

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jul 2026

### Studying the effect of family-based empowerment model on self-efficacy and quality of life in hypertensive patients visiting comprehensive health centers

#### Protocol summary

##### Study aim

Determining the effect of family-based empowerment model on self-efficacy and quality of life in hypertensive patients visiting comprehensive health centers

##### Design

Two arm parallel group randomized trial, not blinded, randomized by drawing, done on 70 patients.

##### Settings and conduct

The study site was Hijrat and Musa Ibn Jafar Health Center in Zahedan. No blinding was performed in this study.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Hypertension was diagnosed at least 6 months ago; having the ability to read and write; being at the age of 25-65 years old. Non-inclusion criteria: Has not participated in a training program during the last 6 months.

##### Intervention groups

Intervention group: Family-centered empowerment based on steps in 4 sessions of 60 minutes for 4 weeks individually, with the participation of the patient and a family member, in a suitable place for training in comprehensive health centers of Zahedan and preferably during office hours using PowerPoint, educational video and the tutorial will be done. Control group: the control group will not receive any training.

##### Main outcome variables

Quality of life; self-efficacy

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20201016049043N1**

Registration date: **2020-11-21, 1399/09/01**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-11-21, 1399/09/01**

Update count: **0**

##### Registration date

2020-11-21, 1399/09/01

##### Registrant information

###### Name

Mahsa Asadollahi hamedani

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 3867 4594

###### Email address

mahsaa.asadollahi@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-08-22, 1399/06/01

##### Expected recruitment end date

2021-08-23, 1400/06/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Studying the effect of family-based empowerment model on self-efficacy and quality of life in hypertensive patients visiting comprehensive health centers

##### Public title

The effect of family-based empowerment model in hypertensive patients

##### Purpose

Supportive

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

Diagnosed high blood pressure from at least 6 months ago  
 Caregiver has at least reading and writing literacy  
 Being at the age of 25-65 years old

**Exclusion criteria:**

Participating in a training program similar to the current training program during the last 6 months

**Age**

From **25 years** old to **65 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **70**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Sampling will be done in several stages. First, urban areas are considered as clusters, then two areas are randomly selected, and then from each area, a center is identified by drawing a number, and the centers are allocated to intervention or control by drawing a number. Samples from selected centers will then be selected simply and consecutively and based on inclusion criteria.

**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 Zahedan University of Medical Sciences

**Street address**

Medical Sciences Campus, Dr. Hesabi square, Zahedan

**City**

Zahedan

**Province**

Sistan-va-Balouchestan

**Postal code**

9816743463

**Approval date**

2020-08-10, 1399/05/20

**Ethics committee reference number****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**

Self-efficacy score in the specific self-efficacy questionnaire of hypertensive patients

**Timepoint**

At the beginning of the study (before the intervention) and 1 month and 3 months after the intervention

**Method of measurement**

Specific self-efficacy of hypertensive patients questionnaire

**2****Description**

Quality of life score in the quality of life questionnaire specific to hypertensive patients.

**Timepoint**

Measurement of quality of life at the beginning of the study (before the intervention) and 1 month and 3 months after the intervention.

**Method of measurement**

Quality of life questionnaire specific to hypertensive patients

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: Family-centered empowerment based on steps or pattern according to the training program designed for each group in 4 60-minute sessions for 4 weeks individually, with the active participation of the patient and a family member (at least the main caregiver of the family) in the form of discussion and questions and answers will be done by the researcher in a suitable place for training in comprehensive health centers and preferably during office hours using teaching aids such as PowerPoint, educational videos and educational booklets and the control group will not receive any training. Step 1 (Understanding the threat): The first step in the family-

centered empowerment model is to increase the intensity and sensitivity perceived in order to sensitize and raise the level of information of patients and their families through lectures and discussions about the nature and complications of the disease, aggravating factors Disease, nutritional factors, exercise and effective factors in disease control will be implemented. At the end of the training session, questions and answers will be done to ensure the understanding of the content. Step 2 (Self-Efficacy): At this stage, problem solving or problem solving will be implemented. For this purpose, problem solving sessions (two 60-minute sessions) will be held individually for patients and their families. In these sessions, patients and families will be confronted with problems and the problem-solving process, and will be asked to discuss concrete examples of their situation and what they have done to improve the problem. Also in this session, practical methods of measuring weight and blood pressure (in detail) and the consequences of not controlling these two variables and its normal amount will be explained. Patients and families will then be asked to practice this skill. At this stage, the best way to solve patients' problems will be selected and the client's skills will be emphasized. Step 3 (self-confidence and increase self-confidence): At this stage, the patient will be asked to teach the family the issues raised in the previous sessions during the session with the help of the researcher, and if help and guidance is needed, the researcher will do this. The purpose of this step is to increase patients' self-confidence due to their ability to provide information to family members and family support. To ensure and follow up on this step, a number of questions related to the training issues will be given to the patient to complete with family members and submit to the researcher (one week). Step 4 (Evaluation): Process evaluation during the process Intervention in all sessions will be done with questions and answers about the items mentioned in the previous sessions. The final evaluation will be done one and three months after the intervention in the two groups by completing the questionnaires of quality of life and self-efficacy. Also, during the research, the researcher will be in contact with the research units by phone in order to solve possible problems and questions.

**Category**

N/A

**2**

**Description**

Control group: Get routine care. In terms of observing ethical issues at the end of the intervention, an educational booklet based on valid scientific texts will be prepared under the supervision of experts in this field and will be provided to participants in both intervention and control groups.

**Category**

N/A

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Hijrat Health Center

**Full name of responsible person**

Mrs Fatemeh Ardalan

**Street address**

Daneshgah 31, Daneshgah boulevard, Zahedan

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MAHSAA.ASADOLLAHI@GMAIL.COM

**2**

**Recruitment center**

**Name of recruitment center**

Musa Ibn Ja'far Health Center

**Full name of responsible person**

Mrs Zahra Mir

**Street address**

In front of Mostafa Khomeini 27, Mostafa Khomeini street, Zahedan

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**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Zahedan University of Medical Sciences

**Full name of responsible person**

Noor Mohammad Bakhshani

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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**  
Zahedan 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**  
Zahedan University of Medical Sciences

**Full name of responsible person**  
Dr Alireza Salar

**Position**  
Associate professor

**Latest degree**  
Ph.D.

**Other areas of specialty/work**  
Nursery

**Street address**  
School of Nursing and Midwifery, Mashahir square;  
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salar293@gmail.com

## Person responsible for scientific inquiries

### Contact

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

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Dr Alireza Salar

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Associate professor

**Latest degree**  
Ph.D.

**Other areas of specialty/work**  
Nursery

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## Person responsible for updating data

### Contact

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

**Full name of responsible person**  
mahsa asadollahi hamedani

**Position**  
researcher-student

**Latest degree**  
Bachelor

**Other areas of specialty/work**  
Nursery

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School of Nursing and Midwifery, Mashahir square;  
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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

Yes - There is a plan to make this available

### Data Dictionary

Not applicable

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

All data is potentially shareable after unidentified individuals. Questionnaires containing information of patients in this study, including age, sex and any other information that is collected and analyzed are available.

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

Access 5 months after the end of the intervention

**To whom data/document is available**

Researchers working in academic and scientific institution  
وابسته به سازمان معتبر باشد

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

Be affiliated with a reputable organization

**From where data/document is obtainable**

email: mahsaa.asadollahi@gmail.com

**What processes are involved for a request to access data/document**

Send message via email and receive a reply within 7 working days

**Comments**