Development and feasibility testing of a pre-treatment swallowing intervention package for patients with head and neck cancer

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A thesis submitted for the degree Doctor of Philosophy

University College London
Declaration

I, Roganie Govender confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated.
Abstract

Dysphagia is a highly prevalent and significant problem affecting function and quality of life in patients treated for cancers of the mouth or throat. Based on available evidence, pre-treatment swallowing exercise interventions show promise in improving post-treatment swallowing outcomes for patients. Poor patient adherence undermines clinical trials of swallowing exercises. However, this behavioural issue has not been fully acknowledged in the design of previous interventions. This research aimed to devise an optimized pre-treatment swallowing intervention package, which was subsequently tested in a feasibility trial. A series of five sequential studies was undertaken to inform the development and feasibility of the new intervention. State-of-the-art behaviour change methods were employed to determine best strategies to improve patient adherence.

Study 1, a systematic review, was conducted to identify the behavioural strategies used in swallowing exercise interventions and their association, if any, with intervention efficacy. In addition to core strategies used in most swallowing interventions, self-monitoring, social support, behavioural practice and delivery by a credible source were more prevalent in effective interventions. Study 2, a patient interview study, highlighted the key barriers and facilitators to patient adherence. Psychological capability was the greatest barrier, evidenced by patient reports of not fully understanding reasons for the exercises, forgetting, and not having a system to keep track. Social support, having a routine or trigger for exercises, and the desire to avoid tube feeds were key facilitators. Study 3, a think-aloud study, indicated that a swallowing video-animation was useful and acceptable to patients in improving understanding about swallowing, thus potentially beneficial for the new intervention. In Study 4, findings and insights from these studies were synthesized and combined with other essential components such as a swallowing assessment, to model the pre-treatment swallowing intervention package. Feedback from patients and clinicians informed the final content of the new intervention prior to its use in the feasibility randomized trial (Study 5). Key success criteria for feasibility were achieved. It is anticipated that the new intervention will proceed to testing in a small multi-centre pilot study.
Acknowledgements

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Special thanks to all the patients who have participated in this research, and to members of the patient-public involvement group. This thesis is inspired and motivated by the many patient stories of hope and despair I have encountered as a dysphagia clinician.

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# Table of Contents

Chapter 1  Introduction and Background ............................................................... 14
1.1 Overview ............................................................................................................. 14
1.2 Background to Head and Neck Cancer ...................................................... 14
1.3 Treatments for HNC and their impact on swallowing function .......... 16
1.4 Behavioural swallowing interventions ....................................................... 19
1.5 Evolving practice for swallowing rehabilitation of HNC patients treated on the National Health Service .............................................................. 20
1.6 The role and context of pre-treatment swallowing exercises .......... 22
1.7 Broad aim of the research .............................................................................. 24
1.8 Context Limitations .......................................................................................... 24
1.9 Summary of Chapter ...................................................................................... 27

Chapter 2  Theoretical frameworks and aims of the thesis .......................... 28
2.1 Introduction ........................................................................................................ 28
2.2 Philosophical Framework – Evidence Based Medicine ............................. 28
2.3 Methodological Framework – MRC Complex Interventions Framework .. 29
2.4 Intervention Development Framework – Behaviour Change Wheel .... 32
2.5 Other Intervention content ............................................................................. 36
2.6 Plan of studies for this thesis .......................................................................... 36
2.7 Aims and research questions .......................................................................... 37
2.8 Patient- Public Involvement ........................................................................... 40
2.9 Study approvals and registrations ................................................................. 40
2.10 My contribution to the work reported in this thesis................................... 41
<table>
<thead>
<tr>
<th>Chapter 3</th>
<th>Study 1: Behaviour change strategies used in swallowing exercise interventions for patients with head and neck cancer – A systematic review</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.1</td>
<td>Introduction</td>
</tr>
<tr>
<td>3.2</td>
<td>Background and rationale for Study 1</td>
</tr>
<tr>
<td>3.3</td>
<td>Methods</td>
</tr>
<tr>
<td>3.4</td>
<td>Analysis</td>
</tr>
<tr>
<td>3.5</td>
<td>Results - Synthesis of study and intervention characteristics</td>
</tr>
<tr>
<td>3.6</td>
<td>Exploring relationships between behavioural strategies and effectiveness</td>
</tr>
<tr>
<td>3.7</td>
<td>Exploring relationships between comparator group and effectiveness.</td>
</tr>
<tr>
<td>3.8</td>
<td>Type and timing of outcome measures and intervention effectiveness:</td>
</tr>
<tr>
<td>3.9</td>
<td>Discussion</td>
</tr>
<tr>
<td>3.10</td>
<td>Conclusion</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chapter 4</th>
<th>Study 2: Patient experience of swallowing exercises after head and neck cancer: A qualitative study examining barriers and facilitators using behaviour change theory</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.1</td>
<td>Introduction</td>
</tr>
<tr>
<td>4.2</td>
<td>Background</td>
</tr>
<tr>
<td>4.3</td>
<td>Methods</td>
</tr>
<tr>
<td>4.4</td>
<td>Analysis</td>
</tr>
<tr>
<td>4.5</td>
<td>Results</td>
</tr>
<tr>
<td>4.6</td>
<td>Discussion</td>
</tr>
<tr>
<td>4.7</td>
<td>Conclusion</td>
</tr>
</tbody>
</table>
Chapter 5  Study 3: Helping head and neck cancer patients understand
dysphagia: Exploring the use of video-animation using think-aloud
methodology

5.1  Introduction

5.2  Background and rationale for this study

5.3  Method: A think-aloud study

5.4  Analysis

5.5  Results

5.6  Discussion

5.7  Conclusion

Chapter 6  Study 4. Intervention development: Modelling the new
swallowing intervention package

6.1  Introduction

6.2  Identifying the evidence base

6.3  Identifying and developing theory

6.4  Modelling the new intervention and outcomes

6.5  Stakeholder Consultation

6.6  The new intervention - SIP SMART

6.7  Discussion

Chapter 7  Protocol for the SIP SMART feasibility randomized controlled trial

7.1  Background

7.2  Aims of the SIP SMART feasibility study

7.3  Methods

7.4  Safety Considerations

7.5  Data Collection and Management

7.6  Analysis

7.7  Discussion
Chapter 8  Study 5: Findings of the feasibility study ............................................ 186
8.1  Introduction .................................................................................................... 186
8.2  Recruitment .................................................................................................. 186
8.3  Patient participation and acceptability of randomization ...................... 190
8.4  Research Processes and completeness of data collection ..................... 197
8.5  Candidate outcome measures and sample size estimation ................. 205
8.6  Summary of success criteria for the feasibility study ......................... 209
8.7  Discussion .................................................................................................... 210
8.8  Conclusions ................................................................................................. 218

Chapter 9  General Discussion and Conclusions ................................................. 219
9.1  Overview ..................................................................................................... 219
9.2  Summary of work undertaken and main findings ............................... 219
9.3  Reflection on how the studies worked together to inform the SIP
     SMART intervention ..................................................................................... 221
9.4  Limitations of this work.......................................................................... 226
9.5  Next steps in the intervention development and testing work ............. 227
9.6  Reflections on the methodology and frameworks ............................... 228
9.7  Comparison of this work with the latest swallowing intervention
     studies in head and neck cancer ................................................................. 231
9.8  Contributions of this thesis................................................................... 236
9.9  Concluding Remarks ............................................................................... 240

Bibliography ...................................................................................................... 241

Appendices ........................................................................................................ 263
## Table of Tables

<table>
<thead>
<tr>
<th>Table Reference</th>
<th>Description</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Table 2-1</td>
<td>Overview of thesis studies and chapters</td>
<td>39</td>
</tr>
<tr>
<td>Table 2-2</td>
<td>Study registrations and approvals</td>
<td>40</td>
</tr>
<tr>
<td>Table 3-1</td>
<td>Search strategy for Medline</td>
<td>50</td>
</tr>
<tr>
<td>Table 3-2</td>
<td>BCTs identified and examples from studies included in the review</td>
<td>56</td>
</tr>
<tr>
<td>Table 3-3</td>
<td>Intervention functions identified and examples from studies included in the review</td>
<td>60</td>
</tr>
<tr>
<td>Table 3-4</td>
<td>Study characteristics and description of sample</td>
<td>65</td>
</tr>
<tr>
<td>Table 3-5</td>
<td>Quality ratings of studies included in the review</td>
<td>73</td>
</tr>
<tr>
<td>Table 3-6</td>
<td>Behavior Change Techniques identified from review studies</td>
<td>75</td>
</tr>
<tr>
<td>Table 4-1</td>
<td>Characteristics of sample</td>
<td>91</td>
</tr>
<tr>
<td>Table 4-2</td>
<td>Examples of key barriers</td>
<td>95</td>
</tr>
<tr>
<td>Table 4-3</td>
<td>Examples of key facilitators</td>
<td>96</td>
</tr>
<tr>
<td>Table 5-1</td>
<td>Example of thematic analysis from think-aloud study</td>
<td>115</td>
</tr>
<tr>
<td>Table 6-1</td>
<td>Excerpt of the behavioural analysis using COM-B and TDF</td>
<td>146</td>
</tr>
<tr>
<td>Table 6-2</td>
<td>Intervention Functions suitable for the new intervention</td>
<td>147</td>
</tr>
<tr>
<td>Table 6-3</td>
<td>Behaviour change techniques suitable for the new intervention</td>
<td>148</td>
</tr>
<tr>
<td>Table 6-4</td>
<td>Outline plan SIP SMART: Swallowing Intervention Package- Self-Monitoring, Assessment &amp; Rehabilitation Training</td>
<td>159</td>
</tr>
<tr>
<td>Table 6-5</td>
<td>Complexity dimensions of SIP SMART using the Intervention Complexity Assessment Tool (ICAT)</td>
<td>164</td>
</tr>
<tr>
<td>Table 7-1</td>
<td>Outcome measures and time-points</td>
<td>180</td>
</tr>
<tr>
<td>Table 8-1</td>
<td>Patient responses to trial participation questionnaire</td>
<td>192</td>
</tr>
<tr>
<td>Table 8-2</td>
<td>Baseline characteristics of all patients randomized</td>
<td>195</td>
</tr>
<tr>
<td>Table 8-3</td>
<td>Completeness of swallowing outcome measures across time-points for both groups</td>
<td>200</td>
</tr>
<tr>
<td>Table 8-4</td>
<td>Summary of reasons that helped or hindered undertaking exercises</td>
<td>205</td>
</tr>
<tr>
<td>Table 8-5</td>
<td>Swallow related outcomes and between group effect sizes</td>
<td>207</td>
</tr>
<tr>
<td>Table 8-6</td>
<td>Calculation of sample size for comparing two means</td>
<td>209</td>
</tr>
<tr>
<td>Table 8-7</td>
<td>Feasibility criteria for success</td>
<td>210</td>
</tr>
<tr>
<td>Figure</td>
<td>Description</td>
<td>Page</td>
</tr>
<tr>
<td>--------</td>
<td>------------------------------------------------------------------------------------------------</td>
<td>------</td>
</tr>
<tr>
<td>Figure 1-1</td>
<td>Types of behavioural swallowing interventions showing common examples</td>
<td>20</td>
</tr>
<tr>
<td>Figure 1-2</td>
<td>Typical pathway for a patient newly diagnosed with head and neck cancer</td>
<td>26</td>
</tr>
<tr>
<td>Figure 2-1</td>
<td>Use of the *MRC framework for development and evaluation of complex interventions and evidence based medicine to model a new SIP</td>
<td>31</td>
</tr>
<tr>
<td>Figure 2-2</td>
<td>The Behaviour Change Wheel</td>
<td>33</td>
</tr>
<tr>
<td>Figure 2-3</td>
<td>Overview of research plan</td>
<td>37</td>
</tr>
<tr>
<td>Figure 3-1</td>
<td>Logic Model of a swallowing exercise intervention</td>
<td>46</td>
</tr>
<tr>
<td>Figure 3-2</td>
<td>PRISMA flowchart showing process of study selection</td>
<td>52</td>
</tr>
<tr>
<td>Figure 4-1</td>
<td>Use of the COM-B and TDF to devise the interview schedule</td>
<td>90</td>
</tr>
<tr>
<td>Figure 5-1</td>
<td>Still image of the video-animation app showing a normal swallow</td>
<td>113</td>
</tr>
<tr>
<td>Figure 6-1</td>
<td>Generic model of the basic structure of rehabilitation treatment theories</td>
<td>132</td>
</tr>
<tr>
<td>Figure 6-2</td>
<td>Proposed causal relationship for the new swallowing intervention</td>
<td>134</td>
</tr>
<tr>
<td>Figure 6-3</td>
<td>Overview of the intervention development</td>
<td>136</td>
</tr>
<tr>
<td>Figure 6-4</td>
<td>Screenshot of the Tactus Dysphagia Therapy App</td>
<td>141</td>
</tr>
<tr>
<td>Figure 6-5</td>
<td>Tailoring exercises to physiological impairment</td>
<td>141</td>
</tr>
<tr>
<td>Figure 6-6</td>
<td>Process of devising intervention content</td>
<td>144</td>
</tr>
<tr>
<td>Figure 7-1</td>
<td>Trial flowchart</td>
<td>176</td>
</tr>
<tr>
<td>Figure 8-1</td>
<td>Accrual into SIP SMART feasibility trial</td>
<td>187</td>
</tr>
<tr>
<td>Figure 8-2</td>
<td>Percentage breakdown of all potentially eligible patients</td>
<td>188</td>
</tr>
<tr>
<td>Figure 8-3</td>
<td>CONSORT diagram showing flow of participants through the trial</td>
<td>197</td>
</tr>
<tr>
<td>Figure 8-4</td>
<td>Percentage of patients who reported satisfactory to good adherence across time-points</td>
<td>204</td>
</tr>
</tbody>
</table>
### Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
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<td>BEHAVIOUR CHANGE TECHNIQUE</td>
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<td>BEHAVIOUR CHANGE TECHNIQUE TAXONOMY V1</td>
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</tr>
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</tr>
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<td>ICER</td>
<td>INCREMENTAL COST-EFFECTIVENESS RATIO</td>
</tr>
<tr>
<td>IF</td>
<td>INTERVENTION FUNCTION</td>
</tr>
<tr>
<td>ISRCTN</td>
<td>INTERNATIONAL STANDARD RANDOMISED CONTROLLED TRIAL NUMBER</td>
</tr>
<tr>
<td>MASA</td>
<td>MANN ASSESSMENT OF SWALLOWING ABILITY</td>
</tr>
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</tr>
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</tr>
<tr>
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<td>Full Form</td>
</tr>
<tr>
<td>--------------</td>
<td>-----------</td>
</tr>
<tr>
<td>MRC</td>
<td>MEDICAL RESEARCH COUNCIL</td>
</tr>
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</tr>
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</tr>
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</tr>
<tr>
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</tr>
<tr>
<td>PPI</td>
<td>PATIENT-PUBLIC INVOLVEMENT</td>
</tr>
<tr>
<td>PRISMA</td>
<td>PREFERRED REPORTING OF ITEMS FOR SYSTEMATIC REVIEWS AND META-ANALYSIS</td>
</tr>
<tr>
<td>PSS</td>
<td>PERFORMANCE STATUS SCALE</td>
</tr>
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</tr>
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</tr>
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</tr>
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</tr>
<tr>
<td>SIP SMART</td>
<td>SWALLOWING INTERVENTION PACKAGE- SELF MONITORING, ASSESSMENT, REHABILITATION TRAINING</td>
</tr>
<tr>
<td>SLT</td>
<td>SPEECH AND LANGUAGE THERAPIST</td>
</tr>
<tr>
<td>SPIRIT</td>
<td>STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTION TRIALS</td>
</tr>
<tr>
<td>SPSS</td>
<td>SWALLOWING PERFORMANCE STATUS SCALE</td>
</tr>
<tr>
<td>TDF</td>
<td>THEORETICAL DOMAINS FRAMEWORK</td>
</tr>
<tr>
<td>TIDIER</td>
<td>TEMPLATE FOR INTERVENTION DECSRIPTION AND REPLICATION</td>
</tr>
<tr>
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</tr>
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<tr>
<td>UK</td>
<td>UNITED KINGDOM</td>
</tr>
<tr>
<td>VFS</td>
<td>VIDEOFLOUROSCOPY</td>
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<td>WST</td>
<td>WATER SWALLOW TEST</td>
</tr>
</tbody>
</table>
Chapter 1  Introduction and Background

“You don’t know what it’s like not being able to eat your favourite foods until it starts to happen, until you can’t eat spaghetti with seafood or you can't eat cereal for breakfast, because muesli, it’s like eating glass or something. You don’t know that’s going to happen. Suddenly, you know as time goes by, the things that you can eat lessen and lessen, and it gets a bit boring eating soup for weeks. Maintaining being able to eat and drink what I like in the future, for me, would be a high priority.”

(48 year-old male, following chemo-radiation therapy for head and neck cancer)

1.1 Overview

The ability to eat and drink is a basic human function, need and right that may be affected when an individual is diagnosed with a head and neck cancer. The majority of patients who undergo treatments for cancer of the head and neck experience difficulty in swallowing, also known as dysphagia, at some stage during their cancer journey. This chapter provides the relevant background and sets the context for the research described in this thesis. Relevant literature and current health service practices are discussed as a basis for informing the research aim and exemplifying the motivation for this work.

1.2 Background to Head and Neck Cancer

Head and neck cancer (HNC) is an umbrella term that includes cancers that may arise in any anatomical structure within the oral cavity, pharynx, larynx, paranasal sinuses, nasal cavity or salivary glands. The term also refers to bone tumours of the jaw. Cancers of the head and neck frequently spread to adjacent neck nodes via the lymphatic system. Most commonly, they affect the squamous cells lining the moist surfaces of the mouth and throat resulting in squamous cell carcinoma. An average estimate for the world-wide incidence of HNC has been reported to be approximately 550 000 new cases per year, with an average mortality rate of approximately 300 000 deaths per year (Parkin et al., 2005). Recent publications of global cancer statistics have provided further detail on patterns of HNC incidence by
reporting oral cavity, pharyngeal, and laryngeal cancers separately. The incidence of laryngeal cancer has decreased whilst oropharyngeal\(^1\) cancers have increased (Simard et al., 2014).

The most common risk factors for HNC are smoking and alcohol. Together, they present a synergistic risk that can be up to 35-fold higher for those individuals with highest use of alcohol and tobacco compared to abstainers (Dal Maso et al., 2015).

The human papilloma virus has also been associated with a rise in head and neck cancer, particularly in the oropharyngeal subsites (Chaturvedi et al., 2013). In a recent meta-analysis of European populations, the prevalence of human papilloma virus was reported to be as high as 40% in head and neck cancers in general and up to 66% in cancer arising in the tonsil (Abogunrin et al., 2014). Another known risk factor for oral carcinogenesis is the chewing of betel nut or products derived from betel nut, which is reported to be practiced by approximately 10% of the world’s population although predominantly in Asian countries (Sharan et al., 2012). The import and sale of betel nut products in the UK is unregulated (Sharan et al., 2012) and some parts of England and Wales with greater concentrations of ethnically diverse populations have seen an increased incidence of oral cavity cancer linked to the use of betel products (Csikar et al., 2013).

The health implication of these changing etiological factors means that not only is the incidence and prevalence of head and neck cancer on the rise (mainly oral and oropharyngeal subsites), but the age and gender demographic is also gradually changing. Many younger people of both genders are developing head and neck cancer. The current lifetime risk for a newborn infant developing head and neck cancer is 1 in 84 for males and 1 in 160 for females (Cancer Research UK, 2012). Survival rates in England and Wales have shown steady improvement due to advances in treatment and changes in service delivery (Audit data for Head and Neck Oncology - DAHNO, 2013). Better survivorship demands greater attention to the functional burden experienced by individuals. For survivors of head and neck

\(^1\) Oropharyngeal - contiguous structures of the mouth and throat such as base of the tongue and tonsils; broadly classified as oropharyngeal tumours to aid description for treatment purposes.
cancer, dysphagia is one of the most highly rated problems affecting function and quality of life (QOL) (Metcalfe, Lowe & Rogers, 2014; Wilson, Carding & Patterson, 2011).

Dysphagia may result from the presence of a cancer in the mouth or throat, and/or from the treatments aimed at curing or controlling the disease.

1.3 Treatments for HNC and their impact on swallowing function

The main modalities for treating head and neck cancer include surgery, radiotherapy, chemotherapy or some combination of the three. Surgery involves the removal of the cancer and usually includes a margin of tissue around the cancer. This may include for example, resection of part or all of the tongue, cheek, pharynx or jaw. Muscles and nerves may also be resected or compromised during the surgery. Defects left by the absence of structures are sometimes reconstructed with surrounding local tissue or microvascular free flaps or grafts.

Radiotherapy involves the use of high-energy radiation beams precisely targeted to destroy cancer cells. It is usually delivered in small daily doses over several weeks, allowing the normal cells within the field of radiation to recover between doses. Chemotherapy aims to destroy cancer cells or prevent cell division by the use of drugs, usually taken orally or delivered via an injection into muscle or veins. In the treatment of HNC, chemotherapy is often added to the radiotherapy treatment regime to further sensitize the cells to radiation (Al-Sarraf, 2002). It may also act systemically against micro-metastases offering improved overall survival (Pulte & Brenner, 2010). Whilst this form of treatment may preserve the structures, function is rarely spared given the severe acute and long-term side effects of chemoradiation (Wall et al., 2013; Paleri et al., 2014). The addition of chemotherapy to the radiotherapy regime may improve survival but is also known to exacerbate toxicities causing greater swallowing problems (Nguyen et al., 2007; Christianen et al., 2015). Other types of treatment such as photodynamic therapy and biological therapies are continually being researched and tested in clinical trials, but these are outside the scope of this thesis.
Difficulty swallowing may occur before, during and/or after treatment for HNC. Up to two-thirds of patients may experience some degree of dysphagia before treatment begins (Russi et al., 2012). It is often the primary symptom that prompts individuals to visit their doctor. Dysphagia is therefore a prominent symptom on the screening checklist for HNC (National Institute for Health and Care Excellence Improving Outcomes Guidance – NICE IOG, 2004).

Dysphagia in HNC patients occurs most commonly during the course of chemoradiation treatment. In the acute stages, patients experience changes to the mucosal lining of the mouth typically presenting as redness, soreness and ulceration. They may also have reduced saliva production resulting in thick, viscous secretions making it uncomfortable to eat. Due to the lack of saliva, patients may also develop an increased propensity to oral fungal infections. As the dose and intensity of treatment increases, it is commonplace for the initial discomfort to become painful, reducing the desire to eat and drink by mouth (Wall et al., 2013). The duration of these heightened acute symptoms extends beyond the last radiotherapy treatment, and usually persists for 2-3 weeks post-treatment. As this could mean a time frame of 10-12 weeks, many patients are advised to have a prophylactic gastrostomy tube inserted to support their nutritional requirements (Shaw et al., 2015). While most patients experience gradual recovery, few return to normal levels of functioning for eating and drinking even at three years after treatment (Barnhart et al., 2018). To compound the issue some patients develop new late onset problems such as post radiation fibrosis that is also known to severely impact swallowing function (De Felice et al., 2018; Hutcheson et al; 2013a).

One systematic review of the evidence relating to physiological changes to the swallow mechanism following chemoradiation found a prevalence of over 75% impairment of key swallowing structures across 19 studies (Wall et al., 2013). Reduced elevation of the larynx, reduced retraction of the base of tongue and reduced pharyngeal contraction and epiglottis function were amongst the most common physiological changes. Impaired closure of the inlet to the airway was also a highly prevalent feature. These changes in physiology bring about functional
difficulties that are often reported by the patient as food sticking in the throat, (residue) or food and drink going down the wrong way (aspiration).

Individuals who are treated with surgery as the primary modality are likely to experience alterations to the swallowing anatomy and physiology as a consequence of structures within the mouth and throat requiring a total or partial resection. Reconstructive surgery to fill defects arising from structures that have been removed (such as the use of bulky flap tissue) can also sometimes limit swallow function. A review by Kreeft et al. (2009) reported increased oral and pharyngeal transit times, and increased aspiration rates at one year following surgery. During the immediate post-surgical period, patients are often required to remain nil by mouth to allow time for healing. Not using the swallowing muscles for as little as two weeks may lead to detraining and disuse atrophy (Duarte et al., 2013).

Regardless of treatment modality, some form of re-training, compensation and/or adaptation must occur for individuals to relearn or regain satisfactory swallow function following treatment. Muscles and nerves responsible for the safety and efficiency of the swallowing process may be compromised. This may produce problems related to airway protection resulting in aspiration of food and drink into the lungs. Aspiration is a potentially serious and sometimes life threatening condition known to occur in almost half of HNC patients (Lee, Kim & Park, 2015). Swallow efficiency, or the effort involved in the transit and clearance of food from the mouth through the oesophagus is also frequently impaired (Wall et al., 2013). Swallowing rehabilitation, including swallowing exercises, is necessary to facilitate the process of regaining swallow function following treatment for HNC. The success of a swallowing exercise programme depends on patient adherence and consequently requires some change in patient behaviour. Patients are usually required to perform daily exercises to improve the strength and/or range of movement of muscles involved in swallowing. They may also be asked to modify the textures of foods eaten or use certain strategies to facilitate safe swallowing.
1.4 Behavioural swallowing interventions

A speech and language therapist (SLT) usually provides swallowing rehabilitation following an assessment of an individual’s swallow function. These interventions are typically referred to as behavioural swallowing therapy. In the medical domain, the term is mainly used to distinguish this rehabilitative intervention from other types of interventions such as surgical or pharmacological. At the time of planning this research, neither the concept of behaviour change, nor ways of facilitating change were explicitly being applied to the development of swallowing interventions in any systematic way. In other words, patient adherence behaviour in relation to swallowing exercises and advice may have been expected or presumed as part of rehabilitation interventions, but it was often not a target component of the intervention.

As indicated in the previous section, the mainstay of swallowing rehabilitation interventions is still based on the use of swallowing exercises, swallowing strategies, postural strategies or diet modifications aimed at improving the safety and efficiency of swallowing (Lazarus, 2017). A brief description from the seminal work by Logemann (1998) on this subject is provided below and illustrated in Figure 1-1:

- **Swallowing exercises**: designed to change swallow physiology, target strength and range of movement e.g. tongue exercises or laryngeal elevation exercises.
- **Swallowing strategies**: brings specific neuromuscular aspects of the swallow under voluntary control.
- **Positional strategies** (compensation): used to facilitate a swallow but does not result in any change to physiology e.g. head turn, chin tuck.
- **Diet modification** (type of compensation): changing textures of food to facilitate safer/more efficient swallowing.

Figure 1-1: Types of behavioural swallowing interventions showing common examples

The delivery of these interventions may be supported by specific adjuncts such as the use of devices to facilitate performance of the exercises. This may include for example the use of a jaw-stretch device such as a TheraBite (Atos Medical, Sweden) or the use of metred-volume cups to regulate bolus size. The interventions are recommended by the SLT, with the subliminal expectation that patients will take responsibility to adhere to the advice. Until recently, this advice was usually provided after patients had completed their cancer treatment and were encountering problems with eating, drinking and swallowing.

1.5 Evolving practice for swallowing rehabilitation of HNC patients treated on the National Health Service

Rehabilitation in healthcare traditionally referred to the process of enabling individuals to achieve their optimal function and QOL after a disabling event, disease or condition (Waddell & Burton, 2004). For patients with HNC, swallowing and communication morbidity resulting from surgical and non-surgical treatments
are referred to the SLT who is trained in the assessment and management of these functions. The SLT is part of the core head and neck multidisciplinary team (MDT) that is responsible for the care of patients receiving treatment on the National Health Service (NHS).

Traditionally, patients would see a SLT following their cancer treatment for rehabilitation of their swallowing and communication difficulties. A gradual shift in practice occurred following publication of the NICE Improving Outcomes Guidelines (2004), which recommend that patients should also see a SLT prior to their treatment to inform them of the likely impact to their swallowing and speech function. This information giving is viewed as a necessary part of the process of informed consent. As a consequence of this early involvement, a growing number of studies have begun to focus on this early intervention phase. In support, an emerging number of functional outcome studies have indicated that swallow function pre-treatment could be a strong predictor of long term swallow function post-treatment (Van Der Molen et al., 2011; Patterson et al., 2011; Kalavrezos et al., 2014).

However, implementation of the NICE recommendation is currently variable. In some centres, patients are provided with brief information by the SLT at the time of seeing their medical consultant in a multidisciplinary clinic setting. In other centres, separate SLT consultations take place. This may include documentation of baseline functional measures for swallowing and communication, advice on diet modification, and sometimes the recommendation to commence a general protocol of swallowing exercises. At the time of planning this study, the latest report from the UK National Database of Head and Neck Oncology (DAHNO) audit (DAHNO, 2013) indicated that only 29 percent of HNC patients in England and Wales were recorded as having a pre-treatment SLT consultation. Given the clinical and financial resource implications of a separate pre-treatment SLT consultation, implementation will likely only increase if there is clear specification as to the optimal content of the consultation, together with evidence supporting its benefit on patients’ outcomes. Aside from information giving, there is a need to define what interventions
administered before treatment (pre-habilitation) may improve patient experience and/or post treatment function.

1.6 The role and context of pre-treatment swallowing exercises

The physiological rationale supporting the practice of prophylactic swallowing exercises has been previously described in the literature (Kraaijenga et al., 2015; Hutcheson et al., 2013b). Strength based exercises and/or range of movement exercises targeted at the swallowing musculature may prevent muscle atrophy and reduce and/or delay the impact of radiation-induced fibrosis (Duarte et al., 2013; Hutcheson & Lewin, 2013; Carnaby-Mann et al., 2012; King et al., 2016). Pre-conditioning through exercises has been reported to be helpful in surgical interventions too (Jensen et al., 2016). Cancer pre-habilitation is acknowledged in the literature as an emerging opportunity to improve outcomes for patients (Silver & Baima, 2013; Treanor, Kyaw & Donnelly, 2017).

While a detailed review of the principles of exercise physiology is outside the scope of this thesis, attention may helpfully be drawn to key considerations applicable to the current work. In their review of the principles of strength training exercises for dysphagia, Burkhead, Sapienza & Rosenbek (2007) describe swallowing as a ‘sub-maximal activity’ meaning that the muscular force required to swallow food and drink is below the maximal force that can be generated by the swallowing muscles. Swallowing ability can therefore be adequate for the purpose of eating and drinking even when muscles are not at maximal physiological functioning. However, individuals who are at a reduced level of functioning are likely to reach the ‘tipping point’ at which they experience dysphagia much earlier. Crucially in the context of this work, muscles involved in swallowing can be strengthened and range of motion increased prior to oncological treatments. Optimizing physiological reserve may allow patients to retain the ability to eat and drink safely for a longer duration before the effects of treatment begin to cause dysphagia. Detraining effects caused through periods of being nil by mouth may be reduced. Furthermore, the post treatment period can be better utilized as patients will already be familiar with the
rehabilitation process thus enhancing recovery and potentially improving utilization of healthcare resources.

A recent systematic review investigated the effectiveness of any type of pre-habilitation (defined as one or more components of psychological support, education, exercise) in newly diagnosed adult cancer patients (Treanor, Kyaw & Donelly, 2017). The authors concluded that pre-habilitation appears to be of benefit to patients, but further trials are necessary to determine intervention effectiveness in specific cancer populations and on specific outcomes. They added that studies should also examine the cost-effectiveness in relation to usual care. Interestingly, the authors of this review cite a conference abstract (accessed independently) in which the incremental cost-effectiveness ratio (ICER) of pre-treatment swallowing exercises to post-treatment swallowing rehabilitation was calculated as part of a business case at a US hospital (Focht, Simpson & Martin-Harris, 2011). Pre-treatment swallowing intervention was found to have a dominant ICER of $142,972 and 15.88 Quality Adjusted Life Years (QALYs) per 100 patients. These authors suggested that pre-treatment swallowing exercises were more effective and less expensive than post-treatment exercises. There appears therefore to be potential for a pre-treatment swallowing intervention to improve physiological, functional and QOL outcomes, while also optimizing the use of health service resources by reducing costs in the longer term.

A small number of randomized clinical trials have attempted to address the effectiveness of pre-treatment swallowing exercises with mixed results (Carnaby-Mann et al., 2012; Mortensen et al., 2015; Van Den Berg et al., 2015; Lazarus et al., 2014; Kotz et al., 2012; van der Molen et al., 2011; Logemann et al., 2009). A recent Cochrane review concluded that there is insufficient evidence for recommending prophylactic exercises with HNC patients and therefore efficacy remains uncertain despite good biological plausibility (Perry et al., 2016). Most studies included in the review demonstrated limitations in design, and were undermined by poor patient adherence. There was also a lack of consistent outcome measures across studies that made pooling of data difficult. The review authors also discussed lack of data
about the optimal type and frequency of exercises. Given these uncertainties, the practice of providing prophylactic swallowing exercises varies amongst clinicians working in the NHS (Roe et al., 2012), and at the time of this thesis there were no published UK studies supporting the effectiveness of pre-treatment swallowing exercise interventions in the HNC population (Perry et al., 2016). Yet anecdotally, many clinicians will attest to the benefits of prophylactic exercises. The need to devise a pre-treatment swallowing intervention that can be tested within the NHS context is therefore an important starting point in addressing this knowledge gap.

For this thesis, the term ‘intervention’ is defined similarly to its use in other feasibility research: “Any program, service, policy or product that is intended to ultimately influence or change people’s health, social, environmental, and organizational conditions as well as their choices, attitudes, beliefs and behaviours. Interventions should focus on changeable behaviours and objectives; be based on critical, empirical evidence relating behaviour to health, be relevant to the target populations, and have the potential to meet the intervention’s goals.” (Bowen et al., 2010, p 452).

1.7 Broad aim of the research

The aim of this research is to devise a pre-treatment swallowing intervention package (SIP) for patients on a NHS head and neck cancer pathway. Such an intervention package would need to include multiple components that reflect the most up to date national guidelines as well as best practice evidence and professional knowledge. As highlighted above, the new SIP would be optimized through specific focus on changing patient adherence behaviour using relevant evidence and/or theory. The goal of this new SIP would be to improve swallowing outcomes for each patient after his or her treatment for HNC.

1.8 Context Limitations

The development of the new SIP has been restricted to a fixed time-point before cancer treatment begins. There is usually a small window of opportunity between patient diagnosis and the start of treatment that may be capitalized for this new intervention. An illustration of the typical pathway and the point at which this
intervention can be delivered is presented in Figure 1-2. As shown, several different professionals aside from the surgeon and oncologist are involved in the typical pre-treatment pathway.
Figure 1-2: Typical pathway for a patient newly diagnosed with head and neck cancer
1.9 Summary of Chapter

This chapter has provided an overview of the essential background relevant to the goal of this thesis: development and feasibility testing of a pre-treatment swallowing intervention package. The main points are listed below:

- HNC is now affecting many more people due to the increased incidence of human papilloma virus induced cancer. Patients are often younger at diagnosis, have better prognosis and are surviving longer.

- Dysphagia is the predominant functional morbidity of HNC and its treatment and is reported to be the most significant factor affecting QOL for patients.

- Dysphagia in HNC may be caused by the presence of a tumour and its impact on nerves and muscles. Treatments such as surgery, radiotherapy and chemotherapy exacerbate swallowing problems. Patients present with dysphagia before, during and after treatment. Late-effects of treatment such as fibrosis may also occur.

- Rehabilitation of swallowing dysfunction is usually carried out by SLTs who recommend swallowing exercise interventions and/or diet modifications.

- Previous swallowing intervention studies have demonstrated poor patient adherence. However, the role of behaviour science in developing swallowing exercise interventions that are explicitly designed to address behaviour change has not been previously explored.

- Changes in practice precipitated by limited evidence suggest that there may be some benefit in undertaking pre-treatment swallowing exercises to improve post-treatment swallowing outcomes. The latest systematic review called for more high quality studies that focused on improving issues of poor adherence and inconsistent study outcomes and time-points.

- Devising a cohesive pre-treatment SIP suitable for testing in a controlled trial is the first step to determining the effectiveness of ‘dysphagia pre-habilitation’ for patients with HNC.
Chapter 2  Theoretical frameworks and aims of the thesis

2.1  Introduction

The task of devising a swallowing intervention package (SIP) that can be accommodated within an existing NHS pathway of care requires simultaneous attention to multiple aspects aside from the methods through which intervention content is devised. It also requires an understanding of the physical context of the environment and organization, an appreciation of the broader policies that govern practice within the discipline, and knowledge of the systematic process by which an intervention may evolve from development through to implementation. In planning this project, I have used three key frameworks that collectively offer structure to support the primary aim of this thesis. Broadly, they reflect the philosophical, methodological and intervention development perspectives that underpin this work. This chapter provides a brief summary of each of these frameworks and demonstrates how they have been used to develop the stages of the research and the sub-aims for this thesis.

2.2  Philosophical Framework – Evidence Based Medicine

Evidence Based Medicine (EBM) is defined as the integration of the best available scientific research evidence, combined with clinical expertise and patient preferences (Sackett et al., 1996). This is the philosophy that underlies many of the interventions introduced into the NHS, and is therefore the guiding philosophy for the current work. EBM is well established in the idea that the effect of a medical treatment or intervention is best tested in comparable groups of patients who either receive or do not receive the intervention. It is the basis for which systematic reviews of randomized controlled trials (RCTs) of interventions are often cited as the highest level of evidence on which to make treatment decisions. In his account of the philosophy of EBM, Howick (2011) proposes that EBM “requires clinical expertise for producing and interpreting evidence, performing clinical skills, and integrating the best research evidence with patient values and circumstances” (p188). In devising a new SIP, best available evidence will be combined with clinical
expertise and patient preferences through a series of individual studies. In this thesis, a feasibility study is reported as the first step toward designing an RCT. Figure 2-1 illustrates how the philosophy of EBM is aligned with the over-arching methodological framework described in the next section.

2.3 Methodological Framework – MRC Complex Interventions Framework

The UK Medical Research Council (MRC) published its first guidance on the development and evaluation of complex interventions in 2000. This was subsequently updated (2006) and a summary was later published in the British Medical Journal (Craig et al., 2008). The MRC guidelines have since become a widely used framework for structuring scientific studies by highlighting key phases in the research process from intervention development through to implementation. Complex interventions are characterized by the multiple interacting components within the intervention, the complexity of the behaviours required from those delivering and receiving the intervention, the need for multiple outcome measures and the flexibility to provide some degree of tailoring in the intervention (Craig et al., 2008, p.979). Given the multi-faceted nature of such interventions, the MRC framework encourages the use of qualitative, mixed and novel methodologies during the intervention development phase.

The MRC framework also recognizes stages such as intervention modelling, often a desk-based activity that is sometimes referred to as ‘paper modelling’ to differentiate it from simulation type studies (MRC, 2000). This preliminary work could be vital for optimizing a new intervention prior to testing. Furthermore, using mixed methods enables the researcher to apply multiple perspectives to the problem, and provides an opportunity to triangulate findings and gather information about parameters that may be difficult to quantify through formal measures of assessment (Ozawa & Pongpirul, 2014). This thesis focuses on the first two phases of the MRC framework for the development and evaluation of complex interventions: development and feasibility testing (see Figure 2-1). The development stages include: 1) identifying the evidence base, 2) identifying or developing theory, 3) modelling process and outcomes. These stages are
exemplified through the studies reported in Chapter 3 to Chapter 6. The feasibility testing is described in Chapters 7 and 8.
Figure 2-1: Use of the *MRC framework for development and evaluation of complex interventions and evidence based medicine to model a new SIP

*Source: Craig et al., (2008)*
### 2.4 Intervention Development Framework – Behaviour Change Wheel

The MRC framework identifies the use of theory as an important consideration for the development phase of complex interventions, but it does not direct the researcher in how to access or embed theory into the design of a new intervention. Given the numerous behaviour change theories that exist, it was necessary to seek a method to incorporate insights from theory into the design of the new SIP. The Behaviour Change Wheel (BCW) is an accessible method through which researchers or intervention designers without prior knowledge of behaviour change might access relevant theories in designing and testing interventions that require behaviour change (Michie, Van Stralen & West, 2011; Michie, Atkins & West, 2014). The BCW was therefore selected for the guidance it offered in developing an intervention supported by theory, using a systematic approach.

The BCW was chosen above other methods such as the Intervention Mapping approach (Bartholomew, Parcel & Kok, 2006), which in my view requires prior knowledge of theory. Furthermore, training in the use of BCW was readily available to me, and there was a larger body of literature using this approach, from which much could be learned. A brief overview of the behaviour change method and tools used in this thesis is provided below, mainly as an introduction and reference for its use in the chapters that follow. Critical commentary of its application is reserved for the concluding chapters.

#### 2.4.1 Definition of behaviour in the context of this thesis

In this thesis, I have used the term behaviour as defined by Davis et al. (2015):

> “Anything a person does in response to internal or external events. Actions may be overt (motor or verbal) and directly measurable, or covert (activities not viewable but involving voluntary muscles) and indirectly measurable. Behaviours are physical events that occur in the body and are controlled by the brain” (p. 327).

Applying this definition to dysphagia management, therapy directed at helping a patient perform daily tongue strengthening exercises may be classified as changing
behaviour. However, therapy directed at helping a patient adjust to negative feelings about post-radiation taste changes does not constitute behaviour change. Behaviour is therefore distinguished from a thought, feeling or attitude. In discussing behaviour change within dysphagia management of the HNC population, the target behaviour is usually but not restricted to the performance of swallowing exercises.

2.4.2 The Behaviour Change Wheel and its related components

The BCW is a deliberately broad and all-encompassing framework for designing a wide range of behaviour change interventions (see Figure 2-2). Its use within this thesis is primarily to guide the design of the intervention by applying the science of behaviour change to increase patients’ adherence to exercises, which may improve their swallowing outcomes.

Figure 2-2: The Behaviour Change Wheel

Source: Michie, Atkins & West, 2014
2.4.2.1 The hub of the wheel: Sources of behaviour - COM-B model

At the hub of the BCW is the COM-B model of behaviour, which proposes that three key components are necessary for behaviour: Capability, Opportunity and Motivation. For any behaviour to occur, an individual must have both the physical and psychological Capability to perform the behaviour. This may for example, relate to the mental and physical skills, knowledge, strength and stamina to carry out swallowing exercises. The physical and social environment for example having the time, physical space, resources, support from others affords Opportunity. Motivation may be described as reflective where an individual is consciously involved in planning. This is based on their evaluation of whether something is good or bad to do, on whether it meets their goals, and on their self-belief that they can perform a given behaviour in spite of obstacles. Non-reflective or automatic motivation on the other hand is driven not by conscious reflection, but by impulses, emotional reaction or reflexive processes, such as a trigger to perform the behaviour habitually (e.g. brushing one’s teeth before going to bed).

The COM-B Model is compatible with its precursor, the Theoretical Domains Framework (TDF) that was initially developed in recognition of the need to synthesize the large number of behavioural theories into a more integrated and accessible form for those wishing to design and implement evidence-based interventions (Michie et al., 2005). The updated TDF consists of a comprehensive set of 14 domains into which all determinants of adherence to or implementation of a behaviour can be organized: knowledge, cognitive and interpersonal skills, memory and decision processes, behavioural regulation, social influences, social professional role and identity, beliefs about capabilities, optimism, intentions, goals, beliefs about consequences, re-inforcement and emotion. The TDF was validated through a rigorous process that resulted in 112 theoretical constructs being grouped into the 14 domains (Cane, O’Connor & Michie, 2012). All domains represented by the TDF can be mapped onto the overarching COM-B model that describes behaviour as the interaction of the three essential components: Capability, Opportunity and Motivation.
To summarize, the TDF helped to identify the unique constructs from many different overlapping theories of behaviour. These constructs were grouped into 14 main theoretical domains. For an even broader classification, the 14 domains can all be grouped under the three components of the COM-B model. Thus for a broad analysis of behaviour, an intervention designer may seek to understand how each of the three essential components interact in helping or hindering the occurrence of a given target behaviour. For a more detailed analysis, one may draw on the TDF. As these are compatible, they may also be used together depending on the needs of the task (Michie, Atkins & West, 2014).

2.4.2.2 The inner circle of the wheel – Intervention functions

The inner circle consists of nine intervention functions. These function categories reflect the broad methods through which an intervention may influence behaviour. They are classified as follows: Education, Training, Enablement, Modeling, Restrictions, Environmental Restructuring, Persuasion, Incentivization and Coercion (Michie, Atkins, & West, 2014). An intervention may simultaneously serve more than one of these functions. For instance, in using a TheraBite jaw-stretching device, behaviour may be facilitated by enablement (provision of the device) and training (demonstration and practice in use of device). Further explanation of intervention functions are provided later in the thesis at the point at which they are used within the empirical studies.

2.4.2.3 The outer circle of the wheel – Policy categories

The outer circle of the wheel comprises seven policy categories that support practical implementation of an intervention: service provision, legislation, communication/marketing, environmental/social planning, guidelines, fiscal measures and regulation (Michie, Atkins & West, 2014). For the current SIP, the intervention is being designed as part of service provision accommodated within an NHS cancer care pathway. However, if the intervention is shown to be effective in a future trial, it may be important in contributing to updated practice guidelines and service delivery policy for pre-treatment speech and language therapy services.
2.4.3 The Behaviour Change Technique Taxonomy

The Behaviour Change Technique Taxonomy Version 1 (BCTTv1) is a list of 93 hierarchically organized behaviour change techniques (Michie et al., 2013). A behaviour change technique (BCT) may be defined as the smallest active component of an intervention designed to change behaviour. A BCT should be: observable and replicable, linked to a target behaviour, and contain the active ingredient postulated to bring about a change in the underlying mechanism driving behaviour (Michie et al., 2013). BCTs may be used individually or in combination with other BCTs. The description of swallowing interventions can be made more specific if consistent terminology is used to fully describe all components of an intervention, not just the type and regimen of swallowing exercises. BCTs can help facilitate the process of specifying behaviour change content of swallowing interventions. This may help researchers to more reliably identify effective strategies that can then be replicated in future interventions.

2.5 Other Intervention content

The intervention development framework described above focused on the behaviour change aspects of intervention development. The methods used to determine other intervention content such as swallowing assessment and the selection of swallowing exercises will be discussed in Chapter 6.

2.6 Plan of studies for this thesis

The overview of the philosophical, methodological and intervention development approaches described above have been integrated in designing the overall research plan for this thesis. The thesis consists of five studies, an overview of which is provided in Table 2-1. A schema of the studies is provided in Figure 2-3 below.
2.7 Aims and research questions

The broad aims for this thesis are as follows:

1. To use latest developments in behavioural science and swallowing assessment to devise a pre-treatment swallowing intervention package for patients with head and neck cancer.

2. To conduct a feasibility analysis to examine important parameters such as recruitment and retention, acceptability of randomization, and collection of data to inform the selection of a primary outcome measure for a future definitive trial.

To meet these aims, this thesis will address the following research questions that are based on the guidance offered by the theoretical frameworks discussed above, as well as knowledge gaps and recommendations for improving interventions
highlighted from the latest Cochrane systematic review (Perry et al., 2016) on pre-treatment exercises.

1. Which behaviour change components (BCTs and intervention functions) have been described in previously published clinical trials of swallowing interventions, and how did they relate to intervention efficacy?

2. What are the barriers and facilitators to carrying out swallowing exercises as experienced by patients with HNC?

3. Does increasing patient knowledge and understanding about the process of swallowing promote engagement with swallowing exercises?

4. How best can a new SIP be modelled based on multiple sources of information (including new studies in this thesis), and the guiding principles of EBM, MRC complex interventions framework and the BCW?

5. How best to test the new SIP for its feasibility in a clinical trial within the NHS?

6. Is it feasible to undertake a fully powered RCT to compare the new SIP with current usual care?

Each of the above questions will be addressed in a separate chapter. An overview of individual studies and chapters is presented in Table 2-1.
### Table 2-1: Overview of thesis studies and chapters

<table>
<thead>
<tr>
<th>Chapter 3: Study 1</th>
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<tr>
<td>A systematic review of previous swallowing exercise interventions for patients with head and neck cancer. The purpose was to identify which BCTs and intervention functions were already being used in published interventions, and which might be associated with improved outcomes.</td>
</tr>
<tr>
<td>Given that a Cochrane review was already registered (although not published) at the time of undertaking Study 1, this study did not aim to duplicate the key question being addressed by the Cochrane review i.e. Does the intervention work? Instead, it complemented the Cochrane review by using a narrative synthesis approach to examine what may make the intervention work, and why might it work in some contexts and not others. This information was viewed as useful for determining how to improve new interventions, and could provide valuable insights for the current development of a new SIP.</td>
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<tr>
<th>Chapter 4: Study 2</th>
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<tr>
<td>An interview study of patients who had completed treatment for HNC, aimed at understanding patients’ experiences of swallowing rehabilitation exercises.</td>
</tr>
<tr>
<td>This study was important in highlighting key barriers and facilitators to performing exercises that could be relevant in designing the new SIP.</td>
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<tr>
<th>Chapter 5: Study 3</th>
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<tbody>
<tr>
<td>A think-aloud study to determine the acceptability and potential usefulness of a video-animation in helping patients understand the process of swallowing.</td>
</tr>
<tr>
<td>It was observed from Study 1 that very few interventions detailed how patients were provided information about their swallowing problems, yet not understanding reasons for doing swallowing exercises was highlighted as a barrier to patient adherence in a previous study by Shinn et al., (2013). Study 3 was undertaken as a preliminary investigation to determine whether a video-animation of swallowing was acceptable to patients and if it could potentially be included in the new SIP.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chapter 6: Study 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>This chapter is best described as the Modelling phase of the MRC complex interventions framework. It consists of multiple activities including the paper modelling of the intervention, drafting of intervention manuals, seeking and obtaining feedback from relevant stakeholders, and refining the intervention.</td>
</tr>
<tr>
<td>All sources that inform the development of the intervention are drawn together in a single chapter that outlines the content of the new SIP.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chapters 7 and 8: Study 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feasibility study – protocol and results</td>
</tr>
</tbody>
</table>
2.8 Patient-Public Involvement

This project was funded by the National Institute for Health Research (NIHR), via a personal award (Grant number: CDRF-2013–04–020). In accordance with the NIHR recommendations, the focus of the overall project was discussed with members of the study patient-public involvement group (PPI) at an early stage, prior to application for NHS ethics approval. The PPI group comprised three patients previously treated for HNC and three lay members of the public without HNC. The three patients were recruited from the outpatient HNC clinic as they had indicated prior interest in helping with research as a way of ‘giving back’. The three lay members were recruited via word of mouth and through a show of interest in the research work being undertaken. All received basic information about participation in PPI work available on the INVOLVE website. In addition, the patients attended the PPI workshops run by University College London (UCL) and University College London Hospital (UCLH), Joint Research Office. All members received remuneration for their time and participation. The group contributed to many aspects of the project. This will be further discussed where relevant within individual studies.

2.9 Study approvals and registrations

All studies within this thesis have been conducted in line with NHS Health Research Authority (HRA) guidelines. Mandatory and recommended authorizations, approvals and registrations have been obtained and/or completed. These are listed in Table 2-2. (see Appendix 2-1 to 2-5 for ethics approval and study registrations).

Table 2-2: Study registrations and approvals

<table>
<thead>
<tr>
<th>Organization/Acronym</th>
<th>Reference Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research and Development/ study sponsor: R&amp;D UCL sponsor</td>
<td>14/0175</td>
</tr>
<tr>
<td>Integrated Research Application System (IRAS) and NIHR Cancer Research Network Portfolio</td>
<td>170315</td>
</tr>
<tr>
<td>Systematic Review Database – PROSPERO</td>
<td>CRD42015017048</td>
</tr>
<tr>
<td>International Standard Randomized Controlled Trial Number – ISRCTN</td>
<td>ISRCTN40215425</td>
</tr>
</tbody>
</table>
2.10 My contribution to the work reported in this thesis

I conceived and designed the overall research plan, and plan for individual studies for this thesis prior to my fellowship application, with input from: Professor Jane Wardle, Professor Stuart Taylor, Dr Christina Smith and Dr Benjamin Gardner. I also received feedback on the study design from the NIHR Research Design Service (London RDS).

I undertook all work in applying for the necessary approvals and registrations with guidance from my supervisory team, and support from the study research nurse, Ms Teresita Beeston.

In Study 1 (Chapter 3: Systematic Review), I received support from a subject librarian (Ms Daphne Grey) who undertook the literature searches and initial study screening jointly with me. I undertook all analyses for the review. Dr Benjamin Gardner and Dr Christina Smith undertook second rater analysis of 25% of the studies included in the review as part of the study protocol. I drafted the complete manuscripts of both the study protocol and results submitted for publication. My supervisory team provided me with critical feedback on iterative revisions.

In Study 2 (Chapter 4: Patient interview study), I received support from the UCLH speech and language therapy team in identifying and recruiting patients. I undertook all interviews and performed all analyses independently. Dr Caroline Wood provided second rater analysis on three interview transcripts as part of the study design. I drafted the complete manuscript of the study that was submitted for publication. I received critical feedback on iterative revisions I made, from my supervisory team.

In Study 3 (Chapter 5: Think-aloud study), I conducted and performed all analyses. Three members of the PPI group were involved in verifying the analyses as part of the study design.

I have undertaken all work involved in modelling the new intervention, with critical feedback from my supervisory team. Consultation with other SLTs and patients was
part of the intervention development process. A clinical psychologist, Dr Claire Friedemann-Smith acted as a group facilitator during the consultation with SLTs. I wrote the manual for the new intervention. The manual for usual care was written collaboratively with the UCLH head and neck speech and language therapy team.

For the feasibility study, I received support from the UCLH head and neck multidisciplinary team in recruiting patients to the study. The research nurse (Ms Teresita Beeston) and research facilitator (Ms Jane Piga) assisted me with approaching and consenting patients. I received help from the research facilitator in the collection of questionnaire outcome measures. I delivered the new intervention to all patients randomized to the intervention group. The UCLH head and neck SLT team delivered the ‘care as usual’ intervention. The SLT team collected clinical outcome measures for all patients. I received support from a data manager (Mr Darren Fripp) in entering data. I received statistical advice and support from an advisor (Professor Penny Roy) for the quantitative analyses, and sample size estimation. I drafted the complete manuscript of the feasibility study protocol submitted for publication. My supervisory team provided me with critical feedback on iterative revisions.
Chapter 3  Study 1: Behaviour change strategies used in swallowing exercise interventions for patients with head and neck cancer – A systematic review

3.1  Introduction

Using the MRC complex interventions framework and the behaviour change tools outlined in Chapter 2, this chapter presents the rationale for, and findings of, a systematic review of the behaviour change strategies used in swallowing interventions. Management of dysphagia frequently requires patients to change their established patterns of behaviour for example, they may be required to modify the textures of food they eat, thicken fluids, use particular compensatory techniques and/or undertake daily swallowing exercises. These changes may be challenging for patients, but the consequences of non-adherence to dysphagia recommendations can be serious. This may include malnutrition, dehydration, aspiration-related pneumonia, poor swallowing efficiency and reduced health-related quality of life, and possibly earlier mortality (Krekeler et al., 2017; Malagelada et al., 2015).

Non-adherence to swallowing exercises in the head and neck cancer (HNC) population is reported to be high, and consequently undermines efforts to investigate the effectiveness of prophylactic exercises on post-treatment outcomes (Shinn et al., 2013; Perry et al., 2016). However, little is known about how patient adherence is facilitated in current swallowing exercise interventions or how best to improve adherence in this group of patients. A recent review of patient adherence to dysphagia recommendations across multiple population groups reported the average adherence was between 22% and 52% (Krekeler et al., 2017). In undertaking such a review, the authors have highlighted the concept of adherence within swallowing intervention studies and the issues surrounding the measurement of adherence. The World Health Organization (WHO) report defines

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2 The protocol for Study1 has been published in Systematic Reviews (Govender et al., 2015) and the results in BMC Cancer (Govender et al., 2017a). This chapter includes content from both publications under the CC-BY license (see Appendix 3-1 and 3-2 for published papers).
patient adherence as “the extent to which a person’s behaviour corresponds with agreed recommendations from a health care provider” (WHO, 2003). Increasing adherence to treatment could have a greater impact on health than trying to change the treatment itself. In other words, adherence should be made a greater focus. Adopting this perspective transforms the concept of patient adherence from a peripheral marker of study quality into a concept central to the intervention.

3.2 Background and rationale for Study 1

The MRC complex intervention guidelines highlight that multiple components at different levels may interact to bring about desired health outcomes (Craig et al., 2008). Effectiveness of swallowing exercise interventions is determined not just by the exercises but also by the broader behaviours demonstrated by SLT clinicians delivering the intervention and patients receiving the intervention. Pragmatic trials of complex interventions performed under real-world conditions are acknowledged to be influenced by context factors (Raine et al., 2016) such as how interventions are implemented (where, by whom) and how patients respond to this (uptake/adherence) (Bate et al., 2014).

This thesis makes an argument for optimizing individual components of a complex intervention (Collins et al., 2012) as a strategy for improving overall effectiveness of the intervention (Levati et al., 2016). Newer paradigms in systematic reviewing such as realist reviews focus on understanding how and why interventions work in some situations and not others, rather than confining the question to whether interventions do or do not work (Moher et al., 2015a). In their paper on analysis of intervention components, Sutcliffe et al. (2015) argue the importance of recognizing and identifying the critical components of complex interventions. They highlight that outcomes of complex interventions cannot be solely ascribed to the primary content, in this case swallowing exercises. Traditional systematic reviews that focus exclusively on pooling effect sizes may overlook other aspects that influence outcomes. This narrower focus could limit our ability to differentially examine the evidence and to gather important information that may improve future interventions.
Logic models are a helpful way to conceptualize complexity of interventions in systematic reviews. They provide a visual representation of different components and illustrate how these components may potentially relate to one another within a particular system (Rohwer et al., 2016). To advance the argument for optimizing individual components, as a starting point I have devised a logic model based on professional knowledge and clinical experience of working with head and neck cancer patients in a NHS setting for more than 17 years. The model is introduced here to provide context for this review, but will also be drawn upon later in the thesis in Chapter 6 that describes the intervention development process.

In this model (see Figure 3-1), behaviour change strategies are highlighted as part of the intervention content recognizing their potential to be ‘active ingredients’ that may influence outcomes. The model also shows that swallowing exercise interventions for patients with HNC are normally implemented by trained professionals such as speech and language therapists within a healthcare setting, and as part of a wider cancer care pathway. This information is known from interaction with the community of SLTs across the cancer networks, as well as from special interest group meetings, and national audits. Generally, the content of the intervention tends to be focused on type, frequency, and intensity of different swallowing exercises. Accordingly, previous reviews have been largely concerned with these exercise parameters. For example, in a review of types of swallowing exercises, Langmore & Pisegna (2015) concluded that exercises such as the Shaker (head lift exercise) and Mendelsohn manoeuvre (larynx elevation exercise) have good efficacy in improving swallowing function. A more general review of swallowing interventions for HNC patients concluded that some evidence exists that exercises improve swallowing function. (Cousins et al., 2013). As previously mentioned, a Cochrane review concluded that the evidence for pre-treatment swallowing exercises in improving swallowing safety and efficiency is lacking due to insufficiently robust studies, heterogeneity of outcome measures across studies, and poor patient adherence (Perry et al., 2016). Whilst there is much to be learned from these reviews, the broader perspective proposed in the logic model presented in this thesis may facilitate better understanding of the existing evidence. The theoretical and practical insights achieved from examining the evidence using a wider lens could improve the content and design of future studies.
Figure 3-1: Logic Model of a swallowing exercise intervention

**PROBLEM**
High prevalence of dysphagia after HNC treatments.

**GOAL**
Optimize post-treatment swallowing

**IMPLEMENTATION**
- Policy - Patients seen as part of a multidisciplinary cancer care pathway.
- Health Care System

**CONTEXT**
- Hospital setting
- Facilities/resources
- Specialist Staff
- Specialist equipment
- Practice Guidelines

**PARTICIPANTS:** Patients with HNC

**INTERVENTION**
Theory/Assumptions: swallowing exercises will improve flexibility and range of movement of muscles after cancer treatments if patients adhere to them. This will improve swallowing function.

- **Intervention Components**
  - Swallowing exercises
  - BCTs eg. self-monitoring
  - Intervention functions eg. Education

- **Intervention Execution**
  - Timing (pre, peri, post treatment)
  - Duration
  - Dose and intensity

- **Intervention Delivery**
  - Setting – hospital
  - Dysphagia specialist (usually speech therapist)
  - Individual face-face consultations

**OUTCOMES**
Intermediate outcomes
- Health related behaviour change – adherence.

Health Outcomes
- Improved swallow physiology
- Improved swallow function
- Improved nutrition
- Improved health-related QOL and general wellbeing

Non-Health Outcomes
- Better social re-integration
- Return to work
As highlighted in the model, behavioural strategies used to promote adherence to the exercises may have a potentially crucial influence on outcomes, but are frequently overlooked. This review employs established tools from behavioural science discussed in Chapter 2: the Behaviour Change Wheel (BCW) and Behaviour Change Technique Taxonomy Version1 (BCTTv1). As BCTs are anticipated to contain the active ingredient that might be responsible for changing patient behaviour, it seems worthwhile trying to ascertain which BCTs are being used in swallowing exercise interventions, and whether any BCTs can be identified as occurring more frequently in effective interventions. BCTs contained within an intervention need to be conveyed via some means to the recipient. The broad category through which this may occur is termed an intervention function in the BCW. The BCT information about health consequences can serve the intervention function Education. It can at the same time serve the function of Persuasion if the particular stimulus used to educate also evokes feelings that may prompt an individual to take action, that is perform the intended behaviour. An example of this might be the type of poster often seen in dental practices where pictures of dental caries accompany advice about regular flossing or brushing of teeth.

In Chapter 1, a case was presented for the biomechanical reasoning why swallowing exercises should improve swallowing physiology. Patient adherence to exercises then becomes a crucial factor in ensuring the success of swallowing exercise interventions. It is logical therefore that this aspect be given appropriate consideration when designing new interventions.

3.2.1 Aim and scope of the review

The purpose of this review was to identify the specific behaviour change strategies reported in interventions to improve swallowing function after HNC. Where possible, relationships between the presence of these components and intervention effectiveness were explored. It is proposed that BCTs that occur more often (at least twice as frequently) in effective interventions may be useful to include in future interventions (Gardner et al., 2015). A narrative synthesis approach was used for the analysis (Popay et al., 2006) which included features such as type of comparator
group. To my knowledge, this is the first attempt to apply this method of reviewing swallowing interventions within the field of dysphagia. This work is therefore exploratory in nature.

3.3 Methods

This review was registered on the PROSPERO systematic review database (CRD42015017048). A protocol (see Appendix 3-1) has been published detailing the methods that were reported in accordance with the PRISMA-P guidelines [Preferred Reporting of Items for Systematic Reviews and Meta-analysis] for systematic reviews (Moher et al., 2015b). These methodological items are explained below.

3.3.1 Eligibility Criteria

Studies were assessed for eligibility using the specific criteria denoting participant group, intervention, comparator group and outcomes, commonly referred to as PICO criteria (Schardt et al., 2007). These criteria were as follows:

**Types of studies:** Only peer-reviewed studies published in English were included. Randomized and non-randomized studies were included provided that an intervention group and a suitable comparator or control group was part of the study design. No date restrictions or minimum sample size were applied.

**Types of participants and population group:** Individuals over the age of 18, diagnosed with head and neck cancer (excluding brain), and having or had treatment via one of the main modalities of surgery, radiotherapy, chemo-radiation, or combinations thereof, were eligible for inclusion.

**Types of intervention/s:** In this review ‘behavioural intervention’ refers to swallowing exercises, instructions to adhere to specific diet texture recommendations and swallowing strategies, and instructions for swallowing compensations and manoeuvres. It required the patient to perform a particular behaviour on a regular basis. Interventions that included a device (for example, TheraBite, Theraspoons, spatulas) as part of an exercise package were also included.
provided the device was part of a programme to improve swallowing outcomes. Interventions designed solely to treat trismus or improve mouth opening were excluded if no other functional swallowing outcome was assessed. Medical, surgical, prosthetic, pharmacological and neuromuscular or electrical stimulation type interventions were excluded.

**Type of comparator group:** Randomized or non-randomized studies that included an independent comparator group were eligible. The comparator group could have received no treatment (non-active comparator), usual care (active or non-active), different treatment (active) or sham exercise (active).

**Types of outcome measures:** The main outcome of interest was swallowing function. For inclusion, the study had to report at least one swallow-related outcome measure, such as swallow safety, swallow efficiency, swallow related QOL, oral diet intake or a surrogate marker such as feeding tube use, and textures of food tolerated. The outcome could have been assessed via an established patient reported questionnaire, clinician rated measure or instrumental assessment tool such as the modified barium swallow.

### 3.3.2 Identification of Studies

Six electronic health databases were searched: Medline, CINAHL, EMBASE, AMED, PsychInfo, and the Cochrane Library including CENTRAL. Additional searches were carried out on Google Scholar, Web of Science and the meta-registries of Trials Databases (ClinicalTrials.gov and ISRCTN). Additionally, the WHO International Clinical Trials Registry Platform (ICTRP) and the Australian New Zealand Clinical Trials Register (ANZCTR) were searched. A hand-search of reference lists of directly relevant systematic reviews and included articles identified from the main screening were also undertaken.

**Search Strategy:** A search strategy to identify relevant studies was developed in conjunction with a subject librarian (DG). Initial terms were identified from other relevant reviews and from MeSH headings of key articles from an initial scoping exercise. The terms deglutition OR swallow* OR Dysphagi* in combination with the exploded terms for “head and neck neoplasms” were used. Other key terms were
therap* OR rehabilitation OR exercise OR behav* OR “swallowing training.” The search was focused to capture the most relevant reports by limiting to clinical trials and reviews, and excluding oesoph* and brain neoplasms. The search was limited to English language but no date limitation was applied. An example of one of the search strategies used (Medline) is illustrated in Table 3-1. All searches were undertaken by the author (RG) jointly with a subject librarian in December 2014, and updated in June 2015 prior to completion of the data extraction process. One intervention (van der Molen et al., 2011) found to have two additional related reports based on longer follow-up times for the same sample and intervention, was treated as one study.

**Table 3-1: Search strategy for Medline**

<table>
<thead>
<tr>
<th>Search History</th>
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<tbody>
<tr>
<td>Evidence Services</td>
</tr>
<tr>
<td>1. MEDLINE; exp DEGLUTITION/ OR exp DEGLUTITION DISORDERS/</td>
</tr>
<tr>
<td>2. MEDLINE; (degulition OR swallow* OR dysphagi*).ti,ab</td>
</tr>
<tr>
<td>3. MEDLINE; exp HEAD AND NECK NEOPLASMS/</td>
</tr>
<tr>
<td>4. MEDLINE; (“head and neck” OR otorhinolaryng* OR “head neck” OR “head-neck” OR oral OR oropharyn* OR hypopharyn* OR laryn* OR nasopharyn* OR pharyn* OR throat OR mouth OR HNSCC OR SCCHN).ti,ab</td>
</tr>
<tr>
<td>5. MEDLINE; (cancer* OR carcinoma* OR neoplas* OR tumor* OR tumour* OR malignan* OR SCCA).ti,ab</td>
</tr>
<tr>
<td>6. MEDLINE; exp REHABILITATION/</td>
</tr>
<tr>
<td>7. MEDLINE; exp BEHAVIOR/</td>
</tr>
<tr>
<td>8. MEDLINE; (therap* OR rehabilitation OR exercise* OR behav* OR “swallowing training”).ti,ab</td>
</tr>
<tr>
<td>9. MEDLINE; 1 OR 2; 67740 results.</td>
</tr>
<tr>
<td>10. MEDLINE; 4 AND 5; 143824 results.</td>
</tr>
<tr>
<td>11. MEDLINE; 3 OR 10; 310277 results.</td>
</tr>
<tr>
<td>12. MEDLINE; 6 OR 7 OR 8; 3852180 results.</td>
</tr>
<tr>
<td>13. MEDLINE; 9 AND 11 AND 12; 3060 results.</td>
</tr>
<tr>
<td>14. MEDLINE; 13 [Limit to: (Publication Types Clinical Trial, All or Systematic Reviews)]; 258 results.</td>
</tr>
<tr>
<td>15. MEDLINE; (esophag* OR oesophag* OR brain).ti</td>
</tr>
<tr>
<td>16. MEDLINE; *ESOPHAGEAL NEOPLASMS/; 32758 results.</td>
</tr>
<tr>
<td>17. MEDLINE; 15 OR 16; 349564 results.</td>
</tr>
<tr>
<td>18. MEDLINE; 14 not 17 [Limit to: (Publication Types Clinical Trial, All or Systematic Reviews)]; 151 results.</td>
</tr>
<tr>
<td>19. MEDLINE; 18 [Limit to: English Language and (Publication Types Clinical Trial, All or Systematic Reviews)]; 140 results.</td>
</tr>
<tr>
<td>20. MEDLINE; (rehabilitation OR exercise* OR behav* OR “swallowing training”).ti,ab</td>
</tr>
<tr>
<td>21. MEDLINE; exp EXERCISE THERAPY/</td>
</tr>
<tr>
<td>22. MEDLINE; exp BEHAVIOR/ OR exp REHABILITATION/</td>
</tr>
<tr>
<td>23. MEDLINE; 20 OR 21 OR 22; 2136331 results.</td>
</tr>
<tr>
<td>24. MEDLINE; 9 AND 11 AND 23; 1096 results.</td>
</tr>
<tr>
<td>25. MEDLINE; 24 [Limit to: English Language and (Publication Types Clinical Trial, All or Systematic Reviews)]; 101 results.</td>
</tr>
<tr>
<td>26. MEDLINE; 25 not 17 [Limit to: English Language and (Publication Types Clinical Trial, All or Systematic Reviews)]; 90 results.</td>
</tr>
</tbody>
</table>
3.3.3 Data management and selection

Articles from all searches were combined and duplicates removed. The subject librarian and the author (RG) independently screened titles and abstracts against eligibility criteria. The full-text versions of studies deemed eligible by either individual were obtained. The articles were imported into Mendeley Web (bibliographic database) for easy access amongst other members of the review team. This included an SLT expert in dysphagia (CS) and a psychologist trained in the use of BCTTv1 (BG). Multiple reports of the same intervention study were grouped together for data extraction. Studies were assessed for inclusion using a customized form. The form consisted of a table with a complete list of all the full-text studies retrieved and the specified inclusion and exclusion criteria. The author (RG) together with the other member of the team with expertise in dysphagia (CS) independently selected one of three categories (include, exclude, unsure) for each study. Reasons were recorded for studies that were excluded, and uncertainties were resolved through discussion. A third member of the team (BG) was available to assist with any disagreements. The final list of studies to be included in the review was imported into NVivo10 (QSR International), a relational database for organizing and analyzing qualitative data. Figure 3-2 depicts the PRISMA flowchart (Liberati et al., 2009) showing the study selection process.
3.3.4 Data Extraction

A pre-agreed and piloted data extraction form was used to collect the relevant information from the selected studies (see Appendix 3-3). Study quality, study characteristics and intervention characteristics were extracted.

Study quality: For consistency with other reviews, data was extracted on study quality using an 11-item checklist (van Tulder et al., 2003) previously employed to assess the quality of dysphagia clinical trials (Carnaby & Madhavan, 2013). Each of the 11 items was given a score of 1 if the criterion was met, yielding a summary
score of 0 (lowest) to 11 (highest quality). The criteria used in this checklist indicated that scores of $\geq 6$ reflect studies of good quality (van Tulder et al., 2003). Studies were not excluded on the basis of quality because the aim was to ascertain any evidence, however weak, of potential links between BCTs and effects. Assessing study quality and potential risk of bias are still considered important for the synthesis of findings, even if only exploratory in nature. Studies of poor quality reduce the certainty and confidence in their findings and call for greater caution in their interpretation and application (Popay et al., 2006).

**Study characteristics:** Data were extracted on study characteristics (author, year, country of origin, setting, type of study); patient characteristics (diagnostic and treatment group, sample size, age range, gender and baseline swallow function); treatment (information about the type of treatment and comparator groups); and outcome measures (length of follow-up and all swallow related outcomes). Heterogeneity in the type and time-points of outcome measures was anticipated, but an attempt was made to extract data at or as close to the time intervals of 1, 3, 6 and 12 months after treatment. Outcomes included measures derived from instrumental assessments such as modified barium swallow (MBS) or videofluoroscopy. Clinical measurements included weight or the water swallow test (WST) (Hughes & Wiles, 1996) and functional scales such as the Functional Oral Intake Scale (FOIS) (Crary, Mann & Groher, 2005) and Performance Status Scale (PSS) (List et al., 1990). Patient-reported and QOL measures such as the MD Anderson Dysphagia Inventory (MDADI) (Chen et al., 2001) and the European Organization for Research and Treatment of Cancer (EORTC QOL C-30) (Groenvold et al., 1997) questionnaire were also considered.

**Intervention characteristics:** For this review, the focus was to identify the behaviour change strategies (BCTs) and intervention functions present in the interventions. The target behaviour in each study was recorded. This was either regular performance of swallowing exercises or regular implementation of a

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3 The terms videofluoroscopy, modified barium swallow and x-ray swallow all refer to the same procedure and may be used inter-changeably.
prescribed diet modification with or without specific swallowing strategies. The
intention was to code for whether a named theory of behaviour or behaviour
change was mentioned in the Abstract, Introduction, or Method, but no studies
were found to have used a named theory. BCTs and intervention functions were
identified using BCTTv1 and the BCW (Michie et al., 2013; Michie, Atkins & West,
2014). Both BCTs and intervention functions were only coded when they were
unambiguously present in the intervention descriptions. For example, if the
intervention included a TheraBite device (Atos Medical, Sweden) to maintain
mouth-opening function, the intervention function Education was coded if it was
clear that the intervention explicitly required that patients be informed and
understood how the device and exercise works to maintain the ability to open the
jaw. This may have included information about the impact of radiotherapy on jaw
movement and the consequences of doing or not doing the exercise. The function
category Training was coded where it was clear that the patient was taught skills on
how to perform the exercises using the device. The BCT demonstration on how to
perform the behaviour was coded if the patient was presented with an observable
demonstration, but not if only provided with written instructions; this was coded as
instruction on how to perform the behaviour. Table 3-2 and Table 3-3 respectively
illustrate the BCTs and intervention functions identified and coded in this review,
together with examples from the review papers.

As the only member of the review team with both the clinical background of the
subject, as well as the training to code BCTs, the author (RG) extracted all data for
this review. A second member of the review team (SLT-CS) independently extracted
data for four (27%) randomly selected studies, as a means of judging agreement.
The psychologist (BG) identified BCTs and intervention functions for this sub-
sample. Inter-rater agreement was judged according to Cohen’s criteria which
suggests that K=0.6 reflects a substantial agreement. Agreement was therefore
substantial or better for all criteria evaluated: selection of full-text articles assessed
for inclusion (K=0.86), study quality (K=0.74) and presence of BCTs (K=0.66)
(Landis & Koch, 1977). As proposed in the systematic review by Gardner et al.
(2015), a conservative approach to calculating kappa for BCTs was adopted. This is
based on BCTs judged to be present by either of the coders. Agreement based on
the complete taxonomy of 93 BCTs would expectedly be much higher due to the likely agreement on the high number of absent BCTs.
Table 3-2: BCTs identified and examples from studies included in the review

<table>
<thead>
<tr>
<th>BCT</th>
<th>Description (taken from BCTTv1)</th>
<th>Example/s</th>
</tr>
</thead>
<tbody>
<tr>
<td>Goal setting (behaviour)</td>
<td>Set or agree a goal in terms of the behaviour to be achieved.</td>
<td>Participants were instructed to perform these exercises for 10 repetitions, 5 times a day (Carroll, 2007).</td>
</tr>
<tr>
<td></td>
<td>NB: if goal also defines a specific context, frequency, duration or intensity – also code Action planning.</td>
<td>Intervention patients were asked to perform 3 sets of 10 repetitions of each exercise on a daily basis (Kotz, 2012).</td>
</tr>
<tr>
<td>Problem solving</td>
<td>Analyze or prompt the person to analyze factors influencing the behaviour and generate or select strategies that include overcoming barriers/increasing facilitators (includes relapse prevention and coping planning).</td>
<td>If acute side effects restricted the performance of the exercises, patients were instructed to accomplish as much as possible and to resume to the complete exercise program whenever possible. Patients were encouraged to continue oral food intake if in any way possible and safe (Mortensen, 2015).</td>
</tr>
<tr>
<td>Action planning</td>
<td>Prompt detailed planning of performance of the behaviour (must include at least one of context, frequency, duration, intensity). Context may be environmental (physical or social) or internal (physical, emotional, or cognitive- includes implementation intentions.)</td>
<td>The Shaker exercise consisted of three 1-min head lifts in the supine position with a 1-min rest between lifts [5]. These sustained head-raising exercises were followed by 30 consecutive repetitions of head raisings in the same supine position. For both sustained and repetitive head raising, volunteers were instructed to raise the head high enough to be able to observe their toes without raising their shoulders (Logemann, 2009). Using a 3-times-a-day paradigm, an individual could coordinate the exercises with either breakfast, lunch, and dinner or morning, noon, and night to promote better recall (Kotz, 2012)</td>
</tr>
<tr>
<td>Review behaviour goals</td>
<td>Review behaviour goals jointly with the person and consider modifying goals or behaviour change strategy in light of achievement. This may lead to re-setting the same goal, a small change or setting a new goal or in addition to first, or no change.</td>
<td>At follow-ups, the directions could sometimes be changed to a ‘hold and release’ technique, depending on the need and/or compliance of the patient (Ahlberg, 2011).</td>
</tr>
<tr>
<td>BCT</td>
<td>Description (taken from BCTTv1)</td>
<td>Example/s</td>
</tr>
<tr>
<td>---------------------------------------------------------------------</td>
<td>-----------------------------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Review outcome goals</td>
<td>Review outcome jointly with person and consider modifying goals in light of achievement.</td>
<td>The outcomes after discharge was recorded by the patient or caregiver in a diary and reviewed at monthly telephone interviews (Carnaby-Mann, 2012)</td>
</tr>
<tr>
<td>Monitoring of behaviour by others without feedback</td>
<td>Observe or record behaviour with the person’s knowledge as part of a behaviour change strategy.</td>
<td>25 patients were started on a protocol of swallowing exercises 2 weeks prior to the start of radiation and returned to the clinic at 2 weeks and 6 weeks into their radiation treatment to monitor progress and compliance with the protocol (Kulbersh, 2006).</td>
</tr>
<tr>
<td>Feedback on behaviour</td>
<td>Monitor and provide informative or evaluative feedback on performance of the behaviour (e.g. Form, frequency, duration, intensity).</td>
<td>Intervention patients participated in weekly face-to-face swallowing therapy sessions with the same head and neck speech pathologist (T.K.), who ascertained the patients’ compliance with the swallowing exercises and reinforced learning to ensure proper technique (Kotz, 2012)</td>
</tr>
<tr>
<td>Self monitoring of behaviour</td>
<td>Establish a method for the person to monitor and record their behaviour(s) as part of a behaviour change strategy.</td>
<td>Patients were instructed to keep a log of their daily performance to further encourage adherence to the swallowing exercise protocol (Kotz, 2012)</td>
</tr>
<tr>
<td>Monitoring of outcome of behaviour without feedback</td>
<td>Observe or record outcomes of behaviour with the person’s knowledge as part of a behaviour change strategy.</td>
<td>At the clinical screening of swallowing, the patient was asked to complete one swallow of two bolus sizes (5 and 15 ml) of four consistencies: thin liquid, thick liquid, paste, and cookie. Movement of the floor of the mouth, hyoid, and thyroid cartilage was evaluated by manual palpation during the act of swallowing. The following swallowing parameters were clinically evaluated: oral manipulation and transport of bolus, presence of aspiration, laryngeal elevation, need for several swallows, delayed initiation of swallowing, and nasal regurgitation. Aspirations were noted as cough, need to clear the throat, wet voice, or sudden breathing difficulties (Ahlberg, 2011)</td>
</tr>
</tbody>
</table>
| Biofeedback                                                         | Provide feedback about the body (e.g. Physiological or biochemical state) using an external monitoring device | 19 patients received treatment with video-endoscopic biofeedback (Denk, &
<table>
<thead>
<tr>
<th>BCT</th>
<th>Description (taken from BCTTv1)</th>
<th>Example/s</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>as part of a behaviour change strategy.</td>
<td>Kaider 1997).</td>
</tr>
<tr>
<td>Social support (unspecified)</td>
<td>Advise on, arrange or provide social support (e.g. From friends, relatives, colleagues, or staff) or non-contingent praise or reward for performance of behaviour. It includes encouragement and counseling, but only when it is directed at the behaviour.</td>
<td>Each patient had to appoint a guardian who was responsible to oversee the patient’s everyday training (Tang, 2011). Each patient in both the exercise and swallow treatment groups attended swallowing therapy sessions once every week for 45 minutes throughout the time they were undergoing RT/chemotherapy (Virani, 2013)</td>
</tr>
<tr>
<td>Social support (practical)</td>
<td>Advise on, arrange or provide practical help for performance of behaviour. (arranging pain control to enable continuation of exercises.)</td>
<td>The principal investigator contacted each subject weekly by phone to document compliance with the exercise programmes, as well as too determine pain levels and assess the need for medications per the pain-related questions on the HNCI (Lazarus, 2014)</td>
</tr>
<tr>
<td>Instruction on how to perform the behaviour</td>
<td>Advise or agree on how to perform the behaviour (includes skills training)</td>
<td>When training in the Mendelsohn manoeuvre, subjects were provided verbal, visual, and tactile cues, as well as written instructions (Lazarus, 2014)</td>
</tr>
<tr>
<td>Demonstration of the behaviour</td>
<td>Provide an observable sample of the performance of the behaviour directly in person or indirectly (e.g via film, pictures, for the person to aspire to or imitate), includes modeling.</td>
<td>Standardized high-intensity swallowing therapy (“pharyngocize”) included a battery of exercises (e.g., falsetto, tongue press, hard swallow, and jaw resistance/strengthening using the TheraBite Jaw Motion Rehabilitation System) and dietary modification, under the direction of the study speech pathologist, twice daily for the duration of the CRT (Carnaby-Mann, 2012).</td>
</tr>
<tr>
<td>Prompts and cues</td>
<td>Introduce or define environmental stimulus with the purpose of prompting or cueing the behaviour. The prompt or cue would normally occur at the time or place of performance.</td>
<td>Using a 3-times-a-day paradigm, an individual could coordinate the exercises with either breakfast, lunch, and dinner or morning, noon, and night to promote better recall (Kotz, 2012).</td>
</tr>
<tr>
<td>Behavioural</td>
<td>Prompt practice or rehearsal of the performance of the behaviour one or more times in a context or at a time</td>
<td>Subjects were trained until they could independently demonstrate the</td>
</tr>
<tr>
<td>BCT</td>
<td>Description (taken from BCTTv1)</td>
<td>Example/s</td>
</tr>
<tr>
<td>---------------------</td>
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</tr>
<tr>
<td>practice/rehearsal</td>
<td>when the performance may not be necessary, in order to increase habit and skill.</td>
<td>exercises during the baseline training session (Lazarus, 2014) The rehabilitation training exercises were performed 3 times per day. Each exercise was repeatedly practiced for 15 cycles at each time for a total of 45 cycles per day (Tang, 2011).</td>
</tr>
<tr>
<td>Habit formation</td>
<td>Prompt rehearsal and repetition of the behaviour in the same context repeatedly so that the context elicits the behaviour.</td>
<td>Participants were encouraged to integrate the exercise into other daily activities such as brushing teeth (Van der Molen, 2011)</td>
</tr>
<tr>
<td>Generalization of target behaviour</td>
<td>Advise to perform the wanted behaviour, which is already performed in a particular situation, in another situation.</td>
<td>The exercises were trained with the patient and written and drawn instructions were given for doing the exercises at home (Van Den Berg, 2014).</td>
</tr>
<tr>
<td>Credible source</td>
<td>Present verbal or visual communication from a credible source in favour of or against the behaviour. (code this BCT if source generally agreed as credible (e.g. Health professionals, words used to indicate expertise or leader in field) and if the communication has the aim of persuading.</td>
<td>Patients were seen by an experienced and dedicated occupational therapist (the profession undertaking dysphagia therapy in Denmark (Mortensen, 2015). Intervention patients participated in weekly face-to-face swallowing therapy sessions with the same head and neck speech pathologist (T.K.), who ascertained the patients’ compliance with the swallowing exercises and reinforced learning to ensure proper technique (Kotz, 2012).</td>
</tr>
<tr>
<td>Adding objects to the environment</td>
<td>Add objects to the environment in order to facilitate performance of the behaviour.</td>
<td>The stretch exercise of the E rehabilitation consisted of a passive and slow opening of the mouth using the TheraBite device (Van Der Molen, 2011).</td>
</tr>
</tbody>
</table>

NB: A complete list of BCTs in the taxonomy (BCTTv1) and a full description can be found in Michie, Atkins & West (2014)
Table 3-3:  Intervention functions identified and examples from studies included in the review

<table>
<thead>
<tr>
<th>Intervention Function</th>
<th>Definition</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Education</td>
<td>Increasing knowledge or understanding</td>
<td>The importance and necessity of the exercises were emphasized to the patients and the guardians. (Tang, 2011) All patients received education about normal and disordered swallowing and had ample time to ask questions. (Van Den Berg, 2014)</td>
</tr>
<tr>
<td>Persuasion</td>
<td>Using communication to induce positive or negative feelings or stimulate action.</td>
<td></td>
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<tr>
<td>Incentivization</td>
<td>Creating an expectation of reward.</td>
<td></td>
</tr>
<tr>
<td>Coercion</td>
<td>Creating an expectation of punishment or cost</td>
<td></td>
</tr>
<tr>
<td>Training</td>
<td>Imparting skills</td>
<td>The patients were instructed, both verbally and with written information, on how to perform mobility exercises for the tongue and larynx (Mendelson’s maneuver). (Ahlberg, 2011)</td>
</tr>
<tr>
<td>Restriction</td>
<td>Using rules to reduce the opportunity to engage in the target behaviour (or to increase the target behaviour by reducing the opportunity to engage in competing behaviours)</td>
<td></td>
</tr>
<tr>
<td>Environmental</td>
<td>Changing the physical or social context</td>
<td></td>
</tr>
<tr>
<td>Restructuring</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Modelling</td>
<td>Providing an example for people to aspire to or imitate</td>
<td></td>
</tr>
<tr>
<td>Enablement</td>
<td>Increasing means/reducing barriers to increase capability (beyond education and training) or opportunity beyond environmental restructuring.</td>
<td>E rehabilitation consisted of a passive and slow opening of the mouth using the TheraBite device. (Van Der Molen, 2011)</td>
</tr>
</tbody>
</table>
3.4 Analysis

A meta-analysis was not undertaken due to the small number of studies and the large variability. Furthermore, it would not have been as informative for the purpose of addressing the study questions. Instead, a qualitative method was employed combining the use of summary tables and qualitative exploration of the data. The synthesis approach advocated by Popay et al. (2006) was used to describe and explore findings. Results are structured and presented in line with the key steps of this approach as listed below:

1. *Developing a theory or model of how the intervention might work:* A logic model illustrating the interaction of various components of the intervention within a health service system has been presented in Figure 3-1.

2. *Preliminary synthesis of the findings:* A summary of the characteristics of the included studies tabulating the same features across all studies is provided. Additionally, summary tables are included of the intervention characteristics (behavioural strategies) extracted from studies and examples of these strategies obtained from content analysis of the study reports.

3. *Exploring relationships in the data:* Observations of relationships between studies that may explain differences in outcomes and the direction and size of intervention effects. It was assumed that BCTs that featured at least twice as frequently in studies that showed a statistically significant positive effect on at least one outcome measure (p < 0.05) in favour of the intervention group may show some promise, or at least justify more rigorous evaluation.

4. *Assessing the robustness of the synthesis:* This involved reflection on the number and quality of the studies included, and the methods used in synthesizing the findings.
3.5 Results - Synthesis of study and intervention characteristics

3.5.1 Study Selection

Of 374 articles identified from the combined searches, 254 remained after de-duplication (see Figure 3-2). The full-text of 29 articles were examined more closely and 14 were excluded for reasons that included: no measure of a swallowing outcome, no behavioural intervention, protocol paper, or studies of mixed populations with no sub-group analysis for patients with head and neck cancer. Fifteen studies, each reporting one intervention, were eligible for review. No additional studies were included following the hand-search of reference lists.

3.5.2 Study Characteristics

The 15 studies were undertaken across seven countries (USA, seven studies; Netherlands and China, two studies; Denmark, Sweden, Austria, Japan, one study). All were carried out in a university hospital, medical centre or cancer centre. All studies sought to evaluate the impact of swallowing exercises, on one or more swallow related outcomes. Eight were randomized trials: (Van Der Molen et al., 2011; Mortensen et al., 2015; Van Den Berg et al., 2015; Lazarus et al., 2014; Kotz et al., 2012; Carnaby-Mann et al., 2012; Tang et al., 2011; Logemann et al., 2009) and seven were non-randomized controlled trials: (Ohba et al., 2014; Virani et al., 2013; Zhen et al., 2012; Ahlberg et al., 2011; Carroll et al., 2008; Kulbersh et al., 2006; Denk & Kaider, 1997). Six studies reported a comparator group of ‘no treatment’ (Kotz et al., 2012; Carnaby-Mann et al., 2012; Tang et al., 2011; Zhen et al., 2012; Ahlberg et al., 2011; Carroll et al., 2008) and two of delayed treatment (Ohba et al., 2014 and Kulbersh et al., 2006). In two studies, treatment as usual was described as dietary advice without exercise (Mortensen et al., 2015 and Van Den Berg et al., 2015). The comparator group for the remaining five studies used a different swallowing exercise protocol described as usual care for that setting.

Follow-ups took place between one and 12 months. The measure used for baseline swallowing status varied greatly, with five studies providing no report of swallowing function at baseline: (Ohba et al., 2014; Ahlberg et al., 2011; Zhen et al., 2012;
Carroll et al., 2008; Kulbersh et al., 2006). At least 14 different outcome measures relating to swallow function were reported across the studies and at varied time intervals (see Appendix 3-4). The most frequently used measures (7/15) were: modified barium swallow and use of a feeding tube as a surrogate marker of swallow (dys)function. The PSS or a patient rated diet texture score, mouth opening, penetration-aspiration scale (PAS), MDADI and weight measures were also used across multiple studies, although less frequently. Almost all studies reported a combination of instrumentally derived (objective), patient-reported and/or clinician rated outcomes measures. Two studies (Zhen et al., 2012 and Kulbersh et al., 2006) reported on just the MDADI, and one study (Denk & Kaider, 1997) reported on a diet texture score alone.

### 3.5.3 Sample characteristics

A total of 995 participants was reported at the commencement of the studies (729 males, 257 females, nine unclear). Sample size ranged from 18 to 374. Average age across studies was 59.4 years. Both the gender and age demographics are broadly reflective of the epidemiology of HNC (Pytynia, Dahlstrom & Sturgis.,2014), Simard, Torre & Jemal, 2014).

Patients’ HNC diagnosis ranged from stage II to stage IV disease. The sites included the oral cavity, oropharynx, hypopharynx, nasopharynx and larynx. The majority of studies (12/15) focused on the group of patients treated with radiotherapy or chemo-radiation. Of these 12 studies, ten focused on pre-treatment swallowing interventions. Three of the 15 studies (Zhen, et al., 2012; Logemann et al., 2009 and Denk & Kaider, 1997) targeted patients who were treated with surgery as the main modality. Study and sample characteristics are summarized in Table 3-4.

### 3.5.4 Quality Assessment

Quality assessment of all studies is shown in Table 3-5. Only one study (Carnaby-Mann et al., 2012) achieved a score ≥6 and met the criteria for good quality (van Tulder et al., 2003). In 7/15 studies, there was at least one item for which information was missing or could not be deduced from the study report. Scores
ranged from 0-7 out of 11. No study complied with criteria requiring that the therapist and subject were blinded to the intervention (15/15)
### Table 3-4: Study characteristics and description of sample

<table>
<thead>
<tr>
<th>Author/year Country of Origin.</th>
<th>Setting</th>
<th>Type of study</th>
<th>Type of intervention (I) Control (C )</th>
<th>Oncology Treatment, sample characteristics</th>
<th>Sample size T= total I = new treatment, C=control</th>
<th>Gender (M:F)</th>
<th>Sample age for (I) and (C) groups. (mean and SD/mean)</th>
<th>Baseline Swallowing status</th>
<th>Length of Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mortensen 2015 [33] Denmark</td>
<td>University hospital</td>
<td>RCT (pre-treat)</td>
<td>(I) Individualized dietary advice, exercise protocol of standard exercises – 10reps/3x daily (C)= usual care, individual dietary advice. VFS and advice as needed. (active control)</td>
<td>Cancer of larynx, pharynx, oral cavity (T2-T4), unknown primary. Planned for radiotherapy with/without chemo. No previous oncology treatment.</td>
<td>T=39 I= 19 C= 20</td>
<td>34:5</td>
<td>(I) SPSS =1.44 (C) SPSS = 1.38</td>
<td>(I) 58 (39-77) C= 59 (40-74)</td>
<td>11 months</td>
</tr>
<tr>
<td>Author/year</td>
<td>Setting</td>
<td>Type of study</td>
<td>Type of intervention (I)</td>
<td>Oncology Treatment, sample characteristics</td>
<td>Sample size</td>
<td>Sample age for (I) and (C) groups. (mean and SD/range)</td>
<td>Gender (M:F)</td>
<td>Baseline Swallowing status</td>
<td>Length of Follow-up</td>
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<tr>
<td>Van Den Berg 2014 [34] Netherlands</td>
<td>University medical centre</td>
<td>RCT (pre-treat)</td>
<td>(I) = combined diet counseling and individualized swallow therapy. (C)= weekly individual diet counseling for better nutrition. (active control)</td>
<td>Patients with stage II-IV HNC treated with postoperative radiation with/without chemotherapy.</td>
<td>T=120 I=60 C=60</td>
<td>(I) PSS mean =78 (SD =26) (C)PSS mean =75 (SD=25)</td>
<td>89:31</td>
<td>Not reported</td>
<td>30 weeks</td>
</tr>
<tr>
<td>Ohba 2014 [40] Japan</td>
<td>University hospital</td>
<td>Retro-spective case-control design (peri-treatment)</td>
<td>(I) = shaker exercise during CRT. (C)=Mendelsohn manoeuvre only when dysphagia developed (delayed active)</td>
<td>Advanced HNC, laryngeal, oropharyngeal, hypopharyngeal cancers.</td>
<td>T=51 I=21 C=30</td>
<td>I=65 (53-80) C=63 (49-89)</td>
<td>46:5</td>
<td>Not reported</td>
<td>2-4 weeks</td>
</tr>
<tr>
<td>Author/year Country of Origin.</td>
<td>Setting</td>
<td>Type of study</td>
<td>Type of intervention (I) Control (C)</td>
<td>Oncology Treatment, sample characteristics</td>
<td>Sample size T= total l = new treatment, C=control</td>
<td>Gender (M:F)</td>
<td>Sample age for (I) and (C) groups. (mean and SD/range)</td>
<td>Baseline Swallowing status</td>
<td>Length of Follow-up</td>
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<tr>
<td>Lazarus 2014 [35] USA</td>
<td>Medical centre</td>
<td>RCT (post-treat)</td>
<td>(I) = isometric tongue exercises with traditional exercises. (C)= traditional exercises including ROM. (active control)</td>
<td>Patients with stage II-IV oral and oro-pharyngeal cancer, who previously underwent radiotherapy with/without chemo.</td>
<td>T=23 l=12 C=11</td>
<td>22:1</td>
<td>l=62.3 (SD, 8.06) C=61.7 (SD, 7.27)</td>
<td>(I)OPSE mean = 44.63 (dysphagia if less than 39) Tongue strength=44.63 (C) OPSE =59.6 tongue strength=49.3</td>
<td>10 weeks</td>
</tr>
<tr>
<td>Virani 2013 [41] USA</td>
<td>Cancer centre</td>
<td>Non randomized trial – matched groups. (pre-treat)</td>
<td>(I) = behavioural swallow exercises (C)= repetitive swallowing tasks (active control)</td>
<td>Newly diagnosed HNC of the oral cavity, oropharynx, nasopharynx, larynx or unknown primary due to undergo radiotherapy with/without chemo.</td>
<td>T=50 l=26 C=24</td>
<td>40:10</td>
<td>l=64 (24-90) C=60 (43-85)</td>
<td>(I)FOIS =6.5 (C) FOIS =6.6</td>
<td>3 months</td>
</tr>
<tr>
<td>Author/year Country of Origin.</td>
<td>Setting</td>
<td>Type of study</td>
<td>Type of intervention (I) Control (C )</td>
<td>Oncology Treatment, sample characteristics</td>
<td>Sample size</td>
<td>Sample age for (I) and (C) groups. (mean and SD/range)</td>
<td>Gender (M:F)</td>
<td>Baseline Swallowing status</td>
<td>Length of Follow-up</td>
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</tr>
<tr>
<td>Kotz 2012 [35] USA</td>
<td>Academic medical centre</td>
<td>RCT (pre-treat)</td>
<td>(I) = behavioural swallow exercises (5sets) (C ) = no active treatment</td>
<td>Patients with HNC receiving CRT, excluding any surgery or previous radiation or previous history of dysphagia.</td>
<td>T=26 I=13 C=13</td>
<td>I = 57 (SD, 10) C = 62 (SD, 11)</td>
<td>20:6</td>
<td>I) FOIS =7 PSS =100 (C) FOIS =7 PSS =100</td>
<td>12 months</td>
</tr>
<tr>
<td>Carnaby-Mann 2012 [37] USA</td>
<td>University Hospital Cancer Centre</td>
<td>RCT 3-arms (pre/peri)</td>
<td>(I) = pharyngocise and diet modification. (C) = usual care consisting of supervision for safe swallowing. Sham therapy – buccal extension manoeuvre –daily schedule. Active control – sham, and no treatment group</td>
<td>Newly diagnosed with oropharyngeal cancer and planned for external beam radiotherapy with/without chemo. TNM stage 1-4</td>
<td>T=58 I=20 C=20 Sham =18</td>
<td>I = 59 (SD, 10.4) C = 54 (SD, 11.3) sham = 60 (SD, 12.2)</td>
<td>44:14</td>
<td>(I) MASA = 195.1 SD = 5.9 (C) MASA = 195.5 SD = 4 sham = 194.7 SD = 3.5 scores &gt;178 suggest no dysphagia.</td>
<td>6 months</td>
</tr>
<tr>
<td>Author/Year</td>
<td>Country of Origin</td>
<td>Setting</td>
<td>Type of study</td>
<td>Type of intervention (I)</td>
<td>Control (C)</td>
<td>Oncology Treatment, sample characteristics</td>
<td>Gender (M:F)</td>
<td>Sample size</td>
<td>T= total</td>
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<tr>
<td>Zhen 2012</td>
<td>China</td>
<td>Hospital</td>
<td>Quasi-experiment</td>
<td>Parallel cluster study</td>
<td>(I) = 30 minutes swallow training daily for 2 weeks</td>
<td>(C) = no active treatment</td>
<td></td>
<td></td>
<td>T=46</td>
</tr>
<tr>
<td>Ahlgren 2011</td>
<td>Sweden</td>
<td>Hospital</td>
<td>Non randomized parallel groups</td>
<td>(pre-treat) = no active treatment</td>
<td>(pre-treat) = no active swallowing exercises</td>
<td>(C) = no active treatment</td>
<td></td>
<td></td>
<td>T=256</td>
</tr>
<tr>
<td>Tang 2011</td>
<td>China</td>
<td>University Hospital</td>
<td>RCT</td>
<td>(post-treat) = exercises and jaw stretch</td>
<td>Received radiotherapy – long term post-treatment</td>
<td></td>
<td></td>
<td></td>
<td>T=46</td>
</tr>
<tr>
<td>Ahlgren 2011</td>
<td>Sweden</td>
<td>Hospital</td>
<td>Non randomized parallel groups</td>
<td>(pre-treat) = no active treatment</td>
<td>(pre-treat) = no active treatment</td>
<td>(C) = no active treatment</td>
<td></td>
<td></td>
<td>T=318</td>
</tr>
<tr>
<td>Tang 2011</td>
<td>China</td>
<td>University Hospital</td>
<td>RCT</td>
<td>(post-treat) = exercises and jaw stretch</td>
<td>Received radiotherapy – long term post-treatment</td>
<td></td>
<td></td>
<td></td>
<td>T=46</td>
</tr>
<tr>
<td>Ahlgren 2011</td>
<td>Sweden</td>
<td>Hospital</td>
<td>Non randomized parallel groups</td>
<td>(pre-treat) = no active treatment</td>
<td>(pre-treat) = no active treatment</td>
<td>(C) = no active treatment</td>
<td></td>
<td></td>
<td>T=318</td>
</tr>
<tr>
<td>Tang 2011</td>
<td>China</td>
<td>University Hospital</td>
<td>RCT</td>
<td>(post-treat) = exercises and jaw stretch</td>
<td>Received radiotherapy – long term post-treatment</td>
<td></td>
<td></td>
<td></td>
<td>T=46</td>
</tr>
<tr>
<td>Author/year Country of Origin.</td>
<td>Setting</td>
<td>Type of study</td>
<td>Type of intervention (I) Control (C)</td>
<td>Oncology Treatment, sample characteristics</td>
<td>Sample size</td>
<td>Gender (M:F)</td>
<td>Sample age for (I) and (C) groups. (mean and SD/range)</td>
<td>Baseline Swallowing status</td>
<td>Length of Follow-up</td>
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<tr>
<td>Van Der Molen [22] 2011 Netherlands</td>
<td>Cancer Centre</td>
<td>RCT (pre-treat)</td>
<td>(I) device based rehab protocol using therabite (C) standard treatment of best evidence-based exercises (active control)</td>
<td>Stage III-IV HNC (oral cavity, oropharynx, hypopharynx, larynx, nasopharynx) planned for curative chemo-radiation treatment.</td>
<td>T=55 I=27 C=28</td>
<td>39:10</td>
<td>I=56 (37-78) C=57 (32-75)</td>
<td>Baseline function of each group not reported. Overall mean at pre-treatment: FOIS =7</td>
<td>*10 weeks 2 years, 6 years FU in later papers.</td>
</tr>
<tr>
<td>Logemann 2009 [39] USA</td>
<td>7 settings university hospitals cancer centres</td>
<td>RCT (post-treat)</td>
<td>(I) shaker exercise (C) traditional swallow therapy (active control)</td>
<td>Patients with prolonged oro-pharyngeal dysphagia of at least 3-month duration</td>
<td>T=19 I=8 C=11</td>
<td>16:3</td>
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<td>Author/year Country of Origin</td>
<td>Setting</td>
<td>Type of study</td>
<td>Type of intervention (I) Control (C)</td>
<td>Oncology Treatment, sample characteristics</td>
<td>Sample size</td>
<td>Gender (M:F)</td>
<td>Sample age for (I) and (C) groups. (mean and SD/range)</td>
<td>Baseline Swallowing status</td>
<td>Length of Follow-up</td>
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<tr>
<td>Carroll 2007 [44] USA</td>
<td>University hospital</td>
<td>2-arm Retrospective Case control Study (pre-treat)</td>
<td>(I) pre-treatment swallowing exercise protocol. (C ) usual care - swallow rehab as problems arose post treatment. (no active pre-treat exercises)</td>
<td>Patients with advanced squamous cell cancer of the oropharynx,hypopharynx and larynx treated with chemo-radiation.</td>
<td>T=18 I=9 C=9</td>
<td>12:6</td>
<td>I =57.5 (SD, 9.6) C=60.7</td>
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<tr>
<td>Kulbersh 2006 [45] USA</td>
<td>University Hospital</td>
<td>2-arm Prospective cohort study (pre-treat)</td>
<td>I) pre-treatment swallowing exercise protocol (C) exercises given at first visit after treatment. (delayed intervention)</td>
<td>All patients diagnosed with HNC with/without nodal disease but without metastatic disease</td>
<td>T=37 I=25 C=12</td>
<td>28:9</td>
<td>I =55.1 (SD, 9.6) C=66.3 (SD, 10)</td>
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<td>Author/year Country of Origin.</td>
<td>Setting</td>
<td>Type of study</td>
<td>Type of intervention (I) Control (C )</td>
<td>Oncology Treatment, sample characteristics</td>
<td>Sample size T= total I = new treatment, C=control</td>
<td>Gender (M:F)</td>
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<td>Denk 1997 [46] Austria</td>
<td>ENT deartment</td>
<td>Non-randomised, 2-arm parallel group study (post-treat)</td>
<td>(I) therapy with video-endoscopic biofeedback. (C) conventional swallow therapy. (active control)</td>
<td>Patients with prolonged post-operative aspiration following resection of malignant tumours of the oropharyngeal swallowing structures.</td>
<td>T=33 I=19 C=14</td>
<td>25:8</td>
<td>I=54 (37-68) C=53 (37-79)</td>
<td>Prolonged post-op aspiration, with tube feeding</td>
<td>Variable, based on time to establish oral intake</td>
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</table>

Notes: (I) = intervention group ; (C) = control group ; T = total sample; RCT= randomised controlled trial; HNC = head and neck cancer; SPSS = swallowing performance status scale; PSS = performance status scale; OPSE = oro-pharyngeal swallow efficiency; FOIS= functional oral intake scale; MASA = Mann swallowing assessment; WST=water swallow test; IID= inter-incisor distance;
* Later papers linked to this study include follow-up measures at 2-years, and 6 years.
### Table 3-5: Quality ratings of studies included in the review

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<tr>
<th>Quality criteria</th>
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<th>Van Den Berg</th>
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<th>Virani</th>
<th>Kotz</th>
<th>Carnaby Mann</th>
<th>Zhen</th>
<th>Ahlberg</th>
<th>Tang</th>
<th>Van Der Molen</th>
<th>Logemann</th>
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3.5.5 Intervention characteristics

Twenty individual BCTs were each identified in at least one intervention (see Table 3-6). The average number of BCTs per intervention was seven, with a range of four to ten. The BCT instruction on how to perform the behaviour was reported in all interventions (15/15), with 14/15 including setting behavioural goals (for example, perform jaw exercises 3x/day) and 13/15 including action planning (for example, perform exercises before mealtimes). A further four BCTs that appeared prominently in some interventions were practical social support, behavioural practice/rehearsal, self-monitoring, and credible source.

A total of three Function categories were each identified in at least one intervention. Training was identified in all interventions (15/15), Education in 12/15 and Enablement in 5/15 (for example, providing patients with a TheraBite device).

Regular performance of the prescribed swallowing exercises was the target behaviour for all interventions. Due to the small number of studies and the variation in exercise content, no attempt was made to group interventions according to the exercise type.
Table 3-6: Behavior Change Techniques identified from review studies

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<th>Tick (√) = BCT present</th>
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<th>V.D. Berg</th>
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<th>Virani</th>
<th>Kotz</th>
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<td>4</td>
<td>8</td>
<td>10</td>
<td>7</td>
<td>8</td>
<td>7</td>
<td>7</td>
<td>6</td>
<td>6</td>
</tr>
</tbody>
</table>
3.6 Exploring relationships between behavioural strategies and effectiveness

The three most commonly used BCTs, which appeared in >85% of interventions, were *instruction on how to perform the behaviour*, *setting behavioural goals* and *action planning*. These BCTs may arguably form the cornerstone of exercise therapy interventions so it is unsurprising that they were identified in >85% of interventions. Four BCTs were used in at least twice as many interventions that produced positive effects relative to those with no such effects: *practical social support*, *behavioural practice/rehearsal*, *self‐monitoring*, and *credible source*.

3.7 Exploring relationships between comparator group and effectiveness

The data was examined to explore any relationship between active and non-active comparator groups and intervention effectiveness. Of five studies reporting no evidence of a significant positive effect of the intervention on any outcome, four had an active control group where similar behavioural strategies were used in both the intervention and comparator groups (Van Den Molen et al., 2011; Mortensen et al., 2015; Van den Berg et al., 2015; Lazarus et al., 2013), while one study used parallel groups on different sites (Ahlberg et al., 2011). The active comparator group was given a different exercise regime (often described as usual care), or may have not been given a swallowing exercise device that was included in the intervention group.

Of the ten interventions that demonstrated evidence of positive effects on at least one swallowing outcome measure (see Appendix 3-2), five had a non-active comparator group (Kotz et al., 2012; Carnaby-Mann et al., 2012; Tang et al., 2011; Zhen et al., 2012; Carroll et al., 2008). In two studies, intervention was delayed for the control group and therefore effectively represents a non-active comparator group (Ohba et al., 2014 and Kulbersh et al., 2006). Two studies had an active comparator group that received a different exercise intervention (Virani et al., 2013 and Logemann et al., 2009). One study used similar exercise interventions, but the intervention group included *biofeedback* by providing the patient with visual feedback of swallowing during a fibreoptic endoscopic assessment (Denk & Kaider,
One study (Carnaby-Mann et al., 2012) had 3 groups: a treatment group receiving swallowing exercises, a group receiving sham exercises using a similar regime, and a usual care group who received safe-feeding advice from the hospital team but no exercise intervention. The authors found a statistically significant difference between each of the active groups (swallowing exercises and sham exercises) versus the usual care group, but a smaller difference (favouring the swallowing exercise group) between the two active groups performing swallowing exercises and sham exercises.

Acknowledging the small number of studies, these findings seem to indicate that employing active comparator groups, particularly when similar behavioural strategies are used, are less likely to demonstrate statistically significant positive effects. Interestingly, a positive effect was still found in one study (Denk & Kaider, 1997) where both groups received similar exercise interventions, but different non-exercise content (intervention group received biofeedback, a named BCT).

### 3.8 Type and timing of outcome measures and intervention effectiveness:

Outcomes that significantly improved with the exercise intervention did so mostly at 1 month post oncological treatment, with a general decline in effect at the later time-points after treatment. Four studies measured outcomes at 12 months (Mortensen et al., 2015; Kotz et al., 2012; Carroll et al., 2008; Kulbersh et al., 2006) but only one (Kulbersh et al., 2006) showed a significant difference in favour of the intervention by this time-point. In one study (Kotz et al., 2012), outcomes were measured at multiple time-points. Significant differences were observed at 3 and 6 months post-treatment but not at 9 and 12 months (see Appendix 3-4). Another study (Mortensen et al., 2015) charted a rapid decline in patient adherence to swallowing exercises over the first 12 months following treatment.

Outcomes broadly classified as objective measures (PAS, MBS score, mouth opening, feeding tube) were more frequently improved by the intervention when compared to patient reported and clinician rated measures.
This exploration of the data has highlighted the potential impact that BCTs, choice of comparator group and timing of outcome measures may have on intervention effectiveness. Implications of these findings are expanded upon in the Discussion.

### 3.9 Discussion

Fifteen controlled clinical trials (eight randomized) were identified at the time of undertaking this review, representing the best available evidence of swallowing interventions for patients with HNC. From these study reports, three function categories and 20 different BCTs that characterize swallowing exercise interventions were extracted. Three BCTs were present in almost all interventions: *instruction on how to perform the behaviour*, *setting behavioural goals* and *action planning*. Four other BCTs occurred more frequently in effective interventions: *practical social support*, *behavioural practice/rehearsal*, *self-monitoring*, and *credible source*. One may cautiously expect that these seven BCTs could be useful if combined in a new swallowing exercise intervention. Likewise, the new swallowing intervention package might draw upon but not necessarily be restricted to the intervention functions of *Education, Training and Enablement* identified in previous interventions.

By specifically isolating and reporting these BCTs, it is hoped that authors will see benefit in using consistent descriptions of the non-exercise content of swallowing exercise interventions. This could improve the ability of researchers to replicate studies more accurately. Indeed, in time it may be possible to devise interventions that test the effectiveness of specific BCTs or groups of BCTs used in swallowing exercise interventions for this patient population, and to link these to underlying theory and mechanisms of change (Michie et al., 2016). In so doing, we may be better placed to understand why interventions work, for whom and in which contexts (Moher, et al., 2015a).

The data was also examined for any relationships that may elucidate the interaction of different components of this complex intervention. For example, studies that employed active comparator groups using similar BCTs to the intervention group
were more likely to demonstrate non-significant results. Furthermore, in a trial that employed three groups [an exercise group, a sham exercise group, and a non-active control group] (Carnaby-Mann et al., 2012), the authors reported that the active sham exercise group that received similar BCTs to the pharyngocize (exercise treatment) group achieved much better outcomes compared to the non-active control group. It may therefore be the constituent BCTs that were responsible for improving intervention effectiveness, by stimulating greater adherence to the prescribed treatment. Whilst the authors themselves did not specifically make reference to BCTs, they did question whether the “benefits obtained from the sham group could be ascribed to the placebo effect of behavioral attention” (Carnaby-Mann et al., 2012 p.219). Equally, they speculated that the sham exercise (done diligently) might have had an intrinsic benefit from the increased movement of oral musculature. Regardless, these findings raise the possibility that BCTs may be functioning as active ingredients influencing intervention outcomes.

For most studies where both the intervention and active comparison group used similar BCTs, no statistical significance in outcomes between groups was reported. This might be because the interventions given to both groups were too similar, or because of a lack of power due to small sample sizes. However, it does raise other interesting questions: what contribution do BCTs make to intervention outcomes? How does their presence in usual care/placebo interventions impact effect size? From this review, it seems that swallowing intervention studies with active comparator groups that include similar BCTs to the intervention will very likely show diminished effect sizes. This phenomenon has been reported elsewhere. For example, Karlsson & Bergmark (2015) analyzed the control groups used in psychosocial interventions for substance abuse in Cochrane and Campbell reviews. They highlight that a mixed picture may emerge when control groups are poorly described as intervention effects vary with absolute versus relative treatment efficacy. In other words, a new treatment compared with a no treatment control group is more likely to demonstrate better effect. Reporting of swallowing exercise interventions tends to focus mainly on the treatment group and often provides only cursory reference to the usual care group. The findings of this review highlight that
the same methodological care should be taken in devising the treatment manuals for the intervention and comparator groups ensuring that behaviour change components are also specified, given their potential to impact patient adherence and subsequent outcomes. This may prevent conclusions that imply pre-treatment swallowing exercises have no benefit. A more accurate conclusion might be that the ‘new intervention’ was not shown to demonstrate any significant additional benefit relative to usual care.

The variability in the type and time-point of the primary outcome measures for clinical trials in this field restricts the ability to satisfactorily pool data. Consequently, it is challenging to compute effect sizes and to address the question of efficacy of swallowing interventions in patients with head and neck cancer. Generally, it was observed that in studies that reported a positive outcome, this was mostly seen in the short term. One reason for this may be because patients do not continue with their exercises long term. In his analysis of behaviour maintenance, Rothman (2000) highlighted that the psychological factors that underpin initiation of a new behaviour differ from those that predict maintenance of the behaviour. By implication, different BCTs may be required for these distinct phases. Behavioural strategies such as habit formation, requires that an individual repeatedly perform the behaviour in the same context such that it becomes automatic. This automaticity may promote maintenance of exercises as it may over-ride conscious intentions (Gardner, 2015). Habit formation could therefore have an important role to play in maintaining patient adherence to swallowing exercises over the longer term.

In this review, outcomes collected after 6 months showed little difference between groups. This was especially relevant for patient-reported outcomes that arguably may also reflect patients’ changing expectations and adaptation over time, and not just functional swallowing status. Furthermore, this mirrors the usual trajectory of behaviour change where short-term goals are given priority. It was also noted that few studies collected objective measures of swallowing in the longer term, making it difficult to assess changes in swallow physiology at later time-points.
Standardizing outcome measures and agreeing on the key evaluation time-points will greatly progress efforts to understand if pre-treatment swallowing exercise interventions are indeed beneficial for this group of patients and over what time period. Consideration should also be given to the expected trajectory of swallowing recovery after head and neck cancer treatment including the possible onset of late effects of treatment such as post radiation fibrosis known to impair swallow function (Hutcheson et al., 2012).

3.9.1 Assessing the robustness of the synthesis

Robustness of a synthesis is usually determined by 1) the methodological quality of the included studies, 2) methods used to minimize bias in the synthesis process, and 3) whether detailed information has been provided on the type of studies included/excluded (Popay et al., 2006). This review meets the latter two criteria by providing detailed information through pre-registration and the availability of a protocol (Govender et al., 2015). Methodological quality of the available evidence was rated as poor with only one study meeting more than 50% of the applied quality criteria. However, it is acknowledged that for this type of intervention, it is usually difficult to blind the therapist and subject to the intervention. Attrition is a common feature for studies that involve patients who may be feeling ill and undergoing a complex intervention within a multifaceted cancer care pathway. Moreover, randomized studies within this field are only beginning to emerge (Carnaby-Mann & Madhavan, 2013). Excluding studies that did not meet quality criteria may therefore have been a disadvantage in addressing the primary aims in this exercise. Furthermore, complex interventions may require a differing emphasis on the markers of study quality as they are frequently evaluated within the context of pragmatic clinical trials. Since undertaking this review, new methods of evaluating quality in complex interventions have begun to emerge that may be more suitable for future use (Raine et al., 2016).
### 3.9.2 Limitations and Challenges

This review is limited by the fact that the accuracy of the coding scheme relies on the quality of published intervention reports, which are often not sufficiently detailed to extract all necessary components of the intervention (Abraham et al., 2014). It is possible therefore that the intervention itself may have included strategies that have not been coded in this review. Descriptions of the treatment delivered to comparator groups in particular were poor, and in some cases decisions about the presence of BCTs in the comparator group had to be based on the reporting authors’ implicit suggestions that interventions were identical apart from the specific exercise protocol used in each of the active groups.

Despite the BCT taxonomy being developed within the field of behavioural science, there is on-going debate amongst experts in behaviour change as to its merits. Critics have questioned the value of coding BCTs, suggesting it creates a level of abstraction that detracts from the detailed content analysis of interventions (Ogden, 2016a). In my view, the counter argument is that in a clinical field that has focused mainly on exercise protocol content, drawing attention to broader more abstract process-based mechanisms can only enrich our understanding of complex interventions. The taxonomy brings structure, organization and a common language to this process. For example, coding a BCT such as *self-monitoring* may not tell us how the self-monitoring was done, but it does highlight that the use of self-monitoring may be relevant to changing adherence behaviour, particularly when it is frequently observed in successful interventions.

### 3.9.3 What this review adds

This review applied a behaviour change perspective to studies within head and neck cancer swallowing rehabilitation, with a specific focus on identifying the behavioural strategies that may impact patient adherence to exercises, and consequently swallowing outcomes. Such an analysis is absent in the current literature. The aim was to better understand the complexity of swallowing exercise interventions, their design and the reporting of such interventions. The review
addresses the question of *what* might bring about change by isolating the specific components within an intervention, other than the nature of the treatments to which patients are encouraged to adhere, that may influence behaviour (Petticrew et al., 2013). It therefore expands on the findings from previous related reviews (Cousins et al., 2013, Perry et al., 2016, Langmore & Pisegna, 2015; McCabe et al., 2009) and goes some way to highlighting additional components that may be present and active in this complex intervention. Given the relative paucity of high quality data, the review did not attempt to definitively answer the question of which BCTs are most effective in promoting adherence, but instead aimed to highlight those that were prevalent in successful interventions. Using this as a starting point, we may begin to design future interventions incorporating specific BCTs or groups of BCTs to examine more closely whether they strengthen interventions aimed at improving swallowing function via swallowing exercises. Clearly, BCTs are only one part of trial design and equal attention should be placed on other important aspects such as precise definition of the whole intervention package in prospective study protocols and intervention manuals.

This approach was intended to inspire greater thought toward understanding the make-up of complex interventions. It also offers new perspectives in the interpretation of findings from clinical trials of swallowing exercises where it is clear that evaluating effectiveness is hampered by poor adherence.

### 3.10 Conclusion

The effectiveness of swallowing interventions depends in part on patient adherence to exercises. Adherence may be improved through the use of BCTs. The review has provided preliminary information about which BCTs occur in reports of complex swallowing interventions and has highlighted that behavioural components may be *active ingredients* of change that impact intervention outcomes. It is likely that many BCTs are used in clinical practice, and there will be some bias towards the techniques that researchers tend to report. Nevertheless, introducing the taxonomy of BCTs helps equip dysphagia researchers with the tools and the language to improve consistency in how complex interventions are specified in research protocols, intervention manuals and the published reports of intervention studies.
In time, the approach can also be used in examining fidelity in the delivery of interventions through field-testing and observational methods. Its merits and weaknesses can only be adequately evaluated as the body of work adopting this approach increases. In the context of this thesis, findings from this review will be revisited in Chapter 6 and Chapter 7, which respectively describe the development of the new SIP and the protocol for a feasibility trial.
Chapter 4  Study 2: Patient experience of swallowing exercises after head and neck cancer: A qualitative study examining barriers and facilitators using behaviour change theory.4

4.1  Introduction

The findings of the systematic review discussed in the previous chapter indicate which BCTs clinicians use in swallowing exercise interventions, and provide an indication of those which may be associated with better outcomes. These results offer a moderate level of empirical evidence for including certain BCTs [setting behavioural goals, action planning, instruction on how to perform the behaviour, social support, self-monitoring of behaviour, credible source and behavioural practice] in the proposed new swallowing intervention package (SIP). Obtaining further corroboration from other data sources may strengthen this evidence, and at the same time highlight other useful BCTs. Accordingly, the study reported here (Study 2) focuses on understanding patient barriers and facilitators to performing swallowing exercises using the theoretical lens of the TDF (Cane, O’Connor & Michie, 2012) and the COM-B model (Michie, Van Stralen & West, 2011). This systematic approach to analyzing adherence behaviours of HNC patients will inform the selection of BCTs linked to the theoretical constructs of behaviour change relevant for this population.

4.2  Background

In addition to the findings from Study 1 (reported in Chapter 3), other related systematic reviews highlight that studies aiming to establish the effectiveness of swallowing exercise interventions often neglect to adequately recognize the role of exercise adherence (Krekeler et al., 2017; Perry et al., 2016), and may consequently portray effective interventions as ineffective. Improving patient adherence is one

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4 Study 2 was published in Dysphagia (Govender et al., 2017b). Content from the publication has been included in this chapter under the CC-BY license (see Appendix 4-1 for publication).
way of optimizing exercise interventions prior to evaluation, although the most effective methods to improve adherence remain unclear.

Techniques to increase adherence are likely to be more effective if they are informed by in-depth exploration of patients’ experiences of their swallowing exercises, probing both barriers and facilitators to adherence.

Patients presenting with HNC undergo a protracted journey from diagnosis through to treatment, rehabilitation and long-term follow-up with up to two-thirds experiencing dysphagia before treatment (Russi et al., 2012). The swallowing sequelae of surgical and non-surgical treatments are well documented and often predictable (Wall et al., 2013; Kreeft et al., 2013; Paleri et al., 2013). Clinicians have a unique opportunity to intervene early in the patient pathway (Roe & Ashforth, 2011; Patterson & Wilson, 2011), and establish swallowing exercise programmes that may potentially enhance post-treatment outcomes (Kulbersh et al., 2006; Carroll et al., 2008; van der Molen et al., 2011; Ahlberg et al., 2011; Carnaby-Mann et al., 2012; Kotz et al., 2012; Van Den Berg et al., 2015; Mortensen et al., 2015). In a retrospective study of prophylactic swallowing exercises, patients who adhered most to their exercises were more likely to be tolerating a more regular diet one month post-treatment than non-adherers. Similarly, dependency on a gastrostomy tube was reported to be higher in patients who were non-adherent to exercises (Duarte et al., 2013). These observational findings suggest that patients who adhere to their exercises achieve better functional outcomes.

Some work has been undertaken to understand underlying reasons for non-adherence to swallowing exercises. In a survey of 109 patients, Shinn et al. (2013) reported that rates of complete non-adherence (did not do the exercises at all) were high (55%) with a further 36% reporting only partial adherence. Common reasons given by patients for non-adherence during the telephone survey were: not having a swallowing problem at the time, not understanding the need for exercises, finding exercises difficult, forgetting to do them, being too busy, experiencing pain, nausea and fatigue.
A later study (Cnossen et al., 2016) examined adherence to a 12-week preventative programme, with a specific focus on investigating whether demographic factors (age gender), clinical factors (tumour site and stage, and treatment modality) and health related Quality of Life (HRQOL) were associated with exercise performance and adherence. The percentage of patients who adhered to the programme at least once daily for the duration of the study was 70% at six weeks, dropping to 38% at week 12. The addition of chemotherapy to the radiotherapy regime (treatment modality) was the only statistically significant factor associated with poorer exercise performance. This concurs with the findings of Shinn et al., (2013) who reported that pain, nausea, and fatigue were major barriers in patients having chemo-radiation. Other demographic factors were not found to have any significant impact on adherence.

Previous studies have used mainly deductive methods to identify reasons for non-adherence, based on commonly endorsed researcher-generated ideas. Inductive methods using in-depth interviews that seek to spontaneously elicit the reasons, belief systems, attitudes and underlying values from patients, provide a rich source of context relevant information from a patient perspective. This may yield important additional barriers to exercise performance and adherence that may be highly relevant, but possibly less intuitive to the researcher. As this approach elicits the overall experience of patients, we may also learn which factors facilitate doing the exercises. Optimizing facilitators is another way of potentially improving the design of interventions. To my knowledge, no previous study has explored the problem of poor patient adherence to swallowing exercises amongst the HNC population using in-depth patient interviews guided by a theoretical framework. Theoretical frameworks of behaviour change, rooted in behavioural science, offer useful tools for exploring and organizing reasons for adherent/non-adherent behaviours. It has been suggested that interventions aimed at modifying behaviour are more likely to be successful if based upon theory. Theory allows researchers to be more systematic and explicit in investigating mechanisms of change (French et al., 2012; Michie et al., 2016), and has been demonstrated to have useful application in other aspects of speech and language therapy practice requiring
behaviour change (Johnson et al., 2016). By using theory, we may accumulate knowledge incrementally, building on existing scientific knowledge.

The purpose of the present study was to identify barriers and facilitators (things that hinder or promote adherence) to performing swallowing exercises. This represents the first step in what has been referred to as a ‘behavioural analysis’ (Michie, Atkins & West, 2014). Identifying key barriers and facilitators (those most commonly reported by patients as being important to them) can inform the design of a new intervention. A behaviour analysis ascertains which factors need to change in order to increase patient adherence to exercises. Using the theoretical models introduced in the intervention development section (see Section 2.4.2), it then becomes possible to establish which broad components of behaviour (Capability, Opportunity, Motivation), and which domains of the TDF need to be the focus of a new swallowing intervention to improve adherence.

4.3 Methods

4.3.1 Design

Face to face semi-structured interviews were used to explore and understand the personal meanings, experiences and issues pertinent to individuals in the context of their swallowing rehabilitation. A topic guide was developed that allowed participants the flexibility and freedom to narrate their experience of eating and drinking and swallowing rehabilitation over the course of their cancer treatment. Questions and probes were used to ensure that topics of interest were covered in adequate depth.

4.3.2 Theoretical Framework

I have drawn upon the theoretical models from behavioural science discussed in Chapter 2, The Theoretical Domains Framework (TDF) (Michie et al., 2005; Cane, O'Connor & Michie, 2012) and the COM-B (Capability, Opportunity, Motivation-Behaviour) model (Michie et al., 2011) to guide understanding of patients’ exercise adherence behaviours, and experience of swallowing rehabilitation. The framework
and model were used both in developing the interview schedule as well as in informing the content analysis approach utilized (see Figure 4-1). The topic guide, developed using the TDF (Michie et al., 2005; Cane et al., 2012) as a basis for question prompts, is included in Appendix 4-2.

The topics included in the interview schedule were designed to ensure comprehensive coverage of the key components that drive behaviour. This included aspects such as knowledge of swallowing exercises, ease of carrying out exercises, beliefs about exercises, feelings and emotions, and support for doing exercises. The interview opened with a general and broad question: *Can you tell me how you got on with eating and drinking at the time of your treatment?* Follow-up questions and probes were introduced as part of the narrative flow rather than as individual discrete questions. Patients were encouraged to speak freely about their experiences with swallowing rehabilitation.
Figure 4-1: Use of the COM-B and TDF to devise the interview schedule

Source: Adapted from Michie, Atkins & West, 2014
4.3.3 Participants and Sampling

All participants (patients) were recruited via SLT clinicians working in the head and neck cancer centre at a UK metropolitan teaching hospital. Clinicians were asked to identify patients who had received treatment for advanced head and neck cancers. Patients who were between three and 18 months post-treatment were sought, as they were deemed sufficiently beyond the acute phase of recovery but still likely to reliably recall their experiences. Patients were required to have undergone swallowing rehabilitation including a minimum of three swallowing exercise consultations with a SLT.

The sample size was determined using the ‘ten plus three’ rule for data saturation (Francis et al., 2010). An initial target of ten patients was set, with a view to achieving a point where three consecutive interviews could be undertaken without new themes emerging. As a previous study (Cnossen et al., 2016) showed that some factors such as treatment modality have a significant influence on adherence, it was necessary to obtain a diverse sample to ensure a good representation of different factors. For this reason, midway through the recruitment, selected characteristics of participants were examined (age, gender, treatment modality and swallow function). Attempts were then made to purposively recruit participants with characteristics that were lacking from the existing sample to acquire a broad range of experiences. Table 4-1 shows a summary of participant characteristics.

Table 4-1: Characteristics of sample

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Sample (n=13)</th>
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<tbody>
<tr>
<td>Age: n (mean)</td>
<td></td>
</tr>
<tr>
<td>60 years and over</td>
<td>4 (63)</td>
</tr>
<tr>
<td>Under 60 years</td>
<td>9 (50)</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>9</td>
</tr>
<tr>
<td>Female</td>
<td>4</td>
</tr>
<tr>
<td>Treatment</td>
<td></td>
</tr>
<tr>
<td>Surgery and chemo-radiation therapy</td>
<td>4</td>
</tr>
<tr>
<td>Chemo-radiation therapy</td>
<td>5</td>
</tr>
<tr>
<td>Surgery and chemotherapy</td>
<td>1</td>
</tr>
</tbody>
</table>
All patients provided written consent (patient information leaflet and consent form included in Appendix 4-3 and 4-4). Interviews took place in a quiet room at the Macmillan Support Centre within the hospital. Participants were given a £25 shopping voucher and offered travel re-imbursement. I conducted all interviews; no patients interviewed were previously known to me. Interviews lasted 40 minutes on average. A few minutes were spent before each interview completing basic biographic data and allowing time for questions about the study. This afforded patients time to relax into the environment and an opportunity for the interviewer to establish rapport. Interviews were digitally recorded and professionally transcribed verbatim. To ensure full anonymity on the recording, participants chose a pseudonym for themselves at the interview outset. Transcripts were imported into NVivo 10 (QSR International) to organize analysis.
4.4 Analysis

I performed the analysis in three stages, drawing upon the content analysis method (Graneheim & Lundman, 2004). Content analysis is well suited to research questions that use context relevant information generated from interviews to re-populate pre-specified theoretical constructs (Francis et al., 2010). The first stage familiarity with data and initial coding involved listening to the recording, making notes and assigning initial codes to sections of text. The second stage involved refinement of codes and development of a codebook. Codes were grouped into clusters that reflected broader themes and duplicate or redundant labels were removed. This was a recursive process that often required reading and re-reading content coded with the same label across interviews to ensure that it was an accurate depiction of the concept. Once a satisfactory coding system was achieved, codes were matched to the domains of the TDF. The codebook (see Appendix 4-5) allowed for verification by a second coder (CW), with expertise in both qualitative analysis and the use of the TDF. The second coder used the codebook and definitions to independently code three randomly selected transcripts. The third stage was the verification of coding and peer debrief. This served to examine reliability and improve validity thereby adding rigour to the analysis (Morse, 2015). The peer debrief focused on three aspects which were: comprehensiveness of the codebook (all relevant content could be attributed a code label), degree of agreement for the presence of codes (percentage agreement by both coders for the presence of codes in each transcript), and degree of uncertainty (any uncertainty with regard to description of code labels, TDF domain to which a code was assigned, and need for new codes). Agreement on the presence of codes was above 90% for each of the transcripts. Uncertainties were resolved through discussion. Following this process, I undertook a final reading of the transcripts to ensure that all content was appropriately coded particularly where changes were made following the peer debrief. At the final step, coded material was re-aligned to the theoretical model to determine which domains may need to be targeted to improve adherence.
4.5 Results

A total of 13 patients was interviewed to achieve data saturation. As indicated in Table 4-1, a range of patient characteristics was achieved. Table 4-2 and Table 4-3 illustrate the key barriers and facilitators identified in greater than 50% of interview transcripts, and the corresponding mapping onto the relevant COM-B component.
Table 4-2: Examples of key barriers

<table>
<thead>
<tr>
<th>Key Barriers</th>
<th>COM-B</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inadequate knowledge of how treatment will affect own swallowing.</td>
<td>psychological capability</td>
<td>The doctor scribbled down a few symptoms that I would suffer after the radiotherapy, one of which was sore throat and one of which was maybe problem with the swallowing, or something along these lines. (P12) They told me I will need a feeding tube, I will have a feeding tube. Even if I don’t use it they are going to give me a feeding tube, because, I don’t know, for example, nine out of ten patients, at some point during treatment, won’t be able to take food. So I will definitely need one. (P 13)</td>
</tr>
<tr>
<td>Inadequate understanding of why exercises given pre-treatment</td>
<td>psychological capability</td>
<td>I understand someone sitting there explaining to me that you will need to do these exercises to help you swallow, but I don’t think the emphasis was how important they were, for me. I don’t think I actually took that on board. (P3) I was given some leaflets on swallowing exercises and told that I would probably get a dry mouth and that would cause problems with swallowing. (P 11)</td>
</tr>
<tr>
<td>Forgetting to do exercises, no system of keeping track</td>
<td>psychological capability</td>
<td>It was a bit random; I would just do it when I remembered, some of the time. (P1) I think what I’m remembering and what I’m saying is because there wasn’t a discipline around it, sometimes they slipped a bit. (P 9)</td>
</tr>
<tr>
<td>Overwhelmed by information at a difficult time (emotion)</td>
<td>automatic motivation</td>
<td>Loads and loads of stuff was happening that was unfamiliar and a bit scary, and so, you know, I, sort of, felt a bit bombarded with stuff. (P1) There was a lot to take in during that period. This is something else to take in as well, necessary but not life... This isn’t going to save your life; this is going to make it better afterwards. Very important. But as a patient, when you are faced with a life-threatening situation, I think that wouldn’t be a priority and you’d want to push that away for now. (P5)</td>
</tr>
<tr>
<td>Pain and fatigue</td>
<td>physical capability</td>
<td>I tried to do some of the exercises some of the days. And some of the exercises I just couldn’t do because of the pain I was actually experiencing that particular day. (P 3) When I got tired from the chemotherapy and so forth, I think I let it all, kind of, go a bit. (P 2)</td>
</tr>
<tr>
<td>Key Facilitators</td>
<td>COM-B</td>
<td>Examples</td>
</tr>
<tr>
<td>------------------------------------------------------</td>
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<tr>
<td>Support from clinician and family</td>
<td>social opportunity</td>
<td>So I think it was before and it was during, right up until I could eat again, I was constantly getting advice and help (P13)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>I started doing exercises, the throat exercises and eventually... it took some time, but I was told by my family as well that don’t give up. Because at that time I was just about to be a grandfather as well and that also gave me the strength. (P10)</td>
</tr>
<tr>
<td>Desire to prevent negative consequences from treatment</td>
<td>reflective motivation</td>
<td>But I don’t know, I just knew I had to eat, you know. And my object was not to use that... what do you call it? The tube they stick in you. And I managed it. I didn’t really use the tube. (P6)</td>
</tr>
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<td></td>
<td></td>
<td>I thought, well, if you don’t use muscles, they, sort of, stop working, don’t they? I’ve seen it with people with broken legs. If they don’t use them the muscles wither. And so I thought if that’s just going to happen to my throat, I don’t want that happening. (P7)</td>
</tr>
<tr>
<td>Knowing how to do the exercises (skills)</td>
<td>physical capability</td>
<td>The exercises themselves were pretty simple exercises using the tongue and biting, protruding the tongue between your lips and holding onto the tongue and trying to swallow, to do with breathing and holding your breath while you swallow. They were pretty simple tasks. (P3)</td>
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<td></td>
<td></td>
<td>After the first week you could do them whatever they were, even just go through them through your head. Yes. It would be like going to the gym and doing ten different classes and you know all the steps. It’s the very same. It’s familiarity, isn’t it? (P4)</td>
</tr>
<tr>
<td>Having a routine and/or having a trigger to do the exercises (behavioral regulation)</td>
<td>psychological capability</td>
<td>My exercises at the beginning, I’d actually write them on the chart. But what I used to do is I’d put them on... I’ve got an iPhone. (P3)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>I had a form from the team and I used to mark down how many - on a Monday, four times, I’d mark it off four times, Tuesday four times, all the way up to Thursday. And I didn’t do them on Friday. It was a Friday morning. I had it marked out on the chart and you give the chart when you come in for the exercises, she’d have a look at it. She’d say, ‘Yes, you are doing well.’ (P4)</td>
</tr>
<tr>
<td>Receiving feedback on outcome (re-inforcement)</td>
<td>automatic motivation</td>
<td>You are achieving something every time. And they tell you, yes, you are doing very good and they tell you it’s open so many centimetres today, and then they’d compare it from last week. They’d have it written down. (P4)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>I took a short drink, the energy drink, and I started drinking it and he was... my son and my daughter as well were so pleasantly surprised. They were, sort of, overcome with joy. So there was a joy that I could drink at least. (P10)</td>
</tr>
</tbody>
</table>
4.5.1 Capability

*Psychological capability* was the primary component identified as a barrier to patients’ adherence to swallowing exercises. This encompasses the psychological skills including mental stamina and the processing of knowledge and information (Michie et al., 2011). Patients recounted being given information but not necessarily relating this to why they might need to do their swallowing exercises. In addition to feeling that the pre-treatment exercises were just a precaution, some patients did not give much credence to the exercises themselves. This is exemplified by the following patient quote.

They just said to me, ‘Do that three times a day, whatever, in the morning and night.’* [talking about the exercises he was given] I thought what’s it going to do?... What they told me, for the amount of times to do it, I thought it was just someone wrote it 100 years ago and it’s still the same rules. (P7, male)

Patients also talked about the number of competing priorities and the cognitive burden of trying to do many different things just to get through treatment. A few patients mentioned the difficulty in knowing what to prioritize.

I met with the speech and language people early on; I met before I started treatment. And they talk about do*[ing] your exercises through treatment as well. But it becomes a matter of priorities when you are in treatment and it’s really rough, and unfortunately that one just gets pushed... well, for me it did, it just gets pushed to the back of the queues, trying to get the mucus out of my system, yes, trying to stay hydrated, trying to keep the pain under control. And when it was really bad, speech and language is the furthest thing from your mind. (P8, male)

*Physical capability* was also a barrier for patients during treatment. Side effects such as pain, nausea, and sticky secretions in the mouth became the predominant pre-occupation and patients looked for an easier solution to obtain their nutritional requirements.
Certainly with a PEG in you needn’t swallow at all. You’ve got to keep your mouth moist but that’s all you need to do. (P12, male)

Some aspects of *Physical and Psychological Capability* were also identified as potential facilitators. In general, patients felt that the exercises were simple and easy to perform once they had learned how to do them and felt confident they were doing them correctly. Patients who incorporated a method for self-regulation, such as marking off the exercises on a chart or using a smart-phone to keep track, reported this to be a helpful strategy.

4.5.2 Opportunity

*Physical opportunity* which encompass the environmental context and resources (Michie, Atkins & West, 2014), did not feature as a commonly reported barrier. However, some patients with children felt that they were less keen to do the exercises with the children around.

> During most of my treatment I spent a lot of my time thinking about the boys rather than myself, so how would things... what I could hide from them or what I could make unscary for them, what I could tell them. (P2, female)

Some patients felt that most of the exercises could be done anywhere:

> Because the exercises generally were over maybe two or three times a day, different exercises. It’s something you could do in the car when you were driving, or whatever, they didn’t have to be in situ. (P5, male)

Whilst others felt that they needed a designated space or preferred privacy for some of the exercises.

> I remember lying on the floor in the landing, I remember lying on the floor in the bedroom trying to fit them all in, There was that sense of needing to have a space to do some of those [reference to Shaker, head lift exercise]. Yes. I think some of the noisy ones I would sometimes do when I walked the dog on the heath. (P9, female)
Some patients felt that the method of information provision (resources) could be improved and that pictures might have enabled a better understanding of the exercises.

I don’t know. Maybe pictures with diagrams or something to show what part of your tongue you should be tensing up, like more emphasis on when you are swallowing, because you weren’t sure really if it was the front of your tongue or the back of your tongue, sort of, to be pushing up. (P11, female)

Additionally, one patient highlighted a need for reviewing the current SLT approach as he felt that some people are resistant to being told what to do.

Prescriptive is the word I was looking for before. I felt that the people I was dealing with generally were kind of prescriptive. Do you know what I mean by that? (PI, male)

*Social opportunity* in the form of social support from others (family members, other patients and clinical staff) was a strong positive influence in facilitating adherence to the exercises. Patients who had someone offering encouragement tended to adhere better to their exercises. A few patients reported that their children would often get involved in overseeing their exercises.

My daughter, who is 7, felt the need to copy me when I was doing my floor exercises, which is a great tonic because it felt like you were making a game of it, which is quite nice. And that’s something to encourage people, if they do have younger children, because it takes that onerous edge to it away, I think. She took over the situation and became my speech therapist, physiotherapist and nurse all rolled into one, bless her cotton socks. In all seriousness, throughout the whole journey of last year she was an enormous encouragement to me without saying a word, to make sure that I could get back to somewhere, near to where I was. That’s what makes life worth living really, the children. (P5, male)
4.5.3 Motivation

Reflective motivation involves the psychological processes that drive behaviours to serve a goal deemed a priority by the individual. It includes conscious planning and weighing up whether performing a particular behaviour is beneficial to the end goal (Michie, Atkins & West, 2014). Additionally, the individual’s belief (self-efficacy) that they can overcome obstacles to performing the behaviour to attain their goal is an important element of Motivation.

I knew if I did not eat I would not have the strength to fight the illness. So I said, for myself, for my family’s sake and everyone’s sake I have to fight. (P10, male)

It’s your own tenacity to get better. (P5, male)

For some patients, motivation was impeded by physical and psychological capability. This included the feeling that there was too much to do, and being uncertain about the relevance of the exercises to their own unique circumstances, particularly if they were given prophylactic exercises.

I don’t know how long the full set is. If you are doing three reps it’s... its hours a day, particularly when you’ve got the emphysema exercises bolted in. And that’s quite hard to achieve. (P12, male)

It’s completely impossible to envisage what your throat and mouth and tongue might feel like if you are a healthy person. So doing things like holding your tongue and trying to swallow [Masako - tongue base exercise], you do it, but you don’t know why, and it feels sort of slightly kind of worrying. (P2, female)

Automatic motivation is less conscious and more reflexive, driven by emotional states, impulses and context triggers. This aspect of the COM-B model is represented by the theoretical constructs of Reinforcement and Emotion on the TDF (Michie, Atkins & West, 2014). Individuals described feeling rewarded by small improvements in their swallowing which motivated them to do their exercises in the hope that they could achieve more. This included receiving positive feedback about the outcome of doing their exercises (for example, increased mouth opening,
biofeedback that they could reduce aspiration) and experiencing an improvement in function (for example, the ability to drink something after a long period of being unable to).

One of the nicest things is when you are…. And you can’t drink water and you rely on all your fluids through the PEG, and you get to the point where you can just get a sip of water down, and you get that sip of water down and you keep working on that sip of water. But you get points where you are thirsty and you want to drink like a normal person. Getting to the point where you can drink is a real breakthrough. That makes a massive difference to just your overall feeling and wellbeing, because you stop bunging fluid in here [pointing to PEG tube]... And you can, you know, have two or three mouthfuls without stopping. (P8, male)

The results presented above suggest that there is potential to optimize all three key components of behaviour to improve swallowing exercise interventions for patients with HNC. However, Capability seems to require the greatest shift to bring about a change in patients’ exercise adherence behaviour.

4.6 Discussion

This study described a theory-based qualitative approach to exploring and categorizing patients’ experiences of their swallowing rehabilitation, and reasons for adherence/non-adherence to swallowing exercises. An inductive approach was used to elicit patient experiences and a deductive method to make a ‘behavioural diagnosis’ using a theoretical framework (Michie et al., 2005; Michie, Van Stralen & West, 2011).

The results confirmed earlier findings regarding common barriers to swallowing exercise adherence (Shinn et al., 2013). Additionally, these findings were categorized according to the three key drivers of behaviour. Patients indicated that they did not clearly understand the reasons for doing exercises, highlighting that Capability was a key barrier. Interview findings suggest that knowledge and understanding of how swallowing will be affected and why exercises are required may not be sufficiently processed by patients, particularly if they are given exercises
at pre-treatment stage. The importance of information provision for this patient population has received considerable research attention (Mills & Sullivan 1999; Semple & McGowan 2002; Llewellyn et al., 2006; Pollock et al., 2008; Horney et al., 2011; Brockbank et al., 2015). Clinicians aim to provide all the necessary information, but research studies suggest that patients may not take in all this information. More information is therefore not necessarily the solution to the barrier of lack of knowledge and understanding. Patients in this study were able to reflect on their own pre-treatment counselling and reported that it was important to find a balance between helping people understand how and why their eating and drinking might be affected and not ‘over-scaring’ them. Patients highlighted that while a great deal of information is provided verbally and in the form of leaflets, they dismiss much of this as they do not consider it personally relevant to them. Many patients reported feeling overwhelmed and therefore chose to filter information they received. Consequently, they dismissed the exercises as being a general precaution, believing that it was not relevant to them. This was particularly the case if they were able to eat and drink adequately at the time.

Some patients preferred not to know about negative consequences of treatment, as they felt that this added to their anxiety. One patient felt that the approach was too prescriptive. These results suggest that there is scope to improve the delivery of information about treatment and its impact on function so that patients clearly understand the relevance to them. At pre-treatment, some patients were keen to learn how they may best help themselves over the course of their treatment. It may therefore be useful to explore ways of creating and capitalizing on a teachable moment that may be co-created by the clinician-patient interaction (Lawson & Flocke, 2009).

As expected, participants reported varying physical capability to perform the exercises. Based on the high numbers of patients who reported that pain was a barrier to doing their exercises, greater effort may be needed to minimize this problem. Other researchers have likewise alluded to the fact that increased and uncontrolled pain and toxicity from treatment reduces patient adherence and
maintenance of swallowing exercise (Carnaby-Mann et al., 2012; Cnossen et al., 2016). One study reported improved pain control and swallowing function in 23 patients treated with gabapentin in the first week of radiotherapy, compared to 23 matched controls who did not receive gabapentin (Starmer et al., 2014). Further work is required to assess the value of administering early pain control for this group of patients in relation to maintenance of swallowing and swallowing exercises.

Patients who were able to master the exercises before treatment and developed a system to build the exercises into their daily routine were better at maintaining them throughout the treatment. It seems reasonable to relate this finding to previous work in behavioural science that has highlighted that forming habits, that is ingrained automatic routines initiated by environmental cues, may be important to maintaining long-term behaviour (Gardner, 2015; Gardner, Phillips & Judah, 2016). Habits form through context-dependent repetition (Gardner, Lally & Wardle, 2012), and whilst initially effortful become easier if the action is repeated with sufficient consistency in the same position within one’s routine (Lally, Gardner & Wardle, 2011; Judah, Gardner & Auenger, 2012). This is particularly crucial in the early stages in order to facilitate habit formation (Lally & Gardner, 2013). The advantage of exercises becoming habitual is that they are more likely to be maintained over time, as they become less reliant on motivation and other cognitive processes such as conscious memory (Gardner, Lally & Wardle, 2012). These insights could be usefully applied in the design of pre-treatment swallowing exercise interventions.

Physical opportunity (environmental and resources) did not feature prominently as a barrier. This may be explained by the fact that most of the swallowing exercises do not require many resources once they are mastered, and for the most part can be done anywhere. Patients who reported time and space concerns also seemed to reflect on whether they used this as an ‘excuse’ to justify to themselves why they may not be doing their exercises. Social opportunity, however, seemed a strong facilitator in that patients who had support from a friend or family member offering
encouragement were more likely to have kept up the exercises. Regular appointments and support from the SLT to keep up the programme also appeared to be an important facilitator. In the systematic review (Study 1) reported in Chapter 3, social support was identified as one of the main behaviour change techniques in successful swallowing exercise interventions.

Reflective motivation is strongly linked to psychological capability (Michie, Atkins & West, 2014). Individuals were unlikely to set a goal such as ‘being able to eat after treatment’ if they did not perceive this as a potential problem that will affect them. Most individuals talked about wanting to avoid a feeding tube, hoping to maintain the ability to eat and drink by mouth throughout the treatment. For patients who recognized that swallowing function might be impaired, a desire to prevent negative consequences such as reliance on a gastrostomy tube was identified as an important facilitator for initiating swallowing exercises. Other patients indicated that despite feeling motivated initially, the ability to follow through with exercises during a challenging course of treatment was often eclipsed by competing priorities. Reduced physical and psychological capability could then negatively impact motivation for some patients, leading to disengagement with the exercises. Indeed, once patients resign themselves to total use of a feeding tube, it is likely that motivation diminishes. The caution to guard against tube dependency has been highlighted by others (Corry 2009; Langmore et al., 2012; Shaw et al., 2015). The importance of good multidisciplinary team working is essential as prophylactic feeding tubes may be necessary in some patients who are predicted to have severe dysphagia that may compromise completion of their chemo-radiation treatment (Mayre-Chilton, Talwar & Gof, 2011; Roe et al., 2015). It is vital that patients are adequately counselled and monitored to prevent subtle shifts in motivation that may occur once a feeding tube is in place.

4.6.1 Limitations and future directions

This study was undertaken on a small sample of patients, although a reasonably diverse group was achieved and a method for data saturation was specified. As with most qualitative studies, findings may be context based and therefore not widely
generalized. However, this study was not looking to find generalizable results, but rather to capture a range of patient views that may need addressing in future interventions. While researcher subjectivity is a frequent concern in qualitative analysis, the availability of a codebook, and the high percentage agreement obtained with a second independent coder suggest that the concepts have credence beyond the sole analysis and interpretation of myself as the lead researcher/interviewer.

Further qualitative studies on barriers and facilitators to swallowing exercise adherence will be useful to expand upon this work. Recognizing that patient adherence is important to the success of interventions, future work is necessary to address how adherence is operationalized as a concept and how best to measure this in empirical studies. Other researchers have pointed out that adherence is sometimes reported on a continuum, and other times as a dichotomy with no clear consensus on how best to measure adherence to home-based swallowing exercises (Cnossen et al., 2016). A study by Krisciunas et al, (2016) concluded that HNC patients’ adherence to using electrical stimulation as a therapy to improve swallowing physiology had no impact on the efficacy of the treatment. However, these findings cannot be extrapolated to all forms of swallowing rehabilitation. Studies that aim to optimize adherence to swallowing exercises before and during treatment are still merited. Without this, it is difficult to verify whether swallowing exercises improve the swallowing function and QOL of patients with HNC.

4.7 Conclusion

Patient adherence is one aspect of the complex intervention involved in swallowing rehabilitation after HNC. This study described the use of a theory-based qualitative approach in examining what drives adherent/non-adherent exercise behaviours in patients with HNC. Categorizing findings according to the behavioural model and framework was the first step. This knowledge can then be used to inform the choice of strategies (behaviour change techniques and intervention functions) to minimize the barriers and enhance the facilitators. This process is discussed further in Chapter 6, which describes the intervention development.
Chapter 5  Study 3: Helping head and neck cancer patients understand dysphagia: Exploring the use of video-animation using think-aloud methodology

5.1 Introduction

Developing a new pre-treatment swallowing intervention package requires attention to multiple components. The first two studies of this thesis focused on identifying the behavioural strategies used in swallowing interventions, and establishing the most important domains of behaviour to target in order to improve patient adherence to prophylactic swallowing exercises. However, patients newly diagnosed with HNC should also understand the ramifications of their disease and its treatment on swallowing function as part of the informed consent process (Clarke et al., 2016; Patterson & Wilson, 2011; National Cancer Action Team, 2010; Collins et al., 2005). This information is provided to patients at a time of considerable distress and amidst much other new information. During pre-treatment counselling of patients planned for surgery and/or chemo-radiation therapy, the process of swallowing which is usually a subconscious activity, needs to be brought into conscious awareness. This is necessary so that patients can be adequately prepared for the changes they will experience in eating and drinking.

Based on the findings in Study 2 of this thesis (reported in Chapter 4), patients are likely to filter out information that they perceive as less personally relevant or salient. Cancer treatments such as surgery and chemo-radiation affect the safety and efficiency of the swallowing mechanism. Patients need to understand that these changes vary in severity and duration, and sometimes last several months after treatment (Brockbank et al., 2015). This could require lifestyle adjustment as some patients may never fully regain the ability to eat a normal oral diet (Hutcheson et al., 2012). Consequently, exploring how best to convey information about dysphagia to HNC patients merits research attention.

5 A version of this chapter has been submitted for publication. The abstract of a poster presentation of this study was published in the conference proceedings for the European Society for Swallowing Disorders and World Dysphagia Summit meeting held in Barcelona, Spain in September 2017.
5.2 Background and rationale for this study

Many healthcare interventions for individuals with cancer increasingly require patients to make changes to their health behaviours before their cancer treatment begins (Silver & Baima, 2013). A few examples are: giving up smoking (Tang et al., 2014; Klemp et al., 2016), reducing alcohol intake (López-Pelayo et al., 2016) and relevant to the present study, undertaking prophylactic swallowing exercises (Kulbersh et al., 2006; Roe & Ashforth, 2011). In this context, patient education serves multiple functions; it advises about treatment and its ramifications and helps patients make changes to their health behaviours (Moore & Johnson, 2015; Adams 2010; Ghisi et al., 2014). Providing the most relevant information in an accessible and acceptable medium could positively influence how patients make decisions and how they respond to behaviour change interventions.

5.2.1 Patient education as part of behaviour change interventions

A recent systematic review on patient adherence to dysphagia recommendations has highlighted a need for more primary research aimed at understanding patient adherence behaviour using theoretical modelling (Krekeler et al., 2017). From the systematic review of interventions aimed at improving swallowing function discussed in Study 1 (reported in Chapter 3), it was noted that education featured as a component (intervention function) in almost all studies. One might therefore infer that clinicians do generally provide patient education during swallowing interventions. Yet in Study 2 (reported in Chapter 4), the qualitative data derived from patient interviews suggested that patients’ knowledge and understanding of how swallowing will change after cancer treatments, and why it may be important to carry out swallowing exercises were inadequate. It might be that there were gaps in the information provided, but it is also likely that this disparity could be the result of when and how information is provided to patients (Lie, 2017).

In a review of patient education as part of health behaviour change interventions, the authors summarized the key requirements for effective education as follows: health information material must be appropriate and understandable to the target
population, communication should be personalized and tailored to the patient’s needs, and development and implementation of health education should be based on the most appropriate behaviour change theory for the target population (Moore and Johnson, 2015). In the context of dysphagia management, education interventions implemented within pre-treatment counselling sessions and swallowing rehabilitation sessions are rarely described in sufficient detail to determine whether they meet the key attributes listed above. Incorporating these attributes when developing new education-based swallowing interventions could translate into improved patient knowledge and understanding, and consequently may increase engagement in health behaviour changes.

5.2.2 Theoretical considerations in presenting health information

Based on Leventhal’s considerable body of work that has spanned decades, there is good evidence to suggest that the way in which individuals perceive and process information about their illness and symptoms influences what actions they will take to reduce any threat to their health (Leventhal, Phillips & Burns, 2016). From his early empirical work, Leventhal suggested that individuals develop mental images of their illness (Leventhal, 1965). This concept was the basis for the ‘common sense representation of illness danger’ that was later developed into a model. It was argued that information presented in a concrete and experiential format illustrating a likely threat, would drive motivation for many individuals (Leventhal, 1965; Leventhal, 1971; Leventhal & Cameron, 1987). Leventhal posited that simply providing information on future potential deleterious effects is often not enough to engage individuals in undertaking preventative health behaviours. These early empirical findings formed the basis of the Common-Sense Model of self-regulation of health and illness (Leventhal, Brissette & Leventhal, 2003).

The Common-Sense Model suggests that individuals who are faced with a health threat form mental images about this threat based on five main dimensions: 1) identity [illness label, symptoms], 2) cause [infection, hereditary, lifestyle], 3) timeline [age of onset, expected duration], 4) consequences [pain, impact on functioning, QOL], 5) controllability [perception of cure or control] (Leventhal,
This mental representation may consequently influence their future health behaviour.

Several studies have reported use of the Common-Sense model in health behaviour change interventions. In a recent systematic review, investigators considered the relationship between patient beliefs in each of the five dimensions of the Common-Sense model and subsequent adherence behaviour. While the review found only a weak relationship between patient beliefs on individual dimensions and patient adherence, the authors added that future work could focus on examining the dimensions as a whole (Aujla et al., 2016). Given that there is some evidence for suggesting that concrete representations of a health threat may positively influence patient behaviour, it was worth exploring whether a more concrete representation of dysphagia might be a useful addition in the new swallowing intervention package.

**5.2.3 Use of video-animation for patient education**

Video-animation is one way of representing information about swallowing in a more concrete format, but it may have other advantages too. In current SLT practice, patient information leaflets are widely used to convey information about swallowing after cancer treatment. However, patient leaflets do not always achieve recommended readability levels (Pothier et al., 2008) and patients may neglect to read them. Animation on the other hand can be used to communicate effectively to patients with differing levels of literacy skills (Meppelink et al., 2015). Video-animation has the potential to relay sequential and dynamic information relatively quickly. It may therefore be a better format for depicting a complex process than written or verbal information alone which may fail to achieve the same clarity (Wilson & Wolf, 2009).

Swallowing is a dynamic and complex process involving rapid and synchronous movements of several muscles in order to move food and drink from the mouth through to the stomach. Patients undergoing treatment for HNC are often required to become familiar with the process of swallowing in order to better manage
aspects of their eating and drinking. To my knowledge, there are no published studies that have specifically assessed the use of video-animation in providing HNC patients with information about the process of normal swallowing. However, video-animations have been used successfully for patient education in other health domains (Nakagami-Yamaguchi et al., 2016; Leiner, Handal & Williams, 2004; Ferguson et al., 2012). In one study on educating patients about periodontal disease (Cleeren et al., 2014), the authors found that recall and retention of knowledge was better in the group of individuals randomized to receive information about periodontitis via a 3D animation video compared with the control group who received the same information presented via picture sketches typically used during a dental consultation. These studies demonstrate that video-animation can be more effective in improving patient knowledge relative to other methods such as print materials, but it is also likely that this format requires individual testing for different target populations (Wilson et al., 2012).

Acknowledging the information presented above, I postulated that video-animation might be a useful medium for increasing patient knowledge about the basic mechanism of normal swallowing. It could also be helpful in facilitating the discussion of how treatments for head and neck cancer would disrupt the process of swallowing. From earlier findings discussed in Chapters 3 and 4, I surmised that improving patient understanding of the specific impact of their treatment could be important for overcoming non-adherence with swallowing exercise interventions. In order to gain insights about how patients comprehend information on swallowing, I was particularly interested in capturing immediate responses from patients as they viewed swallowing video-animations of normal and abnormal swallowing.

5.2.4 Aim of the study

The main aim of this study was to elicit and consider patients’ thoughts as they watched the video-animation. More specifically, I wished to determine whether patients found the images visually acceptable, and the video-animation useful in relaying information about the process of swallowing. While not an explicit aim, I was also keen to note whether patients made any reference to actions that may
suggest that they were thinking about how to ‘control’ the threat of having poor swallowing function after cancer treatment.

5.3 Method: A think-aloud study

In health service research, we seldom have the opportunity to obtain immediate patient feedback and rarely do we have much insight into the processes by which patients reach decisions based on the information provided by clinicians. Think-aloud is a recognized method in qualitative research (Charters, 2003), based primarily on human information processing theory and related work by Ericsson & Simon (1980). Typically, participants are asked to verbalize their thoughts (putting into words their actions, feelings, thinking) whilst engaging in a task, or immediately after. Due to the immediacy of the responses, researchers may be better able to capture the full nuances of actual experience that may be more useful and revealing than for example, surveys or retrospective interviews. The method was therefore a good fit for the aim. Also, it could be accommodated using the same sample of patients already recruited to the interview study (Study 2) reported in Chapter 4. This is explained further in the next section.

5.3.1 Study design and sample

Thirteen patients previously treated for head and neck cancer were recruited to Study 2 reported in Chapter 4 of this thesis. All 13 patients indicated that they were willing to provide feedback on a short video-animation, and so were recruited to the present study. The interview study reported in Chapter 4 focused on patients’ reflections on their experiences of and views towards swallowing rehabilitation exercises, whereas the study described in this chapter focuses solely on ‘think-aloud’ views spontaneously expressed in response to previously unseen swallowing video-animations. Consent was obtained simultaneously for both studies prior to the interview.
5.3.2 Study materials and procedure

The video-animation used was developed by Northern Speech Services USA (www.NorthernSpeech.com) as part of an online training tool that was subsequently modified for a Dysphagia Application (see Figure 5-1). The video-animated images were based on those seen during a modified barium swallow or x-ray swallow, except that the images are more realistic than conventional x-ray images of swallowing. Two videos were played in succession; one depicted a normal swallow and the other a typical post radiotherapy swallow showing increased effort (disordered swallow). A static image was used initially to orientate the patient and to point out the key anatomical structures involved in swallowing such as the tongue, palate and larynx. The video images showed a lateral profile of the head and neck so that key structures and their action during swallowing could be identified. The videos were less than a minute in duration. However, the speed at which they were played could be reduced for the process of swallowing to be viewed more slowly.

Patients were informed that the researcher would show two short videos, one of a normal swallow and the other, an abnormal swallow. The process of normal swallowing was explained during the first video. Patients were shown the videos on a laptop computer, initially at full speed to demonstrate the swiftness of swallowing and then at half speed. Salient aspects of the normal swallowing process were highlighted using the pause button; for example, the researcher pointed out how the larynx moves upward and forward to prevent liquid entering the airway. The disordered swallow animation (second video) was played immediately after without narration. Instead, patients were asked to verbalize their thoughts during the viewing and told that they could request to view the video repeatedly if required. The researcher encouraged the patient to “speak aloud” their thoughts providing minimal prompting. If clarification from the patient was required, the researcher repeated the patient’s own words in a question form (rising intonation) thereby prompting elaboration by the patient. Due to the short duration of the video-animation, it was anticipated that patients would also make related comments.
immediately after watching the video. These comments were included in the dataset for this think-aloud study. Responses were audio recorded and transcribed verbatim for analysis.

Figure 5-1:  Still image of the video-animation app showing a normal swallow

Source: Dysphagia App, Northern Speech Services, USA

5.4 Analysis

The data were analyzed using the six key stages of thematic analysis described by Braun & Clarke (2006). These are: 1) familiarity with the data, 2) generating initial codes, 3) searching for themes, 4) reviewing themes, 5) defining and naming themes, 6) producing the report.
Transcripts of the recordings were imported into NVivo 10 for Mac (QSR International), a software programme that facilitates the analysis of qualitative textual data. In order to gain familiarity with the data, the text was read repeatedly to obtain an overview of content. As the primary researcher, I generated the initial codes to describe a meaning unit or basic idea of interest relevant to the study purpose. These were iteratively reviewed and revised as further transcripts were coded. Final codes were then grouped into categories that reflected broader patterns from which themes were derived. These themes were then reviewed in relation to the research aim and the dataset. Closely related themes were collapsed particularly where this provided cogent answers to satisfy the research aims. As the analysis was focused at a semantic level, the themes were identified directly from what patients had said with no attempt to search for underlying meanings. Interpretation by the researcher was therefore based on the “surface meanings of the data” (Braun & Clarke, 2006 p. 84).

Multiple methods of demonstrating trustworthiness in qualitative results exist (Birt et al., 2016). I invited the Public-Patient Involvement group (PPI) to review the preliminary analysis as a way of ensuring that data interpretation was moderated for researcher bias and that the themes were broadly reflective of the patient experience. The main themes that were identified were discussed and agreed at a meeting with two lay public representatives of the PPI group.

5.5 Results

Four main themes were identified: patient engagement and interest, acceptability of visual imagery and narration, information provision and learning, personal relevance and intended action. An illustration of how the coding was undertaken is provided in Table 5-1.
Table 5-1: Example of thematic analysis from think-aloud study

<table>
<thead>
<tr>
<th>Meaning unit from Transcript</th>
<th>Code assigned</th>
<th>Concept/Category</th>
<th>Key Theme</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is that when you choke when it goes in there? [pointing to airway] So what happens if it [liquid bolus] sticks there? (P7, male). It’s just getting caught up on the epiglottis. Probably dripping down the airways as well. (P6, male)</td>
<td>Pro-active questioning</td>
<td>Information seeking</td>
<td>Patient interest/Engagement</td>
</tr>
<tr>
<td></td>
<td>Commentary on effortful swallow.</td>
<td>Ability to identify abnormal features</td>
<td></td>
</tr>
<tr>
<td>Yes, that’s what I tend to do [repeated swallows], because I get stuff stuck between my tongue and the epiglottis, and that’s where the washing it down with the fluid comes from. Not quite as bad as that, where it’s endangering [referring to risk of aspiration]… going the wrong way (P8, male).</td>
<td>Relating to own swallowing experience</td>
<td>Identifying with image of swallowing difficulty.</td>
<td>Personal Relevance</td>
</tr>
<tr>
<td></td>
<td>Standard looking image</td>
<td>Perception of image</td>
<td>Acceptability of visual image and narration</td>
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<td></td>
<td>Scary image</td>
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<tr>
<td>I think the image is fine. Its not anything that... It looks like a standard sort of x-ray image. It isn’t anything that’s gory or anything like that (P3, male). Its medical, its anatomical, its scary. There’s a lot to absorb. (P2, female)</td>
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<td>You just feel your swallow, but you don’t see. But seeing if it’s moving and what they [muscles] do to make it go the right way, it makes you realise if you don’t keep it active all the time and it stops moving then you are going to get really bad problems when it goes the wrong way. You start choking. And that’s going to put you off swallowing. (P11, female)</td>
<td>Recognizing consequences of reduced muscle movement.</td>
<td>Understanding treatment ramifications</td>
<td>Information provision and learning</td>
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5.5.1 Patient Engagement and Interest

All patients demonstrated interest when viewing the video, making statements such as “That’s pretty amazing!” (P13, female) and “How clever, can I see it again?” (P7, male). There was also evidence of active engagement. Patients proactively sought information and asked relevant questions, indicating curiosity and desire to clearly understand what they were seeing.

Is that the bit that’s really important [pointing to tongue base] where it hits the back of your throat? […] So the tongue becomes weak. What is the exercise for the tongue then? (P10, male).

This is the part that hurts, isn’t it, when it [bolus] goes through here? What’s this one here? (P4, male).

In the absence of a narration accompanying the video of the disordered swallow, most patients either asked questions or provided their own commentary allowing insight into how they processed the information. Patients seemed to have grasped the basic sequence of a normal swallow and many were able to recognize abnormal features evident on the disordered swallow. For several patients, the video offered the opportunity to ask questions about consequences of a disordered swallow using a visual referent. This appeared helpful particularly where patients were unfamiliar with or could not recall the specific terminology.
It’s all coming in here and going down there [pointing to airway]. It [bolus] should be going down there [pointing to oesophagus]. But that [pointing to epiglottis] is presumably, not closing that [pointing to airway] off. And it’s all clustering here. Isn’t pushing into the throat. They try and it doesn’t actually work (P9, female).

It’s [animation] not swallowing, is it? [viewing repeated efforts to swallow, presence of residue] (P4, male).

The stuff [liquid bolus] is stuck behind here, isn’t it? It hasn’t closed up properly. (P12, male).

Is that when you choke when it goes in there? [pointing to airway] So what happens if it [liquid bolus] sticks there? (P7, male).

5.5.2 Acceptability of visual imagery and narration

The video was useful, but it was obvious that patients needed to watch it multiple times for it to be fully appreciated. On first presentation of the video-animation, patients seemed to concentrate intently on the image. This was not unexpected given the complexity of the subject. Sometimes patients indicated that they were uncertain what to focus on until the researcher provided an orientation to the image (“Which bit am I supposed to be looking at?” P1, male). Others made requests for the video to be shown again (“If you could show it a few times and then I would have time to catch up with it and work out what’s going on” P9, female). It was clear from showing the initial animation in real time that patients found it challenging to comprehend (“That plays too quick” P12, male). Repetition appeared important for comprehension.

Make sure that you repeat it a few times, because people have got so much to take in and sometimes it goes past. They hear it, but they don’t take much notice (P11, female).

Slowing the video to at least half speed and providing salient information about key aspects of the swallowing process seemed to aid understanding.

Participants verbalized that it was important to explain the concepts in plain English as the information was new and complex to most people.
I did A-Level Biology, so I know all the bits and stuff. But probably many people wouldn’t (P12, male).

There were some differences of opinion about the visual acceptability of the images. The majority of patients found the video images acceptable, especially when provided with verbal explanations.

I think the image is fine. It’s not anything that... It looks like a standard, sort of, x-ray image. It isn’t anything that’s gory or anything like that (P3, male).

However, one patient felt it was too medical and suggested that a more normal picture of a person eating should be presented first. This could be followed by introducing the idea of looking at what happens inside the mouth by viewing a cross sectional image.

It’s medical, it’s anatomical, it’s scary. There’s a lot to absorb. I’ve seen pictures before, and therefore I sort of can work out a bit what’s there. But it did take me several goes (P2, female).

All patients were positive about the video medium and appreciated the dynamic aspect of being able to see what happens during the process of swallowing. One patient compared the task of viewing the video-animation with his own previous experience of receiving a leaflet with a diagram.

I just got a photocopy of the diagram thing [referring to how information about swallowing was provided during his own pre-treatment counselling]. It’s much clearer, what’s going on, when you can see it from a proper video of it (P6, male).

5.5.3 Information Provision and Learning

Immediately after watching the video, most patients expanded on their views about the experience with little need for prompting. All patients indicated that the video served a useful purpose in providing information about swallowing and what may go wrong, and that the medium supported their understanding of a process they
might not have consciously thought about previously. Patients seemed to reflect on their own experience of being informed about swallowing problems and other side effects of treatment. Most alluded to the difficulty in actually imagining what this would mean for them.

I think in the beginning you don’t really know. People say you might not be able to swallow and you are not going to have any saliva and things like that, and you can’t really imagine what that’s going to be like. You think, well, I’ve swallowed all my life, how difficult can it be? You ain’t going to forget that (P6, male).

Well, I know about it now, but at the very start I wouldn’t have known about it and about what the sensations were going to be. It [the video] shows you... It explains to you what the throat is like, that does, and where the food goes and how it goes down (P4, male).

There was also an indication that patients were processing the information from the video sufficiently well to allow them to identify possible treatment ramifications for themselves.

You just feel your swallow, but you don’t see. But seeing if it’s moving and what they [muscles] do to make it go the right way, it makes you realise if you don’t keep it active all the time and it stops moving then you are going to get really bad problems when it goes the wrong way. You start choking. And that’s going to put you off swallowing (P11, female).

Patients were therefore more active learners as opposed to passively listening to the clinician informing them about likely side effects. One patient highlighted this by comparing it to her own pre-treatment counselling.

They gave me exercises and like, “That’s going to help your swallow,” But, for me, I take it all in more when I see stuff. Definitely. That’s just the kind of learner I am (P13, female).

Most patients endorsed the idea of using the video before treatment, feeling that it would be particularly useful in helping patients understand the need to do their swallowing exercises.
It’s a good idea. It’s a nice way of helping people understand. It’s not massively technical, yes, which is great, but you can illustrate why – ‘Look, your tongue is not getting to the back of your throat, therefore with swallowing it’s not going to go down. If we strengthen it by biting your tongue and trying to get you to swallow [masako exercise], we will make the tongue stronger as it tries to reach, yes, and you will benefit from that later on.’ (P8, male).

And when you see things like that, you do realise you can’t take everything for granted and you do need to keep them exercised (P11, female).

Others felt that the visual information might have encouraged them to do their exercises at the early stages.

If this was shown earlier, I would have taken it more seriously (P10, male).

If somebody had explained that to me at the start, I probably would have went for it all, like. But at the time, I didn’t know anything about exercises (P4, male).

5.5.4  Personal relevance and intended action

Several respondents seemed to identify with the video of the abnormal swallow, indicating that they found it relevant to their own experience.

That’s how I feel. I feel it gets stuck there. I would say mine takes even longer to go down. (P3, male).

Yes, that’s what I tend to do [repeated swallows], because I get stuff stuck between my tongue and the epiglottis, and that’s where the washing it down with the fluid comes from. Not quite as bad as that, where it’s endangering [referring to risk of aspiration]... going the wrong way (P8, male).

Although all respondents had previously received swallowing rehabilitation, it was clear that the video was nonetheless helpful in improving their understanding of the swallowing mechanism, potentially strengthening their intention to carry out post-treatment swallowing rehabilitation exercises.
And even now, looking at that, I think, gosh, I could benefit from those exercises now, because it’s something I recognise in possibly the technique that I use to swallow now. Very interesting (P5, male).

5.6 Discussion

This study used think-aloud methods to gather patient feedback on an educational video-animation depicting the process of swallowing. Thematic analysis indicated that patients found the video-animation interesting and informative in aiding their understanding of a complex process. It instigated curiosity and provided the opportunity for patients to clarify their understanding without the need to refer to technical vocabulary. In this respect, the video-animation appeared to facilitate patient interaction by removing the need to recall names of anatomical structures or to be concerned with correctly phrasing questions. It is possible that understanding was enhanced by patients focusing more on the visual process of swallowing depicted in the animation. This is plausible given that many patients seemed able to identify where components of the swallow were grossly abnormal despite being given only a brief overview of a normal swallow pattern. This recognition of something being abnormal often triggered spontaneous enquiry of how the problem could be prevented or improved.

Patients’ views were largely positive and favourable toward the video-animation suggesting good acceptability for its clinical use. All patients showed interest and willingness to watch the video. Despite the initial observation that the image seemed too complex, later responses suggested that patients preferred the video modality compared to written information and diagrams or verbal information alone. Slowing down the speed of the video and providing relevant narration seemed to demystify the image. Active engagement was evident from the spontaneous commentary, pro-active questioning and information seeking demonstrated by most patients during the task.

The aim in undertaking this study was to obtain “live” patient responses about the acceptability and usefulness of the video-animation in conveying information about
the swallowing process. The present study was not designed to evaluate different presentation formats. However, these results certainly pose the question of whether the use of video images and verbal narration is likely to be superior to the current common practice of a clinician briefly talking through the process of swallowing and providing a leaflet for more information. Print images and accompanying written explanation require visual processing of all content, in the same way that verbal information only is demanding on audio processing (Wilson & Wolf, 2009). In designing health information resources, it is important to consider that working memory has a limited capacity and patients are already under cognitive stress from their diagnosis (Wilson & Wolf, 2009). According to Mayer’s multimedia learning theory (Mayer, 2003), information presented via different modalities has different ‘stores’ within working memory. Applying this to the current study, one might surmise that video-animation with narration not only offers a better medium for conveying a complex and sequential process, but also allows greater cognitive capacity for the individual to process this information by making use of both visual and audio stores.

The findings from this study together with the theoretical insights may offer some explanation for the mismatch between the information that clinicians provide to patients at their pre-treatment counselling, and patients’ understanding and recollection of the swallowing process (Brockbank et al., 2015). The timing at which such information has to be provided is unavoidably distressing for patients by virtue of them receiving a recent cancer diagnosis. However, it may be argued that an optimal presentation medium for both the context and the type of material to be communicated may reduce the cognitive burden for patients. Furthermore, it has been suggested that what patients report they understand is often an over-estimation of comprehension (Chapman et al., 2003). This assertion has been based on work by these authors investigating lay understanding of terms used during cancer consultations. The scope for a SLT clinician to verify comprehension about dysphagia could be increased through the interactive format afforded by the use of video-animations.
Although only one patient voiced concerns about the image being ‘too medical’, patients could be better prepared by providing some information about what to expect before showing the video. In practice, it is anticipated that the video-animation will be one component of the SLT pre-treatment consultation. It could also serve as a helpful introduction for patients when viewing their own x-ray swallow. This may be useful for biofeedback, particularly when discussing the rationale for swallowing exercise interventions. It was evident that patients needed to be allowed time and the opportunity to slow down the speed of the video and to watch it repeatedly if required. Offering some of this control to the patient makes their learning more interactive, fostering a shared responsibility for the acquisition of knowledge. This may increase ‘patient activation’ (Hibbard, 2016) in using this knowledge to inform decisions and formulate intentions to make positive health behaviour changes. These results offer some support for this assertion as several patients indicated that they would have been more inclined to participate in prophylactic swallowing exercise programmes if they had previously fully understood the process of swallowing and the ramifications of treatment on their own ability to eat and drink. Video-animation appeared to make this process more concrete and understandable. It seems that Leventhal’s Common-Sense Model (Leventhal, Brissette & Leventhal, 2003) may indeed have application in developing a pre-treatment swallowing intervention package that endeavours to improve patient adherence to prophylactic exercises. This concept will be expanded upon in the next chapter.

**5.6.1 Study Strengths and Limitations**

The limitations of this study are acknowledged. The sample of patients selected had all received previous information about swallowing during their rehabilitation and so the responses from newly diagnosed patients may differ. However, as the primary purpose was to gather preliminary information, I was mindful of recruiting newly diagnosed patients at this early stage. I therefore wished to test the acceptability on a group of HNC patients who had already been through treatment. While it is recognized that patient responses may therefore have been influenced
by their previous experience, the video-animation itself was new to patients and the think-aloud methodology provided the best option for ‘spontaneous and live’ responses. Notwithstanding these limitations, based on the largely favourable results it seems reasonable to conclude that video-animation may be similarly acceptable to newly diagnosed HNC patients. The data suggest that this medium and content are appropriate, understandable and relevant to patients. Furthermore, despite being a small and preliminary study, useful insights have been obtained about a relatively unexplored aspect of managing patients with dysphagia. This study has highlighted how the format of delivery and communication style may impact patient comprehension and subsequent adherence. These insights may be useful for accumulating knowledge and understanding on this topic, and may be helpful to future research.

5.7 Conclusion

Video-animation appears to be a promising method of conveying complex information about the swallowing process. It could also serve as a focal point for discussing HNC treatment and its possible side effects during pre-treatment consultations with a speech and language therapist. It lends itself well to a participatory interaction style in which patients may be more likely to spontaneously ask questions and become more engaged in acquiring knowledge about preserving good swallowing function. In practice, clinicians have the opportunity to tailor the narration ensuring greater personalization. The effectiveness of these strategies in increasing patients’ understanding of swallowing and their intentions to make health behaviour changes such as undertaking prophylactic swallowing exercises is yet to be determined. However, the use of video-animation certainly appears to be acceptable for inclusion in the new swallowing intervention package.
Chapter 6  Study 4. Intervention development: Modelling the new swallowing intervention package

An intervention development study is “a study that describes the rationale, decision-making processes, methods and findings which occur between the idea or inception of an intervention until it is ready for formal pilot, feasibility or efficacy testing, prior to a full trial or evaluation”

(Hoddinott, 2015)

6.1  Introduction

This chapter provides a formal description of the process of developing the new intervention, including the integration of insights that emerged from the studies described in Chapters 3 to 5. It is framed according to the key steps suggested in the MRC framework for the development and evaluation of complex interventions (Craig et al., 2008). As previously illustrated in Figure 2-1, these are 1) identifying the evidence base, 2) identifying and developing theory, 3) modelling process and outcomes. While steps 1 and 2 have in essence been the subjects of the preceding chapters of this thesis, they are briefly re-visited to demonstrate how they have informed the modelling of the new intervention.

6.2  Identifying the evidence base

In the background chapter of this thesis (Chapter 1), I discussed the mechanistic reasoning for undertaking pre-treatment swallowing exercises and provided an overview of the limited evidence available from observational studies and clinical trials (see Section 1.6). From this, it seemed plausible that a pre-treatment swallowing exercise intervention could be helpful in improving longer-term swallowing outcomes for patients with head and neck cancer. I also surmised from the literature that the task of demonstrating efficacy and effectiveness of such an intervention could be compromised by poor patient adherence to exercises (Shinn et al., 2013). The MRC framework (Craig et al., 2008) advocates that an up-to-date (systematic) review of similar interventions should be the starting point for
developing a new intervention. As a Cochrane review of prophylactic swallowing exercises (Perry, Cotton, & Kennedy, 2014) was registered just as work on this thesis began, it was not appropriate to conduct the same review. Instead, the first study in this thesis was a systematic review that examined similar evidence through a behaviour science lens.

The findings from the Cochrane review (Perry et al., 2016), demonstrated that most studies of swallowing exercise interventions used either tongue strengthening exercises, traditional swallowing exercises (such as laryngeal elevation exercises), jaw exercises (with or without assistance of an adjunctive device) or a generic protocol designed to maintain range of motion of swallowing musculature through treatment. There was no consistency in the exercise regimen used across studies, but the review authors highlighted that many exercise protocols may have been too onerous to undertake during treatment. The review made recommendations for future interventions to consider simpler exercise protocols that patients could tolerate during intensive cancer treatment, and undertake at home. The review authors concluded that there was no robust evidence to date to support the effectiveness of prophylactic exercises. This was largely because all studies were graded as low quality on the risk of bias tool, patient compliance was poor, and several methodological flaws were identified (Perry et al., 2016).

The concurrent systematic review reported in Study 1 of this thesis differed from the Cochrane review by directing the focus toward the identification of behaviour change strategies in swallowing interventions for patients with head and neck cancer. Study 1 provided information on behaviour change content for the new intervention. Three intervention functions, education, training and enablement, were identified from the review and it therefore seemed likely that these would also be relevant for the new intervention. Given their prominence in almost all of the swallowing interventions, the behaviour change techniques (BCTs) of how to perform the behaviour (exercises), goal setting, and action planning appeared to be the core techniques used, and could be considered essential for this type of intervention. Four other BCTs (provision of information from a credible source,
behavioural practice, self-monitoring and social support) were identified more often in effective interventions suggesting that they could be crucial active ingredients that may be contributing to effectiveness. It seemed logical that combining these with the core techniques might be a useful starting point for building BCTs into the new intervention. It was surprising that the review did not identify BCTs linked to providing information about consequences of doing/not doing exercises, as one may presume that this information forms an essential part of such an intervention. It was therefore evident that while the BCTs identified from the review might be useful, they were unlikely to be comprehensive. Furthermore, given the small number of studies and various quality limitations, it was not possible to determine which combinations of BCTs might be most effective. It was also not satisfactory to extrapolate findings from the general body of literature on patient adherence, as in this intervention patients are being asked to adhere to a behaviour under a fairly unique set of circumstances. The exercise intervention is for something that is normally a subconscious activity (swallowing) and not intuitively thought of as needing to be ‘exercised’. Furthermore, patients may not be experiencing problems when the intervention is introduced and are therefore being asked to undertake exercises for something that is anticipated to become a problem after cancer treatment. The combination of these factors suggests that unlike undertaking physical exercise which most people have an awareness of, an intervention promoting swallowing exercises has different and unique challenges. It was therefore necessary to conduct further primary investigation with HNC patients to comprehensively explore the specific barriers and facilitators to adherence that they might experience. Findings from such a study could better inform the development of a new intervention.

6.3 Identifying and developing theory

It is worth noting that none of the interventions identified in Study 1 made any explicit reference to the use of any named Theory of Behaviour, highlighting that most swallowing interventions are probably tacitly based on what dysphagia clinicians believe works best. The MRC guidance (Craig et al., 2008) encourages the
use of theory and it has been suggested that using theory is more likely to result in effective interventions (Michie et al., 2016).

In Chapter 2 of this thesis, a rationale was provided for selecting the Theoretical Domains Framework (TDF) (Cane, O’Connor & Michie, 2012) and COM-B model of behaviour (Michie, van Stralen & West, 2011) to support the implementation of theory in designing the new intervention. Hence, the theoretical basis for the new intervention was identified by applying the TDF and COM-B model to the analysis of patient interviews. In Study 2, in-depth interviews were undertaken to explore patient experiences and views related to the performance of swallowing exercises. The content analysis undertaken for the interview study enabled findings to be mapped to the TDF and the overarching COM-B model. In so doing, one could identify the relevant theoretical constructs that were most likely to influence patient adherence. As pointed out in Chapter 4 (Section 1.2), a behaviour analysis is suggested to be an essential step in deciding appropriate intervention content for bringing about behaviour change (Atkins et al., 2017; Michie, Atkins & West, 2014).

Study 2 showed that psychological capability (processing of knowledge and information) was the crucial barrier to initiating prophylactic exercises, and consequently a key component to target in the new intervention. Patients who reported non-adherence, many of whom did not attempt the exercises at all, seemed to convey a similar sentiment. They felt that swallowing was something natural and the idea of doing exercises for swallowing seemed unnatural. Exercise was interpreted as precautionary advice particularly if swallowing was not problematic at the time. Patients did not fully understand the impact that their treatment would have on their swallowing function or how exercises may work in ameliorating the negative effects. They focused mainly on information about symptoms such as taste alterations and dry mouth, which they were told to expect. For those patients who did attempt exercises, social support, self-monitoring and having a routine were key facilitators of keeping up with exercises through treatment. However, pain and fatigue and a general feeling of being overwhelmed were a hindrance to exercises for all patients. A more detailed analysis of barriers
and facilitators is included in Chapter 4 and Appendix 6.1. The incorporation of these findings into the new intervention is shown later in this chapter (Section 6.4.5).

In addition to deciding about intervention content and the theoretical constructs the intervention content was posited to act upon, it was also necessary to decide on the form of delivery. How information is presented to patients may be crucial to what actions they consequently take (Dombrowski, O’Carroll, & Williams, 2016). Data on how clinicians discuss swallowing and its impact on treatment were lacking from the intervention studies examined in the systematic review.

Head and neck cancer patients are advised about the potential impact of treatment on swallowing as a necessary part of informed consent. This is presented together with other likely side-effects such as taste changes, dry mouth, pain, and fatigue. As swallowing is a subconscious activity, patients tend to focus more on the concrete side-effects such as taste changes and dry mouth. It is perhaps understandable that in this context of many competing priorities, patients may not judge exercises for swallowing as something that may be important, as was found to be the case in Study 2. This is particularly true if patients have not experienced changes to their swallowing from the presence of their cancer. The notion that the treatment will create a long term problem with their swallowing may seem remote and so the advice may be viewed as a general precaution. These ideas align well with the Common-Sense Model (Leventhal, Brissette & Leventhal, 2003) of how patients form mental images of their illness described in Chapter 5.

The literature using the Common-Sense model with head and neck cancer patients is limited (Llewellyn, McGurk, & Weinman, 2007). However, it seems plausible that a more concrete representation of the consequences of cancer treatment on swallowing function would increase patient activation in responding to preventative strategies such as prophylactic swallowing exercises. Particularly if all five dimensions of illness representation (see Section 5.2.2 for further explanation) were carefully conveyed: ensuring that patients grasped the concept of swallowing and dysphagia (label); how their treatment might alter the mechanics of this ‘natural’
process both in the short and long term (cause and timeline); the impact that this may have on them (consequences) and what may be done to minimize the difficulties (controllability). Based on Leventhal’s early work, one might surmise that form of delivery of such information could be important. Study 3 was conducted to gather preliminary data on whether a more concrete representation of normal and abnormal swallowing presented in the format of a video-animation might be acceptable to patients and whether it seemed a useful strategy. This ‘think-aloud’ study suggested that patients found the format engaging and it appeared conducive to facilitating a style that allowed the patient to lead the discussion with questions and comments. Several patients verbalized increased understanding of swallowing, and indicated that they wished to revisit doing their swallowing exercises. As the video-animation was acceptable to patients, it was considered potentially useful to include in the new intervention. It could be valuable in directing the clinician about how best to tailor information relative to each patient’s needs and reflected understanding. It was important to be mindful that the patient group from which the preliminary information was gathered had completed treatment. Patients at the pre-treatment stage are often already under a great deal of emotional distress and a further fear message may be less helpful. It is therefore important that the SLT clinician be able to follow the patient’s lead, as the video-animation could be used to increase the threat or reduce the ‘danger’ that the threat invokes depending on the individual situation. A patient who is fearful that they may never be able to eat and drink by mouth again, may need greater emphasis placed on how rehabilitation will help to optimize function. A patient who does not appear to recognize the impact that radiotherapy will have on swallowing function may be persuaded by drawing attention to how the mechanics of swallowing will change with treatment and why exercises may help maintain the ability to eat and drink. In both cases the ensuing actions for prophylactic exercises should follow ideally in the same session to enhance patients’ perceived control. The Common-Sense Model suggests that behaviour change may be facilitated particularly if individuals are advised about how to reduce or cope with the anticipated threat, and if this is accompanied by specific action planning detailing the what, when and how elements of the

To summarize, the preliminary work undertaken to inform the development of the new intervention has identified the main theoretical component of behaviour (psychological capability) that if improved, might increase patient adherence. Furthermore, the specific BCTs (instruction on how to perform behaviour, goal setting, action planning, social support, credible source, self-monitoring, behavioural practice) and intervention functions (education, training, enablement) already employed in swallowing interventions and most likely to be useful in a future intervention were identified and specified using the most up-to-date and comprehensive BCT taxonomy (BCTTv1) available at the time of this work. Finally, evidence that the form of delivery (concrete representation) may influence patients’ perception of their illness and possible further health actions appeared to be an important consideration in modelling the new swallowing intervention package (SIP).

### 6.4 Modelling the new intervention and outcomes

Thus far, most work has been focused on devising the behaviour change components of the proposed new intervention. This section brings together other components that make up the new pre-treatment swallowing intervention. Looking to the literature, there has been some effort within the field of rehabilitation to create a generic model of rehabilitation treatments. The main model identified from the recent literature is presented in Figure 6-1.
The rehabilitation treatment model proposed by Whyte et al. (2014) represents an effort to classify rehabilitation interventions at a broad level. The model explains that a rehabilitation treatment is made up of essential and other active ingredients postulated to exert an effect on a specific rehabilitation target through some mechanism of action. This mechanism may be known or presumed. The authors define essential active ingredients as “active ingredients [hypothesized to effect a change in the target outcome], selected and delivered by the clinician, that define a particular treatment and distinguish it from other treatments” (Whyte et al., 2014, p. S32 e1). Other active ingredients (non-essential active ingredients) refer to those ingredients known to “moderate the treatment’s effects and may be common to multiple treatments” (p.S32 e1), but are not necessary for the effects to take place. Furthermore, the model recognizes that a rehabilitation intervention may include inactive ingredients that have no actual effect on the target but are delivered as part of the care package.

For my purposes of intervention development, this model had some use. According to Whyte’s model, swallowing exercise content might be considered the essential active ingredient that characterizes the swallowing intervention. On first appearance, it may seem that behaviour change content might then be grouped under other active ingredients. However, the authors further discuss that a behaviour change target (for example, increasing knowledge of exercises)
represents a treatment target in its own right and that an intervention may consist of multiple treatments with different targets. While this argument may be logical, it was only partially helpful in modelling the new SIP in which the intervention is viewed as a whole rather than multiple different treatments. The new SIP is envisaged to have an impact on swallowing function and QOL, and comprises multiple components that are likely to work synergistically to achieve the target outcome. Crucially, the behaviour change aspects are interpreted as being an integral part of the intervention content. From this perspective, Whyte’s model was not an entirely satisfactory fit. It seemed appropriate therefore to consider whether Whyte's model could be developed to better reflect the complex intervention devised in this thesis.

I therefore propose a model that takes account of the general rehabilitation treatment model elements described by Whyte et al. (2014) as well as the behaviour change elements that this thesis argues for. In other words, the intervention has specific rehabilitation targets (for example, increasing mouth opening, or improving tongue range of movement), as well as specific behaviour change targets (for example, increasing behaviour regulation, or increasing behaviour intention). In the context of this work, both represent important intervention content for bringing about a desired outcome such as being able to eat a normal oral diet. In the proposed new model, the intervention content has been broadly classified as behavioural (behaviour change techniques, intervention functions) and non-behavioural content (swallow assessment, swallow exercises, information about side-effects). In some ways this reflects a conceptual differentiation as in practice components may overlap, but when modelling a new intervention specifying content is important in determining the active ingredients. It is also recognized that in modelling a complex intervention package, there may be components that do not have a direct causal link to the outcome measured, but are essential to the service delivery (for example, the clinic environment for the intervention). These components may be similar to those that Whyte et al. (2014) refer to as inactive ingredients. They are not necessarily of no value but simply not attributed with having a direct link with the measured outcome. Figure 1-2 is an
illustration of the ‘working’ model that I propose offers a clearer reflection of the intervention developed in this thesis. It may be applicable beyond this thesis.

**Figure 6-2: Proposed causal relationship for the new swallowing intervention**

This model describes the intervention as comprising behavioural and non-behavioural content, and aspects of delivery. The mediators of change signify those domains that the intervention is presumed to act on in order to bring about a change in outcome. The outcome refers to the measure that is chosen to determine whether the intervention has achieved its intended purpose. The intervention may be unsuccessful if it fails to bring about a change in the determinant (for example, selecting incorrect exercises or less effective BCTs), or fails to target the crucial determinants relevant to changing the desired outcome (for example, not focusing on the most important constructs of behaviour or not targeting the key swallowing impairment). For the intervention being developed in this thesis, the desired outcome is an improvement in swallowing function and swallowing related quality of life after cancer treatment. In this intervention, a change in patient behaviour (adherence to exercises) is an intermediate outcome believed to be critical in achieving the final outcomes. For patients who do not adhere to their swallowing exercises, swallowing outcomes are expected to be poorer than for patients who do. However, it is acknowledged that natural variation amongst patients, spontaneous recovery, and the potential influence of other moderating factors such as individual patient characteristics may also influence outcomes. When future
hypothesis testing is undertaken, these factors will be accounted for through a randomized controlled trial study design.

The next five sub-sections describe how the findings from the studies undertaken as preliminary work in this thesis were synthesized with other sources of information (professional knowledge, clinical expertise and judgement, extant literature, practice guidelines, stakeholder feedback) to devise the components of the new swallowing intervention package. An intervention manual was written to be used during the feasibility testing phase. An overview of this process is illustrated in Figure 6-3.
Figure 6-3: Overview of the intervention development
6.4.1 Mandatory practice guidelines

In Chapter 3, the logic model (see Figure 3-1) illustrates that factors such as national guidelines and policy could impact implementation and must therefore be considered when developing an intervention for clinical practice. The NICE Improving Outcome Guidance (NICE IOG, 2004) has been the main national guideline that cancer centres were to follow. These guidelines define the minimum standard for pre-treatment speech and language therapy as: “The SLT should meet patients before treatment begins to explain rehabilitation strategies to the patient and carer, describing how she (or he) will work with the patient to make the most of his or her potential for recovery of speech, voice and swallowing” (NICE IOG, 2004, p68). In addition, national data audit bodies in head and neck oncology require that a baseline performance status for swallowing [(PSS) - performance status scale-normalcy of diet subscale] be recorded before cancer treatment begins. Both of these pre-treatment requirements may take place in a joint multidisciplinary clinic or during separate outpatient consultations with the therapist. To comply with national guidelines, pre-treatment informational counselling and recording of a swallowing performance status score were both treated as essential components for inclusion in the new intervention. More recent guidelines from professional bodies expand on these recommendations to include offering patients pre-treatment exercises, but these guidelines are not yet mandatory (Clarke et al., 2016).

6.4.2 Baseline swallowing assessment

Swallowing is a multidimensional construct with several different methods for assessing impairment, functioning, and impact on QOL. The modified barium swallow assessment is widely considered to be the current best available tool to assess oral and oropharyngeal swallowing physiology (Kendall et al., 2016; Martin-Harris, 2008). This involves a videofluoroscopic evaluation in which the patient is asked to swallow a range of different food textures mixed with a radio-opaque contrast agent such as barium. The procedure is undertaken in an x-ray suite, and a video-recording captures the swallowing process in real time (Levine & Rubesin,
2017). It is available in most hospitals, and head and neck speech and language therapists will be familiar with the procedure as it is often used for post-treatment swallowing assessment. The expected radiation exposure for the procedure was very small (around 0.44mSv for the standard MBS ImP protocol, Bonilha et al., 2013) and considerably less than the average background radiation experienced by an individual per annum.\(^6\) This amount of radiation exposure was therefore not viewed as a prohibitive factor to including the modified barium swallow in the new intervention. The level of exposure was also considered negligible in the context of patients’ radiation exposure during their overall cancer treatment, and relative to the potential benefit of having the procedure.

The role of the modified barium swallow in the new swallowing intervention package was two-fold: to obtain a baseline assessment and to support the selection of tailored exercises based on each patient’s individual swallowing physiology. In much the same way that behaviour has been expressed in terms of 14 constructs within the Theoretical Domains Framework (to facilitate the use of theory in implementation science), a similar task was undertaken by experts in the field of dysphagia. The Modified Barium Swallow Impairment Profile tool (MBS ImP) was derived from extensive work in identifying the most discernable features that characterize swallowing (Martin-Harris et al., 2008). Swallowing has been broadly categorized into oral, pharyngeal and oesophageal phases with 17 components identifiable during a modified barium swallow assessment. The tool has been validated. It is based on an initial Delphi exercise that confirmed content validity, followed by international expert consensus in identifying discrete components observable during a swallow x-ray assessment. (Martin-Harris et al., 2008). The modified barium swallow impairment profile is the current best evidenced method for analyzing and reporting a swallow assessment (Sandidge, 2009; Nightingale & Newman, 2012). For the purpose of intervention development, the modified barium swallow was chosen for its potential to aid selection and tailoring of swallowing exercises based on identified swallowing impairment. One could have greater

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\(^6\) Public Health England have determined that an adult living in the UK is exposed to an average background radiation from all sources of about 2.7 mSv per annum. [https://www.gov.uk/government/publications/ionising-radiation-dose-comparisons](https://www.gov.uk/government/publications/ionising-radiation-dose-comparisons)
certainty that the exercises would be more likely to be targeting the relevant underlying impairment, for example providing larynx elevation exercises if laryngeal elevation (component 8 on the modified barium swallow impairment profile) was observed to be suboptimal. Further detail about the procedure and scoring has been included in the treatment manual (see Appendix 6-2).

6.4.3 Swallowing exercises

Some speech and language therapists provide general advice and/or leaflets about swallowing exercises that may be undertaken before and during radiotherapy. However, this practice is variable (Roe et al., 2012; Roe & Ashforth, 2011) and patient adherence is known to be poor (Shinn et al., 2013; Krekel et al., 2017). When provided, it is usually a set of generic exercises given to all patients (Roe et al., 2012). There is no standardized regimen; patients may be asked to do their exercises multiple times a day or instructed to do them as much as possible. Clinical trials of swallowing exercises also vary greatly in their protocol design (Perry et al., 2016). Given the heterogeneity of tumour sites within the head and neck, the variation in swallowing impairments and the various combinations of treatments, a single generic protocol is less likely to be as effective as protocols that are tailored. It was therefore important to consider an alternate method for selecting the best exercise protocol.

The options to tailor the exercises were either to select exercises based on anticipated deficits, or on the individual patient assessment of swallowing physiology derived from the modified barium swallow assessment. This could be combined with clinical knowledge about the anticipated functional impact from the patient’s specific tumour site and treatment. Specialist head and neck speech and language therapists should have the skills to do this, particularly if guided by an intervention manual. There is evidence from other fields that demonstrate that tailored treatments are likely to have better uptake or adherence, and may be more effective in achieving desired outcomes (Keele-Smith & Leon, 2003). Furthermore, based on findings from Study 3, it was likely that performing a modified barium swallow assessment would also provide an opportunity to include useful BCTs.
Patients were more likely to be convinced of the need for swallowing exercises if they were able to see “evidence” from their own assessment. Based on anecdotal observations, it is possible that the patients’ perception of the credibility of the speech and language therapist providing the information would be enhanced if the therapist also performed the x-ray assessment prior to providing exercises and advice.

The decision was thus taken to select swallowing exercises based on the modified barium swallow assessment of swallowing physiology. This meant that exercises could be personalized to the individual patient. The clinician could select the most relevant exercises to target areas of poorer function. For example, if it was observed on assessment that a patient had reduced contact between the base of the tongue and the back wall of the throat, exercises to increase tongue base range of movement and strength could be advised. However, as different exercises exist that target different swallowing impairments, it was necessary to ensure quick and ready access to resources to support this decision-making. Use of a dysphagia therapy digital app seemed to offer a good solution. Of the apps available (National Foundation of Swallowing Disorders, 2015), the Tactus Therapy app was the only comprehensive app covering almost all swallowing exercises, and was easy to use. The app is designed for clinicians to select exercises based on the swallowing impairment identified. It is a clinical resource app, rather than a patient app.

Figures 6-4 and 6-5 show how the app may be used to select the relevant exercises. Use of the app is intended to be an adjunct to clinical decision-making, and to serve as a source of ready information if required. SLT clinicians would still be expected to tailor the exercises and the exercise schedule provided to individuals. This may partly be based on the joint goal setting negotiated between the clinician and patient. While the app has options for printable instructions for exercises, other formats such as leaflets with pictures, a swallow exercise DVD and access to online links on “YouTube” were also available and provided according to patient preference.
Figure 6-4: Screenshot of the Tactus Dysphagia Therapy App

Dysphagia Therapy is an exciting new pocket reference tool for clinicians who work with swallowing disorders, created by top SLPs with expertise in disorders of deglutition.

Find therapy options by checking off which impairments you want to treat. Learn about treatment options, refresh your knowledge of assessment, or look up the function of a cranial nerve – all in the palm of your hand.

Dysphagia Therapy offers you additional resources like easy creation of patient handouts and home programs as well as drawings for a quick explanation. You’ll love having it all at hand.

- Find your best options with Therapy Finder
- Review anatomy, physiology, and cranial nerves
- Print handouts and home programs for patients
- Learn, review, or double-check with this handy tool

Figure 6-5: Tailoring exercises to physiological impairment

6.4.4 Provision of information about treatment and side effects

While the provision of information to patients about the impact of cancer treatment on swallowing function is highlighted in the current guidelines (NICE, 2004), there is no specified format for conveying this information. In current practice, SLT clinicians may tell patients about side effects of treatment during a consultation and/or provide information booklets. This has been confirmed as common practice by discussions with SLT stakeholders, presented later in this chapter. However, from interviews with patients (Study 2), most reported being overwhelmed with information. Despite the volume of information provided, there were clear gaps in understanding. Earlier in this chapter, video-animation as a format for delivering information about a potential health threat was discussed with regards to its theoretical basis. The findings from the think-aloud study presented in Chapter 5 showed that video-animation could be a useful education tool for patients. The specific video-animation was selected because it was rated as the best available for education purposes (Smith, 2017). It was therefore reasoned that the video-animation could be an anchor point for the entire discussion including: where the individual’s cancer was, how their swallowing function might be affected, how treatment may impact on eating and drinking and what may be done to manage these side-effects. The style of providing information was presumed to shift from the clinician telling the patient about all possible side effects to one in which the patient might be more participative and information-seeking about their main concerns. Findings from the think-aloud study suggested that reducing the speed of the video, keeping verbal narration to key stages of swallowing, and using lay terminology during explanations were important in facilitating understanding. The positive findings from the study and the largely favourable response to the animation used made it a good choice for inclusion in the new intervention. Narration for the video-animation was not scripted in the intervention manual to allow for flexibility in providing information that was responsive to patient needs. In the planned feasibility study, only one clinician would be delivering the intervention. It is possible that some level of script may be
necessary if this component is retained in the intervention and used more widely in a larger trial.

6.4.5 Essential behaviour change components

The proposed causal model for the new intervention (Figure 6-2) illustrates that behaviour change content is assumed to be as essential as the non-behavioural content in this intervention. Studies 1 and 2 presented in this thesis provided a conceptual understanding about the relevance of behaviour change for the planned swallowing intervention package, as well as data to inform the intervention content. Specific BCTs and intervention functions were selected based on the findings from the preliminary studies and the guidance provided by the Behaviour Change Wheel framework for designing interventions (Michie, Atkins & West, 2014).

Further analysis was undertaken on the patient interview data presented in Chapter 4. While the analysis for Study 2 reported in Chapter 4 addressed a specific research question, additional analysis of the data was undertaken to obtain insights that were useful for the Behaviour Change Wheel (BCW) process of designing an intervention. The BCW guidance recommends the following steps: 1) Understand the behaviour, 2) Identify intervention options, 3) Identify content and implementation options. This process is illustrated in Figure 6-6.
The additional analysis performed on the patient interview data is presented in Appendix 6-1. A snapshot is provided in Table 6-1. This table shows multiple pieces of information and how they are linked: examples of interviewee quotes, mapping of the data (quotes) onto the Theoretical Domains Framework and COM-B model, identification of barriers and facilitators, and suggestions for possible BCTs and intervention functions known to be theoretically linked to the specific behaviour component. A composite list of the intervention functions and BCTs generated from both the systematic review (Study 1) and interview study (Study 2) are presented in Tables 6-2 and 6-3 respectively. The Behaviour Change Wheel includes nine intervention functions and the BCT taxonomy V1 consists of 93 BCTs. The lists presented in Tables 6-2 and 6-3 show a streamlined pool of intervention functions and BCTs derived from the preliminary studies in this thesis. This is arguably a more theoretically relevant and manageable list from which to select behaviour change content for the new intervention.

The clinical knowledge and experience of the researcher was an essential part of the decision-making process in making context relevant choices about what to
include in the new intervention. Implicit in this decision-making was what has been termed the APEASE criteria (Michie, Atkins, & West, 2014). These criteria prompt an intervention designer to consider aspects of affordability, practicability, effectiveness and cost-effectiveness, acceptability, side-effects/safety and equity when devising a new intervention, and should be considered from the outset of the design process. Aspects of the APEASE criteria are integrated into the discussion around intervention components. Consultation meetings with patients and clinicians also informed the content of the new intervention and presented an opportunity to gather preliminary information about the acceptability of the new intervention. An account of the stakeholder meetings will be discussed in the next section, prior to presenting the components of the new intervention.

In addition to content, form of delivery is also important to specify as recommended in the TIDIER (Template for Intervention Description and Replication) guidelines (Hoffmann et al., 2014). As a working definition, “Form of delivery includes all features through which behaviour change content is conveyed: including the provider, format, materials, setting, intensity, tailoring and style” (Dombrowski, O’Carroll, & Williams, 2016, p 733). Certain aspects of delivery of the new swallowing intervention were decided at the outset. This pre-treatment swallowing intervention package was designed for use with newly diagnosed patients on a typical NHS head and neck cancer treatment pathway (see Figure 1-2). It should be accommodated in one to two consultations within the 31 day target timeframe between decision to treat and the start of treatment (NHS England, 2015). As head and neck cancer is usually treated at specialist centres, it was expected that a head and neck specialist speech and language therapist would deliver the new intervention during an outpatient clinic. The intervention would make use of a video-animation, and incorporate multiple types of materials including access to exercises in written form and/or via online “YouTube” links. The intervention would adopt an interactive style that would encourage the patient to discuss their concerns or ask questions related to their eating, drinking and swallowing function, with the clinician providing information accordingly. It was therefore likely to involve a high degree of tailoring.
Table 6-1: Excerpt of the behavioural analysis using COM-B and TDF

<table>
<thead>
<tr>
<th>COM-B component</th>
<th>Linked TDF Domain and Interview codes assigned</th>
<th>Examples of Barriers and Facilitators from interviewee quotes (target behaviour – swallowing exercises)</th>
<th>What needs to change or be optimised? (Target group: HNC patients)</th>
<th>Possible intervention functions and BCTs (Selected for context)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CAPABILITY</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Psychological capability</td>
<td>Knowledge and information on consequences of treatment</td>
<td>I was told that the swallowing would change. I was told to expect changes within the throat area - I may have to adapt how I eat and what I eat, what I drink. I was also told, obviously, that the diet would have to change for a period of time during treatment and, obviously, after my treatment. (P3) The doctor scribbled down a few symptoms that I would suffer after the radiotherapy, one of which was sore throat and one of which was maybe problems with the swallowing, or something along these lines. (P12) They told me I will need a feeding tube, I will have a feeding tube. Even if I don’t use it they are going to give me a feeding tube, because, I don’t know, for example, nine out of ten patients, at some point during treatment, won’t be able to take food. So I will definitely need one. (P13) When I first started seeing the Speech and Language therapist they kept going on about this thing about not getting stuff down your airway, whether it’s food or liquid, because you can get infections and this and that. I just, kind of, thought that this was completely inappropriate to my personal case, if you like, because I felt I was being talked to like a child. (P1)</td>
<td>Barrier if insufficient knowledge Know/ understand the likely impact of own treatment on swallowing function.</td>
<td>EDUCATION Information Provision (health, social and environmental and emotional consequences)</td>
</tr>
<tr>
<td><strong>KNOWLEDGE</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>


Table 6-2 is a list of the potential intervention functions identified from the interview study (Study 2) analysis. Grey shading indicates the intervention functions also identified from the systematic review study (Study 1). Six of the nine intervention functions represented in the Behaviour Change Wheel were identified as relevant to the new intervention. To recap, intervention functions refer to the broad category through which behaviour is changed by a given intervention. Any specific intervention may bring about change through one or more functions. In the new intervention, it is expected for example that use of the video-animation may serve the functions of both education and persuasion.

Table 6-2: Intervention Functions suitable for the new intervention

<table>
<thead>
<tr>
<th>Intervention Function</th>
<th>*Definition</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Education</td>
<td>Increasing knowledge or understanding</td>
<td>Providing information about the impact of radiotherapy on swallowing function.</td>
</tr>
<tr>
<td>Persuasion</td>
<td>Using communication to induce positive or negative feelings or stimulate action.</td>
<td>Using imagery to increase motivation to do swallowing exercises.</td>
</tr>
<tr>
<td>Incentivization</td>
<td>Creating an expectation of reward.</td>
<td>Doing swallowing exercises mean that individual may be able to eat favourite food or maintain current diet texture.</td>
</tr>
<tr>
<td>Training</td>
<td>Imparting skills</td>
<td>Teaching patients how to do a specific swallowing exercise.</td>
</tr>
<tr>
<td>Environmental Restructuring</td>
<td>Changing the physical or social context</td>
<td>Providing a drop-in space and exercise video for patient’s to do their swallowing exercises while waiting for daily radiotherapy.</td>
</tr>
<tr>
<td>Enablement</td>
<td>Increasing means/reducing barriers to increase capability (beyond education and training) or opportunity beyond environmental re-structuring.</td>
<td>Providing patient with a TheraBite device to support jaw mobility/function.</td>
</tr>
</tbody>
</table>

Table 6-3 lists all the BCTs identified as being potentially useful based on the extended analysis performed on the data obtained from Study 2 (Appendix 6-1 ).
BCTs in italics indicate those that were also identified from the systematic review (see Table 3.). BCTs underlined indicate those that were identified from the review, but not the interview study. A total of 37 different BCTs could be suitable for use in the new intervention.

Table 6-3: Behaviour change techniques suitable for the new intervention

*Source: *Selected from BCTTv1, (Michie et al., 2013)

<table>
<thead>
<tr>
<th><em>Grouping and BCTs</em></th>
<th>Grouping and BCTs</th>
<th>Grouping and BCTs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Goals and planning</td>
<td>Feedback and Monitoring</td>
<td>Social Support</td>
</tr>
<tr>
<td>Goal setting behaviour</td>
<td>Feedback on behaviour</td>
<td>Social support (unspecific)</td>
</tr>
<tr>
<td>Problem solving</td>
<td>Self monitoring of behaviour</td>
<td>Social support (practical)</td>
</tr>
<tr>
<td>Action planning</td>
<td>Self-monitoring of outcome of behaviour</td>
<td>Social support (emotional)</td>
</tr>
<tr>
<td>Review behaviour goal</td>
<td>Biofeedback.</td>
<td></td>
</tr>
<tr>
<td>Review outcome goals</td>
<td>Feedback on outcome</td>
<td></td>
</tr>
<tr>
<td>Shaping knowledge</td>
<td>Monitoring of behaviour by others without feedback.</td>
<td></td>
</tr>
<tr>
<td>Instruction on how to perform behaviour</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Natural Consequences</td>
<td>Comparison of behaviour</td>
<td>Repetition and substitution</td>
</tr>
<tr>
<td>Information about health consequences.</td>
<td>Demonstration of the behaviour</td>
<td>Behavioural</td>
</tr>
<tr>
<td>Salience of consequences.</td>
<td>Social comparison</td>
<td>practice/rehearsal</td>
</tr>
<tr>
<td>Information about social and environmental consequences.</td>
<td></td>
<td>Habit formation</td>
</tr>
<tr>
<td>Information about emotional consequences.</td>
<td></td>
<td>Generalization of target</td>
</tr>
<tr>
<td>Reward and Threat</td>
<td>Social reward</td>
<td>Antecedents</td>
</tr>
<tr>
<td>Incentive (outcome)</td>
<td>Non specific incentive</td>
<td>Restructuring the physical environment</td>
</tr>
<tr>
<td>Comparison of outcomes</td>
<td></td>
<td>Restructuring the social environment</td>
</tr>
<tr>
<td>Credible source</td>
<td>Self Belief</td>
<td>Adding objects</td>
</tr>
<tr>
<td>Pros and cons</td>
<td>Verbal persuasion about capability</td>
<td></td>
</tr>
<tr>
<td>Comparative imagining of future outcomes</td>
<td>Self-talk</td>
<td></td>
</tr>
<tr>
<td>Covert Learning</td>
<td>Vicarious consequences</td>
<td></td>
</tr>
</tbody>
</table>
6.5 Stakeholder Consultation

I devised a provisional plan of the new intervention based on the information presented in this chapter so far. Prior to finalizing the new intervention and seeking final approval from the original ethics committee that approved the study, two consultation meetings were held. It is believed that engaging stakeholders during intervention development is one way to verify that interventions are acceptable and appropriate to both patients receiving the intervention, and the clinicians who may be required to deliver the intervention (Shelef et al., 2016). Consultations with patients and speech and language therapy clinicians were thus incorporated into the process prior to producing the final intervention. Based on preceding information in this chapter, a list of components for the provisional new intervention is presented below.

The primary non-behavioural components were:

- baseline assessment of swallowing physiology via a modified barium swallow.
- use of a swallow video-animation to aid patient education about swallowing, to discuss the impact of the cancer treatment on swallowing function, and the reasons for undertaking swallowing exercises.
- targeted swallowing exercises selected on the basis of the MBS findings as well as evidence from the literature.

The main behavioural content as determined from earlier work included:

- *Education, training and enablement* (intervention functions derived from the systematic review) as well as persuasion (persuasive messages may increase preventative behaviour).
The BCTs of instruction on how to perform the behaviour, goal setting and action planning were expected to be core elements. However, the other BCTs identified from Study 1 such as self-monitoring, credible source, social support and behavioural practice would also be included. Furthermore, based on Studies 2 and 3, a key focus of the new intervention was likely to be centred on the behavioural strategies related to information provision.

Feedback on the content of the provisional swallowing intervention described above was sought from SLT clinicians and the project PPI group. The consultations took the form of semi-formal group discussions as opposed to formal studies. An effort was made to invite clinicians from different parts of the country in order to achieve an overview of the breadth of practice. Although not a formal study, the method for convening the expert clinician group is described below. All gave informal verbal consent, and the group was advised that they would be acknowledged in the intervention manual, unless otherwise requested.

6.5.1 Expert speech and language therapy clinician group

The Royal College of Speech and Language Therapists (RCSLT) was contacted for a list of names of expert SLTs working in head and neck cancer around the UK. Ten names were provided and an email was sent to all ten expert clinicians inviting them to attend a meeting in London, for which travel and accommodation expenses were offered. The letter provided a brief overview of my research and the purpose of the meeting. In their role as RCSLT experts/advisers, it was anticipated that despite variation in practice, the group was likely to have good knowledge of the minimum content usually included within pre-treatment consultations. They were made aware that the meeting would take the form of a group discussion with a view to achieving majority agreement on two aspects: 1) to discuss the minimum content of a usual care pre-treatment consultation, 2) to discuss and offer feedback on the proposed content of the new intervention. Four speech and language therapists attended the meeting and two contributed written information about their pre-treatment practice, as they were unable to attend in person. The written
documents were made available to attendees so that the information provided by absent members could be considered in discussions. The geographic regions represented included London, South-East England, North-East England, North West England and West Midlands. Apologies were received from three SLTs who were unable to attend due to prior commitments.

A clinical psychologist with previous experience in running group meetings and who was external to this research project facilitated the meeting. Aims and essential points for the discussion were agreed with the researcher prior to the meeting so that the facilitator had a clear remit. In order to begin the discussion with topics viewed as important to the group, the facilitator asked clinicians to write down three components that they thought formed part of the current speech and language therapy pre-treatment consultation for patients with head and neck cancer. This part of the discussion was to gain information about current practices, and to determine whether the usual care manual to be used for the planned feasibility trial was a reasonable reflection of usual care practice more widely. The production of the usual care manual was undertaken by the clinical speech and language therapy team at University College London hospital, and was not part of the work in this thesis.

The meeting (which lasted about 130 minutes) was audio-recorded and a descriptive analysis of pertinent points made by attendees was clustered under two main topic headings: 1) current speech and language therapy practice for head and neck cancer patients at the pre-treatment stage and, 2) feedback on provisional content of the new pre-treatment swallowing intervention package devised by the researcher.

6.5.1.1 Current speech and language therapy practice in the pre-treatment context

All clinicians (including those who provided written information) indicated that they felt that speech and language therapists needed to meet the patient pre-treatment and explain clearly their role throughout the treatment pathway and the likely
course of rehabilitation. The group felt that this was especially important as some pre-treatment consultations take place jointly with a dietitian and clinical nurse specialist in the same room, and patients often confuse the role of the dietitian and speech and language therapist. As one clinician indicated:

explaining the speech and language therapy role is essential, because I think most people who come to clinic don't know what we do. They think it's to do with their speech only.

Practicalities of time and space resources in a busy clinic, and the desire to avoid multiple visits make joint clinics an attractive solution. At the same time, some concern was expressed about how well this model served patients in terms of what they understood from this combined and condensed consultation. It was evident from the discussions that efforts to standardize an intervention may be thwarted by the variability in the length of time available to the therapist, and whether this was done separately or within the context of a multi-professional consultation in which time was shared. While the average duration appears to be around 45 minutes, it was also highlighted that in some services the pre-treatment consultation involves the therapist meeting the patient for five minutes in the corridor at a busy joint head and neck clinic, and providing a booklet of information or an exercise sheet. Clinicians felt that any evidence that could demonstrate the need for greater resources at the pre-treatment stage will be helpful. The general feeling was that the current system was too rushed and standard recommendations about the minimum time allocated for pre-treatment might be helpful. As one group member expressed:

That would be one thing to try and standardize [...], "In order to provide something of quality, you need X amount of time to do it." There's nowhere that says that at the moment, so that could be helpful.

This was an important discussion point as members of the group were likely to be amongst the most proactive lobbyists for a change in practice guidelines if the appropriate evidence was available.
Three other key points were raised in the discussion of care as usual. Firstly, whether any baseline swallowing assessment was performed and what this might constitute. All group members agreed that some form of baseline assessment should be done, and all indicated that to their knowledge most centres appeared to be collecting a baseline normalcy of diet score on the performance status scale (PSS). Some performed more detailed assessment to give them more of an idea of how the patient’s swallowing function may be affected and what they might expect from future rehabilitation. Secondly, how information was provided to patients about the side-effects and ramifications of treatment to their swallowing and speech function. There seemed to be considerable variation in who performed this role and how it was done. Some reported having a lengthy discussion and covering all side-effects as it was important for patients to understand this before consenting to treatment, while others provided some verbal information and gave patients booklets with detailed information. In some cases, nurse specialists and doctors provided this information. Thirdly, the decision about whether or not to provide patients with prophylactic exercises in light of uncertain evidence was considered. The group was split on this decision. One view was that there is at least some evidence and so exercises should be provided to all patients:

We give them [patients] a one-sided sheet, which is based on MD Anderson, because we couldn't come up with a protocol that fits everyone […]. So, we went with the only one that's kind of been reported on […] the MD Anderson protocol.

An alternative view was also expressed:

I'm not wholly convinced of the evidence for them [swallowing exercises], that's my dilemma. I feel really against a sort of carte blanche, "Patients need to be given prophylactic swallowing exercises." I think I'm in a position now where I feel that I can't not mention prophylactic exercises because there is evidence out there that might suggest that they are helpful. So, I wouldn't want to keep that information from patients, I try and present a balance.

The discussion about the practice of prophylactic exercises mirrored the uncertainty in the literature, and provides further support for a clinical trial on this topic.
Prophylactic exercises, if provided, were prescribed to patients undergoing chemoradiation rather than surgery. The rationale given by the group was that anatomy alters substantially with surgery, therefore exercises are better provided after surgery. Despite some variation in practice, the group agreed that patients should be made aware of the exercises, and given a choice about whether to do them. In the UCLH usual care manual, patients were offered an exercise sheet with instructions for a standard exercise regime.

From the discussion, it appeared that as a minimum, speech and language therapists meet the patient pre-treatment and provide brief verbal information and information booklets even if not able to do an independent consultation. When seen at an independent or multidisciplinary consultation, baseline functional measures may be taken and patients are provided with information about the impact of treatment on swallowing function. Exercises are sometimes provided and sometimes not. If provided, this is usually a standard set of exercises, most often in the form of an exercise leaflet with instructions and illustrations. Based on the discussion, the service offered at UCLH (representing the care as usual arm in the feasibility trial) is probably at the better resourced end of the spectrum as patients are offered an individual consultation with the speech and language therapist.

6.5.1.2 Feedback on components of the new intervention (SIP SMART)

During the latter half of the meeting, the researcher presented an outline of potential content for the new intervention explaining that this was derived from earlier work from the thesis identifying barriers and facilitators to exercises. The group agreed that the behavioural components of the intervention were important, but frequently not described or even recognized as essential to the success of the intervention. As one participant commented:
I think it really illustrates how complex the intervention is [...] What might help you to do these exercises?” There’s all that sort of stuff, the behavioural sort of things - or cognitive, their expectations - that we do or need to do on top of the actual intervention itself.

The group felt that there was a need for specific techniques and clinical skills to foster a different style of interaction that could better support these aspects that were not the “the actual intervention”.

The group facilitator encouraged discussion about specific points from the presentation of barriers and facilitators. For example, the group was prompted to consider how best to utilize the finding that social support might be an important facilitator. They felt that where possible, patients should be encouraged to bring a friend/relative/carer whom they felt could be of support to them to the pre-treatment consultation. The group reported that carers are already incorporated into their rehabilitation sessions:

I teach the carers as well. I say, "You’re going to be in personal trainer mode".

Another aspect discussed was how to help patients to remember and keep track of their exercises. Suggestions that were discussed included text message reminders, use of digital apps, use of charts and online support group forums. One member of the group suggested that perhaps this was a research question in itself:

I wonder how individual it is. I wonder if that’s part of the intervention, "There are these tools. What do you think is going to work best for you?"

The final discussion point that was raised with the group was the use of a pre-treatment modified barium swallow as both a baseline assessment and to tailor exercises as part of the new intervention. As this is not currently conventional practice, the group voiced some concern about the practicality of performing a modified barium swallow pre-treatment. Specific concerns were raised about having time and slots in the Radiology clinic to fit in this procedure, and whether
the radiation exposure was justified. The group agreed that as this was a study to assess feasibility then it was a good opportunity to put this to the test. In principle, they saw the inclusion of the procedure as useful but had concerns about whether it could be accommodated in practice with limited resources.

The discussion with expert clinicians confirmed that the care as usual intervention planned for the feasibility trial based at UCLH was probably more than the minimum care provided in less-well resourced centres. However, none of the content was considered outside of usual care practice. For the new intervention, it was encouraging to hear acknowledgement that more could be done to improve the behaviour change content of swallowing interventions. The group recognized potential value in considering whether specific behaviour change techniques might increase patient adherence. The feedback on social support was considered helpful to take forward in the intervention. However, they felt that it would be more useful to ask patients about their preferred option for keeping track of exercises.

The discussion was particularly helpful in gaining an early indication of possible problems in implementing SIP SMART. The group discussion highlighted that fitting in the two 45-minute consultations to deliver SIP SMART will be challenging for clinicians who encounter time and space restrictions in clinic, or undertake multi-professional pre-treatment consultations. Furthermore, performing a modified barium swallow in the short window of opportunity before treatment begins may be difficult within the existing resource infrastructure in many NHS head and neck cancer units. The group felt that while there was a convincing rationale for including an x-ray as part of the new intervention, resource limitations might be a prohibitive factor in a larger trial. Creative solutions to address this at potential recruitment sites will be necessary if the intervention is shown to be otherwise acceptable and feasible for a full trial. Speech and language therapists will require some level of training to ensure that they are appropriately skilled to deliver all intervention components. The time invested could be viewed as a useful way of providing continuing professional development to clinicians regardless of the eventual intervention outcome.
6.5.2 Patient-Public Involvement Group

As discussed in earlier chapters, the PPI group met with the researcher (RG) and provided input at various stages of this project. The discussion here relates specifically to one meeting with the group (three members were able to attend), which provided an opportunity for individuals to feedback any general comments about SIP SMART. Members of the group were emailed a description of the intervention to allow them time to review the content ahead of the meeting. PPI group meetings were not audio-recorded as this was agreed at the outset. Instead, handwritten notes about key points were kept. The main points specifically related to feedback about the SIP SMART intervention are summarized.

Firstly, the group felt that the two sessions in SIP SMART would be helpful as people need to feel that “someone is taking the time to discuss their cancer with them”. Linked to this, the group talked about their own experience in forming opinions about who to trust (professionals). They acknowledged the need for professionals to tell patients the side-effects as part of informed consent, but also felt that there might be a better way of doing this. In this respect, they liked the idea of the video-animation. They felt that if the patient could feel comfortable in using the video to ask questions, it would be important to building trust. I interpreted this to mean that if patients perceived that a professional was talking about them and their cancer, they were more likely to come across as believable and therefore trustworthy than if the professional just talked through a list of generally expected side-effects. However, as the focus of this exercise was general feedback, the notion of trust might need to be further explored at another time, and in a more purpose-designed research study.

Secondly, given the concerns raised by clinicians, it was interesting to hear the group’s views on the idea of having a MBS pre-treatment. The group was unconcerned about having the x-ray procedure to assess swallowing before treatment. They felt that many patients might be more “re-assured knowing what’s going on in one’s own body”. They were also particularly positive in their feedback
about the tailored aspect of the exercises commenting that they thought this would be important to patients.

Thirdly, on the point of social support, the group thought it was best to ask patients if they wanted to have a friend or family member to join them for the consultation as this may not suit everyone. In this respect, their views were similar to the expert clinician group.

The patient group was asked specifically for their views on how best to incorporate the behavioural strategy of self-monitoring or keeping track of exercises into the intervention. The group discussed and acknowledged that there was a role for technology (smartphones), but they also felt this may exclude those without smartphones. Furthermore, they felt that from a practical point of view “smartphones have to be charged regularly, and you have to sign in to the app”. Using them to record exercises was likely to become tedious after a while. The group commented that patients might feel that this “is another extra thing to do”, particularly when so much else is going on at pre-treatment and during radiotherapy. Members of the group agreed that a “low tech” option, such as a wall chart or a calendar where one could tick if exercises were done or write in comments might be less burdensome. Two members of the group offered to design a calendar for this purpose, which was subsequently incorporated into the intervention.

In summary, the stakeholder consultations contributed to the decision to include a calendar for self-monitoring. The PPI group felt that it was a good way for patients to keep track of their exercises and was not overly burdensome. Furthermore, other aspects such as the use of an x-ray assessment, tailoring of exercise content and the use of a video-animation were positively received by the PPI group. Patients did not seem concerned about the length of the consultation, and were particularly positive about personalizing the intervention. The outline of the final SIP SMART intervention is presented in Table 6-4.
Table 6-4:  Outline plan SIP SMART: Swallowing Intervention Package- Self-Monitoring, Assessment & Rehabilitation Training

<table>
<thead>
<tr>
<th>Intervention component &amp; Source</th>
<th>Content Description</th>
<th>Behaviour change technique (BCT)</th>
<th>Intervention Function and mode of delivery</th>
<th>Theoretical underpinning (links to TDF/COM-B)</th>
</tr>
</thead>
</table>
| 1. SLT to meet patient before cancer treatment.  
(NICE Improving outcome, guideline, 2004)  
consensus from SLT expert group | Introduction to SLT & role within team.  
(highlight specific role as having expertise in mechanics of swallowing while acknowledging multidisciplinary working. Important for patient to believe and trust in specialist knowledge.) | -Credible source | Education  
Persuasion  
Face-to-face meeting | information provided by credible source - specialist.  
Professional role/identity  
Reflective motivation |
| 2. SLT to undertake baseline swallow assessments.  
Performance status scale – (national audit requirement)  
Oro-motor assessment  
Modified barium swallow – (SIP SMART)  
Modified barium swallow.- best available assessment based on literature | Obtain diet texture score based on performance status scale.  
Undertake modified barium swallow in fluoroscopy suite to assess swallowing.  
NB: Patient should only be shown recording of x-ray swallow after components 3 and 4 are delivered. | -Monitoring of outcome with feedback (reflects baseline function, measure repeated)  
- biofeedback  
- exposure  
- information provision | Education  
Persuasion  
Clinical procedure | patient desire to avoid loss, maintain functional status – Incentive/Reinforcement  
In addition to its assessment function, x-ray swallow can provide biofeedback to patient about his/her swallowing.  
Visual representation of otherwise abstract information. Formulation of intent to preserve function.  
Cognitive, environmental, social & emotional influences. |
<table>
<thead>
<tr>
<th>Intervention component &amp; Source</th>
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<th>Theoretical underpinning (links to TDF/COM-B)</th>
</tr>
</thead>
</table>
| 3. Patient should be counselled/informed about treatment ramifications as part of informed consent. (NICE Improving Outcomes Guidance, 2004) | Establish patient’s understanding/acceptance of diagnosis. Probe patient’s understanding about impact of treatment on swallowing function and QOL more generally. Information provision regarding impact of treatment on swallowing. Advise preventative strategies including swallowing exercises may ameliorate some difficulties. | -Pros and cons  
-Comparative imagining of future outcomes.  
-verbal persuasion about capability  
-self talk  
BCTs associated with natural consequences – health, social, emotional.  
-salience of consequences | Education  
Persuasion  
Face-face | Automatic Motivation (emotion)  
Psychological capability  
Knowledge  
Psychological capability  
Reflective motivation  
video-animation presents a more concrete/experiential account of dysphagia (illness threat) – facilitates intention formation. |
| 4. Information/advice on managing side effects. (Usual care practice) Agreement from SLT group that this is important, but timing of when information is given and how much is variable. Usual care - Tendency to provide large amounts of general information at pre-treatment. SIP SMART – focus on key information and advise patient that side effects will be discussed and managed as required. | Tailored information on managing side effects and preparing for alterations to swallowing function, but maintaining eating and drinking as much as possible through treatment. Try to keep routine of mealtimes. (patient to be informed about discomfort as treatment progresses and provided with pain relief options, solutions for managing dry mouth as required. Surgery patients to be advised as per surgical procedure) | -social support  
- comparative imagining of future outcomes.  
-verbal persuasion about capability  
- adding objects  
-problem solving  
Flexible: (other BCTs eg. framing/reframing may be useful based on individual patient problem solving) | Education  
Enablement  
Face-face (supplement with info leaflets) | Social opportunity  
Physical opportunity  
Psychological capability  
Reflective motivation  
Physical capability  
Coping planning |
<table>
<thead>
<tr>
<th>Intervention component &amp; Source</th>
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</tr>
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</table>
| 5. Tailored exercises (SIP SMART) | Provision of /training in personalized swallowing exercise plan  
Ensure that exercises are demonstrated and practiced in session.  
Provide with necessary equipment such as TheraBite if required.  
Provide information in multiple formats depending on patient preference – written, exercise DVD or online links of swallowing exercises that patient can refer back to.  
Agree and write goals into SIP SMART calendar | -goal setting behaviour  
-action planning  
-instruction in how to perform behaviour  
-demonstration of the behaviour  
-behavioural practice/rehearsal  
-adding objects | Education  
Training  
Enablement | Physical & Psychological Capability  
Reflective Motivation  
knowledge, skills, memory, beliefs about capability, goals |
<table>
<thead>
<tr>
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</table>
| 6. Actively promote adherence (SIP SMART) | Establish a workable routine for doing exercises eg. every morning and evening immediately after cleaning teeth. Encourage patients to record performance on self-monitoring calendar provided as part of SIP SMART. Ask patient to identify a family member/friend who can provide support to do the exercises. Tailor plan with patient, problem solve anticipated barriers and discuss strategies to overcome barriers. | - prompts & cues  
- habit formation  
- social support  
- problem solving  
- self monitoring of behaviour & outcome  
- self talk  
- action planning  
Flexible (tailor according to patient preference or daily routine) | Enablement  
Persuasion  
Face-face | Psychological capability  
Physical capability  
Automatic motivation  
Reflective motivation  
Social opportunity  
implementation intentions – when, how, what, how often |
| 7. Provide contact information for follow-up (usual care) | Patients will be offered the opportunity for a brief follow-up to clarify any information from the session. | Social support | Enablement  
Face-face or telephone | Social Influence Capability |
6.6 The new intervention - SIP SMART

Table 6-4 outlines the main components of the new intervention, which was given the name SIP SMART as an abbreviation to key content – Swallowing Intervention Package: Self-Monitoring, Assessment, and Rehabilitation Training. The table summarizes the final intervention components incorporating refinements following feedback from expert SLTs and the PPI group. Seven key components are identified. Where components overlap with usual care, and differences from the intervention are indicated. A brief description of the content for each component is provided, along with the relevant behaviour change techniques, intervention functions and associated theoretical underpinning.

A manual for the new intervention was designed specifically for use in the feasibility RCT discussed in the next chapter. The multiple sources of information described throughout this development process were incorporated into a practical working manual. Details of the resources and materials required to deliver the intervention have been included in the manual. A copy of the manual is included in Appendix 6-2. The NHS ethics committee also approved the intervention manual as part of a substantial amendment process. It is envisaged that this manual may need modifications if the trial proceeds to further multi-centre pilot work and a full RCT. Some level of clinician training will also be necessary.

6.6.1 Describing complexity in SIP SMART

Recent work by the Cochrane Collaboration to improve systematic reviews of complex interventions advocates a method for describing complexity within a complex intervention (Lewin et al., 2017). The timely guidance from the Intervention Complexity Assessment Tool (ICAT) (Lewin et al., 2017) offered a helpful way to examine the likely complexity dimensions within SIP SMART. My judgement of complexity ascribed according to the tool is shown in Table 6-5.
### Table 6-5: Complexity dimensions of SIP SMART using the Intervention Complexity Assessment Tool (ICAT)

**Source:** Lewin et al., 2017

<table>
<thead>
<tr>
<th>Complexity Dimension</th>
<th>Description of levels</th>
<th>Judgement for SIP SMART</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Active components included in the intervention, in relation to the comparison</td>
<td>-More than one component and delivered as a bundle. -More than one component. -One component.</td>
<td>Seven components outlined, ideally delivered in a bundle in sequential steps by the same SLT for best effect.</td>
</tr>
<tr>
<td>2. Behaviour or actions of intervention recipients or participants to which the intervention is directed</td>
<td>-multi-target -dual target -single target</td>
<td>Multi-target: intervention aims to increase knowledge, undertake swallowing exercises, manage symptoms to allow continuation of oral diet.</td>
</tr>
<tr>
<td>3. Organisational levels and categories targeted by the intervention</td>
<td>-Multi-level -Multi-category -single category</td>
<td>Single category – intervention directed at patients on an individual level.</td>
</tr>
<tr>
<td>4. The degree of tailoring intended or flexibility permitted across sites or individuals in applying or implementing the intervention</td>
<td>-Highly tailored/flexible -moderately tailored/flexible -inflexible</td>
<td>Highly tailored and flexible, but maintaining essential content.</td>
</tr>
<tr>
<td>5. The level of skill required by those delivering the intervention in order to meet the intervention’s objectives</td>
<td>-high level skills -intermediate level skills -basic skills</td>
<td>High level skills – specialist SLTs will require some additional training for the intervention.</td>
</tr>
<tr>
<td>6. The level of skill required for the targeted behaviour (by recipient) in order to meet the intervention’s objectives</td>
<td>-High level skills -intermediate level skills -basic skills</td>
<td>Basic skills to be able to attend to, learn and practice exercises, follow advice.</td>
</tr>
<tr>
<td>7. The degree of interaction between intervention components, including the independence / interdependence of intervention components</td>
<td>-high level interaction -moderate interaction -independent</td>
<td>High level interaction – interdependency and likely synergistic effect eg, MBS and tailored exercises, perceived credibility.</td>
</tr>
<tr>
<td>Complexity Dimension</td>
<td>Description of levels</td>
<td>Judgement for SIP SMART</td>
</tr>
<tr>
<td>-------------------------------------------------------------------------------------</td>
<td>-----------------------------------------------------------------</td>
<td>------------------------------------------------------------------</td>
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</table>
| 8. The degree to which the effects of the intervention are dependent on the context or setting in which it is implemented | - highly context dependent  
- moderately context dependent  
- independent of context | Moderately context dependent – likely transferrable across specialist NHS cancer centres. |
| 9. The degree to which the effects of the intervention are modified by recipient or provider factors | - highly dependent on individual factors  
- moderately dependent on individual level factors  
- largely independent of individual level factors | Highly dependent – may be affected by patient factors and clinician factors. |
| 10. The nature of the causal pathway between the intervention and the outcome it is intended to effect | - pathway variable, long  
- pathway linear, long  
- pathway linear, short | Pathway proposed as essentially linear, but long time period to outcome. |
Table 6-5 draws attention to the various ways in which aspects of complexity may influence intervention effects. The advantage of recognizing aspects of complexity at the intervention development stage is that they can then be proactively considered during evaluation to provide a more complete picture of the results. It may also help explain why interventions may work in some contexts and not others. For instance, an effective intervention that is not adequately delivered may fail to influence the mediator or underlying mechanism that may lead to change in outcome. A concrete example might be a situation where a rushed SLT clinician hurriedly provides information to a patient on why swallowing will be affected to allow time to demonstrate how to do the exercise protocol for a home-based programme. However, given the theoretical underpinning of the intervention, this may fail to impact the “knowledge” construct (mediator), which may subsequently fail to produce the desired behaviour (adherence to swallowing exercise programme). Adherence to swallowing exercises is likely mediated by multiple mechanisms of change, each of which may interact with aspects of complexity. Effectiveness of SIP SMART is likely to depend on both the behavioural and non-behavioural content of the intervention, as well as form of delivery and broader contextual factors. Many, but unlikely all of the factors have been raised in modelling SIP SMART. Much more may be learned from the feasibility trial described in Chapters 7 and 8.

6.7 Discussion

This chapter has detailed the rationale, processes, and decisions taken in devising the SIP SMART intervention. An important outcome of the process was the production of an intervention manual to be used in the feasibility trial. As outlined, SIP SMART comprises seven main components delivered in one to two consultations (90 minutes) prior to the start of head and neck cancer treatment. Intervention development studies seem to be evolving rapidly with significant efforts aimed at unravelling the multiple factors and complexities to consider when designing an intervention. A number of guidelines were published since commencing this work, and every effort has been made to make judicious use of
these where possible. Information presented in the chapter draws on the recommended guidelines for reporting the development and evaluation of complex health interventions (Möhler, Köpke, & Meyer, 2015). Furthermore, description of the intervention content and delivery, and information about context and complexity have likewise been included based on recommendations from the latest guidelines (Hoffmann et al., 2014; Möhler et al., 2015; Pfadenhauer et al., 2017).

Strengths of this development process include the use of findings from prior qualitative studies conducted in this thesis to optimize the intervention content (Levati et al., 2016). Also, obtaining feedback from stakeholders was a useful and time-efficient method of refining the intervention and gaining an early indication of acceptability. At the same time, a possible limitation of adopting this approach is that it can be time consuming and labour intensive, and may therefore have less appeal for many clinical researchers. A detailed process of intervention development has scarcely been reported within the field of dysphagia. The present work could be a catalyst for change amongst dysphagia researchers prompting them to publish details of their own interventions. The benefits seem worthwhile as an entirely unexploited area of understanding and optimizing interventions is opened up for exploration. The next chapter describes how SIP SMART will be taken forward in a feasibility randomized controlled trial.
Chapter 7  Protocol for the SIP SMART feasibility randomized controlled trial

7.1  Background

This chapter describes the protocol for testing the SIP SMART intervention via a feasibility randomized controlled trial. The National Institute for Health Research (NIHR) definitions and guidelines for a feasibility study have been consulted in devising this protocol (www.nihr.ac.uk). The NIHR distinguishes between a pilot and feasibility study. A pilot study is a small-scale study that closely resembles the proposed main trial. It is usually undertaken to ensure that all aspects of the study work together and is chiefly concerned with processes in conducting the trial. In some pilot studies, data may be included in the analysis of the larger trial, often referred to as an internal pilot. In other pilot studies, data may be analyzed separately, referred to as an external pilot. A feasibility study is used to gather important information that allows one to estimate key parameters such as recruitment potential, acceptability of randomization, response rates to questionnaires and other factors necessary to determine whether the study is feasible to conduct. Feasibility studies are not designed to determine efficacy of an intervention. They can however be useful to examine which of several possible outcome measures is most suitable as a primary outcome to determine efficacy and/or effectiveness in a definitive trial.

The protocol for SIP SMART was the first UK based feasibility trial of a pre-treatment swallowing intervention to be registered on the trials database (http://www.isrctn.com/ISRCTN40215425). The protocol has been peer-reviewed and approved by a NHS ethics committee (London South East Ethics Committee-14.LO/1152 – see Appendix 2-2). The protocol (written in future tense) for the feasibility study was prepared in accordance with the standard protocol items recommended for interventional trials (SPIRIT) checklist (Hoffmann et al., 2014).

7 The protocol for the SIP SMART feasibility study was published in BMJ Open (Govender et.al, 2017c). Content from the publication is included in this chapter under the CC-BY license. (see Appendix 7-1 for published protocol)
7.2 Aims of the SIP SMART feasibility study

The specific aims of this feasibility study are to:

- Assess the rate of recruitment of eligible participants and identify any specific barriers to recruitment.
- Determine the acceptability of randomization, and the randomization procedure to patients and the clinical care team.
- Determine retention and attrition over the time course of the study.
- Evaluate the ease of protocol implementation, including research processes, and identify barriers in the clinical setting.
- Evaluate a range of potential outcome measures, including the ease and completeness of data collection across various time-points.
- Determine concordance between potential outcome measures and define the most suitable primary outcome for the definitive study.
- Collect data to inform future sample size calculation.

7.3 Methods

7.3.1 Study population, setting and recruitment plan

The study takes place at a single NHS hospital site [University College London Hospital (UCLH) Head and Neck Cancer Centre] with a catchment population of 1.5million. The study sample will be drawn from the population of patients with newly diagnosed head and neck cancer referred to the cancer centre, and discussed at the weekly multidisciplinary team (MDT) meeting. Potential patients for the study (based on diagnosis) will be identified during the meeting by the clinical researcher (RG), research nurse, or other members of the MDT. The clinical researcher or research nurse will ensure that the treating consultant is aware of potentially eligible patients so that he/she may introduce the study during the clinic consultation with the patient if appropriate. At UCLH, the clinical team (consultant
and other relevant team members) will usually meet patients discussed at a morning MDT meeting, the same afternoon at the joint MDT clinic. The recruitment strategy therefore includes a pre-screening stage that takes place during the morning MDT meeting and a screening stage that occurs in the afternoon head and neck joint MDT clinic. Pre-screening allows for the identification of potential patients based on their diagnosis alone. A list of patients (and their diagnosis) planned for discussion at the weekly meeting is circulated by the MDT co-ordinator to the immediate clinical care team a few days prior to the meeting.

7.3.2 Study sample and inclusion/exclusion criteria

The sample size for this feasibility trial was determined pragmatically using the guidance by Lancaster and colleagues (Lancaster, Dodd & Williamson 2004) who recommend that \( n \) of 30 is sufficient to estimate key parameters in a feasibility study. Based on a conservative annual referral (2012 and 2013 average figures) of approximately 70 newly diagnosed stage III and stage IV head and neck cancer patients to the UCLH Cancer Centre, it was estimated that it will take approximately eight months to recruit 32 patients to this study if 60% of eligible patients are recruited. Eligibility criteria for the study are listed below:

Inclusion criteria:

- Patients with newly diagnosed stage III and stage IV head and neck cancer.
- Discussed at the head and neck MDT and planned for treatment via surgery and/or chemo-radiotherapy or combinations thereof.
- Able to provide informed consent.
- Proficiency in English satisfactory to participate and engage in the intervention.
- Aged 18 and above.
Exclusion criteria:

- Patients with previous head and neck cancer treatment.
- Patients who are mid treatment or those receiving palliation.
- Patients who are to be treated solely by non-standard treatment i.e. not surgery, radiotherapy, chemo-radiotherapy or combinations thereof. Patients treated by chemotherapy, brachy therapy, photodynamic therapy alone will be ineligible.
- Patients who are planned for a total laryngectomy.
- Patients who are considered vulnerable, have significant co-morbidities or who are unable to provide informed consent.
- Patients with brain tumours and other primary sites not within head and neck.

7.3.3 Pre-screening/Screening

All patients who meet the clinical eligibility criteria (pre-screening) identified at each MDT meeting will be recorded on the screening log (Appendix 7-2) by the clinical researcher or research nurse. Screening will take place at the outpatient clinic consultation when treatment options are discussed by the surgeon/oncologist. The clinical researcher will attend the consultations for eligible patients. If appropriate at this stage, the purpose of the study will be explained, and patients will be given the patient information leaflet to take away (Appendix 7-4). Most patients will be booked for repeat visits to the head and neck clinic prior to finalizing their treatment plan. Due consideration will be given to ensuring that the study information is discussed at an appropriate time after the diagnosis. Patients will be given a minimum of 24 hours after receiving the patient information leaflet before a mutually agreed time is arranged to answer any further questions to assist patients in deciding whether to participate. The time frame was chosen because most patients will return to the hospital for other tests the day after their clinic visit. This offers an opportunity to answer questions in person and obtain signed consent if appropriate. Patients will be re-assured that participation is voluntary.
with the freedom to withdraw at any stage, and that participation (and refusal to participate) in the study will not affect or delay their main treatment.

7.3.4 Enrolment/Consent

The clinical researcher or a trained research facilitator will obtain informed consent. Following informed consent and generation of a patient study identification number, the patient will be entered onto the study enrolment log (Appendix 7-3) and randomized to either the SIP SMART intervention or usual care group as detailed below.

7.3.5 Randomization and Allocation

Eligible patients will be randomly assigned in a 1:1 ratio between care as usual (CAU) and intervention groups (see Figure 7-1 trial flowchart). Patients will be stratified by first line treatment: surgery or radiotherapy ± chemotherapy, a known factor that impacts swallowing outcomes (Kalavrezos et al., 2014). It will therefore be necessary to ensure a balance of primary treatment modality across the groups. Due to the small numbers in this study, random block permutations will be employed to ensure a close match in numbers in the intervention and usual care groups at any given point during the trial.

Patients will be allocated to one of two groups using an online computer-generated randomization service provided by an external company (http://www.sealedenvelope.com/). The company is registered with the Information Commissioners Office and inspected by the MHRA (UK trials regulator). Following consent, the clinical researcher or research facilitator will enter the password protected website and complete relevant information regarding first line treatment. Randomization is immediate, and the group allocation is emailed within a few minutes. This process is undertaken in the presence of the patient after signed consent is obtained, ensuring that the allocation is concealed until this point and simultaneously made known to the patient and researcher. Allocation is not blinded as the patient and staff will be aware that the new intervention includes a baseline x-ray of swallowing (MBS). Patients allocated to the CAU group will be
advised that they will be sent an appointment in the post to see a speech and language therapist (SLT) prior to their treatment as per the usual care pathway. Patients allocated to the intervention group are given an appointment and a service information leaflet on having an x-ray swallow to assess how well the muscles and nerves function when swallowing different textures of food and drink. The clinical researcher will deliver the new swallowing intervention package, while CAU will be delivered by one of the specialist head and neck SLTs. All patients are given three questionnaires to complete and return prior to their appointment with the SLT. These questionnaires are listed in Table 7-1. Copies of all study related forms, questionnaires and outcomes are included in the chapter appendix (Appendices 7-2 – 7-13).

In order to facilitate and increase engagement from all members of the MDT, the clinical researcher will give a presentation of the study and key steps for screening and recruitment. It is hoped that this will encourage individuals to discuss any questions or concerns prior to the start of recruitment (see Appendix 7-15 for presentation slides). A single page summary of the study and eligibility criteria will be emailed to members of the MDT after the presentation, scheduled for the first week the study is open to recruitment (Appendix 7-14).

7.3.6 Interventions and Procedures

**Care as Usual (CAU) Group:** Patients in this group will receive the usual pre-treatment care offered by the SLT service prior to their upcoming surgery and/or chemo-radiation. The speech and language therapy clinical team consisting of four members participated in a series of consensus meetings regarding the delivery of usual care to facilitate standardized care and equipoise. All four team members involved in usual care completed Good Clinical Practice training to promote a common understanding of trial related practice and procedures. A usual care manual was written and agreed by the speech and language therapy clinical team prior to commencement of the study to ensure a level of consistency amongst the clinicians.
Usual care pre-treatment is one 45-minute consultation as described below:

- General case history taking and introduction of SLT role.
- Clinical baseline screening of swallowing and communication function. This is usually based on an oro-motor assessment: 100mL water swallow test (Patterson et al., 2011); a clinician rated Performance Status Scale (PSS) indicating the normalcy of diet texture and public eating score (List et al., 1990); and a clinician rated scale for chewing, communication, and swallowing (Nicoletti et al., 2004). Maximal jaw opening using a TheraBite measure and voice quality ratings using the GRBAS [Grade, Roughness, Breathiness, Aesthenia, Strain] scale are also recorded.
- The patient is provided with a general overview of the planned treatment (surgery or chemo-radiation) and information about the likely side effects such as mucositis, taste changes and impact of treatment on swallowing and communication.
- General advice is offered to patients planned for chemo-radiation at this consultation. Patients are sometimes provided with a general exercise sheet that includes instructions for eight different swallowing exercises for example, passive jaw stretches. This is included as part of the information pack given to all patients receiving radiotherapy. Patients are advised that it may be helpful to commence doing the exercises before treatment.

**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 the clinical researcher who completed a five-day intensive training course in behaviour change (UCL Centre for Behaviour Change), and received mentorship from an expert in behaviour change. Specific details of the new intervention were not explicitly shared with clinicians delivering usual care to minimize contamination. Broad differences include the following:
• Patients will undergo an x-ray assessment of their swallow function (MBS) in the fluoroscopy suite at the hospital site. This procedure is part of the SIP SMART intervention informing the selection of targeted exercises, and is used as part of patient education. A standard protocol for this clinical procedure will be adopted for the study (Martin-Harris et al., 2008). The patient will be asked to swallow a variety of food textures. Fluoroscopic images of both the lateral and anterior-posterior plane captured at a rate of 30 frames per second will be recorded on a swallow workstation (Digital Kay Pentax Swallow workstation, USA). This will be available for later analysis of swallow physiology. The fluoroscopy screening time is usually 2-3 minutes.

• Patients will subsequently be shown a video-animation (Dysphagia App, Northern Speech Services: USA) to explain the basic mechanics of swallowing and to orientate them to key structures such as the tongue, base of tongue, airway and oesophagus. Patients will thereafter be shown a recording of their own MBS examination and helped to identify the key structures using this newly acquired knowledge. The clinical researcher will encourage patients to provide commentary and/or ask questions as they watch the video.

• The MBS assessment will be used to tailor the information, advice and exercises given to the patient during the pre-treatment session and to facilitate discussion about the rationale for exercises and possible consequences of not doing exercises.

• Further detail about the intervention content and behavioural strategies used has been provided in Chapter 6 as well as the SIP SMART manual.

Patients in both groups will follow the usual care pathway for SLT rehabilitation post-treatment. The number of SLT rehabilitation sessions for all patients will be recorded. Patients will be informed that exercises may be amended post-treatment based on updated swallowing assessment.
Baseline and follow-up outcome measures

Swallowing is a multi-dimensional ‘construct’ that may be measured by a number of different indicators including patient reported outcome measures, clinician ratings and scores from instrumental assessments such as MBS and fibre-optic endoscopic evaluation of swallowing. This range of outcomes can prove problematic when
synthesizing findings from multiple studies. This feasibility trial will use similar swallowing outcome measures as those employed in other concurrent UK trials for head and neck cancer (Owadally et al., 2015; Petkar et al., 2016). Measures collected as part of routine clinical practice will also be utilized (Table 7-1). Outcome measures will be collected at baseline and 1-month, 3-months and 6-months after treatment. Six months post-treatment represents a relatively stable time-point in the recovery trajectory for HNC patients and was therefore selected as an appropriate endpoint (Perry et al., 2016).

The following measures are included, with the expectation that one may be identified as a suitable primary outcome measure. Data about the collection, performance and completeness of each measure will help inform this decision.

**Performance Status Scale HN (PSS- Appendix 7-7):** This is a scale of functional swallowing ability measuring three items: normalcy of diet texture that an individual is able to eat without difficulty, comfort with eating socially in public, and speech intelligibility. Each item is independently assessed and measured (List et al., 1990). Normalcy of diet is the main item of interest in this trial and is measured on a scale of 0-100 with higher scores reflecting better function. Scoring is based on a semi-structured interview allowing the clinician to determine the most suitable diet texture category that reflects the patient’s functional ability. This measure has reportedly good psychometric properties, good inter-rater reliability and is able to discriminate levels of functioning and change over time in the head and neck cancer population. (List et al., 1990; List et al., 1997; List et al., 1996). It is quick and relatively simple to administer, and is already part of the recommended measures required for minimum dataset collection for the head and neck national audit (DAHNO).

**MD Anderson Dysphagia Inventory (MDADI – Appendix 7-8):** This is a patient reported questionnaire that measures swallowing related QOL. It consists of 20 items rated on a five-point Likert scale. This measure has been reported to have a minimal clinically important difference of 10 points, and can differentiate clinically
relevant groups of head and neck patients such as those with feeding tube dependence, aspiration and those on restricted diet textures (Chen et al., 2001)

Functional Assessment of Cancer Therapy: Head and Neck (FACT-HN – Appendix 7-9): This questionnaire was chosen to measure overall health related QOL. It was selected over the other commonly used QOL measures such as the EORTC and the UWQOL questionnaires as it has been identified as the most preferred by HNC patients in a UK study (Mehanna & Morton, 2006).

Modified Barium Swallow Impairment Profile (MBS ImP - Appendix 7-10): This method of analyzing and rating a MBS represents the most robustly tested and validated method at the present time (Martin-Harris et al., 2008). Seventeen components of swallowing physiology are assessed and rated based on a standard protocol. The procedure will be undertaken at 6-months only. Three SLT clinicians who have completed a 25-hour online training module and obtained the minimum 80% reliability score will provide consensus ratings for these assessments. Standard assessment rating forms developed as part of the MBS ImP will be used to score the MBS examinations. A composite swallow impairment score will be calculated based on the sum of the oral and pharyngeal components of swallowing. The scoring method used to determine an overall single score is newly developed (Professor Bonnie Martin-Harris 2017, personal communication, 17 November). Its utility as a trial outcome measure is therefore yet to be established, with the present feasibility study being one of the first to consider its suitability.

Penetration-Aspiration Scale (PAS - Appendix 7-11): This is a widely-used validated measure of scoring airway protection rated on an ordinal scale of 1-8 (Rosenbek et al., 1996). The assessment is made from direct observation of airway protection during the MBS examination. Scores of 1-5 represent no aspiration (but quantify level of risk using verbal descriptors); scores of 6-8 represent aspiration as evidenced by material entering the airway.

Other clinical swallowing related measures are included as they may be useful to consider as secondary measures (see Appendix 7-6). These were maximal incisor
opening (MIO), Functional Intra-oral Glasgow Scale (FIGS) and the 100mL water swallow test (WST). These measures all provide an indication of swallow function, but are not yet supported by robust psychometric validation studies. Patient weight, body mass index (BMI), and use of feeding tube will also be recorded.

**Self-Efficacy (GSES – Appendix 7-12):** Information on self-efficacy will be collected via the General Self Efficacy Scale (GSES). Perceived self-efficacy is thought to be an important factor influencing an individual’s decision to attempt a particular behaviour (Bandura, 1977). Individuals with higher self-efficacy are more likely to adhere to their exercises.

**Adherence to swallowing exercises (Appendix 7-13):** Standard validated measures of adherence for swallowing exercises are currently lacking (Krekeler et al., 2017). For this feasibility trial, a simple adherence form was devised to capture overall patient reported adherence. The form consists of four questions: 1) name or description of the exercises, 2) approximate number of days when no exercises were done over the last month, 3) approximate number of days when less than prescribed regimen of exercises were done over the last month and 4) a visual analogue scale illustrating patient’s self-assessment of their overall adherence. The form will be scored to obtain a binary outcome. Adherence will be reported as either satisfactory to good adherence or poor to no adherence to exercises. The threshold for categorizing patients as achieving satisfactory to good adherence will be based on a combined score of up to 4 on Q2 and Q3 of the adherence form, and a self-rated overall compliance of at least 50% on the visual analogue scale. A free text question is included to gather further information about any specific reasons for adherence or non-adherence to exercises.

**Randomization and trial participation questionnaire:** As the plan for this thesis does not include interviews with participants on completion of the study, a previously published questionnaire will be used to gather data on patients’ acceptance to participation and randomization (Jenkins & Fallowfield, 2000). The questionnaire consists of 16 questions that have been used previously in Cancer Research UK clinical trials to gather data on patients’ views toward participation and
randomization. The full questionnaire together with the findings will be included in Chapter 8 (Results).

Table 7-1 provides an overview of all the measures and questionnaires to be collected over all time-points in this study. It is divided into those collected as part of usual care, and those additional to the SIP SMART trial. The different time-points are included to provide an indication of how the measures vary over time. It is anticipated that 6-months will be the primary endpoint.

**Table 7-1: Outcome measures and time-points**

<table>
<thead>
<tr>
<th>Measure</th>
<th>T0 Baseline</th>
<th>T1 1 month</th>
<th>T2 3months</th>
<th>T3 6months</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Background information</strong></td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Measures taken as part of usual care</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Performance Status Scale (PSS)</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Maximal incisor opening (mouth opening)</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Functional Intra-oral Glasgow Scale</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>100mL Water swallow test</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td><strong>Additional Measures for Trial</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MD Anderson Dysphagia Inventory</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>General Self Efficacy Scale</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Self Reported Adherence question</td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>*HRQOL – FACT –HN</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Modified Barium Swallow Impairment Score</td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>and Penetration/Aspiration score</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acceptability to participation/randomization</td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Questionnaire</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Health Related Quality of Life - Functional Assessment of Cancer Therapy - Head & Neck

7.4 Safety Considerations

It is not anticipated that any serious safety concerns will arise from this largely behavioural intervention. A MBS may sometimes result in small amounts of aspiration of barium contrast material, but barium pneumonitis is reported to be
rare at less than 1% (Jo et al., 2016). The procedure will be undertaken by experienced SLTs familiar with the protocol for dealing with an adverse event related to barium inhalation. The procedure is also a well-established part of routine clinical practice.

7.5 Data Collection and Management

A number of study specific forms including a case report form (CRF- Appendix 7-5), screening log (Appendix 7-2), enrolment log (Appendix 7-3), training log for any study related training (Appendix 7-16), and study delegation log (Appendix 7-17) were derived from generic templates and adapted to the SIP SMART trial. A study number will replace patient names on all forms, and completion of CRFs will be in accordance with Good Clinical Practice guidelines. A site file containing all relevant documents as stipulated by local Research and Development and governance guidelines will be maintained throughout the study and securely stored in a locked cabinet. All patient-reported questionnaires will be securely filed. A data manager will transfer non-identifiable quantitative data from the questionnaires and CRFs to a specifically designed Microsoft Access database. A random check of approximately ten percent of the data inputted will be reviewed against the original source by the clinical researcher to estimate an error rate. This information will help ensure that robust data management is in place for a more formal trial. The clinical researcher will maintain an electronic diary of relevant information pertaining to the study processes on a password protected laptop computer.

7.6 Analysis

Descriptive analysis and summary statistics will be used to address the aims. Study screening and enrolment logs will be used in determining the total accrual and rate of recruitment into the study. All qualitative information (researcher diary), minutes of study related discussions and meetings would be imported into NVivo 10, a software database to facilitate the organization of qualitative or textual data. The researcher is in a unique position of being embedded within the clinical team, and therefore able to make observations over the duration of the study in a naturalistic
manner. This approach to process analysis may arguably provide more useful information than the use of post-hoc focus groups and interviews that rely on participant memory and may be removed from context (Morgan-Trimmer & Wood, 2016). Observing and collecting information in this way also means that the researcher can note the interplay of other factors (such as, multiple studies competing for the same patient group, how busy the clinic is) that may reveal vital information about the barriers and facilitators to recruitment.

Information on the practicality of implementing the protocol will also be reported. This will include: obtaining timeslots for undertaking MBS, average time taken for the recruitment and consent process, utility of the chosen randomization method, and suitability of the study specific forms including the CRF. This information will be used to optimize components of the protocol and study process in preparation for a larger trial.

As a range of outcome measures will be collected, the suitability of each measure will be considered together with the ease of collection and the quality and completeness of the data collection. Observations will be made of the relationships (concordance and discordance) between the different outcome measures to help inform the most suitable choice of primary and secondary measures for a definitive trial. Important parameters such as standard deviation and estimates of effect size will be used to inform the sample size calculation. Based on the available literature, efforts will be made to specify the target difference (clinically meaningful difference) for the chosen primary outcome. The primary outcome measure will be chosen from potential candidate measures on the basis that it is valid, practical and feasible to obtain and has expert agreement (RCSLT clinical expert group) that it reflects a good summary measure to answer the question of whether the new intervention is effective in improving swallowing function and quality of life for patients with head and neck cancer.

Patient acceptability to participation and randomization will be determined using a previously developed questionnaire (Jenkins & Fallowfield, 2000). Self-reported adherence to the intervention will be explored via a brief study questionnaire.
Previous studies reported that full adherence to exercises during radiotherapy was under 15% (van der Molen et al., 2011; Shinn et al., 2013). In a Danish study of a similar intervention to the current study, an average of 35% of patients reported doing their exercises at least once a day between 1-month and 11-months after treatment (Mortensen et al., 2015). A figure of 35% was therefore selected as the minimum target for the number of patients who report adhering to their exercises.

7.6.1 Criteria for Success

Qualitative and quantitative information will be collected to optimize the design of a future trial. However, the key parameters that will determine feasibility of the study to proceed to the next stage include:

- Recruitment – The study is able to recruit 60% of eligible patients referred into the MDT (an average of four patients a month).
- Willingness to participate and acceptance to randomization – A greater number of patients express positive than negative views as determined by questionnaire evaluation.
- A suitable outcome measure is determined, and sample size can be estimated.
- At least 35% of intervention group patients report satisfactory to good adherence to exercises.

7.7 Discussion

The SIP SMART trial is to my knowledge, the first randomized study in the UK aiming to determine the relative benefit of a tailored pre-treatment SIP compared to current practice of providing generic information about treatment impact. Post-treatment swallowing function is the outcome of interest. Recognizing the typical trajectory of decline in function during the acute phase after treatment, this study focuses on a 6-month endpoint when swallowing function is expected to be stable.
The protocol has been devised with careful consideration of the typical pathway for head and neck cancer patients treated on the NHS, and with first-hand knowledge of the logistics and workings of the clinical context. Efforts have been made to anticipate and incorporate training for clinicians and MDT members to ensure that all individuals associated with the study are adequately prepared for their role. In addition to mandatory Good Clinical Practice training for individuals identified on the study delegation log, clinicians collecting outcome measures will receive a training session to facilitate clarity and consistency of data collection. However, it remains uncertain whether it will be possible to recruit sufficient patients during the narrow window of opportunity between diagnosis and treatment, and whether patients will agree to participate in an additional intervention during this predictably stressful time.

A strength of this protocol is that it has been developed alongside qualitative work that supported the development of the intervention. The MRC guidance for the development and evaluation of complex interventions highlighted the need for adaptations to the conventional RCT that would make the design more useful in health systems research (MRC, 2000). The multiple components of an intervention, the context in which it operates and the involvement of stakeholders, are all acknowledged as important to the success of the intervention. It is therefore essential for researchers to ensure that as many intervention components as possible are optimized prior to a clinical trial by using multiple sources and research approaches. The case for using qualitative methods to enhance RCTs which are designed as pragmatic trials of complex interventions has been well argued (Raine et al., 2016). Thus, patients and clinicians were consulted during the development of the SIP SMART intervention, and the team delivering CAU was involved in devising a CAU treatment manual. It is hoped that these prior steps will increase the acceptability of the intervention, and therefore participation during the feasibility study.

Limitations of the protocol include the lack of blinding, which is difficult to achieve for the current feasibility study. Patients and clinicians are not blinded. It is clear
from the information sheet that only those allocated to the intervention group will receive an x-ray assessment at baseline. In the current protocol, the modified barium swallow is part of the new intervention. However, with greater resources it may be possible to also include this procedure as a baseline swallowing outcome measure. If both groups receive this assessment, it will be easier to blind patients to their allocation group. It is difficult to blind clinicians if CAU is delivered by the clinical team. Due to the feasibility study being undertaken as part of a doctoral research project, the clinical researcher will be involved in delivering the intervention and analyzing the results, but not in the collection of outcomes. Every effort will be made to ensure that the clinical researcher remains blind to the final outcome measures. Unmasking of the participant group allocation and analysis of swallow outcomes will take place under the supervision of a statistics consultant, and only after the last patient has completed the trial. In a future trial, it is anticipated that other clinicians will be trained to deliver the intervention and greater funding may be available to allow for the additional resources that will be necessary to ensure better blinding.

The results of the feasibility study are presented in the next chapter.
Chapter 8  Study 5: Findings of the feasibility study

8.1 Introduction

This chapter presents results from the feasibility study for the SIP SMART pre-treatment swallowing intervention, the protocol for which was detailed in the previous chapter. Findings are reported for each of the main feasibility criteria identified in the protocol and grouped under the following main topic headings: 1) Recruitment, 2) Patient participation and acceptability of randomization, 3) Research processes and completeness of data and 4) Candidate outcome measures and sample size estimation.

8.2 Recruitment

The target recruitment for SIP SMART was set at 32 patients within an eight-month period based on recruitment of 60% of expected referrals (for Stage III, IV cancer) to the UCLH multidisciplinary head and neck cancer team. It was expected that recruitment might be slower in the first month as the MDT became familiar with the SIP SMART trial. However, given the time constraints of this study, recruitment would cease after eight months or earlier if the target was achieved before this time. The criterion stipulated for the rate of recruitment was therefore an average of four patients a month. Recruitment took place between 5 April 2016 and 7 December 2016. The target recruitment of 32 patients was achieved over the course of eight months. The target and actual accrual over this timeframe is shown in Figure 8-1. As anticipated, recruitment was slow in the first month (one patient recruited), but improved over the summer months exceeding the target accrual. The comparatively slower rate of accrual seen over the October/November period coincided with a time when research staff (either the researcher or research facilitator) was away from the head and neck clinic.
8.2.1 Factors affecting recruitment

While the target accrual was attained, a few important issues related to recruitment were highlighted. A total of 106 patients were identified as potentially eligible at pre-screening from the weekly MDT based on the diagnosis of Stage III or Stage IV head and neck cancer over the duration of recruitment, and entered onto the screening log. However, important changes in service configuration took place in the period between the initial planning of this study and recruitment. Notably, increasing numbers of patients discussed at the UCLH MDT meeting were ultimately treated at their local centres. Specifically, the head and neck surgical service from a neighbouring health Trust (Barts Health NHS Trust) was redirected to the UCLH site for the surgery and the acute in-patient part of the patient pathway. Outpatient services remained at the local hospital. Also, patients discussed at the UCLH MDT meeting and due to have radiotherapy were able to access this treatment at their local centres if they lived closer to a hospital equipped to deliver radiotherapy. These changes in service configuration meant that many more patients were discussed at the UCLH MDT meeting and therefore identified as eligible at pre-
screening, but were subsequently not available for recruitment if they did not remain at UCLH for their treatment. Reasons for exclusion are given in the pie chart below (see Figure 8-2).

![Pie chart showing percentage breakdown of patients included/excluded](image)

**Figure 8-2  Percentage breakdown of all potentially eligible patients**

Figure 8-2 shows that 34% of patients (36 patients) were excluded at the point of discussion at the MDT meeting as these patients were due to be treated and/or followed up at hospitals other than the primary site for this study. These patients were therefore not approached for participation as this study was based at a single site only. A combined total of 24% of patients identified at pre-screening were excluded during screening at the clinic based on the following eligibility criteria: 1) Eleven patients had unsatisfactory proficiency in English determined by requirement for an interpreter at consultations, 2) Six patients presented with medical co-morbidities and pre-existing dysphagia unrelated to head and neck cancer, 3) Nine patients had to have a change in treatment plan that included the decision to proceed with a total laryngectomy, or the decision for treatment with palliative intent. Where it was evident that patients were not going to meet the
eligibility criteria (for example, advised by a consultant of co-morbidity, or advised by a nurse specialist that a patient had reduced proficiency in English), these patients were excluded without being seen ‘face-to-face’ in the clinic by the research team.

The researcher or research facilitator at the head and neck clinic approached a total of 48 patients for a ‘face to face’ screening. Nine were ineligible (part of the 24% stated above) and excluded due to one or more of the reasons identified. The remaining 32 patients were enrolled onto the study and randomized. Seven eligible patients declined to participate in the study. Although there was some overlap in the reasons provided, the main reasons given for declining participation were as follows: three patients did not want to be involved in anything extra while trying to get through treatment, two patients were concerned that participation would require attending additional appointments and visits to the hospital, and two patients reported that they were already signed up to another clinical trial. None of the patients reported declining on the basis of anything in the patient information leaflet or any concerns about the intervention itself. No patients reported that their decision to not participate was based on not wishing to be randomized. Thus, a total of 39 patients were eligible from the ‘face-to-face’ clinic screening and 32 were recruited.

Due to the short window of opportunity to approach and consent patients, it was essential to co-ordinate which member of the study team (clinical researcher or research facilitator) would see the patient at their clinic visit, and to ensure that the treating consultant was given advanced notice. Despite this, five patients identified from the MDT meeting during pre-screening were missed in the clinic. This was either due to how busy the clinic was on a given day and competing priorities for the research facilitator or clinical researcher (n=3), or because surgery was to be performed at short notice precluding participation in the SIP SMART protocol (n=2). Midway through recruitment, a study card was attached to the medical notes to serve as a reminder to clinic staff to alert the research team before patients left the clinic to avoid potential patients being missed.
To summarize, multiple factors may affect recruitment of potentially eligible patients identified on their diagnosis alone (pre-screening method used in this study). These include: patient pathway and where patients are treated, language barriers, change of initial treatment plans from the original MDT discussion, patient co-morbidities and patients missed at busy clinics. Of the patients approached in the clinic, 15% actively declined participation (7/48). In the protocol, it was estimated that the study could recruit 60% of patients with Stage III and IV head and neck cancer referred to the UCLH MDT (estimated to be approximately 70 patients per annum based on 2013 hospital data). Given that 106 patients were identified at the MDT on the basis of diagnosis alone, this study recruited 30% of patients. Reasons that explained this were described in terms of service changes. Despite this, the stipulated criterion for recruitment was still met, as the overall number of patients discussed at the MDT meeting was much higher than predicted during the study planning. An average of four patients a month, and a total accrual of 32 patients over the study duration were achieved.

8.3 Patient participation and acceptability of randomization

Prior to this study, it was uncertain how NHS patients who have recently received a diagnosis of head and neck cancer would respond to participating in a pre-treatment swallowing intervention study, or how accepting they would be of randomization. The researcher observed that staff and patients seemed to “like” the randomization procedure used in this study. As described in the protocol (Chapter 7, Section 7.3.5), randomization was done using a secure online system created for SIP SMART. Once the relevant information was entered onto the system in the presence of the patient, he or she was invited to press the key on the computer that triggered the randomization. Group allocation was also confirmed by an immediate email sent to the researcher. As randomization took place in the presence of the patient, it could have helped with acceptance of the concept.

It was an important criterion for success that most patients expressed positive views about participation in the trial and that they accepted the idea of randomization. Given the paucity of data on this issue for the target population, a clinical trials questionnaire was used to gather patients’ views toward participation
and randomization. A published questionnaire previously used by Cancer Research UK for cancer clinical trials was employed (Jenkins & Fallowfield, 2000). Twenty-four patients returned the questionnaire. Their responses are summarized in Table 8-1 below.
Table 8-1: Patient responses to trial participation questionnaire

<table>
<thead>
<tr>
<th>No</th>
<th>Statement</th>
<th>Agree</th>
<th>Unsure</th>
<th>Disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>%</td>
<td>CAU</td>
<td>INT</td>
</tr>
<tr>
<td>1</td>
<td>I thought the trial/study offered the best treatment available</td>
<td>100</td>
<td>12</td>
<td>12</td>
</tr>
<tr>
<td>2</td>
<td>I believed the benefits of treatment in the trial would outweigh the side effects.</td>
<td>71</td>
<td>6</td>
<td>11</td>
</tr>
<tr>
<td>3</td>
<td>I was satisfied that either treatment in the trial would be suitable.</td>
<td>83</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>4</td>
<td>I was worried that my illness would get worse unless I joined the trial.</td>
<td>17</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>5</td>
<td>The idea of randomization worried me.</td>
<td>17</td>
<td>4</td>
<td>-</td>
</tr>
<tr>
<td>6</td>
<td>I wanted a doctor to choose my treatment rather than randomized by computer</td>
<td>54</td>
<td>8</td>
<td>5</td>
</tr>
<tr>
<td>7</td>
<td>The doctor told me what I needed to know about the trial.</td>
<td>67</td>
<td>9</td>
<td>7</td>
</tr>
<tr>
<td>8</td>
<td>I trusted the doctor treating me.</td>
<td>96</td>
<td>12</td>
<td>11</td>
</tr>
<tr>
<td>9</td>
<td>I was given too much information to read about the trial.</td>
<td>42</td>
<td>7</td>
<td>3</td>
</tr>
<tr>
<td>10</td>
<td>I was given enough information to read about the trial.</td>
<td>88</td>
<td>11</td>
<td>10</td>
</tr>
<tr>
<td>11</td>
<td>I knew I could leave the trial at any time and still be treated.</td>
<td>100</td>
<td>12</td>
<td>12</td>
</tr>
<tr>
<td>12</td>
<td>I did not feel able to say no.</td>
<td>4</td>
<td>1</td>
<td>-</td>
</tr>
<tr>
<td>13</td>
<td>I wanted to help with the doctor’s research</td>
<td>100</td>
<td>12</td>
<td>12</td>
</tr>
<tr>
<td>14</td>
<td>I feel that others with my illness will benefit from the results of the trial.</td>
<td>100</td>
<td>12</td>
<td>12</td>
</tr>
<tr>
<td>15</td>
<td>The doctor wanted me to join the trial.</td>
<td>38</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>16</td>
<td>Others, for example, family or friends, wanted me to join the trial.</td>
<td>42</td>
<td>7</td>
<td>3</td>
</tr>
</tbody>
</table>

192
Patients reported high agreement with several statements indicating they felt that the trial offered the best treatment available, they were satisfied that either treatment group would be suitable, were given sufficient information about the trial and were aware that they could leave the trial at any time without their care being compromised. Given a choice, just over half of patients indicated that they wanted their doctor to choose their treatment rather than being randomized by a computer. However, only four patients reported being worried by the idea of randomization. Only one patient responded that they did not feel that they could say no to participation but were aware that they could leave the trial at any stage if they so wished. All patients indicated that they wanted to help with the research, and felt that other patients would benefit from the results.

Twenty-two patients completed the additional question asking for the single most important reason for deciding to take part in the trial. The two most frequent reasons identified were: (Q8) I trusted the doctor treating me (27%) and (Q14) I feel that others with my illness will benefit from the results of the trial/study (27%). Other reasons selected by multiple respondents included: (Q1) I thought the trial/study offered the best treatment available (14%) and (Q13) I wanted to help with the doctor’s research (18%). For the remaining patients (14%), one patient selected each of the following statements as the most important reason for participation: (Q3) I was satisfied that either treatment in the trial would be suitable, (Q4) I was worried that my illness would get worse unless I joined the trial and (Q12) I did not feel able to say no. These findings suggest that on the whole patients newly diagnosed with head and neck cancer are willing to participate in this type of trial often for altruistic reasons, although trust in the medical professional seems to be an important factor. Two patients reported reasons (Q4 and Q12) that suggest greater attention may be necessary to ensure that every patient fully understands their choices when approached for participation.

In summary, most patients reported positive views towards participation in the trial and were not worried by the idea of randomization, but given a choice just over half indicated that they preferred their “doctor” to choose their treatment rather than
be randomized by a computer. Researcher diary notes indicate that as patients were aware that the researcher was involved with the new intervention, many had hoped that they might be offered the new intervention. This suggests that patients may have had some tacit belief that the new intervention would be better. As patients did not report high concern over the idea of randomization, it seems that it was acceptable to them even if they were not allocated to the group they may have desired. This is further supported by the fact that only one patient (allocated to CAU) actually disagreed with the statement: *I was satisfied that either treatment in the trial would be suitable*. Based on these findings, patient participation and acceptability to randomization was considered to be mainly positive and therefore a successful feasibility outcome.

8.3.1 Baseline characteristics of patients randomized

All patients who were recruited and enrolled onto the study were randomized in accordance with the protocol. Despite a small sample size, the groups were generally well balanced, and any differences attributed to chance. A summary of baseline information is provided in Table 8-2. The average age of participants across the groups was 57 years with five times as many males than females recruited. This is broadly reflective of the population of patients who present with head and neck cancer, with a much higher incidence in males compared to females, although the male: female ratio across oral and oropharyngeal cancers is closer to 3:1 (Pytynia, Dahlstrom & Sturgis, 2014; Simard, Torre & Jemal, 2014; Tataru et al., 2016). The average age (57 years) reflects the patient demographic. The sample included a higher proportion of patients with oropharyngeal cancer that tends to be associated with the human papillomavirus and generally manifests before 60 years of age. It is possible that this demographic may differ in parts of the country where other etiological factors (for example, chewing betel products) play a more dominant role in cancer incidence. The sample also included the most common curative options for treatment. Stratification by first line treatment ensured a balance between the groups. The higher proportion of patients who received chemo-radiation therapy compared with surgery as first line treatment is reflective of the tumour site (mainly
oropharyngeal) and staging. The placement of a prophylactic feeding tube for individuals with advanced tumours undergoing chemo-radiation is in keeping with the practice guidelines at the institution. Baseline weight and body mass index were comparable across groups. Information regarding baseline smoking and alcohol history has not been included in the summary table as this information was inconsistently reported on the case report form. Baseline measures of swallow functioning have not been included in the summary table as these are shown in Table 8-5 together with final outcomes at 6-months for ease of comparison.

Table 8-2: Baseline characteristics of all patients randomized

<table>
<thead>
<tr>
<th>Participant demographics</th>
<th>Intervention group (n=16)</th>
<th>Care as usual group (n=16)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age mean (SD)</td>
<td>58.6 (12.4)</td>
<td>55.2 (9.4)</td>
</tr>
<tr>
<td>Gender n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>15 (93.8%)</td>
<td>12 (75.0%)</td>
</tr>
<tr>
<td>Female</td>
<td>1 (6.3%)</td>
<td>4 (25.0%)</td>
</tr>
<tr>
<td>Ethnicity n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>11 (68.8%)</td>
<td>12 (75.0%)</td>
</tr>
<tr>
<td>Asian/Asian British</td>
<td>3 (18.8%)</td>
<td>1 (6.3%)</td>
</tr>
<tr>
<td>Black/ Black British</td>
<td>0 (0%)</td>
<td>1 (6.3%)</td>
</tr>
<tr>
<td>Chinese</td>
<td>2 (12.5%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Other</td>
<td>0 (0%)</td>
<td>2 (12.5%)</td>
</tr>
<tr>
<td>Marital status n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Married</td>
<td>4 (25.0%)</td>
<td>10 (62.5%)</td>
</tr>
<tr>
<td>Single/separated</td>
<td>5 (31.3%)</td>
<td>5 (31.3%)</td>
</tr>
<tr>
<td>Widowed</td>
<td>1 (6.3%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Co-habiting</td>
<td>2 (12.5%)</td>
<td>1 (6.3%)</td>
</tr>
<tr>
<td>Divorced</td>
<td>4 (25.0%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Employment status n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Full-time</td>
<td>7 (43.8%)</td>
<td>1 (6.3%)</td>
</tr>
<tr>
<td>Part-time</td>
<td>3 (18.8%)</td>
<td>1 (6.3%)</td>
</tr>
<tr>
<td>Self-employed</td>
<td>1 (6.3%)</td>
<td>5 (31.3%)</td>
</tr>
<tr>
<td>Not employed</td>
<td>3 (18.8%)</td>
<td>6 (37.5%)</td>
</tr>
<tr>
<td>Retired</td>
<td>2 (12.5%)</td>
<td>3 (18.8%)</td>
</tr>
<tr>
<td>Occupation n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Manager/director</td>
<td>2 (12.5%)</td>
<td>1 (6.3%)</td>
</tr>
<tr>
<td>Graduate professional</td>
<td>4 (25.0%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Associate professional/technical</td>
<td>1 (6.3%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Participant demographics</td>
<td>Intervention group (n=16)</td>
<td>Care as usual group (n=16)</td>
</tr>
<tr>
<td>-------------------------------</td>
<td>---------------------------</td>
<td>----------------------------</td>
</tr>
<tr>
<td>Admin/secretarial</td>
<td>1 (6.3%)</td>
<td>2 (12.5%)</td>
</tr>
<tr>
<td>Skilled trade</td>
<td>2 (12.5%)</td>
<td>5 (31.3%)</td>
</tr>
<tr>
<td>Sales/customer services</td>
<td>1 (6.3%)</td>
<td>1 (6.3%)</td>
</tr>
<tr>
<td>Caring/leisure</td>
<td>4 (25%)</td>
<td>6 (37.5%)</td>
</tr>
<tr>
<td>Other</td>
<td>1 (6.3%)</td>
<td>1 (6.3%)</td>
</tr>
<tr>
<td><strong>Tumour stage n (%)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>III</td>
<td>6 (37.5%)</td>
<td>6 (37.5%)</td>
</tr>
<tr>
<td>IV</td>
<td>10 (62.5%)</td>
<td>10 (62.5%)</td>
</tr>
<tr>
<td><strong>Tumour site n (%)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral cavity</td>
<td>5 (31.3%)</td>
<td>3 (18.8%)</td>
</tr>
<tr>
<td>Nasopharynx</td>
<td>1 (6.3%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Oropharynx</td>
<td>9 (56.3%)</td>
<td>10 (62.5%)</td>
</tr>
<tr>
<td>Hypopharynx/larynx</td>
<td>1 (6.3%)</td>
<td>3 (18.8%)</td>
</tr>
<tr>
<td><strong>Cancer treatment n (%)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surgery</td>
<td>1 (6.3%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Radiotherapy</td>
<td>4 (25%)</td>
<td>1 (6.3%)</td>
</tr>
<tr>
<td>Surgery &amp; radiotherapy</td>
<td>1 (6.3%)</td>
<td>2 (12.5%)</td>
</tr>
<tr>
<td>Radiotherapy &amp; chemotherapy</td>
<td>9 (56.3%)</td>
<td>11 (68.8%)</td>
</tr>
<tr>
<td>All three</td>
<td>1 (6.3%)</td>
<td>2 (12.5%)</td>
</tr>
<tr>
<td><strong>Other treatment n (%)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nasogastric tube</td>
<td>4 (25%)</td>
<td>4 (25%)</td>
</tr>
<tr>
<td>Gastrostomy tube</td>
<td>10 (62.5%)</td>
<td>11 (68.8%)</td>
</tr>
<tr>
<td>Neither/NA</td>
<td>2 (12.5%)</td>
<td>1 (6.3%)</td>
</tr>
<tr>
<td><strong>Weight Baseline mean (SD)</strong></td>
<td>72.5 (15.4)</td>
<td>78.5 (15.4)</td>
</tr>
<tr>
<td><strong>BMI Baseline mean (SD)</strong></td>
<td>24.7 (3.8)</td>
<td>27.1 (4.2)</td>
</tr>
</tbody>
</table>

### 8.3.2 Flow of patients through the trial

An illustration of the flow of participants randomized to either care as usual or intervention groups is shown in Figure 8-3. Although data were missing from some patients at some time-points, no patients formally dropped out of the study. Three patients died over the course of the study, all related to the cancer.
8.4 Research Processes and completeness of data collection

Over the course of the feasibility study, the researcher kept diary notes that were anticipated to provide useful information about research processes such as protocol implementation and data collection. This qualitative information is reported here to supplement the more quantitative data presented in the results.

8.4.1 Protocol Implementation

Prior meetings and/or presentations to key individuals involved with the study seemed to be an important element in ensuring good compliance with the study protocol. Members of the multidisciplinary team were made aware of the study through a formalized MDT research presentation where support for recruitment
was obtained. The main hurdle was making certain that consultants in a busy clinic remembered to mention the study to patients flagged during the pre-screening, and that relevant patients were introduced to either the researcher or research facilitator. Where possible, this situation was managed by the researcher/research facilitator ensuring they were visible to the consultant when the relevant patient was called into the consulting room. A typical head and neck cancer clinic at UCLH may have up to 10 consultant surgeons and oncologists and occasionally patients were missed and not provided with a patient information leaflet if the researcher was busy with another patient or simply not visible to the consultant. Midway through the study, a study card and patient information sheet was attached to the front of the patient’s notes as a safeguard and prompt to the consultant. The recruitment process was generally considered to work well, but it was highly dependent on the researcher and/or research facilitator being present and visible in the weekly clinics.

The clinical speech and language therapy team also received training for their role in collecting clinical outcomes and good support was attained from all team members. It may be observed in the next section (Table 8-3) that swallowing outcome measures were most complete at baseline and six months. This was probably because additional support from the research facilitator was available at these two time-points. The research facilitator met patients on the day of their 6-month MBS swallow assessment to collect final questionnaires, and ensured that clinicians completed the clinical outcome measures prior to the MBS procedure. Outcome measures collected at 1-month and 3-months were less complete as these measures were collected during routine clinic appointments scheduled to coincide with these time-points. SLT clinicians were less likely to make additional efforts to obtain the outcome measures at these time-points most possibly due to time constraints, forgetting, or perhaps not having relevant resources at hand (for example, 100mL of water for the water swallow test or TheraBite measure to obtain maximal incisor opening). A few patients also failed to attend these appointments but were happy to complete questionnaires and return them by post. Clinical outcome measures were therefore missing for these patients. If these time-points
are to remain in a future trial, some adjustments may be necessary to improve collection of data.

Finally, it was important to ascertain any resource barriers to the inclusion of a modified barium swallow (MBS) procedure both as part of the intervention, and at 6-months as a swallowing outcome measure. At UCLH, the head and neck SLT team have a twice-weekly clinic for performing MBS assessments. This feasibility study made provision for the possibility that the MBS procedure may need to be carried out outside of these clinic slots. However, this was only necessary for one patient. All other patients were accommodated without difficulty into the existing clinic slots. The study protocol required a standardized assessment and evaluation using the Modified Barium Swallow Impairment Profile (Martin-Harris et al., 2008). All members of the clinical speech and language therapy team undertook this training prior to their involvement with the study. This was therefore not a barrier during the feasibility study, but may present as such in a further trial. Offering training as part of a future multi-centre trial may incentivize clinicians to get involved with the study.

8.4.2 Collection and completeness of swallowing outcomes

The quality assessment tool used in Study 1 (van Tulder et al., 2003) recommends that missing data for a longer term trial should be under 30%, meaning that minimum data completeness for each measure should be at least 70%.
Table 8-3  Completeness of swallowing outcome measures across time-points for both groups

<table>
<thead>
<tr>
<th>Measure</th>
<th>Obtained Intervention [INT] no (%)</th>
<th>Obtained Care as usual [CAU] no(%)</th>
<th>Comments or reasons for non-completion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline (T0) [expected INT = 16, CAU =16]</td>
<td></td>
<td></td>
<td>One patient did not complete questionnaires at appointment, and did not respond to requests to return them at next visit.</td>
</tr>
<tr>
<td>FACT</td>
<td>16 (100)</td>
<td>15 (94)</td>
<td></td>
</tr>
<tr>
<td>MDADI</td>
<td>16 (100)</td>
<td>15 (94)</td>
<td></td>
</tr>
<tr>
<td>PSS (normalcy of diet)</td>
<td>16 (100)</td>
<td>16 (100)</td>
<td></td>
</tr>
<tr>
<td>100mL WST</td>
<td>16 (100)</td>
<td>16 (100)</td>
<td></td>
</tr>
<tr>
<td>FIGS (swallowing)</td>
<td>16 (100)</td>
<td>16 (100)</td>
<td></td>
</tr>
<tr>
<td>MIO (jaw opening)</td>
<td>16 (100)</td>
<td>16 (100)</td>
<td></td>
</tr>
<tr>
<td>One Month (T1) [expected INT =16, CAU = 15]</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FACT</td>
<td>13 (81)</td>
<td>15 (100)</td>
<td></td>
</tr>
<tr>
<td>MDADI</td>
<td>13 (81)</td>
<td>15 (100)</td>
<td></td>
</tr>
<tr>
<td>PSS</td>
<td>14 (88)</td>
<td>14 (93)</td>
<td></td>
</tr>
<tr>
<td>100mL WST</td>
<td>*13 (81)</td>
<td>*10 (67)</td>
<td></td>
</tr>
<tr>
<td>FIGS</td>
<td>14 (88)</td>
<td>14 (93)</td>
<td></td>
</tr>
<tr>
<td>MIO</td>
<td>14 (88)</td>
<td>12 (80)</td>
<td></td>
</tr>
<tr>
<td>Three Months (T2) [expected INT = 15, CAU=15]</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FACT</td>
<td>11 (73)</td>
<td>12 (75)</td>
<td></td>
</tr>
<tr>
<td>MDADI</td>
<td>11 (73)</td>
<td>12 (75)</td>
<td></td>
</tr>
<tr>
<td>PSS</td>
<td>11 (73)</td>
<td>8 (53)</td>
<td></td>
</tr>
<tr>
<td>100mL WST</td>
<td>*8 (53)</td>
<td>*8 (53)</td>
<td></td>
</tr>
<tr>
<td>FIGS</td>
<td>11 (73)</td>
<td>8 (53)</td>
<td></td>
</tr>
<tr>
<td>MIO</td>
<td>11 (73)</td>
<td>8 (53)</td>
<td></td>
</tr>
</tbody>
</table>
Table 8-3 shows the completeness of the data collected on all swallowing outcome measures across the four time-points. The measure with the least completeness across time-points was the water swallow test (WST). At one and three months, several patients were scored as zero because clinicians felt tentative about asking patients to drink 100mL of water continuously in the acute stage post treatment or because patients stated that this was not something they could do. It was also noted that for a brief period the water dispenser in the clinic was not available, and the WST was therefore not performed during the consultation. This omission was only discovered during the data input stage but highlights the importance of recognizing that outcome measures collected during a busy clinic are likely to be compromised if necessary resources are not readily available. In a future trial, it may be prudent to carry out periodic checks to ensure that study resources are readily available, and to highlight to clinicians the need to communicate such issues to the principal investigator as early as possible. For most other measures, a

<table>
<thead>
<tr>
<th>Measure</th>
<th>Obtained Intervention [INT] no (%)</th>
<th>Obtained Care as usual [CAU] no (%)</th>
<th>Comments or reasons for non-completion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Six Months (T3)</td>
<td></td>
<td></td>
<td>Improvement in collection of most measures in comparison to 3- months as patients were attending for their MBS swallow assessment at the same time as clinical measures were taken.</td>
</tr>
<tr>
<td>FACT</td>
<td>12 (80)</td>
<td>13 (93)</td>
<td></td>
</tr>
<tr>
<td>MDADI</td>
<td>12 (80)</td>
<td>13 (93)</td>
<td></td>
</tr>
<tr>
<td>PSS</td>
<td>13 (87)</td>
<td>12 (86)</td>
<td></td>
</tr>
<tr>
<td>100mL WST</td>
<td>13 (87)</td>
<td>12 (86)</td>
<td></td>
</tr>
<tr>
<td>FIGS</td>
<td>13 (87)</td>
<td>12 (86)</td>
<td></td>
</tr>
<tr>
<td>MIO</td>
<td>13 (87)</td>
<td>12 (86)</td>
<td></td>
</tr>
<tr>
<td>*MBS Impairment Profile Score</td>
<td>9 (60)</td>
<td>10 (71)</td>
<td>Due to a technical issue – MBS exams could not be rated for 7 patients (INT =4, CAU =3)</td>
</tr>
<tr>
<td>PAS Score</td>
<td>9 (60)</td>
<td>10 (71)</td>
<td>3 patients declined to have the 6-month MBS (INT=2, CAU =1)</td>
</tr>
</tbody>
</table>

* MBS procedure performed on both groups at the final 6-month time-point only
minimum threshold of 70% for each outcome measure was achieved within both study groups (see Table 8-3).

The only other exception to the minimum target for data completeness was the modified barium swallow (MBS) procedure and the penetration-aspiration scale (PAS) where the intervention group achieved just 60%. This was due to a technical problem that occurred when a power surge damaged the equipment with some of the MBS examinations (seven exams from the 6-month endpoint) rendering them unreadable for rating. The number of patients who actually had the MBS procedure was 87% for the intervention group and 93% for the care as usual group. Without the technical incident, data completeness for the MBS and PAS measures would therefore have exceeded the minimum 70% threshold.

The incident was logged according to local R&D and governance requirements. Despite efforts to retrieve the data by an expert data retrieval company (approved by hospital IT and Governance), the data could not be salvaged in a timely manner for inclusion in this thesis. The incident was an unexpected occurrence but one which will need to be considered during a future trial where such assessments will take place at multiple sites with different equipment. Three patients declined to have the 6-month MBS; two reported that their swallowing had improved and they could not attend the appointment within the required timeframe and the other reported that he did not wish to have further exposure to radiation after completing his treatment. While not examined in this study, it is worth noting that if patients who feel they are doing well decline to have the final MBS, this may introduce systematic bias into the results if the best performing patients are missing from the final outcomes. Missing data and drop-outs may therefore change the balance of the groups and will need to be monitored in a future study.

The improvement in overall patient response rate at 6-months for other outcome measures may partly be attributed to the fact that more patients were keen to attend the MBS assessment. From researcher notes, several patients reported that they felt that the x-ray of their swallow was a good way of verifying that they were recovering with swallowing, or as a means of seeking further help if necessary.
For the remaining outcome measures, complete datasets across the four time-points were available for eight patients in the intervention group and 11 in CAU. Excluding the three patients who died, this figure represents an overall total of 66%. If only the baseline and the 6-month endpoint are considered, the figure increases to 86%. This means that despite having multiple outcome measures, data completeness was at 86% when considering the baseline and the 6-month endpoint. While none of the patients dropped out of the study, loss of data due to missing information was 14% when considering the baseline and 6-month endpoint. Patients treated for head and neck cancer usually show a decline in function in the immediate post-treatment phase with gradual recovery over the following months until more stable functioning is achieved at around 6-months after treatment (Patterson et al., 2014; Roe et al., 2014). The pattern of data for all swallowing outcome measures in this feasibility study showed a similar trend. It may therefore be appropriate to consider whether the research process in a future trial would be better served by having just two time-points (baseline and 6-month) for data collection, thereby ensuring a higher percentage of data completeness.

8.4.3 Collection and completeness of adherence data

The criterion stipulated for adherence in the protocol was based on the best available estimate from the literature at the time of devising the protocol (Mortensen et al., 2015). The success criterion would be met if at least 35% of patients in the intervention group reported overall satisfactory to good adherence to the swallowing exercises based on the data from the study specific adherence form (see protocol section 7.3. for description and scoring information). The adherence form was given to both groups, as patients in the CAU group also received a sheet of general exercises at their pre-treatment consultation. Adherence data was gathered at 1-month, 3-months, and 6-months and reflected a composite estimate based on patient reports of their exercise adherence over the preceding month. As was the case with other measures, some patients did not complete the adherence forms. However, sufficient information was still obtained. The completeness of adherence data at each time-point was 77% (24), 70% (21) and
83% (24) respectively, after accounting for the three deaths. Figure 8-4 shows the percentage of patients within each group who demonstrated satisfactory to good adherence based on the responses to the adherence form.

![Percentage of patients with satisfactory to good adherence](image)

**Figure 8-4:** Percentage of patients who reported satisfactory to good adherence across time-points

As can be seen in Figure 8-4, satisfactory to good adherence was greater than the 35% minimum threshold for the intervention group across all time-points thus meeting the stipulated criterion. The results also show comparatively good adherence from the CAU group. Possible explanations for these findings will be elaborated upon in the Discussion.

A summary of the reasons patients noted in response to the question ‘what had helped or hindered them doing their exercises’ is presented in Table 8-4.
Table 8-4: Summary of reasons that helped or hindered undertaking exercises

<table>
<thead>
<tr>
<th>Barriers</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>No time due to several hospital appointments</td>
<td></td>
</tr>
<tr>
<td>Pain in mouth</td>
<td></td>
</tr>
<tr>
<td>Lack of energy</td>
<td></td>
</tr>
<tr>
<td>Doing other exercises for lymphoedema</td>
<td></td>
</tr>
<tr>
<td>Loss of interest in exercises</td>
<td></td>
</tr>
<tr>
<td>Exercises do not seem to be helping - still having difficulty swallowing</td>
<td></td>
</tr>
<tr>
<td>Not strict enough about creating a routine</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Facilitators</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Not working so more time to do exercises</td>
<td></td>
</tr>
<tr>
<td>Family make sure I do them</td>
<td></td>
</tr>
<tr>
<td>Filling in my calendar</td>
<td></td>
</tr>
<tr>
<td>It’s become a routine</td>
<td></td>
</tr>
<tr>
<td>Would like to have feeding tube removed</td>
<td></td>
</tr>
<tr>
<td>Want to get back to eating and enjoying food</td>
<td></td>
</tr>
<tr>
<td>Can see improvement in mouth opening, tightens up when not exercising</td>
<td></td>
</tr>
</tbody>
</table>

Most reasons listed have arisen previously in the patient interview study reported in Chapter 4. The above summary does not distinguish between the groups. However, such an analysis in a future trial may yield interesting information as to how helpful patients find specific intervention strategies aimed at reducing barriers and enhancing facilitators.

8.5 Candidate outcome measures and sample size estimation

Several different measures to assess swallowing were collected with a view to determining which measure would be most suitable for a primary outcome in a definitive trial. In choosing a possible primary outcome, it is important to find a valid and reliable measure that can be easily collected, shows a reasonable effect size and/or has a known minimum clinically important difference (MCID). Specific information about the ease of collection and data completeness for each outcome measure has been reported in the previous section. This section presents data on
the performance of each outcome measure and provides the necessary data for informing a sample size calculation for a future trial.

8.5.1 Choice of outcome measure and parameters for estimating sample size

The calculation of an adequate sample size is an essential part of planning a clinical trial to ensure that the sample is sufficiently large to detect the difference between groups and that results can be generalized to the population. Equally, a sample that is too large will needlessly expose participants to an intervention often at great financial cost (Noordzij et al., 2010). Key parameters for estimating sample size may be derived from a pilot or feasibility study and combined with knowledge from the literature about what constitutes clinically relevant differences between groups (Coon & Cappelleri, 2016).

Table 8-5 displays the main swallow related outcome measures illustrating the mean, standard deviation and 95% confidence interval at baseline and at the final time-point for each measure. While the sample mean provides a single summary statistic, the confidence intervals reflect the range of values within which the population mean can be expected to lie (Gardner & Altman, 1986), thereby providing further useful information. Standard deviation offers an index of the variability between patients on each outcome of interest. It is also useful to estimate the potential magnitude of any difference that the new SIP may produce in the intervention group compared with CAU. This is represented by calculating an effect size using Cohen’s d (Sullivan & Feinn, 2012). Effect size varies for each outcome, and in some cases, small effect sizes may still produce clinically relevant changes at patient level.
Table 8-5: Swallow related outcomes and between group effect sizes

<table>
<thead>
<tr>
<th>Outcome measure</th>
<th>Group</th>
<th>Baseline (T0) mean (±95% CI) SD</th>
<th>Between-group effect size (Cohen’s d)</th>
<th>6-months (T3) mean (±95% CI) SD</th>
<th>Between-group effect size (Cohen’s d)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>FACT-H&amp;N and MDADI: [n(baseline) intervention=16 CAU=15; n (T3) intervention=12 CAU=13]</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FACT-H&amp;N total score</td>
<td>Intervention</td>
<td>104.38 (91.74-117.02) 23.71</td>
<td>0.14</td>
<td>89.98 (79.24-100.72) 16.9</td>
<td>0.83</td>
</tr>
<tr>
<td></td>
<td>Care as usual</td>
<td>101.28 (89.03-113.54) 22.13</td>
<td>0.16</td>
<td>76.9 (68.02-85.78) 14.69</td>
<td>0.83</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MDADI Composite</td>
<td>Intervention</td>
<td>83.49 (75.17-91.81) 15.62</td>
<td>0.36</td>
<td>69.74 (56.42-83.05) 20.95</td>
<td>0.61</td>
</tr>
<tr>
<td></td>
<td>Care as usual</td>
<td>77.82 (68.93-86.72) 16.06</td>
<td>0.39</td>
<td>59.35 (52.03-66.67) 12.11</td>
<td>0.61</td>
</tr>
<tr>
<td><strong>Other measures: [n(baseline) intervention=16 CAU=16; n (T3) intervention=13 CAU=12]</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MIO - Jaw opening</td>
<td>Intervention</td>
<td>46.25 (39.44-53.06) 12.78</td>
<td>-0.15</td>
<td>43.00 (37.24-48.76) 9.53</td>
<td>0.68</td>
</tr>
<tr>
<td></td>
<td>Care as usual</td>
<td>47.81 (43.83-51.99) 9.84</td>
<td></td>
<td>34.33 (24.56-44.10) 15.38</td>
<td></td>
</tr>
<tr>
<td>PSS HN Normalcy of diet</td>
<td>Intervention</td>
<td>70.00 (56.24-83.76) 25.82</td>
<td>-0.22</td>
<td>70.00 (52.21-87.79) 29.44</td>
<td>0.30</td>
</tr>
<tr>
<td></td>
<td>Care as usual</td>
<td>75.63 (62.43-88.82) 24.76</td>
<td></td>
<td>60.83 (41.21-80.46) 30.88</td>
<td></td>
</tr>
<tr>
<td>FIGS Swallowing</td>
<td>Intervention</td>
<td>4.25 (3.84-4.66) 0.78</td>
<td>-0.35</td>
<td>4.15 (3.42-4.89) 1.21</td>
<td>0.53</td>
</tr>
<tr>
<td></td>
<td>Care as usual</td>
<td>4.50 (4.11-4.89) 0.73</td>
<td></td>
<td>3.50 (2.71-4.29) 1.24</td>
<td></td>
</tr>
<tr>
<td><strong>MBS and PAS at T3: (intervention =9 CAU =10) – not performed for both groups at baseline</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PAS</td>
<td>Intervention</td>
<td></td>
<td></td>
<td>3.67 (1.24-6.10) 3.16</td>
<td>0.13</td>
</tr>
<tr>
<td></td>
<td>Care as usual</td>
<td></td>
<td></td>
<td>3.3 (1.36-5.24) 2.71</td>
<td></td>
</tr>
<tr>
<td>MBS Imp (composite)</td>
<td>Intervention</td>
<td></td>
<td></td>
<td>6.44 (4.49-8.38) 2.53</td>
<td>0.24</td>
</tr>
<tr>
<td></td>
<td>Care as usual</td>
<td></td>
<td></td>
<td>5.96 (5.05 – 6.86) 1.27</td>
<td></td>
</tr>
</tbody>
</table>
Table 8-5 shows that effect sizes were large for the FACT-HN (≥ 0.8) and moderate for the MDADI, MIO and FIGS (≥ 0.5) based on the common classification proposed for interpreting Cohen’s d (Sullivan & Feinn, 2012). Published data suggest that an actual difference of 5-12 points on the FACT-HN (Ringash et al., 2004) and 10 points on the MDADI and PSS-HN are generally regarded as clinically meaningful (Hutcheson et al., 2016). The FACT-HN demonstrated the best effect size but may be too generic and more suitable as a secondary outcome. MIO focuses on jaw opening only and is therefore too narrow to capture swallowing function but could also provide useful information as a secondary measure. It is perhaps the easiest measure by which to observe changes that may occur if patients adhere well to their exercises. While the MBS composite score might be the most appropriate measure of swallow physiology, the scoring system is yet to be validated, and it is much more challenging to obtain complete data on this measure. Due to the low numbers available for analysis at 6-months, estimating sample size parameters for this measure were compromised. The PSS-HN is a validated measure (List et al., 1990), easy to collect and could be used as a summary score for swallow function. In this feasibility study, the effect size was relatively small thus requiring a large sample size to detect clinically important changes (calculated to be 340 + 82 accounting for 24% attrition). The MDADI met most criteria for a primary outcome measure and showed a moderate effect size. On balance from the measures available, the MDADI was considered the most suitable selection for a primary outcome. Sample size is therefore estimated for the MDADI patient reported outcome.

8.5.2 Estimation of sample size

An online calculator (http://www.openepi.com) was used to estimate sample size. As noted, variance was much greater in the intervention group than CAU. A pooled standard deviation was therefore used for the calculation (Noordzij et al., 2010).
Table 8-6: Calculation of sample size for comparing two means

<table>
<thead>
<tr>
<th>Input Data</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Confidence Interval (2-sided)</td>
<td>95%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Power</td>
<td>80%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ratio of sample size (Group 2/Group 1)</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Group 1</strong></td>
<td><strong>Group 2</strong></td>
<td><strong>Difference</strong>*</td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>69.74</td>
<td>59.35</td>
<td>10.39</td>
</tr>
<tr>
<td>Standard deviation</td>
<td>20.95</td>
<td>12.11</td>
<td></td>
</tr>
<tr>
<td>Variance</td>
<td>438.903</td>
<td>146.652</td>
<td></td>
</tr>
<tr>
<td>Sample size of Group 1</td>
<td>43</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sample size of Group 2</td>
<td>43</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total sample size</td>
<td>86</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Difference between the means

The calculation is based on estimates for a parallel group RCT with a continuous outcome, 95% confidence interval (alpha level = 0.05) and power of 80%. Using the data obtained from the feasibility study, the sample size required if the MDADI were the primary outcome would be 86 (43 in each group). Based on this feasibility study, the figure will need to be inflated by 10% for attrition due to death and an estimated 14% due to missing data. A sample size of 106 will be required for a future 2-arm parallel group trial.

8.6 Summary of success criteria for the feasibility study

The criteria for success specified in the protocol are summarized in Table 8-7.
Table 8-7: Feasibility criteria for success

<table>
<thead>
<tr>
<th>A priori criteria</th>
<th>Findings</th>
<th>Criterion met? (yes/no)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Criterion 1:</strong> Determine suitable outcome measure, estimate sample size.</td>
<td>MDADI selected. 106 patients will be required for a 2-arm parallel group trial.</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Criterion 2:</strong> Average recruitment of 4 patients a month/ 32 patients over 8-months of recruitment.</td>
<td>32 patients narrowly achieved over an 8-month duration, averaging 4 patients a month.</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Criterion 3:</strong> Patients report more positive than negative views toward participation and randomization.</td>
<td>Questionnaire responses indicate a greater number of positive than negative views toward participation and randomization.</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Criterion 4:</strong> Minimum 35% of intervention group report satisfactory to good exercise adherence.</td>
<td>More than 35% of intervention group respondents reported satisfactory to good adherence.</td>
<td>Yes</td>
</tr>
</tbody>
</table>

8.7 Discussion

SIP SMART is a pre-treatment swallowing intervention for newly diagnosed head and neck cancer patients. The feasibility of conducting a definitive trial to determine whether SIP SMART improves swallowing outcomes post-treatment relative to care as usual was examined. The four main criteria specified in the protocol to determine success from the feasibility trial were satisfied: the target recruitment (32 patients) was achieved at an average rate of four patients a month, the MDADI was identified as a suitable primary outcome for which sample size was estimated, patient responses to the questionnaire on acceptability and randomization was mainly positive and the minimum reported adherence for the intervention group was attained. Furthermore, information on factors affecting recruitment, data collection processes, barriers to protocol implementation and reasons for attrition were identified and explained using quantitative data and researcher observations. An important aim of the feasibility study was to explore a range of swallowing outcome
measures and to examine how they compare. The wide variation in the use of different outcomes for assessing prophylactic swallowing interventions has previously been reported to be a significant impediment to evidence synthesis (Perry et al., 2016; Cousins et al., 2013). Therefore, this issue is discussed in greater detail in the next section.

8.7.1 Challenges in selecting a primary outcome

Identifying a commonly agreed primary outcome within a specific disease entity is a widely pervasive problem across many health disciplines. One response to addressing this problem has been the COMET initiative (Core Outcome Measures in Effectiveness Research), set up to facilitate the process of streamlining the core outcome measures that should be collected in clinical trials of a particular disease specific population (Prinsen et al., 2014). This initiative proposes some helpful definitions. An outcome refers to what is being measured and may be, for example, a construct, concept or domain. In a clinical trial, it is usually the result (outcome) arising from exposure to a causal factor or health intervention. An outcome measurement instrument refers to how the outcome is being measured such as a questionnaire, a laboratory measurement, an imaging test or a clinical assessment (Prinsen et al., 2014). In the COMET initiative, disease specific outcome measures are recommended by an expert panel based on a number of criteria including whether the outcome measurement instruments are valid and reliable with acceptable psychometric properties. The COMET website (http://www.comet-initiative.org) lists two reference papers relevant to measuring core outcomes in head and neck cancer trials that are applicable to this feasibility study (Chera et al., 2014; Ringash et al., 2015). These papers recommend the use of the following measures: the modified barium swallow (MBS - imaging test), Performance Status Scale for head and neck (PSS - clinician rated measure based on interview), MD Anderson Dysphagia Inventory (MDADI – swallowing related QOL measure), Functional Assessment of Cancer Therapy (FACT HN - patient-reported QOL questionnaires), and/or the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-30). These instruments are
believed to be the best available measures of the different dimensions of swallowing for the head and neck population, and consequently were included in the current feasibility trial. It may be argued that as swallowing is a multi-dimensional construct, outcome measures should incorporate physiological, functional and QOL domains. As a result, most swallowing trials examined in the systematic review included multiple outcome measures. This has not been the main problem, but with a poor record of published protocols, a single primary outcome was often not specified. Failure to specify the primary outcome increases the likelihood of reporting the success of a trial based on the most favourable outcome and makes pooling of evidence challenging (Heneghan, Goldacre & Mahtani, 2017). The COMET initiative provides the benefit of a more streamlined toolbox of best available measures, but it does not recommend a primary outcome. It remains incumbent on clinical researchers to decide a-priori about the primary outcome measure on which to estimate sample size, and on which to determine the intervention efficacy (Andrade, 2015). In practice, this recommendation is likely to be improved by the recent publication of a patient reported outcome extension to the SPIRIT guidelines (Calvert et al., 2018) that requires both primary and secondary outcomes to be specified in advance of the conduct of the trial.

Given the choice of multiple potentially relevant outcome measures for a swallowing intervention for head and neck cancer patients, one possible solution is to consider all measures on a continuum of how closely they align to the target intervention. This has been previously referred to as a proximal – distal continuum (Brenner, Curbow & Legro, 1995). In the case of swallowing exercise interventions, the concepts of swallow safety (airway protection), and swallow efficiency (transit of food bolus) were selected as the primary outcomes in the latest Cochrane review of swallowing exercises (Perry et al., 2016). Swallowing safety and efficiency are arguably the main parameters that the exercise intervention is postulated to affect and thus considered more closely aligned (proximal measure) to the intervention than for example, the Functional Assessment of Cancer Therapy questionnaire that provides a measure of more general health related QOL. The more distal the outcome measure, the more likely that other factors aside from the intervention
may influence the outcome (Brenner, Curbow & Legro, 1995). For SIP SMART, while swallow safety was measured using the Penetration-Aspiration Scale (Rosenbek et al., 1996), and swallow efficiency was computed from a modified barium swallow score, these measures derived from the x-ray assessment were found to be sometimes challenging and often time-consuming to obtain in this feasibility study.

Conversely, clinician rated measures of diet texture (PSS-normalcy of diet) and patient reported QOL measures showed the highest percentage for data completeness in the feasibility trial. Other factors influencing the choice of a primary outcome measure include its importance to patients and clinicians and whether the minimum clinically important difference (MCID) is known (Andrade, 2015). It is therefore also important to reflect on which of these measures would be the most relevant to patients and policymakers (Heneghan, Goldacre & Mahtani, 2017).

The choice of a primary outcome measure may therefore be a compromise in finding the best, validated measure that is most closely approximated to the intervention objective, and best satisfies the factors mentioned above. In the UK, there has been some attempt to harmonize the outcome measures used in head and neck cancer trials measuring dysphagia as an outcome (Patterson, Brady & Roe, 2016). Recent clinical trial protocols specified the MD Anderson Dysphagia Inventory as a primary outcome (Owadally et al., 2015; Petkar et al., 2016). The target interventions in these trials were not swallowing interventions per se. Instead, these interventions aimed to minimize the negative impact on swallowing by reducing target dose of radiation to specific anatomical structures (dysphagia-aspiration related structures) important in swallowing.

In this feasibility study, an independent assessment was made of the range of COMET measures suggested for dysphagia trials in head and neck cancer. Based on the favourable data from this feasibility trial and the explanations provided above, the MD Anderson Dysphagia inventory was identified as the current best available outcome measure for a larger trial. This does not preclude the inclusion of the other measures suggested by the COMET initiative as secondary outcomes. Also, as other
measures of swallow functioning are developed and validated, it may be possible to consider an outcome that is more proximal to the target intervention.

8.7.2 Practical lessons for a future trial

The recruitment strategy of using the weekly multidisciplinary meeting list for pre-screening worked well and would be relatively straightforward to implement in a larger multi-centre trial. However, it was clear that the number of patients who proceed to be recruited to the trial is difficult to estimate from the multidisciplinary meeting lists for a variety of reasons. In a future trial, it may be important to map the different treatment pathways that exist at each centre, and to clarify how these will impact eligibility for inclusion in the trial. Ensuring that all members of the MDT are familiar with the trial makes it easier to approach patients during the clinical consultations. A particularly useful strategy was to flag potential patients to the treating consultant at the start of the clinic, and to ensure a study card was attached to the front of the medical notes so that the clinical researcher could be alerted when the patient was being seen. This was a simple strategy that could be replicated in a larger trial provided that adequate research nurse support is also available. Given the very narrow window of opportunity to enrol patients onto this pre-treatment intervention study, these strategies would need to be well implemented and have full MDT support to achieve good recruitment.

Another factor that may influence recruitment is the challenge presented by language barriers. Given the diversity of patients who are likely to present with head and neck cancer, a significant proportion will be excluded from participation unless specific provision is made for translation services for patients without sufficient proficiency in English. Methods such as the use of NHS language line phone services or using relatives to translate are unsuitable within the context of this clinical trial. Use of interpreter services may therefore need to be built into study costs.

The method used for randomization was well received by both patients and clinicians, as it was transparent and done immediately after consent. Once the
relevant data was entered onto the study website, patients were offered the 
opportunity to press the key on the computer to randomize. This simple gesture 
was popular with patients. An email with the allocation group was received almost 
instantly ensuring that the allocation was concealed until the point at which both 
the patient and researcher were made aware of the outcome simultaneously. The 
element of chance was therefore apparent to patients possibly increasing their 
acceptance. Previous research has indicated that patients may decline participation 
in trials if they have a preference for one arm of the trial or if they are worried 
about the idea of randomization (Jenkins & Fallowfield, 2000). From the 
questionnaire responses in this feasibility study, no patients indicated that they 
were concerned about being randomized. This suggests that patients understood 
the concept of chance and were satisfied that either the new intervention or CAU 
would be suitable. No patients dropped out following randomization. However, 
one patient expressed great disappointment at not being allocated to the 
intervention but understood the random nature of the allocation. This patient 
remained in the trial but declined to have the final MBS assessment. The reasons 
reported for participation in this trial were consistent with those reported in other 
cancer trials (Jenkins & Fallowfield, 2000). It is therefore expected that patients 
would be no less likely to agree to participate in a future larger trial, despite 
recruitment occurring at a difficult time pre-treatment.

8.7.3 Other considerations for a future trial

It is noteworthy that three patients died (approximately 10%) over the duration of 
this trial, an important consideration given the nature of the disease and expected 
survival. This study did not distinguish between cancers that were HPV positive 
(better prognosis and survival) and those that were not. A study sample with 
greater numbers of advanced cancer due to non-HPV positive disease may 
therefore show greater attrition due to generally poorer survival.

The pattern of data completeness was highest at baseline and 6-months. Patients 
who did not complete outcomes over the interim time-points failed to do so mainly 
because they did not attend their hospital appointment during the time-frame in
which the interim measures were collected. Overall, missing data at 6-months was under 30%, and generally considered acceptable for longer term outcomes (van Tulder et al., 2003). Patient-reported questionnaires showed most completeness in data collection suggesting that this type of measure may be easiest to collect in a future trial.

Several study-related forms were devised for the feasibility study and most could be used in a larger trial. Some may require modification. The case report form, for example, was detailed, and it may be possible to reduce the amount of information collected. In this study, information on smoking and alcohol could be reduced to simpler yes/no questions without the level of detail included in the current case report form.

This feasibility study made use of a study specific form to capture information on exercise adherence. The target was to obtain a minimum of 35% of patients achieving at least satisfactory to good adherence based on figures reported in a previous similar trial undertaken in Europe (Mortensen et al., 2015). There remains much debate about how to measure adherence to swallowing exercises. Some researchers have suggested that adherence should be measured in terms of both frequency and intensity of exercises, highlighting the challenges for measuring adherence in clinical trials (Wells & King, 2017; Krekeler et al., 2017). It is possible that the measurement method used in this study was too generalized, and that figures were consequently better than might be expected if more stringent criteria were applied. In the absence of any formal measure, the study specific form devised for SIP SMART used a combination of questions (reflecting frequency and intensity) to classify responses into satisfactory to good versus poor to no adherence. Further work may be necessary to ascertain whether a more suitable method may be available to capture adherence in a larger trial or whether the current method provides a good enough reflection of adherence given that most current methods rely on patient self-report. Researcher effort and patient burden involved in obtaining more detailed and specific adherence information will be important considerations when making this decision in a future trial.
8.7.4 Limitations of the feasibility study

This study was conducted as part of a doctoral fellowship. The researcher was therefore a key driver in the study and may have acted as a facilitator for successful recruitment, as well as for the success of some of the research processes. For this success to be replicated, it will be crucial to identify key individuals (principal investigators) to drive the project and enlist a similar level of multidisciplinary support at other sites. Failure to ensure this is likely to be met with poorer recruitment in a larger trial.

For the feasibility trial, implementation of the intervention was done solely by the clinical researcher and was therefore well controlled. The researcher was able to accommodate performing the pre-treatment MBS that was part of the new intervention at short notice. Patients in the care as usual group did not receive a baseline MBS, as it was not part of usual care. This would have required additional resources from the clinical team. Practical implementation of the protocol will therefore need to be carefully planned for each site taking into account available resources. Further to this, it will be necessary for some training in the new intervention so that it can be delivered with good fidelity. These aspects have not been addressed by the current feasibility study.

Patients, clinicians and the researcher were all aware of group allocation as blinding was not attempted in this feasibility trial. The researcher was not involved with the collection of outcome data and made every effort to maintain distance until the completion of the study. Improved processes to ensure blinding should be further explored prior to a definitive trial.

It is perhaps also a limitation that a qualitative interview with participants at the end of the study was not undertaken. This may have provided valuable information for further refinements of the intervention itself and/or the study processes. However, given the time constraints this could not be accommodated as part of the current programme of work.
8.8 Conclusions

SIP SMART is a feasible intervention that can be accommodated in a typical NHS pre-treatment head and neck cancer pathway. A few important issues need to be addressed prior to proceeding to a main trial. This includes training of other speech and language therapists to deliver the intervention and considering practical implementation of the protocol at different hospital sites. Such issues could be addressed in a small-scale multi-centre pilot study prior to a definitive trial.
Chapter 9  General Discussion and Conclusions

9.1  Overview

In this chapter, I will provide 1) a summary of work undertaken and the main findings, 2) a reflection on how the studies worked together to inform the new intervention, 3) limitations of this work, 4) next steps for intervention development and testing, 5) reflections on the methodology, 6) a comparison of this work with the latest studies in the field of dysphagia in patients with head and neck cancer, 7) contribution of this work to policy, practice and future research and 8) concluding remarks.

9.2  Summary of work undertaken and main findings

Dysphagia has been identified as a highly prevalent and significant morbidity of head and neck cancer and its treatment (Wilson et al., 2011; Metcalfe, Lowe & Rogers, 2014; Moore et al., 2014; Rogers et al., 2016). As the prevalence of head and neck cancer continues to increase, primarily due to the human papilloma virus, many younger people are now affected and living longer with significant swallowing morbidities (see Chapter 1). A pre-treatment swallowing intervention incorporating prophylactic swallowing exercises has thus far presented uncertain evidence about its potential to improve swallowing function for patients after treatment (Perry et al., 2016). The case for an optimized pre-treatment swallowing intervention addressing the shortcomings from previous clinical trials was made. This thesis was structured around two main aims: 1) developing an optimized pre-treatment swallowing intervention and, 2) performing a feasibility study to gather data for informing the design and conduct of a future trial to evaluate the intervention. The ultimate goal is to improve swallowing function and quality of life for individuals treated for head and neck cancer.

The plan for the thesis was positioned within the overall structure of compatible frameworks: Evidence Based Medicine, the Medical Research Council’s framework for the development and evaluation of complex interventions, and the Behaviour
Change Wheel (see Chapter 2). The broad aims and more specific questions of the research were outlined.

Study 1 was reported in Chapter 3, and addressed the first of the research questions through a systematic review: Which behaviour change strategies were described in previous swallowing intervention trials for patients with head and neck cancer and how did they relate to intervention effectiveness? This study identified that the behaviour change techniques (BCTs) instruction on how to perform exercises, setting behavioural goals and action planning appeared in almost all swallowing exercise interventions. Self-monitoring, behavioural practice, social support and intervention delivery by a credible source were behaviour change techniques that appeared more frequently in effective interventions. While these findings were not considered to be strong evidence in light of the review limitations, they did offer a rationale for including these behaviour change strategies in the new intervention.

Study 2 was reported in Chapter 4, and provided a theory-informed analysis of patients’ swallowing exercise adherence through the identification of barriers and facilitators framed in behaviour science terms. Findings from this interview study suggested that psychological capability was the most significant component of behaviour that needed to change. Based on barriers and facilitators identified, behaviour change strategies that targeted knowledge (not understanding reasons for pre-treatment exercises), attention and decision processes and behavioural regulation (self-monitoring) were likely to change patient behaviour and improve adherence to exercises.

Study 3 was reported in Chapter 5, and explored the potential use of an active format of delivering information by showing a swallowing video-animation and eliciting patient thoughts via think-aloud methods. The findings from this study suggested that video-animation was a useful format for relaying complex information and for facilitating good patient engagement. The study did not compare multiple formats, and study limitations precluded conclusions about it being a superior format. Nevertheless, it was shown to be acceptable and useful to
patients and appeared to increase patient understanding of the swallowing mechanism and the need for swallowing exercises. It was therefore considered appropriate to include in the new intervention.

Chapter 6 described a modelling study (Study 4) that consisted of a series of steps to determine the content for the new intervention. A model was proposed illustrating that a swallowing exercise intervention comprises both exercise and non-exercise content (i.e. behaviour change content) as well as aspects of intervention delivery. Findings from the empirical studies mentioned above were combined with other sources of information. The main result of this process was the production of an outline plan for the SIP SMART intervention and the production of a draft intervention manual that could be used for feasibility testing.

The protocol for testing SIP SMART via a feasibility randomized controlled trial was presented in Chapter 7. The key parameters that the feasibility study addressed were in relation to patient recruitment, data collection processes, patient adherence and information for an appropriate primary outcome and sample size calculation.

The target recruitment of 32 patients was achieved, criteria for the completeness of data collection, and patient adherence were met, and a potential primary outcome and provisional estimate of sample size were offered (see Chapter 8). Although no formal hypothesis testing was undertaken, findings gave some indication of a positive trend in favour of the intervention.

9.3 Reflection on how the studies worked together to inform the SIP SMART intervention

This thesis comprised three empirical studies that contributed to the fourth study, formalized as a ‘desk-based modelling study’. In Study 4, multiple sources of information were combined to determine the content for the new intervention. Preparatory work undertaken to optimize a health intervention prior to its use in a clinical trial is important to reduce cost and waste in research (Levati et al., 2016).
The MRC guidelines for the development and evaluation of complex interventions (Craig et al., 2008) support the use of qualitative methods in devising intervention content. At the same time, a central tenet of the Evidence Based Medicine philosophy is that the highest level of evidence available (i.e. systematic reviews) should ideally inform clinical practice (Howick 2011; Heneghan et al., 2017). Likewise, the National Institute of Health Research recommend that a (systematic) review be undertaken (if not already available) prior to instigating a new clinical trial. Accordingly, the first study in this thesis was a systematic review, albeit one that used a non-conventional approach.

Medical and Health Sciences are gradually beginning to consider alternatives to the more traditional type of systematic review (Munn et al., 2018). At the same time that this review was being planned, a Cochrane review examining a similar question was registered and a protocol published (Perry, Cotton & Kennedy, 2014). The rationale for proceeding to undertake a separate review was to examine a similar body of literature using a behaviour science lens. The principal argument was that while the Cochrane review would provide an answer to the question ‘Does the intervention work?’, findings were unlikely to be informative about why the intervention may or may not work, and how it might be improved. Given that the primary aim of this thesis was to devise an optimized new intervention, examining the studies from a broader perspective could offer information that might be more useful. It is now well acknowledged that realist reviews can augment the traditional Cochrane type review by providing a richer source of information about how interventions could be improved (Tugwell, Knotterus & Idzerda, 2013; Moher et al., 2015a; Munn et al., 2018).

Study 1 complemented the registered Cochrane review (Perry, Cotton & Kennedy, 2014) which investigated the efficacy of pre-treatment swallowing exercises in patients with head and neck cancer. My systematic review explored which behaviour change strategies were employed in swallowing exercise interventions and how they might have been associated with intervention effectiveness. However, much more was gleaned from the review than the identification of the
key behaviour change techniques and intervention functions that appear in swallowing interventions. Proposing a ‘systems logic model’ (Figure 3-1) as part of the narrative synthesis approach (Popay et al., 2006), highlighted at an early stage the multiple factors that may impact intervention effectiveness. These ‘other’ factors were subsequently recognized and duly considered during the modelling of the new intervention. Study 1 therefore provided insights for this intervention development work beyond what might have been ascertained from the Cochrane review alone.

The literature study provided an important source of information about which behavioural strategies are used in swallowing interventions. It also highlighted that none of the studies applied any named Theory or provided a theoretical rationale for how these strategies were selected. It was therefore logical to firstly consider what the main behavioural target should be. Study 2 (Chapter 4) was undertaken to explore, using a qualitative method, why patients may or may not adhere to their swallowing exercises. Previous knowledge on this important issue has been based mainly on ad-hoc reports, clinician perceptions, and a telephone survey asking patients for reasons that prevented them carrying out their exercises (Shinn et al., 2013). Study 2 used an approach unique (to my knowledge) to the dysphagia literature on this topic, that is an in-depth theory-based interview that facilitated greater understanding of which components of behaviour to target to improve adherence.

Further to answering the question posed in Study 2 (what are the barriers and facilitators to exercise adherence?), additional analysis was performed on the interview data (discussed in Chapter 6) to generate a list of behavioural strategies that could address the barriers and support the facilitators. This analysis is part of the Behaviour Change Wheel (BCW) approach to designing interventions (Michie, Atkins & West, 2014) where one moves through a series of steps to determine which BCTs and intervention functions can be used to address the behavioural targets determined from the initial analysis of barriers and facilitators (understanding of the behaviour). In the context of the thesis, this additional
analysis provided an opportunity to corroborate the behavioural strategies identified in Study 1, providing a means of triangulating findings (Shneerson & Gale, 2015). Drawing on evidence from the literature studies and directly from patients, and applying this evidence using professional knowledge and clinical expertise as done in Study 4, is also consistent with the Evidence Based Medicine philosophy and the MRC guidelines for the development and evaluation of complex interventions (see Figure 2-1).

Studies 1 and 2 both highlighted a critical factor that appeared to be missing from current pre-treatment swallowing interventions. In Study 1, no BCTs that related specifically to patients’ knowledge and understanding of swallowing and swallowing exercises were identified in any intervention by either of the BCT coders. In Study 2, inadequate knowledge and understanding of swallowing was identified as a major barrier to patients undertaking their exercises. In other words, many of the interventions in the review focused on advising patients about performance of the behaviour, such as providing instruction on exercises and facilitating action planning. Insufficient attention was given to ensuring good knowledge and understanding, which is a precursor to intention formation and motivation to carry out the exercises. Knowledge alone is no guarantee that patients will perform their exercises. However, in this intervention knowledge may be crucial to developing behaviour intentions and initiating swallowing exercises, especially when patients may not perceive a problem at the time that the exercises are introduced. Study 3 was designed to explore a method to address this disparity.

Study 3 (Chapter 5) employed a novel think-aloud method to gather data about the usefulness and acceptability of a video-animation to convey information about the process of swallowing to patients. There were examples in the literature demonstrating that video-animation has previously been useful in improving knowledge and understanding in health interventions (Cleeren et al., 2014; Ferguson 2012; Ghisi et al., 2014). Based on the work by Leventhal, Brisette & Leventhal (2003), there also appeared to be good evidence for presenting information in a more concrete form. Video-animation represents a concrete and
active format, especially if it can be used in an interactive way. The literature suggests that active formats (such as videos) might be more likely to support behaviour change than passive formats such as an information leaflet (Albarracín et al., 2005; Wang et al., 2012). Drawing on the theoretical insights offered by the work of Leventhal, and other evidence in the literature, this exploratory think-aloud study highlighted the role that form of delivery may have on patient understanding, and possibly their subsequent behaviour.

This study also demonstrated that although the patients had already completed their treatment, they still appeared to gain a new understanding from the think-aloud task that in turn prompted some patients to voice their intention to start post-treatment exercises. This was further ‘evidence’ to suggest that patients probably did not fully understand the need for swallowing exercises when they were initially provided. Improving psychological capability was therefore likely to be more important at the pre-treatment stage in initiating a new behaviour, while a BCT such as self-monitoring may become increasingly important once the behaviour is adopted. Other determinants of behaviour such as remembering to do the exercises, and persisting with the exercises are also important to patient adherence. Patients with HNC need to initially recognize the importance of swallowing exercises, but they also need to be supported in undertaking and maintaining their exercise regime beyond completion of cancer treatment. Determinants of patient adherence for this group should be expected to change along the care pathway. It is likely that interventions will need to focus on different components of behaviour at different stages from pre-treatment through to long term survivorship when other strategies such as habit may become more relevant for maintenance of the exercises (Kwasnicka et al., 2016; Gardner, 2015).

To summarize, the SIP SMART intervention comprised both behavioural and non-behavioural content (and delivery). Findings and insights obtained from the three empirical studies described above were used in combination to support the selection of the behavioural content for SIP SMART, as this aspect was least developed within the field of dysphagia. In contrast, swallowing exercise content
was more available from the dysphagia literature, and I was also able to draw on my professional knowledge and clinical experience of working with HNC patients. Thus, the modelling of the new intervention undertaken in Study 4 benefited from the findings generated through the empirical studies, current best practice guidelines and evidence, my own professional knowledge and experience, and from the input of other SLT clinician and patient stakeholders.

9.4 Limitations of this work

Limitations of each study were discussed within individual chapters. Summarized here are the main limitations from the empirical studies that could have influenced the findings used in modelling SIP SMART.

In Study 1, certain limitations of the review process precluded firm conclusions. Studies were not excluded on the basis of the quality ratings. Risk of bias was likely to be high in the literature as a whole, as only one study achieved a good rating based on the quality assessment. This finding was consistent with that of Perry et al. (2016). Outcome measures were diverse and most studies reported results in terms of statistical significance only, which is arguably not the best indicator of intervention effectiveness (Sullivan & Feinn, 2012). Moreover, coding interventions based on published studies can only be as good as the specification of content provided by authors, which is typically poor (Abraham et al., 2014). None of the studies included in the review had published prior protocols. As non-exercise content has been poorly recognized in swallowing exercise interventions (i.e. not related to type or frequency of exercise, exercise related devices), coding such content from published reports may not have adequately resembled the intervention that was actually delivered. Despite these shortcomings, it was still possible to code BCTs and obtain a picture of which behavioural strategies appear to be reported in swallowing interventions, partly meeting the objective of the review. Given the paucity of such data in the dysphagia literature, the BCTs identified offered a good starting point for intervention development, even if the evidence for which BCTs contribute to effective interventions is currently weak.
It could be construed as a limitation that the patients recruited for Studies 2 and 3 were a group of patients not ‘newly diagnosed’ and also that the same group was used for both studies. However, given the sensitivity of this subject, and the context of this work, it was not considered ethically appropriate to conduct this study on newly diagnosed patients with head and neck cancer. Patients who had recently completed their treatment were therefore considered to be the most suitable group who could still provide the relevant information to answer the study questions. Given the time constraints, it was most efficient to design the studies in a manner that allowed both research questions to be answered using the same patient group. However, the possibility that the interview process from Study 2 could have influenced the task in Study 3 is acknowledged. As the purpose of Study 3 was exploratory, the conduct of the study was satisfactory to justify the inclusion of video-animation in the new intervention.

9.5 Next steps in the intervention development and testing work

The intervention developed in this thesis was delivered solely by me (as the researcher and clinician), at a single site during the feasibility testing and will therefore need to be tested more widely before this project can proceed to a definitive trial. Next steps will therefore include devising a training session for other SLT clinicians, refinement of the intervention manual, and decisions around if and how to monitor fidelity to intervention delivery. Given the degree of flexibility and tailoring permitted in SIP SMART, clear guidelines about the core content that must be retained will need to be specified in the treatment manual. It will also be necessary to evaluate the research process at other hospital sites. To this end, a small-scale pilot trial of four hospital sites is envisaged. Additionally, economic analysis and cost-effectiveness may be built into the next study. This plan is in keeping with the guidance from the National Institute of Health Research on the progression from feasibility trials to full-scale randomized controlled trials.
9.6 Reflections on the methodology and frameworks

For this thesis, I chose compatible over-arching methodological and intervention development frameworks to structure the studies and to systematically explore the research questions and develop the thesis argument.

The MRC framework for the development and evaluation of complex interventions (Craig et al., 2008) was well suited to framing the two main phases of this work: intervention development and feasibility testing. Documenting the process of intervention development has come to the fore as part of the general movement to improve the quality and reporting of complex intervention trials (Hoffmann et al., 2014; Möhler et al., 2015). In the past, published reports of trial results typically provided only a short section documenting the intervention components. At the present time, researchers are encouraged to invest greater effort in intervention development studies or desk-based modelling and to publish this as part of protocols ahead of trial reports (Hoddinott, 2015). None of the dysphagia intervention studies examined as part of the systematic review reported the process by which the interventions were developed. This study is therefore amongst the first within the sphere of dysphagia to adopt this approach. Others are gradually emerging which describe preliminary work. For instance, the research group developing a patient swallowing exercise app has also reported their development work through a series of papers (Constantinescu et al., 2017a; Constantinescu et al., 2017b; Constantinescu et al., 2017c). As published reports of this type of work increase, literature will begin to amass about how to systematically improve swallowing interventions, by increasing our understanding of both the successes and errors of previous interventions.

Aside from desk-based or ‘paper’ modelling (Moher et al., 2016; MRC 2000), intervention development may include several other processes, one of which is consultation with key stakeholders. As the time taken from intervention development to implementation can often be quite lengthy, newer hybrid approaches combine research phases where stakeholders may be involved early on at the intervention development stage (Gitlin, 2013). This thesis offers an example
of how semi-formal discussions with stakeholders can be incorporated into intervention development. For example, in the discussions about how best to operationalize the behaviour change technique of *self-monitoring*, clinicians suggested exploring different options including patient diaries and the use of digital technology such as smartphones and tablets (iPads). While the patient group also discussed digital technology, their final consensus was that a simple system such as a therapy calendar put up in a prominent place in the patient’s home might be preferable. The prevailing viewpoint was that it was easier to tick off the exercises on the calendar without having to sign in on a device such as an iPad. The perspective from the patient group was that during the early stages of treatment, additional “burdens” should be avoided and things should be kept as simple as possible. This was not to suggest that for some people digital devices may indeed be helpful, or that they may be more useful during post-treatment rehabilitation. As a result of this feedback, the new intervention used a simple calendar devised by a member of the patient-public involvement group to support self-monitoring. Thus, input from stakeholders could be incorporated early in the process rather than after the intervention was developed.

To summarize, the intervention development study incorporated multiple steps that did not fit conventionally with a typical research study but is a well-recognized process of the MRC framework (Craig et al., 2008). An attempt was made to describe as fully as possible what was done and how decisions were taken to model and devise the new intervention. In this respect, it meets the definition of an intervention development study as proposed by Hoddinott (2015). The feasibility study was undertaken in accordance with the guidance provided by the National Institute for Health Research (NIHR). While feasibility studies are often carried out in developing new medical interventions, I have found only a few examples in the dysphagia literature.

The BCT taxonomy Version1 (Michie et al., 2013) was chosen as it offers a systematic method for extracting BCTs from intervention descriptions. Training in its use is relatively straightforward and available. As proponents of the taxonomy
suggest, it provides a common language and a shared method through which behavioural concepts can begin to be explored by clinical researchers outside the field of psychology (Johnston, 2016). Within psychology, there is some debate as to the value of coding interventions using the BCT taxonomy. Critics argue that coding BCTs is too reductionist, systematized and oversimplified to capture the nuances of variation in individuals and contexts (Ogden, 2016a). The counter-argument is that without systematization, evidence synthesis would be hindered being too unwieldy and time consuming to gain an understanding of the specific active ingredients operating within interventions (Larsen et al., 2016; Michie & Johnston, 2017).

The use of the Theoretical Domains Framework (Cane, O’ Connor & Michie, 2012) and the COM-B model (Michie, et al., 2011) in Study 2 of this thesis is to my knowledge the first attempt to analyze patient adherence to swallowing exercises using a behaviour change framework. Steps for performing such an analysis are well documented in the psychology literature (Michie, Atkins & West, 2014). However, there has also been negative critique of the approach for being too formulaic, with some researchers preferring a more inductive type analysis (Ogden, 2016b). Personal reflection on using and applying this framework is that it has been a useful guide to deciding which determinants of behaviour to target. Knowledge and selection of exercise-based content for a pre-treatment swallowing intervention is more readily available to dysphagia researchers and clinicians than knowledge about how to improve non-exercise content in an intervention. In my view, use of the framework within this thesis has not prevented application of independent and critical judgement. On the contrary, it has prompted me to think more broadly about the key targets for a given intervention in a specific context. As a new researcher, I found that the Behaviour Change Wheel (BCW), which incorporates the COM-B model, offered a useful practical guide for the steps that should be considered when developing a behaviour change intervention.
9.7 Comparison of this work with the latest swallowing intervention studies in head and neck cancer

Since completing the empirical studies in this thesis, I noted that the latest swallowing intervention studies for patients with HNC (published in 2016 or later) have demonstrated a marked shift toward actively examining patient adherence to swallowing exercises compared with those examined in the systematic review (Study 1) of this thesis (2015 and earlier). A formal search was not repeated, but five studies were identified from personal literature alerts that had specific relevance to the aims of this thesis, in that they all relate to pre or peri-treatment swallowing interventions for patients with head and neck cancer. They are mentioned here as it presents a timely opportunity for comparison with the intervention devised in this thesis, and to place this work within the context of other work in the field. Importantly, these papers also demonstrate the direction in which research is progressing on this topic thus highlighting how the work in this thesis may be expected to have impact on future research.

The first, an Australian study (Wall et al., 2016), compared service delivery methods for a prophylactic exercise programme in a three-arm trial. The authors reported poor adherence across all three groups with only 25% of patients completing the prescribed exercises. Although no statistically significant difference in overall adherence was found across the groups, the authors noted that patients who attended to see a clinician for part of the programme had the best adherence.

The second study published around the same time, took place in the Netherlands. This study investigated adherence to a guided home-based prophylactic swallowing exercise programme (Cnossen et al., 2016). Adherence (exercises at least once a day) was reported to be 70% in the first six weeks, dropping to 38% at week 12. This study highlighted issues around the measurement of adherence in this population and proposed using a method that grouped adherence into categories of low, moderate and high for the frequency with which patients performed their exercises in a day. The authors reported that 20% of their sample (n=50) did not complete the
diary log of exercises, calling into question whether other methods may be more suitable.

A randomized controlled trial of pre-habilitation including combined swallowing and physiotherapy exercises (SYNK trial) was recently reported from Denmark (Hajdú et al., 2017). This trial is still ongoing but from the paper of their internal pilot study, the authors reported that of nine eligible patients, six were recruited to the study and interim adherence to swallowing exercises was above 90% for these patients. Based on the intervention description, it is likely that several helpful behaviour change techniques such as social support from the clinician, feedback on behaviour and regular review of goals were included in the intervention that involved twice weekly face-to-face contact with the clinician. However, it is yet to be determined whether patients will tolerate this regime, and if they will be able to maintain this during independent practice.

A randomized controlled trial from the USA examined a set protocol of prophylactic swallowing exercises provided to patients in the intervention group in addition to usual care (Messing et al., 2017). The authors reported that 19 patients in the intervention group (66%) completed the adherence journal. Across the six weeks of treatment, 28% of patients were able to do at least 40% of the exercises. This study indicated positive results up to six months in favour of the intervention group, but the difference between groups was not maintained at 24-months.

The last study identified was also undertaken in the USA. This was a feasibility study primarily aimed at testing a new mobile phone application (Vibrent™) designed to provide exercise instructions, reminders and options for logging practice adherence for patients undergoing radiotherapy (Starmer et al., 2017). This study found an average adherence rate of 29% for using the app over a 3-month period from pre-treatment until after completion of radiotherapy. Some of the reasons that patients provided for not using the app included: not liking the constant notifications that they could not delete, performed the exercises but forgot to log them, had no time, or had issues with their internet connection. The authors did not assess any swallowing outcomes as part of this study, but reported
their intention to incorporate patient feedback and findings from the feasibility study to improve the design of the mobile app.

Finally, although not yet published, early findings from a non-randomized feasibility study of a pre-treatment swallowing exercise intervention undertaken in Scotland were presented at the UK Swallowing Research Group meeting held in London in February 2018. This intervention was described as being developed in partnership with patients and all members of the multi-disciplinary team. The aim was to devise a swallowing intervention package that consisted of “an exercise schedule, staff manual and SiP package for patients including written materials, exercise videos, reminder materials, and an electronic e-SiP app to support adherence” (Wells et al., 2016, p2). In this study, patients in the intervention group were given the option of having an e-swallowing intervention package by being loaned iPads for the duration of the study. Of 36 patients recruited to this study, only three were reported to have taken up the offer of the iPad (Professor Mary Wells 2018, personal communication, 2 February). Given that the uptake for using iPads was found to be poor in this study, it might be that this option is more burdensome than helpful during the early stages of treatment as predicted by the patient-public involvement group discussions mentioned in Chapter 6 of this thesis. Timing in employing different behavioural strategies (such as the use of digital technology for monitoring) may therefore be quite an important consideration when developing swallowing exercise interventions for patients with head and neck cancer.

The above summary of studies published in the last two years indicates that there is clearly an increased awareness amongst dysphagia researchers that more needs to be done to improve adherence in this group of patients. However, the emphasis in these studies shows that efforts are focused mainly on capturing adherence information for clinician monitoring (logging of exercises using diaries, apps), or manipulating a specific component to observe its influence on adherence. For example, in the study by Wall et al. (2016), the aim was to manipulate the intervention delivery method to examine its impact on adherence to exercises. Whereas, the ongoing study by Hajdú et al. (2017) is aimed at considering an
implementation change to current practice. Their intervention proposes introducing pre-habilitation by an occupational therapist and physiotherapist into the care pathway where it currently does not exist. In the study by Starmer et al. (2017), the use of digital app to increase adherence is examined. The effect of using the app on changing swallowing outcomes is expected to be the subject of future investigation.

The main focus of the paper by Cnossen et al. (2016) was to examine adherence to their previously developed standard prophylactic programme “Head Matters” in a new group of patients having intensity modulated radiotherapy with and without the addition of chemotherapy. They wished to observe changes in exercise adherence over a 12-week period and to consider the impact of other possible moderating variables such as chemotherapy. The study by Messing et al. (2017) is the only complete pre-treatment swallowing intervention trial from those cited above, and their results suggest some indication of short-term benefit in favour of the exercise group.

The most contemporaneous work within this specialist field (related to this thesis) demonstrates that the direction of research is moving towards increasing patient self-management, with improvement in exercise adherence being a high priority for achieving better functional outcomes. Prophylactic exercises for this group of patients, who will almost always experience some degree of dysphagia as a consequence of cancer treatment, remains an important research focus (Ciucci et al., 2016). The work undertaken in this thesis has therefore been timely. It has provided an example of how a systematic and theory based pre-treatment swallowing intervention was developed using state-of-the-art methods in behaviour change (Behaviour Change Wheel – Michie et al., 2014), and dysphagia management (Modified Barium Swallow Impairment Profile – Martin Harris et al., 2008). In this respect, it offers a unique contribution not evidenced in other contemporary studies of this subject. As may be observed from the overview provided, other studies have focused on how clinicians can monitor adherence, or have attempted to test whether solutions for increasing adherence in other health interventions (for example the use of mobile apps) can be used to increase adherence in the head and neck cancer population.
Much has been learned from this thesis that could explain some of the findings reported by the studies above. It was evident from the behavioural analysis undertaken in Study 2, that most head and neck patients find the course of treatment extremely challenging. It was clear that exercise regimes at this point in the care pathway should not be too onerous, and was more likely to be followed if personalized. Almost all of the above studies demonstrated that patients did less than the full exercise regime or simply stopped exercising as they progressed through radiotherapy treatment. Another relevant insight from Study 2 was that patients were more likely to do their exercises if they believed that it was going to prevent them losing their current functional ability to eat and drink, than if they believed that they were given the exercises for general wellbeing and to make their muscles stronger. The premise for the ongoing intervention described by Hajdú et al. (2017) is based on the latter and so it remains to be seen how well patients adhere through treatment. Most pre-treatment interventions are based on a standard generic protocol of strengthening and range of movement exercises. In contrast, the exercises in the SIP SMART intervention were targeted to patients’ individual swallowing physiology based on an x-ray swallow assessment.

Furthermore, while many researchers are now concerned with capturing adherence information in great detail, this strategy might be adding to patient burden and having the opposite effect. The behaviour change techniques of self-monitoring and monitoring of behaviour by others are two distinct techniques. Patients may need a simple strategy that allows self-regulation, but in order to understand adherence better, researchers have introduced fairly complex monitoring that requires patients to input detailed practice data into an app or diary. Based on the above-mentioned studies, reports of patient uptake of using a phone app or iPad were generally disappointing. This is consistent with information gleaned from the patient stakeholder group (discussed in Chapter 6) who advised that the type of monitoring system should not represent an additional burden to patients during treatment. In the future, the possibility of wearable technology that automatically monitors swallowing exercises may indeed be helpful, but at the current time
recording details of swallowing practice on an app do not appear to be entirely satisfactory and may inadvertently be increasing patient burden.

All of the latest studies are useful in advancing our understanding of what may work or not work in swallowing exercise interventions for patients with HNC. The theory-based intervention devised in this thesis takes a unique approach by first attempting to optimize the intervention. Its potential to increase patient adherence as an interim outcome to improving swallowing function and quality of life is yet to be determined.

9.8 Contributions of this thesis

This thesis set out to address key issues identified in the literature that were found to undermine efforts in establishing the efficacy of a pre-treatment swallowing exercise intervention. A set of uniquely designed and novel studies informed the development of an optimized swallowing intervention package that was subsequently tested in a feasibility randomized controlled trial. The implications of this work for research, practice and policy are described below.

9.8.1 Implications for research

To my knowledge, this thesis has been amongst the first within the field of dysphagia research to use comprehensive frameworks and tools from behavioural science in optimizing a swallowing intervention.

Reflecting on the potential contribution of Study 1, perhaps the greatest gain may be expected in raising awareness amongst researchers of the non-exercise content of swallowing interventions. The use of the BCT taxonomy (Michie et al., 2013) made it possible to characterize interventions in a way that has not been previously reported in the dysphagia literature. Indeed, non-exercise content was given little attention in developing or describing previous interventions, as seen from the analysis of studies in the systematic review. Intervention delivery was notionally reported in these studies as ensuring compliance to the exercise protocol, and patient adherence was usually documented as a marker of study quality. As Study 1
was the first review of its type within the field of dysphagia, it has not been possible to directly compare the main findings with other studies. Nonetheless, I have observed that since the publication of my review protocol (Govender et al., 2015), more dysphagia researchers have paid greater attention to how the non-exercise content of interventions is specified. Some have adopted BCT descriptions making reference to my publications from Study 1 (Wells et al., 2016; Toft & Stringer, 2017; Starmer et al., 2017; Constantinescu et al., 2017b; Beck et al., 2017). Others since have also recognized the importance of making patient adherence a greater focus when designing swallowing exercise interventions (Wells & King 2017; Krekeler et al., 2017). The research implications of Study 1 have therefore already been evidenced by the fact that other researchers have used and cited early publications from this thesis.

Study 2 presented an example of using in-depth theory-based interviews and analysis to understand head and neck cancer patients’ behaviour related to the performance of swallowing exercises. The publication from Study 2 has recently been cited in the dysphagia literature as a good example of how in-depth interviews may be used to inform intervention development (Patterson & Dawson, 2017). The use of comprehensive behavioural frameworks (TDF and COM-B) can usefully inform the development of new interventions by ensuring that the most crucial determinants of the target behaviour are addressed by the intervention. The difference in using a comprehensive theoretical model versus choosing to focus on a single pre-selected Theory may be observed by considering another qualitative interview study which similarly aimed to establish head and neck cancer patients’ experiences of swallowing exercises (Constantinescu et al., 2017a). This study was undertaken in Canada around the same time as Study 2, and it was encouraging to see that similar barriers and facilitators arose across these studies. While SIP SMART focused on addressing a key barrier, Constantinescu et al. (2017a) used their interview study to support the development of an app to improve adherence via self-monitoring and the use of games technology (Constantinescu et al., 2017b). They therefore chose to focus on what may be considered a key facilitator to adherence (self-monitoring), but it is uncertain whether this alone will be sufficient
to overcome any barriers to initiating swallowing exercises present in the pre-treatment HNC population. Following publication of Study 2 (Govender et al., 2017b), the research group involved in developing the swallowing exercise app have invited me to give a talk on the application of the COM-B model in addressing patient adherence to swallowing exercises (Professor Jana Rieger (2018), personal communication, 5 January). Potential future collaboration with the group could be mutually beneficial in developing improved swallowing exercise interventions.

Beyond the specific examples provided above, the methods used in this thesis may be applied to research in other population groups with dysphagia, but also more widely to other rehabilitation targets that require behaviour change. Reporting of future swallowing exercise interventions will be improved if behaviour change strategies are coded and specified in protocols, supplementary material and intervention development papers. This will allow easier replication of studies, but more importantly may also highlight why interventions work in some situations and not others. These opinions are embodied in several of the latest publications that signify a movement toward improving the quality of both the design and reporting of complex interventions (Cotterill et al., 2018; Möhler et al., 2015; Boutron et al., 2017; Lewin et al., 2017; Whyte et al., 2014; Dijkers et al., 2014) To my knowledge, there have been no publications within the field of dysphagia that have explicitly described the process of intervention development, meaning that this thesis may provide a helpful benchmark for future researchers. Furthermore, the feasibility study and the publication of a protocol may be influential in encouraging dysphagia researchers (and others) to give greater attention to feasibility studies that can help to improve the quality of RCTs within the field. In so doing, the quality of research and the confidence in research findings may be improved.

9.8.2 Implications for practice

Achieving good patient adherence to home-based swallowing rehabilitation exercises is one of the biggest challenges facing dysphagia clinicians. This thesis brings advances from the field of behavioural science into the dysphagia domain, and raises awareness amongst clinicians of the many dimensions to the complex
interventions that are delivered in clinical practice. Clinicians may therefore be prompted to think about how they may facilitate change in behaviour as part of their clinical interventions.

Behaviour change is a key element of rehabilitation interventions, yet the science of behaviour change is not routinely used in designing rehabilitation interventions. Since beginning this work, I have had requests from clinicians to provide training in how they may be able to use insights from behaviour change science to improve their therapy. To this end, a colleague and I have delivered training at a study day for SLTs supported by members of the UCL Centre for Behaviour Change (Applying behaviour change theory and techniques to SLT intervention: Homerton Hospital London, 11 March, 2016). Further training days are planned during which knowledge gained from this thesis will be shared with SLT clinicians, and perhaps more widely within the allied health profession.

The intervention developed as part of this thesis is at an early stage. However, if it is shown to be effective in a larger trial, the intervention has the potential to improve the quality of life for patients with head and neck cancer. It may also reduce the costs associated with long-term tube feeding, reduce dependency on hospital care, and possibly facilitate return to work if patients feel better socially adjusted by being able to eat in public.

9.8.3 Implications for policy

As discussed in Chapter 1, the Improving Outcomes Guidance for head and neck cancer (NICE, 2004) is currently inconsistently implemented (Roe et al., 2012; DAHNO, 2012). Newer guidelines are similarly inconsistently applied (Clarke et al., 2016). These guidelines recommend that patients with head and neck cancer should be provided with pre-treatment swallowing exercises, but with uncertain evidence it has proved challenging to commission resources to adequately support this. Disparities in practice therefore persist, as highlighted by the expert SLT stakeholder group consulted during this thesis. The work in this thesis could contribute to the evidence to support greater investment of specialist SLT input at the front end of
treatment for patients with head and neck cancer. It is anticipated that in time, a pre-treatment swallowing intervention package may be written into the relevant policy guidelines so that it is widely implemented and available to all patients on the NHS. SLT clinicians will become more skilled at delivering a higher quality and consistent care package. As a result, service requirements for this aspect of speech and language therapy could be more readily described, justified and commissioned.

### 9.9 Concluding Remarks

This thesis has described the development and feasibility testing of a pre-treatment swallowing intervention package for newly diagnosed patients treated for head and neck cancer on the NHS. This thesis differs from other studies of pre-treatment swallowing interventions by using a systematic process and a state-of-the-art behaviour change framework to first optimize the intervention. It owes much to many of the latest intervention development guidelines and frameworks on which I have drawn. Based on feedback I have received, and the use of findings from early publications arising from this thesis by other researchers, it would appear that this work has already had some impact on speech and language therapy and on other allied healthcare researchers who are also exploring ways to systematically develop interventions. However, efficacy and effectiveness of the new intervention developed as part of this thesis is yet to be determined. Further work that includes training other speech and language therapists to deliver the intervention is necessary. Conducting a small multi-centre pilot study would be a useful next step. To this end, I have already obtained further research funding in the form of an interim fellowship to develop a proposal for taking this work forward on completion of the PhD.
Bibliography


interventions within systematic reviews: development, content and use of a new tool (iCAT_SR). *BMC Medical Research Methodology*, 17(1).


Appendices

Appendix 2-1: RandD approval ................................................................. 265
Appendix 2-2: NHS ethics Favourable Opinion 31.07.14 ...................... 266
Appendix 2-3: Substantial amendment approval .................................. 271
Appendix 2-4: Prospero entry of SR ................................................. 274
Appendix 2-5: Trial registration .............................................................. 278
Appendix 3-1: Protocol for systematic review ..................................... 284
Appendix 3-2: Systematic review publication ...................................... 292
Appendix 3-3: Data extraction template ............................................... 307
Appendix 3-4: Outcome measures at 4 time-points ............................ 310
Appendix 4-1: Barriers and Facilitators to swallowing exercises ........ 312
Appendix 4-2: Interview prompts based on TDF ............................... 323
Appendix 4-3: Patient information Leaflet-qualitative interviews ........ 325
Appendix 4-4: Patient consent form-qualitative interview .................. 329
Appendix 4-5: Code book and peer debrief ......................................... 331
Appendix 6-1: Behavioural analysis using COM-B and TDF to determine what needs to change and how this may be achieved .................. 340
Appendix 6-2: SIP SMART INTERVENTION MANUAL ....................... 363
Appendix 7-1: Protocol manuscript in BMJ open ................................ 385
Appendix 7.2: SIP SMART Screening Log ............................................ 396
Appendix 7.3: SIP SMART Enrolment Log ............................................ 397
Appendix 7.4: Patient information leaflet feasibility study. 2.02.16 ........ 398
Appendix 7.5: SIP SMART Case report form ........................................ 404
Appendix 7.6: Outcome measures form.SIP SMART ............................ 423
Appendix 7.7: PSS.HN ........................................................................ 425
Appendix 7.8: MD Anderson Dysphagia Inventory ............................ 427
Appendix 7.9: FACT-HN_ENG_pdf ..................................................... 429
Appendix 7.10: MBSImP-CompScoreDefs .......................................... 432
Appendix 2-1: RandD approval

NHS PERMISSION FOR RESEARCH (R&D Approval)

Dear Colleague/s

IRAS ID: 150312 (Please quote in all correspondence)
REC Ref: 14/LO/1152
Study Title: Development and preliminary testing of a tailored pre-treatment swallowing intervention package for patients with head and neck cancer.

NHS permission for the above research has been granted for the following NHS Trusts and/or Independent Contractors:

<table>
<thead>
<tr>
<th>Trust/Independent Contractor</th>
<th>Name of PI / LC</th>
<th>Date of Permission</th>
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<tr>
<td>University College London Hospitals</td>
<td>Roganie Govender</td>
<td>29/09/2014</td>
</tr>
<tr>
<td>NHS Foundation Trust</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Permission is based on the REC favourable opinion given on 31/07/2014.

Permission is granted on the understanding that the study is conducted in accordance with the Research Governance Framework, ICH GCP, and the policies and procedures of the Trust/s [http://www.crn.nihr.ac.uk/resources/trusts-covered-by-crn-north-thames/?h=42].

Permission is only granted for the activities for which a favourable opinion has been given by the REC [and which have been authorised by the MHRA].

Specific Conditions of Permission (if applicable)

None

Please ensure that all amendments are notified to the Permission Centre governance office in line with current NIHR guidance¹. Please also ensure that the office is notified of any changes in status to the project, for example if the site should close before the stated end date and of any urgent safety measures enacted.

Yours sincerely,

Director of Research and Development
UCL/UCLH/Royal Free Joint Research Office
Cc: Chief Investigator, Sponsor Contact, Research Site R&D Office/s

¹ http://www.crn.nihr.ac.uk/Resources/NIHR%20CRN%20CC/CSP/20130503_CSP%20amendments%20guidance_v1.0Final.pdf

Template Version 3 – 2 April 2014
Study title: Development and preliminary testing of a tailored pre-treatment swallowing intervention package for patients with head and neck cancer.

REC reference: 14/LO/1152
Protocol number: 14/0176
IRAS project ID: 150312

Thank you for your letter of 30 July 2014, responding to the Committee’s request for further information on the above research and submitting revised documentation.

The further information was considered in correspondence by a Sub-Committee of the REC. A list of the Sub-Committee members is attached.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to make a request to postpone publication, please contact the REC Manager, nrescommittee.london-southeast@nhs.net.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

A Research Ethics Committee established by the Health Research Authority
Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at [http://www.ndforum.nhs.uk](http://www.ndforum.nhs.uk).

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations.

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publicly accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to contest the need for registration they should contact ; the HRA does not, however, expect exceptions to be made.

Guidance on where to register is provided within IRAS.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS sites

The Committee has not yet completed any site-specific assessment (SSA) for the non-NHS research site(s) taking part in this study. The favourable opinion does not therefore apply to any non-NHS site at present. We will write to you again as soon as an SSA application(s) has been reviewed. In the meantime no study procedures should be initiated at non-NHS sites.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

A Research Ethics Committee established by the Health Research Authority
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**Statement of compliance**

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

**After ethical review**

_A Research Ethics Committee established by the Health Research Authority_
Reporting requirements
The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback
The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:
http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Training
We are pleased to welcome researchers and R&D staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

14/L.O/1152
Please quote this number on all correspondence

With the Committee’s best wishes for the success of this project.

Yours sincerely

Research Ethics Committee (REC) Assistant

pp Professor
Chair
Email:nrescommittee.london-southeast@nhs.net

Enclosures:
List of names and professions of members who were present at the meeting and those who submitted written comments
"After ethical review – guidance for researchers"

Copy to: University College London Hospitals NHS Foundation Trust

A Research Ethics Committee established by the Health Research Authority
NRES Committee London - South East

Attendance at Sub-Committee of the REC

Committee Members:

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<td>Senior Cancer Information Nurse</td>
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<td>Retired Clinical Pathologist</td>
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Also in attendance:

<table>
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<tr>
<th>Name</th>
<th>Position (or reason for attending)</th>
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<tr>
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Appendix 2-3: Substantial amendment approval

24 February 2016

Roganie Govender
Via Email

Dear Roganie Govender

**Study title:** Development and preliminary testing of a tailored pre-treatment swallowing intervention package for patients with head and neck cancer.

**REC reference:** 14/LO/1152
**Protocol number:** 14/0170
**Amendment number:** One
**Amendment date:** 05 February 2016
**IRAS project ID:** 150312

The Substantial Amendment proposed to include a new treatment manual.

The original ethics application covered both the development phase, and the feasibility study. Approval was given for both stages of the research project on the proviso that the new intervention manual will be submitted to ethics as an addendum to the protocol.

Minor changes were made to the patient information leaflet to accommodate for specific aspects of the new intervention that patients should be made aware of at consent stage. All other aspects related to behavioural strategies adopted by the clinician and involve no invasive intervention for the patient.

The above amendment was reviewed on 24 February 2016 by the Sub-Committee in correspondence.

**Ethical opinion**

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

The Sub Committee recommended you reconsider the use of bright red and green font. In particular, the jokey font used on page 9 and page 65 is not in keeping with the rest of the text font used.

**Approved documents**

The documents reviewed and approved at the meeting were:

<table>
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<th>Version</th>
<th>Date</th>
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A Research Ethics Committee established by the Health Research Authority
Notice of Substantial Amendment (non-CTIMP) | One | 05 February 2016
Other [SIP SMART Intervention manual] | 1.3 | 29 January 2016
Participant information sheet (PIS) [Feasibility Study Pil] | 1.5- Tracked | 02 February 2016
Research protocol or project proposal [SIP SMART protocol] | 1.5- Tracked | 03 February 2016

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

We are pleased to welcome researchers and R & D staff at our NRES committee members’ training days – see details at http://www.hra.nhs.uk/hra-training/

14/LO/1152: Please quote this number on all correspondence

Yours sincerely

On behalf of Professor
Chair

E-mail: nrescommittee.london-southeast@nhs.net

Copy to: Research Portfolio Coordinator JRO UCL
Professor University College London Hospitals

A Research Ethics Committee established by the Health Research Authority
London - South East Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 24 February 2016

Committee Members:

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Appendix 2-4:  Prospero entry of SR

PROSPERO International prospective register of systematic reviews

Components of behavioural interventions aimed at improving swallowing outcomes in head and neck cancer patients: a systematic review
Roganie Govender, Benjamin Gardner, Christina H Smith, Stuart Taylor, Daphne Grey

Citation

Review question(s)
Main Aim: To identify the “active ingredients” of behavioural interventions described in studies aimed at improving swallowing outcomes following treatment for head and neck cancer, when compared to a control group.

Which behaviour change functions and techniques are reported in current intervention studies aimed at improving swallowing function in head and neck cancer patients?

How does the above relate to reported outcomes/effect sizes?

Is there a named theory mentioned in the abstract, introduction or method?

Searches
We will search the following electronic health databases: MEDLINE, CINAHL, EMBASE, AMED, PsycINFO and the Cochrane Library. Additional searches will be carried out on Google Scholar, Web of science and Trials Database (clinicaltrials.gov and ISRCTN). The reference lists of related reviews, and of selected articles will be hand searched for any additional studies. The search will not be date restricted, but will be restricted to peer reviewed articles relating to adults (over 18) and published in English. Filters for clinical trials and systematic reviews will be applied. The full search strategy will be made available in a published protocol.

Types of study to be included
We will include randomised and non randomised studies provided that a suitable comparator group is included as part of the study design.

Condition or domain being studied
Swallowing difficulties in patients treated for head and neck cancers.

Participants/population
Inclusion: Individuals over the age of 18 diagnosed with head and neck cancer and receiving/had received treatment via one of the key treatment modalities - surgery, radiotherapy, chemoradiotherapy or combinations thereof.

Exclusion: Children (under 18), without a head and neck cancer diagnosis. Individuals with brain cancer, or oesophageal cancer alone will not be included.

Intervention(s), exposure(s)
Behavioural interventions (swallowing exercises, specific diet texture recommendations) that require the individual patient to perform a particular behaviour on a regular basis will be included. Interventions that include a device (for example, therabite, theraspoois, spatulas) as part of an exercise package will also be included provided that it is part of a programme to improve swallowing outcomes. Interventions designed solely to treat trismus or improve mouth opening will be excluded if no swallowing outcome is assessed. Medical, surgical, prosthetic, pharmacological and electrical stimulation type interventions will be excluded.
Comparator(s)/ control
Comparator groups may include an active or inactive control. Individuals within this group should ideally be similar to the intervention group with regard to demographic, disease and oncological treatment variables. Control groups may include standard or usual care at the time of the study, or sham exercise groups.

Context
Hospital setting, Cancer Centres, Outpatient departments.

Outcome(s)
Primary outcomes
Mean difference in swallowing outcome score (at follow-up) between intervention and comparator groups.

Outcomes will be sought at key points post treatment - 1, 3, 6, 12 months post treatment.

Secondary outcomes
Tube feed use at follow-up time points.

presence/absence of tube at last follow-up

Data extraction, (selection and coding)
Initial screening of titles and abstracts using the inclusion criteria will be carried out by two members of the review team, and any discrepancies will be resolved through discussion. Full texts will be obtained for all studies which fit the inclusion criteria.

All full text articles will be reviewed by two members of the team using a pre-agreed template form. Studies will be independently assessed against the listed eligibility criteria and given a category of include, exclude or unsure. Not meeting any one of the key eligibility criteria (PICO) will eliminate the study from the review. Disagreements will be resolved through discussion and the intervention of a third member of the team if required.

A customised pre-piloted form will be used for data extraction. The form will include information about the study setting, participants, study design, methodological quality, intervention, outcomes at baseline and follow-up and specific aspects relating to the theory base, and behaviour change functions and techniques. One member of the team will extract data and code all studies. A second team member will review a minimum of 25% of studies randomly selected. Agreement will be calculated with the kappa measure.

Risk of bias (quality) assessment
A published tool (Van Tulder et al; 2003) will be used for quality assessment. A summary of the quality assessment will be provided as part of the narrative synthesis. Studies will not be excluded on the basis of this assessment.

Strategy for data synthesis
We are planning a narrative synthesis based on the approach described by Popay et al (2006). If possible we will aim to provide summaries of intervention effects for each study by calculating risk ratios and standardised mean differences as appropriate to the type of outcome. However, based on the findings in related reviews, we do not anticipate being able to carry out a meta-analysis.

Analysis of subgroups or subsets
None planned

Dissemination plans
The review findings will be published in a relevant peer reviewed journal. We also plan to present these findings at national and international conferences.

Contact details for further information
Miss Govender
Organisational affiliation of the review
University College London Hospital

Review team
Miss Roganie Govender, Head & Neck Cancer Centre, University College London Hospital/UCL
Dr Benjamin Gardner, Dept of Psychology, Kings College London
Dr Christina H Smith, Dept of Psychology & Language Sciences, University College London
Professor Stuart Taylor, Centre for Medical Imaging, University College London
Ms Daphne Grey, Bloomsbury Healthcare Library, UCLH

Anticipated or actual start date
03 November 2014

Anticipated completion date
30 June 2015

Funding sources/sponsors
NIHR CDRF award (2013-04-020)

Conflicts of interest
None known

Other registration details
None

Language
English

Country
England

Subject index terms status
Subject indexing assigned by CRD

Subject index terms
Behavior Therapy; Deglutition; Deglutition Disorders; Head and Neck Neoplasms; Humans

Any other information
This review is being undertaken as part of the planning for the development of a new swallowing intervention package for patients with head and neck cancer.

Reference and/or URL for protocol

https://www.crd.york.ac.uk/PROSPEROFILES/17048_PROTOCOL_-_20170114.pdf

Stage of review
Completed and published

Date of registration in PROSPERO
04 March 2015
**UNIVERSITY of York**
Centre for Reviews and Dissemination

**Date of publication of this revision**
29 March 2017

**Details of final report/publication(s)**

**DOI**
10.15124/CRD42015017048

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**PROSPERO**
International prospective register of systematic reviews

The information in this record has been provided by the named contact for this review. CRD has accepted this information in good faith and registered the review in PROSPERO. CRD bears no responsibility or liability for the content of this registration record, any associated files or external websites.
Appendix 2-5: Trial registration

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

Condition category  
Cancer

Date applied  
23/10/2014

Date assigned  
23/10/2014

Last edited  
20/09/2016

Prospective/Retrospective  
Retrospectively registered

Overall trial status  
Ongoing

Recruitment status  
Recruiting

**Plain English Summary**


**Trial website**

[]

**Contact information**

**Type**

Scientific

**Primary contact**

Miss Roganie Govender

**ORCID ID**

http://orcid.org/0000-0003-2249-434X [http://orcid.org/0000-0003-2249-434X]
Contact details
Head & Neck Cancer Centre
Ground Floor Central
250 Euston Road
London
NW1 2PQ
United Kingdom
- Roganie.Govender@uclh.nhs.uk [mailto:Roganie.Govender@uclh.nhs.uk]

Additional identifiers

EudraCT number
ClinicalTrials.gov number
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 hypothesis

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
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

Trial setting
Hospitals

Trial type
Treatment

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

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

Intervention
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

Drug names

Primary outcome measures
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 trial start date
Overall trial end date
30/08/2017

Reason abandoned

Eligibility

Participant 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
Patient

Age group
Adult

Gender
Both

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

Participant 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

Recruitment start date
Recruitment end date
07/12/2016

Locations
Countries of recruitment
United Kingdom

Trial participating centre
University College London Hospital
Head & Neck Cancer Centre First Floor East 250 Euston Road
London
NW1 2PQ
United Kingdom

Sponsor information
Organisation
University College London

Sponsor details
Joint Research Office
1st Floor
Maple House – Suite B
149 Tottenham Court Road
London
W1T 7DN
United Kingdom

Sponsor type
University/education

Website

Funders
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.

IPD Sharing plan:
The current data sharing plans for the current study are unknown and will be made available at a later date

Intention to publish date
31/12/2017

Participant level data
To be made available at a later date

Results - basic reporting

Publication summary

Publication citations

Additional files

Editorial Notes
20/09/2016: The overall trial dates have been updated from 06/10/2014 - 01/09/2016 to 29/04/2013 - 30/08/2017 and the recruitment dates has been updated from 06/10/2014 - 01/09/2016 to 06/10/2014 - 07/12/2016. The recruitment for the interview phase takes place between 06/10/2014-16/12/2014 with a pause in recruitment before recruitment for the feasibility study commences on 05/04/2016 - 07/12/2016. In addition, the IPD sharing statement has been added and the outcomes reformulated for clarity. 10/08/2016: Cancer Help UK lay summary link added.
Appendix 3-1: Protocol for systematic review
Background

Head and neck cancer is a cluster term that refers to cancers that arise in the oral cavity, pharynx, larynx, paranasal sinuses, nasal cavity or salivary glands. Since the 1990s, trends have suggested a 30% increase for oral cancer and a 50% increase for oropharyngeal cancer [1]. Risk factors for the increase include oral human papillomavirus (HPV) infection and betel nut chewing, as much as the more commonly reported smoking- and alcohol-related causality. The age at which individuals develop head and neck cancer has dropped, meaning that many are still actively employed. Cancer Research UK [2] have estimated the current lifetime risk for a newborn infant of developing head and neck cancer is 1 in 84 for males and 1 in 160 for females. Advances in treatment have improved 5-year survival rates, but this has resulted in a corresponding increase in functional burden such as swallowing difficulties. There are therefore a greater number of individuals, often still of employment age, living longer following their cancer treatment, but with significant functional morbidity. The need to optimise interventions to reduce this morbidity has become increasingly important.

Dysphagia (difficulty in swallowing) is a highly prevalent morbidity following oncological treatment for head and neck cancers, affecting most patients at some stage over the course of treatment [3, 4]. The presence of a lump in the mouth or throat may result in problems with eating and drinking, but the treatments for cancer (surgery, radiotherapy, chemotherapy) also cause alterations to swallowing function which may persist for many months or even years [5, 6]. Some individuals never regain the ability to eat and drink normally following treatment. Surgery may involve the removal of important oropharyngeal or laryngeal structures with resultant changes to the anatomy and physiology for normal swallowing. The side effects of radiotherapy include a dry mouth, taste changes, fibrosis and stiffening of tissues, which all affect the movement of this finely tuned dynamic process. Dysphagia is also a known late-effect of radiotherapy, meaning that new swallowing symptoms may arise years after the treatment is completed [7]. Difficulty swallowing is often rated as the most significant factor affecting quality of life amongst survivors of head and neck cancers [8, 9]. It has also been identified by head and neck cancer patients, as one of the highest priorities for rehabilitation [10].

Description of the condition as related to the target population

Individuals who are diagnosed with head and neck cancer may experience some changes to their swallowing function as one of the early symptoms that prompt their visit to a doctor. Usually, most patients continue to maintain an oral diet at this stage. However, the treatments for this type of cancer are known to have a significant impact on the physiology of normal swallow function [3, 4]. Most notably, problems may be associated with swallow safety (aspiration of food and drink into the lungs) or swallow efficiency (prompt and timely transit of food and drink from the mouth through to the oesophagus with complete clearance). The result is that patients are often left with poorer swallowing function after treatment. Wall et al. found a prevalence of over 75% impairment in key swallowing structures across the included studies following chemoradiation [4]. Likewise, surgical interventions may require the complete excision of important structures responsible for airway protection against aspiration, or may result in nerve damage that may affect the timing and co-ordination required for normal swallowing. Reviews on this topic [11–13] suggest that there is value in behavioural interventions such as swallowing exercises in improving the post-treatment function of these patients.

Description of the intervention and how it may work

In this paper, the term behavioural interventions will include reference to swallowing exercises and strategies, use of a device as part of swallowing exercise and/or specific diet texture instructions. They are defined by the need for patients to perform the recommended behaviour on a regular basis—daily or several times a day. Interventions may be introduced before, during or after oncological treatment.

Swallowing exercises aim to improve muscle strength and range of motion, and consequently muscle function. During oncological treatment, patients may become deconditioned and suffer muscle atrophy due to the less frequent use of the swallowing musculature. They may be required to remain nil by mouth for a time while recovering from surgery, or they may be encumbered by pain, macroglossia and other side effects during radiotherapy reducing their oral intake of food and drink. Performing swallowing exercises may maintain the functioning of the oropharyngeal musculature thereby facilitating better recovery of function and possibly preventing the development of fibrotic changes in the muscles [14].

What is the current evidence for behavioural swallowing interventions in head and neck cancer patients?

Recent systematic reviews have been primarily concerned with identifying the type of intervention and its impact on swallowing outcomes [11], or establishing the methodological quality of previous trials [15]. A review by Cousins et al. [11] found some evidence in support of interventions targeting swallowing and jaw mobility after head and neck cancer, but heterogeneity in outcomes and interventions meant that meta-analysis was not
possible. This review highlighted that evidence is limited, and the authors recommended larger, high-quality studies with multiple outcome measures to represent both patient-reported and objective outcomes. However, the review stopped short of a detailed analysis of the intervention descriptions (what happens in the intervention), identifying the key content only as swallowing exercises, electrical stimulation, use of a mechanical jaw stretch device, or combinations thereof. The Carney and Madavan review [15] focused on the methodological quality of randomised trials of behavioural interventions in the field of dysphagia rehabilitation. Forty percent of studies in this review were specifically relevant to the head and neck cancer population, but there was no specific information extracted on what makes the interventions effective. An ongoing review by Perry et al. [16] focuses on the effect of swallowing exercises on oral swallowing, aspiration and other related adverse events in patients with advanced head and neck cancer. Based on their published protocol [16], we expect to examine a similar body of evidence to Perry et al. While the Perry et al. review has the specific purpose of examining the swallowing exercises (e.g., type, dose, frequency) in randomised trials using Cochrane methodology, our review will look more broadly at clinical trials (randomised and non-randomised) with a focus on the behavioural techniques used in these interventions. We believe that these reviews will complement each other offering a broader and more balanced picture of the current evidence in this field.

For behavioural swallowing interventions to impact swallowing function, we need behaviour change to occur: we can only determine the outcome of an exercise intervention if we are confident that the exercises have been performed as prescribed. Behaviour change cannot be assumed; many behaviour change interventions may fail, not because the intervention is ineffective in modifying the clinical outcome, but because the individual fails to adhere to the recommended advice. This phenomenon has been recognised in the swallowing rehabilitation literature; a previous retrospective study of 497 patients reported a statistically significant difference in functional swallowing status (return to full oral diet) in patients who adhered to their exercises compared with those who did not [14]. Within the clinical context of patient care, we need to ensure that optimised behaviour change techniques are part of our intervention design in order to maximise the chance that the patients are carrying out the recommended advice and behaviour. While findings from previous and ongoing reviews will undoubtedly contribute to knowledge, understanding and clinical choices, a more complete analysis of swallowing intervention effectiveness also requires assessment of the potential contribution of the behaviour change strategies used. Recent advances in behavioural science have been found to be useful in unpacking the components of complex interventions aimed at changing people's behaviour. This approach has been applied in other domains such as diet and physical activity [17,18]. Its application to the field of swallowing rehabilitation is novel.

Why is it important to do this review? Over the last decade, great progress has been made in our understanding of swallowing physiology, the impact of oncological treatments on swallowing physiology, and patient-reported functional outcomes and quality of life. As noted from the reviews already cited, evidence is accumulating for behavioural interventions that aim to improve the swallowing outcomes for this target population. However, it is clear that the evidence is weakened by the lack of high-quality intervention studies. Any discipline can be advanced by the adoption of progressive and transposable methods developed in other disciplines. Guidance on complex intervention research designs [19], as well as improvements in characterising complex interventions using comprehensive frameworks [20,21], are examples of this. They take account of the fact that several interacting components of an intervention may impact the outcomes.

We therefore ask the question: Which behaviour change components are reported in swallowing interventions for head and neck cancer patients, and how frequently do they occur in interventions deemed to be effective? This review will examine and characterise the behaviour change components that have been reported in previous swallowing intervention studies with the view to informing the development of new interventions in this field. A clear description of these components will be useful in transparently describing the content of this complex intervention. Specifying intervention content in a consistent way is desirable for replication of effective interventions, and avoiding replication of ineffective interventions. This in turn enhances the ability of the field to accrue evidence that will allow greater confidence in answering questions about what works. It is unlikely at this stage, that we will be able to conclusive about which behavioural components are most effective, but we can map how frequently they occur in interventions reported to be effective or non-effective.

In this review, we will make use of the Behaviour Change Wheel (BCW) [21], a comprehensive, theoretically based approach to support the design, evaluation and refinement of behavioural interventions. The BCW encompasses a model of behaviour as well as function and policy categories. The model describes nine intervention functions (Education, Training, Persuasion, Coercion, Restriction, Modelling, Enablement, Incentivisation and Environmental Restructuring), and seven policy categories.
that include service provision and guidelines. It takes account of the broad range of factors that influence behaviour change interventions and is supported by a taxonomy of 93 behaviour change techniques [22] to assist in the identification of the ‘active ingredients’ present in interventions. Behaviour change techniques (BCTs) are defined as observable and replicable components of behaviour change interventions [23] that represent the proposed active ingredients of an intervention. The BCT taxonomy provides a standardised and coherent terminology to aid description and identification of BCTs, which are often inconsistently reported [24]. We plan to identify the intervention functions and BCTs employed in the selected studies for this review. It has been suggested that interventions that are explicitly theory-based are more effective, but a recent review [25] has highlighted that the majority of health interventions show no link to theory. We will therefore note whether any theory is mentioned in the abstract, introduction or method, using the Theory Coding Scheme (TCS) [26]. To our knowledge, no reviews within the field of dysphagia rehabilitation have characterised interventions using this approach. The BCW, the BCT taxonomy and the TCS are validated tools that can be applied retrospectively to descriptions of interventions. In this review, they will provide a toolkit offering structure and coherence to the processes of extraction and synthesis of intervention components.

**Aim**

In this review, we aim to:

a) Identify the behavioural intervention components reported in the published literature of swallowing interventions for patients with head and neck cancer.

b) Examine how frequently these behavioural components occur in interventions deemed to be effective vs non-effective.

**Methods/design**

We have consulted the PRISMA-P guidelines [27] in preparing this protocol.

**Criteria for including studies in this review**

**Types of studies**

Only peer-reviewed studies published in English will be included. Randomised and non-randomised studies will be included provided that an intervention group and a suitable comparator/control group is part of the study design. We will not apply any date restrictions or minimum sample size.

**Types of participants/population group**

Individuals over the age of 18, diagnosed with head and neck cancer (excluding brain) and having/had treatment via one of the main modalities of surgery, radiotherapy, chemotherapy or combinations thereof.

**Types of interventions**

In this review, ‘behavioural intervention’ makes reference to swallowing exercises, instructions to adhere to specific diet texture recommendations and swallowing strategies: instructions for swallowing compensations and manoeuvres. It requires the patient to perform a particular behaviour on a regular basis. Interventions that include a device (for example, theraTape, theraSpoon, straws) as part of an exercise package will also be included provided the device is part of a behaviour change programme to improve swallowing outcomes. Interventions designed solely to treat trismus or improve mouth opening will be excluded if no swallowing outcome is assessed. Medical, surgical, prosthetic, pharmacological and neuromuscular or electrical stimulation type interventions will be excluded.

**Type of comparator group**

The comparison group may be an active or inactive control. For review purposes, an active control refers to a group that is still given some intervention (usual care or sham exercises) rather than no intervention at all. It is recognised that in the clinical context of cancer treatment, it may be ethically inappropriate to have a parallel group with no treatment. Therefore, standard treatment, usual care at the time of the study, or usual care and a sham exercise group will be acceptable as controls.

**Types of outcome measures**

The main outcome of interest is swallowing function. At least one measure of swallowing must therefore be reported as an outcome. These measures usually fall into three categories: objective or instrumental measures, clinician-rated measures and patient-rated measures.

**Identification of studies**

**Information sources**

The following electronic health databases will be searched: MEDLINE, CINahl, Embase, AMED, PsychInfo and the Cochrane Library including CENTRAL. Additional searches will be carried out on Google Scholar, Web of Science and the meta-registries of Trials Databases (ClinicalTrials.gov and ISRCTN). We will also search the WHO International Clinical Trials Registry Platform (ICTRP) and the Australian New Zealand Clinical Trials Register (ANZCTR). In addition, we will handsearch the reference lists of any directly relevant systematic reviews as well as the included articles for any additional studies.
Search strategy

A search strategy to identify relevant studies will be developed in conjunction with a subject librarian. We have identified initial terms from other relevant reviews and from MeSH headings of key articles from an initial scoping exercise. We will use the terms deglutition OR swallow* OR Dysphagia* in combination with the exploded terms for head and neck neoplasms.* We will also use the terms therapy OR rehabilitation OR exercise OR behav* OR swallowing training.* The search will be focused to capture the most relevant reports by limiting to clinical trials and reviews, and excluding oesophag* and brain neoplasms. We will limit the search to English language but not apply a date limitation. An example of the search strategy used in MEDLINE is illustrated in Table 1.

Study records

Data management and selection

Articles from all searches will be combined and duplicates removed. Titles and abstracts will be screened against eligibility criteria by two members of the review team (RG and DG), a specialist head and neck speech and language therapist and a subject librarian. The full-text versions of studies deemed eligible by either team member will be obtained. The articles will be imported into Mendeley (library database) for easy access amongst the review team members. Multiple reports of the same intervention study will be grouped together for data extraction. Studies will be assessed for eligibility using a pre-agreed template form. The form will specify the eligibility criteria and consist of a table with a complete list of all the full-text studies retrieved.

Two reviewers with expertise in dysphagia (RG, CS) will independently select one of three categories (include, exclude, unsure) for each study. Repeat articles relating to the same study sample will be grouped together. Reasons will be recorded for studies that are excluded. Uncertainties and discrepancies will be resolved through discussion. A third member of the research team (RG) will be available to assist in resolving any disagreements. The final list of studies to be included in the review will be imported into NVIVO 10 (QSR International), a relational database for organising and analysing qualitative data. A PRISMA Flowchart will be completed to summarise this process.

Data extraction

A pre-agreed and piloted data extraction form will be used to collect the relevant information from the selected studies. This will include study characteristics such as type of study, participants, length of follow-up, outcomes and quality assessment. Intervention characteristics will include information about the target behaviours, theory basis, intervention functions, BCTs as well as fidelity in delivering the intervention. Data will be extracted from all studies by one member of the team (RG). Two other members of the team (CS or BG) will independently extract data for a minimum of 25% of studies randomly selected using a random list generator (http://www.random.org/). Independent coding of study characteristics will be done by CS and intervention characteristics by BG. Two review authors (RG and BG) are trained in the use of the Behaviour Change Technique Taxonomy v1 [22] and will code studies using this as fidelity in delivering the intervention.
framework. To ensure consistency in interpreting the framework, the two reviewers will independently code a small number of studies from those not selected, before coding the selected studies. Uncertainties can then be discussed prior to the coding of the studies included in the review. Inter-rater agreement will be calculated for the study characteristics as a whole and for each of the intervention characteristic (target behaviours, intervention function, BCT) independently. This will be computed using the kappa measure [28] and interpreted according to the classification proposed by Landis and Koch [29]. For the BCT coding, we will adopt a conservative approach to calculating agreement based on the BCTs judged to be present by either of the two coders. We will however also report kappa scores for all 93 BCTs with recognition that these scores may be inflated due to agreement on the absence of most of the 93 BCTs.

Quality assessment

As part of the data collection process, we will use the 11-item scale described by van Tulder [30] to assess the methodological quality of the selected studies. This information will be used to provide a summary of the quality ratings of the studies included, for descriptive purposes only. We have expanded on our reasons for this choice in the ‘Discussion’ section.

Data synthesis
Quantitative synthesis

Based on other similar reviews [11, 15], we anticipate variation in outcomes, instruments used to derive outcomes and other aspects of intervention content and delivery. Calculating and pooling effect sizes is therefore untenable. It is also anticipated that outcomes may be reported at multiple timepoints such as 3, 6, 12 months post-treatment. We will use the most commonly reported timepoint (e.g. 6 months) to derive statistical significance of change in outcome, but if necessary, we will report effects at multiple timepoints. Swallowing outcomes will be broadly categorised into patient-reported outcomes, clinician-rated outcomes and outcomes derived from instrumental and/or other objective measures. Where multiple outcome measures in the same study vary with regard to effectiveness, the primary swallowing outcome will take precedence. A possible template table (Additional file 1: Table SI) provides a visual representation of how we may report these findings. The presence of specific behavioural components across studies will be tabulated and frequency and ratio measures computed. This information will allow the reader to tell at a glance how many intervention components have been used more frequently in effective than ineffective interventions, and exactly how much more frequently. We will provide further information on the table by indicating the types of outcome measures reported. The studies will also be ordered according to their quality rating summary score. We may also tabulate the full quality assessment of individual studies for descriptive purposes.

Narrative synthesis

We have consulted the guidance on conducting a narrative synthesis described by Popay and colleagues [31] and anticipate the use of their general framework that describes four main elements:

- Developing a theory of how the intervention works, why and for whom
- Developing a preliminary synthesis of findings of included studies
- Exploring relationships in the data
- Assessing the robustness of the synthesis (p11)

This framework (we anticipate structuring the synthesis using the latter three elements) will inform our synthesis and discussion of findings. In addition, we will provide a perspective on the clinical and research implications of this review.

Discussion

This review will offer a novel method for characterising behavioural interventions to improve swallowing function using established frameworks from the discipline of behavioural science. Previous reviews have not deconstructed the intervention processes, so while they provide a valuable summary of the available evidence, there is a significant gap in terms of providing information on what happens and why. Consequently, we remain uncertain about how best to improve the design of behavioural interventions to facilitate better outcomes. In this review, we will provide a synthesis of the ‘active ingredients’ or proposed mechanisms of behaviour change described in the swallowing intervention studies that currently represent best available evidence for the population of interest. We will also endeavour to comment on the use of theory in informing our current interventions. As this approach is new in the field, it is not our intention to be conclusive about which BCTs are most effective. We do however wish to note how frequently they are reported in interventions deemed effective vs non-effective. This mapping of information will be useful in aiding the selection of content for future swallowing interventions. While it will not be possible to conclude that the BCT itself is responsible for effects, any such observed covariance of intervention components with effectiveness will help point intervention designers in the right direction.
We will report on the quality of the included studies, but as we do not anticipate any pooling of data or meta-analysis, studies with poorer quality ratings will be retained. Nonetheless, we see value in performing a quality assessment: we believe that a summary of study quality will provide a useful snapshot of the methodological rigour of previous studies in this field and expands upon previous work that aimed to describe the quality of clinical trials in swallowing rehabilitation [15]. For ease of comparison, we have chosen to use the same quality assessment tool used in the review by Carnaby and Madhavan [15]. Discussion about quality assessment will be integrated into our narrative synthesis. It will help contextualise findings and as suggested by Popay and colleagues is also helpful in assessing the robustness of the synthesis [31].

This review is the first attempt to apply the behaviour change framework and taxonomy to the literature on swallowing rehabilitation interventions. We anticipate that descriptions of interventions are likely to lack detail but have decided against contacting authors for further information. We have instead decided to code these interventions based solely on the information which authors have made publicly available including appendices and published intervention manuals. While we are aware of the need to distinguish between reporting and conduct of the intervention, we also believe that consumers of research are usually only in a position to interpret studies based on the published report. The data extraction will therefore also be inability to access information available to all readers. We anticipate that the findings could be useful in promoting better reporting of future studies. Better specified interventions are more easily replicated and while it is not an explicit intention of the review, raising awareness of this may be a welcome influence on intervention design.

This review adopts a new framework that we hope will help clinicians identify and begin to understand the behaviour change components of the complex therapy interventions they provide to their patients. We are presented with new challenges in the quest to assimilate the evidence for interventions. As articulated by Petticrew [32], it may be necessary to expand our enquiry from 'what works' when swallowing interventions are delivered to 'what happens' that might make them work. We are required to explore a broader question to ascertain what has happened in previous interventions, as opposed to focusing solely on intervention effects. For a field which is relatively new to evidence synthesis and with relatively few high-quality randomised studies, this approach offers a way of systematically gathering the available evidence as a first step to developing hypotheses for further testing.

**Reporting and dissemination of findings**

We plan to report this review in accordance with the PRISMA guidelines [33] and to publish the findings in a peer-reviewed journal. We also expect to present these findings at relevant national and international scientific meetings.

**Additional file**

Additional file 1: Table S1. Frequency of RCTs in interventions reported to be effective or ineffective at 6-month follow-up.

**Abbreviations**

- RCT: Randomized controlled trial
- PICO: Patient, Intervention, Comparator, Outcome
- HRQoL: Health Related Quality of Life
- FT: Full text

**Computing interests**

The authors declare that they have no competing interests.

**Authors’ contributions**

RG and RG conceived of the study and designed the protocol. CS and ST contributed to further refinement of the protocol. GG assisted with the search strategy and preliminary screening. RG drafted the manuscript, which was reviewed by all authors. We provided critical feedback. The final manuscript was approved by all authors.

**Acknowledgements**

None.

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**Author details**


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**References**


Appendix 3-2: Systematic review publication

Swallowing interventions for the treatment of dysphagia after head and neck cancer: a systematic review of behavioural strategies used to promote patient adherence to swallowing exercises

Roganie Govender, Christina H. Smith, Stuart A. Taylor, Helen Barratt and Benjamin Gardner

Abstract

Background: Dysphagia is a significant side effect following treatment for head and neck cancers, yet poor adherence to swallowing exercises is frequently reported in intervention studies. Behaviour change techniques (BCTs) can be used to improve adherence, but no review to date has described the techniques or indicated which may be more associated with improved swallowing outcomes.

Methods: A systematic review was conducted to identify behavioural strategies in swallowing interventions, and to explore any relationships between these strategies and intervention effects. Randomised and quasi-randomised studies of head and neck cancer patients were included. Behavioural interventions to improve swallowing were eligible provided a valid measure of swallowing function was reported. A validated and comprehensive list of 93 discrete BCTs was used to code interventions. Analysis was conducted via a structured synthesis approach.

Results: Fifteen studies (8 randomised) were included, and 20 different BCTs were each identified in at least one intervention. The BCTs identified in almost all interventions were: instruction on how to perform the behavior, setting behavioural goals and action planning. The BCTs that occurred more frequently in effective interventions, were: practical social support, behavioural practice, self-monitoring of behaviour and credible source for example a skilled clinician delivering the intervention. The presence of identical BCTs in comparator groups may diminish effects.

Conclusions: Swallowing interventions feature multiple components that may potentially impact outcomes. This review maps the behavioural components of reported interventions and provides a method to consistently describe these components going forward. Future work may seek to test the most effective BCTs, to inform optimisation of swallowing interventions.

Keywords: Dysphagia, Head neck cancer, Swallowing exercises, Behavior change techniques, Adherence, Complex interventions
Background
Swallowing difficulties (dysphagia), which affect 60–75% of patients treated for head and neck cancer (HNC) [1], arise both from the presence of a tumour and as a consequence of its treatment [2]. Dysphagia is a major patient concern after cancer treatment due to the detrimental impact on patients’ quality of life (QoL) [3]. Improvement of swallowing function and earlier restoration of eating and drinking after surgery or chemoradiation treatments may be achieved with swallowing rehabilitation exercises [4, 5]. Despite this, non-adherence to swallowing exercises in this population is reported to be high [6].

The World Health Organization report defines patient adherence as “the extent to which a person’s behaviour corresponds with agreed recommendations from a healthcare provider” [7]. This report highlights that adherence is influenced by multiple factors, and that increasing adherence to treatment could have a greater impact on health than trying to improve the efficacy of the treatment to which patients are encouraged to adhere. Adopting this perspective transforms the concept of patient adherence from a peripheral marker of study quality into a concept central to the intervention. The Medical Research Council’s “complex intervention” guidelines highlight that multiple components at different levels may interact to bring about desired health outcomes [8]. Effectiveness of swallowing exercise interventions are determined not just by the exercises but also the broader ‘behaviours of those delivering and receiving the intervention’ (p.97). Complex interventions that take place as pragmatic trials under real-world conditions [9] are influenced by context factors; how interventions are implemented (where, by whom) and how patients may respond to this (uptake/adherence) [10].

Newer paradigms in systematic reviews such as a realist reviews focus on understanding how and why interventions work in some situations and not others, rather than simply investigating whether they do or do not work [11]. Sutcliffe and colleagues [12] argue the importance of recognising and identifying the critical components of complex interventions highlighting that outcomes of complex interventions cannot be solely ascribed to the primary content, in this case swallowing exercises. Traditional systematic reviews that focus exclusively on pooling effect sizes may overlook other aspects that influence outcomes. This limits our ability to differentially examine the evidence and to gather important information that may improve future interventions.

The system in which the intervention takes place and the possible interactions that may occur can be represented as a logic model [13] (Fig. 1). Swallowing exercise interventions for patients with HNC are normally implemented by trained professionals such as speech therapists within a healthcare setting, and as part of a wider cancer care pathway. The content of the intervention tends to be focused on type, timing and intensity of different swallowing exercises. Accordingly, previous reviews have been largely concerned with these exercise parameters. Langmore and Baegna [14] suggest that exercises such as the Shaker (head lift exercise) and Mendelsohn manoeuvre (larynx elevation exercise) have good efficacy in improving swallowing function. A general review of interventions to improve eating and drinking after HNC [15] concluded
that some evidence exists to support exercises to improve swallowing function and jaw movement in patients treated for HNC but acknowledged that larger controlled studies are needed. A recent Cochrane review [16] concluded that the evidence for pre-treatment swallowing exercises in improving swallowing safety and efficiency is lacking due to insufficiently robust studies, heterogeneity of outcome measures across studies, and poor patient adherence. Whilst there is much to be learned from these reviews, the broader perspective proposed in our logic model may facilitate better understanding of the existing evidence that could improve the content and design of future studies (Fig. 1).

As highlighted in our model, behavioural strategies used to promote adherence to the exercises are an important part of the intervention content that may be frequently overlooked yet such strategies may have a potentially crucial influence on outcomes. This review employs established tools from Behavioural Science, in particular the Behaviour Change Technique Taxonomy (BCTTv1) [17] that defines 93 discrete behaviour change techniques (BCTs) thereby facilitating a standardised description of the techniques that can be used to change behaviour. BCTs represent the smallest observable and replicable components that may bring about a change in behaviour [17], and therefore may be potentially active ingredients in an intervention [18]. The success of exercise interventions is dependent on good adherence. It is logical therefore that this aspect of the intervention be given appropriate consideration.

In this review, we aim to identify the specific behaviour change strategies reported in interventions to improve swallowing function after HNC. We also explored where possible, relationships between the presence of these components and intervention effectiveness. We propose that BCTs that occur at least twice as frequently in successful interventions may be useful to include in future interventions. We used a narrative synthesis approach [19] and as part of this we also explored the trial methods used more broadly (for example type of comparator group), providing discussion of possible associations with the study outcomes. To our knowledge this is the first attempt to apply this method of reviewing swallowing interventions within this field, and by its nature the work is exploratory.

Methods
The review is registered with PROSPERO (CRD42015017048), and a protocol reporting full methodological detail has been published [20].

Eligibility Criteria
Studies were eligible for inclusion where they met the following PICO criteria [21]. Participants were adults diagnosed with head and neck cancer, treated via one of the key treatment modalities of surgery, radiotherapy, chemo-radiotherapy or combinations thereof. Interventions that were eligible included behavioural interventions to improve swallowing such as swallowing exercises or instructions to adhere to a specific diet texture, and other specific swallowing strategies. Studies that included an independent comparator group were eligible - these could be randomised or non-randomised studies. The comparator group could have received no treatment (non-active comparator), usual care (active or non-active) or a different treatment (active) or sham exercise (active). For inclusion, the study had to report at least one swallow-related outcome measure which could be for example, swallow safety, swallow efficiency, swallow related QOL, oral diet intake or a surrogate marker such as feeding tube use, and textures of food tolerated. Evaluation could be via an established patient reported questionnaire, clinician rated measure or instrumental assessment tool such as videofluoroscopy.

Identification of studies
Six electronic health databases were searched: Medline, CINAHL, EMBASE, AMED, PsychINFO, and the Cochrane Library including CENTRAL. Additional searches were carried out on Google Scholar, Web of Science and the meta-registries of Trials Databases (ClinicalTrials.gov and ISRCTN). Additionally, the WHO International Clinical Trials Registry Platform (ICTRP) and the Australian New Zealand Clinical Trials Register (ANZCTR) were searched. A hand-search of reference lists of directly relevant systematic reviews and included articles identified from the main screening was also undertaken.

The search strategy was developed in conjunction with a subject librarian, following an initial scoping exercise. Medical Subject Headings from key articles and other related reviews were examined to determine the final search terms. The search was limited to clinical trials and reviews published in English. No date limit was applied.

Searches were carried out by a speech and language therapist (RG) and subject librarian (DG) in December 2014, and updated in June 2015 prior to completion of the data extraction process. One study [22] found to have two additional related reports based on longer follow-up times for the same sample and intervention, was treated as one study. Figure 2 depicts the PRISMA flowchart [23] showing the study selection process (Fig. 2).

Data extraction
Study quality
For consistency with other reviews, data was extracted on study quality using an 11-item checklist [24] used previously to assess the quality of dysphagia clinical
Fig. 2 PRISMA flowchart showing process of study selection.

Each of the 11 items (Table 2) is given a score of 1 if the criterion is met, yielding a summary score of 0 (lowest) to 11 (highest quality). Van Tulder and colleagues [24] suggest that scores of ≥6 reflect studies of good quality. Studies were not excluded on the basis of quality because we aimed to ascertain any evidence. However, weak, or potential links between BCTs and effects. Assessing study quality and potential risk of bias is still important when synthesizing findings even if only exploratory in nature [19].

Study characteristics
Data were extracted on study characteristics (author, year, country of origin, setting, type of study), patient characteristics (diagnostic and treatment group, sample size, age range, gender and baseline swallow function), treatment (information about the type of treatment and comparator groups), and outcome measures (length of follow-up and all swallow related outcomes). We anticipated heterogeneity in the type and time-points of outcome measures but an attempt was made to extract data at or as close to the time intervals of 1, 3, 6 and 12 months after treatment. They included measures derived from instrumental assessments such as modified barium swallow or videofluoroscopy, clinical measurements such as weight or the water swallow test (WST) [26], functional scales such as the Functional Oral Intake Scale (FOIS) [27] and Performance Status Scale (PSS) [28], patient-reported and QOL measures such as the MD Anderson Dysphagia Inventory (MDADI) [29] and European Organisation for Research and Treatment of Cancer (EORTC QOL-C-30) [30] questionnaire.

Intervention Characteristics
For this review, we were particularly interested in identifying the behaviour change strategies (Additional file 1: Table S1 and Additional file 2: Table S2) present in the interventions. We recorded the target behaviour in each
study, which was either regular performance of swallowing exercises or regular implementation of a prescribed diet modification with or without specific swallowing strategies. We intended to code whether a named theory of behaviour or behaviour change was mentioned in the Abstract, Introduction, or Method, but no studies were found to have mentioned theory. We identified behaviour change strategies using BCTTv1. We also documented Intervention Function categories. Michie and colleagues [31] propose a list of nine Function categories that reflect the broad methods through which an intervention may influence behaviour: Education, Training, Enablement, Modeling, Restrictions, Environmental Restructuring, Persuasion, Incentivisation and Coercion. Both BCTs and intervention functions were only coded when they were unambiguously present in the intervention descriptions. For example if the intervention included a TeraBite device (Atox Medical, Sweden) to maintain mouth opening function — the intervention function Education was coded if it was clear that the intervention explicitly required that patients be informed and understand how the device and exercise works to maintain the ability to open the jaw. This may extend to information about the impact of radiotherapy on jaw movement and the consequences of doing/not doing the exercise. The function category Training was coded where it was clear that the patient was taught skills on how to perform the exercises using the device. The BCT demonstration on how to perform the behaviour was coded if the patient was presented with an observable demonstration, but not if only provided with written instructions; this was coded as instruction on how to perform the behaviour.

A clinician (RG) extracted data for all included studies. A speech and language therapist (CS) and health psychologist (RG) independently extracted data for four (27%) randomly selected studies. Inter-rater agreement, assessed using Cohen’s kappa, was ‘substantial’ K = 0.6’ or better for selection of full-text articles assessed for inclusion (K = 0.86), study quality (K = 0.74) and BCTs (K = 0.66) [32].

Analysis
A meta-analysis was not used due to the small number of studies and the large variability. Furthermore, it would not have been as informative for the purpose of addressing our study questions. Instead we selected a qualitative method that combined the use of summary tables, and qualitative exploration of the data.

We used a synthesis approach [19] to describe and explore our findings. Results are structured and presented in line with the key steps of this approach as listed below:

1. Developing a theory or model of how the intervention might work: Our logic model illustrating the interaction of various components of the intervention within a health service system has been presented above.
2. Preliminary synthesis of the findings — We summarise the characteristics of the included studies tabulating the same features across all studies. Additionally, we present summary tables of the intervention characteristics (behavioural strategies) extracted from studies and examples of these strategies obtained from content analysis of the study reports.
3. Exploring relationships in the data — We present observations of relationships between studies that may explain differences in outcomes and the direction and size of intervention effects. We assumed that BCTs that featured at least twice as frequently in studies that showed a statistically significant positive effect on at least one outcome measure (p < .05) in favour of the intervention group may show some promise, or at least justify more rigorous evaluation.
4. Assessing the robustness of the synthesis — We reflect on the number and quality of the studies included, and the methods used in synthesising the findings.

Results
Synthesis of study and intervention characteristics
Study selection
Of 374 articles identified from the combined searches, 254 remained after de-duplication. Twenty-nine articles were retained following title and abstract screening, of which 15 studies, each reporting one intervention, were eligible for review. No additional studies were included following the hand-search of reference lists.

Study characteristics
The 15 studies were undertaken across seven countries (USA, 7 studies; Netherlands and China, 2 studies respectively; Denmark, Sweden, Austria, Japan, 1 study respectively). All were carried out in a university hospital, medical centre or cancer centre. All studies sought to evaluate the impact of swallowing exercises, on one or more swallow-related outcomes. Eight were randomised trials [22, 33–39], and seven were non-randomised controlled trials [40–46]. Six studies reported a comparator group of ‘no treatment’ [36–38, 42–44] and two of delayed treatment [40, 45]. In two studies, treatment as usual was described as dietary advice without exercise [33, 34]. The comparator group for the remaining studies used a different swallowing exercise protocol described as usual care for that setting.
Follow-ups took place between one and 12 months. The measure used for baseline swallowing status varied greatly, with 5 studies [40, 42–45] providing no report of swallowing function at baseline. At least 14 different outcome measures relating to swallowing function were reported across the studies and at varied time intervals (Additional file 3: Table S3). The most frequently used measures (7/15) were modified barium swallow and use of a feeding tube as a surrogate marker of swallowing (dys)function. The PSS or a patient rated diet texture score, mouth opening, penetration-aspiration scale (PAS) [47], MDAI and weight measures were also used across multiple studies, although less frequently. Almost all studies reported a combination of instrumentally derived (objective), patient-reported and/or clinician rated outcomes measures. Two studies [42, 45] reported on just the MDAI, and one study [46] reported on a diet texture score alone.

Sample characteristics
A total of 995 participants were reported at the commencement of the studies (Table 1; 729 males, 257 females, nine unclassified). Sample size ranged from 18 to 374. Average age across studies was 59.4 years. Both the gender and age demographics are broadly reflective of the epidemiology of HNC [48, 49].

Patients’ HNC diagnosis ranged from stage II to stage IV disease. The sites included the oral cavity, oropharynx, hypopharynx, nasopharynx and larynx. The majority of studies (12/15), focused on the group of patients treated with radiotherapy or chemo-radiation. Of these 12 studies, ten focused on pre-treatment swallowing interventions. Three of the 15 studies [39, 42, 46] targeted patients who were treated with surgery as the main modality (Table 1).

Quality assessment
As indicated in Table 2, only one study [37] achieved a score >6 and met the criteria for good quality [24]. In 7/15 studies, there was at least one item for which information was missing or could not be deduced from the study report. Scores ranged from 0–7 out of 11. No study complied with criteria requiring that the therapists and subject were blinded to the intervention (15/15) (Table 2).

Intervention characteristics
Twenty individual BCTs (Table 3) were each identified in at least one intervention. The average number of BCTs per intervention was seven, with a range of four to ten. The BCT instruction on how to perform the behaviour was reported in all interventions (15/15), with 14/15 including setting behavioural goals (for example, perform jaw exercises 3×/day) and 13/15 including action planning (for example perform exercises before mealtimes) (Additional file 1: Table S3).

A total of three Function categories were each identified in at least one intervention. Training was identified in all interventions (15/15), Education in 12/15 and Enablement for example providing patient with a Thera-Bite device in 5/15 (Additional file 2: Table S2).

Regular performance of the prescribed swallowing exercises was the target behaviour for all interventions. Due to the small number of studies, and the variation in exercise content we made no attempt to further group interventions according to the exercise type (Table 3).

Exploring relationships between behavioural strategies and effectiveness
Frequency of behavioral intervention components and intervention effectiveness
The three most commonly used BCTs that appeared in >85% of interventions were instruction on how to perform the behaviour, setting behavioural goals and action planning. These BCTs may arguably form the cornerstone of exercise therapy interventions so it is unsurprising that they were identified in >85% of interventions. Four BCTs were used in at least twice as many interventions that produced positive effects relative to those with no such effects - practical social support, behavioural practice/rehearsal, self-monitoring, and credible source.

Exploring relationships between trial methods and effectiveness
Influence of comparator group on intervention effectiveness
We wished to explore any relations between active and non-active comparator groups and intervention effectiveness. Of five studies [22, 33–35, 43] reporting no evidence of a significantly positive effect of the intervention on any outcome, four had an active control group where similar behavioural strategies were used in both the intervention and comparator groups, except Aihlberg [43] who used parallel groups on different sites. The active comparator group represented either a different exercise regime (often described as usual care), or may have omitted the use of a swallowing exercise device that was included in the intervention group.

Of the ten interventions that demonstrated evidence of positive effects on at least one swallowing outcome measure (Additional file 3: Table S3), five [30–38, 42, 46] had a non-active comparator group. In two studies [40, 45], intervention was delayed and therefore effectively represents a non-active comparator group. Two studies had an active comparator group that received a different exercise intervention [39, 41]. One study [46] used similar exercise interventions but the intervention group included biofeedback by providing the patient with visual feedback of swallowing during a fibroptic
<table>
<thead>
<tr>
<th>Author/year</th>
<th>Country of Orlgn.</th>
<th>Setting</th>
<th>Type of study</th>
<th>Type of Intervention</th>
<th>Oncology Treatment, sample characteristics</th>
<th>Sample size</th>
<th>Gender</th>
<th>Sample age for (E) and (C) groups (mean ± SD/range)</th>
<th>Baseline Swallowing status</th>
<th>Length of Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mørtenen 2015</td>
<td>(DD) Denmark</td>
<td>University hospital</td>
<td>RCT (pre-treat)</td>
<td>Improved diet and exercise, protocol of standard exercises, initial visual dietary advice, SIS and advice as needed (active control)</td>
<td>Cancer of larynx, oropharynx, or unknown primary. Awarded for radiotherapy with or without chemo. No previous oncology treatment.</td>
<td>T=30 I=19</td>
<td>E=58 (58-78)</td>
<td>C=59 (40-74)</td>
<td>SF-36 1.94</td>
<td>11 months</td>
</tr>
<tr>
<td>Van Den Berg 2014</td>
<td>[44] Netherlands</td>
<td>University medical centre</td>
<td>RCT (pre-treat)</td>
<td>Combined dietary counselling and individualized swallowing therapy (C) vs. week dietary advice (E, active control)</td>
<td>Patients with stage IV HNC treated with postoperative radiation therapy with or without chemotherapy</td>
<td>T=120 I=60</td>
<td>E=63 (33-80)</td>
<td>C=60 (40-80)</td>
<td>SF-36 mean 51 (SD=25)</td>
<td>30 weeks</td>
</tr>
<tr>
<td>Ohba 2014</td>
<td>[42] Japan</td>
<td>University hospital</td>
<td>Prospective case-control design (post-treatment)</td>
<td>Inhale exercise during CRT (C) = Mendor in the same proportion only when dysphagia developed (delayed active)</td>
<td>Advanced HNC, laryngeal, oral pharyngeal, hypopharyngeal cancers.</td>
<td>T=51 I=21</td>
<td>E=65 (53-80)</td>
<td>C=63 (49-80)</td>
<td>Not reported</td>
<td>24 weeks</td>
</tr>
<tr>
<td>Lanzos 2014</td>
<td>[42] USA</td>
<td>Medical centre</td>
<td>RCT (post-treat)</td>
<td>Inhale tongue exercises with traditional exercises (C) vs. traditional exercises (E, active control)</td>
<td>Patients with stage IV oral and oropharyngeal cancer, who previously underwent radiotherapy with or without chemo.</td>
<td>T=33 I=12</td>
<td>E=63 (SD, 0.00)</td>
<td>C=60 (SD, 0.00)</td>
<td>OPG mean 41 (SD=25)</td>
<td>10 weeks</td>
</tr>
<tr>
<td>Visani 2013</td>
<td>[41] USA</td>
<td>Cancer centre</td>
<td>Non-randomized trial – matched groups (pre-treat)</td>
<td>Inhale swallowing exercises (C) vs. repetitive swallowing tasks (E, active control)</td>
<td>Newly diagnosed HNC of the oral cavity, oropharynx, nasopharynx, larynx or unknown primary due to undergoing radiotherapy with or without chemo.</td>
<td>T=52 I=26</td>
<td>E=64 (SD, 0.00)</td>
<td>C=60 (SD, 0.00)</td>
<td>OPG mean 66 (SD=25)</td>
<td>3 months</td>
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<tr>
<td>Katz 2012</td>
<td>[39] USA</td>
<td>Academic medical centre</td>
<td>RCT (pre-treat)</td>
<td>Inhale swallowing exercises (C) vs. no active treatment</td>
<td>Patients with HNC receiving CRT, excluding any surgery or previous radiation or previous history of dysphagia.</td>
<td>T=26 I=13</td>
<td>E=62 (SD, 0.00)</td>
<td>C=62 (SD, 0.00)</td>
<td>PS5 67 (SD=21)</td>
<td>12 months</td>
</tr>
<tr>
<td>Gambale-Mann 2013</td>
<td>[40] USA</td>
<td>University Hospital Cancer Centre</td>
<td>RCT 3 arms (pre-treat)</td>
<td>Inhale swallowing exercises (C) vs. swallowing exercises, oral care, swallowing exercises, and swallowing exercises, oropharyngeal and hypopharyngeal cancer and planned for external beam radiotherapy with or without chemotherapy.</td>
<td>Newly diagnosed HNC of the oral cavity, oropharynx, nasopharynx, larynx or unknown primary due to undergoing radiotherapy with or without chemo.</td>
<td>T=58 I=20</td>
<td>E=60 (SD, 0.00)</td>
<td>C=60 (SD, 0.00)</td>
<td>PS5 67 (SD=21)</td>
<td>6 months</td>
</tr>
<tr>
<td>Study ID</td>
<td>Country</td>
<td>Setting</td>
<td>Design</td>
<td>Intervention</td>
<td>Comparator</td>
<td>Study Start</td>
<td>Study End</td>
<td>Duration</td>
<td>Number</td>
<td>Follow-up</td>
</tr>
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<tr>
<td>Zhao 2012 [42] China</td>
<td>University Hospital</td>
<td>Quasi-experiment</td>
<td>Parallel</td>
<td>Daily schedule, Active control = sham, and no treatment group</td>
<td>Active treatment = daily schedule, Active control = sham, and no treatment group</td>
<td>All patients were post建设工程 surgery, MDCAT score of 60 or lower on screening.</td>
<td>T = 46.1, C = 23</td>
<td>C = 23</td>
<td>2917</td>
<td>Not reported</td>
</tr>
<tr>
<td>Ahnberg 2011 [48] Sweden</td>
<td>University Hospital</td>
<td>Randomized controlled trial</td>
<td>Parallel</td>
<td>Pre-treatment swallowing exercise, Active treatment intervention</td>
<td>Pre-treatment swallowing exercise, Active treatment intervention</td>
<td>Patients diagnosed with HNC due to receive curative radiotherapy</td>
<td>T = 37.4</td>
<td>C = 190</td>
<td>2531</td>
<td>Not reported</td>
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<tr>
<td>Tang 2011 [50] China</td>
<td>University Hospital</td>
<td>Parallel</td>
<td>Pre-treatment swallowing exercise, Active treatment intervention</td>
<td>Pre-treatment swallowing exercise, Active treatment intervention</td>
<td>Previously diagnosed with neoplastic cancer and received radiotherapy – long term post-treatment, Stage IB/NiC (local extension, oropharyngeal, hypopharyngeal, larynx, nasopharynx) planned for curative chemoradiation treatment.</td>
<td>T = 46.1, C = 23</td>
<td>3211</td>
<td>C = 23</td>
<td>3211</td>
<td>Not indicated separately for groups</td>
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<tr>
<td>Van der Maren 2011 Netherlands</td>
<td>Cancer Centre</td>
<td>RCT</td>
<td>Pre-treatment swallowing exercise, Active treatment intervention</td>
<td>Pre-treatment swallowing exercise, Active treatment intervention</td>
<td>Stage II/III (distant spread: oral cavity, oropharynx, hypopharynx, larynx, nasopharynx) included for curative chemoradiation treatment.</td>
<td>T = 55.1, C = 28</td>
<td>3910</td>
<td>C = 28</td>
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<td>University Hospital</td>
<td>RCT</td>
<td>Pre-treatment swallowing exercise, Active treatment intervention</td>
<td>Pre-treatment swallowing exercise, Active treatment intervention</td>
<td>Patients with prolonged oro-pharyngeal dysphagia of at least 3 month duration</td>
<td>T = 551.1, C = 11</td>
<td>163</td>
<td>C = 11</td>
<td>163</td>
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<td>Carroll 2007 [44] USA</td>
<td>University Hospital</td>
<td>2-arm Retrospective Case Control Study</td>
<td>Pre-treatment swallowing exercise protocol, Active treatment intervention</td>
<td>Pre-treatment swallowing exercise protocol, Active treatment intervention</td>
<td>Patients with advanced squamous cell carcinoma of the oropharynx, hypopharynx and larynx, treated with chemoradiation.</td>
<td>T = 18.1, C = 9</td>
<td>126</td>
<td>C = 9</td>
<td>126</td>
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<td>Kolber 2006 [45] USA</td>
<td>University Hospital</td>
<td>2-arm Prospective cohort study</td>
<td>Pre-treatment swallowing exercise protocol, Active treatment intervention</td>
<td>Pre-treatment swallowing exercise protocol, Active treatment intervention</td>
<td>Patients with HNC within 12 months disease without metastatic disease</td>
<td>T = 37.1, C = 12</td>
<td>289</td>
<td>C = 12</td>
<td>289</td>
<td>Not reported</td>
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<tr>
<td>Denk 1997 [46] Austria</td>
<td>ENT department</td>
<td>Non-randomized</td>
<td>2-arm parallel</td>
<td>Pre-treatment swallowing exercise, Active treatment intervention</td>
<td>Pre-treatment swallowing exercise, Active treatment intervention</td>
<td>Patients with prolonged post-operative aspiration following resection of malignant tumours of the oro-pharyngeal swallowing structures.</td>
<td>T = 33.1, C = 14</td>
<td>258</td>
<td>C = 14</td>
<td>258</td>
</tr>
</tbody>
</table>

Notes: (I) = Intervention group; (C) = control group; T = total sample; RCT = randomized controlled trial; HNC = head and neck cancer; SPSS = swallowing performance status scale; PSS = performance status scale; OAR = oropharyngeal swallowing efficiency; FSS = functional oral intake scale; MSA = Mann swallowing assessment; WST = water swallowing test; ID = inter-decker distance. *Later papers linked to this study include follow-up measures at 2 years, and 6 years.
Table 2: Quality assessment ratings for all studies included in the review

<table>
<thead>
<tr>
<th>Mortensen</th>
<th>Van Den Berg</th>
<th>Ohta</th>
<th>Laczus</th>
<th>Yani</th>
<th>Rotz</th>
<th>Carnaby</th>
<th>Mann</th>
<th>Zhen</th>
<th>AHiberg</th>
<th>Tang</th>
<th>Van Der Logemann</th>
<th>Caroll</th>
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endoscopic assessment. One study [37] had 3 groups: a treatment group receiving swallowing exercises, a group receiving sham exercises using a similar dose schedule and a usual care group who received only self-feeding advice by the hospital team when required but not an exercise intervention. The authors found a statistically significant difference between each of the active groups (swallowing exercises and sham exercises) and the usual care group, but a smaller difference (favouring the exercise group) between the swallowing exercise group vs sham exercise group.

Again we acknowledge the small number of studies, however our findings seem to indicate that employing active comparator groups particularly when similar behavioural strategies are used, are less likely to demonstrate statistically significant positive effects. Interestingly, a positive effect was still found in one study [46] when both groups received similar exercise interventions, but different non-exercise content (intervention group received biofeedback, a named BCT).

Type and timing of outcome measures and intervention effectiveness

Outcomes that significantly improved with the exercise intervention did so mostly at 1 month post oncological treatment, with a general decline in effect at the later time-points after treatment. Four studies measured outcomes at 12 months [33, 36, 44, 45] but only one [45] showed a significant difference in favour of the intervention by this time-point. In one study [36], outcomes were measured at multiple time-points; significant differences were observed at 3 and 6 months post-treatment but not at 9 and 12 months (Additional file 3: Table S3). Another study [33] charted a rapid decline in patient adherence to swallowing exercises over the first 12 months following treatment.

Outcomes broadly classified as objective measures (PAS, MBS score, mouth opening, feeding tube) were more frequently improved by the intervention, when compared to patient reported and clinician rated measures.

This exploration of the data has highlighted the potential impact that BCTs and trial methods such as choice of comparator group and timing of outcome measures may have on intervention effectiveness. Implications of these findings are expanded upon in the Discussion.

Discussion

We identified 15 controlled clinical trials (8 randomised) that currently represent the best available evidence of
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swallowing interventions for patients with HNC, and extracted three function categories and 20 different BCTs that characterize these interventions. By specifically isolating these BCTs, we may encourage more consistent descriptions of the non-exercise content of swallowing exercise interventions in the literature increasing our ability to replicate studies more accurately. Indeed, in time it may be possible to devise interventions that test the effectiveness of specific BCTs or groups of BCTs used in swallowing exercise interventions for this patient population, and to link these to underlying theory and mechanisms of change [50]. In so doing, we may be better placed to understand why interventions work, for whom and in which contexts [11].

We also examined the data for any relationships that may elucidate the interaction of different components of this complex intervention. For example, studies that employed active and comparator groups using a sham approach to the intervention group were more likely to demonstrate non-significant results. Furthermore, in a trial that employed three groups [37], (an exercise group, a sham exercise group, and a non-active control group), the authors reported that the active sham exercise group that received similar BCTs to the sham exercise group achieved much better outcomes compared to the non-active control group. It may therefore be the constituent BCTs that were responsible for intervention effectiveness, by stimulating greater adherence to the prescribed treatment. Whilst the authors themselves did not specifically make reference to BCTs, they did question whether the ‘benefits obtained from the sham group could be ascribed to the placebo effect of behavioral attention’ (p.219). Equally they speculated that the sham exercise (done diligently) might have had an intrinsic benefit from the increased movement of oral musculature. Regardless, these findings raise the possibility that BCTs may be functioning as active ingredients influencing intervention outcomes. For most studies where both the intervention and active comparison group used similar BCTs, no statistical significance in outcomes between groups was reported. This might be because the interventions given to both groups were too similar, or because of a lack of power due to small sample sizes. However it does raise other interesting questions: What contribution do BCTs add to intervention outcomes, and how does their presence in usual care/placebo interventions impact effectiveness? Reporting of swallowing exercise interventions tends to focus mainly on the treatment group and often provides only cursory reference to the usual care group. The findings of this review highlight that the same methodological care should be taken in devising the treatment manuals for the intervention and comparator groups, ensuring that behaviour change components are also specified, given their potential to impact patient adherence and subsequent outcomes. This may prevent hasty conclusions that imply swallowing exercises have no benefit, rather than the conclusion that the “new intervention” was not shown to demonstrate any significant additional benefit over usual care.

The variability in the type and time-point of the primary outcome measures for clinical trials in this field restricts the ability to satisfactorily pool data or compute effect sizes to address the efficacy of swallowing interventions in patients with head and neck cancer. We generally observed that in studies that reported a positive outcome, this was mostly seen in the short term. One reason for this may be because patients do not continue with their exercises long term. Behavioural strategies such as habit formation, requires that an individual repeatedly perform the behaviour in the same context and that it be determined. This means the latter may promote maintenance of exercises as it may over-ride conscious intentions [51] and could have a role to play in improving swallowing outcomes longer term. We also observed that outcomes collected after 6 months showed little difference between groups. This was especially relevant for patient-reported outcomes that may be very different from those that predict maintenance of the behaviour. By implication, different BCTs may be required for these distinct phases. It was also noted that few studies actually collected objective measures of swallowing in the longer term, making it difficult to assess changes in swallowing physiology at later time-points. Standardizing outcome measures and agreement on the key evaluation time-points will greatly assist efforts to understand if swallowing exercise interventions are indeed beneficial for this group of patients and over what time period. Consideration should also be given to the expected trajectory of swallowing recovery after head and neck cancer treatment including the possible onset of late effects of treatment such as post radiation fibrosis known to impair swallowing function [53, 54].

Assessing the robustness of the synthesis
According to Popay and colleagues [19], robustness of a synthesis is usually determined by 1) the methodological quality of the included studies, 2) methods used to minimize bias in the synthesis process, and 3) whether detailed information has been provided on the type of studies included/excluded. This review met the latter two criteria by providing detailed information via a
published protocol. Methodological quality of the available evidence was rated as poor with only one study meeting more than 50% of the applied quality criteria. It is however acknowledged that for this type of intervention, it is usually impossible to blind the therapist and subject to the intervention. Attrition is a common feature for studies that involve a complex intervention within a multifaceted cancer care pathway, and randomised studies within this field are only beginning to emerge [16, 25]. Excluding studies that did not meet quality criteria may therefore have disadvantaged our ability to address our primary aims in this exercise. Furthermore, complex interventions may require a differing emphasis on the markers of study quality as they are frequently evaluated within the context of pragmatic clinical trials. Since developing our protocol, new methods of evaluating quality in complex interventions have begun to emerge that may be more suitable for future use [9].

Limitations and challenges

This review is limited by the fact that the accuracy of the coding scheme relies on the quality of published intervention reports, which are often not sufficiently detailed to extract all necessary components of the intervention [55]. It is possible therefore that the intervention itself may have included strategies that have not been coded in this review. Descriptions of the treatment delivered to comparator groups in particular were poor, and in some cases decisions about the presence of BCTs in the comparator group had to be based on the authors’ implicit suggestions that interventions were identical apart from the specific exercise protocol used in each of the active groups.

Despite the BCT taxonomy being developed within Behavioural Science, there is ongoing debate amongst experts in behaviour change as to its merits. Critics have questioned the value of coding BCTs, suggesting it creates a level of abstraction that detracts from the detailed content analysis of interventions [56]. As a counter argument, we believe that in a clinical field that has focused mainly on exercise protocol content, drawing attention to broader more abstract process based mechanisms can only enrich our understanding of complex interventions. The taxonomy brings structure, organization and a common language to this process. For example, coding a BCT such as self-monitoring may not tell us how the self-monitoring was done, but it does highlight that the use of self-monitoring may be relevant to changing adherence behaviour, particularly when it is frequently observed in successful interventions.

What this review adds

This review applied a behavior change perspective to studies within head and neck cancer swallowing rehabilitation, with a specific focus on identifying the behavioral strategies that may impact patient adherence to exercises, and consequently swallowing outcomes. Such an analysis is absent in the current literature. Our aim was to interrogate discussion and greater thought about the complexity of swallowing exercise interventions, their design and the reporting of such interventions. It addresses the question of what might bring about change by isolating the specific components within an intervention, other than the nature of the treatments to which patients are encouraged to adhere, that may influence behaviour [57]. It therefore expands on the findings from previous related reviews [15, 16, 58, 59] and goes some way to highlighting additional components that may be present and active in this complex intervention. Given the relative paucity of high quality data, the review did not attempt to definitively answer the question of which BCTs are most effective in promoting adherence, but instead aimed to highlight those that were prevalent in successful interventions. Using this as a starting point, we may begin to design future interventions incorporating specific BCTs or groups of BCTs to examine more closely whether they strengthen interventions aimed at improving swallowing function via swallowing exercises. Clearly BCTs are only one part of trial design and equal attention should be placed on other important aspects such as precise definition of the whole intervention package in prospective study protocols and intervention manuals.

This approach seeks to generate new discussion toward understanding the make-up of complex interventions. It also offers new perspectives in the interpretation of findings from clinical trials of swallowing exercises where it is clear that evaluating effectiveness is hampered by poor adherence.

Conclusion

The effectiveness of swallowing exercises depends in part on adherence to exercises. This review looks at BCTs – these seem to promote adherence. The review has provided preliminary information about which BCTs occur in reports of complex swallowing interventions and has highlighted that behavioural components may be active ingredients of change that impact intervention outcomes. It is likely that many BCTs are used in clinical practice, and there will be some bias towards the techniques that researchers tend to report. Nevertheless, introducing the taxonomy of BCTs helps equip dysphagia researchers with the tools and the language to improve consistency in how complex interventions are specified in research protocols, intervention manuals and the published literature study. In time, the approach can also be used in examining fidelity in the delivery of interventions through field testing and observational methods. Its merits and weaknesses can only be
adequately evaluated as the body of work adopting this approach increases.

Additional files

Additional file 1: Table S1. BCTs, descriptions and examples from included studies where identified. NB: A complete list of BCTs in the taxonomy (BCTv1) and a full description can be found in Michie, Atkins & West (i-o). DOI: 10.1262/4912

Additional file 2: Table S2. Intervention Function definitions and examples from included studies where identified. NB: Further general examples of Intervention Functions can be found in Michie, Atkins & West (i-o). DOI: 10.1262/4912

Additional file 3: Table S3. Outcome measures obtained at four time points post oncology treatment. DOI: 10.1262/4912

Abbreviations
BCT: Behaviour change technique; BCTv1: Behaviour change technique taxonomy Version 1; EORTC: European Organisation for Research and Treatment of Cancer; FOS: Functional oral intake scale; HNC: Head and neck cancer; MBS: Modified Barium Swallow; MDADI: MD Anderson Dysphagia Inventory; PAS: Penetration aspiration scale; PRAMS: Preferred Reporting of Items for Systematic reviews and Meta Analyses; PSS Performance status scale; QOL: Quality of life; WST: Water swallow test.

Acknowledgements
The authors wish to thank Daphne Gay for her assistance with the Database searches. We also thank Professor Jane Wardle and Charles Abraham for their useful discussions and debate during the planning of this review. Jane Wardle passed away on 26 October 2015.

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Availability of data and material
All data generated or analysed during this study are included in this published article and its supplementary information files.

Authors’ contributions
RG and SC conceived and designed the study, CS and ST contributed to further refinement of the protocol, RG and CS carried out screening of articles, RG extracted all data and CS extracted a percentage of data and double extracted, RG analysed all data and drafted the manuscript, RG, ST, HS provided critical feedback throughout iterative revisions. All authors approved the final manuscript.

Competing interests
The authors declare that they have no competing interests.

Consent for publication
Not applicable.

Ethics approval and consent to participate
Not applicable.

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Published online: 10 January 2017

References
### Appendix 3-3: Data extraction template

<table>
<thead>
<tr>
<th><strong>Background information</strong></th>
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<tbody>
<tr>
<td>Author and year</td>
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<tr>
<td>Date coded &amp; coder</td>
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<tr>
<td>Country</td>
</tr>
<tr>
<td>Setting(s)</td>
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</table>

<table>
<thead>
<tr>
<th><strong>Methodological characteristics</strong></th>
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<tbody>
<tr>
<td>Number of arms / interventions</td>
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<tr>
<td>Study design</td>
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<tr>
<td>Length of follow-up</td>
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<tr>
<th><strong>Study quality: Van Tulder scale – yes(y) no (n) don’t know (Dk)</strong></th>
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<tbody>
<tr>
<td>A. Was there a method of randomization using an adequate procedure?</td>
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<td>B. Was the treatment allocation concealed?</td>
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<td>C. Were the groups similar at baseline regarding the most important prognostic indicators?</td>
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<tr>
<td>D. Was the patient blinded to the intervention?</td>
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<tr>
<td>E. Was the care provider blinded to the intervention?</td>
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<tr>
<td>F. Was the outcome assessor blinded to the intervention?</td>
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<tr>
<td>G. Were co-interventions avoided or similar? Was there control for co-interventions?</td>
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<td>H. Was the compliance acceptable in all groups?</td>
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<tr>
<td>I. Was the withdrawal/drop-out rate described &amp; acceptable? (i.e. &lt;20% short term and &lt;30% long term with no substantial bias)</td>
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<tr>
<td>J. Was the timing of outcome assessment in all groups similar?</td>
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<td>K. Did the analysis include an intention-to-treat analysis?</td>
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<td><strong>Total N (all groups)</strong></td>
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<tr>
<td><strong>Gender M : F</strong></td>
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**Intervention group participants**

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<thead>
<tr>
<th>N (at baseline)</th>
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<td>N (at follow-up)</td>
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<td><strong>Age mean(SD) at baseline</strong></td>
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<tr>
<td><strong>baseline swallow function</strong></td>
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<td><strong>Treatment/intervention</strong></td>
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<td><strong>Primary outcomes</strong></td>
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<tr>
<td><strong>Secondary outcomes</strong></td>
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**Control group participants**

<table>
<thead>
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<td>N (at follow-up)</td>
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<tr>
<td><strong>baseline swallow</strong></td>
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<tr>
<td><strong>Treatment /intervention</strong></td>
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<tr>
<td><strong>Primary outcomes</strong></td>
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<tr>
<td><strong>Secondary outcomes</strong></td>
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<table>
<thead>
<tr>
<th><strong>Which behaviour(s) are targeted?</strong></th>
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<td><strong>If multiple behaviours, what is the primary behavioural target?</strong></td>
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<tr>
<td><strong>Intervention function(s) (see BCW paper; delete as appropriate)</strong></td>
<td><strong>Education</strong> <strong>Persuasion</strong> <strong>Incentivisation</strong> <strong>Coercion</strong></td>
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</table>
### Training
- Restriction
- Environmental restructuring
- Modelling
- Enablement

**BCTs used (see BCTTv1) - List**

- Theory (for intervention techniques) mentioned in abstract, intro, methods
- Theory used to select/develop intervention techniques
- Who is the intervention delivered by
- Is fidelity measured?

**Control treatment details**

- Active or inactive control group?
  - If active ctrl: Number and nature of behavioural categories targeted by control treatment
  - If active ctrl: Intervention function(s)
  - If active ctrl: BCTs used
  - If active ctrl: Setting
- Who is the control treatment delivered by
- Is fidelity measured?

**Outcomes**

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<th>timing</th>
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List all swallow related measures.
List all time-points
Indicate positive, negative, no change.

If similar outcomes at similar time-points – then sub analysis can be done with forest plots if appropriate (need min 3 studies)

*Any comments:*
## Appendix 3-4: Outcome measures at 4 time-points

### Outcome measures at 1-month after treatment

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<th>OUTCOMES at or around 4 Weeks, (1month)</th>
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<th>P</th>
<th>C</th>
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### Outcome measures at 3 months post treatment

| OUTCOMES at or around 32 weeks, (2months) | O | P | C | M | V | D | D | R | L | T | E | K | T | D | W | N | T | O | Q |
| T2 weighted MRI                          | O | O | 0 | O |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| VPS/MBS scores                           | O | O | 0 | O |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| PAS (Ringenbeck)                         | O | O | 0 | O |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Tongue strength                          | O | O | 0 | O |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Mouth opening                            | O | O | 0 | O |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Weight                                   |   | O | O | O |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Feeding tube                             |   | O | O | O |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| VPS or diet texture score                |   | O | O | O |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| NST/volume measures                      |   | O | O | O |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| MASA                                     |   | C | O | O |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| FOSS                                     |   | C | O | O |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Obanac                                   |   | P | P | P |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| MBIADI                                   |   | P | P | P |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| QoL measure                              |   | P | P | P |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
Appendix 4-1: Barriers and Facilitators to swallowing exercises

Patient Experiences of Swallowing Exercises After Head and Neck Cancer: A Qualitative Study Examining Barriers and Facilitators Using Behaviour Change Theory

Roganie Govender, Caroline E. Wood, Stuart A. Taylor, Christina H. Smith, Helen Barratt, Benjamin Gardner

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Abstract Poor patient adherence to swallowing exercises is commonly reported in the dysphagia literature on patients treated for head and neck cancer. Establishing the effectiveness of exercise interventions for this population may be undermined by patient non-adherence. The purpose of this study was to explore the barriers and facilitators to exercise adherence from a patient perspective, and to determine the best strategies to reduce the barriers and enhance the facilitators. In-depth interviews were conducted on thirteen patients. We used a behaviour change framework and model [Theoretical domains framework and COM-B (Capability-opportunity-motivation-behaviour) model] to inform our interview schedule and structure our results, using a content analysis approach. The most frequent barrier identified was psychological capability. This was highlighted by patient reports of not clearly understanding reasons for the exercises, forgetting to do the exercises and not having a system to keep track. Other barriers included feeling overwhelmed by information at a difficult time (lack of automatic motivation) and pain and fatigue (lack of physical capability). Main facilitators included having social support from family and friends, the desire to prevent negative consequences such as long-term tube feeding (reflective motivation), having the skills to do the exercises (physical capability), having a routine or trigger and receiving feedback on the outcome of doing exercises (automatic motivation). Linking these findings back to the theoretical model allows for a more
systematic selection of theory-based strategies that may enhance the design of future swallowing exercise interventions for patients with head and neck cancer.

**Keywords** Dysphagia · Swallowing exercises · Adherence · Behaviour change · Qualitative interviews · Content analysis · Theory-based interventions

**Background**

Rehabilitation of swallowing function after treatment for head and neck cancer (HNC) requires patients to adhere to swallowing exercise interventions. However, adherence is generally reported to be poor [1-3]. Studies aiming to establish the effectiveness of exercise interventions for this population often neglect this aspect [4, 5], and may consequently portray effective interventions as ineffective. Improving patient adherence is one way of optimizing interventions prior to evaluation, although the most effective methods to improve adherence remain unclear. Techniques to increase adherence are likely to be more effective if they are informed by in-depth exploration of patients’ experiences of their swallowing exercises, probing both barriers and facilitators to adherence.

Patients presenting with HNC undergo a protracted journey from diagnosis through to treatment, rehabilitation and long-term follow-up with up to two-thirds experiencing dysphagia before treatment [6]. The swallowing sequence of surgical and non-surgical treatments is well documented and often predictable [7-9]. Clinicians have a unique opportunity to intervene early in the patient pathway [10, 11], and establish swallowing exercise programmes that may potentially enhance post-treatment outcomes [3, 12-18]. In a retrospective study of prophylactic swallowing exercises, patients who adhered most to their exercises were more likely to be tolerating a more regular diet one month post-treatment than non-adherents. Similarly, dependency on a gastrostomy tube was reported to be higher in patients who were non-adherent to exercises [19].

Some work has been undertaken to understand underlying reasons for non-adherence to swallowing exercises. In a telephone survey, Shinh et al. [1] reported that rates of complete non-adherence (did not do the exercises at all) were high (35%) with a further 36% reporting only partial adherence. Common reasons given by patients for non-adherence were as follows: not having a swallowing problem at the time and lack of understanding of the need for exercises, finding exercises difficult, forgetting to do them, being too busy, experiencing pain, nausea, and fatigue.

A more recent study [20] examined adherence to a 12-week preventative programme and investigated whether demographic (age, gender), clinical (tumour site and stage, and treatment modality) and health-related quality of life (HRQOL) were associated with exercise performance. The percentage of patients who adhered to the programme at least once daily for the duration of the study was 70% at 6 weeks, dropping to 38% at week 12. The addition of chemotherapy to the radiotherapy regime was the only significant factor associated with poorer exercise performance. This concurs with the findings of Shinh et al. [1] who reported that pain, nausea and fatigue in patients having chemo-radiation were barriers.

Previous studies have used mainly deductive methods to identify reasons for non-adherence, based on commonly endorsed researcher-generated ideas. Inductive methods using in-depth interviews that seek to spontaneously elicit the reasons, belief systems, attitudes and underlying values from patients provide a rich source of context-relevant information from a patient perspective. This may yield important additional barriers to exercise performance and adherence that may be highly relevant, but possibly less intuitive to the researcher. As this approach elicits the overall experience of patients, we may also learn which factors facilitate doing the exercises. Optimizing facilitators is another way of potentially improving the design of interventions. To our knowledge, no study has explored the problem of poor patient adherence to swallowing exercises amongst the HNC population using in-depth patient interviews guided by a theoretical framework. Theoretical frameworks of behaviour change, rooted in behavioural science, offer useful tools for exploring and organizing reasons for adherence/non-adherence. It has been suggested that interventions aimed at modifying behaviour are more likely to be successful if based upon theory. Theory allows researchers to be more systematic and explicit in investigating mechanisms of change [21], and has been demonstrated to have useful application in other aspects of speech and language therapy practice requiring behaviour change [22]. In using theory, we may accumulate knowledge incrementally, building on existing scientific knowledge.

This study is part of a larger project aimed at developing an optimized swallowing intervention package for patients with HNC. The purpose of the present study is to identify key factors (those most commonly reported by patients as being important to them) that may inform the design of a new intervention. Using behaviour change theory, the identification of barriers and facilitators (things that hinder or promote adherence) to performing swallowing exercises represents the first step in a behavioural analysis [23]. Categorizing findings according to a behavioural model...
could help identify the most useful strategies to minimize the barriers and enhance the facilitators.

The study received full ethical approval from a National Health Service (NHS) ethics committee (14/LO/152).

Methods

Design

We used face-to-face semi-structured interviews to explore and understand the personal meanings, experiences and issues pertinent to individuals in the context of their swallowing rehabilitation. We developed a topic guide that allowed participants the flexibility and freedom to narrate their experience of eating and drinking and swallowing rehabilitation over the course of their cancer treatment. Questions and probes were used to ensure that topics of interest were covered in adequate depth.

Theoretical Framework

We have drawn upon theoretical models from behavioural science namely, The theoretical domains framework (TDF) [34, 25] and the COMB (Capability, opportunity, motivation behaviour) model [26] to guide understanding of patients’ exercise adherence behaviours and experience of swallowing rehabilitation. The framework and model were used both in developing the interview schedule as well as informing the content analysis approach used.

A topic guide was developed using the TDF [34, 25] as a basis for prompt questions. The TDF consists of a comprehensive set of 14 domains into which all determinants of adherence to implementation of a behaviour can be organized: knowledge, cognitive and interpersonal skills, memory and decision processes, behavioural regulation, social influences, social professional role and identity, beliefs about capabilities, optimism, intentions, goals, beliefs about consequences, re-inforcement and emotion.

The TDF can be mapped onto the over-arching COMB model [26] which posits that three key components are necessary for any behaviour—capability, opportunity and motivation. For a behaviour to occur, an individual must have both the physical and psychological capability to perform the behaviour in terms of the mental and physical skills, knowledge, strength and stamina. The physical and social environment for example having the time, physical space, resources, support from others affords Opportunity. Motivation may be described as reflective where an individual is consciously involved in planning. This is based on his/her evaluations of whether something is good or bad to do, on whether it meets their goals, and their self-belief that they can perform a behaviour in spite of obstacles. Automatic motivation on the other hand is driven by impulses, emotional reaction or reflexive processes such as a trigger to perform a behaviour that has become habitual. Performing daily swallowing exercises is the primary target behaviour in most swallowing interventions, and is therefore the main subject of enquiry in this qualitative study. Figure 1 depicts how the topic guide (available as supplementary information) was developed using the theoretical framework to ensure comprehensive coverage of the key components that drive behaviour.

The topics included aspects such as knowledge of swallow exercises, ease of carrying out exercises, beliefs about exercises, feelings and emotions, and support for doing exercises. The interview opened with a general and broad question: Can you tell me how you got on eating and drinking at the time of your treatment? Follow-up questions and probes were introduced as part of the narrative flow rather than as individual discrete questions. Patients were encouraged to speak freely about their experiences with swallowing rehabilitation.

Participants and Sampling

All participants (patients) were recruited via clinicians working in the head and neck cancer centre at a UK...
Clinicians were asked to identify patients who had received treatment for advanced head and neck cancers. Patients who were between 3 and 18 months post-treatment were sought, as they were deemed sufficiently beyond the acute phase of recovery but still likely to reliably recall their experiences. Patients were required to have undergone swallowing rehabilitation including a minimum of three swallowing exercises consultations with a speech and language therapist (SLT).

The sample size was determined using the ‘ten plus three’ rule for data saturation [27]. An initial target of ten patients was set, with a view to achieving a point where three consecutive interviews could be undertaken without new themes emerging. Importantly, it was necessary to include sufficient diversity in the sample to ensure a good representation of socio-demographic factors. For this reason, midway through the recruitment, selected characteristics of participants were examined (age, gender, treatment modality and swallow function). Attempts were then made to purposively recruit participants with characteristics that were lacking in the existing sample, in order to ensure a broad range of experiences. Table 1 shows a summary of participant characteristics.

### Procedure

All patients provided written consent. All interviews were conducted by the lead researcher (RG), who is also a SLT clinician, previously unknown to the patients. Interviews lasted 40 min on average. A few minutes were spent before each interview completing basic biographic data and allowing time for questions about the study. This afforded patients time to relax into the environment and an opportunity for the interviewer to establish rapport. Interviews were digitally recorded and professionally transcribed verbatim. To ensure full anonymity on the recording, participants chose a pseudonym for themselves at the interview outset. Transcripts were imported into NVivo 10 (QSR International) to organize analysis.

### Analysis

The analysis was undertaken by the researcher (RG) in three stages, drawing upon the content analysis method. Content analysis is well suited to research questions that use context-relevant information generated from the interviews to re-populate pre-specified theoretical constructs [27]. Familiarity with data and initial coding involved listening to the recording, making notes and assigning initial codes to sections of text. Refinement of codes and development of a codebook were then undertaken by the researcher (RG). Codes were grouped into clusters that reflected broader themes and duplicate or redundant labels were removed. This was a recursive process that often required reading and re-reading content coded with the same label across interviews to ensure that it was an accurate depiction of the concept. Once a satisfactory coding system was achieved, codes were matched to the domains of the TDF. A working codebook was developed by the lead researcher/first coder (RG) to allow verification by a second coder (CW), with expertise in both qualitative analysis and the use of the TDF. Verification of coding and peer debrief was undertaken by the second coder (CW) using the codebook to independently code three randomly selected transcripts. This served to examine
reliability and improve validity thereby adding rigour to the analysis [28]. The peer debrief focused on three aspects which included *comprehensiveness of the codebook* (all relevant content could be attributed a code label), *degree of agreement for the presence of codes* (percentage agreement by both coders for the presence of codes in each transcript) and *degree of uncertainty* (any uncertainty with regard to description of code labels, TDF domain to which code assigned, need for new codes). Agreement on the presence of codes was above 90% for each of the transcripts. Uncertainties were resolved through discussion. Following this process, the first coder (RG) undertook a final reading of the transcripts to ensure that all content was appropriately coded, particularly where changes were made following the peer debrief. At the final step, coded material was realigned to the theoretical model to determine which variables may need to be targeted to bring about change.

Results

A total of 13 patients were interviewed to achieve data saturation. As indicated in Table 1, a range of patient characteristics was achieved. Tables 2 and 3 illustrate the key barriers and facilitators identified in greater than 50% of interview transcripts, and the corresponding mapping onto the relevant COM-B component.

**Capability**

*Psychological capability* was the primary component identified as a barrier to patients’ adherence to swallowing exercises. This encompasses the psychological skills including the mental stamina and processing of knowledge and information [26]. Patients recounted being given information but not necessarily relating this to why they might need to do their swallowing exercises. In addition to feeling that the pre-treatment exercises were just a precaution, some patients did not give much credence to the exercises themselves. This is exemplified by the following patient quote:

They just said to me, ‘Do that three times a day, whatever, in the morning and night.’ [talking about the exercises he was given] I thought ‘what’s it going to do?... What they told me, for the amount of times to do it, I thought it was just someone wrote it 100 years ago and it’s still the same rules (P7, male).

Patients also talked about the number of competing priorities during treatment and the cognitive burden of trying to do many different things just to get through

<table>
<thead>
<tr>
<th>Table 2</th>
<th>Key barriers to swallowing exercises</th>
<th>COM-B</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inadequate knowledge of how treatment will affect own swallowing</td>
<td>Psychological capability</td>
<td>The doctor scribbled down a few symptoms that I would suffer after the radiotherapy, one of which was sore throat and one of which was maybe problems with the swallowing, or something along these lines (P12)</td>
<td>They told me I will need a feeding tube. I will have a feeding tube. Even if I don’t use it they are going to give me a feeding tube, because, I don’t know, for example, nine out of ten patients, at some point during treatment, won’t be able to take food. So I will definitely need one (P13)</td>
</tr>
<tr>
<td>Inadequate understanding of why exercise given pre-treatment</td>
<td>Psychological capability</td>
<td>I understand someone sitting there explaining to me that you will need to do these exercises to help you swallow, but I don’t think the emphasis was how important they were, for me. I don’t think I actually took that on board (P3)</td>
<td>I was given some leaflets on swallowing exercises and told that I would probably get a dry mouth and that would cause problems with swallowing (P11)</td>
</tr>
<tr>
<td>Forgetting to do exercise, no system of keeping track</td>
<td>Psychological capability</td>
<td>It was a bit random; I would just do it when I remembered, some of the time (P1)</td>
<td>I think what I am remembering and what I’m saying is because there wasn’t a discipline around it, sometimes they slipped a bit (P9)</td>
</tr>
<tr>
<td>Overwhelmed by information at a difficult time (emotion)</td>
<td>Automatic motivation</td>
<td>Loads and loads of stuff was happening that was unfamiliar and a bit scary, and so, you know, I, sort of, felt a bit bombarded with stuff (P1)</td>
<td>There was a lot to take in during that period. This is something else to take in as well, necessary but not life... This isn’t going to save your life; it is going to make it better afterwards. Very important. But as a patient, when you are faced with a life-threatening situation, I think that wouldn’t be a priority and you’d want to push that away for now (P5)</td>
</tr>
<tr>
<td>Pain and fatigue</td>
<td>Physical capability</td>
<td>I tried to do some of the exercises some of the days. And some of the exercises I just couldn’t do because of the pain I was actually experiencing that particular day (P3)</td>
<td>When I got tired from the chemotherapy and so forth, I think I let it all, kind of, go a bit (P2)</td>
</tr>
</tbody>
</table>
Table 3 Key facilitation to swallowing exercises

<table>
<thead>
<tr>
<th>Key facilitation</th>
<th>COM-B</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Support from clinician and family</td>
<td>Social opportunity</td>
<td>So I think it was before and it was during right up until I could eat again,</td>
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<tr>
<td></td>
<td></td>
<td>I was constantly getting advice and help (P13).</td>
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<td></td>
<td></td>
<td>I started doing exercises, the throat exercises and eventually... it took</td>
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<td>some time, but I was told by my family as well that don’t give up.</td>
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<td>Because at that time I was just about to be a grandfather as well and</td>
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<td>that also gave me the strength (P10).</td>
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<td>But I don’t know. I just knew I had to eat, you know. And my object was</td>
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<td>not to use that... what do you call it? The tube they stick in you. And</td>
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<td></td>
<td>I managed it. I didn’t really use the tube (P6).</td>
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<td>I thought, well, if you don’t use muscles, they, sort of, stop working,</td>
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<td></td>
<td>don’t they? I’ve seen it with people with broken legs. If they don’t use</td>
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<td></td>
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<td>them the muscles wither. And so I thought I just do that... it’s just</td>
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<td>going to happen to my throat, I don’t want that happening (P7).</td>
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<tr>
<td>Knowing how to do the exercises (skills)</td>
<td>Physical capability</td>
<td>The exercises themselves were pretty simple exercises using the tongue</td>
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<td>and bring, protruding the tongue between your lips and holding onto the</td>
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<td>tongue and trying to swallow, to do with breathing and holding your breath</td>
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<td>while you swallow. They were pretty simple tasks (P3).</td>
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<tr>
<td>Having a routine and/or having a trigger to do the exercises (behavioural regulation)</td>
<td>Psychological capability</td>
<td>After the first week you could do them whatever they were, even just go</td>
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<td></td>
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<td>through them through your head. Yes it would be like going to the gym and</td>
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<td></td>
<td>doing ten different classes and you know all the steps. It’s the same.</td>
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<td></td>
<td>It’s familiarity, isn’t it? (P4).</td>
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<tr>
<td>Receiving feedback on outcome (enforcement)</td>
<td>Automatic motivation</td>
<td>My exercises at the beginning, I’d actually write them on the chart. But</td>
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<td>what I used to do is I’d put them on... I’ve got an iPhone (P5).</td>
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<td>I had a form from the team and I used to mark down how many - on a Monday,</td>
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<td>four times, I’d mark it off four times. Tuesday four times, all the way</td>
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<td>up to Thursday. And I didn’t do them on Friday. It was a Friday morning,</td>
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<td>I had it marked out on the chart and you give the chart when you come in</td>
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<td>for the exercises, she’d have a look at it. She’d say, ‘Yes, you are doing</td>
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<td></td>
<td></td>
<td>well!’ (P4).</td>
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<td></td>
<td>You are achieving something every time. And they tell you, yes, you are</td>
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<td>doing very good and they tell you it’s open so many centimetres today, and</td>
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<td>then they’d compare it from last week. They’d have it written down (P4).</td>
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<td>I took a short drink, the energy drink, and I started drinking it and he</td>
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<td>was... my son and my daughter as well were so pleasantly surprised. They</td>
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<td></td>
<td></td>
<td>were, sort of, overcome with joy. So there was a joy that I could drink</td>
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<td></td>
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<td>at least (P10).</td>
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</tbody>
</table>

A few patients mentioned the difficulty in knowing what to prioritise.

I met with the speech and language people early on; I met before I started treatment. And they talk about doing your exercises through treatment as well. But it becomes a matter of priorities when you are in treatment and it’s really tough, and unfortunately that one just gets pushed... well, for me it did, it just gets pushed to the back of the queue, trying to get the mucus out of my system, yes, trying to stay hydrated, trying to keep the pain under control. And then when it was really bad, speech and language is the furthest thing from your mind (P9, male).

Physical Capability was also a barrier for patients during treatment when side-effects such as pain, nausea and the presence of sticky secretions in the mouth took precedence and patients looked for an easier solution to obtaining their nutritional requirements.

Certainly with a PEG in you needn’t swallow at all. You’ve got to keep your mouth moist but that’s all you need to do (P12, male).

Some aspects of Physical and Psychological Capability were also identified as potential facilitators. Generally patients felt that the exercises were simple and easy to perform once they learned to do them and were confident they were doing them correctly. Patients who incorporated a method for self-regulation, such as marking off the exercises on a chart or using a smartphone to keep track reported these to be helpful strategies.
Opportunity

Physical opportunity factors, which encompass the environmental context and resources [23], generally did not feature as a commonly reported barrier. However, a few patients with children felt that they were less keen to do the exercises with the children around.

DURING MOST OF MY TREATMENT I SPENT A LOT OF MY TIME THINKING ABOUT THE BOYS RATHER THAN MYSELF, SO HOW WOULD THINGS... WHAT COULD I HIDE FROM THEM OR WHAT COULD MAKE UNCOMFORTABLE FOR THEM, WHAT COULD I TELL THEM (P2, FEMALE).

Some patients felt that most of the exercises could be done anywhere:

BECAUSE THE EXERCISES GENERALLY WERE OVER MAYBE TWO OR THREE TIMES A DAY, DIFFERENT EXERCISES. IT'S SOMETHING YOU COULD DO IN THE CAR WHEN YOU WERE DRIVING, OR WHATEVER, THEY DIDN'T HAVE TO BE IN SITU (P3, MALE).

While others felt that they needed a space or preferred privacy for some of the exercises:

I REMEMBER LYING ON THE FLOOR IN THE LANDING. I REMEMBER LYING ON THE FLOOR IN THE BEDROOM TRYING TO FIT THEM ALL IN. THERE WAS THAT KIND OF NEEDING TO HAVE A SPACE TO DO SOME OF THOSE [REFERENCE TO SHAKE, HEAD LIFT EXERCISE]. YES, I THINK SOME OF THE NOISY ONES I WOULD SOMETIMES DO WHEN I WALKED THE DOG ON THE HEAD (P9, FEMALE).

The provision of resources relates to physical opportunity to perform the exercises. Some patients felt that the method of information provision could be improved and that pictures might have enabled a better understanding of the exercises.

I DON'T KNOW. MAYBE PICTURES WITH DIAGRAMS OR SOMETHING TO SHOW WHAT PART OF YOUR TONGUE YOU SHOULD BE TUNING UP, LIKE MORE EMphasis ON WHEN YOU ARE SWALLOWING, BECAUSE YOU Weren'T SURE REALLY IF IT WAS THE FRONT OF YOUR TONGUE OR THE BACK OF YOUR TONGUE, SORT OF, TO BE PUShING UP (P11, FEMALE).

Additionally, one patient in particular highlighted the need for re-structuring in the approach taken as many people are resistant to being told what to do.

Prescriptive is the word I was looking for before. I felt that the people I was dealing with generally were kind of prescriptive. Do you know what I mean by that? (P1, MALE).

Social opportunity in the form of social support from others (family members, other patients and clinical staff) was a strong positive influence in facilitating adherence to the exercises. Patients who had someone offering encouragement tended to adhere better to their exercises. A few patients reported that their children would often get involved in over-seeing their exercises.

My daughter, who is seven, felt the need to copy me when I was doing my floor exercises, which is a great tonic because it felt like you were making a game of it, which is quite nice. And that's something to encourage people, if they do have younger children, because it takes that onerous edge to it away, I think.

She took over the situation and became my speech therapist, physiotherapist and nurse all rolled into one, bless her cotton socks. In all seriousness, throughout the whole journey of last year she was an enormous encouragement to me without saying a word, to make sure that I could get back to somewhere, near to where I was. That's what makes life worth living really, the children (P5, MALE).

Motivation

Reflective motivation involves the psychological processes that drive behaviours that serve a goal deemed a priority by the individual. It includes conscious planning and weighing up whether performing a particular behaviour is beneficial to the end goal [23]. Additionally, the individual’s belief (self-efficacy) that they can overcome obstacles to performing the behaviour in order to attain their goals is an important element of motivation.

I know if I did not eat I would not have the strength to fight the illness. So I said, for myself, for my family’s sake and everyone’s sake I have to fight (P10, MALE).

It's your own tenacity to get better (P5, MALE).

For some patients motivation was impeded by physical and psychological capability: the feeling that there was too much to do, or the uncertainty about the relevance of the exercises to their own unique circumstances, particularly if they were given prophylactic exercises.

I don’t know how long the full set is. If you are doing three reps it’s... it’s hours a day, particularly when you’ve got the emphysema exercises bolted in. And that’s quite hard to achieve (P12, MALE).

It’s completely impossible to envisage what your throat and mouth and tongue might feel like if you are a healthy person. So doing things like holding your tongue and trying to swallow [manako—tongue base exercise], you do it, but you don’t know why, and it feels sort of slightly kind of worrying (P2, FEMALE).
Automatic Motivation is less conscious and more reflexive, driven by emotional states, impulses and context triggers. This aspect of the COM-B model is represented by the theoretical constructs of Reinforcement and Emotion on the TDF [23]. Individuals described feeling rewarded by small improvements in their swallowing which motivated them to do their exercises in the hope that they could achieve more. This included receiving positive feedback about the outcome of doing their exercises (for example increased mouth opening, seeing with biofeedback that they could reduce aspiration) or experiencing an improvement in function such as the ability to drink something after a long period of being unable to.

One of the nicest things is when you are.... And you can’t drink water and you rely on all your fluids through the PEG, and you get to the point where you can just get a sip of water down, and you get that sip of water down and you keep working on that sip of water. But you get points where you are thirsty and you want to drink like a normal person. Getting to the point where you can drink is a real breakthrough. That makes a massive difference to just your overall feeling and wellbeing, because you stop hanging fluid in here [pointing to PEG tube]. And you can, you know, have two or three mouthfuls without stopping (P8, male).

The results presented above suggest that there is potential to optimize all three key components of behaviour to improve swallowing exercise interventions for patients after HNC. However, capability seems to require the greatest shift in order to bring about a change in patients’ exercise adherence behaviour.

Discussion

This study described a theory-based qualitative approach to exploring and categorizing patients’ experiences of their swallowing rehabilitation and reasons for adherence/non-adherence to swallowing exercises. We used an inductive approach to elicit patient experiences and a deductive method to make a ‘behavioural diagnosis’ using a theoretical framework [24, 26].

Our results confirmed earlier findings regarding common barriers to swallowing exercise adherence [1]. Additionally, we categorized these findings according to the three key drivers of behaviour which may then inform the selection of appropriate behavioural strategies. Patients indicated that they did not clearly understand the reasons for doing exercises highlighting that capability was a key barrier. Interview findings suggest that knowledge and understanding of how swallowing will be affected and why exercises are required may not be sufficiently processed by patients, particularly if they are given exercises at pre-treatment stage. The importance of information provision for this patient population has received considerable research attention [29–34]. On the one hand, clinicians aim to provide all the necessary information, yet researchers report that patients may not take in all this information.

More information is therefore not necessarily the solution to the barrier of lack of knowledge and understanding. Patients in this study were able to reflect on their own pre-treatment counselling and reported that it was important to find a balance between helping people understand how and why their eating and drinking might be affected and not “over-scaring” them. Patients themselves highlighted that while a great deal of information is provided verbally and in the form of leaflets, they dismiss much of it as they do not consider it personally relevant to them. Many patients reported feeling overwhelmed and therefore chose to filter information they received. Consequently, they dismissed the exercises as being a general precaution, believing that it was not relevant to them. This was particularly the case if they were able to eat and drink adequately at the time.

Some patients preferred not to know about negative consequences of treatment, as they felt that this added to their anxiety. One patient in particular felt that the approach was too prescriptive. These results suggest that there is scope to improve delivery of information about treatment and its impact on function so that patients clearly understand the relevance to them. At pre-treatment, some patients were keen to learn how they may best help themselves over the course of their treatment. It may therefore be useful to explore ways of creating and capitalizing on a teachable moment that may be co-created by the clinician-patient interaction [35].

As expected, participants reported varying physical capability to perform the exercises. Based on the higher numbers of patients who reported that pain was a barrier to doing their exercises, greater effort may be needed to minimize this problem. Other researchers have likewise alluded to the fact that increased and uncontrolled pain and toxicity from treatment reduce patient adherence and maintenance of swallowing exercises [16, 20]. A study by Starmer et al. [36] reported improved pain control, and swallowing function in 23 patients treated with gabapentin in the first week of radiotherapy compared to 23 matched controls who did not receive gabapentin. Further work is required to assess the value of administering early pain control for this group of patients in relation to maintenance of swallowing and swallowing exercises.

Patients who were able to master the exercises before treatment and developed a system to build the exercises into their daily routine were better at maintaining them throughout the treatment. It seems plausible to relate this...
finding to previous work in behavioural science that has highlighted that forming habits, that are ingrained automatic routines initiated by environmental cues, may be important to maintaining long-term behaviour [37, 38]. Habits form through context-dependent repetition [39], and while initially effortful becomes easier if the action is repeated with sufficient consistency in the same position within one’s routine [40, 41]. This is particularly crucial in the early stages in order to facilitate habit formation [42]. The advantage of exercises becoming habitual is that they are more likely to be maintained over time, as they become less reliant on motivation and other cognitive processes such as conscious memory [39]. These insights could be usefully applied in the design of pre-treatment swallowing exercise interventions.

Physical opportunity (environmental and resources) did not feature prominently as a barrier. This may be explained by the fact that most of the swallowing exercises do not require many resources once they are mastered, and for the most part can be done anywhere. Patients who reported time and space concerns also seemed to reflect on whether they used this as an “excuse” to justify to themselves why they may not be doing their exercises. Social opportunity, however, seemed a strong facilitator in that patients who had support from a friend or family member offering encouragement were more likely to have kept up the exercises. Regular appointments and support from the SLT to keep up the programme also appeared to be an important facilitator.

In our earlier literature review study, we identified social support as one of the main behaviour change techniques in successful swallowing exercise interventions [5].

Reflective motivation is strongly linked to psychological capability [23]. Individuals were unlikely to set a goal such as being able to eat after treatment if they did not perceive this as a potential problem that will affect them. Most individuals talked about wanting to avoid a feeding tube, hoping to maintain the ability to eat and drink by mouth throughout the treatment. For patients who recognized that swallowing function might be impaired, a desire to prevent negative consequences such as reliance on a gastrostomy tube was identified as an important facilitator for initiating swallowing exercises. Other patients indicated that despite feeling motivated initially, the ability to follow through with exercises during a challenging course of treatment was often eclipsed by competing priorities. Reduced physical and psychological capability could then negatively impact motivation for some patients, leading to disengagement with the exercises. Indeed once patients resign themselves to total use of a feeding tube, it is likely that motivation diminishes. The caution to guard against tube dependency has been highlighted by others [43–45]. The importance of good multidisciplinary team working is essential as prophylactic feeding tubes may be necessary in some patients who are predicted to have severe dysphagia that may compromise completion of their chemo-radiation treatment [46, 47]. It is vital that patients are adequately counselled and monitored to prevent subtle shifts in motivation that may occur once a feeding tube is in place.

Limitations and Future Directions

This study was undertaken on a small sample of patients, although a reasonably diverse group was achieved and a method for data saturation was specified. As with most qualitative studies, our findings may be context based, and therefore not widely generalized. However, we were not looking to find generalizable results, but rather to capture a range of patient views that may need addressing in future interventions. We have also provided a detailed methodology and encourage repeat studies in different contexts. While researcher subjectivity is a frequent concern in qualitative analysis, the availability of a codebook and the high percentage agreement obtained with a second independent coder suggest that the concepts have credence beyond the sole analysis and interpretation of the lead researcher/interviewer.

Further qualitative studies on barriers and facilitators to swallowing exercise adherence will be useful to expand upon this work. Recognizing that patient adherence is important to the success of interventions, future work is necessary to address how adherence is operationalized as a concept and how best to measure this in empirical studies. Other researchers have pointed out that adherence is sometimes reported on a continuum, and other times as a dichotomy with no clear consensus on how best to measure adherence to home-based swallowing exercises [20]. A recent study [48] concluded that HNC patients’ adherence to using electrical stimulation as a therapy to improve swallowing physiology had no impact on the efficacy of the treatment. However, we cannot extrapolate this finding to all forms of swallowing rehabilitation. Studies that aim to optimize adherence to swallowing exercises before and during treatment are still merited. Without this, we have little means of verifying whether swallowing exercises improve the swallowing function and QoL of patients with HNC.

Conclusion

Patient adherence is one aspect of the complex intervention involved in swallowing rehabilitation after HNC. Researchers and clinicians working with dysphagic patients may wish to pro-actively consider ways of improving adherence when designing interventions [5]. This study described the use of a theory-based qualitative approach in examining what drives adherence/non-adherent exercise behaviours in patients with HNC. Insights gained by
adopteing this approach can help inform the development of new swallowing interventions for patients with HNC.

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Compliance with Ethical Standards Conflict of Interest The authors declare that they have no conflict of interest.

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References
### Appendix 4-2: Interview prompts based on TDF

Interview prompt questions based on the Theoretical Domains Framework.

*adapted from Michie, Atkins and West, 2014

<table>
<thead>
<tr>
<th>Domain (definition)</th>
<th>Theoretical constructs represented within each domain</th>
<th>Interview prompt questions&lt;sup&gt;+&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Knowledge (An awareness of the existence of something)</td>
<td>Knowledge (including knowledge of condition /scientific rationale); Procedural knowledge; Knowledge of task environment</td>
<td>Can you tell me about how you got on with eating and drinking at the time of your treatment? Can you tell me about anything you did or were advised to do to help with eating and drinking? Can you tell me a bit about how/what happened when you were first given the exercises?</td>
</tr>
<tr>
<td>Skills (An ability or proficiency acquired through practice)</td>
<td>Skills; Skills development; Competence; Ability; Interpersonal skills; Practice; Skill assessment</td>
<td>Were you able to perform the swallowing exercises? How did you find the swallowing exercises?</td>
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<tr>
<td>Memory, attention and decision processes (The ability to retain information, focus selectively on aspects of the environment and choose between alternatives)</td>
<td>Memory; Attention; Attention control; Decision making; Cognitive overload / tiredness</td>
<td>Did you feel that you would be able to carry out the exercises regularly as advised?</td>
</tr>
<tr>
<td>Behavioural regulation (Anything aimed at managing or changing objectively observed or measured actions)</td>
<td>Professional identity; Professional role; Social identity; Identity; Professional boundaries; Professional confidence; Group identity; Leadership; Organizational commitment</td>
<td>Did you have a way of monitoring whether you did the exercises regularly?</td>
</tr>
<tr>
<td>Social/professional role and identity (A coherent set of behaviours and displayed personal qualities of an individual in a social or work setting)</td>
<td>Professional identity; Professional role; Social identity; Identity; Professional boundaries; Professional confidence; Group identity; Leadership; Organizational commitment</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Beliefs about capabilities (Acceptance of the truth, reality, or validity about an ability, talent, or facility that a person can put to constructive use)</td>
<td>Self-confidence; Perceived competence; Self-efficacy; Perceived behavioural control; Beliefs; Self-esteem; Empowerment; Professional confidence</td>
<td>Were you confident that you were able to do the exercises correctly?</td>
</tr>
<tr>
<td>Optimism (The confidence that things will happen for the best or that desired goals will be attained)</td>
<td>Optimism; Pessimism; Unrealistic optimism; Identity</td>
<td>What did you feel the exercises were doing for you?</td>
</tr>
<tr>
<td>Beliefs about consequences</td>
<td>Beliefs; Outcome expectancies; Characteristics of outcome expectancies; Anticipated regret; Consequents</td>
<td>Did you feel that it was important to do the exercises?</td>
</tr>
<tr>
<td>-------------------------------------------------------------------------------------------</td>
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</tr>
<tr>
<td>(Acceptance of the truth, reality, or validity about outcomes of a behaviour in a given situation)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intentions</td>
<td>Stability of intentions; Stages of change model; Trans-theoretical model and stages of change</td>
<td>How did you decide whether or not to do the exercises?</td>
</tr>
<tr>
<td>(A conscious decision to perform a behaviour/act in a certain way)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Goals</td>
<td>Goals (distal / proximal); Goal priority; Goal / target setting; Goals (autonomous / controlled); Action planning; Implementation Intention</td>
<td>Tell me about how much, and how often you did the exercises?</td>
</tr>
<tr>
<td>(Mental representations of outcomes or end states that an individual wants to achieve)</td>
<td></td>
<td>Were there days when you did not do the exercises – why was that?</td>
</tr>
<tr>
<td>Reinforcement</td>
<td>Rewards (proximal / distal, valued / not valued, probable / improbable); Incentives; Punishment; Consequences; Reinforcement; Contingencies; Sanctions</td>
<td>Were there days when you did not feel like doing the exercises but did them anyway – what do you think made you do them?</td>
</tr>
<tr>
<td>(Increasing the probability of a response by arranging a dependent relationship, or contingency, between the response and a given stimulus)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Emotion</td>
<td>Fear; Anxiety; Affect; Stress; Depression; Positive / negative affect; Burn-out</td>
<td>How did it make you feel having to do swallowing exercises?</td>
</tr>
<tr>
<td>(A complex reaction pattern, involving experiential, behavioural, and physiological elements, by which the individual attempts to deal with a personally significant matter or event)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Environmental context and resources</td>
<td>Environmental stressors; Resources / material resources; Organizational culture/climate; Salient events / critical incidents: Person x environment interaction; Barriers and facilitators</td>
<td>Can you tell me more about when and where you did the exercises?</td>
</tr>
<tr>
<td>(Any circumstance of a person's situation or environment that discourages or encourages the development of skills and abilities, independence, social competence, and adaptive behaviour)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Social influences</td>
<td>Social pressure; Social norms; Group conformity; Social comparisons; Group norms; Social support; Power; Intergroup conflict; Alienation; Group identity; Modelling</td>
<td>Were other people around/involved when you were doing your exercises – How did they respond?</td>
</tr>
<tr>
<td>(Those interpersonal processes that can cause individuals to change their thoughts, feelings, or behaviours)</td>
<td></td>
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</tr>
</tbody>
</table>
Appendix 4-3: Patient information Leaflet-qualitative interviews

Information about the Research

Swallowing intervention package for patients with head and neck cancer.

You are being invited to take part in a research study. Before you decide, you need to understand why the research is being done and what it will involve for you. Please take time to read the information carefully. Talk to others about the study if you wish. The patient information sheet consists of two parts. Part 1 tells you the purpose of the study and what will happen to you if you take part. Part 2 tells you more about how the study will be conducted. Please ask if there is anything that is unclear or if you would like more information.

Part 1 of the Patient Information Sheet

What is the purpose of the study?
We know that patients who have had surgery or radiotherapy to treat cancer in the mouth or throat may experience some difficulty in swallowing. These problems may persist for a long time after treatment. Speech and language therapists play an important role in the rehabilitation of speech and swallowing after treatment. We are interested in devising a swallowing intervention package which will commence before the cancer treatment begins. We hope that this will improve the swallowing outcomes for patients. We are interested in collecting information from patients who have had treatment for head and neck cancer and have some experience of swallowing rehabilitation. This information will help us in devising a pre-treatment swallowing intervention package for newly diagnosed patients.

Why have I been invited?
You have been invited as you have received treatment to the head and neck area and have had a period of swallowing rehabilitation. We are keen to interview you to find out how you found the rehabilitation programme, whether you were able to do the swallowing exercises regularly and what factors helped or prevented you from carrying out your swallowing exercises. This information will be very valuable in developing new intervention programmes for others who develop swallowing difficulties after treatment.
Do I have to take part?
It is up to you to decide whether or not to take part. After reading the information sheet, if you are happy to participate you will be asked to sign a consent form to show you have agreed to take part. You are free to withdraw at any time without giving a reason. This will not affect the standard of care you receive.

What will happen to me if I take part?
If you are happy to participate, you will be invited to the hospital for a face to face interview with the researcher about your experience of swallowing rehabilitation. You will also be shown a 5 minute video presentation of what the new intervention will consist of and asked to talk through your impressions. You will be required to sign a consent form prior to the interview. The interview will last approximately 40 minutes and will be audio recorded.

Expenses and Payments
We will give you a £25 shopping voucher for your time and participation. We are also able to provide travel re-imbursement for public transport.

What do I have to do?
You do not need to do anything right now. The clinical researcher will telephone you within a week of you being sent this information sheet. You may ask any further questions you have about the research at this stage. You do not have to prepare in any way to take part in the study. There is no right or wrong answer to any of the interview questions. The researcher is interested in your personal views and experience of the rehabilitation of your swallowing.

What are the advantages of taking part?
There is no clear advantage for you, however your feedback will help in the development of new strategies and interventions to improve swallowing outcomes for individuals treated for head and neck cancer.

What are the disadvantages of taking part?
There are no disadvantages to taking part as your standard of care will not be affected. You will be required to attend the hospital for the interview. We will try to arrange this at the most convenient time for you.

Will my taking part be kept confidential?
We will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in Part 2.

This completes Part 1. If the information in Part 1 interests you and you are considering participation, please read the additional information in Part 2 before making any decision.

Part 2 of the Patient Information Sheet

What if relevant new information becomes available?
If any new information such as new symptoms regarding your speech and swallowing function is noted for which you are not already receiving input, you will be referred to the appropriate clinician.

**What will happen if I do not want to carry on with the study?**
If you decide to take part you are still free to withdraw at any time and without giving a reason. A decision to withdraw will not affect the standard of care you receive. If you withdraw from the study, only the data collected up to your withdrawal will be used.

**What if there is a problem?**
If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. You may also contact the Patient Advice & Liaison Service (PALS) at UCLH. PALS can be contacted at:

**Patient Advice & Liaison Service**
University College London Hospitals NHS Foundation Trust
Ground Floor
University College Hospital
235, Euston Road
London
NW1 2PQ
Tel: 0207 380 9975

In the unlikely event that something does go wrong and you are harmed during the research and this is due to someone’s negligence then you may have grounds for a legal action for compensation against the NHS trust but you may have to pay your legal costs. Please note that there are no compensatory mechanisms in place for “non negligent harm” (this means harm that is not due to somebody’s fault). In this case, the normal National Health Service complaints mechanisms will still be available to you (if appropriate).

**Will my taking part in this study be kept confidential?**
Information collected about you during the research may be shared with other healthcare professionals in the hospital but only with your permission and if it will help your care. Any information about you that leaves the hospital will have your name and address removed so that you cannot be recognised from it. The interview will be audio recorded and transcribed word for word for later analysis. The recording will be stored for up to 10 years as part of the research data collected. Some of your responses may be quoted in publications but no references will be made which may identify you personally. The chief investigator will be responsible for safety and security of your personal data, and only the chief investigator, clinical researcher and specifically authorised individuals involved with the study will have access to the data.

**What will happen to the results of the research study?**
When we have finished analysing all of the patient interviews, we would like to send you a broad summary of the findings (written in everyday language) in the post, so that you can let us know whether you agree with our analysis. If you are happy to do this, you will be asked to send back
your comments on our findings in a stamped addressed envelope. The findings will inform the
development of the new swallowing intervention package. The new intervention package will
need to undergo further testing to determine whether it does in fact offer any additional benefit to
patients over the current practice. The results will also be written up for publication in a scientific
journal. Please be assured you will not be identified in any report or publication. You may request
a copy of the results after publication.

Who is funding and organising the study?
This study is being funded by the National Institute of Health Research (NIHR) as part of a
personal fellowship awarded to the clinical researcher, Roganie Govender. The researcher is
hosted by University College London Hospital and is working collaboratively with academic
departments at UCL. This research is in part fulfillment of the requirements for the clinical
researcher’s doctoral degree.

Who has reviewed the study?
This study has been reviewed by the NIHR. In addition, all research in the NHS is looked at by an
independent group of people, called a research ethics committee to protect your safety, rights,
wellbeing and dignity. This study has been reviewed and given favourable opinion by the London
South-east National Research Ethics Committee.

Contact for further information
If you have any further questions, please don’t hesitate to contact the clinical researcher,
indicated below.

Roganie Govender
Consultant Speech and Language Therapist
NIHR Doctoral Research Fellow
Head and Neck Cancer Centre
University College London Hospitals NHS Foundation Trust
250 Euston Road
First Floor East
NW1 2PQ
Tel: 02034472156
Email: Roganie.Govender@uclh.nhs.uk

Thank you very much for considering taking part in this study. If you are happy to participate, we
will provide you with a consent form to sign and a copy of this information sheet.

Nicholas Kalavrezos
Consultant Head & Neck Surgeon
Lead Clinician (Head & Neck Service)

Stuart Taylor
Professor of Medical Imaging
Chief Investigator for study
Appendix 4-4: Patient consent form-qualitative interview

CONSENT FORM

Swallowing intervention package for patients with head and neck cancer.

1. I confirm that I have read and understand the information sheet dated..................
   (version............) for the above study. I have had the opportunity to consider the information, ask
   questions and have had these answered satisfactorily.

2. I understand that my participation is voluntary and that I am free to withdraw at any time without
   giving any reason, and without my medical care or legal rights being affected.

3. I understand that relevant sections of my medical notes and data collected during the study, may
   be looked at by individuals from the sponsor of the trial (University College London) and responsible
   persons authorised by the sponsor, from regulatory authorities or from the NHS Trust, where it is
   relevant to my taking part in this research. I give permission for these individuals to have access to
   my records.

4. I consent to use of audio taping, with possible use of word for word quotation. I understand that
   published quotations where used will not contain any information which identifies me.

5. I understand that if I am unable to make independent informed decisions during this study (loss
   of capacity), only data collected up until this change in capacity will be retained for analysis.

6. I understand that the results will only be discussed with relevant medical professionals if it has a
   bearing on my care, and with my permission

7. I agree to take part in the above study.
<table>
<thead>
<tr>
<th>Name of Patient</th>
<th>Date</th>
<th>Signature</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of Person taking consent</td>
<td>Date</td>
<td>Signature</td>
</tr>
<tr>
<td>Name of Chief Investigator</td>
<td>Date</td>
<td>Signature</td>
</tr>
</tbody>
</table>

*(if different to the person taking consent)*
Appendix 4-5: Code book and peer debrief

<table>
<thead>
<tr>
<th>TDF/codes</th>
<th>Explanation for when to code</th>
<th>RG 3</th>
<th>CW 3</th>
<th>RG 7</th>
<th>CW 7</th>
<th>RG 9</th>
<th>CW 9</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>BEHAVIOURAL REGULATION</strong></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Feedback about performance</td>
<td>feedback from others</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>forgetting to do exercises</td>
<td>All references to forgetting to perform exercises, rather than unwilling to.</td>
<td></td>
<td></td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>keeping track of exercises</td>
<td>Use of diary, charts or other <strong>tangible</strong> methods to record exercises done for purpose of self monitoring or monitoring by others.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>promoting routine</td>
<td><strong>Methods of</strong> creating/promoting routine, eg exercises done just before mealtimes.</td>
<td></td>
<td></td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>sequence of exercises</td>
<td>Reference to order of exercises</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>time of day of performing exercises</td>
<td>References to time of day of doing exercises.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td><strong>BELIEFS ABOUT CAPABILITY</strong></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>ease of doing exercises</td>
<td>How easy/difficult were the exercises</td>
<td></td>
<td></td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>quantity of exercises</td>
<td>Any reference to number of exercises, and impact on performing them.</td>
<td></td>
<td></td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>uncertainty if performing exercises correctly</td>
<td>Knowing/believing that exercises are being done correctly</td>
<td></td>
<td></td>
<td>✓</td>
<td>✓</td>
<td></td>
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</tr>
<tr>
<td>Self efficacy</td>
<td>Text that refers to individuals self-belief in own ability</td>
<td></td>
<td></td>
<td>✓</td>
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<tr>
<td>BELIEFS ABOUT CONSEQUENCES</td>
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</tr>
<tr>
<td>belief about whether exercises work text</td>
<td>which describes beliefs about whether or not exercises work,</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(negligible) consequences done regularly or</td>
<td>not</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
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</tr>
<tr>
<td>desire to prevent negative consequences</td>
<td>References to doing exercises prophylactically, or</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
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</tr>
<tr>
<td>expectation of benefit</td>
<td>desire to do exercises to prevent negative consequences.</td>
<td></td>
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</tr>
<tr>
<td>understanding temporal change in swallowing</td>
<td>References to an understanding that swallow function</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>EMOTION</td>
<td>will be variable during and beyond treatment and that</td>
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</tr>
<tr>
<td>Feeling overwhelmed</td>
<td>References to information overload, lots going on</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>fear of unknown-unfamiliarity/uncertainty</td>
<td>Fear of what the future holds, fear of cancer, not</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mood changes</td>
<td>knowing what to expect, how bad things are/will be,</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>unfamiliarity with being ill/hospital setting.</td>
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<tr>
<td></td>
<td>References to variable state of mind from feeling fine,</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td></td>
<td>positive to feelings of hopelessness, depressed, inability</td>
<td></td>
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<td></td>
<td>to cope.</td>
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<tr>
<td><strong>feelings hearing about possible future consequences</strong></td>
<td>Emotions related to receiving information/advice about what could happen.</td>
<td>✓</td>
<td></td>
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<tr>
<td><strong>unpleasant consequence of exercise</strong></td>
<td>References to feelings of discomfort, distress, anxiety, physical unpleasantness when doing exercises.</td>
<td>✓</td>
<td></td>
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</tr>
<tr>
<td><strong>Feelings of guilt/regret</strong></td>
<td>Text that refers to feelings of guilt or regret related to not doing exercises</td>
<td>✓ ✓</td>
<td></td>
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<td></td>
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</tr>
<tr>
<td><strong>Feeling of pride/achievement</strong></td>
<td>Text that refers to a sense of pride/accomplishment in doing exercises.</td>
<td>✓ ✓</td>
<td></td>
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</tr>
<tr>
<td><strong>ENVIRONMENTAL CONTEXT AND RESOURCES</strong></td>
<td></td>
<td>✓</td>
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<tr>
<td><strong>information overload</strong></td>
<td>References to the amount of information and how/when this was presented/chunked.</td>
<td>✓ ✓</td>
<td></td>
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<td></td>
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</tr>
<tr>
<td><strong>normalising exercises for children</strong></td>
<td>References to reaction of children to exercises and/or ways in which the exercises were explained to children.</td>
<td>✓ ✓</td>
<td></td>
<td></td>
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</tr>
<tr>
<td><strong>physical context of being given information</strong></td>
<td>References to the way in which clinics are run/structured and the environment when being given information eg busy clinic with students, multiple people in and out of room.</td>
<td>✓ ✓ ✓ ✓</td>
<td></td>
<td></td>
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</tr>
<tr>
<td><strong>requiring props for exercises</strong></td>
<td>Reference to the need for props to carry out exercises.</td>
<td>✓ ✓</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td><strong>Physical environment for doing exercises</strong></td>
<td>References to where exercises are done, factors within the environment which impact exercise behaviour.</td>
<td>✓ ✓ ✓</td>
<td></td>
<td></td>
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</tr>
<tr>
<td><strong>clinicians involved in treatment</strong></td>
<td>References to context of clinicians (personnel resource) delivering intervention (same/multiple), and impact on encouraging/discouraging exercise behaviour eg not enough time with clinician, different clinician each visit.</td>
<td>✓</td>
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</tr>
<tr>
<td>GOALS</td>
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</tr>
<tr>
<td><strong>frequency of exercises</strong></td>
<td>References to being instructed to carry out exercises a required number of times, and/or reported performance of exercise frequency expressed as a goal of what individual aimed to achieve in a day.</td>
<td>✓</td>
<td>✓</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>INTENTIONS</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Decision to do exercises-mental processes</strong></td>
<td>References to the thought processes, reasoning, intentions and conscious decision-making about whether or not to do the exercises.</td>
</tr>
<tr>
<td><strong>duration of swallow exercises – stability of intentions</strong></td>
<td>References to stability of intent to do exercises over a prolonged period</td>
</tr>
<tr>
<td><strong>exercises post treatment</strong></td>
<td>References to doing/not doing exercises in the longer term post treatment.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>KNOWLEDGE</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Knowledge/information on consequences of treatment</strong></td>
<td>References to knowledge of/information given about the consequences of cancer treatment on swallow function.</td>
</tr>
<tr>
<td><strong>Knowledge about pre-treatment swallowing exercises</strong></td>
<td>References to knowledge of/information given about exercises pre-treatment. Includes text about individual’s interpretation of why exercises were advised pre-treatment.</td>
</tr>
<tr>
<td><strong>perception of advice</strong></td>
<td>References that reflect what individual thought/felt about the advice (including delivery) and doing</td>
</tr>
<tr>
<td>Knowledge/ information about how to perform exercises.</td>
<td>References that demonstrate knowledge of how to do exercises. Include text where individual describes how information was given and/or procedural knowledge was acquired eg demonstration by clinician, leaflets etc.</td>
</tr>
<tr>
<td>------------------------------------------------------</td>
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</tr>
<tr>
<td><strong>MEMORY, ATTENTION, DECISION PROCESS</strong></td>
<td></td>
</tr>
<tr>
<td>conflict between intention and action</td>
<td>References to the mental conflict between intent to do exercises and carrying out the behaviour.</td>
</tr>
<tr>
<td>engagement and memory of exercises</td>
<td>References to memory of the exercises, and effort to actively engage in attending to the task.</td>
</tr>
<tr>
<td>formulating decision about how to prioritise information</td>
<td>References to thought processes involved in choosing between alternatives, or prioritizing doing the exercises.</td>
</tr>
<tr>
<td>Attention to advice</td>
<td>References to whether or not individual took heed, attended to the advice/info given. Includes text where individual describes filtering out the advice if they were not experiencing difficulty swallowing at the time.</td>
</tr>
<tr>
<td>prompt to do exercises</td>
<td>References to a prompt/memory trigger to do exercises.</td>
</tr>
<tr>
<td><strong>OPTIMISM</strong></td>
<td></td>
</tr>
<tr>
<td>Reasons for doing exercises</td>
<td>References to reasons, or text which implies that individual had belief (optimism) that things will be better if they did the exercises.</td>
</tr>
<tr>
<td>uncertain if advice relevant to self</td>
<td>References to text which suggest some uncertainty (lack of optimism) about whether the exercises were</td>
</tr>
<tr>
<td><strong>REINFORCEMENT</strong></td>
<td></td>
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<tr>
<td>feeling rewarded by small improvements in swallow</td>
<td>References to intrinsic reward - improvement in swallow function.</td>
</tr>
<tr>
<td>health professional re-inforcing advice/praise</td>
<td>References to praise or other re-inforcement to encourage exercise behaviour. If just providing support without a reward element - code as support from clinician.</td>
</tr>
<tr>
<td>lack of tangible reward outcome</td>
<td>Text referring to the lack of a tangible reward or noted improvement.</td>
</tr>
<tr>
<td>Late onset of swallowing problems</td>
<td>Text suggesting that due to late onset of problems, little incentive to do exercises pre-treatment.</td>
</tr>
<tr>
<td><strong>SKILLS</strong></td>
<td></td>
</tr>
<tr>
<td>demonstration and checking of exercises by clinician</td>
<td>Text suggesting that skills to carry out exercises were demonstrated and/or checked for competence. Knew how to do exercises.</td>
</tr>
<tr>
<td>physical strength to do exercises</td>
<td>Ability to carry out exercises physically.</td>
</tr>
<tr>
<td><strong>SOCIAL INFLUENCES</strong></td>
<td></td>
</tr>
<tr>
<td>Support from clinician</td>
<td>Text that suggests faith and trust in clinician (credible), and personality of clinician delivering the intervention can influence the behaviour.</td>
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<tr>
<td>support from family</td>
<td>References to support from family in encouraging behaviour</td>
</tr>
<tr>
<td>support from other patients</td>
<td>Text that suggests that other patients may have a</td>
</tr>
<tr>
<td></td>
<td>positive impact on influencing exercise behaviour.</td>
</tr>
<tr>
<td>OTHER</td>
<td></td>
</tr>
<tr>
<td>medication to help pain</td>
<td>Text that describes medication to help pain – help to</td>
</tr>
<tr>
<td></td>
<td>continue exercises/eating.</td>
</tr>
<tr>
<td>Patient related barriers</td>
<td>Patient factors which impacted on exercises – pain,</td>
</tr>
<tr>
<td></td>
<td>fatigue, Anxiety etc.</td>
</tr>
<tr>
<td>Barriers to eating</td>
<td>References to factors which hindered eating and</td>
</tr>
<tr>
<td></td>
<td>drinking eg dry mouth, pain, ulcers.</td>
</tr>
<tr>
<td>NEW INTERVENTION</td>
<td></td>
</tr>
<tr>
<td>Aid to recall advice from</td>
<td>References to having info in a format that can be</td>
</tr>
<tr>
<td>consultation (NI)</td>
<td>reviewed at a later stage eg DVD.</td>
</tr>
<tr>
<td>Feedback on performance of</td>
<td>References to being shown/given information to</td>
</tr>
<tr>
<td>exercises (NI)</td>
<td>confirm that exercises were being done correctly.</td>
</tr>
<tr>
<td>Feedback on videoswallow</td>
<td>Text elicited from watching video animation – feedback</td>
</tr>
<tr>
<td></td>
<td>on the use of material presented and if/how it may</td>
</tr>
<tr>
<td></td>
<td>influence adherence behaviour.</td>
</tr>
<tr>
<td>Framing need for preventative exercises</td>
<td>Text that describes in patient’s words what they believe</td>
</tr>
<tr>
<td></td>
<td>may be useful in explaining the value of preventative</td>
</tr>
<tr>
<td></td>
<td>exercises.</td>
</tr>
<tr>
<td>Hearing other patients experiences</td>
<td>Text that advocates the use of real life experiences of patients to convey information.</td>
</tr>
<tr>
<td>-----------------------------------</td>
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</tr>
<tr>
<td>Linking benefit to eating and drinking</td>
<td>Text that makes reference to being clear that the exercises are to have a real life impact on eating. De-medicalising information.</td>
</tr>
<tr>
<td>Personalising information and care</td>
<td>Text that refers to tailoring information, making specific to patient’s situation, problem. Feeling that the care package is designed for the individual, rather than a general set of exercises.</td>
</tr>
<tr>
<td>Prompt to do exercises (NI)</td>
<td>Reference to a memory trigger to do exercises.</td>
</tr>
<tr>
<td>Self monitoring system (NI)</td>
<td>Reference to having a system in place to monitor behaviour.</td>
</tr>
<tr>
<td>Setting clear goals and schedules (NI)</td>
<td>References to knowing exactly what exercises to do, how many and how frequently.</td>
</tr>
</tbody>
</table>

**Peer Debrief:**

We aimed to focus on 3 aspects during the debrief meeting:

1. Comprehensiveness of Codebook: Was coder 2 able to code all relevant sections of text (sometimes patient’s spoke about things outside the research scope) according to the codes in the codebook devised by coder 1?
2. Degree of uncertainty: What, if any uncertainties arose from either coder wrt a) wording of description of when to code, b) which TDF category codes belonged to, c) need for separate/new codes.
3. How well did coders 1 and 2 agree for the presence of codes across the interviews coded?

1. and 2: CW raised queries re missing codes under EMOTION
• Two new codes added – RG agreed that this was not adequately covered by existing codes, and that this content was codable and potentially useful to research question.
• Feelings of guilt/regret and feelings of pride/achievement....
• RG added a code under CAPABILITY – self efficacy. There was no code that adequately captured this aspect – noted in interview 7 eg you've got to find strength. Only yourself can... Yourself is the most important doctor. You know, people can help you swallowing this and that. It's yourself as well.... When something is wrong I concentrate everything on trying to fix it....
• RG query – are these 2 codes sufficiently different? Decision to do exercises-mental processes and attention to advice.
• RG query – health professional re-enforcing advice/praise, personality of individual delivering intervention(support from clinicians) and multiple clinicians involved in treatment appear to have overlap. – re-enforcing perhaps needs to be distinguished from support which should be coded as support from clinician. Re-enforcement in this context should perhaps be solely as it relates to reward/praise - example therapist being congratulatory --- Needs some discussion.

3. See table above for agreement for presence of codes.

Interview 7:

CW coded 2 additional codes (19) compared to RG (18) - (late onset of swallowing problems and physical environment for doing exercises) RG added and coded self efficacy

Interview 9:

NB: Changes made to codebook – RG recoded on the basis of these changes. Also – made decision to code second part of interview using yellow codes as well – reading through, it is possible to code sections of text that clearly relate to patient’s previous experience, and to distinguish this from their suggestions for new intervention. Will still use codes for new intervention (even where there is overlap, but will add NI next to code to suggest it was not elicited as part of the patient’s experience but their views on future intervention.
Appendix 6-1: Behavioural analysis using COM-B and TDF to determine what needs to change and how this may be achieved

<table>
<thead>
<tr>
<th>COM-B component</th>
<th>Linked TDF Domain and Interview codes assigned</th>
<th>Examples of Barriers and Facilitators from interviewee quotes (target behaviour – swallowing exercises)</th>
<th>What needs to change or be optimized? (Target group: HNC patients)</th>
<th>Possible intervention functions and BCTs (Selected for context)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CAPABILITY</strong></td>
<td></td>
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<tr>
<td></td>
<td><strong>KNOWLEDGE</strong></td>
<td>I was told that the swallowing would change. I was told to expect changes within the throat area - I may have to adapt how I eat and what I eat, what I drink. I was also told, obviously, that the diet would have to change for a period of time during treatment and, obviously, after my treatment. (P3) The doctor scribbled down a few symptoms that I would suffer after the radiotherapy, one of which was sore throat and one of which was may be problems with the swallowing, or something along these lines. (P 12) They told me I will need a feeding tube, I will have a feeding tube. Even if I don’t use it they are going to give me a feeding tube, because, I don’t know, for example, nine out of ten patients, at some point during treatment, won’t be able to take food. So I will definitely need one. (P 13) When I first started seeing the Speech and Language therapist they kept going on about this thing about not getting stuff down your airway, whether it’s food or liquid, because you can get infections and this and that. I just, kind of, thought that this was completely inappropriate to my personal case, if you like, because I felt I was being talked to like a child. (P 1)</td>
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<td></td>
<td></td>
<td></td>
<td>Barrier if insufficient knowledge Know/ understand the likely impact of own treatment on swallowing function.</td>
<td>EDUCATION Information Provision (health, social and environmental and emotional consequences)</td>
</tr>
<tr>
<td>knowledge about pre-treatment swallowing exercises</td>
<td>I understand someone sitting there explaining to me that you will need to do these exercises to help you swallow, but I don’t think the emphasis was how important they were, for me. I don’t think I actually took that on board. (P 3) When I was first told that I’d got cancer, they sat me down, they gave me all the instructions. They told me that I had all these exercises I had to do. They said because the radiotherapy was going to strip back all the tissues in the throat, and I would have difficulty swallowing and I’d find it, sort of, difficult. They had to get me back into the habit of swallowing as well because I’d tend to get out of the habit of swallowing because I’d be using the PEG. (P 6) I was given some leaflets on swallowing exercises and told that I would probably get a dry mouth and that would cause problems with swallowing. (P 11)</td>
<td>Barrier if insufficient knowledge relevant to own recovery. Facilitator if better understood. Know/understand the purpose of pre-treatment exercises and the relevance and importance to self and own recovery.</td>
<td>EDUCATION Information Provision Biofeedback (about own swallow)</td>
<td></td>
</tr>
<tr>
<td>perception of advice</td>
<td>I’ll be very, very honest with you. I thought she was only saying it just to, sort of, be on my guard in case it was to happen to me. But I thought it would not happen to me. (P 10) They just said to me, ‘Do that three times a day, whatever, in the morning and night.’ I thought what’s it going to do? You think I’ll shout. You can feel it moving. Or other things – stretch my mouth, I was stretching my neck. What they told me, for the amount of times to do it, I thought it was just someone wrote it 100 years ago and it’s still the same rules. You get what I’m saying? That’s what I thought. In my mind it was a silly practice and I thought there were other ways to do it. (P 7)</td>
<td>Barrier if advice misunderstood Clear and consistent delivery of information by clinician. Opportunity to check interpretation and understanding.</td>
<td>EDUCATION PERSUASION Credible source Salience of consequences</td>
<td></td>
</tr>
</tbody>
</table>
| Knowledge/Information about how to perform exercises. | I'd been given a sheet that would explain clearly the exercises that had been described to me during the therapy. And they were quite clear and concise. And the speech therapists were actually very aware that they needed to make sure that I understood exactly what they wanted me to do. (P 5)  
Because I do remember sheets being... not chucked at me, that's wrong, but... and I'd go home with them in my bag and get them out and variously look at them and try and work them out, whatever. But they were all separate bits of paper, and I was, sort of, thinking, oh maybe, maybe, a, sort of, coherent schedule. Not too rigid, but one that recognises you are doing a lot in your life at that point. (P 9)  
I was just given the diagrams and I was told these are the exercises you've got to do. If they had gone in-depth more to say that, 'Sure, it will happen to you. Don't ignore it. It can happen to you and it happens to so many people. So if you don't do it you may lose your way of eating and so forth,' I'd better take it seriously. (P 10) | Barrier if not clear how to perform exercises.  
Simplify and tailor advice, consider alternate forms to exercise sheets, e.g. exercise DVD. | Education Training  
Enablement  
Instruction on how to perform behaviour.  
Demonstration  
Behavioural practice  
Feedback on performance  
Biofeedback  
Adding objects (props) |

| Memory, Attention, Decision Process |

| Conflict between intention and action | I tried to do exercises. I had the printed sheets that the hospital supplied. And I tried to do the exercises but I found that there were quite large spaces in between many days where I didn't do any exercises cos of how I was feeling. (P 3) | Barrier  
Consider ways of overriding lack of action. | Enablement  
Social support  
Problem solving |
| Engagement and memory of exercises | Theres a tug with those exercises – you know you should do them, so you have that, kind of, childish response – ‘Well, I’ll do them later’. Even though it’s good for you, you still don’t do them. (P 2) | Habit formation
Comparative imagining of future outcomes |
|---|---|---|
| Formulating decision about what to prioritize | I think because I didn’t get out of the habit of swallowing. Because although it was really painful, I’d keep doing it. Every day I was necking morphine and then getting through the exercises. (P 6) If I’d done it earlier on before things got grizzly, then I would have been more familiar with the exercises. As it was, I could never remember all of them and it always felt like there were quite a lot of them. (P 2) | Facilitator if habitual
Capitalize on making exercises familiar and habitual when patient is feeling relatively well. |
| Attention to advice | I wish I could say yes, as soon as I left the hospital I was doing them every day and they helped me, but I can’t. | ENABLEMENT
Barrier
Establish familiarity and routine before treatment to reduce the need to focus (prioritize) on learning exercises during treatment. 

ENABLEMENT
Problem solving
Pros and cons
Social support |
<table>
<thead>
<tr>
<th>Prompt to do exercises</th>
<th>Behaviours and difficulties</th>
<th>Problem solving if not heeding advice.</th>
<th>Positive reinforcement if heeding advice</th>
</tr>
</thead>
<tbody>
<tr>
<td>But what I used to do is I’d put them on... I’ve got an iPhone. I’d put them on my iPhone and my reminder would go off for me to do the exercises. Because I wouldn’t remember to do them. So I’d put it in the phone, the phone would buzz and remind me to do the exercises. (P 3)</td>
<td>reasons for not attending to advice and intervene accordingly – personalize.</td>
<td></td>
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<tr>
<td>I used meal times as a trigger. Because my meal times and snack times are pretty regular. (P 8)</td>
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<tr>
<td>I think after my medication, when I was taking it, that reminded me I had got to do it for 20 minutes and before I was eating or drinking. (P 11)</td>
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<tr>
<td>BEHAVIOURAL REGULATION</td>
<td></td>
<td></td>
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<tr>
<td>Feedback about performance</td>
<td>Facilitator</td>
<td>ENABLEMENT</td>
<td></td>
</tr>
<tr>
<td>Because you are achieving something every time. And they tell you, yes, you are doing very good and they tell you it’s open so many centimetres today, and then they’d compare it from last week. They’d have it written down. (P 4)</td>
<td>Establish a method for feedback about performance.</td>
<td>Feedback on behaviour. Feedback on outcomes Self monitoring</td>
<td></td>
</tr>
<tr>
<td>Interviewer: Did you have a sense of knowing whether you were doing the exercises correctly? participant: Yes, because whenever I came in I’d be asked to demonstrate it. So I got quite good feedback. (P 9)</td>
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</tbody>
</table>
| forgetting to do exercises | It was a bit random; I would just do it when I remembered, some of the time. (P 1)  
There were times when I’d, sort of, forget. But then I used to say, “No, if I forget one day, that means that there is a weakness in me somewhere and I won’t be able to fight it.” (P10)  
I think what I’m remembering and what I’m saying is because there wasn’t a discipline around it, sometimes they slipped a bit. (P 9) | Barrier | ENABLEMENT  
Link to prompts, creating a routine. (leads to habit)  
Prompts, cues | |
| keeping track of exercises | My exercises at the beginning, I’d actually write them on the chart. But what I used to do is I’d put them on... I’ve got an iPhone. (P 3)  
I had a form from the team and I used to mark down how many - on a Monday, four times, I’d mark it off four times, Tuesday four times, all the way up to Thursday. And I didn’t do them on Friday. It was a Friday morning. I had it marked out on the chart and you give the chart when you come in for the exercises, she’d have a look at it. She’d say, ‘Yes, you are doing well.’ I did the exercises with her, as well, and then she would give you an increase, and she’d measure my opening of my mouth. (P 4) | Facilitator | ENABLEMENT  
Self monitoring  
Review behaviour goals  
Consider introducing ways of keeping track that assist self monitoring of exercises and/or monitoring by others. | |
| promoting routine | One of the specialists said do the exercises when you brush your teeth, which would mean that you would at least be doing your exercises twice a day. But I think I should have stuck to that. I should have started like that and kept going with it, because that would have been helpful. (P 2)  
I didn’t have a pattern so much for them, whereas if I could have said, actually, you need to do those at 9 o’clock, 12 o’clock and 4 o’clock, whatever, I, sort of, think I wonder | Facilitator | ENABLEMENT  
Routine is seen as useful to performing exercises regularly.  
Encourage creating a |
<table>
<thead>
<tr>
<th>CAPABILITY</th>
<th>SKILLS</th>
</tr>
</thead>
<tbody>
<tr>
<td>PHYSICAL CAPABILITY</td>
<td>demonstration and checking of exercises</td>
</tr>
<tr>
<td>Whether that would have made me more... it would have made me more disciplined about it. (P 9)</td>
<td>It was shown to me, and then I got the written information on how to do it as well. But when you are at home you don't know really if you are doing it correctly. It's a bit hard because it... like pushing your tongue up and swallowing hard. It says 'hold your muscles', and you are not sure if it's tongue or throat or back muscles to hold, because you forget things when you have been shown once. Then, when you are at home by yourself and you are reading it, you are not quite so sure. (P 11)</td>
</tr>
<tr>
<td>routine</td>
<td>Facilitator</td>
</tr>
<tr>
<td>I would just do whatever one I thought I would do first. I didn't start with exercise A and then do B and C. I would just do whatever came to mind first, do that exercise. And then sometimes you think, ooh, have I forgotten one of the exercises? Then I would look at the sheets and then say, 'I've missed this one,' and then do that one as well. (P 3)</td>
<td>Demonstration and checking is useful, but consider a resource such as a DVD for home practice.</td>
</tr>
<tr>
<td>sequence of exercises</td>
<td>Not a clear factor</td>
</tr>
<tr>
<td>I usually did it in the morning just as I got up or in the evening as I was taking out my contact lenses and doing that. (P13) I would do them in the morning, probably after breakfast or sometime in the morning, and later in the afternoon I'd do them as well. But it was completely... It was a bit random; I would just do it when I remembered, some of the time. But I invariably did it two or three times a day. (P1)</td>
<td>May need to be tailored to individual – but helpful to keep to regular times.</td>
</tr>
<tr>
<td>time of day of performing exercises</td>
<td>ENABLEMENT</td>
</tr>
<tr>
<td></td>
<td>Habit formation</td>
</tr>
<tr>
<td></td>
<td>TRAINING</td>
</tr>
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<td></td>
<td>Instruction on how to perform behaviour</td>
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<td></td>
<td>Behavioural practice</td>
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<tr>
<td>MOTIVATION</td>
<td>BELIEFS ABOUT CAPABILITY</td>
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<tr>
<td>Reflective motivation</td>
<td>ease of doing exercises</td>
</tr>
<tr>
<td>I can remember coming into the hospital and being shown how to do the exercises and given the paperwork and sheets with the imageries and things with little pictures on. (P 3)</td>
<td>The exercises themselves were pretty simple exercises using the tongue and biting, protruding the tongue between your lips and holding onto the tongue and trying to swallow, to do with breathing and holding your breath while you swallow. They were pretty simple tasks. (P3)</td>
</tr>
<tr>
<td>I tried to do some of the exercises some of the days. And some of the exercises I just couldn’t do because of the pain I was actually experiencing that particular day. (P 3)</td>
<td>After the first week you could do them whatever they were, even just go through them through your head. Yes. It would be like going to the gym and doing ten different classes and you know all the steps. It’s the very same. It’s familiarity, isn’t it? (P4)</td>
</tr>
<tr>
<td>But then when I got tired from the chemotherapy and so forth, I think I let it all, kind of, go a bit. (P 2)</td>
<td>I do remember there was some that I found hard and I wasn’t as good at doing them (P9)</td>
</tr>
<tr>
<td>Sometimes if I felt really sick or anything like that I’d put it off, but then I’d do it when I felt better. (P 11)</td>
<td>Facilitator</td>
</tr>
<tr>
<td>Barrier</td>
<td>Most exercises generally found to be simple to do once familiar. Provide adequate training and opportunity to check exercises.</td>
</tr>
<tr>
<td>ENABLEMENT</td>
<td>TRAINING</td>
</tr>
<tr>
<td>Problem solving</td>
<td>Demonstration</td>
</tr>
<tr>
<td>Pharmacological support (pain meds)</td>
<td>Feedback on behaviour</td>
</tr>
<tr>
<td>Behavioural practice</td>
<td></td>
</tr>
<tr>
<td>Category</td>
<td>Description</td>
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<td>---------------------------------</td>
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</tr>
<tr>
<td><strong>Quantity of exercises</strong></td>
<td>It felt like a lot, but that’s because I found everything overwhelming. I mean, there only were between six and eight of them. I don’t really think that’s that much. (P2)</td>
</tr>
<tr>
<td></td>
<td>I don’t know how long the full set is. If you are doing three reps it’s... it’s hours a day, particularly when you’ve got the emphysema exercises bolted in. And that’s quite hard to achieve. (P12)</td>
</tr>
<tr>
<td></td>
<td>At the beginning when the information was disseminated, there were a lot of exercises. Too many... After the video of swallowing it was easy. The lady there said you just need two. You have to work on that and that, and these are the two you need to go and do. And that’s much better and much more easier for everybody. If you’ve only got to do two things rather than five, or six or seven, or whatever it was, that makes it much more manageable. (P8)</td>
</tr>
<tr>
<td><strong>Uncertainty if performing exercises correctly</strong></td>
<td>I, kind of, assumed I was doing them correctly because I was just reading off the sheets and copying what it said. (P6)</td>
</tr>
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<td></td>
<td>One is you don’t know if you are doing them right or not, because, as I say, some of them you can’t feel anything. You have to assume that what you are feeling inside is actually what you are supposed to be achieving. They are small exercises. (P12)</td>
</tr>
<tr>
<td></td>
<td>I’ve still no idea whether I am doing them right. (P8)</td>
</tr>
<tr>
<td><strong>Self efficacy</strong></td>
<td>It’s your own tenacity to get better. (P5)</td>
</tr>
<tr>
<td></td>
<td>All I can is you have just got to put up, you know what I mean, you’ve got to find strength. Only yourself can...</td>
</tr>
<tr>
<td>Reason for doing exercises</td>
<td>I felt a bit stupid doing them, to be quite honest, because I felt I can swallow anyway, so pulling all these odd faces and swallowing really loudly, I thought I can do that, so I’m not really sure why I’m exercising it at the moment. (P6) I felt a bit stupid doing them, to be quite honest, because I felt I can swallow anyway, so pulling all these odd faces and swallowing really loudly, I thought I can do that, so I’m not really sure why I’m exercising it at the moment. (P6) it’s completely impossible to envisage what your throat and mouth and tongue might feel like if you are a healthy person. So doing things like holding your tongue and trying to swallow, you do it, but you don’t know why, and it feels sort of slightly kind of worrying but something you don’t give much thought to (P2)</td>
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<td>----------------------------</td>
<td>-------------------------------------------------</td>
</tr>
<tr>
<td>OPTIMISM</td>
<td>Reason for doing exercises</td>
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<tr>
<td></td>
<td>Well, all the exercises were helping me to swallow, helping me to do more and more. So, as I progressed with the exercises, I progressed with swallowing. I was starting to... There was a good while before I started eating, except for really watery porridge, watery food, and I, sort of, progressed on to scrambled egg and eggy bread and things like that. Every couple of weeks I progressed more. So I’m at the stage now where I can eat a lot, but not everything. (P4) I think it was just a thought of not being able to swallow. I didn’t want anything seizing up. (P11)</td>
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<td>Reasons for doing exercises</td>
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<td>BELIEFS ABOUT CONSEQUENCES</td>
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<td>belief about whether exercises work</td>
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<td>But the exercises, I didn’t really do them. I done them for a day. They told me about them, that, what you do, you’ve got to do it for hours and hours for it to work. You know it ain’t going to do any difference. That’s my opinion. Shouting is good. I mean, it sounds silly, but you want that (pointing to throat) to be exercised in any way possible. At the start it was hard to swallow. I went onto a liquidiser and I was liquidising everything. And then Ensures. And slowly, slowly, slowly, slowly, you know. I mean, there’s a lot of damage there now, but I’m coming there, you know. (P7) Would I be worse off now if I hadn’t have done them all? Would I be better off now if I’d done a lot more of them? I just cannot tell. (P8) Difficult to know, because I didn’t know what it would be like if I didn’t do them. All I could go with is well there is evidence that shows that these can be helpful. (P9) I was told, quite early on, use it or lose it, and if you are not sorted out in six months then you could potentially have problems for life. That’s a statement which somebody can say. It probably says it in a book somewhere. But that does me no good at all, because when nothing is changing and they are saying, ‘Try this, try that,’ you know. Exercises take months in themselves to build up muscles. (P12) But I don’t know, I just knew I had to eat, you know. And my object was not to use that... what do you call it? The</td>
<td>Barrier</td>
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<td></td>
<td>Provide relevant information (see knowledge)</td>
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<td></td>
<td>Consider using biofeedback (x-rays of swallow)</td>
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<td>biofeedback</td>
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| desire to prevent negative consequences | tube they stick in you. And I managed it. I didn’t really use the tube. (P6) 
I thought, well, if you don’t use muscles, they, sort of, stop working, don’t they? I’ve seen it with people with broken legs. If they don’t use them the muscles wither. And so I thought if that’s just going to happen to my throat, I don’t want that happening. (P7) | Facilitator | EDUCATION PERSUASION 
Provide realistic information about how exercises may reduce negative consequences | Information provision 
biofeedback |
| expectation of benefit | They can be a bit of a pain sometimes. But most of the time, well, it’s only a couple of minutes and it helps you to keep everything working. (P11) 
Interestingly, being concerned about not letting liquids go down my windpipe are not as important as being concerned about not drinking red wine. Do you see the difference? So, you know, tell me I can drink red wine, and I’ll do the exercises. (P1) 
The only thing that would prevent me from doing them, or would help me to do them, is if I see results quite quickly, because, like I was saying to you, when I was doing the swallowing exercises quite early on, you don’t see any benefit and so you begin to wonder what is the point of doing this. (P1) | Facilitator | INCENTIVISATION 
Non specific incentive 
Provide realistic information about likely benefits. |
| understanding temporal change in swallowing | I was also told, obviously, that the diet would have to change for a period of time during treatment and, obviously, after my treatment. (P3) 
It’s not a ‘just because I feel a lot better now’ that it stops, because we know there’s damage in there now from the treatment and that it will benefit from long-term exercise | Provide sufficient information for patient to understand the changes in swallow function over the | EDUCATION 
Information provision |
| INTENTIONS                                                                 |  | course of treatment and beyond. |  |
|--------------------------------------------------------------------------|  |  |  |
| **Decision to do exercises-mental processes**                           |  |  | EDUCATION PERSUASION |
| As it becomes more familiar and becomes slightly more boring, as it were, it's your own tenacity to get better. Well, it certainly pushed me to carrying on and do the exercises that I needed to do. And as I felt I was improving, if I'm honest, I was less willing to go through all of the exercises all of the times that they were recommended. (P5) |  | Provide information that individual may access when formulating decisions. | Information provision |
| I'm not saying it's wrong. But in my case, swallowing, whistling. Even whistling. Anything to move it, that's the way I done it. (P7) |  |  | Monitoring of outcomes |
| I was like I've got to do it, I've got to get the elasticity back in it. It was just so tight. I couldn't even shovel food into my mouth with a spoon, that was difficult, and then I was like, oh I wish I did it. I mean, I did it. I wasn't terrible, but... But then they did say, "Don't overdo it," I suppose. So it was hard to gauge if I did it enough. I'd like to think I did. But because it was so painful at the end, I was like, oh is there anything else I could have done? (P13) |  |  | Pros and cons |
| **duration of swallow exercises — stability of intentions**               |  | Facilitator | KNOWLEDGE ENABLEMENT |
| I still use my therabite, but that's now a couple of times a day. I think my mouth opens as wide as it's ever going to and I just need to maintain that. (P5) |  | Facilitated by adequate knowledge, established routine, habit. | Information provision |
| So now I do them... I still think I should do them more. I think I should do them three or four times a day, but I do them about twice a day. I do them when I'm walking the dog and when I'm driving the car. And sometimes I do them if I'm, sort of, in bed reading or something like that. (P2) |  |  | Habit formation |
| **exercises post treatment** | It’s no good trying to tell me now after six months that I need to start completing a regime. But if it was upfront, particularly if you did it in the form of an outpatient’s session, then that would be very good. Particularly this shaking manoeuvre exercise, if they’d have told me that at the beginning, I could have done the exercise, I could have gone in with a neck like Hercules, and I’m sure I would have been in better shape... Why that’s been there for so long, I’m not sure (pointing to chin dewlap) (P12)  

My one wish is that possibly I could have been seen more often in order to encourage that discipline to keep doing the exercises, because if there is one thing that keeps you focused, it’s going back to see someone that’s taken the time to give you these exercises and to show them that you have improved. So the more often you see people like that, as opposed to once every two months, maybe once a month or once every couple of weeks, certainly for that first six months, I think that would make a difference, a little bit more regular visits. (P5) | Introduce exercises early, but ensure understanding that they will need to be done after treatment as well. | ENABLEMENT  
Social support |
| **GOALS** |  |  |  |
| **frequency of exercises** | I mean, essentially, they said I could do them as much as I wanted during the day, but the more I did it, obviously, the better, it would help. (P1)  

I used to do them three times a day. I used to get up in the morning and steam, with the kettle and the cloth over my head. I used to do them when I was doing that, because I found the steaming very, very helpful, very easy on the throat. And the exercises were very helpful. (P4)  

My personal goal has always been, sort of, five times a day to try and get them done. That’s my personal goal. Which is probably not enough, but in the real world when you are out there doing stuff, that’s not a bad target. (P8) | Agree specific goals to encourage routine. | ENABLEMENT  
Goal setting |
<table>
<thead>
<tr>
<th>MOTIVATION</th>
<th>REINFORCEMENT</th>
<th>INCENTIVISATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Automatic motivation</td>
<td>feeling rewarded by small improvements in swallow</td>
<td>Facilitator</td>
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<td></td>
<td>I started to drink, sip some water, which was a bit of an achievement. Nothing past down into my throat for a good three weeks, four weeks. Then it was an achievement just a sip of water. (P4)</td>
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<td>I took a short drink, the energy drink, and I started drinking it and he was... my son and my daughter as well were so pleasantly surprised. They were, sort of, overcome with joy. So there was a joy that I could drink at least. (P10)</td>
<td>Provide verbal reward/acknowledge that resuming oral intake after prolonged non-oral feeding is a rehabilitation milestone.</td>
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<td>One of the nicest things is when you are.... And you can’t drink water and you rely on all your fluids through the PEG, and you get to the point where you can just get a sip of water down, and you get that sip of water down and you keep working on that sip of water. But you get points where you are thirsty and you want to drink like a normal person. Getting to the point where you can drink is a real breakthrough. That makes a massive difference to just your overall feeling and wellbeing, because you stop bunging fluid in here (pointing to PEG tube)... And you can, you know, have two or three mouthfuls without stopping. (P8)</td>
<td></td>
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<tr>
<td>• health professional re-inforcing advice/praise</td>
<td>Oh yes, because you are achieving something every time. And they tell you, yes, you are doing very good and they tell you it’s open so many centimetres today, and then they’d compare it from last week. They’d have it written down. (P4)</td>
<td>Facilitator</td>
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<td></td>
<td>Usually every session, or several sessions, they repeat the exercise to make sure you are doing them okay. (P12)</td>
<td>Provide verbal encouragement/praise,</td>
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<tr>
<td>lack of tangible reward outcome</td>
<td>I think that wasn’t having that immediate ‘this is helping me swallow now’. I think it was more ‘this is helping me... this will help me get my swallowing back in the future’. (P9) But from my point of view, if there’s no benefit that you can see, then there’s no point in doing it (P1)</td>
<td>Barrier</td>
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<td>Late onset of swallowing problems</td>
<td>I could eat regular food, probably up until the last maybe week or so of my radiotherapy. I could eat anything. And it was only when my throat started getting really sore that it became difficult. (P1) The chemotherapy started in February 2013, and the first time I felt an effect on my eating, drinking or swallowing was probably after my second session, which was in March, when I had enormous pain in my mouth due to ulceration. (P5)</td>
<td>Barrier</td>
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<tr>
<td>EMOTION</td>
<td>Feeling overwhelmed</td>
<td>Loads and loads of stuff was happening that was unfamiliar and a bit scary, and so, you know, I sort of, felt a bit bombarded with stuff. (P1) All those, sort of, early appointments were in a blur. There was so much I couldn’t remember, because I was in such a state of, sort of, fear before the treatment started, that I think a lot more was explained about the physiological kind of aspects, but I just wanted to know what the worst-case scenario was. (P2) Because I found that there was, like I said before, there was a lot to take in during that period. This is something else to</td>
</tr>
<tr>
<td>fear of unknown-unfamiliarity/uncertainty</td>
<td>take in as well, necessary but not life... This isn’t going to save your life; this is going to make it better afterwards. Very important. But as a patient, when you are faced with a life-threatening situation, I think that wouldn’t be a priority and you’d want to push that away for now. I don’t know. I’m not sure I would. I think I would embrace it provided I thought that it would be of benefit. (P5)</td>
<td>Acknowledge large amount of new information, and discuss ways of managing this.</td>
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<td>Mood changes</td>
<td>I also think that you are very scared, you are not thinking rationally. You’ve been told that you have cancer, and you think your world is going to end. (P3) People don’t really, like myself, they don’t realise how bad it’s going to be when you are starting your treatment. It’s very hard... You are in the unknown, you don’t know, (P4) The most scariest thing was I didn’t really want to have... you one of those things where they stick it there and you can talk. I know what I was saying was wicked, but that was my nightmare. I thought, my God, God help you. It did come into my head – am I going to survive? I didn’t think I was going to survive anyway, to tell you the truth, because they took ages to bring me here. (P7)</td>
<td>Barrier Allow fears to be expressed – provide reassurance if possible.</td>
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<tr>
<td>feelings hearing about possible</td>
<td>But actually the humour that I normally have and the, kind of, jocularity, I lost much sooner than I thought I would. (P2) From a personal perspective, I suffer from hither to thither, you know, very positive, let’s bring it on, to ‘Oh my God, the pain in my mouth is so bad, I can’t cope with this. (P5)</td>
<td>Forewarn patient that its normal to have good and bad days. Consider options for support mechanisms eg clinical nurse support.</td>
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**ENABLEMENT**

**Social support (emotional)**
| future consequences | I’m thinking, you know, but I’m completely fine. So I found all that a bit, kind of, adding to my difficulty of being in hospital and stuff, and undergoing all this quite alien and traumatic experience. I felt this was kind of like threatening and foreboding of something that probably was never going to happen. So I found that a bit uncomfortable. (P1)  

The CNS said “You are going to have a tough one getting this lady to have a feeding tube.” And it was just the whole squeamish... like I couldn’t imagine myself being in the shower and having this, kind of, inside me. I just felt it was like a hole in my body. I don’t want a hole in my body with like a plug. You know, like a plug in the bath. I’m so squeamish anyway, I don’t even like my blood being taken. I couldn’t be comfortable. I couldn’t sleep. I couldn’t dress myself knowing that was there, it was always going to be on my mind. (P13) | patients may only hear the worse case scenario. | Information provision  
Social support (emotional) |
| unpleasant consequence of exercise | When I was doing it last year and that was happening, it was actually easier for me to swallow the normal way, not holding my breath, than do it as they were saying, do it by holding my breath, because if I held my breath it would make me cough and it would go up my nose. So it was a bit pointless, really. So I didn’t pursue it. (P1) | Not commonly reported – address if arises. | Problem solving |
| Feelings of guilt/regret | Like anything in life, the ones that were harder, I wasn’t as good at. I still know there was a bit of guilt about my exercises. I still feel that there was some I didn’t do as much as I should have done, and maybe I would have recovered. (P9)  

Feeling guilty because I hadn’t. They asked me to do them and I said I would. So ashamed into it, really. (P6) | Provide clear goals and support attainment. | ENABLEMENT  
Social support |
<p>| | Some people quite like counting, and it gives you a sense of | | |</p>
<table>
<thead>
<tr>
<th>OPPORTUNITY</th>
<th>ENVIRONMENTAL CONTEXT AND RESOURCES</th>
<th>Facilitator</th>
<th>ENABLEMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical opportunity</td>
<td>information overload</td>
<td>Provide positive reinforcement</td>
<td>Social support</td>
</tr>
</tbody>
</table>

- *I don’t know. I just still think that there is so much to absorb, so much information to absorb. (P3)*
- *I did get given often lots and lots of booklets and this and that about all kinds of different stuff, but I never read them. (P1)*
- *The reason I suspect I didn’t was because it was so focused on the treatment and the PEG, the this, the that, the other, that I don’t remember the overlay of speech and language on top of it at that point. I think there was enough going on. (P9)*
- *See feeling overwhelmed*

| Normalizing exercises for children | | ENABLEMENT |
|----------------------------------|| Social support (emotional) |

- *They knew I had a throat problem, they knew I was getting help, and they knew I ended up in hospital because they kept seeing me here a few times. But I never told them it was cancer. I just said it was a throat problem and I was having treatment. I told them in advance that it would get worse and I told them in advance that I would have problems eating and problems speaking. So they knew what was coming. (P9)*
- *During most of my treatment I spent a lot of my time*
- *If relevant, provide opportunity for patients to express feelings about doing exercises in front of children.*
- *Problem solving*
| Physical context of being given information | You are in that room maybe for five, 10 minutes and it goes so quick. And also there’s other people in the room with you, and there has to be, people that are training and learning themselves, so your actual interview is being stopped and started because the specialist may be explaining to the student that’s there as well. Which I haven’t got a problem with. It’s all necessary. (P3)  
most of the people I saw were very, sort of, pragmatic and, I have to say, a little bit cold. What’s that other word? Very sort of [pause] giving stuff like it’s from a text book, like I was just another patient. (P1)  
It was a couple of weeks after my treatment was finished I was invited to classes, a six-week course, attending on a Friday from 12 till 1, or 12 till 2, and they gave you a programme of exercises to do. (P4) | Barrier | Environmental restructuring  
Restructuring physical environment |
|-------------------------------------------|-----------------------------------------------|-----------------------------------------------|--------------------------------------------------|
| Requiring props for exercises | There’s one exercise where you push your tongue against a pallet or flat stick or similar, and I hardly ever did that one. I still hardly ever do it, because I never keep anything with me. (P2)  
So if it was done in a format of maybe a DVD or something, you could revert back to it, you could look at it again. Rather than just have this one interview with a specialist, you could then go back to it. (P3)  
I don’t know. Maybe pictures with diagrams or something to show what part of your tongue you should be tensing up, like more emphasis on when you are swallowing, because you weren’t sure really if it was the front of your tongue or | Provide suitable material to enable patients to feel confident carrying out exercises outside the clinic. | Enablement  
Adding props |
| Physical environment for doing exercises | Because the exercises generally were over maybe two or three times a day, different exercises. It's something you could do in the car when you were driving, or whatever, they didn't have to be in situ. (P5) When nobody else was around. Either in the bathroom or in the bedroom I'd do them. Or if I was walking out to the shops or something like that I'd be doing the swallowing exercises. I remember lying on the floor in the landing, I remember lying on the floor in the bedroom trying to fit them all in, There was that sense of needing to have a space to do some of those. Yes, I think some of the noisy ones I would sometimes do when I walked the dog on the heath. (P9) | This may be tailored to patient, and discussed as part of promoting a routine. | ENABLEMENT
Problem solving
Habit formation
Generalization of target behaviour |
| clinicians involved in treatment | Prescriptive is the word I was looking for before. I felt that the people I was dealing with generally were kind of prescriptive. Do you know what I mean by that? (P1) I think each time you come into the hospital as well, maybe if there was another way that you could be with the same person each time you came. I think changing, seeing different faces, you don't build or get a chance to build that bond. (P3) But at the early stages you had five minutes with the dietician and the speech therapist and they'd ask you a couple of questions between them. This was after you'd seen the doctor. So they should have emphasised more at the earlier stage when you go direct, in the direct interview with the speech therapist. (P4) | Barrier |
| | Consider reducing the number of different clinicians involved in rehabilitation. | ENVIRONMENTAL RESTRUCTURING
Restructuring social environment |
<table>
<thead>
<tr>
<th>OPPORTUNITY</th>
<th>SOCIAL INFLUENCES</th>
<th>Facilitator</th>
<th>EDUCATION ENABLEMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Social opportunity</td>
<td>Support from Clinician&lt;br&gt;I used to attend those classes every Friday, which was really quite a benefit. (P4) &lt;br&gt;I can only say that when I first came here within this centre to have my treatment, I met one of the oncologists and he said to me that they would make me better, they would cure my cancer. And when you get told things like that by a member of staff it gives you a confidence to continue, it gives you a confidence to walk away and feel strong. And I think having that bond with that member of staff is so important. (P3) &lt;br&gt;So I think it was before and it was during, right up until I could eat again, I was constantly getting advice and help (P13)</td>
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<td>Information provision&lt;br&gt;Social support</td>
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<td>Support from Family</td>
<td>I was living on my own but I had my family around me, which was very helpful. I’ve got three daughters. Very helpful. (P4) &lt;br&gt;My daughter, who is 7, felt the need to copy me when I was doing my floor exercises, which is a great tonic because it felt like you were making a game of it, which is quite nice. And that’s something to encourage people, if they do have younger children, because it takes that onerous edge to it away, I think. She took over the situation and became my speech therapist, physiotherapist and nurse all rolled into one, bless her cotton socks. In all seriousness, throughout the whole journey of last year she was an enormous</td>
<td>Facilitator</td>
<td>ENABLEMENT&lt;br&gt;Social support</td>
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| support from other patients | I think patients that have experienced what this journey is and the changes that are going to happen maybe could make someone view it in a different light, make someone see it in a different way. Possibly, as I say, whether it would be done in some kind of format, whether it be online on a computer or DVD, or something like that. Maybe, just with past patients that have experienced it, that could really hit home how important it is. (P3)

I only did that myself in the other radiotherapy department, talking to another gentleman there. There were other chaps there that were having similar treatment to me. They were saying how they felt that day. And I would then say to them, ‘Oh I got this particular drug that helped me with saliva in my mouth,’ the one I have here now, the saliva ease. And the chap I was talking to didn’t know about that. And then he went in and he asked the doctor, and he got that and it helped him. (P4) | Facilitator | ENABLEMENT
PERSUASION
Social support
Vicarious consequences |
Swallowing Intervention Package: Self-Monitoring, Assessment & Rehabilitation Training (SIP SMART)

A tailored programme for patients who are undergoing treatment for head and neck cancer

ISRCTN: 40215425

Intervention manual

Version 1.3
29 January 2016
<table>
<thead>
<tr>
<th>DESCRIPTION</th>
<th>PAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient pathway – where this intervention fits</td>
<td>4</td>
</tr>
<tr>
<td>Preparing for the consultation</td>
<td>5</td>
</tr>
<tr>
<td>Session 1 - Goals and materials required</td>
<td>7</td>
</tr>
<tr>
<td>Session 1 - Explaining purpose of consultation to patient</td>
<td>8</td>
</tr>
<tr>
<td>Session 1 - Swallowing Assessment procedures</td>
<td>9</td>
</tr>
<tr>
<td>Session 1 - Ending the session</td>
<td>12</td>
</tr>
<tr>
<td>Session 2 - Building a therapeutic relationship</td>
<td>13</td>
</tr>
<tr>
<td>Session 2 - Facilitating patient understanding of treatment impact</td>
<td>14</td>
</tr>
<tr>
<td>Session 2 - Facilitating patient understanding of pre-habilitation</td>
<td>15</td>
</tr>
<tr>
<td>Session 2 - Providing a tailored programme</td>
<td>16</td>
</tr>
<tr>
<td>Session 2 - Exploring patient concerns</td>
<td>17</td>
</tr>
<tr>
<td>Session 2 - Ending the session</td>
<td>18</td>
</tr>
<tr>
<td>Additional Resources</td>
<td>19</td>
</tr>
</tbody>
</table>
SIP SMART INTERVENTION MANUAL

Preface

This manual is based on an optimized swallowing intervention package (SIP) derived from both the literature and preliminary studies conducted to inform the content of the intervention. The intervention is aimed at patients who have been diagnosed with an advanced head and neck cancer and are due to commence cancer treatment (surgery, radiotherapy, chemo-radiation). The time period from diagnosis to the start of treatment is usually around 3-4 weeks in most UK NHS centres, but may be longer. The SIP SMART intervention is designed to take place over 2 clinical consultations during this pre-treatment stage. The manual is written in a way that takes due consideration of the present context (University College London Hospital) in which this intervention will be implemented. In its current form, it is solely for use in the SIP SMART feasibility study. It is written for the speech & language therapist undertaking the intervention, and for the purpose of specifying the content of the intervention for research purposes. It may be used to assess fidelity in delivering the intervention.

Acknowledgement of Contributors

The following individuals contributed to a stakeholder consultation meeting during which aspects of the current pre-treatment speech therapy consultation, as well as suggestions for the new intervention were discussed. All individuals were invited in their capacity as expert clinicians, recognized by the Royal College of Speech & Language Therapists (RCSLT).

Thanks to SLTs: Dr Joanne Patterson, Dr Justin Roe, Ms Camilla Dawson, Mr Chris Payten, Ms Eileen Gilmartin, Ms Sarah Pilsworth & Ms Jane Thornton.

Dr Claire Friedemann Smith is also acknowledged for her role in facilitating the meeting.

Thank you also to members of the SIP SMART study patient group (PPI) for their feedback on aspects of the new intervention included in this manual.

Roganie Govender
Simple pathway for patients receiving treatment for Head and Neck Cancer

- **Patients referred via GP, dentist, other specialist.**
  - 2-week wait guidelines.
  - Cancer confirmed

- **Time to start of treatment varies from 3 - 4 weeks for most patients but can be longer for various reasons.**
  - Patient undergoes pre-treatment with SLT, dietitian and clinical nurse specialist.
  - Dental checks if for radiation.
  - Anaesthetic pre-checks

- **Patient referred discussed at MDT**

- **MDT clinic:** Diagnosis given, treatment options discussed.

- **Clinic visit:** Results of further tests, treatment plan finalized

- **treatment**

- **First year post treatment**

- **Patient follow-up for up to 5 years post treatment. Further intervention as required.**

**Pre-treatment SIP**

- **Provider:** SLT
- **Setting:** Hospital Clinic
- **Recipient:** patient
- **Intensity:** 2 consultations prior to treatment.
Pre-Consultation Information Gathering

Checks prior to booking appointment

✓ Patient has been discussed at a multidisciplinary team meeting prior to the pre-treatment consultation with a speech & language therapist.
✓ The patient should be aware of their head and neck cancer diagnosis.

Key tasks to be completed prior to consultation:

1. obtain information about tumour type/stage/exact location
2. confirm proposed treatment plan with the relevant multidisciplinary team member (surgeon or oncologist)
3. obtain medical and other relevant notes including social history
4. ensure adequate preparation to discuss treatment impact on functional outcomes
Before the consultation....

**PROVIDER TIPS**

- Most information can be obtained from the MDT proforma available in the patient electronic notes.
- It is helpful to confirm the treatment plan/details about the radiation fields, chemotherapy regime, extent of surgical resection, reconstruction plans etc with the relevant oncologist or surgeon.
- In most cases the clinical nurse specialist (who should be present when patient is informed of their cancer diagnosis) may have further information about the patient’s personal or social situation that may be relevant to the consultation. It is useful to ask if there is anything important for the SLT to know about the patient’s circumstances in advance of the pre-treatment consultation.
- Ensure sufficient background preparation particularly for less common cancers, complex surgical procedures and reconstruction techniques that may not be frequently seen. This may require the clinician to do some background reading and information gathering prior to the consultation. Discuss with a senior colleague as necessary.
SESSION 1: Fluoroscopy Suite

CHECKLIST

Materials Needed

Medical notes/e-notes
Case history form
Pen torch
Spatula
TheraBite measure (for measuring jaw opening)
Clipboard and pens for questionnaire completion
MDADI questionnaire
Self-Efficacy scale
Performance Status Scale
Set-up in fluoroscopy suite – as per modified barium swallow protocol attached.

Goals:

Obtain completed baseline patient reported outcome measures.

Complete Performance Status Scale (clinician rated)

Undertake a screening oral-motor assessment

Undertake a modified barium swallow assessment (MBS)

Approximate time – 40 minutes
NB: Patient information on MBS procedure provided at time of making appointment.
Introducing self and purpose of visit

PROVIDER TASKS

The X-ray department receptionist will usually call the fluoroscopy suite to advise that the patient has checked in.

WELCOME patient

- **Confirm patient’s name and date of birth**: Ask the patient if this is their preferred name.
- **Introduce Self and role**: say *I am a speech and language therapist working with people having treatment at the head and neck centre. I specialize in swallowing, speech and voice problems. You may already know or have been given some information about changes that may occur to your swallowing during your treatment. The reason for seeing you today is to assess how well everything is currently working when you swallow. Are you happy for me to proceed?*
- **Ask patient if they have any questions about the modified barium swallow/ information leaflet.** Re-assure of no discomfort during the procedure.
- **Radiographer & radiation protection checks/ patient gets changed**: Advise patient that the radiographer will meet them shortly. Ask if they will be happy to complete questionnaires while they wait.
- **Give patient the MDADI and GSES questionnaires to complete**: Say – *I would like you to complete these questionnaires while you wait. This will provide us with information on how things are for you now before you start your treatment. You may be asked to complete them again at a later stage after your treatment. Questionnaires should take no more than 10 minutes to complete.*

**NB**: All of the above may take place outside of the fluoroscopy screening suite.
Fluoroscopy Suite – modified barium swallow

PROVIDER TASKS

BEFORE COMMENCEING PROCEDURE

➢ Collect completed questionnaires

➢ Conduct oral motor exam – Record results on standard form

➢ Obtain Performance Status Scale Score - record current diet texture tolerated by patient.

RADIOGRAPHER POSITIONS PATIENT

➢ Allergies: Confirm patient has no allergies to contrast (usually barium/ EZHD) or food substances being used.

➢ Image requirements: Ensure that the radiographer is aware of the requirements to obtain a good image for the specific swallow analysis. Images should be captured at 30 frames per second. Fluoroscopy recording should be made on the Digital Kay Pentax Swallow Workstation.

➢ Perform modified barium swallow – see attached protocol for procedure and scoring information.
Example of a good image

(image source: courtesy of Katherine Kendall, MD)

Timing information on the counter (also available on the swallow workstation) allows for the analysis of timing in relation to bolus flow and co-ordination of swallow structures.

A coin (disk) of known diameter (5 pence = 18mm) taped to the patient’s chin allows for calibration of the video image to assess displacement measures at a later stage.
Ensure a good image is maintained during the procedure

Certain structures need to be visible in the image frame in order to make measures:

- Posterior Nasal Spine
- C1 to C6
- Ring

(image source: courtesy of Katherine Kendall, MD)

- Patient is usually positioned to obtain a lateral view at the start of the procedure.
- The entire pharynx (C1–C6) should be visible on all frames.
- The protocol should begin in “hold” position to observe structures at rest.
After the procedure ...

**PROVIDER TIPS AND TASKS**

➤ It is anticipated that patients may demonstrate some swallowing impairment even at baseline. Occasionally there may be a concern about a serious swallow safety issue (e.g., risk of airway obstruction, severe aspiration) that requires management outside the skills of the Speech Therapist. Such a patient should be referred to the appropriate team.

➤ If the patient demonstrates an essentially *safe* swallow, Re-assure. Ask them to continue eating and drinking as they are.

➤ Advise patient that as part of their informed consent process, you would like to arrange a further appointment to discuss how treatment may impact on their swallowing function. Invite patient to bring along a significant other or someone who they believe might be of support during their treatment. Indicate that you will discuss their swallowing video in further detail at that appointment, and that you might discuss ways in which they may be able to minimize the negative side effects of treatment.

➤ Provide an opportunity for the patient to ask questions about any immediate concerns.
SESSION 2: Clinic Room

Task 1: Establish rapport, Explore patient’s perspective

PROVIDER GOALS

Meet patient in waiting room, check if they would like an accompanying family member/friend to join them for the consultation.

- Promoting trust, support, shared decision-making.
- Establish patient’s understanding of treatment and functional impact.

Say to patient: *I imagine that you may have had lots of information since your diagnosis – how have you found this?*

Determine from response how patient is feeling/coping with information about treatment. Listen if patient suggests any strategies they have found helpful (may be useful to draw upon in delivering current information)

*This appointment is a follow-up from your swallowing assessment. Is it okay if we spend a few minutes talking about how your treatment may affect your ability to drink, eat and swallow food?*

Example prompt questions:

- Have you already thought about or read about how your eating/swallowing may be affected by the treatment?
- Can you tell me about how you imagine things may be different for you with eating and drinking after your treatment from what you have read or already been told?
- *How (if at all) would these changes affect your daily life. How do you think this might make you feel? (may elicit patient views on alternate feeding etc)*
Task 2: Facilitate patient understanding of likely impact of treatment on swallowing

**PROVIDER GOALS AND TASKS**

- Readiness/willingness to engage in pre-habilitation, pre-treatment exercises.
- Explain normal swallow function and how treatment may impact on swallowing.

On a scale of 0-10 where do you feel you are currently with your eating, drinking, swallowing function. (ask patient to provide score - NB: patient’s baseline may range from no problems to significant problems)

Based on discussion - On a scale of 0 - 10 do you have an idea where you might be about 3 months after your treatment (or surgery) has finished.

<table>
<thead>
<tr>
<th>0</th>
<th>5</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Completely normal</td>
<td>Unable to eat or drink by mouth. Tube fed.</td>
<td></td>
</tr>
<tr>
<td>Able to eat all food textures with no difficulty</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

I would like to show you a short video clip of how swallowing works – Other patients have found it useful to see rather than to try and imagine what might be happening in the throat. It’s a video animation that makes it easier to then understand what your own swallowing assessment shows. Are you happy for me to show this?

Show video animations on computer and explain key aspects of swallowing to orientate patient to viewing an image of a bolus being swallowed.

Show patient mpeg of their x-ray swallow (on hospital computer).

Encourage questions and observations from patient, and provide information accordingly. Draw attention to aspects such as the tongue base (muscular structure) that needs to have strength and good range of motion to move food along the throat. Tailor information about patient’s treatment to illustrate how function may be affected by the radiotherapy or surgery to the specific structures targeted by the cancer treatment (surgery and/or radiotherapy).
Provide information/advice on pre-treatment exercises and strategies to mitigate anticipated problems.

**PROVIDER TIPS**

The information below should be presented in a manner that the clinician feels is best tailored to the individual patient. Where possible anchor concepts to something meaningful to the patient.

**Explain rationale of current swallowing exercise intervention:**
- Swallowing involves the use of several muscles – everyone is slightly different. Treatment will affect muscle strength, and range of movement.
- Commencing specific exercises early to build reserve and reduce muscle wasting (detraining and atrophy) when it becomes difficult to eat. Use analogy such as not walking for a long time after an operation (muscle wasting). Being given knee exercises/pelvic floor exercises etc before surgery.
- May help with quicker recovery of function after treatment.
- Will help to maintain eating and drinking as much as possible through treatment, and reduce longer term/later effects.
- May be easier to become familiar with swallowing exercises whilst still feeling relatively well.
- Patient can take some control of own recovery from the start – exercises are usually a part of the rehabilitation after treatment.

**Encourage questions.**
Ask patient how important the above is for them in the current context – Allow patient to verbalize intention.
Select tailored exercises based on patient’s swallowing assessment, treatment/surgical plan. Use specific behaviour change techniques to increase adherence

**PROVIDER TASKS**

- Describe each exercise, how it works and provide demonstration of how to perform the exercise. Show partner/family too if present. (patients may wish to have access to the exercises on a DVD or you-tube link, and/or in written format – this should be provided based on patient preference)
- Ask patient to practice exercise, check and provide feedback accordingly.
- Jointly decide upon and agree with the patient the number of sets and repetitions for each exercise.
- Ask patient to plan two 10-15 minute time-points in the day when the exercises could be done regularly at the same time in their routine (eg after cleaning teeth in the morning and evening)
- Provide patient with the exercise recording calendar (developed for intervention) – request that they hang the calendar in a place where they will see it daily to prompt doing the exercises, and can easily access it to record their daily exercise. Ask them to fill in their exercise plan on the calendar.
- Ask patient if and how partner/family could support them and incorporate accordingly.
- Advise patient that they will receive a telephone follow-up within a week – encourage that every effort should be made to build the exercises into a routine (explain long term nature of exercises which hopefully will become easier in time)

On a scale of 0 – 10, how confident do you feel that you will be able to carry out the exercise programme daily?

0 .......................................................... ........................................ 10

I am not at all confident

I am extremely confident

**Nb:** see appendix for link to selection of exercises.
What to do if things don’t go to plan...

**PROVIDER TIPS**

Can you tell me about what makes you feel more/less confident? Facilitate problem solving towards solutions that increase confidence.

Use the confidence question to initiate a discussion of any barriers that the patient may be experiencing and work with them in finding possible solutions/alternatives if things don’t go to plan. This helps the patient understand that it’s okay not to do the exercises in very difficult circumstances – but helps them to plan a strategy to get back into their routine as quickly as possible.

Plan for 5-10 minutes of discussion tailored to the specific barriers that the patient may have. Facilitate process by first encouraging patient to offer ways of overcoming barriers (based on past experience, resources that can be drawn upon etc). If appropriate/relevant – suggest that other patients who have had similar concerns have found it helpful to do xyz. This approach gives patients the opportunity to be more involved in the decision-making.
Closing the session...

**PROVIDER TIPS**

- Check whether patient has any questions.
- Check that they are clear on the exercise programme and have all the relevant material to take away with them.
- Acknowledge that it is a difficult time – and re-assure that all members of the team have considerable experience working within head and neck cancer. Explain that they will most likely see another speech and language therapist on the ward and during their radiotherapy treatment. Re-assure that members of the team communicate with each other to maintain continuity of care.
- **Say I think it's great that you are willing to do something now that could reduce the impact to your swallowing function. I will give you a call in a week (or specify if time pre-arranged) to check how you are getting on.**

************

Approximate time for consultation: 45-50 minutes
Additional Resources:

- The MBS ImP Protocol may be accessed online at www.mbsimp.com

- Swallowing exercise recording calendar

Speech & Language Exercise Recording Calendar

January 2016 — June 2017
As you have agreed to participate in the SIP SMART clinical trial, we are providing you with this calendar.

Your Speech & Language Therapist will prescribe swallowing exercises designed just for you to maintain your swallowing function during and after your treatment.

Please complete the calendar as advised by your Speech & Language Therapist to help you to keep a daily record of your exercises.

You may be asked to bring the calendar with you to your appointments.

Thank you.
• Selecting exercises

Exercises should be selected based on the findings of the swallow assessment. Target exercises specific to the impairment in physiology observed on the modified barium swallow. Where it is clear that specific structures will incur reduction in function due to treatment, exercises to maintain and optimize function should be provided pre-treatment.

Multiple Exercise sources exist, including apps (such as www.TactusTherapy.com)

*Images below reproduced with permission from Tactus Therapy.
Therapy Finder

Select the Impairments or Observations you wish to treat

Hyolaryngeal Excursion
- Impaired hyolaryngeal excursion
- Aspiration after the swallow
- Penetration after the swallow
- Vallecular residue
- Pyriform sinus residue

Laryngeal Closure
- Impaired cough reflex
- Impaired protection of the airway
- Impaired vocal fold closure
- Aspiration during the swallow
- Penetration during the swallow
Appendix 7-1: Protocol manuscript in BMJ open

BMJ Open

Improving swallowing outcomes in patients with head and neck cancer using a theory-based pretreatment swallowing intervention package: protocol for a randomised feasibility study

Roganie Govender,1,2 Christina H Smith,3 Benjamin Gardner,2,4 Helen Barratt,5 Stuart A Taylor6

ABSTRACT

Introduction: The incidence of head and neck cancer (HNC) in the UK is rising, with an average of 31 people diagnosed daily. Patients affected by HNC suffer significant short-term and long-term post-treatment morbidity as a result of dysphagia, which affects daily functioning and quality of life (QoL). Pretreatment swallowing exercises may provide additional benefit over standard rehabilitation in managing dysphagia after primary HNC treatment, but uncertainty about their effectiveness persists. This study was preceded by an intervention development phase to produce an optimised swallowing intervention package (SIP). The aim of the current study is to assess the feasibility of this new intervention and research processes within a National Health Service (NHS) setting.

Method and analysis: A two-arm non-blinded randomised controlled feasibility study will be carried out at one tertiary referral NHS centre providing specialist services in HNC. Patients newly diagnosed with stage III and IV disease undergoing planned surgery and/or chemoradiation treatments will be eligible. The SIP will be delivered pre-treatment, and a range of swallowing-related and QoL measures will be collected at baseline, 1, 3 and 6 months post-treatment. Outcomes will test the feasibility of a future randomised controlled trial (RCT), detailing rate of recruitment and patient acceptability to participation and randomisation. Salient information relating to protocol implementation will be collated and study material such as the case report form will be tested. A range of candidate outcome measures will be examined for suitability in a larger RCT.

Ethics and dissemination: Ethical approval was obtained from an NHS Research Ethics Committee. Findings will be published open access in a peer-reviewed journal, and presented at relevant conferences and research meetings.

Trial registration number: ISRCTN02154256; Pre-results.

Strengths and limitations of this study

- Use of a randomised controlled trial design to minimise bias and differences between groups.
- Study design incorporates prior qualitative work to optimise adherence to the intervention.
- Method includes consultation with clinicians involved in usual care to devise a usual care protocol to facilitate consistency.
- Limited to one hospital site.
- Patients and clinicians are not blinded to randomisation allocation.
the problems associated with eating and drinking after primary HNC treatments (surgery, chemo-radiotherapy) are an important part of the care delivered to patients diagnosed with HNC.2

Current UK practice for managing dysphagia in HNC Traditionally, patients would have seen a speech and language therapist (SLT) following their cancer treatment for rehabilitation of their swallowing and communication difficulties. A gradual shift in practice occurred following publication of the National Institute for Health and Care Excellence (NICE) Improving Outcomes Guidance,20 which recommend that patients should also see an SLT prior to their treatment to inform them of the likely impact to their swallowing and speech function. This information giving is also viewed as a necessary part of the process of informed consent. In support, an emerging number of functional outcome studies have indicated that swallowing function pre treatment could be a strong predictor of long-term swallow function post-treatment.11-13

Implementation of the NICE recommendation is currently variable. In some centres, patients are provided with brief information by the SLT at the time of seeing their medical consultant in a multidisciplinary clinic setting. In other centres, separate SLT consultations take place, which include documentation of baseline functional measures for swallowing and communication, as well as advice on diet modification and the recommendation to start a general protocol of swallowing exercises. The latest report from the UK National Database of Head and Neck Oncology (DAHINO)24 indicated that only 29% of patients with HNC in England and Wales were recorded as having a pretreatment SLT consultation. Given the clinical and financial resource implications of a separate pretreatment SLT consultation, implementation will likely only increase if there is clear specification as to the optimal content of the consultation, together with evidence supporting its benefit on patients’ outcomes. Aside from information giving, there is a need to define what interventions administered before treatment (prehabilitation) may improve patient experience and/or post-treatment function.

The role and context of pretreatment swallowing exercises The physiological rationale for prophylactic swallowing exercises has been previously described in the literature. Strength-based exercises and/or range of movement exercises aimed at the swallowing musculature may prevent muscle atrophy and reduce or delay the impact of radiation-induced fibrosis.15-28 Preconditioning through exercises has been reported to be helpful in other types of surgery.29 Swallowing is described as a ‘suboptimal activity’ meaning that it can be adequate for the purpose of obtaining oral nutrition even when not at maximal physiological functioning. While it seems intuitive that pretreatment swallowing exercises should be helpful in increasing physiological reserve, reducing muscle atrophy and possibly delaying the onset of fibrosis, uncertainty about its effectiveness in improving swallowing for patients with HNC persists.23 Few randomised clinical trials have attempted to address this knowledge gap, with mixed results.17-20,25 Trials evaluating the effects of pretreatment swallowing exercises suffer limitations in study design, and the lack of consistent outcome measures across studies is problematic.23 Uncertainty also remains as to the optimal type and frequency of exercises although such considerations are less relevant to tailored interventions guided by prior physiological assessment. The practice of providing prophylactic swallowing exercises varies among UK clinicians,30 and to date there is no published UK data supporting the effectiveness of pretreatment swallowing exercise interventions in the HNC population.31 Any pretreatment intervention package will need to address often poor patient adherence to swallowing exercises.32-34 Improved adherence may be achieved by facilitating a change in patient behaviour. A new intervention will also need to be compatible with the broader cancer care pathway as described in figure 1.

Development of a tailored pretreatment swallowing intervention package (SIP) In preparation for the feasibility study described in this manuscript, an optimised SIP was developed by the researchers, guided by the methodology proposed by the Medical Research Council (MRC) for devising complex interventions incorporating multiple components that may interact in producing outcomes.35 The scope of the current work relates to the development and feasibility testing phases of a complex intervention, but the framework also includes evaluation and implementation phases.36 The new SIP—Swallowing Intervention Package: Self-Monitoring, Assessment, Rehabilitation Training (SIP SMART) was devised using current best evidence of swallowing assessment,37 as well as insights from our earlier studies exploring the behavioural dimensions of this complex intervention; a systematic review of the literature38 and a patient interview study (submitted manuscript).

In our systematic review of behavioural swallowing intervention studies,37 we used a published taxonomy (BCTTvs)39 of 93 hierarchically organised behaviour change techniques (BCTs), to identify the BCTs reported in the literature. BCTs may be defined as the smallest active ingredient of an intervention that may bring about a change in behaviour; for example, demonstration of the behaviour or self-monitoring of the behaviour.
We summarised that the BCTs that were more frequently associated with successful interventions were more likely to be successful in future interventions.

We also carried out semi-structured interviews with a group of patients (n=15) who had completed treatment for HNC to obtain their views and experiences of swallowing rehabilitation exercises, and in addition obtained feedback from respondents about the potential use of video animations (Dysphagia App, Northern Speech Services, USA) as an educational tool in explaining the basic mechanics of swallowing. The barriers and facilitators to exercise adherence revealed in our qualitative study informed our behavioural analysis and the subsequent selection of BCTs for the SIP SMART intervention.

We ensured that the new SIP would meet mandatory guidelines for information provision and informed consent, and that it could feasibly be incorporated within the existing cancer pathway for patients with HNC. The new SIP was discussed and refined by clinician (Royal College of Speech and Language Therapy expert clinician group (RCSLT)) and patient (patient-public involvement group (PPI)) stakeholder groups. Intervention manuals were produced for the new intervention and usual care in collaboration with the stakeholder groups. Figure 2 is a schematic diagram illustrating an overview of this process and how it links to the MRC complex interventions framework.

Although another complementary non-randomised UK trial of pretreatment swallowing intervention is planned, our SIP SMART trial is unique as it is based on an optimised pretreatment intervention using tailored exercises selected after physiological assessment of swallowing, and is directly informed by theoretically derived BCTs. Furthermore, comprehensive evaluation of a new SIP is likely best performed using a randomised controlled trial (RCT) design. Given the uniqueness of our SIP and proposed future RCT evaluation, a feasibility study was deemed imperative to ascertain viability within a NHS context, and to identify and address potential barriers to future roll out on a larger scale.

In particular, the aims of this feasibility study are as follows:

- Assess the rate of recruitment of eligible participants and identify any specific barriers to recruitment.
- Determine the acceptability of randomisation, and the randomisation procedure to patients and the clinical care team.
- Determine retention and attrition over the time course of the study.
- Evaluate the ease of protocol implementation, including research processes, and identify barriers in the clinical setting.
- Evaluate a range of potential outcome measures, including the ease and completeness of data collection across various time points.
- Determine concordance between potential outcome measures and define the most suitable primary outcome for the definitive study.
- Collect data to inform future sample size calculation.
**METHODS AND ANALYSIS**

**Study design**

This study forms the preliminary testing phase described within the MRC complex interventions framework. Following on from our development work, we will conduct a two-arm parallel group non-blinded randomised controlled feasibility study. The SPIRIT (Standard Protocol Items for Randomised Interventional Trials) checklist was used to inform the content of this protocol.

**Study population, setting and recruitment plan**

The study will take place at a single NHS hospital site (Head and Neck Cancer Centre) with a catchment population of 1.5 million. The study sample will be drawn from the population of patients with newly diagnosed HNC referred to the cancer centre, and discussed at the weekly multidisciplinary team (MDT) meeting. Potential patients for the study (based on diagnosis) will be identified during the meeting by the researcher (RG), research nurse or other members of the MDT. The research team will ensure that the treating consultant is aware of potentially eligible patients so that he/she may introduce the study during the consultation with the patient if appropriate. For this feasibility study, sample size was determined pragmatically using the general guidance suggested by Lancaster and colleagues who recommend that n of 30 is sufficient to estimate key parameters in a feasibility study. Based on a conservative annual referral of ~70 newly diagnosed stage III and stage IV patients with HNC to the Head and Neck Centre, we estimated that it will take about 9 months to recruit a total of 32 patients to this study based on recruiting 60% of eligible patients. Eligibility criteria for inclusion in the study are listed in box 1.

**Pre-screening/screening**

All patients who meet the clinical eligibility criteria identified at each MDT meeting will be recorded on the study screening log by the researcher or research nurse.

**Figure 2** Key stages of the "MRC complex interventions framework that informed the development and preliminary testing of the SIP SMART intervention. * Source: Caig et al. BMJ 2006. MRC, Medical Research Council; SIP SMART, Swallowing Intervention Package: Self-Monitoring, Assessment, Rehabilitation Training.

**Box 1 Inclusion and Exclusion Criteria**

**Inclusion:**
- Patients with newly diagnosed stage III and stage IV head and neck cancer.
- Discussed at the head and neck MDT and planned for treatment via surgery and/or chemoradiotherapy or combinations thereof.
- Able to provide informed consent.
- Proficiency in English satisfactory to participate/engage in the intervention.
- Aged 18 and above.

**Exclusion:**
- Patients with previous head and neck cancer treatment.
- Patients who are in remission or those receiving palliation.
- Patients who are to be treated solely by non-standard treatment that is not surgery, radiotherapy, chemoradiotherapy or combinations thereof. Patients treated by chemoradiotherapy, brachytherapy and photodynamic therapy alone will be ineligible.
- Patients who are planned for a total laryngectomy.
- Patients who are considered vulnerable or unable to provide informed consent.
- Patients with brain tumours and other primary sites not within head and neck.

Screening will take place at the outpatient clinic consultation when treatment options are discussed by the surgeon/oncologist. The researcher/clinician will attend the consultations for eligible patients. If appropriate at this stage, the purpose of the study will be explained and patients will be given the patient information leaflet to take away. Most patients will be booked for repeat visits to the head and neck clinic prior to finalising their treatment plan. Due consideration will be given to ensuring that the study information is discussed at an appropriate time after the diagnosis. Patients will be given a minimum of 24 hours after receiving the patient information sheet before a mutually agreed time is arranged to
answer any further questions to assist patients in deciding about whether to participate. The time frame was chosen because most patients return to the hospital for their test the day after their clinic visit. This offers an opportunity to answer questions in person and obtain signed consent if appropriate. Patients will be reassured that participation is voluntary with the freedom to withdraw at any stage, and that participation in the study will not affect or delay their main treatment.

Enrollment/consent
Informed consent will be obtained by the researcher/clinician (RG) or a trained research nurse. Following informed consent and generation of a patient study identification number, the patient will be entered onto the study enrollment log and randomized to either the SIP SMART intervention or usual care group as detailed below.

Randomization and allocation
Eligible patients will be randomly assigned in a 1:1 ratio between usual care and intervention groups (Figure 3 for trial flow chart). Patients will be stratified by first-line treatment; surgery or chemoradiation, a known factor that impacts swallowing outcomes.05 It will therefore be necessary to ensure a balance of primary treatment modality across the groups. Owing to the small numbers in this study, random block permutations will be employed to ensure a close match in numbers in the intervention and usual care groups at any given point during the trial.

Patients will be allocated to one of two groups using an online computer-generated randomisation service provided by an external company: http://www.sealedenvelope.com/. The company is registered with the Information Commissioners Office (ICO) and inspected by the MHRA (UK trials regulator). Following consent, the researcher or research nurse will enter the password-protected website and complete relevant information regarding first-line treatment. Randomisation is immediate, and the group allocation is emailed within a few minutes. This process is undertaken in the presence of the patient after signed consent is obtained, ensuring that the allocation is concealed until this point and simultaneously made known to the patient and researcher. Allocation is not blinded as the patient and staff will be aware that the new intervention includes a baseline videofluoroscopy or X-ray of swallowing. Patients allocated to the usual care group are advised that they will be sent an appointment in the post to see an SLT prior to their treatment as per the usual care pathway. Patients allocated to the intervention group are given an appointment and a further information leaflet on having a videofluoroscopy to assess how well the muscles and nerves function when swallowing different textures of food and drink. All patients are given three questionnaires to complete and return prior to their appointment with the SLT.

Interventions and procedures
Usual care group: This group will receive the usual pretreatment care offered by the SLT prior to their upcoming surgery and/or chemoradiation. The SLT clinical team consisting of four members participated in a series of consensus meetings regarding the delivery of usual care to facilitate equipoise. All four team members involved in the delivery of usual care have also undergone good clinical practice (GCP) training. A usual care manual was written and agreed by the SLT clinical team prior to initiation of the study to ensure a level of consistency among the clinicians. Usual care pretreatment is one 45 min consultation as described below:

- General case history taking and introduction of SLT role.
- Clinical baseline screening of swallowing and communication function. This is usually based on an oro-motor assessment; 100 mL water swallow test40 a clinician-rated Performance Status Scale indicating the normality of diet texture and public eating score,41 and a clinician-rated scale for chewing, communication and swallowing.42 Maximal jaw opening using a Therabite measure and voice quality ratings using the GRBAS (Grade of Hoarseness, Roughness, Breathiness, Asthenia, Strain) rating scale are also recorded.

- The patient is provided with a general overview of the planned treatment (surgery or chemoradiation) and information about the likely side effects such as mucositis and taste changes and impact of treatment on swallowing and communication function.

- General advice and exercises are offered to patients planned for chemoradiation at this appointment. Patients are provided with a general exercise sheet that includes instructions for eight different swallowing exercises, for example, passive jaw stretches. This is included as part of the information pack and is made available at the end of the presentation.

- Patients are advised that they may be helpful to start doing the exercises before treatment.

Intervention group: Patients in the intervention group will be pretreated according to the SIP SMART protocol that includes the specific components of the new intervention in addition to all aspects of usual care. The intervention takes place over two 45 min consultations that may follow each other on the same day or over a day or two between them depending on patient preference. The new intervention will be delivered by one clinician (RG) who completed a 5-day intensive training course in behaviour change (UCL Centre for Behaviour Change), supplemented by on-line training in coding ICDs, as well as ongoing mentorship from an expert in behaviour change. Specific details of the new intervention have not been explicitly shared with clinicians delivering usual care to minimise contamination. Broad differences include the following:

- Patients will undergo a radiological assessment of their swallow function in the fluoroscopy suite at the
Identification of eligible patients
Patients identified by researcher/research nurse at weekly MDT meeting. Eligible patients flagged to treating consultant, seeing patient at Head and Neck Clinic (usually the same afternoon).

Screening in Head & Neck Clinic
Consultant will inform patient of study. Invite SLT/research nurse to provide further information if appropriate. Patient information leaflet will be given, and participants will be advised that they will be contacted after minimum 24 hrs for a decision or to answer further questions. If agreeable, arrangements made to see patient at earliest opportunity to obtain signed consent, generate study ID and randomise.

RANDOMISATION
(stratified by first line treatment)

TREATMENT (SURGERY/CHEMO-RADIATION)

STUDY FOLLOW-UP
T1 = 1 month
T2 = 3 months
T3 = 6 months

STUDY FOLLOW-UP
T1 = 1 month
T2 = 3 months
T3 = 6 months

USUAL CARE
Patient will receive usual care intervention. Key features include: Information giving - likely impact of treatment on swallow and communication function. Baseline measures of function eg FSS. General exercise sheet (6 different exercises) provided for radiotherapy patients who are advised that it may be helpful to commence exercises before treatment. (Based on NICE guidelines, 2004)
T0 - Study specific measures taken

SIP SMART INTERVENTION
Patient will receive a baseline modified barium swallow to assess swallow physiology and inform the selection of tailored and targeted exercises to optimise physiological reserve (personalised care). Actively promote adherence using behavioural theory and selected behaviour change techniques and functions. Information giving on treatment impact, and recording of mandatory baseline measures similar to usual care.
T0 - study specific measures taken

Figure 3  Trial flow chart.
explain the basic mechanics of swallowing and to orientate them to key structures such as the tongue, base of tongue, airway, and oesophagus. Patients will thereafter be shown their own videofluoroscopy and helped to identify the key structures using this newly acquired knowledge. The clinician will encourage the patient to provide commentary and or ask questions as they watch their own swallowing.

The videofluoroscopy assessment will be used to tailor the information, advice and exercises given to the patient during the pretreatment session and to facilitate discussion about the rationale for exercises and possible consequences of not doing exercises.

Further detail about the intervention content and behavioural strategies used is provided in the SIP SMART manual. This is not included in this paper, but can be requested from the first author.

Patients in both groups will follow the usual care pathway for SLT rehabilitation post treatment (see figure 5 for trial flow chart). The number of SLT rehabilitation sessions for all patients will be recorded. Patients will be informed that exercises may be amended post treatment based on updated swallowing assessment.

Baseline and follow-up outcome measures

Swallowing is a multidimensional phenomenon that may be measured by a number of different indicators including: patient-reported outcome measures, clinician ratings and scores from instrumental assessments such as videofluoroscopy and fibre-optic endoscopic evaluation of swallowing. This range of outcomes can prove problematic when synthesising findings from multiple studies. In this feasibility trial, we have selected a similar panel of swallowing outcome measures to that used in concurrent UK trials for HNC (radiation and surgery-based trials using a swallowing outcome measure), as well as measures collected as part of routine clinical practice (table 1). Outcome measures will be collected at baseline and 1, 3 and 6 months after treatment. Six months represents a relatively stable time point in the recovery trajectory for patients with HNC and was therefore selected as an appropriate end point.

Patient weight, body mass index and use of feeding tube will also be recorded at all time points. The MD Anderson Dysphagia Inventory (MADI) will be used to determine swallowing-related QOL. We have chosen to collect information on health-related QOL via the Functional Assessment of Cancer Therapy and Head and Neck subscale (FACT-HN) as this questionnaire was identified as the most preferred by patients with HNC when compared with other QOL questionnaires.

At 6 months, a videofluoroscopy will be conducted on all patients using the standardised Modified Barium Swallow Impairment Profile Protocol (MBI Imp Profile), and analysis. Three SLT clinicians who have completed a 25 hour online training module and obtained the minimum 80% reliability score will provide consensus ratings for these assessments. Standard assessment rating forms developed as part of the MBI Imp Profile will be used to score the videofluoroscopies. We will also rate aspiration from the videofluoroscopies, based on the widely used 8-point Penetration-Aspiration Scale (PAS).

As we anticipate that adherence to swallowing exercises should be associated with better swallowing, we will also collect intermediate outcomes on adherence using two simple questions developed for this trial. The questions will ask about percentage adherence over a specified time, and a free text question to gather further information about any specific reasons for adherence/ non-adherence to exercises.

Safety considerations

We do not anticipate any serious safety concerns arising from this largely behavioural intervention. The use of the videofluoroscopy as part of the intervention is sometimes associated with aspiration of barium contrast material but barium pneumonitis is reported to be rare.
at <1%.47 The additional radiation exposure associated with the procedure is roughly the equivalent of 2 months of background radiation that an adult in the UK may experience from the environment, and considered minor in the context of the patient's overall treatment. The procedure will be undertaken by an experienced SLT familiar with the protocol for dealing with an adverse event related to barium intubation. The procedure is also a well-established part of routine clinical practice.

Data collection and management
We devised a number of study specific forms including a case report form (CRF), screening log, enrolment log, training log for any study-related training and file note entry forms for any relevant ad hoc communication. Patient names will be replaced by a study number on all study forms and completion of CRFs will be in accordance with GCP guidelines. A site file containing all relevant documents as stipulated by local research and development and governance guidelines will be maintained throughout the study and securely stored in a locked cabinet. Patient-reported questionnaires will also be securely filed. Non-identifiable quantitative data will be transferred from the questionnaires and CRFs to a specifically designed Microsoft Access database by a data manager. The database will first be tested using mock data to ensure that it meets the requirements for data entry. A random check of ~10% of the data inputted will be reviewed against the original source by the researcher (RG) to estimate an error rate. This information will help ensure that a robust data management plan is in place for a more formal trial. The researcher will maintain an electronic diary of relevant information pertaining to the study processes on a password-protected laptop computer.

Analysis
We will use mainly descriptive analysis and summary statistics to address our aims. Study screening and enrolment logs will be used in determining the rate of recruitment into the study. All qualitative information (researcher diary), minutes of study-related discussions and meetings will be imported into NVIVO 10, a software database to facilitate the organisation and thematic coding of qualitative or textual data. The researcher is in a unique position of being embedded within the clinical team, and therefore able to make observations over the duration of the study in a naturalistic manner. This approach to process analysis arguably may provide more useful information than the use of post hoc focus groups and interviews that rely on participant memory and may be removed from context.48 Observing and collecting information in this way also means that the researcher can observe the interplay of other factors (eg, multiple studies competing for the same patient group, prevailing views of the treating consultant about the value of the proposed intervention and how busy the clinic is) that may reveal vital information about the barriers and facilitators to recruitment.

We will also report on the practicality of implementing the protocol, for example, obtaining timeslots for videofluoroscopy; average time taken for the recruitment and consent process; utility of the chosen randomisation method and suitability of the study-specific forms including the CRF. This information will be used to optimise components of the protocol and study process in preparation for a larger trial.

A range of outcome measures will be collected, we will look at the suitability of each measure, the ease of collection and the quality and completeness of the data collection. We will observe the relationships (correlation and disconnection) between the different outcome measures to help inform the most suitable choice of primary and secondary measures for a definitive trial. Important parameters such as SD and estimates of effect size will be used to inform the sample size calculation. Based on the available literature, we will aim to specify the target difference (clinically meaningful difference) for the chosen primary outcome. The primary outcome measure will be chosen from potential candidate measures on the basis that it is valid, practical and feasible to obtain and has expert agreement (RCSI clinical expert group) that it reflects a good summary measure to answer the question of whether the new intervention is effective in improving swallowing.

Patient acceptability to participation and randomisation will be determined using a previously developed questionnaire.49 Self-reported adherence to the intervention will be explored via a brief study questionnaire. Previous studies reported that full adherence to exercises during radiotherapy was under 15%.50 In a Danish study of a similar intervention to the current study, an average of 35% of patients reported doing their exercises at least once a day between 1 month and 11 months after treatment.51 We have therefore selected 35% as the minimum target adherence for our study.

Criteria for success
This study will be viewed as feasible to proceed to a definitive trial if
- a suitable outcome measure is determined, and sample size estimated;
- recruitment rate into the trial reaches an average of four patients a month;
- patients report generally positive views about participation and acceptance to randomisation as determined by questionnaire evaluation;
- patients in the intervention group are more adherent than those in usual care, with at least 35% of intervention group patients reporting satisfactory to good adherence to exercises.

DISCUSSION
To the best of our knowledge, this is the first randomised UK study of a behavioural swallowing exercise
intervention for patients with HNC registered on the trials database. By undertaking a feasibility study and identifying key uncertainties, any future study may be optimised to make best use of resources. This study follows earlier work on intervention development bringing together expertise from different fields including clinical dysphagia management and behaviour change. It benefits from the use of newer paradigms in health research including the use of consultative and consensus meetings to derive a treatment manual to specify the content of usual care, a common omission when reporting such interventions. It is likely to provide a rich source of information about how readily patients with a new diagnosis of HNC will accept and participate in a self-management type intervention. It will also provide a preliminary indication of the recruitment potential for rehabilitation therapy trials for this population. A recent UK study that randomised HNC patients to either a pretreatment gastrostomy tube or a nasogastric tube reported recruiting only 23% of eligible patients, highlighting the importance of this feasibility work. It is well known that the treatment of HNC involves a complex care pathway with multiple disciplines being involved, particularly at the pretreatment stage. The feasibility of undertaking a clinical trial at this point in the patient pathway is compounded by the challenges of approaching patients to participate in a trial shortly after receiving a cancer diagnosis. Insights from this study may therefore have more widespread relevance for future studies of this population.

Limitations of the study include the inability to blind participants and staff to the randomisation allocation as all patients in the intervention group will receive a videofluoroscopy as part of the intervention. Based on the limited number of individuals trained in rating videofluoroscopies using the MBS impairment profile, the same SLTs involved in usual care delivery will be rating the assessments. For this reason, we have chosen to use a consensus rating from three clinicians as this method is likely to introduce the least bias. We have not planned to evaluate fidelity in delivering the intervention at this stage, as only one individual will be delivering the intervention (RG). In a larger trial, training will be required by all clinicians before delivering the intervention and fidelity checks will be built into the research process. In spite of these limitations, the current study represents a first and important step towards examining the feasibility of undertaking a full-scale RCT within NHS hospitals to determine the effectiveness of a pretreatment swallowing intervention for patients with HNC, delivered by SLTs.

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6. Centre for Medical Imaging, University College London, London, UK

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The authors would like to thank the patients and clinicians who participated in the development of the SIP SMART intervention, as well as all members of the UCLH Head and Neck MGT for their support with this study. We are grateful for the assistance of the research support team, in particular the research nurse and research support practitioner. The authors also wish to acknowledge the contribution of Professor Jane Wardle during the early planning stages of this study. Jane Wardle passed away on 28 October 2015.

Contributors
RG provided the original study concept and drafted the manuscript. CBS and SAT contributed to editing the study design. SAT is the chief investigator. CBS, BG, HB and SAT provided critical feedback in revising the manuscript. RG is the lead researcher. All authors approved of the final manuscript.

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Disclosure
The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health.

Competing interests
None declared.

Ethics approval
This manuscript is based on Protocol V.1 dated 03.02.16 (submitted and approved by the London South East NHS Research Ethics Committee (14/LO/152))

Dissemination
A lay summary of the study is available on the CRUK website. Final results of this feasibility study will be publicly available through open access publication in a peer-reviewed journal, and presented at relevant conferences and research meetings.

Provenance and peer review Not commissioned; externally peer reviewed.

Data sharing statement The intervention manual will be available from the first author on completion of the study.

Trial status
Ongoing data collection.

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References


Improving swallowing outcomes in patients with head and neck cancer using a theory-based pretreatment swallowing intervention package: protocol for a randomised feasibility study

Roganie Govender, Christina H Smith, Benjamin Gardner, Helen Barratt and Stuart A Taylor

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## Appendix 7.2: SIP SMART Screening Log

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<th>Patient Information Sheet Version and date (dd/mm/yyyy)</th>
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*University College London Hospitals NHS Foundation Trust*

Protocol Name: SIP SMART
Short Title: Swallowing Intervention Package
Site Investigator: Stuart Taylor (PI); Roganie Govender (PhD student)

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CM UCLH / T2B Subject Screening Log
version 1.2 (modified by SC)  
Date: 19.3.16

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396
## Appendix 7.3: SIP SMART Enrolment Log

**Protocol Name:** SIP SMART  
**Short Title:** Swallowing Intervention Package  
**Site Investigator:** Stuart Taylor (PI); Roganie Govender (PhD student)

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<th>Subject's Study Number</th>
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NHS Foundation Trust

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397
Information about the Research

Swallowing intervention package for patients with head and neck cancer.

You are being invited to take part in a research study. Before you decide, you need to understand why the research is being done and what it will involve for you. Please take time to read the information carefully. Talk to others about the study if you wish. The patient information sheet consists of two parts. Part 1 tells you the purpose of the study and what will happen to you if you take part. Part 2 tells you more about how the study will be conducted. Please ask if there is anything that is unclear or if you would like more information.

Part 1 of the Patient Information Sheet

What is the purpose of the study?
We know that patients who have surgery or radiotherapy to treat cancer in the mouth or throat are likely to experience some difficulty in swallowing. These problems may persist for a long time after treatment. Speech and language therapists play an important role in the rehabilitation of speech and swallowing after treatment. We are interested in finding out whether a swallowing intervention package introduced before the start of cancer treatment could enhance the recovery of swallow function after treatment. The package will consist of a baseline swallowing assessment and tailored exercises, advice and education. The purpose of this study is to conduct preliminary testing of the new intervention. We also wish to establish the feasibility of performing a larger study to determine whether the new intervention offers any benefit over the current usual care practice. To do this, patients need to be randomly allocated to the intervention group or the usual care group. Randomisation means you will have a 50% chance of being in one or the other group. This process is done by a computer without the clinicians and researchers being able to influence which group you will fall into. Whether you decide to participate or not, you will still receive the current usual care. Participation means that you have a 50% chance of receiving usual care plus the new intervention.
Why have I been invited?
We would like to include you in this study as you have recently been diagnosed with a head and neck cancer for which you are being offered treatment at UCLH. All patients who have been diagnosed with a cancer of the mouth or throat during the study period will be invited to participate if they meet the study criteria. The decision to invite you to participate is made by the head and neck multidisciplinary team (MDT) during the MDT meeting where your case and results are discussed.

Do I have to take part?
It is up to you to decide whether or not to take part. After reading the information sheet, if you are happy to participate you will be asked to sign a consent form to show you have agreed to take part. You are free to withdraw at any time without giving a reason. This will not affect the standard of care you receive. Your primary treatment for the cancer will not be affected or influenced in any way by your decision.

What will happen to me if I take part?
Sometimes we don't know which way of treating patients is best. To find out, we need to compare different treatments. We put people into groups and give each group a different treatment. The results are compared to see if one is better. To try to make sure the groups are the same to start with, each patient is put into a group by chance (randomly). In this study there are two groups, (one is usual clinical care and the other is usual care and the proposed swallowing intervention package), so there is a 50% chance of you falling into the intervention group. The intervention group will receive the new pre-treatment swallowing intervention package in addition to all elements of usual care practice. The control group (the comparison group) will receive the usual care practice that patients normally undergo in the head and neck cancer pathway. If you decide to take part in the study you will be randomly allocated to a group. The usual care group (control group) will receive the normal pre-treatment assessment offered by the speech and language therapy team to patients before their cancer treatment. Individuals in the intervention group will undergo a baseline x-ray of their swallowing and one additional pre-treatment consultation session to deliver the new intervention. The intervention is non-invasive and will involve a tailored swallowing exercise programme and specific guidance and education which you will be required to commence before your cancer treatment begins.

Expenses and Payments
No payment will be made for participation in this study. It will form part of your cancer care. However if you need to make a special trip into the hospital for an extra consultation to do with participation in this study, we will reimburse your travel costs for the additional trip.

What do I have to do?
Regardless of which group you are allocated to, you will be required to complete up to 5 questionnaires at different time points from before your treatment starts up to 6 months post completion of your cancer treatment. These questionnaires will relate to your swallowing function, health related quality of life, your adherence to the intervention programme and how you felt
about participating in a randomized study. The questionnaires will be given to you at your clinic visit or posted to you with a self addressed envelope for return. We will telephone you to remind you to complete the questionnaires at the specified time.

**Usual Care Group (Control)** – You will be offered a pre-treatment session with a speech and language therapist in the hospital who will provide you with relevant information about your upcoming treatment and the likely impact on your speech and swallowing. You will also be advised about the process of rehabilitation after your cancer treatment and any general advice as appropriate. This is usual care and is offered to all patients regardless of participation in this study. This group will receive the care that is currently advised by national guidelines as best practice. You will also receive swallowing exercises as part of current usual care rehabilitation.

**Intervention Group** - You will be asked to have an x-ray of your swallowing which will take place in the fluoroscopy suite on the lower ground floor of the main hospital. During the assessment, you will be required to stand or sit for about 10 minutes against a flat vertical board with the x-ray tube in front. It is open on both sides so you should not feel claustrophobic. You will be asked to swallow a small quantity of liquids and foods (yoghurt, banana, biscuit) which is mixed with a substance called barium sulphate. This allows us to take x-ray images and view the process of swallowing. Separate to this, you will also have a pre-treatment speech and language therapy session where you will be advised about your upcoming treatment and the likely impact on your speech and swallowing. This session will take place in the hospital and will last about 45 minutes. You will have an additional session to provide you with tailored swallowing exercises, specific guidance and education about swallowing function. Again, this will take place in the hospital and last around 45 minutes. You will be required to commence the programme on the same day. You will be encouraged to maintain the programme until your treatment begins and throughout the treatment and after the treatment process under the guidance of the speech and language therapist. You will be required to keep a daily record of your progress. This pre-treatment intervention will be in addition to the usual care practice.

After treatment (surgery or radiotherapy), all follow-up appointments (both groups) will be scheduled in accordance with the usual practice in the speech and language therapy department. At 3 months and 6 months post treatment, further information will be collected via questionnaires. Post treatment x-ray swallows may also be performed if required as part of your usual clinical care.

**What are the advantages of taking part?**
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.

**What are the disadvantages or risks of taking part?**
There are no disadvantages to taking part as your standard of care will not be affected and your primary cancer treatment will not be influenced in any way. As explained above, participation in the study will require some of your time, for example in completing questionnaires.

If you are randomised to the intervention group you will be required to have an x-ray of your swallowing as part of the research. This x-ray is often done after your treatment as part of your routine clinical care, however if you are randomised to the intervention group, you will have one additional x-ray of your swallowing before your treatment. The radiation exposure for this procedure is extremely small and carries negligible risk of harm. It is roughly equivalent to about 2 months of normal background radiation experienced by an adult in the UK from the environment. The x-ray itself poses no significant discomfort. Further information on the procedure is available as a separate patient information leaflet. This will be provided to you if you are going to have the procedure.

Will my taking part be kept confidential?
We will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in Part 2.

Will my GP be informed of my involvement?
With your permission, your GP, and other doctors who may be treating you, will be notified that you are taking part in this study. It may be necessary to share with them the results of your swallowing assessments which could have a bearing on your care.

This completes Part 1. If the information in Part 1 interests you and you are considering participation, please read the additional information in Part 2 before making any decision.

Part 2 of the Patient Information Sheet

What if relevant new information becomes available?
If any new information regarding your speech and swallowing function is noted for which you are not already receiving input, you will be referred to the appropriate clinician.

What will happen if I don’t want to carry on with the study?
If you decide to take part you are still free to withdraw at any time and without giving a reason. A decision to withdraw will not affect the standard of care you receive. If you withdraw from the study, only the data collected up to your withdrawal will be used.

What if there is a problem?
If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. You may also contact the Patient Advice & Liaison Service (PALS) at UCLH. They can be contacted at:
Patient Advice & Liaison Service
University College London Hospitals NHS Foundation Trust
In the unlikely event that something does go wrong and you are harmed during the research and this is due to someone’s negligence then you may have grounds for a legal action for compensation against the NHS trust but you may have to pay your legal costs. Please note that there are no compensatory mechanisms in place for “non negligent harm” (this means that the harm is not due to somebody’s fault). In this case, the normal National Health Service complaints mechanisms will still be available to you (if appropriate).

Will my taking part in this study be kept confidential?
Information collected about you during the research may be shared with other healthcare professionals in the hospital with your permission. Any information about you that leaves the hospital will have your name and address removed so that you cannot be recognised from it. The responses to the questions as well as identifiable information will be kept on a password protected computer. Any hardcopy data will be stored in locked cupboards in the offices of the chief investigator. The chief investigator will be responsible for the safety and security of your personal data, and only the chief investigator, clinical researcher and specifically authorised individuals involved with the study will have access to the data. Anonymised data only may be kept for up to 10 years after the study.

What will happen to the results of the research study?
Once the study is finished, results will be analysed to establish how easy it was to recruit to the study and how well the protocol could be carried out. The outcome measures used to look at the difference in performance of the two groups will also be carefully looked at. This early testing will provide the necessary information to plan a larger study to evaluate the new swallowing intervention package. Only then can we establish whether it provides a significant benefit over the current practice. The findings will be written up for publication in a scientific journal. You may request a copy of the results after publication.

Who is funding and organising the study?
This study is being funded by the National Institute of Health Research (NIHR) as part of a personal fellowship awarded to the clinical researcher, Roganie Govender. The researcher is hosted by University College London Hospital and is working collaboratively with academic departments at UCL. This research is in part fulfilment of the requirements for the clinical researcher’s doctoral degree.

Who has reviewed the study?
This study has been reviewed by the NIHR. In addition, all research in the NHS is looked at by an independent group of people, called a research ethics committee to protect your safety, rights,
wellbeing and dignity. This study has been reviewed and given favourable opinion by the London South-east National Research Ethics Committee.

If you decide you would like to take part then please read and sign the consent form. You will be given a copy of this information sheet and the consent form to keep. A copy of the consent form will be filed in your patient notes, one will be filed with the study records and one may be sent to the Research Sponsor.

Further information and Contact Details
If you have any further questions, please contact Roganie:

Roganie Govender  
Consultant Speech and Language Therapist  
NIHR Doctoral Research Fellow  
Head and Neck Cancer Centre  
University College London Hospitals NHS Foundation Trust  
250 Euston Road  
Ground Floor Central  
NW1 2PQ  
Tel: 02034472156  
Email: Roganie.Govender@uclh.nhs.uk

Thank you very much for considering taking part in this study. If you are happy to participate, we will provide you with a consent form to sign and a copy of this information sheet.

Nicholas Kalavrezos  
Consultant Head & Neck Surgeon  
Lead Clinician (Head & Neck Service)

Stuart Taylor  
Professor of Medical Imaging  
Chief Investigator for study
CRF Completion Instructions

General
Complete the CRF using a black ballpoint pen and ensure that all entries are complete and legible.

Avoid the use of abbreviations and acronyms.

The CRF should be completed as soon as possible after the scheduled visit.

Do not use subject identifiers anywhere on the CRF, such as name, hospital number etc., in order to maintain the confidentiality of the subject. Ensure that the header information (i.e. subject’s initials and ID number) is completed consistently throughout the CRF. Missing initials should be recorded with a dash (i.e. D-L).

Each CRF page should be signed and dated by the person completing the form. The ‘completed by’ Name in the footer of each page must be legible and CRFs should only be completed by individuals delegated to complete CRFs on the Site Delegation log (and signed by the PI).

Ensure that all fields are completed on each page:
- If a test was Not Done record ND in the relevant box(es)
- Where information is Not Known write NK in relevant box(es)
- Where information is not applicable write NA in the relevant box(es)

Corrections to entries
If an error is made, draw a single line through the item, then write the correct entry on an appropriate blank space near the original data point on the CRF and initial and date the change.

Do NOT
- Obscure the original entry by scribbling it out
- Try to correct/modify the original entry
- Use Tippex or correction fluid

Medications taken by the subject during the trial should be recorded on the “Concomitant Medications Log” using the generic name whenever possible, except combination products which will be recorded using the established trade name. All non-IMP’s mentioned in the protocol should also be recorded on the “Concomitant medication Log” for the duration of the trial.

Verbatim Adverse Event terms (initial medical term) should be recorded as the final diagnosis whenever possible.

Complete all dates as day, month, year i.e. 13/NOV/2008. Partial dates should be recorded as NK/NOV/2008.

All times are to be recorded in 24 hour format without punctuation and always use 4-digits; i.e. 0200 or 2130. Midnight is recorded as 0000.

Weights should be recorded to the nearest 0.1 kg.

Source documents such as lab reports, ECG reports etc. should be filed separately from the CRF (if not in the medical notes) for each subject and be signed and dated by a delegated investigator as proof of review of the assessment during the trial. Questionnaire should be considered as the CRF appendices (except standard approved questionnaire e.g. EQ-5D)

If a subject prematurely withdraws from the trial a single line must be drawn across each uncompleted page to correspond with the last visit of the subject as mentioned on the “Trial Completion” page.

The protocol deviation/violation/serious breach log should be used to record comments relating to each CRF visit that cannot be captured on the page itself. This includes reason for delayed or missed protocol visits or trial assessments, unscheduled visits etc.
The Chief Investigator (for lead site)/Principal Investigator is responsible for the accuracy of the data reported on the CRF. The C/I/P must sign and date the Principal Investigator’s Sign Off page to certify accuracy, completeness and legibility of the data reported in the CRF.

**Serious Adverse Events (SAEs)**
SAEs should be faxed within 24 hours of the site being aware of the event using the trial specific SAE report form to 020 3108 2312 or preferably emailed to sae@ucl.ac.uk

**Storage**
CRF documents should be stored in a locked, secure area when not in use where confidentiality can be maintained. Ensure that they are stored separately to any other documents that might reveal the identity of the subject.
VISIT 1 (SCREENING) INCLUSION CRITERIA

Date of Assessment: __/__/____

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<th>The following criteria MUST be answered YES for participant to be included in the trial (except where NA is appropriate):</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Newly diagnosed stage III/IV head &amp; Neck cancer (not restricted to SCC)</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>2. Discussed at UCLH MDT – planned for surgery and/or chemoradiotherapy or combinations thereof</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>3. Able to provide informed consent</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>4. Proficiency in spoken English satisfactory to participate/engage in intervention</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>5. Aged 18 and above</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

*If any of the above criteria is answered NO, the participant is NOT eligible for the trial and must not be included in the study. Please list reason(s) for ineligibility for screen failure on Participant Eligibility Review page.*

EXCLUSION CRITERIA

Date of Assessment: __/__/____

<table>
<thead>
<tr>
<th>The following criteria MUST be answered NO for the participant to be included in the trial:</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Patient mid treatment/receiving palliation</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>2. Patient is being treated solely by non-standard treatment ie chemotherapy alone, brachytherapy, photodynamic therapy</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>3. Patient is unable to consent/considered vulnerable (MCA)</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>4. Patient has a brain tumour /primary tumour not within head &amp; neck</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

*If any of the above criteria is answered YES, the participant is NOT eligible for the trial and must not be included in the study. Please list reason(s) for ineligibility for screen failure on Participant Eligibility Review page.*

Completed by:

Name ____________________________ Signature ____________________________ Date __/__/____

SIP SMART feasibility, Study CRF Version 1.2 Date 15/03/2016 Page 4 of 19
### PARTICIPANT ELIGIBILITY REVIEW

**End of Screening Visit Checklist:**

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Does the participant satisfy the inclusion and exclusion criteria to date?</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>2. Have all Screening Visit procedures been completed?</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>3. Is the participant still willing to proceed in the trial?</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

**Participant’s eligibility Investigator Sign-Off:**

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is the participant eligible to take part in the Clinical Trial?</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

Investigator’s Signature: ________________ Date: __/__/____

(DO / MMM / YYYY)

Investigator’s Name: ________________

Reason(s) for screen failure:

1. 

2. 

3. 

### RANDOMISATION/ENROLMENT

**Participant Randomisation/Enrolment**

| Participant study Number allocated: | ______ |
| Date of Randomisation/Enrolment: | __/__/____ |

(DO / MMM / YYYY)

Completed by:

<table>
<thead>
<tr>
<th>Name</th>
<th>Signature</th>
<th>Date</th>
</tr>
</thead>
</table>
**SIP SMART**

**Subject Screening No.**

**Patient Initials**

**Site**

**UCLH**

---

**DEMOGRAPHIC DATA**

**Date of Assessment:** __/__/____

**Date of first trial-related procedure:** __/__/____

**Informed Consent:**

**Date participant signed written consent form:** __/__/____

**Name of person taking informed consent:** __________________________

---

**Demographic Data:**

**Date of Birth:** __/__/____

**Ethnicity:**

- White
- White British
- White Irish
- White Other
- Mixed race
- White & Black Caribbean
- White & Black African
- White & Asian
- Other mixed background
- Asian or Asian British
- Indian
- Bangladeshi
- Pakistani
- Other Asian background
- Black or Black British
- Caribbean
- African
- Black Other
- Other

---

**Completed by:**

**Name** __________________________

**Signature** __________________________

**Date** __________________________

---

SIP SMART feasibility, Study CRF Version 1.2 Date 15/03/2016 Page 6 of 19

---

409
### SIP SMART

**Sponsor No.** 14/0175

**Subject/Screening No.**

**Patient Initials**

**SRO** UCLH

---

**Sex:**
- Male
- Female

**Marital Status:**
- Married
- Co-habiting
- Single/separated
- Divorced
- Widowed

**Employment:**
- Employed full time
- Not employed
- Employed part time
- Retired
- Self-employed

**Occupational Category**
- Manager/director
- Graduate professional occupation
- Associate professional/technical
- Administrative/secretarial
- Skilled trade occupation
- Sales/customer services
- Caring/leisure/other service industry
- Plant/machine operatives
- Other
  - please state below

---

**Completed by:**

<table>
<thead>
<tr>
<th>Name</th>
<th>Signature</th>
<th>Date</th>
</tr>
</thead>
</table>

SIP SMART feasibility, Study CRF Version 1.2 Date 15/03/2016  
Page 7 of 19
# Medical History

**Date of Assessment:** __/__/____

<table>
<thead>
<tr>
<th>Has the patient had any relevant medical history?</th>
<th>No</th>
<th>Yes, Complete below</th>
</tr>
</thead>
<tbody>
<tr>
<td>Condition / illness /surgical procedure</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Start date (DD/MM/YYYY)</td>
<td>Stop date (DD/MM/YYYY)</td>
<td>Or still if ongoing at screening Visit?</td>
</tr>
<tr>
<td><strong>/</strong>/____</td>
<td><strong>/</strong>/____</td>
<td></td>
</tr>
<tr>
<td><strong>/</strong>/____</td>
<td><strong>/</strong>/____</td>
<td></td>
</tr>
<tr>
<td><strong>/</strong>/____</td>
<td><strong>/</strong>/____</td>
<td></td>
</tr>
<tr>
<td><strong>/</strong>/____</td>
<td><strong>/</strong>/____</td>
<td></td>
</tr>
<tr>
<td><strong>/</strong>/____</td>
<td><strong>/</strong>/____</td>
<td></td>
</tr>
<tr>
<td><strong>/</strong>/____</td>
<td><strong>/</strong>/____</td>
<td></td>
</tr>
<tr>
<td><strong>/</strong>/____</td>
<td><strong>/</strong>/____</td>
<td></td>
</tr>
<tr>
<td><strong>/</strong>/____</td>
<td><strong>/</strong>/____</td>
<td></td>
</tr>
<tr>
<td><strong>/</strong>/____</td>
<td><strong>/</strong>/____</td>
<td></td>
</tr>
</tbody>
</table>

Completed by:

<table>
<thead>
<tr>
<th>Name</th>
<th>Signature</th>
<th>Date</th>
</tr>
</thead>
</table>

SIP SMART feasibility, Study CRF Version 1.2 Date 15/03/2016  Page 8 of 19
### BASLINE PHYSICAL EXAM

**Date of Assessment:** __/__/____

<table>
<thead>
<tr>
<th>System</th>
<th>*Abnormal</th>
<th>Normal</th>
<th>Not done</th>
<th>*If noted ABNORMAL, please provide brief description and comment if clinically significant or not (CS/NCS)</th>
</tr>
</thead>
<tbody>
<tr>
<td>General Appearance</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral motor exam</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Jaw opening</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dentition</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hearing</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vision</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Respiratory (observation at rest)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Muscular-Skeletal</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Neurological</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Others (please specify)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

---

Completed by:

Name: ____________________________    Signature: ____________________________    Date: __/__/____

SIP SMART feasibility, Study CRF Version 1.2 Date 15/03/2016  Page 9 of 19
# Baseline Measures

<table>
<thead>
<tr>
<th>Were baseline measures performed?</th>
<th>□ No (comment below) □ Yes, Complete below</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comment*:</td>
<td></td>
</tr>
</tbody>
</table>

| Date of measures:                | ___/___/______ |
|                                  | (DD/MM/YYYY)   |

| Weight: ___ ___ . ___ kg         | Height: ___ . ___ m |

| WST: volume................ capacity ................. speed ................. |
|---------------------------------|---------------------|

| Jaw opening using therabite:    | ________________-mm |

| PSS HN Normalcy of Diet .......... public eating .................. |
|---------------------|---------------------|

| FIGS SCORES: SPEECH ...... CHEWING ............... SWALLOWING ............. |
|---------------------|---------------------|

| GRBAS SCORE ................. |
|---------------------|---------------------|

---

**Completed by:**

<table>
<thead>
<tr>
<th>Name</th>
<th>Signature</th>
<th>Date</th>
</tr>
</thead>
</table>

---

SIP SMART feasibility, Study CRF Version 1.2 Date 15/03/2016 Page 10 of 19
SMOKING / ALCOHOL STATUS

Date of Assessment: __/__/____

Has the participant ever smoked? □ No  □ Yes, Complete below

☐ Current Smoker
- Participant’s average daily use:
  - Number of cigarettes: ______
  - Number of cigars: ______
  - Number of pipes: ______
- Smoked for ____ months/years

☐ Former smoker
- When smoking, participant’s average daily use:
  - Number of cigarettes: ______
  - Number of cigars: ______
  - Number of pipes: ______
- Smoked for ____ months/years
- Date when smoking ceased: __/__/____

Participant’s alcohol consumption

- Participant’s average consumption per week
  - Number of units/pints of wine/beer: ______
  - Number of units of spirits: ______

Completed by:
Name: ____________________________ Signature: ____________________________ Date: ____________________________

SIP SMART feasibility, Study CRF Version 1.2 Date 15/03/2016  Page 11 of 19
### SUMMARY OF PLANNED CANCER TREATMENT

<table>
<thead>
<tr>
<th>Details of tumour staging</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Details of Surgery</td>
<td></td>
</tr>
<tr>
<td>Details of Radiotherapy</td>
<td></td>
</tr>
<tr>
<td>Details of Chemotherapy</td>
<td></td>
</tr>
<tr>
<td>Other Interventions</td>
<td></td>
</tr>
<tr>
<td>(eg PEG/RIG)</td>
<td></td>
</tr>
</tbody>
</table>

Completed by:  
Name  
Signature  
Date

SIP SMART feasibility, Study CRF Version 1.2 Date 15/03/2016  
Page 12 of 19
SUMMARY OF SLT PRE-TREATMENT

Clarify if any changes from intervention manual. Specify any adaptations/tailoring

Consultation 1 - Date ................... Time ................... Venue ...........................................

Notes:

---

Consultation 2 - Date ................... Time ................... Venue ...........................................

Notes:

Completed by:

Name ___________________________ Signature ___________________________ Date ___________________________

SIP SMART feasibility, Study CRF Version 1.2 Date 15/03/2016 Page 13 of 19
## ADVERSE EVENTS

<table>
<thead>
<tr>
<th>AE No</th>
<th>Event Name</th>
<th>Start date (DD/MM/YY)</th>
<th>Stop date (DD/MM/YY)</th>
<th>Serious?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### COMMENT:

I have reviewed the AEs on this page and have assessed them for seriousness, causality, severity and outcome and confirm that, to the best of my knowledge, it accurately reflects the study information obtained for this participant.

PI signature ____________________________________________

Date: __________________

Completed by:

Name __________________________ Signature __________________________ Date ___________________
POST TREATMENT FOLLOW-UP

Please record SLT therapy interventions up to and including the 6 month follow-up.
(eg – number of SLT rehab sessions, MBS, FEES) Date and comment (free text)

<table>
<thead>
<tr>
<th>Interval</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Between pre-treatment and 1 month post treatment: (T0 – T1)</td>
<td></td>
</tr>
<tr>
<td>Between 1 month and 3 months post treatment: (T1 – T2)</td>
<td></td>
</tr>
<tr>
<td>Between 3 months and 6 months post treatment: (T2-T3)</td>
<td></td>
</tr>
</tbody>
</table>
## FOLLOW-UP OUTCOME MEASURES

Include date sent/date received

<table>
<thead>
<tr>
<th>Measure</th>
<th>baseline</th>
<th>1 month</th>
<th>3 months</th>
<th>6months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Performance Status Scale (PSS) – normalcy of diet (clinician rated based on diet texture history)¹</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Date sent/administered</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date received</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MD Anderson Dysphagia Inventory¹</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Date sent/administered</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date received</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>General Self Efficacy Scale &amp; exercise subscale²</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Date sent/administered</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date received</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Self Reported Adherence</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Date sent/administered</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date received</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HRQOL – FACT-HN⁴</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Date sent/administered</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date received</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acceptability to Randomisation Questionnaire³</td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Date sent/administered</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date received</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Completed by:
Name: 
Signature: 
Date: 

SIP SMART feasibility, Study CRF Version 1.2 Date 15/03/2016
Page 16 of 19
Did participant complete the trial?

☐ Yes, please provide date of last visit:

___/___/20___
(DD/MMM/YYYY)

☐ No, please provide date of withdrawal and complete below:

___/___/20___
(DD/MMM/YYYY)

Early Withdrawal: please tick most appropriate reason for participant not completing the trial:

☐ Adverse Events related: please state related AE: __________________________ (add details to AE page)

☐ Participant’s decision, specify: __________________________

☐ Investigator’s decision, specify: __________________________

☐ Sponsor’s decision

☐ Lost to follow up

☐ Patient deceased

☐ Other, specify: __________________________
**Principal Investigator’s Signature Statement:**

I have reviewed this CRF and confirm that, to the best of my knowledge, it accurately reflects the study information obtained for this participant. All entries were made either by me or by a person under my supervision who has signed the Delegation and Signature Log.

**Principal Investigator’s Signature:**

____________________________

**Date of Signature:** __/____/____

(DD / MMM / YYYY)

**Principal Investigator’s Name:**

____________________________

**Once signed, no further changes can be made to this CRF without a signed data query form.**
### Appendix 7.6: Outcome measures form.SIP SMART

#### SIP SMART Outcome measures and time-points

<table>
<thead>
<tr>
<th>Measure</th>
<th>T0 baseline</th>
<th>T1 1 month</th>
<th>T2 3 months</th>
<th>T3 6 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Background information</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Measures taken as part of usual care</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Performance Status Scale (PSS)</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Maximal incisor opening (mouth opening)</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Functional Intra-oral Glasgow Scale</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>100ml Water swallow test</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td><strong>Additional Measures for Trial</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MD Anderson Dysphagia Inventory</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>General Self Efficacy Scale</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Self Reported Adherence question</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>HRQOL – FACT –HN</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Modified Barium Swallow Impairment Score and Penetration/Aspiration score</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acceptability to participation/randomisation Questionnaire</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Patient ID Date Time-point (please circle above)

- PSS Normalcy of diet ...........................................
- Public Eating ....................................................
- FIGS: Chewing ....................................................
- Swallowing .......................................................
- Speech ............................................................
- WST- total time/no. of swallows ..........................
- Volume- (100/no. swallows) ................................
- Capacity- (ml/sec) ...........................................
- Speed- (sec/per swallow) ....................................
- Mouth opening in mm ...........................................
PSS scores: (List et al. 1990)

<table>
<thead>
<tr>
<th>Performance Status Scale for Head &amp; Neck: Normalcy of diet &amp; public eating subscales</th>
<th>Normalcy of Diet</th>
<th>Public Eating</th>
</tr>
</thead>
<tbody>
<tr>
<td>100- Full diet (no restrictions)</td>
<td>100- No restrictions</td>
<td></td>
</tr>
<tr>
<td>90- Full diet (with liquid assistance)</td>
<td>75- No restrictions of place, but restricts diet when in public</td>
<td></td>
</tr>
<tr>
<td>80- All meats</td>
<td>50- Eats only in presence of selected persons in selected places</td>
<td></td>
</tr>
<tr>
<td>70- Carrots, celery (crunchy)</td>
<td>25- Eats only at home in presence of selected persons</td>
<td></td>
</tr>
<tr>
<td>60- Dry bread and crackers</td>
<td>0- Always eats alone</td>
<td></td>
</tr>
<tr>
<td>50- Soft, chewable foods (pasta)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>40- Soft foods requiring no chewing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>30- Puree foods</td>
<td></td>
<td></td>
</tr>
<tr>
<td>20- Warm liquids</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10- Cold liquids</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0- Non-oral feeding</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

FIGS scores: (Nicoletti et al. 2004)

<table>
<thead>
<tr>
<th>Speech</th>
<th>Chewing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clearly understood always</td>
<td>Any food, no difficulty</td>
</tr>
<tr>
<td>Requires repetition sometimes</td>
<td>Solid food, with difficulty</td>
</tr>
<tr>
<td>Requires repetition many times</td>
<td>Semisolid food, no difficulty</td>
</tr>
<tr>
<td>Understood by relatives only</td>
<td>Semisolid food, with difficulty</td>
</tr>
<tr>
<td>Unintelligible</td>
<td>Cannot chew at all</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Swallowing</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Any food, no difficulty</td>
<td>5</td>
</tr>
<tr>
<td>Solid food with difficulty</td>
<td>4</td>
</tr>
<tr>
<td>Semisolid food only</td>
<td>3</td>
</tr>
<tr>
<td>Liquids only</td>
<td>2</td>
</tr>
<tr>
<td>Cannot swallow at all</td>
<td>1</td>
</tr>
</tbody>
</table>

Timed Water Swallow Test calculation

Ask the patients to drink 100ml of water quickly but comfortably. Count the number of swallows, and the number of seconds taken to drink the cup, including any clearing swallow at the end. Also note if the patient shows any overt signs of aspiration/penetration with a Y/N. Calculate the following parameters:

- **Volume**: (ml consumed per swallow); total volume (100) divided by number of swallows taken
- **Capacity**: (ml consumed per second); total volume (100) divided by number of seconds to finish the 100mls
- **Speed**: (time per swallow); total time taken divided by number of swallows taken

Appendix 7.7:  PSS.HN

PERFORMANCE STATUS SCALE FOR HEAD & NECK CANCER PATIENTS - PSS-HN

Suggestions for Administration

These performance scales may be rated by health professionals (e.g., physicians, nurses, nutritionists) or other personnel (e.g., clerks, data managers). Ratings are determined through use of an unstructured interview format.

Normalcy of Diet

Begin by asking the patient what kinds of foods (s)he has been eating. Ask what foods are difficult to eat. Based on the patient's response, choose an item at the low end of the scale. Move up the scale giving examples of foods in each category and asking the patient if (s)he is eating those food items. Even if the patient says that (s)he eats everything, inquire about specific items beginning with 50, soft chewable foods and moving upwards. Stop at the item at, and above which the patient cannot eat. The patient then receives the score below that. If the patient indicates that (s)he is eating a full diet, also inquire whether (s)he needs to drink more liquids than usual with meals; eating a full diet with intake of extra fluids is scored 90. If the patient can take foods orally, but is also using a feeding tube, score based on solid food.

Public Eating

Score the Public Eating scale by asking the patient where (s)he eats (in a restaurant, at home, at friends/relatives' homes, etc.) and with whom (s)he eats (always alone, with family/friends, etc.). Ask patient if (s)he chooses different foods (softer, less messy, etc.) when eating with others. When was the last time the patient ate in a restaurant, cafeteria, MacDonald's, picnic, family reunion? Choose the score beside the description that best fits the patient. A patient on a restricted diet, (e.g., tube feeding, pureed foods) who does not eat in public but will join others in a public eating setting should be rated 75. Score 999 for inpatients.

Understandability of Speech

This scale is scored based on the interviewer's ability to understand the patient during conversation (in this case, based on conversation about patient's diet and social activities). Choose the score beside the description that best fits the patient. See if you can understand the patient if you are looking away while (s)he is talking.

Special Considerations for Inpatients: Administration of the PSS-HN varies somewhat for inpatients. Score the Normalcy of Diet and Understandability of Speech Scale as indicated. The Eating in Public Scale is not applicable as inpatients generally have little opportunity to eat with others or leave their hospital rooms. Inpatients receive a score of 999 on the Eating in Public Scale.
**Performance Status Scale for Head and Neck Cancer Patients: PSS-HN**

<table>
<thead>
<tr>
<th>Normalcy of Diet / ___ /</th>
<th>Public Eating / ___ /</th>
</tr>
</thead>
<tbody>
<tr>
<td>100 Full diet (no restrictions)</td>
<td>100 No restriction of place, food or companion (eats out at any opportunity)</td>
</tr>
<tr>
<td>90 Full diet (liquid assist)</td>
<td>75 No restriction of place, but restricts diet when in public (eats anywhere, but may limit intake to less &quot;messy&quot; foods (e.g., liquids)</td>
</tr>
<tr>
<td>80 All meat</td>
<td>50 Eats only in presence of selected persons in selected places</td>
</tr>
<tr>
<td>70 Raw carrots, celery</td>
<td>25 Eats only at home in presence of selected persons</td>
</tr>
<tr>
<td>60 Dry bread and crackers</td>
<td>0 Always eats alone</td>
</tr>
<tr>
<td>50 Soft chewable foods (e.g., macaroni, canned soft fruits, cooked vegetables, fish, hamburger, small pieces of meat)</td>
<td>999 Inpatient</td>
</tr>
<tr>
<td>40 Soft foods requiring no chewing (e.g., mashed potatoes, apple sauce, pudding)</td>
<td></td>
</tr>
<tr>
<td>30 Pureed foods (in blender)</td>
<td></td>
</tr>
<tr>
<td>20 Warm liquids</td>
<td></td>
</tr>
<tr>
<td>10 Cold liquids</td>
<td></td>
</tr>
<tr>
<td>0 Non-oral feeding (tube fed)</td>
<td></td>
</tr>
</tbody>
</table>

**Understandability of Speech / ___ /**

| 100 Always understandable | |
| 75 Understandable most of the time; occasional repetition necessary | |
| 50 Usually understandable; face-to-face contact necessary | |
| 25 Difficult to understand | |
| 0 Never understandable; may use written communication | |


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Appendix 7.8: MD Anderson Dysphagia Inventory

The M.D. Anderson Dysphagia Inventory

This questionnaire asks for your views about your swallowing ability. This information will help us understand how you feel about swallowing.

The following statements have been made by people who have problems with their swallowing. Some of the statements may apply to you.

Please read each statement and circle the response which best reflects your experience in the past week.

My swallowing ability limits my day-to-day activities.
- Strongly Agree
- Agree
- No Opinion
- Disagree
- Strongly Disagree

E2. I am embarrassed by my eating habits.
- Strongly Agree
- Agree
- No Opinion
- Disagree
- Strongly Disagree

F1. People have difficulty cooking for me.
- Strongly Agree
- Agree
- No Opinion
- Disagree
- Strongly Disagree

P2. Swallowing is more difficult at the end of the day.
- Strongly Agree
- Agree
- No Opinion
- Disagree
- Strongly Disagree

- Strongly Agree
- Agree
- No Opinion
- Disagree
- Strongly Disagree

E4. I am upset by my swallowing problem.
- Strongly Agree
- Agree
- No Opinion
- Disagree
- Strongly Disagree

P6. Swallowing takes great effort.
- Strongly Agree
- Agree
- No Opinion
- Disagree
- Strongly Disagree

E5. I do not go out because of my swallowing problem.
- Strongly Agree
- Agree
- No Opinion
- Disagree
- Strongly Disagree
F5. My swallowing difficulty has caused me to lose income.
   Strongly Agree  Agree  No Opinion  Disagree  Strongly Disagree

P7. It takes me longer to eat because of my swallowing problem.
   Strongly Agree  Agree  No Opinion  Disagree  Strongly Disagree

P3. People ask me, "Why can't you eat that?"
   Strongly Agree  Agree  No Opinion  Disagree  Strongly Disagree

E3. Other people are irritated by my eating problem.
   Strongly Agree  Agree  No Opinion  Disagree  Strongly Disagree

P8. I cough when I try to drink liquids.
   Strongly Agree  Agree  No Opinion  Disagree  Strongly Disagree

F3. My swallowing problems limit my social and personal life.
   Strongly Agree  Agree  No Opinion  Disagree  Strongly Disagree

*F2. I feel free to go out to eat with my friends, neighbors, and relatives.
   Strongly Agree  Agree  No Opinion  Disagree  Strongly Disagree

P5. I limit my food intake because of my swallowing difficulty.
   Strongly Agree  Agree  No Opinion  Disagree  Strongly Disagree

P1. I cannot maintain my weight because of my swallowing problem.
   Strongly Agree  Agree  No Opinion  Disagree  Strongly Disagree

E6. I have low self-esteem because of my swallowing problem.
   Strongly Agree  Agree  No Opinion  Disagree  Strongly Disagree

P4. I feel that I am swallowing a huge amount of food.
   Strongly Agree  Agree  No Opinion  Disagree  Strongly Disagree

F4. I feel excluded because of my eating habits.
   Strongly Agree  Agree  No Opinion  Disagree  Strongly Disagree

*Thank you for completing this questionnaire!*


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Appendix 7.9: FACT-HN_ENG_pdf

FACT-H&N (Version 4)

Below is a list of statements that other people with your illness have said are important. Please circle or mark one number per line to indicate your response as it applies to the past 7 days.

<table>
<thead>
<tr>
<th>PHYSICAL WELL-BEING</th>
<th>Not at all</th>
<th>A little bit</th>
<th>Somewhat</th>
<th>Quite a bit</th>
<th>Very much</th>
</tr>
</thead>
<tbody>
<tr>
<td>QP1 I have a lack of energy</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>QP2 I have nausea</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>QP3 Because of my physical condition, I have trouble meeting the needs of my family</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>QP4 I have pain</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>QP5 I am bothered by side effects of treatment</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>QP6 I feel ill</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>QP7 I am forced to spend time in bed</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>SOCIAL/FAMILY WELL-BEING</th>
<th>Not at all</th>
<th>A little bit</th>
<th>Somewhat</th>
<th>Quite a bit</th>
<th>Very much</th>
</tr>
</thead>
<tbody>
<tr>
<td>QF1 I feel close to my friends</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>QF2 I get emotional support from my family</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>QF3 I get support from my friends</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>QF4 My family has accepted my illness</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>QF5 I am satisfied with family communication about my illness</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>QF6 I feel close to my partner (or the person who is my main support)</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>QF7 Regard less of your current level of sexual activity, please answer the following question. If you prefer not to answer it, please mark this box and go to the next section.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>QF8 I am satisfied with my sex life</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>
FACT-H&N (Version 4)

Please circle or mark one number per line to indicate your response as it applies to the past 7 days.

<table>
<thead>
<tr>
<th>EMOTIONAL WELL-BEING</th>
<th>Not at all</th>
<th>A little bit</th>
<th>Somewhat</th>
<th>Quite a bit</th>
<th>Very much</th>
</tr>
</thead>
<tbody>
<tr>
<td>QE1</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>QE2</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>QE3</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>QE4</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>QE5</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>QE6</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>FUNCTIONAL WELL-BEING</th>
<th>Not at all</th>
<th>A little bit</th>
<th>Somewhat</th>
<th>Quite a bit</th>
<th>Very much</th>
</tr>
</thead>
<tbody>
<tr>
<td>QF1</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>QF2</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>QF3</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>QF4</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>QF5</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>QF6</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>QF7</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>
FACT-H&N (Version 4)

Please circle or mark one number per line to indicate your response as it applies to the past 7 days.

<table>
<thead>
<tr>
<th>ADDITIONAL CONCERNS</th>
<th>Not at all</th>
<th>A little bit</th>
<th>Somewhat</th>
<th>Quite a bit</th>
<th>Very much</th>
</tr>
</thead>
<tbody>
<tr>
<td>I am able to eat the foods that I like</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>My mouth is dry</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>I have trouble breathing</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>My voice has its usual quality and strength</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>I am able to eat as much food as I want</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>I am unhappy with how my face and neck look</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>I can swallow naturally and easily</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>I smoke cigarettes or other tobacco products</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>I drink alcohol (e.g. beer, wine, etc.)</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>I am able to communicate with others</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>I can eat solid foods</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>I have pain in my mouth, throat or neck</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

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## Appendix 7.10: MBSImP-CompScoreDefs

### The MODIFIED BARIUM SWALLOW IMPAIRMENT PROFILE: MBSImP™

#### Components, Scores, and Score Definitions

**ORAL Impairment**

**Component 1—Lip Closure**
- 0 = No labial escape
- 1 = Interlabial escape; no progression to anterior tip
- 2 = Escape from interlabial space or lateral juncture; no extension beyond vermillion border
- 3 = Escape progressing to mid-arch
- 4 = Escape beyond mid-arch

**Component 2—Tongue Control During Swallow**
- 0 = Cohesive bolus between tongue to palatal seal
- 1 = Escape to lateral buccal cavity/roof of mouth (FOM)
- 2 = Posterior escape of less than half of bolus
- 3 = Posterior escape of greater than half of bolus

**Component 3—Bolus Preparation/Mastication**
- 0 = Timely and efficient chewing and mashing
- 1 = Slow prolonged chewing/mashing with complete re-collection
- 2 = Disorganized chewing/mashing with solid pieces of bolus unchewed
- 3 = Minimal chewing/mashing with majority of bolus unchewed

**Component 4—Bolus Transport/Transportation**
- 0 = Erratic tongue motion
- 1 = Delayed initiation of tongue motion
- 2 = Slowed tongue motion
- 3 = Repetitive/organized tongue motion
- 4 = Minimal to no tongue motion

**PHARYNGEAL Impairment**

**Component 5—Soft Palate Elevation**
- 0 = No bolus between soft palate (SP)/pharyngeal wall (PW)
- 1 = Trace column of contrast or air between SP and PW
- 2 = Escape to nasopharynx
- 3 = Escape to naso/oropharynx
- 4 = Escape to nostril with/without emission

**Component 6—Laryngeal Elevation**
- 0 = Complete superior movement of thyroid caricature with complete approximation of arytenoids to epiglottic petiole
- 1 = Partial superior movement of thyroid caricature/partial approximation of arytenoids to epiglottic petiole
- 2 = Minimal superior movement of thyroid caricature with minimal approximation of arytenoids to epiglottic petiole
- 3 = No superior movement of thyroid caricature

**Component 7—Anterior Hyoid Excursion**
- 0 = Complete anterior movement
- 1 = Partial anterior movement
- 2 = No anterior movement

**Component 8—Epiglottic Movement**
- 0 = Complete inversion
- 1 = Partial inversion
- 2 = No inversion

**Component 9—Laryngeal Vestibular Closure — Height of Swallow**
- 0 = Complete, no air/stain in laryngeal vestibule
- 1 = Inner/mid-vestibule; no stain in laryngeal vestibule
- 2 = None, wide columnal air/stain in laryngeal vestibule

**Component 10—Pharyngeal Stripping Wave**
- 0 = Present — complete
- 1 = Present — diminished
- 2 = Absent

**Component 11—Pharyngeal Contraction (A/P VIEW ONLY)**
- 0 = Complete
- 1 = Incomplete (Pseudovestibulectomy)
- 2 = Unilateral Bulging
- 3 = Bilateral Bulging

**Component 12—Pharynx Segment Opening**
- 0 = Complete distension and complete duration; no obstruction of flow
- 1 = Partial distension/partial duration; partial obstruction of flow
- 2 = Minimal distension/minimal duration; marked obstruction of flow
- 3 = No distension with total obstruction of flow

**Component 13—Tongue Base (TB) Retraction**
- 0 = No contrast between TB and posterior pharyngeal wall (PW)
- 1 = Trace column of contrast or air between TB and PW
- 2 = Narrow column of contrast or air between TB and PW
- 3 = Wide column of contrast or air between TB and PW
- 4 = No visible posterior motion of TB

**Component 14—Pharyngeal Residue**
- 0 = Complete pharyngeal clearance
- 1 = Trace residue within or on pharyngeal structures
- 2 = Collection of residue within or on pharyngeal structures
- 3 = Majority of contrast within or on pharyngeal structures
- 4 = Minimal to no pharyngeal clearance

**ESOPHAGEAL Impairment**

**Component 15—Esophageal Clearance Upright Position**
- 0 = Complete clearance; esophageal coating
- 1 = Esophageal retention
- 2 = Esophageal retention with retrograde flow below pharyngoesophageal segment (PES)
- 3 = Esophageal retention with retrograde flow through PES
- 4 = Minimal to no esophageal clearance

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8-Point Penetration-Aspiration Scale (PAS)

Score | Description of Events
--- | ---
1. | Material does not enter airway
2. | Material enters the airway, remains above the vocal folds, and is ejected from the airway.
3. | Material enters the airway, remains above the vocal folds, and is not ejected from the airway.
4. | Material enters the airway, contacts the vocal folds, and is ejected from the airway.
5. | Material enters the airway, contacts the vocal folds, and is not ejected from the airway.
6. | Material enters the airway, passes below the vocal folds, and is ejected into the larynx or out of the airway.
7. | Material enters the airway, passes below the vocal folds, and is not ejected from the trachea despite effort.
8. | Material enters the airway, passes below the vocal folds, and no effort is made to eject.

Appendix 7.12: Self-efficacy

Questionnaire 2 - General Self-efficacy Scale

Below are ten statements about yourself which may or may not be true. Using the 1-4 scale below, please indicate your agreement with each item by placing the appropriate number on the line following that item.

Please be open and honest in your responding.

The 4-point scale:

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not at all true</td>
<td>Hardly true</td>
<td>Moderately true</td>
<td>Exactly true</td>
</tr>
</tbody>
</table>

1. I can always manage to solve difficult problems if I try hard enough.   ___
2. If someone opposes me, I can find the means and ways to get what I want.   ___
3. It is easy for me to stick to my aims and accomplish my goals.   ___
4. I am confident that I could deal efficiently with unexpected events.   ___
5. Thanks to my resourcefulness, I know how to handle unforeseen situations.   ___
6. I can solve most problems if I invest the necessary effort.   ___
7. I can remain calm when facing difficulties because I can rely on my coping abilities.   ___
8. When I am confronted with a problem, I can usually find several solutions.   ___
9. If I am in trouble, I can usually think of a solution.   ___
10. I can usually handle whatever comes my way.   ___


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Appendix 7.13: SIP SMART adherence questionnaire

Adherence to Swallowing Exercises

Patient ID: Date:

A) Can you tell me which swallowing exercises you were asked to do by the speech therapist? (patient may provide name, description, or demo). Please list:

B) Over the last month, how many days did you NOT DO ANY swallowing exercises? (Please circle number):
1. Few, if any (<7)
2. 7-13
3. 14-20
4. Most, (>20)

C) Over the last month, how often did you DO LESS than the prescribed number. Please circle number
1. Never/almost never (0-25% of the time)
2. Sometimes (26-50% of the time)
3. Usually (51-75% of the time)
4. Always/almost always (76-100% of the time)

Place a dot on the rule below that best describes how well you believe you have adhered to/carried out your exercise programme over the last month.

![Ruler Scale]

Not at all Fully

Reasons: What helped or prevented you doing the exercises. Please list any reasons/comments

Thank you
Appendix 7.14: SIP SMART MDT memo

Dear Colleagues

I am attaching a brief summary of the SIP SMART trial – presented at the Head & Neck MDT on 23/03/16.

Research Summary
Individuals diagnosed with head and neck cancer often experience swallowing problems as a result of the tumour in the mouth or throat. The treatments for this cancer (surgery or radiotherapy) cause further predictable problems in eating, drinking and swallowing. These problems may last a long time after treatment and often never return to normal function. The purpose of this research is to devise and conduct preliminary testing of a pre-treatment swallowing intervention package for patients with head and neck cancer. Ultimately the research addresses the question: Does a tailored pre-treatment swallowing intervention package (SIP) enhance post treatment swallowing outcomes in patients treated for head and neck cancer? The package will be devised with input from qualitative interviews from patients who have completed treatment for head and neck cancer and from theory and literature reviews. It will include a swallowing assessment, targeted swallowing exercises, tailored information and advice and relevant behavioural techniques to promote adherence. This is a non-invasive behaviour change intervention aimed at helping patients get into the habit of regular swallowing exercises and to optimise their swallowing function before their cancer treatment begins. The critical window for physiological recovery after treatment will be better utilised as patients will already be familiar with the swallowing rehabilitation process. This may be useful in minimizing the impact of muscle atrophy and post radiotherapy fibrosis on swallowing function. A small-scale study of the SIP is planned in patients with advanced head and neck cancer receiving treatment at UCLH. This randomised feasibility study will provide salient information for a definitive trial comparing SIP SMART with current usual care.
### Study Eligibility Criteria

<table>
<thead>
<tr>
<th>Inclusion</th>
<th>Exclusion</th>
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<tr>
<td>• Patients with newly diagnosed stage III and stage IV head and neck cancer.</td>
<td>• Patients who are mid treatment or those receiving palliation.</td>
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<td>• Discussed at the UCLH head and neck MDT and planned for treatment via surgery and/or chemoradiotherapy or combinations thereof.</td>
<td>• 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.</td>
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<tr>
<td>• Able to provide informed consent</td>
<td>• Patients who are considered vulnerable (MCA) or unable to provide informed consent.</td>
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<td>• Proficiency in spoken English satisfactory to participate/engage in the intervention.</td>
<td>• Patients with brain tumours and other primary sites not within head and neck.</td>
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<td>• Aged 18 and above</td>
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**Note:** Eligible Patients will be identified at the head and neck MDT and flagged up with the patient’s named consultant prior to the clinic visit.

This is a non-blinded 2-arm study with patients randomised to usual care or the new intervention. All patients who consent to be part of the clinical trial will receive current usual care, those randomised to the new intervention will receive further components of the new intervention. This will include a pre-treatment modified barium swallow assessment.

Please feel free to contact me if you have any queries.

Thank you for your support with this study.

Best Wishes
Roganie Govender (NIHR Clinical-Academic Doctoral Fellow)

[ Roganie.Govender.13@ucl.ac.uk](mailto:Roganie.Govender.13@ucl.ac.uk)
[Roganie.Govender@uclh.nhs.uk](mailto:Roganie.Govender@uclh.nhs.uk)
Appendix 7.15: Process mapping SIP SMART

31/12/2017
**Intervention Procedure**

1. **Preparation and Planning**
   - Identify patient demographics.
   - Ensure informed consent.

2. **Data Collection**
   - Collect baseline data.
   - Monitor treatment outcomes.

3. **Follow-up**
   - Review treatment effectiveness.
   - Adjust treatment protocols as necessary.

**Data Management**

**Where**
- **Source data**: patient records
- **Data entry**: electronic database

**How**
- **Baseline measures**: recorded in medical records
- **Follow-up**: questionnaire

**Who**
- **Research coordinator**: manages data entry
- **Data manager**: input of outcomes
- **BF = BURN

**Adverse Events**

- Treatment-related adverse events not anticipated.
- Adverse events reported on CRF and logged.
- Research nurse support in logging/reporting adverse events.

**Questions / Discussion**

- Contact: morgan.govender.12@ucl.ac.uk
**Delegation of Duties Log**

<table>
<thead>
<tr>
<th>Study Number:</th>
<th>150312</th>
<th>Study Title:</th>
<th>Swallowing Intervention Package</th>
<th>Site ID:</th>
<th>UCLH</th>
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**Investigator Name:** Prof Stuart Taylor (PI)  Roganie Govender (PhD student)

**Legend**

Use this legend to complete the General Duties column. For each individual listed in the Name column, enter the letter(s) (e.g., a, c, e) from the legend below that correspond to their protocol-related duties in the General Duties Column. If there are significant protocol-related duties that are not already included in the legend, add them in the empty spaces provided below.

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<td>a.</td>
<td>co-ordination of trial</td>
<td>h.</td>
<td>patient randomisation</td>
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<td>b.</td>
<td>maintain site file</td>
<td>i.</td>
<td>data management</td>
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<td>c.</td>
<td>obtain all necessary approvals</td>
<td>j.</td>
<td>maintain screening/enrolment logs</td>
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<td>d.</td>
<td>screening of patients</td>
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<td>e.</td>
<td>inform patients of trial</td>
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<td>confirm patient eligibility</td>
<td>m.</td>
<td>delivery of intervention</td>
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<td>obtain patient informed consent</td>
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# Delegation of Duties Log

**Study Number:** 150312  
**Study Title:** Swallowing Intervention Package  
**Site ID:** UCLH

**Investigator Name:** Prof Stuart Taylor (PI)  
Roganie Govender (PhD student)

This log should include the Principal Investigator, subinvestigator(s), trial/study coordinator(s), and all other clinical staff who routinely see trial subjects or who have specific data collection/interpretation duties. This log should also include any contracted specialists performing protocol-required examinations. Add new or replacement staff as appropriate.

<table>
<thead>
<tr>
<th>Name (please print)</th>
<th>Trial Role</th>
<th>General Duties (see legend)</th>
<th>Initials</th>
<th>Signature</th>
<th>Date of Duties From (DD-MM-YYYY)</th>
<th>Date of Duties To (DD-MM-YYYY)</th>
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<th>Date of PI Signature</th>
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Appendix 7.17: SIP SMART training log

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