Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jul 2026

The Effectiveness of Cognitive- Behavioral Group Therapy (CBGT) on Anxiety, Self-Esteem, Quality of Life, Pain Self-Efficacy and Hope in Patients with Multiple Sclerosis (MS)

Protocol summary

Study aim

The Aim of Study Will be to Investigate the Effectiveness of Cognitive- Behavioral Group Therapy (CBGT) on Anxiety, Self- Esteem, Quality of Life, Pain Self-Efficacy and Hope 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, Anxiety disorder based on Beck Anxiety Inventory with a score higher than 26,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 Cognitive- Behavioral Group Therapy Sessions for 6 Weeks (10 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 (10 two-hour sessions for 10 weeks) will continue Center’s usual care plan of the group.

Main outcome variables

Increase Self- Esteem, Hope, Pain Self-Efficacy, Improvement of Quality of Life and Decreased Anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150413021727N3**
Registration date: **2019-01-02, 1397/10/12**
Registration timing: **prospective**

Last update: **2019-01-02, 1397/10/12**
Update count: **0**

Registration date

2019-01-02, 1397/10/12

Registrant information

Name

Zahra Gholami

Name of organization / entity

Islamic Azad University of Torbat-e-Jam.

Country

Iran (Islamic Republic of)

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+98 51 5251 0552

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-05, 1397/10/15

Expected recruitment end date

2019-03-01, 1397/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effectiveness of Cognitive- Behavioral Group Therapy (CBGT) on Anxiety, Self-Esteem, Quality of Life, Pain Self-Efficacy and Hope in Patients with Multiple Sclerosis (MS)

Public title

The Effect of Cognitive- Behavioral Group Therapy (CBGT) on Anxiety, Self- Esteem, Quality of Life, Pain Self-Efficacy and Hope 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 and being randomly into one of the study groups Diagnosis of MS by a neurologist Anxiety disorder based on Beck Anxiety Inventory with a score higher than 26 Completing the agreement form

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

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: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Subjects Will be Assigned to Experimental and Control Groups Randomly With the Aid of Random Numbers Table.

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

Street address

Tohid Shahr ,Hakim Sabzevari University

City

Sabzevar

Province

Razavi Khorasan

Postal code

9617976487

Approval date

2018-11-13, 1397/08/22

Ethics committee reference number

IR.HSU.REC.1397.018

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

Anxiety Score in Beck Anxiety Inventory

Timepoint

Measurement of Anxiety before Intervention and 80 Days after the Onset of Cognitive- Behavioral Group Therapy.

Method of measurement

Beck Anxiety Inventory (BAI)

2

Description

Self- Esteem Score in Coopersmith Inventory

Timepoint

Measurment of Self- Esteem before Intervention and 80 Days after Onset of Cognitive- Behavioral Group Therapy

Method of measurement

Coopersmith Self-Esteem Inventory

3

Description

Quality of Life Score in Quality of Life Inventory

Timepoint

Measurement of Quality of Life before Intervention and 80 Days after the Onset of Cognitive- Behavioral Group Therapy.

Method of measurement

The Short Form Quality of Life Inventory

4

Description
Hope Score in Adult Hope Inventory
Timepoint
Measurement of Hope before Intervention and 80 Days after the Onset of Cognitive- Behavioral Group Therapy.
Method of measurement
Adult Hope Inventory

5

Description
Pain Self-Efficacy Score in Self Pain Efficacy Inventory
Timepoint
Measurement of Pain Self-Efficacy before Intervention and 80 Days after the Onset of Cognitive- Behavioral 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 10 weeks) will continue Center's usual care plan of the group
Category
Behavior

2

Description
Experimental group: The Intervention group will attend cognitive- behavioral group therapy sessions for 10 weeks (10 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
Zahra Robati
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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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Web page address
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 University of Semnan- Mahdishahr

Full name of responsible person
Zahra Robati
Position
Master of Clinical Psychology
Latest degree
Master
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http://psy.semnan.ac.ir

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
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
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available