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SIP SMART: Swallowing Intervention package - Self Monitoring, Assessment & Rehabilitation Training

Submission date 23/10/2014	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 23/10/2014	**Overall study status** Completed	
Last Edited 05/03/2021	**Condition category** Cancer	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-to-help-people-with-swallowing-after-treatment-for-head-and-neck-cancer

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
17043

Study information

Scientific Title
Development and preliminary testing of a tailored pre-treatment swallowing intervention package for patients with head and neck cancer

Acronym
SIP SMART

Study objectives
Key Question: Does a tailored pre-treatment swallowing intervention package improve post treatment swallowing outcomes in head and neck cancer patients compared to current usual care?

Preliminary work:
To devise and define the swallowing intervention package.
To specify a protocol to test the intervention.
To undertake a feasibility study to gather salient information to inform a larger, more definitive trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES committee London- South East; 31/07/2014; ref. 14/LO/1152

Study design
Randomised; Interventional and Observational; Design type: Prevention, Process of Care, Treatment, Qualitative

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
Topic: Cancer; Subtopic: Head and Neck Cancer; Disease: Head and Neck

Interventions
The study design is informed by the MRC complex intervention guidelines (Craig et. al, 2008)

The Development phase (intervention design) will be informed by literature reviews, in-depth patient interviews and paper modelling of the intervention.
The Preliminary testing phase - feasibility study using stratified block randomisation. 1:1 allocation to treatment or usual care group. Patients will be followed up for 6 months from date of surgery (if surgery only) or date of final radiotherapy treatment (if radiotherapy or combined modality treatment).

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Swallowing related QOL is measured using the MD Anderson Dysphagia Inventory (MDADI) at baseline, 1, 3 and 6 months
2. Swallowing physiology is measured using a modified barium swallow at 6 months

Secondary outcome measures
1. Health Related QOL is measured using FACT – QOL at baseline, 1, 3 and 6 months
2. Swallowing function and Normalcy of diet is measured using the Performance Status Scale (PSS) at baseline, 1, 3 and 6 months

Overall study start date
29/01/2013

Completion date
30/08/2017

Eligibility

Key inclusion criteria
Qualitative Interviews:
1. Patients who have completed treatment for advanced head and neck cancer
2. A minimum of 3 months post treatment
3. Had input from a SLT as part of their cancer care
4. Able to provide informed consent and willing to be interviewed for 40 minutes
5. Proficiency in English satisfactory for interview/participation in intervention
6. Aged 18 and above

Preliminary testing : feasibility study
1. Patients with newly diagnosed stage III and stage IV head and neck cancer
2. Discussed at the UCLH head and neck MDT and planned for curative treatment via surgery and /or chemoradiotherapy or combinations thereof

3. Able to provide informed consent
4. Proficiency in English satisfactory to participate/engage in the intervention
5. Aged 18 and above

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Interview study (13) feasibility trial (32)

Key exclusion criteria
1. Patients who are mid treatment or those receiving palliation
2. Patients who have been treated solely by non standard treatment ie not surgery, radiotherapy, chemoradiotherapy or combinations thereof. Patients treated by chemotherapy, brachy therapy, photodynamic therapy alone will be ineligible.
3. Patients who are considered vulnerable or unable to provide informed consent
4. Patients with brain tumours and other primary sites not within head and neck

Date of first enrolment
06/10/2014

Date of final enrolment
07/12/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University College London Hospital
Head & Neck Cancer Centre
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Sponsor information

Organisation
University College London

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Sponsor type
University/education

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Government

Funder Name
NIHR (UK)

Results and Publications

Publication and dissemination plan
Manuscripts currently under review and further publication of results are planned over 2017 - 2018.

Intention to publish date
30/04/2019

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made 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?
Plain English results				No	Yes
Protocol article	protocol	27/03/2017		Yes	No
Results article	results	29/04/2020	05/03/2021	Yes	No
HRA research summary			26/07/2023	No	No