Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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)

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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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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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Person responsible for scientific inquiries

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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