Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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
City
qazvin
Province
Qazvin
Postal code
ندارد
Phone
+98 28 3333 9049
Email
hosboali@qums.ac.ir

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
City
qazvin
Province
Qazvin
Postal code
59811 -34197
Phone
+98 28 3333 6001
Email
info@qums.ac.ir
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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Province
Qazvin
Postal code
4145753345
Phone
009833336001
Email
m.elahinia@qums.ac.ir

Person responsible for scientific 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
City
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Qazvin
Postal code
4145753345
Phone
009833336001
Email
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Person responsible for updating data

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
City
Qazvin
Province
Qazvin
Postal code
4145753345
Phone
009833336001
Email
m.elahinia@qums.ac.ir

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