VIA MEDICA
RESEARCH PAPER
ISSN 2450–7458
e-ISSN 2450–8187

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The Effect of Training About Sleep Hygiene on HbA1c Levels of Type 2 Diabetes Mellitus Patients: A Randomized Controlled Trial

ABSTRACT

Objective: In this study, we aimed to reveal whether training on sleep hygiene have an effect on blood glucose regulation of type 2 diabetes patients.

Materials and methods: Those with even protocol numbers were included in the case group and those with odd numbers were included in the control group. Pittsburgh sleep quality index was applied face-to-face to all patients included in the study and at the first admission sleep hygiene training was given to the case group. HbA1c values were noted separately as first and second visit for both groups. Those with known sleep disorders and language or psychiatric problems that would prevent them from answering the questionnaire were excluded from the study. Differences between demographic and clinical features of groups were evaluated using chi-square and Student's *t*-tests. Comparisons of the case and control groups before and after sleep hygiene training were evaluated using ANCOVA test adjusted for BMI and DM duration.

Results: A total of 347 type 2 diabetes patients included in this randomized controlled trial (113 case 234 control). Significant difference was observed in the HbA1c values measured before and after the training of the case group. The second mean HbA1c (8.13 ± 2.03%) of the control group was significantly higher than the second mean HbA1c (7.51 ± 1.42%) values of the case group (p = 0.004).

Conclusions: Our study revealed that in addition to classical diabetes treatment, sleep hygiene training also has a positive effect on blood glucose regulation of patients. (Clin Diabetol 2022; 11; 5: 303–308)

Keywords: type 2 diabetes mellitus, sleep hygiene, sleep quality, patient education, randomized controlled trial

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Clinical Diabetology 2022, 11; 5: 303–308
DOI: 10.5603/DK.a2022.0046
Received: 23.02.2022 Accepted: 13.08.2022

Introduction

The biopsychosocial approach to chronic diseases is one of the most important features of family medicine clinical practice. One of the most important of these diseases is type 2 diabetes (T2DM), which has a high prevalence and incidence worldwide. It is known that many biopsychosocial factors, including sleep hygiene, play a role in the development of the disease. It is desirable to regulate these factors as much as possible to reduce the risk of acute complications and avoid chronic sequelae of the disease [1].

There is a two-way relationship between T2DM and sleep. While insomnia may occur due to complications of T2DM, it is also thought that insomnia is effective in the development of T2DM [2]. A study of 7239 patients with T2DM found that approximately 77% of patients experienced symptoms of insomnia [3].

Laboratory studies and meta-analyses on decreased sleep quality and blood glucose regulation have provided evidence that even short-term decreases in

sleep quality can have detrimental effects on glucose regulation [4–6].

While the relationship between sleep quality and blood glucose regulation was clearly shown in many cross-sectional studies, very few studies aimed to observe the effect of sleep quality correction on blood glucose regulation. As a result of this, of the 35 guidelines addressed in a meta-analysis conducted in 2020 only 14 guidelines included sleep in their recommendations, whereas optimizing sleep duration and quality and the management of sleep disorders were discussed as a therapeutic approach in 6 guidelines. In these also only 3 guidelines recommended optimal sleep duration as a therapeutic target of life style intervention and self-management education with one guideline identifying optimal sleep as a means of achieving glycemic targets in T2DM [7].

The aim of this study is to put forth whether the patient education that includes simple lifestyle changes to increase sleep hygiene will have an effect on blood glucose regulation of T2DM patients and in this way to provide evidence for guidelines on diabetes management.

Materials and methods

Ethical approval

Ethical evaluation and approval for this study was obtained from the Local Ethics Committee of Dışkapı Yıldırım Beyazıt Training and Research Hospital with the decision date: 27.11.2017.
No:43/06.

Trial registry number

NCT04918004

Sample size and patient selection

In the power analysis based on the tests to be used, when Type 1 error (α) = 0.05, Type 2 error (1-β) = 0.95, effect size is considered as 0.5; it was calculated that the sample size should be 210 (105 for each group) in total.

Considering the possible data losses, all patients (n = 530) who were admitted to our clinic with the diagnosis of T2DM during the study period were assessed for eligibility to inclusion in the study. Those with known sleep disorders and language or psychiatric problems that would prevent them from answering the questionnaire and patients whose treatment (either drug or any other interventions which may affect glucose metabolism for instance dietary changes, exercise etc.) was changed during the first interview were excluded from the study. Patients with even protocol numbers were included in the case group and those with odd numbers were included in the control group. The modified CONSORT flowchart for the study is given in Figure 1 [8].

Study design

This randomized controlled intervention study was conducted in a family medicine outpatient clinic of a tertiary hospital in Ankara Turkey.

During their first visit, besides routine diabetes control including HbA1c measurements, all patients included in the study were given a questionnaire consisting of 20 questions prepared by the researchers, including sociodemographic data, questions about diabetes and sleep problems, and Pittsburgh Sleep Quality Index Turkish form (PSQI) which is one of the most frequently used index in studies on sleep quality by face-to-face interview technique [9]. In addition, each patient included in the case group was given sleep hygiene training, the content of which was created by the researchers, and a brochure containing 10 lifestyle changes related to sleep hygiene. The recommendations in the brochure are given in Table 1.

At the next visit of all participants, a second-visit PSQI was administered in addition to the HbA1c level measurement. In addition, a statement-based "sleep hygiene education compliance questionnaire" was administered to the case group, questioning whether they complied with 10 lifestyle changes in the sleep hygiene recommendations material (Tab. 1) given to them at the first visit.

Statistical analysis

In evaluating the demographic data obtained from the study, descriptive statistical methods, frequency, percentage, mean, standard deviation were used. The compliance of the data to normal distribution was examined with the Kolmogorov-Smirnov test. Quantitative variables were expressed as mean ± standard deviation and categorical variables as number (n) and percentage (%). In terms of quantitative variables, Student's *t*-test was used for the data that provided the assumption of normal distribution in the examination of the difference between groups. The Chi-Square test was also used to compare the relationship between categorical variables. As there was a difference between BMI and diabetes duration between the randomized case and control groups ANCOVA test adjusted for BMI and diabetes duration were used for comparing before and after training PSQI and HbA1c values.

A statistically significant difference was accepted when the p value was < 0.05. All statistical analyses and power analysis were performed using TURCOSA (Turcosa Analytics Ltd Co, Turkey) statistical software.

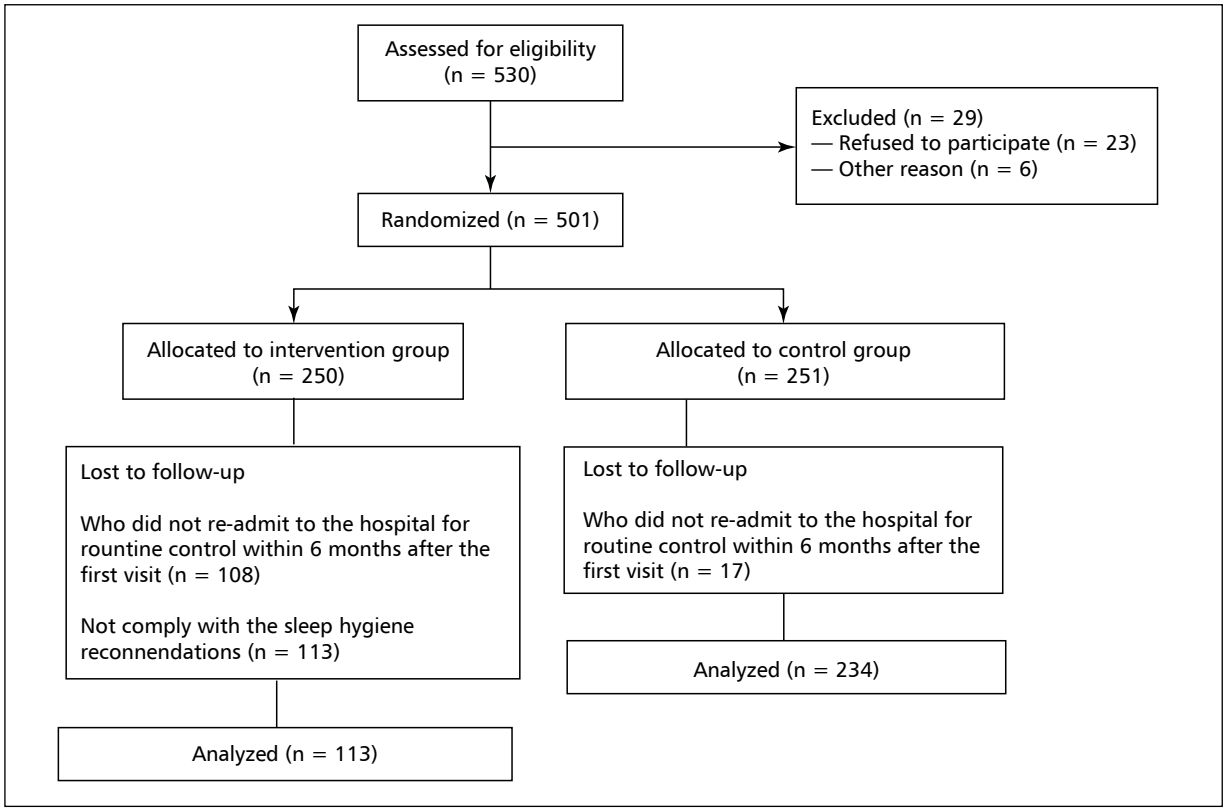

Figure 1. The Modified CONSORT Flowchart of the Study

Table 1. Recommendations in the Sleep Hygiene Leaflet

- Enter the bed when you feel sleepy. If you lie in bed for more than half an hour, get out of bed. When you feel sleepy again, go back to bed
- Do not sleep more than 1 hour during the daytime
- Avoid heavy and fatty meals in the evening; do not go to bed very hungry or very satiated. Avoid beverages such as coffee, tea, coke, energy drinks and alcohol
- Exercise or walk regularly in the evening, but avoid physically strenuous activities 3–4 hours before bedtime
- In order for your body clock to work properly, live regularly. Get out of bed at the same time every day. Wake up at the time you should wakeup in the morning, even if you went to bed at a different time of the night. Follow this rule, even on the weekend, and make it a habit to always get up at the same time. Sleeping and awakening times are important in maintaining sleep patterns
- Use the bed for sleep purposes only. Do not do activities such as eating, watching TV, reading a book, or planning the next day in bed
- Make sure your bedroom is quiet and dark
- Avoid exciting activities such as watching horror movies or reading adventure books before going to bed
- Try to avoid a stressful life
- Never take sleeping pills without your doctor's knowledge

Results

There was no difference in gender distribution, education, marital status, employment status, smoking and alcohol use, among the case and control groups. A statistically significant difference was found between the case and control groups in terms of the duration of diabetes ($p = 0.004$) and BMI ($p = 0.005$). It was thought that this difference was due to the high number of patients with diabetes for more than 10 years in the control group. The comparison of demographic and clinical features of the study groups is given in Table 2.

The first-visit mean PSQI scores were 11.97 ± 4.0 for the case group; and 10.41 ± 4.83 for the control group; the difference between both groups was found to be statistically significant in the favor of the case group (Student's *t*-test $p = 0.003$). According to the PSQI scaling, 96.5% ($n = 109$) of the case group and 88.9% ($n = 208$) of the control group were in the poor sleep category. The difference between the two groups was statistically significant in favor of the case group (Chi-square test $p = 0.002$).

The comparison of PSQI scores and HbA1c values of the case and control groups before and after sleep hygiene training is given in Table 3.

When the PSQI total scores of the case and control groups were examined, it was observed that the aver-

Table 2. Demographic and Clinical Features of the Study Groups (n = 347)

Feature	Case (n = 113)	Control (n = 234)	P
Age [years] (mean ± SD)	56.6 ± 9.4	58.6 ± 10.1	0.085*
Body mass index [kg/m^2] (mean ± SD)	32.9 ± 5.6	31.1 ± 5.3	**0.005***
First visit HbA1c [%]	7.8 ± 1.7	7.9 ± 1.9	0.351
Gender n (%)			
Female	85 (32.1)	180 (67.9)	0.727*
Male	28 (34.1)	54 (65.9)	
Education status n (%)			
Illiterate	22 (29.7)	52 (70.3)	0.917**
Primary school	78 (33.5)	155 (66.5)	
High school	9 (34.6)	17 (65.4)	
College/University	4 (28.6)	10 (71.4)	
Marital status n (%)			
Married	97 (34.9)	181 (65.1)	0.063**
Single	16 (23.2)	53 (76.8)	
Duration of diabetes n (%)			
Less than 5 years	46 (45.5)	55 (54.5)	**0.004****
5–10 years	23 (28.0)	59 (72.0)	
More than 10 years	44 (26.8)	120 (73.2)	
Smoking n (%)			
Yes	15 (33.3)	30 (66.7)	0.906**
No	98 (32.5)	204 (67.5)	
Alcohol use n (%)			
Yes	1 (20.0)	4 (80.0)	0.546**
No	112 (32.6)	230 (67.4)	

*Student's *t*-test; ** Chi square test; ANCOVA — adjusted for BMI and DM duration
BMI — body mass index; DM — diabetes mellitus; HbA1c — glycated hemoglobin; SD — standard deviation

Table 3. The Comparison of PSQI Scores and HbA1c Values of the Case and Control Groups Before and After Sleep Hygiene Training

	Before training			After training		
	Case (mean ± SD)	Control (mean ± SD)	P*	Case (mean ± SD)	Control (mean ± SD)	P*
PSQI components						
Subjective sleep quality	1.65 ± 0.95	1.51 ± 0.92	0.233	1.27 ± 0.86	1.50 ± 0.91	**0.023**
Sleep latency	2.02 ± 0.97	1.71 ± 1.12	**0.006**	1.43 ± 1.08	1.66 ± 1.08	0.129
Duration of sleep	2.03 ± 0.91	1.65 ± 1.08	**0.001**	1.35 ± 1.09	1.63 ± 1.07	**0.046**
Sleep efficiency	2.12 ± 1.03	1.64 ± 1.28	**< 0.001**	1.38 ± 1.21	1.63 ± 1.28	0.114
Sleeping disorder	1.71 ± 0.62	1.73 ± 0.67	0.629	1.59 ± 0.66	1.72 ± 0.67	0.107
Drug use	0.33 ± 0.86	0.42 ± 0.93	0.422	0.21 ± 0.71	0.44 ± 0.94	**0.026**
Day time functions	2.13 ± 0.92	1.86 ± 1.07	0.023	1.66 ± 1.01	1.84 ± 1.06	0.248
Total score	11.97 ± 4.00	10.41 ± 4.83	**0.002**	8.90 ± 4.22	10.50 ± 4.85	**0.008**
HbA1c [%]	7.76 ± 1.67	7.95 ± 1.88	0.564	7.51 ± 1.42	8.13 ± 2.03	**0.020**

ANCOVA — adjusted for BMI and DM duration
BMI — body mass index; DM — diabetes mellitus; HbA1c — glycated hemoglobin; PSQI — Pittsburgh Sleep Quality Index; SD — standard deviation

age PSQI score was significantly different in favor of the control group before the training (p = 0.002). After the training, this score was totally changed in favor of the case group (p = 0.008). Similar to the total scores, there was also improvement in all subgroups of PSQI in favor of the case group. In addition to those find-

ings, while there was no significant difference between the averages of HbA1c levels of the case and control groups before the training ($p = 0.564$), a statistically significant difference was observed between the HbA1c values after the training in favor of the case group ($p = 0.020$). While the mean HbA1c value in the case group decreased by 3.22%, it increased by 2.26% in the control group. (Tab. 3).

In the comparison of the PSQI mean scores of the case group before and after the training, which we conducted to evaluate the effectiveness of the training, we found that the difference was statistically significantly higher in terms of the post- training scores ($p < 0.001$).

Discussion

The mechanisms underlying the relationship between sleep quality and glycemic control remain unclear. Evidence suggests that sleep disturbance and glucose regulation create a cycle through multiple pathophysiological pathways [10]. Disturbances in these pathways lead to impaired self-management of diabetes [11], increase in leptin resistance [12], increased calorie intake due to sleep disturbance [7] and impaired decision making (for example, unhealthy food selection and sedentary behavior) [13]. A meta-analysis involving 3258 adult patients showed that poor sleep quality and short sleep duration, demonstrated by the PSQI are associated with increased HbA1c [6].

It has been known for a long time that interventions to diabetic patients through therapeutic education have a significant impact on their metabolic control [14]. However the studies mentioning patient education in diabetes represent only 2.62% of the total number of the studies dealing with this disease [15]. In addition, almost all of these studies are based on cross-sectional studies. Of course, a non-random set of evidence, such as observational evidence, can be used to evaluate the efficacy or effectiveness of an intervention. However, generally the most appropriate type of study is a randomized controlled trial, and guidelines developed for diseases primarily consider the results obtained from randomized controlled trials as recommendations. In this context, we aimed to reveal the effects of sleep hygiene recommendations, which we think will make a significant contribution to the metabolic control of diabetic patients, with a randomized controlled clinical trial

In our study, a significant increase in sleep quality and a significant decrease in HbA1c values were found after sleep hygiene training given to the case group. In a study similar to our study, performed with 31 cases, a 3-month sleep training program was applied to the case group and a significant improvement was observed in the PSQI scale and HbA1c values in the patients in the intervention group compared to the control group [16].

In a review conducted with a total of 26 studies, it was emphasized that good sleep quality will reduce HbA1c by 35 % [10]). In our study, a 3.22% decrease was found between the average first and second HbA1c levels of the case group. It was thought that our lower rates might be due to the fact that the patients could not be followed up for a longer period of time with repeated training and the compliance of the cases with the sleep hygiene recommendations was questioned based on their statements.

Our study has also several limitations. First of all, since the case and control groups were chosen according to the random sampling method, complete homogeneity could not be achieved in some data in the case and control groups. Secondly, the PSQI scale, which evaluates sleep quality subjectively, was used in our study. People may have misperceptions about their duration of going to sleep. This limitation can be avoided with studies to be performed with polysomnographic measurements.

Another limitation of our study was that we only used the intervention (sleep education) to provide educational information about sleep and/or sleep hygiene tips in general, out of 11 different intervention categories grouped by Albakri, Drotos, and Meertens mainly on the basis of the techniques used in the interventions [17]. We think that this limitation causes the change we see in sleep quality and HbA1c levels to be limited. In order to fully reveal the effects of this situation on sleep quality and metabolic control, studies using relaxation techniques, aromatherapy and/or massage, psychotherapy, etc. or a combination of these are needed.

Conclusions

Our study revealed that sleep hygiene education, which will be added to classical diabetes treatment, has a positive effect on blood glucose regulation of T2DM patients. With the increase in the number of studies with high evidence value, interventions to alleviate sleep problems in individuals with diabetes will be included more in the guidelines and will increase the quality of diabetes care.

Funding

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

Conflict of interest

None declared.

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