Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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

City

Tehran

Province

Tehran

Postal code

1693934615

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

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

City
Tehran

Province
Tehran

Postal code
1449614535

Phone
+98 21 6435 1000

Fax

Email
PR@iums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Abbas Motevalian

Street address
School of Nursing and Midwifery, Iran University of Medical Sciences, Rashid Yasimi St., Valiasr St

City
Tehran

Province
Tehran

Postal code
1996713883

Phone
+98 21 4365 1000

Fax
+98 21 8820 1978

Email
motevalian.a@iums.ac.ir

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

Street address
Unit 4, No. 18, East Ladan St., Golzar St., Tehran

City
Tehran

Province
Tehran

Postal code
1693934615

Phone
+98 21 2293 0168

Email
ahadi1347@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Masoumeh Kheirkhah

Position
Associate Professor

Latest degree
Ph.D.

Other areas of specialty/work
Midwifery

Street address
Faculty of Nursing and Midwifery, Iran University of Medical Sciences, Rashid Yasemi St, Vali-e-Asr St, Tehran, Iran

City
Tehran

Province
Tehran

Postal code

1996713883

Phone

+98 21 4365 1000

Email

shivakheirkhah1345@gmail.com

Person responsible for updating data

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

Street address

Unit 4, No. 18, East Ladan St., Golzar St., Noboniad Square, Tehran

City

Tehran

Province

Tehran

Postal code

1693934615

Phone

+98 21 2293 0168

Email

ahadi1347@ gmail

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