# SWAT 197: Effectiveness and cost effectiveness of providing a pen at recruitment on participant retention in randomised trials

**Objective of this SWAT**
1) To evaluate the effectiveness of giving a pen at the point of recruitment on participant retention in randomised trials
2) To evaluate the cost-effectiveness of giving a pen at the point of recruitment on participant retention in randomised trials

Study area: Retention, Follow-up
Sample type: Participants, Patients
Estimated funding level needed: Low

**Background**
Attrition or non-response of participants, resulting in missing outcome data, is a serious issue in randomised trials, with the impact on trial validity being more serious with higher proportions of participants with missing outcome data.[1]

Non-monetary incentives are one approach that may improve retention. There is some evidence that using pens as a non-monetary incentive increases response rates and time to response for trial follow-up questionnaires.[2,3] Further to this, a Cochrane Review of retention interventions [4] identified one trial [5] that evaluated the impact of giving a pen at recruitment on participant retention. The review concluded that this single study provides moderate-certainty evidence and large potential effect sizes. Giving people a pen at the point of recruitment is relatively easy and cheap intervention to implement and further evaluation is required to establish whether it has an impact on retention.

**Interventions and comparators**
Intervention 1: Giving a pen at recruitment. The intervention will be a pen given to participants at the point of recruitment (eligibility confirmed and consent obtained). This could be incorporated into any trial where recruitment takes places face-to-face or via post. The pen may include a logo of the research institution and/or the name and logo of the trial. It might be given to any potential participant of the host trial at the point of being approached (e.g. included in an invitation pack) or at the point of enrolment (e.g. during a consent appointment).
Intervention 2: Comparator: Not given a pen at recruitment.

Other strategies for maximising retention rates are also allowable provided they are the same across both SWAT groups.

Index Type: Incentive, Method of Follow-up

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

**Outcome measures**
Primary: Retention rate defined as the proportion of participants for whom outcome data are obtained.
Secondary: 1) Cost-effectiveness (cost per participant retained for pen incentive compared to no pen incentive); 2) Time to collection of outcome data (days from scheduled date); 3) Number of reminders sent to participants before completion of follow-up assessment; 4) Impacts of the retention strategy on all subsequent follow-up time-points; 5) Other outcomes, such as questionnaire completeness (e.g. primary outcome measure obtained) when data collection is via self-report questionnaire, to be defined as appropriate to the host trial.

**Analysis plans**
Demographic characteristics, including age, sex and ethnic group (if available), will be presented descriptively, as mean (standard deviation) or number (%), as appropriate. An ‘intention-to-treat’ analysis will be performed including all randomised participants analysed in the SWAT group to which they were randomised, regardless as to whether they received the pen at recruitment or not.

Any randomised participant who does not provide outcome data for any reason (including participants who were deceased or withdrawn from the host trial) will be categorised as 'No' for the primary outcome. Where possible, the effects of the strategies in different patient populations will be explored, including sex, age and ethnicity.

Primary outcome analysis:
Comparison of the retention rate between the pen group and the no pen group will use logistic regression. The regression model will include the randomised group factor and any SWAT stratification or minimisation factors (e.g. host trial treatment group). The between-groups difference will be presented as number (%) and as both adjusted absolute (i.e. risk difference) and relative (i.e. odds ratio or relative risk) effect estimates, with 95% confidence intervals from the logistic regression model.

Secondary outcome analysis
The between-groups difference in time taken to collection of outcome data will be analysed using techniques suitable for time to response (event) data such as Kaplan-Meier curves, log-rank test or Cox regression (adjusted for SWAT stratification/minimisation factors). Time zero will be set as 'day before expected completion date' (equivalent to adding 1 to the time variable to avoid exclusion from the analysis set).

For self-report questionnaires, the analysis of questionnaire completeness will be as for the primary outcome.

The incremental cost per retained participant between the pen group and comparator is the difference in costs between the groups, divided by the difference between groups in retention rates. Direct costs of the retention strategies, and indirect costs associated with administering the strategies and the comparators will be included.

The following sensitivity analysis will be performed for the primary analysis:
• Excluding participants who did not or could not receive allocation as allocated
• Excluding participants who were retrospectively found to have been deceased or withdrawn from the host trial before the expected completion date.
Subgroup analysis may also be performed for key demographic subgroups (e.g. age and gender) by adding interaction terms to the logistic regression or Cox regression model, where sample sizes are deemed sufficiently large.

Meta-analyses will include data from existing SWATs and will estimate differences in retention rates between the intervention and comparator groups. Within the meta-analysis, remote self-completion of questionnaires by trial participants and face to face data collection should be evaluated in subgroups and a combined treatment effect should be presented only if it is deemed that the effects are homogeneous between subgroups.

**Possible problems in implementing this SWAT**
1. In the case of a trial with an internal pilot, the SWAT is likely to be somewhat dependent on the success of the host trial progressing beyond the internal pilot. Should the host trial close after the internal pilot, the number of participants in the SWAT is likely be far lower than originally planned.
2. This SWAT is limited to trials which use face-to-face or postal methods for recruitment. Given the recent increase in remote trial delivery, the number of trials for which this could be applicable may be reduced.

**References**
1. Dumville JC, Torgerson DJ, Hewitt CE. Reporting attrition in randomised controlled trials. BMJ 2006;332(7547):969-71. doi:10.1136/bmj.332.7547.969
2. Bell K, Clark L, Fairhurst C, et al. Enclosing a pen reduced time to response to questionnaire mailings. Journal of Clinical Epidemiology 2016;74:144-50. doi: 10.1016/j.jclinepi.2015.12.004.
3. Mitchell AS, Cook L, Dean A, et al. Using pens as an incentive for questionnaire return in an orthopaedic trial: an embedded randomised controlled retention trial [version 2; peer review: 1 approved, 1 approved with reservations]. F1000Research 2021;9:321

4. Gillies K, Kearney A, Keenan C, et al. Strategies to improve retention in randomised trials. Cochrane Database of Systematic Reviews 2021;(3):MR000032. doi: 10.1002/14651858.MR000032.pub3.
5. Whiteside K, Flett L, Mitchell A, et al. Using pens as an incentive for trial recruitment of older adults: An embedded randomised controlled trial. F1000Research 2019;21;8:315. doi: 10.12688/f1000research.18300.1.

**Publications or presentations of this SWAT design**

1. Whiteside K, Flett L, Mitchell A, et al. Using pens as an incentive for trial recruitment of older adults: An embedded randomised controlled trial. F1000Research 2019; 21;8:315. doi: 10.12688/f1000research.18300.1.

**Examples of the implementation of this SWAT**

1. Whiteside K, Flett L, Mitchell A, et al. Using pens as an incentive for trial recruitment of older adults: An embedded randomised controlled trial. F1000Research 2019; 21;8:315. doi: 10.12688/f1000research.18300.1.

People to show as the source of this idea: Cara Mooney, Claudia Silviera, Linda O'Neill, Chris Sutton, Jack Grierson, Catherine Arundel
Contact email address: c.d.mooney@sheffield.ac.uk
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Revisions made by:
Date of revisions: