Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of massage on anxiety and vital signs of patients with primary hypertension

Protocol summary

Summary

The aim of this study is to evaluate the effect of back massage on vital signs and anxiety in patients with essential hypertension.This study is a randomized clinical trial in the city of Shiraz, Imam Reza the clinic will be on 90 patients with primary hypertension eligible.Patients randomly assigned enter an intervention or control group and Intervention group back massage the neck and back (shoulders to waist) will be done for 10 minutes and the control group will rest for 10 minutes.Inclusion criteria: Age between 30 to 70 years ؛ History, is not of blood pressure drop skin disorders and spine؛ Non Anti-anxiety drugs and sedative؛ The absence of diabetes and hypertension disease (kidney problems, adrenal gland tumors, congenital heart defects) is effective.Exclusion Criteria: Back pain due to spinal cord injury, herniated or degenerating discs؛ Patients who have undergoing surgery lumbar؛ No Inclusion criteria.Study population and sample size in this study:will be evaluated 90 patients with essential hypertension.Intervention: The intervention group, back massage done for 10 minutes, 2 sessions a week for 6 weeks.The control group, patients rested for 10 minutes a week doing 2 sessions of for 6 weeks.The primary outcome variables: back massage and stress influence on the vital signs of patients with essential hypertension.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013112615552N1**
Registration date: **2014-02-23, 1392/12/04**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-02-23, 1392/12/04

Registrant information

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Mehdi Moghadasi
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Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2013-04-21, 1392/02/01

Expected recruitment end date

2013-07-08, 1392/04/17

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of massage on anxiety and vital signs of patients with primary hypertension

Public title

Effect of back massage on Vital signs and anxiety

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Age between 30 to 70 years ؛ History, is not of blood pressure drop skin disorders and spine؛ Non Anti-anxiety drugs and sedative؛ The absence of

diabetes and hypertension disease (kidney problems, adrenal gland tumors, congenital heart defects) is effective.Exclusion Criteria: Back pain due to spinal cord injury, herniated or degenerating discs؛ Patients who have undergoing surgery lumbar؛ No Inclusion criteria.

Age
From **30 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
In this study randomization is done with table of random numbers.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Shiraz University of Medical Sciences

Street address
The central building of of Shiraz Medical University,St, Haft Tir, Zand Street .

City
Shiraz

Postal code
7134814336

Approval date
2013-05-15, 1392/02/25

Ethics committee reference number
88-6603

Health conditions studied

1

Description of health condition studied
essential hypertension.

ICD-10 code
I10-115

ICD-10 code description
Diseases of the circulatory system

Primary outcomes

1

Description
blood pressure

Timepoint
blood pressure before and after the intervention, 2 times a week for 6 weeks and three days after the intervention was measured .

Method of measurement
blood pressure With Digital manometer-mmHg

2

Description
Anxiety

Timepoint
the level of anxiety before the first session and after the first session, after the third week, after six weeks and three days after the intervention, was measured

Method of measurement
Spielberger form

3

Description
heart rate

Timepoint
heart rate before and after the intervention, 2 times a week for 6 weeks and three days after the intervention was measured.

Method of measurement
per minute

Secondary outcomes

empty

Intervention groups

1

Description
The intervention group will rest for 5 minutes then will be recorded vital signs,Vital signs before the intervention will be recorded 2 times per week for 6 weeks،Spielberger anxiety form، will be filled only 1 times in all 6 weeks, after 5 minutes of rest،Then in the intervention group, after applying an oily substance (sesame oil) 10 min back massage done of the neck and the back (from shoulder to waist)،back massage will be done 2 times a week for 6 weeks for patients ،Then vital signs will be measured after a 10 minute massage, two times per week for 6 weeks and Spielberger anxiety form،will be filled immediately after the end of the first session, the end of weeks 3, 6, and 3 days after intervention for patients.as well as vital signs will be and control recorded، 3 days after the intervention.

Category

Behavior

2

Description
The Control group will rest for 5 minutes then will be recorded vital signs,Vital signs before the intervention will be recorded 2 times per week for 6 weeks،Spielberger anxiety form، will be filled only 1 times in all 6 weeks, after 5 minutes of rest،in the control group, patients will rest 10 minute ،Then vital signs will be measured after a 10 minute rest, two times per week for 6 weeks and Spielberger anxiety form،will be filled immediately after the end of the first session, the end of weeks 3, 6, and 3 days after intervention for patients.as well as vital signs will be and control recorded، 3 days after the intervention.

Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Clinic Specialty and Subspecialty Imam Reza
Full name of responsible person
Mehdi Moghadasi
Street address
City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research Deputy Shiraz University
Full name of responsible person
Dr. Ali Poostforoosh
Street address
Fifth Floor, Shiraz University of Central Building, Boulevard Jame Jam, Shiraz .
City
Shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research Deputy Shiraz University
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
Shiraz University of Medical Sciences
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Mehdi Moghadasi
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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