SWAT 124: Exploring the impact of ineligibility on individuals expressing interest in a trial aimed at improving daily functioning regarding perceptions of self, research and likelihood of future participation: A PPI-infused qualitative SWAT

Objective of this SWAT
The objective of this exploratory, qualitative SWAT is to explore and evaluate (1) the impact of ineligibility on patient's perceptions of themselves, the nature of research and likelihood of expressing interest in future research studies; (2) methods for enhancing communication with patients about their ineligibility; (3) strategies for enhancing recruitment in research trials, more broadly; and (4) the feasibility of using patient and public involvement (PPI) in the analysis of the resulting qualitative data.

Study area: Recruitment, Ineligibility,
Sample type: Participants, Patients, Researchers
Estimated funding level needed: Very Low

Background
Although much research has been conducted on ineligibility with respect to recruitment rates, reasons for ineligibility, sample size impact, cohort representativeness and processes for inadvertent randomisation (e.g. 1, 2) various database searches yield no research examining the impact of being deemed ineligible. A better understanding of this phenomenon may enhance the design and implementation of future research, given that being deemed ineligible may have negative impacts on how patients perceive themselves, the nature of research, as well as the likelihood of expressing interest to participate in future research. As this research focuses on patients' experience of being deemed ineligible, the infusion of Patient & Public Involvement (PPI) within the analysis will facilitate more accurate interpretation of the resulting data. The objectives of this SWAT align with guidelines[3] and further aim to inform the currently 'weak' evidence base available for informing routine research trial decisions,[4] such as how best to recruit participants and utilise PPI.[5]

Interventions and comparators
Intervention 1: Cohort of patients ineligible for main trial

Index Type: Method of Recruitment , Participant Information , Other Eligibility criteria

Method for allocating to intervention or comparator
Those deemed ineligible for main trial

Outcome measures
Primary: A qualitative understanding of the (1) impact of ineligibility on patient's perceptions of themselves, research and likelihood of expressing interest in future research studies; (2) potential methods for enhancing dialogue with patients about their ineligibility; (3) potential for development of strategies for enhancing recruitment in research trials, more broadly; and (4) feasibility of using PPI in the analysis of these data.
Secondary: None.

Analysis plans
Twenty semi-structured interviews will be conducted. In light of current ineligibility rates from the host trial (i.e. 28% of 145 thus far) and assuming a 50% rate of consent, purposeful sampling through maximum variation will be used to select 40 individuals, based on reason for ineligibility, location, age, gender and MS type. Data will be analysed thematically through interpretive phenomenological analysis (IPA), given the SWAT's focus on the experience of being deemed ineligible for the main trial. Analysis will be 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). Specifically, a researcher with expertise in qualitative research methodology (who will also conduct the interviews) and a PPI member (i.e. to be trained in IPA) will lead the data analysis, with support from NVivo software. Two participants will then be asked to member-check the analyses, which will allow for confirming trustworthiness of findings

reflecting the experiences of those deemed ineligible. Subsequently, findings will be presented to the host-trial's existing PPI panel for consultation regarding their implications (and further analysis, if necessary). PPI is an effective means of enhancing the likelihood of successful research by involving people with lived experience of a particular condition (i.e. MS) as partners throughout the research process; thus the feasibility of including PPI in data analysis process and its potential benefits on study outcomes will also be explored (e.g. through interview and reflective diary) in conjunction with guidance from PPI Ignite collaboration.

Possible problems in implementing this SWAT

The nature of ineligibility may affect the findings, which may nor may not affect replication in other studies. For example, being ineligible based on not meeting the threshold for cognitive difficulty in the host trial may be construed as positive; whereas being ineligible based on having a comorbid neurological disease might be construed as negative. This potential will be addressed in the reporting of findings.

References

1) Bennette CS, Ramsey SD, McDermott CL, et al. Predicting low accrual in the National Cancer Institute's cooperative group clinical trials. JNCI: Journal of the National Cancer Institute 2012; 108(2): pii: djv324.
2) 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.
3) Treweek S, Bevan S, Bower P, et al. Trial Forge Guidance 2: how to decide if a further Study Within A Trial (SWAT) is needed. Trials 2020; 21(1): 1-9.
4) Goldsmith LP, Morshead R, McWilliam C, et al. Co-producing Randomized Controlled Trials: How Do We Work Together? Frontiers: Public Participation in Health Care: Exploring the Co-Production of Knowledge. Frontiers in Sociology 2020. doi.org/10.3389/fsoc.2019.00021.
5) Boivin A, L'Espérance A, Gauvin FP, et al. Patient and public engagement in research and health system decision making: A systematic review of evaluation tools. Health Expectations 2018; 21(6): 1075-84.

Publications or presentations of this SWAT design

Examples of the implementation of this SWAT

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Date of idea: 16/JAN/2020
Revisions made by: N/A
Date of revisions: