4.6 Planned follow-up

4.6.1 Follow-up schedule

The hospital stay is typically between 8 and 14 days. Patients are routinely followed up clinically every three months in the first year, six monthly in the second year and annually thereafter.

Participating patients will complete baseline measurements prior to random allocation. On the day 3 and 6 post-surgery patients will complete assessments of pain and blinding. At randomisation and at each study assessment time point (6 days, 3 weeks and 6 weeks post-surgery and 3 months, 6 months, 9 months, 12 months, 18 months, 24 months and 36 months* after randomisation), participants will be assessed by the doctor for current health status (performance status World Health Organisation assessment, dysphagia scores, and pain scores) and undergo a clinical examination to check for signs of disease recurrence. They will be weighed in kilograms (kg) using calibrated electronic clinic scales. Height in centimetres will be measured before randomisation in the hospital to allow calculation of body mass index. Lung function measurements will be taken during the first week post-surgery, at days three and six as a minimum, using a portable device at the bedside[1].

*NB 36 month follow-up will only be completed if it falls within the planned length of the study.

Patients recruited to the feasibility study who have not completed the follow-up period when the feasibility study closes will be followed up as part of the main trial. Patients from the feasibility study will not be re-consented for being followed up under the main study (the follow-up questionnaires and timepoints are the same and the study is still being managed by the University of Bristol).

4.6.2 Assessment of patient reported outcomes

Pre-surgery questionnaires will be given to patients to complete themselves when they attend for hospital visits as outlined in **Table 1**. A portable device will be used to measure lung function at the bedside. Participants may elect to complete the questionnaires at home and return by post in a stamped addressed envelope which will be provided. Follow up questionnaires will be posted by sites or in some circumstances the central study management team, if agreed specifically between the site and the central study management team. If questionnaires are not returned within 2 weeks, follow up calls will be made (if appropriate the questionnaire can be read to the participant over the phone, a second set posted for completion, or an appointment arranged to coincide with an outpatient appointment with the clinical team). To ensure that time points are followed the database will issue reminders for upcoming and overdue follow time-points until follow-up data has been collected or a reason given why follow-up data will not be completed.

4.6.3 Study within a trial evaluating retention

We will conduct a study within a trial (SWAT) to evaluate the impact of including a “withdrawal slip” that patients can complete to indicate that they wish to miss a timepoint or withdraw from further follow-up. The withdrawal slip will emphasise the importance of the questionnaire data to the research as patient feedback has indicated that patients do not always realise the value

[1] Where day 3 or 6 falls on a Saturday/Sunday, the measurement should be taken on the closest week day (e.g. day 3 falls on a Saturday, the lung function should be assessed on the Friday).

of their responses to questionnaires. The withdrawal slip has been developed in response to, and in discussion with, the ROMIO PPI group.

SWAT population
All patients randomised to the ROMIO study will be randomised in the SWAT. Patients will not be consented separately to be randomised in the SWAT as there is no additional burden or risk to the patient by including them in the SWAT. Patients will be randomised by the study statistician and randomisation will be stratified by centre and surgical approach (OO, LAO or TMIO).

SWAT intervention
Both groups will continue to receive the reminder calls as per the study protocol. Where follow-up reminder calls are made and a second "reminder" copy of the postal questionnaire is sent, patients will be randomised to either:

- receive withdrawal slips with any "reminder" postal questionnaire(s) sent, or
- only receive the "reminder" postal questionnaire(s).

If the patient is randomised to receive the withdrawal slip with the "reminder" postal questionnaire, this will apply to any timepoint that a second "reminder" postal questionnaire is sent.

SWAT sample size
There is no formal sample size calculation for this SWAT as numbers are limited to the number of patients participating in the ROMIO study. SWATs often do not have sample size calculations as they are intended to be analysed through meta-analysis[31]. This SWAT will be submitted to the SWAT repository held by the Northern Ireland Network to enable other studies to adopt it.

SWAT outcomes
The primary outcome of the SWAT will be the number of questionnaires that are returned in each group. Secondary outcomes will be the number of participants who missed one or more timepoints and the number of participants withdrawing from the study.

The continuation of the SWAT will be reviewed approximately every 6 months by the SEG.