Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation the effect of performing oral exercises on unstimulated salivary flow rate in elderly: A Randomized Clinical Trial

Protocol summary

Study aim
Determining the effect of oral exercise on unstimulated salivary flow rate in elderly people

Design
This phase 3, randomized, controlled, parallel-group, open-label clinical trial involves 60 elderly individuals with dry mouth. Randomization will be performed using the RAND function in Excel software.

Settings and conduct
The study was conducted in elderly care centers in Gorgan city; This study is performed on the elderly population; Blinding is not performed in this study.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Elderly individuals over 60 years of age of both sexes, informed consent to participate in the study, and a non-stimulated salivary flow rate of less than or equal to 0.1 min\ml by the Draining method; The individual's ability to cooperate in performing the exercises. Exclusion criteria: Inability to perform physical exercises (e.g., Parkinson's disease, psychiatric disorders such as dementia); Neck trauma; History of radiotherapy; Hearing, visual, or speech impairments; Impaired saliva secretion in specific diseases (e.g., Alzheimer's disease, multiple sclerosis, Sjögren's syndrome).

Intervention groups
Intervention Group: Elderly individuals with dry mouth who perform oral exercises targeting the tongue, facial expression muscles, salivary glands, and swallowing. Control Group: Elderly individuals with dry mouth who do not receive any intervention.

Main outcome variables
Unstimulated salivary flow rate

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250309065005N1**
Registration date: **2025-06-08, 1404/03/18**
Registration timing: **prospective**

Last update: **2025-06-08, 1404/03/18**
Update count: **0**

Registration date
2025-06-08, 1404/03/18

Registrant information

Name
Esra Baghdadi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 3335 9155

Email address
esra.baghdadi@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-06-21, 1404/03/31

Expected recruitment end date
2025-08-21, 1404/05/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation the effect of performing oral exercises on unstimulated salivary flow rate in elderly: A Randomized Clinical Trial

Public title
Evaluation of the effect of oral exercises on salivary flow

rate in elderly

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Elderly people over 60 years of age of both sexes Non-stimulated salivary flow rate of less than or equal to 0.1 ml/min by the Draining method The individual's ability to cooperate in performing exercises

Exclusion criteria:

(Inability of a person to perform physical exercises (Parkinson's disease, mental disorders such as dementia) Neck trauma History of radiotherapy Mouth breathing habit Hearing, vision, and speech problems (Disorders in saliva secretion in certain diseases (such as Alzheimer's, multiple sclerosis, and Sjögren's syndrome)

Age

From **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

To ensure the uniform distribution of the two variables “smoking status” and “drug use” across the intervention and control groups, stratified randomization was performed as follows: Four strata were first defined by combining the variables: Smoker + drug user Smoker + non-drug user Non-smoker + drug user Non-smoker + non-drug user Within each stratum, the rand function in Excel was used to generate random sequences. To maintain balance, participant allocation was conducted in blocks of four, each block contained two participants assigned to the intervention group (code 1) and two to the control group (code 0). Final random sequences for each stratum were separately generated and stored in numbered, sealed envelopes to ensure allocation remained blinded to researchers until the time of assignment.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Gorgan University of Medical Sciences

Street address

Golestan University of Medical Sciences, Shastcolla street, Gorgan

City

Gorgan

Province

Golestan

Postal code

4913983635

Approval date

2025-02-01, 1403/11/13

Ethics committee reference number

IR.GOUMS.REC.1403.435

Health conditions studied

1

Description of health condition studied

Dry Mouth

ICD-10 code

R68.2

ICD-10 code description

Dry mouth, unspecified

Primary outcomes

1

Description

Unstimulated salivary flow rate

Timepoint

Baseline 4 weeks and 8 weeks later

Method of measurement

Graduated tube , Cotton roll, Digital Scale

Secondary outcomes

1

Description

Severity of dry mouth

Timepoint

At the beginning of the study, 4 weeks, 8 weeks later

Method of measurement

Xerostomia Inventory questionnaire

2

Description

Salivary pH

Timepoint

At the beginning of the study, 4 weeks, 8 weeks later

Method of measurement

Graduated tube, pH meter

Intervention groups

1

Description
Intervention group: Oral exercises include exercises for the tongue, facial muscles, salivary glands, and swallowing. The patient is advised to perform oral exercises twice a day, in the morning and evening.1. Facial Muscle Exercises: 1.1 Take a deep breath – while closing your eyes tightly, pull your lips to both sides of your face. 1.2 Open your eyes and mouth completely. 1.3 Close your mouth tightly – fill your cheeks with air – move the air in your cheeks to the right and left. After each set of exercises (1-3), rest your face for approximately 10 seconds. Repeat exercises (1-3) three times. 2. Tongue Exercises: 2.1 Fully extend your tongue, then retract it. 2.2 Extend your tongue and move it to the right and left. 2.3 Lick around your mouth with your tongue. 2.4 Fully extend your tongue, move it up and down to lick your nose and chin. 2.5 Press your upper lip with your tongue. 2.6 Press your lower lip with your tongue. 2.7 Alternately press your right and left cheeks with your tongue. Repeat each of exercises (1-7) approximately five times.3. Exercises for Salivary Glands: 3.1 Parotid Glands: Place four fingers (index finger to little finger) on your cheeks and rotate the area of the upper molars from back to front (10 times). 3.2 Sublingual Glands: Gently press the tongue upwards from under the chin with the thumbs of both hands (10 times). 3.3 Submandibular Glands: Press the soft inner part of the jaw with your thumbs and press from under the ear to the tip of the chin in 4-5 areas (5 times).4. Exercises for Swallowing: 4.1 Neck: Move your neck to the left and right (5 times). 4.2 Shoulders: Raise your shoulders and shorten your neck, then relax (10 times). 4.3 Swallowing: Hold your breath and swallow your saliva (3 times). 4.4 Speech: While keeping your mouth open, loudly pronounce "pa," "ta," "ka," "ra" (3 times).
Category
Rehabilitation

2

Description
Control group: No intervention is performed in the control group.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Gorgan Elderly Home
Full name of responsible person
Esra Baghdadi
Street address
Ṣhahriar County, Gorgan, Golestan Province
City
Gorgan
Province
Golestan
Postal code
4913983635
Phone
+98 921 694 3706
Email
esra.baghdadi@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Gorgan University of Medical Sciences
Full name of responsible person
Dr. Roshandel
Street address
Dental Research center, Gorgan Dental College ,Shahriar fifth, Shahriyar County, Gorgan, Golestan
City
Gorgan
Province
Golestan
Postal code
4913983635
Phone
+98 17 3262 8052
Fax
Email
Esra.baghdadi@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Gorgan 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
Gorgan University of Medical Sciences
Full name of responsible person
Esra Baghdadi
Position
Dentistry Student
Latest degree

A Level or less
Other areas of specialty/work
Dentistry
Street address
Villa 13th , Villashahr , Gorgan
City
Gorgan
Province
Golestan
Postal code
4913887579
Phone
009817326228052
Email
Esra.baghdadi@yahoo.comd

Person responsible for scientific inquiries

Contact
Name of organization / entity
Gorgan University of Medical Sciences
Full name of responsible person
Nazanin Mortazavi
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
Dental Research Center, Gorgan Dental College ,Shahriyar fifth ,Shahriar County, Gorgan , Golestan
City
Gorgan
Province
Golestan
Postal code
4938134820
Phone
+98 17 3450 2115
Email
mortazavi_nazanin@yahoo.com
Web page address
https://goums.ac.ir/cv/1982/%D9%85%D8%B1%D8%AA%D8%B6%D9%88%DB%8C

Person responsible for updating data

Contact
Name of organization / entity
Gorgan University of Medical Sciences
Full name of responsible person
Esra Baghdadi
Position
Dental student
Latest degree
A Level or less
Other areas of specialty/work
Dentistry
Street address
Villashahr street
City
Gorgan
Province
Golestan
Postal code
4913983635
Phone
+98 17 3262 2885
Email
Esra.baghdadi@yahoo.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
Yes - There is a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Yes - There is 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
Title and more details about the data/document
Data will be made available upon request by contacting the corresponding author (Dr. Nazanin Mortazavi) after anonymization.
When the data will become available and for how long
The access period starts 6 months after the results are published
To whom data/document is available
Researchers working in academic and scientific institutions in the country can access the data and other documents of this study by writing a request from (Gorgan Dental School Research Center).
Under which criteria data/document could be used
The documents will be available to the applicants after obtaining permission from the project managers and the research director of Golestan University of Medical Sciences and with a written request from (Gorgan Dental School Research Center). Obviously, the administrative procedures take time and we try to complete the application within one month from the date of application.
From where data/document is obtainable
Gorgan, Shahrek Shahriar, Shahryar 5, Gorgan Faculty of Dentistry, Dental Research Center, Mrs. Shabani, Research Center Expert. Postal code 4913983635 phone number 01732622885 email: s.shabani8791@gmail.com
What processes are involved for a request to access data/document
Researchers working in academic and scientific

institutions in the country can access the data and other documents of this study by writing a request from (Gorgan Dental School Research Center). The documents will be available to the applicants after obtaining permission from the project managers and the research director of Golestan University of Medical Sciences. Obviously, the administrative procedures take time and we try to complete the application within one month from the date of application.

Comments