

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 2026

The effect of self-management program based on 5A model on self-efficacy in the elderly men patients with hypertension

Protocol summary

Summary

The aim of this study is to evaluate the effect of 5A model based self-management program on self-efficacy in the old men patients with hypertension. This study will be conducted among two groups in which 60 elderly men patients with hypertension will be randomly allocated to two intervention and control groups. Randomization method: random allocation of patients into intervention and control groups will be done by even and odd numbers through sortition. Interventions: patients in intervention group will be educated (two one hour sessions) based on 5A self-management model through giving lecture, question and answer and group discussion. Intervention includes 5 steps. First step: assessment of knowledge, attitudes and beliefs of patients using a self-made form about hypertension. Second step: patient guidance about health risks and benefits of behavior change. Third step: to reach an agreement with the patients on setting realistic goals. Fourth step: helping to develop practical programs (along with family members). Fifth step: follow up. In the control group no intervention will be done for the patients. Intervention will be done during 12 weeks for patients in the intervention group. The inclusion criteria include age range of 60-75 years and over a 6-month history of hypertension and the main exclusion criterion include lack of desire to participate in the study. Self-efficacy questionnaire for chronic disease and self-efficacy questionnaire for patients with hypertension in both groups will be completed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017020632413N1**

Registration date: **2017-03-18, 1395/12/28**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-03-18, 1395/12/28

Registrant information

Name

Mojtaba Moradi

Name of organization / entity

Babol University of Medical Sciences

Country

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Phone

+98 11 5524 0627

Email address

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Babol University of Medical Sciences.

Expected recruitment start date

2017-02-15, 1395/11/27

Expected recruitment end date

2017-05-17, 1396/02/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of self-management program based on 5A model on self-efficacy in the elderly men patients with hypertension

Public title

The impact of self-management programs on self-efficacy of elderlies.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: male patients with high blood pressure diagnosed by a Physician at the age of 60-74 years; desire to participate in the study; history of more than 6 months of hypertension; speaking in Farsi; the ability to read and write; and absence of mental-cognitive impairment disorders; the absence of visual and hearing problems; not having job history in the health care system; the absence of malignant diseases; heart failure, kidney failure, hyperthyroidism, depression and mental illness; no history of severe mental crisis in the last 3 months; ability to perform activities of daily living; access to telephone. Exclusion criteria: no desire to participate in the research.

Age

From **60 years** old to **75 years** old

Gender

Male

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Randomization method: random allotment of patients into intervention and control groups will be by even and odd numbers by using sortition.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Babol University of Medical Sciences

Street address

Babol University of Medical Sciences, Ganjafrooz Street

City

babol

Postal code

4717647745

Approval date

2016-12-24, 1395/10/04

Ethics committee reference number

MUBABOL.HRI.REC.1395.62

Health conditions studied

1

Description of health condition studied

hypertension

ICD-10 code

I10

ICD-10 code description

Essential (primary) hypertension

Primary outcomes

1

Description

self-efficacy

Timepoint

Three months after the intervention

Method of measurement

1) Self-efficacy in Chronic Disease Questionnaire. 2) Self-efficacy in Hypertention Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: this group will be educated (two one hour sessions) based on 5A self-management model through giving lecture, question and answer and group discussion. Intervention includes 5 steps. First step: assessment of knowledge, attitudes and beliefs of patients using a self-made form about hypertension. Second step: patient guidance about health risks and benefits of behavior change. Third step: to reach an agreement with the patients on setting realistic goals. Fourth step: helping to develop practical programs (along with family members). Fifth step: follow up.

Category

Lifestyle

2

Description

In the control group no intervention will be done for the patients.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Sadatshhr Health Center

Full name of responsible person

Gholi Taleb

Street address

Sadatshahr Health Services Center-Ramsar

City

Ramsar

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research Babol University of Medical Sciences.

Full name of responsible person

Ali Akbar Moghadam Nia

Street address

Babol University of Medical Sciences, Ganjafrooz Street

City

Babol

Grant name

-

Grant code / Reference number

-

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

Yes

Title of funding source

Vice Chancellor for Research Babol 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

Babol University of Medical Sciences

Full name of responsible person

Mahboobeh Nasiri

Position

Master of Science - Faculty Member

Other areas of specialty/work

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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