

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Investigation the effect of progressive muscle relaxation on sexual dysfunction in women with multiple sclerosis in Rafsanjan, 2023

Protocol summary

Study aim

Determining the effect of progressive muscle relaxation technique on sexual dysfunction in women with multiple sclerosis in Rafsanjan city in 2023

Design

A clinical trial with a control group, with parallel groups, without blinding, randomized, on 80 patients, a simple lottery randomization method was used.

Settings and conduct

Obtaining a score of less than 28 from the FSFI questionnaire designed is considered as having a sexual disorder; the progressive muscle relaxation technique is one of the complementary treatments that is used as the contraction and expansion of 16 groups of muscles.

Participants/Inclusion and exclusion criteria

- Age 20-45 years
- Obtaining a score less than 28 from the FSFI questionnaire
- More than six months have passed since the diagnosis of the disease
- Married and having intermittent sex with her husband and not intending to divorce
- Extended Disability Status Scale (EDSS) score less than equal to 4.5
- Absence of pregnancy and menopause
- Not using sleeping pills, alcohol, drugs, etc.
- Non-use of common complementary treatments at the same time
- Not using any kind of sexual drugs
- Not having other chronic and acute physical and mental illnesses
- The husband's absence of known sexual disorders
- Not being in the acute stage of the disease

Intervention groups

Intervention group: performing progressive muscle relaxation on sexual performance
Control group: no intervention will be done.

Main outcome variables

Sexual performance score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230610058439N1**

Registration date: **2023-08-28, 1402/06/06**

Registration timing: **prospective**

Last update: **2023-08-28, 1402/06/06**

Update count: **0**

Registration date

2023-08-28, 1402/06/06

Registrant information

Name

Shaghayegh Azarang rooy

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 5801 3622

Email address

azarang98@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-01, 1402/06/10

Expected recruitment end date

2023-10-02, 1402/07/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation the effect of progressive muscle relaxation on sexual dysfunction in women with multiple sclerosis in Rafsanjan, 2023

Public title

Investigation the effect of progressive muscle relaxation on sexual dysfunction in women with multiple sclerosis in Rafsanjan, 2023

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Age 20-45 Obtaining a score less than 28 from the FSFI questionnaire More than six months have passed since the diagnosis of the disease Married and having intermittent sex with her husband' and not intending to divorce Ability to perform daily personal tasks without assistance from others Extended Disability Status Scale (EDSS) score less than equal to 4.5 Absence of pregnancy No menopause Not using sleeping pills, alcohol, drugs and drugs affecting sexual function Not using common complementary treatments such as yoga, Pilates, meditation at the same time Not using any kind of sexual drugs Not having other chronic and acute physical and mental diseases according to the medical record The husband's absence of known sexual disorders Not being in the acute stage of the disease Not having cognitive disorders

Exclusion criteria:

Unwillingness to cooperation Having lethargy and weakness or reduced level of consciousness being admitted to the hospital

Age

From **20 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

First, the sampling will be purposeful and based on the study entry criteria, for this purpose, the eligible samples will be selected and divided into two groups based on the average score obtained from the FSFI questionnaire. Then, the allocation of samples in two intervention and control groups will be done by simple random drawing

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

Sampling is first purposeful and selected based on the criteria for entering the study, then based on the score obtained from the FSFI questionnaire, they are divided into two intervention and control groups, and finally they will be allocated to the two groups by a simple random method. The intervention group will receive progressive muscle relaxation training and no intervention will be

performed on the control group.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Rafsanjan University of Medical Sciences

Street address

Rafsanjan - Imam Ali Boulevard - Central Organization

City

Rafsanjan

Province

Kerman

Postal code

7717933777

Approval date

2023-05-14, 1402/02/24

Ethics committee reference number

IR.RUMS.REC.1402.022

Health conditions studied**1****Description of health condition studied**

Sexual dysfunction in women with multiple sclerosis

ICD-10 code

G35

ICD-10 code description

Multiple sclerosis

Primary outcomes**1****Description**

Sexual performance score in the 19-question questionnaire of intimacy and sexual activity in multiple sclerosis (MSISQ19)

Timepoint

The measurement of the sexual function score will be before the intervention and 6 weeks after the intervention of muscle relaxation.

Method of measurement

The sexual performance score is measured using a 19-question questionnaire of multiple Sclerosis Intimacy and Sexuality

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The Jacobson method of progressive muscle relaxation will be practiced every day for 20 minutes up to 6 weeks at home, at night before going to sleep. The subjects will be asked to wear comfortable clothes. Take out the watch, jewelry, etc. and lie down in a quiet and alone environment without noise or disturbing factors or sit on a chair with complete comfort and then do the sixteen muscle groups, starting from the hands, forearms, and arms. , shoulders, forehead, eyes and nose bridge, cheeks and jaw, mouth, neck, chest, waist or back, stomach, hips, thighs, legs, soleus muscle and finally the whole body, along with the tail Contract for 5 seconds (so that the client notices the contraction and stiffness of the muscle) and then expand and relax the muscles during exhalation for 10 seconds.

Category

Other

2

Description

Control group: no intervention will be done in the control group.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Special Diseases Department of Ali Ibn Abi Talib Hospital

Full name of responsible person

Shaghayegh Azarang rooy

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Taleghani Blvd., Ayatollah Saidi Square, Hazrat Ali Ibn Abitalib Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Dr Sode Khanamani Falahatipur

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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

Rafsanjan 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

Rafsanjan University of Medical Sciences

Full name of responsible person

Dr. Tayebeh Negahban Bonabi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Full name of responsible person

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Latest degree

Ph.D.

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available