Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Nov 2026

Effectiveness of unified protocol of transdiagnostic treatment on psychological symptoms, fatigue, emotion regulation, health anxiety, sleep quality, and sexual satisfaction in patients with multiple sclerosis

Protocol summary

Study aim

Present study aims to investigate the effectiveness of unified protocol of transdiagnostic treatment (UP) on psychological symptoms, fatigue, emotion regulation, health anxiety, sleep quality, and sexual satisfaction in patients with multiple sclerosis (MS).

Design

This randomized and single-blind clinical trial with parallel and control groups will be conducted on 48 patients who will be randomly selected using the simple random.

Settings and conduct

Patients referring to Moheb Mehr Hospital Neurology Clinic, Tehran, Iran are chosen as the participants of the study. In this single-blind study, sealed opaque envelopes will be used to conceal the sequencing. Intervention group will receive 12 sessions of online psychotherapy based on unified protocol of transdiagnostic treatment and control group will not receive the treatment intervention. The responsible for data collection is blind to group allocation and the type of intervention.

Participants/Inclusion and exclusion criteria

Statistical society of the study includes all of the MS patients in Tehran, and selected sample will be 48 patients referred to neurology clinic of Moheb Mehr Hospital. Main inclusion criteria include confirmation of diagnosis of MS, being at least 20 y/o, being sexually active, fixed dosage of medicine since 3 month before the beginning of treatment, and not having severe psychiatric and physical illnesses.

Intervention groups

Intervention group will receive 12 sessions of online psychotherapy based on unified protocol of transdiagnostic treatment and control group will not receive the treatment intervention.

Main outcome variables

Improving psychological symptoms (depression, anxiety, stress), fatigue, emotion regulation, health anxiety, sleep quality, and sexual satisfaction in MS patients.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221230056986N1**
Registration date: **2023-06-17, 1402/03/27**
Registration timing: **prospective**

Last update: **2023-06-17, 1402/03/27**
Update count: **0**

Registration date

2023-06-17, 1402/03/27

Registrant information

Name

Amir Mahdi Katani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2303 1548

Email address

katani@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-23, 1402/06/01

Expected recruitment end date

2024-08-22, 1403/06/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effectiveness of unified protocol of transdiagnostic treatment on psychological symptoms, fatigue, emotion regulation, health anxiety, sleep quality, and sexual satisfaction in patients with multiple sclerosis

Public title
Effectiveness of transdiagnostic treatment on psychological parameters in multiple sclerosis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Confirmation of relapsing-remitting multiple sclerosis diagnosis by neurologist Age least 20 years Being sexually active Mastery in Persian language and reading and writing literacy Fixed dosage of medicine from 3 months before beginning the treatment Being physically able to participate in weekly sessions Not being diagnosed with severe psychiatric disorders Not being diagnosed with another serious or chronic physical illness Not having the history of receiving psychological treatments
Exclusion criteria:
Age
From **20 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant

Sample size
Target sample size: **48**
Randomization (investigator's opinion)
Randomized
Randomization description
The process of random allocation of study participants to two groups; intervention group and control group included both creating a random sequence and concealing the random allocation. Firstly, using the random sequence rule, 48 papers for participants of the intervention and control groups (which are marked with A and B and are not defined to avoid bias) were thrown into a lottery container and then the papers were removed from the lottery container -without replacement- and the created sequence is recorded Then, using the snooze method, 48 envelopes were prepared and each of the random sequences created is recorded on a card and placed in the envelopes in order, and the envelopes were also numbered. Then, the envelopes were given to the participants based on the order of entering the study, so the grouping of each was determined.
Blinding (investigator's opinion)
Single blinded
Blinding description
Patients referring to Moheb Mehr Hospital Neurology Clinic, Tehran, Iran are chosen as the participants of the study. In this single-blind study, sealed opaque envelopes will be used to conceal the sequencing. Intervention group will receive 12 sessions of online psychotherapy based on unified protocol of transdiagnostic treatment and control group will not receive the treatment intervention. The responsible for data collection is blind to group allocation and the type of intervention.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahid Beheshti University of Medical Sciences
Street address
Shahid Beheshti University of Medical Sciences, Yaman St. Velenjak
City
Tehran
Province
Tehran
Postal code
1985717443
Approval date
2019-09-24, 1398/07/02
Ethics committee reference number
IR.SBMU.MSP.REC.1398.669

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
Psychological symptoms
Timepoint
Before intervention, after intervention, three month after

intervention

Method of measurement

Depression, Anxiety, Stress Scale (DASS-21)

2

Description

Fatigue

Timepoint

Before intervention, after intervention, three month after intervention

Method of measurement

Fatigue Severity Scale (FSS)

3

Description

Quality of sleep

Timepoint

Before intervention, after intervention, three month after intervention

Method of measurement

Pittsburgh Sleep Quality Index (PSQI)

4

Description

Sexual Satisfaction

Timepoint

Before intervention, after intervention, three month after intervention

Method of measurement

Larson Sexual Satisfaction Questionnaire (LSSQ)

5

Description

Emotion regulation

Timepoint

Before intervention, after intervention, three month after intervention

Method of measurement

Cognitive Emotion Regulation Questionnaire (SERQ)

6

Description

Health anxiety

Timepoint

Before intervention, after intervention, three month after intervention

Method of measurement

Health Anxiety Questionnaire (HAQ)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 12 sessions of online psychotherapy based on unified protocol of transdiagnostic treatment

Category

Treatment - Other

2

Description

Control group: Not receiving treatment intervention

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Moheb Mehr Hospital Neurology Clinic

Full name of responsible person

Reza Hajmanouchehri

Street address

Khalilzadeh alley, after Vanak square, Valiasr St.

City

تهران

Province

Tehran

Postal code

1319919697

Phone

+98 21 85555

Email

info@moheb.com

Web page address

https://www.moheb.com/mohebmehr/home/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

Shahid Beheshti University of Medical Sciences, Yaman St. Velenjak

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 2243 9781

Email

Mpajouhesh@sbmu.ac.ir

Web page address

https://research.sbmu.ac.ir/index.jsp?pageid=2554&p=1

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Amir Mahdi Katani

Position
Phd Student

Latest degree
Ph.D.

Other areas of specialty/work
Psychology

Street address
No 11, west Eram alley, south Bahar St, west Ferdows Blvd.

City
Tehran

Province
Tehran

Postal code
1484647366

Phone
+98 21 4411 6678

Email
amir.katani.1993@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Amir Mahdi Katani

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Person responsible for updating data

Contact

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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
Not applicable

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
SPSS file of participants data, treatment protocol of study, and informed consent form will be available if necessary.

When the data will become available and for how long
After execution of study

To whom data/document is available

Editor in chief of scientific journals

Under which criteria data/document could be used

At request of editor in chief of scientific journals

From where data/document is obtainable

By email: amir.katani.1993@gmail.com

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

Data will be sent by email after request.

Comments