

# SWAT 98: Delivering site set-up training to groups of sites versus individually

## Objective of this SWAT

To compare group-based training during the set-up of a trial versus visiting the site to conduct a Site Initiation Visit (SIV) to investigate the impact of the training method upon key site performance metrics.

Study area: Recruitment, Retention, Data Quality

Sample type: Healthcare Professionals, Researchers

Estimated funding level needed: Low

## Background

At the start of a trial, Site Initiation Visits (SIV) are often conducted to deliver training to the Principal Investigator and their local research team to open the site to recruitment. The time required to visit all sites, particularly for large trials, can be burdensome during the resource intensive period of trial set-up. However, there is currently little evidence about the best way to deliver trial training to sites for sites to perform well. Evaluating methods of training was the top priority identified by trialists at a workshop looking at recruitment and retention of participants to trials [1]. Two systematic reviews have been undertaken investigating training in clinical trials. The first showed there are a variety of different training methods described in trials [2] and the second concluded that more research is needed to determine what kind of training and support can improve recruitment [3]. A small study which retrospectively reviewed recruitment data and data completeness collected for two trials showed that, whilst face-to-face training (either at SIV or by a group training session) was associated with better recruitment than remote training (i.e. telephone or DVD), no difference was seen between the two types of face-to-face training [4].

## Interventions and comparators

Intervention 1: Group-based training, by conducting collaborators' meetings, followed by a "take-away" training package (e.g. DVD). We plan on holding two collaborators' meetings to allow for non-availability of site staff.

Intervention 2: Site Initiation Visit training. All sites randomised to the control group will be trained on a per-site basis by the trial manager and neonatologist.

Index Type: Training method

## Method for allocating to intervention or comparator

Randomisation

## Outcome measures

Primary: We will use relevant outcome measures developed through a Delphi-consensus building study [5]. The primary outcome will be: actual recruitment versus target recruitment (i.e. the difference between actual recruitment rates and target treatment rates expressed as a percentage), at the end of the trial.

Secondary: Percentage of randomised participants with a query for primary outcome data; percentage of expected participants with complete data for primary (length of hospital stay) and important secondary outcomes of the host trial necrotising enterocolitis (NEC) and late-onset sepsis (LOS); percentage of randomised participants with at least one protocol violation.

## Analysis plans

Descriptive statistics will be used to summarise the outcome data and key baseline measures by randomised groups. Analysis of the primary outcome measure will use a linear mixed model to compare the between group differences in outcome over time. The model will be adjusted for the level of experience of the site PI and the total number of births within the site at 30+0 to 32+6 weeks gestation per month (as stated in the Site Selection Questionnaire, completed by the site). For the secondary outcomes, the between group differences will be determined using Beta regression models (or fractional response model if appropriate), adjusting for the same covariates as primary analysis. Estimates of treatment effects will be presented with the associated 95% CI.

## **Possible problems in implementing this SWAT**

We anticipate some challenges in implementing this SWAT:

1. Organising the two group meetings (intervention arm) to ensure they are held at a time-point that is relevant to all the sites randomised to these arms may be logistically challenging, although clear communication with the sites should prevent this from being a major problem.
2. Poor attendance at group-based meetings – we will ensure that during the trial set-up period, sites will be made aware of the SWAT and that they may be randomised to the intervention arm, which will result in them needing to travel to a group meeting. We will reduce the risk of poor attendance by ensuring clear communication with the Principal Investigator and site team and, in particular, giving them ample notice in order to make arrangements.

## **References**

1. Bower P, Brueton V, Gamble C, et al. Interventions to improve recruitment and retention in clinical trials: a survey and workshop to assess current practice and future priorities. *Trials* 2014; 15:399.
2. Gravani A, Nicolson A, Lane A, et al. Training of staff within randomised controlled trials (RCTS) of healthcare interventions: a systematic review of the literature. *Trials* 2015;16(suppl2):P186.
3. Townsend D, Mills N, Savovic J, et al. A systematic review of training programmers for recruiters to randomised controlled trials. *Trials* 2015;16:432
4. Mitchell EJ, Duley L, Williams H, et al. Impact of training for site staff recruiting into trials of rare skin diseases: experiences from stop gap and blister. *Trials* 1013;14(suppl1):P134.
5. Whitham D, Turzanski J, Montgomery A et al. Development of a standardised set of metrics for monitoring site performance in multicentre randomised trials: a Delphi study. *Trials* 2018;19:557

## **Publications or presentations of this SWAT design**

## **Examples of the implementation of this SWAT**

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