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Pretreatment rehabilitation of swallowing difficulties in people with head and neck cancer

Submission date 03/03/2022	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 04/03/2022	**Overall study status** Completed	
Last Edited 09/06/2025	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims
People with cancer in the mouth or throat (head and neck cancer) usually have difficulty in swallowing food and drink at some stage before, during and/or after cancer treatment. Dysphagia (difficulty in swallowing) may persist for months or years after treatment due to side-effects of surgery and chemo/radiotherapy.
The aim of this research is to determine whether a pre-treatment swallowing intervention package improves patients' ability to eat and drink thus increasing their quality of life. The SIP SMART prehabilitation intervention comprises multiple components including: tailored information, educational counseling, personalized exercises, and specific strategies to help engage with advice and exercises.

This is a pilot study in which a small-scale version of the anticipated large clinical trial will be tested at six NHS hospitals randomised into two groups.

Who can participate?
Patients aged 18 years or older, newly diagnosed with head and neck cancer will be approached to take part.

What does the study involve?
Participation will not affect cancer treatment. One group will receive the routine "usual care" which involves meeting with the speech and language therapist (SLT) for general advice and provision of a generic swallowing exercises leaflet. The intervention group will receive the new prehabilitation package incorporating the components mentioned above. The SLTs at the intervention hospitals will all receive training in the prehabilitation package. This pilot study will provide important information about whether hospitals can recruit a sufficient number of patients to the trial, and about whether patients remain in the study long enough (six months after completion of treatment) to collect all necessary outcome measures. Other factors that may affect results in a large trial will also be explored. This includes whether SLTs deliver the intervention as planned and what patients feel about the intervention and their engagement with it.

What are the possible benefits and risks of participating?
Benefits: We cannot promise that this study will help you but the information we get from this study will help improve the treatment for people with head and neck cancer. This study is incorporated into the pathway of care for patients having treatment for head and neck cancer. Patients who participate in trials benefit from close monitoring by the research team in addition to the clinical team. It is not clear at this stage whether the pre-treatment intervention will prove more beneficial than the current usual care. The information gathered from this study will help towards answering this question.
Risks: Your surgeon or oncologist will discuss with you the specific side effects of surgery and or chemotherapy and radiotherapy depending on your specific treatment. The current SIP SMART intervention is designed to reduce one of the most significant effects of cancer treatment to the head and neck, that is difficulty in eating, drinking and/or swallowing food and liquid. SIP SMART is non-invasive and we found no serious side effects for this intervention during the preliminary study. Participation will require some of your time, for example in completing questionnaires and adhering to the exercises.

Where is the study run from?
University College London (UK)

When is the study starting and how long is it expected to run for?
November 2020 to July 2024

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

Who is the main contact?
Dr Roganie Govander, roganie.govender@nhs.net

https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-swallowing-exercises-for-people-with-a-head-and-neck-cancer-sip-smart-2

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
305731

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
145979, CPMS 52016, NIHR300427, IRAS 305731

Study information

Scientific Title
Prehabilitation of swallowing difficulties in people with head and neck cancer: A pilot cluster randomised trial and process evaluation

Acronym
SIP SMART 2

Study objectives
People newly diagnosed with head and neck cancer who participate in a complex pre-habilitation behaviour change intervention tailored to educate, counsel and facilitate swallowing exercises over and above routine usual care will achieve better dysphagia related quality of life at six months, compared with usual care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/03/2022, London Bridge Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, UK; +44 20 7104 8202; Juliana.araujo@hra.nhs.uk), ref: 22/LO/0150

Study design
Interventional pilot cluster randomized trial

Primary study design
Interventional

Secondary study design
Process evaluation

Study setting(s)
Hospital

Study type(s)

Other

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Head and neck cancer

Interventions
Standard care group: Patients recruited at sites randomised to usual care will receive the standard of care offered by the SLT service prior to their upcoming cancer treatment. Usual care may include information about the upcoming treatment and its impact on swallowing as well as the provision of a generic swallowing exercise leaflet. Patients will be asked to complete all study related questionnaires at baseline, one, three and 6 months after treatment completion.

Intervention Group: Patients in the intervention group will receive the SIP SMART intervention. The intervention takes place over two 45-minute consultations that may follow each other on the same day or with a day or two between them depending on patient preference. The new intervention will be delivered by SLTs who have completed a bespoke 2-day training course in behavioural counselling delivered by externally commissioned trainers with experience in behaviour change interventions in healthcare. Further detail about the intervention content is provided in an intervention manual available to trained clinicians at the intervention sites.

Intervention Type
Behavioural

Primary outcome measure
Recruitment/retention will be measured by:
1. Proportion of hospitals invited who agree to participate in the RCT (test of sampling, recruitment and retention approaches for hospital sites) – pre-trial logs.
2. Proportion of people with head and neck cancer approached in both trial arms who agree to provide outcome data for research evaluation – based on screening logs.
3. The proportion of patients in the intervention and control groups for whom it is possible to collect follow-up data to the point of assessing the primary outcome (clinical effectiveness as determined by the MDADI score) and data relevant for an economic evaluation (cost effectiveness) – data completeness at 6-month follow-up.
4. Proportion of missing data on each outcome at all data points measured in both arms – data completeness at baseline, one month, three months and six month time-points.
5. Proportion of patients who report satisfactory adherence to the intervention as measured by a study customised adherence questionnaire at one, three and 6 months.
6. Acceptability will be assessed via process evaluation of factors related to context and implementation at pre-trial, during trial and post-trial that may impact the future main trial. This will involve focus group discussions and one-to-one interviews with patients and staff.

Secondary outcome measures
1. Dysphagia related QOL will be measured by the MDADI at baseline, one, three and six months.
2. Clinical assessment of swallow function will be measured using the water swallow test, maximal inter-incisor jaw opening and the head and neck performance status scale for normalcy of diet and public eating at baseline, one, three and six months.
3. Health related quality of life will be assessed using the Functional Assessment of Cancer

Therapy (FACT_HN) at baseline, one, three and six months.
4. Change in nutritional parameters including weight and feeding tube status at baseline, one, three and six months will also provide proxy indicators for swallowing function.

Economic outcomes:
5. Costs associated with the intervention and usual care using NHS treatment tariffs
6. Health care utilisation costs, time and travel and productivity losses using the UK Cancer costs Questionnaire (UKCC - Version3)
7. Incremental cost per change in MDADI score between 1 month post treatment and 6 months.

Overall study start date
01/11/2020

Completion date
30/07/2024

Eligibility

Key inclusion criteria
1. Adults over the age of 18 years.
2. Both males and females.
3. Clinical and Radiological diagnosis of new stage III/IV tumour of the head and neck (oral cavity, oropharynx, nasopharynx, hypopharynx, mandible, maxilla, unknown primary with planned bilateral neck radiation)
4. Discussed at the multidisciplinary team (MDT) meeting and planned for treatment with curative intent via surgery, radiotherapy, chemoradiotherapy or combinations thereof.
5. Able to provide informed consent.
6. Patients who do not have English as their first language but for whom appropriate translation services as per local hospital practice is in place.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 72; UK Sample Size: 72

Key exclusion criteria
1. Patients with a previous diagnosis of head and neck cancer.
2. Patients who have not consented prior to cancer treatment, or those receiving palliation.
3. Patients who are to be treated solely by non-standard treatment such as photodynamic therapy, brachytherapy or chemotherapy alone.

4. Patients who are planned for a total laryngectomy or long-term tracheostomy.
5. Patients who are vulnerable and/or have significant co-morbidities as determined by the clinical team and/or with a score of 4 on the WHO performance status scale.
6. Patients who have long-term medical history of neurological conditions resulting in known pre-existing dysphagia.
7. Patients with brain tumours and other primary sites not within head and neck.
8. Patients who are unable to provide informed consent

Date of first enrolment
18/07/2022

Date of final enrolment
30/09/2023

Locations

Countries of recruitment
United Kingdom

Study participating centre
Uclh
250 Euston Road
London
United Kingdom
NW1 2PQ

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

Study participating centre
Sunderland Royal Hospital
Kayll Road
Sunderland
United Kingdom
SR4 7TP

Study participating centre

James Cook University Hospital
Marton Road
Middlesbrough
United Kingdom
TS4 3BW

Study participating centre
Luton and Dunstable University Hospital
Lewsey Road
Luton
United Kingdom
LU4 0DZ

Study participating centre
North Middlesex Hospital
Sterling Way
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N18 1QX

Sponsor information

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Sponsor type
University/education

Website
http://www.ucl.ac.uk/

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Government

Funder Name
NIHR Academy

Funder Name
National Institute for Health 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
30/07/2025

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Other	Sub-study looking at allied health professional participation in the NIHR Associate Principal Investigator scheme	14/05	09/06	Yes	No