Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effectiveness of Stress Management With Cognitive-Behavioral Approach on Distress Tolerance and Cognitive Emotion Regulation Strategies in patients with Multiple Sclerosis.

Protocol summary

Study aim

investigate The effectiveness of Stress Management With Cognitive-Behavioral Approach on Distress Tolerance and Cognitive Emotion Regulation Strategies in patients with Multiple Sclerosis

Design

Clinical trial with control group, randomized, phase 2 on 30 patients,

Settings and conduct

Cognitive-behavioral stress management treatment sessions will be held in groups for 120 minutes at the Chronic Disease Care Research Center of the School of Nursing and Midwifery, Ahvaz Jundishapur University of Medical Sciences. After 10 sessions of treatment, all subjects (experiment and control groups) will answer the questions of fatigue questionnaires and coping styles again in one post-test session. In order to observe the ethical principles in the research, after the intervention, briefing sessions will be held for the control group.

Participants/Inclusion and exclusion criteria

Inclusion criteria include: 18-45 years old, definitive diagnosis by a neurologist, informed consent to participate in the study Exclusion criteria included: receiving psychiatric treatment, absence of more than two sessions in educational interventions, willingness to leave the study

Intervention groups

The strategies and techniques used in the sessions are taken from Anthony, Ironson, and Schneiderman, a practical guide to cognitive-behavioral stress management, written in 2007 and translated by Al-Mohammad, Jokar, and Neshat Doost in 2009. The number of sessions is 10 sessions and the duration of the sessions is 120 minutes. While each session consists of two parts: one part includes stress management techniques that form the cognitive part of stress management therapy and the other part, relaxation exercises that teach the behavioral part of stress management treatment.

Main outcome variables

Stress Management With Cognitive-Behavioral Approach, Distress Tolerance, Cognitive Emotion Regulation Strategies,

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210414050967N1**
Registration date: **2021-05-08, 1400/02/18**
Registration timing: **retrospective**

Last update: **2021-05-08, 1400/02/18**
Update count: **0**

Registration date

2021-05-08, 1400/02/18

Registrant information

Name

Mohammadreza Pirmoradi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2256 0418

Email address

pirmoradi.mr@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2016-12-21, 1395/10/01

Actual recruitment start date

2016-09-22, 1395/07/01

Actual recruitment end date

2017-01-20, 1395/11/01

Trial completion date

2017-04-21, 1396/02/01

Scientific title

The effectiveness of Stress Management With Cognitive-Behavioral Approach on Distress Tolerance and Cognitive Emotion Regulation Strategies in patients with Multiple Sclerosis.

Public title

Effect of Stress Management in Multiple Sclerosis.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All MS patients are members of Ahwaz MS Association. Age range between 18 and 45 years Have at least a diploma Definitive diagnosis of the disease by a neurologist

Exclusion criteria:

Non-membership in Ahwaz MS Association. Age under 18 and over 45 years Having an undergraduate education

Age

From **18 years** old to **45 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Actual sample size reached: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, simple random sampling method was selected. If a sample of size n is selected from a community of size N in such a way that each possible sample of n has the same chance of being selected, it is called simple random sampling. For this purpose, The names of patients with a fatigue score higher than 36 were written in the list and a code was considered for each patient regardless of the specific order. Then all patients with even codes were selected as a sample.

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 Ahwaz Jundishapur University of Medical Sciences

Street address

Iran, Ahvaz

City

Ahvaz

Province

Khouzestan

Postal code

61357-15794

Approval date

2016-09-15, 1395/06/25

Ethics committee reference number

ajums.REC.1392.60

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

Distress Tolerance

Timepoint

Before and after the intervention (pre-test and post-test)

Method of measurement

Distress Tolerance Scale

2

Description

Cognitive Emotion Regulation Strategies

Timepoint

Before and after the intervention (pre-test and post-test)

Method of measurement

Cognitive Emotion Regulation Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Cognitive-behavioral stress

management treatment during 10 120-minute group sessions performed weekly.

Category
Behavior

2

Description
Control group: Does not receive intervention.

Category
Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
انجمن ام اس اهواز

Full name of responsible person
Hani Rahimi

Street address
بلوار امام خمینی، کوچه 31

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74331-84799

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hani.psy86@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Hani Rahimi

Street address
Imam Khomeini Boulevard, 31 Alley

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Ahwaz University of Medical Sciences

Proportion provided by this source
1

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Hani Rahimi

Position
دانشجوی دکترا

Latest degree
Master

Other areas of specialty/work
Psychology

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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
All data is potentially shareable after unidentified individuals.
When the data will become available and for how long
Access period starts 6 months after the results are published
To whom data/document is available
The data of this project will be available for researchers working in academic and scientific institutes
Under which criteria data/document could be used
Any use of data must be done in coordination with the developer
From where data/document is obtainable
Shahid Chamran University of Ahvaz
What processes are involved for a request to access data/document
Applicants should first correspond with the responsible author by e-mail and if possible, the desired information will be provided
Comments