Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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: exprimental 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 Center,Qods St,Semnan Province, Semnan, IranQods St

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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

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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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Latest degree
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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