Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of progressive muscle relaxation techniqe 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 techniqe 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.
Age
From **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

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

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65178-38698

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+98 81 3838 0150

Email
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.

Street address
Hamedan- Mahdye Street- Shahid Fahmedeh Boulvar- Hamedan University of Medical Sciences

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bashirian@umsha.ac.ir

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
Hamedan University of Medical Sciences

Full name of responsible person

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Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for updating data

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Full name of responsible person

Efat Sadeghian.

Position

Assistant Professor

Latest degree

Ph.D.

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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