Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2019-09-06, 1398/06/15
Expected recruitment end date
2020-01-05, 1398/10/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

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

Public title
The effect of sexual health education on sexual dysfunction and sexual quality of life in women with multiple sclerosis
Purpose
Education/Guidance
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
Age
From **18 years** old to **50 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **72**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization will be done by using random numbers in Excel software (Rand () function).
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 Shahid Beheshti University of Medical Sciences
Street address
Shahid Beheshti University of Medical Sciences., Arabi Ave., Daneshjoo Blvd., Velenjak.
City
Tehran
Province
Tehran
Postal code
1983963113
Approval date
2018-02-26, 1396/12/07
Ethics committee reference number
IR.SBMU.PHNM.1396.1003

Health conditions studied

1

Description of health condition studied
Multiple Sclerosis
ICD-10 code
G35
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
City
Tehran
Province
Tehran
Postal code
1416864731
Phone
+98 21 6695 1187
Email
Vidaghasemi89@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Seyyed ali ziaei
Street address
Shahid Beheshti University of Medical Sciences, Arabi Ave., Daneshjoo Blvd., Vele.njak
City
Tehran
Province
Tehran
Postal code
1983963113
Phone
+98 21 2243 9781
Email
Intl_office@sbmu.ac.ir
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

Street address
School of Nursing and Midwifery, Shahid Beheshti University of Medical Sciences, Niayesh intersection., Vali-e-Asr street.,

City
Tehran

Province
Tehran

Postal code
1985717443

Phone
+98 21 8820 2512

Email
Vidaghasemi89@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
دکتر معصومه سیمبر

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Reproductive Health

Street address
School of Nursing and Midwifery, Shahid Beheshti University of Medical Sciences, Niayesh intersection., Vali-e-Asr street.,

City
tehran

Province
Tehran

Postal code
1985717443

Phone
+98 21 8820 2512

Email
Msimbar@gmail.com

Person responsible for updating data

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

Street address
School of nursing and midwifery, Shahid Beheshti University of Medical Sciences, Niayesh Intersection., Vali-e-Asr

City
tehran

Province
Tehran

Postal code
1985717443

Phone
+98 21 8820 2512

Email
Vidaghasemi89@gmail.com

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