

# 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

##### 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

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**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

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**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

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**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**

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

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**Full name of responsible person**

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**Position**

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**Province**

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**Postal code**

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**Email**

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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**