Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of Group Therapy Based on metacognitive Model of Detached Mindfulness on Cognitive functions in patients with Multiple sclerosis

Protocol summary

Summary

This study aimed to determine the effect of group therapy based on the metacognitive model of detached mindfulness on cognitive performance in patients with multiple sclerosis.The study is a quasi-experimental research which was designed in two groups (intervention and control groups), in three stages of pre-test, post-test, and two months follow-ups. The independent variable of group therapy was based on the metacognitive model of detached mindfulness. It was applied in the interventional group and its effect on the test scores of post-test and follow-up was investigated and compared with the control group. Studied samples were selected among all patients referred to health care centers of Farshchian during 2016. First, the subjects were randomly selected from available samples, then in the patient list, 70 patients were randomly selected as a pilot study and were randomly divided into two intervention and control groups using the Randomizer site. Each of these groups consisted of 35 individuals. Intervention group during eight week sessions (each session lasting one hour) were treated by group therapy based on the metacognitive model of detached mindfulness. In the first session (before treatment) and eighth session (after treatment) the intervention group patients were asked to perform neuropsychological tests (Pre-test and post-test). It should be noted that the time taken to complete the neuropsychological tests for any member of the intervention and control groups was ranged from 45 minutes to one hour. follow-up session was held after two months in the same place.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT20161112728119N5**
Registration date: **2016-12-09, 1395/09/19**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2016-12-09, 1395/09/19

Registrant information

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Marzieh Nazaribadie
Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Hamedan University of Medical Sciences

Expected recruitment start date

2015-12-31, 1394/10/10

Expected recruitment end date

2016-12-31, 1395/10/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Group Therapy Based on metacognitive Model of Detached Mindfulness on Cognitive functions in patients with Multiple sclerosis

Public title

The effect of Group Therapy Based on metacognitive Model of Detached Mindfulness on Cognitive functions in patients with Multiple sclerosis

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria Cases diagnosed with multiple sclerosis with EDSS=4; and the same medication regimen; Those with age ranges between 18 and 45 years; People with diploma or higher education level. Exclusion criteria Mental (psychosis) and physical disorders are required to receive medication or a special diet, such as diabetes; Absence for more than two sessions.
Age
From **18 years** old to **45 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
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
The Ethics Commitee of Hamadan University of Medical Science
Street address
Hamadan
City
Hamadan
Postal code
65167-4-8741
Approval date
2016-11-21, 1395/09/01
Ethics committee reference number
IR.UMSHA.REC.1395.382

Health conditions studied

1

Description of health condition studied
Multiple sclerosis
ICD-10 code
G35
ICD-10 code description
Multiple sclerosis

Primary outcomes

1

Description
Cognitive performances
Timepoint
Pre.post and follow
Method of measurement
Inverntory

Secondary outcomes

1

Description
Cognitive performances
Timepoint
Pre, post and follow
Method of measurement
Inventory

Intervention groups

1

Description
The control group will not receive treatment
Category
Behavior

2

Description
Intervention in interventional group is group therapy based on metacognitive model of detached mindfulness is treatment that is applied on the experimental group and evaluated impact on cognitive performance.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Frschian Hospital
Full name of responsible person
Marzieh Nazaribadie
Street address
Hamadan
City
Hamadan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research,Hamadan University of Medical Sciences
Full name of responsible person
Sohila Panahi
Street address
Hamadan
City
Hamadan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for Research,Hamadan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty