SWAT 238: Does the implementation of a central study team improve recruitment in a primary care, data enabled randomised trial for children with asthma?

Objective of this SWAT
To assess the effects on recruitment of (1) implementing a central study team to assist with study tasks, and (2) the use of an expression of interest form and remote consent options (telephone and electronic consent) in a trial of childhood asthma.

Additional SWAT Details
Primary Study Area: Recruitment
Secondary Study Area: Barriers and facilitators; Incentives and engagement; Sites and staff; PPI
Who does the SWAT intervention target: Healthcare Professionals; Patients
Estimated resources needed to conduct the SWAT: Low
Estimated cost of the SWAT (£): 5000 £14,500

Findings from Implementation of this SWAT
Reference(s) to publications of these findings:
Primary Outcome Findings:
Cost:

Background
Incorporating the use of routinely collected data in randomised trials has been theorised to have several benefits such as improving feasibility by reducing costs through more efficient resource use, widening research scope by making questions previously not amenable to trials more answerable, and enabling novel trial design methods. Whilst data-enabled trials have the potential to address challenges commonly faced in the conduct of paediatric research, in particular the identification, recruitment, and follow-up of participants, an understanding of the barriers and facilitators of using routinely collected data from the perspective of trial sites is crucial.

ASYMPTOMATIC (ISRCTN70543802) is the first primary care data-enabled randomised trial for childhood asthma (https://asymptomatic-trial.org.uk). In this study, Central Practice Research Datalink provides sites with lists of pre-screened patients. These lists are screened by practices and eligible patients are invited to the study. Consent discussions take place by telephone or in-person and written consent is collected for participants. Challenges in screening and recruitment include variable resources between sites, such as practice staff and Research Development Network (RDN) support, and the fact it a longer time commitment is needed to complete trial tasks than was initially anticipated.

Recruitment information from the ASYMPTOMATIC trial will be used to assess the impact on recruitment of the two interventions investigated in this Study Within a Trial (SWAT). The information will include the number of participants screened, invited, and enrolled at each site. Site support from the central team will be documented on a site-by-site basis. We will seek information from sites about their experiences and barriers and facilitators to recruitment. We will do this using an electronic survey delivered online to all study personnel listed on a site delegation log. The survey will include questions about ease of protocol implementation, ease of access to central study support, perceived barriers or facilitators to successful recruitment, and overall satisfaction with participation as a trial site. Categorical data will be summarised using frequencies and percentages. Free text responses will be reviewed and thematically coded. The categorical responses and themes identified from free text responses will be used to inform an interview topic guide. We will seek consent from respondents for an optional follow-up qualitative interview and use the topic guide to further explore themes identified from the survey. Interviews will be transcribed and thematically analysed.

Host Trial Population: Children
Host Trial Condition Area: Respiratory Conditions

Interventions and Comparators
Intervention 1: Implementation of a central study team for support with trial tasks (screening patient lists, follow up contact and consent discussions). The start of this will be defined as the date an honorary contract is signed with a site.
Intervention 2: Lack of a central study team to support trial tasks (covering the period from the opening of a site and the date an honorary contract is signed with the site).
Intervention 3: Implementation of an expression of interest form and remote consent options (telephone and e-consent), defined as the date sites were provided with the substantial amendment approving these changes.
Intervention 4: Lack of an expression of interest form and remote consent options (telephone and e-consent) covering the period from the opening of a site to the date that sites were provided with the substantial amendment approving these changes.

Method for Allocating to Intervention or Comparator:
Before and after.

Outcome Measures
Primary Outcomes: Recruitment rate per open site per month, overall and split according to time period (before/after SWAT intervention) and whether sites received help from the central team.
Secondary Outcomes: Consent mode preference, site/RDN satisfaction with trial participation, and their perspective on barriers and facilitators to trial participation.

Analysis Plans
Recruitment rates will be summarised using descriptive statistics, with 95% confidence intervals (CI) provided. The following comparisons will be made, showing differences in recruitment rates and 95% CI:
Recruitment rates before/after intervention, using the average recruitment rate per open site per month;
Central team supported versus unsupported sites in the post-intervention period will be compared, using the average recruitment rate per open site per month.

These comparisons will be interpreted in light of the fact that multiple recruitment-focused interventions introduced simultaneously. As such, it will not be possible to formally distinguish the impact of each intervention using the recruitment rates. However, exploratory analyses will compare the experiences (as reported qualitatively in the survey) of central team supported versus unsupported sites, as well as the feedback regarding the impact of the various interventions (e-consent and RDN support) on sites. Furthermore, given that the cohorts being compared are not randomised, there may be confounding (e.g. in terms of the impact of changes over time generally, when comparing recruitment rates before/after the SWAT intervention; and the impact of differences in site characteristics between those that are central team supported or unsupported sites).

We will use inductive thematic analysis to identify themes in free text responses to the survey. This will include categorisation of responses into “recruitment barriers”, “recruitment facilitators” and “other aspects of trial conduct”. Comments will be coded and grouped into sub-themes before being grouped into over-arching themes. The frequency of codes will be measured.

Possible Problems in Implementing This SWAT
Reliance on engagement from GPs. Response bias (i.e. only sites performing well might complete the survey or consent to take part in interviews). Other contemporaneous changes, such as the introduction of an unconditional voucher incentive for patient reported outcome completion, and webinars for open sites.

References Cited in This Outline

References to This SWAT

Source of This SWAT

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