Research Square

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Enhancing Diet Quality in Early Stages of Change in Individuals at High Risk for Diabetes

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Abstract

Aims

This study examines how readiness for change affects adherence to nutritional counseling and health outcomes in adults at high risk for diabetes, comparing a lifestyle intervention with usual care.

Materials and methods

To address this aim, a secondary analysis of a multicenter randomized controlled pilot trial (NCT05689658) compared the Brazilian Diabetes Prevention Program (PROVEN-DIA) to standard nutritional counseling over three months. Readiness for change, diet quality (measured by the Wheel of Cardiovascular Health Diet; high-quality diet > 70% of the graphical area), physical activity, smoking, body weight, blood pressure, and HbA1c were assessed at baseline and at three months. Participants were classified by stage of change and clustered: precontemplation/contemplation, preparation, or action/maintenance.

Results

Of 220 participants (71.8% women; mean age 48 ± 10 years; 65.5% with obesity; 38.2% with prediabetes), those in the PROVEN-DIA group at precontemplation/contemplation were more likely to report high diet quality at three months (OR = 4.7, 95% CI = 1.2–17.8). For those in the action/maintenance and preparation stages, the odds were 2.9 (95% CI: 0.5–18.3) and 1.9 (95% CI: 0.8–4.6), respectively. Health parameters improved in all groups and change stages, but no significant interaction was observed between time, stage, and group.

Conclusion

Findings show that adults at high risk for diabetes and those in earlier stages who received the PROVEN-DIA intervention were more likely to report improved diet quality than those in the control group after 3 months.

Introduction

Diabetes mellitus (DM) is a chronic, progressive condition characterized by persistent hyperglycemia [1]. Evidence suggests a critical window of approximately three to six years between the onset of type 2 DM and the development of cardiovascular diseases, underscoring the importance of early detection and intervention [2]. This highlights the urgent need for strategies targeting both DM prevention and the effective management of prediabetes, a condition associated with an elevated risk of progression to type 2 DM [2]. The global prevalence of prediabetes is currently estimated at 9.1% when defined by impaired glucose tolerance (IGT) and 5.8% when defined by impaired fasting glucose (IFG) [3].

Current recommendations for prediabetes emphasize lifestyle modifications, particularly the adoption of a healthy diet and regular physical activity [4]. Although no single dietary pattern has been definitively established as superior, associations between specific foods and disease risk are well documented [4, 5].

Beyond dietary interventions, promoting adherence to treatment may exert a greater influence on health outcomes than modifications to specific medical therapies [6]. Positive outcomes are more likely when individuals demonstrate willingness to adopt lifestyle changes [7]. Therefore, assessing patient capabilities, access, motivation, and barriers is critical when developing nutritional therapy strategies [4].

Understanding the mechanisms underlying motivation is essential for the success of interventions designed to promote adherence, given the complexity of human behavior. The Transtheoretical Model is notable for integrating multiple perspectives to facilitate behavioral change. The initial step in applying this model is to identify an individual’s stage of readiness for change.8 In early stages, such as contemplation, individuals acknowledge the complexity of their behavior but have not yet committed to change [8]. At this point, strategies that raise awareness can help individuals recognize the problem and progress toward more proactive stages of change [8]. This study aims to evaluate the impact of individuals' readiness for change on adherence to nutritional counseling and subsequent health outcomes. The analysis focuses on individuals at high risk for diabetes who received a lifestyle modification intervention, compared to those who received usual care.

Methods

Study design

This study presents a secondary analysis of data from a randomized, open-label, multicenter clinical trial. It uses an intention-to-treat approach to compare the 'Programa de Prevenção de Diabetes' (Brazilian Diabetes Prevention Program - PROVEN-DIA) with standard Nutritional Guidance. The participants are individuals at high risk of type 2 DM (NCT05689658) [9].

The PROVEN-DIA pilot ran from May to October 2023 across five regions in Brazil: Rio Grande do Sul (South), Bahia (Northeast), Minas Gerais (Southeast), Tocantins (North), and Goiás (Central-West). Trial sites promoted and recruited participants through local media, social media, and health service partnerships. Eligible people at screening were invited for an in-person eligibility check and enrollment.

Trained staff explained the study and got written consent from participants. Enrollment followed. The study followed the Declaration of the Americas, local rules, and was approved by the A Beneficência Portuguesa de São Paulo Ethics Committee (CAAE 65491122.7.1001.5483).

A standardized operations manual is required to ensure consistent implementation across all study sites. This manual outlines protocol procedures and intervention content. All researchers completed a centralized, two-day training covering theoretical and practical aspects of intervention delivery. Weekly virtual meetings provided ongoing guidance and support. This ensured fidelity and uniformity across diverse regions.

Study Population

Adults aged 18 to 65 years with a prior diagnosis of prediabetes were enrolled, as defined by fasting blood glucose levels between 100 and 125 mg/dL, 2-hour post-oral glucose tolerance test blood glucose between 140 and 199 mg/dL, haemoglobin A1c (HbA1c) levels between 5.7 and 6.4%, or a high risk score on the CDC Prediabetes Risk Test [10] during the screening period. Additional eligibility criteria included a body mass index (BMI) greater than 24.9 kg/m², internet access, ownership of a personal mobile device, residence in proximity to the study center, and no history of nutrition counseling within the previous six months. Exclusion criteria comprised a confirmed diagnosis of type 2 diabetes, detectable human immunodeficiency virus antibodies, a history of cardiovascular disease such as stroke or acute myocardial infarction, chronic conditions affecting life expectancy or study participation, concurrent enrollment in another randomized clinical trial, and pregnancy or breastfeeding. Further details regarding inclusion and exclusion criteria are provided in protocol NCT05689658.

At baseline, the readiness for change stage of all participants was assessed using a simplified lifestyle change motivation algorithm based on the Transtheoretical Model of Change [8]. Participants were asked to rate their satisfaction with their current lifestyle, diet, and physical activity using the options: “very dissatisfied,” “dissatisfied,” “neutral,” “satisfied,” or “very satisfied.” Those selecting “very dissatisfied,” “dissatisfied,” or “neutral” were further questioned regarding their intention to change. Participants with no intention to change were categorized as being in the “precontemplation” stage. Those intending to make changes within three to six months were classified as in the “contemplation” stage, while those planning changes within one to two months were placed in the “preparation” stage. If participants responded “satisfied” or “very satisfied,” the duration of their satisfaction was assessed. A period of less than one year indicated the “action” stage, whereas a period of more than one year indicated the “maintenance” stage (**Supplementary Fig. 1**) [10].

Randomization

Participants were randomized in a 1:1 ratio to either the “Programa de Prevenção de Diabetes” or Usual Care. The randomization sequence was generated electronically in blocks and stratified by center using validated software. Allocation concealment was maintained through a centralized, automated online system accessible at all times. Group assignments were disclosed only after participant registration in the electronic system to preserve confidentiality. Blinding of participants and researchers was not feasible due to the nature of the intervention.

Usual Care

Participants in the control group attended an initial face-to-face session and a follow-up visit after three months. They received standardized guidance aligned with Ministry of Health Guidelines to promote healthy dietary habits and physical activity. The recommendations followed the Dietary Guidelines for the Brazilian Population [12] and included the World Health Organization's recommendation of 150 minutes of moderate-intensity physical activity per week [13]. Both resources are commonly implemented in Brazilian primary care. Participants were also provided with an educational brochure summarizing all dietary and physical activity guidelines for reference during the three-month period.

Intervention: Programa de Prevenção ao Diabetes

The intervention was based on the Diabetes Prevention Program (DPP) [14], a well-established American initiative. However, it was primarily structured using Brazilian educational materials and national clinical guidelines [15]. Participants in the PROVEN-DIA group had the same objectives as those in the control group. These objectives were implemented through a structured intervention program. The program was

designed to facilitate and promote adherence to targeted behaviors - specifically, improving dietary quality and engaging in at least 150 minutes of moderate-to-vigorous physical activity per week.

The PROVEN-DIA program included six in-person meetings over three months: individual meetings on days 1, 30, and 90, and group meetings on days 15, 45, and 75 (Fig. 1). Lifestyle change goals were set together to make sure plans fit each person. Usually, three simple goals were chosen: two about eating and exercise, and one that could be either. At each visit, participants discussed progress and changed goals as needed to fit their situation.

Dietary goals emphasized adherence to a healthy, cardioprotective dietary pattern as recommended by the Brazilian Cardioprotective Nutritional Program [16] and the Dietary Guidelines for the Brazilian Population [12]. The BALANCE program classifies foods by the colors of the Brazilian flag according to nutritional quality - encouraging frequent consumption of green-group foods (fruits, vegetables, skimmed milk, beans), moderate intake of yellow-group foods (grains, nuts, oils), limiting blue-group foods (animal proteins), and avoiding red-group (ultra-processed) foods. Although originally for cardiovascular disease prevention, BALANCE was adapted for diabetes prevention by restricting daily carbohydrate intake to 45–48%, consistent with a moderate carbohydrate-restricted diet. Physical activity goals followed the Physical Activity Guide for the Brazilian Population [17], targeting at least 150 minutes of moderate-to-vigorous physical activity per week. To support adherence, participants accessed instructional exercise videos via QR codes in educational materials and through WhatsApp for home-based implementation.

The program also included five structured telephone sessions conducted by the facilitators. Each session used a standardized protocol. Facilitators reinforced commitment to individualized goals, assessed progress, identified potential barriers, and provided motivational support. These weekly calls occurred between in-person sessions. They complemented face-to-face meetings by promoting adherence and delivering tailored guidance based on participants' reported needs and challenges.

Participants received a printed booklet containing educational content, tools for tracking diet and physical activity, and space for notes and personal reflections. Further details regarding the intervention plan are available in the main publication of the PROVEN-DIA pilot study [9]. The intervention was implemented uniformly for all participants in the PROVEN-DIA group, regardless of their stage of readiness for change. Attendance at each session was recorded, and goal achievement was self-reported through a questionnaire during data collection consultations.

Outcome measurements

The primary outcome of this sub-analysis was an improvement in self-perceived diet quality at three months, assessed according to baseline readiness for change. Secondary outcomes included weight, BMI, waist circumference, physical activity, blood pressure and HbA1c values.

At both baseline and the three-month follow-up visits, all participants underwent assessments encompassing lifestyle factors (diet, physical activity, smoking), anthropometric measurements, clinical evaluations, and laboratory tests.

Diet quality assessment

Dietary quality was assessed using the Wheel of Cardiovascular Health Diet at baseline and three months following nutritional counseling.

The Wheel of Cardiovascular Health Diet, a validated tool, includes 11 food groups: red meat, fish, seeds and nuts, fruits, vegetables, ultra-processed foods, dairy, processed meat, beans, whole grains, and sugar-sweetened beverages [18, 19]. Each group is paired with recommended frequency and portion sizes, as specified by the Cardiovascular Health Diet Index.[20] The wheel allows participants to rate their dietary adherence as "excellent" (consistent adherence), "very good" or "good" (frequent adherence), "poor" (rare adherence), or "very poor" (minimal or no adherence). Intake rated as "excellent" or "very good" was considered adequate for that food group [20]. Among individuals at high cardiovascular risk, self-reported dietary assessments using the Wheel of Cardiovascular Health Diet were positively associated with evaluations conducted by nutritionists using a food frequency questionnaire [18].

The Wheel of Cardiovascular Health Diet is depicted as a radar chart, with the total area, calculated as "$\pi \times \text{radius}^2$", representing 100% dietary quality. Overall diet quality was determined by the percentage of the chart area completed; participants scoring above 70% were classified as having a high-quality diet [19].

Participants were classified as having "increased," "unchanged," or "decreased" diet quality by comparing the Wheel of Cardiovascular Health Diet graphic area at three months to baseline (three-month value minus baseline). They were further grouped as adherents (increase of more than 10 percentage points) or non-adherents (less than 10 percentage points) [19].

Physical Activity

Physical activity level was assessed using the short version of the International Physical Activity Questionnaire (IPAQ) [21]. The questionnaire generates a continuous score, expressed in MET-minutes/week, and classifies participants as having low physical activity if they engage in up to 599 metabolic equivalent tasks/minute/week of sustained activities [21]. In this study, participants were classified as having a sedentary lifestyle if they were classified as having low physical activity.

Physical activity level was assessed using the short version of the International Physical Activity Questionnaire (IPAQ) [21]. This instrument generates a continuous score, reported in MET-minutes per week. Participants were classified as having low physical activity if they engaged in up to 599 MET-minutes per week of sustained activity [21]. In the present study, individuals classified as having low physical activity were considered to have a sedentary lifestyle.

Anthropometric measurements

Trained researchers collected anthropometric measurements, including weight, height, and waist circumference [22]. Weight was measured with participants barefoot and in light clothing, performed using a scale, mechanical or digital platform with a minimum accuracy of 100 g. Height was measured with participants barefoot, using a stadiometer attached to the scale, portable, fixed, or tape measure type with 1cm precision. Waist circumference was measured in duplicate at the midpoint between the lowest rib margin and the iliac crest [23], using a measuring tape made of strong, inelastic, and flexible material, with an accuracy of 0.1 cm. The cut-off points for waist circumference were defined as > 80 cm for women and > 94 cm for men, based on established values by the World Health Organization [24]. BMI was calculated as weight (kg) divided by height (m) squared, and participants with a BMI ≥ 30 kg/m² were classified as having obesity [25].

Clinical variables

Sitting blood pressure was measured three times following a 5-minute rest period, using an automatic electronic blood pressure monitor calibrated and validated by the National Institute of Metrology, Quality, and Technology (INMETRO) in accordance with established guidelines [26]. Hypertension was defined as systolic blood pressure of at least 140 mmHg or diastolic blood pressure of at least 90 mmHg, measured on two separate occasions, or the use of antihypertensive medication [26].

Blood samples were obtained after an 8 to 12-hour fasting period. HbA1c was measured using high-performance liquid chromatography. Participants with HbA1c values between 5.7% and 6.4% were classified as having prediabetes according to the American Diabetes Association criteria [27].

Risk of developing prediabetes was assessed using the Prediabetes Risk Test, which consists of questions regarding health and lifestyle. Participants who scored five or higher were considered at risk for prediabetes [10].

Other variables

Data regarding education, medication use, skin color, and smoking status were self-reported by participants during the initial visit. Individuals with no formal education or only primary education were classified as having a low level of education. Medication use was also assessed at the last visit, also according to the participants' self-report. In terms of skin color, participants were categorized as either white or non-white, and for smoking status, they were classified as current smokers or non-smokers.

Socioeconomic status was determined using the Brazilian Economic Classification Criteria [28], which evaluates household possessions, the education level of the householder, and access to public utility services. Participants were categorized as A1, B1, B2, C1, C2, or D/E, representing the highest to lowest economic classes. For the purposes of this study, participants with a socioeconomic level of C1, C2, or D/E were classified as low income.

Statistical analysis

A convenience sampling method was employed. The PROVEN-DIA study estimated a total sample size of 220 participants (110 per group), providing 90% power to detect a between-group difference of 50 minutes in mean weekly physical activity time [29] and a 1-point difference in the mean red BALANCE Index score [30], with a 5% significance level and a 20% anticipated attrition rate. The entire estimated sample was included in this secondary analysis.

The Shapiro-Wilk test was used to assess the normality of variables. Descriptive analyses were performed, presenting continuous variables as mean (standard deviation) or median (interquartile range), according to their distribution.

Participants were grouped according to randomization and further stratified into three subgroups based on Stage of Readiness for Change: ‘Precontemplation or Contemplation’, ‘Preparation’, and ‘Action or Maintenance’. This stratification balanced sample sizes, as the majority of participants were in the preparation stage, thereby preserving statistical power and enabling meaningful comparisons across behavioral readiness levels. Subgroup characteristics were compared using ANOVA with Bonferroni post hoc test, Fisher's Exact Test, or Chi-square tests.

Multivariable analyses were conducted using binary regression models, regression models estimated by Generalized Estimating Equations (GEE) adjusted for sex or the Wilcoxon test to assess health outcomes, including weight, BMI, waist circumference, systolic blood pressure, diastolic blood pressure, and HbA1c. Participants lost to follow-up were retained in the statistical analysis according to the intention-to-treat principle.

A p-value of less than 0.05 (two-tailed) was considered statistically significant. All analyses were performed using IBM SPSS version 18.0 (PASW Inc., Chicago, IL).

Results

The study included all 220 participants from the PROVEN-DIA cohort. The majority were women (71.8%), with a mean age of 48 years (± 10). Among the participants, 16.4% had attained only basic education, defined as being illiterate or having completed elementary school. Obesity was present in 65.5% of the sample, and 38.2% had a diagnosis of prediabetes. In terms of readiness for change, 3.2% of participants were in the precontemplation stage, 33.2% in contemplation, 53.2% in preparation, 4.5% in action, and 5.9% in maintenance. Comparison of baseline characteristics between randomization groups indicated a higher proportion of female participants in the intervention group (78.9% vs. 64.9% in the control group; p = 0.03). Regarding skin color, age, low income, education level, current smoker, obesity, altered waist circumference, risk of prediabetes, and prediabetes, the proportion was not different between the randomization groups (data not shown).

Participants were assigned to three groups according to their stage of readiness for change: precontemplation/contemplation (n = 80, 36.4%), preparation (n = 117, 53.2%), and action or maintenance (n = 23, 10.4%). The distribution of participants across these stages was similar between the randomization groups. Table 1 presents baseline characteristics by stage of change and randomization group (control and intervention). In the intervention group, age and the proportion of participants with obesity differed across stages of change. In the control group, participants in earlier stages of change exhibited a more sedentary lifestyle and a lower proportion of individuals at high risk for diabetes.

Table 1
Baseline characteristics of the individuals included in the present study according to the randomization stage of change (n = 220).

	Intervention Group (n = 109)				Control Group (n = 111)			
	Precontemplation or contemplation	Preparation	Action or maintenance	P	Precontemplation or contemplation	Preparation	Action or maintenance	P
n	**47**	**53**	**9**	-	**33**	**64**	**14**	-
Non-white skin color	32 (68%)	36 (68%)	6 (67%)	1.000[a]	26 (79%)	45 (70%)	11 (79%)	0.678[†]
Age, (years)	47.2 ± 10.7[α]	46.9 ± 9.1[α]	56.3 ± 4.9[β]	**0.023**[b]	45.9 ± 9.3[α]	51 ± 8.6[α]	51.8 ± 9.9[α,β]	**0.020**[b]
Woman	38 (81%)	42 (79%)	6 (67%)	0.597[a]	24 (73%)	41 (64%)	7 (50%)	0.317[†]
Obesity[c]	37 (79%)[a]	38 (72%)[a]	2 (22%)[b]	**0.005**[a]	24 (73%)	36 (56%)	7 (50%)	0.191[†]
Altered waist circumference[d]	47 (100%)	48 (91%)	8 (89%)	0.052[a]	32 (97%)	61 (95%)	12 (86%)	0.292[†]
Hypertension	19 (40%)	21 (40%)	5 (56%)	0.697[a]	17 (52%)	32 (51%)	5 (36%)	0.601[†]
High risk of prediabetes[e]	30 (64%)	31 (59%)	4 (44%)	0.562[a]	12 (36%)[a]	21 (33%)[a]	11 (79%)[b]	**0.006**[†]
Prediabetes	15 (32%)	20 (38%)	4 (44%)	0.688[a]	11 (33%)	31 (48%)	3 (21%)	0.104[†]
Low income[f]	23 (49%)	19 (36%)	5 (56%)	0.307[a]	13 (39%)	25 (39%)	6 (43%)	1.000[†]
Low education level[g]	9 (19%)	6 (11%)	4 (44%)	0.057[a]	6 (18%)	9 (14%)	2 (14%)	0.929[†]
Sedentary lifestyle[h]	31 (66%)	34 (64%)	3 (33%)	0.185[a]	22 (67%)[a]	43 (67%)[a]	4 (29%)[b]	**0.028**[†]
Current Smoking	5 (11%)	10 (19%)	1 (11%)	0.510[a]	5 (15%)	13 (20%)	1 (7%)	0.549[†]

Data are presented as mean ± standard deviation or as the number of cases for the total group (percentage). [a]Chi-square or Fisher's exact test. [b]Analysis of variance (ANOVA) with Bonferroni post-hoc test. [c]Participants with a BMI of 30 kg/m² or higher were classified as having obesity [25]. [d]Altered waist circumference was defined as 80 cm or greater in women and 94 cm or greater in men, according to the cut-off points for the Brazilian population [24]. [e]Participants with a score of five or higher were considered at risk for prediabetes [9]. [f]Participants were classified as low income if their socioeconomic level was C1, C2, or D/E [28]. [g]Participants with no formal education or who had completed only primary education were classified as having a low level of education. [h]Patients were classified as having low physical activity if they engaged in up to 599 metabolic equivalent tasks per minute per week of sustained activities [20]. Values followed by different superscript Greek letters within the same line indicate statistically significant differences (p < 0.05).

A higher proportion of participants in the intervention group reported improved diet quality, defined as achieving a total area on the Wheel of Cardiovascular Health Diet exceeding 70%, irrespective of stage of readiness for change (P < 0.02 across all groups). In contrast, within the control group, only those in the preparation stage reported improved diet quality (Fig. 2). In the intervention group, 14% of participants experienced a decrease in dietary quality, 26% reported no change, and 60% adhered to nutritional counseling. In the control group, 26% showed decreased diet quality, 33% reported no change, and 41% adhered to dietary recommendations. Therefore, a greater proportion of participants in the intervention group [n = 59 (60.2%)] achieved at least a 10 percentage point improvement in diet quality compared to the control group [n = 38 (41.3%); P = 0.013], regardless of readiness for change. **Supplementary Appendix Table 1** details the proportions of participants' self-perceived diet quality for each Wheel of Cardiovascular Health Diet component before and after counseling, stratified by stage of change and randomization. Participants in the intervention group reported improvements in self-perceived diet quality, particularly for fruit, ultra-processed foods, processed meats, and sugar-sweetened beverages, regardless of stage of readiness for change.

Table 2 summarizes changes in anthropometric measures, blood pressure, and glycemic control before and after nutritional counseling, stratified by stage of change and randomization. In the intervention group, participants in the precontemplation/contemplation and action/maintenance stages demonstrated reductions in waist circumference after three months (P < 0.01). The interaction between stage and time was not statistically significant (P = 0.060). Weight and BMI decreased in the precontemplation/contemplation and preparation stages (P < 0.05). Diastolic blood pressure declined in the preparation and action/maintenance stages, while HbA1c decreased only in the preparation stage. In the control group, reductions in systolic blood pressure and HbA1c were observed in the precontemplation/contemplation and preparation stages (P < 0.05 for both). A decrease in BMI was observed only among individuals in the precontemplation/contemplation stage.

Table 2
Response of Anthropometric Measures, Blood Pressure and Glycemic Control in Individuals Before and After Nutritional Counseling According to Stage of Change and Randomization (n = 220)

	Precontemplation or Contemplation			Preparation			Action or Maintenance			P[a]	P[b]
n	**80**	**Baseline**	**3-month**	**117**	**Baseline**	**3-month**	**23**	**Baseline**	**3-month**		
Weight, kg											0.292
Intervention	47	**92.7 ± 3**	**92.0 ± 3***	53	**93.6 ± 3**	**92.6 ± 3****	9	78.9 ± 3	78 ± 3	0.705	
Control	33	91.3 ± 3	90.4 ± 3	64	93.6 ± 3	89.0 ± 2	14	87.0 ± 6	86.2 ± 5	0.590	
BMI, kg/m²											0.120
Intervention	47	**34.6 ± 1**	**34.3 ± 1***	53	**34.0 ± 1**	**33.6 ± 1****	9	28.2 ± 1	27.9 ± 1	0.745	
Control	33	**33.3 ± 1**	**32.8 ± 1***	64	32.3 ± 1	32.3 ± 1	14	31.5 ± 1	31.3 ± 1	0.316	
Waist circumference, cm											0.439
Intervention	47	**109 ± 2**	**106 ± 2****	53	105 ± 2	104 ± 2	9	**99 ± 3**	**95 ± 3****	**0.060**	
Control	33	103 ± 2	104 ± 2	64	103 ± 2	102 ± 2	14	97 ± 3	96 ± 3	0.346	
Systolic blood pressure, mmHg											0.990
Intervention	47	125 ± 3	124 ± 3	53	125 ± 2	122 ± 2	9	127 ± 5	125 ± 5	0.750	
Control	33	**128 ± 4**	**122 ± 4***	64	**125 ± 2**	**121 ± 2***	14	127 ± 5	125 ± 4	0.706	
Diastolic blood pressure, mmHg											0.712
Intervention	47	84 ± 2	81 ± 2	53	**81 ± 2**	**78 ± 2****	9	**82 ± 4**	**73 ± 3****	0.167	
Control	33	83 ± 2	79 ± 3	64	80 ± 1	79 ± 2	14	77 ± 2	78 ± 3	0.478	
HbA1c, %											0.740
Intervention	44	5.6 ± 0.1	5.5 ± 0.1	50	**5.7 ± 0.1**	**5.5 ± 0.1***	9	5.6 ± 0.1	5.6 ± 0.1	0.204	
Control	32	**5.7 ± 0.7**	**5.5 ± 0.5***	60	**5.7 ± 0.1**	**5.5 ± 0.1****	13	5.8 ± 0.6	5.6 ± 0.3	0.681	

Values are presented as mean and standard deviation. Interaction P-value: [a]Effect of the interaction between stages of change and time within each randomization group. [b]Effect of the interaction between stages of change and time among all participants, accounting for intervention effects using Generalized Estimating Equations regression adjusted for sex. *P < 0.05, **P < 0.01 indicates significant changes between baseline and three months.

Among participants in the precontemplation/contemplation stage, those who received the PROVEN-DIA intervention had 4.7 times the odds [95% confidence interval (CI) 1.2 to 17.8] of achieving high diet quality (> 70% of the Wheel of Cardiovascular Health Diet area) of to the control group. In the preparation stage, intervention recipients had 1.9 times odds (95% CI 0.8 to 4.6), and in the action or maintenance stage, 2.9 times odds (95% CI 0.5 to 18.3) than their control group counterparts (Fig. 3).

Discussion

Among adults at high risk for diabetes, most participants were in the preparation stage of behavior change. Those who received the PROVEN-DIA intervention achieved higher diet quality compared to the control group, indicating the intervention's effectiveness in promoting healthier eating habits. This effect was most pronounced among individuals in the early stages of readiness for change, suggesting that the program's structured and supportive approach may be particularly beneficial for individuals not yet consistently practicing healthy behaviors. While both groups demonstrated improvements in health parameters across all stages of change, the lack of a significant interaction among time, stage of change, and group suggests that these improvements were not differentially affected by the intervention over time or by stage of change.

A greater proportion of participants in the intervention group reported improved diet quality across all stages of readiness for change. In contrast, in the control group, only those in the preparation stage demonstrated improvement (see **Supplementary Appendix Fig. 1**). These findings differ from a secondary analysis of the Special Diabetes Program for Indians Diabetes Prevention [31], which reported greater adherence to healthy eating in the action and maintenance stages compared to earlier stages. The observed differences may be attributable to variations in the nutritional approaches. The Special Diabetes Program for Indians was based on the DPP intervention, which utilized the food pyramid for dietary guidance [14], whereas the present study implemented the Wheel of Cardiovascular Health Diet. This tool facilitates increased awareness of food choices and supports nutrition counseling focused on patient empowerment [18].

Lifestyle interventions, including healthy eating, are recognized strategies for preventing type 2 diabetes [14]. However, maintaining adherence to these interventions is often difficult. Individuals in the action and maintenance stages of readiness for change are generally more likely to sustain new behaviors and achieve positive outcomes. The present findings suggest that the PROVEN-DIA intervention may also benefit individuals with lower initial motivation to adopt lifestyle changes. The Wheel of Cardiovascular Health Diet, which uses visual and accessible language to increase awareness of dietary choices, may have contributed to the improvements in diet quality observed during the intervention period.

The PROVEN-DIA program utilizes a structured lifestyle modification protocol tailored for diabetes prevention. This protocol consists of regular individual and group sessions led by nutritionists, as well as weekly remote support from a facilitator to help participants achieve predefined goals. Another clinical trial reported that participants who received telephone-based support showed greater advancement in their stage of change for healthy eating compared to those in the control group [32].

Reductions in weight and BMI were observed, particularly among participants in the intervention group who were at the initial stage of readiness for change. No significant differences were found across the stages of change, which aligns with previous literature [33]. Participants in the control group also received lifestyle modification guidance based on the Wheel of Cardiovascular Health Diet.

This study presents several limitations and strengths. Although the randomized clinical trial used a probabilistic sample that included all eligible participants, an imbalance in the distribution across stages of change was identified. This imbalance is anticipated, as voluntary enrollment often indicates greater readiness for change, but it may introduce bias in statistical analyses. Additional limitations include the short follow-up period, the inability to implement blinding due to the nature of the intervention, and limited statistical power resulting from analyses based on secondary data. Diet quality and physical activity were self-reported, which may introduce recall and social desirability bias. The sample was predominantly female (71.8%) and included a high proportion of individuals with obesity (65.5%), which may limit generalizability. Furthermore, the greater likelihood of improved diet quality among participants in the precontemplation/contemplation stage who received the intervention, compared to those in the control group, showed wide confidence intervals (OR = 4.7; 95% CI = 1.2–17.8), suggesting variability and possible underpowering for subgroup analyses. Future research should extend the monitoring period, increase sample size, and further examine whether the intervention supports progression through the stages of readiness for change. Despite these limitations, the study utilized a randomized clinical trial with a standardized protocol, providing a comprehensive approach to health using validated, culturally adapted tools for the Brazilian population. The Wheel of Cardiovascular Health Diet was a central component, intended to enhance dietary awareness and help participants identify areas for improvement.

The PROVEN-DIA study is a multicenter initiative that recruited participants from five regions of Brazil. This design indicates that the lifestyle change program may be effective across diverse cultural contexts within the country, enhancing its applicability and generalizability for future public health policies targeting diabetes prevention. However, further studies with larger and more regionally diverse samples are necessary to strengthen the generalizability of these findings.

In summary, the PROVEN-DIA intervention led to improved diet quality after three months of nutritional counseling, independent of participants' readiness for change. Notably, improvements were observed among individuals at the earliest stages of readiness for change at baseline. The incorporation of the Wheel of Cardiovascular Health Diet to increase dietary awareness during counseling may have contributed to these outcomes. These results suggest that individuals with lower motivation to adopt lifestyle changes can also benefit from the PROVEN-DIA intervention. Further clinical trials in diverse populations with extended intervention and follow-up periods are recommended to validate these findings.

Declarations

Conflict of interest

All authors declare no conflicts of interest.

Author Contribution

Concept and design: A.C.B.F., J.C.A, Acquisition of data: A.V.A., O.G.K., A.P.P.F.C., J.B., S.L.P., V.S.S. Analysis or interpretation of data: A.V.A., J.C.A. Drafting of the manuscript: A.V.A. Critical revision of the manuscript for important intellectual content: J.C.A., A.C.B.F. Statistical analysis: A.V.A, J.C.A. Supervision: J.C.A.

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Data Availability

Data Availability Statement: The data are not publicly available due to privacy. Data and materials will be made available upon reasonable request to the corresponding author, following the completion of a specific form provided by Beneficência Portuguesa de São Paulo and in accordance with the institution's data sharing policies.

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Figures

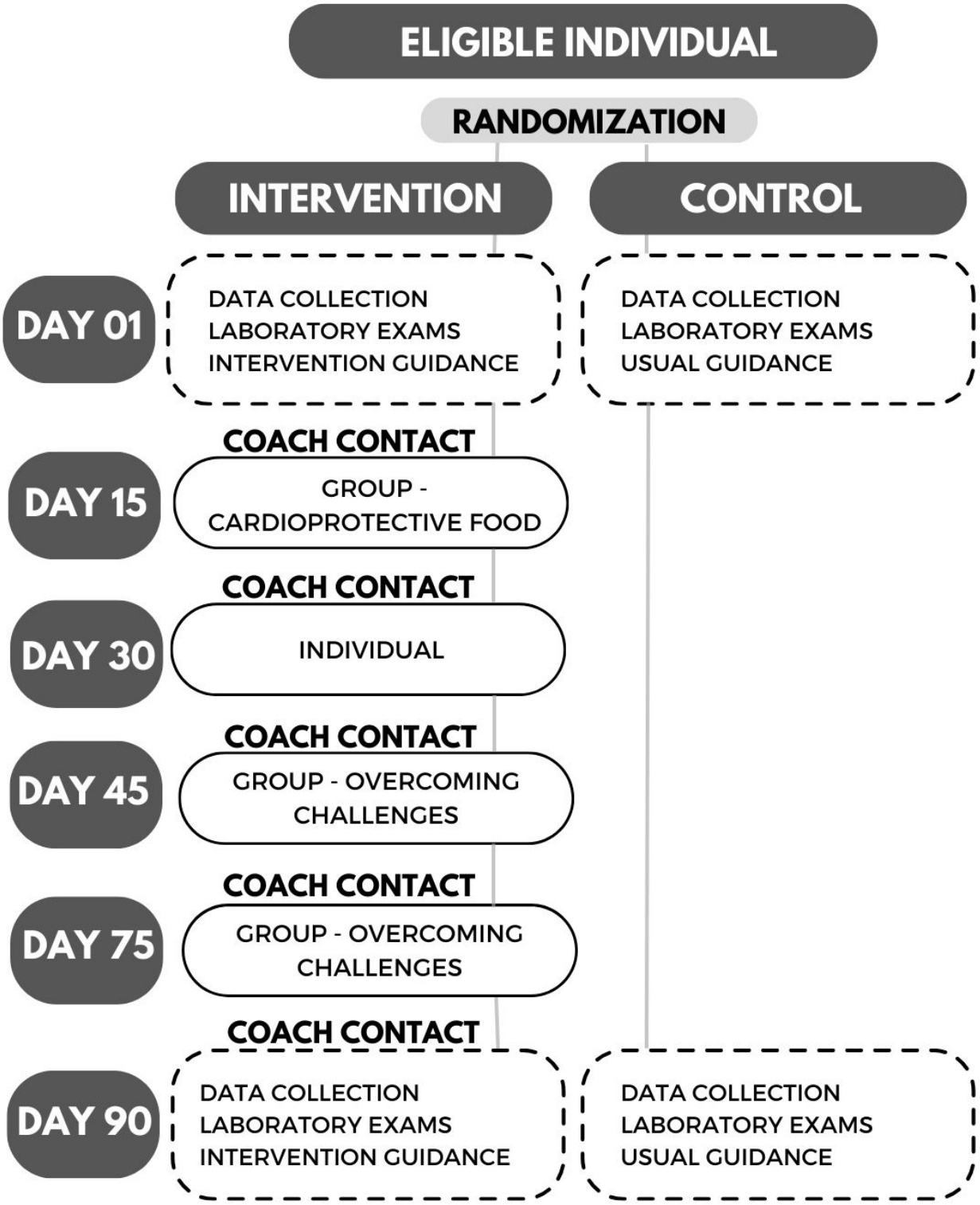


Figure 1

Protocol of the randomized clinical trial. Source: Prepared by the authors.

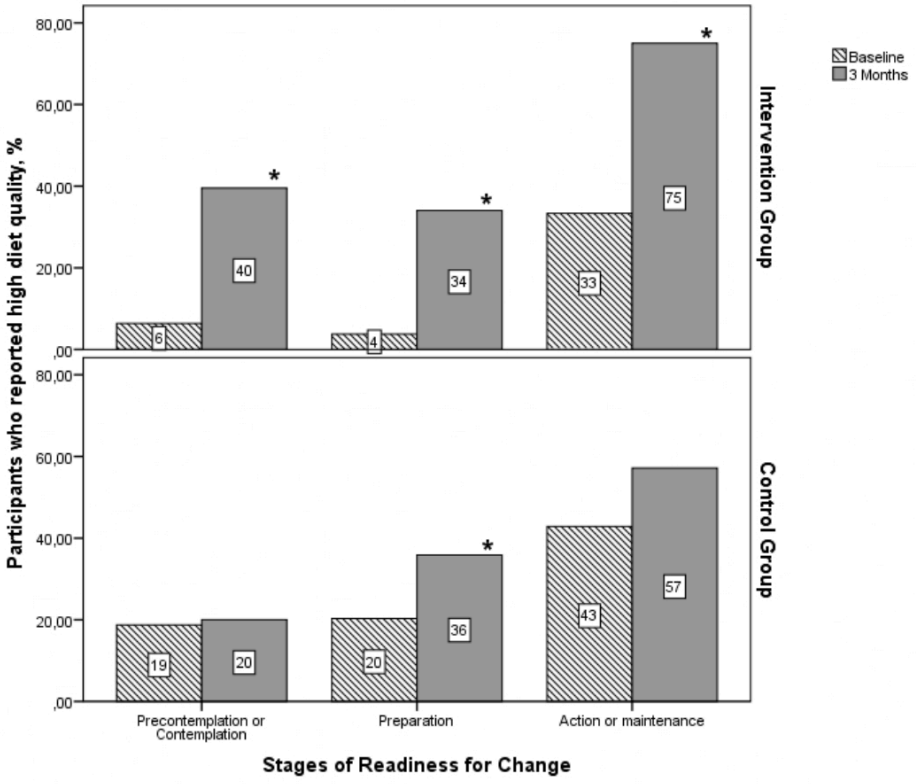


Figure 2

Proportion of participants who reported an improvement in overall diet quality based on the Wheel of Cardiovascular Health Diet (area >70%) according to intervention type and stage of change: lines = baseline; gray = 3 months post-randomization. * P<0.002 (Generalized Estimating Equations regression).

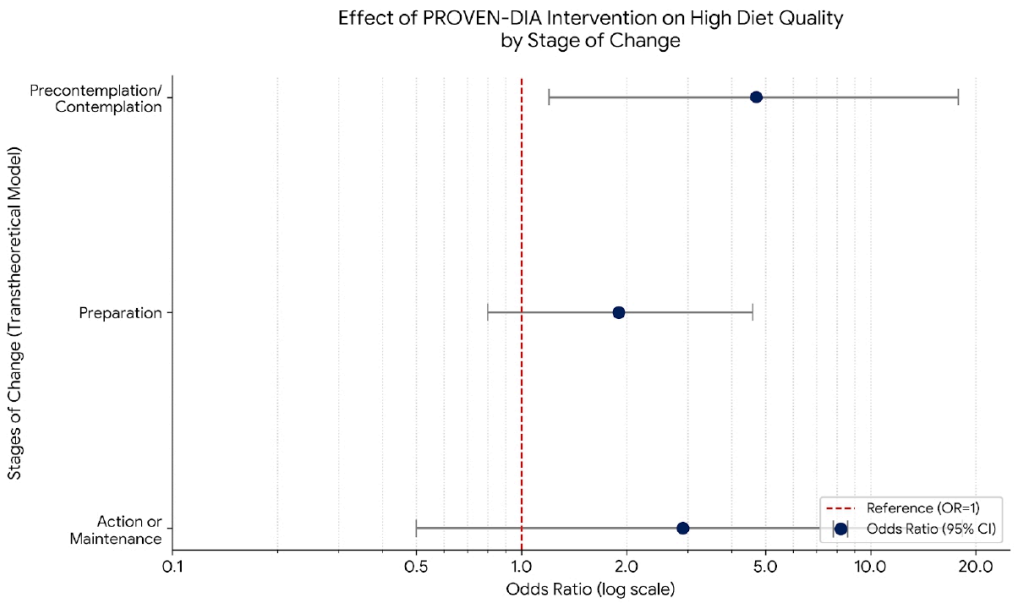


Figure 3

The odds of participants in the PROVEN-DIA intervention group improving diet quality, compared to the control group, were analyzed by the readiness stage of change using binary regression models. The dependent variable was high diet quality, defined as an area greater than 70% on the Wheel of Cardiovascular Health Diet.

Supplementary Files

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- SupplementarymaterialTABLE01.docx
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