



## Clinical trial

## Effect of short-term hand reflexology on anxiety in patients before coronary angiography: A randomized placebo controlled trial



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## ABSTRACT

**Introduction:** Most patients experience moderate to severe anxiety before coronary angiography. The use of complementary approaches may be helpful for managing patients' anxiety before invasive procedures. This study aimed to investigate the impact of hand reflexology on patients' anxiety before coronary angiography.

**Methods:** In this randomized placebo controlled clinical trial, 90 patients (45 patients in intervention and placebo groups) who were candidates for coronary angiography for the first time were recruited. Twenty minutes prior to the coronary angiography procedure, hand reflexology was given to the intervention group. The patients in the placebo group received general hand massage without any stimulation of reflexology points. Data were collected using the Spielberger anxiety inventory.

**Results:** The mean state anxiety level in the intervention group decreased from  $(49.82 \pm 1.74)$  at baseline to  $(42.67 \pm 1.47)$  after the intervention ( $p = 0.0001$ ). The groups did not show any significant differences in trait anxiety comparing scores before and after the intervention.

**Conclusion:** Hand reflexology alleviated anxiety without any adverse effects on patients before coronary angiography. Therefore, it can be recommended as a non-pharmacological nursing intervention along with other methods to relieve patients' anxiety. However, future studies with a larger sample size is needed to further examine the efficacy of the hand reflexology intervention on patients' psychological aspects.

## 1. Introduction

Cardiovascular diseases are the most important causes of morbidity and mortality all over the world [1]. It is caused by narrowing and blockage of coronary arteries, leading to the reduction of the myocardial blood flow, heart muscle necrosis and eventually death [2]. Clinically, many techniques have been applied to diagnose coronary artery diseases [3]. Methods used for the diagnosis and treatment of cardiovascular diseases may increase anxiety and fear of death among patients [4]. The prevalence rates of anxiety in patients with severe heart problems or cardiac interventions are 70–80% and 20–25%, respectively [5]. Coronary angiography is one of the most common invasive medical procedures used for the diagnosis of coronary artery diseases, and influences the treatment process [6,7]. Annually, two million patients with heart diseases in the USA and 18,000 patients in Iran undergo coronary angiography. This number is increasing, given this procedure's reliability and accuracy as a diagnostic test [8].

Coronary angiography is the insertion of a catheter through the brachial or femoral artery into the aorta and left ventricle. Images of coronary arteries are visualized by injecting contrast media through a catheter. This procedure is used for the diagnostic assessment to confirm or determine the extent and severity of cardiomyopathy [9,10]. In general, invasive diagnostic tests are known to cause stress and anxiety in patients [11]. They may experience severe anxiety and emotional distress, while waiting for the procedure [12]. The overall incidence rate of anxiety in cardiac patients is significantly higher than patients with other kind of diseases [13]. According to the international literature, more than 80% of cardiac patients' experience and report anxiety before coronary angiography [14]. In addition, patients that undergo repeated coronary angiography procedures report anxiety levels similar to those patients who experience it for the first time [15]. The most common factors involved in patients' anxiety are individual's previous experiences, pain, stress, unfamiliar environment, fear of unknowns, the results of the procedure, need for surgery, experience of unfamiliar

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conditions, being physically separated from the family, uncertainties related to the diagnosis and fear of complications [16,17]. Anxiety during a critical procedure increases the risk of physical and psychological injuries [18]. It has been shown that more than 82% of patients undergoing this procedure experience fear and anxiety before coronary angiography due to a lack of familiarity with this procedure [19].

Anxiety may also have a negative effect on the therapeutic outcome of patients with coronary angiography [20]. While anxiety before coronary angiography is an inevitable phenomenon, it can also have remarkable adverse effects on different parts of the body, especially the heart. In this regard, Hanifi et al., suggested that patients' anxiety before coronary angiography should be addressed in nursing interventions [21] to prevent related complications and increase patients' wellbeing [22]. In addition, any action taken to reduce patients' anxiety should be performed as closely to the time of the procedure as possible through supportive interventions [23]. Interventions for alleviating patients' anxiety are an inherent part of nursing practice [7].

### 1.1. Complementary and alternative therapies for reducing anxiety

Anxiety can be reduced by both pharmacological and non-pharmacological methods. One of the most common pharmacological methods used for alleviating anxiety is the use of benzodiazepines. However, pharmacological anxiolytic agents are usually short-acting and produce various side effects [24]. The most notable non-pharmacological methods are the use of complementary and alternative therapies such as muscle relaxation, aromatherapy, meditation, music therapy, guided visual imagery, yoga, medicinal plants, therapeutic touch, massage therapy and reflexology [25,26]. Some studies have investigated the anxiolytic effects of complementary therapies among patients who were candidates for coronary angiography. For instance, Vardanjani et al. found that foot reflexology reduced anxiety among coronary angiography's candidates [27]. Mansoorzadeh et al. also showed that acupressure significantly alleviated anxiety among patients undergoing coronary angiography [28]. However, Astley et al. found that audiovisual techniques had no significant effects on anxiety among patients undergoing coronary angiography [29]. Besides, Taylor found no significant reduction in anxiety levels in Chinese patients undergoing music therapy or sensory information [30]. Moreover, a 10-min massage intervention before the coronary angiography procedure did not sufficiently decrease patients' stress [31]. The use of other complementary treatment approaches such as Sumac (*Rhus coriaria* L., Anacardiaceae) as a novel adjunctive treatment and Lemon balm for cardiovascular diseases have been suggested by previous studies [32,33].

### 1.2. Significance of reflexology massage for reducing anxiety

Reflexology massage as a popular complementary intervention is based on the use of pressure specific reflex areas of feet, hands and ears corresponding with particular points of the body [34]. In clinical terms, reflexology massage is the application of pressure primarily on hands, feet and ears that causes physiological reactions in the body [35]. According to the reflex theory, organs, glands and other parts of the body are linked to specific points in hands and feet [36].

While reflexology interventions for alleviating anxiety are cost-efficient and easy to implement [7], they have not yet been incorporated into routine nursing care [37,38]. The mechanisms underlying the effects of reflexology massage are not clearly understood, but it appears that the pressure applied in reflexology has an effect beyond a simple touch. A probable mechanism may be that hand massage stimulates the parasympathetic nerve activity, decreases the sympathetic nervous activity and/or reduces the secretion of epinephrine and norepinephrine [39]. Reflexology massage consists of supportive touch and helps the circulation of blood, promotes mental and psychological peace, feeling of wellbeing and enhances mood [40]. Moreover, it can facilitate the

therapeutic relationship between healthcare team members and patients through alleviating their anxiety and stress during healthcare interventions [41].

Hands are one of the body areas believed to hold many reflex points. Hand reflexology as a technique is compatible with time restrictions imposed before medical procedures and can be manually performed by trained healthcare staff in 10 min. Some studies investigated the effect of hand massage on the reduction of anxiety in different patients. Brand et al. showed that hand massage significantly reduced preoperative anxiety in patients undergoing outpatient surgeries [42]. Fu et al. reported that hand massage decreased disruptive behaviors in patients with dementia [43]. Reflexology massage as a non-invasive intervention is used in various clinical settings. While most studies evaluated the effect of foot reflexology in different clinical settings [24,8,26,27], few studies have assessed the effect of hand reflexology on anxiety in patients undergoing invasive cardiac procedures. Therefore, the purpose of this study was to investigate the effect of hand reflexology on patients' anxiety before coronary angiography.

## 2. Materials and methods

### 2.1. Design

This randomized placebo controlled clinical trial was conducted in a high turnover coronary angiography laboratory of a large tertiary referral teaching hospital in an urban area of Iran, between December 2014 and April 2015.

### 2.2. Participants and sampling

Female patients who were waiting for coronary angiography were chosen to participate. No patients declined to participate. Only female patients were recruited to eliminate the gender influence on the anxiety level. The inclusion criteria were as follow: (a) being the candidate for coronary angiography for the first time, (b) age above 18 years, (c) having no experience of previous invasive procedures such as *trans*-esophageal echocardiography, (d) physically and mentally able to fill out questionnaires, (e) being referred for an elective coronary angiography, (f) no known skin disorders, (g) not receiving anxiolytics or reflexology massage 48 h before the study and (i) normal upper extremities in terms of congenital malformations, fractures and others orthopedic disorders. Furthermore, exclusion criteria were (a) any severe change and instability in hemodynamic variables during the intervention (b) refusing to complete the reflexology session and (c) declining to complete the study's questionnaires.

The sample size was calculated using the following statistical formula:  $n = 2(z_{1-\alpha/2} + z_{1-\beta})^2 \frac{25}{(\mu_0 - \mu_1/\sigma)}$ . Mean1 = 8, mean2 = 5.9, allocation ratio = 1, power = 80,  $\alpha = 5$ , method = two sample,  $z$  for 1-power = 0.84,  $z$  for alpha double sided = 1.96.

$n = 2 * (1.96 + 0.84)^2 / ((8 - 5.9) / 3.5)^2 = 43.5556 = 44$  with a 3-percent dropout rate for interventional studies [27].

Data was available for all 90 patients and could be analyzed.

### 2.3. Measurement tools

Data collection tools were (1) a demographic data form including patient's age, marital status, employment, education level, place of residency and history of hospitalization, if any (Table 1); (2) The Spielberger's anxiety inventory. The state-trait anxiety inventory questionnaire was developed by Spielberger (1970) for investigating state and trait anxiety levels stemmed from the two-factor theory of anxiety of Spielberger. The state-trait anxiety inventory as a self-assessment questionnaire was consisted of short phrases and contained two separate scales consisting a total of forty items. The state anxiety scale referred to an individual to describe how he/she felt at a given moment and in certain circumstances and answer her/his feelings about

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