ISRCTN98899535 https://doi.org/10.1186/ISRCTN98899535

The impact of high-volume or high-intensity tongue strength training on tongue strength in healthy older adults

Submission date
26/10/2023

Recruitment status
No longer recruiting

Registration date
08/02/2024

Overall study status
Ongoing

Last Edited
15/10/2025

Condition category
Oral Health

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Reduced tongue strength is an important contributor to swallowing problems (dysphagia). Therefore, there has been growing interest in improving tongue strength with tongue-strengthening exercises (TSE) in patients with dysphagia. Conflicting outcomes of progressive resistance exercises on tongue strength and swallowing function have been described in both healthy volunteers and patients. Similar to strength training in the fields of sports medicine and physical rehabilitation, the desired outcome of TSE highly depends on the dose parameters of the exercise protocol (i.e. intensity or exercise load, the number of repetitions (reps), frequency of practice and training duration) and patient adherence. Currently, the optimal exercise dose and impact of different exercise loads and numbers of reps are relatively unknown. In physical rehabilitation there is growing evidence that resistance training with lower loads completed to muscle fatigue (high number of reps) can induce similar strength gains as traditional higher load training with a small number of reps. These findings might be of interest, given that high-load resistance training is not always feasible or preferred in patients with severe muscle weakness and may be contraindicated in some cases. Therefore, this study aims to investigate whether TSE with lower loads and high repetitions can produce similar training effects on tongue strength compared to higher loads with few repetitions.

Who can participate?
Healthy volunteers without swallowing problems, with a minimum age of 70 years.

What does the study involve?
Participants are randomly allocated to one of two groups. Irrespective of their group, all participants practice 3 days per week for 8 weeks. Training takes place at the patient's home or nursery home and is supervised by one of the researchers. The first group will complete tongue strength training, performing 150 reps of tongue-palate presses with low resistance per training day. The second group receives high-resistance training, performing 50 reps each day. Isolated tongue strength and tongue strength during swallowing are measured at the start of the study, after 4 weeks of training, at the end of the training, and 4 weeks after finishing the training program.

What are the possible benefits and risks of participating?
A key benefit of participation is an increased functional reserve of tongue strength, observed as increased tongue strength after completing the study. This could prevent/delay swallowing problems due to reduced tongue strength in the context of presbyphagia (swallowing problems in the elderly). There are no risks or side effects associated with participating in the study.

Where is the study run from?
Antwerp University Hospital (Belgium)

When is the study starting and how long is it expected to run for?
October 2023 to October 2026

Who is funding the study?
Antwerp University Hospital (Belgium)

Who is the main contact?
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
B3002023000164

Study information

Scientific Title
Exercise dose for tongue strength training in healthy adults: high-volume or high-intensity training?

Acronym
EDA-VIT

Study objectives
High-volume tongue strength training can induce similar maximum strength gains as high-intensity strength training

Ethics approval required
Ethics approval required

Ethics approval(s)

approved 23/10/2023, Ethics committee of Antwerp University Hospitals (Drie Eikenstraat 655, Antwerp, 2650, Belgium; +32 (0)3 821 38 97; ethisch.comite@uza.be), ref: 5821

Study design
Single-centre interventional two-arm randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment, Efficacy

Health condition(s) or problem(s) studied
Tongue strength

Interventions
Healthy older adults will be randomized to one of two treatment arms. Participants are assigned to one of the two therapy groups based on a sequence generated by the online randomization tool at https://www.randomizer.org, following a parallel group design. Irrespective of their group, all participants practice 3 days per week for 8 weeks. Training takes place at the patient's home or nursery home and is supervised by one of the researchers. The first group will complete low-resistance tongue strength training, performing 150 repetitions (reps) of tongue-palate presses with 30% 1RM progressive resistance per training day. The second group receives high-resistance training, performing 50 reps with 80% 1RM progressive resistance each day. A successful repetition is defined as reaching the target resistance for 3 seconds, using the biofeedback on the LED by the IOPI. Resistive loads will be adjusted every 2 weeks according to the principle of progressive overload.

The Iowa Oral Performance Instrument versions 2.1 and 2.3 (IOPI Medical LCC, Redmond, WA USA) are used for maximum isolated tongue strength measurements (MIP), maximum tongue strength measurements during swallowing (Pswal) and for monitoring tongue-palate pressures during training. The IOPI is a portable instrument connected to an air-filled bulb. A digital display shows the produced peak pressure (kilopascal, kPA) during tongue-palate presses. For training sessions, the target tongue pressure is set. During training, a vertical series of LED lights provides biofeedback based on the pressure applied.

Intervention Type
Behavioural

Primary outcome(s)
Isolated tongue strength represented by Maximum Isometric Pressure (MIP) measured anteriorly (MIPa) and posteriorly (MIPp) in both treatment arms. MIP is measured with the Iowa Oral Performance Instrument version 2.1. and 2.3 (IOPI Medical LCC, Redmond, WA USA). Participants are instructed to press the bulb as hard as possible against the palate. The highest value obtained over three trials was used for MIP. MIPa and MIPp are performed at baseline, after 4 and 8 weeks of training and 4 weeks after the last training session to document possible detraining effects.

Key secondary outcome(s))

1. Tongue strength during swallowing represented by Pswal measured anteriorly (PswalA) and posteriorly (PswalP) in both treatment arms. Pswal is measured with the Iowa Oral Performance Instrument version 2.1. and 2.3 (IOPI Medical LCC, Redmond, WA USA). Participants are instructed to swallow (saliva) as hard as possible with the bulb in an anterior and posterior position. The highest pressure obtained over three trials is used for Pswal. PswalA and PswalP are performed at baseline, after 4 and 8 weeks of training and 4 weeks after the last training session to document possible detraining effects.
2. Frailty index measured with the Clinical Frailty Scale, a 9-point scale completed by the researcher. This index reflects the Frailty risk and general health of the subject. The frailty index is assessed at baseline, after 4 and 8 weeks of training and 4 weeks after the last training session.
3. Nutritional status assessed by means of the Mini Nutritional Assessment (MNA), a standardised questionnaire to measure the risk of malnutrition in the geriatric population. The MNA is assessed at baseline, after 4 and 8 weeks of training and 4 weeks after the last training session.

Completion date
01/10/2026

Eligibility

Key inclusion criteria
1. Minimum age 70 years (Van den Steen et al., 2018)
2. Belgian origin
3. Dutch native speaker (Vanderwegen et al., 2012)
4. MIPa and MIPp within Belgian normative data (Vanderwegen et al., 2012)

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Senior

Lower age limit
70 years

Upper age limit
100 years

Sex
All

Total final enrolment
51

Key exclusion criteria

1. History of dysphagia
2. Cognitive deficit (based on the MoCA-score < pc 8) (Thissen et al, 2010; Kessels et al., 2022)
3. Positive dysphagia screening (Yale Swallowing Protocol) (Suiter et al., 2014)
4. If participants drop out for a whole exercise week (i.e. if patients miss three consecutive therapy sessions)

Date of first enrolment
06/11/2023

Date of final enrolment
01/10/2025

Locations

Countries of recruitment
Belgium

Study participating centre
Antwerp University Hospital
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Sponsor information

Organisation
Antwerp University Hospital

ROR
https://ror.org/01hwamj44

Funder(s)

Funder type
University/education

Funder Name
Universitair Ziekenhuis Antwerpen

Alternative Name(s)

Antwerp University Hospital, University Hospital Antwerp, UZA

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Belgium

Results and Publications

Individual participant data (IPD) sharing plan
The dataset generated during and/or analyses during the current study will be stored in a non-publicly available repository

IPD sharing plan summary
Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes