Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of impact of PLISSIT (Permission, Limited Information, Specific Suggestion, Intensive Therapy) model and personal counseling on sexual function in married women suffer from multiple sclerosis with sexual dysfunction

Protocol summary

Summary
This is a randomized clinical trial study. It will be conducted in Iranian Community of Multiple Sclerosis Patient Support. One-hundred and twenty women who are married and have sexual problems randomly will be assigned to control, experimental group-A and experimental group-B. The experimental group-A will receive consultation based on PLISSIT (Permission, Limited Information, Specific Suggestion, Intensive Therapy model by a trained midwife, the experimental groups-B will receive personal consultation and the control group will receive routine sexual consultation. Demographic and obstetric information will be gathered through standard questionnaire. FSFI(Female Sexual Function Index) questionnaire will be used for assessing sexual function. Data will be collected from participants at three points: before consultation, 2 months and 3 months after consultation. Mann-Whitney, T-tests and x2 will be used for data analysis

General information

Acronym

IRCT registration information
IRCT registration number: **IRCT2014012113542N2**
Registration date: **2014-07-25, 1393/05/03**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date
2014-07-25, 1393/05/03

Registrant information
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Zohreh Khakbazan
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Tehran University of Medical Sciences
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Recruitment status
Recruitment complete

Funding source
Tehran University of Medical Sciences

Expected recruitment start date
2014-02-04, 1392/11/15

Expected recruitment end date
2014-04-20, 1393/01/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of impact of PLISSIT (Permission, Limited Information, Specific Suggestion, Intensive Therapy) model and personal counseling on sexual function in married women suffer from multiple sclerosis with sexual dysfunction

Public title
Comparison of impact of PLISSIT (Permission, Limited Information, Specific Suggestion, Intensive Therapy) model and personal counseling on sexual function in married women suffer from multiple sclerosis with sexual dysfunction

Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria: women who are married, do not suffer from any other chronic disease, and have sexual problems (FSFI score<28). they should have sexual relationship with their husband. Exclusion criteria: If a woman does not want to continue take parting in this study or becomes pregnant or does not come to all sessions of intervention, she will be omitted.
Age
No age limit
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **120**
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
Ethics Committee of Tehran University of Medical Sciences
Street address
The 6th floor of The central organization of Tehran University of Medical Sciences, at the corner of Qods Street , Keshavarz street.
City
Tehran
Postal code
Approval date
2013-12-21, 1392/09/30
Ethics committee reference number
130/2187/92/ه

Health conditions studied

1

Description of health condition studied
Sexual dysfunction
ICD-10 code
F52
ICD-10 code description
Sexual dysfunction, not caused by organic disorder or disease

Primary outcomes

1

Description
Sexual function
Timepoint
Before the intervention; two monthes and three monthes after intervention
Method of measurement
Female Sexual Function Index questionnare

Secondary outcomes

1

Description
Quality of life
Timepoint
Two monthes and three monthes after intervention
Method of measurement
SF36 questionnaire

Intervention groups

1

Description
The experimental group-A: will receive consultation based on PLISSIT model (Permission-limited Information-Specific Suggestion-Intensive Therapy) by a trained midwife during 4 weeks that in each week one session will be conducted.
Category
Behavior

2

Description
The control group: will receive routine sexual consultation.
Category
Other

3

Description
The experimental groups-B: will receive personal consultation during 4 weeks that in each week one session will be conducted.
Category
Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Iran Multiple Sclerosis Society

Full name of responsible person
Sahraeean

Street address
Iran Multiple Sclerosis Society, Mohammad Alley, Vesal Street, Enghelab Street, Tehran

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Masoud Yonesian

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The 6th Floor of The central organization of Tehran University of Medical Sciences, Qods Street, Keshavarz Street.

City
Tehran

Grant name

Grant code / Reference number

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

Title of funding source
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
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Position
Master Sciences Student of Midwifary

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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