

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

The effect of foot massage on anxiety and blood pressure in hypertensive patients Referred to cardiac specialty hospitals clinics affiliated to Tehran University of Medical Sciences in1390

Protocol summary

Summary

This is a randomized intervention study which it also has a control group. Study group is included patients with at least two-year hypertension experience. Samples are chosen using convenience sampling method. Participants will be matched two by two according to the drug they use to decrease blood pressure, and then we will do a random allocation. Patients will be asked to complete a written consent form. We will use Thai reflexology foot massage method for two one-hour sessions lasting one month in massage therapy center. Also, patient's blood pressure, pulse and relaxation feeling will be controlled before and after the massage therapy. Moreover, demographic, pharmaceutical and illness questionnaire will be used to assess patients' anxiety level along with validated Spielberger's questionnaire. Inclusion criteria are involved: 1) having no mental and disability disorders history and 2) having 40-65-year-old. Exclusion criteria also are included: having history of cancer, gout, bone tuberculosis, autoimmune, severe knee arthritis, rheumatism, chemotherapy, last two-year bone fracture down the knee area, any history of recent last two-year surgery and last five-year cardiac surgery (all of these criteria are considered in order to prevent damages which might affect participants during their massage). 14 samples were selected for each group through doing a preliminary study and using average result and over-viewing previous studies. In order to prevent from sample loss (considering 25% chance of sample loss), we selected 18 samples for each group. It is estimated that the study will take 9 months.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201201038606N1**

Registration date: **2012-05-10, 1391/02/21**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2012-05-10, 1391/02/21

Registrant information

Name

Sahar Sajedi

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences and Health Care Services

Expected recruitment start date

2012-05-21, 1391/03/01

Expected recruitment end date

2012-07-22, 1391/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of foot massage on anxiety and blood

pressure in hypertensive patients Referred to cardiac specialty hospitals clinics affiliated to Tehran University of Medical Sciences in1390

Public title

Effects of foot massage on anxiety and blood pressure

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1- Hypertensive patients with at least 2 years experience with a minimum pressure of 140/90 2- Without any history of mental disorders and disability. 3- Patients are in the age group 40-65 4- Patient is physically able to participate in the intervention until the end of it. 5- Preferably they live in Tehran. Exclusion criteria: 1-Any history of cancer, gout, bone tuberculosis, autoimmune, severe knee arthritis, rheumatism, chemotherapy, bone fracture in the knee area down to last 2 years, any history of recent surgery to last 2 years, history of cardiac surgery to last 5 years (all of them prevent damages due to the participants during their massage) 2- Lossing any of Inclusion criteria.

Age

From **40 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **36**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

School of Nursing and Midwifery, Tehran University of Medical Sciences and Health care Services

Street address

School of Nursing and Midwifery, Nosrat Street, Tohid Square, Tehran, Iran

City

Tehran

Postal code

Approval date

2012-04-21, 1391/02/02

Ethics committee reference number

90-04-61-14761-50320

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

F06.4

ICD-10 code description

A disorder characterized by a partial or complete loss of the normal integration between memories of the past, awareness of identity and immediate sensations, and control of bodily movements (see F44.-), but arising as a consequence of an organic disorder

2

Description of health condition studied

High blood pressure

ICD-10 code

I10

ICD-10 code description

High blood pressure

Primary outcomes

1

Description

Anxiety

Timepoint

2 times. Once before the first intervention and once after the last intervention

Method of measurement

standard Spielberger's questionnaire

2

Description

Blood Pressure

Timepoint

Before and after each massage session

Method of measurement

According mmHg using a mercury sphygmomanometer

Secondary outcomes

1

Description

Pulse

Timepoint

Before and after each massage session

Method of measurement

Enumeration

2

Description

Relaxation feeling

Timepoint

Before and after each massage session

Method of measurement

100-mm visual analog scale

Intervention groups

1

Description

In control group, validated Spielberger questionnaire will be completed to assess the level of manifest and latent anxiety in 2 steps (in first visit and see after a month) and research teammate (he doesn't know who is in case or control group) will control and record blood pressure and the rest of vital signs.

Category

Other

2

Description

Intended intervention is Thai reflexology foot massage that Participants in the study will be massaged in 1 month, 2 times a week; each session lasting one hour in massage therapy center has been considered. Massage therapy in this center will be did free by a Massager who has massage therapy degree that is approved by the Ministry of Health, Thailand and also he is member of the traditional medicine group, brightest talents center of Tehran University of Medical Sciences. So that after the person entering in the massage center, to change clothes and Washing and disinfecting legs will go to special washing and changing clothes room. After that, the feet will be dried and the person will sit down on a massage chair. The massager after doing a series of specific movements on the left foot starts to do massage with foot massage special oil and cream. Then with using a special timber called a steak, specific actions will be done on foot. Then Massage oils and creams are used again. After several movements, the person is given foot massage to above the knee. After this step, the left foot is wrapped in towel. Right foot is performed massage as the left foot. Then somewhere of the left foot is squeezed to massage effects be moved to the whole body (reflexology). And after that somewhere of the right foot is squeezed as left foot. Then on both feet simultaneously perform certain movements and massage will be completed. Before and after the each massage session Systolic and diastolic blood pressure will be controlled and will be recorded in a chart by researcher. Also, with using a 100 mm visual analog scale, patient's relaxation feeling will be determined by him. After a month, validated Spielberger questionnaire will be completed to assess the level of manifest and latent anxiety and research teammate (he doesn't know who is in case or control group) will control and record blood pressure and the rest of vital signs.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Cardiac specialty hospitals clinics covered by Tehran University of Medical Sciences

Full name of responsible person

Tahereh Najafi

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences and Health care Services

Full name of responsible person

Dr. Fotouhi

Street address

Sixth Floor, Central organization of Tehran University of Medical Sciences and Health care Servicess,ghods street ,keshvarz Boulevard, Tehran, Iran, Ghods st.

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran University of Medical Sciences and Health care Services

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences and Health care Services

Full name of responsible person

Tahereh Najafi

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Assistant Professor

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty