

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 2026

The Effect of Community Based Interventions on Promoting the Life Style of Elderly People with Hypertension Based on Health Belief Model in 1398

Protocol summary

Study aim

Determining the effect of community-based interventions on improving the lifestyle of elderly people with high blood pressure in Khorramabad city based on the health belief model.

Design

Clinical trial, with control group, random stratified blocking.

Settings and conduct

The present study is a clinical trial study of Shahdar, on the elderly with hypertension, referring to the comprehensive health centers of Khorramabad with the method of sampling stratified random blocks in 2019-2020. Data Gathering Tools, Demographic Questionnaire, Hill-Bone treatment adherence scale, Assessment of Elderly Physical Activity (PASE), The study of perceptions and nutritional status in the elderly with hypertension is designed based on awareness structures, self-efficacy, commitment to program implementation and dietary follow-up of the health promotion model. Using 2.1, 3 Gpower software (due to the complexity of the formula cannot be calculated manually),

Participants/Inclusion and exclusion criteria

1- Having an age of 84-60 years 2- Mild to moderate blood pressure 3- No history of vascular disease 4- no mobility problems 5- Tendency to participate in research, speaking in Persian, Lori and laki 6- Lack of hearing and speech problems 7- Elderly death

Intervention groups

It includes a number of elderly men and women aged 84-60 years (eligible) with high blood pressure who are covered by comprehensive health centers selected for research in 2019-2020.

Main outcome variables

Physical activity- Nutritional Perceptions- Adherence to treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180721040540N4**

Registration date: **2020-05-21, 1399/03/01**

Registration timing: **prospective**

Last update: **2020-05-21, 1399/03/01**

Update count: **0**

Registration date

2020-05-21, 1399/03/01

Registrant information

Name

Heshmatolah Heydari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 66 3312 0160

Email address

heidari.h@lums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-25, 1399/03/05

Expected recruitment end date

2020-11-25, 1399/09/05

Actual recruitment start date

2020-11-25, 1399/09/05

Actual recruitment end date

2020-11-25, 1399/09/05

Trial completion date

2020-12-25, 1399/10/05

Scientific title

The Effect of Community Based Interventions on Promoting the Life Style of Elderly People with Hypertension Based on Health Belief Model in 1398

Public title

The Impact of Community-Based Interventions on Promoting Lifestyle

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

60-84 years old Hypertension based on the diagnosis of a specialist (duration of at least 12 months). Take at least one blood pressure lowering medication or change lifestyle for control. Confirmation of entry for study by physician designated research centers hypertension have (140/90 -159/99 mmHg mild hypertension) hypertension have (160/100-179 /109 mmHg medium Hypertension) No need for surgical treatment in recent months No history of coronary artery disease, Kidney Lack of physical disability or mental disorder Minimum literacy No mobility problems (able to perform daily activities without dependence on others) Lack of cognitive impairment and severe disabilities in walking independently (Walker, Wheelchair Dependency) Willingness to participate in research Spoken in Farsi, Larry and Lucky Lack of hearing and speech problems

Exclusion criteria:

Recent history for advanced and malignant disease Taking psychotropic drugs Drug use

Age

From **60 years** old to **84 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Actual sample size reached: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

The method of sampling was convenience method. Eligible subjects with using the Permuted block randomization will have located in the intervention or control groups. The Sex(Male and female), and level of hypertension of subjects, will consider as stratified in the inside of blocks.

Blinding (investigator's opinion)

Not 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 in Research of Lorestan University of Medical Sciences

Street address

Kelometr 5 Kamalvand Khoramabad- Boroujerd Road, Lorestan University Of Medical Sciences

City

Khorramabad

Province

Lorestan

Postal code

68149-93165

Approval date

2020-05-02, 1399/02/13

Ethics committee reference number

IR.LUMS.REC.1399.039

Health conditions studied

1

Description of health condition studied

Improving the lifestyle of the elderly with hypertension

ICD-10 code

I10

ICD-10 code description

Essential (primary) hypertension

Primary outcomes

1

Description

physical activity

Timepoint

Before, one month, two months and three months later

Method of measurement

Questionnaire of Physical activity scale for the elderly

2

Description

Nutritional perceptions

Timepoint

Before, one month, two months and three months later

Method of measurement

Questionnaire

3

Description

Adherence to treatment

Timepoint

Before, one month, two months and three months later

Method of measurement

Adherence to Hill-Bone High Blood Pressure Treatment

4

Description

Self- efficacy

Timepoint

Before, one month, two months and three months later

Method of measurement

Questionnaire

Secondary outcomes

1

Description

Blood pressure changes

Timepoint

Before, one month, two months and three months later

Method of measurement

Mercury manometer

Intervention groups

1

Description

Intervention group: The interventions in this s sessions based on the health belief model, The researcher teaches the elderly and their caregivers about the importance of diet, timely use of prescribed medications and physical activity. The workshop sessions will be conducted in a workshop manner (lectures, questions and answers, and a review of the content of the previous session) along with the presentation of educational booklet with very simple content. The duration of group training will be between 30 and 40 minutes in comprehensive health centers or any place where the individual and her family are available and have full satisfaction with the location of the training. Training sessions will be intervened 24 times during 3 months and will be held 2 days a week according to the conditions of the elderly studied. Individual home training will take place two weeks after group training. In addition, the researcher will be in constant contact tudy will include training with the samples in person or by phone during this period. The contents of the booklet include explanations on how to consume age-appropriate diets rich in protein, milk, and low-fat products to strengthen bones, fish consumption, and Brains such as almonds and walnuts and whole grains and fruits and vegetables as well as side effects Their medications and the effect of exercise on vitality and health and the effects of high blood pressure as well as the need Medical follow-up will be in collaboration with a cardiologist and nutritionist. Control group: They will receive their usual care from the health staff and at the end of the study, educational interventions will be provided to this group.

Category

Behavior

2

Description

Control group: the control group will receive routine services of comprehensive health centers.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Lorestan University of Medical Sciences

Full name of responsible person

Dr. Heshmatolah Heydari

Street address

Kilometr 5 Khorramabad- Boroujerd Road

City

Khorramabad

Province

Lorestan

Postal code

68149-93165

Phone

+98 66 3312 0174

Fax

+98 66 3312 0173

Email

Hidari74@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Khoram-Abad University of Medical Sciences

Full name of responsible person

Dr. Ebrahim Fallahi

Street address

Kilometr 5 Khorramabad- Boroujerd Road

City

Khorramabad

Province

Lorestan

Postal code

68149-93165

Phone

+98 66 3312 0172

Fax

+98 66 3312 0173

Email

research@lums.ac.ir

Web page address

<http://research.lums.ac.ir/>

Grant name

Grant code / Reference number

Is the source of funding the same sponsor

organization/entity?

Yes

Title of funding source

Khoram-Abad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Khoram-Abad University of Medical Sciences

Full name of responsible person

Heshmatolah Heydari

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Kilometr 5 Khorramabad- Boroujerd Road

City

Khorramabad

Province

Lorestan

Postal code

68149-93165

Phone

+98 66 3312 0174

Fax

+98 66 3312 0173

Email

Hidari74@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Khoram-Abad University of Medical Sciences

Full name of responsible person

Dr. Heshmatolah Heydari

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Kilometr 5 Khorramabad- Boroujerd Road

City

Khorramabad

Province

Lorestan

Postal code

68149-93165

Phone

+98 66 1233 0174

Fax

+98 66 1233 0173

Email

hidari74@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

Khoram-Abad University of Medical Sciences

Full name of responsible person

Heshmatolah Heydari

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Kiloumetr 5 Khorramabad- Boroujerd Road

City

Khorramabad

Province

Lorestan

Postal code

6815644667

Phone

+98 66 3312 0174

Fax

+98 66 3312 0173

Email

Hidari74@gmail.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Because of confidentiality

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The final report of the dissertation and questionnaires will be shared

When the data will become available and for how long

After final registration of the dissertation and publication of articles related to the project

To whom data/document is available

Research team members, university research officials, project supervisors, editors of special journals, Researchers in the field of medical sciences

Under which criteria data/document could be used

Doing research to improve the lifestyle of the elderly

From where data/document is obtainable

Responsible researcher

What processes are involved for a request to access data/document

Coordinating with the researcher through email, Refer to the library of the Faculty of Nursing, Lorestan University of Medical Science

Comments

There are no specific cases