

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The Effectiveness of Group Therapy Based on Acceptance and Commitment on Meaning in Life, Distress Tolerance, Pain Self-Efficacy and Quality of Life in Patients with Multiple Sclerosis (MS)

Protocol summary

Study aim

The Aim of Study Will be to Investigate the Effectiveness of Acceptance and Commitment Group Therapy on Meaning Life, Distress Tolerance, Quality of Life and Pain Self-Efficacy in Patients with Multiple Sclerosis (MS).

Design

In an Experimental Study With a Pretest-Posttest Control Group Design, 20 Patients With (MS) Will be Selected Through Convenience Sampling Method.

Settings and conduct

The Society for the Protection of Patients With Multiple Sclerosis in Mashhad and Will be Assign to Two Experimental and Control Groups, Each Contain 10 Individuals.

Participants/Inclusion and exclusion criteria

The inclusion criteria: Aged between 20 to 50 years, having at least a high school diploma, Willingness to participate in the study and being randomly into one of the study groups, Diagnosis of MS by a neurologist, Completing the agreement form. The exclusion criteria: Having physical and mental diseases, Receiving intrudent pharmacological and non pharmacological treatments, Patients with any serious psychological disorders (including psychotic disorders or active substance abuse), Having a neurological disorder other than MS, Education less than fifth elementary.

Intervention groups

Experimental Group: The Intervention group will attend Acceptance and Commitment Group Therapy Sessions for 8 Weeks (8 sessions of two hour). In General, the Treatment Plan for this Group Will be to at Assess Previous Session Homework, Teaching a New Technique and Giving Homework for Future Session. Control group: The control group simultaneously (8 two-hour sessions for 8 weeks) will continue Center's usual care plan of the group.

Main outcome variables

Increase Meaning Life, Distress Tolerance, Pain Self-Efficacy and Improvement of Quality of Life.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180218038786N1**

Registration date: **2019-02-08, 1397/11/19**

Registration timing: **registered_while_recruiting**

Last update: **2019-02-08, 1397/11/19**

Update count: **0**

Registration date

2019-02-08, 1397/11/19

Registrant information

Name

Zahra Robati

Name of organization / entity

Semnan University

Country

Iran (Islamic Republic of)

Phone

+98 23 3362 4250

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-04, 1397/11/15

Expected recruitment end date

2019-03-16, 1397/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effectiveness of Group Therapy Based on Acceptance and Commitment on Meaning in Life, Distress Tolerance, Pain Self-Efficacy and Quality of Life in Patients with Multiple Sclerosis (MS)

Public title

The Effect of Group Therapy Based on Acceptance and Commitment on Meaning in Life, Distress Tolerance, Pain Self-Efficacy and Quality of Life in Patients with Multiple Sclerosis (MS)

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Aged between 20 to 50 years Having at least a high school diploma Willingness to participate in the study being randomly into one of the study groups Diagnosis of MS by a neurologist

Exclusion criteria:

Patients with any serious psychological disorders (including psychotic disorders or active substance abuse). Receiving intrudent pharmacological and non pharmacological treatments Having a neurological disorder other than MS Education less than fifth elementary

AgeFrom **20 years** old to **50 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **20****Randomization (investigator's opinion)**

Randomized

Randomization description

The allocation method will be simple random. Hiding the assignment using a computer is that the computer creates random numbers between zero and one. If the random number is less than 0/005, the individual will be assigned to the test group, and if the random number is greater than 0/005, the individual will be entered into the control group. In this process, people who enter the study list will not be aware of how the treatment is allocated before the intervention.

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**

Ethic Committee of Hakim Sabzevari University

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Tohid Shahr ,Hakim Sabzevari University

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Sabzevar

Province

Razavi Khorasan

Postal code

9617976487

Approval date

2018-11-13, 1397/08/22

Ethics committee reference number

IR.HSU.REC.1397.019

Health conditions studied**1****Description of health condition studied**

Multiple Sclerosis (MS)

ICD-10 code

G35

ICD-10 code description

Multiple Sclerosis (MS)

Primary outcomes**1****Description**

Quality of Life Score in Quality of Life Inventory

Timepoint

Measurement of Quality of Life before Intervention and 60 Days after the Onset of Acceptance and Commitment Group Therapy.

Method of measurement

The Short Form Quality of Life Inventory

2**Description**

Meaning Life Score in Meaning in Life Question

Timepoint

Measurement of Meaning Life before Intervention and 60 Days after the Onset of Acceptance and Commitment Group Therapy.

Method of measurement

Meaning in Life Question

3**Description**

Distress Tolerance Score in Distress Tolerance Scale
Timepoint
Measurement of Distress Tolerance before Intervention and 60 Days after the Onset of Acceptance and Commitment Group Therapy.
Method of measurement
Distress Tolerance Scale

4

Description
Pain Self-Efficacy Score in Self Pain Efficacy Inventory
Timepoint
Measurement of Pain Self-Efficacy before Intervention and 60 Days after the Onset of Acceptance and Commitment Group Therapy.
Method of measurement
Self Pain Efficacy Inventory

Secondary outcomes

empty

Intervention groups

1

Description
Control group: The control group simultaneously (two-hour sessions for 8 weeks) will continue Center's usual care plan of the group
Category
Behavior

2

Description
Intervention group: The Intervention group will attend acceptance and commitment group therapy sessions for 8 weeks (8 sessions of two hour). In general, the treatment plan for this group will be to at assess previous session homework, teaching a new technique and giving homework for future session.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
The Society Protection of Patients With MS
Full name of responsible person
Faezeh Dalalmoghadam
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Hakim Sabzevari University
Full name of responsible person
Ahmad Farzaneh
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Tohid Shahr, Hakim Sabzevari University
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Research@hsu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Hakim Sabzevari 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
The Islamic Azad University of Neyshabour
Full name of responsible person
Faezeh Dalalmoghadam
Position
Psychologist

Latest degree

Master

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No More Information

Study Protocol

No - There is not 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

No - There is not 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

Undecided - It is not yet known if there will be a plan to make this available