Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effectiveness of Dialectical Behavior Therapy (DBT) on mood swings, Intolerance of Uncertainty and interpersonal problems in women with Multiple Sclerosis (MS)

Protocol summary

Study aim

Investigating the effectiveness of dialectical behavior therapy (DBT) on mood swings, intolerance of ambiguity, and interpersonal problems in women with multiple sclerosis (MS)

Design

Clinical trial with control and experimental groups, purposive sampling, randomized, on 40 patients. A random number table was used for randomization.

Settings and conduct

The present research sessions were held once a week online and in groups for 60-90 minutes over a period of 3 months on the Google Meet platform.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Received a diagnosis of Multiple Sclerosis (MS) from a neurologist , Gender : Female Ages 20–45 ,Expanded Disability Status Scale (EDSS) score less than 4, Settling in inactive periods of the disease (stable, no relapse, no new lesions on MRI) Exclusion criteria: Suffering from chronic psychological disorders such as depression, anxiety, and psychotic and bipolar disorders Receiving concurrent psychological treatment Suffering from chronic physical illnesses such as high blood pressure, diabetes, and lung diseases. Receiving a course of corticosteroids (methylprednisolone) in the last month. Suicidal thoughts

Intervention groups

The intervention group underwent dialectical behavior therapy training once a week for 60-90 minutes over 3 months. The control group did not receive any psychological treatment and only received their usual medication treatments.

Main outcome variables

Mood swings score on the Positive and Negative Mood Inventory (PANAS). Tolerance of ambiguity score on the Freestone Intolerance of Ambiguity Inventory (IUS) -27. Interpersonal problems score on the Barkham Interpersonal Problems Inventory (IIP-32).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250308064981N1**
Registration date: **2026-07-09, 1405/04/18**
Registration timing: **retrospective**

Last update: **2026-07-09, 1405/04/18**
Update count: **0**

Registration date

2026-07-09, 1405/04/18

Registrant information

Name

Fateme Shams

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-05-19, 1404/02/29

Expected recruitment end date

2025-07-21, 1404/04/30

Actual recruitment start date

2025-07-12, 1404/04/21

Actual recruitment end date

2025-10-18, 1404/07/26

Trial completion date
2026-02-14, 1404/11/25

Scientific title
The Effectiveness of Dialectical Behavior Therapy (DBT) on mood swings, Intolerance of Uncertainty and interpersonal problems in women with Multiple Sclerosis (MS)

Public title
DBT for people with Multiple Sclerosis
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Received a diagnosis of Multiple Sclerosis (MS) from a neurologist Gender : Female Age 20-45 years Expanded Disability Status Scale (EDSS) score less than 4 Settling in inactive periods of the disease (stable, no relapse, no new lesions on MRI)
Exclusion criteria:
Suffering from chronic psychological disorders such as depression, anxiety, psychotic disorders, and bipolar disorder. Suffering from chronic physical conditions such as high blood pressure, diabetes, lung diseases, and heart diseases. Receiving concurrent psychological treatment Receiving corticosteroid pulse therapy (methylprednisolone) within the last month Suicidal thoughts
Age
From **20 years** old to **45 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **40**
Actual sample size reached: **36**
Randomization (investigator's opinion)
Randomized
Randomization description
Initially, patients interested in participating in the study were examined by a neurologist (with an MS fellowship) and underwent an initial interview with a psychologist (the researcher). Patients meeting the study's inclusion criteria were identified and selected using purposive sampling. During the first meeting, to adhere to ethical guidelines, the researcher provided participants with information regarding the study (number and duration of sessions, session format, etc.), randomization (assignment to experimental or control groups), data confidentiality, and the right to withdraw from the study at any time; informed consent for participation was then obtained. Following the matching of participants based on age and education, assignment to the experimental and control groups was carried out randomly using a table of random numbers. A random number table consists of a large set of numbers generated entirely at random without any discernible pattern or order and arranged in a tabular format. To utilize the table, a method was employed in which even numbers were assigned to the experimental group and odd numbers to the control group. Furthermore, the two groups were matched regarding all known factors and confounding variables.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Other
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kashan University of Medical Sciences
Street address
Room 3529, Research Vice-Chancellor, Kashan University of Medical Sciences, 5th km of Ravand Road, kashan
City
kashan
Province
Isfehan
Postal code
8715973474
Approval date
2025-03-08, 1403/12/18
Ethics committee reference number
IR.KAUMS.MEDNT.REC.1403.255

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
Mood swings score in the PANAS positive and negative mood questionnaire
Timepoint
A pre-test will be taken before the intervention begins, and a post-test will be taken after the intervention (3

months).

Method of measurement

Positive and Negative Emotion Scale (PANAS)

2

Description

Tolerance of Uncertainty score on the Freestone Intolerance of Uncertainty Questionnaire (IUS_27)

Timepoint

A pre-test will be taken before the intervention begins, and a post-test will be taken after the intervention (3 months).

Method of measurement

Freestone Intolerance of Uncertainty Scale (IUS_27)

3

Description

Interpersonal Problems Score on the Barkham Inventory of Interpersonal Problems(IIP-32)

Timepoint

A pre-test will be taken before the intervention begins, and a post-test will be taken after the intervention (3 months).

Method of measurement

Barkham Inventory of Interpersonal Problems(IIP-32)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: First, the participants will be given a pre-test. The pre-test includes 3 questionnaires to assess and measure dependent variables. Then, the intervention group will receive dialectical behavior therapy for 3 months (12 sessions, one session per week) and finally, they will be given a post-test.

Category

Rehabilitation

2

Description

Control group: Participants will first be given a pre-test. They will not receive any psychological treatment and will only receive their usual medication. Then they will be given a post-test.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Multiple Sclerosis Research Center in Sina Hospital

Full name of responsible person

Dr zahra Ebadi

Street address

Hassan Abad Square, Imam Khomeini St., Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Dr. Gholam ali Hamidi

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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

Kashan University of Medical Sciences

Proportion provided by this source

10

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

2

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person
Dr. Manouchehr Moradi Sabzevar
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Vice President for Research and Technology, 6th Floor, Central University Organization, corner of Qods Street, Keshavarz Boulevard, Tehran
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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
Tehran University of Medical Sciences

Proportion provided by this source
10

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
Kashan University of Medical Sciences
Full name of responsible person
Fateme Shamsi
Position
Collegian
Latest degree
Bachelor
Other areas of specialty/work
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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Demographic information including: age, education, marital status, employment status; duration of illness. Information related to participants' scores on questionnaires measuring the variables under study. Data entered into SPSS program
When the data will become available and for how long
6 months after results are published
To whom data/document is available
Researchers working in universities and scientific centers
Under which criteria data/document could be used
For research and articles in the fields of psychology, psychiatry, neurology and neuroscience
From where data/document is obtainable
fatemehshams.psy@gmail.com
What processes are involved for a request to access data/document
Go to the email listed on the site and submit a request
Comments