

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 2026

### The effect of group training and tele-nursing on medication/diet adherence and blood pressure control in the elderly with hypertension

#### Protocol summary

##### Study aim

Determining the effect of group training and tele-nursing on adherence to diet, diet and blood pressure control in the elderly with hypertension

##### Design

Using the balance block randomization approach, individuals will be assigned to three groups of 30, including tele-nursing, group training, and random allocation control. First, written consent will be obtained from all selected individuals, emphasizing the confidentiality of information, and then individuals will be divided into one of three groups, including 1- tele-nursing, 2- group training, and 3- control.

##### Settings and conduct

Ilam province, Abdanan city

##### Participants/Inclusion and exclusion criteria

At least six months have passed since the diagnosis of hypertension. Do not have speech, hearing or vision problems. Be literate. Be able to understand conversation in Persian and Kurdish. It is possible to make direct telephone calls to the patient.

##### Intervention groups

Basic information will be collected from all groups. In this study, the pressure level of the participants is measured. Control group will have no intervention but the study of a booklet. A 6 - week training intervention will continue. Topics will include explanations of high blood pressure and its control procedure, the right to measure the blood pressure pressure, the healthy diet, weight control, interruption of smoking, and adherence to consumption, stress management and anxiety, physical activity, monitoring of care, and For the participants participating in the category of group training for six weeks, a 45 - 60 - minute training session is considered every week. For the Company for 6 weeks, 2 - 20 minutes each week is considered to be 10 - 20 minutes

##### Main outcome variables

medication adherence: diet adherence: blood pressure control

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220130053886N1**

Registration date: **2022-07-16, 1401/04/25**

Registration timing: **retrospective**

Last update: **2022-07-16, 1401/04/25**

Update count: **0**

##### Registration date

2022-07-16, 1401/04/25

##### Registrant information

##### Name

RAZIEH MOHAMADZADEH

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 84 3362 2636

##### Email address

razi.m1376@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-04-30, 1401/02/10

##### Expected recruitment end date

2022-06-20, 1401/03/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of group training and tele-nursing on medication/diet adherence and blood pressure control in the elderly with hypertension

**Public title**

effect of group training and tele-nursing on medication/diet adherence and blood pressure control

**Purpose**

Education/Guidance

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

Their age is 60 to 74 years. Be at least six months have passed since the diagnosis of hypertension. Do not have speech, hearing or vision problems. Be literate. Be able to understand conversation in Persian and Kurdish. It is possible to make direct telephone calls to the patient. Do not suffer from debilitating physical and mental illnesses (stroke, Parkinson's, multiple paralysis, epilepsy, depression, etc.). Lack of employment in the treatment staff

**Exclusion criteria:**

For whatever reason, they can not follow the training program. Do not attend more than one in-person or telephone session. Hospitalization or death during the study. Do not want to continue reading.

**Age**

From **60 years** old to **74 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **90**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

According to the equal proportion of people covered by each center, based on the entry and exit criteria, 18 to 22 people will be selected from each center until the desired sample size (90 people) is provided. Then, using the balance block randomization approach, individuals will be given to three groups of 30 people, including tele-nursing, group training, and random allocation control. To perform balance block randomization, 3 permutations will be determined first, which include the following order: 1: ABC 2: BAC 3: BCA 4: CAB 5: CBA 6: ACB A will be the symbol of the group training group, B will be the symbol of the tele-nursing group and C will be the symbol of the control group. Then, using stata software and alloc package, a random sequence will be created and each person who enters the study will be assigned to groups based on this sequence.

**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 Ilam University of Medical Sciences

**Street address**

Shahid Norouzi Alley, Shahriar St, Baqer Sadr, Abdanan

**City**

Abdanan

**Province**

Ilam

**Postal code**

6971863311

**Approval date**

2022-03-16, 1400/12/25

**Ethics committee reference number**

IR.MEDILAM.REC.1400.245

**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**

blood pressure control

**Timepoint**

Measurement of blood pressure before the intervention and every week until the end of the study

**Method of measurement**

Using a sphygmomanometer

**2****Description**

medication adherence

**Timepoint**

Before the intervention began, and at the end of the intervention, and again a month after the intervention ended

**Method of measurement**

hell bone questionnaire

### 3

#### **Description**

diet adherence

#### **Timepoint**

Before the intervention began, and at the end of the intervention, and again a month after the intervention ended

#### **Method of measurement**

hell bone questionnaire

### **Secondary outcomes**

empty

### **Intervention groups**

#### 1

#### **Description**

Intervention group1: group training. A small group of people is assembled in a peaceful environment, and after training on blood pressure and its way of controlling it, the researcher is allowed to interact with each other about the issue discussed. For the participants participating in the category of group training for six weeks, a 45 - 60 - minute training session is considered every week.

#### **Category**

N/A

#### 2

#### **Description**

Intervention group2: tele-nursing. the purpose of this study is to provide training and follow - up patients with پرفشاری blood pressure by the researcher over the past six weeks and twice a week. Over the course of the phone conversation, about 10 to 20 minutes and phone conversations include information on diet, diet, lifestyle, and answers to their questions.

#### **Category**

N/A

### **Recruitment centers**

#### 1

#### **Recruitment center**

##### **Name of recruitment center**

Abdanan County Health Network

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

Dr Saman Rashidi

##### **Street address**

Imam Khomeini street

##### **City**

Abdanan

##### **Province**

Ilam

##### **Postal code**

6971863311

##### **Phone**

+98 84 3362 4052

#### **Email**

msa.aghili@gmail.com

### **Sponsors / Funding sources**

#### 1

#### **Sponsor**

##### **Name of organization / entity**

Ilam University of Medical Sciences

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

Dr Mohammad Reza Kafashian

##### **Street address**

Ilam University of Medical Sciences Campus,  
Research Blvd, Banganjab, Ilam.

##### **City**

Ilam

##### **Province**

Ilam

##### **Postal code**

6931851147

##### **Phone**

+98 84 3333 4060

##### **Email**

info@medilam.ac.ir

#### **Grant name**

#### **Grant code / Reference number**

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

Yes

#### **Title of funding source**

Ilam 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**

Ilam University of Medical Sciences

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

Dr Afsane Raiesi far

##### **Position**

Assistant Professor

##### **Latest degree**

Ph.D.

##### **Other areas of specialty/work**

Nursery

##### **Street address**

Ilam, Banganjab, Research Blvd., Ilam University of  
Medical Sciences Campus

##### **City**

ilam

**Province**  
Ilam  
**Postal code**  
6931851147  
**Phone**  
+98 84 3333 4060  
**Email**  
a.raiesifar@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Ilam University of Medical Sciences  
**Full name of responsible person**  
Dr Afsane Raiesi far  
**Position**  
Assistant Professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Nursery  
**Street address**  
Ilam, Banganjab, Research Blvd., Ilam University of  
Medical Sciences Campus  
**City**  
Ilam  
**Province**  
Ilam  
**Postal code**  
6931851147  
**Phone**  
+98 84 3333 4060  
**Email**  
a.raiesifar@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Ilam University of Medical Sciences

**Full name of responsible person**  
Dr Afsane Raiesifar  
**Position**  
Assistant Professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Nursery  
**Street address**  
Ilam, Banganjab, Research Blvd., Ilam University of  
Medical Sciences Campus  
**City**  
Ilam  
**Province**  
Ilam  
**Postal code**  
6931851147  
**Phone**  
+98 84 3333 4060  
**Email**  
a.raiesifar@gmail.com

## 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

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

### Clinical Study Report

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

### Analytic Code

Not applicable

### Data Dictionary

Not applicable