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Title: Effect of aromatherapy massage on anxiety, depression and physiologic parameters in older patients with the acute coronary syndrome: A randomized clinical trial

Running Title: Effect of aromatherapy massage on acute coronary syndrome

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Trial Registration

The Iranian Registry of Clinical Trial ID: IRCT201512027529N8

Conflicts of interest

None of the authors have any conflicts of interests with regards to this research.

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Authorship statement

All the authors confirm that all listed authors meet the authorship criteria and that all authors are in agreement with the content of the manuscript.

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Contributions

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Effect of aromatherapy massage on anxiety, depression and physiologic parameters in older patients with the acute coronary syndrome: A randomized clinical trial

A B S T R A C T

This study aimed to investigate the effect of aromatherapy massage on anxiety, depression and physiologic parameters in older patients with acute coronary syndrome. This randomized controlled trial was conducted on 90 older women with acute coronary syndrome. The participants were randomly assigned into the intervention and control groups (n=45). The intervention group received reflexology with lavender essential oil, but the control group only received routine care. Physiologic parameters, the levels of anxiety and depression in the hospital were evaluated using a checklist and the hospital's anxiety and depression scale, respectively before and immediately after the intervention.

Significant differences in the levels of anxiety and depression were reported between the groups after the intervention. The analysis of physiological parameters revealed a statistically significant reduction ($p< 0.05$) in systolic blood pressure, diastolic blood pressure, mean arterial pressure and heart rate. However, no significant difference was observed in the respiratory rate. Aromatherapy massage can be considered by clinical nurses an efficient therapy for alleviating psychological and physiological responses among older women suffering from acute coronary syndrome.

Summary statement

What is already known about the topic?

• Depression and anxiety in cardiac care units are often not managed adequately.

• Older adults with acute coronary syndrome may suffer from negative emotions more than other age groups.

What this paper adds?

• This study showed the positive effect of aromatherapy massage on alleviating anxiety and depression among older women with acute coronary syndrome.

• Aromatherapy massage can be considered a complementary therapy and used along with routine interventions for relieving psychological and physiological problems among older women hospitalized in cardiac care units.

Key words: acute coronary syndrome, anxiety, depression, physiologic parameters,

1. Introduction

Acute coronary syndrome (ACS) is the type of ischemic heart disease (IHD) in which coronary arteries are obstructed or closed (Govindaraju, Badruddin et al. 2013). ACS leads to the reduction of the oxygen supply to heart muscles due to atherosclerosis or coronary artery spasm. Therefore, an increase in the myocardial oxygen demand, in cases of tachycardia or severe anemia, enhances the vascular injury and finally may lead to ACS (Cho, Min et al. 2013) .

As a major public health issue in developing countries, ACS has become highly prevalent, responsible for about 35 percent of all deaths across the world. In other words, almost one million deaths occur each year due to ACS. Accordingly, about 40 percent of ACS-related deaths occur in high-income countries with a share of 28 percent in low to middle-income countries (McKinley, Dracup et al. 2009, Mohammadpur, Mohammadian et al. 2014). ACS is one of the leading causes of hospitalization in the cardiac care unit (CCU) (Han and Park 2002). Poor functional statues in the activities of daily livings among patients with ACS result in anxiety and depression (Bauer, Caro et al. 2012).

Anxiety affects the function of the body's organs and also causes negative health-related consequences in patients with myocardial infarction (MI) (Huffman, Mastromauro et al. 2011). Moreover, the progression of cardiac ischemia and even dysrhythmia are the significant negative consequences of anxiety and depression (Huffman, Celano et al. 2010). More than half of these patients report the symptoms of anxiety due to the: 1) unfamiliar hospitalization's environment, 2) sudden diagnosis of ACS, 3) isolation from the family, 4) being encountered with strangers, 5) loss of individuality and independence, 6) unexpected care routines and 7) critical situations (McKinley, Fien et al. 2012). In addition, these patients encounter many fearful situations such as: 1) life-threatening conditions, 2) the probability of an additional MI and 3) the fear of the unknowns (Arora, Anand et al. 2010). Such discomforts accelerate the release of catecholamine and cause physiologic responses such as an increase in the blood pressure (BP), heart rate (HR), respiratory rate (RR) and dyspnea, possibly exacerbating the development of MI (Frasure-Smith and Lesperance 2008).

The use of medication to relieve anxiety and depression in patients with ACS reduces the level of patients' alertness and may cause further health-related complications (de Jong-Watt and Arthur 2004). Therefore, choosing an appropriate method for alleviating patients' anxiety and depression without the use of drugs is of great importance (Rejeh, Heravi-Karimooi et al. 2015).

Currently, more attention is paid to complementary and alternative medicine (CAM) strategies, because they have fewer complications and are easy to access (Mohammadpur, Mohammadian et al. 2014). These strategies are highly recommended in older patients with an impaired metabolism and increased sensitivity to the side effects of drugs (Perković-Vukčević, Vuković-Ercegović et al. 2016). For instance, cognitive and cardiovascular adverse effects among older people, after the use of tranquilizers and cardiovascular drugs, are very common (Sztramko, Chau et al. 2011). CAM can help healthcare providers with the management of signs and symptoms related to cardiovascular disorders including ACS (Greenfield, Pattison et al. 2008).

Aromatherapy is one of the recommended non-pharmacological CAM strategies for symptom management in hospitalized patients. It is the most widely used complementary therapy in nursing practice and is the therapeutic use of essential oils extracted from plants and administered through the olfactory system (inhalation) or the skin (massage) (Buckle 2001, Kyle 2006).

A number of essential oils (lavender, geranium, jasmine, rosemary, rose, evening primrose oil, and chamomile) are used for relieving psychological symptoms such as anxiety and depression (Taavoni, Darsareh et al. 2013). Lavender has particularly been used for a long time in traditional medicine with an effect on the central nervous system leading to the release of encephalin, serotonin and endorphins (Heidari Gorji, Ashrastaghi et al. 2015). Lavender (Lavandula angustifolia) is widely used in different contexts (Hashemi, Hajbagheri et al. 2015). Previous studies have confirmed the sedative effects of Lavender on the parasympathetic system. Also, it has been found that lavender promotes the heart function and coronary blood flow (Bikmoradi, Seifi et al. 2015). Several studies suggested that aromatherapy and massage had positive effects on physiologic parameter and the level of anxiety and depression (Edge 2003, Hur, Oh et al. 2007, Chang 2008). Moreover, the risk of hospitalization in the CCU among older patients is more than other groups of patients (Ancona, Arca et al. 2004).

Therefore, the aim of this study was to investigate the effect of aromatherapy massage on anxiety, depression and physiological parameters in older patients with ACS. The research hypothesis for this study was as follows: an aromatherapy massage intervention for older patients with ACS will result in significant differences between an intervention group and control group in terms of anxiety, depression, systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP), heart rate (HR) and respiratory rate (RR).

2. Materials and methods

2.1. Aims

The aim of this study was to identify the effect of aromatherapy massage on anxiety, depression and physiologic parameters in older patients with ACS.

2.2. Design

This was a randomized controlled trial with a pre-intervention–post-intervention design. A convenience sample of 90 older patients were randomly allocated into either the intervention or the control group. They were hospitalized for one day in the CCU and diagnosed with ACS. The patients in the intervention group received aromatherapy massage with lavender; those in the control group only received routine care delivered by nurses in the CCU.

2.3. Setting and participants

This study was conducted in a high turnover CCU of a teaching hospital in Tehran, Iran from July 2014 to December 2015.

Ninety older women, aged 60 years and over, were chosen using a convenience sampling method. None of the participants were excluded from the study. As a result, all of them were randomized into either the intervention or the control groups (n = 45 in each group).

The following inclusion criteria were considered for the recruitment of the participants: 1) diagnosed with ACS; 2) 60 years old and above (the beginning of the old age in developing countries); 3) able to understand and communicate in Farsi language and follow instructions; 4) not taking any anxiolytics and sedative drugs during the last four hours before the intervention; 5) not receiving alternative and complementary medicines during the last 48 hours before the intervention; 6) not having foot ulcers; 7) no history of drug addiction; 8) no history of asthma, eczema and allergy and 9) passing the olfactory heath test and the abbreviated mental test (score ≥ 7).

Only female patients with ACS were recruited for this study in order to eliminate any gender influence on the level of anxiety or depression. The exclusion criteria were: 1) any hemodynamic instability during the intervention; 2) refusing to complete the intervention session and 3) any allergic reaction to the essential oils or perfumes. It was noted that no harm or side effects occurred throughout the trial.

2.4. Sample size

The sample size was determined using a statistical power analysis ($\alpha = 0.05$, $\beta = 15\%$, power = 90%, Altman's Nomogram). It was also based on a sample size determined in a previous study (Mahmoudirad, Ghaedi Mosolo et al. 2014).

2.5. Randomization

Following receiving the ethical committee's approval at the university and obtaining the permission to enter the CCU, the nurse manager in the CCU was informed of the study's purpose and the selection criteria to help with the identification of eligible participants. A convenience sample of older women, meeting the inclusion criteria, was chosen, with no patient declining to participate.

The allocation of the participants to the groups happened during the week that the researcher (TB) visited the hospital. A system of sealed envelopes was used for the random assignment of the eligible participants into the groups with each envelope assigned to a specific group. The sampling process continued until a sufficient number of the participants were recruited into each group (Figure1). It is noted that the second author (NR) generated the random allocation sequence, the first author (TB) enrolled participants and assigned participants to interventions. It was impossible to control the participants' or staffs' awareness of the group assignment due to the nature of the intervention (aromatherapy massage) and lavender smell. However, the data analyst (SDT) was unaware of the group assignment. In addition, the randomization code was available only to a research fellow who was not connected to this study. The code was disclosed to the researchers when the statistical data analysis was completed.

2.6. Measurements

The instrumentation for this research included several instruments. These included: 1) personal and medical information form, 2) measurement of physiological parameters, 3) an abbreviated mental test, and 4) Hospital Depression and Anxiety Scale (HADS).

2.6.1. The personal and medical information form

The personal and medical information form measured demographic characteristics, including: 1) age, 2) marital status, 3) employment status, 4) educational level, 5) living status and 6) any history of hospitalization.

2.6.2. Measurement of physiological parameters

The physiological indicators were measured one minute before and after the intervention when the participants were at rest. These parameters included: 1) SBP, 2) DBP, 3) MAP, 4) HR and 5) RR. These data were extracted from participants' charts before and after the intervention. The participants' blood pressure (BP) was measured on their left arm using a mercury sphygmomanometer, after they rested for 15 minutes while lying on their back. Instead of a pulse rate, the participants' HR was monitored through the monitoring machine. Also, MAP was measured and reported by this machine. The RR was also measured for one minute without the participants being aware of the measurement.

2.6.3. Abbreviated Mental Test

The abbreviated mental test (AMT) rapidly assesses older individuals for the presence of cognitive disorders. Older individuals, with a score greater than 7 were considered normal. A score lower than 7 out of 10 indicated cognitive impairment (Faraji, Fallahi khoshknab et al. 2013). The Cronbach's alpha coefficient of the AMT was reported as 0.76 (Bakhtiyari, Foroughan et al. 2014).

2.6.4. Hospital Anxiety and Depression Scale (HADS)

The HAD scale evaluated the levels of anxiety and depression in the participants. The instrument consisted of 14 items, seven for each subscale of anxiety (HADS-A) and depression (HADS-D). The participants rated each item on a self-rating scale from zero to three. The scoring system ranged from the absence of symptoms (score 0) to the maximal presentation of symptoms (score 3). Therefore, a higher score indicated a higher level of anxiety or depression (Zigmond and Snaith. 1983). Correlations between the two subscales varied from 0.40 to 0.74 with a mean of 0.56. The Cronbach's alpha for the HADS-A varied from 0.68 to 0.93 with a mean of 0.83, while the alpha for the HADS-D was from 0.67 to 0.90 with a mean 0.82 (Bjelland, Dahl et al. 2002). The reliability and validity of the Iranian version of the hospital depression and anxiety scale (HADS) was assessed (Montazeri, Harirchi et al. 1999). Also this scale was used in patients with coronary heart diseases in a previous study (Barth and Martin 2005). The cut-off score of greater than 8 for the diagnosis of either anxiety or depression was suggested (Stafford, Berk et al. 2007). The quantitative scoring of both subscales ranged from 0 to 27. Scores greater than or equal to five were associated with mild anxiety or depression. Scores greater than or equal to ten were associated with moderate anxiety or depression. Scores greater than or equal to 15 were associated with moderately severe anxiety or

depression, while scores equal to or greater than 20 indicated severe anxiety or depression (Kroenke, Spitzer et al. 2001).

2.7. Intervention

The researcher (TB) explained the study's purpose, benefits and potential risks to those patients meeting the inclusion criteria. It should be noted that nursing work patterns and nurse staff remained unchanged throughout the study process. During the intervention, the researcher applied the aromatherapy massage to participants exactly as planned. She successfully passed the required training courses with regard to aromatherapy massage under the supervision of specialists in the field of traditional and complementary medicine. The control group received routine care delivered by nurses in the CCU, while the participants who were assigned to the intervention group received the aromatherapy massage intervention in addition to routine care. Routine care was consisted of medication administration based on physicians' orders and scheduled nursing interventions delivered to all patients hospitalized in the CCU.

The intervention was performed in the patient's bed. The nursing staff or family members were asked not to enter when the participant was taking part in the study in order to minimize noises and disruptions, and enhance relaxation. All participants in the intervention group were placed in a supine position and a pillow was placed under their knees. The intervention and evaluation of its effect were carried out in the evening.

The researcher washed her hands with warm water and applied a moderate amount of almond oil (6 drops) to her hands. After general foot massage, relaxing techniques included effleurage movements (ten times), stretching fingers by holding them between thumbs and other fingers (five times in both directions) and moderate rotational movements around the ankle (five times). The reflex zones of solar plexus, pituitary gland, brain, heart, large and small intestines, vertebral column, adrenal and kidney were used for the stimulation. The researcher exerted the firm downward pressure with her thumbs in the above-mentioned areas for: 1) 14 seconds in the solar plexus, 2) 40 seconds in the pituitary gland (5 times), 3) 5 seconds in the brain area, 4) 10 seconds in heart area 5) 5 times for each intestine and 6) 5 times for the adrenal gland and kidney. The rubbing technique was used for the adrenal and kidney reflex zones. Prior to, and after the aromatherapy massage intervention, the levels of depression and anxiety in the hospital, and physiologic parameters were measured.

2.8. Ethical considerations

The institutional review board approval (decree number: 41-228111) was granted by the university in which the authors worked. All participants signed written informed consent when they were invited to take part in the study. The ethical consideration of this study conformed to the Declaration of Helsinki 1995, revised 2001. Numbers, rather than names were used to de-identify the participants to ensure their confidentiality and anonymity. Since this intervention used a CAM strategy, no harm was anticipated for the participants. However, this study was carried out under the supervision and control of a cardiologist in the CCU. No patient withdrew from the study and no harm was identified as occurring to any participants throughout the study process.

2.9. Data analysis

Statistical analyses were performed using the SPSS version 21.0 software (SPSS Inc., Chicago, IL). After the data collection, data analysis was performed using descriptive statistics (frequency, percentage, mean and standard deviation) and inferential statistics (independent t-test, chi-squared test, Cramer's V test, and Cohen test). The Kolmogorov-Smirnov test was carried out to examine the normal distribution of the data. The level of statistical significance was considered $p < 0.05$.

3. Results

3.1. The demographic characteristics of the participants at the baseline

All 90 older women were eligible for inclusion in this study and were approached. All participants agreed to participate and fully completed throughout the study process. The independent t-test and chi-square test showed no statistically significant differences between the two groups in terms of age, marital status, employment status, educational level, living status, and history of hospitalization (Table 1).

3.2. Hospital Anxiety and Depression Scale scores

The statistical analysis with regard to the level of anxiety demonstrated that, after the intervention, the level of anxiety was significantly lower in the intervention group ($x2 = 12.95$, $df = 3$, $p = 0.005$) as compared with the control group. According to the Cramer's V test, the correlation between the intervention and level of anxiety was moderate ($v2 = 0.379$).

The means and standard deviations of anxiety changed from 12.31 ± 5.22 (before the intervention) to 8.04 ± 4.71 (after the intervention) in the intervention group, and from 11.66 ± 4.24 to 11.07 ± 3.19 in the control group. The effect size for the difference in reported anxiety between the groups was 0.75, demonstrating a large effect size of the aromatherapy massage intervention (Table 2).

In relation to the participants' level of depression, a statistical significant difference between the groups was demonstrated ($x2 = 16.512$, $df = 3$, $p = 0.001$). Also, the Cramer's V test revealed a moderate correlation between the aromatherapy massage intervention and the level of depression ($v2 = 0.428$). The means and standard deviations for depression changed from 12.51 ± 5.40 (before the intervention) to 8.08 ± 4.71 (after the intervention) in the intervention group, and from 11.71 ± 4.29 to 11.11 ± 3.42 in the control group (Table 2).

3.3. Physiologic parameters

The comparison of the physiological parameters for the intervention and control groups were shown in Table 3. There were no statistical significant differences between the groups before the intervention except for RR. While SBP, DBP, MBP and HR significantly reduced after the intervention, no statistically significant difference was found in RR in the intervention group after the intervention. The assessment of the Cohen test demonstrated an average effect size in SBP, DBP, MBP, but a small effect size in HR (Table 3).

4. Discussion

The present study was conducted to investigate the effect of aromatherapy massage on anxiety, depression and physiological parameters among older women with ACS. After the intervention, aromatherapy massage significantly improved the levels of anxiety and depression and decreased SBP, DBP, MBP and HR as compared with the baselines. However, despite a clinical decline in RR, no statistically significant reduction was reported.

Psychological issues, caused by an ACS in older people, can have negative impacts on their lives, and these additional problems should be managed by health care professionals. Many studies suggested different treatment modalities for the management of anxiety and depression, and the equilibration of physiologic parameters, but an interest in the use of complementary and alternative therapies among older patients with heart diseases is increasing (Sibbritt, Davidson et al. 2015). Various studies have confirmed the efficacy of non-pharmacological measures such as aromatherapy massage for relieving psychological symptoms in different groups of patients(Cooke and Ernst 2000, Okamoto, Kuriyama et al. 2005), but immediate consequences and benefits of this therapy on the levels of anxiety and depression are still unknown.

In the present study, most participants reported the initial high levels of anxiety and depression. However, after the aromatherapy massage intervention, the participants showed statistically significant reductions in their symptoms as compared with those of the control group. These findings are supported by the findings of previous studies on the use of essential oil massage for relieving similar symptoms (Wilkinson, Aldridge et al. 1999, Domingos Tda and Braga 2015). In addition, a recent study examined the impact of aromatherapy massage on psychological parameters and found that aromatherapy massage also improved patients' anxiety and depression (Wu, Cui et al. 2014).

According to the findings of this study, aromatherapy massage reduced the psychological symptoms of the participants. These reductions might be attributed to the relaxant effects of lavender on the autonomic nervous system with an associated effect on the patient's emotions. Perry et al. (2006) also emphasized the anti-anxiety mechanism of the linalool in lavender. Other studies among animals showed that the pharmacologic effect of lavender was similar to that of diazepam (Umezu 2000, Perry and Perry 2006). In addition, according to one hypothesis, the use of essential oils may also help reduce the blockage of the olfactory pathways and lead to anti-depressant effects (Yim, Ng et al. 2009, Hongratanaworakit 2011).

In contrast, Koriyama et al (2005) did not report any significant reduction in the anxiety level with a course of aromatherapy or massage (Kuriyama, Watanabe et al. 2005). Sodden et al. (2004) and Chang et al. (2008) reported a significant reduction in the level of depression after receiving the treatment in patients with cancer, but the treatment had no effect on the level of anxiety (Soden, Vincent et al. 2004, Chang 2008). Despite the gradual reduction of anxiety in patients with breast cancer in the Imanishi et al.'s (2009) study, researchers did not find any statistically significant difference in the participants' level of depression (Stevensen 1994, Imanishi, Kuriyama et al. 2009). Several factors including type of patients, underlying disorders, the duration and method of intervention, patient's psychological conditions or the amount and type of aroma may contribute to the conflicting findings on the effects of lavender on participants' psychological symptoms.

As a complex process, aromatherapy massage consists of aroma oil for the olfactory stimulation, and a massage as a tactile stimulation. This combination therapy may improve participants' physiologic parameters through the absorption of the aroma oil by the skin and subsequent stimulation of the olfactory system. This therapeutic remedy can affect the parasympathetic nervous system, stabilizing the patient's physiologic parameters and metabolism and, eventually, maintaining the patient's level of relaxation (Imura, Misao et al. 2006, Kim and Kim 2012, Eguchi, Funakubo et al. 2016).

In this study, changes in BP were seen in those participants with reduced anxiety and depression after the intervention. As other studies also indicated that BP was decreased with the reduction of anxiety, it was believed that aroma foot massage might reduce BP through reducing the participant's anxiety (Eguchi, Funakubo et al. 2016). In addition, other studies also reported the decreased levels of SBP, DBP and MBP after aroma self-foot reflexology massage (Hur, Oh et al. 2007, Kim and Kim 2012, Bahrami, Rejeh et al. 2016). In contrast, Rho et al. (2006) stated that aromatherapy massage had no statistically significant differences in BP and HR between the two groups (Rho, Han et al. 2006).

Complementary medicine experts believe that during, and immediately after the intervention, some changes in the HR, RR or temperature may be created. Therefore, such interventions should be provided in more than one session to be able to assess and document its benefits (Gunnarsdottir and Jonsdottir 2010). This phenomenon, known as a cleansing process, can be the reason for the lack of changes in RR in this study. Unlike our findings Stevenson and Chang believe that respiratory rate decrease as an immediate effect of massage with the essential oil (Stevensen 1994, Chang 2008). Also Domingos et al. (2015) stated that the application of a mixture of essential oils through massage in children with first-degree burns made a significant decrease in the HR and RR (Domingos Tda and Braga 2015).

This study has several strengths. The researchers evaluated the effects of complementary therapies in older women as a neglected area of research in relation to complementary therapy. This was also the first study to examine the effect of aromatherapy massage in patients with ACS. Furthermore, studies on the biological outcomes following aromatherapy massage have been very limited. This study was conducted in one hospital with a group of homogeneous participants to prevent any threat to the generalization of the findings. However, further studies in other hospitals with a larger sample size from both genders are suggested.

Limitations and recommendation for future research of the study

Although this research demonstrated that aromatherapy massage can have beneficial effects on psychological and physiological symptoms, a lack of long-term massage and follow up may have limited the full effect of the intervention.

Another challenge was the inability to distinguish the effects of aromatherapy from the effects of massage. However, the researchers hypothesized that a combination of aroma oil and massage might have increased the effectiveness of the intervention. Therefore, future studies focusing on the comparison of massage with and without essential oils are suggested. Also, it is recommended to continue the aromatherapy massage for at least one month.

Further studies on the application of aromatherapy massage in the CCU are also proposed to investigate its effect concerning patients' sedation levels and address the above-mentioned limitations. Contradictions in physiologic parameters in different studies warrant the necessity of further examination of the effect of aromatherapy massage. On the other hand, if the effectiveness of aromatherapy massage are confirmed in future clinical settings, healthcare providers should consider their use for treatment purposes.

5. Conclusion

Aromatherapy massage can be considered an efficient therapy for alleviating anxiety, depression and physiological responses among older women suffering from the acute coronary syndrome. The researchers suggest that this non-pharmacologic intervention can be used by clinical nurses, along with other measures, to relieve patients' physiologic and psychological responses during the provision of care in the CCU. Adding complementary therapies in health care settings, especially the CCU, may provide an alternative for the high use of medications in the aging population.

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Disclosure

The authors declare no conflict of interest.

Conflict of interest

None of the authors have any conflicts of interests with regards to this research.

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Contributions

Study design: TB, NR;

Data collection: TB, NR;

Data analysis: SJ, SDT;

Manuscript preparation and critical revision: TB, NR, MV, CS;

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Table 1. The demographic characteristics of the participants

Characteristics	**Total (n = 90)**	**Intervention group (n = 45)**	**Control group (n = 45)**	**Statistical test and *P* value**
Age Mean ± SD	73.300±7.801	73.97±7.69	72.62±7.93	t=-0.823 df=88 p =0.413
Education level, n (%) Illiterate Primary Diploma	66(73.3) 20(22.2) 4(4.4)	36(45.5) 8(40) 1(25)	30(45.5) 12(60) 3(75)	X^2=2.345 df=2 p =0.310
Marital status, n (%) Single Married Widow	4(4.4) 26(28.9) 60(66.7)	3(75) 11(42.3) 31(51.7)	15(57.7) 1(25) 29(48.3)	X^2=1.682 df=2 p=0.431
Employment status, n (%) Housewife Retired Disable	65(72.2) 7(7.8) 18(20.0)	32(49.2) 3(42.9) 10(55.6)	33(50.8) 4(57.1) 8(44.4)	X^2=0.380 df=2 p=0.827
Living status, n (%) Alone With spouse With children	38(42.20 26(28.9) 26(28.9)	18(47.4) 12(46.2) 15(57.7)	20(52/6) 14(53/8) 11(42/3)	X^2=0.874 df=2 p=0.646
History of hospitalization, n (%) Yes No	60(66.7) 30(33.3)	28(46.7) 17(56.7)	32(53.3) 13(43.3)	Fisher's exact p =0.503

* P values indicated the statistical significance of differences between the intervention and control groups using the independent t-test and chi-square test.

Table 2. The comparison of the levels of anxiety and depression before and after the intervention

Variables	Intervention group (n %)	Control group (n %)	Statistical test and *P* value	Cohens'd (Cramer's v^2)
Before the intervention				
Anxiety				
Normal	8(17.8)	11(24.4)		
Mild	8(17.8)	11(24.4)	X^2=1.808	
Moderate	13(28.9)	9(20.0)	df=3	
Severe	16(35.6)	14(31.1)	P^a=0.613	
QRS (Mean ± SD)	12.31±5.22	11.67±4.24	Leven's test=0.206 t=-0.642 df=88 p=0.523	
Depression				
Normal	8(17.8	9(20)		
Mild	8(17.8	15(33.3)	X^2=3.660	
Moderate	10(22.2)	6(13.3)	df=3	
Severe	19(42.2)	15(33.3)	P^a=0.301	
QRS (Mean ± SD)	12.51±5.40	11.71±4.29	Leven's test=0.122 t=-0.778 df=88 p=0.439	
After the intervention				
Anxiety				
Normal	20(44.4)	5(11.1)		
Mild	11(24.4)	20(44.4)	X^2=12.956	0.75
Moderate	9(20.0)	11(24.4)	df=3	(0.379)
Severe	5(11.1)	9(20.0)	P^a=0.005	
QRS (Mean ± SD)	8.04±4.71	11.07±3.19	Leven's test=0.032 t=3.560 df=77.36 p=0.001	
Depression				
Normal	21(46.7)	4(8.9)		
Mild	12(26.7)	19(42.2)	X^2=16.512	0.74
Moderate	8(17.8)	12(26.7)	df=3	(0.428)
Severe	4(8.9)	10(22.2)	P^a=0.001	
QRS (Mean ± SD)	8.04±4.71	11.11±3.42	Leven's test=0.071 t=3.512 df=88 p=0.001	

*P values indicated the statistical differences between the groups using chi-squared test for the qualitative rating system of anxiety and depression. P-value reported for the quantitative rating system using t-test by considering the equality of variances.

Cramer's v^2 showed the correlation between the intervention, anxiety and depression.

Cohen's d represented the effect size of the intervention on anxiety and depression, while considering their qualitative scoring systems. QRS stands for the quantitative rating system.

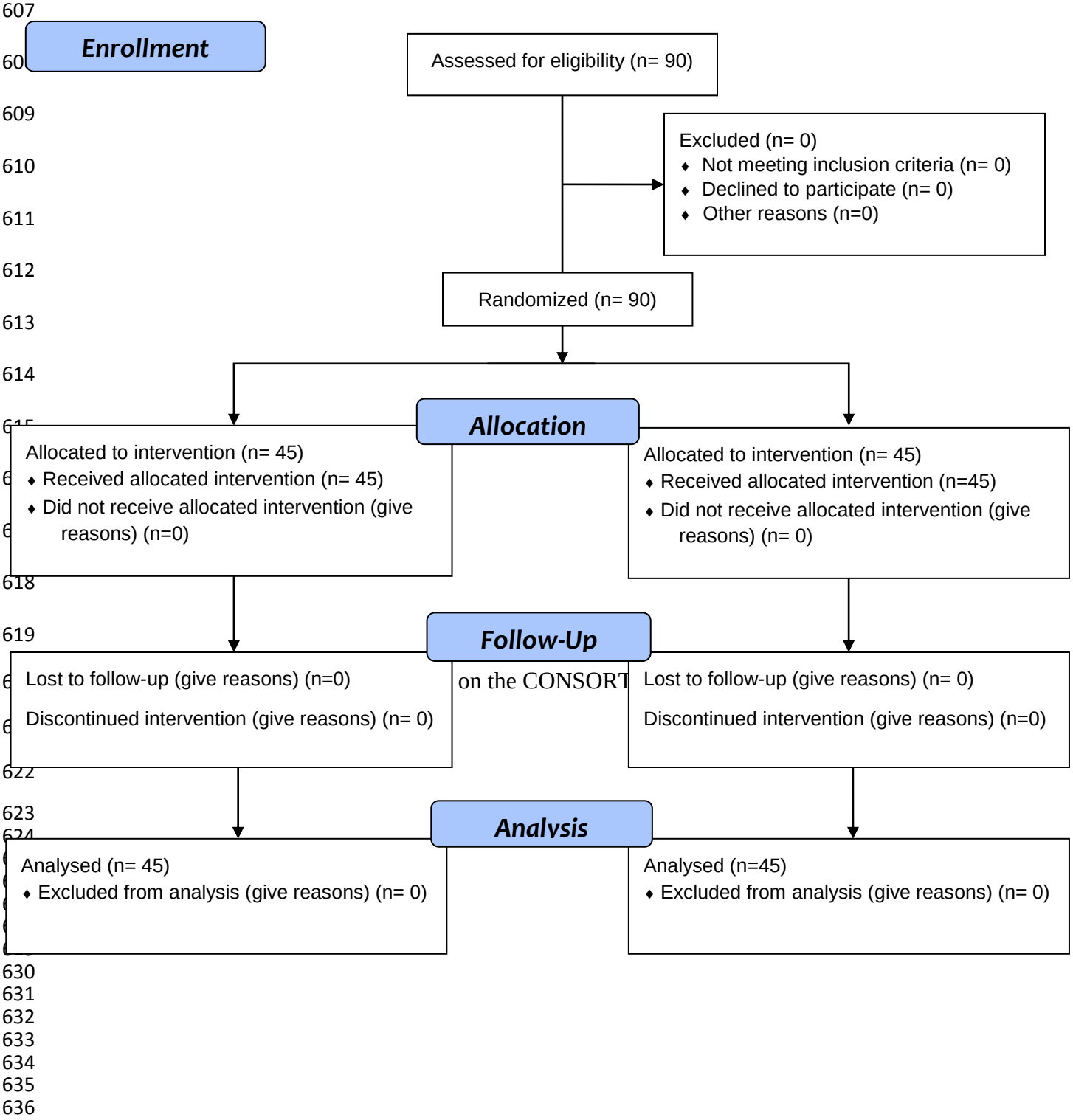
Table 3. The comparison of physiologic parameters before and after the intervention

Parameter	Group	SBP Mean±SD	DBP Mean± SD	MAP Mean±SD	HR Mean±SD	RR Mean±SD
Before intervention	Control	128.42±18.83	76.13±12.84	94.33±16.34	81.24±11.77	14.20±2.89
	Intervention	129.51±11.66	80.31±9.71	94.63±7.94	76.53±11.19	18.00±2.34
Statistical test		Leven's=0.002	Leven's=0.278	Leven's=0.000	Leven's=0.961	Leven's=0.405
P value		t=-0.330 df=73.42 p=0.743	t=-1.74 df=88 p=0.085	t=-0.10 df=63.71 p=0.913	t=1.94 df=88 p=0.055	t=-6.84 df=88 p<0.001
After intervention	Control	126.89±19.15	76.20±12.23	93.78±16.42	79.47±9.22	14.16±2.89
	Intervention	118.31±10.03	71.19±6.50	85.60±7.18	74.82±11.74	16.27±2.03
Statistical test		Leven's=0.000	Leven's=0.000	Leven's=0.000	Leven's=0.046	Leven's=0.044
P value		t=2.661 df=66.44 p=0.010	t=2.42 df=67.04 p=0.018	t=3.06 df=60.25 p=0.003	t=2.08 df=83.33 p=0.040	t=-3.99 df=78.95 p<0.001
Effect size (Cohen's d)		d=0.65 r=0.31	d=0.54 r=0.26	d=0.78 r=0.36	d=0.41 r=0.20	

* ($p < 0.05$)

Data are represented as means ± standard deviation. P-values indicated differences between the groups using the independent t-test by considering the equality of variance.

Cohen's d represented the effect size of the intervention on physiologic parameters.
SBP: systolic blood pressure
DBP: diastolic blood pressure
MAP: mean arterial pressure
HR: heart rate
RR: respiratory rate



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