Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the Effectiveness of Mindfulness and Body Psychotherapy on Hippocampal Modulation (Volume and Function) and Depression and Executive Function in Patients with Post-Stroke Depression

Protocol summary

Study aim

The main purpose of this study was to find if body psychotherapy and mindfulness interventions that improve the symptoms of depression can change (increase) the hippocampal volume in depressed patients after stroke.

Design

This study is a three-group clinical trial with pre-test and post-test quasi-experimental design. This study has two intervention groups and one control group. The number of patients is 30 women who are randomly divided into three groups.

Settings and conduct

The intervention center is the Anna Mehr Elderly Center. Methods: First, the purposeful sampling will be done based on the patients' scores on the Beck Depression Inventory and the NIHSS test score. It will be taken as a pretest. Patients will be randomly assigned to either intervention or control groups. After the intervention, the questionnaires and computerized tests will be completed again as well as analyzing the recorded scores and comparing the results in the pre-test and post-test stages.

Participants/Inclusion and exclusion criteria

Inclusion criteria: The lesion is located in the left hemisphere; they have a history of stroke only once. Non-inclusion criteria: The patient has a history of a second or more strokes; a history of another chronic illness.

Intervention groups

Intervention group 1: The group that receives the conscious mind. This group includes ten female patients. The intervention is administered to patients during sixteen one-hour sessions, two days a week. Intervention group 2: The second group receives physical therapy intervention. This group includes ten female patients who receive physical therapy intervention for one hour a day, three days a week. Control group: This group consisted of ten female patients who don't receive any intervention.

Main outcome variables

Depression, executive function, function and volume of hippocamp

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190812044518N1**
Registration date: **2019-10-08, 1398/07/16**
Registration timing: **retrospective**

Last update: **2019-10-08, 1398/07/16**
Update count: **0**

Registration date

2019-10-08, 1398/07/16

Registrant information

Name
Sahar sadae Nazm Bojnourdi

Name of organization / entity
Ferdowsi of University

Country
Iran (Islamic Republic of)

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+98 58 3222 6225

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sdoctornazmb@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-11, 1397/11/22

Expected recruitment end date
2019-02-21, 1397/12/02
Actual recruitment start date
2019-02-11, 1397/11/22
Actual recruitment end date
2019-03-10, 1397/12/19
Trial completion date
2019-07-15, 1398/04/24

Scientific title
Comparison of the Effectiveness of Mindfulness and Body Psychotherapy on Hippocampal Modulation (Volume and Function) and Depression and Executive Function in Patients with Post-Stroke Depression

Public title
Comparison of the Effectiveness of Mindfulness and Body Pysichotherapy on Hippocampus Modulation
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Lasting more than three months after a stroke a left hemisphere lesion confirmed by a neurologist and an MRI or CT scan A history of having stroke only for one time ability to read and write depression test score above ten
Exclusion criteria:
The patient has a history of a second stroke Simultaneous use of tobacco and smoking The patient has a history of other chronic illnesses The patient has a history of psychological illness other than depression Patient with aphasia and impaired consciousness The patient has acute economic problems
Age
From **35 years** old to **65 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **36**
Actual sample size reached: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization using statistical site
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 Bojnourd University of Medical Sciences
Street address
Bojnourd University of Medical Sciences, Janbaz Blvd, Talghni street
City
Bojnourd
Province
North Khorasan
Postal code
94149-74877
Approval date
2019-08-23, 1398/06/01
Ethics committee reference number
IR.NKUMS.REC.1398.033

Health conditions studied

1

Description of health condition studied
Post-stroke depression
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Depression score in Beck Questionnaire
Timepoint
Depression test scores are measured before the intervention as pre-test and also in the first intervention group at the end of the eighth week of mindfulness intervention and in the second intervention group at the end of the twelfth week, body pcychotherapy intervention.
Method of measurement
Beck Depression Questionnaire

2

Description
National Institutes of Health(NIH) Stroke Scale Questionnaire Score
Timepoint
National Institutes of Health(NIH) Stroke Scale Questionnaire Score is measured before the intervention as pre-test and also in the first intervention group at the end of the eighth week of mindfulness intervention and in the second intervention group at the end of the twelfth week, body pcychotherapy intervention.
Method of measurement
National Institutes of Health(NIH) Stroke Scale Questionnaire

3

Description
Wechsler Digit Span measurement tool Score
Timepoint
Wechsler Digit Span measurement tool Score is measured before the intervention as pre-test and also in the first intervention group at the end of the eighth week of mindfulness intervention and in the second intervention group at the end of the twelfth week, body pcychotherapy intervention.
Method of measurement
Wechsler Digit Span measurement tool

4

Description
Course block Computer Psychological Test Score
Timepoint
Course block Computer Psychological Test Score is measured before the intervention as pre-test and also in the first intervention group at the end of the eighth week of mindfulness intervention and in the second intervention group at the end of the twelfth week, body pcychotherapy intervention.
Method of measurement
Course block Computer Psychological Test

Secondary outcomes

1

Description
Wisconsin Card Test score
Timepoint
Wisconsin Card Test score is measured before the intervention as pre-test and also in the first intervention group at the end of the eighth week of mindfulness intervention and in the second intervention group at the end of the twelfth week, body pcychotherapy intervention.
Method of measurement
Wisconsin Card Test

2

Description
London Tower Test score
Timepoint
London Tower Test score is measured before the intervention as pre-test and also in the first intervention group at the end of the eighth week of mindfulness intervention and in the second intervention group at the end of the twelfth week, body pcychotherapy intervention.
Method of measurement
London Tower Test

Intervention groups

1

Description
Intervention group 1: This intervention group receives mindfulness for sixteen one-hour sessions, two days a week. This stress reduction protocol is designed by Kabat Zain (1990). Techniques in this section include relaxation, meditation and meditation along with simple yoga exercises.
Category
Rehabilitation

2

Description
Intervention group 2: This group receives physical therapy intervention for thirty-six one hour sessions, three days a week. This protocol is based on a mix motor and psychological exercises designed by Rohrichet in 2013. Among the techniques in this section are systematic relaxation, balance exercises and rhythmic exercises with breathing and eye movement desentisation reprossesing.
Category
Rehabilitation

3

Description
Control group: Ten patients who don't receive any intervention in this group.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Wellbeing - Mehrana Elderly Center
Full name of responsible person
Dr. Azam Benny Hashim Rad
Street address
Vali Asr 2 alley., Vali Asr street., Farhangian Town
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Postal code
941461-4201
Phone
+98 58 3226 4707
Email
sdoctornazmb@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ferdowsi University of Mashhad

Full name of responsible person
Dr. Ali Ghanaie Chamanabad
Street address
Ferdowsi University of Mashhad, Azadi Square,
City
Mashhad
Province
Razavi Khorasan
Postal code
9177948974
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+98 51 3880 2000
Fax
Email
pr@um.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Ferdowsi University of Mashhad

Proportion provided by this source
100

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact

Name of organization / entity
Mashhad Ferdowsi University
Full name of responsible person
Sahar Sadat Nazm Bojnourdi
Position
Postgraduate student
Latest degree
Bachelor
Other areas of specialty/work
Psychology
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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Latest degree
Bachelor
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9414614201
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Person responsible for updating data

Contact

Name of organization / entity
Mashhad Ferdowsi University
Full name of responsible person
sahar sadat nazm bojnourdi
Position
Postgraduate student
Latest degree
Bachelor
Other areas of specialty/work
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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

Not applicable

Title and more details about the data/document

Data can be shared transparently and without identification variables

When the data will become available and for how long

Start access period one year after publishing the results in a reputable journal

To whom data/document is available

Data will be available only to university researchers and university affiliates

Under which criteria data/document could be used

The data will be available only for the purpose of modeling the process and comparing the results and forecasting the scientific results...

From where data/document is obtainable

Sending e mail to responsible author for access to data Email sdoctornazmb@gmail.com

What processes are involved for a request to access data/document

The data will be made available to the researcher one or two weeks after receiving the email from the applicant.

Comments