

**DEVELOPMENT AND VALIDATION OF PSYCHO-SOCIAL PROGRAM
(PSP) FOR MENTAL HEALTH PROBLEMS AMONG PATIENTS WITH
TYPE 2 DIABETES MELLITUS (T2DM): A RANDOMIZED CONTROL
TRIAL**

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**DEPARTMENT OF APPLIED PSYCHOLOGY
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PAKISTAN
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DEVELOPMENT AND VALIDATION OF PSYCHO-SOCIAL PROGRAM (PSP) FOR MENTAL HEALTH PROBLEMS AMONG PATIENTS WITH TYPE 2 DIABETES MELLITUS (T2DM): A RANDOMIZED CONTROL TRIAL

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Trials structured Study Protocol template

Title

Trial's guidance:

DEVELOPMENT AND VALIDATION OF PSYCHO-SOCIAL PROGRAM (PSP) FOR MENTAL HEALTH PROBLEMS AMONG PATIENTS WITH TYPE 2 DIABETES MELLITUS (T2DM): A RANDOMIZED CONTROL TRIAL

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Abstract

Trials guidance:

Background: Type 2 diabetes mellitus (T2DM) is a chronic condition that requires ongoing self-management to prevent complications. However, psychosocial factors such as depression, diabetes-related distress (DD) (Schmitt et al., 2021), health anxiety (HA), stigma and lack of social support can significantly hinder patients' ability to manage their quality of life (QOL) and treatment adherence (TA) effectively (Gonzalez Heredia et al., 2021). Despite the well-established impact of psychosocial factors on diabetes related mental health outcomes, few psychological structured programs (Hamdani et al., 2024) comprehensively address the need for psychosocial support for diabetes patients (Khowaja et al., 2023 & Saenz et al., 2022). This study aims to develop and validate Psycho-Social Program (PSP) for individuals with T2DM, addressing their emotional, behavioral, and social challenges to improve overall mental health outcomes.

Methods: we will conduct randomized control trial with pre- and post- baselines using reliable and validated tools such as DDS, PHQ-9, SHAI, DSAS, MSPSS, DQOL and GMAS. Total N=80 diabetic patients would be divided into experimental n=40 and waitlist n=40 participants. Participants would be taken from different hospitals of the Faisalabad. Patient's age range would be 30-40 years. Peoples with type-1 diabetes and patient with other medical illnesses such as heart disease, cancer patient would be excluded from our study.

Discussion: The main purpose of this study is to evaluate the effectiveness of a PSP in improving mental health outcomes among patients with Type 2 diabetes mellitus (T2DM). The program aims to help participants manage depression, reduce diabetes-related distress, enhance social support, improve quality of life (QOL), and increase adherence to treatment. Participants will receive PSP as part of the intervention, and pre- and post-assessments will be conducted to measure changes in psychological well-being and behavioural functioning. This study is expected to **provide** evidence-based guidance for mental health interventions in Type 2 diabetes patients and contribute to better treatment outcomes, supporting both patients and healthcare providers in improving overall well-being.

Trial registration: Trial would be register.

Keywords

Psycho-Social Program, Type 2 Diabetes Mellitus, Depression, *Stigma*, *Social Support*, *Diabetes Quality of Life*, *Treatment Adherence*, *Diabetes Patients*

Administrative information

Trials guidance: please include this text in your submitted protocol just above the Administrative information table:

Note: the numbers in curly brackets in this protocol refer to SPIRIT checklist item numbers. The order of the items has been modified to group similar items (see <http://www.equator-network.org/reporting-guidelines/spirit-2013-statement-defining-standard-protocol-items-for-clinical-trials/>).

Title {1}	<p>Psycho-social program (PSP) for mental health problems among patients with type 2 diabetes mellitus (T2DM): a randomized control trial.</p> <p>Design. Randomized Control Design</p> <p>Population. Patients with Type II Diabetes</p> <p>Intervention. Psycho-Social Program</p>
Trial registration {2a and 2b}.	Research proposal accepted from the ethical committee and reviews of institution then trial would be register.
Protocol version {3}	Trial would be register.
Funding {4}	This research is not funded.
Author details {5a}	<p>Ms Sana Latif</p> <p>Dr. Qasir Abbas.</p>
Name and contact information for the trial sponsor {5b}	No one sponsor of this research.
Role of sponsor {5c}	We have no sponsor in our study.

Introduction

Background and rationale {6a}

Type 2 diabetes mellitus (T2DM) is a chronic metabolic disorder characterized by insulin resistance and hyperglycemia, affecting millions of individuals worldwide (Galicia-Garcia et al., 2020). According to the International Diabetes Federation (IDF), the global prevalence of diabetes continues to rise, with T2DM accounting for approximately 90% of all cases. The global prevalence of impaired glucose tolerance is estimated to be 7.5% (374 million) in 2019 and projected to reach 8.0% (454 million) by 2030 and 8.6% (548 million) by 2045 (Saeedi et al., 2019). Despite advancements in medical treatment, achieving optimal glycemic control remains a challenge for many patients (Khursheed et al., 2019). Research indicates that psychosocial factors, such as stress, depression, anxiety, and lack of social support, significantly impact diabetes self-management and overall health outcomes (McCoy & Theeke, 2019). Addressing these factors is crucial, as they are often overlooked in traditional diabetes care, which primarily focuses on pharmacological and dietary interventions (Khunti et al., 2025).

Diabetes Distress (DD) is common in Type II Diabetes Mellitus, and is linked with poor diabetes control (Tran et al 2021, Zhaung 2020 & _Geleta, et al., 2020). Diabetes distress is a

worldwide problem in people with diabetes mellitus of all ages and has been demonstrated across various populations and cultures (Onyenekwe et al., 2020). Diabetes distress is defined as an emotional state that leads towards the feelings of stress, guilt, and denial that arise from living with diabetes and associated with the burden of self-management (Kreider 2017). This is often unrecognized responses that arise when individual are overwhelmed when facing the responsibility of managing a chronic life-long disease (Aljuiad 2018). Diabetes distress is an essential predictor of clinical outcomes in type II diabetes mellitus such as poor self care, self-management, and reduced treatment adherence among patients with diabetes (Bawa et al.,2020 & Kretchy et al., 2020).

Diabetes distress and depression are the most common mental problem factors in diabetes , they are highly correlated and affect diabetes self-management, health behavior and related health outcomes (Andreas 2021 & Trans et al., 2021). Depression is a common co-morbidity in individuals with diabetes, compared to those without diabetes (Ellis & Edge 2010), affecting approximately 20% of all patients (Daneiol et al 2012). In Pakistan the prevalence was reported as 49.2% for depression in patients with Diabetes Mellitus (Malik et al.,2019).

Diabetes also leads to other psychological problems such as health related anxiety which is an obsessive and irrational worry about having a serious medical condition. Health anxiety has been infrequently examined in individuals with diabetes (Claude et al., 2013). Diabetes distress lead to health related anxiety because patients with chronic illness such as diabetes commonly experience fears of illness or symptoms recurring or worsening as it leads toward lower adherence to treatment, fewer positive health behaviors; and increased medical costs (Lebel 2020). There is a significant association between anxiety and depression among patient with diabetes (Sharma et al., 2021).

Diabetes has a significant negative impact on mental health and quality of life (Knowles et al., 2020). Diabetes distress is associated with reduced quality of life, because patients with diabetes are often burdened by multiple co-morbidities and disease complications that contributes to develop these problems among diabetic patients (Burno et al 2019). Diabetes distress, depression and anxiety leads toward decreased health related quality of life among diabetic patients (Onyenekwe et al., 2020). Clinical depression is highly prevalent in diabetes, being up to two times more common among patients with diabetes than those without and also reduces overall quality of life and life expectancy among diabetic patients (Alzahrani et al 2019).

Diabetes distress and diabetes self-management share a complex relationship. When individuals experience high levels of diabetes distress and depression, they feel overwhelmed, frustrated, or emotionally burdened by the demands of managing their condition (Schmitt et al., 2021). This emotional strain can lead to reduced motivation, avoidance of self-care behaviors, and lower adherence to essential diabetes management tasks such as monitoring blood glucose, following dietary plans, and taking medications as prescribed. Over time, poor self-management result in deteriorating health outcomes, further increasing distress and creating a negative cycle (Lin et al., 2017).

Social support serves as a crucial buffer against the challenges posed by diabetes distress. It encompasses emotional, informational, and practical assistance from family, friends, and healthcare providers. Robust social support has been linked to improved self-care behaviors, and enhanced QOL (Baek et al., 2014). A systematic review found that social support positively affects medication adherence and disease management, leading to reduced stress and improved acceptance of the condition. Adequate social support can mitigate diabetes distress by providing emotional reassurance and practical assistance. Conversely, lack of support may exacerbate feelings of isolation and stress. Research indicates that individuals with higher social support experience lower levels of diabetes-related distress (Parviniannasab et al., 2024).

Diabetes stigma and diabetes distress are significant psychosocial challenges faced by individuals living with diabetes. Diabetes stigma involves negative attitudes, blame, and stereotypes from society, often leading to feelings of shame or guilt, particularly for those with type 2 diabetes who may be unfairly judged for their lifestyle choices (Xing et al., 2023). This stigma can result in

discrimination and internalized negative beliefs, further exacerbating emotional struggles. Both stigma and distress can lead to mental health issues like anxiety and depression, and reduced QOL(Wang et al., 2021).

The biopsychosocial model provides a comprehensive framework for understanding and managing diabetes by considering the interconnected roles of biological, psychological, and social factors(Ozturk et al., 2023 ; Amsah et al., 2022). Traditionally, diabetes care focused primarily on biological aspects such as insulin resistance, hyperglycemia(Rahman et al., 2021), and medication management (Thottapillil et al., 2021). While these elements remain crucial, the biopsychosocial model emphasizes that diabetes is not merely a biological condition but a complex interplay of various dimensions. Biological factors include genetic predisposition, obesity, and metabolic disturbances, which form the foundation of diabetes pathology. Effective management requires addressing these aspects through medications, lifestyle modifications, and regular health monitoring (Hunt, 2024).

Existing literature support that different psychological interventions has been used to manage psychological problems of patients with diabetes such as cognitive behavioral therapy (CBT) helps people change thinking and behavior to manage mental health conditions (Abbas et al., 2023), diabetes self-management education (DSME) provides significant effectiveness to lifestyle changes and the self-care of T2DM patients (Ernawati et al., 2021), motivational interviewing (MI) is a patient centered, following, and directing communication approach that places the responsibility for decision-making and effective in reducing HbA1C, depressive symptoms, emotional distress, and increasing self-efficacy. Mindfulness based intervention (MBI) increases levels of mindfulness and non-judgmental acceptance, and decreases negative reactivity and repetitive negative thinking, which in turn lead to improving adherence to medical care and the ability to manage negative emotion (Ni et al., 2021), and diabetes wellbeing program (DWELL) for diabetes led to significant improvements in metabolic health measures and produced significant positive changes across a range of psychological measures such as patient empowerment, illness perceptions, eating behaviors and self-care behaviors (Hatzidimitriadou et al., 2025).

While existing psychological therapies are effective for addressing general psychological issues such as depression or anxiety, they often fall short in addressing the unique, multifaceted challenges faced by individuals with diabetes (Diribe et al., 2024). Diabetes introduces specific stressors, including the constant burden of self-management (Yu et al., 2020) (e.g., blood glucose monitoring, dietary restrictions), health anxiety, and societal stigma, which generic therapies may not fully tackle (Akshatha & Nayak, 2024 & Harvey, 2015) . A tailored psychosocial program is necessary because it integrates biological, psychological, and social factors(Kusnanto et al., 2018) into a holistic approach, as outlined by the Biopsychosocial Model (Amsah et al., 2022). For instance, it can combine medical care with emotional, and social support lead to reduction of diabetes distress, health anxiety and stigma, thus improving QOL and treatment adherence providing a more comprehensive solution. In essence, a tailored psycho-social program will fill the gaps left by existing therapies, offering a comprehensive, diabetes-specific approach that addresses the unique needs of individuals living with diabetes (Bajwa, 2024) (Cimo & . Dewa, 2025).

Objectives {7}

The current study is designed to measure the role of PSP with T2DM patients. There are following objectives of this current study, such as

- To investigate the impact of Psycho-Social Program (PSP) for reducing diabetes-related distress, ad depression among T2DM patients
- To investigate the impact of Psycho-Social Program (PSP) for reducing health anxiety and stigma among T2DM patients
- To investigate the impact of Psycho-Social Program (PSP) for improving quality of life, and treatment adherence among individuals with T2DM.

Hypothesis of the Study

After review of the literature, the following hypotheses such as;

- Psycho-social program (PSP) will play a significant role to reduce mental health problems among patients with T2DM.
- Psycho-social program (PSP) will play a significant role to reduce diabetes distress, among patients with T2DM.
- Psycho-social program (PSP) will play a significant role to reduce depression among patients with T2DM.
- Psycho-social program (PSP) will play a significant role to reduce health anxiety among patients with T2DM.
- Psycho-social program (PSP) will play a significant role to reduce stigma among patients with T2DM.
- Psycho-social program (PSP) will play a significant role for enhancing quality of life, and treatment among individuals with T2DM

Trial design {8}

Randomized control trial design would be used in this study. It would be two arm study and there would be two groups an experimental and wait-list control group. Experimental group will receive intervention and another group would be placed in waitlist. In this research, parallel group design would be used. We will give treatment to all participants in a parallel way. Allocation ratio and framework would be equivalence i.e., treatment group and control group would be equal number of participants.

Methods: Participants, interventions and outcomes

Study setting {9}

Randomized control trial design would be used in this study to find out the impact of PSP for psychiatric comorbidity and adherence to treatment among patients with T2DM.

Participants

In this study, the participants would be patients diagnosed with type II diabetes mellitus. For this purpose, N=80 diabetic patients would be approached from different hospitals of Faisalabad. Sample would be comprised of male and female with type II diabetes mellitus. In order to collect the data for our study, purposive sampling technique would be used. Patient age range would be 30-40 years. Participants would be divided into two group each group will be comprised of n=40. One group will be experimental group and second group will be wait-list control group.

Eligibility criteria {10}

The patients diagnosed with Type II Diabetes Mellitus (T2DM) male and female participants aged 30-40 years will be included in our study. The participants from different hospitals or clinic of Faisalabad will be included in our study. The patient with Type 1 Diabetes Mellitus (T1DM) would be excluded from our study. The patient with other serious co-morbid medical illness such as cancer, heart problems, and stroke will be excluded from our study. The patient with physical disability would be excluded from our study.

Who will take informed consent? {26a}

Researcher will be taken consent from all of the participants through consent form.

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

Informed consent will be given and confidentially would be ensures. Researcher will guide the participant that their participation would be volunteer.

Interventions

Psycho-Social Program (PSP) would be used as a intervention strategy for the diabetes

patients to deal with their diabetes distress, health anxiety, depression, quality of life and adherence to treatment.

Explanation for the choice of comparators {6b}

Psycho-Social Program (PSP) would be used as a intervention strategy for T2DM patients to deal with their depression, stigma, social support, quality of life and adherence to treatment.

Intervention description {11a}

Structured intervention program for the patients with mental health problems, who availed cognitive behavior therapy and who availed both medication and cognitive behavior therapy is given.

Session	Target Goals	Objectives	Techniques
Session 1	Introduction & Goal Setting	Build rapport and set individual goals for self-management.	Group introductions, g Motivational Interview
Session 2	Managing Diabetes Distress	Address emotional responses and coping strategies.	CBT techniques: thou, cognitive restructuring
Session 3	Enhancing Self-Management Skills	Build skills for medication, diet, and glucose management.	Self-monitoring logs, , exercises.
	Building Motivation and Resilience	Foster motivation and long-term adherence.	Group reflections, suc reinforcement.
Session 4	Social Support and Relationship Building	Strengthen social networks for emotional support.	Peer support groups, r exercises.
	Stress Management and Emotional Well-being	Develop stress management techniques to reduce burnout.	Guided mindfulness s exercises.
Session 5	Muscle relaxation and breathing exercise	Engage family in supporting diabetes management.	Family counseling ses communication skill-t

Criteria for discontinuing or modifying allocated interventions {11b}

Those participants who will not interested in intervention due to their time if they will not come at their session time as well as they quit the intervention then we will remove in our research and if we will need to modify the treatment plan then we will modify the intervention according to the participants benefit.

Strategies to improve adherence to interventions {11c}

Strategies to learn how to manage depression, stigma, and enhance social support, quality of life, and adherence to treatment through deep breathing exercise, problem solving worksheet, exposure therapy and role playing.

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

Participants will be permitted to follow the guideline given by the therapist as to take care of their mental health by following the assignment for each session and prohibited to perform any activity that can hinder to improve their adherence such as avoid becoming worried, anxious etc.

Provisions for post-trial care {30}

We have study follow up plan and in-contact with hospital doctors then we will assess the participants after 6 months

Outcomes {12}

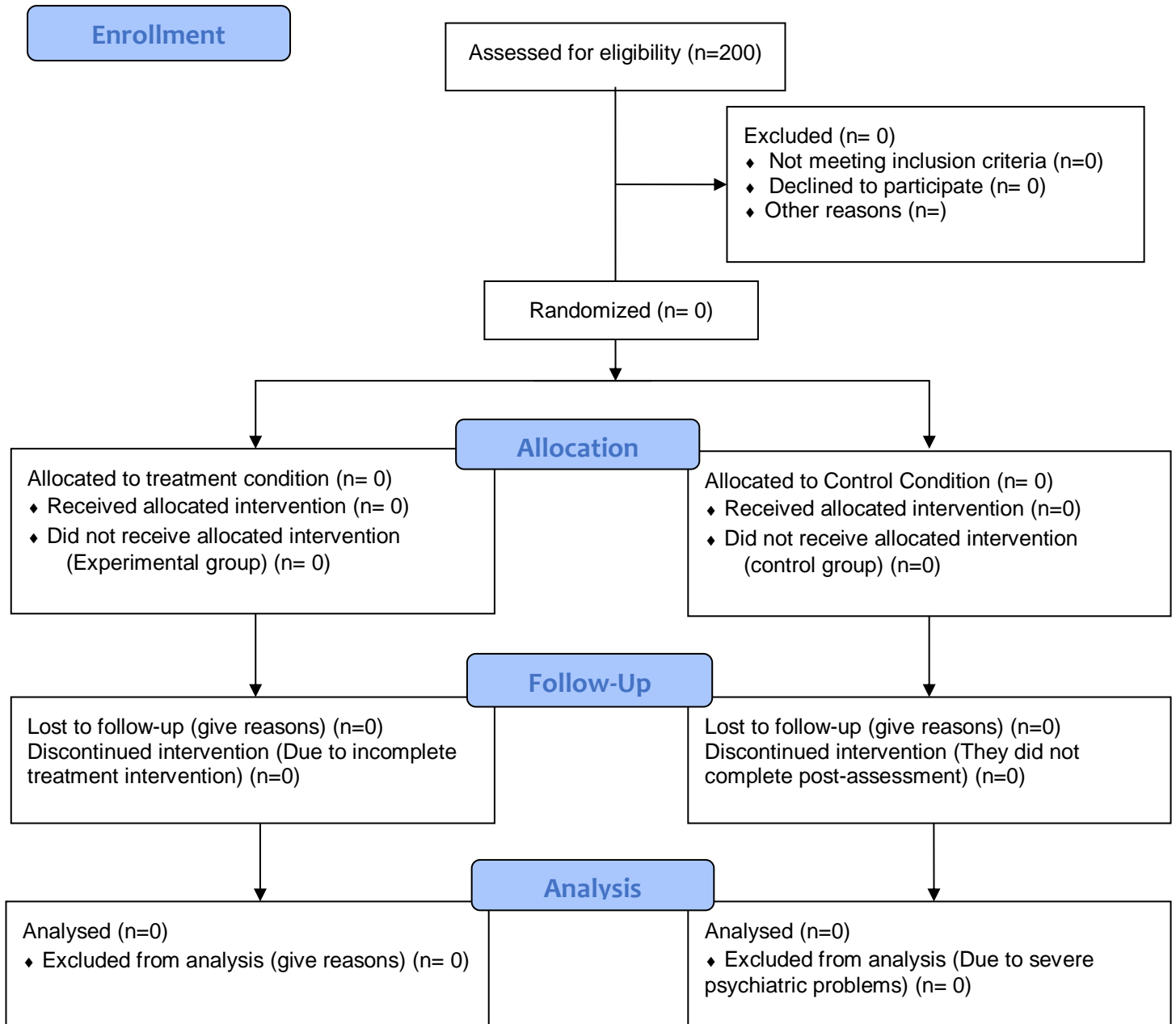
This study would provide valuable information to the mental health practitioners to treat and develop the guidelines and protocol for patients with T2DM. PSP played substantial role as supportive intervention to develop insight, motivation and positive attitude toward treatment as well as to enhance adherence to treatment among patients with T2DM. And there would be substantial decrease in the stigma and depression, and increase social support, quality of life and adherence to treatment among patients with T2DM after the completion of the intervention program.

Participant timeline {13}

In this research, the patient would be diagnosed with T2DM. For this purpose, N=80 diagnosed patients with T2DM would be taken from hospital. Sample would be comprised of both males and females. In order to collect the sample for the desired study, purposive sampling technique would be used. Patient's age range would be between 20 to 40 years. Participant would be divided into two groups. In group one, the diagnosed patients of T2DM who are availing antiretroviral therapy

group diagnosed T2DM patients would be taken and cognitive behaviour therapy would not be provided to them. Each of the group will be comprised of n= 40

CONSORT Flowchart Diagram of T2DM



Note: This diagram completed after the completion of this research.

Sample size {14}

In this study, patients would be recruited from different hospital of Faisalabad. Participants' enrollment started after trial registration and a three to four months period would be allocated to each patient to achieve treatment goals. Initially patients would be assessed for eligibility, inclusion and

exclusion criteria would be checked. In the next step, participants would be allocated to interventions after the baseline assessment. Then participants would receive the interventions.

Recruitment {15}

The participants would be recruited from the settings of hospitals of Faisalabad.

Assignment of interventions: allocation

Initially researcher would take permission from hospital of Faisalabad and data would be collected from hospital. Informed consent would be given and confidentiality would be ensured. Structured interview would be performed, the first meeting with experimental and waitlist control group would be to explain the nature and purpose of this intervention. The first group will receive PSP and second group will not receive PSP. Total 6-8 structured sessions of PSP would be conducted by following the training modules of cognitive behavior therapy. After conducting interviews with the T2DM patient's one on one assessment thoroughly conducted on each patient who will receive cognitive behavior therapy to record their baseline score. Then sessions of PSP will be conducted with T2DM patients, each session will agenda session. The review of each session will be performed with the help of session record sheet. After the completion of intervention program the comparison of both groups will be recorded separately and then compare for findings the difference and to check the effects of the intervention.

Sequence generation {16a}

Initially researcher would take permission from hospital and data would be collected from hospital. Informed consent would be given and confidentiality would be ensured. Structured interview would be performed, the first meeting with experimental and waitlist control group would be to explain the nature and purpose of this intervention. The experimental group will receive PSP and control group will not receive PSP. Total 8 structured sessions of cognitive behavior therapy would be conducted by following the training modules of PSP. After conducting interviews with the patients on one assessment thoroughly conducted on each patient who will receive cognitive behavior therapy to record their baseline score. Then sessions of cognitive behavior therapy will be conducted with patient, each session will be agenda session. The review of each session will be performed with the help of session record sheet. After the completion of intervention program, the comparison of experimental and control groups will be recorded separately and then compare for findings the difference and to check the effects of the intervention.

Concealment mechanism {16b}

Intervention would be provided physically i.e., face to face interaction between researcher and participants.

Implementation {16c}

Therapist will generate the allocation sequence and would enroll the T2DM diagnosed patients. And then participants would be randomly assign to the experimental and waitlist control group.

Assignment of interventions: Blinding

Who will be blinded {17a}

No one will be blinded after assignment to interventions. At initial of the study, researcher describe the purpose and procedure of the study to the participants and take consent from all participants then researcher would start the study.

Procedure for unblinding if needed {17b}

In this research, researcher and participants would be unblind because the purpose of this to promote and manage their depression, stigma and enhance social support, quality of life and

adherence to treatment. Before, starting the study researcher would take informed consent from all of the patient and give briefing about the study. Then those patients show willingness to take part in the study then research recruit those patients.

Data collection and management

Plans for assessment and collection of outcomes {18a}

Following assessment tools would be used to collect the data from T2DM patients.

Demographic form.

A demographic form will be formed to obtain necessary information about each patient i.e. age of the patient, education, socioeconomic status, and family system, and total family members, marital status, duration of illness, hospital name. This form will be used for further analysis of the result section.

Diabetes Distress Scale (DDS-17 Polonsky, Fisher, Esarles, Hesseler & Mullan 2005).

Diabetes Distress Scale (DDS-17) is used to assess the distress related to diabetes. It consists of 17 items. Each item of the DDS-17 has a six-point Likert scale from 1 (indicating no problem) to 6 (indicating a very serious problem). The total DDS-17 score was calculated by summing a patient's responses to the 17 items and dividing by the number of items on the scale. DM distress was considered clinically significant (moderate distress) if the total score was > 2 , and severe if the score was ≥ 3 . DDS-17 also assesses other components including emotional-related distress, physician-related distress, regimen-related distress, and interpersonal-related distress. Its reliability was reported 0.87 Cronbach's alpha.

The Patient Health Questionnaire (PHQ-9; Ahmad 2018).

The PHQ-9 is the nine item depression scale of the Patient Health Questionnaire. It is based directly on the diagnostic criteria for major depressive disorders in Diagnostic and Statistical Manual Fourth Edition. The PHQ-9 scores "0" (not at all) to "3" (nearly every day). We will use Urdu version of this scale translated by Ahmed, Akhtar, & Shah (2018).

Short Health Anxiety Inventory (SHAI; Salkovskis, 2002)

The SHAI contains 18 items that assess health anxiety independently of physical health status. Items assess worry about health, awareness of bodily sensations or changes, and feared consequences of having an illness. The SHAI has demonstrated good reliability, criterion validity, and sensitivity to treatment (Salkovskis et al., 2002).

Revised Version of Diabetes Quality of Life Questionnaire (RV-DQOL 13 Bujang et al. 2018).

Diabetes quality of life Questionnaire (RV-DQOL) instrument has been used to measure quality of life among diabetes patients. It consists of 13 items has three domains such as Satisfaction, Impact, Worry. Patients respond to all items on a 5-point Likert scale. A score of 1 indicates no impact, no worries, or always satisfied. A score of 5 represents always affected, always worried, or never satisfied. The reliability was 0.92 and 0.84, for worry, 0.98 and 0.60, for satisfaction and, for "impact", 0.99 and 0.57, respectively (Bujang et al 2018).

Multidimensional Scale of Perceived Social Support (MSPSS Zimet, 2016)

We will measure perceived social support using MSPSS 12-item, 7-point Likert-type scale (1 = Very strongly disagree, 2 = Strongly disagree, 3 = Mildly disagree, 4 = neutral, 5 = Mildly agree, 6 = Strongly agree, and 7 = Very strongly agree). A composite score is obtained by adding the scores on all 12 items and dividing it by 12. Cronbach alpha for the scale is 0.72 for our sample.

Diabetes Stigma Assessment Scale (DSAS-2 Browne et al., 2016)

This scale assesses the perceived stigma experienced by individuals with diabetes across three dimensions: social rejection, self-stigma, and discrimination. The DSAS-2 consists of 19 items rated on a 6-point Likert scale, ranging from 1 (Strongly Disagree) to 6 (Strongly Agree).

Higher scores indicate greater perceived stigma. The DSAS-2 has been widely used and validated in various populations with diabetes.

Plans to promote participant retention and complete follow-up {18b}

Major focus was given to patients' level of motivation and attitude toward treatment. Participants would be given motivation by the therapist to be the part of study to achieve a better mental health and avoid the distress associated with their illness. The participants who will leave the study incomplete and would show less interest for being a part of study would be discontinuing the study. .

Data management {19}

Data manage on the SPSS. First, patient screen out and then select patient who meet inclusion criteria. Next step is baseline assessment to experimental and control group, and after that give PSP to the experimental group then comparison between experimental and control group. At last, compare the pre and post assessment of the patients through paired sample T-test.

Confidentiality {27}

Demographic sheet would be used to collect personal information of the participants. Confidentiality would be ensured to the client that their information would be used only for research purpose and would be kept in privacy.

Plans for collection, laboratory evaluation and storage of biological specimens for genetic or molecular analysis in this trial/future use {33}

N/A

Statistical methods

Statistical methods for primary and secondary outcomes {20a}

Statistical Analysis with descriptive statistics (M, SD, f), Chi-square statistics and t-test for matchable group characteristics, and repeated measures ANOVA for pre-and post-outcomes evaluation will be conducted. In this study sample sizes will be calculated using G-Power Software. All analyses will be conducted using SPSS-26.

Interim analyses {21b}

Dr. Qasir Abbas play as an interim analysis. He provides guidelines about the study.

Methods for additional analyses (e.g. subgroup analyses) {20b}

Descriptive statistics (i.e., Mean, Standard Deviation, Frequencies etc) will be used to calculate demographic characteristics of the sample.

Methods in analysis to handle protocol non-adherence and any statistical methods to handle missing data {20c}

We will follow the expert opinion to handle any issues related to non-adherence and missing data in our data.

Plans to give access to the full protocol, participant level-data and statistical code {31c}

All statistical computation would be calculated by using SPSS 24.0.

Oversight and monitoring

Composition of the coordinating center and trial steering committee {5d}

The participants would be recruited from the hospital Faisalabad.

Composition of the data monitoring committee, its role and reporting structure {21a}

Supervisor; Dr. Qasir Abbas will monitor.

Adverse event reporting and harms {22}

In case if we face any inauspicious event in our study the entire research team will act upon to encounter and to prevent the harm to the study participant.

Frequency and plans for auditing trial conduct {23}

Once we conduct the trial then, we will provide the trial to participants.

Plans for communicating important protocol amendments to relevant parties (e.g. trial participants, ethical committees) {25}

All protocols will be designed after consultation with ethical committees, BOS etc and Institutional Review Board (IBR), then my topic are approved.

Dissemination plans {31a}

No sponsor for the study.

Discussion

Before initiating the study, research team will ensure to foreclose any practical or operational issues involved in performing the study to avoid future troublesome.

Trial status

Research proposal accepted from the Ethical Committee and Institutional Review Board (IBR) then trial would be register.

Abbreviations**The list of abbreviations is:**

Psycho-Social Program (PSP)

Diabetes Distress (DD)

Patient Health Questionnaire PHQ-9

Multidimensional Scale of Perceived Social Support (MSPSS)

Declarations

I, Ms Sana Latif, solemnly declare that the work submitted in thesis entitled “psycho-social program (psp) for mental health problems among patients with type 2 diabetes mellitus (t2dm): a randomized control trial” is my own and will not be presented to any other institution or university for the degree. Neither work will be plagiarized. It is an original work.

This work will be completed at the Institute of Applied Psychology, Government college University Faisalabad under the supervision of Dr. Qasir Abbas.

Acknowledgements

First of all, I thank to Allah Almighty for his faithfulness and protection throughout my study that will be made it possible for me to encounter this success. I take this great opportunity to sincerely thank a number of people and institution who will be made it possible for my research paper

My gratitude goes to my supervisor Dr. Qasir Abbas for dedicated to support and endless that he will offer me throughout my research process. He will put great effort in helping me in accomplishing this work successfully. Without his effort, this research would not have been what it looks like now. I will also very thankful to the chairperson of our institute. I would also express my great and sincere thanks to the administration of hospital and clinics and participants who will take part in our study to give permission and allow conducting this experiment. My special thanks will go to my supportive family that I can't find words to explain.

Authors' contributions {31b}

Sana Latif Student of PhD Applied Psychology from GCUF

Dr. Qasir Abbas as a supervisor

Funding {4}

There is no any kind of funding in research.

Availability of data and materials {29}

Data will be available if journal demand or for the beneficial informant for the researchers

Ethics approval and consent to participate {24}

After review of literature, the topic was decided. Then proposal is prepared and submitted in the Department Research Committee for technical review. Afterwards proposal will be defended in the meeting of the Board of advance Studies. Then, permission would be taken from department of Applied Psychology, Government College University Faisalabad. Reliable and valid psychological testing tools would be used in current study. Scale's permission would be taken from the authors.

In the process of study, we would adhere to four key elements for the person's right and dignity, competency, responsibility, integrity. Permission letters were taken from the head of department of Applied Psychology and then it will be submitted to the higher authorities of different colleges. A complete procedure of getting permission from the colleges will be ethically conducted. The complete idea of study implementation will be discussed with the Consultants to ensure a pure true experimental study. After their confirmation of order letter, the process of collecting desired information from targeted sample will be precede ahead. Inform the patients about possible risks and benefits of the study as by explaining it clearly to the subjects, also told the purpose of the study clearly. Obtain their written informed consent before involved the patients into the study, give the participants necessary details before collection of data. The subjects would be assured that their personal information will keep confidential and only used for research purpose.

Consent for publication {32}

This research will be conducting by Sana Latif, student of Institute of Applied Psychology under the supervision of Dr. Qasir Abbas. The purpose of this research is to explore the impact of PSP to reduce the level of diabetes distress and depression, and to improve the level of social support, quality of life and treatment adherence among patient with T2DM. During this research you will be to fill demographic sheet and questionnaires. All of your information regarding research will be kept confidential and used only for research purpose. If you want to quit the research, you have to complete right to quit the research at any point.

Competing interests {28}

There is no Financial and other competing interests for principal investigators for the overall trial and each study site.

Authors' information (optional)

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References

- Abbasi-Ghahramanloo, A., Soltani-Kermanshahi, M., Mansori, K., Khazaei-Pool, M., Sohrabi, M., Baradaran, H. R., Talebloo, Z., & Gholami, A. (2020). Comparison of SF-36 and WHOQoL-BREF in Measuring Quality of Life in Patients with Type 2 Diabetes. *International journal of general medicine*, 13, 497–506. <https://doi.org/10.2147/IJGM.S258953>
- Adnan, M., & Aasim, M. (2020). Prevalence of Type 2 Diabetes Mellitus in Adult Population of Pakistan: A Meta-Analysis of Prospective Cross-Sectional Surveys. *Annals of Global Health*, 86(1), 7. DOI: <http://doi.org/10.5334/aogh.2679>
- Bujang, M. A., Adnan, T. H., Mohd Hatta, N., Ismail, M., & Lim, C. J. (2018). A Revised Version of Diabetes Quality of Life Instrument Maintaining Domains for Satisfaction, Impact, and Worry. *Journal of diabetes research*, 2018, 5804687. <https://doi.org/10.1155/2018/5804687>
- Chandra, M., Raveendranathan, D., Johnson Pradeep R, Patra, S., Rushi, Prasad, K., & Brar, J. S. (2020). Managing Depression in Diabetes Mellitus: A Multicentric Randomized Controlled Trial Comparing Effectiveness of Fluoxetine and Mindfulness in Primary Care: Protocol for DIAbetes Mellitus ANd Depression (DIAMAND) Study. *Indian journal of psychological medicine*, 42(6 Suppl), S31–S38. <https://doi.org/10.1177/0253717620971200>
- Fisher, L., Hessler, D.M., Polonsky, W.H., Mullan, J. (2012). When is diabetes distress clinically meaningful? Establishing cut-points for the Diabetes Distress Scale. *Diabetes Care*, 35, 259-264.
- Ghaffar, N. (2020). Diabetic patient's self-care and management visiting to the Lahore General Hospital Pakistan.
- Harrington, N. (2005a). The Frustration Discomfort Scale: Development and psychometric properties. *Clinical Psychology and Psychotherapy*, 2, 374–387. <https://www.who.int/news-room/fact-sheets/detail/diabetes>
- Hu, Y., Li, L., & Zhang, J. (2020). Diabetes Distress in Young Adults with Type 2 Diabetes: A Cross-Sectional Survey in China. *Journal of Diabetes Research*, 2020.
- Jalali, N., Kojidi, H. T., Badrfam, R., & Zandifar, A. (2021). The relationship between personality disorder, depression and eating disorder with treatment adherence in patients with type 2 diabetes; a cross-sectional study in diabetic patients in Iran. *Journal of Diabetes & Metabolic Disorders*, 1-7.
- Jeronimus, Bertus & Laceulle, Odilia. (2017). Frustration. 10.1007/978-3-319-28099-8_815-1.
- Kalra, G., Gill, S., & Tang, T. S. (2020). Depression and diabetes distress in South Asian adults living in low-and-middle-income countries: A scoping review. *Canadian Journal of Diabetes*, 44(6), 521-529.
- Kalra, Sanjay et al. "Emotional and Psychological Needs of People with Diabetes." *Indian journal of endocrinology and metabolism* vol. 22,5 (2018): 696-704. doi:10.4103/ijem.IJEM_579_17
- Khalighi, Z., Badfar, G., Mahmoudi, L., Soleymani, A., Azami, M., & Shohani, M. (2019). The prevalence of depression and anxiety in Iranian patients with diabetes mellitus: A systematic review and meta-analysis. *Diabetes & metabolic syndrome*, 13(4), 2785–2794. <https://doi.org/10.1016/j.dsx.2019.07.004>
- Kroenke, K., Spitzer, R. L., & Williams, J. B. (2001). The PHQ-9: validity of a brief depression severity measure. *Journal of general internal medicine*, 16(9), 606–613. <https://doi.org/10.1046/j.1525-1497.2001.016009606.x>
- Lal, B Suresh. (2016). DIABETES: CAUSES, SYMPTOMS AND TREATMENTS.
- Lebel, S., Mutsaers, B., Tomei, C., Leclair, C. S., Jones, G., Petricone-Westwood, D., ... & Dinkel, A. (2020). Health anxiety and illness-related fears across diverse chronic illnesses: A systematic review on conceptualization, measurement, prevalence, course, and correlates. *Plos one*, 15(7), e0234124.

- Martino, G., Caputo, A., Bellone, F., Quattropani, M. C., & Vicario, C. M. (2020). Going Beyond the Visible in Type 2 Diabetes Mellitus: Defense Mechanisms and Their Associations With Depression and Health-Related Quality of Life. *Frontiers in Psychology*, 11, 267.
- Miller, F., Anderson, M., Tucker, D., Vaz, K., Brown, J., Anderson-Jackson, L., & McGrowder, D. A. (2020). Diabetes: Biopsychosocial Features Affecting Metabolic Control and Treatment Adherence. In *Biopsychosocial Perspectives and Practices for Addressing Communicable and Non-Communicable Diseases* (pp. 106-133). IGI Global
- Morisky, D. E. (2008). Predictive validity of a medication adherence measure for hypertension control. *Journal of clinical hypertension*, 10, 348-354.
- Nematollahi, S. (2021). Effect of a Quality of Life Education Program on Psychological Well-Being and Adherence to Treatment of Diabetic Patients. *Journal of Holistic Nursing And Midwifery*, 31(1), 61-67.
- Nikkhah Ravari, O., Mousavi, S. Z., & Babak, A. (2020). Evaluation of the Effects of 12 Weeks Mindfulness-Based Stress Reduction on Glycemic Control and Mental Health Indices in Women with Diabetes Mellitus Type 2. *Advanced biomedical research*, 9, 61. https://doi.org/10.4103/abr.abr_133_20
- Onyenekwe, B. M., Young, E. E., Nwatu, C. B., Okafor, C. I., & Ugwueze, C. V. (2020). Diabetes Distress and Associated Factors in Patients with Diabetes Mellitus in South East Nigeria. *Dubai Diabetes and Endocrinology Journal*, 26(1), 31-37.
- Polonsky WH, Anderson BJ, Lohrer PA, et al. Assessment of diabetes-related distress. *DiabetesCare*. 1995;18(6):754–760. doi: 10.2337/diacare.18.6.754
- Priya G, Kalra S. Mind-Body Interactions and Mindfulness Meditation in Diabetes. *Eur Endocrinol*. 2018 Apr;14(1):35-41. doi: 10.17925/EE.2018.14.1.35. Epub 2018 Apr 18. PMID: 29922350; PMCID: PMC5954593.
- Qasim, R., Masih, S., Hussain, M., Ali, A., Khan, A., Shah, Y., ... & Yousafzai, M. T. (2019). Effect of diabetic counseling based on conversation map as compared to routine counseling on diabetes management self-efficacy and diabetic distress among patients with diabetes in Pakistan: a randomized controlled trial (study protocol). *BMC public health*, 19(1), 1-7.
- Qiu, S., Sun, H., Liu, Y., Kanu, J. S., Li, R., Yu, Y., ... & Zhang, X. (2017). Prevalence and correlates of psychological distress among diabetes mellitus adults in the Jilin province in China: a cross-sectional study. *PeerJ*, 5, e2869.
- Safren SA, Gonzalez JS, Wexler DJ, Psaros C, Delahanty LM, Blashill AJ, Margolina AI, Cagliero E. A randomized controlled trial of cognitive behavioral therapy for adherence and depression (CBT-AD) in patients with uncontrolled type 2 diabetes. *Diabetes Care*. 2014;37(3):625-33. doi: 10.2337/dc13-0816. Epub 2013 Oct 29. Erratum in: *Diabetes Care*. 2016 Jun;39(6):1065. PMID: 24170758; PMCID: PMC3931377.
- Saqib Lodhi, F., Raza, O., Montazeri, A., Nedjat, S., Yaseri, M., & Holakouie-Naieni, K. (2017). Psychometric properties of the Urdu version of the World Health Organization's quality of life questionnaire (WHOQOL-BREF). *Medical journal of the Islamic Republic of Iran*, 31, 129. <https://doi.org/10.14196/mjiri.31.129>
- Schmidt, C. B., van Loon, B. P., Vergouwen, A. C. M., Snoek, F. J., & Honig, A. (2018). Systematic review and meta-analysis of psychological interventions in people with diabetes and elevated diabetes-distress. *Diabetic Medicine*, 35(9), 1157-1172.
- Sharma, K., Dhungana, G., Adhikari, S., Bista Pandey, A., & Sharma, M. (2021). Depression and Anxiety among Patients with Type II Diabetes Mellitus in Chitwan Medical College Teaching Hospital, Nepal. *Nursing Research and Practice*, 2021.
- The WHOQOL Group. The World Health Organization Quality of Life assessment (WHOQOL): Development and general psychometric properties. *Soc Sci Med*. 1998;46:1569–1585.
- Tran, N., Nguyen, Q., Vo, T. H., Le, T., & Ngo, N. H. (2021). Depression Among Patients with Type 2 Diabetes Mellitus: Prevalence and Associated Factors in Hue City, Vietnam. *Diabetes*,

metabolic syndrome and obesity : targets and therapy, 14, 505–513.
<https://doi.org/10.2147/DMSO.S289988>

- Wagner, J. A., Bermudez-Millan, A., Damio, G., Segura-Perez, S., Chhabra, J., Vergara, C., Feinn, R., & Perez-Escamilla, R. (2016). A randomized, controlled trial of a stress management intervention for Latinos with type 2 diabetes delivered by community health workers: Outcomes for psychological wellbeing, glycemic control, and cortisol. *Diabetes research and clinical practice*, 120, 162–170. <https://doi.org/10.1016/j.diabres.2016.07.022>.
- Winkley, K., Upsher, R., Stahl, D., Pollard, D., Kasera, A., Brennan, A., Heller, S., & Ismail, K. (2020). Psychological interventions to improve self-management of type 1 and type 2 diabetes: a systematic review. *Health technology assessment (Winchester, England)*, 24(28), 1–232. <https://doi.org/10.3310/hta24280A>