Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparing the Effectiveness of Cognitive Rehabilitation Therapy and Mindfulness-Based Stress Reduction Therapy on Self-Care and Multidimensional Health Locus of Control Scales in Women with Hypertension

Protocol summary

Study aim
Comparison of the effectiveness of Cognitive Reconstruction Therapy and Mindfulness-Based Stress Reduction in Muitidimensional Health Locus of Control Scales and Self-Care in Women with Hypertension.

Design
A randomized controlled clinical trial with parallel groups, Randomized block, sample size is 45 (15 persons per group)

Settings and conduct
Before the meetings and permits, all three groups completed questionnaires on self-care and health locus of control. Then, experimental group A (cognitive reconstruction) and experimental group B (cognitive therapy based on mindfulness) were grouped weekly among women in Farshchian Heart Clinic in Hamadan. The control group did not intervene.

Participants/Inclusion and exclusion criteria
Inclusion criteria: high blood pressure; a desire to participate in medical intervention; a minimum of literacy, a normal listening ability; informed consent to attend treatment sessions. Non inclusion criteria: chronic hypertension such as diabetes; severe depression; mental disorders requiring immediate treatment; disruption of the normal course of treatment; lack of cooperation; amputation; severe physical disability.

Intervention groups
Intervention group 1: cognitive reconstruction training Intervention group 2: mindfulness-based cognitive therapy Control group: no intervention will be done

Main outcome variables
Health Locus of Control; Self-Care

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200302046671N1**
Registration date: **2020-04-30, 1399/02/11**
Registration timing: **retrospective**

Last update: **2020-04-30, 1399/02/11**
Update count: **0**

Registration date
2020-04-30, 1399/02/11

Registrant information

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maedeh ashrafi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-05-19, 1398/02/29

Expected recruitment end date
2019-09-21, 1398/06/30

Actual recruitment start date
2019-05-19, 1398/02/29

Actual recruitment end date
2019-09-21, 1398/06/30

Trial completion date
2019-09-21, 1398/06/30

Scientific title

Comparing the Effectiveness of Cognitive Rehabilitation Therapy and Mindfulness-Based Stress Reduction Therapy on Self-Care and Multidimensional Health Locus of Control Scales in Women with Hypertension

Public title
Effect of Cognitive Rehabilitation and Mindfulness-Based Stress Reduction on Self-Care and Multidimensional Health Locus of Control Scales
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
high blood pressure willingness to participate in medical intervention minimal literacy ability to listen normally conscious consent to attend therapy sessions
Exclusion criteria:
Having chronic physical illness with high blood pressure such as diabetes having severe depression having mental disorders requiring immediate treatment disrupting the normal course of treatment amputation and severe physical disability lack of cooperation
Age
No age limit
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
Actual sample size reached: **45**
Randomization (investigator's opinion)
Randomized
Randomization description
Using the block randomization method by the statistical consultant, the following randomization is done in 3 groups of Cognitive Rehabilitation Therapy, Mindfulness-Based Stress Reduction Therapy, and control: First, the list of names of qualified people is provided and coded. In block randomization, the number of participants in all groups will be very close, this is done by building blocks of sequences and intersections so that the same number of participants are allocated to study groups within each group. First, we encode the groups based on the Latin letters as follows: A =Cognitive Rehabilitation Therapy, B = Mindfulness-Based Stress Reduction Therapy, and C control group In this study, with three groups A, B, and C, we create the following six groups and assign the numbers 1 to 6 to each: ABC-ACB-BAC-BCA-CAB-CBA Then, using the table of random numbers, we contract that if the numbers 1, 2, 3, 4, 5, 6, and 6 appear in order, one of these blocks will be selected, and if another number appears, we will assume it to be null and void and move on to the next selection. In fact, we have obtained a random sequence of numbers with a table of random numbers, which we consider the order of the assigned allocation for each number. In this way, the number of people in the groups will be almost equal.
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
Hormozgan University of Medical Sciences
Street address
No 59, Yase Sharghi 1 Alley, Golriz street, Baasat square
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Hamedan
Province
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Postal code
6515918154
Approval date
2019-12-07, 1398/09/16
Ethics committee reference number
IR.HUMS.REC.1398.322

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-care
Timepoint
Measurement will be done in pre-test, post-test, and follow-up three months after post-test
Method of measurement
European Care Behavior Questionnaire

2

Description
Health Locus of Control
Timepoint
Measurement will be done in pre-test, post-test and follow-up three months after post-test

Method of measurement
Multidimensional Health Locus of Control scale

Secondary outcomes

empty

Intervention groups

1

Description
The first intervention group: In the present study, the meaning of cognitive reconstruction training is 12 treatment sessions based on cognitive reconstruction training Habibi et al.'s (2014), which are two sessions per week (for one and a half months) and each session, 90 minutes were held.
Category
Prevention

2

Description
Intervention group II: Mindfulness-based cognitive therapy Eight 90-minute sessions once a week (for a month and a half) based on mindfulness-based cognitive therapy Segal (2004) protocol and designed as a group experimental group subjects are provided.
Category
Prevention

3

Description
Control group: No Intervention
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Farshchian Hospital
Full name of responsible person
Maedeh Ashrafi
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No 59, Yase Sharghi 1 Alley, Golriz street, Baasat square
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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?
No
Title of funding source
Islamic Azad University
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
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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
Not applicable
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