

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Aug 2026

### Investigating the effect of the implementation of the family health nurse model on self-management of high blood pressure in the elderly

#### Protocol summary

##### Study aim

Investigating the effect of the implementation of the family health nurse model on Hypertension self-management of elders

##### Design

A clinical trial with a control group, with parallel groups, without blinding, randomized on 76 patients, random number table was used for randomization.

##### Settings and conduct

The research population is elderly with high blood pressure covered by comprehensive health service centers in Isfahan City, who were selected using a random number table. Among the number 1 centers of Isfahan where social medicine is located, one center will be randomly selected and one base will be selected as an intervention center and one base will be selected as a control center. The localized model of the family health nurse is implemented.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Elderly aged 60-74 years Willingness to participate in the study Suffering from high blood pressure above 140/90 for at least 6 months Resident of Isfahan The presence of an active person in the elderly home Farsi language No mental disorders Criteria for not entering the study: Having chronic diabetes Having untreated hypothyroidism

##### Intervention groups

Intervention group: For the test group, a self-management program is implemented in the form of a localized family health nurse model. This model includes 3 stages before intervention, intervention, and evaluation, in the pre-intervention stage, preparations are made and in the intervention stage, home visits and identification are carried out. The patient's problems are presented with the service package of the localized family health model. The evaluation is done in 3 stages during, immediately, and 3 months after the intervention. The control group: receives the center's routine care.

#### Main outcome variables

Hypertension self-management

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190806044449N2**

Registration date: **2023-07-23, 1402/05/01**

Registration timing: **prospective**

Last update: **2023-07-23, 1402/05/01**

Update count: **0**

##### Registration date

2023-07-23, 1402/05/01

##### Registrant information

##### Name

Maryamsadat Shahshahani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3792 7585

##### Email address

shahshahani@nm.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-08-08, 1402/05/17

##### Expected recruitment end date

2023-11-08, 1402/08/17

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Investigating the effect of the implementation of the family health nurse model on self-management of high blood pressure in the elderly

**Public title**

Investigating the effect of implementing the family health nurse model on Hypertension self-management

**Purpose**

Education/Guidance

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

Elderly aged 60-74 years Willingness to participate in the study Patients with high blood pressure above 140/90 Living in Isfahan city Diagnosis of high blood pressure for at least 6 months Not suffering from mental disorders Farsi speaking participants Doing daily activities independently The presence of an active person in the elderly home (family health ambassador based on ambassador criteria)

**Exclusion criteria:**

Having chronic diabetes that leads to cardiovascular disorders. Having untreated hypothyroidism

**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: **76****Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization will be done in two stages. At first, referring to Isfahan Health Network 1, a center will be selected as the intervention group by lottery, and then, for the control group to be homogeneous with the subjects of the intervention center in terms of social and economic conditions, one center will be selected as the control group by lottery among the comprehensive health service centers that are located in the vicinity of the center of the intervention group. In the second stage, in the centers selected by the researcher, through the Sib system, the head of the center will prepare a list of all the people who meet the entry criteria and systematically select the subjects, in such a way that the total number of the research population is divided by the required number of subjects to get the K number. Then randomly, the first number below ten is obtained, which is called n. Then the numbers N+K, N+2K, N+3K,... will be selected until the last subject

**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**

Ethical Committee of Isfahan University of Medical Sciences

**Street address**

School of Nursing and Midwifery, Isfahan University of Medical Sciences, Hezar Jerib Ave., Azadi Square

**City**

Esfahan

**Province**

Isfahan

**Postal code**

8174673461

**Approval date**

2023-07-08, 1402/04/17

**Ethics committee reference number**

IR.MUI.NUREMA.REC.1402.056

**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**

High blood pressure self-management score in the Stanford Self-Management Questionnaire

**Timepoint**

Before, immediately and 3 months after the intervention

**Method of measurement**

Stanford chronic disease self-management questionnaire

**2****Description**

hypertension

**Timepoint**

Before, immediately and 3 months after the intervention

**Method of measurement**

Mercury sphygmomanometer

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Intervention group: For this group, the steps of the localized family health nurse model, which was developed by Keshvari et al. in 2013 under the title "Explaining the process of providing health services to families covered by rural health centers in Isfahan City: Designing a suitable model for providing family health care" It has been designed and will be implemented. This model will include three stages (before intervention, intervention, and evaluation). The pre-intervention stage included two preliminary stages and the first meeting with the samples, during the preliminary stage, the necessary measures were taken to meet the people with high blood pressure, and in the first meeting with the samples, after completing the relevant questionnaires, an initial assessment was carried out. They will be done at the center and the home visit time will be coordinated with them. In the intervention stage, which includes (home visits, implementation in the center and provision of a localized family health model service package, formation of self-help groups, and follow-up for 3 months), at least during two home visit sessions and the selection of a family health ambassador, with Use the relevant forms to assess the educational needs of the family with the help of family members, and after identifying the identified problems of the patient, based on nursing diagnoses, nursing care for the affected person is planned with the help of the family and a localized model package that includes individual counseling. , educational booklets and holding training sessions, referral to a doctor, follow-up of internal referrals made by a doctor to a psychiatrist, nutritionist, or specialist doctor, and follow-up of external referrals will be provided according to the needs and problems of each patient. Then, for 3 months, in the form of holding self-help group meetings and conducting monthly care and blood pressure control, he will follow up with the affected people. The evaluation stage of this model will also be done during 3 stages (during the intervention, immediately after the intervention, and 3 months after the intervention) by means of the Stafford Chronic Disease Self-Management Questionnaire and blood pressure measurement.

#### Category

Treatment - Other

### 2

#### Description

Control group: In this study, the control group after being called to the center, performing initial assessment, measuring blood pressure, and completing relevant questionnaires referred to health care providers and receive routine care at the center for 3 months, and after 3 months they complete the questionnaires and Their

blood pressure will be measured again.

#### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Isfahan comprehensive health service centers

##### Full name of responsible person

Hamid Galeh dari

##### Street address

Health Vice District, next to Amin Hospital, Ibn Sina St, Esfahan

##### City

Esfahan

##### Province

Isfahan

##### Postal code

81486-53374

##### Phone

+98 31 3441 6060

##### Email

health@mui.ac.ir

##### Web page address

<https://phc.mui.ac.ir/fa>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Esfahan University of Medical Sciences

##### Full name of responsible person

Gholamreza Asgari

##### Street address

1st Floor, Research and Technology Vice-Chancellor of the University, Headquarters Building No. 4, Isfahan University of Medical Sciences and Health Care Services, Hazar Jarib St.

##### City

Esfahan

##### Province

Isfahan

##### Postal code

81746-73461

##### Phone

+98 31 3668 5149

##### Email

research@mui.ac.ir

##### Web page address

<https://tech.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**

Zohreh Noorollahi

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

Department of Community Health, School of Nursing and Midwifery, Isfahan University of Medical Sciences, Hezar Jerib Street, Azadi Square, Isfahan, Iran

**City**

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**Province**

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**Postal code**

8174673461

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Zohreh.noorollahi@gmail.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Maryam Sadat Shahshahani

**Position**

Faculty Instructor

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

**Street address**

Faculty of Nursing and Midwifery, Isfahan University of Medical Sciences, Hezar Jerib Street, Isfahan, Iran

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**Province**

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shahshahani@nm.mui.ac.ir

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

Esfahan University of Medical Sciences

**Full name of responsible person**

Maryam Sadat Shahshahani

**Position**

Member of the faculty of nursing and midwifery in Isfahan

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

**Street address**

Hazar Jarib St., Isfahan University of Medical Sciences and Health Services, Nursing and Midwifery College

**City**

Esfahan

**Province**

Isfahan

**Postal code**

8174673461

**Phone**

+98 31 3668 7153

**Email**

shahshahani@nm.mui.ac.ir

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

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

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

Results from demographic data, questionnaires and blood tests can be shared anonymously. The study protocol will be announced.

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

Start access period after printing results

**To whom data/document is available**

According to the research title, all interested people will have access to the results.

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

The results will be published in scientific journals and in

addition ; the researchers' emails will be available

**From where data/document is obtainable**

he way to communicate is emails:

shahshahani@nm.mui.ac.ir zohreh.noorollahi@gmail.com

**What processes are involved for a request to access**

**data/document**

It will be answered at least 1 week after request.

**Comments**

Only the results and study protocol will be presented.