

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jul 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3859 1511

##### Email address

asgharianf951@mums.ac.ir

##### 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

mashhad

##### 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

##### Street address

Army Hospital, Bahar Avenue, Mashhad. Iran

##### City

mashhad

##### Province

Razavi Khorasan

##### Postal code

111111111

##### Phone

+98 51 3859 1052

##### Email

asgharianf951@mums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Full name of responsible person

Mohsen Tafaghodi

##### Street address

Department of the Elderly, Nursing AND Midwifery school, Doctrora Crossroad, Mashhad, Iran

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9177899191

##### Phone

+98 51 3841 2081

##### Email

tafaghodim@mums.ac.ir

#### 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**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**Nursing AND Midwifery School, Doctra Crossroad,  
Mashhad, Iran**City**

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**Province**

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bakhshim@mums.ac.ir

Fateme Asgharian

**Position**

Clinical Nurse

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

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Army Hospital, Bahar Avenue, Mashhad. Iran

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

Mashhad University of Medical Sciences

**Full name of responsible person**

Mahmoud Bakhshi

**Position**

Asistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

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**Postal code**

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**Phone**

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**Email**

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

Artesh University of Medical Sciences

**Full name of responsible person****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**