

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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: **IRCT2016112728119N5**

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

Name

Marzieh Nazaribadie

Name of organization / entity

Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 3821 6085

Email address

marzieh.nazari@umsha.ac.ir

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 Committee 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**Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

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Position

Ph.d

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Web page address

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