

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

Comparing the effectiveness of Mindfulness-Based Cognitive Therapy with Diet Modification on swallowing function in patients with Multiple Sclerosis

Protocol summary

Study aim

Effectiveness of Mindfulness-Based Cognitive Therapy on swallowing function in patients with Multiple Sclerosis (MS)

Design

This is a Randomized Control Trial with active control group, parallel group trial with blinded outcome assessment. Block Randomizing method will be used to randomization.

Settings and conduct

This study will be accomplished in MS center of Kashani Hospital in Isfahan. In order to outcome assessment blinding in this single blind study, the evaluator will be unaware of the type of intervention that each patient will receive.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients who are 20-60 years of age; diagnosed with MS based on MRI; dysphagia diagnosis based on MASA examination. Non-inclusion: Have a score below 23 on the Mini Mental State Examination; have relapse of disease in the previous month; have a history of dysphagia prior to MS symptom onset; have severe depression or another known psychiatric diagnosis; patients do not want to participate in the study

Intervention groups

Intervention group: will receive Mindfulness-Based Cognitive Therapy (MBCT) and diet modification. The patients undergo a 8 weekly sessions of 1 h each with additional all-day exercise and homework of 1 h for MBCT. Control group: will receive diet modification. In this group, recommendations for changing the food texture are based on the International Dysphagia Diet Standardisation Committee (IDDSI). All patients in both intervention and control groups will be receive diet modification as a 30-minute session per week.

Main outcome variables

Primary outcome measure is swallowing function and

secondary outcome measures are psychological symptoms and use of emotional regulation strategies.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200521047537N1**

Registration date: **2020-06-26, 1399/04/06**

Registration timing: **registered_while_recruiting**

Last update: **2020-06-26, 1399/04/06**

Update count: **0**

Registration date

2020-06-26, 1399/04/06

Registrant information

Name

zahra sadeghi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

za.sadeghi@uswr.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-09, 1399/03/20

Expected recruitment end date

2020-08-20, 1399/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparing the effectiveness of Mindfulness-Based Cognitive Therapy with Diet Modification on swallowing function in patients with Multiple Sclerosis

Public title
Effect of Mindfulness-Based Cognitive Therapy on swallowing in Multiple Sclerosis

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 Diagnosed MS and MRI confirmation of disease Patients who are 20-60 years of age range Dysphagia diagnosis based on MASA examination
Exclusion criteria:
 Do not want to participate in the study Have a score below 23 on the Mini Mental State Examination (MMSE) Have relapse of disease in the previous month Have a history of dysphagia prior to MS symptom onset Have severe depression or another known psychiatric diagnosis (were taking antidepressant and/or anxiolytic drugs)

Age
From **20 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **44**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomizing will be accomplished using block randomization method. Sequence allocation will be determined through a web portal site (<https://www.sealedenvelope.com/simple-randomiser/v1/ists>). Concealment will be achieved by sequentially numbered, opaque, sealed envelopes.

Blinding (investigator's opinion)
Single blinded

Blinding description
Patients with MS are randomly allocated into one of two intervention or control groups. In this study the assessor are not aware of the groups each patient belongs to.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

University of Social Welfare and Rehabilitation Science

Street address

Koodakyar close-end alley, Daneshjoo boulevard, Evin

City

Tehran

Province

Tehran

Postal code

1985713871

Approval date

2019-07-07, 1398/04/16

Ethics committee reference number

IR.USWR.REC.1398.042

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

Swallowing function

Timepoint

Before and after the treatment

Method of measurement

Mann Assessment of Swallowing Ability (MASA) examination

Secondary outcomes

1

Description

Depression

Timepoint

Pre and post treatment

Method of measurement

Depression subscale of Depression, Anxiety and Stress scale (DASS)-21

2

Description

Emotion regulation

Timepoint

Pre and post treatment

Method of measurement

Emotion Regulation Questionnaire

3

Description

Anxiety

Timepoint

Pre and post treatment

Method of measurement

Anxiety subscale of Depression, Anxiety and Stress scale (DASS)-21

4

Description

Stress

Timepoint

Pre and post treatment

Method of measurement

Stress subscale of Depression, Anxiety and Stress scale (DASS)-21

Intervention groups

1

Description

Intervention group (Combined treatment): Patients in this group will receive Mindfulness-Based Cognitive Therapy (MBCT) with a conventional dysphagia treatment. We use the protocol of MBCT was developed by Segal in 2002. The patients undergo a 8 weekly one-hour sessions with additional all-day exercise and one-hour homework. Also, patients will receive a 30-minute session per week for diet modification as a conventional dysphagia treatment.

Category

Rehabilitation

2

Description

Active control group: The control group will receive diet modification. Recommendations for changing the food texture are based on the International Dysphagia Diet Standardisation Committee (IDDSI). The patients undergo a 30-minute session per week for food texture modification.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Kashani Hospital

Full name of responsible person

Dr. Fereshteh Ashtari

Street address

Kashani Street

City

Isfahan

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Isfahan

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moavenat-amouzeshti@dean.ui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of social welfare and rehabilitation sciences

Full name of responsible person

Dr Zahra Sadat Ghoreishi

Street address

Koodakyar close-end alley, Daneshjoo boulevard, Evin

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centlib@uswr.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

University of social welfare and rehabilitation 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

University of social welfare and rehabilitation sciences

Full name of responsible person

Zahra Sadeghi

Position

Ph.D. candidate

Latest degree

Master

Other areas of specialty/work

Speech therapy

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All patient documentation, including participants' demographic and clinical information, will be shared after making individuals unidentifiable, and also the outcomes can be provided.

When the data will become available and for how long

Access started in 1399

To whom data/document is available

The data will be available to researchers working in academic and scientific institutions

Under which criteria data/document could be used

The information will be made available to researchers who want to continue to plan or compare results with other treatments.

From where data/document is obtainable

Department of Speech Therapy University of Social Welfare and Rehabilitation Sciences Dr. Zahra Sadat Ghoreishi za.ghoreyshi@uswr.ac.ir

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

Visit to department of Speech Therapy of University of Social Welfare and Rehabilitation Sciences. The applicant was provided with information for about a week

Comments