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Respiratory-swallow training in head and neck cancer

Submission date 21/04/2026	**Recruitment status** Recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 22/04/2026	**Overall study status** Ongoing	
Last Edited 22/04/2026	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims
The problem:
In the United Kingdom, 12,200 people are diagnosed with head and neck cancer every year. Difficulties swallowing food and drink following cancer of the head and neck are common. Swallowing difficulties often arise due to the position of the tumour itself (which may be found in the mouth, tongue, voicebox or throat) and after treatment (surgery, chemotherapy and/or radiotherapy). Swallowing difficulties may last a long time and can lead to problems such as fear of eating, losing weight, chest infections, and even death. Swallowing difficulties can also have a negative impact on an individual's mental health. These difficulties can affect how people interact with others and whether they take part in enjoyable activities. Unfortunately, exercises designed to improve swallowing do not always work for a lot of patients with head and neck cancer. This means we need to look for new ways of improving swallowing.
The solution:
New training, which aims to change the breathing-swallowing pattern of patients with swallowing difficulties, has been developed in America. It seems to work well and improves swallowing for people with head and neck cancer. However, this training programme requires a lot of equipment and training to work. We plan to simplify this training and use equipment that is easy to use, both for therapists and patients. This will benefit patients because, if it works, it will be available to lots of people and can be used at home.
This study aims to:
• develop a training package for speech and language therapists and patients.
• train speech therapists to use the programme with patients.
• to see how the training programme works in practice, using simple, easy to use equipment to help coordinate breathing and swallowing
• find out about whether the project is doable, likely to work in the NHS and worth investing in.
• ask patients and therapists about what they think of the training and whether it can be improved.

Who can participate?
You may be able to take part if you:
• have been diagnosed with swallowing difficulties (dysphagia) by your speech and language therapist or have had a swallow test.

• have completed treatment (surgery, radiotherapy, and/or chemotherapy) for head and neck cancer for the first time.
• finished your cancer treatment at least 3 months ago, with treatment given to try to cure the cancer.
• are 18 years of age or older.
• are able to drink fluids (of any thickness)
• are able to hold drink in the mouth and then continue breathing through the nose

What does the study involve?
On your first appointment
We need to check that the study is suitable for you. The researcher will test your:
1. breathing-swallowing pattern. You will be asked to wear special equipment. The equipment will include monitors under your chin and nose and around your chest and stomach .
2. lung range. You will also be asked to blow into a device (called a spirometer) to test the amount of air going in and out of your lungs.
3. swallowing ability. If you have not recently completed a formal examination of your swallow, such as a swallow x-ray (videofluoroscopy) or via a camera passed through the nose (flexible endoscopic evaluation of swallowing (FEES)), you will be asked to complete a FEES test. During the procedure a thin, flexible instrument is passed through your nose. The parts of your throat can then be seen as you swallow liquids and foods.

It will take approximately 15-35 minutes depending on whether you need a swallow test. If you need a swallow test this appointment will need to take place at an NHS clinic, otherwise we can see you at home, if you'd prefer. You may be unable to take part in the study if your breathing-swallowing pattern or swallowing ability is within the normal range or you have a severe lung condition.

There will be two groups:
1. One group will act as a control (with no training)
2. One group will receive training using equipment (biofeedback)

If you are able to take part in the study, a computer will randomly choose whether you will be in one of the swallow training groups or the control group (no swallow training). You have a 50% chance of being in one of the training groups and a 50% chance of being in the control group. We get a computer to do this job because we think this is fairest. There are no people making decisions about which person is in which group.

At your second appointment you will fill out some surveys about your swallowing difficulties. At the same appointment your breathing-swallow pattern will be measured. These tests will take about 30 minutes. You will also have an x-ray video of your swallowing (videofluoroscopy). In the examination you will be asked to swallow a range of foods and drinks of different consistencies. Barium will be added to the food and drink so it shows up clearly on the x-ray. The x-ray will take about 15 minutes.

Swallow training
If you are selected to take part in the swallow training, a speech and language therapist will see you once a week (for up to an hour) for up to 6 weeks. The training will focus on changing the timing of your swallow whilst you drink. If you are selected to train using the equipment you will be asked to wear a respiratory belt around your chest. If you are unable to manage certain drinks or foods the training will be tailored to your needs. These treatment appointments will be videoed so that the research team can monitor whether the training is following the guidelines. The training sessions will take place at an NHS clinic or at your home, depending on your

therapist or your preference. After the training is completed, we will be unable to offer you further training in this technique.

Will I need to attend any other appointments?
You will be invited to attend another two appointments, one week after the training and three months later, even if you are in the control group (no training). Each appointment will last about 45 minutes. The tests completed at your second appointment will be repeated at each follow up appointment. These will include: 1) surveys, 2) measurement of your swallowing (x-ray), and, 3) assessments of your breathing-swallowing pattern. These appointments will take place at an NHS clinic.

You may be invited to an interview to talk about what your experience of taking part in the study was like. This might be during training or after training. Interviews will be audio-recorded and will last up to an hour. You can decide whether or not you would like to take part.

You will receive £20 and travel for every appointment you attend once you are taking part in the study.

What are the possible benefits and risks of participating?
The videofluoroscopy (video x-ray of the swallow) generates real-time moving pictures using radiation. We are all exposed to natural background radiation every day in our environments. The x-ray will give you additional radiation on top of your natural background radiation. Your radiation exposure for each videofluoroscopy is small, about the same as 2-7 weeks of natural background radiation, which you normally receive every day.

If you need a swallow test using an endoscope (FEES) it is possible that you may experience mild discomfort. You will have had one of these before with your ENT doctor. There is a small chance you might have a nose bleed (1%), however this is very rare.

Where is the study run from?
The study is run from the University of Liverpool, UK
You may be eligible to take part in the study if you live in Merseyside or Cheshire.

When is the study starting and how long is it expected to run for?
The study is starting in May 2026 and finishing in February 2028

Who is funding the study?
The National Institute for Health and Care Research (NIHR) funds this study (303061)

Who is the main contact?
The chief Investigator is Dr Michelle Lawton, Michelle.Lawton@liverpool.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
335217

Central Portfolio Management System (CPMS)
61140

National Institute for Health and Care Research (NIHR)
303061

Study information

Scientific Title
Evaluating the feasibility of a respiratory-swallow training intervention to improve swallow function for people with head and neck cancer

Acronym
ReST-HN

Study objectives
This study aims to:
1. Develop a training package for speech and language therapists
2. Train speech and language therapists to use the programme with patients
3. Carry out a study to examine how the training programme would work in practice, using a biofeedback approach
4. Determine whether the project is feasible and likely to be effective within the NHS

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 13/03/2024, London-Camden & Kings Cross REC (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; no telephone number provided; camdenandkingscross.rec@hra.nhs.uk), ref: 24/LO/0164

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Single

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Swallow training in head and neck cancer

Interventions
Development of Respiratory-Swallow Training programme (biofeedback)
A treatment manual will be developed for ReST using biofeedback using the TIDieR framework detailing: the equipment set-up, feedback provision, monitoring and measuring of goals for both interventions.

Respiratory Swallow Training (ReST) using biofeedback group:
Clinicians (Speech and language therapists) at the participating sites will be trained to deliver ReST using biofeedback, as per the treatment protocol. Training will include: theoretical underpinning, treatment procedure, practical application and use of instrumentation. Competency will be determined by successful (100%) identification of optimal respiratory-swallow coordination (exhale-swallow-exhale pattern) using visual feedback.
ReST training sessions with take place up to 1 hour weekly for up to 6 weeks until mastery is reached. An experienced speech and language therapist, who has received training, will deliver ReST using biofeedback to participants at an NHS clinic or the participant's home, dependent of individual preference or clinical availability. Participants will continue to see their treating therapist as part of usual care (if applicable) whilst receiving ReST. The treatment protocol will follow a tripartite design incorporating principles of motor learning as outlined by Martin-Harris & colleagues (2015). Goals will be included which are divided into sub-goals within three learning domains: 1) identification, 2) acquisition, and 3) mastery. Participants will only move onto the next phase when they have demonstrated 90% accuracy (over 10 trials) on any given goal.

1. Identification:
Participants will be presented with a series of static graphical representations of swallowing and respiration via an online programme. These graphics will show the respiratory cycles and the swallowing. Participants will be asked to identify specific targets to demonstrate their ability to recognise: (1) phases of breathing, (2) the swallow trigger, and (3) optimal versus suboptimal swallowing patterns.
Participants will then progress to viewing similar representations presented dynamically on a computer screen. To advance to the next stage, participants must correctly identify targets in at

least 9 out of 10 trials. If fewer than 9 trials are correctly identified, additional practice will be provided and/or earlier learning objectives will be revisited.
This training will be delivered as an online module that can be completed either independently at home or with support from a therapist, according to participant preference.

2. Acquisition:
The aim of the acquisition module is for participants to be able to self-initiate swallows during the expiratory cycle. Participants will view a visual graphical representation of their own respiratory-swallow pattern on the computer screen, via respiratory Inductance plethysmography and a manual switch, which will be pressed by the therapist to mark the swallow. The clinician will provide verbal feedback to participants in relation to accuracy. Teaspoons of thin fluids will be initially trialled, providing they can be safely swallowed. If participants are unable to swallow thin fluids safely, thicker fluids will be trialled as per the findings on instrumental swallow assessment. Swallow initiation during expiration will initially be targeted (with and without visually guided feedback). Only consistencies the participant is safely able to tolerate will be used for training (as per the instrumental swallow assessment). Participants will need to successfully complete 9/10 trials at each stage to move on to the mastery phase.

3. Mastery: The aim of the mastery module is to ensure participants are able to use an optimal respiratory swallow pattern (i.e. exhale-swallow-exhale) with 90% consistency, without visual or verbal feedback. The programme will run for 5-6 weeks.

Usual care group:
Usual care refers to speech and language therapy provided by the treating speech and language therapist as part of routine care. Speech and language therapy (SLT) aims to remediate swallowing, speech and voice difficulties following head and neck cancer. SLT may include assessment (clinician-rated, patient-rated and instrumental), intervention and/or review, which may focus on the use of compensatory strategies, strengthening and range of motion exercises, supporting mood and confidence, working with family/carers and providing information. Therapy is individually tailored and is largely face-to-face, however it may incorporate telehealth or group work. Patients are seen as inpatients, outpatients or in the community. Dysphagia therapy may include but is not limited to: swallow exercises (e.g. effortful swallow, Masako manoeuvre, Mendelsohn manoeuvre, supra-glottic swallow) and non-swallow exercises (e.g. range of movement exercises, tongue strengthening, expiratory muscle strength training). Therapy may also focus on speech and voice training, directly targeting articulation and vocal quality.

Intervention Type
Other

Primary outcome(s)
1. Intervention uptake measured using Screening and enrolment logs recording number of eligible patients and number consenting at Throughout recruitment period

2. Acceptability of the intervention measured using Semi-structured qualitative interview at during and following the intervention

3. Acceptability of randomisation measured using Semi-structured qualitative interview at during and following the intervention

4. Completeness of outcome measures measured using assessment completion records calculating percentage completed at 3 month follow up

5. Adherence to treatment manual measured using Treatment fidelity checklist scored from video-recorded sessions at During intervention period

6. Determinants of implementation and mechanisms of change measured using Semi-structured qualitative interview at during and following the intervention

Key secondary outcome(s))
1. Respiratory swallow coordination measured using Respiratory inductance plethysmography, nasal airflow and submental surface electromyography analysed using LabChart software at Baseline, post intervention, 3 month follow up

2. Lung volume during swallowing measured using Respiratory inductance plethysmography calibrated to lung volume estimates at Baseline, post intervention, 3 month follow up

3. Respiratory swallow pattern measured using respiratory inductance plethysmography and nasal airflow recordings at Baseline, post intervention, 3 month follow up

4. Respiratory pause duration during swallowing measured using nasal airflow recordings at Baseline, post intervention, 3 month follow up

5. Swallow safety measured using Penetration Aspiration Scale scored from videofluoroscopic swallow study at Baseline, post intervention, 3 month follow up

6. Swallow physiology and impairment measured using Modified Barium Swallow Impairment Profile scored from videofluoroscopic swallow study at Baseline, post intervention, 3 month follow up

7. Swallow related quality of life measured using MD Anderson Dysphagia Inventory questionnaire at Baseline, post intervention, 3 month follow up

8. Functional swallow performance measured using Performance Status Scale for Head and Neck Cancer at Baseline, post intervention, 3 month follow up

9. Pulmonary function measured using Spirometry measuring forced expiratory volume in 1 second and forced vital capacity ratio using a digital spirometer at Baseline only

10. Health related quality of life specific to head and neck cancer measured using European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire Head and Neck module HN43 at Baseline, post intervention, 3 month follow up

Completion date
29/08/2028

Eligibility

Key inclusion criteria
1. Have a clinical diagnosis of dysphagia on instrumental assessment using videofluoroscopic swallow study or fibreoptic endoscopic evaluation of swallowing

2. Have dysphagia indicated by outcome measures with penetration aspiration scale score at least 3 and/or DIGEST efficiency grade at least 1
3. Have completed chemotherapy, radiotherapy and or surgical intervention with curative intent for first time diagnosis of squamous cell carcinoma of the head and neck at least 3 months previously
4. Be able to give informed consent
5. Be aged 18 years or above
6. Be able to tolerate fluids orally IDDSI Level 0 to 3
7. Exhibit a suboptimal respiratory swallow pattern exhale to inhale, inhale to inhale, or inhale to exhale in at least 20% of swallow trials
8. Be able to hold a drink orally and resume breathing

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
120 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. A nasogastric tube, laryngectomy or tracheostomy where tube presence will alter respiratory swallow coordination
2. Known neurological disease or insult impacting on swallowing
3. Spinal surgery or insult impacting on swallowing
4. Chronic COPD with forced expiratory volume less than 30% on pulmonary function testing
5. Recent history within the last 3 months of aspiration pneumonia

Date of first enrolment
06/05/2026

Date of final enrolment
29/02/2028

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Clatterbridge Cancer Centre
Clatterbridge Hospital
Clatterbridge Road
Wirral
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CH63 4JY

Study participating centre
Liverpool University Hospitals NHS Foundation Trust
Royal Liverpool University Hospital
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Study participating centre
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Sponsor information

Organisation
University of Liverpool

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publicly available repository (University of Liverpool repository, anonymised raw data will be shared, the data will become available following study completion for a period of 10 years, consent from participants will be obtained)

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 1.7	10/04/2026	21/04/2026	No	No