

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of sexual counseling based on the BETTER model on sexual function and satisfaction in married women suffering from MS

Protocol summary

Summary

Objective: The current study was designed to investigate the effect of sexual counseling based on the BETTER model (Bring up, Explain, Tell information resources, Time, Educate and Record of the counseling process) on sexual function and satisfaction in married women suffering from MS and sexual dysfunction. Methods: This randomized, controlled clinical trial will be conducted in Iran MS Society, Tehran. In this study, married women who have definitive MS diagnosis, have sexual dysfunction and age from 15 to 49 years old, will be enrolled into the study. Participants, after signing informed consent, based on the blocked randomization (block sizes of 4) will be divided in two groups: intervention group (36 persons) and control group (36 persons). Then, a two-part questionnaire on demographic and MS information will be completed, and sexual counseling based on the BETTER model (four coupled sessions between 90-120 minutes and weekly) will be implemented only for the intervention group. Finally, 2 and 3 months after the last session, the status of sexual function and satisfaction of the participants in two groups will be measured using standard questionnaires, Female Sexual Function Index (FSFI) and Index of Sexual Satisfaction (ISS), by telephone interview. The findings of before and after intervention in two groups, control and intervention, will be compared using statistical methods and considering Intention to treat, and impact of the counseling will be determined. At the end of the study, the educational and counseling content will be given to the participants in the control group in order to the ethical considerations.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017100936679N1**

Registration date: **2017-10-20, 1396/07/28**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-10-20, 1396/07/28

Registrant information

Name

Faezeh Ghafoori

Name of organization / entity

School of Nursing and Midwifery, Tehran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

This study is financial supported by Tehran University of Medical Sciences.

Expected recruitment start date

2017-10-27, 1396/08/05

Expected recruitment end date

2017-12-26, 1396/10/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of sexual counseling based on the BETTER model on sexual function and satisfaction in married women suffering from MS

Public title

The effect of counseling on sexual function and satisfaction in women with MS

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age between 15 and 49 years old; Married and living together (not to be divorced); Have sex during the last 6 months; Do not have pregnancy or breastfeeding; Have definitive Diagnosis of MS (membership in Iran MS Society requires a written confirmation of the disease by a neurologist); Have no chronic disease other than MS; To be at a stage of MS disease that can carry out routine activities (EDSS score less than 7); Have no severe depression or fatigue (score less than 29 in the BDI-II questionnaire and score less than 5.1 in the FSS questionnaire); Have sexual dysfunction (score 28 or less than 28 in the FSFI questionnaire); Do not receive special treatment for treatment of sexual dysfunction, including psychotherapy or attending classes; The participant's husband, according to her, does not have any sexual dysfunction; Have access to her within at least the next 4 months; Exclusion criteria: The occurrence of any physical or psychological illness with the approval of doctors in the participant or her spouse that affects their sexual function; MS recurrence or attack during the study; Pregnancy occurrence during the study; Unwillingness of the participant to continue the study; Absence of continuous presence of the participant or her spouse in counseling sessions; Participate in educational or counseling sessions outside the study environment;

Age

From **15 years** old to **49 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**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Tehran University of Medical Sciences

Street address

Enghelab Square, Tehran, Iran

City

Tehran

Postal code**Approval date**

2016-06-08, 1395/03/19

Ethics committee reference number

IR.TUMS.VCR.REC.1395.98

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

Multiple Sclerosis disease (MS)

ICD-10 code

G35

ICD-10 code description

Multiple sclerosis

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

Sexual function

Timepoint

Before the intervention, two and three months after the end of the intervention

Method of measurement

Female Sexual Function Index

2**Description**

Sexual satisfaction

Timepoint

Before the intervention, two and three months after the end of the intervention

Method of measurement

Index of Sexual Satisfaction

Secondary outcomes

empty

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

In the control group: Women in the control group will not receive any intervention by the research team during the study.

Category

N/A

2

Description

In the intervention group: Four sessions of coupled sexual counseling, each session for a minimum of 90 and a maximum of 120 minutes, according to the BETTER model, each session once a week: • First session, implementation of the first and second steps of the model_ Explain, Bring up • Second session, implementation of the third and fourth steps of the model_Time, Tell resources • Third session, the implementation of the fifth step of the model_ Educate • Fourth session, implementation of the sixth step of the Model_ Record

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Iran MS Society

Full name of responsible person

Dr Ghahari

Street address

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

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

School of Nursing and Midwifery, Tehran University of Medical Sciences

Full name of responsible person

Dr Ziba Taghizadeh

Street address

School of Nursing and Midwifery, Tehran University of Medical Sciences, West Nosrat Street, Tohid Square, Tehran, Iran

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Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

School of Nursing and Midwifery, Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

School of Nursing and Midwifery, Tehran University of Medical Sciences

Full name of responsible person

Faezeh Ghafoori

Position

PhD Candidate in Reproductive Health

Other areas of specialty/work

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Person responsible for scientific inquiries

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PhD in Nursing, Full Professor

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty