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The impact of exercise frequency from training tongue strength in healthy older adults.

Submission date
16/04/2019

Recruitment status
No longer recruiting

Registration date
11/06/2019

Overall study status
Completed

Last Edited
11/06/2019

Condition category
Digestive System

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

Plain English summary of protocol

Background and study aims
The tongue plays a crucial role in swallowing. It is the main driving force for pushing the bolus (mixture of food and saliva) from the mouth to the esophagus (food pipe). Decreased tongue strength is shown to contribute significantly to swallowing problems (dysphagia). Dysphagia has a major impact on health care (resulting in pneumonia and the need for feeding tubes) and quality of life. Therefore, the development of successful rehabilitation methods is from major importance. Tongue strength is trainable in a patient-friendly manner, with positive effects from tongue strengthening exercises. A good training program requires an adequate volume of exercise with measurable improvements in combination with a workable degree of effort. Exercise frequency is an important variable of a good training program, since patients and caregivers prefer major improvement with minimized effort. The exercise frequency of most training schemes varies between 3 and 5 times per week. The aim of this study is to compare the gain in tongue strength between training 3 or 5 times per week and to study potential detraining effects 4 and 8 weeks after the training sessions.

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

What does the study involve?
Participants are randomly allocated to tongue strength training either 3 or 5 times per week for 8 weeks. Isolated tongue strength and tongue strength during swallowing are measured at the start of the study, halfway the training program, at the end of the training, and 4 and 8 weeks after finishing the program.

What are the possible benefits and risks of participating?
Benefits from training are an increased functional reserve for tongue strength, observable as increased tongue strength after finishing the protocol. This may avoid/delay the typical symptoms from presbyphagia (swallowing problems in the elderly). There are no risks or side effects of participating in the study.

Where is the study run from?
The study is run from the Antwerp University Hospital, but training sessions are conducted at the patients' nursing home, supervised by one of the researchers.

When is the study starting and how long is it expected to run for?
September 2015 to June 2016

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

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
EFTSE1

Study information

Scientific Title

Tongue strengthening exercises in healthy older adults: effect of exercise frequency. A randomized trial

Acronym
EFTSE

Study objectives
Training 3x/week results in a higher gain in tongue strength than training 5x/week.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 14/07/2014, Ethical Committee of the Antwerp University Hospital (Wilrijkstraat 10, 2650 Edegem; Tel: +32 (0)3 821 35 44; Email: ethisch.comité@uza.be), ref: B300201421549

Study design
Interventional single-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Tongue strengthening exercise as a form of swallowing rehabilitation

Interventions
Participants were randomly assigned to two different treatment arms. Subjects are assigned to one of the two therapy groups based on a sequence generated by the online randomization tool at www.randomizer.org, following a parallel group design. Clinicians involved in the inclusion procedure are blinded to this assignment by using numbered and sealed envelopes. Per week (7 days), the EX3-group (n=10, 5 males and 5 females) performed 3 sessions of TSE on nonconsecutive days, the EX5-group (n=10, 5 males and 5 females) performed 5 sessions of TSE. Both groups trained for a total of 8 weeks. Training sessions were conducted at the patients' nursing-home and supervised by one of the researchers. No additional TSE without the researcher present were allowed. Each training session involved 120 tongue-pressure repetitions, 60 anteriorly and 60 posteriorly. TSE were divided into 24 sets of 5 repetitions with 30 seconds rest following each set and with the target level set at 80% of 1RM in order to

maintain motivation. A successful repetition was defined as reaching the target level for 3 seconds, using the biofeedback on the LED by the IOPI. A new MIP was determined and correspondent levels of resistance were recalculated every 2 weeks according to the principle of progressive overload.
The Iowa Oral Performance Instrument version 2.3 (IOPI Medical LCC, Redmond, WA USA) was used for MIPA, MIPP, PswalA, and PswalP measurements and for monitoring tongue-palate pressures during training.
MIP and Pswal were measured anteriorly (MIPA, PswalA) and posteriorly (MIPP, PswalP) in both treatment arms. For all strength measurements, the instruction was given to press (MIP) or swallow (Pswal) as hard as possible. The highest pressure obtained over 3 trials for maximum tongue strength was used for MIP and the highest pressure obtained over 3 saliva swallows was used for Pswal. A 3-second time frame per attempt was used to reach maximum values. MIPA, MIPP, PswalA, and PswalP were performed at baseline (BL), after 4 and 8 weeks training (4wT and 8wT) and 4 and 8 weeks after the last training session (4wDT and 8wDT) to document possible detraining effects.

Intervention Type
Device

Phase
Phase I

Primary outcome measure
Gain in isolated tongue strength represented by MIP (Maximal Isometric Pressure) measured anteriorly (MIPA) and posteriorly (MIPP) in both treatment arms. For all strength measurements, the instruction was given to press (MIP) as hard as possible. The highest pressure obtained over 3 trials for maximum tongue strength was used for MIP. A 3-second time frame per attempt was used to reach maximum values. MIPA and MIPP were performed at baseline (BL), after 4 and 8 weeks training (4wT and 8wT) and 4 and 8 weeks after the last training session (4wDT and 8wDT) to document possible detraining effects. A margin of 48 hours was tolerated for all described time points to accommodate for rescheduling.

Secondary outcome measures
Gain in tongue strength during swallowing represented by Pswal measured anteriorly (PswalA) and posteriorly (PswalP) in both treatment arms. For all strength measurements, the instruction was given to swallow (saliva) as hard as possible. The highest pressure obtained over 3 trials for maximum tongue strength was used for Pswal. A 3-second time frame per attempt was used to reach maximum values. PswalA and PswalP were performed at baseline (BL), after 4 and 8 weeks training (4wT and 8wT) and 4 and 8 weeks after the last training session (4wDT and 8wDT) to document possible detraining effects. A margin of 48 hours was tolerated for all described time points to accommodate for rescheduling.

Overall study start date
01/09/2015

Completion date
30/06/2016

Eligibility

Key inclusion criteria

1. Minimum age 70 years
2. Living in nursing home
3. Belgian origin
4. Dutch native speaker
5. MIPP and MIPP within normative data

Participant type(s)
Healthy volunteer

Age group
Senior

Sex
Both

Target number of participants
20

Key exclusion criteria
1. Cognitive deficit (MMSE-score > 24)
2. Dysphagia (Yale Swallowing Protocol)

Date of first enrolment
01/10/2015

Date of final enrolment
01/05/2016

Locations

Countries of recruitment
Belgium

Study participating centre
Antwerp University Hospital
Wilrijkstraat 10
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Sponsor information

Organisation
University Hospital of Antwerp

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01hwamj44

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Hospital of Antwerp

Results and Publications

Publication and dissemination plan
Data are collected and analysed, publication is ready (apart from trial registration).

Intention to publish date
01/06/2019

Individual participant data (IPD) sharing plan
Participant level data will be held on an external hard disk locked at the University Hospital of Antwerp. Data may be used in future analyses.

IPD sharing plan summary
Not expected to be made available