

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

16 Sep 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-society@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

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#### Province

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#### 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

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#### Province

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#### Postal code

6717717486

#### Phone

0098314226425

#### Email

fatemehnazarik1991@gmail.com

## Person responsible for scientific inquiries

### Contact

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#### Full name of responsible person

Fatemeh Nazari

#### Position

Graduated

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Master  
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## Person responsible for updating data

**Contact**  
**Name of organization / entity**  
Islamic Azad University  
**Full name of responsible person**  
Fatemeh Nazari  
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Graduated  
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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