Appendix I: Study Within A Trial (SWAT)

Background

A great deal of effort is often expended in recruiting participants to trials. Ensuring that as many of these participants as possible are recruited, retained, and provide outcome data can greatly improve research efficiency and minimise the risk of bias resulting from incomplete data. In FAMOUS, the randomisation of clusters (i.e., sites) means that all eligible patients seen during the trial period will receive care in line with the site's allocation. The strategy of informing patients that the clinic they have attended is participating in research will be delayed until the 12-week time point, at which point the first set of PROMs are due.

Given that patients are being sent information that does not pertain to their hearing aid clinical care, each patient will receive a reminder phone call from their audiology clinic reiterating the details of the FAMOUS trial and the questionnaires. A SWAT will investigate the timing of a single telephone call from the site, during which the questionnaires will be discussed with the patient and find out if they have any further questions or concerns.

Interventions

Group 1: Telephone call at the time of sending to inform them that the questionnaires and consent form are on the way.

Group 2: Telephone call 2–3 days after postage to confirm whether they have received and read the questionnaires and consent form, having given the patient time to read the documents.

Method of allocation

Sites will be randomised in a 1:1 ratio to whether they contact their patients at the time of sending the trial documentation (Group 1) or 2–3 days following postage (Group 2). Timing of contact will be assigned using stratified block randomisation balancing on treatment group (usual or structured care site). The randomisation will be an internal process which is triggered by site allocation to group 1 or 2 and will be communicated to sites as part of their allocation confirmation.

Outcome measures

(i) return rate of 12-week follow-up questionnaire, and

(ii) demographics of populations completing 12-week follow-up questionnaires.

Analysis

A mixed-effects logistic regression model will be used to compare response rates (Group 1 vs Group 2), with a random effect to adjust for clustering within centres. The comparison will be presented as an absolute and relative difference in proportions, along with 95% confidence intervals.

Given the brief site opening period (months 8 to 17) and that recruitment of participants into the SWAT will occur at the 12 weeks post fitting appointment, it will not be feasible to perform an interim analysis on the SWAT and implement a change should one strategy prove more effective. Therefore, the analysis of the SWAT will occur after all patients reach 12 weeks post-fitting.

Dissemination

The SWAT will be registered on the Northern Ireland MRC Trials Hub for Methodology Research SWAT registry. The findings will be made publicly available as soon as possible after the end of the SWAT and will be made available to researchers conducting meta-analysis in this field.