Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effectiveness of dialectical behavior therapy for fatigue, depression, anxiety, stress and quality of life of patients with Multiple Sclerosis.

Protocol summary

Study aim

Effectiveness of dialectical behavior therapy for fatigue, depression, anxiety, stress and quality of life of patients with Multiple Sclerosis

Design

The research is an experimental test (pretest, posttest, and follow up stage) with a control group. Statistical population of the research includes all patients with Multiple Sclerosis in MS center of Isfahan. 30 patients with Multiple Sclerosis were selected by using convenient sampling.They were randomly assigned to two groups: experimental group(15 individuals) and control group(15 individual)

Settings and conduct

After sampling, patients entered the study with informed consent. An individually pretest session was held in MS Association in September 2016.At this stage, patients completed Depression, Anxiety and Stress Scale (DASS-21), Quality of Life Questionnaire (MSQOL-54) and Fatigue Severity Scale (FSS). The assessments were also done in posttest stage. The course of dialectical behavior therapy in the experimental group was 8 sessions as a group and 1 session per week according to the dialectical behavioral therapy guideline of Moshaine.

Participants/Inclusion and exclusion criteria

Having MS diagnostic criteria based on McDonald's criteria Age group (between 25 and 40 years) Having no severe attack and recurrence of the disease Scored above 14 in depression scale (DASS-21) Scored above 25 in anxiety scale (DASS-21) Scored above 19 in stress scale (DASS-21) Ability to communicate and collaborate Having interest in the study and participating in it with consent

Intervention groups

intervention group:Term of Dialectical Behavior Therapy was 8 sessions with one session per week in the test group. Control group: psychological intervention was not performed in this group. Participants solely answered the questionnaires in pretest, posttest and follow up stages.

Main outcome variables

Fatigue; Depression; Anxiety; Stress; Quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210720051948N1**
Registration date: **2021-09-24, 1400/07/02**
Registration timing: **retrospective**

Last update: **2021-09-24, 1400/07/02**
Update count: **0**

Registration date

2021-09-24, 1400/07/02

Registrant information

Name

Fatemeh Nazari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3233 4907

Email address

fatemehnazarik1991@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-08-22, 1395/06/01

Expected recruitment end date

2016-09-22, 1395/07/01

Actual recruitment start date

2016-09-05, 1395/06/15

Actual recruitment end date

2016-10-06, 1395/07/15

Trial completion date
2016-12-20, 1395/09/30

Scientific title
Effectiveness of dialectical behavior therapy for fatigue, depression, anxiety, stress and quality of life of patients with Multiple Sclerosis.

Public title
Effectiveness of dialectical behavior therapy for fatigue, depression, anxiety, stress and quality of life of patients with Multiple Sclerosis

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Having MS diagnostic criteria based on McDonald's criteria being at the age group of between 25 and 40 years Having no severe attack and recurrence of the disease Scored above 14 in depression scale (DASS-21) Scored above 25 in anxiety scale (DASS-21) Scored above 19 in stress scale (DASS-21) being able to communicate and collaborate Having interest in the study as well as inclination to participate in it
Exclusion criteria:

Age
From **25 years** old to **40 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **30**
Actual sample size reached: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
30 patients with Multiple Sclerosis were selected by using convenience sampling. They were randomly assigned to two groups (in a way thet we randomly selected a number from the sample table and move to one side): One experimental group of 15 persons and another control group of also 15 persons.

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
Islamic Azad University of Isfahan(khorasgan)
Street address
Eastern Jey, Arghavaniye
City
Isfahan
Province
Isfehan
Postal code
8155139998

Approval date
2021-08-03, 1400/05/12

Ethics committee reference number
1400041423531

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
Depression, Anxiety, Stress

Timepoint
Prior to the study(before starting treatment), 60 days(right after ending the treatment) and finally 30 days later (after ending the treatment in follow-up stage)

Method of measurement
Depression, Anxiety and Stress Scale (DASS-21)

2

Description
Quality of life

Timepoint
Prior to the study(before starting treatment), 60 days(right after ending the treatment) and finally 30 days later (after ending the treatment in follow-up stage)

Method of measurement
Quality of life questionnaire (MSQOL-54)

3

Description
Fatigue

Timepoint
Prior to the study(before starting treatment), 60 days(right after ending the treatment) and finally 30 days later (after ending the treatment in follow-up stage)

Method of measurement
Fatigue Severity Scale (FSS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: After pretest, term of dialectical behavior therapy was 8 sessions with one session per week in the test group (15 individuals). Follow-up assessment took place in 30 days after posttest stage.
Category
Behavior

2

Description
Control group: In this group psychological intervention was not performed. The only thing that participants did was answering the questionnaires in pretest, posttest and follow-up stage.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
M.S center of Isfahan
Full name of responsible person
Masoud Etemadifar
Street address
Bahonar
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Isfehan
Postal code
6719915976
Phone
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Email
Isfahan-socity@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Gholamreza Manshaee
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Eastern Jey, Arghavaniye
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Isfehan
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81155139998
Phone
+98 31 3535 4001
Email
info@khuisf.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Islamic Azad University
Proportion provided by this source
10
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
Other

Person responsible for general inquiries

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
Fatemeh Nazari
Position
Graduated
Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
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
No - There is not a plan to make this available