Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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
+98 21 2218 0043

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/lists). 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
Province
Isfehan
Postal code
۸۱۸۳۹-۸۳۴۳۴
Phone
+98 31 3233 0091
Fax
Email
moavenat-amouzeshi@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
City
Tehran
Province
Tehran
Postal code
۱۹۸۵۷۱۳۸۳۴
Phone
+98 21 2218 0043
Email
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
Street address
Koodakyar Avenue, Velenjac
City
Tehran
Province
Tehran
Postal code
۱۹۸۵۷۱۳۸۳۴
Phone
+98 21 2218 0043
Fax
+98 21 2218 0043
Email
za.sadeghi@uswr.ac.ir

Person responsible for scientific 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
Street address
Koodakyar Avenue, Velenjac
City
Tehran
Province
Tehran
Postal code
۱۹۸۵۷۱۳۸۳۴
Phone
+98 21 2218 0043
Fax
+98 21 2218 0043
Email
za.sadeghi@uswr.ac.ir

Person responsible for updating data

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
Street address
Koodakyar Avenue, Velenjac
City
Tehran
Province
Tehran
Postal code
۱۹۸۵۷۱۳۸۳۴
Phone
+98 21 2218 0043
Fax
+98 21 2218 0043
Email
z.sadeghi.st@gmail.com

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