

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

The effect of progressive muscle relaxation technique on self-esteem and self-efficacy of patients with Multiple Sclerosis.

Protocol summary

Study aim

Determining the effect of progressive muscle relaxation technique on self-esteem and self-efficacy in patients with multiple sclerosis

Design

Clinical trials with control group (assigning groups to intervention and control in a simple random method). The total sample size is 88 in the control and intervention groups.

Settings and conduct

This study will be conducted in The Multiple Sclerosis Society of Hamedan, progressive muscular relaxation technique will be held in groups of 10-12 people for 4 weeks and 2 times each week.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 18-65 years; Literacy to read and write. Living in Hamadan; The desire to participate in the study and progressive muscle relaxation technique; Expanded Disability Status Scale (EDSS) equal or less than 5.4; Ability to participate in progressive muscle relaxation technique sessions; 6 months after the diagnosis of multiple sclerosis; The ability to do exercises for 20 minutes a day. exclusion criteria: Have other acute and chronic illnesses; Have physical and mental disabilities; constantly using integrative practices and complementary health therapies ; constantly using psychotropic medication

Intervention groups

The 8 sessions of progressive muscle relaxation technique are performed as follows: Session 1: Statement of goals. second session: Provides information on Multiple Sclerosis. third session: Identification of the target muscles and muscle groups. fourth Session: Training on the implementation of techniques and procedures. Fifth session: Practice with the presence of the researcher. Sixth session: Deep breathing training. Seventh session: Practice with the presence of the researcher. Eighth session: Feedback about exercises. The control groups carries out routine care

according to the physician's instructions.

Main outcome variables

The state of self-esteem and Self-efficacy.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170411033378N6**

Registration date: **2019-01-27, 1397/11/07**

Registration timing: **retrospective**

Last update: **2019-01-27, 1397/11/07**

Update count: **0**

Registration date

2019-01-27, 1397/11/07

Registrant information

Name

Efat Sadeghian

Name of organization / entity

Hamedan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 3838 0150

Email address

sadeghian_e@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2018-10-23, 1397/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of progressive muscle relaxation technique on self- esteem and self-efficacy of patients with Multiple Sclerosis.

Public title

Effect of progressive muscle relaxation technique on self-esteem and self-efficacy.

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Age between 18-65 years. Literacy to read and write.
Living in Hamedan. The desire to participate in the study and progressive muscle relaxation technique. EDSS (Expanded Disability Status Scale) equal or less than 5.4. Ability to participate in progressive muscle relaxation technique sessions. 6 months after the diagnosis of multiple sclerosis. The acute stage of the disease is not. The ability to do exercises for 20 minutes a day.

Exclusion criteria:

Have physical and mental disabilities. constantly using integrative practices and complementary health therapies . constantly using psychotropic medication.

AgeFrom **18 years** old to **65 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **88****Randomization (investigator's opinion)**

Randomized

Randomization description

The samples are selected using convenience sampling method from patients referring to the Hamadan Multiple Sclerosis Society who are eligible to enter the study and then assigned by random allocation to two groups of intervention and control.

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**

Ethics committee of Hamedan University of Medical Sciences

Street address

Hamedan University of Medical Sciences, Shahid Fahmideh Street, Hamedan.

City

Hamedan

Province

Hamadan

Postal code

38698 -65178

Approval date

2018-11-06, 1397/08/15

Ethics committee reference number

IR.UMSHA.REC.1397.520

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- esteem.

Timepoint

pre intervention,post intervention,four weeks after intervention

Method of measurement

Rosenberg Self-Esteem Scale.

Secondary outcomes**1****Description**

self-efficacy

Timepoint

pre intervention,post intervention,four weeks after intervention.

Method of measurement

Multiple Sclerosis Self-efficacy Scale

Intervention groups

1

Description

The 8 sessions of progressive muscle relaxation technique are performed as follows: Session 1:Statement of goals. second session: Provides information on Multiple Sclerosis.third session: Identification of the target muscles and muscle groups.fourth Session: Training on the implementation of techniques and procedures. Fifth session: Practice with the presence of the researcher. Sixth session: Deep breathing training.Seventh session: Practice with the presence of the researcher. Eighth session: Feedback about exercises.

Category

Rehabilitation

2

Description

Control group: Usual Nursing Care.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Hamedan multiple sclerosis society.

Full name of responsible person

Efat Sadeghian

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Hamedan University of Medical Sciences, Shahid Fahmideh Street, Hamedan.

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sadeghianefat@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Research and Technology Vice-Chancellor.

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Hamedan- Mahdye Street- Shahid Fahmedeh Boulvar-
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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

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Efat Sadeghian

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Position

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Latest degree

Ph.D.

Other areas of specialty/work

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Position

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Latest degree

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Other areas of specialty/work

Nursery

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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

The whole data will be published after the unidentifiable individuals are shared, which will be published as the final report and article.

When the data will become available and for how long

Starting available 6 months after the publication of results.

To whom data/document is available

Researchers working in academia and those working in the industry can apply for them.

Under which criteria data/document could be used

Anyone who wishes to use the articles to be retrieved is possible with email.

From where data/document is obtainable

Applicants can email their request for receiving the relevant documents and data to sadeghianefat@gmail.com or send it to postal address Hamedan; Shahid Fahmideh street; front of Mardom Park; Faculty of Nursing and Midwifery; Psychiatric Nursing Department; Dr. Efat Sadeghian; Postal code:65178-38698; or Contact by phone number: +98 8138380535 and fax: +98 81 38380447.

What processes are involved for a request to access data/document

Applicants can email their request for receiving the relevant documents and data to sadeghianefat@gmail.com or send it to postal address Hamedan; Shahid Fahmideh street; front of Mardom Park; Faculty of Nursing and Midwifery; Psychiatric Nursing Department; Dr. Efat Sadeghian; Postal code:65178-38698. or contact by phone number: +98 8138380535 and fax: +98 81 38380447. The response will be sent to the Applicants at least one week after reviewing the request.

Comments