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Prophylactic swallowing exercise protocol in head and neck cancer patients: combination of self-directed and supervised training

Submission date
29/12/2025

Recruitment status
Recruiting

Registration date
26/02/2026

Overall study status
Ongoing

Last Edited
26/02/2026

Condition category
Cancer

[ ] 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:
Head and neck cancer (HNC) is a highly prevalent disease on a global scale. In 2022, 2721 new cases were registered in Belgium. Organ-sparing treatments, such as concomitant chemoradiotherapy (CCRT) and radiotherapy (RT), are the standard of care for patients with primary HNC. Despite improvements in these treatments, dysphagia (swallowing problems) remains a prevalent and frequently reported complication following CCRT/RT. Over 50% of HNC patients experience radiation-associated dysphagia (RAD). The consequences of RAD can be severe, including a significantly reduced quality of life, malnutrition, dehydration and aspiration pneumonia. Consequently, it contributes significantly to non-cancer-related deaths in this population. Preventing this common side effect is essential to enhance quality of life (QoL) and extend long-term survival, while limiting the burden on healthcare resources. The growing number of human papillomavirus (HPV)-related oropharyngeal cancer patients and survivors makes prevention paramount.
Recently, further evidence has emerged regarding the beneficial effects of prophylactic swallowing exercises (PSE) on muscle condition, swallowing function and QoL in HNC patients undergoing (chemo)radiotherapy. Unfortunately, these positive effects are undermined by low (13%) to moderate (71%) adherence rates.
Being adherent to PSE during CCRT/RT is crucial. Adherence can be improved through continuous supervision, feedback after successful exercise performance and a close relationship between patients and therapists. The preceding multicentre randomized controlled KOTK-PRESTO trial focused on improving patients' adherence to PSE. Patients were divided into three groups: diary-supported PSE (paper group), app-supported PSE (app group) and therapist-supported PSE (therapist group). These groups differed in the type and extent of adherence-improving measures. All patients received the same PSE program five times a week during the first 4 weeks of CCRT/RT. Patients in the PRESTO-therapist group (PRESTO-T) received face-to-face therapy with a speech and language pathologist (SLP). The PRESTO-paper group and PRESTO-app group performed the first exercise session under the supervision of the SLP. Patients recorded their exercises in a logbook or app. The participants in this study demonstrated higher overall adherence rates in comparison to those achieved in previous studies. A significant positive effect on swallowing function and muscle strength has been

observed in patients who performed ≥75% of the exercises. This overall adherence (OA) rate was exclusively attained in the PRESTO-T group. The PRESTO-paper group approached this cut-off level with an overall adherence of 69%.
Despite the high rates of adherence to these treatments, face-to-face therapy can be burdensome for the patients. This approach requires more appointments and time spent in the hospital, in addition to all the other medical obligations. Furthermore, face-to-face therapy requires substantial human resources and poses considerable logistical challenges. A hybrid solution, combining face-to-face therapy with home practice, has the potential to optimize successful clinical implementation, making the effective PRESTO-program accessible to all HNC patients treated with CCRT/RT.

Who can participate?
Patients aged 18 years or older with head and neck cancer treated with radiotherapy or chemoradiotherapy.

What does the study involve?
Patients will be randomly allocated to one of two treatment groups. Participants in the PRESTO therapist group (PRESTO-T) will receive supervised, face-to-face therapy with a speech language pathologist (SLP) five times a week. The PRESTO hybrid group (PRESTO-H) will perform 50% of the prescribed prophylactic swallowing exercises at home and 50% under direct supervision of an SLP. The proportion of face-to-face contact will increase during the final week of training. Several measures were taken to facilitate adherence. For example, an e-health platform will provide reminders. In addition, with the patient's consent, caregivers will be actively involved. They will receive specific information on how to support the patient and will also be encouraged to attend the treatment sessions. Patients will receive a brochure and access to online information, including videos, and an information session before or during the first week of radiotherapy. The aim is for all patients to complete the 20 exercise sessions.

What are the possible benefits and risks of participating?
A key benefit is evidenced by the findings from the preceding PRESTO trial, which demonstrated a positive effect of prophylactic swallowing exercises on both swallowing function and muscle strength. There are no risks or side effects associated with participating in the study.

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

When is the study starting and how long is it expected to run for?
January 2025 to December 2029

Who is funding the study?
Kom op Tegen Kanker (Belgium), Stand up to Cancer, the Flemish cancer society project id-number: 13359

Who is the main contact?
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Additional identifiers

Project ID number
13359

Study information

Scientific Title
PRESTO-II: the effect of a hybrid version of the PRESTO-program on adherence and swallowing in head and neck cancer patients treated with (chemo)radiotherapy – a multicentre randomized trial

Acronym
PRESTO-II

Study objectives
PRESTO-II demonstrates that the hybrid group (PRESTO-H) is non-inferior to the therapist group (PRESTO-T) regarding adherence and swallowing function, muscle strength and quality of life, in the short-term and long-term. The study will also assess the financial consequences of implementing the results of the study and the efficacy of the PRESTO-program in patients with at least 75% adherence.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 22/09/2025, Ethics committee of Antwerp University Hospital (Drie Eikenstraat 655, Antwerp, 2650, Belgium; +32 (0)3 821 38 97; ethisch.comite@uza.be), ref: 7607

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Uncontrolled

Assignment
Parallel

Purpose
Prevention, Supportive care, Treatment

Study type(s)

Health condition(s) or problem(s) studied
Head and neck cancer treated with radiotherapy or chemoradiotherapy

Interventions
The PRESTO-program is a 4-week prophylactic swallowing exercises (PSE) program, which commences on the first day of radiotherapy. The program is conducted on a 5-day weekly basis. The PSE consist of two evidence-based exercises, alternated on daily basis. These exercises target the main muscle groups involved in the act of swallowing:
1. Tongue strengthening exercises (TSE) are performed with the Iowa Oral Performance Instrument (IOPI), with 120 tongue presses per session, divided into twelve sets of ten repetitions. TSE will be performed since tongue strength is the main bolus-driving force. Reduced tongue strength can cause oral and pharyngeal residue and aspiration.
2. Chin tuck against resistance (CTAR) with an inflatable rubber ball positioned between the chin and the manubrium sterni. Participants are allowed to use one hand to keep the ball in position during the exercise. Patients must perform 150 chin tucks per session, divided into 30 sets of 5 repetitions. The fifth repetition is a combination of a chin-tuck with an effortful swallow. CTAR exercises will be performed since they have a significant effect on the suprahyoid muscles, with a positive effect on laryngeal elevation and upper esophageal sphincter opening. The effortful swallow will be performed since it can improve the tongue-base posterior motion, and it can increase tongue-base pharyngeal-wall pressures. The combination of chin tuck and effortful swallow is hypothesized to stimulate the pharyngeal musculature.

On a weekly basis, maximal tongue muscle strength and suprahyoid muscle strength is remeasured. Patients practice at 80 % of their maximal strength (1-repetition maximum, 1RM). If this resistance is too demanding, patients can temporarily exercise at 60% of 1RM.

Patients are randomly assigned to one of two groups. The PRESTO-therapist (PRESTO-T) will engage in face-to-face practice with the SLP for 5 days a week (100% of the sessions). The PRESTO-hybrid (PRESTO-H) will practice face-to-face with the SLP for 50 % of the sessions. PRESTO-H participants are following a flexible schedule, but patients should never practice for three consecutive days without the supervision of an SLP.

During the first 3 months after radiotherapy (until T6), no swallowing therapy is permitted, except for patients with a FOIS of 1 or 2. Initiation after 3 months after radiotherapy is well documented and considered a real-world setting.

The method of randomisation employed is minimisation. Patients are randomly assigned to one of the two groups with a 1:1 allocation. The following minimisation factors have been selected for consideration: age, treating centre, presence of baseline dysphagia, treatment and tumour site.

Intervention Type
Behavioural

Primary outcome(s)
1. Degree of overall adherence measured using the percentage of exercises performed over the four training weeks at T1 (after 1 training week), T2 (after 2 training weeks), T3 (after 3 training weeks), T4 (after 4 training weeks)

Key secondary outcome(s))
1. Percentage (un)intentional non-adherence measured using qualitative measurement by logbook questions at T1 (after 1 training week), T2 (after 2 training weeks), T3 (after 3 training weeks), T4 (after 4 training weeks)

2. Swallowing function on short- term and long-term measured using Mann Assessment of Swallowing Ability - Cancer (MASA-C), Functional Oral Intake Scale (FOIS), Eating Assessment Tool (EAT-10) at T0 (baseline), T1-4 (during four training weeks), T5 (end of radiotherapy), T6 (3 months after radiotherapy), T7 (6 months after radiotherapy), T8 (12 months after radiotherapy)

3. Swallowing function on short-term and long-term measured using instrumental assessment: Dynamic Imaging Grade of Swallowing Toxicity-Flexible Endoscopic Evaluation of Swallowing (DIGEST-FEES), Pooling score (P-score), Penetration-Aspiration Scale (PAS) at T6 (3 months after radiotherapy), T7 (6 months after radiotherapy), T8 (12 months after radiotherapy)

4. Swallowing function on short-term and long-term measured using dietary recommendations based on IDDSI-Functional Diet Scale at T1-4 (during four training weeks), T5 (end of radiotherapy), T6 (3 months after radiotherapy), T7 (6 months after radiotherapy), T8 (12 months after radiotherapy)

5. Muscle strength in short-term and long-term measured using maximal isometric anterior and posterior tongue pressure (MIPa and MIPp) and suprahyoid pressure measurements at T0 (baseline), T1-4 (during four training weeks), T5 (end of radiotherapy), T6 (3 months after radiotherapy), T7 (6 months after radiotherapy), T8 (12 months after radiotherapy)

6. Quality of life in short-term and long-term measured using MD Anderson Dysphagia Inventory (MDADI) and EORTC QLQ HN35 at T0 (baseline), T5 (end of radiotherapy), T6 (3 months after radiotherapy), T7 (6 months after radiotherapy), T8 (12 months after radiotherapy)

7. Patients' experiences and suggestions measured using weekly interviews with open-ended questions at T1-4 (during four training weeks)

8. Financial consequences: Budget Impact Analysis measured using cost-utility Analysis Questionnaire (Kosten-utiliteitsanalyse KOTK-PRESTO) and EQ-5D-5L Belgium (Dutch)© 2010 EuroQol Group at T0 (baseline), T1-4 (during four training weeks), T5 (end of radiotherapy), T6 (3 months after radiotherapy), T7 (6 months after radiotherapy), T8 (12 months after radiotherapy)

Completion date
31/12/2029

Eligibility

Key inclusion criteria
1. Biopsy proven, newly diagnosed squamous cell carcinoma of the oropharynx and hypopharynx
2. Stage III or IV (TMN8)
3. Treatment with radiotherapy or concomitant chemoradiotherapy with/without induction chemotherapy
4. Sufficient cognitive and language abilities (Montreal Cognitive Assessment - MOCA®-version 8.1 Dutch): cut-off point <22

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Recurrent carcinoma or metastasis from a non-HNC carcinoma
2. Previous (chemo)radiotherapy in the head-neck region with possible impact on swallowing function
3. Major surgery in the head-neck region with possible impact on swallowing function

Date of first enrolment
01/01/2026

Date of final enrolment
31/03/2028

Locations

Countries of recruitment
Belgium

Sponsor information

Organisation
Antwerp University Hospital

ROR
https://ror.org/01hwamj44

Funder(s)

Funder type

Funder Name
Kom op tegen Kanker

Alternative Name(s)

Fight Cancer, komop_tegenkanker

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Belgium

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available