

# Respiratory swallowing therapy in patients with radiation associated dysphagia

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<b>Registration date</b> 28/02/2025	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 28/02/2025	<b>Condition category</b> Signs and Symptoms	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Head and neck cancer (HNC) is worldwide a highly prevalent disease. Approximately one fifth of newly diagnosed patients are at risk to develop oropharyngeal dysphagia. The main clinical symptoms of dysphagia are aspiration (i.e. food entering the airway) and residue (i.e. food that stays behind in the oral cavity, pharynx or larynx). Organ sparing treatment modalities, namely concomitant chemoradiotherapy (CCRT) and radiotherapy (RT), are standard care in patients with primary HNC. Despite continuous improvements and refinements of these treatments, scientific studies show that more than 50% of these patients suffer from treatment related dysphagia or radiation associated dysphagia (RAD). RAD can occur as an acute side effect of CCRT and RT but it can develop to a chronic condition (C-RAD), with up to 40% of patients presenting with dysphagia after (several years of) treatment. RAD is one of the most serious and disabling complications in HNC survivors. It has devastating consequences on the patient's health and well-being, including significantly reduced quality of life, malnutrition, dehydration and aspiration pneumonia and contributes consequently and significantly to non-cancer related mortality in this population.

Recently, there has been increasing clinical and scientific evidence for the positive effect of intensive swallowing rehabilitation on RAD. Training swallowing related muscles is an important strategy in the treatment of RAD. However, an underexposed factor is the coordination of swallowing, more specifically the skills to optimize the coordination between breathing and swallowing. Both functions use the same neural networks in the brainstem and cortex allowing for the tight coupling between their central control of these vital functions. During normal swallowing, inhalation is briefly interrupted by laryngeal closure to prevent aspiration of the bolus into the respiratory tract. Research shows that in typical respiratory swallow patterns (RSP), swallowing occurs during the expiratory phase of breathing or in other words during an expiration-swallow-expiration pattern (E-S-E). It is described that the exhalatory position of the larynx induces a slightly adducted arytenoid-vocal fold position affording a protective setpoint for further laryngeal closure. Moreover, the hyolaryngeal excursion observed during this expiratory phase contributes to the opening of the upper esophageal sphincter (UES). Hence, the occurrence of pathological RSP's (pathRSP) imply reduced airway protection, resulting in an increased risk for aspiration and aspiration pneumonia.

Previous studies confirm the presence of pathRSP in up to 60% of HNC-patients post (CC)RT. It can be hypothesized that swallowing therapy programs aiming to improve the RSP in patients with RAD, may significantly improve the patients' swallowing function. A recent non-randomized study by Martin-Harris and colleagues provided a first indication for the positive effect of treatment of pathRSP by means of visual feedback in a heterogeneous HNC-cohort. However, further research in training RSP, its retention and possible confounding factors is necessary to improve quality care in patients with RAD.

**Who can participate?**

Patients aged 18 years or older, with radiation associated dysphagia after head and neck cancer treatment

**What does the study involve?**

Patients will be randomized to one of two treatment arms, each following a different timeline. Irrespective of their group, all participants will receive the same intervention, namely 4 sessions of respiratory swallow therapy (RES-ST) in a period of two weeks. During these sessions, patients are learned to coordinate their RSP, receiving feedback of from respiratory inductance plethysmography (RIP) and their therapist. Group 1 starts immediately with RES-ST, following a two-week retention period. Group 2 initially serves as a control group during the first two weeks, receiving RES-ST in the last two weeks. To measure the effect and the retention of RES-ST, 3 videofluoroscopic swallowing examinations will take place before the intervention (group 1 and 2), after RES-ST (group 1), after the control period (group 2), after the retention period (group 1) and after RES-ST (group 2).

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

A key benefit of participation is an increased number of normal respiratory swallow patterns, which indicate a safer swallow function. 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?**

January 2024 to June 2028

**Who is funding the study?**

Kom Op Tegen Kanker (Belgium)

**Who is the main contact?**

Drs Charlotte Schellen, [charlotte.schellen@uantwerpen.be](mailto:charlotte.schellen@uantwerpen.be)

## Contact information

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Public, Scientific

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**Additional identifiers****EudraCT/CTIS number**

Nil known

**IRAS number****ClinicalTrials.gov number**

Nil known

## **Secondary identifying numbers**

Nil known

# **Study information**

## **Scientific Title**

The effect of respiratory swallowing therapy in patients with radiation associated dysphagia on swallowing function and quality of life

## **Acronym**

RES-ST

## **Study objectives**

RES-ST will improve the safety of the swallowing function and quality of life of patients with radiation associated dysphagia after head and neck cancer treatment.

## **Ethics approval required**

Ethics approval required

## **Ethics approval(s)**

Approved 28/10/2024, Ethics committee of Antwerp University Hospital (Drie Eikenstraat 655, Antwerp, 2650, Belgium; +32 (0)3 821 38 97; [ethisch.comite@uza.be](mailto:ethisch.comite@uza.be)), ref: 6867

## **Study design**

Single-centre interventional two-arm cross-over randomized controlled trial

## **Primary study design**

Interventional

## **Secondary study design**

Randomised cross over trial

## **Study setting(s)**

Hospital

## **Study type(s)**

Treatment, Efficacy

## **Participant information sheet**

No participant information sheet available

## **Health condition(s) or problem(s) studied**

Dysphagia

## **Interventions**

Patients will be randomized to one of two treatment arms, each following a different timeline. Irrespective of their group, all participants will receive the same intervention, namely 4 sessions of RES-ST in a period of two weeks. These sessions take place at the patient's home or nursery

home and is supervised by one of the researchers. All sessions will consist of at least 100 (food bolus) swallows with the super-supraglottic swallow maneuver (SSGS). These swallows will gradually build up, varying in type of bolus (IDDSI levels) and volume (5-10-15 ml and spontaneous cup swallows). During the swallows, the respiratory inductance plethysmography (RIP) and the speech language therapist provide feedback on the respiratory swallow patterns used. Feedback will start at 100% for each new bolus type and will decrease systemically depending on the skill acquisition to avoid feedback dependency. Besides the 4 sessions, participants will practice daily on their own (two sets of 10 swallows) during the two-week intervention period.

## **Intervention Type**

Behavioural

## **Primary outcome measure**

PAS (Penetration-Aspiration Scale) score at baseline and after RES-ST

## **Secondary outcome measures**

Secondary outcome measures, measured at baseline (T0), two weeks after baseline (T1) and four weeks after baseline (T2):

1. Swallowing function, measured with the Modified Barium Swallow Impairment Profile (MBSImp) and the Dynamic Imaging Grade of Swallowing Toxicity (DIGEST).
2. Patient reported outcome with the Eating Assessment Tool (EAT-10).
3. Respiratory outcome measures: percentage of pathological respiratory swallow patterns and the percentage of normal respiratory swallow patterns.
4. Quality of life, based on the results of the Dysphagia Handicap Index (DHI), the M.d. Anderson Dysphagia Inventory (MDADI) and the Dutch version of the Performance Status Scale for Head and Neck Cancer (D-PSS-HN).

Tertiary/exploratory endpoint:

Data on the following confounders will be collected at baseline:

1. Patient characteristics: age, gender, duration of RAD, frailty (Clinical Frailty Scale), COPD-status (GOLD-criteria). COPD-stage will be determined at the pneumology department. The occurrence of (aspiration) pneumonias before, during and after RES-ST treatment.
2. Disease characteristics: tumor size (TNM-classification), HPV-status and feeding mode (enteral vs oral), gathered through medical records of the patient. The functional oral intake will be questioned by means of the Functional Oral Intake Scale (FOIS) and the Food Intake Level Scale (FILS). The clinical swallow function will be described with the Mann Assessment of Swallowing Ability Scale for Cancer patients (MASA-C).
3. Therapy characteristics: chemotherapy, fractionation, bilateral neck irradiation, duration, time post treatment, all gathered through medical records of the patient.

Data on the following confounders will be collected after two weeks of RES-ST:

1. Attitudes about exercising, based on the results on the Attitudes On Exercise questionnaire
2. Level of patient activation, based on the results on American short form Patient Activation Measure (PAM-13)
3. Perceived effort during exercising, by doing an interview after each session of RES-ST
4. Degree of overall adherence, based on the completion of the four RES-ST sessions

## **Overall study start date**

01/01/2024

## **Completion date**

30/06/2028

## Eligibility

### Key inclusion criteria

1. Diagnosis of radiation-associated dysphagia following head and neck cancer. Based on a deviant result on the Penetration-Aspiration Scale (PAS score > 1) (Rosenbek et al., 1996)
2. ≥ 6 months post cancer treatment. Based on the knowledge that radiation toxicities are clinically classified into acute, subacute, or chronic. Early mucosal injuries (acute <3 months or subacute 3–6 months post irradiation) are attributed to cell death and subsequent inflammation; whereas late deeper tissue responses (chronic >6 months post irradiation) are attributed to damage to the vasculature and/or surrounding connective tissue. Often acute injuries are transient and resolve within a few months after treatment. In order to study the effect of this specific treatment, it's important to include only patients without possible spontaneous recovery as described in the acute phase <6 months (King et al., 2016)
3. Previous swallowing rehabilitation including strength training is allowed, but not simultaneously

### Participant type(s)

Patient

### Age group

Adult

### Lower age limit

18 Years

### Upper age limit

100 Years

### Sex

Both

### Target number of participants

60

### Key exclusion criteria

1. Severe frailty: ≥level 7 @ the Clinical Frailty Scale (Rockwood et al., 2005)
2. Cognitive or language impairments interfering with the therapy/assessments within RES-ST
3. Major surgery in the head and neck

### Date of first enrolment

07/03/2025

### Date of final enrolment

31/12/2027

## Locations

### Countries of recruitment

Belgium

**Study participating centre**  
**Antwerp University Hospital**  
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**Study participating centre**  
**AZ Rivierenland, campus Rumst**  
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## **Sponsor information**

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**Sponsor type**  
Hospital/treatment centre

**Website**  
<https://www.uza.be>

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

## **Funder(s)**

**Funder type**  
Charity

**Funder Name**

Kom op tegen Kanker

**Alternative Name(s)**

Fight Cancer

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Other non-profit organizations

**Location**

Belgium

## **Results and Publications**

**Publication and dissemination plan**

Planned publications in high-impact peer-reviewed journals

**Intention to publish date**

01/03/2028

**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 (Redcap)

**IPD sharing plan summary**

Stored in non-publicly available repository