Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effect Of Expressive Writing On Sexual Self-Concept Of Men With Multiple Sclerosis

Protocol summary

Study aim
Determining the effect of written expression on sexual self-concept of men with multiple sclerosis

Design
Randomized control clinical trial which will done on 70 men with MS. Participants assigned to two study groups by random number table which extracted from www.randomization.com site.

Settings and conduct
The intervention will be performed in a specialized clinic for neurological diseases and multiple sclerosis located in Tehran for 4 weeks and they will express their emotions and express their feelings in writing.

Participants/Inclusion and exclusion criteria
1. Having at least one sex in the last month 2. EDSS number lower than 5.5 approved by neurologist 3. Literate men 4. Access to virtual networks such as WhatsApp 5. Monogamy 6. At least one year from marital date

Intervention groups
The intervention is designed for 4 weeks virtually through WhatsApp along with weekly follow-up. Participants will express their emotions and feelings by writing at least once a week for 15 to 30 minutes. The control group will receive only routine care.

Main outcome variables
Sexual self-concept

General information

Reason for update

Acronym
MS

IRCT registration information
IRCT registration number: **IRCT20211028052892N1**
Registration date: **2021-11-17, 1400/08/26**
Registration timing: **registered_while_recruiting**
Last update: **2021-11-17, 1400/08/26**
Update count: **0**

Registration date
2021-11-17, 1400/08/26

Registrant information

Name
malihe Mohammadzadeh Sabbaghi
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 31 5520 3392
Email address
malihe.m.7776@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-11-06, 1400/08/15

Expected recruitment end date
2022-02-18, 1400/11/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Effect Of Expressive Writing On Sexual Self-Concept Of Men With Multiple Sclerosis

Public title
Expressive Writing and Sexual Self-Concept Of Men With M.S

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:

Having at least one sex in the last month EDSS number lower than 5.5 approved by neurologist Be literate Access to virtual networks such as WhatsApp Monogamy At least one year from marital date

Exclusion criteria:

Suffering from other chronic systemic or psychiatric diseases (such as heart, respiratory diseases, etc.) Infertile Couples Use of psychiatric drugs, alcohol and drug abusers or sexual function affected drugs

Age

From **20 years** old to **50 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be assigned to two intervention and control groups randomly. Randomization will be based on the table of random numbers extracted from www.randomization.com site.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Iran University of Medical Sciences

Street address

Valid Asr St., Rashid Yasemi St., Iran School of Nursing and Midwifery, Tehran

City

Tehran

Province

Tehran

Postal code

1996713883

Approval date

2021-10-22, 1400/07/30

Ethics committee reference number

IR.IUMS.REC.1400.662

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 self-concept

Timepoint

Before, immediately and four weeks after the intervention

Method of measurement

The Multi-dimentional Sexual Self- Concept Questionnaire

2

Description

Sexual self-concept

Timepoint

Before, immediately and four weeks after the intervention

Method of measurement

The Multi-Dimentional Sexual Self- Concept Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

The intervention is designed for 4 weeks virtually through WhatsApp along with weekly follow-up. Participants will express their emotions and feelings by writing at least once a week for 15 to 30 minutes. Educational content will be taught to people via WhatsApp voice message. Also, explanations and how to implement the intervention will be provided to them in writing in the form of a message. During the intervention, communication with participants for weekly follow-up will be established only through telephone and virtual networks, including WhatsApp.

Category

N/A

2

Description

Control group: People in the control group will only receive routine care.

Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
the specialized clinics for neurological diseases and multiple sclerosis
Full name of responsible person
Maliha Mohammadzadeh Sabbaghi
Street address
No. 218, Aria Doctors Complex, Fourth Floor, Unit 14,Mulla Sadra, Between Sheikh Baha'i and Chamran
City
Tehran
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Postal code
8717764898
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+98 21 4365 1000
Email
malihe.m.7776@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr Hossein Keyvani
Street address
Ghaem 8, Hosseinpour Alley, Basij Square
City
Kashan
Province
Isfehan
Postal code
8717764898
Phone
+98 31 5520 3392
Email
malihe.m.7776@gmail.com
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
Maliha Mohammadzadeh Sabbaghi
Position
دانشجو
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
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Position
Student
Latest degree
Bachelor
Other areas of specialty/work
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Person responsible for updating data

Contact
Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Maliha Mohammadzadeh Sabbaghi

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Only part of the data, such as information about the main outcome or the like, can be shared.

When the data will become available and for how long

Access period starts 6 months after printing

To whom data/document is available

Study researchers and academics

Under which criteria data/document could be used

As long as the confidentiality of the data is not violated.

From where data/document is obtainable

Email address: malihe.m.7776@gmail.com

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

After the request, the information will be provided to him through the mentioned email within a few days.

Comments