

Pen incentive to enhance retention

This SWAT has been completed, written up and is in press at NIHR Open Research at the time of writing. Brief summary of methods below.

Objective of this SWAT: To evaluate the effects of providing a pen with the 3-month follow-up questionnaire on retention rates.

Intervention: Pen printed with the trial or university logo

Comparator: The comparator would be standard practice for the host trial, i.e. no pen.

Inclusion criteria: All participants in the intervention arm of the host trial who are due to be sent their 3-month follow-up questionnaire will be included in this sub-study.

Exclusion criteria: Participants who withdraw from follow-up before their 3-month follow-up is due, or those who have already received their follow-up questionnaire prior to the start of the pen sub-study will be excluded.

Outcome measures

Primary outcome: The proportion of participants in each group who return the 3-month questionnaire.

Secondary outcomes: Time to response (length of time taken to return the questionnaire), completeness of response (the number of questions completed) and whether a reminder notice is required (number of participants requiring a reminder mailing divided by the number of participants who were sent a questionnaire).

Sample size calculations

In this SWAT the 240 participants allocated to the intervention arm in the main trial were randomised to either the intervention or control group. This sample size will give 80% power to detect an increase in response rates from 80% in the 'No pen' group to 93% in the 'Pen' group assuming that 10% of participants withdraw before the 3-month follow-up time point.

Method for allocating to intervention or comparator

Simple 1:1 randomisation will be used to allocate intervention participants to receive a pen with the 3-month postal questionnaire or to receive the questionnaire alone.

Analysis plan

Binary data will be compared using logistic regression, time to response by a Cox proportional hazards model, and completeness of response by a linear regression model. All models will adjust for age, gender, and allocation for the factorial trial embedded at the recruitment stage (anyone not randomised into the factorial trial will be considered in the 'no pen and no £5' group).