International Journal of Clinical Trials
Koca R et al. Int J Clin Trials. 2023 Feb;10(1):73-80
http://www.ijclinicaltrials.com
pISSN 2349-3240 | eISSN 2349-3259

DOI: https://dx.doi.org/10.18203/2349-3259.ijct20230053

Protocol

Effects of sleep hygiene education and lavender oil inhalation on sleep quality, fatigue, and health-related quality of life in adults with an ostomy: a randomized controlled trial protocol

Rabia Koca[1]*, Aysel Gurkan[2], Hasan Fehmi Küçük[3]

[1]Institute of Health Sciences, University of Marmara, Maltepe, Istanbul, Turkey
[2]Faculty of Health Sciences, University of Marmara, Maltepe, Istanbul, Turkey
[3]Department of General Surgery, Kartal Dr. Lutfi Kirdar City Hospital, Istanbul, Turkey

Received: 30 November 2022
Revised: 14 January 2023
Accepted: 17 January 2023

***Correspondence:**
Dr. Rabia Koca,
E-mail: rabiaalpkoca@gmail.com

ABSTRACT

Background: It has been shown that the formation of an ostomy affects sleep quality, and sleep problems or insomnia cause fatigue in daily life, reducing the health-related quality of life. This trial aims to investigate the effects of sleep hygiene education and lavender oil inhalation alone and in combination on sleep quality, fatigue, and health-related quality of life in adults with an ostomy.
Methods: This trial has been planned as a randomized controlled clinical trial and will use a 2×2 factor design in which an equal number of participants meeting the inclusion criteria will be randomly allocated to one of four groups. The study sample will comprise 120 adult patients who have undergone ostomy surgery in a city hospital in Turkey. Lavender oil inhalation together with sleep hygiene education will be applied in the first group (n=30), only sleep hygiene education in the second group (n=30), only lavender oil inhalation in the third group (n=30), and no intervention in the fourth group (n=30). The sleep quality of the groups will be evaluated using the Pittsburgh sleep quality index, their fatigue levels with the chalder fatigue scale, and their quality of life with the ostomy a quality-of-life scale.
Conclusions: Non-pharmacological interventions are needed to prevent sleep and/or other problems that may develop due to insomnia in adults with ostomy. By evaluating the effects of these interventions, this trial will provide valuable evidence to guide clinical practice.
Trial registration: This trial was registered in October 2022 (NCT05573256).

Keywords: Ostomy, Sleep hygiene, Lavender oil, Sleep, Fatigue, Quality of life

INTRODUCTION

Ostomy (or stoma) is a surgical opening made in the skin when a problem is not allowing a part of the body to function well and widely used in the treatment of gastrointestinal or urinary system cancers, inflammatory bowel diseases, traumas, congenital anomalies, and mechanical bowel obstructions.[1,2] The global incidence and prevalence of ostomy surgery are not clearly known.[2,3] The estimated number of people with a ostomy was approximately 1 million in China in 2014 and 100,000 in Germany and 43,000 in Sweden in 2018, and ranges from 725,000 to 1 million in the United States of America according to recent data.[4-7] In Turkey, the number of patients with a ostomy was reported to be 28,316 for the period between January 2017 and December 2019.[2]

Although the formation of an ostomy helps prolong life and return to a healthy life, it also causes individuals to

experience various physiological, psychological, and social problems.[3,8] These problems may negatively affect adaptation to and the ability to cope with the ostomy. Studies have shown that problems experienced by individuals with an ostomy negatively affect their ability to adapt to the ostomy and their quality of life, and patients' ostomy adjustment is low to moderate, with their psychosocial adjustment being closely related to their quality of life.[3,6,7,9]

Poor adjustment to a ostomy may also undesirably affect the sleep quality of an individual. It has been reported that ostomy bags and night time equipment restrict sleep comfort and sleeping positions, individuals with a ostomy have to wake up frequently at night to empty stool, urine, or gas from the ostomy bag, and they experience the fear of the bag bursting, detaching, or leaking.[1,9,10,11] The feeling of having to wake up to empty the ostomy bag and sleep problems caused by associated fears can lead to fatigue and reduce the quality of life in individuals with a ostomy throughout the rest of their daily lives.[12] It has been shown that individuals with ostomy have poor sleep quality and consequently low quality of life.[11,12,16]

Sleep is a basic biological function related to fatigue and quality of life, and it is a vital component of life allowing for the body to renew itself and forming the basis of a healthy and long life. Sleep quality refers to an individual's feeling fit and ready for a new day upon waking up.[1,14] Sleep hygiene, defined as the principles and practices that increase sleep quality, is an easy, inexpensive, sleep-enhancing and sleep-quality method that can be applied by the individual to prevent problems that may develop due to mild insomnia and sleep problems.[15]

Sleep hygiene education, whose focus is on behavioral change to improve sleep habits, is considered the primary intervention in individuals with poor sleep quality.[15] Since sleep is a physiological requirement, identifying and eliminating the situations that prevent the individual from sleeping comfortably and educating them about sleep hygiene are among the care responsibilities of the nurses.[16] Although there are studies showing the positive effects of sleep hygiene education in improving sleep quality and reducing fatigue in various populations, only limited studies have been undertaken to investigate the effect of sleep hygiene education on sleep quality in individuals with a ostomy.[12,17,18]

Another promising method in the treatment of sleep problems is aromatherapy, in which essential oils with calming and hypnotic properties are used.[14] In addition, aromatherapy is one of the interventions used to improve patient care and strengthen nursing as a supportive non-pharmacological method in the treatment of pain, anxiety, and problems related to relaxation and stress.[19,20] In a systematic review examining the effects of inhaled essential oils on sleep problems, it was reported that the essential oil that was most investigated for this purpose was lavender (*Lavandula angustifolia*), a species from the Lamiaceace family, which provided low to moderate benefits in the presence of sleep problems.[21] In addition, other studies have shown that lavender oil has the least toxic and allergenic properties and positive effects on anxiety, sleep, fatigue, and quality of life by providing relaxation in different inpatient populations.[19,22,23,25-30] However, to the best of our knowledge, there is no study examining the effect of lavender oil on sleep problems in individuals with a ostomy.

Since sleep problems or insomnia affect the quality of life of an individual with an ostomy, they must be prevented and treated. Easy, inexpensive, safe, convenient, and accessible interventions based on self-care can help reduce the negative effects on health caused by sleep problems or insomnia.[14] This is also among the patient care responsibilities of surgical nurses, especially ostomytherapy nurses.[16,31,32]

In this context, we have designed a prospective study to evaluate the effect of sleep hygiene education and lavender oil inhalation on sleep quality, fatigue, and quality of life in adults with an ostomy, as components that are related to nursing care.

Aim

To investigate the effects of sleep hygiene education and lavender oil inhalation alone or in combination on sleep quality, fatigue, and quality of life in adults with an ostomy.

Null hypothesis

There is no significant difference in sleep quality, fatigue, and quality of life between adults with a ostomy who have not received any intervention and those that have received sleep hygiene education and lavender oil inhalation alone or in combination.

METHODS

Trial design

This study has been designed as a randomized controlled trial with four groups including an equal number of randomly assigned participants. In this trial, the standard protocol items: recommendations for interventional trials (SPIRIT 2013) checklist and the "consolidate standards of reporting trials (CONSORT) recommendations will be followed.

Setting

This trial will be conducted in the general surgery and urology clinics of a city hospital located in Istanbul, Turkey. In the institution where the research is planned to be conducted, ostomy surgery is carried out in urology and general surgery clinics, and patient care and follow-

up are routinely performed as follows: Following the operation decision and scheduling, the physician informs the patient about the surgical intervention to be performed. On the day before or the morning of the operation, above-mentioned clinics contact ostomy and wound care nurses. These nurses mark the ostomy site of the patient. Following the patient's admission to the clinic, the first evaluation of the patient is made by the ostomy and wound care nurses within 24 hours, and patient education is initiated accompanied by the primary caregiver from the family. In this process, the ostomy patient follow-up form, which is routinely used in the institution, is completed. This form includes the patient's contact information, ostomy characteristics, and notes on care assessments. Throughout the period from admission to clinic to discharge, the ostomy care and education of the patient is repeated by the ostomy and wound care nurses every 72 hours. The primary caregiver, who will continue home care with the patient, is also included in the education process.

Eligibility criteria

In light of the literature, the inclusion criteria of the study have been determined as being 18 years or older, at least three months having passed after ostomy, having a clear level of consciousness and no disease or medication use that can negatively affect the level of consciousness, being able to communicate in Turkish, and providing informed written consent to participate in the study.[12,17,27] The exclusion criteria are lavender allergy, respiratory tract infections such as sinusitis and pneumonia, body mass index (BMI) of >40, a diagnosis of sleep disorder, and/or medication use for sleep problems. In addition, patients that decide to withdraw from the study, those that develop an allergy to lavender during the trial, and those that do not comply with the trial procedures and conditions will be excluded.

Interventions

In the trial, lavender oil inhalation together with sleep hygiene education will be applied in group 1, only sleep hygiene education in group 2, and lavender oil inhalation alone in group 3, while no intervention will be undertaken in group 4.

Sleep hygiene education

The participants assigned to groups 1 and 2 will receive sleep hygiene education using the sleep hygiene education brochure, which has been prepared by the researchers based on the literature concerning the improvement of general sleep quality in individuals with a ostomy.[12,15,33,34] This brochure includes recommendations on adjustments related to sleep staging, timing of sleep, planning daily activities, food intake, improving mental control, and ostomy care. The suitability, reliability, and quality of this education material presented to 10 experts before data collection begins.

Lavender oil inhalation

Lavender oil inhalation will be applied to the participants assigned to groups 1 and 3. The lavender essential oil to be used in the study is 2% *Lavandula angustifolia*. This essential oil has been preferred because it is widely used, generally well tolerated with minimal side effects at recommended doses, and has the least toxic and allergenic properties.[22,23] The lavender oil that will be used in the study obtained from Florame organic essential oils and organic cosmetics company (Alda Inşaat Gıda ve Turizm Ticaret Ltd. Şti.). The expiry date of the lavender oil to be used in the trial is 07/2024. In order to preserve the properties of this oil, it will be stored in dark bottles in a cool, dry, and dark place. During the trial, the participants will be asked to practice lavender oil inhalation as follows: Every night before going to bed (21:00-24:00), the participants will drop two drops of 2% lavender essential oil on a 2×2 cm cotton gauze pad in a bowl, place it at distance of 15-20 cm from their pillows, and breath normally for 20 minutes. The participants will be instructed to repeat this process by dripping lavender oil onto a new gauze pad every night for four weeks.[25,27]

Outcomes

The outcomes of this trial are sleep quality, fatigue, and health-related quality of life evaluated using repeated measurements in adults with a ostomy.

Participant timeline

Participants will be selected using the ostomy patient follow-up forms available in the institutional records. The researcher, who works as an ostomy and wound care nurse in the institution where the study is to be carried out, will contact the participants to hold interviews in accordance with their follow-up schedules. During the interviews, individuals with a ostomy will be screened for eligibility, and those that meet the inclusion criteria will be invited to participate in the study. After obtaining informed written consent from the individuals who have accepted to participate in the study, a randomization list will be used to determine the groups to which they will be assigned. The participants will be given a sequence number according to the order of inclusion in the study and will be assigned to one of the four groups according to the numbers in the randomization list.

The follow-up data of individuals with a ostomy will be collected at two different times coded as T_0 and T_1. After being found eligible during the first interview and randomized to the groups (T_0), the descriptive characteristics form, the Pittsburgh sleep quality index (PSQI),[35] the Chalder fatigue scale (CFS),[36] and the Ostomy quality of life scale (SQLS)[37] will be completed. In the follow-up, the participants assigned to group 1 will

be given sleep hygiene education and instructed how to apply lavender oil inhalation. The participants in this group will be given a copy of the sleep hygiene education brochure, lavender oil in a 10 ml bottle and charts on sleep hygiene education and lavender oil inhalation. The participants assigned to group 2 will only be given sleep hygiene education. They will be provided with a copy of the sleep hygiene education brochure and a chart on which to record their sleep hygiene practices. The participants assigned to group 3 will only be instructed on how to apply lavender oil inhalation. The participants in this group will be given lavender oil in a 10 ml bottle. In this process, anything that is not clear to the participants or questions they may have concerning sleep hygiene, lavender oil inhalation, and the use of the charts will be addressed. To support the accurate and regular implementation of these two interventions, the participants will be contacted by phone on the start day and end of each week. During these interviews, the screenshots of seven-day charts will be obtained from the participants and evaluated. Since the scales to be used in this study measure sleep quality, fatigue severity, and quality of life perceived by individuals over the last month, sleep hygiene practices and lavender oil inhalation will be continued for one month. At the end of the fourth week, face-to-face interviews will be held with the participants in each of the four groups. During this interview, charts showing the records on sleep hygiene and lavender oil inhalation practices over the four weeks will be collected from the participants in groups 1, 2 and 3, and PSQI, CFS, and SQLS will be completed again with the participants in each of the four groups (T1).

Figure 1 presents the CONSORT flow chart of the trial.

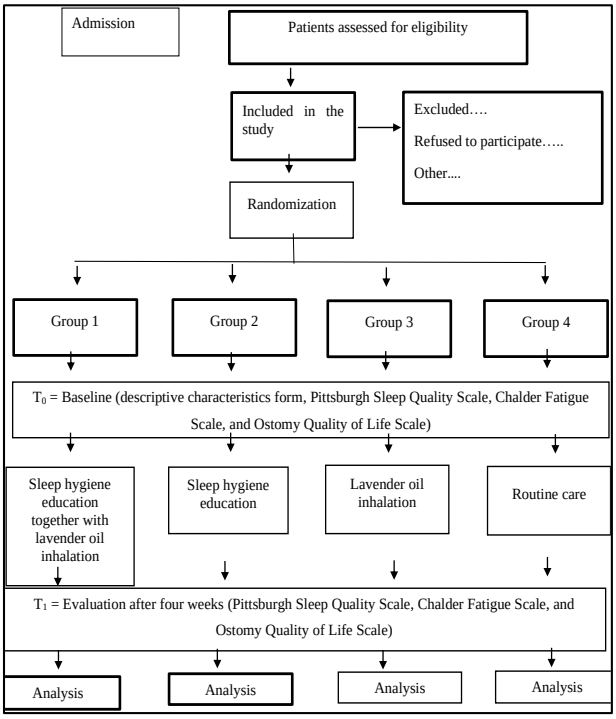

Figure 1: Study flowchart according to CONSORT.

Sample size

The minimum sample size has been calculated with the power analysis using G*power (v 3.1.7) software. From the records of the institution where the study is planned to be carried out, it was determined that the number of ostomy operations performed in the last year (January 2020-January 2021) was 168. The minimum number of participants was then determined as 100 to obtain 80% power at the α=0.05 level using simple random sampling for a known population. Considering the possibility of losses during the study process, it was decided that this number should 120 (n=30 for each group), which is 20% greater than the minimum sample size.

Recruitment and randomization

In this trial, a randomization list created from a computer-based random numbers table (http://www.random.org/lists/) will be used to determine the groups to which the participants will be assigned. In this randomized controlled study, a 2×2 factorial design will be used in which an equal number of participants will be randomly assigned to each group (Table 1).

Table 1: Interventions allocated for each group.

Intervention	Lavender inhalation	No lavender inhalation
Sleep hygiene education	Group 1	Group 2
No sleep hygiene education	Group 3	Group 4

Blinding

Due to the feasibility and nature of the study, the principal researcher and patients cannot be blinded to patient grouping, but the evaluator will be blinded to the groups of the participants.

Data collection

The collection of the data of this trial began on June 14, 2022, and the data collection process is ongoing.

Instruments

In this trial, data will be collected using the descriptive characteristics form, Chalder fatigue scale, PSQI, and SQLS. In addition, patient compliance with interventions (sleep hygiene education and lavender oil inhalation) will be monitored using weekly charts.

Descriptive characteristics form

This form was prepared by the researchers based on the literature and consists of a total of 26 questions, of which 11 are designed to determine the individual characteristics of the participants [gender, age, marital

status, and BMI), education level, employment status, occupation, income level, health insurance status, presence of drug or food allergies, and presence of lavender allergy]; eight to explore factors that may affect sleeping pattern [smoking status, alcohol and caffeine consumption habits, comorbidities, daily sleep duration, number of awakenings at night, presence of any diagnosed disorder that may affect sleeping pattern (anxiety, depression, sleep disorder, sleep apnea, and respiratory tract infection), and presence of any drug use that may affect sleeping patterns]; and seven to determine ostomy-related characteristics (ostomy type, permanent or temporary status, presence of complications, ostomy duration, ostomy care self-skills, and presence of ostomy site marking and the person that marked the ostomy site).[12,17,27]

The Pittsburgh sleep quality index

This scale was developed in 1989 by Buysse et al and has become a widely adopted instrument to determine sleep quality.[35] The reliability and validity analyses of the Turkish version of PSQI were undertaken by Ağargün et al in 1996.[38] The Cronbach alpha internal consistency coefficient of the scale for the Turkish population was found to be 0.80. PSQI provides a valid and reliable standard measurement of sleep quality over the last month. It consists of seven subscales with a total of 19 items, of which 18 are included in scoring. Each item is evaluated over 0-3 points, and the sum of the seven subscale scores constitutes the total PSQI score. The total score that can be obtained from the scale ranges from 0 to 21, and a high total score indicates poor sleep quality. A total PSQI score of ≤5 indicates 'good sleep', and a score of >5 indicates 'poor sleep'.[38] For the scale to be used in this study, permission was obtained from the authors who conducted the validity and reliability analyses of the Turkish version.

The Chalder fatigue scale

This scale was developed by Chalder et al in 1993, and the reliability and validity study of the Turkish version was conducted by Adın in 2019, with the Cronbach alpha value being calculated as 0.89 for the Turkish population.[36,39] CFS measures the severity of the fatigue perceived by the individual during the last one month. The scale consists of 11 items, seven evaluating physical fatigue and four evaluating mental fatigue. There are four options for response to the items in the scale. The overall fatigue score is obtained by summing the scores in the physical and mental fatigue subscales. The physical fatigue subscale score ranges from 0 to 21, the mental fatigue subscale score ranges from 0 to 12, and the total fatigue score ranges from 0 to 33. An increase in the scale score indicates an increase in the severity of fatigue.[39] To use the scale in our study, permission was obtained from the authors who conducted the validity and reliability study in the Turkish population.

The Ostomy a quality-of-life scale

This is a 21-item assessment scale developed by Baxter et al. to measure the quality of life of individuals with a ostomy.[37] Karadağ et al performed the reliability and validity analyses of the Turkish version of the scale and reported the Cronbach alpha internal consistency coefficient as 0.87.[40] The first two items of the scale are related to the individual's overall satisfaction with life and scored between 0 and 100. The remaining items are grouped into three subscales: work/social life (six items), sexuality/body image (five items), and ostomy function (six items). Except for the first two items, the remaining 19 items are scored based on a five-point Likert scale (1: never, 2: rarely, 3: sometimes, 4: often, and 5: always). Minimum and maximum scores for each subscale are 0 and 100, respectively, with high scores indicating an increase in quality of life.[40] To use the scale in this trial, permission was obtained from the authors who conducted the validity and reliability analyses in the Turkish population.

Sleep hygiene application chart

This chart has been prepared to determine whether individuals with a ostomy assigned to groups 1 and 2 regularly perform their daily sleep hygiene practices over the four-week period.

Lavender oil inhalation chart

This form has been prepared as a four-week checklist to determine whether individuals with a ostomy assigned to groups 1 and 3 regularly perform daily lavender oil inhalation as instructed.

Data management

The accurate and complete coding of all data and their entry into the statistics software will be undertaken by the researchers. All original documents, including medical records, scale forms, informed consent forms, and other relevant records obtained during the trial period, will be kept confidential by the researchers. Data will be retained for 10 years after the completion of the study.

Statistical analyses

The number Cruncher statistical system (NCSS LLC, Kaysville, Utah, USA) will be used for statistical analyses. When analyzing the study data, in addition to descriptive statistical methods (mean, standard deviation, median, frequency, and ratio), the Shapiro-Wilk test and box plots will be used to evaluate the conformity of the data to the normal distribution. One-way analysis of variance will be used in the evaluation of the normally distributed variables in the four groups, and the Bonferroni test will be conducted to determine the group causing the significant difference. The Kruskal-Wallis test will be used in the evaluation of variables that do not

show a normal distribution in the four groups, and the Dunn test will be undertaken to determine the group causing the significant difference. The Pearson or Spearman correlation analysis will be performed according to the distribution of variables in the evaluation of the correlations between the scale scores, and linear regression models will be constructed for further evaluations. The Pearson chi-square, Fisher's exact, and Fisher-Freeman-Halton tests will be utilized to compare qualitative data. The results will be analyzed at the 95% confidence interval and $p<0.05$ significance level.

Harms

In this trial, all unexpected and undesirable effects on the participants will be recorded by the researcher and followed up via phone calls.

Auditing

Adaptation to every stage of the research process will be ensured by the researchers. Since the lavender oil used in the study is not available at the institution, the researcher will obtain it from Florame organic essential oils and organic cosmetics company.

Ethical considerations

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

Access to data

All the researchers will have access to all the data during the study period. At the end of the study, the data will be retained for future research.

Ancillary

The participants will not be charged for lavender oil, and the cost will be covered by the researchers.

Dissemination policy

The authors will adhere to the ethical standards of authorship. The results of the study will be shared through publication in an international peer-reviewed scientific journal and presentation in an international congress.

DISCUSSION

The limiting effects of a ostomy and night equipment in terms of sleep comfort and sleeping position and anxiety caused by having to wake up frequently at night to empty stool, urine, or gas from the ostomy bag can result in sleep problems, consequently leading to fatigue and decreased quality of life.[11-13] Studies on sleep hygiene education and lavender oil inhalation have shown the positive effects of these interventions on sleep quality and fatigue in different patient populations.[14,17,18,20,25-28] However, to our knowledge, no study has focused on the effects of the individual and combined use of these two methods on the sleep problems of individuals with a ostomy or compared the effectiveness of these methods. In this context, ostomytherapy nurses have important responsibilities in preventing and improving sleep problems and/or problems that may develop due to insomnia in adults with an ostomy. Problems affecting the adaptation of individuals with an ostomy to their new lives and ostomy education given by ostomytherapy nurses are of critical importance. The results of this study can contribute to the elimination of these problems and to ostomy care education. It is considered that this study will also guide future scientific studies and clinical applications in these patient groups.

CONCLUSION

This is the first trial to evaluate the effects of sleep hygiene education and lavender oil inhalation alone and in combination on sleep quality, fatigue, and health-related quality of life in adults with an ostomy. The research design will provide valuable evidence for the quality of life of adults with an ostomy and allow for the comparison of the effects of using these interventions alone and in combination.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee by Clinical Studies Ethics Board of Marmara University School of Medicine (decision number: 09.2021.1037).

REFERENCES

1. Harputlu D, Talaz D, Cenan D, Karadağ S, Öğce F. Investigation of sleep quality in individuals with stoma. Deuhfed. 2020;13(2):59-66.
2. Yılmaz G, Harputlu D, Pala Mİ, Mert T, Çakıt H, Sücüllü İ et al. A cross sectional evaluation of patients with ostomy in Turkey. Turk J Colorectal Dis. 2021;31:136-42.
3. Ayaz Alkaya S. Overview of psychosocial problems in individuals with stoma: A review of literature. Int Wound J. 2019;16(1):243-9.
4. Luo BJ, Qin HY, Zheng MC. Correlation between social relational quality and hope among patients with permanent colostomies. Int J Nurs Sci. 2014;1:405-9.
5. Ambe PC, Kurz NR, Nitschke C, Odeh SF, Möslein G, Zirngibl H. Intestinal ostomy. Dtsch Arztebl Int. 2018;115(11):182-7.
6. Fingren J, Lindholm E, Petersen C, Hallen AM, Carl sson E. A prospective, explorative study to assess

adjustment 1 year after ostomy surgery among Swedish patients. Ostomy/wound Manage. 2018;64(6):12-22.
7. Zhang Y, Xian H, Yang Y, Zhang X, Wang X. Relationship between psychosocial adaptation and health-related quality of life of patients with stoma: A descriptive, cross-sectional study. J Clin Nurs. 2019;28(15-16):2880-88.
8. Bahayi K, Attaallah W, Yardımcı S, Bulut H, Özten E. Depression, anxiety, sexual dysfunction and quality of life in patients with ileostomy or colostomy. Turk J Colorectal Dis. 2018;28(2):69-75.
9. Temiz Z, Çavdar İ, Özbaş A, Altunsoy M, Akyüz N, Kutlu FY. Sleep quality and factors affecting sleep in ındividuals with an ıntestinal ostomy: a descriptive cross-sectional study. Wound Manag Prev. 2022;5:28-36.
10. Krouse RS, Grant M, Ferrell B, Dean G, Nelson R, Chu D. Quality of life outcomes in 599 cancer and non-cancer patients with colostomies. J Surg Res. 2007;138:79-87.
11. Çavdar İ, Temiz Z, Ozbas A, Can G, Tarhan F, Fındık UY et al. Sleep and quality of life in people with ileal conduit. Scand J Urol. 2016;50(6):472-6.
12. Vorbeck E, Willette-Murphy K, Meiers S, Rudel R, Alakhras M. A descriptive, interventional study to assess the impact of surgical stomas on individuals' sleep perceptions and response to sleep hygiene intervention. Ostomy Wound Manage. 2010;56(1):36-44.
13. Furukawa C, Morioka I. Health-related quality of life and sleep disorders in patients with a urostomy. Is there a relationship? JWOCN. 2017;44(4):358-62.
14. Lillehei AS, Halcón LL, Savik K, Reis R. Effect of inhaled lavender and sleep hygiene on self-reported sleep issues: a randomized controlled trial. J Altern Complement Med. 2015;21(7):430-8.
15. Güneş Z. Role and Strategies of Sleep Hygiene in Promoting Sleep Health. Arşiv Kaynak Tarama Derg. 2018;27(2):188-98.
16. İsmailoğlu EG, Özdemir H. Factors affecting sleep hygiene training of nursing students. J Turk Sleep Med. 2020;3:195-200.
17. ELmetwaly AAM, Mohamed EMH, Abou Elmaati HMB, Mohamed SAM. Sleep hygiene: ımproving sleep quality and fatigue for patients receiving chemotherapy. Am J Nurs. 2019;7(6):1078-85.
18. Borzou S, Khavari F. The effects of sleep hygiene education on fatigue and sleep quality in hemodialysis patients: A quasi experimental study. Avicenna J Nurs Midwifery Care. 2019;27(1):25-34.
19. Özdemir H, Öztunç G. Aromatherapy in Nursing Practice. Turkiye Klinikleri J Nurs Sci. 2013;5(2): 98-104.
20. Lytle J, Mwatha C, Davis K. Effect of lavender aromatherapy on vital signs and perceived quality of sleep in the intermediate care unit: A pilot study. Am J Crit Care. 2014;23:24-9.
21. Fismer KL, Pilkington K. Lavender and sleep: A systematic reviwe of the evidence. Eur J Integr Med. 2012;4(4):e436-47.
22. Cho MY, Min ES, Hur MH, Lee MS. Effects of aromatherapy on the anxiety, vital signs, and sleep quality of percutaneous coronary intervention patients in intensive care units. Evid. Based Complementary Altern. Med. 2013;1-6.
23. Babar A, Al-Wabel NA, Shams S, Ahamad A, Khan SA, Anwar F. Essential oils used in aromatherapy: A systemic review. Asian Pac J Trop Biomed. 2015;5(8):601-11.
24. Watt GVD, Janca A. Aromatherapy in nursing and mental health care. Contemp Nurse. 2008;30(1):69-75.
25. Karadağ E, Samancioglu S, Ozden D, Bakir E. Effects of aromatherapy on sleep quality and anxiety of patients. Intensive Crit. Care Nurs. 2017;22(2):105-12.
26. Ayik C, Özden D. The effects of preoperative aromatherapy massageon anxiety and sleep quality of colorectal surgery patients: A randomized controlled study. Complement Ther Med. 2018;36:93-9.
27. Muz G, & Taşcı S. Effect of aromatherapy via inhalation on the sleep quality and fatigue level in people undergoing hemodialysis. Appl Nurs Res. 2017;37:28-35.
28. Genç F, Karadag S, Akça NK, Tan M, Cerit D. The effect of aromatherapy on sleep quality and fatigue level of the elderly: A randomized controlled Study. Holist Nurs Pract. 2020;34(3):155-62.
29. Hamzeh S, Safari-Faramani R, & Khatony A. Effects of aromatherapy with lavender and peppermint essential oils on the sleep quality of cancer patients: a randomized controlled trial. 2020. Evid. Based Complementary Altern Med. 2020;1-7.
30. Bakhtiari S, Paki S, Baradaranfard F, Mosleh S, Jokar M. Effect of lavender aromatherapy through inhalation on quality of life among postmenopausal women covered by a governmental health center in Isfahan, Iran: A single-blind clinical trial. Complement. Ther Clin Pract. 2019;34:46-50.
31. Karadağ A. Position and ımportance of stomatherapy units and stoma care nurse in colorectal surgery. Kolon Rektum Hast Derg. 2007;17:46-52.
32. Kesgin MT, Çağlar S. Sleep disorders studies in nursing: Literature review of the national context. YBH dergisi. 2020;1(1):1-14.
33. Berti-Hearn L, Elliott B. Colostomy care: A guide for home care clinicians. Home Healthc Now. 2019;37(2):68-78.
34. Caple C. Patient Education: Teaching the Patent with a Stoma. Ed: Pravicoff D. Nursing Reference Center Plus, CINAHL Nursing Guide EBSCOO Publishing, (Ipswich Massachusetts). 2018;1-14.
35. Buysse DJ, Reynolds III CF, Monk TH, Berman SR, Kupfer DJ. The Pittsburgh sleep quality index: A new instrument for psychiatric practice and research. Psychiatry Res.1989;28(2):193-213.

36. Chalder T, Berelowitz G, Pawlikowska T, Watts L, Wessely S, Wright D et al. Development of a fatigue scale. J Psychosom Res. 1993;37(2):147-53.
37. Baxter N, Jacobson T, Maidl L, Young-Fadok TM. A stoma quality of life scale. Dis Colon Rectum. 2006;205-12.
38. Ağargün MY, Kara H, Anlar O. Validity and reliability of the Pittsburgh sleep quality index. Turk Psikiyatri Derg. 1996;7(2):107-15.
39. Adın RM, Turkish Adaptation of Chalder Fatigue Scale and Investigating Its Psychometric Properties in Young Adults, Hacettepe University, Graduate School of Health Sciences, Physical Therapy and Rehabilitation Program, Master of Science Thesis, Ankara. 2019.
40. Karadağ A, Öztürk D, Çelik B. Adaptation of quality life scale for the ostomy patients into Turkish. Turk J Colorectal Dis. 2011;21(4):173-81.

Cite this article as: Koca R, Gurkan A, Küçük HF. Effects of sleep hygiene education and lavender oil inhalation on sleep quality, fatigue, and health-related quality of life in adults with an ostomy: a randomized controlled trial protocol. Int J Clin Trials 2023;10(1):73-80.