SWAT 132: Patient Support Group for Research (PURPOSE)

Objective of this SWAT
To determine the effects of using patient support groups to support recruitment and retention for a clinical trial

Study area: Recruitment, Retention
Sample type: Participants
Estimated funding level needed: Low

Background
Recruitment rates for clinical trials can be poor and many patients who are keen to be involved in clinical trials are denied the opportunity to participate because they are not informed about the research.

Furthermore, patients are keen to ensure that clinical trials are delivered quickly so that clinical research questions can be answered and they are generally supportive of research. Patients support groups often have a remit of promoting and supporting research.

Action for Pulmonary Fibrosis (APF) is the UK national Interstitial Lung Disease (ILD) charity with a remit to support patient support groups, give patients a voice, raise awareness of ILD and support research. There are nearly 50 ILD patient support groups in the UK and all specialist centres potentially involved with the NIHR-funded TIPAL trial of the addition of lansoprazole to the treatment of patients with idiopathic pulmonary fibrosis (ISRCTN13526307) have an affiliated support group. ILD patient support groups meet every 2 to 4 months, with interim mailing of newsletters. The groups are attended by between 20 and 60 patients or relatives.

This SWAT (called PURPOSE) will be a cluster-randomised pilot trial of patient-facilitated research awareness involving APF support groups linked with a NHS Trust that has confirmed interest in both the TIPAL trial and this PURPOSE study. These are referred to as TIPAL sites below.

Interventions and comparators
Intervention 1: Each intervention site will self-elect a patient research champion or champion team, who would lead the intervention (a study-specific research awareness campaign). APF will train the champions and support them with information and details about research. The intervention is likely to include activities such as discussion about research within the group, provision of generic and study-specific information about TIPAL, writing and dissemination of newsletters, and provision of links to web-based information videos (see below) in collaboration with the group secretary. The champion will be able to have informal discussions with members of the group during the meetings and involve feeder groups at local district general hospitals. We anticipate that this intervention will work by empowering people to support research, educating patients about research and introducing some degree of competition between centres. This “patient-facilitated recruitment” will be undertaken in addition to a “standard recruitment approach”.
Intervention 2: At the control sites, local PIs are able to discuss research with groups as standard practice but there will be no formal method of enhancing recruitment through sites.

Index Type: Method of Recruitment

Method for allocating to intervention or comparator
Cluster Randomised by Trust

Outcome measures
Primary: Difference in the number of TIPAL trial participants between the SWAT intervention and control sites (obtained from the main trial screening log) and difference in the numbers of TIPAL participants who withdraw from the clinical trial in the SWAT intervention and control sites (obtained from the main trial database).
Secondary: Number of self-reported self-referrals to participate in TIPAL (obtained from the main trial screening log); total contact hours of champions with participants (measured by an exit questionnaire sent to the champions); attendance of champions at training meeting and monthly teleconference (recorded during the events); difference in the completeness of the primary

endpoint in TIPAL participants between the SWAT intervention and control sites (obtained from the TIPAL database); perceived change in APF support group members' general knowledge and enthusiasm about research (measured by an exit questionnaire sent to all members of all APF support group involved in the PURPOSE study).

Analysis plans
The analysis will be based on the intention-to-treat principle but, because this SWAT is a cluster trial, a mixed model will be used. For the outcome measures that are counts, a Poisson mixed model will be used adjusting for the stratification factors an offset of the size of the hospital will be used. The choice of offset is to control for the different sizes of hospitals in the study, the assumption being that the recruitment rate should depend on the size of the hospitals, with large hospitals recruiting greater number of patients.

Possible problems in implementing this SWAT
The initial design included face-to-face patient support groups of a vulnerable population. Since funding for the main trial was confirmed, the COVID-19 pandemic has led to the widespread cancellation of patient support groups. The intervention therefore has been changed to reflect the change to virtual support groups.

References

Publications or presentations of this SWAT design

Examples of the implementation of this SWAT

People to show as the source of this idea: Matt Hammond
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Date of idea: 1/SEP/2019
Revisions made by:
Date of revisions: