SWAT 209: Views and experiences of participants and healthcare professionals to recruitment, randomisation and other features of the IIH Intervention Trial

Objective of this SWAT
To identify ways to facilitate the achievement of the recruitment target of the IIH host trial: (1) for patients eligible to participate in the IIH Intervention trial, to explore their views and experiences of: recruitment approach, randomisation, barriers and facilitators to participation, and acceptability of treatment allocations; and (2) for healthcare professionals (HCP), to explore their views and experiences of recruitment, randomisation, including perceived barriers and facilitators, equipoise, appropriateness and acceptability of treatment allocations, and perceptions of trial processes.

Study area: Recruitment
Sample type: Participants, Healthcare Professionals, Patients
Estimated funding level needed: Low

Background
There is a need to develop and rigorously evaluate strategies for improving recruitment into trials by embedding these processes in host trials. A qualitative evaluation will be conducted as a Study Within A Trial (SWAT) within the first 10 months of recruitment to the IIH Intervention Trial (ISRCTN57142415) to explore in depth the feasibility, acceptability, and appropriateness of the trial processes for participants and healthcare professionals. This evaluation will also help in the development of optimal recruitment strategies.

This pragmatic qualitative evaluation is aligned with the Medical Research Council (MRC) framework for evaluation of complex interventions: (1) Data collection will continue until the research team judges that the data and sample have sufficient depth and breadth to address the SWAT objectives. (2) Based on predictions that within the first 10 months of the host trial, 60 patients will be screened with a conversion to recruitment rate of 50% (30 patients recruited), it is anticipated that having the SWAT open for 10 months will generate an acceptable number of responses; but, if data saturation occurs earlier, the Trial Management Group (TMG) may decide to close the SWAT early. A dynamic approach will be used to facilitate real time feedback to the IIH Intervention Trial TMG to identify potential trial and trial process issues (e.g. with recruitment) so that these can be addressed rapidly, thus increasing the likelihood of successfully meeting the recruitment target of the host trial (138 participants). Results will also be provided to the IIH Intervention Trial's Trial Steering Committee (TSC) to inform their discussion and subsequent recommendations to the TMG, National Institute of Health and Care Research Health Technology Assessment (NIHR HTA) programme (funder) and study sponsor (University of Birmingham, UK).

Interventions and comparators
Intervention 1: Information will be collected using an online survey/questionnaire (REDCap), via an individual email invitation link.

Index Type: Questionnaire Format

Method for allocating to intervention or comparator
Non-Random

Outcome measures
Primary: Prioritised lists of the barriers for participating in the trial (patient perspective) and reasons for participating to the trial (patient perspective).
Secondary: Prioritised lists of HCP perceived barriers and perceived facilitators, focused on equipoise, appropriateness and acceptability of treatment, suitability of patient-facing documentation and perceptions of trial consent processes

Analysis plans
Surveys will be open-ended and free text. Therefore, following survey completion and before formal analysis by the statistician of the host trial, a suitably qualified member of the trial management team (or their delegate) will perform content analysis of the answers to all surveys to

identify and generate a list per patient/HCP of recruitment/randomisation barriers and facilitators, and acceptability of treatment allocations. This will then allow the qualitative answers from the questions to the survey to be analysed in a quantitative manner by the trial's statistician. These lists will then be passed to the trial statistician for quantitative analyses and generation of prioritised lists.

All analysis will be exploratory and no comparison between populations will be sought.

Binary and categorical variables will be presented as success rates (presented as n/N where n is the number of success and N is the total evaluable sample size) and percentage. The prioritised lists will be generated based on the observed frequency of factors mentioned during interview (i.e. those mentioned more often will be deemed to be more important and so placed higher, with the factor of highest importance being that mentioned most frequently). Where there are ties in the observed frequency of reporting, these factors will be judged to be of equal importance.

Analysis will take place and conclusions relayed iteratively to facilitate alterations to the host trial.

Possible problems in implementing this SWAT
None anticipated.

References

Publications or presentations of this SWAT design

Examples of the implementation of this SWAT

People to show as the source of this idea: IIH Intervention Trial Management Group
Contact email address: IIHintervention@trials@bham.ac.uk
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Revisions made by: N/A
Date of revisions: