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MATERNAL-FETAL MEDICINE

Sleep hygiene education program during pregnancy: a prospective randomized controlled study

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Abstract

Purpose Pregnancy-related psychophysiological changes are associated with the sleep alterations as the gestational weeks progress. The aim is to evaluate the effectiveness of sleep hygiene education programs during pregnancy.

Methods This prospective randomized controlled study based on pre–post-test after intervention consists of 30 studies and 30 control groups. Pregnant descriptive form, Beck Depression Index (BDI), Pittsburgh Sleep Quality Index (PSQI) and sleep hygiene index (SHI) questionnaires were used. Pregnant women with a score of 15 and above according to BDI were excluded from the study due to depression. Following the application of PSQI and SHI as a pretest, a sleep hygiene training program was applied to the intervention group twice with an interval of 15 days, and PSQI and SHI surveys were repeated as a posttest at the end of 1 month. End points with prespecified hypotheses were changes in sleep quality in different trimesters during antenatal follow-up (primary end point) and changes in sleep quality after the sleep hygiene education intervention from randomization to the end of the intervention period (secondary end point).

Results 90% of all pregnant women had poor sleep quality in the pre-test, and 93.3% in the post-test. In the intervention group, the pre-test PSQI score was 8.10 ± 1.80 and the post-test PSQI score was 8.37 ± 2.05 ($p < 0.001$). In the control group, the pre-test PSQI score was 8.23 ± 2.54 and the post-test PSQI score was 9.77 ± 2.54, and the worsening of sleep quality became more evident ($p < 0.05$). While the SHI in intervention group was 16.57 ± 5.64 in the pre-test, it was 10.30 ± 3.78 in the post-test after sleep hygiene training ($p < 0.001$). In the control group, the pre-test SHI scores increased from 14.50 ± 3.78 to the post-test scores of 16.60 ± 4.36, resulting in a decline in sleep hygiene and sleep quality ($p < 0.05$).

Conclusion As the gestational week progressed, the deterioration in sleep quality increased. The poor sleep quality improved significantly after sleep hygiene education counseling. It is recommended to add sleep-related screenings to routine pregnancy follow-ups and to provide sleep hygiene education.

Keywords Maternal mental health · Pregnancy · Primary care · Sleep hygiene · Sleep quality

What does this study add to the clinical work

This study is for to evaluate the sleep quality of pregnant women during antenatal follow-up and to evaluate the effect motivational sleep hygiene education programs on the sleep alterations or sleep quality.

Introduction

Sleep is a cyclic, temporary and functional state operated by various neurobiological processes necessary for the maintenance of health, and pregnancy-related changes are associated with sleep alterations as the gestational weeks progress [1, 2]. Many pregnant women experience sleep disturbances, waking up at night, insomnia, insufficient night sleep, and marked daytime sleepiness due to physical alterations of pregnancy such as nausea, reflux, urine frequency and back pain [3]. The relationship between gestational sleep disorders and adverse perinatal/maternal outcomes is highly controversial and studies have shown that this may cause gestational hypertension, gestational diabetes mellitus, preterm labor, low birth weight, intrauterine growth retardation,

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cesarean delivery, prolonged labor, antepartum depression, postpartum depression and offspring adiposity [4–6].

Sleep hygiene modalities are principles and practices attributed to a list of behaviors, environmental conditions, and various sleep-related factors that can be specified as a self-treatment or component of multimodal therapy for patients with insomnia, circadian rhythm disorders and sleep disorders such as obstructive sleep apnea [7]. These modalities are known as a set of methods to improve both sleep quality and duration in an inexpensive, easy, non-pharmacological sleep-enhancing way [7, 8].

This prospective designed randomized controlled study aim is to evaluate the sleep quality of pregnant women during antenatal follow-up and to evaluate the effect of motivational sleep hygiene education programs on the sleep alterations or sleep quality.

Methods

Study design and participants

This was a prospective randomized controlled study conducted with every consecutive pregnant woman who met the inclusion criteria in Giresun University Gynecology and Pediatrics Training and Research Hospital gynecology and obstetrics outpatient clinic between May 2021 and January 2022.

The inclusion criteria were healthy pregnant women over 18 years of age, with at least 14 weeks of live, singleton pregnancy, and at a social level to read and answer the survey questions. The exclusion criteria were fetal and obstetric complications, maternal chronic diseases, medical treatment usage other than iron and micronutrient supplements, history of miscarriage in their previous pregnancies, multiple pregnancies, working in night shifts and previously diagnosed sleep disorders.

The power analysis calculation was performed using the "G-Power 3.1.9.2" package program. Assuming that the difference of 3.3 points between the PSQI scores between the two groups after the training would be considered significant, it was calculated that a total of 52 individuals, including at least 26 patients in each group, should be included in the study at the $d = 1.03$ effect size, 95% power and 0.05 error level [9].

Data collection

A total of 82 pregnant women who met the inclusion criteria were enrolled during the research process. Firstly, Beck Depression Scale (BDI) was applied to the volunteers. Two pregnant women who scored 15 points or more according to BDI were excluded from the study due to depression. They were referred to psychiatrists due to the suspicion of depression. The rest of the 80 pregnant women were randomly assigned by flipping coins to the intervention and control groups and PSQI and SHI scales were administered to both groups as pre-test. The participants in the intervention group were given individual sleep hygiene training through motivational face-to-face meetings and printed education booklet, and 2 weeks later interviewed by phone for control purposes in terms of the applicability of the training. At the end of the first month, the participants in the intervention and control groups were administered the PSQI and SHI scale as a post-test. All training was given by the same physician, face-to-face training lasted approximately 20 min and telephone call with standard items was 15 min.

Sleep hygiene education program

Sleep hygiene counseling refers to a list of behaviors, environmental conditions, and other sleep-related factors that can be adjusted as a stand-alone treatment or component of multimodal therapy for insomnia patients. The sleep hygiene booklet that we presented face to face to the intervention group was prepared according to the latest researches on sleep quality strategies [10].

Sleep hygiene principles and practices to improve sleep quality are environmental regulations such as the control of environmental temperature, noise and light, and behavioral habits of individuals such as going to bed at the same time every day, adjusting total sleep time, staying away from stress, staying calm, exercising and avoiding stimulant intake such as smoking, alcohol and caffeine.

Initially, 38 pregnant women in the intervention group and 42 pregnant women in the control group were enrolled. In the following period of the study, a total of 20 women dropped from the study, Eight in the intervention group and 12 in the control group. Eight pregnant women in the intervention group were excluded from the study for the following reasons: three had a change of residence and could not be reached by phone, one had an increased risk of fetal trisomy, one had uterine bleeding, one had fetal hypoplastic left heart syndrome, one had miscarriage, and one had gestational diabetes mellitus requiring insulin. The reasons for excluding 12 pregnant women in the control group from the study were as follows: three of them could not be reached, two had an increased risk of fetal anomaly, one had gestational diabetes mellitus, one had drug use due to acute bronchitis, one had hypothyroidism, one had venous insufficiency, one had rhythm disorder, one had premature birth, one had emergency cesarean delivery due to ablatio placenta. Finally, the study was completed

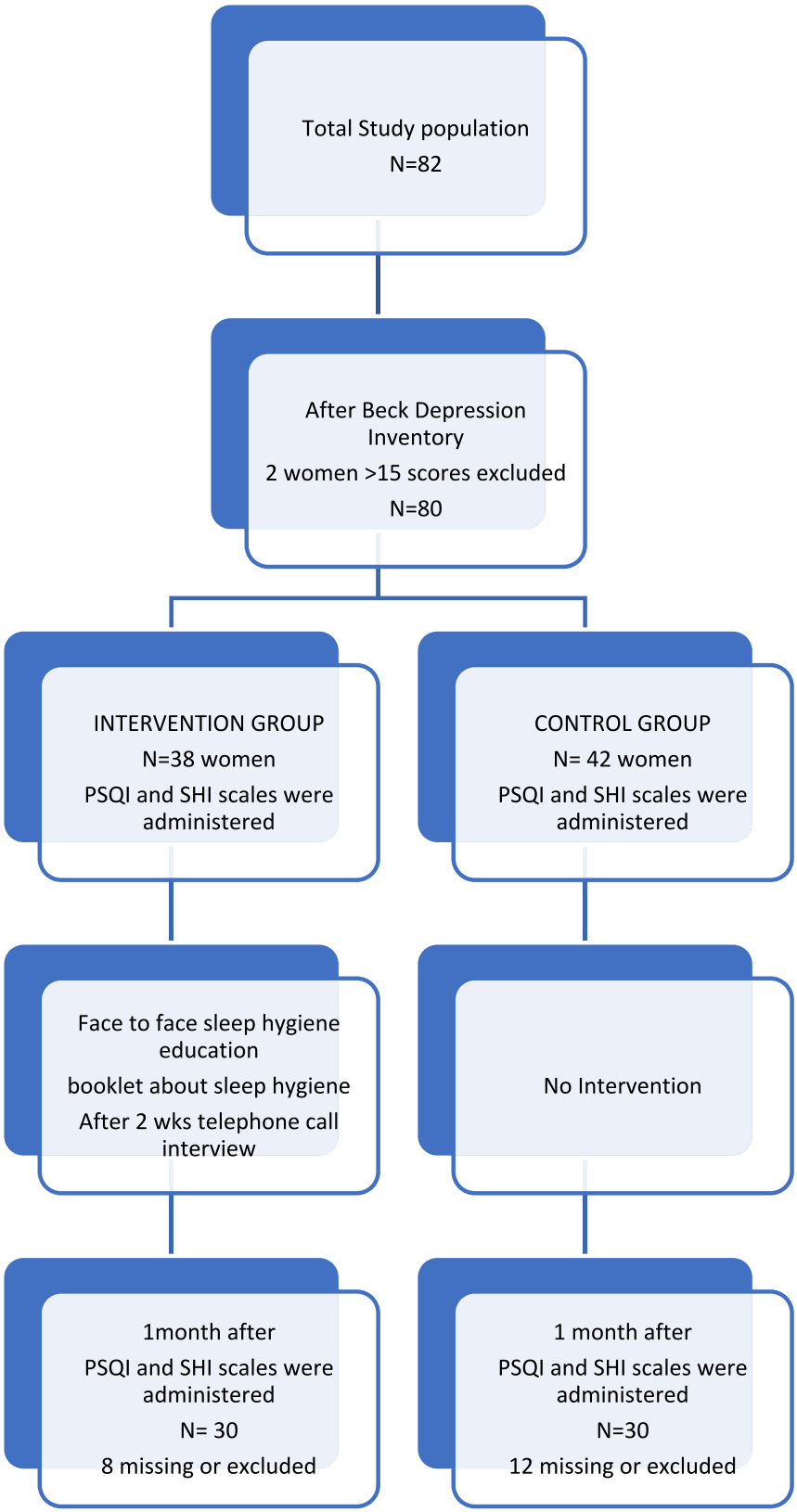

Fig. 1 The flowchart of the study recruitment

with a total of 60 pregnant women, 30 in control and 30 in intervention group (Fig. 1).

Pregnant descriptive form

A form containing comparable parameters in both groups such as sociodemographic information, number of pregnancies, gestational week, height–weight, marital status, education level, income level, occupation, exercise status, use of sleeping materials, frequency of doctor checkups, place of residence, smoking, alcohol use, number of individuals living at home and number of children was created as a questionnaire.

Beck Depression Inventory

BDI is a 21-item self-report survey validated in Turkish language used to measure the physical, cognitive and behavioral depressive symptoms of individuals over the past 2 weeks with response options scored from 0 to 3 [11, 12]. The total score ranges from 0 to 63, and those with 15 or higher score indicates more severe depression and were excluded from the study [11].

Pittsburg Sleep Quality Index (PSQI)

The PSQI is a self-report survey validated in Turkish language that evaluates sleep quality of individuals over a 1-month time interval [13, 14]. The survey consists of 19 items distributed into 7 components: daytime dysfunction, use of sleeping medication, sleep disturbances, subjective sleep quality, sleep latency, sleep duration and habitual sleep efficiency. Each item received a value from 0 to 3 and the total score of these seven components gives the overall sleep quality score ranging 0–21. Overall, a score higher than 5 indicates poor sleep quality, and a score of 15 and above indicates severe sleep disorder [13].

Sleep hygiene index (SHI)

The SHI validated in Turkish language is a 13-item self-report survey which measures inadequate sleep hygiene as defined in the international classification of sleep disorders [15, 16]. Each item shows the frequency of practicing sleep-related behavior ranging from 1 to 5. The total score ranges from 13 to 65, with a higher score indicating worse sleep hygiene [15].

End points

The primary end point was the rate of sleep disturbances with increasing gestational age observed during antenatal follow-up. The secondary end point for which data were presented in the current study included post-intervention changes with the sleep hygiene education program.

Statistical analysis

Mean standard deviation, median, minimum-maximum values were given in descriptive statistics for continuous data, and number and percentage values were given for discrete data. Kolmogorov–Smirnov test was used to examine the conformity of the data with normal distribution. In the comparison of continuous data with two-group independent variables, Student's T test was used for normally distributed data, and Mann–Whitney U test was used for non-normally distributed non-parametric data. The Kruskal–Wallis test was used to determine which group caused the difference between the means of three or more groups in non-normally distributed groups. Wilcoxon test was used for comparison of scale scores before and after intervention (within group), and Mann–Whitney U test for comparison between groups. Chi-square and Fisher's exact tests were used for group comparisons (cross tables) of nominal variables. Spearman's correlation coefficient was used to examine the relationships between scale scores. IBM SPSS Statistics 20 program was used and $p < 0.05$ was accepted as statistically significant.

Results

The demographic characteristics of the intervention and control groups are given in Table 1. The groups show a homogeneous distribution and there was no difference between the age, height, weight, BMI, education level, occupation, income level and place of residence of the pregnant women between groups ($p > 0.05$). The rate of having more than five individuals (≥ 5) at home in the control group was statistically significantly higher than in the intervention group ($p < 0.05$). There was no significant difference between the number of pregnancies, number of children, weeks of pregnancy, exercise status, use of sleeping materials and frequency of pregnancy controls in the intervention and control groups ($p > 0.05$) (Table 1).

The daily exercise duration of pregnant women exercising in the intervention and control groups was 30 min for both groups ($p = 0.791$). The most common exercise type of the pregnant women in the intervention group who exercised was walking with 90.5%, while the second most common exercise was Pilates with 9.5%. The exercise type of pregnant women in the control group was 100% walking ($p = 0.49$) (Supplementary 1). The number of people using sleeping materials was equal in both groups ($n = 9$). The most frequently used sleeping material was a

Table 1 The demographic and obstetric data of the intervention and control groups

	Intervention (n = 30) Avr. ± SS Median (min–max)	Control (n = 30) Avr. ± SS Median (min–max)	Statistics	*p*
Age	29.07 ± 5.03	27.70 ± 5.60	$t = 0.994^b$	0.325
	29 (20–39)	27 (18–40)		
Height	161.33 ± 6.27	158.70 ± 6.52	$t = 1.593^b$	0.117
	162 (150–175)	157.5 (148–172)		
Weight	69.93 ± 11.25	67.97 ± 12.37	$t = 0.664^b$	0.522
	67.5 (48–95)	67 (49–97)		
BMI	26.96 ± 4.69	26.96 ± 4.44	$t = -0.003^b$	0.997
	26.6 (19.8–37.1)	26.2 (20.1–34.5)		
	n (%)	*n* (%)		
Education				
Primary school	1 (3.3)	2 (6.7)	$\chi^2 = 0.708^b$	0.957^b
Secondary school	7 (23.3)	8 (26.7)		
High school	9 (30)	9 (30)		
University	13 (43.3)	11 (36.7)		
Occupation				
Housewife	20 (66.7)	23 (76.7)	$\chi^2 = 1.763^b$	0.566
Civil servant	2 (6.7)	3 (10)		
Other employees	8 (26.7)	4 (13.3)		
N of individuals in the family				
2	7 (23.3)	13 (43.3)	$\chi^2 = 8.986^b$	0.026
3	14 (46.7)	5 (16.7)		
4	7 (23.3)	5 (16.7)		
≥ 5	2 (6.7)	7 (23.3)		
Income				
Very low	1 (3.3)	4 (13.3)	$\chi^2 = 3.745^b$	0.3
Low	16 (53.3)	18 (60)		
Moderate	10 (33.3)	5 (16.7)		
High	3 (10)	3 (10)		
Residency status				
City	14 (46.7)	14 (46.7)	$\chi^2 = 0.575^b$	0.751
Town	11 (36.7)	9 (30)		
Village	5 (16.7)	7 (23.3)		
Social insurance				
Full insurance	2 (6.7)	3 (10)	$\chi^2 = 1.929^b$	0.895
Semi insurance	22 (73.3)	20 (66.7)		
Limited insurance	3 (10)	5 (16.7)		
Private	2 (3.3)	2 (6.7)		
None	1 (3.3)	0 (0)		
Smoking				
Yes	2 (6.7)	2 (6.7)	$\chi^2 = 0.000^b$	1
No	28 (93.3)	28 (93.3)		
Alcohol				
No	30 (100)	30 (100)		
Gestational week	27 (14–35)	27.5 (14–35)	U = 411.5	0.568
	n (%)	*n* (%)		
Parity				
1	9 (30)	15 (50)	$\chi^2 = 3.307^b$	0.157
2	15 (50)	8 (26.7)		
3	6 (20)	7 (23.3)		

Table 1 (continued)

	Intervention (n = 30) Avr. ± SS Median (min–max)	Control (n = 30) Avr. ± SS Median (min–max)	Statistics	*p*
Live births				
0	9 (30)	15 (50)	$\chi^2 = 3.307^b$	0.157
1	15 (50)	8 (26.7)		
2	6 (20)	7 (23.3)		
Antenatal visits				
3–5 times	8 (26.7)	10 (33.3)	$\chi^2 = 2.947^b$	0.229
6–9 times	19 (63.3)	13 (43.3)		
10–17 times	3 (10)	7 (23.3)		
Exercise during pregnancy				
Yes	21 (70)	18 (60)	$\chi^2 = 0.659^b$	0.417
No	9 (30)	12 (40)		
Using sleep material				
Yes	9 (30)	9 (30)	$\chi^2 = 0.000^b$	1
No	21 (70)	21 (70)		

[a]Mann–Whitney *U* test, [b]Chi-square test/Fisher's exact test

Table 2 Pre-test and post-test comparison of the PSQI scores of the pregnant women in the intervention and control groups

	Intervention (*n* = 30) Avr ± SS median(min–max)	Control (*n* = 30) Avr ± SS median(min–max)	Test statistics	*p*
Pre-test PSQI	8.10 ± 1.80	8.23 ± 2.54	$U = 445.5^a$	0.946
	8 (5–12)	8 (5–16)		
Post-test PSQI	8.37 ± 2.05	9.77 ± 2.54	$U = 313.0^a$	0.041
	8 (5–12)	9 (5–15)		
Test statistics	$Z = -0.712^b$	$Z = -3.875^b$		
p	0.477	< 0.001		

[a]Mann–Whitney *U* test, [b]Wilcoxon test

pregnancy-specific pillow in both groups, with a frequency of 44.4% in the intervention group and 55.6% in the control group (Supplementary 2).

While the progressive worsening of sleep quality due to the progression of the gestational week was observed in both groups, it was at a significant level in the control group according to PSQI scores (8.23 ± 2.54 vs. 9.77 ± 2.54) ($p < 0.001$) (Table 2). The pre-test PSQI scores of the pregnant women were similar in both groups ($p > 0.05$). Although PSQI score increased in both post-test groups, the rate of increase in the intervention group was slowed down, and it followed a horizontally close to parallel curve (Fig. 2).

The pre-test SHI score of the pregnant women in the intervention group was higher than that of the control group before the intervention (16.57 ± 5.64 vs. 14.50 ± 3.78) (p = 0.043). However, statistically significant improvement was achieved in the intervention group after the intervention (16.57 ± 5.64 vs. 10.30 ± 3.78) ($p < 0.001$). On the contrary, the post-test SHI scores of the pregnant in the control group were found to be significantly higher than the pre-test

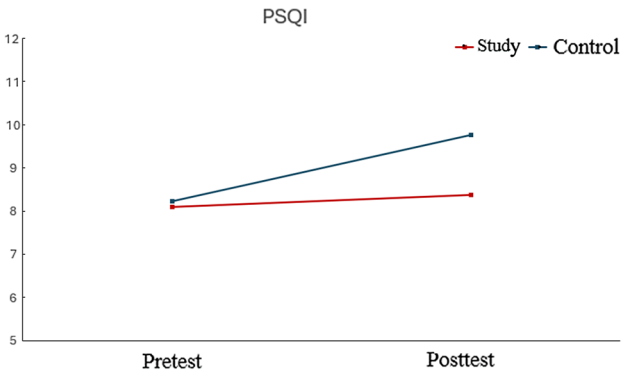

Fig. 2 Graphical display of the pre–post-test PSQI scores of the pregnant women in the intervention and control groups

scores, which indicate poor sleep quality (16.60 ± 4.36 vs 14.50 ± 3.78) ($p < 0.001$) (Table 3) (Fig. 3). There was no correlation between pre-test or post-test PSQI scores and

Table 3 Comparison of pre-test–post-test sleep hygiene scores (SHI) of pregnant women in the intervention and control groups

	Intervention ($n=30$) Avr ± SS median(min–max)	Control ($n=30$) Avr ± SS median(min–max)	Test statistics	p
Pre-test SHİ	16.57 ± 5.64	14.50 ± 3.78	$U=313.5$[a]	0.043
	17 (5–29)	14 (7–26)		
Post-test SHİ	10.30 ± 3.78	16.60 ± 4.36	$U=122.5$[a]	< 0.001
	9.5 (5–19)	17 (7–31)		
Test statistics	$Z=-4.446$[b]	$Z=-3.871$[b]		
p	< 0.001	< 0.001		

[a]Mann–Whitney U test, [b]Wilcoxon test

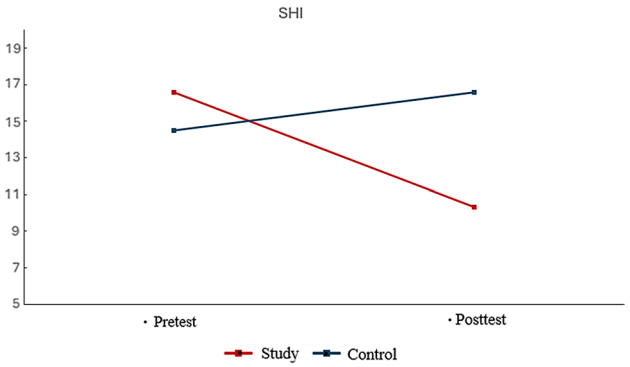

Fig. 3 Graphical display of pre–post-test SHI scores of pregnant women in the intervention and control groups

pre-test or post-test SHI scores between the intervention and control groups ($p > 0.05$).

Pre-test PSQI scores of 90% of all pregnant women ($n = 54$) were greater than 5 which indicates poor sleep quality. There was only one pregnant woman with a score greater than 15, which means severe sleep disorder. Post-test PSQI scores of 93.3% of all pregnant women ($n = 56$ pregnant women) were greater than 5 which indicates poor sleep quality (Table 4) When comparing the second trimester and third trimester, no statistically significant difference was detected in the pre-test PSQI scores, while the post-test PSQI scores were significantly better in the intervention group in the second trimester ($p = 0.031$).

PSQI components of pregnant women in the intervention and control group were similar in the pre-test ($p > 0.05$). However, in the post-test, subjective sleep quality and sleep latency were significantly better in the intervention group than control group (0.97 ± 0.80 vs. 1.53 ± 0.68; 1.57 ± 0.77 vs. 2.00 ± 0.83 respectively; $p < 0.05$). In the intervention group, the post-test daytime dysfunction score of pregnant women was significantly lower than the pre-test score (1.37 ± 0.71 vs. 0.90 ± 0.60, $p < 0.001$) (Supplementary 3).

There was no difference between pre-test subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbance, total PSQI score and SHI score between pregnant women who exercised and those who did not ($p < 0.05$). There was no difference between the pre-test PSQI components, total PSQI score and SHI score between pregnant women who used sleeping materials and those who did not ($p > 0.05$). There was also no correlation between BMI values and pre-test–post-test PSQI scores ($p > 0.05$).

Discussion

This study shows that the sleep hygiene education program improved sleep quality among a group of pregnant women. Most importantly, as the gestational weeks progressed, the worsening of sleep quality was observed in both educated and non-educated groups. Although this worsening progression was significant in the non-educated control group, it was not significant and slowed down in the educated group. SHI scores were significantly decreased in the intervention

Table 4 Distribution of PSQI total scores of pregnant women in the intervention and control groups based on whether they had good sleep quality or poor sleep quality

	Total (n=60) n (%)	Intervention (n=30) n (%)	Control (n=30) n (%)	Test statistics	p
Pretest PSQI					
≤5	6 (10)	1 (3.3)	5 (16.7)	$\chi^2=2.963$	0.195
>5	54 (90)	29 (96.7)	25 (83.3)		
Posttest PSQI					
≤5	4 (6.7)	3 (10)	1 (3.3)	$\chi^2=1.071$	0.612
>5	56 (93.3)	27 (90)	29 (96.7)		

group which shows the positive effect of education on the sleep hygiene and sleep quality during pregnancy. On the other hand, SHI scores in the non-educated control group increased, which shows the decline in sleep quality. We also determined that 90% of all pregnant women had poor sleep quality in the pre-test, whereas 93.3% of the pregnant women had poor sleep quality in the final test. This study showed that the sleep hygiene education programs are understandable, easy to apply and has a positive effect on sleep hygiene and quality. Our findings highlight the need to screen the sleep quality and to provide sleep hygiene education in primary care or obstetric clinics.

In a study conducted by Ko et al. [17] on 689 Korean pregnant women, sleep disorders were very common in pregnant women and 96.2% reported generally poor sleep quality (PSQI > 5) and 80.7% reported very poor sleep quality (PSQI > 10) [17]. Similarly, Yang et al. [18] demonstrated that 87% of pregnant women had sleep disorders (PSQI > 5) and that these were most common in the third trimester [18]. Symptoms such as nocturnal urination, reflux, fatigue, increase in BMI, restless leg syndrome, increased spine and lower back pain, and snoring during pregnancy as a result of the growing fetus in the abdominal area increase with the progression of gestation weeks and also increase the deterioration in the sleep quality [19, 20]. Similarly, in our study, a significant difference was found between the post-test PSQI scores of pregnant women in the second trimester and those in the third trimester ($p < 0.05$), and the post-test PSQI scores of pregnant women in the third trimester were found to be more likely to be over 5. The fact that the sleep quality in the third trimester was found to be worse than that of pregnant women in the second trimester shows that our study is compatible with the literature.

Tsai et al. examined the relationship between the 30-item sleep hygiene practice scale, sleep actigraphy measurements, and PSQI scores of 197 pregnant women [21]. They showed that pregnant women with poor sleep quality also have poor sleep hygiene habits. These findings therefore support avoiding physically, emotionally, or cognitively stimulating activities before bed as a sleep hygiene intervention. Similarly in our study, we showed a positive regression in the SHI scores in the post-test with the sleep hygiene education intervention.

Sönmez and Derya examined the effect of sleep hygiene education given two times to pregnant women with restless legs syndrome and similarly found improvement in the intervention group [9]. In the study by Ladyman et al. [22] examining sleep training intervention in pregnant women with a history of depression, the second trimester PSQI score of the pregnant women was 5.87 ± 2.20 and the third trimester PSQI score was found to be 6.93 ± 2.15, which were lower than the PSQI scores in our study due to depression [22]. They also showed positive improvement results in sleep quality and hygiene with the sleep training intervention [22]. According to the study of Ladyman et al., [22] the sleep training program seems to be easily applicable and minimizes depressive symptoms in pregnant women with a history of depression [22]. Liu et al. [23] examined the relation of maternal sleep duration and sleep quality with newborn telomere length, which is a sign for lifelong health, and found that pregnant women who sleep longer than 10 h with low quality have newborns with shorter telomere length [23]. Thus, sleep hygiene education is an important intervention for the newborn as well as mother.

The strengths of our study are the fact that face-to-face or telephone follow-ups were made by the same researcher in the follow-up processes. It was conducted in a randomized manner to continue the research without conflict of interest for data processing, homogeneity was ensured between the groups and the Turkish validity and reliability of the approved measurement tools were used. As far as we know, this is the first study in literature evaluating the sleep hygiene indices of pregnant women in our country. In this respect, this may be a pioneering study within the scope of the evaluation of sleep hygiene in healthy pregnant women in our country. Among the weaknesses, as this study carried out shortly after the COVID-19 pandemic period, pregnant women may have been more stressed than normal due to the pandemic or that their sleep quality may have been affected due to the pandemic. Studies with more participants, in which objective methods such as actigraphy and polysomnography are used in the evaluation of sleep, as well as different screening questionnaires, may provide clinicians with a better view in this area.

Conclusion

The sleep hygiene education during pregnancy in primary care or obstetric polyclinics seems to be an easy, accessible, understandable, applicable, cost-effective and effective application for mother health and comfort. The need for screening and education about sleep hygiene during pregnancy, which is considered an important public health issue, is obvious. We recommend sleep hygiene modalities which can be presented to pregnant women in family health centers, healthy life centers, childbirth education programs, hospitals and all accessible health institutions with videos, brochures and organized training hours.

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collection of data. SAT and HA contributed to the drafting and revision of the manuscript. All authors read and approved the final manuscript.

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Data availability The authors confirm that the data supporting the findings of this study are available within the article and its supplementary materials.

Declarations

Conflict of interest The authors have no conficts of interest to declare that are relevant to the content of this article.

Ethical approval The study complied with the Declaration of Helsinki and was approved by the Gümüşhane University Scientific Research and Publication Ethics Committee, dated 14.04.2021 and numbered 2021/3.

Informed consent Written informed consents were obtained from all participants before the recruitment to the study.

Ethical approval The study complied with the Declaration of Helsinki and was approved by the Gümüşhane University Scientific Research and Publication Ethics Committee, dated 14.04.2021 and numbered 2021/3.

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