Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Effectiveness of Extended-PLISSIT model on intimacy and sexuality in married women suffer from multiple sclerosis with sexual dysfunction

Protocol summary

Summary

This is a randomized clinical trial study and it's aim is to assess the effectiveness of sexual counseling based on Extended-PLISSIT (Permission, limited Information, Specific Suggestion, Intensive Therapy) model on intimacy and sexuality in married women suffer from multiple sclerosis with sexual dysfunction who are registered in Iranian Community of Support for Multiple Sclerosis Patients. The study will be conducted in Iranian Community of Support for Multiple Sclerosis Patients. After written permission and ethical committee approval will be obtained, 90 women who have including criteria and will voluntarily accept to participate in the study (given their written informed consent) will be assigned to experimental (45 women) and control (45 women) groups. The experimental group will receive consultation based on Extended-PLISSIT model (Permission, limited Information, Specific Suggestion, Intensive Therapy) by a trained midwife (4 weekly 60 to 90 minutes sessions). The control group will receive routine services of this organization. Multiple Sclerosis Intimacy and Sexuality Questionnaire will be used to assess sexual function. Data will be collected from participants at three points: before consultation, 2 months and 3 months after consultation. During the follow-up period the researcher will call these women and she will give them a phone number to call her whenever there were a problem. Suitable statistics tests will be used for data analysis.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014092817965N1**
Registration date: **2014-10-16, 1393/07/24**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-10-16, 1393/07/24

Registrant information

Name
Fatemeh Daneshfar
Name of organization / entity
Faculty of Nursing and Midwifery of Tehran University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 19 1222 4417
Email address
daneshfar1987@yahoo.com

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2014-10-12, 1393/07/20

Expected recruitment end date

2014-12-11, 1393/09/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of Extended-PLISSIT model on intimacy and sexuality in married women suffer from multiple sclerosis with sexual dysfunction

Public title

Effectiveness of Extended-PLISSIT model on intimacy and sexuality in married women suffer from multiple sclerosis who have sexual dysfunction

Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria: Being married; age between 18 to 55; being registered in Iranian Community of Support for Multiple Sclerosis Patients (certain diagnosis of Multiple Sclerosis); having at least one of the Multiple Sclerosis related sexual dysfunction (primary, secondary or tertiary) according to MSISQ-19 (Multiple Sclerosis Intimacy and Sexuality Questionnaire); EDSS (Expanded Disability Status Scale) less than 7 Exclusion criteria: Pregnancy; progress of Multiple Sclerosis related disability (EDSS more than 7); deny to continue taking part in the study
Age
From **18 years** old to **55 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **90**
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
Central building of Tehran University of Medical Sciences, Qods street, Keshavarz street, Tehran
City
Tehran
Postal code
Approval date
2014-09-23, 1393/07/01
Ethics committee reference number
93-02-99-26076-122195

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
Multiple Sclerosis Intimacy and Sexuality
Timepoint
before consultation, 2 months and 3 months after consultation
Method of measurement
Multiple Sclerosis Intimacy and Sexuality Questionnaire-19

Secondary outcomes

empty

Intervention groups

1

Description
The control group will receive routine services of this organization.
Category
N/A

2

Description
The experimental group will receive consultation based on Extended-PLISSIT model (Permission, limited Information, Specific Suggestion, Intensive Therapy) by a trained midwife (4 weekly 60 to 90 minutes sessions). MSISQ-19 (Multiple Sclerosis Intimacy and Sexuality Questionnaire) will be used to assess sexual function. Data will be collected from participants at three points: before consultation, 2 months and 3 months after consultation. During the follow-up period the researcher will call these women and she will give them a phone number to call her whenever there were a problem.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Iranian Community of Support for Multiple Sclerosis Patients

Full name of responsible person
Hasan Babaei
Street address
Iranian Community of Support for Multiple Sclerosis Patients, Karim Khan street, Haft-e-Tir square, Tehran
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Masood Yunesian
Street address
Central building of Tehran University of Medical Sciences, Qods street, Keshavarz street, Tehran
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
Faculty of Nursing and Midwifery of Tehran University of Medical Sciences
Full name of responsible person
Fatemeh Daneshfar
Position
Master science student of midwifery
Other areas of specialty/work
Street address
13th eastern alley, Takhti (Radio darya) street
City
Chalus
Postal code
4661893453
Phone
+98 11 5222 4417
Fax
+98 11 5224 1265
Email
daneshfar1987@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Faculty of Nursing and Midwifery of Tehran University of Medical Sciences
Full name of responsible person
Zahra Behboodi Moghadam
Position
Assistant
Other areas of specialty/work
Street address
Faculty of Nursing and Midwifery of Tehran University of Medical Sciences, Nosrat street, Tehran, Iran
City
Tehran
Postal code
1419733171
Phone
+98 21 6694 3187
Fax
+98 21 6694 3187
Email
Bahar_behboodi@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Faculty of Nursing and Midwifery of Tehran University of Medical Sciences
Full name of responsible person
Fatemeh Daneshfar
Position
Master science student of midwifery
Other areas of specialty/work
Street address
13th eastern alley, Takhti (Radio darya) street
City
Chalus
Postal code
4661893453
Phone
+98 21 5222 4417
Fax
+98 11 5224 1265
Email
Daneshfar1987@yahoo.com; Daneshfar1987@gmail.com
Web page address

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