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Aromatherapy massage versus reflexology on fatigue and cardiovascular parameters in older patients with the acute coronary syndrome: A randomized controlled trial

Short Title: aromatherapy massage versus reflexology

Authors

Tahereh Bahrami, Nahid Rejeh*, Majideh Heravi-Karimooi, Mojtaba Vaismoradi, Seyed Davood Tadrisi, Gholamreza Amin, Christina Sieloff

*Correspondence: Nahid Rejeh, Associate Professor, Elderly Care Research Center- Department of Nursing, Faculty of Nursing and Midwifery, Shahed University, University (opposite Holy Shrine of Imam Khomeini-Khalij Fars Expressway, Postal/zip code: 3319118651), Tehran. Iran.
Tel: +98 02166418590 Email: reje@shahed.ac.ir nrejeh@yahoo.com

The addresses of the institutions at which the work was carried out

Elderly Care Research Center- Department of Nursing, Faculty of Nursing and Midwifery, Shahed University, University (opposite Holy Shrine of Imam Khomeini-Khalij Fars Expressway, Postal/zip code: 3319118651), Tehran. Iran. Tel: +98 02166418590

Trial Registration

The Iranian Registry of Clinical Trial ID: IRCT201512027529N8

1 Tahereh Bahrami, M.Sc., Shahed University, Department of Nursing, Faculty of Nursing and Midwifery, Tehran. Iran. Email: btahereh@rocketmail.com

Nahid Rejeh (PhD) Associate Professor, Elderly Care Research Center- Shahed University, Department of Nursing, Faculty of Nursing and Midwifery, Tehran. Iran. Email: nrejeh@yahoo.com

Majideh Heravi-Karimooi (PhD) Associate Professor, Elderly Care Research Center- Shahed University, Department of Nursing, Faculty of Nursing and Midwifery, Tehran. Iran. Email: Majidehherav@yahoo.com

Mojtaba Vaismoradi (PhD, MScN, BScN), Researcher, Faculty of Professional Studies, Nursing and Health Sciences, Nord University, NO-8049 Bodø, Norway. Email: mojtaba.vaismoradi@nord.no

Seyed Davood Tadrisi (MScN) Faculty of Nursing, Baqiyatallah University of Medical Science, Tehran, Iran. Email: sdt1344@gmail.com

Gholamreza Amin (PhD) Professor of Medical Sciences, Faculty of Pharmacy pharmacogenetics group, Tehran University, Tehran, Iran. Email: amin@tums.ac.ir

Christina Sieloff (PhD, RN) Associate Professor, College of Nursing, Montana State University, Bozeman, Montana, USA. Email: csieloff@montana.edu
Conflict of interest

None of the authors has any conflict of interests concerning this research.

Acknowledgments

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Funding

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Ethical approval

Shahed University Review Board, No. 41-228111

Study registry number

Iranian Registry of Clinical Trials (IRCT) approval: 201512027529N8

Author contribution

TB: Substantial contributions to the conception or design of the work, the acquisition, analysis, or interpretation of data for the work, Drafting the work or revising it critically for important intellectual content, Final approval of the version to be published.

NR: Substantial contributions to the conception or design of the work, the acquisition, analysis, or interpretation of data for the work, Drafting the work or revising it critically for important intellectual content, Final approval of the version to be published.

MHK: interpretation of data for the work, Drafting the work or revising it critically for important intellectual content, final approval of the version to be published.

MV: The acquisition, analysis, or interpretation of data for the work, Drafting the work or revising it critically for important intellectual content, final approval of the version to be published.
Effects of aromatherapy massage versus reflexology on fatigue and cardiovascular parameters in older patients with the acute coronary syndrome: A randomized controlled trial

Summary

**Background:** Fatigue and abnormalities in cardiovascular parameters are recognized as major problems for patients with acute coronary syndrome. Non-pharmacological nursing interventions are useful for controlling this fatigue and reducing patients’ suffering during hospitalization.

**Objective:** The present study was conducted to compare the effects of aromatherapy massage and reflexology on fatigue and cardiovascular parameters in patients with acute coronary syndrome.

**Design:** This randomized clinical trial was conducted with 135 female older patients with acute coronary syndrome who were hospitalized on a cardiac care unit in 2014. The patients were selected using a random sampling method and then were randomly divided into three groups: aromatherapy massage, reflexology, and control. The fatigue severity and cardiovascular parameters were assessed through the Rhoten fatigue scale and a checklist, respectively. Measurements in the groups were performed before and immediately after the intervention. Data analysis was performed using descriptive and analytical statistics via the SPSS software.

**Results:** Aromatherapy massage significantly decreased fatigue, systolic blood pressure, mean arterial pressure and O₂ saturation greater than reflexology. However, reflexology reduced heart rate more than aromatherapy massage (P < 0.05). Moreover, no significant changes were observed in diastolic blood pressures compared to the control group (P = 0.37).
**Key words:** acute coronary syndrome, aromatherapy massage, cardiovascular parameters, fatigue, reflexology
1. Introduction

Fatigue is one of the most common distressing symptoms in patients with acute coronary syndrome (ACS), impeding patients’ active lifestyle (1, 2). The progression of fatigue may negatively affect the ACS and exaggerate this disease (3, 4). Moreover, fatigue alters autonomic nervous activities and may lead to abnormalities in cardiovascular parameters (5, 6). In addition, fatigue is a poorly understood phenomena that requires a multidisciplinary approach for management (7).

Despite the use of various medications for symptom relief in patients with ACS, pharmacologic modalities may not be able to offer a thorough remedy of the disease or its symptoms including fatigue (8, 9). Several non-pharmacological approaches such as cognitive behavior therapy, progressive relaxation training and multimodal psychosocial care programs are used for fatigue control (10). Of the complementary and alternative medicine (CAM) services, massage and aromatherapy are the most powerful therapeutic interventions for overcoming fatigue (11, 12) in patients with ACS.

Aromatherapy is a holistic intervention applied through inhalation or massage (13, 14). Aromatherapy massage consists of the use of essential oil, extracted from the vapor of volatile essence of plants, through massage. Lavender (Lavandula angustifolia) is widely used in different contexts (15, 16). Previous studies have confirmed the sedative effects of linalyl acetate on the parasympathetic system. Also, it has been found that lavender promotes the heart function and coronary blood flow (14, 17, 18). Tisserand et.al. (1988) suggested lavender may have a similar function to the benzodiazepines and can promote the effects of gamma-amino-butyric acid in the amygdala (19). Several studies reported that lavender resulted in reduced fatigue in different patients groups(20, 21). For instance, in randomized controlled studies, Balouchi et al. (2016) and Chen et al. (2015) found that aromatherapy with lavender significantly decreased fatigue (22, 23). Tahmasebi et al. (2014) in a quasi-experimental clinical trial also stated that lavender alleviated cardiovascular parameters in cardiovascular patients (24).

Another complementary therapy approach with a potential beneficial effect for reducing fatigue is reflexology (25). Reflexology is an ancient practice using the thumb and fingers on hands, feet and ears via stimulating some areas called reflex zones. A reflex zone corresponds with an organ, gland or body parts and is proposed to help with the body’s self-improvement (7, 26, 27). Reflexologists claim that massage pressure on the reflex zone increases blood supply to the corresponding organ associated with the area being massaged (28). Reflexology is useful for managing adverse physical and psychological symptoms of a disease and its treatment process. In addition, reflexology can reduce fatigue (26, 29). A randomized controlled trial reported that reflexology significantly decreased fatigue after eight reflexology sessions (30). However, another randomized controlled trial study, with healthy volunteers, demonstrated that reflexology did not affect cardiovascular parameters (31).
Few studies have focused on the comparison of aromatherapy massage and reflexology. In addition, the authors did not find any study investigating the effects of these modalities on patients with ACS. The aim of this study was to compare the effects of aromatherapy massage and reflexology on fatigue and cardiovascular parameters in female older patients with ACS.

2. Methods

2.1. Design

This randomized controlled trial involved 135 female older patients with an acute coronary syndrome who were assigned to one of three groups including: 1) reflexology (n=45), 2) aromatherapy massage (n=45) and 3) a control group (n= 45). The primary outcome measures were the effect of reflexology and aromatherapy massage on patient reported fatigue and their cardiovascular parameters before treatment and after the treatment (Figure 1).

2.2. Setting

The patients were recruited from high turnover coronary care units (CCU) of a large tertiary referral teaching hospital in an urban area of Iran, between from July 2014 to December 2015.

2.3. Sample

All patients with ACS, hospitalized in the CCU, were invited to take part in the study.

2.4. Eligibility criteria

2.4.1. Inclusion criteria

The inclusion criteria were patients: 1) aged above 60 years; 2) no anxiolytics and sedative drugs in the last 4 hours; 3) no alternative and complementary health care services in the last 48 hours; 4) absence of foot ulcers; 5) no history of drug addiction, asthma, eczema and allergy; and 6) passing the olfactory test and the abbreviated mental test (score ≥ 7).

2.4.2. Exclusion criteria

Any instability in cardiovascular parameters during the intervention or unwillingness to enter the study were the exclusion criteria.

2.5. Interventions and control groups

2.5.1. Control group

The patients in the control group received the usual care in the CCU.
2.5.2. Reflexology group

Reflexology, the stimulation of specific zones on the feet associated with different organs, based on the Ingham method of reflexology, was administered to the reflexology intervention group (32). The researcher, who was qualified to administer reflexology, performed the intervention once the patients were comfortable in a bed in the supine position. Nursing and medical professionals were instructed not to disturb the patient during the intervention or the rest period unless it was necessary. Furthermore, the patients were asked to refrain from speaking during the intervention unless it was necessary and try to feel the sensations of their body and express feelings, which could help the intervention. A pillow was placed under the patients’ knees to facilitate the massage. The investigator washed her hands with warm water and performed general foot massage with six drops of almond oil dropped in each foot. Relaxation techniques used for loosening the foot and preparing it for reflexology 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).

Afterward, systematic reflexology focused on reflex zones corresponding to the patients’ solar plexus (14 seconds), pituitary gland (40 seconds), brain (5 seconds), heart (10 seconds), intestines (5 seconds), vertebral column (5 times), adrenal gland and kidney (5 times) were performed. These actions were performed using a firm downward pressure of the thumb and rubbing pressing for stimulating intestines and kidneys. Prior to, and after, the reflexology intervention, the levels of anxiety, depression, and cardiovascular parameters were assessed. The total duration of the reflexology intervention was 20 minutes.

2.5.3. Aromatherapy massage group

The aromatherapy massage, using lavender essential oil, was consisted of Linalool (27.11 %) and Linalyl acetate (23.33%) acetate. Essential oil was formulated in the ratio of 3:3:2:2 ml. in 100 ml. of coconut carrier oil. Lavender essential oil was chosen through consultation with the Department of Pharmacognosy, faculty of Pharmacy, Tehran University of Medical Sciences. Reflexology, with ten drops of the essential oil, formed the aromatherapy massage. The massage was applied to each foot (total 20 drops) on the same reflex zones as the reflexology group. The total duration of the aromatherapy massage lasted for 20 minutes.

2.6. Measures

2.6.1. The demographic and medical information form.

The demographic characteristics form was designed using the international literature. It included questions such as age, marital status, employment status, educational level, living status and history of hospitalization.
2.6.2. Cardiovascular parameters

Systolic blood pressure (SBP), diastolic blood pressure (DBP), mean atrial pressure (MBP), heart rate (HR), respiratory rate (RR) and O₂ saturation (SpO₂) data were measured using a standard and calibrated monitoring machine.

2.6.3. The Rohten fatigue scale (RFS).

The RFS was a 10 cm. line with extremely positive statements constituting one end and extremely negative statements the other end. The most positive and negative fatigue statements were scored 0 and 10, respectively. According to the visual analogue scale (VAS), the rating of this line included 0 (lack of fatigue), 1-3 (low fatigue), 4-6 (moderate fatigue), 7-9 (high fatigue) and 10 (severe fatigue) (33).

2.6.4. Abbreviated mental test (AMT).

The AMT rapidly assessed patients with cognitive disorders. Patients with a score greater than 7 were considered normal. Patients with a score lower than 7 out of 10 were diagnosed with a cognitive impairment (34). In terms of reliability, the Cronbach's alpha coefficient of the AMT was reported as 0.76 (35).

2.7. Data collection

All patients with ACS, hospitalized in the first day in the CCU, were invited to take part in the study. They were allocated into the groups using sealed, opaque, and tamper-proof envelopes using the printed tables of random numbers. The RFS and the cardiovascular parameters checklist was completed by a nurse staff before and immediately after the intervention for all groups.

2.8. Data analysis

2.8.1. Sample size

The sample size was 135 patients. A sampling formula was used to determine the number of required patients with the consideration of \( \alpha = 0.05 \), \( \beta = 90\% \), Altman’s Nomogram and also using the sample size in a previous study (36).

2.8.2. Statistical procedures

Data was analyzed using descriptive and inferential statistics via the SPSS software (SPSS Inc., Chicago, IL). Data analysis was performed using descriptive statistics (frequency, percentage, mean and standard deviation) and inferential statistics (one-way ANOVA, Chi-squared test, Tukey's, Cramer's and Phi test and Cohen’s d test). The impact of the interventions on the post-
intervention fatigue and cardiovascular parameters were investigated. The chi square test was used to assess whether there were any significant differences between the fatigue reported by the patients in each group. Cardiovascular parameters, using one-way ANOVA and LSD, were assessed for determining between the group effects of the interventions. The Eta correlation ratio was used to examine the relationship between the rating scale and the interventions, but the pair wise comparisons were performed by using the Cohen's d test. The Kolmogorov-Smirnov test examined the normal distribution of the data. The alpha was set at $p < 0.05$. In addition, the Leven’s test was used to report the homogeneity of the variance. The Cramer’s and phi correlation ratio examined the relationship between the interventions and fatigue.

2.9. Ethical Considerations

This study was approved by the Ethical Commission affiliated with Shahed University, Tehran, Iran. The aim and the method of the study were explained to each patient and an informed verbal consent form was signed by those who agreed to take part in this study. The confidentiality and anonymity of the participants were ensured by using code numbers instead of names. Patients could also withdraw from the study at any time without penalization.

3. Results

3.1. The demographic characteristics of the participants

One hundred thirty five patients met the inclusion criteria and were randomized into the three groups. The study population had a mean age of 72.78 ± 7.65 years. The ANOVA and Chi-square test showed no statistically significant differences between the groups in terms of age, marital status, employment status, educational level, living status, and history of hospitalization (Table 1).

3.2. Fatigue

Significant differences were reported in the levels of fatigue between the patients in the control and the intervention groups ($x^2 = 51.262, P = 0.001$). Most of the patients (63%, $n= $) reported severe levels of fatigue. However, after the interventions 57 percent of them ($n= $) showed moderate fatigue. The pair wise comparison of the groups revealed that both intervention groups showed a reduction of the levels of fatigue ($p = 0.001$., However, the Crammer’s and Phi test indicated the larger effect of aromatherapy massage on the reduction of the level of fatigue as compared with reflexology ($\Phi = 0.67$) (Table2).

3.2.1. Cardiovascular parameters

The one way ANOVA was used to assess the effect of aromatherapy massage and reflexology on the cardiovascular parameters. Furthermore, the interaction between the interventions and the response variables (SBP, DBP, HR, RR, SpO$_2$, MAP) were measured using Eta correlation ratio.
Tukey’s LSD test analyzed the pairwise comparison of the groups. In addition, Cohen's d indicated which intervention was more effective in controlling fatigue and cardiovascular variables.

3.2.1.1. Systolic blood pressure

The results of the ANOVA test showed a significant reduction of the SBP (p = 0.01) in ???. There was a direct association between the SBP and the interventions (η²p=0.065). The result of Tukey’s test revealed that aromatherapy massage was responsible for the SBP reduction (p = 0.005) and Cohen's d showed the medium effect of this intervention (d=0.58).

3.2.1.2. Diastolic blood pressure

The results of the ANOVA test showed that there was no significant reduction in DBP (P < 0.98).

3.2.1.3. Heart rate

The results of the ANOVA test showed a significant reduction in HR (p = 0.01). Also, there was a direct association between the patients’ HR and the interventions (η²p = 0.062). The result of the Tukey’s test revealed that reflexology was responsible for the HR reduction (P = 0.01) and Cohen's d showed a medium effect of this intervention (d = 0.65).

3.2.1.4. Respiration rate

According to the ANOVA test, a significant reduction resulted in the patients' RR (p = 0.04). Moreover, there was a direct association between the patients’ RR and the interventions (η²p = 0.079). The Tukey’s test revealed that both aromatherapy massage and reflexology decreased the patients’ RR (p < 0.05) and Cohen's d showed a medium effect of the aromatherapy massage and reflexology (d = 0.62, d = 0.50).

3.2.1.5. Oxygen saturation

A significant reduction in the patients’ SpO2 (p = 0.001) was reported by the ANOVA test. Also, there was a direct association between the patients’ RR and the interventions (η²p=0.107). The Tukey’s test revealed that both aromatherapy massage could decrease the patients’ SpO2 (p = 0.01) and Cohen's d showed the large effect of the aromatherapy massage (d = 1.04).

3.2.1.6. Mean arterial pressure

The results of the ANOVA tests revealed a significant reduction in the patients’ MAP (p = 0.04). There was a direct association between the patients’ MAP and the interventions (η²p = 0.080). According to the Tukey’s test, the aromatherapy massage was responsible for the the
patients’ MBP reduction (P = 0.01) and Cohen's d showed a medium effect of this intervention (d = 0.58).

4. Discussion

This study was conducted with the aim of comparing the effects of aromatherapy massage and reflexology on fatigue and cardiovascular parameters in patients with the acute coronary syndrome.

The results of this study demonstrated that aromatherapy massage and reflexology had more effects on fatigue and cardiovascular parameters, except DBP, as compared with the control group. Moreover, both interventions decreased fatigue severity in patients with ACS, but this reduction was greater with the aromatherapy massage group as compared with the reflexology group. The combination of massage therapy and lavender essential oil appeared to accelerate the removal of catabolites and fortified the heart (37).

Similar to the current study, in a previous study, aromatherapy massage administered to middle-aged female patients also reduced their fatigue (38). In addition, Fellowes et al. (2008) in a review study stated that aromatherapy massage reduced fatigue in patients with cancer (39). In contrast, findings of a long-term randomized controlled trial by Metin and et al. (2016) demonstrated that reflexology reduced fatigue earlier than aromatherapy massage. This postponement may be due to the time required for essential oil absorption in inflamed joints (40, 41).

The comparison of the patients’ cardiovascular parameters before and after the intervention demonstrated that aromatherapy massage reduced patients’ RR and had a greater effect on controlling patients’ SpO2. However, patients’ DBP showed no changes in either of the intervention groups. Reflexology seemed to have a greater effect on reducing patients’ HR, while aromatherapy massage better controlled patients’ SBP, MAP and SpO2 rather than reflexology.

Eguchi et.al. (2016) reported that aroma foot massage decreased patients’ SBP and DBP. Furthermore, Hur et al. (2007) achieved the same results among climacteric women (42, 43). Yi et al. (2002) reported that patients’ SBP, DBP, and HR differed significantly between aromatherapy and control groups in pre-surgery patients. Kaur et al. (2012) suggested that three reflexology sessions could significantly decrease patients’ SBP, increase DBP, reduce HR and improve SpO2. However, no statistically significant differences were found in patients’ BP and HR (44). Such cardiovascular contradictions may be due to differential response times among individuals and the reflexology map locations used, making it difficult for the methods and findings to be reproduced. Possibly, nonspecific effects such as the sympathy, verbal and psychological communication between the researcher and patients during a massage could have affected the hemodynamic status of an individual organ (28).
This study supports the distinction between the effect of massage and essential oil from only massage by using reflexology in both intervention groups. Therefore, a more useful intervention was suggested.

5. Limitation and recommendation for further research

Few studies have compared the effects of aromatherapy massage and reflexology on patients’ fatigue and cardiovascular parameters. Therefore, further studies are needed to identify additional effective non-pharmacologic interventions.

Replication research, using the same outcome measures and scales, could lend support to the current findings. Moreover, longer follow ups can further describe the full impact of the interventions.

The impossibility of data collector and patients’ blinding could be a potential bias. Also, the homogeneous nature of the samples makes the generalizability of the findings difficult to all patients with the ACS.

Further research could explore the effects of aromatherapy massage and reflexology on physiologic and psychological symptoms (anxiety, depression and sleep disturbance) following hospitalization for patients with ACS when providing holistic nursing care.

6. Conclusions

The findings of this study confirmed that aromatherapy massage and reflexology could be used as non-pharmacologic interventions for managing fatigue and cardiovascular parameters in patients with ACS. Along with routine care, nurses can independently use these non-pharmacologic and safe interventions for improving the quality of care delivered to patients.
References:


Table 1. The demographic characteristics of the samples

<table>
<thead>
<tr>
<th>Demographic Groups</th>
<th>Mean±SD</th>
<th>df</th>
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</tr>
<tr>
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<td>0.685</td>
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<tr>
<td>2</td>
<td>72.86±7.98</td>
<td>132</td>
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<td>3</td>
<td>73.97±7.69</td>
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<td>2</td>
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<td>Retired</td>
<td>2 (4.4%)</td>
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<tr>
<td>Out of Work</td>
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<tr>
<td>Total</td>
<td>45 (100%)</td>
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<td>104 (77%)</td>
<td>45</td>
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<tr>
<td>Diploma</td>
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<td>45</td>
<td></td>
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<tr>
<td>Total</td>
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<tr>
<td>Widow</td>
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<tr>
<td>Total</td>
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<td>Alone</td>
<td>19 (42.2%)</td>
<td>45</td>
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<td>Spouse</td>
<td>15 (33.3%)</td>
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<td>With child</td>
<td>11 (24.4%)</td>
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<td>Total</td>
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<td>Total</td>
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<td>32 (71.9%)</td>
<td>45</td>
<td>4.46</td>
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<tr>
<td>No</td>
<td>38 (28.1%)</td>
<td>45</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>45 (100%)</td>
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p-values indicated significance of the differences between the intervention and control groups using the one-way ANOVA (quantitative variable) given the equality of variance.

The Chi-square test was used to evaluate the qualitative parameters.

Control group = 1; Reflexology intervention group = 2; Aromatherapy massage intervention group = 3
Table 2. The comparison of the fatigue severity before and after the interventions.

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Group</th>
<th>Low</th>
<th>Moderate</th>
<th>High</th>
<th>Severe</th>
<th>Total</th>
<th>$X^2$</th>
<th>df</th>
<th>Sig</th>
<th>Cramer’s phi</th>
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</thead>
<tbody>
<tr>
<td>Fatigue</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Before the intervention</td>
<td>1</td>
<td>2(4.4%)</td>
<td>10(22.2%)</td>
<td>8(17.8%)</td>
<td>25(55.6%)</td>
<td>45(100%)</td>
<td>4.061</td>
<td>6</td>
<td>0.668</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>1(2.2%)</td>
<td>9(20%)</td>
<td>6(13.3%)</td>
<td>29(64.4%)</td>
<td>45(100%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>0(0)</td>
<td>10(22.2%)</td>
<td>4(8.9%)</td>
<td>31(68.9%)</td>
<td>45(100%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>3(2.2%)</td>
<td>29(21.5%)</td>
<td>18(13.3%)</td>
<td>85(63%)</td>
<td>135(100%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| Fatigue After the intervention |       |      |          |       |        |        |       |    |      |               |
| No fatigue | 1     | 3(6.7%) | 9(20%)  | 8(17.8%) | 9(20%) | 16(35.6%) | 45(100%) | 51.262 | 8  | 0.001 | $\Phi=0.62$  |
|            | 2     | 2(4.4%) | 11(24.4%) | 24(53.3%) | 6(13.3%) | 2(4.4%) | 45(100%) |       |    |      | $\Phi_C=0.44$ |
|            | 3     | 0(0%)  | 20(44.4%) | 25(55.6%) | 0(0%)  | 0(0%)  | 45(100%) |       |    |      |               |
| Total      |       | 5(3.7%) | 40(29.6%) | 57(42.2%) | 15(11.1%) | 18(13.3%) | 135(100%) |       |    |      |               |

| Fatigue After the intervention |       |      |          |       |        |        |       |    |      |               |
| No fatigue | 1     | 3(6.7%) | 9(20%)  | 8(17.8%) | 9(20%) | 16(35.6%) | 45(100%) | 19.889 | 4  | 0.001 | $\Phi=0.47$  |
|            | 2     | 2(4.4%) | 11(24.4%) | 24(53.3%) | 6(13.3%) | 2(4.4%) | 45(100%) |       |    |      | $\Phi_C=0.47$ |
| Total      |       | 5(3.7%) | 40(29.6%) | 57(42.2%) | 15(11.1%) | 18(13.3%) | 135(100%) |       |    |      |               |

p-values indicated significant of the differences between the groups using the Chi-square test. Also, the pair wise comparison was performed using the Tukey’s LSD test.

The Cramer’s Phi correlation ratio was used to report correlations between interventions and fatigue severity.

Control group = 1; Reflexology intervention group = 2; Aromatherapy massage intervention group = 3
Table 3. The comparison of the cardiovascular parameters before and after the interventions.

<table>
<thead>
<tr>
<th>Cardiovascular indicators</th>
<th>group</th>
<th>Baseline M ±SD</th>
<th>Post interventions M ±SD</th>
<th>Baseline p-value (between groups)</th>
<th>Post interventions p-value (between groups)</th>
<th>ES η²p</th>
<th>Post test (LSD)</th>
<th>Cohen’s d</th>
<th>Effect seize</th>
</tr>
</thead>
<tbody>
<tr>
<td>SBP</td>
<td>1</td>
<td>128.42±18.83</td>
<td>126.89±19.15</td>
<td>0.85</td>
<td>0.01</td>
<td>0.065</td>
<td>(1,2) 0.510</td>
<td>(1,3) 0.005</td>
<td>(1,3) d=0.58 r=0.28</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>127.76±12.99</td>
<td>124.80±13.89</td>
<td></td>
<td></td>
<td></td>
<td>(1,2) 0.01</td>
<td>(1,3) 0.25</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>129.51±11.66</td>
<td>117.78±10.76</td>
<td></td>
<td></td>
<td></td>
<td>(1,2) 0.07</td>
<td>(1,3) 0.31</td>
<td></td>
</tr>
<tr>
<td>DBP</td>
<td>1</td>
<td>75.67±12.10</td>
<td>76.20±12.23</td>
<td>0.05</td>
<td>0.37</td>
<td></td>
<td>(1,2) 0.94</td>
<td>(1,3) 0.01</td>
<td>(1,3) d=0.64 r=0.31</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>75.87±12.15</td>
<td>73.76±11.72</td>
<td></td>
<td></td>
<td></td>
<td>(1,2) 0.01</td>
<td>(1,3) 0.25</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>81.20±11.76</td>
<td>73.13±8.65</td>
<td></td>
<td></td>
<td></td>
<td>(1,2) 0.07</td>
<td>(1,3) 0.31</td>
<td></td>
</tr>
<tr>
<td>MAP</td>
<td>1</td>
<td>94.33±16.34</td>
<td>93.78±16.42</td>
<td>0.57</td>
<td>0.04</td>
<td>0.080</td>
<td>(1,2) 0.94</td>
<td>(1,3) 0.01</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>97.11±15.34</td>
<td>94.69±16.25</td>
<td></td>
<td></td>
<td></td>
<td>(1,2) 0.01</td>
<td>(1,3) 0.25</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>94.63±7.94</td>
<td>85.60±7.18</td>
<td></td>
<td></td>
<td></td>
<td>(1,2) 0.07</td>
<td>(1,3) 0.31</td>
<td></td>
</tr>
<tr>
<td>H.R</td>
<td>1</td>
<td>80.36±8.80</td>
<td>79.96±8.96</td>
<td>0.07</td>
<td>0.01</td>
<td>0.062</td>
<td>(1,2) 0.01</td>
<td>(1,3) 0.25</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>77.16±13.72</td>
<td>73.60±10.47</td>
<td></td>
<td></td>
<td></td>
<td>(1,2) 0.01</td>
<td>(1,3) 0.25</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>74.82±11.74</td>
<td>76.53±11.19</td>
<td></td>
<td></td>
<td></td>
<td>(1,2) 0.07</td>
<td>(1,3) 0.31</td>
<td></td>
</tr>
<tr>
<td>R.R</td>
<td>1</td>
<td>15.18±3.64</td>
<td>15.18±3.64</td>
<td>0.19</td>
<td>0.04</td>
<td>0.079</td>
<td>(1,2) 0.005</td>
<td>(1,3) 0.03</td>
<td>(1, 2) d=0.62 r=0.30</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>15.64±1.81</td>
<td>17.04±2.17</td>
<td></td>
<td></td>
<td></td>
<td>(1,2) 0.005</td>
<td>(1,3) 0.03</td>
<td>(1, 3) d=0.50 r=0.25</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>18.00±2.34</td>
<td>16.69±2.29</td>
<td></td>
<td></td>
<td></td>
<td>(1,2) 0.07</td>
<td>(1,3) 0.31</td>
<td></td>
</tr>
<tr>
<td>SpO2</td>
<td>1</td>
<td>89.80±4.11</td>
<td>89.82±4.14</td>
<td>0.10</td>
<td>0.001</td>
<td>0.107</td>
<td>(1,2) 0.06</td>
<td>(1,3) 0.01</td>
<td>(1, 3) d=0.50 r=0.25</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>91.22±4.01</td>
<td>92.09±3.90</td>
<td></td>
<td></td>
<td></td>
<td>(1,2) 0.01</td>
<td>(1,3) 0.25</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>91.20±2.40</td>
<td>92.51±1.81</td>
<td></td>
<td></td>
<td></td>
<td>(1,2) 0.07</td>
<td>(1,3) 0.31</td>
<td></td>
</tr>
</tbody>
</table>

Data were presented as means ± standard deviation. p-values indicated the difference between the groups using the one-way ANOVA using the equality of variance. The pair wise comparison of the groups was conducted using the Tukey’s LSD test.

The Eta correlation ratio was used to report the correlation between interventions and cardiovascular parameters.

The Cohen’s d represented the effect size of the interventions on cardiovascular parameters

SBP = systolic blood pressure; DBP = diastolic blood pressure; MAP = mean arterial pressure;
HR = heart rate; RR = respiratory rate; SpO₂ = O₂ saturation

Control group = 1; Reflexology intervention group = 2; Aromatherapy massage intervention group = 3
Figure 1. The process of the study according to the Consort flow diagram (2010)

- Enrollment
  - Assessed for eligibility (n=135)
    - Excluded (n=0)
      - Not meeting inclusion criteria (n=0)
  - Randomized (n=135)
    - Allocated to Reflexology (n=45)
      - Received allocated intervention (n=45)
    - Allocated to control group (n=45)
    - Allocated to Aromatherapy massage (n=45)
      - Received allocated intervention (n=45)

- Allocation

- Follow-Up
  - Lost to follow-up (n=0)
    - Lost to follow-up (n=0)
    - Lost to follow-up (n=0)

- Analysis
  - Analysed (n=45)
  - Analysed (n=45)
  - Analysed (n=45)