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Effectiveness of a low-intensity nurse-led lifestyle intervention on glycaemic control in individuals with prediabetes: The PREDIPHONE randomized controlled clinical trial

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ABSTRACT

Background: Lifestyle changes can effectively prevent diabetes onset in individuals with prediabetes. Although nurse-led interventions have proven to be cost-effective and feasible in the management of diabetes and hypertension in primary care, low-intensity lifestyle interventions for people with prediabetes led by nurses remain poorly evaluated.
Objective: To assess whether a low-intensity nurse-led telephone lifestyle intervention is effective in reducing fasting plasma glucose levels in individuals with prediabetes.
Design: A two-arm, parallel, randomized controlled clinical.
Settings: Five Primary Care Centres in the Balearic Islands, Spain.
Participants: A total of 206 participants were enrolled, 103 in each group.
Methods: Consenting participants aged 25–75 years, with fasting plasma glucose levels of 100–125 mg/dL, and body mass index $\geq$27 and $<$ 40 kg/m2 were randomly assigned (1:1) to either a 9-month nurse-led telephone lifestyle intervention (intervention) or short text messages with general lifestyle advice (control). Research staff and the statistician were masked to group allocation. The primary outcome was fasting plasma glucose at 9-month follow-up, analyzed per protocol and by intention-to-treat.
Results: Among the 206 participants (103 in each group), 189 (91·8 %; n = 91 in the intervention group, n = 98 in the control group) completed the 4-month follow-up and 181 (87·9 %; n = 87 in the intervention group, n = 94 in the control group) completed the 9-month follow-up. Among the 206 randomized participants, 52.9 % were women, 73.8 % were obese, and 69.4 % were of Spanish nationality. Differences in fasting plasma glucose between groups at 9-months were not statistically significant (Intervention group n = 85 mean 103·4 mg/dL [SD 9·6] vs Control group n = 91 mean 104·8 mg/dL [SD 9·7]; adjusted mean difference 1·1 mg/dL [95 % CI -1·6 to 3·8]; p-value = 0·43). Difference in waist circumference at 9 months were statistically significant (Intervention group n = 85 mean 100.6 cm [SD 10.2] vs Control group n = 91 mean 104.0 cm [SD 10.2]; adjusted mean difference 1.9 cm [95 % CI 0.6 to 3.3]; p-value $<$0.01). At 9-month follow-up, diet quality improved in the intervention group (intervention group n = 86 mean 8.4 points [SD 2.0] vs control group n = 93 mean 7.5 points [SD 2.1], adjusted mean difference − 1.3 points [95 CI -1.7 to −0.7]; p-value $<$0.01). Likewise, sedentary behavior presented statistically significant differences at 9-month follow-up (intervention group n = 86 mean 5.4

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H/d [SD 1.8] vs control group n = 93 mean 6.3 H/d [SD 1.9], adjusted mean difference 1.0 H/d [95 CI 0.5 to 1.4]; p-value <0.01).
Conclusions: These results do not support the effectiveness of a low-intensity nurse-led telephone lifestyle intervention in reducing fasting plasma glucose in individuals with prediabetes, although changes in diet quality and sedentary behavior were observed.
Registration: https://clinicaltrials.gov/study/NCT04735640?term=prediphone&rank=1 NCT04735640. Registered 03/02/2021, first recruitment 13/04/2021.
Tweetable abstract: A nurse-led phone intervention had no significant benefits on glucose levels in patients with prediabetes. @GlobalHealth_rg.

What is already known

- High-intensity interventions prevent diabetes but are difficult to apply in practice.
- Low-intensity interventions could be easier to implement.
- Pragmatic nurse-led low-intensity interventions in prediabetes remain understudied.

What this paper adds

- Our nurse-led phone intervention shows no effect on glucose control in prediabetes.
- High-intensity interventions remain a better option to prevent type 2 diabetes.
- Further research is needed to translate high-intensity interventions into practice.

1. Background

Type 2 diabetes is one of the leading causes of morbidity and mortality worldwide, whose prevalence has steadily increased during recent decades (G. B. D. Diabetes Collaborators, 2023; N. C. D. Risk Factor Collaboration, 2016). As a consequence, the global health expenditure for type 2 diabetes has dramatically risen to US$ 966 billion in 2021, and is predicted to further increase to US$ 1054 billion in 2045 (International Diabetes Federation, 2021; Sun et al., 2022). Type 2 diabetes is generally diagnosed at an earlier age in men, whereas women remain largely undiagnosed, or tend to show a higher burden of physical and psychosocial risk factors at the time of diagnosis (Kautzky-Willer et al., 2023). Type 2 diabetes is highly likely to develop in individuals with elevated fasting plasma glucose above normal but below diabetes thresholds, a state known as prediabetes (Richter et al., 2018; Tabak et al., 2012).

In 2021, the global prevalence of prediabetes was around 5.8 % (Rooney et al., 2023), with men presenting a higher prevalence than women (Vatcheva et al., 2020). Up to 50 % of individuals with prediabetes progress to type 2 diabetes within 5 years (Richter et al., 2018), and up to 70 % over their lifetime (Tabak et al., 2012). Furthermore, cardiovascular risk in people with prediabetes is significantly higher as compared to individuals with normal glycaemic levels (Arias-Fernandez et al., 2023; Falguera et al., 2020). Therefore, prediabetes is a window of opportunity for the prevention and reduction of the burden of chronic diseases, which may in turn benefit the economy of the health systems, the health and quality of life of individuals, their families and the community (Standl et al., 2019). However, prediabetes is often overlooked by healthcare professionals. In fact, less than 25 % of individuals with this condition receive lifestyle advice or follow-up (Wu et al., 2019).

Lifestyle changes, such as diet and physical activity can effectively prevent or delay type 2 diabetes and its associated complications in individuals with prediabetes (Hemmingsen et al., 2017). The Diabetes Prevention Program (DPP) showed a reduced incidence of 34 % at 10-year follow-up with an intensive lifestyle program, while metformin reduced it by 18 % when compared to placebo (Knowler et al., 2009). Another landmark trial, the Finnish Diabetes Prevention Study, showed a 38 % relative risk reduction in type 2 diabetes incidence after an average follow-up of 9 years compared to usual care (Lindstrom et al., 2013).

Despite substantial evidence supporting the effectiveness of intensive diabetes prevention programs over the past two decades, the impact of global diabetes prevention efforts has been modest (Golovaty et al., 2023). This modest impact could be explained by the time and resources required for the implementation and maintenance of such high-intensity programs (Sanchez et al., 2018). Programs based on less intensive and pragmatic lifestyle change interventions could offer a valuable alternative, as they require fewer resources (Golovaty et al., 2023). However, while low-intensity interventions show promising, they remain poorly evaluated and represent a critical gap in evidence base (Golovaty et al., 2023; Holloway et al., 2023; Kappes et al., 2023; Tseng et al., 2023). Within the primary care context, a low-intensity program could be feasible and cost-effective, especially if led by primary care nurses.

Low-intensity nurse-led interventions in people with type 1 and type 2 diabetes have been shown to reduce fasting plasma glucose and HbA1c levels, increase medication adherence, and improve cholesterol and blood pressure levels (De la Fuente Coria et al., 2020; Holloway et al., 2023). Additionally, a systematic review of nurse-led interventions in people with hypertension significantly reduced blood pressure values (Kappes et al., 2023). When nurses possess advanced skills and are able to work autonomously with their quota of patients, they can provide continuity of care, reduce the volume of unplanned medical visits, improve patients' auto-efficacy, engagement and disease self-management, ultimately leading to significantly reduced health expenditure (Baker and Fatoye, 2017; Cengiz and Korkmaz, 2023; Coster et al., 2018; Platini et al., 2022). Focusing on the latter, a systematic review found that for each $1 spent on self-management programmes led by nurses and including patients with chronic obstructive pulmonary disease, there was a positive return in economic savings estimated at $4.8 (Baker and Fatoye, 2017). Moreover, an economic analysis in primary care demonstrated that increasing nursing staff leads to a savings of $60,000 annually from avoidable complications and improved productivity at the national level (Coster et al., 2018). To the best of our knowledge, no evidence exists on the effectiveness of low-intensity nurse-led pragmatic interventions delivered by phone to people with prediabetes (De la Fuente Coria et al., 2020; Holloway et al., 2023; Kappes et al., 2023).

Therefore, the main aim of this study was to evaluate the effectiveness of a 9-month nurse-led telephone lifestyle intervention vs short text messages on lifestyle advice in improving glycaemic control in individuals with prediabetes.

2. Methods

2.1. Study design

The PREDIPHONE study (Effects of a 9-month nurse-led telephone personalized lifestyle intervention versus automated SMSs on nutritional and physical activity advice on glucose profile in adults with prediabetes) was a two-arm, parallel, randomized controlled clinical

trial conducted in five primary care centres in Majorca, Balearic Islands, Spain. The trial protocol was previously published and includes additional information (Abbate et al., 2021). This study was registered on Clinicaltrials.gov on February 3, 2021 (NCT04735640).

2.2. Participants

A total of 206 participants were enrolled in the study, 103 were allocated to the intervention group and 103 to control group. Inclusion criteria were: age between 25 and 75 years; body mass index (BMI) $\geq$27 and < 40 kg/m2; and fasting plasma glucose between 100 and 125 mg/dL according to the American Diabetes Association criteria (American Diabetes Association, 2025). Exclusion criteria were: documented history of diabetes diagnosis and/or use of antidiabetic treatment; fasting plasma glucose $\geq$126 mg/dL; current use of systemic glucocorticoids medication; initiation of a lifestyle modification intervention focused on diet or physical activity in the previous three months; any hematologic disease affecting HbA1c results; hospital admission or major surgery in the previous three months; terminal illness, dementia, cognitive impairment, institutionalization, or any medical or psychological condition that could limit the participation; pregnancy; and/or concurrent participation in another clinical trial.

The Balearic Islands Health Information Research Platform (PRISIB) provided study nurses with a list of potentially eligible individuals from the participating primary care centres, who met age and fasting plasma glucose inclusion criteria. After a careful revision of each electronic medical record, patients confirmed as eligible were contacted by telephone and invited to participate. During the screening visit, all included patients provided written informed consent, and eligibility criteria were confirmed. Screening and recruitment took place between May 2021 and September 2022.

2.3. Sample size calculation

The sample size was estimated using fasting plasma glucose as the primary outcome, based on differences in fasting plasma glucose observed in the DPP (Knowler et al., 2009). A sample size of 212 (106 in each group) would allow to detect a difference of at least 4 mg/dL considering a SD of 8 mg/dL in fasting plasma glucose between the intervention and control group, assuming an alpha risk of 0.05, a beta risk < 0.10 (two-sided) and considering a drop-out rate of 20 %.

2.4. Randomization and masking

Randomization was performed in a 1:1 ratio to either the control or intervention group, using the online open-source Oxford Minimization and Randomization (OxMaR) programme (O'Callaghan, 2014). Minimisation factors included sex (women/men), age (< 40/$\geq$40 years), and obesity (presence/absence). These specific characteristics were selected as they are recognized as independent risk factors for the development of type 2 diabetes (Fazeli et al., 2020; Maggio and Pi-Sunyer, 2003; Tramunt et al., 2020). The allocation was performed by study nurses and was masked to all research staff, the statistician, and the principal investigator. Due to the inherent nature of the intervention, the participants and those delivering the intervention were not masked.

2.5. Data collection

The study methods have been previously described in the published protocol (Abbate et al., 2021). Briefly, study data were collected at baseline, 4-months, 9-months, and 15-months for all participants. Data on sociodemographic characteristics (age, sex self-report (women/men), birthplace, marital status, education level, employment status), family history of type 2 diabetes, tobacco and alcohol consumption, relevant concomitant diseases and medications, and height (m) were collected at baseline visit. Data on diet quality (14-item Mediterranean Diet adherence questionnaire)(Martinez-Gonzalez et al., 2012), leisure physical activity (REGICOR physical activity questionnaire) (Molina et al., 2017), sedentary behavior (Nurses' Health Study questionnaire) (Martinez-Gonzalez et al., 2005), anthropometry (BMI, and waist circumference), systolic and diastolic blood pressure, and blood samples (fasting plasma glucose, HbA1c, high-density lipoprotein cholesterol [HDL-c], low-density lipoprotein cholesterol [LDL-c], triglycerides [TG], blood uric acid, aspartate aminotransferase [GOT], alanine aminotransferase [GTP] and gamma- glutamyl transferase [GGT]) were collected at each visit.

2.6. Outcomes

The primary outcome was fasting plasma glucose at 9-month follow-up. Secondary outcomes included HbA1c, HDL-c, LDL-c, TG, blood uric acid, GOT, GTP, GGT, BMI, waist circumference, and systolic and diastolic blood pressure. Intermediate outcomes included differences in diet quality, physical activity, and sedentary behavior.

2.7. Study Intervention

Participants allocated to the intervention group received personalized dietary and physical activity advice supported by and including the 5 A's elements (Assess, Advise, Agree, Assist, and Arrange) of the behavior change model (Whitlock et al., 2002). The intervention included a first face-to-face session and 8–12 telephone consultations with a duration of 20–30 min over the 9-month follow-up. During the face-to-face session, the participant and the study nurse agreed upon an initial checklist of behavioral change goals and designed a personalized plan to address potential barriers to reaching such goals. The dietary advice followed four consecutive steps: food choices, macronutrient proportion, serving size, and caloric restriction. Concurrently, physical activity advice included five progressive steps, starting from one day per week (d/w) of aerobic exercise and one d/w of strength training, gradually increasing to three d/w of each. At follow-ups, during each phone call, the checklist and the plan were reviewed and updated, according to the patient's progress and compliance to the intervention. Informative booklets on healthy diet and physical activity were provided at baseline to support the intervention.

Participants in the control group received between 4 and 5 standardized short text messages to their mobile phone (160 characters) per week (for a total of 150 short text messages), automatically sent by the Balearic Islands Health Service. The short text messages were developed by a multidisciplinary team including patients and contained general advice on healthy lifestyle, focusing on diet and physical activity. Also, the short text messages included additional resources like websites or videos, practical tips, motivational messages, and information about community programmes. A welcome message was sent at the beginning of the intervention to verify the correct delivery and access to the text messages. These messages were not personalized and did not allow for two-way communication. Examples of text messages sent to the control group can be found in Table A.1.

2.8. Statistical analysis

Statistically significant values were p-values < 0.05 and 95 % confidence intervals (CI) were reported. The Kolmogorov–Smirnov test was used to measure the normality of the variables. All analysis was conducted in SPSS v.25 (IBM, New York, USA) and Stata v.16 (StataCorp, Texas, USA) programs.

The primary analysis was conducted per-protocol, and by intention to treat (ITT). The per-protocol analysis included participants who completed the intervention period (intervention group n = 85; control group n = 91). The intention to treat analysis included the 206 participants initially randomized, and missing values were replaced using the multiple imputation model (MICE) (White et al., 2011). Fasting plasma

glucose, measured at 4, 9 and 15-months, was analyzed using general linear modeling (ANCOVA), adjusted for baseline data and minimization factors. This model considered person as a random effect, and time (4, 9 or 15-months), and minimization factors (sex, age, and presence of obesity) as covariates.

Secondary and intermediate outcomes were analyzed using the same ANCOVA adjusted for baseline variables and minimization factors.

All the analyses were performed by the statistician who was masked to the participants identity and double-checked by a second member of the research group. There was a data and safety monitoring committee.

2.9. Ethical considerations

The trial protocol (Abbate et al., 2021) was approved by the Balearic Islands Health Research Ethics Committee (CEI-IB Ref No: IB 3947/19 PI). The research was conducted according to the guidelines in the Declaration of Helsinki. Only those individuals who agreed to sign the written informed consent after receiving the appropriate information about the study were included.

3. Results

3.1. Participants baseline characteristics

Participants were enrolled and randomized between April 13, 2021, and August 30, 2022; final follow-up was on September 27, 2023. A total of 801 individuals were assessed for eligibility and 225 were invited to the screening visit. Finally, 206 individuals were randomized to either the intervention (n = 103) or control group (n = 103). Of the 103 participants assigned to the IG, 101 received the intervention (98.1). At 4 months, 189 participants (91.4 %) returned for follow-up and 187 (90.8 %) had available data on fasting plasma glucose. At 9 months, 181 participants (87.8 %) returned for follow-up, and 176 (85.4 %) had available data on fasting plasma glucose. At 15 months, 167 participant (81.1 %) returned for the final visit, and 162 (78.6 %) had available data on fasting plasma glucose. Loss to follow-up at 4-month/9-month/15-month was due to: lost contact (8/11/20), pregnancy (0/1/1), health reasons (1/1/2), non-adherence (5/7/10), and change of residence (1/3/4). The study flow diagram is shown in Fig. 1.

Among the 206 randomized participants, 52.9 % were women, 73.8 % were obese, and 69.4 % were of Spanish nationality (Table 1). Mean age was 59.37 [SD 10.51] years, and mean fasting plasma glucose was 108.7 [SD 6.4] mg/dL (Tables 1 and 2).

3.2. Primary outcome

There were no statistically significant differences in fasting plasma glucose between groups at 9-month follow-up (intervention group n = 85 mean 103.4 mg/dL [SD 9.6] vs control group n = 91 mean 104.8 mg/dL [SD 9.7]; adjusted mean difference 1.1 mg/dL [95 % CI -1.6 to 3.8]; p-value = 0.43). Fig. A.1 shows changes in fasting plasma glucose across the intervention period per study group.

3.3. Secondary outcomes

At 4-month follow-up, a statistically significant difference was observed in GOT levels (intervention group n = 86 mean 21.5 IU/L [SD 6.7] vs control group n = 96 mean 23.3 IU/L [SD 11.5]; adjusted mean difference 2.1 IU/L [95 % CI 0.1 to 4.2]; p-value = 0.04); however, this difference was not sustained at 9- or 15-month follow-up. There was a statistically significant difference in waist circumference at 4-month follow-up (intervention group n = 88 mean 101.0 cm [SD 10.2] vs control group n = 95 mean 104.3 cm [SD 9.6]; adjusted mean difference 1.9 cm [95 % CI 0.6 to 3.2]; p-value <0.01), which was sustained at 9 months (intervention group n = 85 mean 100.6 cm [SD 10.2] vs control group n = 91 mean 104.0 cm [SD 10.2]; adjusted mean difference 1.9 cm [95 % CI 0.6 to 3.3]; p-value <0.01), but not at 15-month follow-up. At 9- or 15-month follow-up, there were no differences between groups in HbA1c, HDL-c, LDL-c, TG, Blood Uric Acid, GTP, GGT, BMI, systolic or diastolic blood pressure (Table 2 and A.2). When data were imputed, only GGT showed a statistically significant different between groups at 9-month follow-up (adjusted mean difference 16.9 IU/L [95 % CI 0.9 to 32.9]; p-value = 0.04) (Table 2).

3.4. Intermediate outcomes

Table 3 and Table A.3 provide data on diet quality, physical activity, and sedentary behavior by group at 4- 9-, and 15-month follow-up. At 4-month follow-up, diet quality improved in the intervention group (intervention group n = 89 mean 8.3 points [SD 2.1] vs control group n = 95 mean 7.4 points [SD 2.1], adjusted mean difference − 1.1 points [95 CI -1.6 to −0.7]; p-value <0.01), which was maintained at 9-month follow-up (intervention group n = 86 mean 8.4 points [SD 2.0] vs control group n = 93 mean 7.5 points [SD 2.1], adjusted mean difference − 1.3 points [95 CI -1.7 to −0.7]; p-value <0.01), as well as at 15-month follow-up (intervention group n = 82 mean 9.3 points [SD 3.1] vs control group n = 83 mean 8.2 points [SD 2.6], adjusted mean difference − 1.2 points [95 CI -1.7 to −0.6]; p-value <0.01).

Likewise, sedentary behavior presented statistically significant differences at 4-month (intervention group n = 89 mean 5.6 H/d [SD 1.9] vs control group n = 95 mean 6.1 H/d [SD 1.8], adjusted mean difference 0.6 H/d [95 CI 0 0.2 to 1.0]; p-value <0.01), which persisted at 9-month follow-up (intervention group n = 86 mean 5.4 H/d [SD 1.8] vs control group n = 93 mean 6.3 H/d [SD 1.9], adjusted mean difference 1.0 H/d [95 CI 0.5 to 1.4]; p-value <0.01). These differences also persisted at 15-month follow-up (intervention group n = 81 mean 5.7 points [SD 1.9] vs control group n = 84 mean 6.2 points [SD 1.8], adjusted mean difference 0.7 points [95 CI 0.2 to 1.2]; p-value <0.01).

No statistically significant differences were found in physical activity between groups.

3.5. Outcomes stratified by sex

Tables A.4 and A.5 provide group differences stratified by sex. In women, statistically significant differences between groups were observed in TG and waist circumference at 9-month follow-up (Table A.4). In men, the only statistically significant difference was observed in waist circumference at 9-month follow-up (Table A.5).

3.6. Additional observations

No adverse effects were observed during the study. At 9-month follow-up, 3 (1.5 %) participants progressed to type 2 diabetes, while 68 (38.6 %) reverted to normoglycemia. At 15-month follow-up, 1 (0.5 %) participant progressed to type 2 diabetes, while 65 (31.6 %) reverted to normoglycemia.

4. Discussion

This low-intensity nurse-led telephone lifestyle intervention, involving individual with prediabetes and overweight/obesity, showed no effect in reducing fasting plasma glucose, or ameliorating secondary outcomes such as HbA1c, HDL-c, LDL-c, TG, blood uric acid, GOT, GTP, GGT, BMI, systolic and diastolic blood pressure, and physical activity levels at 9 months follow-up compared to receiving short text messages, with findings relevant to both women and men. This is not in accordance with our hypothesis that a less intensive and pragmatic intervention could be as effective as, and more efficient than a high-intensity one (Golovaty et al., 2023). The lack of effect was despite a reduction in waist circumference, enhancement in dietary quality and reduction of sedentary behavior.

One possible explanation for the observed significant differences in

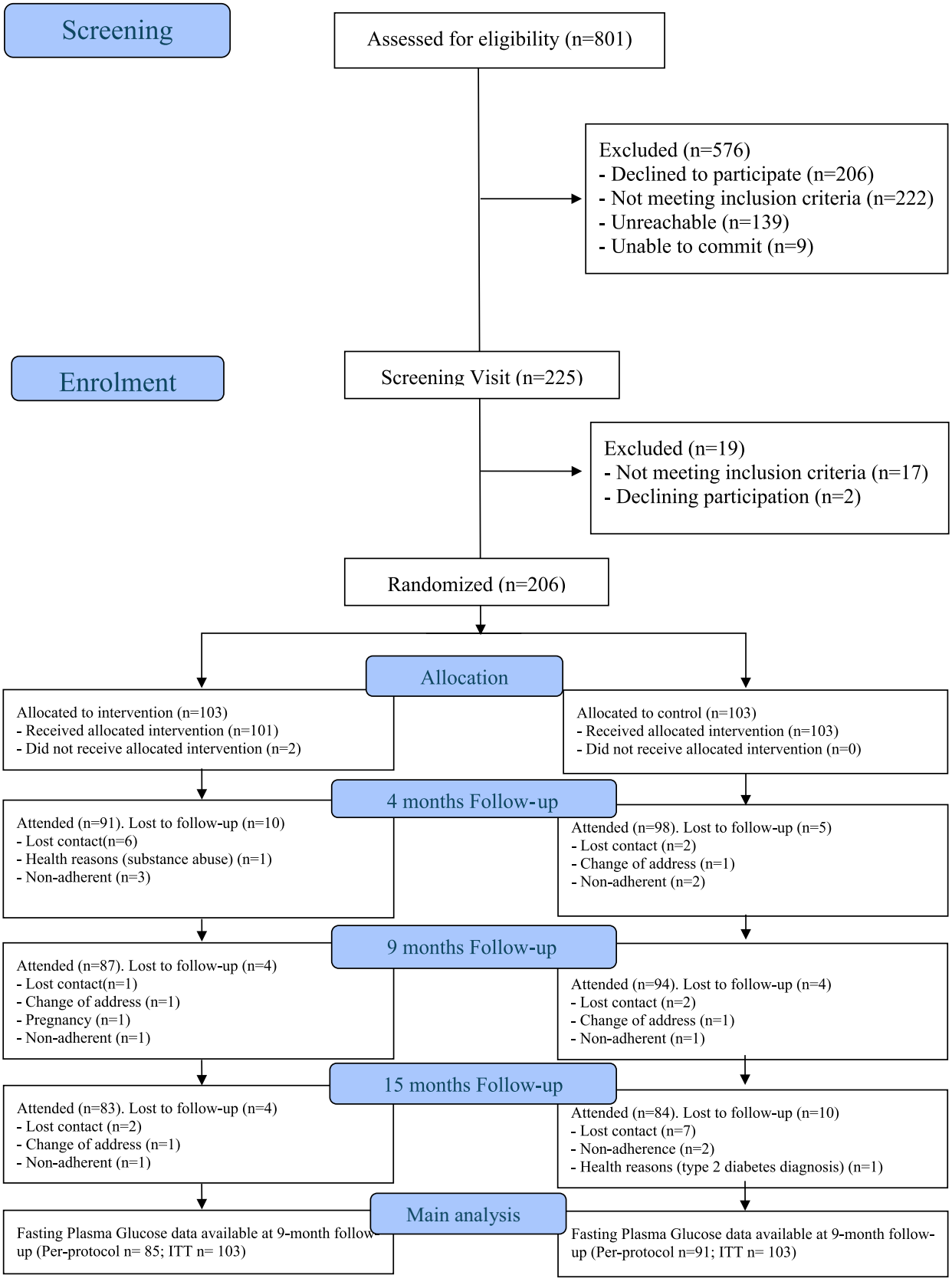

Fig. 1. Flow diagram.

Table 1
Baseline characteristics of participants.

	Whole Sample (N = 206)	Intervention (N = 103)	Control (N = 103)
Age years - Mean ± SD	59.37 ± 10.51	58.89 ± 9.76	59.84 ± 11.23
Women – no. (%)	109 (52.9)	55 (53.4)	54 (52.4)
Birthplace – no. (%)			
Spain	143 (69.4)	68 (66.0)	75 (72.8)
Central and South America	43 (20.9)	28 (27.2)	16 (15.6)
Africa	12 (5.8)	3(2.9)	9 (8.7)
Other	8 (3.9)	4 (3.9)	3 (2.9)
Marital status – no. (%)			
Married/domestic	140 (68)	73 (70.9)	67 (65.0)
Partnership	49 (23.8)	22 (22.3)	26 (25.2)
Divorced/separated/ widowed	17 (8.3)	7 (6.8)	10 (9.7)
Single			
Social Class – no. (%)			
Blue collar	164 (79.6)	80 (77.7)	84 (81.6)
White collar	42 (20.4)	23 (22.3)	19 (18.4)
Education level – no. (%)			
University degree	33 (16.0)	21 (20.4)	12 (11.7)
Secondary education	79 (38.3)	45 (43.7)	34 (33.0)
Primary education	83 (40.3)	33 (32.0)	50 (48.5)
None	11 (5.3)	4 (3.9)	7 (6.8)
Family History of T2D – no. (%)	111 (53.9)	55 (53.4)	56 (54.4)
Sedentary – no. (%)	65 (31.6)	36 (35.0)	29 (28.2)
BMI categories – no. (%)			
Overweight	54 (26.2)	27 (26.2)	27 (26.2)
Obesity	152 (73.8)	76 (73.8)	76 (73.8)
Tobacco – no. (%)			
Never	93 (45.1)	47 (45.6)	46 (44.7)
Former	84 (40.8)	44 (42.7)	40 (38.8)
Current	28 (13.5)	11 (10.7)	17 (16.5)
Low HDL-c – no. (%)	33 (16.0)	20 (19.4)	13 (12.6)
High TG – no. (%)	77 (37.4)	44 (42.7)	33 (32.0)
Hypertension – no. (%)	136 (66.0)	64 (62.1)	72 (69.9)
Dyslipidaemia – no. (%)	186 (91.2)	92 (89.3)	94 (91.3)
Medication – no. (%)			
Antihypertensive treatment	104 (50.5)	49 (47.6)	53 (51.5)
Hypolipidemic treatment	90 (43.7)	43 (41.7)	45 (43.7)
Antiplatelet treatment	19 (2.2)	9 (8.7)	8 (7.8)

Note: T2D, type 2 diabetes; HDL-c, high-density lipoprotein cholesterol; TG, triglycerides; SD, standard deviation; %, percentage.

waist circumference, dietary quality, and sedentary behavior between groups, despite the overall lack of effect on primary and secondary outcomes, could be the subjective nature of these measures. Dietary quality and sedentary behavior questionnaires were administered by researchers, making results possibly subjected to the Clever Hans effect (Samhita and Gross, 2013). Additionally, the study was non-blinded, which might also have introduced assessment bias during data collection for these subjective measures (Rothman et al., 2008).

Our study aimed to fill in the paucity of evidence on the effectiveness of low-intensity interventions, as suggested by an expert consensus on diabetes prevention through lifestyle changes (Golovaty et al., 2023). In line with our results, few previous pragmatic randomized controlled trials also found no statistically significant differences in reducing BMI or improving glycaemic status with a low-intensity lifestyle intervention (4–5 sessions over one year or 6 sessions over six months, along a digital app) (Hesselink et al., 2015; Lakka et al., 2023). According to a systematic review, this limited effect—or rather not achieving a weight reduction of at least 5 %—could be explained by a generalized non-adherence and high drop-out rates due to a weak employment of evidence-based behavioral change strategies (Tseng et al., 2023). In our case, although we used evidence-based behavioral change strategies, such as 5 A's and goal setting, we believe that the nature of the intervention was not intensive enough to engage participants for significant changes in weight or glycaemic status.

Conversely, high-intensity interventions such as the DPP and the Diabetes Prevention Study—characterized by frequent sessions of insensitive behavioral change therapy—have been shown to effectively achieve a $\geq$ 5 % weight loss within the first year (Knowler et al., 2009; Lindstrom et al., 2013). Moreover, although the initial weight difference between the lifestyle intervention and control groups decreases over time, over the 10-year follow-up the weight in the intervention group does not return to baseline values, showing the lasting effect of these high-intensity programs (Knowler et al., 2009; Lindstrom et al., 2013).

A possible explanation for our results could be related to the delivery of the lifestyle advice (diet and physical activity). Our pragmatic intervention was delivered via 8–12 telephone consultations over 9 months and only one face-to-face session. A previous metanalysis concluded that technology-mediated type 2 diabetes prevention interventions had a marginal effect on decreasing fasting plasma glucose levels and body weight, unless they were DPP-based. Specifically, the non DPP-based interventions showed a weight loss of 2.4 kg, while the DPP-based ones showed a weight reduction of 4.8 kg. The only successful telephone-delivered intervention was DPP-based (including 28 consultations with a primary care provider or a dietitian in the first year and a minimum of 12 sessions in the second year), and showed a 4.6 kg weight reduction (Bian et al., 2017). When technology-mediated DPP-based interventions are coupled with frequent face-to-face behavioral support their effectiveness is further improved compared to remote or no support (Joiner et al., 2017; Villegas et al., 2022). Although our lifestyle intervention was evidence-based, it was not DPP-based, and the behavioral support was exclusively delivered by phone.

Also, our intervention was delivered individually. Although this type of delivery could help build a patient-care provider trust relationship, group interventions have been shown to be more effective in improving clinical, lifestyle, and psychosocial outcomes in people with prediabetes and type 2 diabetes, possibly due to improved adherence (De la Fuente Coria et al., 2020; Odgers-Jewell et al., 2017). Peer support in group-based interventions promotes mutual and close relationships, whilst enhancing the effectiveness of the interventions (Lakka et al., 2023; Odgers-Jewell et al., 2017). Moreover, group interventions offer cost-effective and time-efficient solutions for the prevention of type 2 diabetes (De la Fuente Coria et al., 2020).

The lack of effectiveness of our intervention should not be attributed to the fact that it was nurse-led, but rather to its low intensity; in fact, high-intensity nurse-led interventions have been shown to be feasible and effective in managing type 2 diabetes (Holloway et al., 2023; Kappes et al., 2023). In a pragmatic cluster randomized trial on the efficacy of a nurse-led telephone intervention at different call frequencies in people with prediabetes, fasting plasma glucose was reduced in the high-frequency group only (Holloway et al., 2023). Therefore, nurse-led interventions should be high-intensity, and further research should focus on their implementation in primary care.

Finally, in Spain, primary care centres are strategically located across neighborhoods, facilitating easy healthcare access and community engagement and interaction. However, our study was neither driven nor conducted by the community. A recent systematic review about community-driven interventions among young individuals with prediabetes suggested that these interventions can reduce weight. Nevertheless, it concluded that methodologically robust and long-term studies are needed to evaluate whether the beneficial effects could last over time (Spurr et al., 2024). Furthermore, community-driven initiatives in urban areas among the general population strongly improve the sense of community, social capital, and social cohesion within the neighborhood, which can lead to health improvement in the long term (Nickel and von dem Knesebeck, 2020). Community-driven interventions could offer an opportunity for type 2 diabetes prevention (Spurr et al., 2024), but further validation and comprehensive studies are needed.

Table 2
Changes in values between baseline, 4-month follow-up, and 9-month follow-up of the participants according to group.

	Whole Sample		Intervention		Control		Adjusted mean differences (95 % CI) Control VS Intervention	p-value	ITT Analysis. Imputed adjusted mean differences (95 % CI) Control VS Intervention	p-value
	N	Mean ± SD	N	Mean ± SD	N	Mean ± SD				
FPG - mg/dL										
Baseline	206	108.7 ± 6.4	103	108.7 ± 6.6	103	108.7 ± 6.2				
4 months	187	103.2 ± 10.6	89	103.4 ± 10.7	98	103.1 ± 10.6	−0.5 (−3.4, 2.4)	0.75	−0.7 (−3.8, 2.3)	0.62
9 months	176	104.1 ± 9.6	85	103.4 ± 9.6	91	104.8 ± 9.7	1.1 (−1.6, 3.8)	0.43	1.1 (−1.9, 4.2)	0.47
HbA1c - %										
Baseline	158	5.90 ± 0.34	79	5.91 ± 0.32	79	5.89 ± 0.37				
4 months	175	5.86 ± 0.33	86	5.82 ± 0.33	89	5.89 ± 0.33	0.1 (−0.0, 0.1)	0.23	0.1 (−0.0, 0.1)	0.29
9 months	166	5.89 ± 0.34	80	5.85 ± 0.29	86	5.32 ± 0.39	0.1 (−0.0, 0.1)	0.12	0.1 (−0.0, 0.2)	0.13
HDL-c - mg/dL										
Baseline	197	49.72 ± 10.65	98	48.70 ± 10.82	99	51.46 ± 12.82				
4 months	183	50.57 ± 10.18	89	50.30 ± 10.32	94	50.83 ± 10.10	−0.9 (−2.6, 0.7)	0.27	−1.3 (−3.1, 0.4)	0.13
9 months	176	51.74 ± 10.46	85	51.32 ± 10.86	91	52.14 ± 10.12	−0.3 (−2.0, 1.4)	0.70	−0.4 (−2.1, 1.3)	0.66
LDL-c - mg/dL										
Baseline	194	119.3 ± 29.5	95	119.1 ± 29.0	99	118.7 ± 30.9				
4 months	183	118.1 ± 29.6	89	116.1 ± 27.9	94	119.9 ± 31.1	3.4 (−2.8, 9.7)	0.29	3.7 (−3.2, 10.7)	0.29
9 months	174	120.1 ± 31.3	83	119.9 ± 31.5	91	120.3 ± 31.2	1.7 (−5.6, 9.0)	0.65	2.1 (−5.7, 10.0)	0.59
TG - mg/dL										
Baseline	199	150.6 ± 139.0	100	171.1 ± 185.2	99	129.8 ± 59.4				
4 months	184	140.9 ± 71.8	89	142.6 ± 76.0	95	137.5 ± 68.0	−0.12 (−18.5, 18.3)	0.99	4.1 (−16.3, 24.6)	0.69
9 months	176	133.1 ± 74.1	85	133.4 ± 81.7	91	132.8 ± 66.7	10.9 (−5.6, 27.5)	0.19	11.8 (−6.9, 30.5)	0.22
Blood Uric Acid - mg/dL										
Baseline	190	5.8 ± 1.5	98	5.8 ± 1.6	92	5.7 ± 1.4	0.1 (−0.2, 0.3)	0.60	0.1 (−0.1, 0.4)	0.36
4 months	181	5.7 ± 1.4	86	5.7 ± 1.4	95	5.8 ± 1.4	0.0 (−0.2, 0.3)	0.73	0.1 (−0.1, 0.3)	0.46
9 months	173	5.5 ± 1.4	84	5.6 ± 1.5	89	5.5 ± 1.3				
GOT - IU/L										
Baseline	191	24.3 ± 12.1	97	25.1 ± 13.2	94	23.4 ± 10.8				
4 months	182	22.4 ± 9.5	86	21.5 ± 6.7	96	23.3 ± 11.5	2.1 (0.0, 4.2)	0.04*	1.4 (−1.0, 3.9)	0.23
9 months	175	23.0 ± 12.5	85	22.3 ± 8.6	90	23.7 ± 15.4	1.9 (−1.1, 4.9)	0.22	1.9 (−1.5, 5.3)	0.28
GTP - IU/L										
Baseline	193	27.4 ± 18.6	97	29.2 ± 23.3	96	25.6 ± 12.0				
4 months	186	25.0 ± 12.4	88	24.5 ± 11.9	98	25.3 ± 12.9	1.2 (−1.3, 3.8)	0.35	1.0 (−1.8, 3.8)	0.49
9 months	175	24.2 ± 11.2	84	23.5 ± 10.0	91	24.9 ± 12.2	2.3 (−0.4, 5.0)	0.09	2.1 (−0.8, 5.0)	0.15
GGT - IU/L										
Baseline	193	43.5 ± 59.1	96	47.7 ± 75.6	97	39.4 ± 35.7				
4 months	185	39.2 ± 43.7	88	35.1 ± 32.6	97	39.9 ± 41.9	8.6 (−0.6, 17.8)	0.07	9.1 (−0.9, 19.0)	0.07
9 months	175	38.4 ± 63.9	84	32.3 ± 24.8	91	44.0 ± 85.2	12.9 (−2.4, 28.2)	0.10	16.9 (0.9, 32.9)	0.04*
BMI - kg/m2										
Baseline	206	32.3 ± 3.5	103	32.1 ± 3.4	103	32.4 ± 3.6				
4 months	185	31.6 ± 3.5	90	31.4 ± 3.4	95	31.7 ± 3.7	0.2 (−0.1, 0.4)	0.31	0.1 (−0.2, 0.5)	0.43
9 months	179	31.5 ± 3.6	86	31.3 ± 3.4	93	31.8 ± 3.8	0.2 (−0.2, 0.6)	0.27	0.3 (−0.2, 0.7)	0.21
WC - cm										
Baseline	206	105.4 ± 10.1	103	104.6 ± 10.5	103	106.2 ± 9.6				
4 months	183	102.7 ± 10.0	88	101.0 ± 10.2	95	104.3 ± 9.6	1.9 (0.6, 3.2)	<0.01*	2.0 (0.6, 3.5)	<0.01*
9 months	176	102.4 ± 10.3	85	100.6 ± 10.2	91	104.0 ± 10.2	1.9 (0.6, 3.3)	<0.01*	2.0 (0.5, 3.5)	<0.01*
Systolic BP - mmHg.										
Baseline	206	136.7 ± 14.6	103	134.7 ± 14.4	103	138.6 ± 14.6	2.0 (−1.2, 5.3)	0.22	2.0 (−1.6, 5.6)	0.29
4 months	183	132.6 ± 14.6	88	130.2 ± 14.1	95	134.7 ± 14.8	0.1 (−3.4, 3.6)	0.96	0.4 (−3.3, 4.0)	0.84
9 months	177	134.4 ± 14.4	85	133.7 ± 13.6	92	135.1 ± 15.1				
Diastolic BP - mmHg.										
Baseline	206	84.4 ± 9.3	103	84.6 ± 9.2	103	84.3 ± 9.5	0.1 (−2.0, 2.3)	0.91	0.2 (−2.1, 2.5)	0.86
4 months	183	82.5 ± 9.1	88	82.5 ± 8.8	95	82.6 ± 9.4	−1.3 (−3.3, 0.8)	0.23	−1.5 (−3.6, 0.6)	0.16
9 months	177	82.2 ± 8.7	85	83.0 ± 8.9	92	81.5 ± 8.4				

Note: 95 % CI, 95 % confidence intervals; FPG, fasting plasma glucose; HDL-c, high-density lipoprotein cholesterol (HDL-c); LDL-c, low-density lipoprotein cholesterol; TG, triglycerides; GOT, aspartate aminotransferase; GTP, alanine aminotransferase; GGT, gamma-glutamyl transferase; BMI, body mass index; WC, Waist circumference; BP, blood pressure; ITT, Intention to treat; SD, standard deviation; %, percentage.

4.1. Limitations

Our study and results present some limitations. First, given that 30.6 % of the sample were migrants, the intervention may not have effectively addressed their unique cultural or socioeconomic requirements. Secondly, there was no community or patient involvement during the design of the intervention, thus possible preferences were not considered. Additionally, the active control group receiving short text messages could have experienced a minor effect that may have influenced our results. Due to the COVID-19 pandemic, the timeline, and financial limitations, we could not reach the planned sample size, although we have enough statistically power to test the main outcome. Many potential participants declined to visit the Primary care centre for the baseline visit, complicating and significantly slowing down the recruitment phase and potentially affecting the representativeness and generalisability of the results to non-pandemic conditions (Abbate et al., 2021). Despite these limitations, the high follow-up rate (85 %) and the pragmatic nature of the intervention provide a degree of confidence that

Table 3
Changes in intermediate outcomes between baseline, 4-month follow-up, and 9-month follow-up according to group.

	Whole Sample		Intervention		Control		Adjusted mean differences (95 % CI) Control VS Intervention	
	N	Mean ± SD	N	Mean ± SD	N	Mean ± SD		p-value
Diet quality -								
Baseline	205	7.0 ± 2.0	102	6.9 ± 2.0	103	7.2 ± 2.0		
4 months	184	7.8 ± 2.2	89	8.3 ± 2.1	95	7.4 ± 2.1	−1.1 (−1.6, −0.7)	<0.01*
9 months	179	7.9 ± 2.1	86	8.4 ± 2.0	93	7.5 ± 2.1	−1.3 (−1.7, −0.7)	<0.01*
PA – M/w								
Baseline	206	389.1 ± 389.1	103	370.8 ± 370.2	103	407.5 ± 408.1		
4 months	184	487.1 ± 423.5	89	501.0 ± 410.6	95	474.1 ± 436.9	5.3 (−47.6, 58.3)	0.84
9 months	179	479.9 ± 467.0	86	521.0 ± 528.6	93	442.3 ± 400.9	2.6 (−43.6, 48.9)	0.91
Sedentary Behavior – H/d								
Baseline	206	5.8 ± 1.9	103	5.9 ± 2.0	103	5.7 ± 1.7		
4 months	184	5.8 ± 1.9	89	5.6 ± 1.9	95	6.1 ± 1.8	0.6 (0.2, 1.0)	<0.01*
9 months	179	5.9 ± 1.9	86	5.4 ± 1.8	93	6.3 ± 1.9	1.0 (0.5, 1.4)	<0.01*

Note: 95 % CI, 95 % confidence intervals; PA, physical activity; M/w, minute per week; H/d, hour per day; SD, standard deviation.

the results can inform similar low-intensity, primary care-based interventions aimed at preventing type 2 diabetes in individuals with prediabetes.

5. Conclusions

In conclusion, this low-intensive nurse-led telephone intervention had no statistically significant benefits in improving fasting plasma glucose or other secondary parameters, except waist circumference, in people with prediabetes. Some intermediate variables, such as diet quality and sedentary behavior, were improved and remained consistent throughout the 9-month follow-up. Our results indicate that efforts should be made to culturally adapt and implement high-intensity type 2 diabetes prevention programs that have been proven effective, rather than focusing on testing new low-intensity interventions. Further research could also evaluate nurse-led and community-driven interventions in an effort to successfully prevent type 2 diabetes.

CRediT authorship contribution statement

María Arias-Fernández: Writing – original draft, Visualization, Investigation, Formal analysis. **Aina Huguet-Torres:** Writing – review & editing, Investigation, Formal analysis. **Manuela Abbate:** Writing – review & editing, Visualization, Validation, Supervision, Methodology, Investigation, Data curation. **Sergio Fresneda:** Writing – review & editing, Methodology, Investigation. **Marina Torres-Carballo:** Writing – review & editing, Investigation. **Ana Carvalho-Azevedo:** Writing – review & editing, Data curation. **Aina M. Yañez:** Writing – review & editing, Validation, Supervision, Project administration, Methodology, Formal analysis, Conceptualization. **Miquel Bennasar-Veny:** Writing – review & editing, Supervision, Resources, Project administration, Methodology, Funding acquisition, Conceptualization.

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Declaration of competing interest

The study investigators declare no conflict of interest.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ijnurstu.2025.105034.

Data availability

The dataset generated during and/or analyzed in the current study is available from the corresponding author (M.A.) upon reasonable request.

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