SWAT 249: Optimising the content of a reminder text message to maximise uptake of the BEST4 screening trial capsule sponge test appointment

Objective of this SWAT
This SWAT will evaluate versions of the reminder text message with different wording informed by behaviour change techniques that target known recruitment barriers in order to maximise uptake of the capsule sponge test appointment.

The primary objectives are to evaluate (a) the difference in booking a BEST4 Screening Trial appointment between different versions of a reminder text message to book a capsule sponge test appointment; and (b) the difference in appointment attendance between different versions of a reminder text message to book a capsule sponge test appointment.

An exploratory objective is to evaluate whether results to evaluate the primary objectives may differ by subgroups defined by demographic, clinical or psychological factors.

Additional SWAT Details
Primary Study Area: Recruitment
Secondary Study Area: EDI; Barriers and facilitators; Incentives and engagement; Prompts
Who does the SWAT intervention target: Participants
Estimated resources needed to conduct the SWAT: Low
Estimated cost of the SWAT (£):

Findings from Implementation of this SWAT
Reference(s) to publications of these findings:
Primary Outcome Findings:
Cost:

Background
Recruiting participants to trials can be challenging with nearly 50% of trials extending recruitment or failing to meet targets.[1-3] Poor recruitment risks underpowered trials, delaying or missing clinically meaningful findings, raising ethical concerns, and increasing costs.

The BEST4 Platform is adopting a novel, cost-effective recruitment strategy by using text messages to invite potential participants to enrol online in the Heartburn Health bioresource. This approach will allow us to cost-effectively invite sufficient people to the Platform with broad eligibility criteria to ensure inclusivity. However, patient and public involvement (PPI) contributors have highlighted potential barriers, including trust in the text message, remembering to respond, and understanding the information. Pilot data suggests uptake may be lower than expected.

A randomly selected subset of Heartburn Health participants will be offered a capsule sponge test as part of the BEST4 Screening Trial, which aims to assess whether screening with this test can reduce oesophageal cancer mortality. Achieving high uptake is essential for trial power. Incorporating wording that targets certain behaviour change techniques and modifying the timing of the invitations and reminders to ease friction in the booking process may encourage uptake of the test and ensure the trial can achieve its aims.

We would like to optimise our invitation and enrolment strategy using Studies Within a Trial (SWATs). A SWAT is an established methodology of embedding an evaluation of an intervention in a host trial to improve some part of the trial process.[4] We will use an adaptive trial design (4,5) and interventions will be informed by the Theoretical Domains Framework and developed using behaviour change techniques.[6-8] By running sequential SWATs, we can continuously test and optimise our recruitment strategy, incorporating the most effective interventions over time.

Host Trial Population: Adults
Host Trial Condition Area: Gastrointestinal

Interventions and Comparators
Intervention 1: Versions of the reminder text message with different wording informed by the following behaviour change techniques: scarcity, altruism, social norms, reframing, commitment and consistency.

Method for Allocating to Intervention or Comparator: Randomisation

Outcome Measures
Primary Outcomes: Difference in the proportion of people offered a capsule sponge test and sent a reminder text message who book an appointment between the SWAT groups; difference in the proportion of people offered a capsule sponge test and sent a reminder text message who attend a capsule sponge appointment between the SWAT groups.

Secondary Outcomes:

Analysis Plans
The interventions will be compared using the “Champion vs Challenger” approach. Each SWAT evaluation to investigate electronic content (e.g. SMS content) will be designed to (1) learn about the size of differences in `response' to different content in the electronic pathway, and (2) maximise uptake to BEST4 and the capsule sponge test. To achieve the first objective each evaluation will be planned in order to have sufficient power to select a new "challenger" intervention, if it improves the primary outcome measure by a given amount (e.g. 10% relative difference).

For the second objective, we plan to stop the SWAT early if data accrued to date suggests that we have a low (pre-selected) probability to accept the new "challenger" given the data to date (i.e. stop for futility). In addition, we will also require at least “moderate” evidence that the "challenger" is better than the "champion". This is because the "champion" will have already demonstrated effectiveness in previous evaluations; if there is only a small absolute difference observed in favour of the challenger then we wish for the champion to be retained.

To meet these objectives analysis will proceed as follows.

1. The target number of events before analysis will be defined prior to each evaluation of a new challenger, based on achieving 90% power to accept the challenger if it is a certain amount better (e.g. 10% relative higher response), given the degree of evidence sought (e.g. Type I level (frequentist approach), or probability superior (Bayesian approach)). The degree of evidence required to choose the challenger will be set prior to each evaluation of a new challenger.

2. The trial will continue until target sample size is exceeded, or early stopping is initiated.

3. If the target number of events is achieved, a decision rule based on level of evidence required will be used and the challenger will be recommended if the level of evidence required is met.

4. The same logic to choose between champion or challenger given the data will be used to evaluate conditional power (and futility) that the challenger could beat the champion, conditional on data accrual to date.

Sample size: This will be determined adaptively. Before each evaluation of a new challenger, investigators will choose the method of analysis, level of evidence sought (e.g. Type I error (frequentist analysis) or probability of superiority (Bayesian analysis)), target effect size for sample size calculation (e.g. Relative 10%), and conditional power for futility (e.g. <1% = STOP). These will be used to define stopping rules. For illustration, for a SWAT to evaluate Heartburn Health text message content, we anticipate response to the Heartburn Health invitation may be approximately 3%. If the challenger has a true response of 3.3%, then the stopping rule based on the number of events required to obtain 90% power to correctly select the challenger using a (frequentist) null hypothesis test at different alpha levels would be as follows:

- **At alpha 0.05, 3,720 events would be needed, corresponding to approximately 114,375 invitations.**
- **At alpha 0.10, 2,840 events would be needed, corresponding to approximately 87,319 invitations.**
- **At alpha 0.20, 1,920 events would be needed, corresponding to approximately 59,032 invitations.**
- **At alpha 0.30, 1,410 events would be needed, corresponding to approximately 43,352 invitations.**
- **At alpha 0.40, 1,000 events would be needed, corresponding to approximately 30,746 invitations.**
- **At alpha 0.50, 690 events would be needed, corresponding to approximately 21,215 invitations.**

These figures represent the number of events that would need to be exceeded to initiate analysis in order to have 90% power to accept the "challenger" when testing at the (one-sided) alpha level, assuming a 10% relative increase in uptake. The expected number of invitations is shown if the true response rate for the champion is 3%, and the challenger is 3.15%.

For each evaluation of a new challenger, the sample size will be planned to achieve a certain level of power for a given type I error, whether a Bayesian or frequentist decision rule and test for futility is used.

Possible Problems in Implementing This SWAT

Some participants (e.g., those with low technological literacy, first languages other than those used for the text messages) may engage differently with the text message interventions, affecting uptake. Also, technical delivery issues (e.g., delivery failures, spam filters) may occur and affect the results (e.g. messages not received or opened).

References Cited in This Outline

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4. Treweek S, et al. Trial Forge Guidance 1: What is a Study Within A Trial (SWAT)? Trials 2018; 19: 139.

5. Pallmann P, et al. Adaptive designs in clinical trials: Why use them, and how to run and report them. BMC Medicine 2018; 16: 29.

6. Gillies K, et al. Systematic Techniques to Enhance rEtention in Randomised controlled trials: The STEER study protocol. Trials 2018; 19: 197.

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8. Cane J, O'Connor D, Michie S. Validation of the Theoretical Domains Framework for Use in Behaviour Change and Implementation Research. Implementation Science 2012; 7: 37.

References to This SWAT

Source of This SWAT

People to show as the source of this idea: Professor Rebecca Fitzgerald, Dr Emma Lidington, Dr Elisavet Moschopoulou, Professor Jo Waller, Professor Peter Sasieni, Dr Shyma Jundi, Dr Adam Brentnall, Wayne Tam, Nicholas Cristofani-Wykes, Abdoulie Gibba, Cancer Research UK (CRUK) Cancer Prevention Trials Unit (CPTU) - Queen Mary University of London
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