

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

The Effect of Progressive Muscle Relaxation Technique on the quality of sleep and fatigue in patients with multiple Sclerosis

Protocol summary

Summary

50 patients with MS were randomly divided into two groups (intervention= 25) and (control= 25). For the intervention group, teaching relaxation techniques will be done as a team work for 4 days. Then this technique will be practice at home by the patients ,30 to 45 minutes , for two months. In the control group there was no intervention. After the necessary training and creating relaxation in the intervention groups, the quality of sleep and fatigue will be assessed before and after intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015112923600N2**
Registration date: **2016-03-15, 1394/12/25**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-03-15, 1394/12/25

Registrant information

Name

Fateme Zargarani

Name of organization / entity

Tehran Medical Branch , Islamic Azad University

Country

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Recruitment status

Recruitment complete

Funding source

Deputy of research and technology, Golestan University of Medical Science

Expected recruitment start date

2015-12-22, 1394/10/01

Expected recruitment end date

2016-06-21, 1395/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Progressive Muscle Relaxation Technique on the quality of sleep and fatigue in patients with multiple Sclerosis

Public title

The Effect of Progressive Muscle Relaxation Technique on the quality of sleep and fatigue

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Having age between 15 to 60 years, Ability to read and write, Not in the acute phase, Living in Gorgan, EDSS desired Expanded Disability Status (Score between 0 and 5.5) Exclusion criteria: Drug addiction, Relapse in three months, Not participating in meetings, Withdrawal from continuing to work for any reason, History of relaxation techniques, The risk of other serious health disorders, Serious psychiatric disorder, Sedating medications

Age

From **15 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 50

Randomization (investigator's opinion)

Randomized

Randomization description

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 the Golestan University of Medical Sciences

Street address

Golestan university of Medical Science, Deputy of research and technology

City

Gorgan

Postal code

Approval date

2015-11-22, 1394/09/01

Ethics committee reference number

IR.GOUMS.REC.1394.198

Health conditions studied

1

Description of health condition studied

quality of sleep and fatigue

ICD-10 code

F10-F19

ICD-10 code description

Mental and behavioural disorders

Primary outcomes

1

Description

sleep quality

Timepoint

Before and after intervention

Method of measurement

Pittsburgh Sleep Quality Index

2

Description

Fatigue

Timepoint

Before and after intervention

Method of measurement

Fatigue severity scale index

Secondary outcomes

1

Description

The recurrence rate in the last year

Timepoint

At the beginning of the study

Method of measurement

According to the person

Intervention groups

1

Description

Intervention Group have 25 patient with MS. For the intervention group, learning relaxation techniques can be done as a group for 4 days. Techniques for homework at home by the patient for 30 to 45 minutes runs for two months

Category

Other

2

Description

In the control group there was no intervention

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

MS Society of Gorgan

Full name of responsible person

Fatemeh Zargarani

Street address

5 Azar Hospital

City

Gorgan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy of Research and Technology- Golestan University of Medical Sciences

Full name of responsible person

Fatemeh Zargarani

Street addressDeputy of Research and Technology, Golestan
University of Medical Sciences**City**

Gorgan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding sourceDeputy of Research and Technology- Golestan University
of Medical Sciences**Proportion provided by this source**

100

Public or private sector*empty***Domestic or foreign origin***empty***Category of foreign source of funding***empty***Country of origin****Type of organization providing the funding***empty***Person responsible for general inquiries****Contact****Name of organization / entity**Deputy of Research and Technology- Golestan
Research Center of Psychiatry**Full name of responsible person**

Fatemeh Zargarani

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)***empty***Study Protocol***empty***Statistical Analysis Plan***empty***Informed Consent Form***empty***Clinical Study Report***empty***Analytic Code***empty***Data Dictionary***empty*