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### Paper:

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

3

4 **Running Title:** Effect of aromatherapy massage on acute coronary syndrome

5

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21 **Trial Registration**

22 The Iranian Registry of Clinical Trial ID: IRCT201512027529N8

23

24 **Conflicts of interest**

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

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**Ethical approval**

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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**

Study design: TB, NR;

Data collection: TB, NR;

Data analysis: SJ, SDT;

Manuscript preparation: TB, NR, MV, CS;

Final approval of the version to be submitted: TB, NR, MHK, MV, CS;

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

55

56 **A B S T R A C T**

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

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

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71

72 **Summary statement**

73 *What is already known about the topic?*

- 74 • Depression and anxiety in cardiac care units are often not managed adequately.  
75 • Older adults with acute coronary syndrome may suffer from negative emotions more than other age groups.

76 *What this paper adds?*

- 77 • This study showed the positive effect of aromatherapy massage on alleviating anxiety and depression among older  
78 women with acute coronary syndrome.  
79 • Aromatherapy massage can be considered a complementary therapy and used along with routine interventions for  
80 relieving psychological and physiological problems among older women hospitalized in cardiac care units.

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

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## 84 1. Introduction

85 Acute coronary syndrome (ACS) is the type of ischemic heart disease (IHD) in which coronary arteries are  
86 obstructed or closed (Govindaraju, Badruddin et al. 2013). ACS leads to the reduction of the oxygen supply to heart  
87 muscles due to atherosclerosis or coronary artery spasm. Therefore, an increase in the myocardial oxygen demand,  
88 in cases of tachycardia or severe anemia, enhances the vascular injury and finally may lead to ACS (Cho, Min et al.  
89 2013).

90 As a major public health issue in developing countries, ACS has become highly prevalent, responsible for about 35  
91 percent of all deaths across the world. In other words, almost one million deaths occur each year due to ACS.  
92 Accordingly, about 40 percent of ACS-related deaths occur in high-income countries with a share of 28 percent in  
93 low to middle-income countries (McKinley, Dracup et al. 2009, Mohammadpur, Mohammadian et al. 2014). ACS is  
94 one of the leading causes of hospitalization in the cardiac care unit (CCU) (Han and Park 2002). Poor functional  
95 statuses in the activities of daily livings among patients with ACS result in anxiety and depression (Bauer, Caro et al.  
96 2012).

97 Anxiety affects the function of the body's organs and also causes negative health-related consequences in patients  
98 with myocardial infarction (MI) (Huffman, Mastromauro et al. 2011). Moreover, the progression of cardiac ischemia  
99 and even dysrhythmia are the significant negative consequences of anxiety and depression (Huffman, Celano et al.  
100 2010). More than half of these patients report the symptoms of anxiety due to the: 1) unfamiliar hospitalization's  
101 environment, 2) sudden diagnosis of ACS, 3) isolation from the family, 4) being encountered with strangers, 5) loss  
102 of individuality and independence, 6) unexpected care routines and 7) critical situations (McKinley, Fien et al.  
103 2012). In addition, these patients encounter many fearful situations such as: 1) life-threatening conditions, 2) the  
104 probability of an additional MI and 3) the fear of the unknowns (Arora, Anand et al. 2010). Such discomforts  
105 accelerate the release of catecholamine and cause physiologic responses such as an increase in the blood pressure  
106 (BP), heart rate (HR), respiratory rate (RR) and dyspnea, possibly exacerbating the development of MI (Frasure-  
107 Smith and Lesperance 2008).

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

112 Currently, more attention is paid to complementary and alternative medicine (CAM) strategies, because they have  
113 fewer complications and are easy to access (Mohammadpur, Mohammadian et al. 2014). These strategies are highly  
114 recommended in older patients with an impaired metabolism and increased sensitivity to the side effects of drugs  
115 (Perković-Vukčević, Vuković-Ercegović et al. 2016). For instance, cognitive and cardiovascular adverse effects  
116 among older people, after the use of tranquilizers and cardiovascular drugs, are very common (Sztramko, Chau et al.  
117 2011). CAM can help healthcare providers with the management of signs and symptoms related to cardiovascular  
118 disorders including ACS (Greenfield, Pattison et al. 2008).

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

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

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

## 138 **2. Materials and methods**

### 139 2.1. Aims

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

### 142 2.2. Design

143 This was a randomized controlled trial with a pre-intervention–post-intervention design. A convenience sample of  
144 90 older patients were randomly allocated into either the intervention or the control group. They were hospitalized  
145 for one day in the CCU and diagnosed with ACS. The patients in the intervention group received aromatherapy  
146 massage with lavender; those in the control group only received routine care delivered by nurses in the CCU.

### 147 2.3. Setting and participants

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

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

153 The following inclusion criteria were considered for the recruitment of the participants: 1) diagnosed with ACS; 2)  
154 60 years old and above (the beginning of the old age in developing countries); 3) able to understand and  
155 communicate in Farsi language and follow instructions; 4) not taking any anxiolytics and sedative drugs during the  
156 last four hours before the intervention; 5) not receiving alternative and complementary medicines during the last 48  
157 hours before the intervention; 6) not having foot ulcers; 7) no history of drug addiction; 8) no history of asthma,  
158 eczema and allergy and 9) passing the olfactory health test and the abbreviated mental test (score  $\geq 7$ ).

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

163

#### 164 2.4. Sample size

165 The sample size was determined using a statistical power analysis ( $\alpha = 0.05$ ,  $\beta = 15\%$ , power = 90%, Altman's  
166 Nomogram). It was also based on a sample size determined in a previous study (Mahmoudirad, Ghaedi Mosolo et al.  
167 2014).

#### 168 2.5. Randomization

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

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

#### 182 2.6. Measurements

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

186 *2.6.1. The personal and medical information form*

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

189 *2.6.2. Measurement of physiological parameters*

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

197 *2.6.3. Abbreviated Mental Test*

198 The abbreviated mental test (AMT) rapidly assesses older individuals for the presence of cognitive disorders. Older  
199 individuals, with a score greater than 7 were considered normal. A score lower than 7 out of 10 indicated cognitive  
200 impairment (Faraji, Fallahi khoshknab et al. 2013). The Cronbach's alpha coefficient of the AMT was reported as  
201 0.76 (Bakhtiyari, Foroughan et al. 2014).

202 *2.6.4. Hospital Anxiety and Depression Scale (HADS)*

203 The HAD scale evaluated the levels of anxiety and depression in the participants. The instrument consisted of 14  
204 items, seven for each subscale of anxiety (HADS-A) and depression (HADS-D). The participants rated each item on  
205 a self-rating scale from zero to three. The scoring system ranged from the absence of symptoms (score 0) to the  
206 maximal presentation of symptoms (score 3). Therefore, a higher score indicated a higher level of anxiety or  
207 depression (Zigmond and Snaith. 1983). Correlations between the two subscales varied from 0.40 to 0.74 with a  
208 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  
209 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  
210 the Iranian version of the hospital depression and anxiety scale (HADS) was assessed (Montazeri, Harirchi et al.  
211 1999). Also this scale was used in patients with coronary heart diseases in a previous study (Barth and Martin 2005).  
212 The cut-off score of greater than 8 for the diagnosis of either anxiety or depression was suggested (Stafford, Berk et  
213 al. 2007). The quantitative scoring of both subscales ranged from 0 to 27. Scores greater than or equal to five were  
214 associated with mild anxiety or depression. Scores greater than or equal to ten were associated with moderate  
215 anxiety or depression. Scores greater than or equal to 15 were associated with moderately severe anxiety or



216 depression, while scores equal to or greater than 20 indicated severe anxiety or depression (Kroenke, Spitzer et al.  
217 2001).

## 218 2.7. Intervention

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

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

232 The researcher washed her hands with warm water and applied a moderate amount of almond oil (6 drops) to her  
233 hands. After general foot massage, relaxing techniques included effleurage movements (ten times), stretching  
234 fingers by holding them between thumbs and other fingers (five times in both directions) and moderate rotational  
235 movements around the ankle (five times). The reflex zones of solar plexus, pituitary gland, brain, heart, large and  
236 small intestines, vertebral column, adrenal and kidney were used for the stimulation. The researcher exerted the firm  
237 downward pressure with her thumbs in the above-mentioned areas for: 1) 14 seconds in the solar plexus, 2) 40  
238 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  
239 intestine and 6) 5 times for the adrenal gland and kidney. The rubbing technique was used for the adrenal and kidney  
240 reflex zones. Prior to, and after the aromatherapy massage intervention, the levels of depression and anxiety in the  
241 hospital, and physiologic parameters were measured.

## 242 2.8. Ethical considerations

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

## 250 2.9. Data analysis

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

## 256 3. Results

### 257 3.1. The demographic characteristics of the participants at the baseline

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

### 262 3.2. Hospital Anxiety and Depression Scale scores

263 The statistical analysis with regard to the level of anxiety demonstrated that, after the intervention, the level of  
264 anxiety was significantly lower in the intervention group ( $\chi^2 = 12.95$ ,  $df = 3$ ,  $p = 0.005$ ) as compared with the  
265 control group. According to the Cramer's V test, the correlation between the intervention and level of anxiety was  
266 moderate ( $v^2 = 0.379$ ).

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

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

### 276 3.3. Physiologic parameters

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

#### 282 4. Discussion

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

287 Psychological issues, caused by an ACS in older people, can have negative impacts on their lives, and these  
288 additional problems should be managed by health care professionals. Many studies suggested different treatment  
289 modalities for the management of anxiety and depression, and the equilibration of physiologic parameters, but an  
290 interest in the use of complementary and alternative therapies among older patients with heart diseases is increasing  
291 (Sibbritt, Davidson et al. 2015). Various studies have confirmed the efficacy of non-pharmacological measures such  
292 as aromatherapy massage for relieving psychological symptoms in different groups of patients(Cooke and Ernst  
293 2000, Okamoto, Kuriyama et al. 2005), but immediate consequences and benefits of this therapy on the levels of  
294 anxiety and depression are still unknown.

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

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

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

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

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

330 Complementary medicine experts believe that during, and immediately after the intervention, some changes in the  
331 HR, RR or temperature may be created. Therefore, such interventions should be provided in more than one session  
332 to be able to assess and document its benefits (Gunnarsdottir and Jonsdottir 2010). This phenomenon, known as a  
333 cleansing process, can be the reason for the lack of changes in RR in this study. Unlike our findings Stevenson and  
334 Chang believe that respiratory rate decrease as an immediate effect of massage with the essential oil (Stevenson  
335 1994, Chang 2008). Also Domingos et al. (2015) stated that the application of a mixture of essential oils through  
336 massage in children with first-degree burns made a significant decrease in the HR and RR (Domingos Tda and  
337 Braga 2015).

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

344

#### 345 **Limitations and recommendation for future research of the study**

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

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

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

358

## 359 **5. Conclusion**

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

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## 370 **Disclosure**

371 The authors declare no conflict of interest.

372

## 373 **Conflict of interest**

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

375

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378

## 379 **Contributions**

380 Study design: TB, NR;

381 Data collection: TB, NR;

382 Data analysis: SJ, SDT;

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

384 Final approval of the version to be published: TB, NR, MHK, MV, CS;

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

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549 \* P values indicated the statistical significance of differences between the intervention and control groups

550 using the independent t-test and chi-square test.

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

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

573 Cramer's v<sup>2</sup> showed the correlation between the intervention, anxiety and depression.

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

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577 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
<b>Before intervention</b>	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
<i>Statistical test</i>		Leven's=0.002	Leven's=0.278	Leven's=0.000	Leven's=0.961	Leven's=0.405
<i>P value</i>		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
<b>After intervention</b>	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
<i>Statistical test</i>		Leven's=0.000	Leven's=0.000	Leven's=0.000	Leven's=0.046	Leven's=0.044
<i>P value</i>		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
<b>Effect size (Cohen's d)</b>		d=0.65 r=0.31	d=0.54 r=0.26	d=0.78 r=0.36	d=0.41 r=0.20	

578 \* (p &lt;0.05)

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

581 Cohen's d represented the effect size of the intervention on physiologic parameters.

582 SBP: systolic blood pressure

583 DBP: diastolic blood pressure

584 MAP: mean arterial pressure

585 HR: heart rate

586 RR: respiratory rate

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