

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

AgeFrom **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

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Province

Isfahan

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81486-53374

Phone

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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.

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Province

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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

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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

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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

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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.