

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

Investigation and comparison the effect of group therapy based on meta cognitive model of detached mindfulness on therapy on stress, anxiety, depression, fatigue and well - being in patients with Multiple sclerosis

Protocol summary

Study aim

This study aimed to determine the effect of group therapy based on the meta-cognitive model of detached mindfulness on stress, anxiety, depression, fatigue and well - being in patients with multiple sclerosis

Design

Studied samples were selected among all patients referred to health care centers of Farshchian during 2019. 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 Randomized site. Each of these groups consisted of 35 individuals

Settings and conduct

Intervention group during eight week sessions (each session lasting one hour) were treated by group therapy based on the meta-cognitive model of detached mindfulness. In the first session (before treatment) and eighth session (after treatment) the intervention group patients were asked to complete questionnaires of study (Pre -test and post-test). Follow-up session was held after two months in the same place.

Participants/Inclusion and exclusion criteria

Inclusion criteria Cases diagnosed with multiple sclerosis
Exclusion criteria Mental (psychosis) and physical disorders are required to receive medication or a special diet, such as diabetes; .

Intervention groups

The study is a quasi-experimental research which was designed in two groups (intervention and control groups), in three stages of per-test, post-test, and two months follow-ups. The independent variable of group therapy was based on the meta-cognitive model of detached mindfulness. It was applied in the international group and its effect on the test scores of post-test and follow-up was investigated and compared with the

control group

Main outcome variables

stress, anxiety, depression, fatigue and well - being

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190210042666N1**

Registration date: **2019-04-06, 1398/01/17**

Registration timing: **registered_while_recruiting**

Last update: **2019-04-06, 1398/01/17**

Update count: **0**

Registration date

2019-04-06, 1398/01/17

Registrant information

Name

Mona Arji

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3824 9499

Email address

mona.arji7@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-01, 1397/12/10

Expected recruitment end date

2020-02-29, 1398/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation and comparison the effect of group therapy based on meta cognitive model of detached mindfulness on therapy on stress, anxiety, depression, fatigue and well - being in patients with Multiple sclerosis

Public title

The effect of Group Therapy Based on meta-cognitive Model of Detached Mindfulness on stress, anxiety, depression, fatigue and well - being in patients with Multiple sclerosis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Cases diagnosed with multiple sclerosis with EDSS=4 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;

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

Studied samples were selected among all patients referred to health care centers of Farshchian during 2019. 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 Randomized site. Each of these groups consisted of 35 individuals

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 Sciences

Street address

Hamadan

City

Hamadan

Province

Hamadan

Postal code

65167-4-8741

Approval date

2019-02-10, 1397/11/21

Ethics committee reference number

IR.UMSHA.REC.1397.770

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**

stress, anxiety, fatigue and well - being and depression

Timepoint

Before and after the intervention and two months after the completion of the intervention

Method of measurement

Inventory

Secondary outcomes**1****Description**

Stress, anxiety, fatigue and well - being and depression

Timepoint

Before and after intervention and two months after the intervention

Method of measurement

Inventory

Intervention groups**1****Description**

Intervention group: 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 stress, anxiety, depression, fatigue and well - being.

Category

Behavior

2

Description

Control group: Routine care

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Farschian Hospital

Full name of responsible person

Mona Arji

Street address

Hamadan,Farschian Hospital

City

Hamadan

Province

Hamadan

Postal code

6515957133

Phone

+98 81 3824 9499

Email

Mona.arji@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Said Bashirian

Street address

Hamadan

City

Hamadan

Province

Hamadan

Postal code

6517838736

Phone

+98 81 3838 0717

Email

s_Bashirian@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Mona Arji

Position

Ph.d

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

Street address

Hamedan

City

Hamedan

Province

Hamadan

Postal code

65167-4-8741

Phone

+98 81 3824 9499

Email

mona.arji7@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

mona arji

Position

Ph.d

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

Street address

Jahanpour Street, Etemadiyeh district

City

Hamadan

Province

Hamadan

Postal code

65167-4-8741

Phone

+98 81 3824 9499

Fax

+98 81 3826 9808

Email

mona.arji7@gmail.com

Phone

+98 81 3824 9499

Email

mona.arji7@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

mona arji

Position

Ph.d

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

Street address

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Postal code

65167-4-8741

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Due to the the lack of any data in the outset of the study, we are not able to share with other people.

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

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