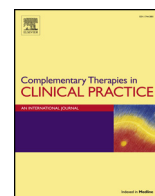




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Comparing the effects of massage and aromatherapy massage with lavender oil on sleep quality of cardiac patients: A randomized controlled trial



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ABSTRACT

Introduction: Sleep disorder is a common problem in cardiac patients. This study aimed to investigate the effect of massage and aromatherapy massage on sleep quality of cardiac patients.

Materials and methods: in this study, 150 subjects were randomly allocated into 1)massage, 2)aromatherapy massage and 3)control. In the massage group, the subjects received hands and feet massage using sweet almond oil. In the second group, the massage was performed on the same areas using a mixture of lavender and sweet almond oil. Data collection tool included Pittsburgh Sleep Quality Index (PSQI). Before and after the intervention, the PSQI was completed by the subjects.

Results: There was a significant difference between the mean scores of PSQI before and after the intervention in the intervention and control groups, but this difference was not statistically significant between the two intervention groups.

Conclusion: Massage and aromatherapy massage can improve the sleep quality in cardiac patients.

1. Introduction

Evidence suggests that sleep quality of patients admitted to cardiovascular units is not desirable for various reasons such as pain, fear of death, and invasive procedures and these patients may be awake for about 30%–40% of their sleep time [1,2]. The relationship between inadequate sleep and cardiovascular disease has been proven by the research [3–5]. Poor quality of sleep, as a stressful condition, causes the release of epinephrine and norepinephrine, which increases the need for oxygen for myocardium that leads to ischemia. Although medication improves the quality of sleep in patients, multiple complications of sleep drugs and the response of individuals to them are critically important [6]. Non-pharmacological methods that are called complementary therapies are safer and less harmful than drug treatments [7]. One of these methods is aromatherapy. Aromatherapy, which is a type of complementary therapy, has recently attracted the attention of many researchers [8]. Aromatherapy means the purposeful use of aromatic oils to promote and improve health [9]. Aromatherapy is used through massage, inhalation and bathing with mineral and herbal substances [7]. One of these aromatic oils is lavender. The results of various studies have shown the sedative and analgesic properties of this

plant [7,10–12]. Linalool and Linalyl acetate are the main components of lavender. These compounds have analgesic and sedative properties, stimulate the parasympathetic system that leads to decreased heart rate and improved heart function [7]. Massage is also one of the complementary therapies used in health care as an adjunct therapy [13]. Massage can stimulate the central nervous system and lead to a decrease in heart rate and respiration, creating a sense of calm [14]. If massage is performed along with aromatic oils, it is called aromatherapy massage, in which case these oils can quickly get absorbed by skin and enter the bloodstream [15,16]. Several studies have examined the role of massage and aromatherapy massage in improving sleep quality. In this regard, the results of Jacobs et al. (2016) and Kashani et al. (2014) studies showed that massage has a positive effect on sleep quality [17,18]. However, in a study of Williams (2006), the aromatherapy massage with lavender did not affect the quality of sleep [19]. Also, the results of Park et al. (2012) study showed that, massage, and aromatherapy massage had the same effect on the quality of sleep in cardiac patients [20]. The results of a clinical trial showed that, adding lavender oil did not increase the effect of massage [21]. On the other hand, Oshvandi et al. (2014) pointed to the positive effect of foot massage on improving the quality of sleep in cardiac patients [6]. In the

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studies conducted on the effects of massage and aromatherapy massage on the quality of sleep, the important point is to note the contradictory and controversial results. Therefore, the researcher in this study decided to study the effect of two methods of massage and aromatherapy massage on the quality of sleep in patients with heart disease.

2. Research hypotheses

The research hypotheses were:

1. Massage may improve the quality of sleep in cardiac patients.
2. Aromatherapy massage may improve the quality of sleep in cardiac patients.
3. Massage and lavender oil aromatherapy massage may improve the sleep quality of cardiac patients.

3. Materials and methods

3.1. Trial design

This randomized clinical trial was conducted over 6 months between December 2016 and May 2017.

3.2. Participants

The research population comprised of all patients admitted to the medical wards of Imam Ali Hospital in Kermanshah (a city in the west of Iran). The inclusion criteria included having consent to participate in the study, being diagnosed with cardiac disorders, both male and female sexes, being between 18 and 65 years old, having stable vital signs, obtaining scores of greater than five from the PSQI, having no history of allergies or eczema, being hospitalized for at least 48 h, being a no smoker and having no drug and/or alcohol addiction, having no history of neuropsychiatric disease and taking psychiatric medications, not having any physical pain, not drinking caffeinated beverages 1 h before going to bed, and having no coagulation disorders (as the massage can then be associated with complication). The exclusion criteria included: discharge before the end of the study period, patient's unwillingness to continue with the study, patient's malaise during the study, and receiving benzodiazepines, opiate, sedation and/or oxygen, on the nights of the intervention.

3.3. Sample size

The sample size was calculated according to Ashwandi et al. study [6] assuming $\sigma = 3.24$ and the mean of intervention and control groups 18.90 and 15.33 respectively, with the confidence level of 95% and the test power of 90%. The minimum sample size was estimated to be 38 individuals per group but in order to enhance the power of the study and obtain more reliable results, 50 subjects were assigned in each group and a total of 150 patients were examined. The formula used to determine the sample size was as follow:

$$n = \frac{2\sigma^2(z_{1-\alpha} + z_1 - \beta)}{(\mu_1 - \mu_2)^2}$$

$$n = \frac{2(2.92)^2(5.66^2 + 4.87^2)}{(18.90 - 15.33)^2} = 38$$

3.4. Outcomes

The data gathering tool in this study included Pittsburgh Sleep Quality Index (PSQI). The socio-demographic questionnaire was used to collect of socio-demographic and clinical characteristics of the participants. The socio-demographic questionnaire was designed by the

researchers and contained 17 questions related to age, gender, level of education, marital status, place of residence, history of diabetes, history of hypertension, history of smoking, history of heart attack, history of heart surgery, history of drug use, history of infection and skin disease, history of hemorrhagic diseases, history of massage and aromatherapy massage, and taking anticoagulant medications. Quality of sleep was assessed by the PSQI. The validity of this tool has been confirmed in several studies [22,23]. Buysse et al. (1989) used the Cronbach's alpha coefficient and obtained the internal consistency of 0.83 for the PSQI [24]. Reliability and validity of the Persian version of the PSQI has been approved by Farahi-Moghadam in Iranian society with Cronbach's alpha coefficient of 0.77 [25]. The reliability of the PSQI has been reported 0.88 by Hosseinabadi et al. [26]. The PSQI consists of seven components and nine questions, but question 5 has 10 sub-questions, therefore in general, this index contains 19 questions with the score of 0–3 in a 4-point Likert scale. The total score of the PSQI is between 0 and 21. Obtaining a total score of more than 5 from the PSQI indicates a serious sleep problem [26–28]. Before the intervention, the PSQI was completed by the subjects. Since some of the subjects in this study had a low level of education, the questionnaire was completed by patients in the presence of researcher in order to provide the necessary explanations if needed. On the morning of the eighth day, when the patients were awaked and were ready to respond, the PSQI was completed by them once again (Fig. 1).

3.5. Randomization

Eligible subjects entered the study by convenient sampling then, using block randomization, they were randomly assigned into three groups of massage, aromatherapy massage and control. Due to the existence of three independent groups in the present study, 24 blocks of six were formed. Patients who had the inclusion criteria were included in the study by convenient sampling method and subjects were randomly assigned into one of the two intervention groups and the only control group. In fact for three groups of the study a block of six from all 24 blocks of six were randomly selected and patients, as specified in the block, were assigned to first treatment group (A), second treatment group (B) and control group (C). In this way, six patients (in each group, two patients) were studied each time. For the next time another block was chosen randomly and patients were allocated to one of the three groups of the study according to the selected block. Some blocks of six were as follow: AA BB CC, AB AB CC, AC BB CA.

3.6. Interventions

This study was approved by the Research and Technology Deputy of Kermanshah University of Medical Sciences with the number: 95554. After receiving permission from the authorities of Imam Ali Hospital, the sampling was conducted. At first, the purpose of this study was explained to subjects as well as to their family members, and then, patient's consent to participate in the study was obtained from them and they were also assured their information and answers would remain confidential. Additionally, we informed the patients of being completely free to leave the study at any time with any reason. The intervention in both groups for female subjects was carried out by the researcher who is also a female herself, and for the male patients, a trained male nurse performed the intervention. In order to provide standard massage, both therapists studied a book about massage and aromatherapy [16]. Additionally, educational video clips were viewed on this subject. Then both therapists were trained by a physical medicine specialist. First, the therapists merely saw four massage treatments performed by a specialist, during which, necessary explanations were provided by him. In the following training sessions, each of the therapists performed two massage treatments independently in the presence of the specialist. Eventually the physical medicine specialist confirmed the competency of both therapists. The intervention was performed for

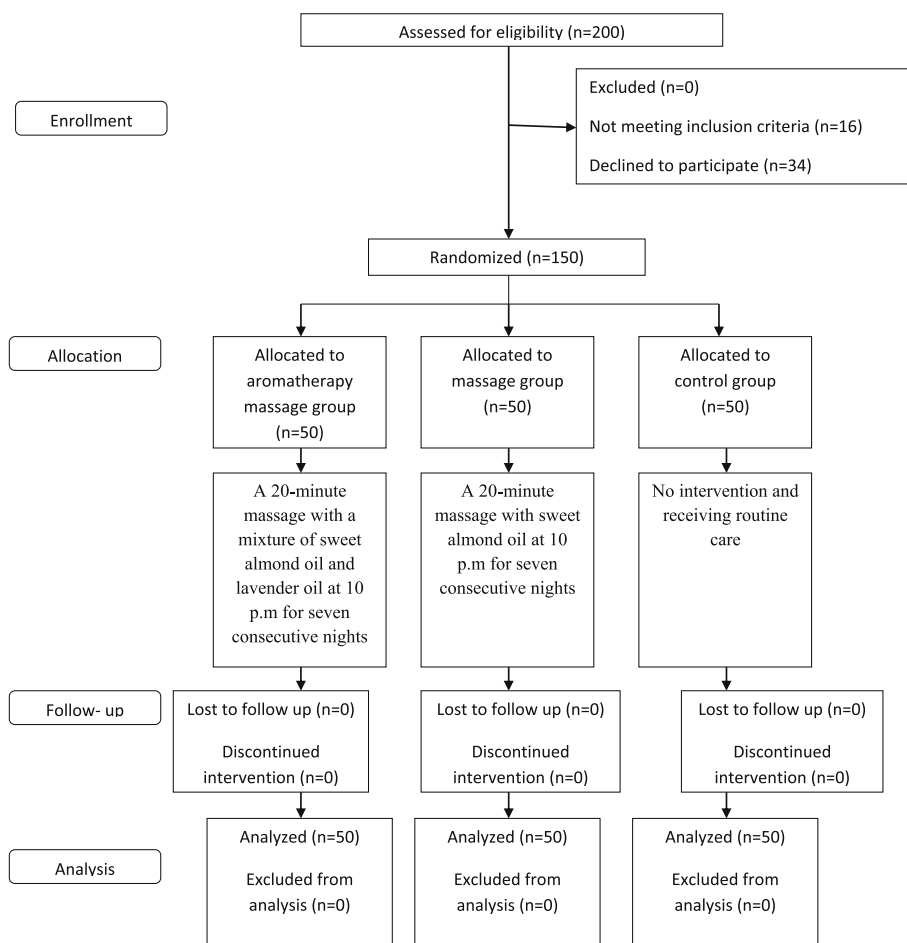


Fig. 1. Consort diagram of the study.

seven nights before sleep at 10 pm. In the massage group along with usual care, using sweet almond oil, the hands and feet (both feet from sole of the foot to the knee and hands from palm to the elbow) were given a massage for 20 min. This duration (performing massage for 20 min) is supported by various studies [20,29–31]. On each leg, the simple massage was started from the sole of the foot with the movements of thumbs from the fingers to the heel. Then, applying a deep pressure by the palm of the hand, the posteriors sides of legs were massaged from the ankle up to the knee and then back down to the foot with gentle pressure. On each hand, the simple massage was started from the palm of the hand with the movements of thumbs from the fingers to the wrist. Then the posterior sides of the hands were massaged by deep pressure applied with the palm of the hand and then back down to the wrist by gentle pressure. Meanwhile, in aromatherapy massage group along with usual care the same areas with the same technique were massaged for 20 min using a mixture of lavender and sweet almond oil (10–15 mL of sweet almond oil mixed with lavender essential oil with dilution of 1.5%). The concentration of essential oil used in this study was based on the literature review, which showed that studies have used both concentrations of 1 and 2%. Therefore, in the present study, the mean concentration of 1.5% was used [19–21]. The sweet almond oil and the lavender essential oil were provided by Barij Essence Pharmaceutical Company (Kashan, Iran). The Control group received routine care.

3.7. Blinding

All study interventions were performed by the same researchers who were not blind to the study.

3.8. Statistical methods

Data were analyzed by the Statistical Package for the Social Sciences (SPSS V.22.0; SPSS Inc., Chicago, IL, USA). The Kolmogorov-Smirnov test was used to determine the data normality. Also, to investigate the homogeneity of the groups, one-way ANOVA was applied for age and body mass index variables that had abnormal distribution. For variables with non-normal distribution such as work experience, Kruskal-Wallis H test was used to determine whether or not the groups are homogeneous in terms of these variables. Considering the significant difference in the history of high blood pressure among the study groups, the classification method was used to control its confounding effect on the results. The Chi-square test was carried out to examine the qualitative variables such as gender and history of taking hypnotics. The Kruskal-Wallis H test was also used to compare the three groups in terms of sleep quality. In order to compare the groups two by two in terms of sleep quality, the Mann-Whitney U test was used. Also, to compare each group before and after the intervention, the Wilcoxon signed rank test was performed. The significance level was set at 0.05.

3.9. Ethical considerations

This study was approved by the Ethical Review Committee of Kermanshah University of Medical Sciences with reference number: ir.kums.rec.1395.511. It was also registered at the Iranian Registry of Clinical Trials with the registration number: IRCT201603094736N12. The study procedure was explicitly described for all subjects and they were assured that their information would remain completely confidential. Furthermore, the written informed consent was obtained from

Table 1
Demographic characteristics of samples in massage, aromatherapy massage and control groups.

Variables		Groups			P
		Massage	Aromatherapy massage	Control	
		No (%)	No (%)	No (%)	
Age	20–35	6 (12)	6 (12)	5 (10)	0.722 ^a
	36–50	22 (44)	20 (40)	17 (34)	
	51–65	22 (44)	24 (48)	28 (56)	
	Total	50 (100)	50 (100)	50 (100)	
Gender	Female	21 (42)	22 (44)	20 (40)	0.921 ^b
	Male	29 (58)	28 (56)	30 (60)	
	Total	50 (100)	50 (100)	50 (100)	
Marital status	Single	2 (4)	2 (4)	3 (6)	. ^c
	Married	48 (96)	48 (96)	47 (94)	
	Total	50 (100)	50 (100)	50 (100)	
History of massage	Yes	2 (4)	4 (8)	3 (6)	. ^c
	No	48 (96)	46 (92)	47 (94)	
	Total	50 (100)	50 (100)	50 (100)	
History of aromatherapy massage	Yes	2 (4)	1 (2)	1 (2)	. ^c
	No	48 (96)	49 (98)	49 (98)	
	Total	50 (100)	50 (100)	50 (100)	
History of using hypnotic medication	Yes	9 (18)	6 (12)	8 (16)	0.698 ^d
	No	41 (82)	44 (88)	42 (84)	
	Total	50 (100)	50 (100)	50 (100)	

^a One-way ANOVA.

^b The Chi-square test.

^c Not analyzed.

^d The Chi-square test.

them and they were informed that they are free to leave the study if they wish to do so.

4. Results

From the total subjects, 74 were in the age range of 51–65 years. The mean and standard deviation of their age was 49.33 ± 10.55 years. Most of the patients (58%, n = 87) were male, married (83.3%, n = 143), urban residents (77.8%, n = 126), overweight (76.5%, n = 124) and had secondary school education (36.4%, n = 59). The medical diagnosis for most patients was coronary artery disease (58.6%, n = 95). Also, 18.5% of the participants (n = 30) had a history of diabetes, 26.5% (n = 43) had a history of hypertension, 34% (n = 55) had a history of myocardial infarction and only 3.7% (n = 6) had a history of valve replacement surgery. Statistical analysis indicated no significant difference in socio-demographic characteristics between the three groups except for the history of high blood pressure. The results of the classification method showed that study groups are significantly different in both layers with and without history of high blood pressure, therefore the confounding effect of this variable on the results was controlled (Table 1). Since, only patients with sleep disorder were included in the study, all subjects had poor sleep quality before the intervention. However, after the intervention the number of patients who had poor sleep quality dropped to only four patients in the massage group and three in the aromatherapy massage group. In the control group, 48 patients had poor sleep quality after intervention (Table 2). The Kruskal–Wallis H test showed that before the intervention the three groups of study were not statistically different from each other in terms of sleep quality, while there was a statistically significant difference between them after the intervention. Also the results of Wilcoxon signed-rank test showed a significant difference in the massage, aromatherapy massage and control groups before and after the intervention in terms of sleep quality. Although the sleep quality variable in the control group changed before and after the intervention, most patients (n = 48) in this group still had poor sleep quality

Table 2
Sleep quality in massage, aromatherapy massage and control groups.

Groups	Sleep quality score		
	Median ± IQR ^a before intervention	Median ± IQR ^a after intervention	Result of Wilcoxon signed-ranked test
Massage	10 ± 2	3 ± 1	Z = -6.191 P < 0.001
Aromatherapy massage	9.5 ± 2.5	3 ± 2	Z = -6/178 P < 0.001
Control	9 ± 1	8 ± 2	Z = -3/562 P < 0.001
Result of Kruskal-Wallis test	$\chi^2 = 1/643$ P = 0.44	$\chi^2 = 93/991$ P < 0.001	

^a Interquartile Range.

Table 3
Comparing the study groups in terms of sleep quality by Mann-Whitney U test.

Groups	Median ± IQR ^a after intervention	Test result
Massage	3 ± 1	Z = -8/182 P < 0.001
Control	8 ± 2	Z = -8/475 P < 0.001
Aromatherapy massage	3 ± 2	Z = -8/475 P < 0.001
Massage	3 ± 1	Z = -0.53 P = 0.59
Aromatherapy massage	3 ± 2	

^a Interquartile Range.

(Table 3). Since there was a significant difference between the three groups of massage, aromatherapy massage and control in terms of Pittsburgh sleep quality after the intervention, it seemed necessary to examine the groups two by two in terms of this variable. For this purpose, the Mann-Whitney U test was used. The results indicated no significant difference between the two groups of massage and aromatherapy massage in terms of Pittsburgh sleep quality after the intervention. However, the comparison of the two intervention groups with the control group showed a significant difference between them in terms of sleep quality after the intervention. No adverse effects were observed during the study period.

5. Discussion

The aim of this study was to investigate the effect of aromatherapy massages (using sweet almond oil and lavender) and massage alone (using sweet almond oil) on the quality of sleep in patients with heart disease. The results showed that sleep quality in the massage and aromatherapy massage groups was significantly different before and after the intervention. This finding is consistent with the study of Oshvandi et al. [6], which aimed to investigate the effect of foot massage on the quality of sleep in patients with ischemic heart disease. Additionally, Kaur et al. (2014) in their study examined the effect of hand and foot massage on postoperative pain in patients with open heart surgery, and the results indicated that massage is effective in reducing pain [29]. Bahrami et al. (2017) also studied the effect of aromatherapy massage on anxiety, depression and physiological parameters in older patients with acute coronary syndrome, which showed a positive effect of this intervention on the variables [32]. Given the prevalence of pain and anxiety in cardiac patients, these patients experience significant level of pain and anxiety depending on the severity of their disease. Pain and anxiety can affect the quality of sleep. Therefore, given the positive impact of massage and aromatherapy massage on the pain and anxiety of cardiac patients, these interventions can improve the quality of sleep in cardiac patients by reducing their levels of pain and anxiety. In spite of the differences in the methods of intervention in our study and the

studies of Bahramiet al. and Kaur et al., we can say that the results of our study are in line with the results of these studies.

Studies have provided various reasons for the positive impact of massage on sleep quality. While the main mechanism of massage is still unknown, various physiological responses have been suggested in this regard. These mechanisms include increased lymph flow throughout the body, shifting the autonomic nervous system (ANS) from a state of sympathetic response to a state of parasympathetic response, and increased blood lactate clearance [33–36]. Massage, by making local biochemical changes, may lead to increased neurological activity at the spinal cord and subcortical nuclei, affecting the patient's perception of pain. In general, massage potentially decrease anxiety, depression and pain by increasing serotonin and endorphin [35–37]. However, Williams et al. (2006) in their study concluded that massage therapy with lavender essential oil had no effect on improving the sleep quality of children with autism [19]. Our results are not in line with this study. One of the main reasons for this discrepancy can be a very low sample size in the Williams' study compared to our study. The different method of aromatherapy massage and the lack of control group in the Williams' study can be considered as another possible reason for this discrepancy. On the other hand, the comparison of the two intervention groups in the present study showed that adding of lavender essential oil did not increase the effect of sweet almond oil, and both massage methods were equally effective in improving the quality of sleep in patients with heart disease. This result is in line with the findings of Park et al. (2016) study [20]. A noteworthy point in the Park et al. (2016) study is its study subjects that had been selected from patients with various diagnoses, which could have limited its generalizability to cardiac patients. Among other factors that have limited the generalizability of Park et al. study is its relatively small sample size (30 patients) and the relatively short duration of intervention period (5 days), while in our study, the sample size was larger and the duration of the intervention was longer. Babashahi et al. (2012) concluded that aromatherapy massage was more effective than almond oil massage in reducing preoperative anxiety [30]. As patients with heart problems have serious health concerns and are very afraid of heart attack, this anxiety can cause sleep disturbances in them and reduce their sleep quality. Considering the positive effect of the two methods of aromatherapy massage and massage with almond oil in the study of Babashahi et al., it is likely that these methods have been effective in reducing the anxiety and subsequently improving the sleep quality of cardiac patients; the result that we also achieved in our study. On the other hand, the results of above study showed that aromatherapy massage was more effective than massage with almond oil alone, but we did not find a statistically significant difference between the two methods of massage. The reason for this discrepancy can be related to the difference in the sample size in the two studies. Additionally, in the Babashahi's study the back of patients was massaged, while in our study we performed massage on the hands and feet of patients. Therefore, the difference in the location of the massage may also be another reason for this discrepancy. It should be noted that in our study the sample size was larger.

We encountered several limitations in the current study. The subjects were massaged by two therapists, which can be considered as the main limitation of this study. Although both therapists were trained by identical specialist, studied same book [16], and same article [38] also watched similar educational films, performing massage by two therapists could have affected the outcome of study. Additionally, in the statistical analysis, it was not possible to study the homogeneity of the groups in terms of marital status, and the history of massage and aromatherapy massage due to the high number of cells with a frequency of less than five. Environmental factors such as noise and light can disturb the patients' sleep. The researcher made every effort such as remove extra lights and minimizing environmental sounds such as the sound of devices to reduce these factors. Each person may also have a unique sleep pattern that could have affected the outcome of the study.

6. Conclusion

The results of this study showed that massage and aromatherapy massage with lavender oil can help to improve the sleep quality of cardiac patients. Therefore considering the positive impact of the mentioned methods, their affordability, and lack of any reported adverse effects, the use of massage and aromatherapy massage is recommended to improve the sleep quality of cardiac patients. In our study, only cardiac patients were examined. Therefore, it is suggested that more studies should be designed and conducted to assess the effect of aromatherapy massage and massage on the sleep quality of other patients. Since the use of objective tools such as Polysomnography provides a better understanding of patients' sleep quality status, further research using this tool can provide more reliable findings on the effects of aromatherapy massage and massage on the sleep quality.

Conflicts of interest

No Conflict of interest.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.ctcp.2019.03.005>.

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