Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Determining the effect of counseling based on PLISSIT model on sexual quality of life of married women with multiple sclerosis

Protocol summary

Study aim
Determining the effect of counseling based on PLISSIT model on sexual quality of life of married women with multiple sclerosis referring to MS center in Isfahan in 2019

Design
A randomized controlled Clinical trial

Settings and conduct
The research environment in this study is Isfahan MS Research Center. The participants in the experimental group will enter the study after obtaining permission from the physician and participated in 4 face-to-face individual training and counseling sessions, which will last 45 to 75 minutes per session and one session per week . All the research subjects will complete the questionnaires after two weeks and two months after the intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Married women who were diagnosed with multiple sclerosis at least 6 months ago; having sex during the last 6 months; being married longer than one year; having at least one sex problem; not suffering from other acute or chronic illness other than multiple sclerosis; not dealing with severe crises such as the deaths of close relatives over the past six months; having secondary and higher education and being available within the next month. Exclusion criteria : Severe marital conflicts (self-reported), pregnancy

Intervention groups
Experimental group: based on the PLISSIT model, face to face counseling was conducted weekly in 4 sessions and each session lasted between 45-75 minutes. Control group: they received no intervention and only pre-test and post-test were taken from the participants in this group. In addition, all the research subjects were asked to perform the follow-up and complete the questionnaires after two weeks and two months after the intervention. In order to observe ethical issues, a control group was also provided with an educational guide on the sexual quality of life.

Main outcome variables
sexual quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190614043890N1**
Registration date: **2020-04-19, 1399/01/31**
Registration timing: **retrospective**

Last update: **2020-04-19, 1399/01/31**
Update count: **0**

Registration date
2020-04-19, 1399/01/31

Registrant information

Name
Zahra Kazemi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 5736 2939

Email address
kazemi2619@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-06-22, 1398/04/01

Expected recruitment end date
2019-07-21, 1398/04/30

Actual recruitment start date
2019-07-23, 1398/05/01

Actual recruitment end date

2019-08-21, 1398/05/30

Trial completion date

2019-10-15, 1398/07/23

Scientific title

Determining the effect of counseling based on PLISSIT model on sexual quality of life of married women with multiple sclerosis

Public title

The Effect of PLISSIT Model on sexual Quality of Life of Women with Multiple Sclerosis

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Married women who were diagnosed with multiple sclerosis at least 6 months ago Having Sex during the last 6 months Being married longer than one year Having at least one sexual problem Not suffering from other acute or chronic illness other than multiple sclerosis Not dealing with severe crises such as the deaths of close relatives over the past six months Having secondary and higher education Being available within the next month

Exclusion criteria:

pregnancy marital conflicts

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **62**

Actual sample size reached: **62**

Randomization (investigator's opinion)

Randomized

Randomization description

Selected samples were randomly assigned into two groups of control and experimental using cellphone. Sample size was calculated based on the statistical formula of 28 individuals in each group. It should be noted that 10% increase in the sample size was considered due to the probability of sample loss; therefore, 31 individuals were considered in each group.

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

Ethics Committee of Isfahan Islamic Azad University (Khorasgan)

Street address

Arghouniyah Blvd., Jey Street

City

Esfahan

Province

Isfehan

Postal code

39998-81551

Approval date

2019-07-14, 1398/04/23

Ethics committee reference number

IR.IAU.KHUISF.REC.1398.113

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

sexual quality of life

Timepoint

14 and 60 days after training

Method of measurement

Sexual quality of life questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Experimental group: based on the PLISSIT model, face to face counseling was conducted weekly in 4 sessions and each session lasted between 45-75 minutes.

Category

Lifestyle

2

Description

Control group: they received no intervention and only

pre-test and post-test were taken from the participants in this group. In addition, all the research subjects were asked to perform the follow-up and complete the questionnaires after two weeks and two months after the intervention. In order to observe ethical issues, a control group was also provided with an educational guide on the sexual quality of life..

Category
Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center
MS Center

Full name of responsible person
Mahsa Sadat Mousavi

Street address
Bahonar street, Khademi crossroad, Hedayat street, Javad alley

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Kazemi2619@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University

Full name of responsible person
Majid Toghyani

Street address
Jey Street, Arghavani Blvd.

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Fax
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mousavi1315@gmail.com

Web page address
http://new.khuisf.ac.ir/index.aspx?tempname=newmain&lang=1&sub=1

Grant name
-

Grant code / Reference number
-

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

Title of funding source
Islamic Azad University

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Islamic Azad University

Full name of responsible person
Zahra kazemi

Position
Nurse

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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Person responsible for scientific inquiries

Contact

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Full name of responsible person
Mahsa Sadat Mousavi

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Midwifery

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Person responsible for updating data

Contact
Name of organization / entity
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Full name of responsible person
Mahsa Sadat Mousavi
Position
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Latest degree
Ph.D.
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Demographic variables with university permission may be shared after unidentifiable individuals.
When the data will become available and for how long
Data will be available 3 to 6 months after the results are published in journal.
To whom data/document is available
The target group is academic researchers who have access to the data that interests them.
Under which criteria data/document could be used
Analysis on demographic variables is permitted.
From where data/document is obtainable
Refer to the corresponding author's email. mousavi1315@gmail.com
What processes are involved for a request to access data/document
It will be available in the journal 3 to 6 months after publication.
Comments
It also seems that the implementation of this model does not require advanced educational technologies and if healthcare professionals attend PLISSIT workshops, they can use the first three levels of the model for their patients, as a result, sexual problems are diagnosed and treated in the early stages.