PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (**http://bmjopen.bmj.com/site/about/resources/checklist.pdf**) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

ARTICLE DETAILS

TITLE (PROVISIONAL)	Prevalence, Nature and Trajectory of Dysphagia post Oesophageal Cancer Surgery: A Prospective Longitudinal Study Protocol
AUTHORS	Hayes, Michelle; Gillman, Anna; Wright, Brona; Dorgan, Sean; Brennan, Ian; Walshe, Margaret; Donohoe, Claire; Reynolds, John; Regan, Julie

VERSION 1 – REVIEW

REVIEWER	Tham, Tony Ulster Hospital, Dundonald, Belfast
REVIEW RETURNED	06-Dec-2021

GENERAL COMMENTS	This is an important study as dysphagia happens not infrequently after oesophagectomy and studies of this subject appear to be few. Patient involvement in the study protocol and the measurement of PROMS (patient reported outcomes) are strengths. Major comments: • Six months follow up of dysphagia post oesophagectomy does seem like a short period. There is an opportunity to follow up these patients for 1-2 years as it may take up to this period for patients to fully recover from an oesophagectomy. • Excluding patients unable to cooperate with a videofluoroscopy at post op day 4 and 5 could potentially exclude a large number of patients and bias the results as an inability to cooperate with a videofluoroscopy at this time period may actually be a predictive factor for dysphagia. • It would be useful if nutrition markers such as weight, hand grip are also measured as this may have an association with dysphagia.

VERSION 1 – AUTHOR RESPONSE

	Reviewer's Comment	Authors' Response
1	Strengths and limitations section: Can you please make it clearer why the 3rd bullet point is a methodological strength or replace this point with an alternative strength? This section should contain up to 5 short points, no longer than one sentence each, that relate specifically to the methods. The novelty, aims, results or expected impact of the study should not be summarised here.	This has been corrected now, thank you. The following strength/limitation has been added to the manuscript. 'This prospective longitudinal study will evaluate dysphagia post oesophagectomy, across all open surgical approaches (including transthoracic and transhiatial).'

		'Other limitations include the single-centre study design, excludes those who undergo a complex post-operative course (e.g., anastomotic leak) who may present with an oropharyngeal dysphagia, and the long-term time point is limited to six months post-discharge.'
2	The sample size section needs expanding. Please ensure that you are providing enough information for others to reproduce your sample size calculation. What previous literature are you referring to?	The sample size has been reviewed and the following has been added to the manuscript. 'This is an exploratory longitudinal study in an area with limited previous research or group comparisons and no reporting of effect size. Based on previous literature in this cancer cohort to estimate an effect size 0.5 at a significance level of 0.05 and a power of 0.8, a sample size of 60 is calculated for repeated measures. This sample estimate is consistent with other publications in this area [58, 59].'
3	The discussion summarises your study's strengths but can this section also discuss the study's limitations?	The study's limitations has been reviewed and the suggested changes have been made to the document. 'This study has some limitations that we acknowledge. Firstly, the risk of post-operative complications including ARDS, pneumothorax, risk of re-intubation, delirium, anastomotic leak who require medical interventions, will prevent recruitment into this study. Failure to collect data on patients with complex post operative needs who may potentially present with an oropharyngeal dysphagia is recognised as a limitation. Patient retention may be challenging due to the increased risk of cancer recurrence in this population, ultimately impacting their ability to participate during the different time points. For this reason, it was decided to recruit patients up to 6-months post resection rather than one year following oesophagectomy.'
4	Please include the relevant page number(s) from the manuscript next to each reporting item in the STROBE checklist or state 'n/a' next to items that are not applicable to your study. We appreciate that as this is a study protocol a number of items will be not applicable.	Apologies, this will be rectified in the reporting items section.

5	Six months follow up of dysphagia post oesophagectomy does seem like a short period. There is an opportunity to follow up these patients for 1-2 years as it may take up to this period for patients to fully recover from an oesophagectomy.	This has now been addressed and discussed in further detail regarding the rationale for 6-month follow-up timeframe. 'The author acknowledges that the 6-month timeframe may not fully capture swallowing impairment and QOL measures following surgery, however this research group is also conducting another major study, examining the prevalence, nature and impact of dysphagia one-year post oesophagectomy and into survivorship.'
6	Excluding patients unable to cooperate with a videofluoroscopy at post op day 4 and 5 could potentially exclude a large number of patients and bias the results as an inability to cooperate with a videofluoroscopy at this time period may actually be a predictive factor for dysphagia.	The authors acknowledge that exclusion of patients unable to cooperate with VFS on POD 4/5 may exclude a large number of patients. However, it was important to ensure that participants were evaluated at specific timepoints. If this timepoint was widened, participants may have spontaneously recovered from a swallow viewpoint. Furthermore, based on the oesophageal cancer ERAS protocol developed by international experts, POD 4/5 is when this clinical population are typically initiated on an oral diet. Hence, POD 4/5 this clinically relevant timepoint and it is important to identifying aspiration in this population at this time.
7	It would be useful if nutrition markers such as weight, hand grip are also measured as this may have an association with dysphagia.	This has now been addressed and expanded upon. Specific measures of nutrition markers have been included in the data collection can be viewed in Figure 1 and Table 1. The following measures will be collected: 1. Functional Oral Intake Scale (FOIS) 2. International Dysphagia Diet Standardisation Initiative (IDDSI) 3. Strength, Assistance With Walking, Rise From a Chair, Climb Stairs, and Falls (SARFC-F) 4. Malnutrition Screening Tool (MST) 5. Participants' weight and BMI will be collected

VERSION 2 – REVIEW

REVIEWER	Tham, Tony Ulster Hospital, Dundonald, Belfast
REVIEW RETURNED	26-May-2022

GENERAL COMMENTS	The authors have responded to the reviewers' comments satisfactorily.