

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 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 Multidimensional 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

Name

maedeh ashrafi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3823 3493

Email address

m.ashrafi@iaukishint.ac.ir

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

City

Hamedan

Province

Hamadan

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

Street address

No 59, Yase Sharghi 1 Alley, Golriz street, Baasat square

City

Hamedan

Province

Hamadan

Postal code

6515918154

Phone

+98 81 3823 3493

Email

m.ashrafi@iaukishnt.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Ali Reza Rosta

Street address

Islamic Azad University of Kish International Branch;
Free Zone Organization Square; Sana'i Boulevard;
Kish Island

City

Kish

Province

Hormozgan

Postal code

7941775883

Phone

+98 76 4442 2720

Fax

+98 76 4442 3957

Email

Info@iaukishnt.ac.ir

Web page address

http://iaukish.ir/

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

Name of organization / entity

Islamic Azad University

Full name of responsible person

maedeh ashrafi

Position

student

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

Street address

Baasat Square, Golriz Street, Yas sharghi Alley 1, N 59

City
hamedan
Province
Hamadan
Postal code
6515918154
Phone
+98 81 3823 3493
Email
m.ashrafi@iaukishint.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Islamic Azad University
Full name of responsible person
farhadjomehri
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Psychology
Street address
Allameh Tabataba'i University; headquarter of university building; Dehkadeh square; Olympic Village
City
Tehran
Province
Tehran
Postal code
۱۴۸۹۶۸۴۵۱۱
Phone
+98 21 4473 7636
Email
farhadjomehri@yahoo.com
Web page address
<https://atu.ac.ir/>

Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University
Full name of responsible person
Maedeh Ashrafi
Position
student
Latest degree
Ph.D.
Other areas of specialty/work
Psychology
Street address
No 59, Yase Sharghi 1 Alley, Golriz street, Baasat square
City
Hamedan
Province
Hamadan
Postal code
6515918154
Phone
0098818233493
Email
m.ashrafi@iaukishint.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

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