Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 Nov 2026

Investigating Effect of a Multifaceted Intervention on Blood Pressure Control and Drug Compliance in Patients with Uncontrolled Hypertension

Protocol summary

Study aim
The purpose of this study is to diagnose effect of multifaceted intervention on blood pressure control and drug compliance among uncontrolled hypertension patients.

Design
A controlled clinical trial was randomly conducted on 72 patients in Emergency of Alzahra hospital, Isfahan University of Medical Sciences from April to June 2018.

Settings and conduct
Subsequent to consent form, samples were randomly divided into intervention and control groups. Multifaceted intervention includes: encouragement interviews and a four-week training (90 minutes per session), a drug reminder box, family support and 4 phone follow ups. Morisky Questionnaire was used before and one month after the intervention. Blood pressure was measured in both groups at baseline and one month later.

Participants/Inclusion and exclusion criteria
Inclusion criteria: At least one year background of hypertension with doctor approval؛ Under hypertension medical therapy؛ Recorded hypertension higher than 140/190 mmHg at the time of emergency reception.

Intervention groups
intervention and control groups

Main outcome variables
Multifaceted intervention promoted drug compliance and reduced systolic and diastolic blood pressure. Thus patients are recommended to use it as a supplement after their discharge.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20110821007391N6**
Registration date: **2018-10-19, 1397/07/27**
Registration timing: **retrospective**
Last update: **2018-10-19, 1397/07/27**
Update count: **0**

Registration date
2018-10-19, 1397/07/27

Registrant information
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Maryam Eghbali Babadi
Name of organization / entity
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-04-04, 1397/01/15

Expected recruitment end date
2018-04-19, 1397/01/30

Actual recruitment start date
2018-04-04, 1397/01/15

Actual recruitment end date
2018-04-19, 1397/01/30

Trial completion date
2018-06-20, 1397/03/30

Scientific title
Investigating Effect of a Multifaceted Intervention on Blood Pressure Control and Drug Compliance in Patients with Uncontrolled Hypertension

Public title
Effect of a Multifaceted Intervention on Blood Pressure Control and Drug Compliance

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

At least one year background of hypertension with doctor approval Under hypertension medical therapy Recorded hypertension higher than 140/190 mm Hg at the time of emergency reception Accompaniment of one family member Not having a background of Alzheimer's disease

Exclusion criteria:

Development of serious problems, life threatening or any disability or death, for the study sample during the study Dissatisfaction or withdrawal from the study

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **72**

Actual sample size reached: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

Envelopes containing cards with numbers one and two were given to participants, in the case of selecting the number one, depending on the intervention and the choice of the number two, they were placed in the control group

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

Ethics committee of Isfahan University of Medical Sciences

Street address

Hezar-Jerib Ave., Isfahan University of Medical Sciences

City

Isfahan

Province

Isfehan

Postal code

8174673461

Approval date

2018-02-19, 1396/11/30

Ethics committee reference number

IR.MUI.REC 1396.3.841

Health conditions studied

1

Description of health condition studied

Essential (primary) hypertension

ICD-10 code

ICD-I10

ICD-10 code description

Essential (primary) hypertension

Primary outcomes

1

Description

Blood Pressure

Timepoint

Before and after education

Method of measurement

Blood Pressure measurement device

2

Description

adherence to drug therapy

Timepoint

Before and after education

Method of measurement

Morisky medication adherence questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: For intervention group, 10-member groups with family member, an encouragement interview along with delivering a seven-part medication reminder box for one week medication. Then three training sessions (90 minutes) was held in 3 weeks and emphasis was placed on family support for medication. Also, four telephone contacts with study samples and a family member were made at the end of each week for 10 minutes by appointment. Training sessions were relevant to nature and side-effects of diseases and the consequences of not taking hypertension medication, methods of controlling the disease via appropriate lifestyle .Other approached included presenting information through lectures, Power Points, discussion between participants, and training booklet. Additionally, the content of phone contact was Q & A sessions regarding reinforcement of contents, strengthening family support technique and utilization of medication reminder box finalizing with uncovering potential

problems of study samples.

Category

Lifestyle

2

Description

Control group: Before and a month later, control group participants were invited for data collection. In the meantime, in order that ethical codes are followed, study samples in the control group were given a drug reminder box and a training booklet with regard to discussions on the training sessions.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Emergency of Al-Zahra Hospital

Full name of responsible person

Azam alsadat Mirniam

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan 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

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

Maryam Eghbali Babadi

Position

Faculty Member

Latest degree

Ph.D.

Other areas of specialty/work

Nursing

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
In the future, I'll print this research.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available