

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 2026

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

#### Protocol summary

2014-02-23, 1392/12/04

##### 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.

##### Registrant information

###### Name

Mehdi Moghadasi

###### Name of organization / entity

Shiraz University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 66 2444 0402

###### Email address

moghadasi\_m@sums.ac.ir

##### 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

#### 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

##### 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 undergone 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 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

#### Full name of responsible person

Mehdi Moghadasi

#### Position

Senior nursing student

#### Other areas of specialty/work

#### Street address

No. 6, Gulshan Lane 4 , Street 15 meters Kaveh

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

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#### Full name of responsible person

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## Person responsible for updating data

### Contact

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Mehdi Moghadasi

#### Position

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#### Other areas of specialty/work

#### Street address

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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*