Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Effectiveness of Short-Term Object Relations Therapy on Self-Efficacy, Identity Reconstruction, Trauma-Related Shame and kinesiophobia in Patients with Multiple Sclerosis (MS)

Protocol summary

Study aim

Investigating the effectiveness of short-term object relations therapy on self-efficacy, identity reconstruction, trauma-related shame, and fear of movement in patients with multiple sclerosis (MS)

Design

The clinical trial has a control group, parallel group, unblinded and randomized (sealed envelope). It is conducted on 36 people with multiple sclerosis referred to Al-Zahra and Kashani Hospitals located in Isfahan. The sealed envelope method was used for randomization.

Settings and conduct

36 eligible individuals were randomly assigned to two experimental and control groups (18 each). Both groups completed the Multiple Sclerosis Self-Efficacy Scale (MSSS), the Identity Reconstruction Scale (IRAS), the Trauma-Related Shame Scale (TRSI), and the Tampa Fear of Movement Scale (TSK) at pretest. The experimental group will participate in 14 sessions of 90-minute, short-term object relations group psychotherapy with the 2009 Ostadter protocol on-site. The control group will receive no therapy. Finally, both groups will complete a posttest.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 20 to 50 years old, minimum literacy and ability to complete questionnaires, willingness to participate, and signing an informed consent form
Exclusion criteria: Severe psychiatric disorders (active psychosis, severe substance dependence, etc.), receiving other concurrent psychotherapy interventions during the study period

Intervention groups

18 eligible individuals who complete the research questionnaires as a pretest but do not receive any treatment. Intervention group: 18 eligible individuals who participated in short-term object relations psychotherapy sessions after the pretest.

Main outcome variables

Self-Efficacy; Identity Reconstruction; Trauma-Related Shame; kinesiophobia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251019067681N1**
Registration date: **2025-11-09, 1404/08/18**
Registration timing: **prospective**

Last update: **2025-11-09, 1404/08/18**
Update count: **0**

Registration date

2025-11-09, 1404/08/18

Registrant information

Name

Ghazal Mesghali

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-11-11, 1404/08/20

Expected recruitment end date

2025-12-11, 1404/09/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effectiveness of Short-Term Object Relations Therapy on Self-Efficacy, Identity Reconstruction, Trauma-Related Shame and kinesiophobia in Patients with Multiple Sclerosis (MS)

Public title

The effectiveness of short-term object relations therapy on patients with multiple sclerosis.

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

20 to 50 years old Minimum literacy and ability to complete questionnaires Willingness to participate and sign informed consent

Exclusion criteria:

Having severe psychiatric disorders (active psychosis, severe substance dependence, etc.) Receiving other concurrent psychotherapy interventions during the study period

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **36**

Randomization (investigator's opinion)

Randomized

Randomization description

Experimental and control groups: After selecting the sample, the next step involves dividing people into experimental and control groups using a random method. How to perform randomization: First step: After selecting the voluntary sample, all selected people are placed on a list (numbers from one to 36 are assigned to people). Second step: From these individuals, a random method is used with sealed and opaque (numbered) envelopes to divide them into experimental and control groups. Each person randomly selects an envelope and is divided into the corresponding group.

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

Research Ethics Committees of Islamic Azad University- Najafaba Branch

Street address

Islamic Azad University, Najafabad Branch, Daneshgah Boulevard, Najafabad, Isfahan, Iran

City

Najafabad

Province

Isfehan

Postal code

۸۵۱۴۱۴۳۱۳۱

Approval date

2025-09-25, 1404/07/03

Ethics committee reference number

IR.IAU.NAJAFABAD.REC.1404.223

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

Self-Efficacy

Timepoint

Before intervention and after intervention

Method of measurement

Multiple Sclerosis Self-Efficacy Questionnaire (MSSS) Rigby et al. 2003

2

Description

Identity Reconstruction

Timepoint

Before intervention and after intervention

Method of measurement

Identity Reconstruction Questionnaire for Multiple Sclerosis (IRAS) Stapleman et al.

3

Description

Trauma-Related Shame

Timepoint

Before intervention and after intervention

Method of measurement

Trauma-Related Shame Inventory (TRSI)

4

Description
kinesiophobia
Timepoint
Before intervention and after intervention
Method of measurement
Tampa Scale (TASK-11)

Secondary outcomes

empty

Intervention groups

1

Description
Control group: 18 participants who meet the inclusion criteria will be randomly assigned to the control group and will complete the Multiple Sclerosis Self-Efficacy Scale (MSSS), the Stapelman et al. Identity Reconstruction Inventory (IRAS), the Trauma-Related Shame Inventory (TRSI), and the Tampa Fear of Movement Scale (TSK), but will not receive any treatment.
Category
Behavior

2

Description
Intervention group: 18 patients with multiple sclerosis referred to Kashani and Al-Zahra hospitals in Isfahan, who meet the inclusion criteria, will participate in the study as the intervention group randomly. They will complete the Multiple Sclerosis Self-Efficacy Scale (MSSS), the Identity Reconstruction Scale (IRAS), the Trauma-Related Shame Scale (TRSI), and the Tampa Fear of Movement Scale (TSK) as a pre-test, then they will undergo 14 sessions of 90 minutes in the Ostadter 2009 short-term object relations group psychotherapy sessions. And after completing the sessions, they will complete the Multiple Sclerosis Self-Efficacy Scale (MSSS), the Identity Reconstruction Scale (IRAS), the Trauma-Related Shame Scale (TRSI), and the Tampa Fear of Movement Scale (TSK) as a post-test.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Didar Counseling and Psychology Center
Full name of responsible person
Gholamreza Talebi
Street address
2nd Floor, Padna Building, No. 44, Amin Alley Corner, Opposite Seyed Al-Shohada Hospital, Pol-Shiri, Isfahan, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Islamic Azad University
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
Islamic Azad University
Full name of responsible person
Ghazal Mesghali

Position
Master's student
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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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Demographic data and the main outcome results of the research can be shared after de-identification and preserving the privacy of individuals.
When the data will become available and for how long
Data can be made available 4 months after the results are published and after personally identifiable information is removed.
To whom data/document is available
The study data and documentation will be available to researchers and scholars working at reputable academic and scientific institutions.
Under which criteria data/document could be used
Research data and documentation may be used for scientific and research purposes. Users must undertake to keep non-identifiable data confidential.
From where data/document is obtainable
If you need data, please contact ghazal.mesghali7412@iau.ir
What processes are involved for a request to access data/document
After receiving and reviewing the request from the researcher, the request will be responded to as soon as possible.
Comments