

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 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

Email address

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 Assistance of 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,cholesterol,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

Position

PhD. Candidate of health education and health promotion

Other areas of specialty/work

Street address

Isfahan University of Medical Sciences

City

Isfahan

Postal code

Phone

+98 31 3775 1953

Fax

Email

sh_daniali@yahoo.com; sh_daniali@hlth.mui.ac.ir

Web page address

Person responsible for scientific 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

Position

PhD. Candidate of health education and health promotion

Other areas of specialty/work

Street address

Isfahan- School of health ,Isfahan University of

Medical Sciences Isfahan,Iran

City

Isfahan

Postal code

8174885113

Phone

+98 31 3775 1953

Fax

Email

sh_daniali@yahoo.com; sh_daniali@hlth0mui.ac.ir

Web page address

Isfahan

Postal code

8174885113

Phone

+98 31 3775 1953

Fax

Email

sh_daniali@yahoo.com; sh_daniali@hlth.mui.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Seyede Shahrbanoo Daniali

Position

PhD student of Health education and health promotion

Other areas of specialty/work

Street address

Isfahan

City

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