

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### The effect of expressive writing on sexual dysfunction, quality of life and body image of women with multiple sclerosis

#### Protocol summary

##### Study aim

To determine the effect of expressive writing on levels of sexual dysfunction, quality of life and body image in women with multiple sclerosis

##### Design

Phase 2 Randomized Trial Based on Random Number Table with Control Group. The design of this study was based on 4 groups of Solomon, with 2 main intervention and control groups (52 each), each one divided into 2 groups (26 each). Primary Intervention and Control Groups: no Completion of pre-test questionnaire (to reduce the effect of pre-test questionnaires on their attitudes), secondary Intervention and control groups: Completion of the pre and post test questionnaires

##### Settings and conduct

Sampling is in The referral specialized clinic for neurological diseases in Tehran. According to the random numbers table, the individuals in the intervention group receive individual training and in the control group, after explaining the goals, they are told that they will receive training after completing the first group course

##### Participants/Inclusion and exclusion criteria

Minimum literacy, Obtain a EDSS disability score of less than 4.5, At least one year after diagnosis, No use of drugs affecting sexual desire and sexual function in couples, No chronic other disease, Having sex at least once a month during the past month, No pregnancy or lactation, No traumatic event occurring three months prior to intervention according to patient, Access and ability to use virtual networks such as WhatsApp, Lack of communication between participants and other clients in that center,

##### Intervention groups

Intervention: Individuals in the intervention group at home start writing 3 pages of morning assignments for 6 weeks and write whatever comes to their mind.  
Control: They continue their treatment routinely and are visited by a physician every 3 months. This method will explain to control subjects at the end of study

#### Main outcome variables

Sexual dysfunction; Quality of Life; Body image

#### General information

##### Reason for update

##### Acronym

MS

##### IRCT registration information

IRCT registration number: **IRCT20110629006917N4**

Registration date: **2019-12-27, 1398/10/06**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-12-27, 1398/10/06**

Update count: **0**

##### Registration date

2019-12-27, 1398/10/06

##### Registrant information

##### Name

Leila Amini

##### Name of organization / entity

Tehran University of Medical Science

##### Country

Iran (Islamic Republic of)

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##### Email address

l-amini@tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-11-22, 1398/09/01

##### Expected recruitment end date

2020-03-20, 1399/01/01

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effect of expressive writing on sexual dysfunction, quality of life and body image of women with multiple sclerosis

**Public title**

The effect of expressive writing on sexual dysfunction, quality of life and body image of women with MS

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

Minimum literacy Obtain an EDSS disability score of less than 4.5 to the physician's diagnosis At least one year after diagnosis Having sex at least once a month during the past month Access to and ability to use virtual networks such as WhatsApp Women with Multiple Sclerosis

**Exclusion criteria:**

Taking drugs that affect sexual function use of psychotropic drugs, alcohol, opiates, hallucinogens or drugs affecting sexual desire and sexual function in couples, as reported by the patient or registered in the case Chronic disease other than MS in research units pregnancy or lactation traumatic event occurring three months prior to intervention according to patient Relationship between participants with other clients in that center or non-membership of a virtual shared group

**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: **104**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

the allocation of samples in 4 groups A1 and B1 groups without pre-test, and groups A2 and B2 groups with pre-test and post-test will determine by computer random number table. And sampling will continue until completion of sample size in each The subgroups.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Factorial

**Other design features**

This study was designed as a four-group Solomon study to minimize the impact of pre-test questionnaires on attitude and subjectivity of research units. In this way we

will have two intervention and two control groups and one intervention and one control group will complete pre-test and post-test questionnaires and the other two groups will answer only post-test questionnaires (Delavar, 2016). the explanation of the four groups is as follows. Control group A1: Includes those in the control group without pre-test, who will only complete the post-test questionnaires. Control group A2: Including control group who will complete the questionnaires in two stages before and after the intervention. Intervention group B1: Includes those in the intervention group without pre-test who will only complete the post-test questionnaires. Intervention group B2: Includes those in the intervention group who will complete the questionnaires in two stages before and after the intervention.

**Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

iran national committee for Ethics in Biomedical Research

**Street address**

Floor 13, Block A, Ministry of Health & Medical Education Headquarters, Between Zarafashan & South Falamak, Qods Town, Tehran, Iran.

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**Approval date**

2019-10-15, 1398/07/23

**Ethics committee reference number**

IR.IUMS.REC.1398.763

**Health conditions studied****1****Description of health condition studied**

Multiple Sclerosis (MS)

**ICD-10 code**

G35

**ICD-10 code description**

Multiple sclerosis

**Primary outcomes****1****Description**

Sexual dysfunction

**Timepoint**

Before intervention and immediately after intervention, four weeks and eight weeks after intervention

#### **Method of measurement**

The Multiple Sclerosis Intimacy and Sexuality Questionnaire-19 (MSISQ-19)

### **2**

#### **Description**

Quality of Life

#### **Timepoint**

Before intervention and immediately after intervention, four weeks and eight weeks after intervention

#### **Method of measurement**

Multiple Sclerosis Quality of Life-54 (MSQOL-54)

### **3**

#### **Description**

Body image

#### **Timepoint**

Before intervention and immediately after intervention, four weeks and eight weeks after intervention

#### **Method of measurement**

Fisher Body Image Test

## **Secondary outcomes**

empty

## **Intervention groups**

### **1**

#### **Description**

Intervention group: This group consists of 52 married women aged 18-45 years with multiple sclerosis who will be divided into two subgroups of 26 based on Solomon's design. The first group is the intervention group without pre-test and only completes the questionnaires after the intervention. The second group will complete the questionnaires in both stages before and after the intervention. The overall six-week intervention period is designed, with participants completing assignments each week. A commitment and service contract will be provided to the participants of the intervention groups and signed prior to starting writing at home to consider performing the work as part of their duties. Finally, the research units execute the program at home on a daily basis for 6 consecutive weeks. At the core of this method of writing are two central tools of writing: morning pages and an in-person artist appointment. Morning pages are such that they will write their morning pages every morning during these 6 weeks of intervention. Generally speaking, the morning pages consist of 3 regular handwritten pages, They write freely and without thinking and do not give up on paper. There is no wrong way to write the morning pages. Even if nothing comes to mind, the three pages say "nothing comes to mind." The definition of an in-house artist meeting is that they cultivate awareness every week for a full time (eg two hours). This appointment can be the best of the kind of tour, recreation and play they can plan in advance, and

will not be canceled against any interference with or obstructions. At this meeting, no one is going to bring anyone, and we will tell them that this is a chance to listen to what you are saying. They will be told that there are probably many reasons to avoid doing this and the most common is to say that I am not in good financial shape, but the artist within you is a child who spends more time with her parents than It is money only and they can only go to shops and this principle is essential for self-care. For the sake of convenience, participants will be given five thousand dollars a week to donate to an artist within themselves. There are also a number of creative assignments each week that will be performed on different days until the end of each week. At the end of each week, an assessment will be made of how the assignments will be completed by completing the checklist

#### **Category**

Rehabilitation

### **2**

#### **Description**

Control group: This group consists of 52 married women aged 18-45 years with multiple sclerosis who will be divided into two subgroups of 26 based on Solomon's design. The first group is the intervention group without pre-test and only completes the questionnaires after the intervention. The second group will complete the questionnaires in both stages before and after the intervention. The control group is routinely monitored. After completion of the intervention group, a Justification meeting will be held for both control groups and a weekly service plan will be presented.

#### **Category**

Rehabilitation

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Specialized Clinic for Neurological Diseases and Multiple Sclerosis

##### **Full name of responsible person**

Dr. Seyed Massoud Nabavi

##### **Street address**

Mulla Sadra, Between Sheikh Baha'i and Chamran, No. 218, Arya Medical Complex, Fourth Floor, Unit 13

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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?**

No

**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**

Leila Amini

**Position**

Assistant Professor of Reproductive Health School of Nursing and Midwifery Iran University of Medica

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Reproductive Health

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## Sharing plan

### **Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

### **Justification/reason for indecision/not sharing IPD**

"No more information".

### **Study Protocol**

No - There is not a plan to make this available

### **Statistical Analysis Plan**

No - There is not a plan to make this available

### **Informed Consent Form**

No - There is not a plan to make this available

### **Clinical Study Report**

No - There is not a plan to make this available

### **Analytic Code**

No - There is not a plan to make this available

### **Data Dictionary**

No - There is not a plan to make this available