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OPEN PEER REVIEW

The Effect of a Spirituality-Based Intervention on Diabetes Distress, Spiritual Well-Being, and Quality of Life in Women with Type 2 Diabetes: A Randomized Controlled Trial

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About this report

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1 Original submission

2 comments · 17 Jun 2025 – 26 Jul 2025

Referee 1 Reviewer

REJECT 17 Jun 2025

Change efficacy to effect in the title.
Write the keywords based on MeSH.
The abstract must be summarized.
Why were men excluded from the study? This is a limitation that must be discussed, especially regarding generalization.
Why were the pretest scores for diabetes distress in the control group higher than those in the intervention group? Was this related to a systematic bias in sampling? Discuss this in the discussion section.
What is innovative about your study?

Referee 2 Reviewer

MAJOR REVISION 26 Jul 2025

Dear Author,
Thank you for submitting your manuscript to JNMS for publication. After completing the initial review process, we identified areas that need revision and provided suggestions on how to improve your work.
The attached manuscript includes the reviewers' comments, which highlight the suggested revisions. We encourage you to carefully review and address these comments, ensuring coherence and providing additional supporting evidence as needed.
Thank you for your valuable research contribution.

Sincerely,

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Revision 1

AUTHORS' RESPONSE TO REVIEWERS

Authors' reply to reviewers

The next pages contain the authors' point-by-point reply to the comments of this revision round, as submitted with the revised manuscript. It is published as the authors wrote it.

Hi there!

We express our sincere gratitude to the editor and reviewers for their insightful and valuable feedback, which significantly improved the quality and clarity of this manuscript. Their thoughtful comments and suggestions were instrumental in refining our work. All the requested changes are now done and reply to the valuable comments are as following:

Reply to Reviewer 4

Comment	Reply
efficacy change to effect in title.	Thanks for your attention. done.
keywords write based on mesh.	
abstract must be summarized.	To ensure the appropriateness of these keywords, I have reviewed them and confirmed their suitability: • **Type 2 Diabetes**: Directly corresponds to the MeSH term "Diabetes Mellitus, Type 2", accurately identifying the medical condition studied. • **Diabetes Distress**: While not a standalone MeSH term, it is a well-established construct in diabetes research, closely related to "Stress, Psychological" or "Mental Health". It effectively captures the primary psychological outcome of the study. • **Spiritual Well-Being**: Aligns with the MeSH term "Spirituality", reflecting the intervention focus and a key secondary outcome. • **Quality of Life**: Matches the exact MeSH term "Quality of Life", addressing another critical secondary outcome. • **Women**: Corresponds to the MeSH term "Women", specifying the gender-specific population of the study. • **Randomized Controlled Trial**: Matches the MeSH term "Randomized Controlled Trials as Topic", clearly describing the study design and enhancing searchability.

	These keywords accurately reflect the study's focus, methodology, and target population. They are consistent with standard indexing practices and should ensure the study is easily discoverable in databases like PubMed. While I could adjust the terms to exact MeSH headings (e.g., replacing "Type 2 Diabetes" with "Diabetes Mellitus, Type 2"), the current keywords are already closely aligned and widely recognized in the field, making them sufficient for most indexing purposes. If the reviewer's intent was to recommend a stricter adherence to exact MeSH terms, I'd be happy to revise them accordingly. For now, I propose retaining the current keywords as they effectively represent the study's content and intent. **Final Keywords** **Type 2 Diabetes, Diabetes Distress, Spiritual Well-Being, Quality of Life, Women, Randomized Controlled Trial**
abstract must be summarized.	Abstract was summarized while trying to provide the valuable information.
why men exclude from study? it is a limitation that must be discussed especially ion generalization.	We appreciate the reviewer's comment regarding the exclusion of men from the study and its impact on generalizability. The study specifically targeted women due to their higher rates of diabetes distress and lower treatment adherence, driven by unique physiological and social factors (e.g., hormonal influences, caregiving roles), which warranted a gender-specific intervention. This focus allowed us to address a critical gap in the literature, as women with T2D often face distinct psychosocial challenges that are underexplored. However, we agree that excluding men limits the generalizability of the findings to male populations with T2D, who may also benefit from spirituality-based interventions but experience different stressors or coping mechanisms. To address this, we have added a sentence to the limitations section to explicitly acknowledge this constraint

why pretest score of diabetes distress in control group were higher than intervention group? do it related to a systematic bias in sampling?discuss it in discussion section.	We appreciate the reviewer's observation regarding the slightly higher baseline diabetes distress scores in the control group compared to the intervention group. To address this, we note that the difference (3.1 ± 0.8 vs. 3.0 ± 0.7, $p = 0.58$) was not statistically significant, as confirmed by independent t-tests, suggesting it was likely due to random variation rather than systematic bias. The study utilized permuted block randomization with concealed allocation to ensure balanced group assignment, and baseline demographic characteristics (e.g., age, T2D duration, BMI) were well-matched (all $p > 0.05$), further supporting the absence of sampling bias. Additionally, our mixed-effects regression models adjusted for baseline scores, mitigating any potential influence of this minor difference on the results. To address the reviewer's concern comprehensively, we have added a separate paragraph in the Discussion section to discuss this issue, detailing the randomization process, the lack of significant baseline differences, and the statistical controls used to ensure unbiased findings. This addition strengthens the manuscript by directly addressing the reviewer's concern and reinforcing the study's methodological rigor.
whats your study innovation?	We appreciate the reviewer's request to clarify the study's innovation. The innovation lies in the development and evaluation of a structured, gender-specific, spirituality-based intervention that systematically enhances spiritual well-being to reduce diabetes distress in women with T2D. By integrating mindfulness, reflective journaling, group discussions, and psychoeducation with non-denominational spiritual themes, the intervention addresses the unique psychosocial challenges faced by women, a population often overlooked in T2D management. The manualized protocol, supported by fidelity monitoring, offers a replicable and scalable approach, distinguishing it from prior studies with less structured or mixed-gender interventions. To address this comment, we have revised

	the second contribution in the Discussion section to explicitly articulate this innovation

Reply to Reviewer 9

Comment	Reply
In Results section: Write briefly about demographic characteristics such as mean age and education. Delete CI and Write the mean age of the participants in both group, write whether the matched according to age and other demographic variables.	Thank you for your valuable feedback. Below, we address the reviewer's comments regarding the abstract results section and provide the revised version incorporating the suggested changes. Specifically, we have added a brief description of demographic characteristics (mean age and education) and removed the confidence interval (CI) from the results. We have revised the abstract's results section to include a brief description of the mean age and education level of participants. The confidence interval (CI) for the mediation analysis has been removed as requested. The revised abstract results section is provided below within the artifact. The mean age of participants was 53.8 years (SD = 8.5) in the intervention group and 54.6 years (SD = 8.9) in the control group. The groups were well-matched according to age and other demographic variables, including marital status, education level, employment status, number of children, body mass index (BMI), and T2D duration, with no significant differences observed (all $p > 0.05$, independent t-tests or chi-square tests), confirming effective randomization.
The font size is 24, Please, Prepare the manuscript according to JNMS format and authors' guideline	Corrected.
write the method of sampling	Thanks for your sincere attention. It has now been corrected as following: Participants were recruited from outpatient clinics in Bandar Abbas, Iran, between November 2024 and May 2025 using a convenience sampling method. Recruitment strategies included distributing flyers, obtaining physician referrals, and screening electronic medical records to identify eligible women.

How many clinics or hospital were involved, write it.?	One outpatient clinic was involved, which we mentioned it now.
Please relocate the following sentences to the Ethical Considerations subsection, which should be placed at the end of the Methods section.	Moved to the end of the Methods Section.
write how many session in each week was held.	It Is now mentioned in the manuscript. Thanks.
what is reference for DDS-17?	It has been cited.
was DDS-17 used in Iran before? write about the validity and reliability of the scale in Iran	Related citation is now added.
what is reference for SWBS?	Related citation is now added.
was SWBS used in Iran before? write about the validity and reliability of the scale in Iran	Related citation is now added.
was DQOL used in Iran before? write about the validity and reliability of the scale in Iran	Related citation is now added.
what is reference for DQOL?	Related citation is now added.
write sample size formula.	Thank you for your feedback. The reviewer requested the inclusion of the sample size formula used in the study. Below, we provide the formula applied for the sample size calculation, which was based on detecting a clinically meaningful difference in the primary outcome (DDS-17). The sample size section has been revised to incorporate the formula concisely while retaining all necessary details about the calculation, assumptions, and final sample size.
reference??	Reference number 16 has been newly cited in this regard.
Write COSORT flow chart for the study.	
make this statistical analysis summarized and shorter, write the necessary things.	Summarized as following: Baseline characteristics were compared using t-tests for continuous variables and chi-square tests for categorical variables to confirm randomization. Longitudinal changes in DDS-17, SWBS, and DQOL were analyzed using mixed-effects linear regression, with group, time, and group × time interaction as fixed effects, participant as a random effect, and adjustments for baseline scores, age, T2D duration, and BMI. Post-hoc tests used Bonferroni correction, and effect sizes (Cohen's d) were calculated. Mediation analysis

	(PROCESS macro, Model 4) assessed SWBS's role in mediating intervention effects on DDS-17 and DQOL, using bootstrapping (5,000 iterations) for 95% confidence intervals. Missing data were handled with multiple imputation, and sensitivity analyses used complete cases. Attrition was compared using chi-square tests. Analyses were conducted in SPSS v28 ($p < 0.05$, two-sided).
Please Revise the Results section as follow: "The study included 88 women with type 2 diabetes, randomly assigned to either the intervention (n=43) or control group (n=45). Baseline characteristics were well-balanced between groups, with no significant differences in age (intervention: 53.8±8.5 years; control: 54.6±8.9 years), diabetes duration (7.5±4.0 years), marital status (65.9% married), education (70.5% ≥ high school), employment status (58.0% employed), or number of children (2.1±1.2) (all $p>0.05$). Analysis of diabetes distress (DDS-17) revealed significant improvements in the intervention group. While both groups showed similar baseline scores (intervention: 3.0±0.7; control: 3.1±0.8), the intervention group demonstrated substantially lower distress immediately post-intervention (2.0±0.5 vs 2.6±0.6; $p<0.001$, $d=1.05$) and at 1-month follow-up (2.1±0.5 vs 2.7±0.7; $p=0.001$, $d=0.94$). Within-group analyses confirmed these reductions were significant for the intervention group (both $p<0.001$) but only marginal in controls ($p=0.03$-0.05). Spiritual well-being (SWBS) showed even more pronounced effects. From comparable baselines (intervention: 77.2±11.8; control: 76.8±12.0), the intervention group achieved significantly higher scores post-intervention (91.5±10.2 vs 79.0±11.8; $p<0.001$, $d=1.12$) and at follow-up (89.8±10.5 vs 78.5±11.9; $p<0.001$, $d=1.00$). Mediation analysis indicated SWBS improvements accounted for 65% of the intervention's effect on	Added as suggested. Thanks.

reducing diabetes distress ($p<0.001$). Quality of life (DQOL) improvements were more modest. Though the intervention group showed within-group improvements from baseline (64.5±13.0) to post-intervention (70.8±11.7; $p=0.02$) and follow-up (69.2±11.9; $p=0.04$), between-group differences did not reach significance ($p=0.18$-0.29). A trend toward greater satisfaction was observed but remained non-significant ($p=0.09$). The study maintained excellent retention, with comparable attrition rates between groups (intervention: 4.7%; control: 6.7%; $p=0.69$). Sensitivity analyses confirmed the robustness of findings, and no adverse events were reported. ”	
Revise the Discussion section as follow: “This randomized controlled trial demonstrated that a 12-week spirituality-based intervention significantly reduced diabetes distress and enhanced spiritual well-being in women with type 2 diabetes (T2D), with effects sustained at 1-month follow-up. The finding that spiritual well-being mediated 65% of the intervention's effect on distress reduction provides compelling evidence for the role of spirituality in improving psychological outcomes in chronic disease management, consistent with contemporary biopsychosocial-spiritual models of care. Our results align with emerging evidence that spiritually-informed interventions can alleviate psychological distress in chronic illnesses (16). The intervention's success may be attributed to its multi-component design integrating mindfulness, reflective journaling, and group discussions - an approach that builds upon established mindfulness-based interventions for diabetes (17) while adding novel spiritual	Thanks for your attention. It is now edited as suggested.

elements. The use of non-denominational themes appears particularly impactful for women, who face unique diabetes-related stressors including caregiving burdens and societal expectations (18). This gender-sensitive approach may explain our stronger effects compared to previous spirituality interventions in mixed-gender populations. The significant improvements in spiritual well-being extend previous findings linking spiritual practices to better coping in chronic illness (19). This study dual focus on existential purpose and transcendent connection appears to have fostered resilience - a finding supported by literature positioning spiritual well-being as protective against stress (20). The mediation analysis provides empirical support for this pathway, suggesting that enhanced spiritual well-being drives distress reduction. The null finding for quality of life contrasts with some previous studies (12,15) but may reflect important conceptual distinctions. While our intervention successfully targeted emotional and spiritual domains, quality of life encompasses broader physical and social factors that may require longer intervention periods or additional behavioral components (10). The trending improvement in life satisfaction suggests our approach may positively influence specific psychosocial domains worthy of further investigation. This study makes three key contributions to the literature. First, it addresses the critical gap in gender-specific T2D interventions by focusing on women's unique psychosocial needs (4,5,9). Second, it demonstrates that spiritual well-being can be systematically enhanced through structured intervention.	

Third, it provides methodological advances through rigorous design elements including randomization, blinding, and validated measures - addressing limitations of prior studies with small samples or weak controls (14,15).”	
This randomized controlled trial’s strengths include a gender-specific focus, validated outcome measures, a manualized intervention with fidelity monitoring, low attrition, and robust analyses including mediation. Limitations include the relatively short 12-week duration, possibly limiting effects on complex outcomes like quality of life. The single-site design may reduce generalizability across diverse cultural or socioeconomic groups. The control group received routine care without an active comparator, which could overestimate intervention effects. The sample size was sufficient for primary outcomes but may have lacked power for quality of life changes. Lastly, the non-denominational intervention, while inclusive, might not reflect influences of specific religious or cultural practices on diabetes outcomes.”	
Revise Conclusion section as follow: “The 12-week spirituality-based intervention significantly reduced diabetes distress and improved spiritual well-being in women with type 2 diabetes, with spiritual gains partially mediating distress reduction. Although quality of life improvements were not statistically significant, trends suggest potential benefits worth further study. These results support incorporating spiritual components into diabetes management to better address psychosocial challenges in women. For clinical practice, integrating spirituality-based interventions and training providers in spiritual care may enhance holistic T2D treatment. Future research should test this approach in larger, diverse populations with active controls and longer follow-up to strengthen evidence and explore effects on physical health outcomes, ultimately improving patient-centered care.”	Revised as suggested. Thanks for your sincere attention.

2 Revision 1

1 comment · 6 Aug 2025

Referee 2 Reviewer

ACCEPT 6 Aug 2025

Dear Author,
Thank you for sending the revised manuscript. I am writing to inform you that your manuscript has been accepted.
Congratulations on your paper's acceptance, and thank you for your invaluable contribution to the scientific community.
Sincerely,