Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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, Tehran,Iran,

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 910 990 4886

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

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

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 8670 2212

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

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
1449614535

Phone
+98 21 4416 7405

Email
mehrdadkhalili110@gmail.com

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

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
1449614535

Phone
009844167405

Email
Lghelichi@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Mehrdad Khalili Badamyar

Position
master student

Latest degree
Bachelor

Other areas of specialty/work
Speech therapy

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
1449614535

Phone
+98 21 4416 7405

Email
mehrdadkhalili110@gmail.com

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