

# Tongue strengthening exercises in head and neck cancer patients: does level of resistance matter?

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<b>Registration date</b> 19/02/2015	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 27/10/2020	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Reduced tongue strength (TS) is an important contributing factor to early and late dysphagia (swallowing difficulties) in head and neck cancer (HNC) patients previously treated with chemoradiotherapy (CRT). The evidence is growing that tongue-strengthening exercises (TSE) can improve TS and swallowing function in both healthy and dysphagic subjects. However, little is known about the impact of specific features of an exercise protocol for TS on strength and/or swallowing function). Previous research in sports medicine and physical rehabilitation shows that degree of exercise load is an influential factor for increasing muscle strength in the limb skeletal muscles. Since the tongue is considered a muscular hydrostat (a structure that helps manipulate food), it remains to be proven if the same concepts will apply. This study investigates the effect of 3 TSE protocols with different degrees of exercise load on TS and swallowing.

### Who can participate?

Adult head and neck cancer patients previously treated with chemoradiotherapy and suffering from chronic dysphagia.

### What does the study involve?

Participants will be randomly assigned to a training schedule of 60, 80, or 100% of their maximal TS respectively. They will be treated during 8 weeks, 3 times a week, executing 120 repetitions of the assigned exercise once per training day. Exercise load is progressively adjusted every two weeks. Patients are evaluated before, during and after treatment by means of TS measurements, fiber optic endoscopic evaluation of swallowing (FEES) and quality of life questionnaires.

### What are the possible benefits and risks of participating?

A possible benefit is the increase of tongue strength to some degree, in some participants. There are no risks for patients participating in this 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?  
March 2014 to December 2027

Who is funding the study?  
Antwerp University Hospital and Federal Cancer Plan Belgium

Who is the main contact?  
Prof Gwen Van Nuffelen

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Gwen Van Nuffelen

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
NKR\_2014\_01

## Study information

**Scientific Title**  
Effect of intensive tongue strength therapy on anterior and posterior tongue strength, dysphagia and dysphagia related quality of life.

**Study objectives**

1. Tongue strengthening exercises improve tongue strength in head and neck cancer patients.
2. Tongue strengthening exercises improve functional swallowing in this population.
3. Tongue strengthening exercises improve swallowing related quality of life.
4. The effect of tongue strengthening exercises depend upon the level of resistance.

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**

Ethical Committee of the Antwerp University Hospital and University of Antwerp, Belgium. Chair: Prof. Dr. Patrick Cras. ref 14/24/253, B300201421549

## **Study design**

Single-centre interventional randomized controlled trial

## **Primary study design**

Interventional

## **Secondary study design**

Randomised controlled trial

## **Study setting(s)**

Hospital

## **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**

Patients with dysphagia following head and neck cancer or neurodegenerative diseases.

## **Interventions**

At enrollment, 45 head and neck cancer patients, whose dysphagia is primarily related to reduced tongue strength, are randomly assigned to a training schedule of 100% (group 1), 80% (group 2), or 60% (group 3) of their maximal TS respectively. Patients will be treated during 8 weeks, 3 times a week, executing once per training day 120 repetitions of the assigned exercise. Exercise load is progressively adjusted every two weeks. Patients are evaluated before, during and after treatment by means of TS measurements, fiberoptic endoscopic evaluation of swallowing (FEES) and quality of life questionnaires.

## **Intervention Type**

Behavioural

## **Primary outcome measure**

1. Tongue strength measurements: Maximum Isometric Pressures (expressed as kPa) anterior and posterior.

The primary measures are evaluated prior to (max 1 week in advance), during (after 4 weeks of therapy), after 8 weeks of therapy and 4 and 8 weeks post treatment.

## **Secondary outcome measures**

1. Swallowing function: the swallowing function will be evaluated using a comprehensive fiber optic endoscopic evaluation of swallowing (FEES) examination, the - Mann Assessment of Swallowing Ability-Cancer (MASA-C), the Functional Oral Intake Scale (FOIS), and a self-evaluation. For the latter a 100 mm visual analogue scale is used with the ends defined as 'I can't swallow' (0) and 'I don't have any swallowing difficulties' (100) respectively. Both the FEES and MASA-C are conducted with 4 different bolus types: 5 and 10 ml of thin liquid, and 5 and 10 ml of yoghurt. Each bolus type is administered 3 times. Outcome measures for FEES are the

Penetration-Aspiration-Scale, the Carnaby- Video Fluoroscopic Examination (C-VFE) scales for dysphagia and aspiration, the Pooling-score and the Boston Residue and Clearance Scale (BRACS).

2. Quality of Life: swallowing-related quality of life will be surveyed by means of the Dutch Swallowing Quality-of-Life Questionnaire (DSWAL-QoL) and the Dysphagia Handicap Index. The secondary outcome measures are evaluated prior to (max 1 week in advance), during (after 4 weeks of therapy), after 8 weeks of therapy and 4 and 8 weeks post treatment.

**Overall study start date**

01/03/2014

**Completion date**

31/12/2027

## **Eligibility**

**Key inclusion criteria**

1. Head and neck cancer patients previously treated with chemoradiotherapy
2. Men and women older than 18, without cognitive, language, motor, hearing or visual deficits that could interfere with the correct execution of the training.
3. Chronic dysphagia (i.e. present for at least 1 month and no earlier than 6 months after the last day of radiation treatment), primarily related to reduced tongue strength
4. Score 1 or higher for the BRACS-items 'base of tongue' and/or 'valleculae' at baseline judged by an experienced clinician

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

45 (15 per group)

**Key exclusion criteria**

1. History of major oral or head and neck surgery and neurological disorders with an impact on oral function and/or swallowing (amongst others stroke, traumatic brain injury, Parkinson's disease, Amyotrophic Lateral Sclerosis).
2. Concurrent oral motor exercises or swallowing maneuvers to improve swallowing are not allowed during the study period.

**Date of first enrolment**

01/05/2014

**Date of final enrolment**

01/12/2027

## Locations

**Countries of recruitment**

Belgium

**Study participating centre**

Antwerp University Hospital

Edegem

Belgium

-

## Sponsor information

**Organisation**

Antwerp University Hospital (Belgium)

**Sponsor details**

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**Sponsor type**

Hospital/treatment centre

**ROR**

<https://ror.org/01hwamj44>

## Funder(s)

**Funder type**

Government

**Funder Name**

Federal Cancer Plan Belgium

**Funder Name**

Antwerp University Hospital (Belgium)

## Results and Publications

**Publication and dissemination plan**

Publication of the study protocol

publication of the data at completion of the study

Presentation of the data at at least 2 international conferences including the Dysphagia

Research society Meeting

**Intention to publish date**

31/12/2017

**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Available on request

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>	protocol	04/09/2015		Yes	No