

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Effects of oromotor exercises on recovery clinical swallowing function in elderly

Protocol summary

Study aim

Effects of oromotor exercises on recovery clinical swallowing function in elderly

Design

Randomization was undertakenThe elderly using a block randomization technique are allocated into one of two groups: experimental group that receive oromotor exercises and control group that receive compensatory exercises for dysphagia.

Settings and conduct

All elderly peoples are screened by the North-western Dysphagia Patient Check Sheet, and dysphagia was diagnosed by a speech pathologist. In all patients after primary diagnosis of dysphagia, swallowing functions were assessed by Mann Assessment of Swallowing Ability (MASA) , and Dysphagia Handicap Index (DHI). These peoples were allocated into two groups of 10 people: experimental group: that receive oromotor exercises and control group that receive compensatory exercises for dysphagia. For all patients, includes compensatory methods and oromotor exercises are given by the speech pathologist 5 times per week for1 month.

Participants/Inclusion and exclusion criteria

1)Age range of 60-85 2) Clinical diagnosis of Oropharyngeal Dysphagia 3)No history of pneumonia or head and neck surgery and other neurological or general disorders that can influence swallowing function.

Intervention groups

Elderly people are randomized into two groups:experimental group that receive oromotor oromotor exercises include: Tongue-strengthening exercise,Masako Maneuver,Shaker exercises,Expiratory muscle strength training (EMST) and Lip-strengthening exercise) and control group that receive compensatory exercises for dysphagia.

Main outcome variables

Outcome measures in this study included: 1-Scores of the Persian-North-Western dysphagia patient check sheet 2-Scores of the Mann Assessment of Swallowing

Ability (MASA) 3--Scores of the Dysphagia Handicap Index (DHI)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130725014161N2**

Registration date: **2019-03-09, 1397/12/18**

Registration timing: **prospective**

Last update: **2019-03-09, 1397/12/18**

Update count: **0**

Registration date

2019-03-09, 1397/12/18

Registrant information

Name

Jalal Bakhtiyari

Name of organization / entity

Tehran University of Medica Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-06, 1398/01/17

Expected recruitment end date

2019-06-22, 1398/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
2019-03-19, 1397/12/28

Scientific title
Effects of oromotor exercises on recovery clinical swallowing function in elderly

Public title
Effects of oromotor exercises on recovery clinical swallowing function in elderly

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Age range of 60-85 No history of neurological or general disorders that can influence swallowing function and no history of pneumonia or head and neck surgery and Radio therapy No history of tobacco abuse Clinical diagnosis of oro-Pharyngeal Dysphagia At least has literacy to read and write
Exclusion criteria:
 The occurrence of any illness and the problem that affects the function of ingestion is the departure of the individual from the study. Failure to cooperate during the study The Occurrence of any illness or problem that affects the function of swallowing

Age
From **60 years** old to **85 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **20**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization is undertaken using a block randomization technique.

Blinding (investigator's opinion)
Single blinded

Blinding description
Elderly people with Oropharyngeal Dysphagia(OPD)are allocated into one of two groups according to type of intervention of swallowing therapy including:1)oromotor exercises and2)Usual care and Compensatory techniques, none of whom were informed about their groups.In this study the researchers are aware of the groups.

Placebo
Not used

Assignment
Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Semnan University of Medical Sciences

Street address

Semnan University of Medical Sciences (SEMUMS), Central Headquarter of University, Bassij Blvd., Semnan, Iran

City

Semnan

Province

Semnan

Postal code

3514799422

Approval date

2018-08-21, 1397/05/30

Ethics committee reference number

IR.SEMUMS.REC.1397.139

Health conditions studied

1

Description of health condition studied

Dysphagia

ICD-10 code

R13.1

ICD-10 code description

Dysphagia

Primary outcomes

1

Description

Clinical Swallowing Function

Timepoint

One Month after primary assessment

Method of measurement

1-Scores of the Persian- North-Western dysphagia patient check sheet2-Scores of the Mann Assessment of Swallowing Ability (MASA)3--Scores of the Persian - Dysphagia Handicap Index (DHI)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: oromotor exercises(Muscle

Strengthening exercises)
Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Tabatabaee Comprehensive Rehabilitation Center
Full name of responsible person
Elham Fatemi
Street address
Tabatabaee Comprehensive Rehabilitation
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
Dr Parviz Kokhaei
Street address
Semnan University of Medical Sciences (SEMUMS),
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p_kokha@yahoo.com
Grant name
Grant code / Reference number
**Is the source of funding the same sponsor
organization/entity?**
Yes
Title of funding source
Semnan 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
Semnan University of Medical Sciences
Full name of responsible person
Dr.Jalal Bakhtiyari
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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Full name of responsible person

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Latest degree

Ph.D.

Other areas of specialty/work

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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

All participant data will be shared after the encoding including age, sex, severity of dysphagia, test results, and research implementation method.

When the data will become available and for how long

Six months after the publication, the results will be shared.

To whom data/document is available

All researchers, including members of the faculty of universities and students.

Under which criteria data/document could be used

For use in meta-analysis studies or citation data in other relevant studies.

From where data/document is obtainable

Academic Officer; Dr. Jalal Bakhtiyari

Email:bakhtiyari.slp@gmail.com Mobile:00989123717072

What processes are involved for a request to access data/document

Immediately after the call, the information will be sent.

Comments