Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of self-care education based on psychological well-being on self-compassion and Psychological Hardiness in patients with multiple sclerosis

Protocol summary

Study aim
The Effect of Self-Care Education Based on Psychological Well-Being on Self-Compassion and Psychological Hardiness in Patients with Multiple Sclerosis

Design
This is a single-blind randomized controlled trial involving 40 patients with multiple sclerosis. Participants will be allocated in a 1:1 ratio to intervention and control groups using block randomization with a block size of 4. Allocation concealment will be performed using numbered, opaque, sealed envelopes

Settings and conduct
A single-blind randomized controlled trial of 40 patients with multiple sclerosis. Participants will be allocated to intervention or control groups using block randomization. The intervention includes seven 60-minute self-care education sessions based on psychological well-being, with blinded outcome assessment.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Confirmed multiple sclerosis, ≥6 months since diagnosis, no psychiatric disorders, adequate cognitive ability to understand the educational content and complete questionnaires, Persian literacy, and informed consent. Exclusion criteria: Cognitive impairment or disabling conditions affecting participation or questionnaire completion, severe psychiatric disorders affecting participation or responses, and concurrent similar educational or psychological interventions affecting self-compassion or psychological hardiness

Intervention groups
The intervention group consists of patients with multiple sclerosis who will receive a structured self-care education program based on Carol Ryff's model of psychological well-being in seven educational sessions, with each session lasting 60 minutes. The comparison (control) group consists of patients with multiple sclerosis who will receive their usual care throughout the study period.

Main outcome variables
Change in self-compassion score; Change in psychological hardiness score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260718070239N1**
Registration date: **2026-09-13, 1405/06/22**
Registration timing: **registered_while_recruiting**

Last update: **2026-09-13, 1405/06/22**
Update count: **0**

Registration date
2026-09-13, 1405/06/22

Registrant information

Name
Abolfazl Ramezani

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-08-23, 1405/06/01

Expected recruitment end date
2026-12-22, 1405/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of self-care education based on psychological well-being on self-compassion and Psychological Hardiness in patients with multiple sclerosis

Public title

The Effect of Self-Care Education on Self-Compassion and Psychological Hardiness in Patients with Multiple Sclerosis

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of a psychiatric disorder by a physician, medical records, or self-report Lack of a confirmed diagnosis of multiple sclerosis Less than six months since the diagnosis of multiple sclerosis Lack of sufficient cognitive ability to understand the educational content and complete the questionnaires Inability to read and write in Persian language Willingness and informed consent to participate in the study

Exclusion criteria:

Presence of cognitive impairment that prevents the participant from understanding the educational content or completing the research instruments. Presence of a disabling illness or a self-reported condition that prevents effective participation in the educational sessions. Presence of severe psychiatric disorders that may affect the participant's participation in the intervention or ability to respond to the research instruments. Concurrent participation in similar educational programs or psychological interventions that may affect the participant's self-compassion or psychological hardiness.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

The unit of randomization in this study will be the individual participant. A total of 40 eligible participants, after meeting the inclusion criteria and providing written informed consent, will be allocated to either the intervention or control group. Block randomization with a fixed block size of four will be used, with two participants allocated to the intervention group and two participants allocated to the control group within each block. Given two study groups and a block size of four, six possible allocation sequences exist: ABAB, AABB, BABA, BBAA, ABBA, and BAAB, where A represents the intervention group and B represents the control group. Based on the sample size of 40 participants, a total of 10 blocks of four participants will be required. The sequence of blocks will be generated randomly using Randomization.com. Stratified randomization will not be used in this study. After generating the random allocation sequence, allocation concealment will be ensured by placing the group assignment for each participant in sequentially numbered, opaque, sealed envelopes. The envelopes will be opened sequentially according to the order in which eligible participants enter the study, only after completion of the enrollment process and provision of informed consent. The assigned group for each participant will then be determined. Therefore, the allocation sequence will remain concealed until the participant has been definitively enrolled in the study, preventing prior knowledge of the assigned group

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, blinding will be implemented at the outcome assessor level. The outcome assessor will be unaware of the participants' group allocation, and information regarding group assignment will not be disclosed to the outcome assessor. The assessment and evaluation of study outcomes at different stages of the study will therefore be conducted without the outcome assessor being aware of whether participants belong to the intervention or control group.

Placebo

Not used

Assignment

Other

Other design features

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Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of the School of Nursing and Midwifery and the School of Rehabilitation, T

Street address

No. 3, Nofallah Student Dormitory, Corner of Vaziri Alley, Nofallah Street, Enghelab Square, Tehran, Iran.

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1313813178

Approval date

2026-07-10, 1405/04/19

Ethics committee reference number
IR.TUMS.FNM.REC.1405.060

Health conditions studied

1

Description of health condition studied
Multiple Sclerosis(MS)
ICD-10 code
G35
ICD-10 code description
Multiple sclerosis (G35)

Primary outcomes

1

Description
Self-compassion score measured by the Neff Self-Compassion Scale
Timepoint
Self-compassion will be measured before the start of the study, after completion of the seven educational sessions, and eight weeks after the completion of the study
Method of measurement
Self-compassion will be assessed using the 26-item Self-Compassion Scale developed by Kristin Neff and colleagues in 2003. This scale consists of six components, including self-kindness, self-judgment, common humanity, isolation, mindfulness, and over-identification. The self-kindness component includes items 5, 12, 19, 23, and 26. The self-judgment component includes items 1, 8, 11, 16, and 21. The common humanity component includes items 3, 7, 10, and 15. The isolation component includes items 4, 13, 18, and 25. The mindfulness component includes items 9, 14, 17, and 22. The over-identification component includes items 2, 6, 20, and 24. To calculate the self-compassion score, the score of each component will be calculated separately, and the sum of these scores will be considered as the total self-compassion score. Responses will be rated on a 5-point Likert scale ranging from completely disagree = 1 to completely agree = 5. Higher scores indicate higher levels of self-compassion

2

Description
Psychological hardiness score measured by the Kobasa Psychological Hardiness Scale
Timepoint
Psychological hardiness will be measured before the start of the study, after completion of the seven educational sessions, and eight weeks after the completion of the study
Method of measurement
Psychological Hardiness Scale:Psychological hardiness will be assessed using the 20-item Psychological Hardiness Scale developed by Kobasa and colleagues in 1982. This scale consists of three components, including commitment, challenge, and control. The commitment component includes items 1 to 9, the control component includes items 10 to 16, and the challenge component includes items 17 to 20. To calculate the psychological hardiness score, the score of each component will be calculated separately, and the sum of these scores will be considered as the total psychological hardiness score. Responses will be rated on a 4-point Likert scale (never, rarely, sometimes, and often). Higher scores indicate higher levels of psychological hardiness

Secondary outcomes

empty

Intervention groups

1

Description
The intervention in this study consists of a structured self-care education program based on Carol Ryff’s model of psychological well-being, which will be delivered face-to-face by the researcher to participants in the intervention group.The program will be provided to 20 participants in seven educational sessions, with each session lasting 60 minutes, during the study period.The content of the sessions is as follows:Session 1: Introduction of group members, establishment of a therapeutic relationship, introduction to multiple sclerosis, the concept of self-care, the importance of self-care in disease management, and introduction to the concept of psychological well-being.Session 2: Education on self-awareness and identification of emotions, exploration of the relationship between thoughts, emotions, and behaviors, mindfulness training, and practice in identifying and recording emotions.Session 3: Education on values and meaning in life, exploration of the role of meaning and purpose in psychological well-being, introduction to the concept of self-compassion, and training in mindful breathing.Session 4: Education on positive relationships with others, the importance of social support in adaptation to the disease, identification of sources of social support, and self-compassion-related exercises.Session 5: Education on accepting personal responsibility for self-care and disease management, goal setting, strengthening the sense of control over one's life, and exploring barriers to self-care.Session 6: Training in problem-solving skills, identification and modification of dysfunctional thoughts, management of difficult emotions, and planning to achieve personal goals and maintain self-care.Session 7: Strengthening hope and motivation, promoting purposefulness and planning for continued self-care, practicing the expression of positive emotions, reviewing the content of previous sessions, summarizing the program, and answering participants' questions.The educational sessions will be delivered using various educational methods, including presentation of educational materials, lectures, group discussions, question-and-answer sessions, practical exercises, mindfulness and self-compassion exercises, feedback, and homework

assignments. At the end of each session, an exercise or homework assignment related to the session content will be assigned to the participants and reviewed during the subsequent session. The educational content will be delivered by the researcher according to a predetermined educational program.

Category

Behavior

2

Description

Control group: Participants in the control group will receive their usual care throughout the study period and will not participate in the psychological well-being-based self-care education program. Usual care includes the services and care routinely provided to patients with multiple sclerosis by healthcare centers based on their disease condition and treatment plan. Participants in the control group will complete the study assessments and relevant questionnaires at the predetermined time points according to the study protocol.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran Branch of the Iranian Multiple Sclerosis Society

Full name of responsible person

Abdolhossein Houshmand

Street address

Shahid Shams Alley, Vesal Shirazi Street, Near Taleghani Intersection, Enghelab Street, Tehran, Iran

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Email

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https://www.iranms.org/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Research Office, School of Nursing and Midwifery, Tehran University of Medical Sciences

Street address

School of Nursing and Midwifery, Tehran University of Medical Sciences, Maryam Mirzakhani Street, Nosrat Street, Tehran, Iran

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fnm-researchdeputy@tums.ac.ir

Web page address

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Abolfazl Ramezani

Position

Master’s Student in Psychiatric Nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

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Full name of responsible person
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Position
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Latest degree
Bachelor

Other areas of specialty/work
Nursery

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Person responsible for updating data

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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
Due to ethical considerations and protection of participants' privacy, individual-level data will not be shared. The collected data will only be used for research purposes and will be reported in an aggregated and anonymous manner.

Study Protocol
Yes - There is 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
Yes - There is 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

Title and more details about the data/document
...

When the data will become available and for how long
..

To whom data/document is available
..

Under which criteria data/document could be used
..

From where data/document is obtainable
..

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

Comments