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Original Article

Effect of mindfulness-based stress reduction on mental health and sleep quality in women with type 2 diabetes mellitus: A randomized controlled trial

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Abstract

Background and aims: Sleep disorders directly relate to diabetes and its management. The study objective was to examine the effect of the mindfulness-based stress reduction (MBSR) intervention on mental health and sleep quality (SQ) in women with type 2 diabetes mellitus (T2DM) in Isfahan health care centers in Iran.

Methods: Eighty women with T2DM were enrolled in this randomized clinical trial performed at Imam Ali Comprehensive Urban Health Center in Isfahan in 2019. The patients were randomly assigned to the intervention (8 sessions of 2 hours of MBSR training) and control (standard care) groups. SQ and mental health were assessed and compared via the Pittsburgh SQ Index and the Depression, Anxiety, and Stress Scale-21 before and after the intervention in both groups by SPSS 20 using the chi-square test, independent t-test, and paired-samples t-test.

Results: A post-intervention reduction in the overall quality of sleep index was observed in both intervention and control groups (0.7 ± 0.2, $P=0.1$ and 0.17 ± 0.07, $P=0.6$, respectively). There was a significant difference between the subjective SQ and the sleep duration before and after treatment in the intervention group (a score reduction of 0.2 ± 0.09 and 0.3 ± 0.12, respectively, $P=0.03$). Depression, anxiety, and stress scores also decreased significantly after treatment in the intervention group, indicating an improvement in mental health (4.3 ± 2.1, $P<0.001$, 5 ± 2.7, $P<0.001$, and 3.7 ± 1.5, $P<0.001$, respectively).

Conclusion: Overall, mental health, subjective quality, and sleep duration improved in patients with T2DM undergoing MBSR training.

Keywords: Mindfulness-based stress reduction, Sleep quality, Mental health, Type 2 diabetes mellitus

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Introduction

Diabetes mellitus (DM) is one of the most prevalent chronic diseases in the world (1). In 2017, around 6.28% of the global population had DM. By 2030, the worldwide prevalence of diabetes is estimated to increase by 10.1%. (2,3). The prevalence of DM in the adult population in Iran is 14.2%, based on Iran's national STEPS Survey 2021, which reveals an increase compared to 2011, which was 11.4% (4). Sleep quality (SQ) has a mutual relationship with the prevalence and incidence of diabetes. Insomnia can sometimes be caused by diabetes, and it can cause diabetes at other times. In addition, the relationship between the amount and quality of night sleep and the incidence of diabetes has been proved by some studies (5,6). Sleep-wake disorders are described in the 5th edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM-5) as "despite adequate sleep opportunities, sleep difficulties have been present for at least 3 months and have occurred at least 3 days a week". Sleep disorders influence almost all aspects of a patient's life (6).

Unfortunately, the usual method of controlling insomnia (i.e., taking sleeping medications) has systemic side effects. On the one hand, the side effects and, on the other hand, their short-term beneficial effects have recently made researchers attend to complementary medicine treatments, including psychological therapies (7). Therefore, diabetes can be appropriately managed when the psychological components are added to medication (8-10). Mindfulness-based stress reduction (MBSR), which is most common in mind-body medicine, is an intensive training program that uses various formal and informal mindfulness exercises. Mindfulness means awareness of the present with acceptance, preventing rumination, controlling daily events, recognizing automatic thought patterns by focusing on breathing, greater concentration and integration, paying attention to incomplete cognitions, and accepting thoughts. It is a structured group program that reduces stress, pain, and

suffering to boost mental health (11).

Some studies reported the positive effects of MBSR on general well-being, quality of sleep, and mental health in patients with DM (11-13). Similarly, a recent review mentioned that more randomized clinical trials are needed to test the efficacy of mindfulness interventions for sleep problems (14). DM is a highly prevalent disease, and mindfulness is believed to have potentially positive effects on its reduction. Nonetheless, more studies are still needed in this area with an emphasis on specific diseases. Accordingly, this study aims to investigate the impact of MBSR, in comparison with standard care, on SQ and mental health in women with type 2 diabetes mellitus (T2DM) in Isfahan healthcare service centers (a large city in the central part of Iran).

Materials and Methods

Study population

The study was conducted on 80 women with T2DM referred to Imam Ali Urban Health Center of Isfahan in 2019. The sample size was calculated based on a 5% alpha error, 20% beta error, and mean ± standard deviation (SD) of the sleep index in the intervention and control groups equal to 9 ± 3.5 and 11.3 ± 3.5, respectively, and a 10% attrition rate (15). Forty patients were included in each group. The patients were selected through the convenience method and randomly assigned to two intervention and control groups.

The inclusion criteria were 30-65-year-old women with T2DM who had a health record in the Imam Ali Health Service Center, suffered from diabetes for at least six months, had glycosylated hemoglobin between 7% and 9%, and were not treated with insulin. The other inclusion criteria were showing consent to participate in the study, having the ability to attend treatment sessions, having a body mass index less than 35, and having an overall SQ score above five based on the Pittsburgh Sleep Quality Index (PSQI) before intervention. On the other hand, the exclusion criteria were end-organ damage due to diabetes, pregnancy and lactation, alcohol and substance abuse, a history of receiving psychological treatment in the past year, uncontrolled psychological disorders, and a history of chronic diseases such as cancer or any serious medical illness. Moreover, a history of any sleep disorder diagnosed by a physician and a record of taking any medication that affects sleep were the other exclusion criteria. In addition, the participants were excluded from the investigation in the case of being absent for more than one intervention session and taking any sedative-hypnotic medicines during the study.

For the present study, the telephone numbers of middle-aged women with T2DM having health records in the primary healthcare center were obtained from the SIB electronic health record system. They were contacted by phone and invited to participate in a briefing session. The aims and process of the study were explained in this session, and the researcher visited all participants to determine eligibility. After obtaining written informed consent from patients who met the inclusion criteria, they were randomly divided into the intervention and control groups based on the unique identification code assigned to them on the day of the briefing session, using random allocation software, according to Mahmood Saghaei (16). The block randomization method with a block size of 4 and a 1:1 allocation ratio was used to generate the random allocation sequence. To implement the random allocation sequence, a nurse outside the research team invited patients based on the assigned trial group.

Due to the type of intervention, blinding could not be performed on patients; the statistician merely considered it. The intervention and control groups were coded after entering the data into SPSS software (version 20). The assignment of the groups was unclear to the person who analyzed the data. The codes were opened after the analysis.

Data selection

Before conducting the intervention, the demographic checklist, including age, duration of diabetes, education level, employment, marital status, and past and medical history, was completed for both groups. All participants completed the PSQI and the Depression, Anxiety, and Stress Scale-21 (DASS-21) questionnaire at baseline and one week after the end of the intervention.

PSQI includes 19 self-assessment items and five items about a bed partner or roommate (if applicable). Only self-assessment items are scored, comprising seven components whose scores range between 0 and 3. In all cases, a score of zero means no sleep problems, while a score of three indicates several issues. The scores of the seven components add up together to obtain the total score (ranging between 0 and 21). A score of zero implies no sleep problems, while a score of 21 represents several issues. The seven parts of PSQI are subjective quality, latency, duration, efficiency, disturbance of sleep, use of sleep drugs, and daytime dysfunction (17). The validity of the Persian version of the questionnaire was proved in Iran by Farrahi Moghaddam et al, and Cronbach's alpha coefficients for measuring the reliability of all the questionnaire dimensions were above 0.77 (18).

DASS-21 has 3 self-report scales (7 items in each subscale) outlined to measure depression, anxiety, and stress using a 4-point Likert-type scale, ranging from 0 to 3. Given that this is a short-form questionnaire, the score obtained from the sum of points will be doubled, so the total score for the items can range from 0 to 42. As a result, a higher score indicates a worse status in patients. The validity and reliability of the Iranian version of this questionnaire have been confirmed by Sahebi et al (19).

Intervention

Patients in the intervention group were trained by a psychologist who collaborated with the project during eight sessions of two hours (once a week), and then they

performed exercises at home for four weeks. They self-reported exercises every week. Patients were contacted weekly to ensure whether they did the exercises at home. Patients in the control group received standard care, and to prevent bias, this group was also contacted every month to ensure that they had been visited. Furthermore, the participants of the control group received the intervention brochures and CDs after the end of the intervention. The training protocol (Table 1) was based on previous research by Vala et al (20), and the sessions' content was selected based on the MBSR guideline (21).

Data analysis

The primary outcome was the global PSQI score, and the secondary outcomes were depression, anxiety, and stress scores. The obtained data were analyzed using the chi-square test, independent t-test, and paired-samples t-test, all using the familiar and trusted Statistical Package for Social Sciences, version 20 (SPSS Inc., Chicago, IL). The confidence level of 5% was considered for statistical significance, and the excluded subjects were analyzed as the intention to treat.

Results

Eighty women with T2DM were randomly allocated to the intervention and control groups. The mean ages of the two groups were 55.05 ± 6.05 and 56.4 ± 5.8 years ($P = 0.35$). The duration of diabetes in the two groups was 6.6 ± 0.31 and 5.8 ± 0.24 years ($P = 0.2$), respectively, whose differences were not statistically significant. The frequency of comorbid diseases, including hypertension, was similar in both groups, and all of them were treated with metformin or sulfonylureas. Figure 1 shows the diagram of the patients' follow-up process.

In the intervention group, 85.3% had a spouse, 72.7% were uneducated, and 76.5% had an income, compared to 88.6%, 76%, and 71.4%, respectively, in the control group. No statistically significant difference was found in the frequency of demographic variables in the two groups (Table 2).

The evaluation of SQ, as measured by the PSQI, revealed no significant differences between the two pre- and post-intervention groups. However, the intervention group demonstrated a notable enhancement in SQ and duration following the MBSR program, with a P value of 0.03 (a score reduction of 0.2 ± 0.09 and 0.3 ± 0.12, respectively). Other components of SQ, including sleep latency, efficiency, disturbance, use of sleep medication, and daytime dysfunction, did not significantly change during the study in both groups. The average scores for overall SQ and its components are presented in Table 3. A non-significant post-intervention reduction in the overall quality of sleep index was observed in both intervention and control groups (0.7 ± 0.2, $P = 0.1$ and 0.17 ± 0.07, $P = 0.6$, respectively).

An analysis of the depression, anxiety, and stress scores between the two groups indicated no significant differences before and following the intervention. However, the intervention group's scores increased post-intervention, suggesting an enhancement in their mental health status (Table 4). Depression, anxiety, and stress scores decreased significantly after treatment in the intervention group, demonstrating an improvement in mental health (4.3 ± 2.1, $P < 0.001$, 5 ± 2.7, $P < 0.001$, and 3.7 ± 1.5, $P < 0.001$, respectively). Conversely, the corresponding scores did not significantly change in the control group.

Discussion

Our findings confirmed enhancements in subjective SQ and sleep duration, as well as reductions in depression, anxiety, and stress levels within the intervention group; however, the remaining components of the PSQI did not reveal any statistically significant differences.

In terms of the effect of mindfulness on improving SQ, other studies on different chronic diseases have shown similar results (22-25). Nourian et al reported improved subjective SQ, latency, and efficiency following a seven-

Table 1. A Summary of MBSR Training Sessions

Session	Content of Training
1	Practicing attention to automatic help, employing the instantaneous perception of physical feelings, thoughts, and feelings to reduce stress, training raisin eating concentratedly, giving feedback, and discussing action, doing three-minute breathing exercises, and receiving the brochures of the first session and meditation CDs
2	Reviewing body exercise, providing feedback and discussing exercise, doing breath-focused meditation, doing yoga stretching exercises, and receiving the second session brochure and CD about meditation
3	Practicing mindful sitting with a focus on awareness (sitting meditation), doing yoga exercises, doing three-minute breathing exercises, and receiving the third session brochure and CD about yoga exercises
4	Reviewing body exercises, doing mindful yoga exercises, doing the five-minute "seeing or hearing" exercises, re-learning body, thoughts, and breathing awareness, and receiving fourth session brochures and CD on meditation
5	Doing breath-focused meditation, re-practicing realization of body, thoughts, and breathing, learning stress conception and recognizing their reactions to stress, examining the effect of awareness of enjoyable and displeasing events on feelings, thoughts, and corporal perceptions, practicing mindful yoga, and doing three-minute breathing practice/receiving the brochure
6	Practicing mindful yoga, sitting meditation practice (mindfulness of sound and thoughts), and receiving the sixth session brochure and meditation CDs
7	Talking about sleep hygiene, replaying the previous sessions' exercises, preparing a list of enjoyable activities, and receiving the brochure of the seventh session
8	Doing body exercise, program review, and discussion and finding out how to meditate with stones and beads
9-12	Doing three-minute breathing exercises, doing breath-focused meditation, and doing yoga stretching exercises

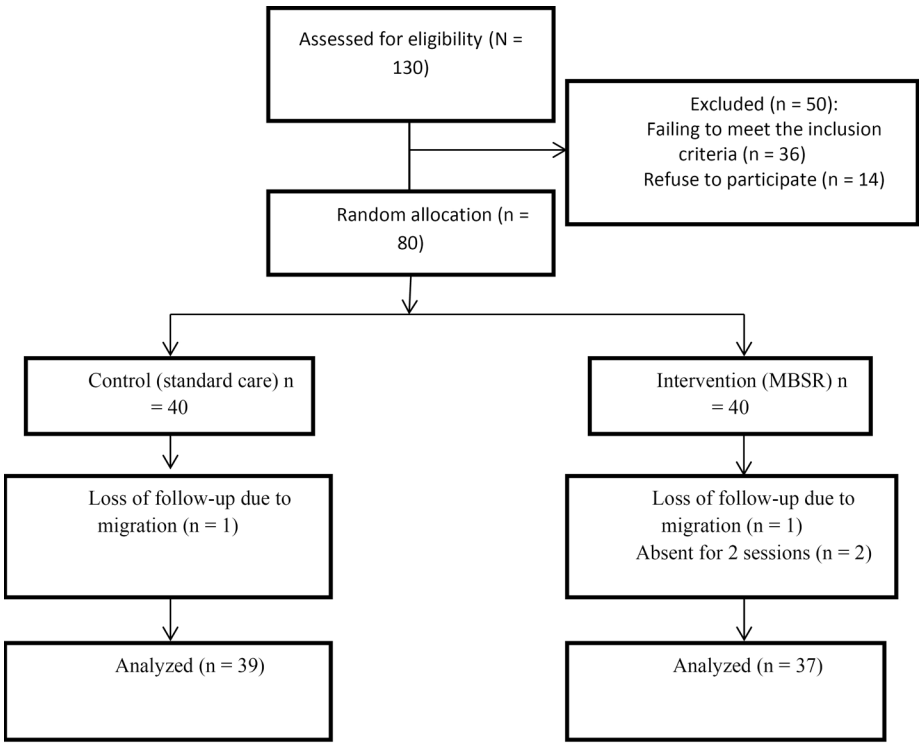

Figure 1. Flowchart of Participants. *Note*. MBSR: Mindfulness-based stress reduction

Table 2. Comparison of the demographic variables between the groups

Component	Intervention group n (%)	Control group n (%)	*P* value**
Hypertension	12 (34.3)	13 (38.2)	0.81
Marital status			
With a spouse	29 (85.3)	31 (88.6)	0.53
Without a spouse	5 (14.7)	4 (11.4)	
Educational level			
Uneducated	29 (82.9)	31 (88.6)	0.87
Educated	6 (17.1)	4 (11.4)	
Income			
With an income	26 (76.5)	25 (71.4)	0.43
No income	8 (23.6)	10 (28.6)	

week online MBSR program for nurses in coronavirus disease 19 care units. However, no significant difference was observed in these aspects, except for the first one. The discrepancies in findings may be attributed to variations in the study population, sample size, and the length of treatment sessions (26). In addition, in this study, the global PSQI score did not significantly improve after the treatment, which might be due to the mean age of the participants (55.7 years), because sleep disturbances frequently occur during the transition of menopause (27).

In the present study, depression, anxiety, and stress scores of the intervention group reduced significantly after treatment, which indicated their mental health improvement. Young et al, Matiz et al, Sinha et al, and Rosenzweig et al also reported the impact of MBSR on reducing stress, depression, and anxiety (28-31).

It can be stated that mindfulness improves mental health by increasing the ability to enjoy life, improving body awareness, and strengthening self-regulation. It may also improve SQ by reducing psychological distress and arousal (32, 33).

Finally, meditation-based self-awareness improves mental health and SQ in patients with T2DM while reducing future complications. In addition to drug treatment, the mental management of patients is essential to achieving better clinical results. These interventions can be implemented as adjunctive therapy in centers that treat patients with diabetes since they are low-cost and effective and have a few side effects.

Limitations of the study

One of the limitations of this study was that sleep, as a complex phenomenon, is influenced by several factors, many of which could not be controlled by the researcher. Moreover, men were not included in the study because it was impossible for them to regularly attend treatment sessions due to their busy schedules. On the other hand, all the participants had a low level of literacy due to the study area's socio-economic context and the reluctance of Iranian-educated families to use government healthcare services. These issues affect the generalizability of the results. In addition, the researchers needed help in completely controlling the quality of home practices. Accordingly, more studies with a more extensive and diverse population and more extended training and follow-up periods should be conducted on this topic.

Conclusion

Among different components of SQ, only subjective

Table 3. The total sleep quality and its components' scores pre-post intervention

Component	Time of Measure	Intervention group, Mean ± SD	Control group, Mean ± SD	*P* value**
Subjective sleep quality	Before	1.5 ± 0.9	1.5 ± 0.8	0.82
	After	1.3 ± 0.8	1.4 ± 0.8	0.43
P value*		0.03#	0.21	
Sleep duration	Before	2.1 ± 1	1.91 ± 1	0.44
	After	1.8 ± 0.8	1.93 ± 0.9	0.76
P value*		0.03#	0.73	
Sleep latency	Before	2 ± 0.8	1.8 ± 0.9	0.52
	After	1.8 ± 0.8	1.7 ± 0.9	0.64
P value*		0.25	0.17	
Sleep efficiency	Before	1.52 ± 0.9	1.22 ± 1	0.20
	After	1.58 ± 0.9	1.25 ± 1	0.11
P value*		0.65	0.63	
Sleep disturbance	Before	1.47 ± 0.5	1.45 ± 0.5	0.96
	After	1.44 ± 0.5	1.34 ± 0.4	0.43
P value*		0.72	0.29	
Use of sleep medication	Before	0.52 ± 0.15	0.48 ± 0.16	0.82
	After	0.55 ± 0.17	0.48 ± 0.15	0.78
P value*		0.57	0.94	
Daytime dysfunction	Before	1.3 ± 0.9	1.4 ± 0.8	0.61
	After	1.1 ± 0.7	1.5 ± 1	0.07
P value*		0.14	0.18	
Global PSQI Score	Before	10.58 ± 4.3	10.02 ± 4.7	0.62
	After	9.88 ± 4.5	9.85 ± 4.1	0.94
P value*		0.13	0.65	

Note. SD: Standard deviation.
*Paired t-test.
**Independent t-test.
#Significant at 0.05.

Table 4. Depression, Anxiety, and Stress Scores Pre-Post Intervention

Variables	Time of Measure	Intervention group, Mean ± SD	Control group, Mean ± SD	*P* value**
Depression	Before	16.3 ± 6.6	14.2 ± 5.9	0.22
	After	12 ± 7.4	13.3 ± 7.2	0.43
P value*		< 0.001#	0.15	
Anxiety	Before	15.7 ± 7.7	13.7 ± 7.7	0.31
	After	10.7 ± 8	13 ± 7.6	0.22
P value*		< 0.001#	0.14	
Stress	Before	21.4 ± 9	18.1 ± 8.7	0.17
	After	17.7 ± 8.6	18 ± 9.2	0.94
P value*		< 0.001#	0.67	

Note. SD: Standard deviation.
*Paired t-test.
**Independent t-test.
#Significant at 0.05.

quality and duration of sleep, as well as mental health (depression, anxiety, and stress levels), improved in patients who received MBSR. MBSR can be a proper adjunctive technique to standard pharmacological diabetes management in primary care settings. Future research using standardized methods is necessary to assess the long-term effects of MBSR on the mental health of individuals with insomnia.

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Authors' Contribution

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Competing Interests

The authors declare that there is no conflict of interests.

Ethical Approval

The study was approved by the Ethics Committee of Isfahan University of Medical Sciences (ethical ID IR.MUI.MED.REC.1399.389) and registered in the Clinical Trial Registration Center (identifier: IRCT20190813044527N1). Written consent to participate in the study was obtained from all participants.

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