

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 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

###### Name

Maryam Eghbali Babadi

###### Name of organization / entity

Isfahan University Of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 3792 7539

###### Email address

eghbali@nm.mui.ac.ir

##### 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**

Isfahan

##### **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

**Street address**

Hezar Jerib Avenue

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**Postal code**

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**Phone**

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mirniam2013@gmail.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Shaghayegh Haghjooy Javanmard

**Street address**

Hezar Jerib Avenue

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sh\_haghjoo@med.mui.ac.ir

**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 updating data****Contact****Name of organization / entity**

Esfahan University of Medical Sciences

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**Province**

Isfahan

**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