Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 ≤ 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

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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 ≤ 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 Yaghob 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
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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