

# 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 4489 9057

###### Email address

f-ghafoori@razi.tums.ac.ir

##### 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

Tehran

## 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

##### City

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

#### Street address

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

School of Nursing and Midwifery, Tehran University of Medical Sciences

#### Full name of responsible person

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PhD in Nursing, Full Professor

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## Person responsible for updating data

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**Position**

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**Other areas of specialty/work**

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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*