SWAT 139: A qualitative investigation of reasoning behind decisions to decline participation in a clinical trial

Objective of this SWAT
To explore the decisions of individuals to decline participation in a clinical trial of a therapy related to their chronic illness.

Study area: Recruitment
Sample type: Decliners to participation
Estimated funding level needed:

Background
Enhancement of recruitment strategies has become an important goal of research design, given that the process of participant recruitment – according to extant methodologies – can be a challenging process (1, 2). In order to develop novel, efficient ways of recruiting participants to research trials, better understanding of potential participants' decision-making regarding participation is necessary. However, this is often overlooked and there is little research evaluating the reasoning behind refusal to participate in research and randomised trials in particular (3, 4). Thus, this SWAT explores individuals' decisions to decline participation in a clinical trial of a therapy related to their chronic illness: the COB-MS trial for people with multiple sclerosis, ISRCTN11462710 (5). It also seeks an understanding of using those engaged in the Patient and Public Involvement (PPI) aspects of the trial in the analyses of these data.

Interventions and comparators
Intervention 1: Individuals who declined participation in the host trial

Index Type: Method of Recruitment, Method of Invitation, Participant Information

Method for allocating to intervention or comparator
Non-random

Outcome measures
Primary: (1) Reasons behind the decision to not participate; (2) potential barriers and enablers for participation; and (3) potential for development of strategies for enhancing the conduct of future trials (in particular in relation to recruitment)
Secondary: An understanding of the feasibility of using PPI in the analysis of these data.

Analysis plans
Seven semi-structured interviews will be conducted with decliners to investigate their reasoning for deciding not to participate in the host trial. A focus group will be conducted with the host trial's PPI panel to review interview findings and further elaborate on emerging concepts and themes. Data will be analysed thematically (6), through an iterative, recursive process; characterised by continual re-reading of the data, data coding and thematic identification (e.g. development of categories/themes and hierarchical ordering). Coding and analysis will be supported by NVivo software.

Possible problems in implementing this SWAT
Due to the measures associated with the COVID-19 pandemic (e.g. the need to conduct the SWAT interviews by telephone and the focus groups online), recruitment and subsequent connectivity issues might be problematic.

References
1. Huang GD, Bull J, Johnston McKee K, et al. Clinical trials recruitment planning: A proposed framework from the Clinical Trials Transformation Initiative. Contemporary Clinical Trials 2018;66:74-9.
2. Hughes-Morley A, Young B, Hempel RJ, et al. What can we learn from trial decliners about improving recruitment? Qualitative study. Trials 2016;17:494.

3. Barnes M, Wiles N, Morrison J, et al. Exploring patients' reasons for declining contact in a cognitive behavioural therapy randomised controlled trial in primary care. British Journal of General Practice 2012;62(598):e371-7.
4. Canvin K, Jacoby A. Duty, desire or indifference? A qualitative study of patient decisions about recruitment to an epilepsy treatment trial. Trials 2006;7(1):32.
5. Dwyer CP, Alvarez-Iglesias A, Joyce R, et al. Evaluating the feasibility and preliminary efficacy of a Cognitive Occupation-Based programme for people with Multiple Sclerosis (COB-MS): protocol for a feasibility cluster-randomised controlled trial. Trials 2020;21(1):269.
6. Braun V, Clarke V. Using thematic analysis in psychology. Qualitative Research in Psychology 2006;3(2):77-101.

Publications or presentations of this SWAT design

Examples of the implementation of this SWAT

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