

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

The effect of education of sexual health promotion package on sexual dysfunction and sexual quality of life in multiple sclerosis women: designed from the results of a mixed-method study

Protocol summary

Study aim

The effect of education of sexual health promotion package on sexual dysfunction and sexual quality of life in multiple sclerosis women

Design

This study is a randomized controlled clinical trial, and 72 women with multiple sclerosis will be randomly assigned into two intervention and control groups.

Settings and conduct

In this study, 72 married women with multiple sclerosis who referred to Iranian MS Society after obtaining informed consent will be randomly assigned into intervention and control groups. In the intervention group, sexual health education and counseling will be provided in 6 sessions, and no education or counseling will be provided to the control group

Participants/Inclusion and exclusion criteria

Inclusion criteria: Married women with multiple sclerosis, age of 18 to 50 years old; having sexual dysfunction (selecting "often" or "always" options in at least one question from the MSISQ-19); having sexual activity during the last six months; EDSS <7; have no severe depression or severe fatigue. Exclusion criteria: Other acute and chronic diseases; being at the stage of recurrence or disease attack and receiving other treatments for sexual dysfunction.

Intervention groups

Multiple sclerosis women in the intervention group will receive Face-to-Face sexual health education and counseling in six sessions -90 minutes during six weeks through lecture, Question-Answer method and role-play. The sexual health promotion package was designed after several stages of quantitative and qualitative research, experts panel, and then searching in the literature. Women in the control group will not receive any intervention by the research team during the study.

Main outcome variables

Sexual dysfunction with Multiple Sclerosis Intimacy and Sexuality Questionnaire-19 (MSISQ-19) and sexual quality of life with sexual quality of life-female (SQOL-F) questionnaire.

General information

Reason for update

The word of "sexual function" was changed to "sexual dysfunction". This change was made because of the MSISQ-19 measures "sexual dysfunction" and it was mentioned by mistake.. It should be noted that during the implementation process, no change was made in the study structure and only the word of "sexual function" was changed to "sexual dysfunction". Also, in order to examine the effect of the intervention more closely, another follow-up was added 1 month after the intervention, and the follow-up times changed to immediately, 1 month, and 2 months after the intervention.

Acronym

IRCT registration information

IRCT registration number: **IRCT20190721044292N1**
Registration date: **2019-09-01, 1398/06/10**
Registration timing: **prospective**

Last update: **2020-04-27, 1399/02/08**

Update count: **1**

Registration date

2019-09-01, 1398/06/10

Registrant information

Name

Vida Ghasemi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8820 2512

Email address vidaghasemi89@sbmu.ac.ir	Not blinded
Recruitment status Recruitment complete	Blinding description Placebo Not used
Funding source	Assignment Parallel
Expected recruitment start date 2019-09-06, 1398/06/15	Other design features
Expected recruitment end date 2020-01-05, 1398/10/15	Secondary Ids empty
Actual recruitment start date empty	Ethics committees
Actual recruitment end date empty	1
Trial completion date empty	Ethics committee
Scientific title The effect of education of sexual health promotion package on sexual dysfunction and sexual quality of life in multiple sclerosis women: designed from the results of a mixed-method study	Name of ethics committee Ethics committee of Shahid Beheshti University of Medical Sciences
Public title The effect of sexual health education on sexual dysfunction and sexual quality of life in women with multiple sclerosis	Street address Shahid Beheshti University of Medical Sciences., Arabi Ave., Daneshjoo Blvd., Velenjak.
Purpose Education/Guidance	City Tehran
Inclusion/Exclusion criteria Inclusion criteria: Iranian Age of 18 to 50 years old Being married Confirmed diagnosis of MS by a neurologist based on McDonald's criteria Have sexual activity during the last six months In a stage of the disease, that is possible for her to perform routine activities including having a sexual relationship with her spouse (EDSS <7) Not pregnant or breastfeeding Selecting "often" or "always" options in at least one question from the MSISQ-19 Have no severe depression or severe fatigue (score less than 29 in the BDI-II and score less than 5/1 in the FSS) Exclusion criteria: Being at the stage of recurrence or disease attack Have other acute and chronic disease Receiving any kind of treatment for sexual dysfunction	Province Tehran
Age From 18 years old to 50 years old	Postal code 1983963113
Gender Female	Approval date 2018-02-26, 1396/12/07
Phase N/A	Ethics committee reference number IR.SBMU.PHNM.1396.1003
Groups that have been masked <i>No information</i>	Health conditions studied
Sample size Target sample size: 72	1
Randomization (investigator's opinion) Randomized	Description of health condition studied Multiple Sclerosis
Randomization description Randomization will be done by using random numbers in Excel software (Rand () function).	ICD-10 code G35
Blinding (investigator's opinion)	ICD-10 code description Multiple sclerosis
	Primary outcomes
	1
	Description Sexual dysfunction
	Timepoint Before the intervention, immediately after the intervention, one and two months after the intervention
	Method of measurement Multiple Sclerosis Intimacy and Sexuality Questionnaire-19 (MSISQ-19)
	2
	Description Sexual Quality of life

Timepoint

Before the intervention, immediately after the intervention , one and two months after the intervention

Method of measurement

sexual quality of life-female (SQOL-F) questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Women with multiple sclerosis in the intervention group will receive Face-to-Face sexual health education in six sessions -90 minutes for 6 weeks with lecture, question-and-answer, and role-playing methods. The sexual health promotion package was designed in 6 steps. 1- Identifying the related factors of sexual dysfunction of these women in a cross-sectional study, 2- Conducting a qualitative study to explaining sexual dysfunction and its related factors in women with MS by conducting interviews with patients and key informants includes psychologists, neurologists, reproductive health, ecologists, and a spouse, 3- Integrating quantitative and qualitative results using the side-by-side method, 4- Designing sexual health promotion strategies in these patients based on Integration results and literature review, 5- Prioritizing these strategies in an experts panel 6-Using these strategies in designing a sexual health promotion package. These packages are based on the patients' needs and include content for patients to learn about and deal with the psychological, physical, sexual symptoms of the disease that affect on improving sexual function, as well as education the communication and negotiation skills with the spouse, problem-solving, education and counseling to enhance sexual intimacy, progressive muscle relaxation, self-esteem, etc.

Category

Behavior

2**Description**

Control group: Women in the control group will not receive any intervention by the research team during the study. This group will attend a one-day sex education workshop and receive a sexual health education package.

Category

N/A

Recruitment centers**1****Recruitment center**

Name of recruitment center

Iranian MS Society

Full name of responsible person

Vida Ghasemi

Street address

Iran MS Society, Shams Street, Vesal Shirazi Avenue, Enghelab Square, Tehran, Iran

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Seyyed ali ziaei

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Shahid Beheshti University of Medical Sciences, Arabi Ave., Daneshjoo Blvd., Vele.njak

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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

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Vida Ghasemi

Position

PhD student

Latest degree

Master

Other areas of specialty/work

Reproductive Health

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School of Nursing and Midwifery, Shahid Beheshti
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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

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Position

Professor

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Person responsible for updating data

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Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Yes - There is 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

Title and more details about the data/document

We can share information about the main outcome. The
data will spread unknown.

When the data will become available and for how long

The data will be an accessible 6-12 month after
publishing the results.

To whom data/document is available

Researchers in academic institutes were allowed to
access data

Under which criteria data/document could be used

With stating the reference.

From where data/document is obtainable

Sending email to corresponding author
through: Msimbar@gmail.com

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

An application letter must include the name of the
applicant, used item, the scientific title of the research
project or article.

Comments