# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

18 Sep 2026

## The Effect Of Family-Centered Empowerment Model (Fcem) On The Blood Pressure And Dimensions Of Empowerment In Elderly People With Hypertension

## Protocol summary

**Summary**

The Aim Of This Study Was To Evaluate The Effect Of Family Centered Empowerment Model On The Blood Pressure And Dimensions Of Empowerment In Elderly People With Hypertension. The Inclusion Criteria Were Comprise Elderly People With 65 Years Old And More; Having Hypertension Disease 140/90 And More And Exclusion Criteria Were Comprise Unwillingness Of Patient Or His Family Member To Continue Cooperation In Empowerment Program. The Study Population Included All Elderly Peoples With Hypertension. The Required Number Of Participants With Using The Pocock Formula, Gigi Table And The Results Of The Pilot Study, 31 Elderly People Were Selected As An Experimental Group And The Same Number As The Control Group. For Experimental Group Family Centered Empowerment Model Was Implemented According To Its Four Steps Perception Threat, Self-Efficacy, Educational Participation And Evaluation In 14 Meeting For 45 Minutes For 4 Months. For Control Group Was Done Usual Care And One Educational Class. Primary Outcome Was The Mean Score Of Blood Pressure After The Intervention.

## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT2014041717315N1**
Registration date: **2014-05-27, 1393/03/06**
Registration timing: **retrospective**

Last update:
Update count: **0**

**Registration date**

2014-05-27, 1393/03/06

**Registrant information**

**Name**

Batool Hedayati

**Name of organization / entity**

Isfahan University of Medical Sciences

**Country**

Iran (Islamic Republic of)

**Phone**

+98 31 1668 7124

**Email address**

keshvari@med.mui.ac.ir

**Recruitment status**

**Recruitment complete**

**Funding source**

Isfahan University of Medical Sciences

**Expected recruitment start date**

2013-06-22, 1392/04/01

**Expected recruitment end date**

2013-07-23, 1392/05/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The Effect Of Family-Centered Empowerment Model (Fcem) On The Blood Pressure And Dimensions Of Empowerment In Elderly People With Hypertension

**Public title**

The Effect Of Family-Centered Empowerment Model On The Blood Pressure And Dimensions Of Empowerment In Elderly People

**Purpose**

Health service research

**Inclusion/Exclusion criteria**

Inclusion Criteria Elderly People With 65 Years Old And

More; Having Hypertension Disease 140/90 And More; Had A File In The Lenjan Health Center; The Interest Of Elderly People And One Of His Family Members To Participate In Research; Having The Minimum Read And Write Literacy; The Ability To Complete The Questionnaire And Participate In The Programs Of Empowerment; Not Having Any Specific Mental Illness; Exclusion Criteria Unwillingness Of Elderly Peoples Or His Family Member To Continue Cooperation In Empowerment Program; Lack Of Interest For Continuing The Completion Of Research Tools; Lack Of Participation In Group Discussion Meetings And Educational Partnership Programs;

**Age**
From **60 years** old to **80 years** old

**Gender**
Both

**Phase**
N/A

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **62**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**

**Blinding (investigator's opinion)**
Single blinded

**Blinding description**

**Placebo**
Not used

**Assignment**
Parallel

**Other design features**
In this study elderly peope were ACCOMPANY with thier active family member

## Secondary Ids

empty

## Ethics committees

**1**

**Ethics committee**

**Name of ethics committee**
Isfahan University Of Medical Sciences

**Street address**
81726-73461, Hezar Jarib Street, Isfahan University Of Medical Sciences, Isfahan, Islamic Republic Of Iran.

**City**
Isfahan

**Postal code**
73461-81726

**Approval date**
2013-05-22, 1392/03/01

**Ethics committee reference number**
392189

## Health conditions studied

**1**

**Description of health condition studied**
hypertension

**ICD-10 code**
110

**ICD-10 code description**
High blood pressure

## Primary outcomes

**1**

**Description**
Mean Of Blood Pressure

**Timepoint**
4 MonthS

**Method of measurement**
Sphygmomanometer

## Secondary outcomes

**1**

**Description**
Mean Score Dimensions Of Empowerment

**Timepoint**
4 months

**Method of measurement**
Dimensions Of Empowerment Questionnaire

## Intervention groups

**1**

**Description**
In This Study Was Implemented Fcem According To Its Four Steps Perception Threat, Self-Efficacy, Educational Participation And Evaluation For Experimental Group.

**Category**
Lifestyle

**2**

**Description**
For Control Group Was Done Usual Care And One Educational Class.

**Category**
Lifestyle

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**
Lenjan Health Center

**Full name of responsible person**
Batool Hedayati

**Street address**
Shariati Street, Lenjan Health Center, Lenjan township, Isfahan, Islamic Republic Of Iran
**City**
Lenjan Township

## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Isfahan University of Medical Sciences
**Full name of responsible person**
Dr. Kazemi, Ph.D. In Nursing
**Street address**
81726-73461, Hezar Jarib Street, Isfahan University Of Medical Sciences, Isfahan, Islamic Republic Of Iran.
**City**
Isfahan
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Isfahan University of Medical Sciences
**Proportion provided by this source**
100
**Public or private sector**
*empty*
**Domestic or foreign origin**
*empty*
**Category of foreign source of funding**
*empty*
**Country of origin**
**Type of organization providing the funding**
*empty*

## Person responsible for general inquiries

**Contact**
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## Person responsible for scientific inquiries

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## Person responsible for updating data

**Contact**

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
*empty*
**Study Protocol**
*empty*
**Statistical Analysis Plan**
*empty*
**Informed Consent Form**
*empty*
**Clinical Study Report**
*empty*
**Analytic Code**
*empty*
**Data Dictionary**
*empty*