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Feasibility of exercises to treat swallowing difficulty after cancer surgery to remove the voice box

Submission date
13/07/2023

Recruitment status
Recruiting

Registration date
21/07/2023

Overall study status
Ongoing

Last Edited
08/08/2023

Condition category
Signs and Symptoms

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

Plain English summary of protocol

Background and study aims
In the UK, 2,400 people each year are diagnosed with cancer of the voice box, which is called the larynx. The total cost of treatment of laryngeal cancer in the UK has been estimated at £96 million over a 5-year period. As part of laryngeal cancer treatment, some patients undergo the removal of the voice box (laryngectomy) and the placement of a permanent hole in the neck for breathing. Common effects of this surgery include needing to leave the table during mealtimes to spit up food stuck in the throat or deal with liquid coming out of the nose. These problems cause embarrassment when eating alone and with others and impact mental health. Despite previous studies indicating that 72% of people with a laryngectomy have problems with swallowing, currently, we do not have enough information to help patients with this problem. As muscle strengthening and stretching exercises have improved swallowing difficulty in those who have a voice box, it is possible that exercises may help people with a laryngectomy enjoy food again without having to undergo further surgery. This proposed research will examine whether patients find the exercises acceptable, suitable and workable to use to improve swallowing after laryngectomy.

Who can participate?
People with laryngectomy aged 18 to 100 years old who have difficulty swallowing and have completed cancer treatment 3 months ago or more

What does the study involve?
Some patients who agree to participate in the study will be randomised to exercise every day for 6 weeks and others will be randomised to continue with their usual care. Swallowing ability will be measured at the start of the study and at 3, 6 and 18 months after exercises are completed. Measurements will include questionnaires completed by participants and clinicians. All patients will additionally be asked to volunteer to have a tube placed into their nose to measure pressure during swallowing with a moving x-ray of the swallow recorded simultaneously. We will ask people about how helpful they found the exercises. We will also look at whether the tools used to measure the change in swallowing ability worked well.

A group of 4 patients has formed an advisory group to help design this study and has agreed to meet 3 times each year over the duration of the study (3 years) to make sure that the information from the study is used in the right way. As a result of the focus group discussion, a laryngectomy patient who has experienced significant swallowing difficulty has agreed to become a patient involvement lead for the study. This patient has influenced the design of the study and has agreed to be available for 4 days each year over the 3-year course of the study to help with tasks related to the study.

Findings will be written for publication in scientific journals with a plain language summary and presented to patients and members of the public via outpatient clinic leaflets, the National Association of Laryngectomy Clubs newsletter and Twitter. Findings will also be used to plan a future study to see whether exercises really work to improve swallowing after laryngectomy surgery.

What are the possible benefits and risks of participating?
The findings of this study will have a positive impact on the care of future and current patients by being a critical step in enabling a later study to happen. The findings of this study and the future one will have the potential to improve the quality of life of patients, prevent unnecessary surgery and reduce healthcare costs for patients who have lost their voice box.

Some participants may find the placement of the tube in their nose to measure pressure a little uncomfortable. If this happens, the tube placed in the nose will be removed.

Where is the study run from?
Imperial College Healthcare NHS Trust and the Royal Marsden NHS Foundation Trust (UK)

Who is funding the study?
National Institute of Health Research (NIHR) (UK)

Who is the main contact?
Dr Margaret Coffey, Senior Clinical Academic Speech and Language Therapist, mcoffey@nhs.net

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
326342

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 326342, CPMS 57806

Study information

Scientific Title
An investigation of the feasibility of exercises as a swallowing difficulty treatment after laryngectomy compared with standard treatment (no intervention) as measured on patient self-report outcome measures and instrumental dysphagia evaluation

Acronym
FEAST

Study objectives
Null hypothesis
Exercise is neither a workable nor acceptable treatment for swallowing difficulty after laryngectomy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics pending as of 13/07/2022
Awaiting Research Governance and Integrity Sponsorship from Imperial College Healthcare Trust prior to submission of IRAS application 346342. Note IRAS application is at an advanced stage of completion

Study design
Multicentre interventional randomised unblinded feasibility study

Primary study design
Interventional

Secondary study design
Feasibility

Study setting(s)
Hospital

Study type(s)
Other

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
Swallowing function after laryngectomy

Interventions
This is a feasibility study with two work packages. A feasibility study design has been chosen as there is limited research in this area. Undertaking a feasibility study allows the researcher to find out whether exercise treatment for swallowing difficulty after laryngectomy is workable and

acceptable to patients and clinicians. This information will help refine the design for a later randomised control trial investigating the effectiveness of exercise treatment for people with laryngectomy.

Project 1: TRAINING WORK PACKAGE
Aim: To establish how to effectively train other Speech and Language Therapists to show people who have undergone laryngectomy surgery to undertake exercises to improve swallow function accurately.

Method and Analysis
The study will involve developing and delivering a training programme and resources with clinicians and patients, to enable effective treatment provision by Speech and Language Therapists (SLTS) A course evaluation tool will be developed. The training programme will be trialled with ten SLTs within the four London Cancer Alliances, over six one-hour sessions.

These sessions will involve a combination of online and face-to-face work to introduce the treatment and how best to deliver it. The effectiveness of the training programme will be evaluated through
(i) check that the intervention can be delivered accurately by clinicians
(ii) online survey of clinicians participating in the training
(iii) analysis of course evaluation results analysis including the percentage of participants passing. This information will refine the SLT training programme for the later RCT.

Project 2: FEASIBILITY WORK PACKAGE
Aim: To establish whether it is workable and acceptable to deliver an exercise treatment to improve swallow function in people who have undergone laryngectomy surgery.

Parameter 1: To establish whether it is workable and acceptable to deliver the treatment (swallow exercises) accurately across two sites.

Method and Analysis Session content and treatment plan will be recorded in the participant's electronic medical notes and research study record. Clinicians providing the intervention will be interviewed for views on treatment acceptability. An assessment of whether the treatment can be delivered as planned at both sites according to the treatment protocol (fidelity) will be undertaken by analysing medical notes and the research study record.

Parameter 2: To establish whether the treatment is workable and acceptable for participants.

Method and Analysis
The treatment will involve participants in the treatment group attending a 60-minute outpatient Speech and Language Therapy appointment once a week for 6 weeks to undertake tongue strengthening and soft tissue therapy exercises including neck positioning and gentle massage. The participants in the treatment group will additionally be asked to independently complete exercises at home 3 times a week. Interviews will be undertaken with participants at the beginning and end of the 6-week treatment period. Key conversations and participant feedback about the treatment will be recorded. Information from interviews and feedback will be analysed to help understand whether the treatment is feasible and acceptable. Patient volunteers will be involved to help analyse information accurately. Information on the percentage of participants who do and do not complete the treatment will be measured.

Parameter 3: To establish workable methods to ensure treatment is carried out accurately.

Method and Analysis
The use of a wearable sensor to record muscle movement when undertaking swallow exercises will be explored as a means of measuring the completion of exercises alongside patient diaries and questionnaires. Participant ability to complete treatment will also be explored through the use of the Behaviour Change Wheel with participants. Things that both help and don't help participants in completing swallow exercises will be measured. Information from ten participant interviews will be used to identify the most suitable method to optimise the participant's ability to complete treatment for the later Randomised Control Trial (RCT).

Parameter 4: To establish the willingness of participants to become involved in the study and to be placed at random in a swallow exercise treatment group or a group that receives no swallow exercise treatment.

Method and Analysis
People with Laryngectomy (PWL) at both Imperial College Healthcare Trust (ICHT) and Royal Marden Foundation Hospital Trust (RMH) will be approached in person and by email to determine willingness to become involved in the study and to be placed at random in a swallow exercise treatment group or a no-treatment group. The proportion of PWL who consent to become involved in the study and in randomisation and recruitment will be measured alongside the number of sessions attended. Views of participants and those who decline participation will be collected through interviews and email responses with a view to optimising recruitment for the later RCT.

Parameter 5: To establish the willingness of clinicians to ask patients to get involved in the study and to place patients at random in a swallow exercise treatment group or a group that receives no treatment.

Method and Analysis
An online survey of HNC SLTs working across UK Cancer Alliances will be undertaken to evaluate clinician willingness to recruit and randomise participants. Percentages of those willing to recruit and randomise participants will be measured. Analysis of information will help identify factors promoting a willingness to ask patients to get involved in the study and to place patients at random into a treatment group and a non-treatment group. This information will help inform the process for randomisation for the later RCT.

Parameter 6: To establish follow-up rates for participants at three, six and eighteen-month intervals.

Method and Analysis
Follow-up will include an 18-month timepoint to evaluate the feasibility of maintaining participation over a time for the RCT. Participant dropout rate will be calculated to estimate appropriate recruitment targets. Reasons for dropout will be identified when possible.

Parameter 7: To establish the number of eligible patients for the future RCT

Method and Analysis
The rate and different methods for the recruitment of patients will be measured as follows:
• PWL attending weekly HNC clinic virtually or face-to-face at both sites
• PWL attending 6-weekly UK-wide ICHT tertiary laryngectomy problem-solving clinic
• Audit of PWL in centres across UK Cancer alliances

Parameter 8: To establish an estimate of the number of participants required for the later RCT

Method and Analysis
Feasibility study information and evidence will be used to estimate the number of participants needed size for the later RCT. Factors informing which will help decide this number include some statistical calculations

Parameter 9: To determine the feasibility of measuring cost-effectiveness outcomes

Method and Analysis
1. Information will be analysed to determine what resource use contributes a significant proportion to total costs in this patient group (e.g., the exercise programme, primary care NHS contacts for swallow management, secondary care NHS contacts, and patient travel costs).
2. The workability and acceptability of obtaining data relating to quality-of-life outcome measures QOL (EQ-5D – 5L) and employment status from patients will be measured through interviews with participants alongside the percentage of participants completing EQ-5D-5L and indicating employment status. The primary focus of this analysis is to facilitate a detailed cost-effectiveness analysis to be undertaken as part of the future RCT.

Parameter 10. To establish whether the following outcome measures (OM) are acceptable to participants
• 100 ml water swallow test - 20 minutes - Clinician reported OM (CROM)
• MDADI - 30 minutes - Patient reported OM (PROM)
• HRM and Videofluoroscopy - 60 minutes - Performance OM (PM)

Method and Analysis
The time involved to complete all OMs for each participant will be calculated to see whether this is 90 minutes or less and acceptable. Participants will complete a questionnaire to examine the perception of burden across the time points for each OM and the acceptability of each of the outcomes including travel to another hospital site for HR. The percentage of positive responses will be measured.

Parameter 11. To establish whether the following OMs are acceptable to clinicians and measure the change in swallow before and after the intervention.
• 100 ml water swallow test - 20 minutes - CROM
• FOIS – 15 minutes - CROM
• PSS-HN – 15 minutes - CROM
• Video fluoroscopy and Pharyngeal Constriction Ratio (PCR) - 15 minutes – PM
• High-Resolution Manometry – 60 minutes - PM
• Goniometer – 10 minutes – PM

Evaluation using a combination of PROM, CROM and PMs will be undertaken by each subject in the treatment and non-treatment group. As HRM and PCR involve radiation exposure, these will be undertaken at baseline and three months only. All other measures will be undertaken at baseline, three months, six months, and eighteen months. HRM is a PM tool used during videofluoroscopic (x-ray) swallow exams to measure. swallow pressure changes. The PCR is a calculation elicited from videofluoroscopy swallow images to measure pharyngeal strength in non-laryngectomy patients. PCR will be investigated as a possible stand-in measure for HRM for future RCT. The final PM is a Goniometer, a valid, well-established tool for the measurement of neck movement and degree of rotation.

Method and Analysis
The time involved for each clinician to complete all OM for each participant will be calculated to

see whether this is <60 minutes and acceptable to clinicians. Scores for each OM will be compared before and after treatment to investigate whether a minimally clinically important difference or other meaningful difference has occurred.
Clinicians will complete a questionnaire about the acceptability and ability of tools to measure the change in swallow before and after the intervention. The percentage of positive responses will be measured.
Data and all appropriate documentation will be stored for a minimum of 5 years after the completion of the study, including the follow-up period.

Other information
The study will take place as part of a 36-month NIHR advanced fellowship which started on 01.02.23. Once recruited into the study, each participant will be involved with the study for a maximum of 20 months. This period includes the 3, 6 and 18 months follow-up time points. Interviews which take place with clinicians or with participants as part of this study will usually take place in clinic rooms at each of the participating sites, Imperial College Healthcare NHS Trust or Royal Marsden NHS Foundation Trust.

Intervention Type
Behavioural

Primary outcome measure
Pressure measurements during swallow measured using High-Resolution Manometry at baseline and 3 months

Secondary outcome measures
1. Number of repeat swallows measured using the 100 ml water swallow test at baseline, and 3, 6 and 18 months
2. Patient report of swallow score measured using the MD Anderson Dysphagia Inventory at baseline, and 3, 6 and 18 months
3. Pharyngeal constriction ratio measurement measured using a videofluoroscopy swallow evaluation at baseline and 3 months
4. Clinician report of diet level score measured using a Functional Oral Intake Scale Timepoints at baseline, and 3, 6 and 18 months
5. Neck range of motion score measured using a goniometer at baseline, and 3, 6 and 18 months
6. Cost-effectiveness measured using the EuroQol EQ-5D-5L health-related quality of life measure at baseline, and 3, 6 and 18 months

Overall study start date
01/02/2023

Completion date
01/02/2026

Eligibility

Key inclusion criteria
1. Person with laryngectomy with self reported swallowing difficulty or diet restriction
2. Person with laryngectomy between 18 and 100 years

Participant type(s)
Patient

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
Both

Target number of participants
40

Key exclusion criteria
1. Person with laryngectomy more than 3 months post surgery or completion of oncological treatment
2. Person with laryngectomy with documented cognitive impairment

Date of first enrolment
01/09/2023

Date of final enrolment
31/12/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Imperial College Healthcare NHS Trust
Speech and Language Therapy Department, Ground Floor, South Wing
Charing Cross Hospital,
Fulham Palace Road
London
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W6 8RF

Study participating centre
Royal Marsden NHS Foundation Trust
SLT Department, 203 Fulham Road
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Sponsor information

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Sponsor type
Hospital/treatment centre

Website
http://www.imperial.nhs.uk/

ROR
https://ror.org/056ffv270

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

Publication and dissemination plan
Planned publication in a high impact peer-reviewed journal

Intention to publish date
20/02/2027

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository - Open Clinica data management system in collaboration with the Clinical Trials Unit at Imperial College London. These data will be pseudonymised.

IPD sharing plan summary
Stored in non-publicly available repository