

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

the effect of implementing self-compassion training program on self-compassion, adherence to treatment and anxiety of patients with multiple sclerosis

Protocol summary

Study aim

Investigating the effect of implementing an educational program on self-compassion and adherence to treatment in patients with multiple sclerosis

Design

The order of the blocks was determined randomly using a table of random numbers, and then the patients will enter the intervention or control group based on the blocks.

Settings and conduct

The program is in the form of 8 sessions during which the self-compassion program will be given theoretically and practically to the patients of the intervention group. The classes schedule will be informed to the samples and they were reminded that participation in all sessions is not mandatory. After one and three months of the implementation of the educational intervention, the post-test will be conducted and the questionnaires will be completed again. The control group will not receive education except usual care.

Participants/Inclusion and exclusion criteria

1- The definitive diagnosis of multiple sclerosis 2- Minimum literacy is a diploma. 3- No history of joint problems, no previous contraction and deformation in joints and neuro-muscular disorders.

Intervention groups

Considering the answers given to the forms and questionnaires by the patients, the designed self-compassion program was implemented. This program was in the format of 8 sessions and the average duration of the sessions was 45 minutes, during which the self-compassion program was theoretically and practically given to the patients of the intervention group, and during three months for the implementation of those patients through the presence of the researcher at the association and with Telephone follow-ups are supported.

Main outcome variables

Adherence to treatment and anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231114060052N1**

Registration date: **2023-12-10, 1402/09/19**

Registration timing: **registered_while_recruiting**

Last update: **2023-12-10, 1402/09/19**

Update count: **0**

Registration date

2023-12-10, 1402/09/19

Registrant information

Name

farshid saeedinezhad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3342 2567

Email address

farshidsaeedinezhad@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-23, 1402/08/01

Expected recruitment end date

2023-12-22, 1402/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

the effect of implementing self-compassion training program on self-compassion, adherence to treatment and anxiety of patients with multiple sclerosis

Public title

the effect of implementing self-compassion training program on self-compassion, adherence to treatment and anxiety of patients with multiple sclerosis

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

The research sample in this study included all patients with multiple sclerosis, members of the Multiple Sclerosis Association of Zahedan city, whose disease was confirmed by a neurologist and at least 6 months had passed since the diagnosis of their disease.

Exclusion criteria:

Occurrence of serious complications of the disease (severe movement disorder, vision), hospitalization or death of the patient during the study. Absence of more than one session in the workshop.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: 80

Randomization (investigator's opinion)

Randomized

Randomization description

After obtaining written consent from the patient's legal guardian, they were assigned to two intervention and control groups by random allocation method and using permutation blocks. Considering that two groups are considered in the study, patients were allocated in six cases of blocks of four. (A care program group and B control group, for example AABB, ABAB, BBAA,...). There were two people from each group in each block. The order of the blocks was randomly determined using a table of random numbers, and then the patients were assigned to the intervention or control group based on the blocks. In this way, the researcher interviewed the patient, for each of the participants, the subject of the research, the objectives, the stages of the research, the voluntary nature of the participation in this research and the confidentiality of the information were explained, and finally, a written consent form was obtained from the patient or family and explained to the samples. It was given that they have the freedom to leave and continue the study, their non-participation or withdrawal will not affect their treatment

Blinding (investigator's opinion)

Single blinded

Blinding description

The patients of the MS center did not know which group they were in (intervention or control) and the training sessions were held in another place where they had no contact with the control group.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

National system of ethics

Street address

Golestan town, Farsh street, address 15

City

SHIRAZ

Province

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Postal code

07189470003

Approval date

2023-09-09, 1402/06/18

Ethics committee reference number

IR.SUMS.NUMIMG.REC.1402.072

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

multiple sclerosis

ICD-10 code

G37.9

ICD-10 code description

Demyelinating disease of central nervous system, unspecified

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

Adherence to treatment and anxiety

Timepoint

Start studying, 1 and 3 months later

Method of measurement

questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: eight 45-minute sessions that were conducted in the form of an eight-day workshop twice a week for four weeks to the patients (in the MS Association of Zahedan) by a researcher and a consultant under the supervision of research team members and a neurologist. Session 1: Acquaintance and awareness: talk about the purpose of the meeting and its overall construction, (goal: checking the expectations of the treatment plan, getting to know the general principles of compassion-focused treatment. Explaining the disease, its causes, symptoms, methods treatment, diagnostic methods and complications of multiple sclerosis). Session 2: Introduction of self-compassion and self-criticism. (Aim: review of the previous session and review of how members deal with themselves (critical and self-compassionate style). Definition of self-criticism and its causes and consequences. Session 3: Introduction of the characteristics and skills of compassion. self and how it affects the mental states of the person, (purpose: review the assignment and review of the previous session; what is self-compassion? examining its characteristics and skills and how it affects the mental states of the person, introducing the three emotional regulation systems and how to interact with them Session 4: Introduction to mental imagery, (goal: Reviewing the assignment and review of the previous session introducing mental imagery and its logic. Teaching imagery practice and its implementation in the group (Imagination of color, place and characteristics of a compassionate person). Session 5: Education self-compassion and introduction of concepts: wisdom, ability, warmth and responsibility (goal: checking the assignment and review of the previous session; cultivating self-compassion and introduction of concepts: wisdom, ability, warmth and responsibility-responsibility in creating compassion, teaching how to portray about self-compassion).Session 6: Teaching self-compassion letter writing (goal: checking the assignment and reviewing the previous session of teaching self-compassion letter writing).Session 7: Explaining the fear of self-compassion and identifying thoughts that prevent the development of self-compassion (goal: Examining the assignment and review of the previous session fear of compassion to self-identify thoughts preventing the development of compassion for oneself and the user on them). their results from the group)

Category

Lifestyle

2

Description

Control group: they will not receive education except usual care and at the same time interval as the intervention group, the post-test will also be done from the control group

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Zahedan city MS center

Full name of responsible person

Ali Raza Durrani

Street address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

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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

Shiraz 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**

Shiraz University of Medical Sciences

Full name of responsible person

Farshid Saidinezhad

Position

student

Latest degree

Master

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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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

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

All personal information is kept confidential

When the data will become available and for how long

2024

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

Free access to the statistical data of this study will be given

From where data/document is obtainable

Vice President of Research and Technology of Shiraz University of Medical Sciences

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

A written request from the Deputy of Research and Technology of Shiraz University of Medical Sciences

Comments