

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 2026

### Influence of theory-based education intervention physical activity in hypertensive patients

#### Protocol summary

##### Summary

The aim of study is determine the effect of theory-based training intervention on physical activity and blood pressure in hypertensive patients. This randomized controlled trial conduct in the city of Shiraz in southern Iran. The population is patients with hypertension select by convenience sampling from patients refer to Shiraz Healthy Heart House. Sample size is 78 persons (39 experimental group and 39 control group). The subjects were randomly assigned to either the experimental group or control group. person performing analyses blinded for study group. Inclusion criteria include: patients with primary hypertension, have a systolic blood pressure of less than 170 mm Hg; have a current physical activity level that is less than the criterion (30 minutes of fast walking five days a week); be in the stage of pre contemplation, contemplation or preparation; and be  $\leq 69$  years of age. Exclusion criteria include: diagnosis of cardiovascular disease, diabetes or depression; history of heart attack or stroke. Intervention based on trans-theoretical model for experimental group conduct that include 30 minutes of fast walking at 40% to 60% of maximum heart rate reserve 5 days a week for 3 months. During implementation, no additional intervention by researchers provide to the control group. The constructs of trans-theoretical model, physical activity and 24-hour ABP before, 3 and 6 months after intervention measure in both groups. Primary outcome is increase physical activity and Secondary outcome is decrease blood pressure.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016061428463N1**

Registration date: **2016-09-07, 1395/06/17**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-09-07, 1395/06/17

##### Registrant information

###### Name

Zahra Motlagh

###### Name of organization / entity

Tarbiat Modares University

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 8288 3817

###### Email address

z.motlagh@modares.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Tarbiat Modares University, Vice Chancellor Of Research

##### Expected recruitment start date

2014-11-26, 1393/09/05

##### Expected recruitment end date

2015-09-17, 1394/06/26

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Influence of theory-based education intervention physical activity in hypertensive patients

##### Public title

Influence of theory-based education intervention physical activity in hypertensive patients

##### Purpose

Treatment

## **Inclusion/Exclusion criteria**

Inclusion criteria were that patients should be diagnosed with primary hypertension; have a systolic BP of less than 170 mm hg; be taking at least one anti hypertension medication; have completed at least 4th grade education, have no orthopedic limitations to walking; be cleared for moderate-intensity walking by a cardiologist; have a current PA level that is less than the criterion (30 minutes of fast walking five days a week); be in the stage of pre- contemplation, contemplation or preparation; and be  $\leq$  69 years of age. Exclusion criteria were diagnosis of cardiovascular disease, diabetes or depression; history of heart attack or stroke; and taking drugs for weight loss

## **Age**

To 69 years old

## **Gender**

Both

## **Phase**

N/A

## **Groups that have been masked**

No information

## **Sample size**

Target sample size: 78

## **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**

Ethics Committee of Tarbiat Modares University

##### **Street address**

Jalal Ale ahmad junction, Tehran, Iran.

##### **City**

Tehran

##### **Postal code**

#### **Approval date**

2014-11-24, 1393/09/03

#### **Ethics committee reference number**

52dr5507

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Primary hypertension

#### **ICD-10 code**

I10

#### **ICD-10 code description**

Essential (primary) hypertension

## **Primary outcomes**

### 1

#### **Description**

Physical activity

#### **Timepoint**

3 and 6 month

#### **Method of measurement**

Questionnaire

## **Secondary outcomes**

### 1

#### **Description**

Blood pressure

#### **Timepoint**

3 month

#### **Method of measurement**

Holter monitoring 24 hour

## **Intervention groups**

### 1

#### **Description**

Intervention group: 30 minutes of fast walking in 40-60% of maximum heart rate reserve, 5 days a week.

#### **Category**

Lifestyle

### 2

#### **Description**

Control group: During implementation, no additional intervention by researchers provide to the control group

#### **Category**

N/A

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Shiraz University of Medical Sciences ,Cardiovascular research Center,

##### **Full name of responsible person**

Zahra Motlagh

##### **Street address**

Mohamad rasol alah Tower of Research,Khalili street,Shiraz,Iran

**City**  
Shiraz

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**  
Tarbiat Modares University, Vice Chancellor Of Research

**Full name of responsible person**  
Dr Yaghub Fatholahi

**Street address**  
Vice Chancellor Of Research, Tarbiat Modares University, Jalal Ale ahmad junction, Tehran, Iran

**City**  
Tehran

### Grant name

### Grant code / Reference number

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

### Title of funding source

Tarbiat Modares University, Vice Chancellor Of Research

### 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**  
Tarbiat Modares University

**Full name of responsible person**  
Zahra Motlagh

**Position**  
Ph.D. student

**Other areas of specialty/work**

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## Person responsible for scientific

## inquiries

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Alireza Hidarnia

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Professor

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## Person responsible for updating data

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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*