SWAT 130: SMS prompts to improve compliance with study procedures

Objective of this SWAT
To assess the effects of different strategies for sending SMS prompts to participants to maximise compliance with study procedures.

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

Background
Retention in clinical research is important for the validity of studies but there are few robust, evidence-based strategies for improving retention in such studies, beyond those targeting questionnaire response [1,2]. This evidence gap is a particular problem for longitudinal studies [3]. Therefore, methodological research into improving retention strategies is warranted and remains a research priority [4,5].

We are conducting a longitudinal observational study of lifestyle measures in people with Huntington's Disease (DOMINO-HD). A fundamental part of the study involves participants wearing an activity tracker for a 12-month follow up period, in which they are required to regularly sync their tracker with an app on their smartphone in order to transmit data to a cloud server. As high data completion rates are vital for the intended analysis, we want to ensure that we obtain as much of the intended data as possible. To do this, we will send reminders to participants using a short message service (SMS), but the optimal strategy for ensuring high levels of compliance, whilst simultaneously achieving high levels of acceptability and hence overall retention of study participants, is unknown.

There is some evidence to suggest that electronic prompts, such as SMS, can improve participant retention in clinical research [6] with specific reference to tailoring or personalising messages [7,8] and the timing of the prompts [9]. However, there are no reports on the use of SMS for promoting participant retention in the long term or on how the frequency of SMS in this scenario may impact on their effectiveness.

Therefore, this SWAT will investigate the relative effectiveness of a routine or a data driven approach to the frequency of prompting participants to comply with study procedures. We plan to perform a process evaluation using follow-up questionnaires with both participants and researchers to explore the feasibility and acceptability of both approaches.

Interventions and comparators
Intervention 1: Comparator Group (Routine messaging): A routine SMS sent on the 8th day following recruitment and weekly thereafter. The content of the message will remain constant throughout and be neutral in tone. An example of such a message would be; "Please remember to wear your Fitbit continuously and sync with the app on your mobile regularly. Thanks very much, the DOMINO-HD team."
If a participant fails to upload more than 50% of the expected data, that is more than 50% of activity data in the preceding 7 days is missing, for a continuous 4-week period, this will prompt a telephone call from the recruiting site to the participant. This will be to see if;
a) the participant is having any technical issues wearing the activity tracker or syncing the data that can be remedied, or
b) if the participant no longer wishes to continue in the study.

Intervention 2: Intervention Group (Data driven messaging): A SMS sent on the 8th day following recruitment and weekly thereafter (as in the comparator group) with the content of this message being dependent on the participant's compliance with uploading data. If the participant has uploaded more than 50% of the expected data in the preceding 7 days, they will receive a positive message of thanks: "We have received your data for xx days this week. Thank you for wearing your Fitbit and for syncing with the App on your mobile phone. We value your ongoing participation in the study, thank you very much, the DOMINO-HD team."
On the other hand, if a participant fails to upload more than 50% of the expected data in the preceding week, they will receive a prompt reminding them of the need to wear the Fitbit and sync

the data: “We have received your data for xx days this week. Please remember to wear your Fitbit continuously and sync with the app on your mobile regularly. Thanks very much, the DOMINO-HD team”
This message will be sent for two consecutive weeks if the participant continues to upload less than 50% of the data required. After the third week of receiving less than 50% of the expected data, the message will be altered again:
“We are having trouble locating data from your Fitbit. Please wear your Fitbit continuously and remember to sync with the app on your mobile. If you are having problems please contact the research team on xxxxxxx. Thanks very much, the DOMINO-HD team”
If the participant continues to fail to upload at least 50% of the expected data for four consecutive weeks, they will receive a telephone call from the participating site (as in the comparator group).

Index Type: Method of Follow-up

Method for allocating to intervention or comparator
Randomisation

Outcome measures
Primary: Total number of wear hours logged (up to and including the 9th week following randomisation [week 1 data are excluded from analysis])
Secondary: Total number of wear hours logged (across the 12 months study period); average number of data synchronisation events per week (Fitbit App with cloud server); average number of days data synchronisation events occur after SMS sent (Fitbit App with cloud server); average number of escalation phone calls made per participant; number of ‘withdrawals’ from DOMINO-HD observational study; participant user experience; researcher user experience

Analysis plans
Primary outcome: The first interim analysis will be performed when 100 participants have provided primary outcome data (total wear hours logged between the 2nd and 9th week following randomisation). We will calculate a p-value based on a one-sided t-test for the mean difference in the primary outcome between the randomised groups. If the p-value is below 0.00026, we will stop the SWAT, conclude that data driven messages increase total wear hours logged, and switch all participants over to the tailored prompting. If not, the analysis will be repeated after 200 participants have provided primary outcome data, this time using a p-value threshold of 0.00706, and if the SWAT is not stopped at this point, we will repeat this after all 300 participants have provided primary outcome data, now with a p-value threshold of 0.02253. We will present the point estimate of the mean difference alongside its 95% confidence interval (CI).

Secondary outcomes: We will present descriptive summaries (e.g. means, frequencies, ranges) by intervention group and estimate mean differences between the two groups alongside 95% CIs. Reasons for withdrawal, if known, will be tabulated by group.

Questionnaires used to evaluate participant perceptions of the SMS messages will use a mix of quantitative and free text questions. Summary quantitative data from the questionnaires will be tabulated by intervention group. Qualitative analysis of free text comments in the questionnaires will be conducted using thematic analysis.

Possible problems in implementing this SWAT
Participants may not want to receive weekly SMS messages. PPI feedback regarding this protocol suggested that it should be made clear during the consent process that this is a fundamental aspect of participating in this study and should not be made optional.

This protocol relies on the integration of collected physical activity data and participants’ contact data with the SMS messaging software. Whilst much of this can be automated, any integration failure will affect implementation.

References
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Publications or presentations of this SWAT design

Examples of the implementation of this SWAT

People to show as the source of this idea: Cheney Drew, Philippa Morgan-Jones, Laura Mills, Nigel Kirby, Vincent Poile, Philip Pallmann and Monica Busse
Contact email address: DrewC5@cardiff.ac.uk
Date of idea: 1/APR/2020
Revisions made by:
Date of revisions: