Swallowing prehabilitation for people with head and neck cancer: A pilot cluster-randomised feasibility study of the SIP SMART intervention, embedded in the NHS cancer care pathway

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Background

Dedicated prehabilitation is only taking place in 20% of head and neck cancer networks in England (GIRFT report, 2025).

Swallowing prehabilitation may help to mitigate some of the negative effects of head and neck cancer treatments on people's ability to eat and drink[1]. This study aimed to assess the feasibility of delivering the SIP SMART (Swallowing Intervention Package: Self-monitoring, Assessment and Rehabilitation Training) which is a theory-based behaviour change swallowing prehabilitation intervention[2]. A two-arm cluster randomised pilot trial design was selected to minimise contamination. NHS hospital sites were the unit of randomisation.

In line with feasibility outcomes[3], this study was not designed to assess effectiveness of the intervention. Pre-specified criteria to inform progression to the main trial that will assess clinical effectiveness, are illustrated in Table 1.

Methods

- Phase II trial (SIP SMART2-ISRCTN12377415), six hospitals/centres randomised.
- Trained clinicians at the intervention sites delivered the manualised SIP SMART intervention which included two 45-minute consultations, x-ray swallow assessment, tailored exercises/advice and specific behaviour change strategies.
- Care as usual involved a single consultation of information giving and provision of a generic exercise sheet.
- In both arms, all eligible adult patients newly diagnosed with Stage II-IV head and neck cancer receiving curative treatments were invited to participate.
- Clinical (MDADI) and health economic data were collected at baseline, 4, 12 and 24 weeks after treatment completion.

Table 1: Progression criteria to inform main trial

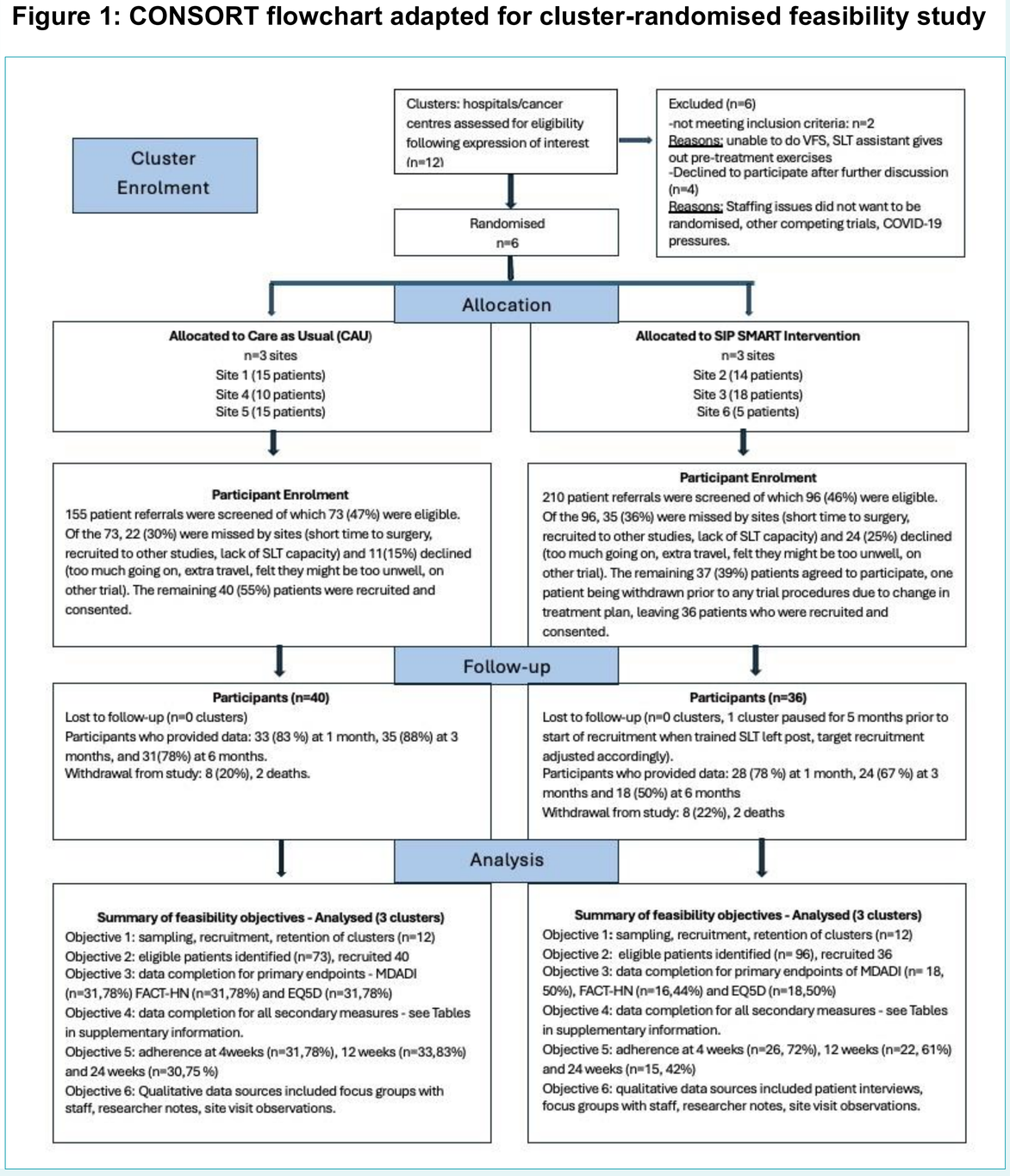
Criterion	Assessment method	Go – proceed to main trial	Amend – proceed with changes	Stop – do not proceed unless changes are possible
Proportion of hospitals who agreed to participate	Test of sampling, recruitment and retention approaches for sites	80% (5/6 sites)	66% (4/6)	50% (3/6 or less)
*12 patients recruited at each site over 6-8 months	Screening logs	5/6 sites achieve target	4/6 sites achieve target	3/6 or less
Proportion of patients in both groups for whom it is possible to collect follow-up data to the point of primary outcome (clinical effectiveness - **MDADI)	Assessment of data completeness	70% + for MDADI	60%- 70%	<60% Consider factors from process evaluation e.g. use of iPad, postal, remote data collection and how this influences follow-up. Presence of research nurse support.

*12 was considered a feasible target based on disease prevalence and average numbers treated per annum at UK cancer centres
**MD Anderson Dysphagia Inventory

Results

- Twelve hospitals expressed interest, six were randomised and provided data to the point of study completion (See Figure 1).
- Patient recruitment across all sites (n=76) reached the target, although two sites fell short of their individual targets.
- The proportion of people recruited vs those eligible for each arm was 39% (95% CI 29,49) for SIP SMART and 55% (95% CI 43, 66) for care as usual.
- The end point data at 24 weeks were completed for 50% (95% CI 33, 67) for SIP SMART and 78% (95% CI 62,89) for care as usual.
- Adherence to the intervention was above 50% at all timepoints.

Figure 1: CONSORT flowchart adapted for cluster-randomised feasibility study



Conclusion

It is feasible to deliver the SIP SMART intervention embedded within the NHS cancer care pathway. A future trial will need to be optimised for efficiency in set-up and follow-up data collection based on learnings from the accompanying process evaluation.

References:
1. Vester S, Muhr A, Meier J et al. Prehabilitation of dysphagia in the therapy of head and neck cancer- a systematic review of the literature and evidence evaluation. Front Oncol 2023; 13:1.
2. Govender R, Smith CH, Barratt H, et al. SIP SMART: A parallel group randomised feasibility trial of a tailored pre-treatment swallowing intervention package compared with usual care for patients with head and neck cancer, BMC Cancer 2020; 20:360.
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