Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of self-management program based on 5A model on coping strategies 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 coping strategies 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. coping strategies questionnaire by research samples at the end of 12 weeks to extract the main outcome (coping strategies) in both groups will be completed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017101132413N2**
Registration date: **2017-11-05, 1396/08/14**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2017-11-05, 1396/08/14

Registrant information

Name

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Name of organization / entity

Babol University of Medical Sciences

Country

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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 coping strategies in the elderly men patients with hypertension

Public title

The impact of self-management programs on coping strategies of elderly

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 **74 years** old
Gender
Male

Phase
N/A
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
Babol University of Medical Sciences
Street address
Babol University of Medical Sciences, Ganjafrooz Street
City
Babol
Postal code
4717647745
Approval date
2017-07-16, 1396/04/25
Ethics committee reference number
mubabol.hri.rec.1396.15

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
coping strategies
Timepoint
Three months after the intervention
Method of measurement
coping strategies 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
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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