# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 2026

## Studying the effectiveness of self-compassion therapy on perceived stress, self-differentiation, and functional flexibility in women with Multiple Sclerosis

## Protocol summary

**Study aim**
Studying the effectiveness of self-compassion therapy on perceived stress, self-differentiation, and functional flexibility in women with multiple sclerosis.

**Design**
A controlled clinical trial with parallel groups, without blinding, randomized, on 40 patients. The rand function of Excel software will be used for randomization.

**Settings and conduct**
The statistical population of this study includes all women with multiple sclerosis (MS) who have been given a definitive diagnosis of MS by a specialist physician and psychotherapist in a clinical interview and who will refer to the Ahvaz MS Association during the study period. In the sample selection stage, convenience sampling method will be used. After selecting the samples to a volume of 40 people based on the study's entry and exit criteria, the participants will be randomly assigned to two groups: "self-compassion therapy training" (intervention group) and "waiting list" (control group).

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: Women aged 20 to 40 years; definite diagnosis of MS by a clinical specialist. Exclusion criteria: Unwillingness to participate in the study, participation in other psychotherapy sessions concurrently with the study.

**Intervention groups**
Intervention group: All people who will receive self-compassion therapy. Control group: All people who will not receive any intervention.

**Main outcome variables**
Perceived stress, self-differentiation, functional flexibility

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20260605069653N1**
Registration date: **2026-06-08, 1405/03/18**
Registration timing: **prospective**

Last update: **2026-06-08, 1405/03/18**
Update count: **0**

**Registration date**
2026-06-08, 1405/03/18

**Registrant information**

**Name**
Maryam Savari

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

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+98 61 3333 3333

**Email address**
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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2026-07-01, 1405/04/10

**Expected recruitment end date**
2026-07-22, 1405/04/31

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
Studying the effectiveness of self-compassion therapy on perceived stress, self-differentiation, and functional

flexibility in women with Multiple Sclerosis

**Public title**
Effectiveness of Self-Compassion Training on Mental Health in Women with Multiple Sclerosis
**Purpose**
Education/Guidance
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Women between the ages of 20 and 40 years Definitive diagnosis of MS by a clinical specialist
**Exclusion criteria:**
Unwillingness to participate in research Participating in other psychotherapy sessions at the same time as the research
**Age**
From **20 years** old to **40 years** old
**Gender**
Female

**Phase**
N/A
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **40**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
The statistical population of this study includes all women with multiple sclerosis who have been given a definitive diagnosis of multiple sclerosis by a specialist physician and psychotherapist in a clinical interview and who will refer to the MS Association during the study period. In the sample selection stage, convenience sampling method will be used. After selecting a sample of 40 people based on the study's entry and exit criteria, participants will be randomly assigned to two groups: "self-compassion therapy training" (intervention group) and "waiting list" (control group). Randomization will be performed using the random block method with variable sizes (4 and 6 people) by an independent statistician who is not involved in the implementation process. The random allocation list will be generated using the RAND function in Excel software and then placed in opaque, sealed, and numbered envelopes so that the researcher and participants are not aware of the allocation sequence (allocation concealment). Opening the envelope and informing the group allocation will only be done when each participant enters the study. To ensure the equality of the baseline variables (such as anxiety level, age), their distribution in the two groups will be examined during the statistical analysis stage.
**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 Islamic Azad University of Ahvaz Branch
**Street address**
Opposite Keshavarz Street, Farhang Shahr, Golestan Highway
**City**
Ahvaz
**Province**
Khouzestan
**Postal code**
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**Approval date**
2026-05-26, 1405/03/05
**Ethics committee reference number**
IR.IAU.AHVAZ.REC.1405.137

## 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**
Perceived Stress
**Timepoint**
1. Pre-test (before the start of the intervention) 2. Post-test (immediately after the end of the intervention period) 3. One-month follow-up after the intervention
**Method of measurement**
The method of measurement will be the Cohen et al. (1983) Perceived Stress Questionnaire.

### 2

**Description**
Self-Differentiation
**Timepoint**
1. Pre-test (before the start of the intervention) 2. Post-test (immediately after the end of the intervention period) 3. One-month follow-up after the intervention
**Method of measurement**
The measurement method will be the Skowron and Friedlander (1998) differentiation questionnaire.

**3**

**Description**
Functional Flexibility
**Timepoint**
1. Pre-test (before the start of the intervention) 2. Post-test (immediately after the end of the intervention period) 3. One-month follow-up after the intervention
**Method of measurement**
The measurement method will be using the Connor and Davidson (2003) Functional Flexibility Questionnaire.

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**
Intervention group: Self-compassion therapy; Duration: 90 minutes; Number of sessions: 8 sessions; Sequence of sessions: twice a week; Tools: Body-focused mindfulness, compassionate imagery, thought-distancing techniques (for resilience), and emotional boundary exercises (for self-differentiation). Session summary: Session 1: Pre-test; Introduction to the concepts of compassion and its connection with acceptance of MS disease conditions. Session 2: Recognition of the "inner critic" and its effect on perceived stress; Separation of one's feelings from the psychological burden caused by the disease. Session 3: Mindfulness training for managing physical pain; Practice soothing breathing to reduce stress responses of the nervous system. Session 4: Strengthening self-differentiation; Learning to have an "observing self" against the psychological pressures of the environment and others. Session 5: Promoting functional flexibility; Using the compassionate letter writing technique to change the response from "avoidance" to "active acceptance". Session 6: Examining barriers and fears to self-compassion; confronting emotions such as grief or anger regarding physical changes. Session 7: Practicing compassionate imagery to rebuild a compassionate view of the "body"; establishing coping strategies for dealing with stressors of illness. Session 8: Integration; focusing on maintaining autonomy and healthy boundaries (differentiation); implementing a post-test and follow-up plan.
**Category**
Treatment - Other

**2**

**Description**
Control group: The control group will not receive any intervention during the research, but to prevent factors that threaten the internal validity of the research, such as compensatory competition from the control group or demoralization, they will receive a self-compassion therapy intervention after data collection.
**Category**
Treatment - Other

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Ahvaz MS Association
**Full name of responsible person**
Maryam Savari
**Street address**
Faculty of Rehabilitation, Golestan Hospital, Golestan Alley
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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Islamic Azad University
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Aslan Egdarnezhad
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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**
Islamic Azad University
**Proportion provided by this source**
100
**Public or private sector**
Private
**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**
Islamic Azad University

**Full name of responsible person**
Maryam Savari

**Position**
Master's student

**Latest degree**
Bachelor

**Other areas of specialty/work**
Psychology

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## Person responsible for scientific inquiries

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**Other areas of specialty/work**
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## Person responsible for updating data

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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**
Not applicable

**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**
Not applicable

**Data Dictionary**
Not applicable