Pharmacophore

ISSN-2229-5402

Journal home page: http://www.pharmacophorejournal.com

Pharmacophore
an International Journal
ISSN 2229-5402

THE EFFECT OF LAVENDER AROMATHERAPY ON SLEEP QUALITY IN THE OLDER ADULTS: A SINGLE BLIND RANDOMIZED CLINICAL TRIAL

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ARTICLE INFO

Received:
03th Jun 2017
Accepted:
29th Nov 2017
Available online:
14th Dec 2017

Keywords: *Aromatherapy, Lavender Oil, Older People*

ABSTRACT

Introduction: Sleep disorders are one of the most common complaints among older people. Lavender Aromatherapy as a safe and sedative sleep enhancing intervention is an alternative to pharmaceutical protocols for sleep disturbances. Therefore, this current study aimed to explore the effect of aromatherapy using lavender on sleep quality in the older people.
Methods: A single-blind randomized controlled clinical trial study was conducted on 80 elders referred to healthcare setting who were randomly allocated into two groups with 40 elderly in each group. The intervention group inhaled lavender essential oil dropped on a cotton ball and attached to their collar, before sleeping for two weeks and discarded it after waking up, while the control group received no intervention. All participants were asked to fill out the Pittsburgh Sleep Quality Index (PSQI) before and after the study. Collected data was analysed via the SPSS version 18 software using t-test and logistic regression.
Results: There was no statistically significant difference between groups in terms of socio-demographic characteristics sleep quality score before intervention ($p > 0.05$). Comparison of the PSQI scores in the groups before and after the intervention was reported a statistically significant difference in sleep quality's mean scores ($P < 0.001$). In the logistic regression analysis, no potential confounding variable influenced sleep quality as the dependent variable ($P > 0.05$). By eliminating all confounders, aromatherapy significantly predicted sleep quality (OR=8.28, CI=1.55- 44.18, P=0.01).
Conclusion: lavender Aromatherapy can be used as a non-invasive, easily applicable, cost-effective method for improving sleep quality.

To Cite This Article: Aleheh Seyyed Rasooli, Arefeh Davoodi bavooli, Parvin Sarbakhsh, Akram Ghahramanian, Sevda Sadeghpoor, (2017), "the effect of lavender aromatherapy on sleep quality in the older adults: a single blind randomized clinical trial", ***Pharmacophore, 8(6S),*** *e-117392.*

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Introduction

Statistics show the rapid growth of older people population in the community [1]. In this respect, developing countries will face the phenomenon of human aging in the future [2]. Aging reduces physical, psychological and social functions and therefore affect sleep quality [3]. The increase in aging population presents many several public health challenges that make them burdens on families, caregivers and the healthcare system, that need to providing appropriate social context to support and help them cope with these changes [4].One of the problems affecting the quality of life of this people is sleep disorders [5]. The common sleep disorders in older adults are early morning awakening, night time awakenings, daily napping, daytime sleepiness, difficulty in falling asleep, decreased total sleep [6-9].

A systematic review conducted by Mollayeva et al. (2015) reported that 15-20 percent of older adults suffered from chronic sleep problems [10]. Sleep as a natural rhythm is a vital component of life and goes under substantial qualitative and quantitative changes with aging [7]. Any disruption in its physiological process can lead to serious physical and psychological problems, reduce the ability of the individual[11], increase the risk of psychological disorders such as depression and dementia [12], reduce the quality and life satisfaction [13], impair motivation and communication [14] increase accidents and errors [15] and lead to the misuse of hypnotic drugs that is the most common method to deal with sleep disorders in older adults. The effectiveness of sleep medications is higher, but temporary and short-term [16]. Moreover, they have side effects such as mental and cognitive dysfunctions reduced quality of life and increased mortality and morbidity [17]. Therefore, the use of complementary medicine as a non-pharmacological method with presumably few or no side-effects should be considered as an alternative safe approach for improving sleep quality in older adults persons [18, 19].

Nowadays, the use and acceptance of alternative medicine is increasing [20].Since the nursing profession has a holistic perspective toward care, complementary medicine is one of the holistic nursing care, therefore it is essential for nurses to provide complementary medicine in their clinical nursing interventions [21, 22].

Aromatherapy as one of the oldest approaches, is the therapeutic use of extracts of herbs and plants, which is absorbed via the skin or inhalation due to low side effects [23]. The chemical components of lavender are Linalool and linalyl acetate, which stimulate the parasympathetic system and show sedative and analgesic properties. In addition, it can relieve pain, reduce stress and facilitate sleep [24]. Previous studies have reported the various therapeutic benefits of lavender on sleep quality in older adults suffering from acute disorders [25] and patients undergoing dialysis [26], menopause women with insomnia [27] and patients' anxiety [28].

Due the high rate of sleep disorders among older adults and its relationship with significant morbidity and mortality rate of older people [29], and ever-increasing demands for non-pharmacologic and non-invasive methods for the treatment of sleep disorders [30] and considering the lack of studies on the effectiveness of aromatherapy on sleep quality of older people, there is a serious necessity of major Nursing Research in the field of improving sleep quality in older adults and especially efforts to scientifically demonstrate the effects of aromatherapy as a holistic nursing interventions [31, 32], therefore we decided to assess the effect of aromatherapy using lavender on sleep quality in older adults.

2. Material and method

2.1. Study design and participants

This single-blinded randomized clinical trial study was conducted on 80 older adults referred to Monempour healthcare setting in Tabriz, Iran between January and February in 2015.

Older adults who met the following inclusion criteria were sampled: be willing to participate in the study, be conscious have the ability to verbally communicate, age equal or above 60 years old, having relative independence in daily activities, having no known mental problem according to his words. The exclusion criteria include older adults with a history of allergies rhinitis, eczema, asthma and respiratory problems, impaired sense of smell and unwillingness to participate in the study.

Aromatherapy with lavender and sleep quality were the independent and dependent variables, respectively. Potential Confounding variables were health status, drug consumption, the history of chronic diseases, age, the presence of the clock in the bedroom and the use of therapeutic pillow and mattress. The most important outcome of this study was the use of aromatherapy with lavender, improvement of sleep quality among older adults.

2.2. Ethical considerations

This study was approved by the Medical Research and Ethical Committee of Tabriz University of Medical Sciences (TBZMED.REC.1394.894). The study was also registered in the Iranian Registry of Clinical Trials (www.irct.ir) with the registration number (No IRCT2015020119919N2). Each participant was verbally provided with information regarding the

study and the contents of the information sheet. All participants signed a consent form in which the study procedures were explained.

2.3. Sample size and randomization

The sample size was calculated by using G-power analysis based on information obtained from study by abdullahzadeh et al. [33], which the means of sleep quality in the intervention were (mean1= 8.2) and (Sd1=4.0) and in control groups (mean 2= 5.0) and (Sd2= 3.7) by given beta equal to 90%, $\alpha = 0.05$, which according to 20% possible attrition rate has been determined as 40 for each group. The eligible participants were allocated randomly to the aromatherapy and control groups using balanced block randomization with blocks of four and the allocation ratio of 1:1. The aromatherapy and control groups were assigned randomly to letters A and B. Thus, for each block of four elders , two were allocated in a random order to each treatment. Six sheets of paper were used to cover all possible states: AABB, ABAB, ABBA, BBAA, BABA, and BAAB. The assignments were then selected using a table of random numbers.

2.4. Intervention

The researcher referred to the selected healthcare setting and using convenience sampling examined all older adults for the inclusion criteria. In the first session of the intervention, the aim and process of this study was explained and written informed consent was obtained of those older adults who met the criteria and agreed to participate in this study willingly, written informed consent was obtained and socio-demographic questionnaire and Pittsburgh Sleep Quality Index [34], was filled out by the research assistant through interviews. After the education, intervention group was given a package containing fourteen cotton balls with a glass of lavender essential oil with a concentration of 2% produced by the Hakim Razi Co, along handbook and Educational pamphlets that written instructions on how to perform lavender aromatherapy every night before sleeping and the checklist of care that participants should mark that when did aromatherapy, delivered to the to each participant. In addition, telephone numbers of participants were received and they were followed in terms of performing the lavender aromatherapy, they were assigned.

The older adults in the intervention group inhaled two drops of the essential lavender oil on a cotton ball from a distance of 3-5 cm, for 20 minutes for 14 days, also the same cotton ball was attached with pins to their collar and discarded after waking up. To ensure of the proper implementation of the intervention at home, the older adults subjects was telephoned every day at six o'clock in the afternoon to remind them of the intervention. The checklist of care delivered to the patient at home was filled out by the participants at the time of telephone follow ups. Two weeks later, all measurements were completed data collection tools through interviews by one Graduate Research Assistant who was blind to the randomization and intervention.

The day before the participants were to complete the questionnaire, a phone call was made to remind them. As for the control group, they were administered the same scales again after 14 days, by the research assistant through interviews, without any intervention. At the end of the intervention, the older adults were thanked by granting gifts.

2.5. Data collection instruments

Data was collected using the socio-demographic questionnaire (The individual information questionnaire included (age, number of children, marital status, education, occupational status, income and medication history and background diseases)and the Pittsburgh Sleep Quality Index [34] which were filled out before intervention and 2 weeks after intervention. The Pittsburgh Sleep Quality Index was developed in 1989 by Buysse and colleagues [34] the most commonly used and best validated questionnaire available to measure sleep quality and sleep disturbance. It consists of 18 questions grouped into seven component scores sleep quality, sleep latency, sleep duration, sleep efficiency, sleep disturbances, use of sleep medications and daytime dysfunction, which yield a global PSQI score ranging from 0 to 21 points (0 indicating no sleep difficulty, 21 indicating severe sleep difficulty).A total PSQI > 5 indicates poor sleep quality [34]. The reliability of the PSQI was reported 0.83 using the alpha Chronbach coefficient. The credibility of the scale with a sensitivity of 89.6% and a specificity of 86.5% in testing subjects compared with controls was reported at the appropriate level by the creators [34].

2.6. Statistical analysis

Data was analysed using descriptive and inferential statistics via the SPSS version 22 [35] through independent t test, paired t test and Chi-square test considered. The level of significance was considered (0.05) at all stages Multivariable logistic regression was performed to determine if findings persisted following adjustment for potential confounders. Confounders were selected for inclusion in multivariable models from variables that were significantly related ($P < .05$). Due to lack of normal distribution of data in the sleep quality components, and to adjust the effectiveness of pre-intervention scores, the difference between before and after intervention scores was calculated and then the Wilcoxon test was used for comparison of components between the groups.

3. Results

A total of 104 older adults were initially screened based on eligibility criteria, but 8 excluded because of ineligibility and 16 who were not eager to participating in the study. Thus, 40 participants were allocated into each group. Finallyof 80 older adults who agreed to participate in this study, two people were excluded because of headache through aromatherapy and lack of following up the aromatherapy program according to the instructions. Therefore, the data analysis was conducted on the data collected from 38 people in the intervention group and 40 people in the control group (Fig 1).

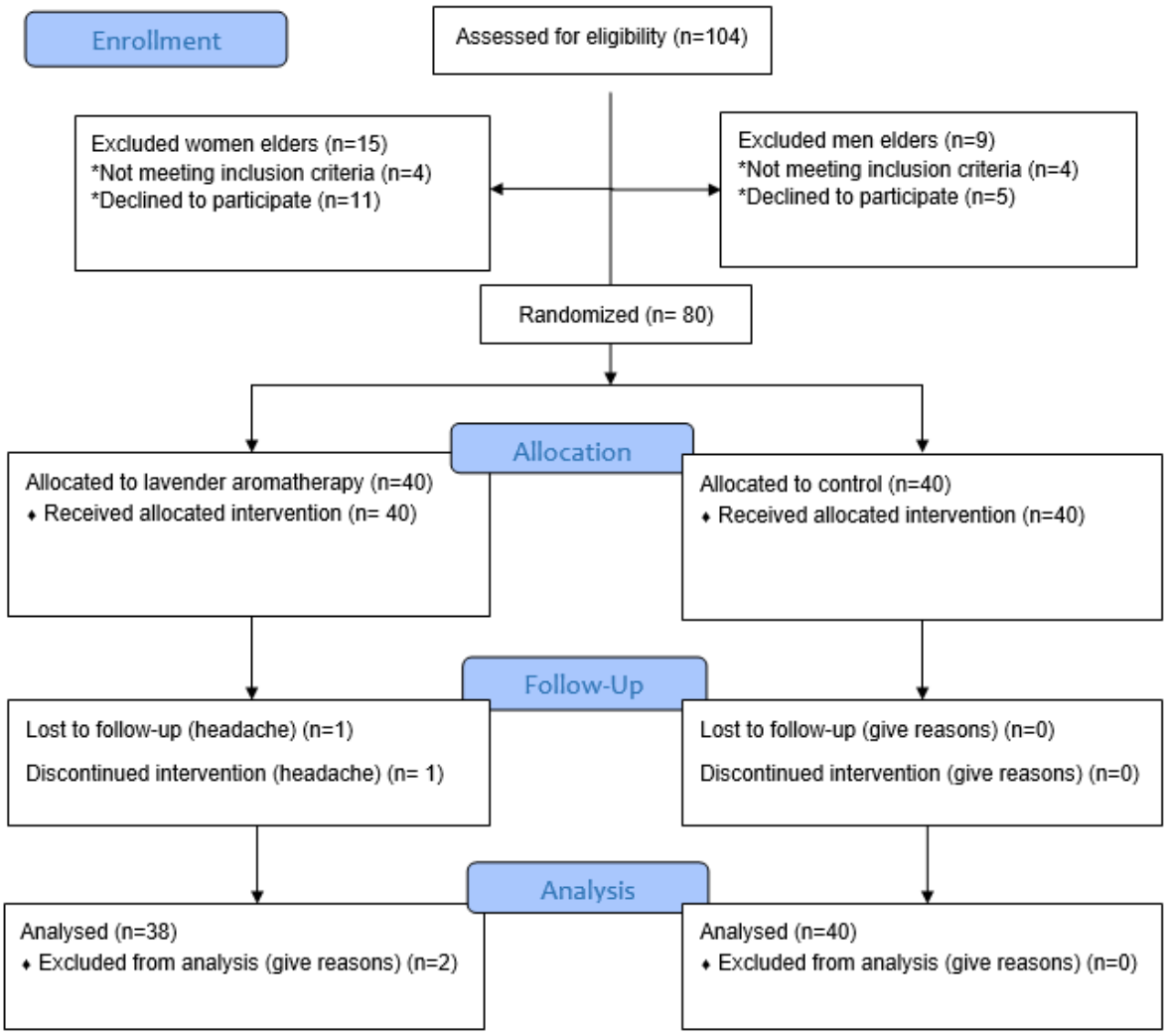

Figure 1. Flowchart of the study

The groups were homogeneous in terms of socio-demographic characteristics and no statistically significant differences were found between the groups (Table 1).

Table 1. Comparison of baseline characteristics in study groups

Characteristics	Intervention group N **(%)**	Control group N (%)	$\chi 2$ value	*P-*
	n=38	**n=40**		
Age	63.92(2.04)	63.70(1.98)	t = 279.40	P***=0.99
Education				
Illiterate	2(5.3)	6(15)		
Elementary	5(13.2)	4(10.0)		
High school	4(10.5)	4(10.0)	$\chi 2$= 2.1	P*=0.72
Diploma	11(28.9)	10(25.0)		
University	16(42.1)	16(40.0)		
Job				
Retired	29(76.3)	26(65.0)	$\chi 2$=1.2	P**= 0.32
Worker	9(23.7)	14(35.0)		
Income Status				
I=O	22(57.9)	25(62.5)		
I>O	5(13.2)	5(12.5)	$\chi 2$=018	P**=0.94
I<O	11(28.9)	10(25.0)		
Children				
zero	2(5.3)	3(7.5)		
One	1(2.6)	4(10.0)	$\chi 2$=4.11	P**=0.53
Two	16(42.1)	16(40)		
Three	11(28.9)	8(20.0)		
Four	6(15.8)	4(10.0)		
More	2(5.3)	5(12.5)		
drugs				
Hypnotic	5(13.2)	6(15.0)	$\chi 2$=0.17	P**=0.91
Other drugs	19(50.0)	21(52.5)		
none	14(36.8)	13(32.5)		
Chronic Diseases				
Yes	29(76.3)	29(72.5)	$\chi 2$=014	P**=0.7
No	9(23.7)	11(27.5)		

Mean (SD), Data represent number (%) except otherwise indicated, * Fisher Exact Test, **Pearson Chi-Square, ***Independent-T test

The means of the PSQI in the intervention group before and after the intervention were 14.18 (4.5) and 5.89 (3.99), respectively, which were statistically significant (P < 0.001). Also, similar statistically significant differences were found

between the components of the PSQI before and after the intervention (P < 0.001). The only exception was observed in daytime dysfunction component (P = 0.28). The comparison of the means of the PSQI before and after the intervention in the control group showed no statistically significant differences in none of the components (P = 0.57), except sleep disturbances component (P = 0.04) (Table 2).

According to the logistic regression analysis, sleep quality was considered dependent variable and age, presence of the watch in the sleep room, the use of therapeutic pillow and mattress, background diseases, use of medication and aromatherapy as the independent variables entered the data analysis. The result was that the logistic regression model with the presence of aromatherapy as the independent variable was able to predict the dependent variable (Table 3).

Table 2. Mean (SD) Scores based on Pittsburgh Sleep Quality Index between two groups

*Paired T-test

	Intervention Group n=38				Control Group n=40			
	Before Mean(SD)	After Mean (SD)	Confidence Intervals (95%)	P	First Assessment Mean (SD)	Second Assessment Mean(SD)	Confidence Intervals (95%)	P
Sleep Quality	0.84(2.31)	0.65(1.07)	1.65 (1.23 ,2.07)	P**<0.001	2.02(1.02)	2.12(0.99)	-0.1 (-0.28, 0.08)	P**= 0.21
Sleep Latency	1.52(0.82)	0.60(0.63)	0.92 (0.66 ,1.17)	P*<0.001	1.52(0.67)	1.60(0.74)	-0.07 (-0.25, 0.10)	P*= 0.41
Sleep Duration	1.92(1.02)	1.02(1.10)	0.89 (0.49 ,1.29)	P**<0.001	1.72(1.17)	1.80(1.11)	-0.07 (-0.35, 0.20)	P**= 0.58
Sleep Efficacy	1.42(1.32)	0.76(1.14)	0.65 (0.21, 1.09)	P*= 0.005	1.40(1.29)	1.37(1.31)	0.02 (-0.19, 0.24)	P*=0.82
Sleep Disturbances	5.94(3.54)	2.28(2.34)	3.65 (2.74, 4.56)	P*<0.001	5.90(3.85)	5.42(3.92)	0.47 (0.01, 0.93)	P*=0.04
Sleep Medications	0.52(0.89)	0.21(0.62)	0.31 (0.14, 0.48)	P**<0.001	0.27(0.71)	0.27(0.71)	0	P**= 1.00
Daytime Dysfunctions	0.52(1.08)	0.34(0.66)	0.18 (-0.15, 0.52)	P*= 0.28	0.50(0.84)	0.47(1.01)	0.02 (0.14, 0.19)	P*=0.76
Total Score	14.18(4.5)	5.89(3.99)	8.28 (7.05, 9.51)	P**<0.001	13.35(5.36)	13.07(5.69)	0.27 (-0.42, 0.97)	P**=0.57

*Wilcoxon

Table 3. Logistic regression analysis with sleep quality as the dependent variable and the variable of interest plus possible confounders

Dependent variable	Variables	β	Wald statistic	P-value	Odds Ratio	Confidence Intervals (95%)	
						Lower bound	Upper bound
Sleep Quality	**age**	-.04	.07	.79	.95	1.36	.66
	clock	1.21	1.63	.20	3.37	21.77	.52
	Lack of medical pillow	23.37	.00	.99	1.41	-.	.00
	Disease related to sleep quality	-1.84	2.52	.11	.15	1.53	.01
	Hypnotic drugs	Referent	1.43	.48			
	Other drugs	-.23	.03	.84	.78	8.65	.07
	No drugs	-1.28	.82	.36	.27	4.44	.01
	No intervention with lavender	2.11	6.12	0.01	8.28	44.18	1.55
	scores	-18.48	.00	.99	.000		

4. Discussion

The results of this study indicated the effectiveness of lavender essential oil aromatherapy on sleep quality in older adults. Mean changes were significant for all components of all PSQI's except daytime dysfunction. The most effect of aromatherapy was on sleep quality and sleep latency. Since the sleep latency is associated with daily anxiety and stress, the less the individuals' stress and anxiety, the sooner they go to sleep and thus, the shorter the sleep latency [36]. Also, sleep disturbances were reduced by lavender aromatherapy. The results of a study by Lillehi et al. (2014) are consistent with our results who reported that lavender aromatherapy improved the subjective sleep quality and patients felt refreshed waking and less daytime fatigue [37].

However, the difference between the study groups in terms of daytime dysfunction was not significant. A probable reason was that the older adults during aromatherapy had no problem in daily activities and staying awake for social activities due to being retired from social activities. In the control group no statistically significant differences were found in none of the components except the sleep disturbances, which can be attributed to relieving sleep disturbances due to sleep medications or the change of their sleep patterns. More studies are suggested to discover the reason for such a finding.

Lavender as an herbal medicine through influencing the limbic system, producing γ-amino butyric acid and inhibiting the release of acetylcholine can improve the quality of sleep and sleep disorders [38]. It appears that these issues justify the reason for the findings of the current study. Since sleep quality is influenced by personal factors such as age [39], health and diseases [40] and occupation [41], aromatherapy using lavender can improve older adults' sleep without influencing the above-mentioned factors. The results of the studies by Li-Wei Chien et al. (2011) [27], lee Jie et al. (2011) [42], Ezgi Karadag et al. (2008) [41] and Lewith et al. (2005) [43] are consistent with our results. The study by Lytel et al. (2014) [40] reported that lavender aromatherapy had no statistically significant effect on patients' sleep quality and vital signs in the intensive care unit. Wiliams et al. (2006) [44] found that lavender aromatherapy had no significant effect on sleep quality in children suffering from autism. Lee Sung et al. (2004) [45] studied the effects of lavender aromatherapy and eucalyptus on mothers' sleep quality and fatigue in the postpartum period. They reported no statistically significant change in sleep duration quality. Raudenbush et al. (2003) [46] studied the effect of Jasmin and lavender on sleep quality and cognitive performance and found no statistically significant differences on the dependent variables. In spite of these controversial results, lavender aromatherapy can improve sleep quality among older adults in the current study.

This contradictionof studies is probably due to limited duration of aromatherapy from a few hours to a few days, limited samples size, and no enough blindnessin the interventions of these studies. Another limitation of the Lee Song's [45] study was that the measurement of the precise effect of aromatherapy on the quality of sleep was impossible. In the study of Raudenbush, (2003) [46] was inadequate blinding may influence participants' reporting, objective outcomes are less at risk of distortion. The study of Lytle [40] was affected by the pilot methodology and duration of intervention and the self-administered and subjective nature of data collection tool.

Therefore, the above-mentioned limitations were controlled in the current study for providing more accurate findings with the possibility of generalizable results.

In this study, the logistic regression model in the presence of aromatherapy as the independent variable could predict the dependent variable. None of the confounders influenced the dependent variable ($P > 0.05$). Also, even after the deletion of all confounders, aromatherapy had a predictive effect on sleep disturbances (OR = 8.28, CI = 1.55-44.18, P = 0.01). In other words, without aromatherapy using lavender in the control group, the chance of sleep disturbances was 8.28 times greater than the intervention group. Therefore, it can be concluded that aromatherapy have improved sleep quality among older adults. Our findings are in line with those of Ko-ye Jung (2012) [47] with the aim of studying the effect of aromatherapy using lavender on sleep quality, stress and depression among older adults hospitalized in a hospital in Korea and Moeini et al. (2010) [48] with the aim of lavender aromatherapy on sleep quality among older adults hospitalized in the intensive care unit of a hospital in Isfahan, Iran.

5. Limitation of study

Although many limitations of the literature on aromatherapy, have already been mentioned, they are briefly summarized here. Different limitations may have affected the findings of the study. Larger, randomized control trials are needed on each of these therapies using more standardized protocols and more objective variables [49].We did not evaluate the participant's psychological indicators such as stress, pain and anxiety mood level that can accelerate or modify the sleep quality [50] as the control of confounders influencing sleep quality is recommended.

Because of the distinct perfume of lavender oil, it was difficult to use a placebo in this study. Older adults may have recognized the lavender oil perfume. As the study was not used placebo, the possibility of a placebo effect cannot be ignored.

6. Conclusion

The pilot study indicates positive findings

Our findings seem to confirm that aromatherapy using lavender essential oil with minimal risk [51] improved sleep quality in older adults. Therefore, it can be used as a non-invasive, easy and cost-effective [52] method for improving their sleep quality by nurses. It is suggested that is used the older people's health program along with the safe methods of care for improving their health condition. Nurses and were enthusiastic about using aromatherapy as sleep- promoting nursing interventionsin in their care, but they lacked knowledge about it. The status of CAM in nursing education programs must be examined.

Conflict of interest

There are no known conflicts of interest and no competing financial relationships exist.

Acknowledgments

We appreciate research deputy of Tabriz University of Medical Sciences for their financial support, the authors would like to thank the participants, Monempoor healthcare setting staff of the research zone and the Hakim Razi Co.

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