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Nurse-Led Multidisciplinary Care for Type 2 Diabetes: Protocol for a Feasibility Pilot Randomized Controlled Trial

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Abstract

Objective: To assess the feasibility of a nurse-led multidisciplinary intervention to improve self-management, psychological distress, and medication adherence in patients with type 2 diabetes (T2D) in Iran, informing a future definitive randomized controlled trial (RCT).

Materials and Methods: This single-blind, parallel-group pilot RCT will recruit 60 adults with T2D (HbA1c> 6.5%) from the Yazd Diabetes Research Center, Iran. Participants will be randomized 1:1 to a 6-month intervention or usual care. The intervention, grounded in self-efficacy theory and motivational interviewing, comprises 3 months of in-person/online counseling (three sessions targeting American Diabetes Association–endorsed self-care behaviors: diabetes knowledge, nutrition counseling, physical activity, glucose monitoring, medication adherence, and cardiovascular risk reduction) delivered by a nurse-led team (endocrinologist, dietitian, psychologist), followed by 3 months of biweekly telephone follow-ups. Feasibility outcomes include recruitment (>70%), retention (>80%), acceptability (Likert score >4/5), and data completeness (>90%). Exploratory outcomes include HbA1c, fasting blood sugar, low-density lipoprotein, blood pressure, anthropometric indices, dietary self-management assessed by the Diabetes Self-Management Questionnaire-Revised, diabetes-related distress measured by the Diabetes Distress Scale-17, and medication adherence evaluated by the Medication Adherence Report Scale-5, collected at baseline, 3 months, and 6 months. Data will be analyzed descriptively (proportions, means, 95% CIs) using SPSS v25.

Results: It is merely a proposed research protocol that can be used in the future.

Conclusion: This pilot will evaluate the feasibility of a culturally tailored, nurse-led multidisciplinary intervention for T2D management in Iran, providing data to refine a definitive RCT and inform care models in resource-constrained settings.

Keywords: Diabetes mellitus, Nurses; Multidisciplinary, Medication adherence, Self-management

QR Code:

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Introduction

Non-communicable diseases (NCDs) remain the leading global cause of mortality, accounting for 71% of all deaths annually (1). Among these, diabetes mellitus (DM), characterized by impaired insulin secretion or utilization, poses a major public health challenge (2). Type 2 diabetes (T2D) represents more than 90% of all diabetes cases (3) and caused 6.7 million deaths worldwide in 2021, with projections indicating it will rank as the seventh leading cause of mortality by 2030 (4). In Iran, the prevalence of T2D is approximately 9.6%, affecting nearly 5 million adults (5).

T2D is associated with microvascular and macrovascular complications that significantly diminish quality of life and impose substantial economic burdens on healthcare systems (6-8). Optimal management requires sustained glycemic control (HbA1c), alongside regulation of cardiovascular risk factors such as hypertension, dyslipidemia, obesity, and unhealthy diet (9). However, many patients fail to achieve adequate control due to challenges in daily self-management, psychological distress, and low medication adherence (10,11). The American Diabetes Association (ADA) emphasizes person-centered care, advocating for patient empowerment and active participation in treatment decisions to enhance self-management (12).

Psychological distress, including anxiety, depression, and diabetes-specific emotional burden, is common and contributes to treatment non-adherence and poor metabolic outcomes (13,14).

Medication adherence varies widely (36-90%) and tends to decline after six months (15). A systematic review found that 43.4% of patients were non-adherent to their antidiabetic medications, which was linked to poor glycemic control. In contrast, effective self-management was associated with improved LDL-C levels (16). Despite the multidimensional nature of T2D, care delivery in many settings, including Iran, remains fragmented, with limited coordination across providers (17). Multidisciplinary care, integrating nurses, physicians, dietitians, and mental health professionals, has been recommended to address these gaps (18,19). Nurse-led models have demonstrated improvements in clinical outcomes, access to care, and reductions in unplanned hospitalizations (20). Evidence also supports the value of nurse-led multidisciplinary care in diverse populations, including patients undergoing hemodialysis and those with diabetic foot complications (21,22). A review further supports the positive impact of nurse-led interprofessional care on patient outcomes (23).

Although multidisciplinary diabetes care has been increasingly emphasized globally, Iranian evidence remains limited, fragmented, and primarily focused on single-component interventions, such as education-only programs, diet counseling, or clinic-based physician-led care (11,24). Few Iranian studies have evaluated integrated, team-based, nurse-led models, and existing studies often suffer from small sample sizes, lack of theoretical grounding, limited follow-up, and absence of feasibility testing before implementation (17,25).

Additionally, the coordination between endocrinologists, dietitians, psychologists, and nurses in Iran is often operationally weak, with no published pilot trials assessing structured nurse-led multidisciplinary interventions for T2D self-management, psychological distress, and medication adherence (22). This highlights a critical evidence gap and underscores the need for feasibility testing prior to a large-scale trial.

Given the rising burden of T2D in Iran, the challenges in self-management and adherence, and the limited evidence on structured nurse-led multidisciplinary models, a pilot study is warranted. This feasibility trial will assess recruitment, retention, acceptability, and data

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collection procedures to inform a future definitive randomized controlled trial (RCT).

Hypothesis

The nurse-led multidisciplinary care intervention is expected to be feasible and demonstrate differences in clinical outcomes, self-management, psychological distress, and medication adherence between the intervention and control groups at three- and six-months post-intervention, without implying efficacy.

Main objective

To assess the feasibility of a nurse-led multidisciplinary care intervention for patients with type 2 diabetes, focusing on clinical outcomes, self-management, psychological distress, and medication adherence.

Specific objectives

1. To evaluate the feasibility of the intervention through recruitment rate, retention rate, intervention acceptability, and data completeness.
2. To determine and compare mean clinical outcomes (FBS, HbA1c, LDL, systolic and diastolic blood pressure) in T2D patients between groups at baseline, three months, and six months.
3. To determine and compare mean diabetes self-management scores in T2D patients between groups at baseline, three months, and six months.
4. To determine and compare mean diabetes-related psychological distress scores in T2D patients between groups at baseline, three months, and six months.
5. To determine and compare mean medication adherence scores in T2D patients between groups at baseline, three months, and six months.
6. To determine and compare mean anthropometric indices (including body weight, body mass index (BMI), waist circumference, hip circumference, and waist-to-hip ratio) and dietary outcomes (including total daily energy intake, macronutrient distribution (carbohydrates, proteins, fats), carbohydrate counting, dietary fiber intake, and adherence to healthy eating patterns) in patients with T2D between groups at baseline, three months, and six months.

Material and methods

Trial design

This protocol describes a single-blind, parallel-group, feasibility pilot RCT evaluating a nurse-led multidisciplinary intervention for adults with T2D. The design adheres to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines, adapted for pilot studies per the CONSORT extension for randomized pilot and feasibility trials, prioritizing feasibility outcomes over efficacy. Participants are randomized 1:1 to either the intervention or usual care control arm, with outcome assessors blinded to minimize detection bias. Participant blinding is not feasible due to the nature of the behavioral intervention. The trial spans 6 months per participant, consisting of a 3-month active intervention phase followed by a 3-month follow-up period. Primary feasibility objectives include achieving a recruitment rate of more than 70% among eligible patients, a retention rate of more than 80% at 6 months, intervention acceptability (as indicated by a mean score greater than 4 on a 5-point Likert scale), and data completeness of more than 90% for outcome measures. These metrics will be reported descriptively, along with 95% confidence intervals, to assess scalability for a definitive RCT.

Study population and setting

The study targets adults with T2D attending the Diabetes Research and Treatment Center, a specialized outpatient facility at Shahid Sadoughi University of Medical Sciences in Yazd, Iran. This setting was chosen for its robust infrastructure, which supports multidisciplinary diabetes care, ensuring real-world applicability. Eligible participants are adults aged ≥18 years with a confirmed T2D diagnosis (≥6 months, verified by medical

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records), HbA1c >6.5% (indicating suboptimal glycemic control) from the most recent test within 3 months or at baseline, proficient in Persian (intervention language), with sufficient cognitive capacity to engage in education and complete questionnaires, access to a telephone for follow-ups, at least two prior center visits in the past year, regular use of oral antidiabetic medications or insulin, full mental competency, and willingness to provide written informed consent and undergo assessments. Exclusion criteria include type 1 diabetes, severe psychiatric or cognitive disorders under treatment, significant sensory impairments (e.g., severe vision/hearing loss) precluding participation, or life-threatening/unstable comorbidities (e.g., advanced renal failure, active cancer, acute cardiovascular/cerebrovascular events). Participants will be withdrawn if they develop treatment-disrupting complications, die, withdraw consent, miss ≥2 in-person sessions, are hospitalized for acute illness, relocate, or become unreachable for follow-ups.

Recruitment, randomization, and allocation concealment

Recruitment employs purposive sampling, targeting patients T2D during routine clinic visits. Following permissions from the university's research deputy and center management, eligible patients will be identified via medical records, physician referrals, clinic posters, and announcements. Study objectives, procedures, and the voluntary nature will be explained verbally and in writing, with written informed consent obtained prior to enrollment.

Sample size is informed by pilot trial guidelines, referencing nurse-led diabetes intervention studies (1,2). Using Whitehead et al. (2016) (3) for effect sizes (10-75 per arm), Browne (1995) (4) for a total of 30, Julius (2005) (5) For≥12 participants per group, and using upper confidence limit/non-central t-distribution methods (α= 0.05, power= 80%), we aim for 30 participants per arm (60 total), allowing for 10-15% attrition.

Randomization employs block randomization (block size 4,1:1 ratio) generated via sealedenvelope.com. An independent statistician prepares the sequence, sealed in 60 opaque, numbered envelopes. A non-involving staff member opens the envelopes sequentially upon enrollment to assign participants to either the intervention group (Group A) or the control group (Group B). Allocation concealment is ensured through the use of sealed envelopes, and assessor blinding minimizes bias.

Interventions

The intervention is a 6-month nurse-led, multidisciplinary program grounded in self-efficacy theory and motivational interviewing (MI), designed to enhance self-management of T2D through integrated care. The team comprises a trained nurse (researcher), an endocrinologist, a dietitian, and a clinical psychologist, fostering collaborative, patient-centered decision-making. The program includes 3 months of in-person or online video counseling sessions and 3 months of telephone follow-ups, with flexibility for patient preferences (e.g., Eita app for video). Intervention fidelity is ensured through MI training (comprising three sessions under the supervision of a psychologist), session logs, and audio recordings (with consent), which are audited biweekly by a supervisor.

Multidisciplinary team roles

Nurse (Researcher):

Leads the intervention, delivering MI-based counseling and follow-ups, coordinating team communication, and providing patient updates to other members. Receives 3 MI training sessions from the psychologist.

Endocrinologist:

Monitors clinical outcomes (HbA1c, LDL-C, blood pressure) during visits, adjusting treatments based on nurse reports.

Dietitian:

Delivers personalized nutrition counseling (in-person/online) per ADA guidelines, focusing on carbohydrate counting and

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distribution, glycemic index of food intake, and dietary habits based on My Plate and My Pyramid guidelines for diabetic patients, with follow-ups as needed.

Psychologist:

Conducts up to three 45-minute sessions (in-person/online) for patients with high distress (based on DDS-17 scores or nurse/physician referral), emphasizing coping strategies.

In-person/online counseling (months 1-3)

Three sessions (baseline, 1.5 months, and 3 months; each 30-45 minutes) target seven ADA-endorsed self-care behaviors: diabetes knowledge, healthy nutrition, physical activity, glucose monitoring, medication adherence, risk reduction, and effective coping/problem-solving. Each session begins with a 2-5-minute multimedia video (text, images, audio) tailored to the session's focus, followed by MI-guided discussions on comprehension, barriers, and personalized goal-setting using techniques like open questions, reflective listening, affirmations, and summaries (Table 1). The first session is held in-person at the center; subsequent sessions are conducted online via video, with SMS reminders sent 48 hours in advance. Active participation in two or more sessions is required for follow-up eligibility. Videos are shared via messaging apps. Table 2 details session content, objectives, materials, and interactive activities.

Telephone follow-up (months 4-6)

Six biweekly calls (20-30 minutes) reinforce self-care behaviors, using MI to assess adherence, identify new learning needs, and facilitate referrals. Calls focus on: (1) reviewing medication and lifestyle adherence, addressing barriers (e.g, referring to endocrinologist for regimen adjustments); (2) identifying educational gaps, coordinating with dietitian/psychologist; (3) reinforcing glucose self-monitoring, troubleshooting errors, and referring for in-person checks if needed. A validated, structured form guides calls, capturing key data.

Control Group

The control group receives standard care, including lifestyle advice during routine clinic visits by center nurses. Assessments were identical to those of the intervention group for comparability and were conducted at baseline, 3 months, and 6 months.

Data Collection

Data are collected at baseline, 3 months (post-intervention), and 6 months (end of follow-up) during in-person clinic visits. Feasibility outcomes include recruitment rate, retention, acceptability (as measured by a Likert-scale questionnaire), and data completeness, which are logged continuously in study records. Clinical outcomes (FBS, HbA1c, LDL, systolic/diastolic blood pressure, and BMI) are measured using standardized laboratory protocols (at no cost to participants) at accredited facilities or local health centers for accessibility. Questionnaires are administered via Google Forms, with verbal guidance to ensure comprehension. Data entry is performed by a blinded assistant to prevent bias.

Data collection tools

Demographic questionnaire:

Researcher-designed, capturing participant code, group, date, demographics (age, gender, marital/employment/education status), comorbidities, diabetes duration, lifestyle factors.

Diabetes self-management questionnaire-revised (DSMQ-R):

This 27-item instrument, originally developed by Schmitt et al. (2013), assesses self-management behaviors across five subscales: diet (e.g, adherence to healthy eating), medication (e.g., consistency in taking prescribed drugs), glucose monitoring (e.g., frequency and accuracy of blood glucose checks), physical activity (e.g, engagement in recommended exercise), and healthcare interaction (e.g, frequency of medical consultations).

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Each item is scored on a 4-point Likert scale (0= does not apply to me, 3= applies to me very much), with higher total scores indicating better self-management. The Persian version, validated by Hosseinzadegan et al. (2021) for Iranian T2D patients, demonstrates high internal consistency (Cronbach's α> 0.8) (6).

Scores are summed for each subscale and overall, with possible ranges from 0 to 81, where higher values reflect stronger self-management practices. The tool is administered via Google Forms with verbal assistance to ensure comprehension.

Diabetes distress scale-17 (DDS-17):

Developed by Polonsky et al. (2005), this 17-item scale measures diabetes-related psychological distress across four subscales: emotional distress (e.g., feeling overwhelmed by diabetes demands), regimen distress (e.g., challenges with treatment adherence),

Table 1. Motivational interviewing techniques and T2D-specific examples

Technique	Description	Goal	Sample question/statement	T2D-specific example
Open-ended questions	Questions avoiding yes/no answers	Encourage open dialogue	"Can you tell me more about the recent changes you made to your diet?"	"What factors make it hard to stick to your meal plan some days?"
Reflective listening	Reflecting the patient's words to show understanding	Enhance self-awareness, empathy	"It sounds like you want to control your diabetes, but stress gets in the way, right?"	Patient: "I'm too tired to cook sometimes." Nurse: "It seems exhaustion makes preparing healthy meals challenging."
Affirmation	Highlighting the patient's strengths	Boost motivation, self-worth	"Your decision to see a doctor again shows how much you value your health."	"It's impressive that you're managing your busy job while trying to control your blood sugar."
Summarizing	Reviewing key points from the patient	Clarify, prepare for next steps	"So, you said healthy eating is important, but work stress interferes, correct?"	"You mentioned medication is important, but I sometimes forget. Want to discuss reminder strategies?"
Developing discrepancy	Exploring gaps between behavior and values	Increase motivation for change	"You say health matters, but you skip pills some nights. How do you see this?"	"You want to stay active for your grandkids, but aren't walking regularly. Can we explore this?"
Rolling with resistance	Avoiding arguments, aligning with resistance	Maintain therapeutic rapport	Patient: "I can't give up sweets." Nurse: "Cutting out sugar feels tough, and that's normal."	"It seems now isn't the right time to change your diet. When might we revisit this?"
Supporting self-efficacy	Reinforcing belief in the ability to change	Build confidence, initiate action	"You cut sweets for a month before; that shows you can make changes."	"Drinking more water is a great step, showing you're in control."
Readiness ruler	Numeric scale (0-10) to assess readiness	Gauge motivation, spark discussion	"On a scale of 0-10, how ready are you to reduce white bread?"	"On a scale of 0-10, how likely are you to take meds daily? What would raise that number?"
Looking forward	Guiding the patient to envision future outcomes	Enhance motivation, visualize change	"If you continue as is, what will your health be like in 5 years?"	"If you keep your blood sugar stable, how might that impact your life?"

Table 2. Essential self-care behaviors for T2D patients across three counseling sessions

Session	Target self-care behaviors	Educational objectives	Content	Tools and methods	Interactive activities
1	Diabetes knowledge, healthy nutrition	Understand T2D and its complications; identify healthy food choices	Definition of diabetes (type 1 vs. type 2), importance of glycemic control, nutrition principles (food groups, glycemic index, meal planning)	Healthy plate visual, multimedia educational video	Assess the patient's dietary habits, identify errors, and co-design a daily meal plan
2	Physical activity, glucose self-monitoring	Explain the benefits of regular activity; teach correct glucose monitoring	Activity recommendations (type, intensity, duration), glucometer use and timing, and interpreting glucose levels	Real/model glucometer, logbook, multimedia video	Practice glucometer use (if feasible), design a tailored daily activity plan
3	Medication adherence, risk reduction, problem-solving/coping	Emphasize regular medication use and risks of non-adherence; identify controllable risks; enhance problem-solving and stress coping	Medication timing and adherence, foot care, blood pressure/lipid control, stress/anxiety management techniques	Foot care checklist, warning signs guide, multimedia video	Create a medication reminder plan, and role-play for managing challenging scenarios

Note: The content includes validated videos and logbooks for monitoring glucose, blood pressure, and foot care. Materials will undergo content validity assessment by an expert panel.

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interpersonal distress (e.g., lack of social support), and physician-related distress (e.g., dissatisfaction with healthcare provider interactions). Each item is rated on a 6-point Likert scale (1= 'not a problem', 6= 'a very serious problem'), with higher scores indicating greater distress. The Persian version, adapted and validated by Jafari et al. (2023) for Iranian populations, shows acceptable reliability (Cronbach's α= 0.75) (7). Subscale scores are calculated as the mean of relevant items (range 1-6), and the total score is the mean across all 17 items, with scores ≥3 indicating moderate to high distress. The tool is administered via Google Forms, with verbal guidance to ensure clarity.

5-Item medication adherence report scale (MARS-5):

Developed by Horne et al. (2001), this 5-item scale assesses medication adherence behaviors (e.g, forgetting, skipping, or adjusting doses). Each item is scored on a 5-point Likert scale (1= always, 5= never), with higher total scores (range 5-25) indicating better adherence. The Persian version, validated by Ghanei Gheshlagh et al. (2015) for Iranian patients with chronic conditions, demonstrates good internal consistency (Cronbach's α> 0.7) (8). Scores are summed across items, with scores of 21 or higher typically indicating high adherence. The tool is administered via Google Forms, with verbal support to ensure accurate responses.

Clinical measurements:

FBS, HbA1c, and low-density lipoprotein (LDL) are measured using standardized laboratory protocols at accredited facilities, at no cost to participants. Blood pressure (systolic/diastolic) and body mass index (BMI) are assessed using calibrated digital devices at the clinic or local health centers for accessibility.

Anthropometric and Dietary Assessments:

Anthropometric indices, including body weight, height, waist circumference, hip circumference, and waist-to-hip ratio, will be measured at baseline, 3 months, and 6 months by trained research staff following standardized WHO protocols. Body weight will be measured to the nearest 0.1 kg using a calibrated digital scale, with participants wearing light indoor clothing and no shoes. Height will be measured to the nearest 0.1 cm using a wall-mounted stadiometer. Waist circumference will be measured midway between the lowest rib and the iliac crest, and hip circumference at the widest point over the buttocks using a non-elastic tape. Body mass index (BMI, kg/m²) and waist-to-hip ratio (WHR) will be calculated accordingly. Each measurement will be taken twice and averaged for accuracy. Anthropometric data will primarily serve to assess feasibility and preliminary trends in weight and body composition changes associated with participation in the multidisciplinary intervention.

Dietary evaluation will focus on habitual eating patterns using a validated 24-hour dietary recall and a semi-quantitative Food Frequency Questionnaire (FFQ) adapted for Iranian adults with T2D. The dietitian will administer the 24-hour recall at each time point (baseline, 3 months, and 6 months) to estimate total daily energy intake, macronutrient distribution (carbohydrates, proteins, and fats), and dietary fiber intake. The FFQ will capture changes in meal regularity, carbohydrate counting practices, portion control, and adherence to healthy dietary patterns recommended by ADA. Nutrient composition will be analyzed using Nutritionist IV software (Iranian food database). Outcomes will include the mean daily energy intake, the percentage of carbohydrates in total calories, and the overall dietary quality score (based on ADA-aligned criteria). Both 24-hour recall and FFQ are subject to recall bias, a common limitation in dietary assessment. This was mitigated by: (1) administration by a trained dietitian using standardized probes and portion size aids (e.g., food models, household measures), (2) multiple recall administrations over time to capture variability, and (3) use of validated, culturally adapted tools.

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Statistical analysis plan

Analyses will be performed using SPSS v25 (significance level: $P< 0.05$). Feasibility outcomes will be reported descriptively as proportions, means, and 95% confidence intervals (CIs). Exploratory outcomes will be analyzed using intention-to-treat (ITT) principles. Within-group changes will be assessed with paired t-tests (or Wilcoxon signed-rank tests for non-normal data). Between-group differences will be evaluated using independent t-tests (or Mann-Whitney U tests for non-normal data). Time effects across baseline, 3 months, and 6 months will be examined using repeated-measures ANOVA (or Friedman tests for non-normal data). If the missing data rate exceeds 5%, multiple imputation by chained equations (MICE) will be applied, assuming the data are missing at random (MAR). Imputation models will include key predictors (age, sex, baseline HbA1c, group allocation) and outcomes. A minimum of 20 imputed datasets will be generated, with results pooled. Sensitivity analyses will compare complete-case and imputed results to assess the robustness of the findings. Subgroup analyses will explore demographic influences (e.g., age, education level) on feasibility outcomes. Qualitative feedback on intervention acceptability, if collected, will be analyzed thematically. As this is a study protocol, no data have been collected or analyzed to date. The above plan describes the intended statistical approach upon study completion and data availability.

Ethical considerations

The study will be conducted at the Diabetes Research and Treatment Center, Shahid Sadoughi University of Medical Sciences, Yazd, Iran, and was registered with the Iranian Registry of Clinical Trials (IRCT) [IRCT Number: IRCT20250914067242N1]. Ethical approval was sought from the Research Ethics Committee of Shahid Sadoughi University [Ethics Code: IR.SSU.REC.1404.072]. All participants will provide written informed consent prior to enrollment. Participation will be voluntary, with the right to withdraw at any time without penalty. Confidentiality and anonymity of data will be strictly maintained, and all procedures will adhere to the principles of the Declaration of Helsinki.

Discussion

This pilot RCT protocol evaluates the feasibility of a nurse-led multidisciplinary intervention to improve self-management, reduce psychological distress, and enhance medication adherence among patients with T2D in Iran, providing critical data for a future definitive RCT. This study introduces a novel, culturally tailored approach in Iran by integrating motivational interviewing (MI) with a multidisciplinary team comprising a nurse, an endocrinologist, a dietitian, and a clinical psychologist, as outlined in the proposal. The primary aim is to assess feasibility metrics-recruitment rate (greater than 70% of eligible patients), retention rate (greater than 80% at 6 months), intervention acceptability (mean Likert score greater than 4/5), and data completeness (greater than 90%)-to determine the intervention's practicality for scaling.

The intervention, grounded in self-efficacy theory and MI as described in the proposal, targets the seven essential self-care behaviors endorsed by ADA (6), including diabetes knowledge, nutrition, physical activity, and stress management. These are delivered through structured in-person/online counseling and telephone follow-ups, designed to overcome barriers like limited healthcare access and cultural stigmas around psychological support in Iran. While studies like Ni et al. (2019) in China demonstrated that nurse-led multidisciplinary care improved HbA1c and quality of life over two years (7), and Tan et al. (2019) in Singapore showed reduced nephropathy progression (8), no such intervention has been tested for T2D in Iran, highlighting the study's novelty. The study's emphasis on MI, a method with evidence of improving adherence in Western settings (9, 10). This approach is adapted here to address

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the needs of Persian-speaking patients, potentially enhancing their engagement in a culturally sensitive manner.

Feasibility outcomes will inform recruitment strategies, participant engagement, and logistical coordination, critical for refining a larger trial. Exploratory outcomes (HbA1c, FBS, LDL, blood pressure, BMI, WHR, FFQ, DSMQ-R, DDS-17, MARS-5) will provide preliminary data on the potential impact, although efficacy is not the primary focus, aligning with the CONSORT pilot guidelines. The study's setting at the Diabetes Research and Treatment Center in Yazd, a high-volume facility, ensures real-world relevance. If feasibility targets are achieved, this model could be adapted for other resource-constrained settings, particularly in low- and middle-income countries. Future research should investigate long-term outcomes, cost-effectiveness, and rural adaptations, building on the findings of this pilot to enhance the delivery of Type 2 diabetes care in Iran and beyond.

Strengths and Limitations

This protocol benefits from its multidisciplinary, nurse-led framework, which is aligned with contemporary diabetes care recommendations. Cultural tailoring of motivational interviewing, use of validated Persian instruments, and flexible delivery modes (in-person/online/telephone) support patient engagement. Methodological features, including single blinding, independent data entry, and HbA1c-based stratification, enhance the internal validity of a feasibility study.

Several challenges may affect implementation. First, coordinating multidisciplinary team schedules within a high-workload clinical environment may limit session fidelity. Second, although online delivery increases flexibility, internet connectivity, device access, and digital literacy, particularly in rural or low-resource areas, it may reduce consistent participation, potentially affecting acceptability and retention metrics. Third, the Diabetes Center's space limitations may restrict private counseling, which in turn may affect patient disclosure and the quality of motivational interviewing. Fourth, cultural hesitancy toward psychological or dietary counseling could diminish engagement. Finally, as with all pilot studies, the small sample size limits the precision of exploratory outcomes and may not reflect broader population heterogeneity. These considerations will guide refinement of procedures, infrastructure support, and engagement strategies for a larger RCT.

Conclusions

This pilot protocol outlines the design and methodology of a nurse-led multidisciplinary intervention for T2D management in Iran. The study will generate essential feasibility data to refine a future definitive randomized controlled trial and contribute to evidence-based models of care in resource-constrained settings.

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Conflict of Interest

The authors declare that they have no financial or non-financial conflicts of interest regarding the present research.

Authors' contributions

FB, RA, and ZR have made substantial contributions to the conception and design of

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the work; FB and ZR obtained funding. ZR, RA, and FB developed the study design and statistical analysis plan. All authors were involved with the design and preparation of study materials. FB and ZR wrote the manuscript. RA, MH, and ST provided critical revisions to the manuscript. All authors have approved the final version of the manuscript.

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