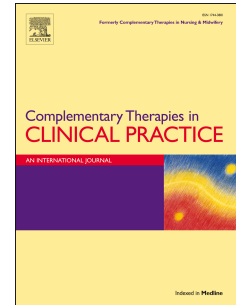


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Effects of geranium aroma on anxiety among patients with acute myocardial infarction: A triple-blind randomized clinical trial

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Conflict of interest statement

The authors declare that they have no conflicts of interest.

Authorship contribution

R, SH. has contributed to Study design, Data collection, Data analysis, Drafting the manuscript Writing, and Critical revisions of Final manuscript. M, GH. has contribute to Study design, Data collection, Study design, Data analysis, Study supervision, Drafting the manuscript writing , and

Critical revisions of Final manuscript. SH, H. has contribute to Study design, Data collection, Data analysis, Study supervision, Drafting the manuscript writing , and Critical revisions of Final manuscript. M, B. has contribute to Study design, Data collection, Drafting the manuscript writing, and Critical revisions of Final manuscript. A, B. has contribute to Study design, Data collection, Drafting the manuscript writing, and Critical revisions of Final manuscript.

Abstract

Objective: This study examined the effects of geranium aroma on anxiety among patients with AMI.

Methods: This randomized, triple-blind, placebo-controlled clinical trial recruited 80 patients with AMI through convenience sampling. The patients were allocated to geranium and placebo groups (n = 40 each) using stratified block randomization. On the second day of admission three drops of geranium essential oil and placebo were poured on absorbing patches attached inside the oxygen masks of the geranium and placebo groups, respectively. The patients were asked to inhale the aroma for 20 minutes a day on two consecutive days.

Results: All stages of the intervention, the two groups had a significant difference in anxiety scores, i.e. geranium aroma caused significantly greater reductions in the anxiety scores ($P < 0.001$).

Conclusion: Inhalation aromatherapy with geranium essential oil is recommended as an easy-to-use, intervention to reduce anxiety among patients with AMI.

Key words: Acute Myocardial Infarction, Anxiety, Geranium, Aromatherapy, Cardiac care unit.

IRCT Number: (IRCT2017011824080N10)

Effects of geranium aroma on anxiety among patients with acute myocardial infarction: A triple-blind randomized clinical trial

1. Introduction

Myocardial infarction (MI) is one of the most prevalent types of coronary artery diseases [1, 2]. In today's industrial world, acute MI (AMI) is among the a major causes of death which requires urgent treatment [3]. It leads to considerable disability, decreases patients' performance and efficiency, and imposes the greatest health care costs [4]. MI causes not only physical problems, but also psychological problems such a anxiety, fatigue, depression, and sleep disorder/disruption [5-10].

MI patients experience high levels of anxiety due to changes occurring in their routine daily life [11]. About 42% of MI patients experience anxiety [12]. Peter et al. found that anxiety was still present and was even exacerbated in MI patients one month after hospital discharge [13]. A number of studies have identified the risk factors of anxiety among MI patients admitted to cardiac care units (CCUs). These risk factors include separation from family, being in an unfamiliar environment, fear of strangers [1], excessive noise, constant light, unpleasant smells, frequent care [5], fear of the disease, sleep disorder/disruption, pain and uneasiness [14], lack of knowledge regarding diagnostic procedures and outcomes, treatment costs, worries about one's ability to take care of themselves and going back to work, and fear of the risk of death [15].

By stimulating the sympathetic nervous system and catecholamine release, anxiety affects patients' physiological responses, e.g. respiratory rate, heart rate, blood pressure, and myocardial oxygen demand, and threatens their life [16, 17]. Moreover, anxiety disturbs coronary circulation and thus exacerbates patients' conditions and cardiovascular complications, and ultimately decreases their quality of life [5, 14, 18].

Patients admitted to CCUs experience severe anxiety during the first 48 hours. Therefore, CCU nurses need to reduce patients' anxiety and improve their quality of life by the administration of independent nursing interventions [1, 16].

Various pharmaceutical treatments (e.g. anti-anxiety medications and tranquilizers) [19] and non-pharmaceutical approaches have been employed to control anxiety in MI patients [6]. Although mentioned medications may reduce anxiety, they have other side-effects including fatigue, dizziness, and restlessness [20]. Therefore, complementary and alternative medicine (CAM), an adjuvant non-pharmaceutical treatment, has received considerable attention from both the patients and healthcare providers in recent years [21]. Aromatherapy is a unique and developing complementary method [1,19]. widely used to alleviate emotional and physical symptoms through the inhalation of vapors or absorption of oils [22]. According to initial clinical trials, aromatherapy is effective in reducing stress, pain, and depression [23]. A number of

essential oils including those extracted from lavender, jasmine, rosemary, rose, geranium, and Roman chamomile, have been utilized for treating psychological symptoms, such as anxiety [24]. Gaye et al. concluded that aromatherapy significantly decreased anxiety [25].

Extensive evidence suggest the natural oil extracted from geranium, more precisely pelargonium, as a safe essential oil with various active ingredients numerous beneficial effects. It stimulates the lymphatic system, enhances wound healing, and possesses antiseptic, anti-microbial, anti-fungal, and anti-eczema properties [26-28]. Moreover, the antioxidant effects, of geranium can lead to decreased levels of anxiety, anger, restlessness, and emotional depression [27, 29, 30].

A review of the literature indicated the absence of studies on the effects of geranium on MI patients' anxiety [20]. In a study on nulliparous women, Rashidi et al. confirmed the effectiveness of aromatherapy with geranium essential oil in reducing anxiety during labor [20]. Najafi et al. reported decreased anxiety in MI patients following inhalation aromatherapy with lavender essential oil [31]. Cho et al. concluded that aromatherapy with Roman chamomile, citrus aurantium, and lavender essential oils decreased anxiety in patients undergoing percutaneous coronary intervention (PCI) [1].

A systematic review by Ernest and Cook suggested aromatherapy to have mild and transient effect. However, considering the unreliable results, incorrect measurements, and small sample sizes of the reviewed studies, the researchers, highlighted the need for further studies to evaluate the effects of aromatherapy on patients' anxiety [33]. Apparently, previous studies have evaluated the effects of aromatherapy with geranium and other essential oils on anxiety in small numbers of patients without cardiac diseases. Moreover, the Methods section of such studies did not include the frequency of aromatherapy sessions, duration of the interventions, or the use of placebo [1, 20, 31]. The therapeutic use of aromatherapy remains controversial due to lack of scientific evidence on effectiveness and safety [22].

2. Objectives

Despite the potential effects of geranium essential oil, no clear evidence is available on its effects on anxiety among AMI patients. Therefore, the present study evaluated the effectiveness of geranium essential oil on anxiety among patients admitted to CCUs due to AMI.

3. Materials and Methods

3.1. Subjects

This randomized, triple-blind, placebo controlled clinical trial was performed during December 2016 - May 2017. A total of 80 patients with MI were selected through non-random consecutive sampling and allocated to (geranium and placebo) groups using stratified block randomization to ensure homogeneity in terms of sex and age.

3.2. Inclusion criteria

The inclusion criteria were age 18-60 years, a definitive diagnosis of AMI based on electrocardiography, the absence of cardiopulmonary resuscitation (CPR) upon emergency room

admission, no history of allergic rhinitis, eczema, or known respiratory disorders such as asthma and chronic obstructive pulmonary disease, no smell and taste disorders, no uncontrolled medical/chronic disorders, orientation to time, place, and self, no known mental illnesses, no history of head trauma or seizures, no diseases causing sleep disruption, e.g. migraine, rheumatoid arthritis, and nocturnal respiratory disorders, no drug addiction, stable vital signs, no pain during the interview and while filling out the questionnaire, no allergy to the used essential oils, not using benzodiazepines, analgesics, or anti-anxiety drugs at least 10 hours prior to the intervention, no history of CAM at least one week before the intervention, and scoring above 20 on the State-Trait Anxiety Inventory (STAI).

3.3. Exclusion criteria

The exclusion criteria were unwillingness to continue participation, cardiac shock, cardiopulmonary arrest, or MI during the intervention, decreased consciousness during the intervention, cardiac dysrhythmia, ventricular fibrillation, cardiogenic shock, use of benzodiazepines, analgesics, or anti-anxiety medications, allergic-respiratory diseases, including dysrhythmia, and hemodynamic instability or death during the study.

3.4. Blinding

Both the researcher who collected the data before and after aromatherapy and the participants were blinded to the grouping. The essential oil vial was covered with a black strip, and its type was unknown to the healthcare provider. The treatments (aromatherapy) and patient evaluations were performed by a cardiac nurse. The geranium and placebo groups received aromatherapy in different times and places. Moreover, the researcher who entered the data into the software and analyzed them was blinded to group allocation.

3.5. Randomization

The patients were randomly assigned to the geranium and placebo groups (n=40 each). Software-generated numbers were used simple randomization. An independent person who was not involved in the study performed the randomization.

3.6. Intervention

The patients in the geranium group, who had hemodynamic-stability (n=40), received pure geranium essential oil diluted with primrose 10% oil to a final concentration of 100% on the second and third days of their CCU stay. Aromatherapy was continued until the third and fourth days of admission. The subjects in the placebo group (n=40) received sunflower oil 12%. Before the intervention, a dark glass container containing natural rosewater was placed under the nostrils of the patients in the geranium group to examine their olfactory nerve. The patients were asked to report identify the aroma and were excluded if they failed.

In the geranium group, a trained nurse poured three drops of geranium essential oil on absorbing patches connected inside the patients' oxygen masks and asked the patients to inhale the aroma for 20 minutes. Based on previous studies, aromatherapy was performed for 20 minutes twice daily (10-11 a.m. and 6-7 p.m.) on two consecutive days [31]. The same procedure, using

sunflower oil, was repeated for the patients in the placebo group. Every day, symptoms such as dyspnea, chest pain, dysrhythmia, and changes in vital signs were checked recorded. None of the patients manifested these symptoms during the study period.

A researcher blinded to the allocation procedure administered the STAI to measure the patients' anxiety 30 minutes before and 15 minutes after the intervention. Data collection was performed using a demographic questionnaire and the STAI. The demographic questionnaire contained items on age, sex, level of education, place of residence, and marital status, history of MI in first-degree relatives, use of prescribed tranquilizers, smoking, and known underlying diseases (Figure 1).

3.7. Data collection instruments

Anxiety was measured using the STAI. The inventory consists of 20 items scored on a four-point Likert scale (1= almost never to 4=almost always). Items 1, 2, 5, 8, 10, 11, 15, 16, 19, and 20 are reverse-scored. The total score ranges between 20 and 80, and scores 21-39, 40-59, and 60-80 indicate mild, moderate, and severe anxiety, respectively. Score 20 shows the absence of anxiety, and higher scores suggest higher anxiety levels [32]. The reliability of the Persian version of the STAI was estimated at 0.93 (Cronbach's alpha) for the state anxiety subscale. Its concurrent validity was confirmed using clinical interviews and comparison with a number of anxiety scales [34]. In the present study, the test-retest reliability of this instrument was calculated as 0.84. To evaluate its face and content validity, the questionnaire was distributed among 10 faculty members of medical universities and revised based on their comments.

3.8. Statistical analysis

Data were analyzed using SPSS 16.0 (SPSS Inc., Chicago, IL, USA). Chi-squared test-s were applied to compare the two groups in terms of frequency distribution and homogeneity of qualitative variables. The normality of continuous variables was assessed using the Kolmogorov-Smirnov test. After ensuring the normality of data, independent t-tests and repeated-measures analysis of variance (ANOVA), considering age as the covariate, were performed to analyze the data, P values less than 0.05 were considered significant.

3.9. Ethical consideration

The study protocol was designed in accordance with the Declaration of Helsinki and approved by the Ethics Committee of Lorestan University of Medical Sciences(LUMS.REC.1395.160). The trial was also registered in the Iranian Registry of Clinical Trials (IRCT2017011824080N10). Written informed consent forms were obtained from all the participants.

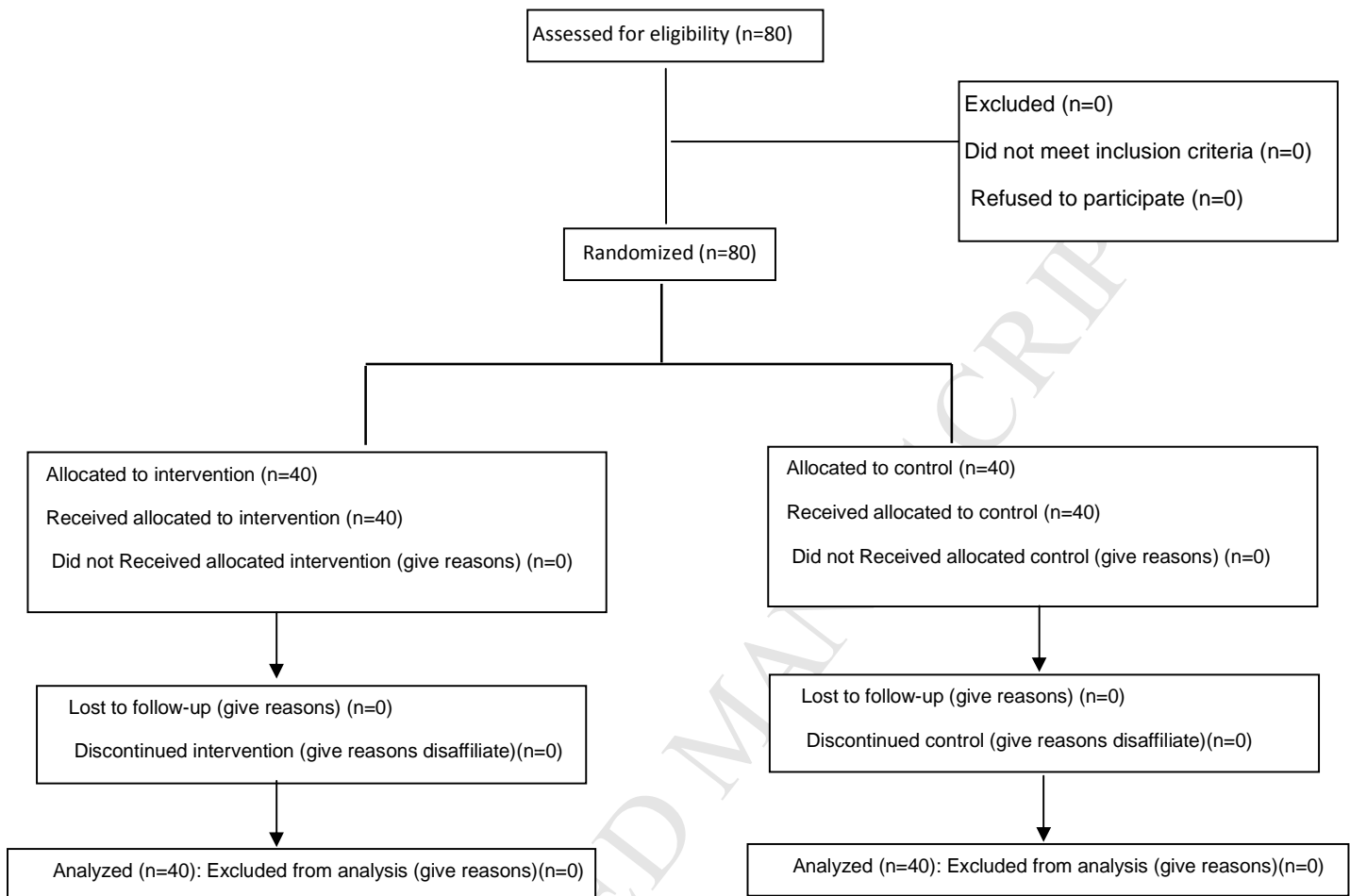


Figure 1. CONSORT flow diagram of the trial

4. Results

4.1. Homogeneity Test of Subjects

In this study, 80 patients with AMI were examined in two groups. Based on the demographic characteristics (Table 1), the two groups were matched in terms of age, sex, level of education, history of diseases, smoking, use of tranquilizers, and the history of MI in first-degree relatives ($P < 0.05$ for all). Moreover, all patients were married.

Table 1. Individual characteristics of patients in the aromatherapy group (received Geranium) and control group (received placebo)

Variables	Experimental (n = 40)	Control (n =40)	P Value
	Mean±SD	Mean±SD	
Age	44/77±11/58	49/25±12/05	0.7 ^a
	N (%)	N (%)	
Gender			
Female	20(50%)	20(50%)	0.7 ^b
Male	20(50%)	20(50%)	
Education			
Illiterate	20(50%)	21(52.5%)	0/71 ^b
Diploma	17(42.5%)	13 (32.5%)	
Over Diploma	3 (7.5%)	6(15%)	
Residency			
Rural	30(75%)	25(62.5%)	0.34 ^b
Urban	10(25%)	15(37.5%)	
Known concurrent diseases			
Yes	23(60%)	25(65%)	0.75 ^b
No	17(40%)	15(35%)	
Family history of MI			
Yes	14(35%)	18(45%)	0.56 ^b
NO	26(65%)	22(55%)	
Tranquilizer consumption			
Yes	17(42.5%)	15(37.5%)	0.50 ^b
NO	23(57.5%)	25(62%)	
Smoking			
Yes	7(17.5%)	7(17.5%)	0.94 ^b

No	33(82.5%)	33(82.5%)
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^a. ANOVA

^b. Chi-Square

4.2. Aromatherapy for the Anxiety

According to repeated-measures ANOVA, differences in the mean anxiety scores were significant over time ($P < 0.001$), i.e. time had a significant effect on anxiety. Based on Table 2, aromatherapy with geranium essential oil significantly reduced the mean anxiety scores at various time intervals over the course of the study ($P < 0.001$). The differences were in the mean anxiety scores were also significant in the placebo group ($P > 0.001$). Such significant reductions can be justified by the great increase in anxiety scores in the evening of the first day of the intervention. The interaction effect of time \times group was significant ($P < 0.001$). Table 2 and Figure 2 show that the two groups had significant differences in terms of changes in the mean anxiety scores. Compared to the placebo group, the geranium group showed a significant reduction in the mean anxiety score after each session of aromatherapy ($P < 0.001$). Nevertheless, two the groups were not significantly different in terms of the mean anxiety scores at baseline ($P > 0.05$).

Table 2. Comparison of mean and standard deviation of anxiety scores between two groups before and after intervention at different times

Intervention Time	Experimental (n= 40) Mean \pm SD	Control (n=40) Mean \pm SD	P Value
Morning of First day			
Before intervention	62.05 \pm 7.52	59.52 \pm 7.47	0.136
After intervention	24.37 \pm 4.9	57.27 \pm 6.58	<0.001
P Value	<0.001	<0.001	
Evening of First day			
Before intervention	59.92 \pm 6.1	58.17 \pm 7.15	0.245
After intervention	24.25 \pm 5.73	72.12 \pm 14.31	<0.001
P Value	<0.001	<0.001	
Morning of second day			
Before intervention	59.25 \pm 6.1	58.3 \pm 6.73	0.513

After intervention	22.52±3.42	56.2±6.46	<0.001
P Value	<0.001	<0.001	
Evening of second day			
Before intervention	57.97±7.26	56.55 ±7.8	0.40
After intervention	22.72±3.38	54.72±6.06	<0.001
P Value	<0.001	<0.001	

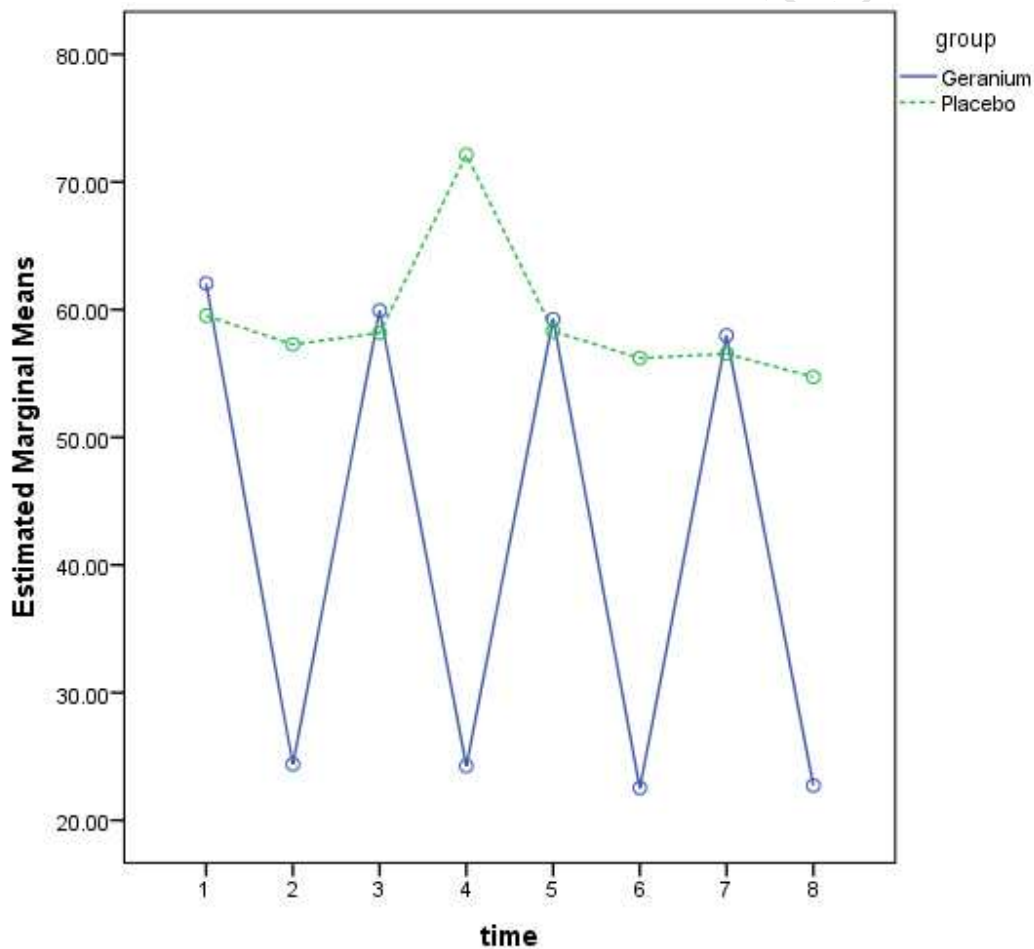


Figure 2. Comparison of the mean changes in the anxiety scores of the two groups during a period of an 8- time evaluation.

5. Discussion

Based on the results of this study, aromatherapy with geranium essential oil caused significantly greater reductions in anxiety compared to placebo. Freshmen argues that, although no strong evidence supports the effectiveness of aromatherapy in treating cardiovascular diseases, aroma may have positive effects on these patients by reducing depression and anxiety [35]. In line with the present study, in a study on children candidate for surgery, Sirousfard et al. found that geranium aroma decreased pain severity over time [27]. Another study also confirmed the effects of geranium aroma 2% on regulating vital signs, e.g. systolic and diastolic blood pressures, among nulliparous women [20].

When an aroma is inhaled, the olfactory system transfers its molecules to the limbic system in the brain. The limbic system then responds to the stimulus and exerts its psychological effects. Geranium aroma seems to have a similar mechanism to that of other aromas, i.e. it applies its anti-anxiety and analgesic effects by stimulating the limbic system. The presence of numerous components such as linalool, borneol, and terpineol, increases the effects of this essential oil on the central nervous system and benzodiazepine receptors, and thus enhances its anti-anxiety and analgesic effects [27, 29].

Previous research has also examined the effects of geranium on other factors. Shahbazzadegan concluded that drinking two cups of geranium tea per day for three weeks decreased certain menopause symptoms, e.g. anxiety, hot flashes, and insomnia. However, such reductions were not significant. The difference between these findings and the results of our study. might have been caused by the differences in the amounts and methods of geranium consumption [36]. Geranium may exert more effects when inhaled, but this needs further research.

In a similar study, Hur et al. indicated that aromatherapy through massage with geranium essential oil once a week for eight weeks significantly decreased menopause symptoms, especially hot flashes and pain. However, it was not clear whether these positive effects were caused by massage, aromatherapy, or a combination of both [37]. Matthys reported that geranium essential oil significantly alleviated the severity of acute bronchitis [38]. Another study indicated that aromatherapy with various essential oils, including geranium essential oil, significantly improved vital signs and anxiety levels during university students' first intravenous injection [39]. Animal studies also reported the anti-depression effects of geranium essential oil on white laboratory mice [40]. Although these studies have been performed on different populations, their results are consistent with those of the present study, and confirm the positive effects of aromatherapy with geranium essential oil.

A review of related literature revealed the effectiveness of inhaling the aroma of other medicinal plants on symptoms of cardiovascular diseases. Najafi et al. showed the beneficial effects of lavender aroma on reducing anxiety among MI patients [31]. Shokri et al. reported a significant reduction in the anxiety scores of MI patients following the administration of oral capsules containing *Ducrosia anethifolia* (Barilax) essential oil. [18]. Since we and Shokri et al. administered medicinal plants through two different routes (inhalation vs. oral use), the

beneficial effects of such plants seem to be independent from the route of administration. Previous studies, generally showed the anti-anxiety effects of aromatherapy. Patients with MI experience high levels of anxiety which can be alleviated using non pharmaceutical approaches such as aromatherapy.

Lytle et al. confirmed the positive effect of aromatherapy on vital signs and sleep quality of patients admitted to intensive care units (ICUs) [41]. Other studies reported the effectiveness of inhaling Rosa damascene [42] and lavender essential oils on reducing anxiety among coronary angiography candidates [42, 43].

Some studies, however, published inconsistent results. Seifi et al. concluded that lavender essential oil had no effects on anxiety among patients undergoing open heart surgery [44]. Mohseni reported that aromatherapy with mint essential oil had no effect on vital signs or the incidence of arrhythmia among MI patients [32]. Generally, some studies are in line with the present study. The reported inconsistencies can be explained by the difference in research population, intervention characteristics (e.g. type of aroma, dosage, and duration of use), and the specific conditions of the patients.

6. Conclusion

Our findings suggested aromatherapy with geranium essential oil as a safe, easy-to-use, and inexpensive method to decrease anxiety levels among AMI patients. Anxiety is an important factor determining patients' comfort. As nurses have a significant role in the emotional support of patients with AMI in CCUs, cardiac nurses are recommended to use reliable evidence to enhance their professional knowledge of aromatherapy and to apply such techniques for decreasing patients' anxiety.

7. Limitations

The duration of the study was short because of the clinical conditions of the patients in CCUs and their transfer to post-coronary care units (PCCUs). Further studies are thus required to examine the long-term effects of aromatherapy considering the unique conditions of each patient. Moreover, the patients' response to aromatherapy may have been influenced by the emotional support they received from nurses and families. Future studies are also recommended to explore the effect of aromatherapy with geranium essential oil on other clinical outcomes of AMI patients, including physiological indicators, pain, sleep quality, and vital signs.

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10. Conflict of interest statement

The authors declare that they have no conflicts of interest.

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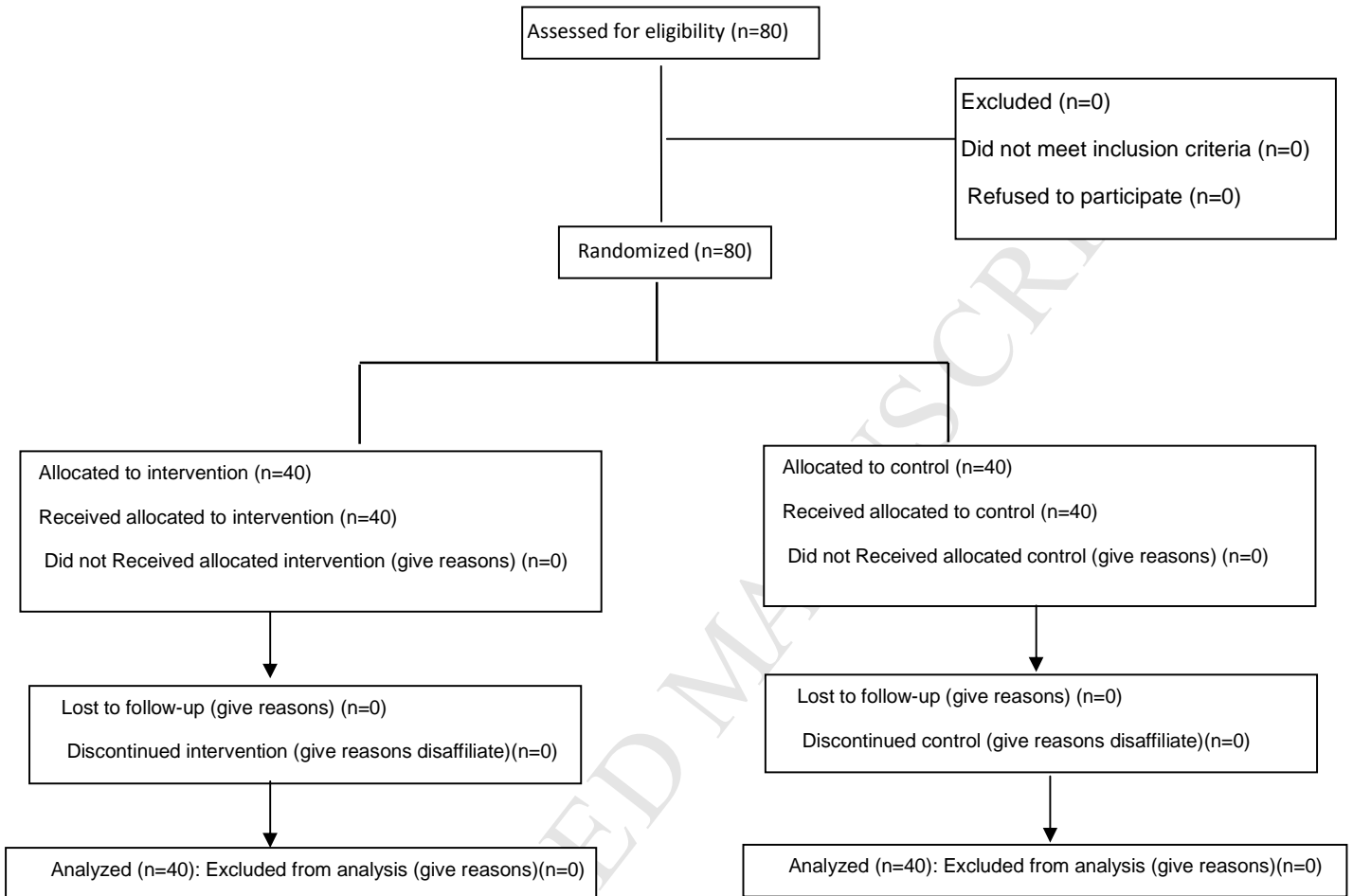


Figure 1. CONSORT flow diagram of the trial

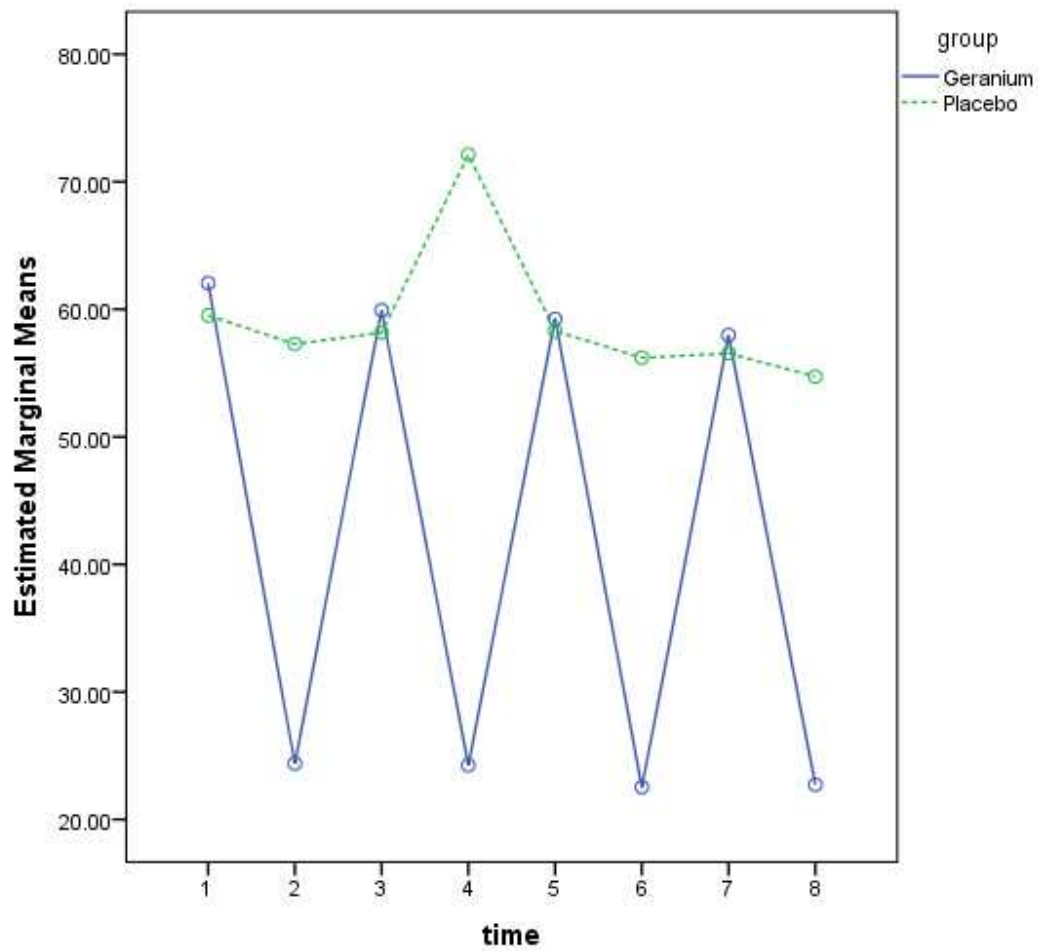


Figure 2. Comparison of the mean changes in the anxiety scores of the two groups during a period of an 8- time evaluation