

# Feasibility and Preliminary Effectiveness of a Nurse-Led Mindfulness-Based Stress Reduction (MBSR) Intervention on Diabetes Distress, Coping, and Glycemic Control among Adults with Type 2 Diabetes: A Study Protocol

Sobia Raoof<sup>1</sup>, Kainat Asmat<sup>2\*</sup>, Huma Rubab<sup>3</sup>, Saba Asim<sup>4</sup>

<sup>1</sup>MSN Student Shifa Tameer-e-Millat University, Islamabad, Pakistan.

<sup>2\*</sup>Associate Professor Faculty of Nursing and Midwifery, Shifa Tameer-e-Millat University, Islamabad, Pakistan.

<sup>3</sup>Assistant Professor Faculty of Nursing and Midwifery, Shifa Tameer-e-Millat University, Islamabad, Pakistan.

<sup>4</sup>Adjunct Assistant Professor Faculty of Nursing and Midwifery, Shifa Tameer-e-Millat University, Islamabad Pakistan.

## ABSTRACT

**Background:** Diabetes distress (DD) is common psychosocial issue among adults with type 2 diabetes mellitus (T2DM) and is associated with maladaptive coping, inadequate self-care practices and suboptimal glycemic control. Despite the high prevalence of DD among adults with T2DM in Pakistan, psychosocial screening and supportive interventions are not well integrated into routine care. Mindfulness-based stress reduction (MBSR) has shown potential in decreasing emotional distress and enhancing coping and glycemic outcomes in people with T2DM. However, evidence regarding the feasibility, acceptability and effectiveness of culturally adapted MBSR interventions in low-resource settings is limited.

**Objective:** This study aims to evaluate the preliminary effectiveness, feasibility, acceptability and perceived usefulness of a nurse-led MBSR intervention in improving DD, coping and glycemic control among T2DM adults in Pakistan.

**Methods and Analysis:** A multi-methods study employing a single-arm pre-test post-test design and qualitative interviews will be conducted at the outpatient department of a public sector tertiary care hospital of AJK, Pakistan. Approximately 60 T2DM adults with moderate or high DD will be recruited using consecutive sampling. The study participants will receive a culturally adapted 4-week nurse-led

MBSR intervention delivered in weekly group sessions. Quantitative outcomes will include DD, coping strategies and HbA1c, measured at baseline and 3-month follow-up. A purposive subsample of participants will be selected for qualitative semi-structured interviews to assess the feasibility, acceptability and perceived usefulness of the intervention. The qualitative data will be analyzed using inductive-deductive hybrid thematic analysis.

**Keywords:** *diabetes distress, coping; feasibility, glycemic control; type 2 diabetes, mindfulness-based stress reduction; Pakistan.*

## INTRODUCTION

Diabetes mellitus (DM) is a chronic, metabolic condition associated with persistent hyperglycemia due to insulin insufficiency, resistance, or both.<sup>1</sup> It is among the greatest global health issues of the 21<sup>st</sup> century, contributing significantly to morbidity, mortality, and healthcare costs.<sup>2</sup> International Diabetes Federation (IDF) estimates that there are about 589 million adults (1 in 9) aged 20-57 years with DM worldwide, and this will rise to 853 million (1 in 7) by 2050.<sup>3</sup> This burden is especially pronounced in low- and middle-income countries (LMICs), where three out of every four adults are affected.<sup>2-3</sup> Pakistan has world's highest age-adjusted prevalence of DM (31.4%), affecting approximately 34.5 million adults. Furthermore, nearly 26.9% cases remain diagnosed, with projections indicating a substantial rise in disease burden by 2050.<sup>3</sup> Type 2 diabetes mellitus (T2DM) is the most common form of DM, representing over 90% of all diagnosed cases.<sup>4-6</sup>

The increasing prevalence of T2DM in Pakistan is driven by rapid urbanization, demographic transition, an aging population, genetic predisposition, and socioeconomic changes.<sup>7</sup> These factors lead to greater exposure to modifiable risk, including sedentary living, poor eating habits, obesity, and environmental stressors such as air pollution.<sup>8</sup> The burden is further exacerbated by inequitable access to healthcare services, lack of resources for timely screening, diagnosis and long-term disease management,

and socioeconomic constraints such as poverty, low education attainment, and unemployment.<sup>9</sup> Consequently, T2DM and its associated micro- and macrovascular complications limit the functional capacity and quality of life while creating a substantial financial strain on individuals, families, and healthcare system.<sup>10</sup>

T2DM requires lifelong self-management such as taking medication as prescribed, maintaining a healthy diet, engaging in regular physical activity, and monitoring blood glucose levels.<sup>11</sup> In addition to its physical demands, T2DM also imposes significant psychosocial burden on individuals, negatively affecting their emotional and psychological health.<sup>12-13</sup> The ongoing demands of disease management, fear of complications, lifestyle restrictions, and socioeconomic pressures collectively result in significant emotional and psychological distress.<sup>14-16</sup> This condition is known as Diabetes Distress (DD), also termed to as diabetes related distress (DRD) or diabetes specific distress (DSD). DD refers to the negative emotional responses and psychological challenges associated with the complex and demanding nature of T2DM management. Unlike clinical depression, DD is specifically linked to the burden of living with and managing T2DM.<sup>12,15-17</sup> Individuals experiencing DD often report difficulties adhering to treatment recommendations, maintaining healthy lifestyle behaviors, and coping effectively with the disease. Evidence from Pakistan indicates that moderate-to-high levels of DD are prevalent among adults with T2DM and are linked to ineffective coping, poor self-management behaviors, and elevated glycated hemoglobin (HbA1c) levels.<sup>18</sup>

Despite the high burden of DD, T2DM care in Pakistan remains predominantly biomedical, with limited integration of psychosocial screening and supportive interventions.<sup>2</sup> Nurses are well positioned to provide such support due to their continuous therapeutic engagement with patients and their central role in chronic care. Recent evidence from a systematic review indicates that psychological interventions delivered by nurses can substantially reduce DD and improve glycemic outcomes.<sup>19</sup>

Among psychological interventions, Mindfulness-Based Stress Reduction (MBSR) has demonstrated promising effects in alleviating emotional distress, enhancing adaptive coping, and improving self-regulation among individuals living with chronic conditions, including T2DM.<sup>20-22</sup> MBSR promotes present-moment awareness and non-judgmental acceptance, which may help individuals better manage DD and improve self-care behaviors. Despite its potential benefits, limited evidence exists regarding feasibility, acceptability, and preliminary effectiveness of culturally tailored nurse-led MBSR interventions within Pakistani context. This study, therefore aims to address this gap by evaluating both feasibility and preliminary effectiveness of a culturally tailored, nurse-led MBSR intervention for adults with T2DM experiencing moderate to high DD. The study findings will generate important feasibility data for planning a future fully powered randomized controlled trial and may support the integration of psychosocial care into routine T2DM services in Pakistan and similar low resource settings.

## **METHODS**

### **Study Design**

A multi-methods feasibility study using a quantitative single-arm pretest-posttest design and qualitative interviews will be conducted. The quantitative component will assess the preliminary effectiveness of the nurse-led MBSR intervention, while the qualitative component will explore participants' views on the intervention' feasibility, acceptability, and perceived usefulness.

### **Study Setting**

The study will be conducted in the outpatient department (OPD) of a public sector tertiary care hospital in Azad Jammu and Kashmir (AJK), Pakistan. The hospital is an International Organization for Standardization (ISO)-certified facility with capacity of 400 beds and functions as a major referral center for DM care across three districts of AJK. The hospital provides specialized OPD services to a large population of adults with T2DM, with approximately 15,000 patients receiving care annually. This setting

was selected due to its high patient volume, diversity of T2DM population, and availability of structured OPD services that are conducive to the delivery of nurse-led educational and psychosocial interventions, including group-based sessions.

## **Study Duration**

The study is expected to take place over a six-month period, from May to October 2026. This timeline will include participants recruitment and baseline data collection, a four-week intervention period, three-month follow-up, and post-intervention assessments including qualitative interviews.

## **Study Population**

The study population will include adults diagnosed with T2DM who attend OPD of study hospital for treatment and follow-up care. Potential participants will be screened for eligibility according to the following criteria.

## ***Inclusion Criteria***

The participants will be included in study if they:

- Are aged  $\geq 18$  years
- Have a confirmed diagnosis of T2DM for at least 6 months
- Are receiving ongoing care from an endocrinologist at study setting
- Have documented HbA1c results within the last 3 months
- Report moderate to high DD, defined as mean item score  $\geq 3$  on Diabetes Distress Scale (DDS), and
- Are able to understand Urdu language

## ***Exclusion Criteria***

The participants will be excluded if they:

- have a documented psychiatric condition or severe cognitive impairment that may limit their ability to provide informed consent or actively participate in the study
- are pregnant, due to differing metabolic and psychosocial considerations
- have severe or unstable comorbid medical conditions (end-stage renal disease, advanced cardiovascular disease etc.) that may influence study outcomes
- have prior exposure to MBSR program or are currently enrolled in another structured coping or psychological intervention.

## **Sampling Technique**

This study will use consecutive, non-probability sampling technique to recruit participants. All adults with T2DM attending the OPD will be screened for eligibility, those who fulfill the inclusion criteria and provide informed consent, will be enrolled consecutively until the target sample size is achieved.

## **Sample Size**

### ***Quantitative Phase (Preliminary Effectiveness)***

The required sample size for the quantitative component is calculated using G\*Power 3.1 software,<sup>23</sup> employing a priori power analysis for a two-tailed paired-samples t-test. This analysis was conducted to estimate within-subject changes between baseline and post-intervention outcomes. An expected effect size (Cohen's d) of 0.40 was used, derived from a previous mindfulness-based intervention study,<sup>24</sup> using a reported mean difference of 0.27 and standard deviation (SD) of 0.67. Assuming an alpha level of 0.05 and statistical power of 80%, the estimated minimum sample size required was 52 participants. Given the feasibility focus of the study and anticipated attrition rate of approximately 15% during the intervention and follow-up period, a total of 60 participants will be recruited. This size is deemed sufficient to evaluate recruitment, retention, adherence to intervention, and acceptability in

feasibility studies, as well as to provide initial effect size estimates to plan a future fully powered clinical trial.<sup>25</sup>

## ***Qualitative Phase (Feasibility, Acceptability and Perceived Usefulness)***

The sample for qualitative component will be based on the principles of information power and data saturation.<sup>26</sup> According to the principle of information power, sample size adequacy is determined by factors such as study aim, sample specificity, quality of dialogue, and analytic strategy.<sup>27</sup> A purposive sub-sample of about 12-15 participants who complete the intervention will be invited to post-intervention interviews. This sample size is deemed adequate for feasibility studies that involve relatively homogeneous participants and narrowly focused objectives.<sup>28</sup> Maximum variation sampling will be employed to ensure a range of participant perspectives based on characteristics such as age, gender, baseline levels of DD, and intervention session attendance. Interviews will continue until thematic saturation is reached, meaning that no new insights are identified from the data.

## **Study Procedure**

The study will be conducted in four sequential phases. Phases I-III comprise the quantitative component and are designed to assess the preliminary effectiveness of the nurse-led MBSR intervention on DD, coping and HbA1c. Phase IV constitutes the qualitative component, aimed at exploring intervention' feasibility, acceptability, and perceived usefulness.

The quantitative component of the study will be guided by the 7A's framework (Aware, Ask, Assess, Advise, Assist, Assign, and Arrange), which provides a structured approach to participant engagement, assessment, intervention delivery, and follow-up.<sup>29</sup> The framework will be used to support methodological consistency, standardized intervention delivery and fidelity throughout the study. The first three components of the framework (Aware, Ask, and Assess) will be implemented during participant

screening and recruitment to enhance awareness of DD and its impact, encourage participants to reflect on their experiences, and assess baseline DD, coping, and HbA1c levels. The remaining components (Advise, Assist, Assign, and Arrange) will guide intervention delivery, home-based mindfulness practice, and follow-up support during the intervention and post-intervention phases.

### ***Phase I: Pre-Intervention (Screening, Enrollment and Baseline Assessment)***

Phase I will involve participant recruitment, eligibility screening, enrollment, and baseline assessment prior to initiation of intervention. During routine OPD visits, adults with T2DM will be preliminary screened by trained research assistant based on the predefined clinical eligibility criteria including disease duration, pregnancy status, and overall clinical stability. Individuals who appear potentially eligible, will receive a brief overview of the study, including its purpose and procedures. Written informed consent will be obtained from individuals who agree to participate before conducting formal eligibility assessment. Potential participants will undergo formal eligibility screening, which will include administration of the DDS. Individuals scoring a mean DDS score  $\geq 3$ , indicating moderate to high DD, will be enrolled in the study. Following enrollment, baseline data collection (T1) will be carried out by a trained data collector who is independent of intervention delivery to reduce potential bias. Data will be collected using face-to-face structured interviews with validated instruments, including a sociodemographic and clinical data form and the GlucoCoper, a DM-specific coping scale. Baseline HbA1c values will be obtained from participants' recent laboratory reports. Pre-intervention procedures guided by the 7A's framework are summarized in Table 1.

**Table 1:** Pre-intervention Application of 7A's Framework (Aware, Ask & Assess)

| Step | A's Component | Timing                           | Activities                                                                                               | Outputs                 |
|------|---------------|----------------------------------|----------------------------------------------------------------------------------------------------------|-------------------------|
| 1    | Aware         | Recruitment and informed consent | Provide brief education regarding diabetes distress (DD), including its common emotional and behavioural | Participants' awareness |

|   |        |                          |                                                                                                                                                                                                          |                                                                                         |
|---|--------|--------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 2 | Ask    | Enrollment               | manifestations in T2DM, and explain the study purpose and procedures<br>Explore participants' experiences, emotional concerns, T2DM-related stressors, and self-management challenges through discussion | enhanced; informed consent obtained<br>Participants concerns and experiences identified |
| 3 | Assess | Baseline assessment (T1) | Administer the DDS and GlucoCoper scale, and obtain HbA1c values                                                                                                                                         | Baseline data on DD, coping, and HbA1c collected                                        |

## Phase II: Intervention

Phase II will involve delivery of culturally adapted, nurse-led MBSR intervention, structured according to the remaining four components of the 7A's framework (Advise, Assist, Assign, and Arrange).

### *Theoretical and Conceptual Foundation of Intervention*

The MBSR intervention is grounded in two complementary theoretical perspectives: the MBSR model,<sup>30</sup> and Stress and Coping Theory.<sup>31-32</sup>

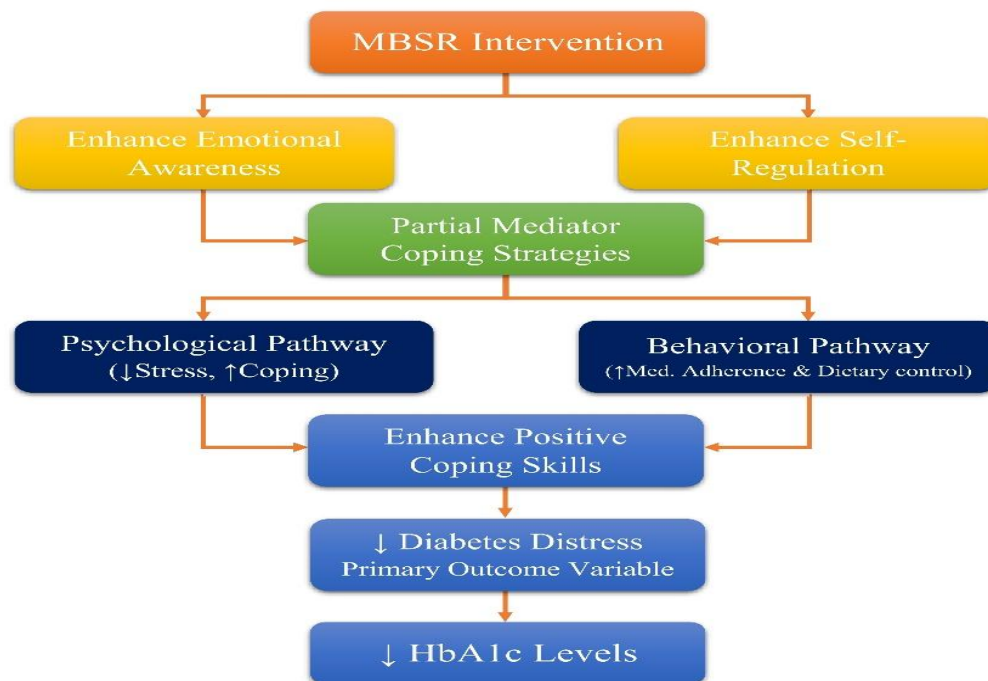
The primary theoretical foundation of the intervention is the MBSR model, which emphasizes present-moment awareness, non-judgmental acceptance, and mind-body integration.<sup>33</sup> In the context of T2DM, mindfulness practices are intended to enhance awareness of emotional and physical experiences related to T2DM management. These practices may help reduce automatic emotional reactivity to T2DM-related stressors and support greater engagement in adaptive self-management behaviours.<sup>16-18</sup> Within this study, MBSR is considered the central therapeutic approach for reducing DD and promoting adaptive coping responses.

The intervention is further informed by the Stress and Coping Theory, which conceptualizes stress as an ongoing interaction between individuals and their environment that is influenced by cognitive appraisal and coping processes.<sup>31-32</sup> Within this framework, DD is understood as arising when individuals perceive the demands of T2DM management to exceed their available coping resources. Mindfulness

practices may support adaptive coping by enhancing emotional regulation, promoting cognitive reappraisal of stressors, and encouraging more effective behavioral responses to T2DM-related challenges.<sup>12,14-15,17</sup> In this study, coping is conceptualized as an important psychological process through which reductions in DD may contribute to improved T2DM self-management and HbA1c.

The conceptual model of the study integrates mindfulness and coping processes to explain the hypothesized pathways through which the intervention may influence outcomes (see Figure 1). The model proposes that engagement in mindfulness practices enhances self-regulation, attentional control, and emotional awareness, thereby reducing emotional reactivity to T2DM-related stressors.<sup>21-22,34</sup> Reduced DD may subsequently facilitate the use of more adaptive coping strategies and greater engagement in health-promoting behaviours.<sup>22,32,34</sup> These behavioral improvements are expected to contribute to improved glycemic control, reflected by reductions in HbA1c levels.

**Figure 1** Conceptual Model of MBSR Intervention



## ***Overview of the Nurse-led MBSR Intervention***

The nurse-led MBSR intervention will be delivered face-to-face in small groups of approximately 8–10 participants in a designated room within the OPD. The program will consist of four consecutive weekly sessions, with each session lasting approximately 60–75 minutes. Although the original MBSR program spans eight weekly sessions with longer durations, this abbreviated format is supported by several controlled studies and a systematic review that have shown brief 4-weekly MBSR sessions can produce meaningful improvements in psychological outcomes such as improve distress, coping, and emotional regulation, compared with longer protocols.<sup>34-35</sup> The abbreviated format was selected to enhance feasibility and participant retention within the local clinical context while maintaining exposure to core mindfulness and coping components.

The intervention will be delivered by the principal investigator (PI), a registered nurse trained in mindfulness facilitation and behavioral intervention delivery. Each session will follow a structured and standardized format, including brief psychoeducation on DD and coping strategies, guided mindfulness exercises, coping skills training, facilitated group discussion and reflection, and collaborative goal setting. Towards the end of each session, participants will be encouraged to practice mindfulness for 15–20 minutes daily throughout the intervention period. To support adherence, culturally adapted Urdu educational materials, worksheets, and guided audio-visual recordings will be provided to accommodate varying literacy levels. Brief WhatsApp or phone call reminders will also be used to encourage regular practice during the intervention period. Table 2 presents the overview of 4-weekly sessions.

**Table 2:** Overview of MBSR Intervention Sessions (Advise, Assist, Assign, and Arrange)

| Session | Duration  | Main Components                                                                                              | Delivery Strategies                                                    |
|---------|-----------|--------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------|
| 1       | 60-75 min | Introduction to DD, overview of MBSR, relationship between DD, coping, and glycaemic control; mindful eating | Psychoeducation, lecture—discussion, guided practice, group reflection |

|   |           |                                                                                                                          |                                                        |
|---|-----------|--------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------|
| 2 | 60-75 min | Mindful walking and adaptive coping strategies (planning, action, optimism, and acceptance)                              | Demonstration, guided practice, interactive discussion |
| 3 | 60-75 min | Body Scan meditation and emotional awareness                                                                             | Demonstration, guided practice, interactive discussion |
| 4 | 60-75 min | Guided breathing exercises and five-senses grounding technique (5-4-3-2-1); relapse prevention and continuation planning | Demonstration, action planning, group reflection       |

## *Fidelity of the Nurse-led MBSR Intervention*

The intervention fidelity will be ensured using the National Institutes of Health (NIH) Behavior Change Consortium framework, which emphasizes standardisation of intervention delivery, participant receipt, and adherence to prescribed activities.<sup>36-37</sup> Table 3 below outlines the fidelity plan of Nurse-led MBSR Intervention.

**Table 3:** Fidelity Plan of Nurse-Led MBSR Intervention

| Sr. | Dimension of Fidelity of Intervention                                                       | Description and Strategies to be Used                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|-----|---------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1   | Delivery of the intervention (delivery as planned)                                          | <ul style="list-style-type: none"> <li>The intervention will be delivered according to a standardised intervention manual outlining session objectives, mindfulness activities, coping strategies, delivery sequence, and duration.</li> <li>All sessions will be conducted in a designated quiet environment within the OPD room to maintain consistency across groups.</li> <li>Fidelity checklists will be completed after each session to assess adherence to planned content, duration, and procedures.</li> <li>Selected sessions will be independently observed by a supervising clinical nurse specialist and psychologist to evaluate consistency and protocol adherence.</li> <li>Outcome assessments will be conducted by trained data collector independent of intervention delivery to minimize measurement bias.</li> </ul> |
| 2   | Receipt of the intervention (participants understanding and mindfulness skills acquisition) | <ul style="list-style-type: none"> <li>Participant understanding and engagement will be enhanced through interactive teaching approaches, including guided demonstrations, supervised practice, reflective discussion, and clarification sessions.</li> <li>The taught mindfulness techniques will be practiced during sessions to support experiential learning.</li> <li>Participants' understanding and ability to perform mindfulness exercises will be assessed through verbal feedback, return demonstrations, and observation during guided activities.</li> <li>Educational videos and Urdu-language printed materials will be used to reinforce learning.</li> </ul>                                                                                                                                                             |

|   |                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|---|--------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 3 | Intervention adherence (application of mindfulness skills in daily life) | <ul style="list-style-type: none"> <li>• Participants will be encouraged to integrate mindfulness practices into their daily routines through structured home-based practice.</li> <li>• Urdu-language educational materials, guided video recordings, and a home-practice logbook will be provided to support continued engagement.</li> <li>• Reminder phone calls and WhatsApp/SMS messages will be used to encourage adherence between sessions and follow-up.</li> <li>• Brief reinforcement discussions will be conducted to identify barriers to practice and support problem-solving strategies for sustaining mindfulness activities over time.</li> </ul> |
|---|--------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

### ***Phase III: Post Intervention (Follow-up)***

Following completion of the 4-week nurse-led MBSR intervention, participants will continue to receive routine T2DM care from their treating endocrinologist and healthcare team in accordance with standard practice. To support continued engagement with mindfulness practices, brief reminder phone calls and SMS/WhatsApp messages will be provided during the follow-up period. Post-intervention follow-up assessment will be conducted three months ( $\geq 12$  weeks) after completion of the intervention. Outcome assessment at follow-up (T2) will be conducted by trained data collector independent of intervention delivery to minimize measurement bias. In addition to outcome assessment, participants will complete a brief follow-up questionnaire to identify any additional psychosocial or educational support received during the post-intervention period and to explore continued use of mindfulness practices introduced during the intervention. Details of the follow-up questionnaire are presented in table 6.

**Table 4:** Post Intervention Follow-up Questionnaire

| Item No. | Assessment Question                                                                                    | Response Format                                                                           |                                                                                                |
|----------|--------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------|
| 1        | Have you received any additional follow-up support other than the intervention provided in this study? | <input type="checkbox"/> Yes                                                              | <input type="checkbox"/> No                                                                    |
| 2        | If yes, what was the primary source of this support?                                                   | <input type="checkbox"/> Physician / Endocrinologist<br><input type="checkbox"/> Educator | <input type="checkbox"/> Nurse / Diabetes<br><input type="checkbox"/> Psychologist / Counselor |

☐ Family / Social Support ☐ Online / Media Resources  
☐ Other (please specify): \_\_\_\_\_

- 3 Which components of the study intervention did you continue to practice after completion of the program?
- ☐ Mindfulness meditation ☐ Body scan exercises  
☐ Breathing/relaxation techniques ☐ Emotional regulation strategies ☐ Coping skills

## Phase IV Qualitative Assessment of Feasibility, Acceptability, and Perceived Usefulness

Phase IV will comprise the qualitative component of the study and will be conducted after completion of the quantitative follow-up assessment (Phase III). The purpose of this phase is to explore participants' views on nurse-led MBSR intervention, including its feasibility, acceptability, perceived usefulness, and perceived sustainability within the local T2DM care context. Semi-structured interviews will be conducted by the second author (KA) in Urdu at a mutually convenient time, either face-to-face in OPD room or via telephone according to participant preference and feasibility. An interview guide will be used to explore experiences related to intervention content, delivery, participant engagement, home practice, and perceptions regarding the role of nurse-led psychosocial support in T2DM care (see Table 7). Field notes will be maintained to document non-verbal cues and contextual observations.

**Table 5:** Semi-structured Interview Guide for Feasibility Assessment

| Focus Area                                  | Core Interview Questions                                                                                                                                           | Follow-up Questions / Probes                                                                                                                                                                    |
|---------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Intervention Content</b>                 | How helpful did you find the content provided during the sessions? How clear and easy to understand was the information presented to you?                          | Which specific mindfulness practices or coping skills did you find most useful? Were any concepts unclear or difficult to understand? Was there anything you felt was missing from the content? |
| <b>Intervention Delivery and Structure</b>  | How did you feel about receiving the intervention at the hospital during your routine diabetes visits? What are your views on the duration and number of sessions? | Would you have preferred a different setting, timing, or mode of delivery? Did the group format work well for you? Were there any challenges you faced in attending the sessions?               |
| <b>Acceptability and Personal Relevance</b> | Overall, how acceptable and relevant did you find the intervention to your personal needs and diabetes-related challenges?                                         | Which aspects of the intervention did you find most engaging or helpful? Were there any parts that felt less relevant to your situation?                                                        |

|                                          |                                                                                                                |                                                                                                                                                                      |
|------------------------------------------|----------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Feasibility of Nurse-led Delivery</b> | How do you feel about nurses delivering mindfulness and stress management support for people with diabetes?    | Did you feel comfortable discussing emotional or stress-related issues with the nurse? Do you think this support could be offered as part of routine diabetes care?  |
| <b>Home Practice and Sustainability</b>  | Since completing the intervention, have you been able to continue the mindfulness or coping practices at home? | What helped you continue (or stopped you from continuing) the practices? What kind of follow-up or ongoing support would help you sustain these practices over time? |
| <b>Perceived Impact</b>                  | In what ways, if any, did the intervention influence how you cope with diabetes-related stress?                | Did you notice any changes in your emotional wellbeing, coping, or daily diabetes self-management? Which changes do you feel may continue long-term?                 |

## Outcomes, Instruments and Schedule of Measurements

The preliminary effectiveness of the intervention will be assessed across three outcomes: DD (primary outcome), coping strategies (mediating outcome), and glycaemic control (secondary outcome). Baseline sociodemographic and clinical data will be collected for sample description and identification of potential contextual factors that may influence outcomes. A structured sociodemographic and clinical datasheet will be used to gather information on participants' gender, age, education, employment, marital status, household income, T2DM duration, treatment regimen, DM family history, DM-related complications and comorbidities, self-monitoring practices and lifestyle behaviors.

### *Diabetes Distress (DD)*

DD will be measured on 17-item Diabetes Distress Scale (DDS-17), a validated instrument designed to assess DM-related emotional distress across four dimensions. These four dimensions include emotional burden, physician-related distress, regimen-related distress, and interpersonal distress.<sup>14,17</sup> The scale uses a 6-point Likert response format ranging from 1 to 6, reflecting participants' experiences over the preceding month. Mean scores will be computed for both the overall scale and its subdomains. Scores <2.0 indicate little or no distress, scores 2.0–2.9 indicate moderate distress, and scores ≥3.0 indicate high

distress. The Urdu version of the DDS-17, previously validated for use in Pakistani populations, will be used in this study to ensure linguistic and cultural appropriateness.<sup>37</sup> Previous studies have reported strong reliability of the scale, with Cronbach's alpha coefficients ranging from 0.89 to 0.92.<sup>14,17,38</sup>

## ***Coping Strategies***

Coping strategies will be measured using the GlucoCoper, a DM-specific coping instrument consisting of six items assessing adaptive coping (acceptance, optimism, planning, and action) and maladaptive coping (negativity and blame).<sup>39-40</sup> Responses are recorded on a visual 10-point "cope-meter" scale. Separate scores will be computed for adaptive and maladaptive coping strategies, while the overall coping score will be obtained by subtracting maladaptive coping scores from adaptive coping scores. As literacy levels may vary among participants, the instrument will be administered through interviewer-administered mode. Previous studies have demonstrated acceptable reliability and significant associations between GlucoCoper scores, DD, and glycemic outcomes.<sup>39-40</sup>

## ***Glycemic Control (HbA1c)***

Glycemic control will be assessed using HbA1c values obtained from participants' laboratory reports. Baseline HbA1c values recorded within the preceding three months will be documented at enrolment, and repeat HbA1c values will be collected at three-month follow-up. HbA1c levels will be interpreted according to the ADA guidelines, where HbA1c <7% indicates adequate glycemic control and HbA1c ≥7% indicates suboptimal control.<sup>15</sup> Table 4 summarizes the outcomes, operational definitions, and measurement instruments.

**Table 6:** Outcome Variables, Definition, and Instruments

| Variable Type   | Outcome           | Definition                                                                                                                                    | Instrument                       |
|-----------------|-------------------|-----------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|
| Primary outcome | Diabetes Distress | Emotional burden and worries specific to individuals with T2DM, including concerns related to disease management, complications, and support. | Diabetes Distress Scale (DDS-17) |

|                          |                   |                                                                                                                        |                                              |
|--------------------------|-------------------|------------------------------------------------------------------------------------------------------------------------|----------------------------------------------|
| <b>Mediating outcome</b> | Coping Strategies | Cognitive and behavioral responses used to manage the internal and external stressors and demands of living with T2DM. | Glucocoper Scale                             |
| <b>Secondary outcome</b> | Glycemic Control  | HbA1c levels used to assess long-term glycemic control; HbA1c <7% indicates satisfactory control.                      | Conventional laboratory blood test for HbA1c |

Outcome measures will be assessed at two points: at baseline prior to the intervention and at three-months after the intervention completion. DD, coping strategies, and HbA1c will be measured at both assessment points using the same instruments and procedures to ensure consistency. The schedule of study activities and assessments is outlined in Table 5.

**Table 7:** Schedule of Events and Measurements

| Study Event                                                              | Screening & Enrollment | Intervention Phase |        |        |        | Follow-Up (3 Months) |
|--------------------------------------------------------------------------|------------------------|--------------------|--------|--------|--------|----------------------|
|                                                                          |                        | Week 1             | Week 2 | Week 3 | Week 4 |                      |
| Study Visits / Time Points                                               | Visit-0 (Baseline)     |                    |        |        |        | Month 3              |
| Informed Consent                                                         | X                      |                    |        |        |        |                      |
| Sociodemographic & Clinical History                                      | X                      |                    |        |        |        |                      |
| DD                                                                       | X                      |                    |        |        |        | X                    |
| HbA1c                                                                    | X                      |                    |        |        |        | X                    |
| Coping Strategies                                                        | X                      |                    |        |        |        | X                    |
| Orientation and Understanding of DD                                      |                        | X                  |        |        |        |                      |
| Introduction to MBSR, Link between DD, coping, and HbA1c, Mindful eating |                        |                    |        |        |        |                      |
| Mindfulness Practice, Mindful walking, Positive coping strategies        |                        |                    | X      |        |        |                      |
| Body Scan Meditation                                                     |                        |                    |        | X      |        |                      |
| Guided Breathing, Five-senses grounding techniques                       |                        |                    |        |        | X      |                      |
| Study Completion                                                         |                        |                    |        |        |        | X                    |

## Data Analysis Plan

Quantitative data will be entered and analyzed using IBM SPSS Statistics version 26. To ensure data accuracy, all entries will be verified against the original data collection forms prior to analysis. Participants' sociodemographic and clinical characteristics will be summarized using descriptive statistics. Categorical variables will be described using frequencies and percentages, while continuous variables will be reported using means and standard deviations. The distribution of outcomes variables will be assessed both visually, through histograms and Q-Q plots, and statistically using the Shapiro-Wilk test.<sup>41</sup>

Prior to inferential analysis, the extent and pattern of missing data will be examined. If missing data are minimal (<5%), analyses will be conducted using complete cases. Where missing outcome data exceed minimal levels and are considered missing at random, multiple imputation (MI) will be performed to reduce bias. Multiple imputed datasets will be generated using relevant study variables, analyzed separately, and pooled using Rubin's rules to obtain final estimates.<sup>42-43</sup> Preliminary intervention effectiveness will be assessed by comparing baseline and three-month follow-up scores for DD, coping strategies, and HbA1c. For normally distributed continuous outcomes, paired-samples t-tests will be used to evaluate within-group changes over time. If assumptions of normality are violated, the non-parametric Wilcoxon signed-rank test will be applied. Cohen's d will be reported for paired t-tests and interpreted according to conventional thresholds as small (0.2), medium (0.5), and large (0.8) effects.<sup>44</sup> For non-parametric analyses, effect size (r) will be calculated using the formula  $Z/\sqrt{N}$ . Quantitative feasibility indicators, including recruitment rate, retention rate, session attendance, and adherence to home practice, will be analyzed descriptively using frequencies, percentages, means, and ranges, as appropriate.

Qualitative interview data will be analyzed using hybrid inductive-deductive thematic analysis approach.<sup>45</sup> Interviews will be transcribed verbatim in Urdu, and translated into English in collaboration

with a linguist expert where required. The analysis process will involve repeated reading of transcripts, generation of initial codes, categorization of related codes, and development of overarching themes reflecting participants' experiences of the intervention. Initial coding will be guided by predefined feasibility domains reflected in the interview guide, including feasibility, acceptability, perceived usefulness, intervention delivery, and sustainability. Additional inductive coding will be undertaken to identify unanticipated experiences or emerging contextual themes. To enhance rigor and trustworthiness, credibility will be supported through peer review of coding and thematic interpretation by members of the research team.

Findings from the qualitative interviews will be triangulated with quantitative feasibility indicators to provide a comprehensive assessment of the feasibility, acceptability, perceived usefulness, and preliminary effectiveness of the nurse-led MBSR intervention.

## **Ethics and Dissemination**

The institutional review board and ethics committee of Shifa Tameer-e-Millat University, Islamabad, Pakistan, has provided the ethical approval of the study (IRB&EC # 081-26). Written permission for data collection has also been obtained from the hospital administration and head of endocrinology department. All participants will be required to sign informed consent before their enrollment in the study. Participants' confidentiality will be maintained by removing personal identifiers information, by assigning each participant a unique code, and by quoting participants anonymously when reporting qualitative findings. All study information will be kept on a password-protected personal computer accessible only to the research team. The results of the study will be published in a peer-reviewed scientific journal and presented at a national conference.

## **DISCUSSION**

This protocol describes a feasibility study evaluating a culturally adapted, nurse-led MBSR intervention for adults with T2DM experiencing moderate to high DD. The study aims to generate preliminary evidence regarding the feasibility, acceptability, perceived usefulness, and potential effectiveness of the intervention in improving DD, coping strategies, and HbA1c within a low-resource healthcare setting in Pakistan. The findings are expected to inform refinement of the intervention and the design of a future fully powered RCT.

The psychosocial burden associated with T2DM is increasingly recognized as an important determinant of health outcomes, yet psychosocial support remains poorly integrated into routine T2DM care in LMICs, including Pakistan. Although mindfulness-based interventions have demonstrated promising effects in reducing psychological distress and improving self-management among individuals with T2DM, most existing evidence originates from high-income settings, with limited evidence regarding feasibility and implementation in resource-constrained healthcare systems. Consequently, there is a need for contextually appropriate and scalable psychosocial interventions that can be integrated into routine T2DM services in LMICs.

Existing evidence supports the effectiveness of mindfulness-based interventions for reducing DD and improving psychological well-being among adults with T2DM. Previous studies demonstrated improvements in DM related stress, emotional well-being, self-management behaviors, and glycemic outcomes following MBSR-based interventions.<sup>20,46-48</sup> Evidence also suggests that structured group-based MBSR interventions combined with home practice components may produce greater improvements in psychological outcomes.<sup>49-50</sup> The current intervention incorporates these evidence-informed components through structured weekly group sessions, guided mindfulness exercises, and supported home practice.

The abbreviated four-week MBSR format used in this study represents a pragmatic adaptation intended to enhance feasibility and participant engagement within a busy OPD setting. Although

traditional MBSR programs are typically longer in duration, emerging evidence suggests that brief structured mindfulness interventions may still produce meaningful psychological benefits, particularly when supported through guided home practice and follow-up reinforcement.<sup>34-35,51</sup> The three-month follow-up assessment included in this study will provide preliminary insight into the short-term sustainability of intervention-related changes in DD, coping, and glycemic control.

The nurse-led delivery model used in this study is especially suited to low-resource settings where specialized mental health services are often limited or inaccessible. Nurses are well positioned to deliver psychosocial interventions because of their sustained therapeutic engagement with patients and their central role in chronic disease management. Task-sharing approaches involving nurse-delivered psychological interventions have shown promising outcomes in chronic disease care<sup>47,50,52</sup> and may represent a feasible and sustainable strategy for strengthening integrated diabetes services in LMICs.

A further strength of this study is the use of a multi-methods feasibility design, which enables simultaneous evaluation of preliminary quantitative outcomes and participants' experiences of the intervention. Triangulation of quantitative and qualitative findings is expected to provide a more comprehensive understanding of intervention feasibility, participant engagement, contextual influences, and implementation challenges. The inclusion of qualitative interviews may also help identify culturally relevant factors influencing adherence, acceptability, and sustainability of mindfulness practices within the local context.

Several limitations of this study should be acknowledged. The single-arm pretest-posttest design without a comparison group restricts the ability to draw causal inferences regarding the effects of intervention. Furthermore, a single-site setting and relatively small sample size may limit generalizability to other populations and healthcare settings. The use of self-reported measures for DD and coping may also introduce response bias. However, these limitations are consistent with the exploratory nature of

feasibility studies, where the primary purpose is to evaluate implementation processes, acceptability, and preliminary outcome trends prior to conducting larger controlled trials.

Overall, this study has the potential to contribute important preliminary evidence regarding the integration of culturally adapted psychosocial interventions into routine T2DM care in Pakistan. By evaluating the feasibility and preliminary effectiveness of a nurse-led MBSR intervention, the study addresses an important gap in T2DM care and may support the future development of accessible, person-centered, and psychologically informed DM services in similar low-resource settings.

## Authors Contribution

SR is the Principal Investigator of the study and conceived the research idea. She led the development of the study protocol, contributed to the study design and methodology, and drafted the manuscript. KA, HR, and SA are co-investigators and members of the supervisory committee. They contributed substantially to the conception and design of the study, provided methodological and scientific guidance during protocol development, and critically reviewed and revised the manuscript for important intellectual content. All authors reviewed and approved the final version of the manuscript for publication.

## Conflicts of Interest

None

## Funding

None

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