Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of the effect of reflexology and muscle relaxation on fatigue and anxiety in patients with multiple sclerosis

Protocol summary

Study aim
Comparison of the effect of reflexology and muscle relaxation on fatigue and anxiety in patients with multiple sclerosis

Design
A single-center double blinded randomized controlled trial, without placebo.

Settings and conduct
This study will be conducted on 105 patients with multiple sclerosis (M.S), at M.S society of Saveh.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Willingness to cooperate in the study and sign the informed consent form; No skin disease with feet involvements; Not having acute infections or ulcer in the feet; 25 to 60 years old patients; No history of taking sedative drugs and no history of psychological problems. Exclusion criteria: Past year's crisis situations (divorce, death of close relatives and serious accidents).

Intervention groups
First intervention group: in the first intervention group reflexology will be conducted three times a week (each time for 30 minutes) for 4 weeks. Second intervention group: In this group, the samples will perform the technique of progressive muscle relaxation three times a week (Sundays, Tuesdays and Thursdays) for 4 weeks and each time for 30 to 45 minutes, in the presence of the researcher. Control group: The samples of the control group will not receive any intervention during this time.

Main outcome variables
Fatigue; Anxiety

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20161210031328N13**
Registration date: **2021-04-15, 1400/01/26**
Registration timing: **prospective**
Last update: **2021-04-15, 1400/01/26**
Update count: **0**

Registration date
2021-04-15, 1400/01/26

Registrant information

Name
Mahbobeh Sajadi

Name of organization / entity
Arak University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-04-19, 1400/01/30

Expected recruitment end date
2021-06-20, 1400/03/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of reflexology and muscle relaxation on fatigue and anxiety in patients with multiple sclerosis

Public title
The effect of reflexology and muscle relaxation on fatigue and anxiety

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

No skin disease with feet involvements. Not having diabetes with peripheral nerve involvement and sensory disorders in the feet. Not having acute infections or ulcer in the feet. 25 to 60 years old patients. No history of taking sedative drugs and no history of psychological problems

Exclusion criteria:

Unwillingness to cooperate in the study. Past year's crisis situations (divorce, death of close relatives and serious accidents)

Age

From **25 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **105**

Randomization (investigator's opinion)

Randomized

Randomization description

At first, the samples were selected using convenience sampling. To generate the random sequence, permutation block randomization will be used. At first, 6 blocks will constructed as "ABC, ACB, BAC, BCA, CAB, CBA", then these blocks are arranged using a random number table, and individuals will assigned to three groups according to A, B and C letters.

Blinding (investigator's opinion)

Double blinded

Blinding description

The present study is a double-blinded in which the data analyst and the participants did not know the random allocation.To prevent the transfer of information between the two groups one day is allocated to the intervention and one day to the control group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak University of Medical Sciences

Street address

Arak University of Medical Sciences, Basij Sq., Sardasht Region

City

Arak

Province

Markazi

Postal code

3848176593

Approval date

2021-02-21, 1399/12/03

Ethics committee reference number

IR.ARAKMU.REC.1399.331

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

F41.9

ICD-10 code description

Anxiety disorder, unspecified

2

Description of health condition studied

Fatigue

ICD-10 code

R53.82

ICD-10 code description

Chronic fatigue, unspecified

Primary outcomes

1

Description

Anxiety score in Spielberger anxiety inventory

Timepoint

Before study and 4 weeks after intervention

Method of measurement

Spielberger anxiety inventory

2

Description

Fatigue score in Smets questionnaire

Timepoint

Before study and 4 weeks after intervention

Method of measurement

Smets multidimensional fatigue inventory

Secondary outcomes

empty

Intervention groups

1

Description

First intervention group: in the first intervention group reflexology will be conducted slowly, with a regular rhythm and with a depth of 1 to 3 mm, three times a week (each time for 30 minutes) for 4 weeks.

Category

Treatment - Other

2

Description

Second intervention group: In this group, the samples will perform the technique of progressive muscle relaxation three times a week for 4 weeks and each time for 30 to 45 minutes, in the presence of the researcher.

Category

Treatment - Other

3

Description

Control group: The samples of the control group will receive routine care during this time.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

M.S Society of Saveh

Full name of responsible person

Maliheh Keykavoosi

Street address

M.S Society, Hazrat-e-zahra Blvd., Alavi Town

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Alireza Kamali

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Deputy of research and technology, Arak University of Medical Sciences, Basij Sq., Sardasht Region

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research@arakmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Mahbobeh Sajadi

Position

Associate 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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Full name of responsible person

Masoud Esmaeili

Position

Masters student of Nursing

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Bachelor

Other areas of specialty/work

Nursery

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Person responsible for updating data

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Other areas of specialty/work

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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

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

It is provided unrecognizably at the request of individuals.

When the data will become available and for how long

The access period will start after the results are printed.

To whom data/document is available

Researchers at other Universities are allowed access.

Under which criteria data/document could be used

Documentation is provided in order to know how the work is done and to critique it.

From where data/document is obtainable

Mahbobeh Sajadi sajadimahbobeh@yahoo.com

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

After stating the purpose of accessing the information, the requested items will be sent via email.

Comments