

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Feb 2026

Assessment the effect of the health promoting lifestyle education in multimedia method on the sexual function and marital satisfaction of womens with Multiple Sclerosis

Protocol summary

Study aim

Assessment the effect of the health promoting lifestyle education in multimedia method on the sexual function and marital satisfaction of womens with Multiple Sclerosis

Design

A clinical trial, control and intervention groups, simple randomization, 58 person per group

Settings and conduct

The field of research is sexual function and marital satisfaction of women with MS and the study site is MS Association in Tehran. After obtaining the necessary permits, sampling will be done with the method of "continuous" . The researcher invites women to participate in the study by placing a notice on the walls of Hazrat Rasool Hospital and Private Neurology Clinic and telephone calls to previous hospital patients based on file access. After give the complete explanations to volunteers, the eligible ones will be selected according to the inclusion criteria. The participants will be randomly assigned to the intervention (IG) and control (CG) groups by simple random Based on the 4,6,8 blocking formula of Sealed Envelope Ltd.2020 . After completing written-consent by both groups and to prevent data leakage, CG will first complete the demographic form and questionnaires, and again will complete the questionnaires after 4 and 12 weeks from the beginning. IG will complete these forms and receive the electronic content of education (ECE) in 4 session. Questionnaires will be completed electronically by IG at weeks 4 and 12. The educational topics health promotion life style for IG will be presented in 4 sessions. Finally, a CD including ECE will be sent to CG.

Participants/Inclusion and exclusion criteria

Married women with MS, if they do not decide to divorce and do not participate in similar programs simultaneously

Intervention groups

Intervention group receive multimedia education and control group receive no intervention

Main outcome variables

Health promoting lifestyle education

General information

Reason for update

change location and sampling method

Acronym

IRCT registration information

IRCT registration number: **IRCT20200203046355N1**

Registration date: **2020-07-25, 1399/05/04**

Registration timing: **prospective**

Last update: **2021-02-12, 1399/11/24**

Update count: **1**

Registration date

2020-07-25, 1399/05/04

Registrant information

Name

Azadeh Ahadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2293 0168

Email address

ahadi1347@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-05, 1399/06/15

Expected recruitment end date

2021-03-05, 1399/12/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Assessment the effect of the health promoting lifestyle education in multimedia method on the sexual function and marital satisfaction of womens with Multiple Sclerosis

Public title
Assessment the effect of the health lifestyle education on the sexual function of womens with MS

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Married Iranian women aged 20-45 years more than six months' history of MS ability to use smartphones married more than one year ago having sex at least once in the past month ability to perform daily personal affairs
Exclusion criteria:
The decision to divorce Pregnancy Menopause Concurrent with another chronic illness Use of sleeping drugs and alcohol and drugs Facing severe crises, including the death of loved ones over the past six months Participate in similar programs to enhance marital satisfaction and sexual function

Age
From **20 years** old to **45 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **116**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants were simply randomized (by simple random allocation) and blocked (using Sealand Envelope website, simple randomizer list-maker) divided into blocks of 4, 6 and 8 people in 2 groups of intervention and control. Also sampling continues until the samples size reached 58 people in each group.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Other

Other design features
After dividing the samples by simple random allocation to the intervention and control groups, the intervention group will receive the necessary training. Then sexual

function and marital satisfaction will be compared at the end of the intervention and follow-up period.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Iran University of Medical Sciences

Street address

Floor 4, No. 18, Ladan sharghi Ave., Golzar Blvd., Sanaye St., Sayad Shirazi Highway, Tehran, Iran

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Postal code

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Approval date

2020-07-14, 1399/04/24

Ethics committee reference number

IR.IUMS.REC.1399.367

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 Function and Marital Satisfaction Score

Timepoint

Baseline, 4 and 12 weeks after baseline

Method of measurement

Questionnaire before and after training and follow-up

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group - health promoting lifestyle education in a multimedia way, with nutrition

components, health responsibility, exercise, self-fulfillment, interpersonal relationships, stress management, in four 40-minute sessions

Category

Other

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

Private neurology clinic in Tehran and Hazrat Rasool Hospital

Full name of responsible person

Azadeh Ahadi

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No. 218, Aria Doctors Complex, Mulla Sadra St, Vanak Square, Tehran, Iran AND Rasoul Akram Hospital, Mansouri St., Sattarkhan St., Tehran, Iran

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

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Full name of responsible person

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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

Iran 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**

Iran University of Medical Sciences

Full name of responsible person

Azadeh Ahadi

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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

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Person responsible for updating data

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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

Yes - There is 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

Sexual function, Marital satisfaction

When the data will become available and for how long

After2021

To whom data/document is available

Researchers, midwives, doctors, and patients with MS

Under which criteria data/document could be used

Scientific promotion of researchers and improvement of
sexual function and marital satisfaction of women with
MS

From where data/document is obtainable

Google scholar

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

Login to Google Scholar and download articles after
searching for a keyword

Comments