Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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
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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.
City
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Province
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Postal code
1985717443
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
Street address
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

Person responsible for general inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Maryam Bakhtiari
Position
Professor
Latest degree
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Psychology
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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