SWAT 178: Effects of SMS pre-notification and reminders on electronic questionnaire return using a sequential multiple assignment randomised trial (SMART) design

Objective of this SWAT
The overall aim of this SWAT is to understand the impact of SMS pre-notification and reminder messages in the context of clinical trials using online data capture for patient-reported questionnaires. The specific objectives are:

1. To evaluate whether SMS pre-notifications affect questionnaire response rates and questionnaire completeness compared with no pre-notifications.
2. To evaluate whether sending reminders targeting specific behaviour change techniques sent to initial non-responders affects questionnaire response rates and questionnaire completeness compared with standard SMS reminders.
3. To establish the optimal embedded SMS intervention with regard to questionnaire response rates and questionnaire completeness.
4. To evaluate whether the effect of SMS reminder type on response rates and questionnaire completeness among initial non-responders varies depending on the use of SMS pre-notifications.
5. To assess the cost per participant of SMS pre-notifications and SMS reminders compared with standard practice.

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

Background
Questionnaire return is a key behavior for many clinical trials, and one which may require additional support if participants are to perform it. Short Message Service (SMS) pre-notifications and reminders offer a low cost and implementable strategy for encouraging questionnaire return. This approach has successfully supported behavior change across a range of other settings, including medication adherence (1,2), smoking cessation (3), physical activity (4), weight loss (5) and chronic disease management (6). However, despite nearly 60% of surveyed UK-based Clinical Trial Units using this strategy (7), there is mixed evidence to support the use of SMS for improving trial retention.

In this SWAT, participants in experimental conditions A, B, and C will be sent a pre-notification text message 24 hours before the host trial's questionnaire, prompting them to complete and return it. Participants in conditions D, E, and F will not receive any such contact before the questionnaire. All questionnaires will be delivered electronically and the return of a questionnaire will be defined as the participant clicking the 'submit' button on the questionnaire webpage.

Six days after sending them the questionnaire, participants in conditions B, C, E and F will receive a reminder SMS message if they have not already returned the questionnaire. Participants in conditions C and F will receive a non-standard message, (BCT: 5.3). Those in conditions B and E will receive a reminder text message that is considered standard as it is based on the 'prompt' BCT, and the content is typical to that deployed by the University of Leeds Clinical Trials Research Unit in routine practice.

All participants in host trials who remain fully participating will be eligible for the SWAT.

All SWAT participants will be randomised to either pre-notification or no pre-notification using block randomisation (with varying block sizes) stratified by their host trial allocation, to avoid imbalance between the SWAT intervention groups. Participants will retain their allocation to SMS pre-notification or no pre-notification at all subsequent follow-ups.

Interventions and comparators
Intervention 1: Pre-notification - SMS message (conditions A, B and C):
'Your [Trial name] questionnaire is due soon, please return it to help research stay up-to-date, so NHS patients receive effective treatment and healthcare initiatives'

Comparator 1: No SMS message (conditions D, E and F)
Intervention 2: Non-standard reminder – SMS message (conditions C and F):
'The NHS relies on having evidence to deliver excellent patient care. Returning your [trial name] questionnaire may help improve the NHS for others in the future'
Comparator 2: Standard reminder – SMS message (conditions B and E):
'Our records show that the [trial name] questionnaire we sent you recently was not completed. Please complete this as soon as possible.'

No SMS reminder message (conditions A and D)

Index Type: Method of Follow-up

Method for allocating to intervention or comparator
Randomisation

Outcome measures
Primary: Questionnaire response rate at one month follow-up.
Secondary: Proportion of participants in each SWAT group who submit the questionnaire within 6 and 11 days of them being sent out; number of days between the questionnaire being sent to participants and it being submitted by them; proportion of non-mandatory questionnaire items that are not completed; proportion of non-mandatory questionnaire measures with complete data; cost of SWAT intervention per participant retained at one month.

Analysis plans
Separate analyses will be carried out for each time-point. Differences in response rates, questionnaire completeness, time to return questionnaires and cost per participant retained will be analysed, and descriptive statistics will be produced for the number of SMS messages sent out at each time-point.

Possible problems in implementing this SWAT
The SWAT may require the time of a programmer or data manager to ensure that it is delivered per protocol.

References
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5. Skinner R, Gonet V, Currie S, Hoddinott P, Dombrowski SU. A systematic review with meta-analyses of text message-delivered behaviour change interventions for weight loss and weight loss maintenance. Obesity Reviews 2020;21(6):e12999.
6. Sahin C, Courtney KL, Naylor PJ, Rhodes RE. Tailored mobile text messaging interventions targeting type 2 diabetes self-management: A systematic review and a meta-analysis. Digital Health 2019;5:2055207619845279.
7. Blatch-Jones A, Nuttall J, Bull A, Worswick L, Mullee M, Peveler R, et al. Using digital tools in the recruitment and retention in randomised controlled trials: survey of UK Clinical Trial Units and a qualitative study. Trials 2020;21:304.

Publications or presentations of this SWAT design

Examples of the implementation of this SWAT

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