

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Comparison of the effectiveness of mindfulness with routine care on resilience ,quality of life and individual independence in patients with spinal cord injury

Protocol summary

Study aim

Determining the effect of mindfulness-based stress reduction method on resilience, quality of life and individual independence of spinal cord injury patients referred to medical centers affiliated to Kerman University of Medical Sciences.

Design

A randomized, double blinded, clinical trial design of 62 patients. Randomization implemented by random function of Excel software.

Settings and conduct

Spinal cord injury patients referred to the rehabilitation centers of Kerman University of Medical Sciences were randomly divided into control and intervention groups. Patients, statistician, and the data control and safety monitoring committee are blinded to the group allocation.

Participants/Inclusion and exclusion criteria

Entry conditions: At least 12 weeks have passed since the onset of the disease and up to a maximum of 5 years ;these people are selected from the 18-year-old age group without any age limit ;The ability to communicate in Farsi ;Having a mobile phone with Android system; The patient has not participated in similar research in the last 3 months Non-entry conditions: Withdrawal of cooperation; Using psychotropic drugs, neuropsychiatric drugs and under the treatment of a psychiatrist; Previous experience of a similar intervention; Diseases associated with lesions in the studied sample

Intervention groups

In this study, the intervention of MBSR (Mindfulness-based stress reduction) is conducted in 90-minute face-to-face sessions weekly in groups of 5-16 people or individually for 8 weeks. Group sessions are held for patients who have the possibility to attend rehabilitation centers. Individual sessions in the researcher's presence are held at the patients' homes. The control group

includes patients with the same conditions except they receive only routine medical care at home.

Main outcome variables

resilience; quality of life; individual independence

General information

Reason for update

Acronym

MBSR ↓ Mindfulness based stress reduction

IRCT registration information

IRCT registration number: **IRCT20220813055673N1**

Registration date: **2022-12-11, 1401/09/20**

Registration timing: **prospective**

Last update: **2022-12-11, 1401/09/20**

Update count: **0**

Registration date

2022-12-11, 1401/09/20

Registrant information

Name

Reyhane Sarabandi

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-05, 1401/10/15

Expected recruitment end date

2023-06-05, 1402/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of mindfulness with routine care on resilience ,quality of life and individual independence in patients with spinal cord injury

Public title

The effect of mindfulness on resilience ,quality of life and individual independence in patients with spinal cord injury

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

At least 12 weeks have passed since the onset of the disease and up to a maximum of 5 years They must have the ability to use a mobile phone, so these people are selected from the 18-year-old age group without any age limit The ability to communicate in Farsi Having a mobile phone with an Android system and media applications The patient has not participated in similar research such as cognitive therapy or psychotherapy in the last 3 months

Exclusion criteria:

Withdrawal of cooperation Using psychotropic drugs, neuropsychiatric drugs and under the treatment of a psychiatrist Previous experience of a similar intervention on the patient Diseases associated with lesions in the studied sample, such as cognitive disorders and physical diseases such as cardiovascular disorders, diabetes, etc.

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **62**

Randomization (investigator's opinion)

Randomized

Randomization description

According to the availability of the list of patients referred to two support centers, the list will be given to the statistician. The statistician who is blinded to the allocation codes to the groups, divides the 62 people with the dropout rate, into either the control or intervention group which is provided by Excel software.

Blinding (investigator's opinion)

Double blinded

Blinding description

The list is provided to the statistician, and he assigns

people to each of the control and intervention groups according to the number of participants, which is 62 people including the dropout, using Excel software and without knowing the allocation of codes to the groups. In this study, statisticians, Data Safety and Monitoring Committee and patients will be blinded to the groups.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Kerman University of Medical Sciences

Street address

No. 2, Ibn Sina Street, Deputy of research and technology Bldg.

City

Kerman

Province

Kerman

Postal code

7616913555

Approval date

2022-11-13, 1401/08/22

Ethics committee reference number

IR.KMU.REC.1401.363

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

spinal cord injury

ICD-10 code

S24.109S

ICD-10 code description

Unspecified injury at unspecified level of thoracic spinal cord, sequela

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

The score of Conner & Davidson resilience Questionnaire

Timepoint

At the point of recruitment day, 8weeks and 1 month later

Method of measurement

Conner & Davidson Resilience questionnaire

2

Description

Spinal cord injury Quality of life

Timepoint

At the point of recruitment day, and 1 month later

Method of measurement

SCI QL23 (Spinal cord injury Quality of life questionnaire)

3

Description

Spinal cord Independence

Timepoint

At the point of recruitment day, 8weeks and 1 month later

Method of measurement

SCIM III(Spinal cord Independence Measure)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this research, the intervention is Mindfulness based stress reduction in the form of 8 weekly face-to-face sessions of 90 minutes in the format of groups of 5-16 people for patients who have the possibility to attend treatment centers and to conduct the same sessions individually with the presence of the researcher at the patients' homes. In between the sessions, the researcher accompanies the patients online and provides them with the educational content of each session in the form of an audio file on the day of the training and reminds them of the daily repetition of the previous sessions.

Category

Rehabilitation

2

Description

Control group: 31 people who answer the questionnaires at all three specified times are included in the control group, which will not receive any special training except routine care at home during the intervention period. If there will be positive effect of the training on outcome measures, the intervention will be conducted for control group too.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Rehabilitation centers of Kerman University of Medical

Sciences

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Omsalimeh Roudi Rashtabadi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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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

Not applicable