Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of Educational Program Based on "self-management Model" to promotion of healthy behavior among Hypertensive women in Health care centers in Isfahan2015

Protocol summary

Summary

Methods: a randomized, double-blind, multi-center, non-randomized phase II trial of a blind, without a placebo controlled, The study population will be 150 middle-aged women (30-65 years old) without other serious diseases such as diabetes that will participate at least 4 sessions from 6 training sessions . Samples are selected randomly by random paired blocks. The control group don't receive any special education . At the first blood pressure, TG, BMI, Cholesterol will be checked. Self -management and quality of life questionnaire will be filled out By interview. we will have weekly sessions For training, at the end every person will pass 6 training session. The number of attendants will be 8-20. The time of each session will be about 120 minutes (by considering of Patience and ability of participants). Topics will be taught self-monitoring ,benefits of exercise, stretching exercise, proper nutrition, meditation, and medication . At the end of the evaluation sessions (body mass index, blood pressure and other blood tests will be done. self-management questionnaire will be compared). Before follow-up, participants in education group will be received text messages weekly by cell phone based on the same topics in training sessions. The third stage will be 6 months after the intervention. The evaluation of the program and the same tests and the same questionnaire will be completed.

General information

Acronym

Self-management of hypertension

IRCT registration information

IRCT registration number: **IRCT2014061218076N1**
Registration date: **2015-05-29, 1394/03/08**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2015-05-29, 1394/03/08

Registrant information

Name
Shahrbanoo Daniali
Name of organization / entity
Health Education and Health Promotion center, Isfahan University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 31 3792 2672
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sh_daniali@hlth.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2015-05-22, 1394/03/01

Expected recruitment end date

2015-12-22, 1394/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Educational Program Based on "self-management Model" to promotion of healthy behavior among Hypertensive women in Health care centers in Isfahan2015

Public title
Self-management education programs in promoting healthy behavior patterns and quality of life
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria: being interested to participate in the study; being middle-aged (65-30 years old); use drug for treatment of hypertension; the duration of diagnosed hypertension occurred at least for 6 months; not being involved in other common educational program related to hypertension at the same time and at least be literate. Exclusion criteria: the people don't want to continue the cooperation; participants who have attended at least two training sessions.
Age
From **30 years** old to **65 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **150**
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
Research Assistanceof Isfahan University of Medical Sciences
Street address
Isfahan University of Medical Sciences
City
Isfahan
Postal code
81746-73461
Approval date
2015-12-01, 1394/09/10
Ethics committee reference number
393790

Health conditions studied

1

Description of health condition studied
Essential (primary) hypertension
ICD-10 code
I10
ICD-10 code description
Essential (primary) hypertension

Primary outcomes

1

Description
Blood pressure
Timepoint
All variables at baseline, 1.5 month latter, and then at the end of 6 months are evaluated
Method of measurement
(mmHg)measured by Mercury sphygmomanometer

2

Description
BMI
Timepoint
All variables at baseline, 1.5 month latter, and then at the end of 6 months are evaluated
Method of measurement
calibrated scale and meter

3

Description
nutritional status
Timepoint
All variables at baseline, 1.5 month latter, and then at the end of 6 months are evaluated
Method of measurement
questionnaire

4

Description
fatigue
Timepoint
All variables at baseline, 1.5 month latter, and then at the end of 6 months are evaluated
Method of measurement
fatigue visual basic

5

Description
pain
Timepoint
All variables at baseline, 1.5 month latter, and then at the end of 6 months are evaluated
Method of measurement
pain visual basic

6

Description
physical activity
Timepoint
All variables at baseline, 1.5 month latter, and then at the end of 6 months are evaluated
Method of measurement
questionnaire

7

Description
depression
Timepoint
All variables at baseline, 1.5 month latter, and then at the end of 6 months are evaluated
Method of measurement
questionnaire

8

Description
paraclinic (Blood)tests:TG,cholestrol,Na of urine(24 hours)
Timepoint
at baseline, and at the end of 6 months are evaluated
Method of measurement
labratory kits

Secondary outcomes

1

Description
Quality of life
Timepoint
At the begining and 6 months later
Method of measurement
Questionnair QOL36 questions that validited among Iranian

Intervention groups

1

Description
After registration of patients who want to participate in research projects. The goals and the process of research will be explained to them. Patient's informed consent will be filled out. If they have inclusion criteria, they participate in the study. Demographic information will be taken. The randomized allocation will be done by The technic of binary block allocation. 75 patients in the intervention group and 75 in control group. 75 patients will be in the intervention group. For the intervention group, the 6 group educational sessions, including 120 minutes will be arranged based on self-care behavior. At the first, intervention group will be received self-management, and self-monitoring of blood pressure questionnaires. Blood tests, Body Mass Index, blood pressure, quality of life will be measured too. After 1.5 months, the questionnaires will be completed again. Text messages will be given to intervention group based on the training subjects through the cell Phone weekly. After 6 months, Quality of life Inventory, self-management questionnaires will be completed. Clinical blood tests and BMI, blood pressure will be measured.75 patients will be in the intervention group. For the intervention group, the 6 group educational sessions, including 120 minutes will be arranged based on self-care behavior. At the first, intervention group will be received self-management, and self-monitoring of blood pressure questionnaires. Blood tests, Body Mass Index, blood pressure, quality of life will be measured too. After 1.5 months, the questionnaires will be completed again. Text messages will be given to intervention group based on the training subjects through the cell Phone weekly. After 6 months, Quality of life Inventory, self-management questionnaires will be completed. Clinical blood tests and BMI, blood pressure will be measured.
Category
Lifestyle

2

Description
75 patients will be in control group. The control group won't participate in education sessions. The control group will receive routine education based on health centers program according to national protocols. At the first, control group will receive self-management, and self-monitoring of blood pressure questionnaires. Blood tests, Body Mass Index, blood pressure, and quality of life will be measured too. After 1.5 months, the questionnaires will be completed again. After 6 months, Quality of life Inventory, self-management questionnaires will be completed. Clinical blood tests and BMI, blood pressure will be m
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Amir Hamze Health Cente
Full name of responsible person
Street address
4th st., Amir Hamze Health Cente, AmiriyehNeighborhood,Isfahan
City
Isfahan

2

Recruitment center
Name of recruitment center
Imam Sajjad Health Center
Full name of responsible person
Street address
,Imam Sajjad Health Center,.Mah Farokhi st. Khanhe Isfhan Neighborhood,Isfahan

City
Isfahan

3

Recruitment center
Name of recruitment center
Rehnan Health center
Full name of responsible person
Street address
Rehnan Health center, Shahid Hasheminezhad square,Rehnan Neighborhood,Isfahan
City
Isfahan

4

Recruitment center
Name of recruitment center
Ladan health center
Full name of responsible person
Street address
35 th st., Ladan Health center,Shahid Ashrafi Esfahani st.Ladan Neighborhood,Isfahan
City
Isfahan

5

Recruitment center
Name of recruitment center
Baharistan's health center (Mehrbod)
Full name of responsible person
Street address
Paradise Boulevard, New Town Baharistan,Baharistan's health center, Baharestan,Isfahan
City
Isfahan

6

Recruitment center
Name of recruitment center
Khadije Kobra Heath center
Full name of responsible person
Street address
- Tiran and Ahangaran alley, doctor Fatemi Street, Kaveh Street,Isfahan
City
Isfahan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Isfahan University of Medical Sciences
Full name of responsible person
Dr. Mohammad Hashemi
Street address
Building No. 4, field staff (setad), Research and Technology Assistance, Hezar Jarib street, Isfahan University of Medical Sciences
City
Isfahan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Isfahan University of Medical Sciences
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
Department of health education & health promotion School of health Isfahan University of Medical Sci
Full name of responsible person
Seyde Shahrbanoo Daniali
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Web page address

Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Seyede Shahrbanoo Daniali

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Other areas of specialty/work

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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