Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison between the effectiveness of attentive rehabilitation of attention & memory, mindfulness-based education and integrated intervention on executive functions, anxiety and cardiovascular indices in patients with hypertension.

Protocol summary

Study aim

The aim of this study was to Comparison between the effectiveness of attentive rehabilitation of attention & memory, mindfulness-based education and integrated intervention on executive functions, anxiety and cardiovascular indices in patients with hypertension.

Design

A randomized clinical trial with 1month follow up with parallel groups and Double blinded

Settings and conduct

Participants were selected from patients coming to the Heshmat Cardiovascular hospital of Rasht. the goal and method of the study were described to the patients and demographic characteristics questionnaires were filled. Then according to inclusion criteria and with study participation consent, 80 patients were selected and randomized into four 20-members groups by Web-based Randomization and according to allocation concealment by using SNOSE. Interventions will be performed in Heshmat Hospital.

Participants/Inclusion and exclusion criteria

Hypertension, Males and females between 30 to 60, have the ability to read and write, without any other physical and psychological illness, without addiction, or consumption of psychoactive drugs.

Intervention groups

group 1. 10 sessions of 1.5hour cognitive rehabilitation (once a week). group 2. Eight 1.5hours sessions of education based on mindfulness (once a week). group 3. 18 sessions of integrated intervention (twice a week). group 4. Control group, No intervention.

Main outcome variables

To gather pre-test, post-test and follow-up information, the following items will be considered, performed, and calculated. anxiety variable according to the Beck anxiety Inventory. executive functions variable as follows. Wisconsin Card Sorting, Stroop Color and Word, Continuous Performance, N-BACK tests 1 & 2. Cardiovascular indexes variable including heart rate, Systolic and diastolic blood pressure and pulse pressure with a digital bronchial sphygmomanometer and stethoscope.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210531051454N1**
Registration date: **2021-06-26, 1400/04/05**
Registration timing: **retrospective**

Last update: **2021-06-26, 1400/04/05**
Update count: **0**

Registration date

2021-06-26, 1400/04/05

Registrant information

Name

Fatemeh Rabipour

Name of organization / entity

Tabriz Azad University

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2021-05-05, 1400/02/15
Expected recruitment end date
2021-06-20, 1400/03/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison between the effectiveness of attentive rehabilitation of attention & memory, mindfulness-based education and integrated intervention on executive functions, anxiety and cardiovascular indices in patients with hypertension.

Public title
Survey of psychological interventions effect on hypertension patients' improvement
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Hypertension Males and females between 30 to 60 have the ability to read and write
Exclusion criteria:
Other physical illnesses Other psychiatric illnesses addiction, or consumption of Psychotropic and psychoactive drugs
Age
From **30 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants were selected from patients coming to the Heshmat Cardiovascular hospital of Rasht. In the first session, the goal and method of the study were described to the patients and demographic characteristics questionnaires were filled. Then according to inclusion criteria and with study participation consent, 80 patients were selected and randomized into four 20-members groups of cognitive rehabilitation, mindfulness, combined and, control by Web-based Randomization (https://www.randomizer.org/) and according to allocation concealment by using Sequentially numbered, sealed, opaque envelopes (SNOSE). based on the research sample size, several aluminum envelopes were prepared and each random sequence were recorded on a card. the cards were placed into the separate envelopes respectively. To maintain the random sequence, the envelopes were numbered in the same way on their outer surface. In the end, the flaps of envelopes were glued and orderly placed in a box. At the beginning of the participants' registration, envelopes will be opened in order and the assigned group of that participant will be revealed.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, participants after obtaining informed consent and being randomly placed in the groups, will not receive any information about how the other groups is intervened, as well as how they themselves are positioned as the experimental group or the control group; and also the statistical analyzer is unaware of each step of randomization, participants grouping and, study setting, and method.
Placebo
Not used
Assignment
Parallel
Other design features
Evaluation of Executive functions variable and anxiety variable are being done using computer.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Islamic Azad University-Tabriz Branch
Street address
East side of Pasdaran Highway
City
Tabriz
Province
East Azarbaijan
Postal code
5157944533
Approval date
2021-04-27, 1400/02/07
Ethics committee reference number
IR.IAU.TABRIZ.REC.1400.020

Health conditions studied

1

Description of health condition studied
Hypertension
ICD-10 code
110
ICD-10 code description
Essential (primary) hypertension. High blood pressure.

Primary outcomes

1

Description
Anxiety
Timepoint
Before and within 1 to 3 days after the end of intervention and a month after the end of intervention.
Method of measurement
Beck Anxiety Inventory (BAI)

2

Description
Executive Functions
Timepoint
Before and within 1 to 3 days after the end of intervention and a month after the end of intervention.
Method of measurement
Stroop Color and Word Test, Wisconsin Card Sorting Test (WCST), The Continuous Performance Test (CPT), N-BACK 1 & 2

3

Description
cardiovascular indices
Timepoint
Before and within 1 to 3 days after the end of intervention and a month after the end of intervention.
Method of measurement
Cardiovascular indices variable including heart rate, Systolic and diastolic blood pressure and pulse pressure with a digital brachial sphygmomanometer and stethoscope were taken and calculated by a cardiovascular specialist.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group. 10 sessions of 1.5hour cognitive rehabilitation (once a week). First session. Explanation of the intended study, All the exercises below with difficulty level 1. Colored Home Task, faces Task, similar windows Task, marked table Task, Segmanted images Task, Acronym Making Task, last colored Task, Animal Tracing Task, Repetitive Images Task, Letter Matching Task and, Delay color Matching Task. Second session. All the first session exercises with difficulty level 2.Third session. All the first session exercises with difficulty level 3. fourth Session. All the first session exercises with difficulty level 4. fifth session. All the first session exercises with difficulty level 5. Sixth session. All the first session exercises with difficulty level 6. Seventh session. All the first session exercises with difficulty level 7. Eighth session. All the first session exercises with difficulty level 8. ninth session. All the first session exercises with difficulty level 9. Tenth session. All the first session exercises with difficulty level 10. Post-test. within the next 1 to 3 days. Follow up. One month later. Hint. Exercises with different stimulants are designed as a hierarchy with different difficulty levels and are presented in 10 graded levels. Stimulants' complexity increase, speed of the presentation, and advancing processing needs were used to progress the exercises. All exercises have a limited time and options like feedback presentation and calculation and smart observation of the scores. The therapist can increase the difficulty level due to the obtained score.
Category
Rehabilitation

2

Description
Intervention group. Eight 1.5hours sessions of education based on mindfulness (once a week). First session. Explanation of the intended study, the introduction of the group members to each other, inform the members about their disease and the role of the psychological factors in appearance and aggravation of the symptoms, determination of the goals and the patient expectation from the therapy, building a nice relationship, having raisin, body scan meditation, distributing CDs and pamphlets and an explanation of the mindfulness therapy method and providing home exercises. Second session. mindfulness of thoughts and emotions, recording pleasant events and providing home exercises. Third session. Sitting meditation, mindful walking, Three-minute mindfulness breathing space and providing home exercises. fourth Session. Looking and hearing meditation and providing home exercises. fifth session. Sitting meditation and providing home exercises. Sixth session. Meditative visualization, explain ambiguous scenarios and providing home exercises. Seventh session. Explain to the relation between mind and activity, discussion about the recurrence symptoms and providing home exercises. Eighth session. Review of the previous contents, reflection, feedback, Mindfulness Reminder Tools, goals survey and providing home exercises. Post-test. within the next 1 to 3 days. Follow up. One month later.
Category
Behavior

3

Description
Intervention group. 18 sessions of integrated intervention (twice a week), Including 10 sessions of 1.5hour cognitive rehabilitation And Eight 1.5hours sessions of education based on mindfulness. First session. Explanation of the intended study, All the exercises below with difficulty level 1. Colored Home Task, faces Task, similar windows Task, marked table Task, Segmanted images Task, Acronym Making Task, last colored Task, Animal Tracing Task, Repetitive Images Task, Letter Matching Task and, Delay color Matching Task. Second session. Introduction of the group

members to each other, inform the members about their disease and the role of the psychological factors in appearance and aggravation of the symptoms, determination of the goals and the patient expectation from the therapy, building a nice relationship, having raisin, body scan meditation, distributing CDs and pamphlets and an explanation of the mindfulness therapy method and providing home exercises. Third session. All the first session exercises with difficulty level 2. fourth Session. mindfulness of thoughts and emotions, recording pleasant events and providing home exercises. fifth session. All the first session exercises with difficulty level 3. Sixth session. Sitting meditation, mindful walking, Three-minute mindfulness breathing space and providing home exercises. Seventh session. All the first session exercises with difficulty level 4.Eighth session. Looking and hearing meditation and providing home exercises.ninth session. All the first session exercises with difficulty level 5. Tenth session. Sitting meditation and providing home exercises. Session 11. All the first session exercises with difficulty level 6. Session 12. Meditative visualization, explain ambiguous scenarios and providing home exercises. Session 13. All the first session exercises with difficulty level 7. Session 14. Explain to the relation between mind and activity, discussion about the recurrence symptoms and providing home exercises. Session 15. All the first session exercises with difficulty level 8. Session 16. Review of the previous contents, reflection, feedback, Mindfulness Reminder Tools, goals survey and providing home exercises. Session 17. All the first session exercises with difficulty level 9. Session 18. All the first session exercises with difficulty level 10. Post-test. within the next 1 to 3 days. Follow up. One month later

Category

Behavior

4

Description

Control group. No intervention. Post-test. simultaneous with the intervention groups. Follow up. simultaneous with the intervention groups.Hint. According to the charter of ethics in research, the control group (waiting list) will receive one of the interventions after the follow-up.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Cardiovascular Diseases Research Center, Department of Cardiology, Heshmat Hospital, School of Medic

Full name of responsible person

Dr. Arsalan Salari

Street address

The beginning of the Bayani alley, Mosalla street (15 Khordad)

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Province

Guilan

Postal code

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Web page address

https://www.gums.ac.ir/gicrc/Default.aspx?tabid=7054

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

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Web page address

https://www.gums.ac.ir/gicrc/Default.aspx?tabid=7054

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Cardiovascular Diseases Research Center, Department of Cardiology, Heshmat Hospital, School of Medicine, Guilan 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
Islamic Azad University of Tabriz
Full name of responsible person
Fatemeh Rabipour
Position
PHD student
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
If there is a scientifically demonstrated research by a relevant study, all of our data after Id concealment can be shared.
When the data will become available and for how long
6 months availability for the articles releasing after the study
To whom data/document is available
Occupied researchers in the universal and scientific institutes
Under which criteria data/document could be used
The study should not be a repetition for current researches. City changes or minor variables variations are not acceptable. Practical changes in the method of the study, duration, and the way of intervention along with theoretical and research background are acceptable.
From where data/document is obtainable
Communication with the researcher Fatemeh Rabipour by Email: Rabipour.f@gmail.com
What processes are involved for a request to access data/document

The data will be released in less than a month of contacting the researcher and presentation of the personal and scientific profile and registered information of the study such as ethical code &... .

Comments