Diabetes, Metabolic Syndrome and Obesity

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STUDY PROTOCOL

A Patient-Centered Self-Management Intervention to Improve Glycemic Control, Self-Efficacy and Self-Care Behaviors in Adults with Type 2 Diabetes Mellitus: A SPIRIT Compliant Study Protocol for Randomized Controlled Trial

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Background: The rising burden of type 2 diabetes mellitus (DM) and its associated complications is affecting the functional capacity of the individuals, their quality of life and demand for healthcare services with significant economic impact on health care systems and the national economies. Given the enormous health and economic impact, preventing type 2 DM progression and reducing the risk of complications require immediate attention. Evidence from western countries suggests that self-management can slow the progression of type 2 DM and minimize the risk of major complications lowering health-care costs. Effective self-management, however, demands patients' confidence and their full commitment to perform self-care tasks necessitating a patient-centered approach. This study aims to test the efficacy of a patient-centered self-management intervention to improve glycemic control, self-efficacy and self-care behaviors in adults with type 2 DM.

Patients and Methods: The study will be carried out as a parallel arm, randomized, controlled trial in four public tertiary care hospitals in Faisalabad, Pakistan. A total of 612 patients with type 2 DM will be recruited and randomly assigned to two groups: a control and an intervention group. The intervention group will receive a patient-centered self-management intervention for eight weeks duration. Subjects will be followed up for three months. The primary outcome will be glycemic control (HbA1c), and secondary outcome variables will include self-efficacy and self-care behaviors all measured at three points in time (baseline, at the end of intervention and at three months follow-up).

Discussion: This randomized controlled trial will provide critical information about the efficacy of patient-centered self-management intervention in improving HbA1c, self-efficacy and self-care behaviors. If successful, this evidence-based care intervention may be provided to all DM patients by updating hospital policies.

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Keywords: education, counselling, HbA1c, patient-centered care, type 2 diabetes, self-management, randomized controlled trial

Introduction

Diabetes mellitus (DM) is one of the major health problems of the 21st century due to its growing prevalence and the risk of increased morbidity and mortality.[1] The International Diabetes Federation (IDF) estimated that by 2021, one in every ten adults aged 20 to 79 had DM, equivalent to 537 million people worldwide.[2] According to the IDF report, prevalence is higher in the Middle East and North Africa, particularly in low- and middle-income countries, where three out of every

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four adults are affected.[2] Pakistan, a low-middle income country with 225 million population, is ranked third among the top 10 countries in terms of absolute rise in DM prevalence.[2] Pakistan has 33 million people (aged 20–79 years) with DM and this number is expected to nearly double (62 million) by 2045.[3] With one in every four adults (26.7%) living with DM in Pakistan, type 2 DM accounts for more than 90% of cases.[3]

The rise in type 2 DM in Pakistan is mostly due to environmental, demographic, socioeconomic and genetic factors with important contributors being sedentary lifestyle, unhealthy eating habits and obesity.[4] Furthermore, a poor healthcare system characterized by inequity in health care services provision, poor socioeconomic conditions, lack of education and unemployment are exacerbating the problem.[5] The rising burden of type 2 DM and its associated complications is affecting the functional capacity of the individuals, their quality of life and the demand for healthcare services.[6] Moreover, it is adding to the financial burden of individuals and their families with significant economic impact on the healthcare system and the national economy.[7] Given its enormous health and economic impact, preventing type 2 DM progression and reducing the risk of associated complications requires immediate attention in order to improve the quality of life of affected individuals and lower the burden of the country's already debilitated healthcare system.

Evidence from western countries suggests that self-management can delay the progress of type 2 DM and can reduce the risk of serious complications thereby, reducing the cost of health care.[8] Effective self-management however, necessitates patients' confidence and their full commitment to perform self-care tasks.[9] A patient-centered approach is therefore necessary because patients must make a determined and self-motivated effort to adopt a healthy lifestyle and to achieve optimum glycemic control. A recent systematic review and meta-analysis provide evidence supporting that patient-centered care improves glycemic control and self-care behaviors in adults with type 2 DM.[10]

Though several studies have been published on self-management of type 2 DM in Pakistan, only a few randomized controlled trials (RCTs) have been published that focus on educational interventions. Type 2 DM is associated with complexity as there are multiple risk factors, mostly involving behavioral or social components, which the individual, family or society has to struggle hard to implement. Therefore, a patient-centered behavioral or social intervention would make a long-lasting impact towards effective disease management. The purpose of this study is to test a patient-centered self-management intervention guided by Social Cognitive Theory, with the goal of improving glycemic control, self-efficacy and self-care behaviors in adults with type 2 DM.

Theoretical Framework

Social Cognitive Theory (SCT) by Albert Bandura,[11] forms the conceptual bases whereas, the model of self-efficacy[12] derived from SCT, provides the framework for this study.

SCT provides a solid theoretical underpinning for understanding how individuals learn and sustain certain behaviors.[13] According to SCT, learning occurs in a social context through the dynamic and reciprocal interaction of the personal (ie, cognitive, affective, and biological events), behavioral and environmental factors.[14] The SCT is appropriate for understanding self-care behaviors of adults with type 2 DM as the reciprocal interaction between the personal, behavioral and environmental factors that directly influence the performance of self-care activities in this population.[15] The main construct of SCT is self-efficacy (the core predictor of behavior) which refers to the confidence an individual has in his or her ability to effectively execute a particular behavior and achieve the desired outcome.[16] According to Bandura, self-efficacy is a very effective predictor of behavior change. Therefore, compared to those with a low level of self-efficacy, people who have a high level of self-efficacy are more likely to succeed when faced with challenges.[16]

The modified self-efficacy model (see Figure 1) exhibits the relationship between self-efficacy, outcome expectations, social-structure, behavior and outcomes. Self-efficacy, outcome expectations and social-structure directly influence behavior whereas; behavior and outcome expectations directly influence outcomes. Moreover, sources of information directly influence self-efficacy of the individual. The basic concept behind using this model in the study is that individual's demographics and perceptions, combined with strong self-efficacy, would result in improved performance of self-care activities, thereby improving glycemic control and self-care behaviors in adults with type 2 DM.

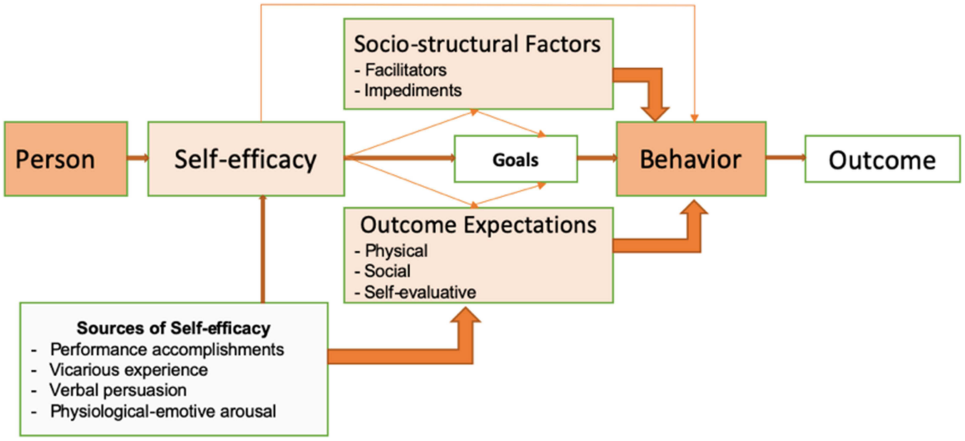

Figure 1 Modified self-efficacy model.

Methods

Study Design

A randomized controlled trial (RCT) with parallel arm design will be used to test the effectiveness of the intervention.

Study Setting

Pakistan's healthcare system is composed of two parts: private and public. The public sector health service delivery system is divided into three levels; primary, secondary and tertiary.[17] Primary level consists of basic health units (BHU) and rural health centers (RHC) which provide curative and preventive health services. The secondary level consists of Tehsil headquarters (THQ) and district headquarters (DHQ) providing technical, therapeutic and diagnostic services. Tertiary level hospitals provide specialized health services for inpatients and referrals from primary and secondary levels.[18] The proposed study will take place in the outdoor patient departments (OPD) of four public tertiary level hospitals in Faisalabad city. Each hospital has an OPD with a turnover of average 50–100 patients per day.

Subjects

Inclusion Criteria

- Adult (aged 18 years or above).
- Diagnosed with type 2 DM for at least 6 months duration.

Exclusion Criteria

- Uncontrolled psychological comorbidity (psychosis, schizophrenia, dementia or severe learning difficulties).
- Type 2 DM patients with HbA1c < 7.
- Severe comorbidity that may limit participation (medical conditions such as cancer, stroke with disabilities, or need for regular dialysis, etc. that preclude complete participation in this study).
- Life expectancy of less than six months as determined by patient's primary physician.
- Living outside of the Faisalabad City.

Sample Size

The required sample size for this study, is calculated through statistical power analysis utilizing G*Power 3.1 software. G*Power 3.1 calculator revealed that using an alpha level (α) of 0.05, a power factor (1-β) of 0.80 and an effect size of 0.23 (the largest of all outcome variables calculated from a previous study with similar characteristics);[19] a sample size of 470 subjects will be required with minimum 235 in each group. Considering the possible dropout of about 30%; 612 subjects will be targeted in this study with 306 in each group.

Recruitment

The principal investigator (PI) will screen all the consecutive medical records at study hospitals to identify potential subjects. The individuals meeting the eligibility from medical records, will be invited for a screening appointment. The individuals fulfilling the inclusion criteria and violating none of the exclusion criteria, will be invited to participate by providing detailed project information and offering the opportunity to ask questions (if any). Subjects who provide the written informed consent will be included in the study.

Randomization

Recruited subjects will be randomized into two groups: (1) the control group (CG) and (2) the intervention group (IG). Stratified permuted block randomization procedure will be used to produce separate random schemes for each setting (hospital A, B, C and D). Sealed envelopes (of block sized CG and IG) will be prepared, shuffled via simple randomization technique and then will be numbered serial-wise to be placed in the boxes (designated for each setting labelled as A, B, C and D). Randomization will be performed by data analyst (DA). PI or any other members of research team will not be involved in randomization to avoid any influence. The PI will be responsible for the randomization plan implementation and documentation. Once the PI has determined that the subject meets the eligibility criteria and has given informed consent to be randomized to either the CG or the IG, the PI will withdraw a numbered, sealed envelope from the box (for that setting) and open it in front of the subject. The PI will document the process and secure the opened envelopes with the serial numbers for record and audit purpose.

Blinding

Due to the nature of the intervention, blinding at all levels is not possible because the subjects receiving the intervention cannot be kept "blinded" or "masked". The research staff designated as data collector (DC) and data analyst (DA) will be blinded about which group the subject is assigned to. Baseline data will be collected on all subjects before randomization to preclude any bias in baseline data collection. Similarly, DCs will be blinded with regards to subjects' group assignment when collecting outcome information.

Independent Variables (Group Assignments)

Control Group (CG)

The subjects in the CG will receive usual care. Usual care at the study hospitals involves consultation with the physician encompassing a brief history taking, blood glucose measurement, record keeping and provision of general education regarding lifestyle modification verbally or in the form of pamphlets.

Intervention Group (IG)

The subjects in the IG will receive usual care as well as a nurse-led PAtient CEntered Self-Management Intervention (PACE-SMI). PACE-SMI is based on the core determinants of human behavior in SCT which include personal (cognitive, affective, biological) factors, efficacy-expectations, sources of information, outcome expectations, behaviors and socio-structural (perceived social support and barriers) factors. The contents of the intervention are further informed by the American Association of Diabetes Educators (AADE) seven self-care behaviors including healthy eating, healthy coping, being active, monitoring, taking medication, reducing risk and problem solving.[20] Table 1 outlines the contents of PACE-SMI with underlying SCT application. PACE-SMI will be delivered for eight weeks duration (comprising 8 weekly face-to-face individualized educational, counselling and behavioral training sessions) in the OPD room at each study hospital by the PI and RA who are nurses with at least bachelor's degree education in nursing and underwent two days of training provided by the PI.

Fidelity of Intervention

The fidelity of the intervention plan (shown in Table 2) is developed in accordance with the recommendations of the National Institute of Health (NIH) behavior change consortium, which provides methodological strategies aimed at monitoring and improving the consistency, reliability and validity of behavioral interventions.[21]

Table 1 Description of the Intervention

Week	Delivery Time (Minutes)	SCT Application	Contents
Week 1	60 30	Physiological/emotive arousal Performance accomplishment, Self-appraisal	General disease knowledge including types, risk factors, clinical manifestations, complications, treatment options and self-management. Group discussion- sharing experiences of diabetes management.
Week 2	60 15 15	Physiologic/emotive arousal Vicarious experience, Verbal persuasion, Performance accomplishment	Self-care behaviors, role of self-care behaviors towards effective management of type 2 DM. Motivational video showing how patients with type 2 DM successfully improved self-care behaviors and avoided diabetes associated acute and chronic complications. Real stories of diabetic patient to serve as a role-model; to follow their daily routine of performing self-care activities. Provision of diabetes self-care guidebook.
Week 3	60	Performance accomplishment, Verbal persuasion, Social-structure; facilitators	Home visit-initiating and maintaining behavioral change with social support as a key strategy. - Observation of personal, social and environmental facilitators helping in initiating and maintaining behavior change. - Observation of physical and social structural difficulties in initiating and ongoing barriers in maintaining behavior change. - Observation and discussion of personalized, family and social support strategies for dealing with the barriers.
Week 4	30 60	Physiologic/emotive arousal Individual (cognitive, personal, behavioral) factors; Social structural factors; Outcome expectations; Goal setting; Source of information: self-appraisal, verbal persuasion. Performance accomplishments	Diet; healthy dietary patterns, choosing the correct food, adjustments in eating plan. - Identifying personal self-management needs, perceptions, beliefs and existing dietary behaviors. - Discussing on benefits of dietary behavioral change by providing examples of healthy and preferred choices over unhealthy and avoiding or limiting options. - Collaborative goal setting based on the interest and confidence subject has in their ability to change dietary behavior and enlisting specific goals in behavioral terms. - Identifying and listing of personal, social and environmental support (facilitators) and barriers (impediments) towards goal attainment (dietary behavior change). - Thinking of and listing strategies and problem solving techniques to overcome personal, social or environmental barriers. - Developing a follow-up plan including telephonic reminders to foster continued performance accomplishment.

(*Continued*)

Table 1 (Continued).

Week	Delivery Time (Minutes)	SCT Application	Contents
Week 5	30 60	Physiologic/emotive arousal Individual (cognitive, personal, behavioral) factors; Social structural factors; Outcome expectations; Goal setting; Source of information: self-appraisal, verbal persuasion. Performance accomplishments	Physical activity; healthy exercise patterns, adjustments in vacation, illness and stress. - Identifying personal self-management needs, perceptions, beliefs and existing behaviors regarding physical activity. - Discussing on benefits of regular physical activity by providing examples of healthy and preferred choices over unhealthy and avoiding or limiting options. - Collaborative goal setting based on the interest and confidence subject has in their ability to adopt physical activity routine and enlisting specific goals in behavioral terms. - Identifying and listing of personal, social and environmental support (facilitators) and barriers (impediments) towards goal attainment (regular physical activity). - Thinking of and listing strategies and problem solving techniques to overcome personal, social or environmental barriers. - Developing a follow-up plan including telephonic reminders to foster continued performance accomplishment.
Week 6	30 60	Physiologic/emotive arousal Individual (cognitive, personal, behavioral) factors; Social structural factors; Outcome expectations; Goal setting; Source of information: self-appraisal, verbal persuasion. Performance accomplishments	Foot hygiene; appropriate use of footwear and socks; foot care. - Identifying personal self-management needs, perceptions, beliefs and existing behaviors of foot care. - Discussing on benefits of foot care by providing examples of foot care recommended over unhealthy foot care practices. - Collaborative goal setting based on the interest and confidence subject has in their ability to adopt daily foot care routine and enlisting specific goals in behavioral terms. - Identifying and listing of personal, social and environmental support (facilitators) and barriers (impediments) towards goal attainment (foot care). - Thinking of and listing strategies and problem solving techniques to overcome personal, social or environmental barriers. - Developing a follow-up plan including telephonic reminders to foster continued performance accomplishment.

(*Continued*)

Table 1 (Continued).

Week	Delivery Time (Minutes)	SCT Application	Contents
Week 7	30 60	Physiologic/emotive arousal Individual (cognitive, personal, behavioral) factors; Social structural factors; Outcome expectations; Goal setting; Source of information: self-appraisal, verbal persuasion. Performance accomplishments	Medication adherence; taking medications, self-regulation, making adjustments. - Identifying personal self-management needs, perceptions, beliefs and existing behaviors of taking medication. - Discussion on benefits of medication adherence by providing examples of compliance and health risks associated with non-compliance. - Collaborative goal setting based on individual needs and preferences and the confidence subject has in their ability to adopt medication routine. - Identifying and listing of personal, social and environmental support (facilitators) and barriers (impediments) towards goal attainment (medication adherence). - Thinking of and listing strategies and problem solving techniques to overcome personal, social or environmental barriers. - Developing a follow-up plan including telephonic reminders to foster continued performance accomplishment.
Week 8	60	Performance accomplishment, Self-appraisal, Verbal persuasion,	Booster session - Reflection on what was learned in the previous sessions. - Performance feedback. - Reviewing behavioral goals fostering continued performance accomplishment and addressing difficulties of maintaining behavior change over time.

Outcomes and Measurement

Table 3 summarizes the specific outcome variables, their definitions and corresponding measurement instruments.

Measurement Tools

Glycemic control (HbA1c) will be measured by collecting venous plasma samples and sending them to the single central laboratory to assure consistency and uniformity in methodology. The DC (trained nurse) will draw the sample and laboratory measurements will be performed by laboratory technician. HbA1c <7% indicates satisfactory glycemic control whereas, HbA1c value ≥7% indicates poor glycemic control.[22]

Self-efficacy will be measured on the diabetes management self-efficacy scale (DMSES). DMSES is a self-administered scale used to assess subjects' perceived confidence in their ability to manage blood sugar, diet, physical activity and foot care. The scale is comprised of 20 items. Each item's response is rated on an 11-point scale ranging from 'cannot do at all (0)' to 'certain can do it' (10) with a total score 0 to 200. A higher score would indicate high self-efficacy. DMSES was developed by Van Der Bijl (1999) to measure diabetes management self-efficacy of patients with type 2 DM. Psychometric properties of DMSES showed acceptable reliability and validity ($\alpha = 0.81$; $r = 0.79$).[24] The translated Urdu version of DMSES (U-DMSES to be used in this study) was reported to have $\alpha = 0.93$.[25]

Self-care behaviors will be measured on the Summary of Diabetes Self-Care Activities (SDSCA) questionnaire. The SDSCA tool developed and revised by Toobert et al; is a self-reported scale to measure self-care activities across diverse components of diabetes self-management.[16] A revised version of SDCA scale measures seven components of diabetes

Table 2 Plan to Enhance the Fidelity of the Intervention

Sr.	Dimension of Fidelity of Intervention	Description and Strategies to Be Used
1	**Delivery of the intervention**: treatment delivery as planned	PI and RAs will deliver the intervention. RAs do not have working relationship with the institution where the study is designed nor the study hospital where the intervention will be administered. To control information bias, PI and RAs will be blinded to the baseline, post-intervention and follow-up results. Further procedures to improve fidelity of delivery of the intervention include: - - Development and use of a manual of operations (MOO) to guide the training of RAs for the delivery of intervention protocol and to ensure consistency and reproducibility. - Uniform and standardized training of RAs. - Availability of essential resources and preparation of environment in which the intervention will be delivered. - Compliance with the intervention protocol by utilizing a checklist and noting any deviation from the protocol. - Observation of ongoing intervention sessions
2	**Receipt of the intervention**: Subjects' demonstration of knowledge and ability to use the treatment.	The following strategies will be used to ensure that the subjects understand the content of the intervention and can use their cognitive and behavioral skills to perform the behaviors trained in the intervention: - Summarizing the content at the end of each session. - Asking pre- and post-session questions to evaluate what is already known and what is taught. - Discussing material (provided) with the subjects. - Structuring behavior change around small achievable goals and objectives. - Using problem-solving techniques while creating situations in which the subject is asked to list strategies for overcoming barriers to behavior change. - Ensuring that subjects can apply the behavioral skills taught in the intervention (eg, choosing from food pyramid, reading food labels, setting timer/step counter, foot inspection, reading and interpreting blood sugar levels). - Having the provider work with subjects via SMS/phone calls to find out if they correctly understand and demonstrate the knowledge and skills taught.
3	**Compliance with the treatment**: Application of behavior change skills learned during the intervention in daily life of the subject.	The following strategies will be used to ensure that the subjects use their personal (cognitive and behavioral) skills and environment to maintain behavioral change: - Provision of Urdu Booklet consisting relevant study materials. - Visiting subjects at their homes to evaluate the facilitators and barriers towards initiating and maintaining behavioral change; keeping a log for each subject and coming up with the strategies or action plan to work on minimizing those barriers. - Following-up through phone call conversations and SMS reminders. - Self-monitoring. - Uniform and consistent measurement of outcomes.

self-management including general diet, specific diet, exercise, blood glucose testing, medication adherence, foot care and smoking.[26] SDSCA is comprised of 25 items with each item measuring the frequency of self-care activities by asking how often several self-care activities were carried out over the past seven days period. Each item's response is rated on a 7-point scale ranging from "0" to "7" with a total score ranging from 0 to 175. A higher score would be the frequency of performing self-care activities.

Measurement Schedule

Primary and secondary outcome variables will be measured at three points in time (at baseline, at the end of intervention and at follow-up after three months from the end of intervention). Table 4 illustrates the schedule for events and measurements for this study.

Table 3 Outcome Variables, Definition, and Instruments

Outcome	Definition	Instrument
Primary Outcome: Glycemic control	"Glycosylated hemoglobin (HbA1C) <7% as satisfactory diabetic control".[22]	Conventional blood test for HbA1c
Secondary Outcomes: 1. Self-Efficacy towards self-management of type 2 DM 2. Self-care behaviors including: • Diet control • Physical activity • Foot care • Medication adherence	"Perceived capability to perform certain self-care behaviours".[12] "The self-care activities independently performed by diabetic patient including diet, exercise, foot care and medication intake".[23]	Diabetes Management Self-efficacy Scale[12] Summary of Diabetes Self-Care Activities (SDSCA) tool[26]

Table 4 Schedule of Events and Measurements

Event Description	Screening & Enrollment Phase	Intervention Phase								Follow-Up Phase	
Study Visits/ Study Days/Weeks)	**Visit-0 *M0**	**1 W1**	**2 W2**	**3 W3**	**4 W4**	**5 W5**	**6 W6**	**7 W7**	**8 W8**	****M1**	*****M2**
Informed Consent	X										
Demographic & Clinical History	X										
HbA1C	X									X	X
Self-Efficacy	X									X	X
Self-Care Behaviors	X									X	X
ECB - Disease Introduction and control and management strategies		X									
ECB – Role of Self-care behaviors, motivational video, role modeling and booklet provision			X								
Home visit				X							
ECB - Diet Control					X						
ECB - Physical Activity						X					
ECB – Foot Care							X				
ECB – Medication Adherence								X			
ECB – Booster									X		
Study completion											X

Notes: *M0 baseline measurements; **M1 first follow-up measurements at the end of intervention; ***M2 last follow-up measurements after three months of the end of intervention.

Follow-Up

In order to evaluate the effect of the intervention over time, the subjects will be followed up for three months starting from the end of intervention. During the three months follow-up, phone conversations and regular SMS reminders would be used to encourage behavior maintenance. Follow-up measurements will be carried out at an in-person visit of the subject to the study hospital.

Table 5 Study Hypotheses and Corresponding Test Statistic

Sr.	Hypotheses	Test Statistic
1	**Ho**: There is no difference in HbA1c between CG and IG **H1**: IG will have a reduction in HbA1c compared to CG	Independent *t*-test
2	**Ho**: There is no difference in self-efficacy between CG and IG **H2**: IG will have a greater self-efficacy towards management of type 2 DM than CG	Chi-square test
3	**Ho**: There is no difference in self-care behaviors between CG and IG **H3**: IG will have improved self-care behaviors than CG.	Chi-square test

Data Management and Analysis

Double data entry will be employed in order to increase the accuracy of data entered into a computerized data file. The data will also be checked for missing values, logical inconsistencies and outliers. The data will be analyzed using the Statistical Package for the Social Sciences (SPSS, version 22.0). The CG and IG' demographic and clinical variables will be described using descriptive statistics (mean and standard deviation (±SD) for continuous variables and frequency and percentage for categorical variables). In order to confirm that randomization worked, important demographic and clinical data will be presented in a table to see the equal distribution between the two groups. Independent *t*-test will be used to determine the differences on continuous data (mean score differences between CG and IG). Chi-square test will be used to determine the differences on categorical data (differences in proportion between CG and IG). Table 5 below shows the hypotheses with corresponding test statistics to be applied.

Intention to treat (ITT) analysis principle will be used to achieve an unbiased estimate of effect of the intervention. ITT is a method in which all randomized subjects are included in the statistical analysis and analyzed based on the group to which they were initially assigned, regardless of the treatment/care they have received.[27]

Discussion

Previous randomized controlled trials of type 2 DM self-management interventions have shown a reduction in HbA1c and improvement in self-care behaviors in several countries.[28–30] Focusing on a patient-centered approach, a recent systematic review and meta-analysis provided the evidence that patient-centered care improves glycemic control (HbA1c) and self-care behaviors in adults with type 2 DM.[10] The stratified analysis of HbA1c in this systematic review and meta-analysis, witnessed the largest effect size in interventions delivered by nurses. To date, nurse-led educational and behavioral intervention have not been formally tested in type 2 DM patients in Pakistan. This will be the first trial to demonstrate a theory-based nurse-led educational, counselling and behavioral intervention in adults with type 2 DM with the goal of empowering them to manage their own care and improving health outcomes in terms of HbA1c, self-efficacy and self-care behaviors. If this study proves successful, the trial will demonstrate that such interventions enable individuals to make informed decisions about their condition, resulting in better health outcomes, a higher quality of life, and a positive impact on the economy of the family and the health system. It's also worth noting that if PACE-SMI shows efficacy in type 2 DM self-management, similar interventions could be applied to other chronic conditions.

This study may also have some limitations. Because this study requires long-term engagement, some subjects may decline to participate or find it difficult to consistently attend all the intervention sessions due to economic and sociocultural differences. To enhance retention, the following procedures will be used: (1) encouraging the subjects to stay in the study and attend all sessions by emphasizing the importance of self-management of their disease, (2) visit reminder in the form of a postcard at the end of each visit and SMS reminder one day prior to the scheduled visit, (3) financial incentive in lieu of traveling cost (to and from the study hospital), (4) two phone numbers of significant others (family, friends or relatives) to locate the missing subject, if he/she has not withdrawn consent and (5) accessing missing subjects in their homes, if given consent for home visits.

Abbreviations

AADE, American Association of Diabetes Educators; DM, diabetes mellitus; DA, data analyst; DC, data collector; IDF, International Diabetes Federation; NIH, National Institute of Health; PCC, patient-centered care; PI, principal investigator; RCT, randomized controlled trial; WHO, World Health Organization.

Ethical Considerations

The trial will be conducted in accordance with the Declaration of Helsinki. This study has been approved by the Institutional Review Board and Ethics Committee (IRB and EC) of Shifa Tameer e Millat University (protocol reference number 335-21) and the Ethical Review Committee (ERC) of the study hospitals under the care of Faisalabad Medical University (protocol reference number 48.ERC/FMU/2020-21/193). Protocol modifications will be accordingly approved by IRB and ERC. This trial has been registered in the US National Library of Medicine Clinical Trial Register (clinicaltrials.gov Identifier: NCT05491252). Following eligibility screening, written informed consent will be obtained after providing information about the project's details which include a brief description of (1) the study's purpose, (2) methodology, (3) duration of the study and (4) subject's right of voluntary participation and withdrawal at any time during the course of the study. The protection and confidentiality of personal data will be guaranteed. To preserve confidentiality, all soft data will be encrypted and kept in a password protected laptop and hard data (paper documents) will be kept in a locked cabinet. If the proposed intervention shows a positive effect in relation to the studied outcomes, the intervention will also be offered to the subjects in the control group at the end of the study. The findings of this trial will be accurately reported and published in a peer-reviewed international scientific journal.

Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

The authors report no conflicts of interest in this work.

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