

29 APPENDIX A: Study within a trial (SWAT)

Evaluation of the impact of text message invite in a pragmatic trial in people with COPD, on participant response and recruitment.

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Background:

Text message (SMS) communication with patients regarding appointments, reminders, and prescriptions for example, is now a routine communication method used in the NHS, both in primary and secondary care. More recently, text message invites were employed in UK nationally important large COVID trials such as Panoramic and Principle and sent to potential participants identified as COVID-19 positive from laboratory testing.^{1,2} The individual impact of this intervention in these trials and generalisability to other clinical trials research in the UK is uncertain, given the unique and urgent situation of the pandemic and therefore imperative need of research in this context, and the fact a number of other different methods to try and maximise participant involvement as much as possible were used in conjunction in these trials.

A literature search (PubMed) retrieved no results for combinations of "SMS invites clinical trials, text invites clinical trials, text message trial recruitment". Text message as an intervention *itself* has been evaluated in a few trials (smoking cessation, weight loss, cervical screening) but not specifically evaluated as a tool to potentially improve participant response and recruitment.^{3,4,5}

People living with COPD, are elderly, and live with significant health and socioeconomic inequalities. Given that areas with high COPD prevalence are often under-represented in clinical research and it is a strategic aim of health research in the UK to improve representation of under-served groups, it would be helpful to assess the intervention of text message invites in a trial outside of COVID, in a condition with relatively high disease prevalence, and with demographic characteristics typical of frequent healthcare users in the UK. Whether they are a cohort that would respond well to a text message invite is unknown, since they are more elderly and perhaps less technology literature than the cohorts of participants recruited to COVID trials. A review of SWAT studies on the Queens University portal identifies 11 studies where SMS have been evaluated in some form, although no study thus far has looked at the effectiveness of this simple intervention on interest and recruitment in trials.⁶

Aim: To determine the impact of text message invite to the OPACE COPD trial on participant recruitment.

Methods:

Healthcare sites that are willing and able to participate in this SWAT within the OPACE trial, will identify eligible participants by screening and send out a text invitation in addition to regular participant invite materials vs no text invite and regular participant invite materials. Text invite will be a standard REC approved text. This will be an additional recruitment tool used in addition to routine participant invite materials.

Statistical analysis:

Simple summary statistics will be used to collate and describe data.

The number of eligible participants identified by screening at a site and sent participant invite materials (+/- SMS) will be recorded. It is anticipated that the SWAT will run for approximately 1 year to enable sufficient recruitment to undertake statistical analysis if this is feasible.

A formal analysis plan for the SWAT will be developed and approved by the trial statistician prior to analysis.

The SWAT is planned to be active within the OPACE trial. If unexpected challenges in implementation of SWAT arise this does not affect the main trial.

References:

1. <https://www.panoramictrial.org/for-healthcare-professionals/documents>
2. <https://www.principletrial.org/health-professionals/information-medical-professionals-centers>
3. Whittaker R, McRobbie H, Bullen C, Rodgers A, Gu Y. Mobile phone-based interventions for smoking cessation. *Cochrane Database Syst Rev.* 2016 Apr 10;4(4):CD006611.
4. Fischer HH, Durfee MJ, Raghunath SG, Ritchie ND. Short Message Service Text Message Support for Weight Loss in Patients With Prediabetes: Pragmatic Trial. *JMIR Diabetes.* 2019 Apr 15;4(2):e12985.
5. Huf S, Kerrison RS, King D, Chadborn T, Richmond A, Cunningham D, Friedman E, Shukla H, Tseng FM, Judah G, Darzi A, Vlaev I. Behavioral economics informed message content in text message reminders to improve cervical screening participation: Two pragmatic randomized controlled trials. *Prev Med.* 2020 Oct;139:106170.
6. <https://www.qub.ac.uk/sites/TheNorthernIrelandNetworkforTrialsMethodologyResearch/SWATSWARInformation/Repositories/SWATStore/>