

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 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

Roghayeh Nourizadeh

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Tabriz 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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**Person responsible for scientific
inquiries**

Contact

Name of organization / entity

Tabriz University of Medical Sciences (Faculty of
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Dr. Roghaiyeh Nourizadeh

Position

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