

The Efficacy of Aromatherapy With Lemon Balm (Melissa Officinalis L.) on Sleep Quality in Cardiac Patients: A Randomized Controlled Trial

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Research

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Abstract

Background: The importance of sleep in physical and mental well-being is generally acknowledged by both health professionals and the general public. This study investigated the effects on inhalation aromatherapy on sleep quality in cardiac patients.

Methods: Ninety-six men and women aged between 20 and 75 were randomized to inhale aromatherapy essential oil from Lemon Balm (*Melissa officinalis* L.) or odorless sesame oil (the placebo) for 30 minutes twice daily for 3 days. Sleep quality by Verran Synder- Halpern (VSH) scale were assessed before and after period.

Results: Compared with the placebo, the experimental group showed that the components such as subjective sleep quality, sleep disturbance, and daytime dysfunction were significantly decreased ($P < 0.005$).

Conclusion: Aromatherapy may be used as an independent nursing intervention for improving sleep quality of cardiac patients.

Background

Cardiovascular disorders are among the primary causes of morbidity and mortality so that they account for 40% of total cardiovascular deaths, especially coronary artery diseases (CADs) [1]. Studies have shown that there will be 25 million cardiovascular victims by 2020. Current statistics indicate that 50% of annual mortalities are induced by CADs. They not only account for a high percentage of deaths [2], but also impose some constraints in the long run on individuals' lives via impairing the general health of the community due to their debilitating nature leading to reduced patient survival [3]. The research conducted so far suggest that the cardiovascular diseases are an influential factor in diminished quality of sleep. The results of the study by Chen (2009) demonstrated that 74% of heart failure patients suffer from sleep disorders. Various factors are related to sleep problems in these patients. These include beta blockers, diuretics, and inhibitors of angiotensin convertor enzyme, presence of respiratory problems, pain, and stress. Moreover, ICU hospitalization may affect the sleep quality in these patients. The factors that impair sleep in ICU/CCU patients include cardiac monitoring and the noises in the ICU ward, lights and illumination, other patients' coughing and moaning, continual care, and personnel's noises during doing their shift [4, 5]. Reduced sleep quality in cardiac patients exerts some negative physical and mental effects, violence, and long hospital stay [6]. Given the numerous effects of sleep on physical and social performance, the diminished sleep quality imposes some problems on the patients, finally predisposing to reduced quality of life [7, 8]. Sleep deprivation in the short term produces some untoward sequelae in health individuals such as reduced glucose action, hypertension, increased cortisol level, and increased sympathetic system activity. Poor sleep quality or drowsiness during the day is associated with damage to health status, poor physical performance, discomfort and malaise, mortality, reduced quality of life, increased risk of affliction with mental disorders, and reduced daily performance [5, 9]. Today, only

medicines are used to control vital signs and sleep of patients in the ICU. Excess use of drugs, especially for elderly patients, induces some complications resulting in delayed recovery, increased hospital stay and costs [10]. To improve sleep quality and vital signs, complementary treatments like music therapy, aromatherapy, and massage therapy that are less expensive with lesser complications or even without any complications can be used. One method investigated in various countries is the effect of aromatherapy on improving concentration rate, decreasing pain and anxiety, etc. [11]. Lemon Balm (*Melissa officinalis* L.) is one of the herbs used in aromatherapy. It belongs to Lamiaceae family. It is used in some countries to treat migraneous headaches, insomnia, gastric problems, and improve heart and memory functions. It is also used as anxiolytic, narcotic, tranquilizer, and antispasmodic [12]. The essence/extract of this medicinal herb is used in various fields such as medical, nutritional, fragrance-making, and cosmetic applications. Its leaves contain 1-25% oily essence. It is highly popular in France so that it has been termed as French tea [13]. A review of literature yielded few studies on the effect of aromatherapy with Lemon Balm (*Melissa officinalis* L.) on sleep quality. One study showed that the use of *Melissa officinalis* L. capsules improves sleep quality in menopausal women. Besides, in another study by Heidari et al. (2015), this medicinal herb decreased depression in the medicinal herb group compared to the placebo group [14]. The use of complementary therapies is still controversial in the healthcare services. The presence of these doubts and suspicions in the community and even in the medical society forms a major challenge for the inclusion of these measures into the nursing performance. This necessitates the existence of a rich research reservoir for the rapid entrance of the category in nursing interventions since the presence of a suitable scientific guide for nurses enables them in providing high quality care on the basis of scientific evidence [15]. On the other hand, few studies have focused on the use of Lemon Balm (*Melissa officinalis* L.) in improving sleep quality of cardiovascular patients and thus necessitating the completion of the related studies [16]. So far, no study of this type has focused on this group of patients and it can be applied as an innovative method along with other treatment modalities. Consequently, the present study explored the effect of aromatherapy with Lemon Balm (*Melissa officinalis* L.) on enhancing sleep quality in CCU patients.

Methods

A single - blinded, randomized clinical trial was designed to investigate the effects of inhalation of aromatherapy with Lemon Balm (*Melissa officinalis* L.) on sleep quality in acute coronary artery syndrome patients.

Trial Participants:

Twenty-five males and twenty females volunteered to participate as the aromatherapy group and twenty-five males and twenty-two females participated as the placebo group of the study; they were aged between 20 and 75 years with acute coronary artery syndrome and were living in Iran. Two individuals did not meet the eligibility criteria and two withdrew their content to participate (Figure 1). The remaining 92 participants were told the purpose and protocol of the experiment and submitted written consent. The study design and protocol were approved by the Ethical Review Committee of the Shahid Beheshti

University of Medical Sciences in Tehran (code IR.SBMU.RETECH.REC.1398.057) and registered in Iranian Registry of Clinical Trials with no. IRCT20120215009014N304.

Inclusion criteria:

The detailed inclusion criteria were:

1. aged between 20 -75;
2. written diagnosis of acute coronary artery syndrome by cardiologist
3. absence of any olfactory problem
4. no history of asthma or allergies to pollen or plants
5. lack of affliction with known mental disorders and hypothyroidism
6. lack of use of other methods of complementary medicine over at least the past week.

Exclusion criteria:

Subjects were excluded when they met one of the following criteria:

1. Had hypothyroidism
2. Had asthma or other respiratory attack conditions
3. lack of cooperation

Criteria for discontinuation:

Subjects would be discontinued from the trial if one of the followings occurred:

1. Had cardiac dysrhythmia like ventricular tachycardia, ventricular fibrillation during the study.
2. Had and cardiogenic shock during the study.
3. lack of cooperation

Written informed consent

Written informed consent was obtained from all eligible participants. Consent form information included descriptions of the study background, detailed treatment procedures, and information on potential benefits and risks. Eligibility of participants was screened by an independent study evaluator. Consent forms were distributed to eligible participants and any questions or concerns regarding the informed consent were discussed. Voluntary signature on the consent form was obtained prior to recruitment.

Randomization and blinding

The patients were assigned to the two groups via lottery by selecting either the A or B ticket. Eligible participants were randomly allocated to one of the two study groups (aroma group and Placebo group) in a 1:1 ratio.

Drug Preparation

Lemon Balm (*Melissa officinalis* L.) as a fragrant herb [17] was first reported by Avicenna to have inotropic effects. Additionally, this herb was found to have strengthening effects on the heart, nerves, and brain with exhilarating effects, in particular [18] In addition, Lemon Balm (*Melissa officinalis* L.) is highlighted to have a role in overcoming nightmares, phobias, and palpitations [19] so far, no significant complications and pharmaceutical interferences have been reported about this herb [13] first, the extract and odorless sesame oil of Lemon Balm, required for the purpose of the study, were purchased from Herbal Extract Pharmaceutical Company under the Ministry of the Industry and Mines health license No. 6884/4.128. They were employed after determining their concentrations using the weighting method by the company.

Intervention

The patients were assigned to the two groups via lottery by selecting either the A or B ticket. It should be noted that the CCU healthcare staff were blind to the patient assignment into the aroma and placebo groups and were not aware of the interventions. First, the olfactory health of the study units was verified by the use of coffee. Then, the demographics questionnaire was completed. Aromatherapy was performed on the case group by attaching a cotton patch measuring 15 x 15 cm soaked in 3 drops of Lemon Balm (*Melissa officinalis* L.) extract to the collars of CCU patients for 30 minutes twice daily for 3 days (9 AM and 9 PM). The same procedure was done for the placebo group using only odorless sesame oil.

Outcome Measures

Sleep quality was measured using the Iranian translation from [20] of VSH Sleep Scale. Sleep quality scale was developed and used by Verran & Snyder in 1987. It is a 15- item visual instrument used to assess sleep in in-patients and measures the participant's perception of previous night's sleep. VSH is a valid scale that includes various parameters like sleep disorders, frequent nocturnal awakening, difficulty in falling asleep, and sleep duration. Each item may receive 0-100 points (measured for every 5 mm) and the participant marks their perception of sleep in this distance. It entails three major sleep scales including sleep disorder (interrupted sleep, delayed sleeping), efficacy (how far sleeping creates liveliness and freshness), and complementary sleep (daily napping and sleeping). The scores of these scales range respectively from 0-700, 0-500, and 0-400. Numerous studies have examined and approved the validity and reliability of this inventory. The study by Mashayekhi et al. (2015) that aimed at determining the validity and reliability of this scale on an Iranian population, confirmed the validity and reliability of this questionnaire [20].

Date Collection

Demographic characteristics and sleep quality were assessed on the day of admission. Outcome measures including sleep quality were assessed again after the last intervention.

Date Analysis

The gleaned data were analyzed using the SPSS software, version 23. The quantitative and qualitative data were described as mean \pm SD and percentage, respectively. In addition, Kolmogorov – Smirnov test and the nonparametric tests were used to examine normal distribution or lack of normality of the data. Finally, independent T-test, and paired T-test was applied to compare the sleep quality of the 2 groups.

Results

On the basis of the findings, most study units in the aroma (54.3%) and placebo (53.2%) groups were male and married. Also, most aroma (33.3%) and placebo (31.9%) patients were aged between 51 and 60 years and most aroma (37.8%) and placebo (46.8%) patients had free jobs. Moreover, the results indicated that the most frequent diagnosis made by the cardiologist was unstable angina. Also, 64.4% of aroma patients and 68.1% of placebo patients had a positive history of HTN, and 53.3% of cases and 44.7% of placebos had a history of DM. There was no significant difference between the aroma and placebo groups in demographic information (Table 1).

The results indicated no significant difference in sleep quality dimensions between the two groups before intervention ($P < 0.05$). Thus, the two groups were the same with respect to “sleep disorders”, “efficacy”, and “complementary sleep” before intervention. Independent t-test was used to compare sleep quality in the two groups after intervention. The aroma and placebo groups were significantly different after intervention in “sleep disorders”, “efficacy”, and “complementary sleep” ($P < 0.05$). As the findings suggest, the mean scores of sleep disorders and complementary sleep are smaller in the aromatherapy group compared to placebos whereas the mean scores of efficacy are greater in the aromatherapy group compared to the placebo group. Paired t-test was applied to examine the effect of treatment on sleep quality and compare the scores of sleep quality dimensions in each group before and after intervention. As it is displayed in the table, there was a significant difference in the mean scores of “sleep disorders” in the placebo group before and after intervention ($P = 0.045$); nonetheless, there was no significant difference in mean scores of “efficacy” and “complementary sleep” in the placebo group before and after intervention ($P < 0.05$). Additionally, the mean scores of “sleep disorders” and “efficacy” were significantly different in the aromatherapy group before and after intervention ($P < 0.001$) so that the mean scores of “sleep disorders” and “efficacy” increased after intervention; however, the mean scores of “complementary sleep” were not different significantly in the aromatherapy group before and after intervention ($P = 0.140$) (table 2).

Discussion

This study examined the effect of aromatherapy with Lemon Balm (*Melissa officinalis* L.) on the quality of sleep in CCU patients. The findings demonstrated a significant difference in sleep quality between the aromatherapy and placebo groups after intervention. In other words, aromatherapy with Lemon Balm (*Melissa officinalis* L.) improved sleep quality in patients in the aroma group. It appears that the effect of

aromatherapy on sleep quality of patients is related to anxiolytic and tranquilizing effects of this medicinal herb. A review of literature by the researcher yielded few studies on the effect of aromatherapy with Lemon Balm (*Melissa officinalis* L.) on sleep quality. Consistent with our findings, the double-blind study by Cerny & Schmid carried out in Germany examined the effect of the synthetic oral supplement of Lemon Balm (*Melissa officinalis* L.) and valerian on sleep disorders of healthy subjects. The patients received valerian cap 360 mg and *Melissa officinalis* L. cap 240 mg *per os* 30 min before bed time for one month. The visual scale of sleep quality (VSH) was used to collect the data. The results indicated improved sleep quality of the patients. However, there was no significant difference in having a good feeling between the two groups [21]. The two studies differed in type of intervention, target group, and the instrument used. Similar results were obtained despite these disparities in the two studies. Furthermore, the study by Taavoni et al. (2013) that investigated the effect of Lemon Balm (*Melissa officinalis* L.) on sleep disorders in menopausal women indicated that 20% of women using Lemon Balm and 8% of women using placebo showed signs of improvement in sleep quality indicating a statistically significant difference between the two. In the study above, Lemon Balm (*Melissa officinalis* L.) cap 250 mg was used for the aromatherapy group and starch cap for the placebo group and intervention consisted of taking the capsules every night for one month [13]. Nevertheless, in the present study, Lemon Balm (*Melissa officinalis* L.) essence was used for the CCU patients as aromatherapy. Besides, Verran & Snyder-Halpern Sleep Scale was used in the present study that is a suitable multi-dimensional instrument for investigating sleep quality. In the study by Cho et al. (2013), aimed at investigating the effect of aromatherapy on anxiety, sleep quality, and vital signs of the patients undergoing percutaneous transluminal coronary artery (PTCA) surgery, aromatherapy with a mixture of lavender, Roman matricaria and orange blossoms with 6:2:0.5 proportions resulted in a significant difference in anxiety between the aroma and placebo groups after intervention [22]. Other studies have explored the effect of Lemon Balm (*Melissa officinalis* L.) on other variables. In the study by Heidari et al. (2015), aimed at investigating the effect of Lemon Balm (*Melissa officinalis* L.) on patients' depression after CABG, 80 CABG patients were randomly assigned into drug and placebo groups. Intervention was given since the first postoperative day. In so doing, each patient received randomly either Lemon Balm (*Melissa officinalis* L.) 500 mg cap or placebo *tid*. After 7 days, depression was measured in the patients of the two groups. The results of the study above showed that Lemon Balm (*Melissa officinalis* L.) reduced depression in the drug group compared to the placebo group ($P=0.008$) [14]. Skoli et al. (2014) showed in their study that consumption of *Melissa officinalis* L. improved mood and cognitive performance [23]. Moreover, Kalvandi et al. (2014) revealed in their study that the use of Lemon Balm) *Melissa officinalis* L. and garden sage diminished significantly the severity of menstrual pain and duration [24]. Considering the results of the present study and those of similar ones, aromatherapy as one branch of complementary medicine may exert some positive effects on improving sleep quality in patients. Finally, inhalational aromatherapy with Lemon Balm (*Melissa officinalis* L.) essence can be used comfortably by nurses as a cheap, harmless, and effective method of complementary medicine not interfering with other medical care procedures. The present study has significant advantages with regard to studies on aromatherapy with Lemon Balm, because studies in Iran and abroad have not referred to the use of this herbal extract as aromatherapy. Besides, one weakness of previous studies is the lack of a placebo group. On the other hand, patients

with acute coronary artery syndrome are exposed to various stressors that intensify their anxiety impacting negatively all aspects of their lives, especially their sleep quality. This may exert detrimental effects on different systems of their body. Hence, to avoid the incidence of such conditions in patients, supplementary safe treatments ought to be applied by nurses along with common therapeutic modalities. The findings of this study are of utmost significance in helping patients to increase their sleep quality. The present study enjoys the strong point of having a placebo group that partially fills the gap in research in this domain. Other strong points of our study are random selection of the samples, single-blindness, and sufficient sample volume.

Conclusion

The results of the present study showed that aromatherapy with Lemon Balm (*Melissa officinalis* L.) improved sleep quality in CCU patients. Since sleep quality is of utmost significance for cardiovascular patients, the use of aromatherapy can serve as a cheap, safe, and complication-free method in alleviating the sleep disorders of patients leading to enhanced quality of sleep.

Abbreviations

(VSH) scale: Verran Synder- Halpern Scale

CADs: coronary artery diseases

ICU: Intensive Care Unit

CCU: Coronary Care Unit

HTN: Hypertension

DM: Diabetes Mellitus

PTCA: Percutaneous Transluminal Coronary Artery

CABG: Coronary Artery Bypass Graft

Tid: three times a day

Declarations

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Conflict of Interests

The authors declare that they have no conflict of interests.

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Availability of data and materials

The datasets used and/or analyzed during the current study would be available from the corresponding author on reasonable request after study completion.

Ethics approval and consent to participate

The study was approved by the Ethical Review Committee of the Shahid Beheshti University of Medical Sciences in Tehran (code IR.SBMU.RETECH.REC.1398.057) and registered in Iranian Registry of Clinical Trials with no. IRCT20120215009014N304. Written informed consent was obtained from all eligible participants.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests

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Tables

Table 1: Frequency distribution of demographic variables in the case and control groups

| P | Test | Placebo (n=47) N (%) | Aroma (n= 45) N (%) | Categories |
|----------|---------------------|-------------------------|------------------------|-----------------|
| | | | | Gender |
| P=0.83 | Chi-square test | 25 (53.2) | 25 (54.3) | Male |
| | | 22 (46.8) | 20 (46.7) | Female |
| | | | | Age groups |
| P= 0.72 | Mann-Whitney test | 7 (14.9) | 3 (6.7) | 31-40 |
| | | 12 (25.5) | 15 (33.3) | 41-50 |
| | | 15 (31.9) | 15 (33.3) | 51-60 |
| | | 13 (27.7) | 11 (24.4) | 61-70 |
| | | 0 | 1 (2.2) | 71-75 |
| | | | | Marital status |
| P=0.99 | Fisher's exact test | 3 (6.7) | 3 (6.4) | Single |
| | | 35 (77.8) | 35 (74.5) | Married |
| | | 2 (4.4) | 2 (4.3) | Divorced |
| | | 5 (11.1) | 7 (14.9) | Widowed |
| | | | | Diagnosis |
| P = 0.78 | Chi-square test | 25 (53.2) | 27 (60) | Unstable angina |
| | | 13 (27.7) | 10 (22.2) | NSTEMI |
| | | 9 (19.1) | 8 (17.8) | STEMI |
| | | | | History of HTN |
| P = 0.82 | Chi-square test | 32 (68.1) | 29 (64.4) | Yes |
| | | 15 (31.9) | 16 (35.6) | No |
| | | | | History of DM |
| P = 0.53 | Chi-square test | 21 (44.7) | 24 (53.3) | Yes |
| | | 26 (55.3) | 21 (46.7) | No |

Table 2: Comparison of mean scores of sleep quality and its dimensions in the study units before and after intervention in the aromatherapy and placebo groups

| | | Aroma group | Placebo group | Independent t-test | P |
|-----------------------------------|------------------------|----------------|------------------|-----------------------|--------|
| Mean ± SD | | | | | |
| Sleep disorder (0-700) | Before intervention | 403.33±140.95 | 387.94±144.274 | t=0.82 | 0.414 |
| | After intervention | 239.56±79.11 | 345.21±82.07 | t=6.28 | <0.001 |
| | Paired t-test | 9.29 | 2.06 | | |
| | P-value | < 0.001 | 0.045 | | |
| Efficacy (0-500) | Before intervention | 229.00±39.41 | 233.40±53.03 | t=0.45 | 0.653 |
| | After intervention | 369.33±33.75 | 252.34±32.19 | t=2.47 | 0.015 |
| | Paired t-test | 6.37 | 1.50 | | |
| | P-value | <0.001 | 0.144 | | |
| Complementary sleep (0-400) | Before intervention | 96.33±46.93 | 107.87± 56.41 | t=1.06 | 0.290 |
| | After intervention | 81.67± 44.18 | 109.04± 58.09 | t=2.53 | 0.013 |
| | Paired t-test | 1.50 | 0.17 | | |
| | P-value | 0.140 | 0.870 | | |

Figures

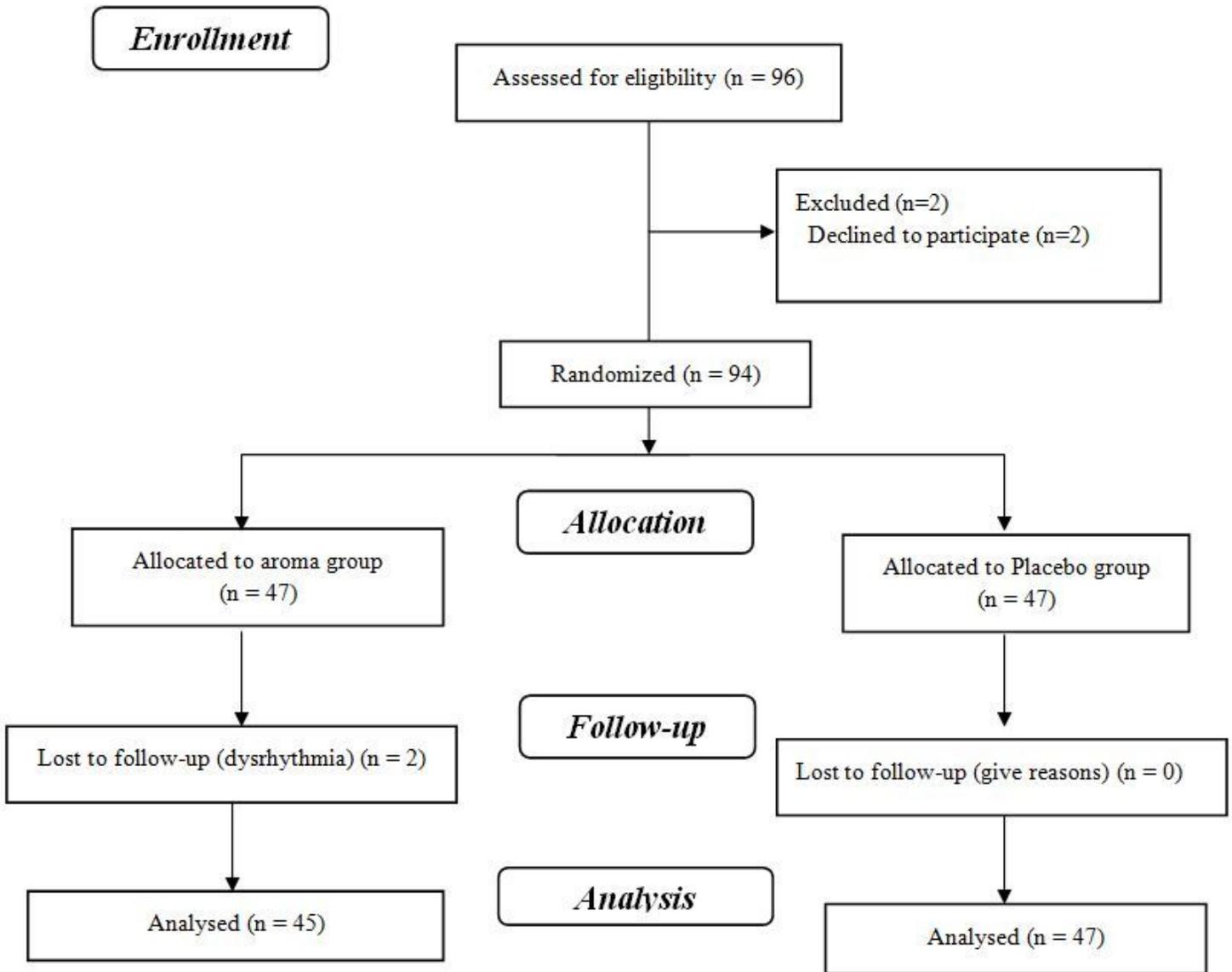


Figure 1

Randomization table