

# **SWAT 131: Modes of data collection for subjective outcomes at follow-up: comparing a choice and a failure-based approach**

## **Objective of this SWAT**

To determine the effects on return rates and nature of responses of the mode of delivery when giving a self-report questionnaire to trial participants.

Study area: Retention

Sample type: Participants

Estimated funding level needed: Unfunded

## **Background**

Retaining participants in trials has been found to be one of the top three challenges for people conducting trials in the UK. It also threatens the ability of a trial to detect differences and can cause bias in the final results if there is differential loss to follow-up within or between groups. This can be particularly the case where follow up is remote to the clinic and is via self-report questionnaire.

There is also concern that subjective outcomes collected via different administration modes (e.g. postal, web or telephone) can be affected by different sorts of reporting bias and therefore challenge the assumption that it is acceptable to combine them. The MODE ARTS Study (1) showed that the largest biasing factor was for interviewer versus self-administered questionnaires, but most of the literature relates to surveys, not trials, and it is reasonable to assume that some of the theoretical factors (such as legitimacy, social desirability, etc) that might affect both response rates and response quality are different in trials.

One of the most important questions in the PRIORITY II study (2) was 'what is the best way to encourage trial participants to undertake follow-up tasks like questionnaires?'. Most trials take a failure-based approach to follow-up and have a single chosen mode and then add additional modes when they fail to get a response (for example sending a questionnaire and then telephoning the person if it is not returned). However, a recent meta-ethnography of qualitative studies (3) around retention developed the argument that the overarching explanation for retention was based on a balancing of a person's sense of self and the trial processes and procedures. Therefore, in order to maximise response and thereby study retention, it might be preferable to provide participants with a choice. However, the potential impact of this on the responses given also needs to be assessed, in particular for subjective outcomes.

## **Interventions and comparators**

Intervention 1: Be given a choice as to mode of follow-up

Intervention 2: Use a failure-based approach in the event of non-response (usual approach)

Index Type: Method of Follow-up

## **Method for allocating to intervention or comparator**

Randomisation

## **Outcome measures**

Primary: Completion of the questionnaire

Secondary: Time to completion, level of missing data, response given (evidence of bias), cost, request to change mode (in the choice group)

## **Analysis plans**

The primary analysis is the comparison of the proportion of participants who return a completed questionnaire in each randomised group. Subgroup analysis should be considered for age, gender and randomisation group (as well as any other factors known to affect response or retention in the study population).

## **Possible problems in implementing this SWAT**

It may be challenging to have two different forms of follow up for patients within a single trial site, but the SWAT could use cluster randomisation if necessary.

## **References**

- 1) Hood K, Robling M, Ingledew D, Gillespie D, Greene G. Mode of data elicitation, acquisition and response to surveys: a systematic review. *Health Technology Assessment* 2012;16(27).
- 2) Brunsdon D, Biesty L, Brocklehurst P, et al. What are the most important unanswered research questions in trial retention? A James Lind Alliance Priority Setting Partnership: the PRioRiTy II (Prioritising Retention in Randomised Trials) study. *Trials* 2019;20:593.
- 3) Skea ZC, Newlands R, Gillies K. Exploring non-retention in clinical trials: a meta-ethnographic synthesis of studies reporting participant reasons for drop out. *BMJ Open* 2019;9:e021959.

## **Publications or presentations of this SWAT design**

### **Examples of the implementation of this SWAT**

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Date of idea: 8/SEP/2020

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Date of revisions: