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

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Iran (Islamic Republic of)

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+98 51 3867 4594

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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

IR.ZAUMS.REC.1399.171

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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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
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Full name of responsible person
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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

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School of Nursing and Midwifery, Mashahir square; Zahedan

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Person responsible for scientific inquiries

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Person responsible for updating data

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Position
researcher-student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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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 institutionوابسته به سازمان معتبر باشدs

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