Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of the early swallowing intervention for prevention of dysphagia in patient with multiple sclerosis

Protocol summary

Study aim
Determining the effectiveness of early swallowing intervention on preventing dysphagia in patients with multiple sclerosis

Design
The clinical trial has a control group, parallel groups, double-blind, and randomized. The sample size was obtained during implementation. use Excel for randomization.

Settings and conduct
The study sample consists of patients with MS referring to medical centers affiliated with Iran and Tehran Universities of Medical Sciences. Patients will be allocated between the two groups using random allocation in creating a random sequence and observing allocation concealment using the variable block method. Given that the sample size of the study will be determined during implementation, precise allocation to blocks is not currently possible, but at least 5 codes for the first method and 5 codes for the second method will be included in each block.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Based on the diagnosis of a specialist, the patient has MS. The participant's MASA score should be between 180-199 The participant does not receive a negative score on the DYMAS screening test. The age range of the participant is 18-55 years. The disease has not relapsed within a month and is not being treated with steroid medications. The patient has not undergone any treatment program to improve her swallowing disorder. Exclusion criteria: Reflux during treatment pregnancy The patient's unwillingness to continue the treatment process Recurrence of the disease

Intervention groups
Patients in the experimental group will receive swallowing therapy interventions such as swallowing maneuvers, oral motor exercises, and sensorimotor exercises. The control group will receive usual care from a nurse or doctor.

Main outcome variables
Early intervention and treatment for patients with MS can help prevent dysphagia.

General information

Reason for update

Acronym
MS

IRCT registration information
IRCT registration number: **IRCT20250609066145N1**
Registration date: **2025-07-15, 1404/04/24**
Registration timing: **registered_while_recruiting**

Last update: **2025-07-15, 1404/04/24**
Update count: **0**

Registration date
2025-07-15, 1404/04/24

Registrant information

Name
Minoo Shahbazifar

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-07-11, 1404/04/20

Expected recruitment end date
2026-05-15, 1405/02/25

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of the early swallowing intervention for prevention of dysphagia in patient with multiple sclerosis

Public title
Early intervention of dysphagia in patient with multiple sclerosis
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Based on the diagnosis of a specialist, the patient has MS. The participant's MASA score should be between 180-199 (with emphasis on signs of inability to close the lips, drooling, decreased strength and range of motion of the tongue, decreased laryngeal ascent, and hoarseness). The participant does not receive a negative score on the DYMAS screening test. The age range of the participant is 18-55 years. The disease has not relapsed within a month and is not being treated with steroid medications. The patient has no history of cognitive or dysarthric speech disorders. The patient does not have psychological disorders. The patient has not undergone any treatment program to improve her swallowing disorder. There is no history of comorbidities such as stroke, Parkinson's, cervical spinal cord injury, concussion, myasthenia gravis, and amyotrophic lateral sclerosis in the patient's medical history.
Exclusion criteria:
Refluxed during treatment pregnancy The patient's unwillingness to continue the treatment process Recurrence of the disease
Age
From **18 years** old to **55 years** old
Gender
Both

Phase
0
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **5**
More than 1 sample in each individual
Number of samples in each individual: **5**
In order to determine the sample size, at least 5 patients will be randomly assigned to each group, and then, based on the analysis during implementation, the overall sample size of the study will be determined.
Randomization (investigator's opinion)
Randomized
Randomization description
The research sample includes patients with MS referring to medical centers affiliated with Iran and Tehran Universities of Medical Sciences, who will be included in the study using a convenience sampling method. Patients who meet the inclusion criteria will be allocated between the two groups using random allocation in creating a random sequence and observing allocation concealment using the variable block method. Given that the sample size of the study will be determined during implementation, it is not possible to specify the exact specifications of the blocks after each block at this time, but at least 5 codes from the first method and 5 codes from the second method will be included in each block. Each block will be placed in a box containing opaque envelopes with two treatment method codes. The blocks will be used for the lottery one after the other. The envelopes will be in the possession of the secretary, who will randomly select an envelope and give it to the patient. The patient then hands the therapist a sheet containing the name of their treatment group. Considering the effect of intervening variables on the dependent variables of the study, when assigning samples to groups, attention is paid to the homogeneity of the two groups in intervening variables.
Blinding (investigator's opinion)
Double blinded
Blinding description
The current study is a double-blind study in which the assessor and patients in the study are blinded.
Placebo
Not used
Assignment
Parallel
Other design features
In order to determine the sample size, at least 5 patients will be randomly assigned to each group, and then, based on the analysis during implementation, the overall sample size of the study will be determined.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Iran University of Medical Sciences
Street address
Faculty of Rehabilitation Sciences, Iran University of Medical Sciences, Mirdamad, Shah Nazari St., Madadkaran St.
City
Tehran
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Tehran
Postal code
89171683192
Approval date
2025-06-13, 1404/03/23
Ethics committee reference number
IR.IUMS.REC.1404.102

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
MASA questionnaire score, Robbins-Kelly test score, patient age
Timepoint
Before intervention, after intervention, 2 months after intervention, 4 months after intervention, 6 months after intervention
Method of measurement
Dymas screening test, Disability Assessment Index, Massa questionnaire, Robbins and Kelly test

Secondary outcomes

1

Description
What is the MASA score in each of the evaluation phases for the therapy group?What is the average score of the Robbins-Kelly test in each of the evaluation phases, divided by treatment groups?
Timepoint
2 months after intervention, 4 months after intervention, 6 months after intervention
Method of measurement
Dysphagia in Multiple Sclerosis screening tool to determine the presence or absence of swallowing disorder, Expanded Disability Status Scale tool to measure the patient's disability, Mann Assessment of Swallowing Ability questionnaire to determine swallowing problems in MS patients, Robbins and Kelly questionnaire to determine the motor part of the speech organs and swallowing

Intervention groups

1

Description
Intervention group: There is an intervention group where patients in this group will receive swallowing therapy interventions such as swallowing maneuvers, sensory-motor interventions, and motor interventions.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Sina Hospital
Full name of responsible person
Leila Ghelichi
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Sponsors / Funding sources

1

Sponsor
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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
Iran 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
Iran University of Medical Sciences

Full name of responsible person
Leila Ghelichi

Position
The master student

Latest degree
Bachelor

Other areas of specialty/work
Speech therapy

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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
In this study, data from the MASA, Robs & Kley, and EDSS questionnaires can be shared as patient outcomes and before and after results after de-identification.

When the data will become available and for how long
The data will be available in a paper about a year from now.

To whom data/document is available
The data will also be accessible just for academic researchers.

Under which criteria data/document could be used
For individuals, only the patient's gender and scores before and after the assessments will be available.

From where data/document is obtainable
Dr.Leila Ghelichi lghelichi@gimail.com Minoo Shahbazifar mino.shahbazifar@gmail.com

What processes are involved for a request to access data/document
After the requester has made a request and explained his/her need for access to the documents, the information will be sent to the requester after review and if the team agrees.

Comments