

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 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 that 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

Isfahan

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

City

Isfahan

Province

Isfahan

Postal code

6719915976

Phone

+98 31 3346 2494

Email

Isfahan-socity@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Gholamreza Manshaee

Street address

Eastern Jey, Arghavaniye

City

Isfahan

Province

Isfahan

Postal code

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

Master

Other areas of specialty/work

Psychology

Street address

Tohid, farshchian alley, no31

City

Isfahan

Province

Isfahan

Postal code

6717717486

Phone

0098314226425

Email

fatemehnazarik1991@gmai.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Fatemeh Nazari

Position

Graduated

Latest degree

Master

Other areas of specialty/work

Psychology

Street address

Tohid , farshchian alley, no31

City

Isfahan

Province

Isfahan

Postal code

6717717486

Phone

0098314226425

Email

fatemehnazarik1991@gmail.com

City

Isfahan

Province

Isfahan

Postal code

6717717486

Phone

0098314226425

Email

fatemehnazarik1991@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

Islamic Azad University

Full name of responsible person

Fatemeh Nazari

Position

Graduated

Latest degree

Master

Other areas of specialty/work

Psychology

Street address

Tohid, farshchian alley, no31

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