Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of counseling based on the Rapport Building, Exploring, Decision Making, and Implementing the Decision (REDI) model versus control group on the sexual satisfaction and quality of sexual life in women with multiple sclerosis: a randomized clinical trial

Protocol summary

Study aim

To assess the effect of counseling based on the Rapport Building, Exploring, Decision Making, and Implementing the Decision (REDI) model versus control group on the sexual satisfaction and quality of sexual life in women with multiple sclerosis

Design

This is a randomized clinical trial with a control group with parallel groups without randomization, in which eligible patients will be randomly assigned to the intervention and control groups using block randomization.

Settings and conduct

This study will be conducted at the multiple sclerosis Center in Hamadan city, involving 60 eligible women with multiple sclerosis. The patients will be randomly assigned to the intervention and control groups through the block randomization. Blinding is not feasible in this trial.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18 to 45 Women with multiple sclerosis Having had active sex in the past 6 months Exclusion criteria: Any physical illness Pregnancy

Intervention groups

Intervention group: Routine multiple sclerosis treatment plus counseling sessions based on the relationship building, exploration, decision-making, and decision-making model for 60 to 90 minutes once a week for four weeks Control group: Only routine multiple sclerosis treatment

Main outcome variables

Primary outcome: Sexual satisfaction score; sexual quality of life score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N552**
Registration date: **2025-03-09, 1403/12/19**
Registration timing: **prospective**

Last update: **2025-03-09, 1403/12/19**
Update count: **0**

Registration date

2025-03-09, 1403/12/19

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 81 1838 0090

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-04-04, 1404/01/15

Expected recruitment end date

2025-06-05, 1404/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of counseling based on the Rapport Building, Exploring, Decision Making, and Implementing the Decision (REDI) model versus control group on the sexual satisfaction and quality of sexual life in women with multiple sclerosis: a randomized clinical trial

Public title

The effect of counseling based on the Rapport Building, Exploring, Decision Making, and Implementing the Decision (REDI) model versus control group on the sexual satisfaction and quality of sexual life in women with multiple sclerosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18 to 45 Women with multiple sclerosis Having had active sex in the past 6 months

Exclusion criteria:

Any physical illness Pregnancy

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: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, random assignment of patients to the intervention and control groups will be carried out using block randomization. To achieve this, four sheets of paper will be prepared - two with the name of the intervention and two with the name of the control. These paper sheets will be pooled and placed in a container. Patients will be selected one at a time without replacement, and for each patient, a paper sheet will be randomly drawn from the container. After each draw, the paper sheets will be returned to the container, and the process will be repeated until the desired sample size is reached.

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 Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2025-01-18, 1403/10/29

Ethics committee reference number

IR.UMSHA.REC.1403.752

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 score

Timepoint

Before intervention and 4 weeks later

Method of measurement

Using the Larson Sexual Satisfaction Questionnaire

2

Description

Sexual quality of life score

Timepoint

Before intervention and 4 weeks later

Method of measurement

Using the Sexual Quality of Life Questionnaire for Women (SQOL-F)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Routine multiple sclerosis treatment plus counseling sessions based on the relationship building, exploration, decision-making, and decision-making model for 60 to 90 minutes once a week for four weeks (including explaining the importance of sex on the quality of couples' relationships, teaching the anatomy and physiology of the reproductive system, expressing sexual needs and problems, explaining the four stages of the sexual response cycle, factors affecting the decrease in sexual desire, physical and psychological differences between men and women, explaining, scrutinizing, and deciding to implement, strategies to enhance sexual desire, improving mental skills to enhance and stimulate sexual arousal, teaching skills to create variety in sexual relationships, teaching various positions in sexual relationships, answering questions, ambiguities, and possible problems of clients in implementing techniques)
Category
Treatment - Other

2

Description
Control group: Only routine multiple sclerosis treatment
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Multiple Sclerosis Center in Hamadan city
Full name of responsible person
Fatemeh Abasi
Street address
School of Nursing and Midwifery, Hamadan University of Medical Sciences, Fahmideh Ave.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Dr. Alireza Soltanian
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info.research@umsha.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Hamedan 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
Hamedan University of Medical Sciences
Full name of responsible person
Fatemeh Abasi
Position
Midwifery Student
Latest degree
Master
Other areas of specialty/work
Midwifery
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Person responsible for scientific

inquiries

Contact

Name of organization / entity
Hamedan University of Medical Sciences

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Position
Reproductive Health Specialist

Latest degree
Ph.D.

Other areas of specialty/work
Reproductive Health

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available