

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

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

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

Contact name

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Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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

United Kingdom

England

Study participating centre

University College London Hospital

Head & Neck Cancer Centre

First Floor East

250 Euston Road

London

United Kingdom

NW1 2PQ

Sponsor information

Organisation

University College London

ROR

<https://ror.org/02jx3x895>

Funder(s)

Funder type

Government

Funder Name

NIHR (UK)

Results and Publications

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?
Results article	results	29/04/2020	05/03/2021	Yes	No
Protocol article	protocol	27/03/2017		Yes	No
HRA research summary			26/07/2023	No	No
Plain English results				No	Yes