Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of Ex-PLISSIT model based sexual counseling on the intimacy and sexuality of married women with multiple sclerosis: a randomized controlled trial

Protocol summary

Summary
The aim of this study is to determine the effect of Ex-PLISSIT model based sexual counseling on the intimacy and sexuality of married women with multiple sclerosis. The participants are 42 married women aged 18 to 45 years with multiple sclerosis in Tabriz. They will randomly be allocated in two groups. In the intervention group, consultation will be held in one session for 90-60 minutes or more sessions if needed (i.e. intensive therapy) in accordance with the EX-PLISSIT model components. Control group will just receive routine care. The primary outcome are intimacy and sexuality before and two months after intervention measured by MSISQ-19.

General information

Acronym

IRCT registration information
IRCT registration number: **IRCT2017051833834N2**
Registration date: **2017-06-18, 1396/03/28**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date
2017-06-18, 1396/03/28

Registrant information

Name
Roghaiyeh Nourizadeh
Name of organization / entity
Tabriz University of Medical Sciences
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Recruitment status
Recruitment complete

Funding source
Tabrize University of Medical Sciences

Expected recruitment start date
2017-05-27, 1396/03/06

Expected recruitment end date
2017-10-22, 1396/07/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of Ex-PLISSIT model based sexual counseling on the intimacy and sexuality of married women with multiple sclerosis: a randomized controlled trial

Public title
The effect of Ex-PLISSIT model based sexual counseling on the intimacy and sexuality of married women with multiple sclerosis: a randomized controlled trial

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: The minimum literacy of secondary school; At least 6 months after diagnosis of MS; sexually active married women; women aged 18-45 years; Ability of listening and speaking; At least one year after marriage; Having a contact number to follow-up; Without major disability (EDSS <7); Exclusion criteria: Pregnant and lactating women; Hospitalization due to MS disease progression or relapse within the last month; Presence of other diseases affecting sexual function; Drug addiction and smoking; Using drugs affect sexual function; Being

treatment due to sexual dysfunction; Women with depression score ≥16 in short form of the Beck Depression Inventory

Age
From **18 years** old to **45 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **42**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Tabriz University of Medical Sciences (Nursing and Midwifery)

Street address
Azady Street / Golgasht (South Shariati)

City
Tabriz

Postal code

Approval date
2017-05-08, 1396/02/18

Ethics committee reference number
IR.TBZMED.REC.1396.115

Health conditions studied

1

Description of health condition studied
Multiple sclerosis

ICD-10 code
G35

ICD-10 code description
Multiple sclerosis

Primary outcomes

1

Description
Intimacy and sexuality

Timepoint
Before and two months after intervention

Method of measurement
MSISQ-19

Secondary outcomes

1

Description
Quality of sexual life

Timepoint
Before and two months after intervention

Method of measurement
SQOL-F

Intervention groups

1

Description
In the intervention group (21 women), consultation will be held in one session for 90-60 minutes or more sessions if needed (i.e. intensive therapy) in accordance with the model components.

Category
Treatment - Other

2

Description
In the usual care control group will be

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
MS Society of East Azerbaijan

Full name of responsible person
Roya Azari Barzandig

Street address

City
Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Dr. Mohammad Reza Rashidi

Street address

Vice President of Research, Tabriz University of Medical Sciences

City
Tabriz

Grant name

Grant code / Reference number

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

Title of funding source
Tabriz 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
Tabriz University of Medical Sciences

Full name of responsible person
Roya Azari Barzandig

Position
MSc of Counseling in Midwifery

Other areas of specialty/work

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Tabriz University of Medical Sciences (Faculty of Nursing and Midwifery)

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Dr. Roghaiyeh Nourizadeh

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PhD in reproductive health

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