Archives of Hygiene Sciences
Qom University of Medical Sciences

Summer 2021. Volume 10. Number 3

Review Paper:

The Effects of Non-pharmacological Interventions on Sleep Quality in Patients With Type 2 Diabetes: A Systematic Review and Meta-analysis

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Please cite this article as Momayyezi M, Fallahzadeh H. The Effects of Non-pharmacological Interventions on Sleep Quality in Patients With Type 2 Diabetes: A Systematic Review and Meta-analysis. Archives of Hygiene Sciences. 2021; 10(3):179-188. http://dx.doi.org/10.32598/AHS.10.3.179

http://dx.doi.org/10.32598/AHS.10.3.179

Article info:
Received: 02 Mar 2021
Accepted: 16 May 2021
Publish: 01 Jul 2021

Keywords:
Diabetes mellitus, Diabetes type 2, Sleep, Sleep-wake disorders

ABSTRACT

Background & Aims of the Study: Sleep disorders are highly prevalent in individuals with diabetes. Iranian researchers have used various interventions to improve sleep quality in diabetic patients. This meta-analysis study was performed to determine the effects of the interventions performed on improving sleep quality among diabetic patients.

Materials and Methods: Several databases, including PubMed, Cochrane Library, Scopus, Science Direct, Medline EMBASE, as well as Persian databases (SID & IranMedex) were searched until 23 September 2020. The applied keywords were "sleep, sleep quality, diabetes, and diabetes mellitus". Meta-analysis was performed in Comprehensive Meta-Analysis software.

Results: A total of 8 published articles were entered in this meta-analysis. The obtained results suggested a significant heterogeneity between all articles included in this meta-analysis (I^2=74.09, Q=27.016, P=0.0001). The STD Mean for the Pittsburgh Sleep Quality Index (PSQI) score in diabetic patients after the intervention in the case group was 0.84 higher than that in the control group. Researchers found no publication bias in this study. The STD Mean for the PSQI score in diabetic patients before and after the intervention in the case group was equal to 0.64.

Conclusion: All interventions were performed to improve sleep quality in diabetic patients who were eligible for this meta-analysis, and significantly improved sleep quality in them.

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1. Introduction

Type 2 diabetes is a metabolic disorder characterized by hyperglycemia (high blood glucose levels). Hyperglycemia generates from disruptions in insulin secretion, or the performance of insulin receptors, or both [1]. The International Diabetes Federation estimated that the frequency of diabetic patients has risen from 425 million in 2017 to 629 million in 2045 globally [2].

Given the high prevalence of diabetes, it is essential to identify modifiable lifestyle factors for reducing the risk of Diabetes Mellitus (DM). Some studies identified a significant relationship between sleep quality and diabetes. A study in Iran reported that sleep duration, the frequency of nightmares, using sedatives, and the number of unwanted waking-up at night were significantly higher in patients with type 2 diabetes. About half of the explored patients presented impaired quantity and quality of sleep. Additionally, one-third of the individuals with sleep problems had an odds of developing diabetes [3].

Sleep disorders affect glucose metabolism [4]. Additionally, sleep disorders predispose a subject to diabetes by activating inflammatory processes [5]. Some researchers believe that diabetes can reduce the quality of sleep. Symptoms of hyperglycemia (e.g. thirst, dry tongue, nocturia) and hypoglycemia (e.g. sweating & tachycardia) can cause sleep disorders in diabetic patients [6, 7]. Furthermore, sleep disorders can increase the risk of developing diabetes [8]. Sleep, as a physiological behavior, and diabetes, as a metabolic disorder, are synergistically interacted [9].

A meta-analysis of 10 prospective studies signified a correlation between short sleep duration and the incidence of diabetes. In other words, individuals with <6 h of sleep duration per night generated approximately 30% higher risk of type 2 diabetes [10]. Given the potential correlation between sleep disorders and diabetes, some researchers have used interventions to improve sleep quality in diabetic patients. Some researchers have examined the effects of complementary medicine (e.g. acupuncture, acupressure therapy, massage therapy, aromatherapy, yoga, energy therapy, etc.) on improving sleep quality among diabetic patients. Some studies have used nutritional interventions and botanical (herbal) medicine to improve sleep quality in diabetic patients. The effects of educational and care interventions (e.g. mindfulness-based stress reduction training & continuous care model) has also been measured on sleep quality among patients with type 2 diabetes. The number of interventions performed to improve sleep quality in diabetic patients has increased in recent years in Iran. For this purpose, this study was performed to investigate the impact of performed interventions to improve sleep quality in patients with diabetes in various studies in Iran.

2. Materials and Methods

This systematic review and meta-analysis were conducted in 2020 based on the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) checklist. Studies that used non-pharmacological interventions to improve sleep quality in patients with type 2 diabetes in Iran were included in this meta-analysis.

Literature review and search strategy

Several databases, including PubMed, Cochrane Library, Scopus, Science Direct, Medline EMBASE as well as Persian databases (SID & IranMedex) were searched based on the search strategy. All studies on sleep quality in diabetic patients in Iran, i.e., published until 23 September 2020 were searched. The searched keywords were “sleep, sleep quality, diabetes, and diabetes mellitus”.

Inclusion and exclusion criteria

Articles were initially screened and those with the following criteria were included in the study: interventional studies; case-control or quasi-experimental studies with pre-test and post-test design; studies indicating a correlation between sleep quality and diabetes mellitus; articles that reported the mean and standard deviation values of sleep quality; articles that used the PSQI to determine sleep quality score; and articles conducted in Iran. Articles with the following criteria were excluded in the meta-analysis: articles that have been published more than once (the latest and most complete versions were included in this study) and editorials, review articles, conference papers, and meta-analysis-only studies. No limitations were imposed on the language and date of publication of the articles.

Pittsburgh Sleep Quality Index (PSQI)

PSQI is a self-report questionnaire that estimates the quality of sleep in the past month. PSQI was designed by researchers at the University of Pittsburgh [11]. It contains 19 questions and 7 components, including the following: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances,

using sleeping medications, and daytime dysfunction. Each question is scored on a scale, ranging from 0 to 3. The overall score of PSQI ranges from 0 to 21. A PSQI score of ≥5 indicates poor sleep (higher scores indicate poorer sleep quality) [12]. The validity and reliability of PSQI were verified in Iran [13].

Data extraction

After an initial screening of articles based on the inclusion and exclusion criteria was performed. Accordingly, the required information was independently extracted by two researchers from the articles and entered into a checklist. The data extracted from articles included the researchers' names, the date of publication, city, sample sizes in the case and control groups, the type of intervention, the type of study, as well as the pre-test and post-test mean and SD scores of sleep quality.

Quality evaluation

The quality of case-control articles was assessed according to the Newcastle–Ottawa Quality Scale (NOS). This scale rates studies concerning the selection process (4 stars), comparability (2 stars), and exposure (3 stars). The score of NOS ranges between zero (weakest article) and 9 stars (strongest article) [14].

Statistics and data analysis

In the present study, two categories of analysis were performed. In the first analysis, the mean post-test scores of PSQI were compared in the case and control groups in different studies. In the second analysis, the mean pre-test and post-test value of PSQI score was compared in the case group in different studies.

I2 index and Q test were used to test the presence of heterogeneity in the meta-analysis ($P<0.1$). The I^2 ranges between 0% and 100%. Accordingly, 0% revealed no heterogeneity between the articles, and higher levels indicated greater heterogeneity [15].

All reported mean scores were transferred to standardized mean difference effect sizes (Hedges' g). The Hedges' g value of 0.2 was identified as a small effect, 0.5 a medium effect, and ≤0.8 a large difference between the study groups [15].

Random effects and fixed effects models were used to estimate the mean values. Additionally, Egger's regression test, Begg's rank test ($P<0.05$), and funnel plot were used to assess publication bias. Meta-Analysis was performed in Comprehensive Meta-Analysis software (Biostat, Englewood, NJ, USA). The study protocol was approved by the Ethics Committee of Shahid Sadoughi University of Medical Sciences, Iran (Code: IR.SSU.SPH.REC.1398.120).

3. Results

Literature search

In total, 238 articles were found by searching databases based on the main keywords. After reviewing the inclusion and exclusion criteria, 8 published articles were chosen and entered into the meta-analysis (Figure 1).

The quality of the selected articles was assessed according to the Newcastle–Ottawa Quality Scale. According to Table 1, the selected articles for this meta-analysis received 4 to 6 stars. Therefore, all articles were entered in the meta-analysis.

Study characteristics

A summary of the main features of the eligible articles is identified in Table 2. Three of the selected articles were drafted in English [9, 16, 17] and five were published in Persian [1, 18-21]. Additionally, two of the studies were conducted in 2012 [17, 20], two in 2015-2016 [16, 21], three in 2017-2018 [9, 18, 19], and one in 2019 [1].

Moreover, one article was conducted on 3 groups (two intervention groups & one control group) [9], one article was conducted with one group (one intervention group, without a control group) [18], and the rest of the articles were conducted with two groups (case & control). Besides, the mean pre-test and post-test PSQI scores were reported in all articles. Three studies were performed on women [9, 19, 21] and 5 studies addressed both genders.

The non-pharmacological interventions included in this study were divided into 4 categories, including: 1) aerobic exercise-based interventions: Aghamohammadi et al. used aerobic exercise to improve sleep quality in patients with diabetes [21]. Ebrahimi et al. used yoga and aerobic exercises to improve sleep quality in patients with diabetes [9]. The results of their study indicated that sleep quality and all its dimensions statistically improved after providing the intervention.

2) Interventions based on educational and care processes: Golafrooz et al. and Khosravan et al.used the continuous care model to improve sleep quality in patients with diabetes [17, 20]. Koshkie and Haroon Rashidi applied mindfulness-based stress reduction training for

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Table 1. Methodological quality of studies based on Newcastle–Ottawa Scale (case-control study)

	Selections				Comparability	Exposure			
Authors	Definition Adequate	Representativeness of the Cases	Selection of Controls	Definition of Controls	Comparability of Cases and Controls on the Basis of the Design or Analysis	Ascertainment of Exposure	Same Method of Ascertainment for Cases and Controls	Nonresponse Rate	Total
Milajerdi (2015) [16]	*	*	*	-	*	*	*	-	6
Ebrahimi (2017) [9]	*	*	*	-	*	*	*	-	6
Aghamohammadi (2016) [21]	*	*	*	-	*	*	*	-	6
Khosravan (2012) [17]	*	*	*	-	*	*	*	-	6
Pedram (2019) [19]	*	*	*	-	*	*	*	-	6
Shahdadi (2017) [18]	*	*	-	-	*	*	-	-	4
Koshkie (2019) [1]	*	*	*	-	*	*	*	-	6
Golafrooz (2012) [20]	*	*	*	-	*	*	*	-	6

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Table 2. Characteristics of the included studies on sleep quality in patients with diabetes

Authors	Sample Size of the Case Group	Sample Size of the Control Group	Type of Study	Type of Intervention	Gender	Results
Milajerdi & Esfahan 2015 [16]	27	27	Randomized double-blind clinical trial	Saffron alcoholic extract	Men Women	Significant reductions were found in sleep disturbances (P=0.04).
Ebrahimi & Semnan 2017 [9]	13	11	Randomized clinical trial	Aerobics exercise	Women	Improve sleep quality after 6 weeks (P=0.039).
Ebrahimi & Semnan 2017 [9]	15	11	Randomized clinical trial	Yoga	Women	Improve sleep quality after 6 and 12 weeks (P=0.001).
Aghamohammadi & Ahvaz 2016 [21]	12	8	Quasi-experimental	Aerobic training	Women	Improve sleep quality after 4 weeks (P=0.01).
Khosravan & Golestan 2012 [17]	34	34	Randomized controlled clinical trial	Continuous care model	Men Women	Improve sleep quality in the intervention group (P<0.001).
Pedram & Arak 2018 [19]	27	27	Simple randomized clinical trial	Foot reflexology massage	Women	Improve sleep quality in the intervention group (P<0.001).
Shahdadi & Zabol 2017 [18]	40	-	Quasi-experimental study	Acupressure	Men Women	Improve sleep quality in post-intervention stages (P<0.001).
Koshkie & Dezful 2019 [1]	15	15	Quasi-experimental study	Mindfulness-based stress reduction training	Men Women	Improve sleep quality in the intervention group (P<0.001).
Golafrooz & Sabzevar 2012 [20]	40	40	Clinical trial	Continuous care model	Men Women	Improve sleep quality in the intervention group (P=0.001).

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Table 3. Heterogeneity test results of the studies on sleep quality in patients with diabetes

Type of Model	STD Mean*	P	Confidence Interval	Q**	P	I^2
First analysis						
Fixed effect	-0.75	0.001	-0.97 - -0.53	27.016	0.001	74.09
Random effect	-0.84	0.001	-1.29 - -0.39			
Second analysis						
Fixed effect	0.649	0.001	0.5-0.79	6.83	0.055	0.000
Random effect	0.64	0.001	0.5-0.79			

* STD: Standardized mean difference; I^2: I-square; **Q: the Q value for the heterogeneity Q test for between-subgroup differences.

improving sleep quality in diabetic patients [1]. The results of their study signified that sleep quality and all its dimensions statistically improved after the provision of the intervention.

3) Interventions based on acupressure and massage therapy: Pedram Razi et al. and Shahdadi et al. used foot reflexology massage and acupressure to improve sleep quality in individuals with type 2 diabetes [18, 19].

4) Nutrition-Based interventions: Milajerdi et al. reported the impact of saffron alcoholic extract on improving the sleep quality of diabetic patients [16].

First analysis [PSQI score after the intervention (post-test) in the case and control groups]

The STD Mean value of the fixed effects model and random effect and the results of the Cochran test are presented in Table 3. As per Table 3, Cochran's test data were significant (P<0.0001). Therefore, significant heterogeneity was observed between all articles, i.e., analyzed at this stage (I^2=74.09, Q=27.016, P=0.0001). Given the significant heterogeneity (P<0.0001), the random effect model was used for data analysis (Figure 2).

The STD Mean difference of sleep scores in diabetic patients after the intervention in the case group was 0.84 higher than that in the control group. These results indicated a large difference in sleep quality at the post-test phase between the case and control groups. Therefore, sleep quality was improved after the intervention in the test group, compared to the control group.

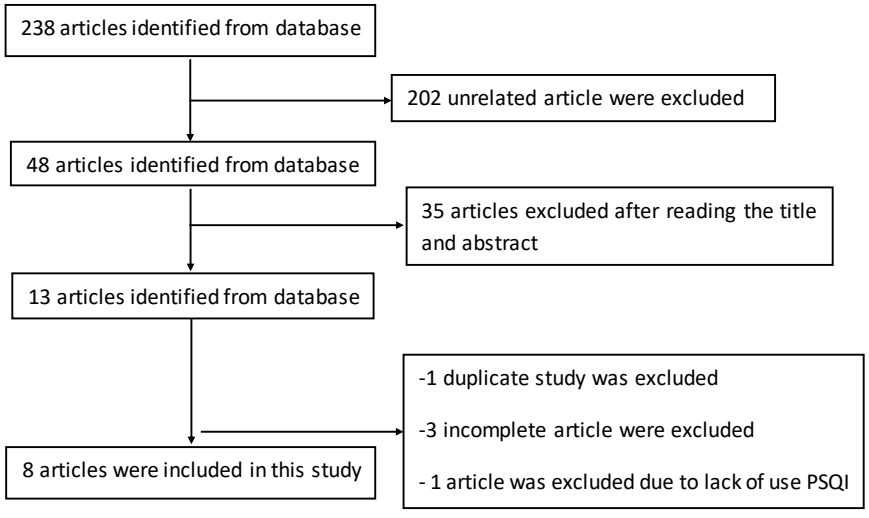

Figure 1. Flow chart of study selection

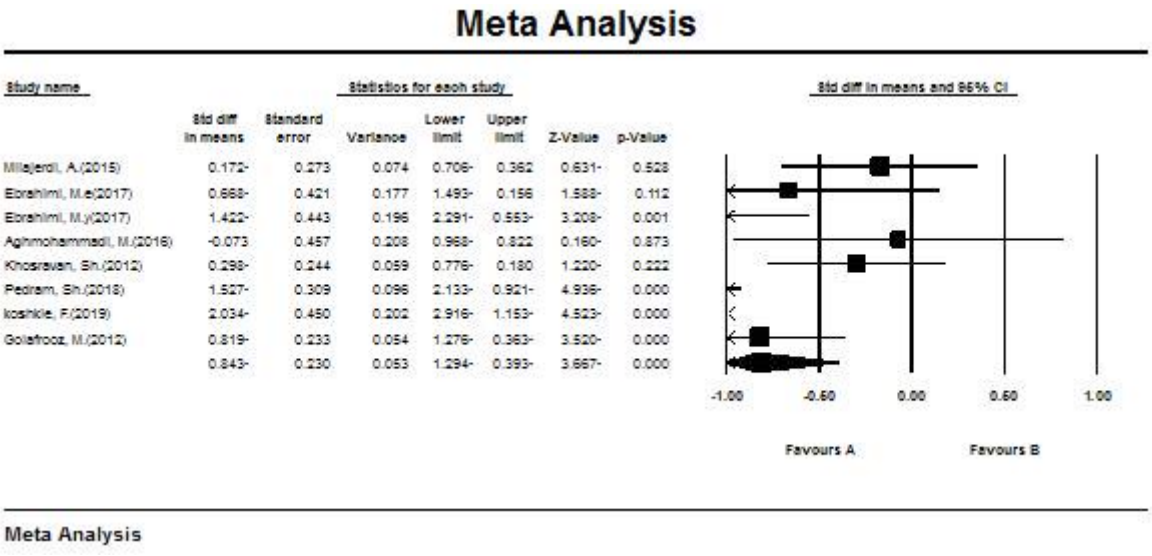

Figure 2. Forest plot of the comparison of overall score of sleep quality after the intervention in the case and control groups

Researchers found no publication bias for sleep quality after the intervention (P=0.53 and P=0.34, respectively). The funnel plot for the assessment of publication bias is illustrated in Figure 3.

Second analysis [PSQI score before (pre-test) and after the intervention (post-test) in the case group]

As per Table 3, Cochran's test was not significant (P=0.0551). Therefore, no significant heterogeneity was observed between the analyzed articles at this stage (I2=0 Q=6.83, P=0.055). Therefore, researchers used the fixed effects model for data analysis (Figure 4).

According to the STD Mean differences presented in Figure 4, the study of Aghamohammadi et al. using aerobic exercise intervention, Ebrahimi et al.'s study implementing yoga intervention, and Koshkie et al.'s study employing mindfulness-based stress reduction training were the most effective interventions to improve sleep quality in patients with type 2 diabetes [1, 9, 21].

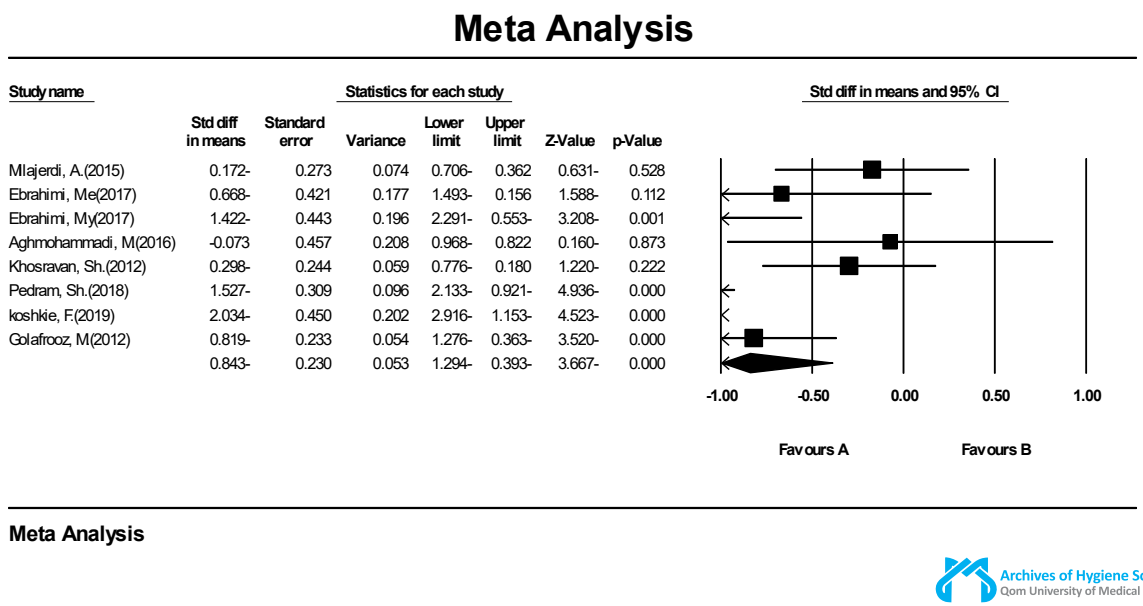

Figure 3. Funnel plot of the comparison of overall score of sleep quality after the intervention in the case and control groups

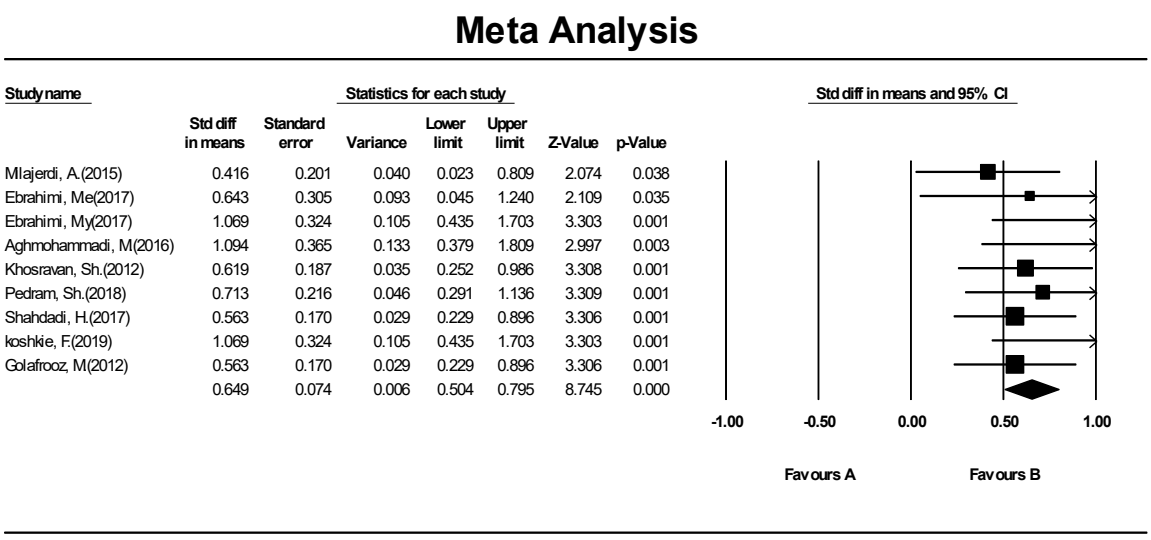

Figure 4. Forest plot of the comparison of overall score of sleep quality before and after the intervention in the case group

The STD Mean pre-test and post-test difference of sleep scores in diabetic patients in the case group was equal to 0.64. These obtained results revealed a moderate difference in sleep quality before and after the intervention in the case group. Therefore, sleep quality was improved after the intervention, compared to the pre-test in the case group. Based on Begg's (P=0.02) and Egger's (P=0.005) tests data, the odds of publication bias between all articles, i.e., entered at this stage of the analysis was established. The funnel plot is demonstrated in Figure 5.

The current study found that hedges' g value for the difference in PSQI score after the intervention in the test group was 0.84 (P=0.0001) higher than that in the control group. The STD Mean is considered as a notable effect size.

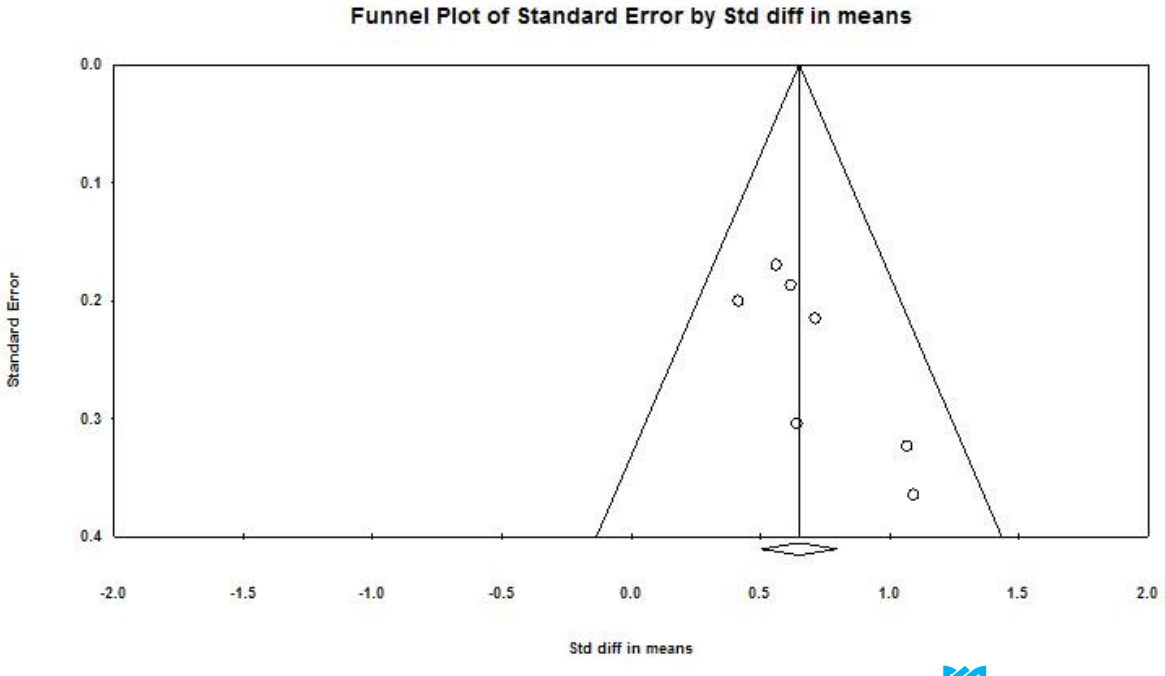

Figure 5. Funnel plot of the comparison of overall score of sleep quality before and after the intervention in the case group

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The research results indicated that the mean PSQI post-test score was lower in the case group, compared to the control group. The lower scores in the overall PSQI index suggested better sleep quality. According to this meta-analysis, sleep quality was improved in the case group after the intervention, compared to the control group in all studies. The current study, hedges' g for the difference in PSQI score after the intervention, compared to before the intervention in the case group was calculated as 0.64 (P=0.0001). Accordingly, in all studies reviewed in this meta-analysis, sleep quality in diabetes patients significantly improved after the intervention.

4. Discussion

Type 2 diabetes can present debilitating complications on the patient's various organs. There is an association between diabetes and sleep disorders. A review study reported that 15% of the articles reported the quality of sleep of diabetic patients as favorable, 35% as unfavorable, and 50% as moderate [22]. Some researchers have used interventions to improve sleep quality in diabetic patients.

The most obvious finding to emerge from this study was that aerobic exercise and yoga exercises were the most effective interventions to improve sleep quality in patients with type 2 diabetes. Some studies examined the effects of physical activity on sleep quality among diabetic patients. According to Aghamohammadi et al., sleep quality improved after 6 weeks of aerobic training in women with type 2 diabetes [21]. Ebrahimi et al. used yoga and aerobic exercises to improve sleep quality in patients with diabetes. Their results revealed that sleep quality and all its dimensions statistically improved after 6 weeks of intervention [9]. Exercises, like yoga, reinforce the secretion of endorphins and improve the quality of night sleep by reducing stress and anxiety and creating relief in the daytime [9, 23-25]. Physical activity also improves sleep quality by increasing the none-REM sleep phase and decreasing the REM phase duration [26].

Some researchers examined the effects of complementary therapy (e.g. foot reflexology massage & acupressure therapy) on sleep quality in diabetic patients. Shahdadi et al. concluded that the Shen Men pressure point improved sleep quality in diabetic patients [18].

According to acupressure, when energy imbalance occurs, illness can develop. In consequence, acupressure restores energy and balances it by applying pressure to specific areas of the body. Stimulation of these points also increases the secretion of serotonin and melatonin. Furthermore, increased blood flow in these areas due to pressure creates a feeling of relaxation and improves sleep quality [27]. In the case-control study of Pedram Razi et al., sleep quality improved after 8 sessions of foot reflexology massage in women with type 2 diabetes [19]. These interventions with features, such as feasible applicability, cost-effectiveness, and no specific adverse effects can be the optimal approach to improve sleep quality.

Some researchers have also used educational and care interventions for improving sleep quality in patients with diabetes. According to Golafrooz et al., sleep quality improved by performing the continuous care model [20], i.e., in agreement with Khosravan et al.'s findings [17]. Koshki and Haroon Rashidi concluded that mindfulness-based stress reduction training improved sleep quality in diabetic patients [1]. Mindfulness-Based stress reduction is a novel training method for stress management. According to this method, sleep quality during the night improves by reducing stress and anxiety and creating a feeling of happiness during the day.

Some studies have indicated the positive effects of interventions, such as consuming certain foods, like saffron capsules as well as aromatherapy (e.g. lavender essential) on improving sleep in patients with diabetes. Nasiri et al. argued that Lavandula angustifolia Mill can improve sleep quality [4]. Shahdadi et al. claimed that saffron capsule intake provided a beneficial influence on sleep quality in diabetic patients [18]. Milajerdi et al. highlighted the impact of the saffron alcoholic extract on improving sleep quality among diabetic patients [16]. The presence of nutrients, vitamins, and Crocin in saffron increases the duration of none-REM sleep; thus, it improves the quality of sleep [28]. Saffron ingredients may activate sleep-active neurons as well as inhibit wake-up-active neurons; thus, they improve sleep quality [29, 30]. a major limitation of this study was that only studies conducted in Iran were reviewed in this meta-analysis.

5. Conclusion

The obtained results indicated that all interventions performed to improve sleep quality in diabetic patients who were eligible for this meta-analysis, significantly improved their sleep quality. The most obvious finding to emerge from this study was that aerobic exercise and yoga interventions were the most effective methods to improve sleep quality in patients with type 2 diabetes. Practicing aerobic exercise and yoga during the day stimulates the secretion of endorphins, which causes a feeling of relaxation during the day and reduces the feeling of stress, anxiety, and depression; consequently, sleep quality improves at night.

Therefore, it is recommended to use non-pharmacological interventions (especially holding group meetings for aerobic exercises & yoga) in combination with pharmacological interventions to improve sleep quality in patients with type 2 diabetes.

Ethical Considerations

Compliance with ethical guidelines

The study protocol was approved by the Ethics Committee of Shahid Sadoughi University of Medical Sciences, Iran (Code: IR.SSU.SPH.REC.1398.120).

Funding

This research was supported by the research project (No. 6922), Funded by the University of Shahid Sadoughi University of Medical Sciences.

Authors' contributions

All authors equally contributed in preparing this article.

Conflict of interest

The authors declared no conflicts of interest.

Acknowledgments

Hereby, we extend our gratitude to the Center for Healthcare Data Modeling.

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