Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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
Hamadan

Province
Hamadan

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 ptessure

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
Street address
Farshchian Cardiology and Cardiology Center, Shahid Fahmida Blvd, Hamedan
City
Hamadan
Province
Hamadan
Postal code
65178
Phone
+98 81 3838 1740
Fax
+98 81 3838 1686
Email
hcvc@umsha.ac.ir
Web page address
http://hcvc.umsha.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Saeed Bashirian
Street address
Hamadan University of Medical Science, Shahid Fahmide boulvard
City
Hamadan
Province
Hamadan
Postal code
65178
Phone
+98 81 3838 0150
Fax
+98 81 3838 1686
Email
hcvc@umsha.ac.ir
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
Street address
Hamadan University of Medical Science, Shahid Fahmide boulevard
City
Hamadan
Province
Hamadan
Postal code
00988138380150
Phone
+98 81 3838 0150
Email
a.azizi@umsh.ac.ir

Person responsible for scientific 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
Street address
Hamadan University of Medical Science, Shahid Fahmide boulevard
City
Hamadan

Province
Hamadan
Postal code
00988138380150
Phone
+98 81 3838 0150
Email
a.azizi@umsh.ac.ir

Person responsible for updating data

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
Street address
Hamadan University of Medical Science, Shahid Fahmide boulevard
City
Hamadan
Province
Hamadan
Postal code
00988138380150
Phone
+98 81 3838 0150
Email
a.azizi@umsh.ac.ir

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