

4.2 Study within a trial (SWAT)

We recognise the need to broaden participation in trials. We have experience within the team of developing illustrated narratives (picture story books) as a means of communicating messages around infection. We will conduct a SWAT to evaluate whether presentation of the study to potential participants using this re-designed, illustrated, narrative based PIS leads to an increased recruitment rate compared with presentation of the study using a standard PIS. We will work with the established team which includes a writer (Lynda Waterhouse) and illustrator (Imogen Fancourt), alongside our patient representatives, to co-design and study the “Effects of including a Picture Book with the Participant Information Sheet on trial recruitment and retention” (SWAT 166 MRC SWAT Repository Store). The SWAT will be cluster randomised at the site level to avoid contamination. Sites will be randomised 1:1 to either an enhanced PIS arm (Illustrated, narrative PIS + standard PIS) or standard PIS only arm. The allocation sequence will be generated by a researcher not involved in the recruitment of participants at sites. As is usual for embedded trials, no formal power analysis or sample size calculation was undertaken as the available sample size is dictated by the number of participants who are approached for consent. The primary outcome for this embedded trial is randomisation into the host trial. This outcome will be analysed at the individual level using a population averaged logit-binomial model (fit by generalised estimating equations) with a single binary indicator for SWAT allocation, and an exchangeable working correlation structure. The odds ratio for allocation will be reported together with a 95% confidence interval and p-value obtained using an appropriate small-sample adjustment. Further exploratory analyses will look at differences in retention between SWAT groups among those patients who are randomised into the host trial. The findings of the SWAT will be made publicly available as soon as possible after the end of the recruitment period. We will also collaborate with York Trials Unit who have completed a similar SWAT to ensure the data collected will facilitate future meta-analysis [24].

24. Cockayne S, et al. An optimised patient information sheet did not significantly increase recruitment or retention in a falls prevention study: an embedded randomised recruitment trial. *Trials*. 2017;18:144.