Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of self-management program based on 5A model on self-care and quality of life in hypertensive elderly patients

Protocol summary

Study aim
Determining the effect of model 5A self-management program on self-care and quality of life in elderly patients with hypertension

Design
A controlled clinical trial with parallel, randomized groups (by Table of random numbers) on 60 patients

Settings and conduct
Sixty elderly patients referred to the heart clinic of Mashhad Army Hospital are divided to intervention and control groups by random sampling using table of random numbers. In the intervention group, a self-management program based on 5A Model will be implemented, which includes 5 stages of evaluation, consultation, agreement, assistance and follow-up (8 weeks). The control group will receive routine actions including face-to-face training and pamphlets.Hun self-care behaviors scale and SF-36 questionnaire will be completed before and the end of the intervention .

Participants/Inclusion and exclusion criteria
Entry conditions: 60 years of age and older- A definitive diagnosis of hypertension by specialist- get a score 7 or higher using the AMT tool- Ability to perform daily activity livings Conditions of non-entry: Cognitive impairment or Acute physical problems - Major depressive disorder or psychological disorders

Intervention groups
In the intervention group, the goal is the implementation a self-management program based on 5A Model, which includes 5 stages of evaluation, counseling, agreement, assistance and follow-up. This program will be presented to the elderly and a member of his family during 4 face-to-face and virtual sessions lasting 1-2 hours. The goals are agreed with the elderly and one of their family members in a individual meeting and Specific self management program is given to them. Then, according to the agreement made with each elderly, Face-to-face and virtual follow-up will be continue for 8 weeks.

Main outcome variables
Self-care and quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210110049983N1**
Registration date: **2021-03-01, 1399/12/11**
Registration timing: **prospective**

Last update: **2021-03-01, 1399/12/11**
Update count: **0**

Registration date
2021-03-01, 1399/12/11

Registrant information

Name
Fateme Asgharian

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-04-04, 1400/01/15

Expected recruitment end date
2021-08-06, 1400/05/15

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-care and quality of life in hypertensive elderly patients

Public title
The effect of self-management program based on 5A model on self-care and quality of life in high blood pressure elderly patients

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
60 years of age and older A definitive diagnosis of hypertension by specialist Informed consent to participate in the study Ability to speak Persian Be literate get a score 7 or higher using the AMT tool Ability to communicate through WhatsApp social network Ability to perform daily activity livings and get a score of 13 or higher using the Bartel ADL tool

Exclusion criteria:
Cognitive impairment such as Alzheimer's, dementia, delirium (severe confusion) Major depressive disorder or psychological disorders Clear speech disorder Clear and uncorrected vision or hearing problems Acute physical problems such as uncontrolled diabetes, heart attack or stroke and lung infection

Age
From **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, as the first step are listed the medical records of all elderly patients with hypertension referred to the cardiac clinic of Mashhad Army Hospital. Then, elderly with inclusion criteria are selected and assigned in a simple random method to the two groups of control and intervention using a table of random numbers.

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
Iran National Committee for ethics in Biomedical Research

Street address
Ethics Committee of Mashhad University of Medical Sciences, Qureshi Building, Daneshgah St., Mashhad, Iran

City
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Province
Razavi Khorasan

Postal code
9137913199

Approval date
2021-01-10, 1399/10/21

Ethics committee reference number
IR.MUMS.NURSE.REC.1399.068

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-care

Timepoint
Beginning and end of the study at the end of week 8

Method of measurement
Han Self-Care Questionnaire

2

Description
Quality of life

Timepoint
Beginning and end of the study at the end of week 8

Method of measurement
SF-36 Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
In the intervention group, a self-management program based on the 5A model will be implemented. This model includes 5 stages of evaluation, counseling, agreement, assistance and follow-up. four face-to-face and virtual sessions with a duration of 1-2 hours will be provided for the elderly and one of his family members, in order to implement training and planning in the field of self-management. The first session will be held in person for one to two hours to implement the first and second stages (evaluation and consultation), which will be held in groups of up to 7 people. Actions in this session include measuring blood pressure and BMI, Introducing the study, assessing the views and concerns of the elderly about hypertension, symptoms, complications and its impact on health and quality of life, as well as introducing the disease and its management methods. In a few days, the second session will be held virtually through WhatsApp for one hour to implement the third stage (agreement) individually for each elderly person and one of the family members. After agreeing on the goals, a specific self-management program will be provided to them and a checklist of individual actions will be sent to the patient, emphasizing the importance of taking notes and reporting actions and blood pressure to the patient and his companion. The third session will be a week later and for 2 hours, to perform the fourth stage (help) in the form of WhatsApp groups of 7 people, with the aim of simplifying the process of self-care and reminding the trainings and controlling the client checklist. The fifth stage (follow-up) is post-agreement follow-up, which is supported by the researcher twice a week, then once a week, bi-weekly, bi-weekly and monthly until the end of week 8 after the intervention by telephone to motivate, support And ambiguities. The final session will be held for 1 hour at the end of week 8 after the start of the intervention in groups of 7 people to complete the test post forms and checklists control.

Category
Lifestyle

2

Description
Control group: In the control group, routine actions include face-to-face training sessions during the doctor's visit and providing an educational pamphlet on hypertension management.

Category
Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center
Mashhad Army Hospital

Full name of responsible person
Fatemeh Asgharian

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Army Hospital, Bahar Avenue, Mashhad. Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
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Grant name

Grant code / Reference number

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

Title of funding source
Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Mahmoud Bakhshi

Position
Assistant Professor

Latest degree
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
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
Yes - There is 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
Demographic and contextual characteristics of study participants
When the data will become available and for how long
After September 1400
To whom data/document is available
all
Under which criteria data/document could be used
Email the responsible author or access databases
From where data/document is obtainable
Email the responsible author or access databases
What processes are involved for a request to access data/document
By email for about a week
Comments