Accepted Manuscript

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Authors: Fatemeh Heidari, Nahid Rejeh, Majideh Heravi-Karimooi, Seyed Davood Tadrisi, Mojtaba Vaismoradi

Please cite this article as: Heidari Fatemeh, Rejeh Nahid, Heravi-Karimooi Majideh, Tadrisi Seyed Davood, Vaismoradi Mojtaba.Effect of Short-Term Hand Reflexology on Anxiety in Patients before Coronary Angiography: A randomized Controlled Trial.*European Journal of Integrative Medicine* https://doi.org/10.1016/j.eujim.2017.09.010

Effect of Short-Term Hand Reflexology on Anxiety in Patients before Coronary Angiography: A randomized placebo Controlled Trial

-*Authors*

Fatemeh Heidari, (MScN, BScN), Shahed University, Department of Nursing, Faculty of Nursing and Midwifery, Tehran. Iran.

Nahid Rejeh*, (PhD, MScN, BScN), Associate Professor, Shahed University, Department of Nursing, Faculty of Nursing and Midwifery, Tehran. Iran.

 Majideh Heravi-Karimooi, (PhD, MScN, BScN), Associate Professor, Shahed University, Department of Nursing, Faculty of Nursing and Midwifery, Tehran. Iran.

Seyed Davood Tadrisi, (MScN, BScN), Faculty of Nursing, Baqiyatallah University of Medical Sciences, Tehran, Iran.

Mojtaba Vaismoradi, (PhD, MScN, BScN), Researcher, Faculty of Nursing & Health Sciences, Nord University, Bodø, Norway.

*Correspondence***:** Nahid Rejeh, Associate Professor, 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: nrejeh@yahoo.com

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±1.74) at baseline to (42.67±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 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. (2012) 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].

1.2. 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].

1.3. 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 minutes. 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 hours 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-α/2+z1-β) 25/ (μ0-μ1/σ). Mean1=8, mean2=5.9, allocation ratio=1, power =80, α=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 the situation. The trait anxiety inventory referred to an individual to describe how he/she felt usually across typical situations that everyone experienced on a daily basis [44]. Both sections comprised 20 questions and each scored between 1= not at all and 4 = very much. The total score for each individual was between 20 (the lowest possible anxiety) and 80 (the highest possible anxiety). The scores obtained from the scale ranged from 20 to 80 with higher scores indicating higher anxiety levels [45]. Validity and reliability of this inventory was confirmed by Tiedeman and Clatworthy (1990). In addition, its reliability using the calculation of a Cronbach alpha coefficient was reported as 0.82 [46].

2.4. Random allocation

The nurse manager in the coronary angiography laboratory was informed of the study's purpose and selection criteria and helped with the identification of eligible samples in a daily manner from the patients' files. Sampling was carried consecutively. The study's purpose, benefits and potential risks were explained to eligible patients who met the inclusion criteria. The samples (n=90) were allocated into the hand reflexology (n=45) and placebo (n=45) groups using a randomized method. To reduce the possible risk of bias, the group allocation code was written on

separate papers, placed in sealed envelopes and kept in an opaque box. Next, a sealed envelope was removed from the box and opened to determine the patient's group. A person who was blind to the study took the sealed envelopes out of the box. After opening the sealed envelopes, they were put back into the box again. The patients were blinded to the intervention and were not informed of their group assignments. This process continued until the desired sample size was accomplished.

2.5. Intervention

The patients allocated to the intervention group, in addition to usual and routine care, received the hand reflexology intervention, while the placebo group received general hand massage without any stimulation of reflexology points. The nurses performed routine care including wearing gown, obtaining ECG, recording baseline assessment data such as the patient's hypersensitivity to seafood, contrast media and iodine, taking vital signs, height and weight. Also, the nurses marked the locations of peripheral pulses and documented their equality and amplitude etc.

Hand reflexology sessions were conducted by the first researcher who was female and had successfully passed the required training under the supervision of specialists in a traditional medicine centre. The accuracy of reflexology massage points and methods of applying pressure were confirmed by a reflexologist. It should be mentioned that the researcher did not use white lab coats to prevent its effects on the patients' anxiety.

All patients were placed in a supine position. Prior to and after hand reflexology, the anxiety level of the patients was measured by a nursing staff who was unaware of the patient's group assignment. Pre-intervention measurements were conducted in a private room after assuring the patient's privacy. The patients received general hand massage of both hands in the following order: the investigator washed her hands with warm water and a moderate amount of sesame oil was used to the hands. After a general hand massage (four minutes), the investigator performed the massage with her thumb, beginning with the right hand and then moving to the left hand, started from the forearm, moving to the wrist, palm, back of the hand and finally fingers. In the intervention group, the patient received two minutes of reflexology massage at the three reflexology points for the pituitary gland, heart and solar plexus (six minutes in total), using a

stimulation with moderate pressure and both hands for a total of twenty minutes (ten minutes per hand).

The solar plexus, pituitary and heart points were located by the investigator. The solar plexus and pituitary points were located according to the provided plot by reflexologists, and the heart point was located according to the Jones et al.'s recommendation [47].

The reflexologist exerted firm downward pressure with her thumb at the points for two minutes in every area. The downward pressure was exerted ten times during each of the two minutes at each reflexology point. The pressure was regulated so that the upper thumb was white, but patients did not feel any pain. Subsequently, a circular rotational massage was applied to the specific points. The investigator who messaged patients was female as well. Similar to the reflexology group, the placebo group received the general hand massage for the same amount of time without any stimulation of the reflexology points. During hand reflexology, all patients' heart rhythms were also being monitored. If hemodynamic instabilities were noted, the patient would be excluded from the study.

2.6. Data collection

Data collection was consisted of two parts as follows: a) baseline demographic information collected through reviewing the patients' medical records or interviewing the patients before the intervention, b) state anxiety was measured before and after the intervention. The questionnaire was filled out by a nurse who was blind to the study 20 minutes before coronary angiography and immediately after the intervention. Also, the statistician who performed data analysis was blind to the group allocation.

2.7. Statistical analysis

Data was analysed by using the Statistical Package for the Social Sciences software (SPSS; SPSS Inc., Chicago, IL, USA) version 16.0. The Kolmogorov-Smirnov test was performed to test the normality of data. Continuous variables were expressed as mean ± standard deviation (mean ± SD). Categorical variables were presented by the use of number and percentage (n %). The quantitative and qualitative variables were compared between the groups before and after the study using independent t-test as well as Chi-square and Fisher's exact tests, respectively. A p-value less than 0.05 was considered statistically significant.

2.8. Ethical consideration

This study was approved by the Ethics Committee affiliated with Shahed University (Decree number: 4-629). All participants gave their informed consent before the study. For illiterate patients, the informed consent form was read by the patients' companions and they were asked to add their finger prints to the form, if they willingly agreed to take part in this study. Verbal informed consent was also obtained. Numbers rather than names were used to identify the patients to ensure confidentiality and anonymity. The results of the study were released to the patients, if they requested. They were informed of the voluntary nature of the study, their right to withdraw at any time without any negative effects on their care and treatment process. The study was carried out under the supervision and control of a cardiologist who was present in case of any adverse events.

The protocol of the study was registered in the Iranian Registry of Clinical Trials (Code No: IRCT201412087529N6).

3. Results

The process of the study was outlined on the CONSORT flow diagram (Figure 1). The response rate was 100% as all patients agreed to participant in study with no drop outs.

3.1. Demographic characteristics

Table 1 summarized the patients' demographic characteristics. No statistically significant differences were reported between the hand reflexology and placebo groups in terms of demographic characteristics and baseline outcome variables. The majority of the patients were illiterate (45.60%), married (68.92%), housewives (95.46%) and lived in the city (72.25%) (p>0.05).

3.2. Anxiety outcome

Before coronary angiography, patients in both groups, no statistically significant differences were reported before the intervention in terms of the mean score of trait anxiety (p>0.05). The between-group comparison showed that before and after the study, there were no statistically significant differences between the groups in terms of the mean score of trait anxiety (p>0.05). (Table 2).

As shown in Table 3, in the intervention and placebo groups, no statistically significant differences were reported before the intervention in terms of the mean score of state anxiety (p>0.05). However, the mean score of state anxiety in the intervention group was significantly lower than the placebo group before (49.82±1.74) and after (42.67±1.47) the intervention (p=0.0001).

4. Discussion

This study aimed at examining the effects of hand reflexology on anxiety in patients undergoing coronary angiography. The findings of this study revealed that hand reflexology reduced anxiety among patients before coronary angiography. After controlling for the gender variable, there were significant differences between the groups.

The level of anxiety in the intervention group decreased significantly (p<0.05). The amount of this reduction in the reflexology group was clinically significant. Moreover, baseline mean anxiety scores ranged from moderate to severe, suggesting that the patients were experiencing much anxiety. The findings of this study were in agreement with the findings of a study by Hudson et al. They showed that hand reflexology had a positive effect on anxiety in patients undergoing a minor surgery with local anesthesia. Patients' anxiety was measured before and immediately after the surgery and anxiety levels were measured using a numeric rating scale [48]. Mei et al. found that the local finger pressure on the reflexology points of limbs modified the function of selected target organs, increased relaxation and improved patients' responses [23]. It was demonstrated that massage had beneficial effects on patients' anxiety [42]. However, contrary to the findings of this study, Gunnarsdottir and Jonsdottir found that reflexology had no significant effects on anxiety among patients undergoing the coronary heart surgery [21]. McVicar et al. in a study on the effect of reflexology on anxiety showed that the reflexology intervention decreased the state anxiety, but showed no evidence for its influence on trait anxiety [49] since trait anxiety, unlike state type, was not a transitory state and needed a long-time intervention.

Wang et al. analyzed five randomized clinical trials and found that reflexology had no extra beneficial effects compared to the non-specific effects produced by massage [50]. Also in a systematic review conducted by Ernst, reflexology had no health benefits over a placebo

response. They indicated that there were limited randomized clinical trials in this field and the methodological quality of the primary studies was often poor [51].

Such contradictory findings can be due differences in samples, eligibility criteria, sampling process, reflexology techniques and the number and length of reflexology sessions. While reflexology and massage therapy have some common aspects, key differences between these techniques are present. In reflexology, pressure is applied to small muscles located in specific points on extremities (hands and feet), but massage involves larger muscles or the whole body [52]. In the placebo group in this study, the simple form of hand massage was applied. Therefore, the reduction of anxiety in the placebo group could be attributed to the positive effect of the presence of the researcher and/or massage. Some specialist believe that there are adverse effects regarding interventions, which are often known as the 'healing crisis'.

The patients in the placebo group showed a significant change in anxiety implying that improvements might be due to the "Hawthorne effect". Sometimes a decrease of anxiety may be attributable to the Hawthorne effect. Since the patients whilst waiting for coronary angiography were aware of the intervention and the study aims, and observed the investigator's activities and felt that they were under supervision, the Hawthorne effect might have happened. Also, the investigator presence or data collection instruments might exacerbate the Hawthorne effect. It is estimated that the Hawthorne effect plus participants' awareness of their allocation can overestimate treatment effects by about 17% [53]. The impact of the Hawthorne effect cannot be estimated due to the ethical requirements for informed consent. All those approached participated and the volunteer bias might have affected the trial outcomes. It is acknowledged that the difficulties of blinding the patients and investigator and the randomized allocation increase the risk of bias in this trial. No adverse clinical effect was observed in this study during the hand reflexology. Therefore, hand reflexology would be considered a safe non-pharmacologic intervention for nursing practice.

4.1. Implications for practice

Hand reflexology as a non-pharmacological intervention is a non-invasive, cost-effective and applicable intervention. It can be considered by healthcare providers for relieving patients' anxiety before invasive procedures. Also, it can be used as one part of the usual care for patients waiting for such procedures. The ability of nurses to use hand reflexology as an intervention for

these patients promotes nursing autonomy in practice. Reflexology as a traditional treatment is prominence once more, and has received increased trends and continuing research as complementary therapies is combined with ancient care. The incorporation of reflexology into routine care and along with pharmacologic methods can provide nurses with a holistic approach to better manage patients' anxiety. It is economically feasible to be implemented, is a complementary intervention and generally acceptable to patients, and also is within the scope of practice for healthcare professionals.

Along with the growing public interest in complementary therapies, nurses need to receive education about the concepts and principles of alternative therapies and complementary therapies. Complementary therapy research centers and organizations can develop programs to provide training and education to nurses and other clinicians and empower them for using such therapies in their daily practice.

4.2. Limitations and recommendation for future research

In this study, the researchers studied the short-term effects of reflexology on patients' anxiety. It may be more beneficial to use it in additional sessions. It is recommended that future research is conducted to study the benefits of hand reflexology after the coronary angiography procedure on patients' anxiety over time. Since anxiety may continue, reflexology should be repeated over time with subsequent measurements of anxiety. In addition, the researchers used a placebo group rather than a simple control group. Therefore, the difference between hand massage as applied to patients in the placebo group and hand reflexology in terms of avoiding the planter reflex points during the manual manipulation remains unclear. Since the completion of the questionnaires using patients' interviews might have affected the patients' answers, the use of other anxiety scales such as the face anxiety scale is suggested. Questionnaires with pictures or numeric allow patients to answer questionnaires (self-report). Limiting this type of research study to patients undergoing their first coronary angiography may help avoid the potential confounding effects associated with prior exposures. Further, providing patients with the opportunity to verbalize their views about whether hand reflexology was beneficial or if they would recommend this type of intervention to others can provide additional information and insight for utilizing this intervention. Lastly, this study was conducted on female patients. Therefore, a similar study with male patients is required to compare the effectiveness of this intervention between genders.

5. Conclusion

There was a significant reduction in the average scores of the level of anxiety in the patients who received hand reflexology. Therefore, this inexpensive, easy-to-apply, non-invasive, simple and safe non-pharmacological technique is suggested to be used by nurses and healthcare providers for managing patients' anxiety before the angiography procedure.

With increasing the interest of the public towards complementary medicine, nurses should be trained and educated about the essentials of applying this treatment modality in clinical practice. Universities and educational centers by adding the content in the curriculum can increase the knowledge and abilities of nurses to apply complementary medicine in practice.

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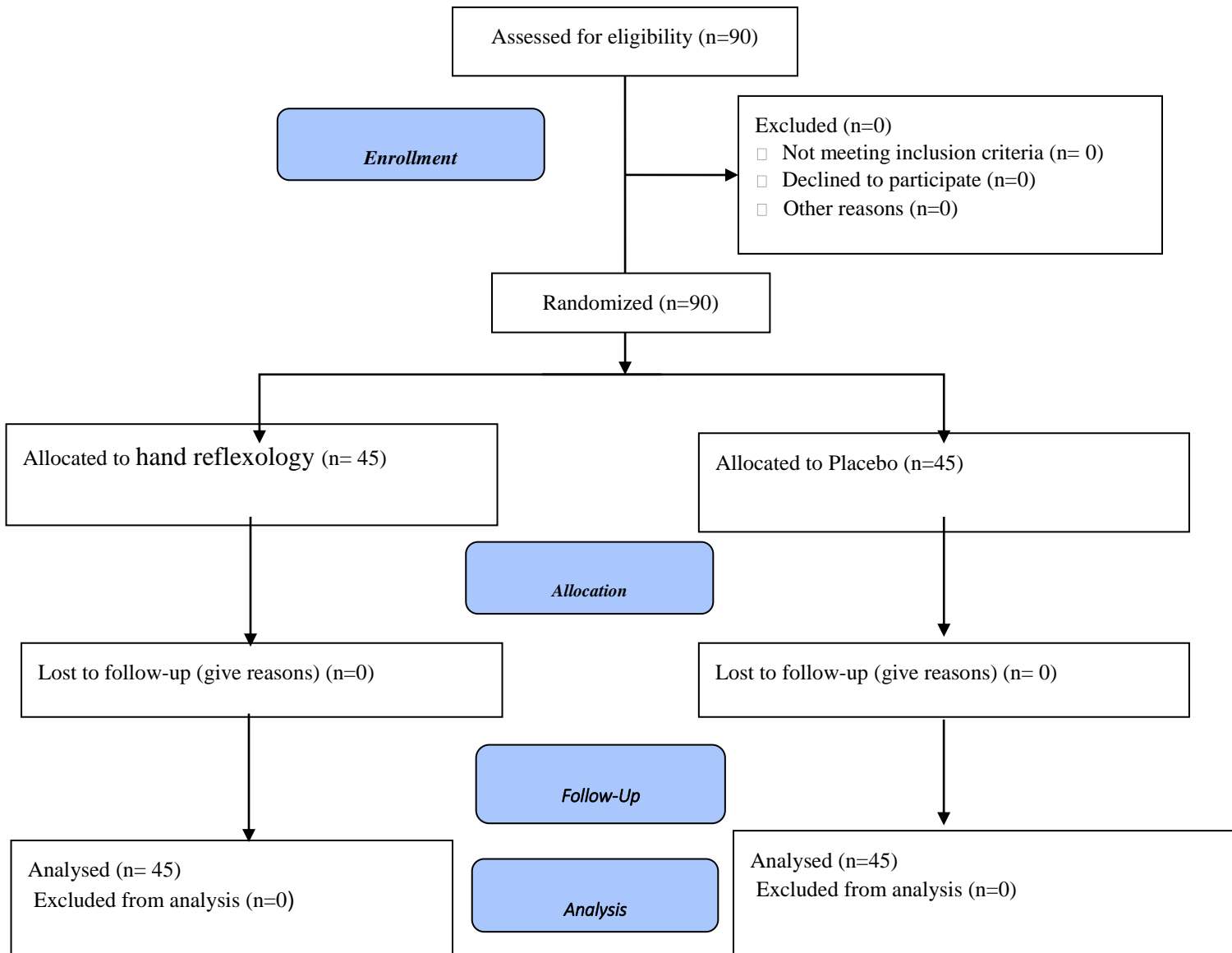
Figure 1. The process of the study according to the CONSORT flow diagram.

Table 1. The demographic characteristics of the patients in the groups

Characteristics	Total (n = 90)	Intervention group (n = 45)	Placebo group (n = 45)	Statistical test and *p* value
Age **Mean ± SD**	58.01 ± 10.29	57.68 ± 9.87	59.33 ± 10.40	t=0.768 *p* =0. 445
Education level, n (%) **Illiterate** **Primary school** **Secondary school**	41(45.60%) 39(43.30%) 10(11.10%)	23(51.10%) 21(46.70%) 1(2.20%)	18(40.00%) 18(40.00%) 9(20.00%)	x^2 = 7.241 df=2 *p* =0. 072
Marital status, n (%) **Married** **Divorced**	62(68.92%) 28(31.08%)	32(71.10%) 13(28.90%)	30(%66.66) 15(%33.34)	Fisher's exact test =0.227 df=1 *p* =0.812
Employment, n (%) **Employee** **Retired** **Housewife**	2(2.22%) 2(2.22%) 86(95.46%)	0(0.00%) 1(2.20%) 44(97.80%)	2(4.40%) 1(2.30%) 42(93.30%)	x^2 =2.047 df=2 *p* =0. 359
Place of residence, n (%) **City** **Village**	65(72.25%) 25(27.75%)	30(66.70%) 15(33.30%)	35(77.70%) 10(23.30%)	x^2 =1.385 df=1 *p* =0. 173
History of hospitalization, n (%) **Yes** **No**	64(71.11%) 26(28.89%)	31(68.88%) 14(31.12%)	33(73.34%) 12(26.66%)	Fisher's exact test =1. 688 df=1 *p* =0. 302
Income, n (%) **Low** **Enough** **High**	3(3.33%) 46(51.06%) 41(45.52%)	2(4.50%) 24(53.30%) 19(42.20%)	1(2.40%) 22(48.80%) 22(48.80%)	t =0.640 df=2 *p* =0. 726

Table 2. The comparison of the trait anxiety before and after the intervention in the groups

Anxiety	Groups	Before the intervention	After the intervention	Statistical test, p value
Trait	Hand reflexology	50.48±1.84	50.07±1.51	t=0.941, P=0.354
	Placebo	50.46±1.86	50.43±1.82	t=0.226, P=0.823
	Statistical test, p value	t=-0.598, P=0.553	t=-0.855, P=0.397	

Table 3. The comparison of the state anxiety before and after the intervention in the groups

Anxiety	Groups	Before the intervention	After the intervention	Statistical test, p value
State	Hand reflexology	49.82±1.74	42.67±1.47	t=13.28, P=0.001
	Placebo	49.71±1.65	48.66±1.78	t=0.320, P=0.752
	Statistical test, p value	t=0.282, P=0.779	t=-15.29, P=0.001	