

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of education based on Levental self-regulation model on self-management of patients with hypertension

Protocol summary

Study aim

Determining the effect of education based on Levental self-regulation model on self-management of patients with hypertension

Design

Randomized clinical trial with parallel groups, 70patients.

Settings and conduct

The study site is the heart clinic of Farshchian Heart Hospital of Hamadan. Intervention group samples will participate in three training sessions using the Levental self-adjustment model, individually, face-to-face, for 45-60 minutes every other day. Control group will receive the routine care.

Participants/Inclusion and exclusion criteria

Inclusion criteria: People aged 40 to 65 years are treated for hypertension, literate, and mentally healthy.

Exclusion criteria: not attending two training sessions, making acute changes in patient status, changing treatment protocol.

Intervention groups

Control group: control group will receive only routine care. Intervention group: intervention group will participate in three individual face-to-face individual training sessions for 45-60 minutes using the Lental self-regulation model.

Main outcome variables

self-management and self-regulatory behaviors in hypertensive patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170123032129N8**

Registration date: **2019-09-06, 1398/06/15**

Registration timing: **registered_while_recruiting**

Last update: **2019-09-06, 1398/06/15**

Update count: **0**

Registration date

2019-09-06, 1398/06/15

Registrant information

Name

Azim Azizi

Name of organization / entity

Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 3838 0150

Email address

a.azizi@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-23, 1398/05/01

Expected recruitment end date

2020-01-21, 1398/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of education based on Levental self-regulation model on self-management of patients with hypertension

Public title

The effect of education based on Levental self-regulation model on self-management of patients with hypertension

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients have the ability to read and write. At least 6 months have passed since the diagnosis of primary hypertension and treatment. Being treated for high blood pressure. Failure to participate in concurrent study affecting study variables. Having the right physical conditions to attend training sessions. Being Psychologically Healthy. Did not have history of cerebrovascular accident and myocardial infarction and other chronic diseases affecting on self-care. Other family member dose not have high blood pressure.

Exclusion criteria:

Receive extensive information on managing blood pressure from other sources or Any significant acute abnormalities, or severe hypertension or crisis Death of patient changing the treatment protocol absence in 2 educational sessions.

Age

From **40 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

Samples will be selected by simple random access. 35 cards with letter A and 35 cards with letter B will be placed in sealed envelopes, and each patient will randomly select one of these cards without substitution.

Card B will be placed in the control group.

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 Hamadan University of Medical Sciences

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Av, Hamadan, Iran.

City

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Province

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Postal code

65178

Approval date

2019-07-07, 1398/04/16

Ethics committee reference number

IR.UMSHA.REC.1398.302

Health conditions studied**1****Description of health condition studied**

Primary high Blood pressure

ICD-10 code

I10

ICD-10 code description

Essential (primary) hypertension

Primary outcomes**1****Description**

Blood pressure

Timepoint

The beginning of the study and 2 months after the end of the intervention

Method of measurement

Brachial digital blood pressure monitor Japanese Alpicado Model ALPK2 K2 1802

2**Description**

Self-management behaviors

Timepoint

The beginning of the study and 2 months after the end of the intervention

Method of measurement

Self-management behaviors questionnaire for patients with high blood ptesure

Secondary outcomes

empty

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

Intervention group: Intervention consists of three individual training sessions. Intervention will be conducted in three face-to-face individual training sessions for 45-60 minutes every other day using Levental self-regulation model.

Category

Lifestyle

2

Description

Control group: Control group samples receive only routine care of the clinic.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Farshchian Heart Hospital

Full name of responsible person

Zohre Kordvarkane

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Farshchian Cardiology and Cardiology Center, Shahid Fahmida Blvd, Hamedan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Saeed Bashirian

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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

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Azim Azizi

Position

PhD in Nursing

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available