

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 Jul 2026

### The Effect of Adherence treatment Program family centered on blood pressure of elderly with hypertension Referred to Healthcare Centeres in Isfahan city in 2019

#### Protocol summary

##### Study aim

The effect of a family-based treatment regimen on blood pressure (systolic and diastolic) in elderly patients with hypertension

##### Design

Clinical trial with test and control group, random allocation

##### Settings and conduct

The researcher initiates an intervention for the test group that includes a family-based diet adherence program based on the concepts of Johnson's drug adherence model. According to the first concept of the model (targeted action) 3 sessions in the center and For the second concept (model of behavior) a meeting will be held at the center and for the third concept (feedback) 2 home visits will be conducted.

##### Participants/Inclusion and exclusion criteria

1. Elderly people who have been diagnosed and treated by a specialist at a specialist hypertensive center. 2. Elderly people with hypertension referring to selected health centers in Isfahan. 3. Be over 60 years old. Exclusion criteria: 1. The patient's unwillingness to continue collaborating in the study 2. Die during the study

##### Intervention groups

This study is a randomized, three-stage, two-group clinical trial study performed before, immediately and three months after the intervention. Available by random assignment, sampling. The researcher makes two cards and writes one number on one card and the other two on the card. On the days of collecting samples at the center, he places the cards on the back of the table so that the number on the card is not specified and then tells each person to choose a card. People who choose Card # 2 fall into the control group.

##### Main outcome variables

The independent variable in this study is family-based

adherence treatment program, which is nominally qualitative. The dependent variable is systolic and diastolic blood pressure in the elderly with a slight continuous hypertension.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20160903029662N6**

Registration date: **2020-02-17, 1398/11/28**

Registration timing: **retrospective**

Last update: **2020-02-17, 1398/11/28**

Update count: **0**

##### Registration date

2020-02-17, 1398/11/28

##### Registrant information

##### Name

Habibollah Hosseini

##### Name of organization / entity

Isfahan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 42250341

##### Email address

h\_hoseini@nm.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-11-11, 1398/08/20

##### Expected recruitment end date

2019-12-11, 1398/09/20

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The Effect of Adherence treatment Program family centered on blood pressure of elderly with hypertension Referred to Healthcare Centers in Isfahan city in 2019

**Public title**

The Effect of Adherence treatment Program family centered on blood pressure of elderly with hypertension Referred to Healthcare Centers in Isfahan city in 2019

**Purpose**

Health service research

**Inclusion/Exclusion criteria****Inclusion criteria:**

1. Elderly people who are diagnosed with hypertension and are treated by a specialist at the center. 2. Elderly people with hypertension referring to selected comprehensive health centers in Isfahan. 3. Be older than 60 years. 4. Elderly and family willing to participate in the study 5. Elderly not have known mental illness. 6. Familiar with Farsi language. 7. In the same intervention programs adherence to treatment regimen Do not have.

**Exclusion criteria:**

1. Patient's unwillingness to continue to participate in the study 2. Death during the study. 3. Problems resulting in disability at each stage of the study. Two sessions and more in intervention programs 5. Secondary hypertension. 2. Death during the study 3. Problems resulting in disability at each stage of the study. 4. Two sessions and more in intervention programs 5. Secondary hypertension.

**Age**From **60 years** old**Gender**

Both

**Phase**

N/A

**Groups that have been masked***No information***Sample size**Target sample size: **70****Randomization (investigator's opinion)**

Randomized

**Randomization description**

Using simple random assignment sampling in two groups of test and control from one comprehensive health service center - Individual Randomization Unit - Randomization Tool: Card

**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**

Isfahan University of Medical Sciences Ethics Committee

**Street address**

Esfahan . School of Nursing and Midwifery, Hezar Jerib Ave.

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Approval date**

2019-11-01, 1398/08/10

**Ethics committee reference number**

IR.MUI.RESEARCH.REC.1398.410

**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**

In this study, the effect of independent variable of family-based diet regimen on blood pressure dependent variables (systolic and diastolic) in elderly patients with hypertension will be investigated.

**Timepoint**

This study was performed before, immediately and three months after the intervention.

**Method of measurement**

In this study, data collection tools are German Richter model mercury barometer, German Richter model medical device, Elderly Blood Pressure Checklist, Needs Assessment Questionnaire and Demographic Questionnaire and Disease Information.

**Secondary outcomes**

empty

## Intervention groups

1

### Description

This study has two groups. "Intervention group" 2. "Control group". The "intervention group" will receive a family-based treatment plan based on the concepts of Johnson's drug adherence model. (Model of Conduct) A meeting will take place at the center and for the third concept (feedback) 2 home visits.

### Category

Other

2

### Description

Control group: The "control group" receives routine care at the health center and at the end of the study the subject leaflet is distributed to the participants.

### Category

Other

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Health Center

#### Full name of responsible person

Habibollah Hosseini

#### Street address

Haftoun Street, Meraj Street, Comprehensive Health Service Center

#### City

Isfahan

#### Province

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#### Postal code

8174673461

#### Phone

+98 31 3668 7140

#### Email

f.melali00@gmail.com

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Esfahan University of Medical Sciences

#### Full name of responsible person

Dr. Mahnaz Norouzi

#### Street address

School of Nursing and Midwifery Isfahan University of Medical Sciences

#### City

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#### Province

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#### Postal code

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#### Phone

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#### Fax

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#### Email

f.melali00@gmail.com

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

#### Full name of responsible person

Habibollah Hosseini

#### Position

faculty member

#### Latest degree

Master

#### Other areas of specialty/work

Health Promotion

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## Person responsible for scientific inquiries

### Contact

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**Position**

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**Latest degree**

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**Other areas of specialty/work**

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

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Not applicable

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Not applicable

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

Consult with relevant professors

**When the data will become available and for how long**

Consult with relevant professors

**To whom data/document is available**

Consult with relevant professors

**Under which criteria data/document could be used**

Consult with relevant professors

**From where data/document is obtainable**

Consult with relevant professors

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

Consult with relevant professors

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

Esfahan University of Medical Sciences

**Full name of responsible person**

Habibollah Hosseini

**Position**

Faculty Member

**Latest degree**

Master

**Other areas of specialty/work**

Health Promotion

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