

# 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

Mehrdad Khalili Badamyar

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3454 9460

##### Email address

mehrdadkhalili110@gmail.com

##### 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

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

**City**  
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

##### Street address

Shahid Hemmat Highway, between Sheikh Fazl A.  
Nouri and Shahid Chamran, Iran University of Medical  
Sciences Iran University of Medical Sciences,  
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1449614535

##### Phone

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##### Email

mehrdadkhalili110@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Iran University of Medical Sciences

##### Full name of responsible person

Iran University of Medical Sciences

##### Street address

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##### Email

info@iums.ac.ir

#### 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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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Leila ghelichi

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Speech therapy

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## Person responsible for updating data

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Iran University of Medical Sciences

**Full name of responsible person**

Mehrdad Khalili Badamyar

**Position**

master student

**Latest degree**

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**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