

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 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

Name

Zohreh Khakbazan

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 21 8898 4339

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khakbazanz871@mums.ac.ir

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

130/2187/92/3

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 questionnaire

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

Street address

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

Tehran University of Medical Sciences

Full name of responsible person

Fatemeh Daneshfar

Position

Master Sciences Student of Midwifery

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