Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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

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Iran (Islamic Republic of)

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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

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Hamadan,Farschian Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Hamedan University of Medical Sciences

Full name of responsible person
Said Bashirian

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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
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Position
Ph.d

Latest degree
Ph.D.

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Psychology

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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