Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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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
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

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Person responsible for scientific inquiries

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Full name of responsible person
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PhD in Nursing, Full Professor

Other areas of specialty/work

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Person responsible for updating data

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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