Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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

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Iran (Islamic Republic of)

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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 Centeres 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 Centeres 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 programs5. 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
Isfehan
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
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Haftoun Street, Meraj Street, Comprehensive Health Service Center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Dr. Mahnaz Norouzi
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School of Nursing and Midwifery Isfahan University of Medical Sciences
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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
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
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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