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Protocol

The effect of sleep hygiene training given to epilepsy patients on seizure frequency and sleep quality: pre-test post-test control group experimental study protocol

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ABSTRACT

Background: Epileptic seizures develop with hyper-synchronization of neuronal networks, causing insomnia, and sleep quality decreases with drug treatment. Insomnia, which occurs with decreased sleep quality, increases epileptic seizure discharges. This study/trial aims to determine the effect of sleep hygiene education given to epilepsy patients on seizure frequency and sleep quality.
Methods: It is non-pharmacological clinical research and was conducted experimentally with a pretest-posttest control group experimental model. Randomization was done using simple random selection. The routine treatment of the first experimental group (n=80 people) continued. Patients were provided with sleep hygiene training, a sleep hygiene training booklet, and an educational video for those who requested it. In the three-month follow-up, sleep hygiene training was repeated in the monthly meetings. The second group, the control group (n=80), continued routine treatment, and no intervention was made for three months. In the planned monthly meetings, sleep quality was evaluated using the PSQI (Pittsburgh sleep quality index). In the monthly meetings, the seizure schedule recorded by the patients and the frequency of seizures were evaluated together with the patients.
Results: In this study, data collection began on June 1, 2023, and the data collection process ended on May 21, 2024, while the data analysis process is ongoing.
Conclusions: With this trial/study, the evidence-based use of sleep hygiene education's effectiveness on the seizures and sleep quality of epilepsy patients will be evaluated.
Trial registration: The trial was registered in clinical trials: (ClinicalTrials.gov Identifier: NCT06352476). Registered on: 10881-669.

Keywords: Epilepsy, Sleep hygiene, Sleep quality, Epileptic seizures, Nursing

INTRODUCTION

The word epilepsy is derived from the words eclipse and seizure. They are temporary, recurrent discharges formed by one, a few, or a cluster of nerve cells in the brain that suddenly exhibit abnormal electrical activity.[1-3] Epilepsy is a non-contagious, neurological, and chronic disease that can be seen in all age groups.[4] An estimated 50 million people worldwide are diagnosed with epilepsy.[4,5] In the central nervous system, hyperactivity of neurons in the cortical and subcortical regions leads to changes in consciousness, as well as motor, autonomic, and sensory changes. Epileptic seizures can be mild, such as carelessness, or convulsions with prolonged contractions of the muscles. Epileptic seizures may not occur at all in a year, or there may be a history of having two or more

seizures in a year or experiencing multiple seizures in a day.[1-3] The exact cause of the disease is not fully known. In the daily lives of people with epilepsy, situations such as home, work, and school are negatively affected. In individuals with epilepsy, this situation leads them from independent roles to semi-dependent and fully dependent roles.[5] Epilepsy patients experience sleep problems such as inability to sleep, difficulty falling asleep, frequent awakenings at night, difficulty waking up in the morning, waking up with shortness of breath, and the need to sleep/sleepiness during the day. They experience the loss of the concept of night and day, and their sleep quality decreases. About one-third of epilepsy patients experience insomnia.[6-9] Human sleep consists of two phases: rapid eye movement (REM) and non-REM (NREM). NREM has three stages and constitutes 80% of sleep. In epilepsy patients, seizure activity can be observed during sleep at a rate of 20%. In seizures originating from the frontal lobe, it can increase to approximately 60%. As the duration of NREM 2 increases, NREM 3 and REM decrease. In the NREM sleep stage, cortical seizure activation increases due to heightened excitability. Seizures can disrupt the sleep cycle, leading to daytime drowsiness. Daytime sleep, on the other hand, can cause nighttime insomnia, increase the frequency of epileptic seizures, and negatively affect the prognosis of the disease. When the REM phase is normal, it inhibits epileptic seizure activity. Generalized seizures are caused by frequent seizures due to cortical hyperexcitability resulting from prolonged REM sleep deprivation. Epilepsy can cause sleep disorders in 30-35% of cases. With focal and generalized seizures, patients experience a decrease in REM sleep duration and an increase in sleep deprivation. Sleep disorders can also cause deficiencies in controlling seizures. There is a vicious cycle between epilepsy and sleep disorders. This cycle leads to diseases such as anxiety and depression.[6-8,10,11] In patients with epilepsy, the REM phase of nighttime sleep is shortened, disrupting sleep quality. This leads to decreased sleep duration, inability to fall asleep, displacement of sleep stages, frequent awakening at night, and excessive daytime sleepiness. It negatively affects medication use and seizure control, worsening the course of the disease.[9,12] Epileptic medications are very diverse and can have either positive or negative effects on the sleep cycle. Communication with family and social circles, work situation, and psychological health also affect sleep quality. Epilepsy patients experience sleep apnea, night terrors, sleepwalking and talking, frequent daytime sleepiness and fatigue, difficulty concentrating, and mild forgetfulness.[6,9,12] Insomnia, sleep apnea, excessive daytime sleepiness, anxiety focus, and generalized seizures trigger and worsen seizures.

Studies report that regular sleep prevents the frequency, severity, and worsening of seizures.[13] Sleep hygiene inhibits the release of stress hormones such as cortisol and noradrenaline from the hypothalamic pituitary and provides epileptic seizure control.[14] Sleep hygiene training improves sleep quality and quality of life in chronic diseases and sleep disorders.[15,16]

Studies including sleep hygiene trainings are needed to prevent seizure recurrences, prevent or treat comorbid psychological diseases, and improve life activities of epilepsy patients.[17] For the circadian rhythm, there should be regular and sufficient sleep circulation, and sleep hygiene education is supportive in the treatment of sleep disorders and psychological illnesses. By promoting melatonin secretion at night and preventing excessive cortisol secretion, it is achieved.[10,18,19] Nurses should support epilepsy patients and their families with patient-centered care models. In the control of seizures and the prevention of sleep disorders, nurses make significant contributions to quality of life through their roles as educators and consultants.[2,3,20,21] There are many studies discussing the importance of sleep hygiene for epilepsy patients, but there is no experimental study with pre-test and post-test that includes sleep hygiene education. Sleep hygiene education is a simple, inexpensive, easily applicable, and non-pharmacological education that adopts a healthy lifestyle and can create permanent behavioral change.

In this context, we designed a study that evaluates the impact of sleep hygiene education on seizure frequency and sleep quality in epilepsy patients through a pre-test and post-test experimental study with patient follow-ups.

Aim

The aim was to investigate the effect of sleep hygiene education given to epilepsy patients on seizure frequency and sleep quality.

Null hypothesis

Sleep hygiene education given to epilepsy patients does not affect seizure control and sleep quality.

METHODS

Trial design

The trial was designed as an experimental study with a pre-test and post-test, involving two groups with an equal number of randomly assigned participants in each group. Standard protocol items: the recommendations for interventional trials (SPIRIT 2013) checklist were followed, and consolidate standards of reporting trials (CONSORT) recommendations were followed.

Setting

The trial was conducted in the neurology outpatient clinics of a public city hospital located in Kayseri, Turkey. The conduct of the research involves patients diagnosed with epilepsy at the institution, who receive monthly, quarterly, semi-annual, and annual follow-ups,

along with treatment and care, in the electrophysiology and neurology outpatient clinics. She is a nurse assigned to the electroencephalography (EEG) unit of the research neurology outpatient clinics, performing EEG recordings. Patients with sleep problems first apply to the neurology outpatient clinics in the institution. Epilepsy patients who complain of sleep disorders should be able to receive support from a neurologist and a neurology nurse. The researcher planned to support patients with sleep disorders diagnosed with epilepsy through this study. Epilepsy patients who agreed to participate in the study were given sleep hygiene training in the city hospital's outpatient clinic room during weekday daytime hours between 12:00 and 13:30. Training booklet was given to the patients, and training videos were given to the patients who wanted.

Eligibility criteria

The eligibility criteria for the study determined by reviewing the literature were as follows: Patients with epilepsy for at least one year and aged 18 years or older, must be able to read and write, have no communication barriers (psychiatric/hereditary problems, must be able to speak and understand Turkish), all patients using antiepileptic drugs (Gabapentin, valproic acid, phenytoin, phenobarbital, carbamazepine, levetiracetam, etc.), patients with a history of three or more seizures in the last year, patients who declare that they have sleep problems, and epilepsy patients with a PSQI score of 5 or higher must be able to give verbal and written informed consent.[22,23]

Ineligibility criteria

Criteria for ineligibility for the study: Patients who underwent surgery during the study, patients with a history of alcohol use, patients using benzodiazepines, sedatives, etc., patients not using antiepileptic drugs, deceased patients, and patients who withdrew from the study voluntarily are those who are not eligible for the study.

Interventions

In the trial, the experimental group identified as the first group was given sleep hygiene training. The control group, designated as the second group, did not receive any education throughout the research, and a sleep hygiene training was conducted once at the end of the study.

Sleep hygiene education application

Patients assigned to the experimental group received sleep hygiene education. In the first meeting, face-to-face consultations were held with the patient in the clinic room, and in other meetings as well. Patients were given a sleep hygiene education booklet. The sleep hygiene education booklet has been created by researchers based on a literature review and expert opinion to improve the patient's sleep health. The sleep hygiene training booklet consists of an introduction, the definition of sleep, the relationship between epilepsy and sleep, factors affecting sleep, recommendations for good sleep hygiene, and a sleep hygiene chart. Recommendations for good sleep hygiene: individuals should go to bed and wake up at the same time every day, both on weekdays and weekends. The appropriate time zone should be determined for the individual to sleep. Each individual requires at least seven hours of sleep per day. The appropriate sleep duration should be adjusted according to the individual. Sleep or wake-up times may vary by 20 (±) minutes within the daily time zone.

Since the sleep hormone starts to be released at 11 pm in the evening, it is more appropriate to choose the sleeping time as 11 pm. If you stay awake for more than 5-10 minutes when going to sleep, you should leave the sleep room and move to the designated sleep ritual room. The improvement of the sleep room's environmental conditions should be quiet, calm, dimly lit, or dark. In the bedroom, you can use dark-colored curtains or blinds. Bright light should be avoided in the bedroom and other rooms of the house. The interior of the house and the bedroom should be well ventilated. In the bedroom, appropriate curtains, an appropriate mattress, an appropriate duvet, and pillows should be used. The bedroom temperature should be 16-19 degrees. If the individual is sensitive to sound and light, a sleep mask and earplugs can be used in the sleep room. The most suitable sleeping position for a good night's sleep is the right lateral position. The sleep ritual room should be dimly lit.

Before sleep, individuals should establish sleep rituals. These rituals include warm showers, meditation, yoga, aromatherapy, listening to music, religious rituals, reading books, relaxation exercises, massages, and breathing exercises. Through rituals, individuals distance themselves from stress and anxiety, achieving a state of positive well-being. If sleep rituals are made routine and practiced for 30 minutes every day, they facilitate falling asleep. Starting the day early allows the individual to benefit more from daylight. Walking in nature for 45 minutes three times a week and doing moderate exercise four to five times a week makes it easier to fall asleep.

Having a regular breakfast is important. Tea and coffee consumption should be reduced. Diuretics should be taken in the early hours of the day. In the morning hours and throughout the day, 12 glasses of water should be consumed. Caffeine should not be consumed during lunchtime and in the afternoon. Cigarettes should not be consumed. Alcohol should not be consumed, and if it is, it should be taken at least six hours before bedtime. For the formation of vitamin D, one should benefit from sunlight for 15 minutes during midday hours. For mental and hormonal health, exposure to sunlight for 15 minutes a day is recommended. Daytime napping is not

recommended as it can cause insomnia at night. Caffeine and diuretic medications and herbal teas should definitely not be consumed in the evening. Dinner should be eaten early, and heavily spiced foods should be avoided. Food consumption should be stopped at least three hours before bedtime. Exercise should not be done in the evening hours, and it should be stopped at least four hours before bedtime. Blue light; spreads from televisions (TV), electronic devices, and phones and can cause insomnia. Since insomnia attacks are triggered, TV should not be watched and phone calls should not be made after eight in the evening. Electronic devices should be avoided and can be used in night mode in emergencies. In the bedroom, there should be no plants or animals. Electronic devices should not be kept in the bedroom. The bedroom should not be used for anything other than sleeping and sexual activity.

Milk, linden, and chamomile tea contribute to falling asleep and maintaining sleep with their calming effects. Milk and dairy products are rich in tryptophan and magnesium and are recommended for sleep disorders. Fluid intake should be reduced after eight in the evening. Stressful and exciting environments should be avoided, and heated discussions should not be held. Sleep quality should be evaluated with sleep diaries. The individual should track themselves daily to see if they are adhering to the sleep schedule and sleep hygiene rules.[24-33]

Outcomes

The results of this trial are the effect of repeated pre-test and post-test measurements on seizure frequency and sleep quality in sleep-disordered adults with epilepsy.

Participant timeline

The researcher is a nurse working in the EEG unit of neurology outpatient clinics. A total of 168 people were invited by a simple random sampling method from epilepsy patients who came to the neurology outpatient clinic, who reported insomnia, who voluntarily accepted to participate in the study and who had the characteristics of inclusion in the study. The 160 people constituted the experimental and control groups. Interviews with the patients were conducted in the outpatient clinic room reserved for informing the patients, together with the patient or the patient and his/her relatives.

First interview in the experimental group; the routine treatment of the patients continued. The interview was conducted face-to-face, and after obtaining consent from the patients, appendix 1 epilepsy patient information form and appendix 3 PSQI were applied.[22,23]

Sleep hygiene training was given, patients were given a sleep hygiene training booklet, and a training video was given to patients who requested it. After the training, patients were given appendix 2 epileptic seizure diary and sleep hygiene schedule, and it was mentioned that they would be requested to bring them for evaluation during the next appointment. The experimental group had a second interview; sleep hygiene education was provided through face-to-face meetings with the patients one month after the first interview. After the training, the PSQI was applied, and the epileptic seizure diary and sleep hygiene chart were requested from the patients and evaluated together. The third meeting of the experimental group; two months after the initial training, sleep hygiene education was provided through face-to-face interviews with the patients. Appendix 3 PSQI was applied, and appendix-2 epileptic seizure diary and sleep hygiene chart were requested from the patients and evaluated together.

The fourth interview of the experimental group was conducted face-to-face with the patients three months after the initial training. Appendix-3 PSQI was applied, and appendix-2 epileptic seizure diary and sleep hygiene chart were requested from the patients and evaluated together, concluding the research.

Control group first meeting; patients continued their routine treatment. The interview was conducted face-to-face, and information about the research and written consents were obtained. Appendix 1 epilepsy patient introduction form, appendix 3 PSQI were applied. Patients were given appendix 2 epileptic seizure diary and sleep hygiene schedule, and it was mentioned that they would be requested to evaluate them together at the next appointment. The control group second interview was conducted one month after the first interview and through face-to-face meetings with the patients.

Appendix 3 PSQI was applied, and appendix 2 epileptic seizure diary and sleep hygiene chart were evaluated with the patients. The control group's third meeting; a face-to-face meeting with the patients was held two months after the first meeting. Appendix 3 PSQI was applied, and appendix 2 epileptic seizure diary and the sleep hygiene chart were requested from the patients and evaluated together.

Control group fourth interview; patients were interviewed face-to-face three months after the first interview. Appendix 3 PSQI was applied, and appendix 2 epileptic seizure diary and sleep hygiene chart were requested from the patients and evaluated together.

The study was terminated with the completion of the forms. Sleep hygiene education and a sleep hygiene education booklet were given to the patients.

The CONSORT flowchart of the experiment is shown in Figure 1, Research protocol/research flowchart/ the CONSORT flowchart of the trial.

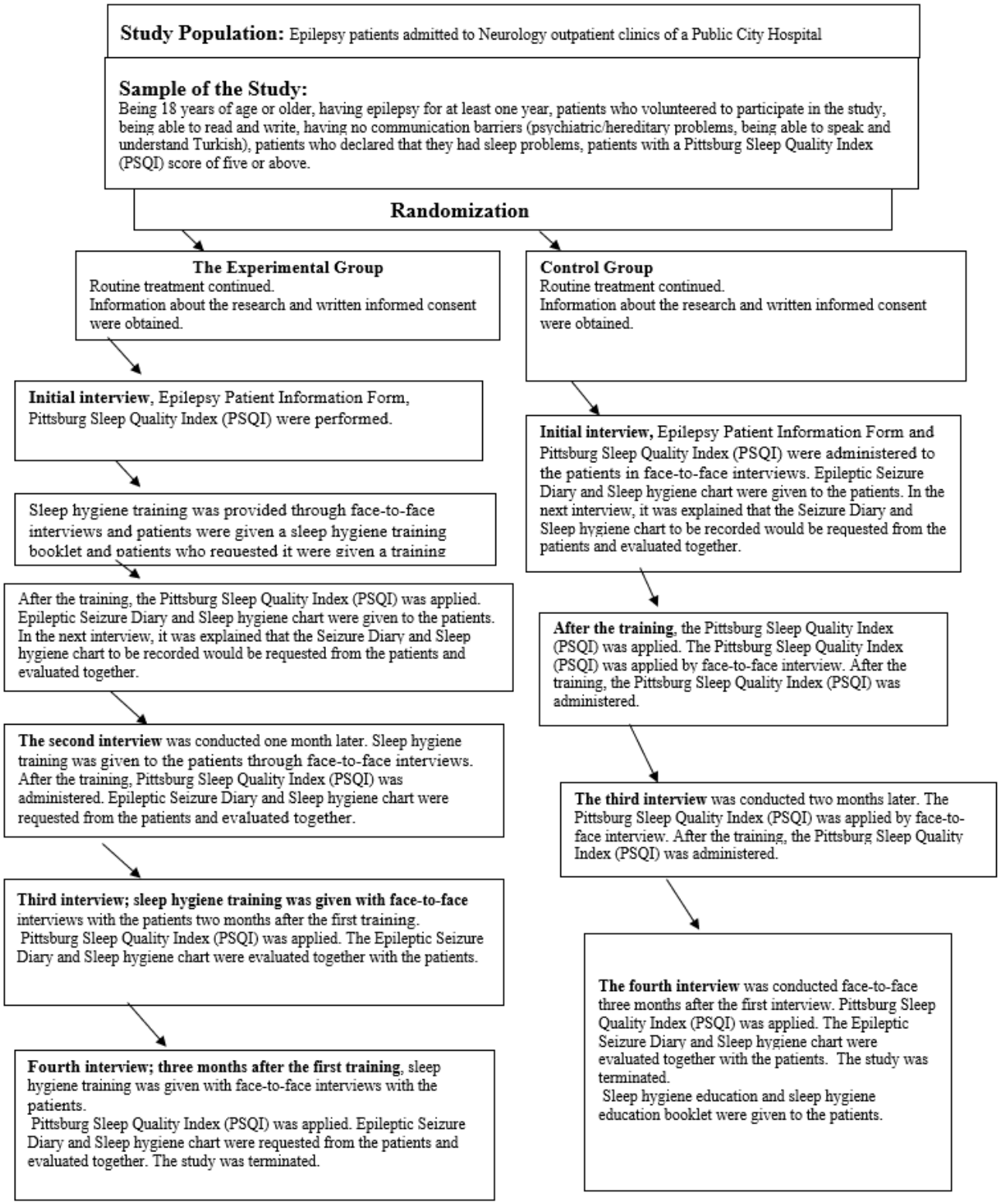

Figure 1: The CONSORT flowchart of the trial.

Sample size

The sample of the study was determined by using G*Power (v3.1.7) power analysis with 80% power, α=0.05 and β=0.3 for both experimental and control groups with a total number of 50 with 25 patients each. Considering situations such as death or withdrawal from the study, and to ensure the study is parametric, it was planned with a total of 160 patients, with 80 patients in the experimental group and 80 patients in the control group. 168 patients were invited to the study, and the study was conducted with 160 patients.

Recruitment and randomization

A Simple randomization method was used to select the patients to be included in the experimental/control group. In simple random selection, patients who came to the EEG unit and neurology outpatient clinic of a public city hospital with even numbered protocol numbers or who came to the institution on even numbered days were included in the experimental group. Patients with odd protocol numbers or those who visited institution on odd-numbered days included in control group for study.[34]

Table 1: The experimental group vs control group.

The experimental group	Control group
80 people	80 people
There is a sleep hygiene educational intervention	There is no sleep hygiene educational intervention

Blinding

During the group assignment in the study, while blinding could not be performed on the patients by the responsible researcher, blinding of evaluator to groups was ensured.

Data collection

The data for this trial started to be collected on June 1, 2023, the data collection process ended on May 21, 2024, and the data analysis process is ongoing.

Instruments

This study was conducted in accordance with the guidelines of the Helsinki declaration of human rights. appendix 1: epilepsy patient information form (a form consisting of 26 questions prepared by the researcher, including questions about sociodemographic characteristics such as age and gender, questions about epilepsy disease, and questions about sleep).[1] Appendix 2: epileptic seizure diary, appendix 3: PSQI.[22,23] Appendix 4: data were collected using the sleep hygiene education booklet. Appendix 1 epilepsy patient introduction form: A-sociodemographic characteristics (9 questions), B-questions related to epilepsy disease (10 questions), C-questions related to sleep (7 questions), totaling 26 questions.[1] Appendix 2: epileptic seizure diary: a form in which the patient records the dates of seizures over a three-month period following sleep hygiene education.

Appendix 3: PSQI: The PSQI was developed by Buyse et al in 1989 to assess sleep quality. The Turkish validity and reliability study was conducted by Ağargün et al. The Cronbach's alpha coefficient is 0.804. The PSQI consists of a total of 24 questions under 10 headings, with the last five questions being evaluations by the bed partner, which are not included in the scoring. Sleep habits (bedtime, wake-up time, time taken to fall asleep, total sleep duration), the frequency of sleep problems experienced during the night, sleep quality, use of sleep medication, and the problem of staying awake during daily activities are the parameters evaluated by the test. It measures the sleep quality over the past month. It is evaluated on a total of 21 points, and a score greater than 5 indicates that the sleep quality is not good.[22,23]

Appendix 4: sleep hygiene training manual: introduction, definition of sleep, the relationship between epilepsy and sleep, factors affecting sleep, good sleep hygiene recommendations, and the sleep hygiene chart. The sleep hygiene training booklet has been created based on literature and expert opinion.

Appendix 5: In study, written consent was obtained from patients in accordance with principle of voluntariness through patient information and consent form.

Sleep hygiene practice schedule

This is the schedule provided in the educational booklet for the first group, which consists of individuals with epilepsy, to track whether they adhere to daily sleep hygiene practices. The patients monitored themselves for three months and initialed this chart daily, indicating whether they adhered to it or not.

Data management

All data were entered correctly into the statistical program by the researcher. All documents, including medical records, questionnaires, informed consent forms, and other relevant records of the patient obtained during the research process, will be kept by the researchers, and personal information will be kept confidential. It will be stated that the information obtained from the patients during the research will be used only for this study and cannot be used for other purposes. Research data will be retained for five years after the end of the study.

Statistical analysis

The data analysis of the research will be carried out by performing the necessary statistical procedures in the computer environment, and the results will be evaluated at a 95% confidence interval and $p<0.05$ significance level. If the data are normally distributed, parametric tests (Student t test, Anova), if they are not normally distributed, nonparametric tests (Wilcoxon, Kruskal-Wallis H Test) and test-retest analysis will be used.

Harms

In this research trial, no unwanted or unexpected effects are anticipated in the participants, since the implementation of sleep hygiene training is not an easy and non-invasive procedure. There were no unwanted or unexpected effects; the researcher followed up with the patients through face-to-face or phone interviews.

Auditing

Patient compliance with the study was ensured through follow-up by researchers. Camera, laptop, and printer were obtained from Marmara university scientific research project unit with budget support.

The survey questions to be administered to the patients were displayed on a computer at a size that the patients could read. The answers they wanted to mark on the computer were marked by the researcher. In order to provide patients with an educational booklet, a booklet was printed using a color printer. Training videos were videotaped, and training videos of the patients were given to the patients who requested them.

Ethical considerations

This study was conducted in accordance with the declaration of Helsinki (WTO general assembly, Fortaleza, Brazil, October 2013) and the principles of the law on medical research involving human subjects, and written informed consent was obtained from all participants during the research process.

Ethics committee approval for this research was obtained from Kayseri city hospital clinical research ethics committee with decision no: 669 dated 21/07/2022. Kayseri city hospital received institutional permission from TUEK (Medical specialty education board).

Access to data

All researchers will have access to their data during and after the research process, and the research data will be preserved for further studies.

Ancillary

No fee was charged to the participants throughout the study. Budget support for the research was received from Marmara university scientific research project unit.

Dissemination policy

In the research, author contribution rates complied with ethical standards regarding authorship. The results of the research are planned to be shared through publication in an international peer-reviewed scientific journal and presentation at an international congress.

DISCUSSION

Manni and Terzaghi, in a review on epilepsy and sleep disorders, reported that epilepsy patients often complain of insomnia and have low quality of life.[7] Insufficient seizure control increases the circulation of tonic-clonic seizures, raising the risk of sudden deaths in epilepsy patients. It negatively affects intellectual development and mental functions, leading to restrictions in work life and social activities, causing the individual to live a semi-dependent or fully dependent life. Sleep deprivation or deficiency triggers epileptiform discharges, increasing seizure activity.[13] Low sleep quality can increase epileptiform discharge activity, leading to increased daytime sleepiness and seizure frequency.[11,38] In 2018, sleep hygiene education provided to hemodialysis patients and other chronic disease patients improved sleep and quality of life, and they recommended providing sleep hygiene education for chronic diseases.[39] Epilepsy patients should pay attention to seizure control through regular medication use, good sleep hygiene, proper nutrition, and a stress-free lifestyle.[1,37] With good sleep hygiene, epileptiform discharges can be controlled, improving sleep quality and quality of life.[13] Research suggests sleep hygiene education for epilepsy patients to correct sleep deprivation. There is evidence that sleep hygiene education conducted for other diseases improves sleep and quality of life. Patients will be provided with sleep hygiene education to increase personal awareness. Sleep hygiene training booklets and videos will serve as a guide in managing insomnia.[10,18,19]

CONCLUSION

This study is the first research trial evaluating the effects of sleep hygiene education given to epilepsy patients on seizure frequency and sleep quality**.** This research design suggests that this intervention, sleep hygiene education, can reduce epileptic seizures, provide psychological and physical well-being, and improve sleep quality and quality of life in adult individuals with epilepsy experiencing sleep disorders/insomnia. Research data will provide an evidence-based approach for subsequent nursing research and initiatives. It will provide the researcher with important gains in conducting, finalizing, and publishing the research.

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Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee by Kayseri City Hospital Ethics Committee (Decision No: 669 dated 21/07/2022)

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