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
Phase2 Randomized Trial Based on Random Number Table with Control Group The design of this study was based on 4groups of Solomon, with 2main intervention and control groups(52each), each one divided into 2groups (26each).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 3pages of morning assignments for 6weeks 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

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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

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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

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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
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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