

Outcome measure

The primary outcome will be the proportion of participants who go on to be randomised to the FIREFLI trial.

Secondary outcomes include:

- a. Proportion of participants who return a screening form
- b. Proportion of participant who are eligible for randomisation
- c. Proportion of participants who remain in the trial at three months post-randomisation (defined as returning at least the first three months' worth of falls calendars from the date of randomisation)

Sample size

As is usual with an embedded trial within a trial, no formal power calculation will be undertaken for the study, as the sample size will be constrained by the number of participants available to mail out to.

Statistical analysis

Binary data will be compared using logistic regression.

20.2 Retention SWAT

There is some evidence to suggest that including a pen with a postal follow-up questionnaire has a positive impact on response rates and number of reminders required. In theory including a pen not only facilitates its completion, but also acts as an acknowledgement of the participant's help with the study, making the recipient more likely to complete it. Participants in the FIREFLI trial will be posted a follow-up questionnaire four months post-randomisation. Participants who do not return their follow-up questionnaire within two weeks will be sent up to two reminder letters plus a copy of the questionnaire by post followed by a telephone call two weeks later.

We will undertake an embedded randomised controlled trial in order to evaluate the effectiveness of including a pen with the first reminder letter for participants who do not return their four month questionnaire within two weeks of it being sent.

Block randomisation, stratified by main trial allocation, with randomly varying block sizes will be used to randomise participants to receive a pen or not with their reminder questionnaire. The allocation schedule will be generated by a York Trials Unit statistician otherwise not involved in the recruitment or follow-up of participants.

Inclusion criteria

For logistical reasons, all participants due to be sent a four month questionnaire will be randomised into the SWAT. However, only those sent a four month questionnaire reminder letter will be included in the analysis.

Exclusion criteria

Participants who withdraw from follow-up before their four month questionnaire is due and those for whom it is not necessary to send a reminder letter will be excluded from the SWAT.

Outcome measures

The primary outcome will be the proportion of participants in each SWAT group who return the questionnaire. Secondary outcomes will include time to response (length of time taken to return the questionnaire), and completeness of response (the number of questions completed).

Sample size

As is usual with an embedded trial within a trial, no formal power calculation will be undertaken for the study, as the sample size will be constrained by the number of participants in the FIREFLI trial who are required to be sent a reminder letter due to non-response to the four month questionnaire.

Statistical analysis

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 main trial allocation.