

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

<b>Submission date</b> 23/10/2014	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 23/10/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 05/03/2021	<b>Condition category</b> Cancer	<input type="checkbox"/> 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

## Study design

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

## Primary study design

Interventional

## 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

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## **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?
<a href="#">Results article</a>	results	29/04/2020	05/03/2021	Yes	No
<a href="#">Protocol article</a>	protocol	27/03/2017		Yes	No
<a href="#">HRA research summary</a>			26/07/2023	No	No
<a href="#">Plain English results</a>				No	Yes