

SWAT 193: Text message invitation to recruit people with COPD to a pragmatic trial

Objective of this SWAT

To determine the impact of a text message invitation on participant response and recruitment for a pragmatic randomised trial.

Study area: Recruitment

Sample type: Participants

Estimated funding level needed: Low

Background

Text message (SMS) communication with patients regarding appointments, reminders and prescriptions for example, is now a routine communication method in the National Health Service (NHS) in the UK, in both primary and secondary care. More recently, text message invitations were used in UK nationally important large COVID-19 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 is uncertain, given the unique and urgent situation of the pandemic and the pressing need for research into treatments for COVID-19, and various other methods were also used in these trials to try to maximise participant involvement. Text messaging as an intervention in its own right has been evaluated in a small number of 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 the 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 invitations in a trial outside of COVID-19, in particular in a condition with relatively high disease prevalence and with demographic characteristics typical of frequent healthcare users in the UK. Whether this is a population that would respond well to a text message invitation is unknown, since they are more elderly and perhaps less technology literate than the cohorts of participants recruited to COVID-19 trials. A review of the SWAT repository identified 11 studies where SMS have been evaluated in some form, but none look at the effectiveness of this simple intervention on interest and recruitment in trials.[6] The OPACE (Optimising azithromycin prevention treatment in COPD to reduce exacerbations) trial is a pragmatic, adaptive design trial in people with COPD on long-term azithromycin and will be the host trial for this SWAT.

Interventions and comparators

Intervention 1: Addition of SMS text message invitation to standard participant invitation materials (invitation letter and participant trial information sheet).

Intervention 2: No SMS text invitation, standard participant invitation materials (invitation letter and participant trial information sheet).

Index Type: Method of Recruitment

Method for allocating to intervention or comparator

Randomisation

Outcome measures

Primary: Recruitment rate (proportion of patients randomised into additional SMS group versus standard invitation group).

Secondary: Comparing SMS group vs standard invitation group:

1. Total number and proportion of patients randomised; 2. Total number and proportion of returned expressions of interest in the host trial; 3. Time to randomisation from sending of invitation materials.

Analysis plans

Simple summary statistics will be used to collate and describe data. It is anticipated that the SWAT will run for approximately one year to enable sufficient recruitment to undertake statistical analysis. It is anticipated that a logistic regression model will be used. The sample size of the SWAT is determined by the host trial and capability of sites to provide SMS invitations. The number of recruits to the host OPACE trial determines the power, but observing a total of 1200 patients recruited into the two SWAT groups (600 in each) would provide 90% power for a 19% improvement in recruitment rates. A formal analysis plan for the SWAT will be developed and approved before analysis begins.

Possible problems in implementing this SWAT

Not all sites in the host trial may be able to provide SMS invitations. However, in sites that can do so, participants will be randomised to additional SMS invitation or standard invitation materials.

References

1. <https://www.panoramictrial.org>
2. <https://www.principletrial.org>
3. Whittaker R, McRobbie H, Bullen C, et al. Mobile phone-based interventions for smoking cessation. Cochrane Database of Systematic Reviews 2016;(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;4(2):e12985.
5. Huf S, Kerrison RS, King D, et al. Behavioral economics informed message content in text message reminders to improve cervical screening participation: Two pragmatic randomized controlled trials. Preventive Medicine 2020;139:106170.
6. <https://www.qub.ac.uk/sites/TheNorthernIrelandNetworkforTrialsMethodologyResearch/SWATSWARInformation/Repositories/SWATStore/>

Publications or presentations of this SWAT design

Examples of the implementation of this SWAT

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Date of idea: 1/SEP/2022
Revisions made by:
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