

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

A comparative study of the effects of two swallowing therapy approaches (Shaker exercise and surface electrotherapy) on the muscle activities and clinical swallowing function in healthy older adults

Protocol summary

Summary

1) Objectives: The present study aims to investigate and compare the effects of two swallowing approaches (shaker exercise and surface electrotherapy) on the myoelectric activity of the neck muscles during swallowing and also on the clinical swallowing function of healthy older adults. 2) Design: Not blinded randomized controlled trial 3) Setting and conduct: After a primary interview and assessment, the older adults eligible for this study will receive a period of treatment. This sample will be randomly divided into two treatment groups. Swallowing assessments will be performed before and after the treatment period. 4) Participants including major eligibility criteria: The main inclusion criteria will include over the age of 60; no history of neurological and/or myopathic disorders; no history of difficulties in swallowing function. The main exclusion criteria will include inappropriateness of the recorded EMG signal; no regular participation in the intervention sessions. 20 non-dysphagic older adults will participate in this study. 5) Interventions: Twenty persons will be randomly assigned to the Shaker exercise or electrotherapy group and will receive treatment for 2 weeks. 6) Main outcome measures: The effects of the mentioned treatment approaches will be studied on the electrophysiologic function of swallowing muscles including the masseter muscle, the submental and infrahyoid muscles during swallowing.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016031026999N1**
Registration date: **2016-05-09, 1395/02/20**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-05-09, 1395/02/20

Registrant information

Name

Marziyeh Poorjavad

Name of organization / entity

Tehran university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 935 404 5795

Email address

m-poorjavad@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of Medical Sciences

Expected recruitment start date

2016-05-09, 1395/02/20

Expected recruitment end date

2016-09-22, 1395/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study of the effects of two swallowing therapy approaches (Shaker exercise and surface electrotherapy) on the muscle activities and clinical swallowing function in healthy older adults

Public title

The effects of two swallowing therapy approaches on swallowing in older adults.

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria: Over the age of 60; having a desire to involve in such a health program; no history of neurological (such as stroke, TBI, MS, ALS, Parkinson, epilepsy and dementia) and/or myopathic disorders; no history of head and neck cancer; no history of chronic neck pain or other neck problems; no history of difficulties in swallowing function. Exclusion criteria: Impropriety of the recorded EMG signals; an intolerance of surface electrotherapy on the neck; no regular participation in the intervention sessions.

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 20

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

1

Registry name

-

Secondary trial Id

-

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Corner of Ghods St, Keshavarz Blvd, Tehran, Iran

City

Tehran

Postal code

Approval date

2014-06-03, 1393/03/13

Ethics committee reference number

IR.TUMS.REC.1394.2180

Health conditions studied

1

Description of health condition studied

aging

ICD-10 code

R94.1

ICD-10 code description

Abnormal results of function studies of peripheral nervous system and special senses

Primary outcomes

1

Description

Mean of submental muscles activity during swallowing

Timepoint

Before intervention. immediately after intervention

Method of measurement

Micro volt. sEMG

2

Description

Mean of infrahyoid muscles activity during swallowing

Timepoint

Before intervention. immediately after intervention

Method of measurement

Micro volt. sEMG

3

Description

Duration of submental muscles activity during swallowing

Timepoint

Before intervention. immediately after intervention

Method of measurement

Seconds, sEMG

4

Description

Duration of infrahyoid muscles activity during swallowing

Timepoint

Before intervention. immediately after intervention

Method of measurement

Seconds, sEMG

5

Description

Time to peak of submental muscles activity during

swallowing
Timepoint
Before intervention. immediately after intervention
Method of measurement
Seconds, sEMG

6

Description
Time to peak of infrahyoid muscles activity during swallowing
Timepoint
Before intervention. immediately after intervention
Method of measurement
Seconds, sEMG

7

Description
Median frequency of submental muscles activity during swallowing
Timepoint
Before intervention. immediately after intervention
Method of measurement
Hertz, sEMG

8

Description
Median frequency of infrahyoid muscles activity during swallowing
Timepoint
Before intervention. immediately after intervention
Method of measurement
Hertz, sEMG

Secondary outcomes

empty

Intervention groups

1

Description
intervention group: Surface electrotherapy on the submental muscles bilaterally for 2 weeks (five consecutive daily sessions per week) using a surface electrical stimulator device with stimulation frequency of 100 Hz, 45 minutes per day.
Category
Rehabilitation

2

Description
Control group: The Head Lift Exercise (Shaker exercise) for 2 weeks (five consecutive daily sessions per week) including 3 sets of exercise a day which consisted of isometric and isokinetic phases of neck exercise. Briefly, the isometric portion of the HLE consists of three sustained 60-s head lifts in the supine position with a 60-s rest period between each trial. This portion is followed

by 30 consecutive repetitions of head-lifts without holding (isokinetic part of the HLE).

Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Emamzadeh yahya neighborhood house
Full name of responsible person
Ms.Forughi
Street address
Emamzadeh yahya neighborhood house, western Abshar alley, Rey street, Tehran, Iran
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research,Tehran University of Medical Sciences
Full name of responsible person
Dr. Masud Yunesian
Street address
Tehran University of Medical Sciences, Corner of Ghods St, Keshavarz Blvd, Tehran, Iran
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research,Tehran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Tehran university of medical sciences
Full name of responsible person
Marziyeh Poorjavad

Position

PhD student of speech therapy

Other areas of specialty/work**Street address**

Department of Speech Therapy, Rehabilitation
faculty, Tehran University of Medical Sciences: Pich
Shemiran, Enghelab St, Tehran

City

Tehran

Postal code**Phone**

+98 21 7753 5132

Fax**Email**

mpoorjavad@yahoo.com ; m-
poorjavad@razi.tums.ac.ir

Web page address**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Tehran university of medical sciences

Full name of responsible person

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mpoorjavad@yahoo.com ; m-
poorjavad@razi.tums.ac.ir

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty