

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 2026

The effectiveness of group therapy based on improving the quality of life on the meaning of life, self-compassion, emotional self-regulation and quality of life of MS patients.

Protocol summary

Study aim

Determining the effectiveness of treatment based on improving the quality of life on the meaning of life, self-compassion and emotional self-regulation and the quality of life in patients with multiple sclerosis

Design

A clinical trial study with a control group of Parallel groups, randomized groups was performed on 42 people, and random generator software was used for randomization.

Settings and conduct

The present study is applied in terms of purpose and available sampling method in the data collection method. This study is a single-blind clinical trial with a control and experimental group. Place of study: The place of study was the MS Research Center of Sina Hospital in Tehran. Study population: All adults with MS disease referring to the MS Research Center of Sinai Hospital. Therapeutic intervention in 8 one-hour group sessions based on Michael Frisch's theory, which is proposed in the book Therapy based on improving the quality of life, will be implemented at the MS Research Center of Sinai Hospital in Tehran. Blinding was not done in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Suffering from multiple sclerosis Expanded Disability Status Scale (EDSS) should be between 0 and 6 In the PANAS questionnaire, the positive emotion score should be at least 25 and the negative emotion score should be at least 35 Willingness to participate in research. Exclusion criteria: Thinking about self-harm or suicide

Intervention groups

Intervention group: Eight one-hour sessions of group therapy based on improving the quality of life will be held based on the theory of Michael Frisch, which is presented in the book Therapy Based on Improving the Quality of Life. Control group: no treatment

Main outcome variables

Meaning of life, self-compassion, emotional self-regulation, quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201009048974N5**

Registration date: **2022-12-06, 1401/09/15**

Registration timing: **registered_while_recruiting**

Last update: **2022-12-06, 1401/09/15**

Update count: **0**

Registration date

2022-12-06, 1401/09/15

Registrant information

Name

Maryam Bakhtiari

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-24, 1401/09/03

Expected recruitment end date

2023-04-23, 1402/02/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of group therapy based on improving the quality of life on the meaning of life, self-compassion, emotional self-regulation and quality of life of MS patients.

Public title

The effectiveness of group therapy based on improving the quality of life in patients with MS

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Suffering from multiple sclerosis Expanded Disability Status Scale (EDSS) should be between 0 and 6 In case of taking psychiatric drugs for depression or anxiety, at least three months have passed since the drug became stable At least six months have passed since receiving the diagnosis of MS In the PANAS questionnaire, the positive emotion score should be at least 25 and the negative emotion score should be at least 35 Willingness to participate in research

Exclusion criteria:

Failure to complete the informed consent form Thinking about self-harm or suicide participating in psychological interventions during the last year

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **42**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be simple randomization. The randomization unit is individual. Through the table of random numbers, which are produced without any particular pattern and order and are completely random and are made into a table, the names of the participants will be collected as a set of numbers and the numbers will be used to categorize different groups. Even numbers are in the intervention group and odd numbers are in the control group.

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 Shahid Beheshti University of Medical Sciences

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

2022-09-06, 1401/06/15

Ethics committee reference number

IR.SBMU.MSP.REC.1401.251

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

Multiple sclerosis disease

ICD-10 code

G35

ICD-10 code description

Multiple sclerosis disease

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

The meaning of life score in Steger et al.'s questionnaire (MLQ)

Timepoint

At the beginning of the study (before the start of the intervention), after the end of the intervention and three months after the end of the intervention

Method of measurement

Questionnaire of the meaning of life Stegar et al

2**Description**

The Self-Compassion score in the Neff questionnaire (SCS)

Timepoint

At the beginning of the study (before the start of the intervention), after the end of the intervention and three months after the end of the intervention

Method of measurement

Scale of Self-Compassion Neff (SCS)

3

Description

Emotional self-regulation score in Hoffman et al.'s questionnaire (2010)

Timepoint

At the beginning of the study (before the start of the intervention), after the end of the intervention and three months after the end of the intervention

Method of measurement

questionnaire of emotional self-regulation Hoffman et al.'s

4

Description

The quality of life score in the quality of life questionnaire for patients with multiple sclerosis (MS) made by Vickery (MSQOL-54)

Timepoint

At the beginning of the study (before the start of the intervention), after the end of the intervention and three months after the end of the intervention

Method of measurement

Vickery quality of life questionnaire for patients with multiple sclerosis (MS) (MSQOL-54)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Eight one-hour sessions of group therapy based on improving the quality of life will be held based on the theory of Michael Frisch, which is presented in the book Therapy Based on Improving the Quality of Life. In the first session, establishing communication, explaining topics related to the theory of improving the quality of life and treatment goals are discussed and a pre-test is taken. In the second session, defining the treatment based on improving the quality of life, introducing the dimensions of the quality of life, and discovering the problematic cases are done. The third session is taught to change the attitude of the quality of life through changing the attitude towards the situation, correcting any kind of distortion or negativity in thinking. In the fourth session, changing goals and criteria for learning and adopting realistic and flexible goals are taught. In the fifth session, strategies including re-prioritization evaluation and emphasis on very important and controllable areas are reviewed. In the sixth session, the last strategy is taught to strengthen the increase of self-satisfaction in another area that was not paid attention to before. The seventh session of training on the three pillars of treatment based on quality of life (inner richness, quality of time and finding meaning) will be conducted. In the eighth session, summation and

post-test will be done.

Category

Treatment - Other

2

Description

Control group: no treatment

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina hospital

Full name of responsible person

Marziye Feizi

Street address

MS Research Center, Sina Hospital, Before Hasan Abad Sq, Imam Khomeini St

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afsin Zarghi

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Vice-Chancellor of Research Affairs, Shahid Beheshti University of Medical Sciences, Next to Taleghani hospital, Erabi Ave., Chamran highway

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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

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Person responsible for general inquiries**Contact****Name of organization / entity**

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Latest degree

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be 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