SWAT 186: Impact of data collection frequency on participant retention in the HEAL-COVID platform clinical trial

Objective of this SWAT
To determine the impact of the frequency of patient reported outcome data collection on participant engagement and retention in a trial with decentralised follow-up.

Study area: Retention, Follow-up, Outcomes
Sample type: Participants
Estimated funding level needed: Medium

Background
HEAL-COVID is a randomised trial that aims to identify treatments that may be beneficial for people discharged from hospital after recovering from COVID-19 (NCT04801940, https://heal-covid.net). HEAL-COVID was designed during the COVID-19 pandemic and aimed to reduce site burden by using a decentralised approach to follow up. The outcomes being measured in HEAL-COVID require routine data and Patient Reported Outcomes (PROs). The primary mechanism for collecting PROs is via an app with provision for telephone calls from a central team to accommodate participants who are unable to use this. This SWAT was designed to determine the impact of the frequency of PRO data collection on participant retention in the decentralised trial follow-up. Participants are randomised to their treatment intervention within HEAL-COVID and then to whether their PROs will be collected weekly to week 4 and then monthly, or weekly to week 12 and then monthly.

HEAL-COVID, including this SWAT, is funded by the National Institute for Health and Care Research (NIHR) in the UK and the Cambridge NIHR Biomedical Research Centre.

Interventions and comparators
Intervention 1: PROs collected weekly to week 4 and then monthly
Intervention 2: PROs Collected weekly to week 12 and then monthly

Index Type: Frequency of data collection

Method for allocating to intervention or comparator
Randomisation

Outcome measures
Primary: Response at 12 weeks
Secondary: 1. Sustained non-completion

Other SWAT comparisons (non-randomised):

2) PRO response rate between App and Telephone users, 3) Crossover between data collection systems (App and telephone), and 4) PRO response rate between active treatment and standard care groups in HEAL-COVID.

Analysis plans
All participants randomised in the main HEAL-COVID trial who are willing to complete the questionnaires will be eligible to participate in this SWAT. All assessments and follow-up of PROs are to be conducted in line with the Schedule of Assessments as described in the HEAL-COVID protocol. A full and detailed statistical analysis plan has been developed and all applicable statistical tests will be two-sided and performed using a 5% significance level with 95% confidence intervals (CIs) presented.

Completion rates of each PRO by participants who have fully completed, partially completed and not attempted the PRO, both overall and split by timepoint will be presented.

A comparison will be made between the demographics of responders and non-responders. Age, sex, ethnicity, recruitment nation, patient preference at randomisation in terms of PROs completion and language of questionnaires will be presented.

All outcomes, excluding sustained non-completion, will be analysed and presented as relative risks with 95% CIs. Full or partial response at 12 weeks will be considered as a 'response' with a sensitivity analysis to consider the robustness of conclusions to this definition.

Sustained non-completion defined as complete absence of completion of questionnaires in two consecutive time points will be analysed using competing risks with death or withdrawal identified as competing risks.

Possible problems in implementing this SWAT
Participants in HEAL-COVID are randomised in hospital and provided with support in onboarding to the app. Participants may decide not to engage with the data collection at home or may switch from the preferred data collection method at a later time point (e.g. move from collection by telephone calls to app). HEAL-COVID includes a standard care treatment group in which no active treatment is provided and because allocation to this trial group may impact engagement with the PRO data collection, this is being considered within a non-randomised secondary SWAT outcome.

References

Publications or presentations of this SWAT design

Examples of the implementation of this SWAT

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Date of idea: 1/NOV/2020
Revisions made by:
Date of revisions: