Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effectiveness of Online vs. In-Person Unified Protocol Group Therapy on Transdiagnostic Components in Patients with Multiple Sclerosis Comorbid with Depression and Anxiety

Protocol summary

Study aim

Evaluating the Effectiveness of Online and In-Person Transdiagnostic Group Therapy (Unified Protocol) on Transdiagnostic Components in Patients with Multiple Sclerosis Comorbid with Depression and Anxiety

Design

A phase 2, randomized, two side blinded, parallel-group clinical trial on 40 patients.

Settings and conduct

The intervention will be conducted at the Omid Zanjan Charity in a group format for MS patients to improve their quality of life, consisting of 12 sessions. Each session will last 45 minutes. According to the Unified Protocol for Transdiagnostic Treatment by Barlow, the modules and the specified number of sessions for each module will be implemented. To minimize bias in outcome assessment and data analysis, a "blinding of outcome assessor and data analyst" method was used.

Participants/Inclusion and exclusion criteria

MS diagnosis confirmed by a neurologist؛Minimum middle school education؛ No substance use disorders؛ No other concurrent psychotherapy؛ Age 20-40 years؛ No severe psychiatric disorders؛ Ambulatory (EDSS <6.5)؛ BDI-II score of 0-16 (mild-moderate depression)؛ BAI score of 0-25 (mild-moderate anxiety) Development of new severe psychiatric conditions؛MS relapse or increase in EDSS to ≥6.5؛ Absence from more than 2 sessions؛ Acute psychological crisis؛ Increase in BDI-II score to >16 or BAI score to >25

Intervention groups

In this study, participants in the intervention group will receive 12 therapy sessions, each lasting 45 minutes. The first intervention group will attend these sessions in person, while the second group will participate online. The primary focus of the sessions will be on cognitive restructuring, body awareness, present-moment awareness (mindfulness), teaching the concepts of opposite action, and the three components of emotion, which include thoughts, bodily sensations, and behaviors.

Main outcome variables

Depression and anxiety severity؛ MS-related quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250708066412N1**
Registration date: **2025-11-01, 1404/08/10**
Registration timing: **retrospective**

Last update: **2025-11-01, 1404/08/10**
Update count: **0**

Registration date

2025-11-01, 1404/08/10

Registrant information

Name

Elahe Karami mamaghani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5542 2884

Email address

eliikaramiii@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-07-30, 1404/05/08

Expected recruitment end date

2025-08-03, 1404/05/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of Online vs. In-Person Unified Protocol Group Therapy on Transdiagnostic Components in Patients with Multiple Sclerosis Comorbid with Depression and Anxiety

Public title

The comparison of the effectiveness of online group therapy and in-person therapy on depression and anxiety in patients with MS (Multiple Sclerosis).

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of Multiple Sclerosis Minimum literacy level (at least middle school education) No history of addiction No other psychological treatments received during the study Age between 20 and 40 years No acute psychiatric disorders No severe physical disability, such as dependence on a wheelchair Score between 0 and 16 on the BDI-II (Beck Depression Inventory-II) Score between 0 and 25 on the BAI (Beck Anxiety Inventory)

Exclusion criteria:

Development of severe psychiatric disorders Relapse of the disease or severe physical disability Development of severe physical disability (such as wheelchair dependence) during the study Absence from more than two sessions Recent experience of an acute psychological crisis Score higher than 16 on the BDI-II Score higher than 25 on the BAI

Age

From **20 years** old to **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Based on the selection criteria, a sample size of 40 individuals has been determined, all of whom are members of the MS Association in Zanjan. The sample will be selected using a convenience sampling method according to the inclusion criteria and will be randomly assigned to two groups: virtual intervention and online intervention. Each of these groups will be further divided into two subgroups of ten individuals. The two intervention groups will receive in-person and online therapy, respectively. Each group will consist of 20 individuals.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this trial, due to the nature of the interventions (online therapy versus in-person therapy), blinding of the participants and therapists was not feasible. The participants and therapists are naturally aware of the type of intervention they are receiving or delivering. However, to minimize bias in the outcome assessment and data analysis, a method of "outcome assessor and data analyst blinding" was employed. Outcome assessors, who were responsible for collecting primary outcome data (such as scores on psychological questionnaires, functional assessments, etc.), were kept unaware of the participants' group allocation. The individual or team who performed the final statistical analyses were unaware of the identity of the groups (i.e., which statistical code corresponded to the "online" group and which to the "in-person" group). The data provided to the analysts were labeled with neutral codes (e.g., "Group A" and "Group B"). The linkage between these codes and the actual group identities was only revealed after the completion of the primary statistical analyses, for the purpose of drafting the results.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Zanjan University of Medical Sciences

Street address

Zanjan University of Medical Sciences Mahdavi Street Karmandan Town Zanjan, Iran

City

Zanjan

Province

Zanjan

Postal code

4513956184

Approval date

2025-01-20, 1403/11/01

Ethics committee reference number

IR.ZUMS.REC.1403.306

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

Fear of Disease Progression

Timepoint

Measurements will be conducted at three time points: before the intervention (baseline), immediately after the intervention completion (post-treatment), and three months after the intervention completion (3-month follow-up)

Method of measurement

The individual's score on the Fear of Disease Progression Questionnaire (FoP-Q)

2

Description

Perceived Stress

Timepoint

Measurements will be conducted at three time points: before the intervention (baseline), immediately after the intervention completion (post-treatment), and three months after the intervention completion (3-month follow-up)

Method of measurement

The participant's score on the Cohen Perceived Stress Scale (PSS)

3

Description

Intolerance of Uncertainty

Timepoint

Measurements will be conducted at three time points: before the intervention (baseline), immediately after the intervention completion (post-treatment), and three months after the intervention completion (3-month follow-up)

Method of measurement

The respondent's Intolerance of Uncertainty Scale (IUS) score

Secondary outcomes

1

Description

Depresion

Timepoint

Measurements will be conducted at three time points: before the intervention (baseline), immediately after the intervention completion (post-treatment), and three months after the intervention completion (3-month follow-up)

Method of measurement

BDI Questionnaire score

2

Description

Anxiety

Timepoint

Measurements will be conducted at three time points: before the intervention (baseline), immediately after the intervention completion (post-treatment), and three months after the intervention completion (3-month follow-up)

Method of measurement

BAI Questionnaire score

Intervention groups

1

Description

Intervention group: In-Person Transdiagnostic Cognitive-Behavioral Therapy (Unified Protocol)** The intervention will be delivered in person using the Transdiagnostic Cognitive-Behavioral Therapy (Unified Protocol) for adults. This protocol consists of eight modules to be implemented over a minimum of 12 sessions. The modules include: (1) goal setting and maintaining motivation, (2) understanding emotions, (3) emotional mindfulness, (4) cognitive flexibility, (5) emotional behavior, (6) understanding and confronting bodily sensations, (7) emotion exposure, and (8) reviewing skills while progressing toward goals and maintaining achievements. The protocol primarily focuses on emotions and their three fundamental components: thoughts, bodily sensations, and behaviors. Within the thought component, emphasis is placed on identifying cognitive errors and cognitive restructuring. The bodily sensation component incorporates techniques to enhance awareness of physical sensations. For the behavior component, participants learn about emotional triggers and opposite action strategies. The intervention culminates with techniques for confronting situational emotions and conducting behavioral experiments. All modules will be delivered across 12 weekly sessions, each lasting 45 minutes, spanning approximately 12 weeks.

Category

Treatment - Other

2

Description

Intervention group: Online Transdiagnostic Cognitive-Behavioral Therapy (Unified Protocol)The intervention will be delivered online using the Transdiagnostic Cognitive-Behavioral Therapy (Unified Protocol) for adults. This protocol consists of eight modules to be implemented over 12 sessions. The modules include: (1) goal setting and maintaining motivation, (2) understanding emotions, (3) emotional mindfulness, (4) cognitive flexibility, (5) emotional behavior, (6)

understanding and confronting bodily sensations, (7) emotion exposure, and (8) reviewing skills while progressing toward goals and maintaining achievements.The protocol primarily focuses on emotions and their three fundamental components: thoughts, bodily sensations, and behaviors. Within the thought component, emphasis is placed on identifying cognitive errors and cognitive restructuring. The bodily sensation component incorporates techniques to enhance awareness of physical sensations. For the behavior component, participants learn about emotional triggers and opposite action strategies. The intervention culminates with techniques for confronting situational emotions and conducting behavioral experiments. All modules will be delivered across 12 sessions, each lasting 45 minutes, spanning approximately 6 weeks with twice-weekly sessions.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Zanjan Province MS Charity Association (Omid)
Full name of responsible person
Kazem Salahi Moghadam
Street address
No 56, Omid Saray Street, Gavazang,
City
Zanjzn
Province
Zanjan
Postal code
4513956184
Phone
+98 24 3343 9095
Fax
Email
info@mscharity.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
Dr.Hossein Din mohammadi
Street address
Zanjan University of Medical Sciences, Mahdavi Street, Karmandan Town, Zanjan, Iran
City
Zanjan
Province
Zanjan
Postal code
4513956184
Phone
+98 24 3301 8100
Email
info@zums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Zanjan 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
Zanjan University of Medical Sciences
Full name of responsible person
Elahe karami
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Psychology
Street address
Dr. Beheshti Hospital, Darvazeh Ark
City
Zanjan
Province
Zanjan
Postal code
1331713161
Phone
+98 992 061 7285
Email
eliikaramiii@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
Elahe karami
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Psychology

Street address
Dr. Beheshti Hospital, Darvazeh Ark
City
Zanjan
Province
Zanjan
Postal code
1331713161
Phone
+98 992 061 7285
Email
eliikaramiii@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
Elahe karami
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Psychology
Street address
Dr. Beheshti Hospital, Darvazeh Ark
City
Zanjan
Province
Zanjan
Postal code
1331713161
Phone
+98 992 061 7285
Email
eliikaramiii@gmail.com

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
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available