of the data. In addition, standardized forms for collection of dates will be used. The blood tests will be carried out in the laboratory with standard techniques. The integrity of all records will be preserved throughout the study, and every form will be meticulously filled out to guarantee that it matches the original data. Following participant inclusion, the data will be checked for accuracy, and any questions or inconsistencies will be checked into and examined of the electronic medical record.

Participant data will be stored on an institutional Google Drive, with access restricted solely to the researchers. This storage arrangement will be maintained for a period of 5 years.

Confidentiality {27}

To ensure data confidentiality, each participant will be assigned a unique code at the time of selection for data analysis. Only the study's research team will have access to the participants' authorized data, which will be securely stored in a file linked to an institutional email.

Plans for collection and storage of biological specimens in this trial/future use {33}

Participants will provide blood samples throughout the study. All collected samples will be analyzed and stored in the clinical pathology laboratory at the Hospital de Clínicas de Porto Alegre. After the completion of the required analyses, the samples will be disposed of and destroyed in accordance with established protocols.

Statistics {20a, 20b, and 20c}

The symmetry of variables will be assessed using the Shapiro–Wilk or Kolmogorov–Smirnov test, as appropriate. Continuous variables with a normal distribution will be reported as mean ± standard deviation or mean with a 95% confidence interval. Continuous variables with an asymmetric distribution will be presented as median and interquartile range, while categorical variables will be expressed as absolute and relative frequencies.

Baseline characteristics of participants randomized to the intervention and control groups will be compared using statistical tests appropriate for the type of data. Depending on the distribution and nature of the variables, Student's t test, Mann–Whitney U test, chi-square test, or Fisher's exact test will be applied.

To assess potential variations in the variables of interest (outcomes), differences (delta) will be calculated for each group at each visit and analyzed using Student's t test for paired samples for symmetric data or the Wilcoxon U test for asymmetric data. Interactions between groups (control and intervention) and time will be examined using Generalized Estimating Equations, with time and randomization treated as fixed effects. Analyses will be adjusted for sex, age, and other potential confounders using Bonferroni post hoc correction. Potential confounding factors, such as weight, diabetes medication use, and physical activity, will be considered and analyzed. Additionally, variables identified as relevant in the univariate analysis may be included as potential confounders, as they could influence the results and are pertinent to the study's objectives. An intention-to-treat approach will be employed for the analysis. For patients who do not adhere to the intervention or have missing data, the last observed measure will be used for data imputation.

The significance level will be set at less than 5% (two-tailed), and all data will be analyzed using SPSS 20.0 (SPSS Inc., Chicago, IL, USA).

Dissemination polity: reproducible research {31c}

The study protocol, data, and results will be made available by the corresponding author upon request.

Oversight and monitoring

Composition of coordinating center {5d}

The coordinating center for this trial is the Hospital de Clínicas de Porto Alegre, with Dr. Almeida JC serving as the principal investigator.

Data monitoring {21a and 21b}

The researchers have received prior training, and the questionnaires will be completed electronically. Records will be stored electronically for easy access and monitoring, and blood tests will be conducted in the laboratory using standardized techniques. These measures are in place to ensure data reliability. To ensure participant safety, this study will be conducted in compliance with Resolution CNS 466/2012 from the National Health Council of Brazil [46] and the General Data Protection Law [24]. The intervention in this study is considered low risk. A preliminary analysis will be conducted at the 4-month mark to evaluate the initial results of the study.

Harms {22}

The team will maintain continuous and close monitoring of participant safety. In the event of any serious adverse event, it will be promptly reported to the responsible researcher, communicated to the Research Ethics Committee of the Hospital de Clínicas de Porto Alegre, Rio Grande do Sul, and appropriate measures will be taken.

Auditing {23}

Adherence to ethical guidelines in the study will be overseen by the Ethics Committee of the Hospital de Clínicas de Porto Alegre. Progress reports on the trial will be submitted every 6 months to ensure compliance with ethical standards.

Protocol amendments {25}

Any changes to the protocol resulting from data revision will be communicated to the Research Ethics Committee, and approval for the modifications will be obtained before implementing any adjustments to the study. In such cases, the protocol will be updated on clinicaltrials.gov.

Dissemination policy: trial results {31a}

The information for this study will be published in the clinicaltrials.gov registry. Furthermore, the results will be disseminated through academic events and peer-reviewed scientific publications.

Discussion

The American Diabetes Association recommends interventions lasting more than 10 h over 6 to 12 months to achieve optimal health outcomes in patients with diabetes [15]. This study hypothesizes that adding group dietary education to the standard individualized treatment at a specialized nutrition outpatient clinic may improve glycemic and lipid profiles and potentially reduce the incidence or progression of complications in patients with type 2 diabetes mellitus over the long term.

According to the American Diabetes Association [3], it is recommended that all individuals with diabetes participate in diabetes self-management education and support to enhance their knowledge, decision-making, and skills for diabetes self-care. Consequently, research indicates that diabetes management interventions are more effective when they provide long-term follow-up with continuous support from healthcare professionals [47, 48]. Moreover, a systematic review by Cradock et al. [4] suggested that increased frequency and a higher number of contacts are associated with more significant reductions in HbA1c.

In a systematic review [48] of 47 studies, group-based education for managing type 2 diabetes was shown to significantly improve various parameters, including HbA1c, fasting glucose, body weight, waist circumference, triglyceride levels, and diabetes knowledge. Experimental studies have demonstrated positive outcomes in HbA1c reduction through individual nutrition education, including web-based and mobile-phone interventions, as well as face-to-face sessions [48]. Furthermore, intervention studies support these findings, showing significant reductions in weight, body mass index, HbA1c, and fasting glucose levels, ultimately reducing the long-term risk of micro- and macrovascular complications [49, 50]. As a result, both individual and group-based approaches offer benefits, with a slightly greater advantage observed when both strategies are employed together [48].

Limitations

The current study has certain limitations, including the inability to blind researchers and participants, and the fact that both groups will receive guidance from nutrition experts potentially attenuating the difference in outcomes between the intervention and control groups. Additionally, being a real-life study, participants may encounter life complications during the follow-up period that could impact their participation in the research.

Trial status {1}

Recruitment for this study commenced in September 2022 and is anticipated to conclude by February 2025. Version 1.0, approved July 21, 2022.

Abbreviations

ADA	American Diabetes Association
CKD-EPI	Chronic Kidney Disease Epidemiology Collaboration
eGFR	Estimated glomerular filtration rate
HbA1c	Glycated Hemoglobin A
HDL	High-density lipoprotein
IES-2	Intuitive Eating Scale-2

IPAQ	International Physical Activity Questionnaire
LDL	Low-density lipoprotein
SARC-F	Simple Questionnaire To Rapidly Diagnose Sarcopenia
SPIRIT	Standard Protocol Items: Recommendations for Interventional Trials
SPSS	Statistical Package for the Social Sciences

Acknowledgements
The authors express their gratitude to the patients and funding for providing financial support for this study.

Research ethics approval {24}
This study was approved by the Research Ethics Committee Hospital de Clínicas de Porto Alegre, Brazil (CAAE: 60045422000005327). The term consent will be obtained from all participants.

Authors' contributions {31b}
The study was conceived by AB, who also played a pivotal role in designing the study, drafting the protocol, and preparing the final manuscript. AB will oversee participant recruitment, data collection, and nutritional evaluation. VMM and OGK will contribute to data collection. AVA is responsible for the randomization process. JCA, who also contributed to the study's conception and design, participated in preparing the final manuscript. All authors have reviewed and approved the final manuscript.

Funding {4}
This study received partial funding from the Financiamento e Incentivo à Pesquisa—Fipe/HCPA (CAAE: 60,045,422.0.0000.5327), the National Council for Scientific and Technological Development (CNPq), and the Coordination of Improvement of Personal Higher Education, Brazil (CAPES, Finance Code 001). AB, OGK, and VMM received federal scholarships from CAPES.

Data availability {29}
The data is not currently publicly available, but it will be accessible to the authors upon request.

Declarations

Consent for publication {32}
The model of informed consent form was included with a supplementary document.

Competing interests {28}
The authors declare that they have no competing interests.

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Received: 27 March 2024 Accepted: 6 January 2025
Published online: 06 March 2025

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