

The impacts of foot reflexology on anxiety among male candidates for coronary angiography: A three-group single-blind randomized clinical trial

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1. Introduction

Cardiovascular disease (CVD) is currently the first leading cause of death worldwide [1]. At the beginning of the 21st century, 25% of all deaths in developed countries were due to CVD [2,3]. Besides, CVD has been known as a major cause of disability in the world [4]. Moreover, its treatment includes different types of medical and surgical treatments and thus, it incurs huge costs to communities and individuals [5]. Studies show that CVD is also the commonest and the most important cause of preventable death in Iran, with a death rate of more than 40% [6].

The most well-known diagnostic technique for diagnosing coronary artery disease is angiography [7]. However, like other medical procedures and interventions, angiography is also associated with different adverse effects. For instance, most patients who are candidates for angiography experience high levels of anxiety [8–11], so that anxiety is considered as one of the most common pre-angiography psychological problems. A study reported that 50% of the candidates for angiography suffer from pre-angiography anxiety [8].

Anxiety can adversely affect physical and mental functioning [12]. It enhances sympathetic activity and thereby, increases heart and respiratory rates, blood pressure, cardiac workload, and myocardial oxygen demand [13], and results in cardiac arrhythmias [14]. Moreover, it causes thrombosis formation through stimulating catecholamine release, damaging arterial walls, and impairing platelet function. It can also affect patients' attitudes towards care services, their expectations, their decision-making ability [13,14], and angiography and treatment outcomes [17–19]. Therefore, effective anxiety prevention and management, particularly through non-pharmacological interventions, are needed to improve patient outcomes [10,15].

There are different non-pharmacological therapies for anxiety management, including massage, relaxation, music, social support, and reflexology [16–18]. As a complementary therapy, reflexology is the gentle massage of the feet, hands, and ears [15,19–23]. Previous studies reported conflicting findings about the effectiveness of foot reflexology in alleviating anxiety among patients who undergo different cardiac

procedures. Some studies showed that the technique has positive effects on cardiac patients' procedural anxiety (24), while some others reported the ineffectiveness of the technique [25,26] [26].

Due to the methodological limitations [33] and the contradictory results of previous studies, some scholars highlighted the necessity for further studies in this area [25–28]. These limitations include, but are not limited to, small sample size and failure to eliminate the confounding effects of gender, prescribing physician, and therapist's presence. The present study was made to provide further evidence concerning the effectiveness of foot reflexology. The aim of the study was to investigate the impacts of foot reflexology on anxiety among male candidates for coronary angiography.

2. Methods

2.1. Design

This study was a three-group single-blind randomized clinical trial.

2.2. Participants

Sample size was calculated by using the sample size calculation formula for experimental studies as well as the results of a similar study [29]. Based on an alpha of 0.05, a beta of 0.80, an effect size of 0.8, and an attrition rate of 15%, it was determined that 50 patients were needed for each study group. Therefore, 150 male candidates for undergoing coronary angiography were conveniently recruited to the study from a total of 213 patients who referred to the study setting for undergoing angiography. The inclusion of only male candidates was due to the fact that the interventionist in this study was a male nurse who, based on cultural and religious beliefs in Iran, could not touch female patients for the purpose of reflexology. Moreover, the inclusion of only male candidates helped us remove the effects of confounders such as gender and multiple interventionists. Sampling was performed during a 120-day time period from 28 February, 2017 to 25 June, 2017. Participants were randomized through block randomization to the three groups of

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experimental, placebo, and control.

Patients were included if they aged 40–80, were completely conscious and not addicted to opioids (based on the data retrieved from their medical records and healthcare providers), had neither health problems nor arterial line in the feet, suffered from no bleeding or mental disorders, received no anxiolytic agent during the past 48 h before the intervention, experienced neither bradycardia nor hypotension, used no pacemaker, participated in no other simultaneous trial, had no history of diabetes mellitus for more than ten years, and obtained a score of greater than 40 for the state subscale of Spielberger's State-Trait Anxiety Inventory. All patients were treated by one prescribing physician.

2.3. Procedure

Each day during sampling, we primarily generated a list of patients who were going to undergo coronary angiography at the next day and identified eligible patients. Then, a research assistant completed the Spielberger's State-Trait Anxiety Inventory for eligible patients through interviewing them at the morning of their angiography (between 06:00 to 08:00).

2.4. Measures

Data were collected using a two-part questionnaire. The first part contained items on participants' demographic characteristics including age, educational and marital status, place of residence, employment, living alone or with family, and previous history of physical health problems. The second part was Spielberger's State-Trait Anxiety Inventory. This inventory includes two subscales which measure state and trait anxiety. The state anxiety subscale comprises twenty items that evaluate feelings at the current moment. The trait anxiety subscale also consists of twenty items which assess general and usual feelings. Trait anxiety is a personality trait which can significantly affect state anxiety. Therefore, trait anxiety was considered in this study as a confounder and its measurement was done for the purpose of controlling its confounding effects. The Persian version of the inventory (generated through the process of forward and back-translation) was reported in an earlier study to have acceptable content validity and reliability [30].

The items of the state anxiety subscale are scored on a four-point scale as follows: "Not at all": 1; "Sometimes": 2; "Usually": 3; and "Very much": 4. Ten items of this subscale are scored reversely. The total score of this subscale ranges from 20 to 80 and is interpreted as follows: 20–29: mild anxiety; 30–49: relatively mild anxiety; 50–69: relatively severe anxiety; and 70–80: severe anxiety. As most of the participants had poor literacy skills, a research assistant who was blind to the groups was invited to interview the participants and complete the questionnaires.

2.5. Manipulation

Patients in the experimental group received foot reflexology from the third author (KH), who had passed a one-year reflexology course in a faculty of Iranian Traditional Medicine in Iran and had a five-year work experience in providing reflexology. Reflexology was provided through compressing and stimulating the solar plexus, heart, and pituitary reflex points at the plantar surface of participants' feet (Fig. 1). According to the principles of reflexology [19], these points can contribute to anxiety [19]. Each participant received reflexology for 20 min. The level of state anxiety was reassessed by the research assistant both 1 h after foot reflexology and immediately before being transferred to angiography room.

Patients in the placebo group received the same reflexology intervention as their counterparts in the experimental group. However, instead of the solar plexus, heart, and pituitary reflex points, the first

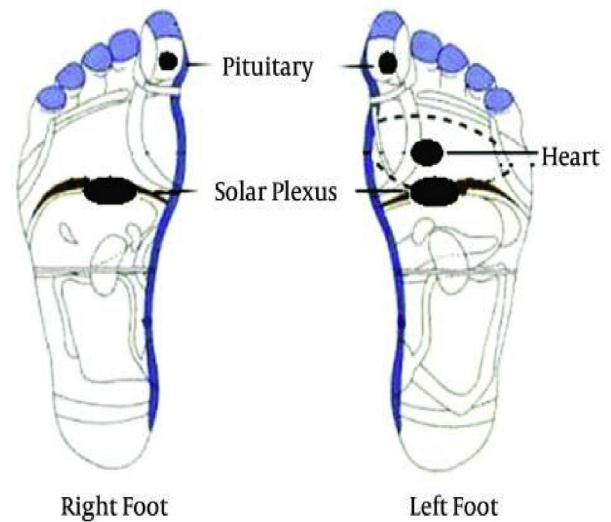


Fig. 1. Solar plexus, heart, and pituitary reflex points (19).

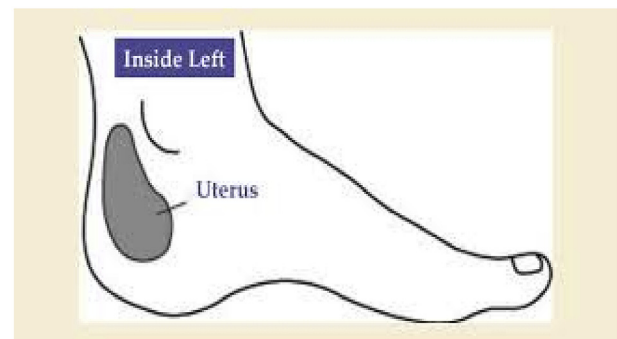


Fig. 2. Uterus reflex point.

author massaged the uterine reflex point at their feet (Fig. 2). Finally, the state anxiety subscale of Spielberger's inventory was recompleted for these patients at the aforementioned measurement time points.

Patients in the control group received no reflexology intervention. Rather, the first author attended their bedside and answered their questions. Then, the level of their anxiety was assessed at the same time points as the patients in the experimental and the placebo groups.

2.6. Ethical considerations

The target population of the study consisted of male candidates for undergoing coronary angiography who referred to Mousavi Hospital as one of the largest teaching hospital in the Northwest of Iran. Ethical approval for this study was obtained from the Ethics Committee of a local university (approval code: ZUMS.REC.1394.145). Informed consent was obtained from all participants.

2.7. Statistical analyses

The SPSS program v. 22.0 was used to analyze the data. The distributions of all study variables were normal and thus, the one-way analysis of variance (ANOVA) and the Chi-square tests were used for comparing the groups in terms of the demographic characteristics and the baseline values of state and trait anxiety. Moreover, the repeated measure ANOVA and the Tukey's post hoc test were used to assess the variations of state anxiety score in each group and also to compare the groups in terms of the variations of state anxiety score across the three measurement time points.

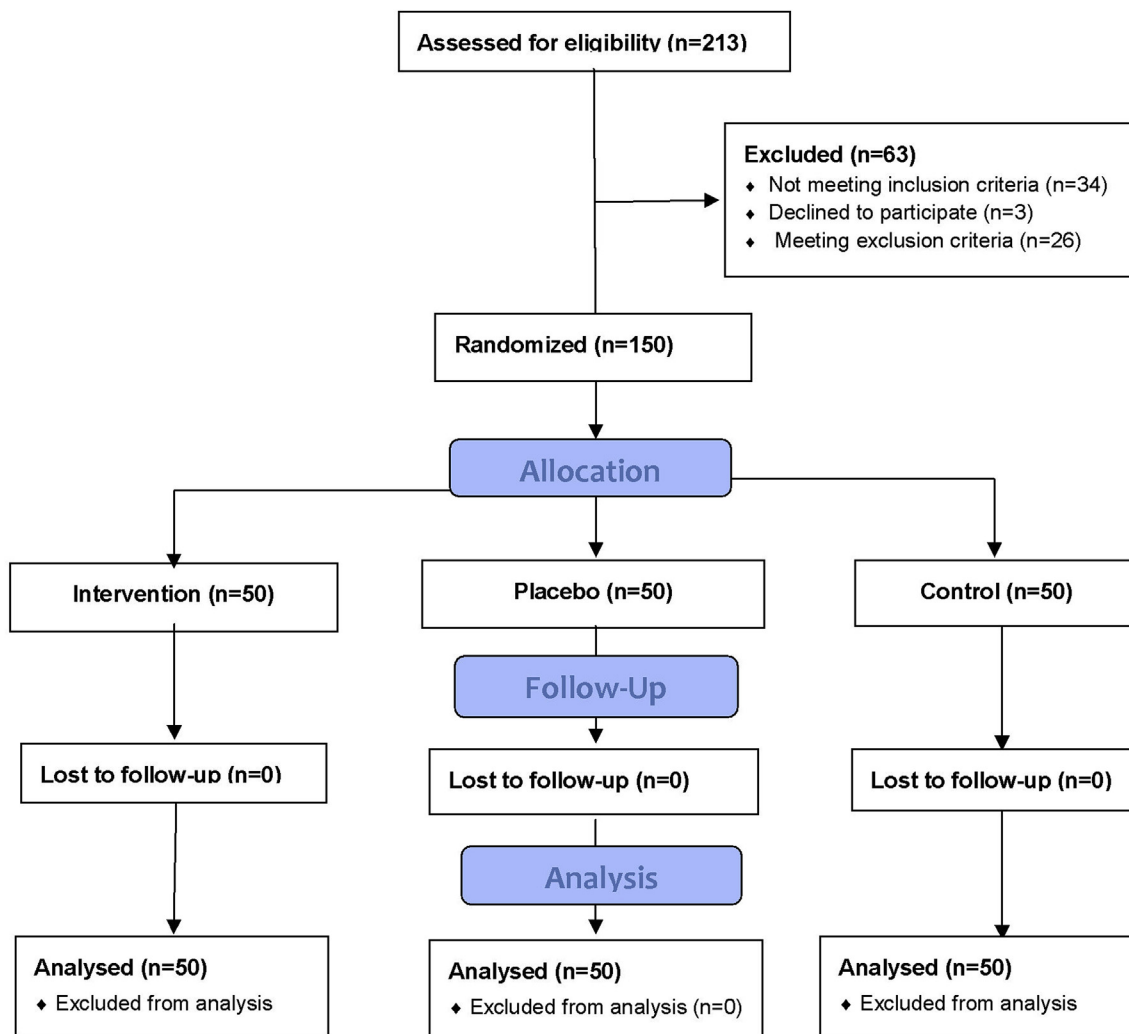


Fig. 3. The process of the study according to the CONSORT flow chart.

3. Results

In total, 150 patients were recruited to the study, all of whom remained in the study until its end (Fig. 3). The mean of participants' age was 66.5 ± 4.6 . Most of them held below-diploma degrees (38%), were married (60%), lived with their wives and children (40%), and suffered from a chronic illness (70%). Study groups did not differ significantly from each other with respect to participants' demographic characteristics as well as their trait anxiety ($P > 0.05$; Table 1).

Table 1
The participants' demographic characteristics.

Marital status: n (%)				
Married	35 (70%)	30 (60%)	30 (60%)	$\chi^2 = 1.43$
Single	15 (30%)	20 (40%)	20 (40%)	$P = 0.48$
Educational status: n (%)				
Illiterate	14 (28%)	16 (32%)	15 (30%)	
Primary	20 (40%)	18 (36%)	19 (38%)	$\chi^2 = 1.71$
Diploma and lower	10 (20%)	12 (24%)	13 (26%)	$P = 0.94$
Higher	6 (12%)	4 (8%)	3 (6%)	
Previous history of surgery: n (%)	16(32%)	16(32%)	13(26%)	$\chi^2 = 0.57$ $P = 0.75$
Previous history of chronic physical illness: n (%)				
Hypertension	39 (78%)	44 (88. 33%)	41 (82%)	$\chi^2 = 1.67$
Diabetes mellitus	53(%)26	27 (55%)	25 (50%)	$P = 0.71$
Baseline trait anxiety (Mean \pm SD)	61.68(5.47)	60.52(5.53)	62.08(4.61)	$F = 1.1$ $P = 0.33$

The results of the one-way ANOVA illustrated that at baseline, there was no significant difference among the groups regarding the level of state anxiety ($P > 0.05$). However, 1 h after the intervention, the difference among the groups was statistically significant ($P < 0.001$). The Tukey's post hoc test revealed that at this time point, the level of state anxiety in the experimental group was significantly lower than the placebo and the control groups ($P < 0.05$). Moreover, at the third measurement time point, the difference among the groups regarding the level of state anxiety was statistically significant ($P < 0.001$). The results of the Tukey's post hoc test illustrated that at this time point, the level of state anxiety in the control group was significantly higher than the experimental and the placebo groups ($P < 0.001$) and the level of state anxiety in the experimental group was significantly lower than the placebo group ($P < 0.001$). The repeated measures ANOVA also indicated a significant difference between the groups across the three measurement time points with regard to the level of the participants' state anxiety ($P < 0.001$; Table 2 and Fig. 4).

4. Discussion

This study sought to investigate the impacts of foot reflexology on anxiety among male candidates for coronary angiography. Findings indicated that at the two measurement time points after foot reflexology (i.e. 1 h after reflexology and immediately before angiography), the level of anxiety among participants in the experimental group was significantly lower than the placebo and the control groups. These

Table 2
Comparing the variations of state anxiety in and among groups across the three measurement time points.

Time	Intervention Group (n = 50)	Control Group (n = 50)	Placebo Group A (n = 50)	F	P value
Baseline	61.68	60.52	62.08	1.1	0.33
One hour after reflexology	47.02	63.40	59.08	82.71	0.001
Immediately before angiography	45.58	59.14	52.08	97.43	0.001
Group: F = 68.61, P < 0.001					
time: F = 139.91, P < 0.001					
group × time: F = 52.57, P < 0.001					

findings denote the effectiveness of foot reflexology in alleviating pre-angiography anxiety.

The exact action mechanism of reflexology has yet remained unknown. However, the Nerve Impulse Theory holds that the stimulation of specific reflex points on the feet can affect the autonomic nervous system and cause the fight-or-flight response. Moreover, reflexologists hold that reflexology stimulates endorphin release and thereby, brings feelings of wellbeing and relaxation [33]. Although some earlier studies also revealed the anxiolytic effects of foot reflexology, they differed from the present study respecting their target populations or reflexology interventions [25–27, 29]. For instance, patients in a study had received general foot massage for relaxation before reflexology. [25]. Another study which was conducted on the candidates for coronary artery bypass graft surgery used reflexology not only on the solar plexus, heart, and pituitary reflex points, but also on the hypothalamus gland, lung, and adrenal gland points [27]. Moreover, a study implemented reflexology only on the solar grid point [29].

Contrary to our findings, a study found [24,29] foot reflexology ineffective in alleviating anxiety among the candidates for coronary artery bypass graft surgery [26]. This contradiction may be due to several reasons. First, the sample size in that study was very small—five patients in the experimental and four patients in the control group. Second, that study included patients who had used anxiolytic agents or had participated in similar trials. Third, participants in that study were going to undergo an extensive surgery and thus, the level of their anxiety might have been too high to be alleviated by foot reflexology.

Study findings also showed that at the third measurement time point, the level of state anxiety in the placebo group was lower than the

control group. This finding may be due to the relaxing effects of massage, irrespective of its type [31,32]. Another explanation for this finding can be the psychological effects of the therapist's presence at patients' bedside and his direct contact with them [33]. It is noteworthy that in order to minimize the effects of therapist-participant relationship, the therapist also attended the bedside of the patients in the control group. Nonetheless, he avoided entering the patients' private zone and touching them. Instead, he simply answered their questions. An important point here is that at the third measurement time point, the level of state anxiety in the experimental group was lower than the placebo group, denoting the greater effectiveness of foot reflexology compared with simple touch therapy.

5. Strengths and limitations

Like other studies, the present study also had some strengths and weaknesses. The first strength was that the study was designed as a randomized controlled trial with a three-group pretest posttest design. Second, we attempted to minimize the confounding effects of factors contributing to pre-angiography anxiety such as the level of knowledge and expertise of the prescribing physician (26, 27) Finally, the groups were homogenous at baseline in terms of participants' demographic characteristics and trait anxiety. Consequently, the significant difference among the groups regarding state anxiety can be more confidently attributed to the study intervention.

The weaknesses of the study were the context-based characteristics of anxiety as well as the inclusion of only male patients. Such weaknesses may restrict the generalizability of the findings. Another limitation of this study was anxiety assessment using a self-report questionnaire. Future studies are recommended to assess the effects of reflexology on anxiety using different anxiety assessment techniques. Comparing the effects of reflexology with the effects of other complementary therapies on different patients outcome (such as blood pressure, heart and respiratory rates, fatigue, and quality of life) can be other areas for further investigation in future studies.

6. Conclusion

This study shows that as a simple and safe non-pharmacological therapy, foot reflexology on the solar plexus, heart, and pituitary reflex points is effective in alleviating anxiety among the candidates for angiography. Thus, nurses can learn reflexology and use it to alleviate anxiety and improve outcomes among this patient population. Of

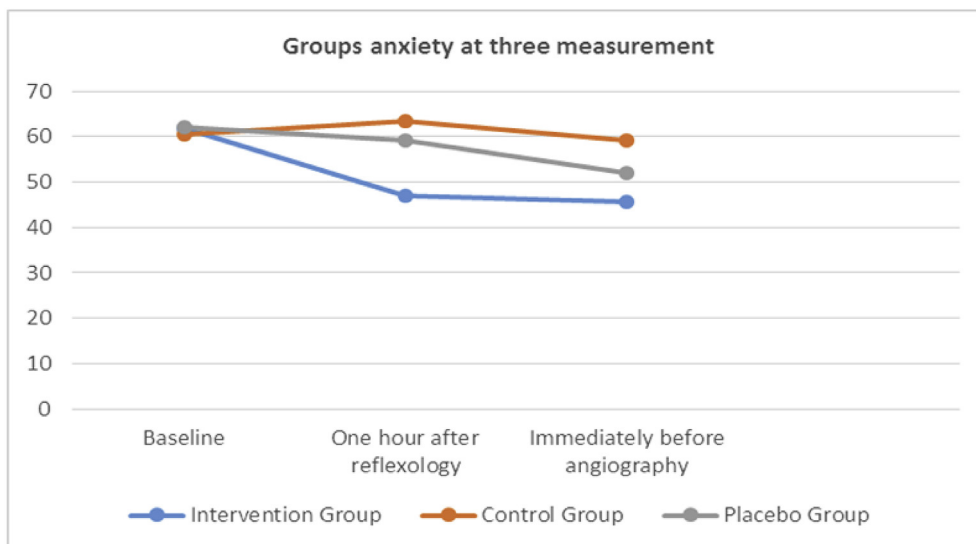


Fig. 4. The level of the state anxiety in the study groups at three measurement time point.

course, more studies are needed to determine the best foot reflexology intervention for anxiety alleviation. This study also indicates the placebo effects of reflexology on non-anxiety points. This finding indicates that nurses can use reflexology, even without having received specialized reflexology-related training, in order to alleviate patients' anxiety.

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Authors' contributions

The second author (KA) guided and supervised all the steps of the study. Intervention conducted with third author (KH). The first author (FR) gathered data. Forth author (SF) participated in data analysis and tables drawing. Moreover, FR and KA played a pivotal role in manuscript writing and translation it into English from Persian.

Conflict of interest

We wish to confirm that there are no known conflicts of interest associated with this study and there has been no significant financial support for this work that could have influenced its outcome.

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This paper is part of an approved research project (ID: A-11-86-6), conducted with ZUMS.REC.1394.145 code of ethics at Zanjan University of Medical Sciences. The study was also registered in the Iranian Registry of Clinical Trials with the code of IRCT2015070723116N.

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