

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 2026

The effect of tele-traditional dysphagia therapy in comparison with tele-usual care on swallowing function in patients with multiple sclerosis

Protocol summary

Study aim

The effect of tele-traditional dysphagia therapy in comparison with tele-usual care on swallowing function in MS

Design

The present study was a one-way blind clinical trial in which a SLP screened for dysphagia in patients with MS using the Dimas ten-item questionnaire. Following the completion of the assessment process, patients are randomly divided into two groups: control (tele-usual care) and experimental (tele-traditional treatment).

Settings and conduct

The SLP of the Eligible patients selected from Sina Hospital and screened dysphagia in patients with MS using the Dimas ten-item questionnaire. If a patient with dysphagia is identified, in order to accurately assess swallowing function and quality of life associated with swallowing, the MASA clinical test (Appendix 3) and the SWAL-QOL questionnaire (Appendix 4) are performed, respectively, and patients are randomly divided into two control and experimental groups.

Participants/Inclusion and exclusion criteria

1. Diagnosis of MS 2. No history of cognitive impairment 3- Confirmation of patient's swallowing disorder based on Dimas questionnaire 4- Age range 60-20 years 5- No recurrence of the disease in a recent month 6- No vision and hearing problems 7- Suitable motor independence for sitting 8. Patients' access to the Internet and telecommunication services (computer / mobile system) Exclusion criteria 1- Deficiency in completing the questionnaire of disease recurrence and occurrence of MS attacks during the treatment period 2. The patient's unwillingness to continue 3. The patient dies 4- Lack of regular participation of the person in sessions

Intervention groups

The control received only tele-usual care and the experimental received both tele-traditional dysphagia treatment and tele-usual care.

Main outcome variables

Determining the effectiveness of tele-traditional dysphagia treatment on swallowing function in dysphagic in MS

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210529051428N1**

Registration date: **2022-02-01, 1400/11/12**

Registration timing: **registered_while_recruiting**

Last update: **2022-02-01, 1400/11/12**

Update count: **0**

Registration date

2022-02-01, 1400/11/12

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-01, 1400/10/11

Expected recruitment end date

2022-03-10, 1400/12/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of tele-traditional dysphagia therapy in comparison with tele-usual care on swallowing function in patients with multiple sclerosis

Public title
tele- dysphagia treatments in patients with multiple sclerosis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosis of MS No history of cognitive impairment Confirmation of patient's swallowing disorder based on Dimas questionnaire Age range 20-60 years No recurrence of the disease in a recent month No vision and hearing problems Independent movement independence for sitting Patients' access to the Internet and telecommunication services (computer / mobile system). Exclusion criteria: Deficiency in completing the questionnaire of disease recurrence and occurrence of MS attacks during the treatment period The patient's unwillingness to continue treatment The patient dies Lack of regular and continuous participation of the person in treatment sessions
Exclusion criteria:
Recurrence of the disease and occurrence of MS attacks during the treatment period The patient's unwillingness to continue treatment Death of the patient Lack of regular and continuous participation of the person in treatment sessions

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

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Data and Safety Monitoring Board

Sample size
Target sample size: **15**

Randomization (investigator's opinion)
Randomized

Randomization description
All MS patients referred to the MS Clinic and MS Research Center of Sina Hospital will be examined. Patients with admission requirements will be included in the study and will be available by control sampling method and block randomization in each of the control groups (usual care) and experimental (usual care and traditional dysphagia therapy). For this purpose, an envelope containing the names of the treatment groups (usual care / traditional dysphagia therapy) will be provided to the clinic secretary. The secretary randomly removes a sheet from the envelope and hands it to the patient. The patient will submit a sheet containing the name of their treatment

group to the therapist.

Blinding (investigator's opinion)
Single blinded

Blinding description
Patients with MS will not be aware of the treatment used. However, the evaluator (speech and language pathologist) or the therapist will know about the treatment groups because the evaluations will be done after the separation of the type.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics committee of Iran University of Medical Sciences

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Shahid Hemmat Highway between Sheikh Fazl ...
Nouri and Shahid Chamran Iran University of Medical Sciences,Tehran,Iran

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Tehran

Province
Tehran

Postal code
1545913487

Approval date
2022-02-01, 1400/11/12

Ethics committee reference number
IR.IUMS.REC.1400.036

Health conditions studied

1

Description of health condition studied
The effect of tele-traditional dysphagia therapy in comparison with tele-usual care on swallowing function in patients with multiple sclerosis

ICD-10 code
G35

ICD-10 code description
Multiple sclerosis

Primary outcomes

1

Description
Swallowing performance score in MASA questionnaire

Timepoint

During 18 sessions of patients evaluation and treatment

Method of measurement

MASA questionnaire

Secondary outcomes

1

Description

Quality of life score

Timepoint

During 18 sessions of patients evaluation and treatment

Method of measurement

SWAL-QOL questionnaire

Intervention groups

1

Description

Intervention group: The first group (experimental group) receives traditional dysphagia treatment in addition to usual care therapy.

Category

Rehabilitation

2

Description

Control group: The second group (control group) receives only usual care therapy.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Hospital Special Center of Patients Association

Full name of responsible person

Mehrdad Khalili Badamyar

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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?

No

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

Mehrdad Khalili Badamyar

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Speech therapy

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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

Not applicable

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

Undecided - It is not yet known if there will be a plan to
make this available