SWAT 227: Adaptive messaging to optimise adherence to remote delivery of a mHealth intervention in randomised trials

Objective of this SWAT
This SWAT will evaluate the effectiveness of personalised adaptive feedback on adherence to a mHealth intervention consisting of home exercise and physical activity, compared to standard reminders. The objective is to optimise the delivery of a mHealth intervention to improve participant engagement with trial activities and adherence in a randomised trial.

Study area: Follow-up, Retention, Adherence to trial protocol
Sample type: Patients
Estimated funding level needed: Very Low

Background
Clinical trial procedures including intervention delivery and data collection have traditionally been conducted using face to face 'site based' approaches, with limited use of digital and mobile technology in the design and conduct of studies. However, although the role of technology has changed in our daily lives, and this accelerated in an unprecedented extent in the COVID-19 pandemic, clinical trials have been slow to incorporate these changes.

Rigorous methodological research is needed to evaluate the effect of technology on trials. Studies Within A Trial (SWAT) comprise self-contained methodology studies in a host trial, to answer questions about how we design, conduct, follow-up, analyse or report results from clinical trials [1].

One potential opportunity and challenge for moving to de-centralised and hybrid trial approaches is how to best leverage technology to keep participants engaged and adherent to trial protocols, including interventions. According to the World Health Organisation, adherence is the extent to which the participant's behaviour corresponds with the trial protocol, which includes taking medications as prescribed and/or making lifestyle modifications in response to interventions, as well as completing other protocol required tasks. Adherence to trial interventions consisting of lifestyle modifications or physical activity are notoriously difficult to ensure and monitor. Leveraging technology to monitor physical activity and provide participants with feedback may provide an opportunity to help address this. Despite the increase in mHealth interventions, the optimal strategy to ensure high levels of compliance, patient engagement and retention is unknown.

This SWAT is aimed at evaluating the effect of personalised adaptive feedback on adherence to a mHealth intervention consisting of home exercise and physical activity, compared to standard reminders. The host trial, ELIVE HF, is a Phase II randomised trial. Participants will receive a home exercise intervention as standard care. This will be remotely delivered as a mHealth intervention using wearable activity monitors, and short messaging system (SMS).

Interventions and comparators
Intervention 1: Personalised adaptive communication, which facilitates delivery of the mHealth exercise intervention by incorporating behaviour change techniques (BCTs), such as goal setting, monitoring, and feedback provided by short messaging system (SMS). Participants will receive two-weekly personalised goal-oriented text messages regarding their physical activity based on real-time monitoring. In addition, participants will receive reminders in cases of non-compliance to Fitbit wear. To promote adherence to Fitbit wearing to monitor physical activity, participants will also receive SMS messages in response to extended periods of apparent non-wear. Participants will have the opportunity to respond to text messages to update their personal goal and will be prompted to do so if they meet their activity goal for two weeks in a row.

The following data will be extracted from the Fitbit for adaptive feedback: Physical activity data (downloaded weekly by investigators) and summarised into reports. The following data will be extracted order to monitor physical activity: Steps per day, minutes per day of exercise (moderate to vigorous intensity as outlined below), distance per day in miles, and floors navigated per day. Data will be captured across physical activity intensities according to three categories as recorded by Fitbit: light, fairly active, and very active. Fitbit "light" activity levels equate to activities of daily

living and therefore will not be considered to be meeting recommended moderate-vigorous intensity exercise.
Intervention 2: Control: standardised reminders. Participants will receive a standard SMS once every two weeks reminding them to follow the home-exercise program. They will receive the same text message regardless of their activity, and their goals will remain static from baseline.

Index Type: Method of Follow-up

Method for allocating to intervention or comparator
Randomisation.

Outcome measures
Primary: Physical activity (average weekly time spent in moderate to vigorous physical activity at 12 weeks).
Secondary:
- Steps taken
- Sedentary time
- Cardiovascular performance, evaluated by the Chester Step test
- Fitbit adherence evaluated by wear-time, and amount of missing data due to non-wear
- Participant retention/participation in the host trial

Analysis plans
Analyses will include descriptive analyses and between-group comparisons. Analyses will be on an intention-to-treat basis, using two-sided statistical significance at the 5% level. Data will be presented as proportions and percentages (adherence rate) or as the median, standard error, and interquartile range (time to the response).

Possible problems in implementing this SWAT
None identified.

References
1. Treweek S, Bevan S, Bower P, et al. Trial Forge Guidance 1: what is a Study Within A Trial (SWAT)? Trials 2018;19(1):139.

Publications or presentations of this SWAT design

Examples of the implementation of this SWAT

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