

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Comparing effect of two counseling method (Leventhal's self-regulation model and BETTER Model) on Sexual Satisfaction & function in Women with multiple sclerosis: A three armed randomized controlled trial

Protocol summary

Study aim

Comparing effect of two counseling method (Leventhal's self-regulation model and BETTER Model) on Sexual Satisfaction & function in Women with multiple sclerosis

Design

This research is a clinical trial study of three randomized controlled groups comparing three groups, which will be conducted on women with multiple sclerosis under observation at the neurology center of Qazvin city. The level of satisfaction and sexual performance in three groups will be measured before, one and three months after the intervention

Settings and conduct

Women with MS referring to the neurology clinic of Bu Ali Hospital in Qazvin who meet the conditions for entering the study

Participants/Inclusion and exclusion criteria

Inclusion criteria: willing to participate in the study- able to understand and speak Persian language- married women (at least one year)- Have definitive Diagnosis of MS by a neurologist using the McDonald Criteria- To be at a stage of MS disease that can carry out routine activities _ EDSS score < 5 not in early diagnosis phase
Exclusion criteria: have depression and taking medication- participate in other counseling sessions at the same time ---pregnancy breast feeding in exacerbation phase

Intervention groups

control group: Do not receive any intervention and routine care
Intervention group 1: three training session using individual Leventhal's self-regulatory model for 60 minutest each session once a week
In the intervention group 2: three sessions of sexual counseling, each session for a minimum of 60 and a maximum of 100 minutes, according to the BETTER model, each session once a week: • First session, implementation of the first and second steps of the model_ Explain, Bring up •

Second session ,third and fourth _Time, Tell resources •
Third session, the implementation of the fifth and sixth step of the model_ Educate- Record

Main outcome variables

sexual function-sexual satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221120056555N1**

Registration date: **2023-02-10, 1401/11/21**

Registration timing: **prospective**

Last update: **2023-02-10, 1401/11/21**

Update count: **0**

Registration date

2023-02-10, 1401/11/21

Registrant information

Name

mehrnoosh elahinia

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3342 0827

Email address

m.elahinia@qums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-06, 1401/12/15

Expected recruitment end date

2023-09-06, 1402/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing effect of two counseling method (Leventhal's self-regulation model and BETTER Model) on Sexual Satisfaction & function in Women with multiple sclerosis: A three armed randomized controlled trial

Public title

Comparing effect of two counseling method (Leventhal's self-regulation model and BETTER Model) on Sexual Satisfaction & function in Women with multiple sclerosis: A three armed randomized controlled trial

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

willing to participate in the study able to understand and speak Persian language married women (at least one year) Have definitive Diagnosis of MS by a neurologist using the McDonald Criteria To be at a stage of MS disease that can carry out routine activities _ EDSS score < 5 not in early diagnosis phase

Exclusion criteria:

have depression and taking medication participate in other counseling sessions at the same time pregnancy breast feeding in exacerbation phase

Age

From **18 years** old

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

random allocation is done as a block of six. For random allocation, balanced block design with six block sizes will be used, and random allocation generation software will be used, and in order to hide the sequence of allocation, the papers identifying the groups of people are respectively placed inside the envelopes in the opaque package and They are coded in the same order, and in this way, code one is assigned to the people of the Leventhal intervention group, code two to the people of the better intervention group, and code three to the control 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 Qazvin University of Medical Sciences and Healthcare Services

Street address

Qazvin - Shahid Beheshti Blvd. - not reaching Valiasr intersection - facing Shahid Beheshti Park - Maudet sub alley - No. 16 - University of Medical Sciences Research and Technology Deputy Building - 1st floor - University Research Ethics Committee Unit

City

Qazvin

Province

Qazvin

Postal code

34197-59811

Approval date

2023-02-05, 1401/11/16

Ethics committee reference number

IR.QUMS.REC.1401.297

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 satisfaction

Timepoint

Before the intervention, one and three months after the end of the intervention

Method of measurement

Sexual satisfaction scale for women

2**Description**

sexual function

Timepoint

Before the intervention, one and three months after the end of the intervention

Method of measurement

Female Sexual Function Index

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group1: three training sessions using Leventhal's self-regulation model individually and face-to-face for 60 minutes weekly, including description of the nature of the disease, symptoms and causes related to it, the consequences of the disease (sexual), the course of the disease, and how to control it and disease care

Category

Behavior

2**Description**

Intervention group 2: Three sexual counseling sessions, each session lasting at least 60 and maximum 100 minutes, according to the BETTER model, once a week: • The first session, implementation of the first and second steps of the model - Explain, Bring up • The second session, the implementation of the third and fourth steps of the Time-Tell resources model. The third session, the implementation of the fifth and sixth steps of the Educate model.

Category

Behavior

3**Description**

Control group: They will not receive any intervention from the research team, but they will receive their routine examinations by the specialist and the treatment team

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Qazvin buAli hospital

Full name of responsible person

Dr.Mozhdehi panah

Street address

Qazvin - West Buali Street, Buali Sina Hospital

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ندارد

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Qazvin University of Medical Sciences

Full name of responsible person

محمد قوامی

Street address

Qazvin - Shahid Bahonar Boulevard - Qazvin University of Medical Sciences. Faculty of Nursing and Midwifery

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Qazvin University of Medical Sciences

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**

Qazvin University of Medical Sciences

Full name of responsible person

Mehrnoosh Elahinia

Position

Master's student in counseling in midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

No.510,royayi alley, lakan blvd , rasht town , guilan

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Email

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Qazvin University of Medical Sciences

Full name of responsible person

Mehrnoosh Elahinia

Position

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Person responsible for updating data**Contact****Name of organization / entity**

Qazvin University of Medical Sciences

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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

Not applicable

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Study data can be shared after de-identifying individuals

When the data will become available and for how long

6 months after the results are published

To whom data/document is available

The data of this research will be available for researchers working in academic and scientific institutions

Under which criteria data/document could be used

The data obtained from this study will only be available for conducting similar studies

From where data/document is obtainable

m.elahinia@qums.ac.ir mehrnoosh elahinia

What processes are involved for a request to access data/document

Initial correspondence via e-mail, face-to-face meeting and presentation of a work proposal similar to the current research, providing sufficient evidence for the similarity of your research with the current research, study of the proposal by the current research executive, decision-making and announcement of the result by the current research executive to the researcher in order to obtain the available data. Placing the data file for use on site

Comments