Delivering site set-up training to groups of sites versus individually: a randomised study within a trial

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Background

Site initiation visits (SIVs) 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. 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 number one 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].

We have embedded a Study Within a Trial (SWAT) into the FEED1 Trial, which is comparing feeding methods in preterm infants. The objective of the SWAT is 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. If group-based training is shown to be effective, there could be significant benefits to funders and trial teams, in particular in reducing the length of time it takes to set-up a trial and open all sites.

SWAT design

Population
All sites involved in the FEED1 Trial

Intervention
Group-based training, by conducting collaborators' meetings, followed by a "take-away" training package

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

Outcomes*
- Actual recruitment versus target recruitment
- Percentage of eligible individuals (women) who have consented
- Percentage of infants with queries for primary outcome data
- Percentage of expected infants with complete data for primary outcome and clinically most important secondary outcomes
- Percentage of infants with at least one protocol violation
- Associated costs (direct and in-direct) of delivering the training

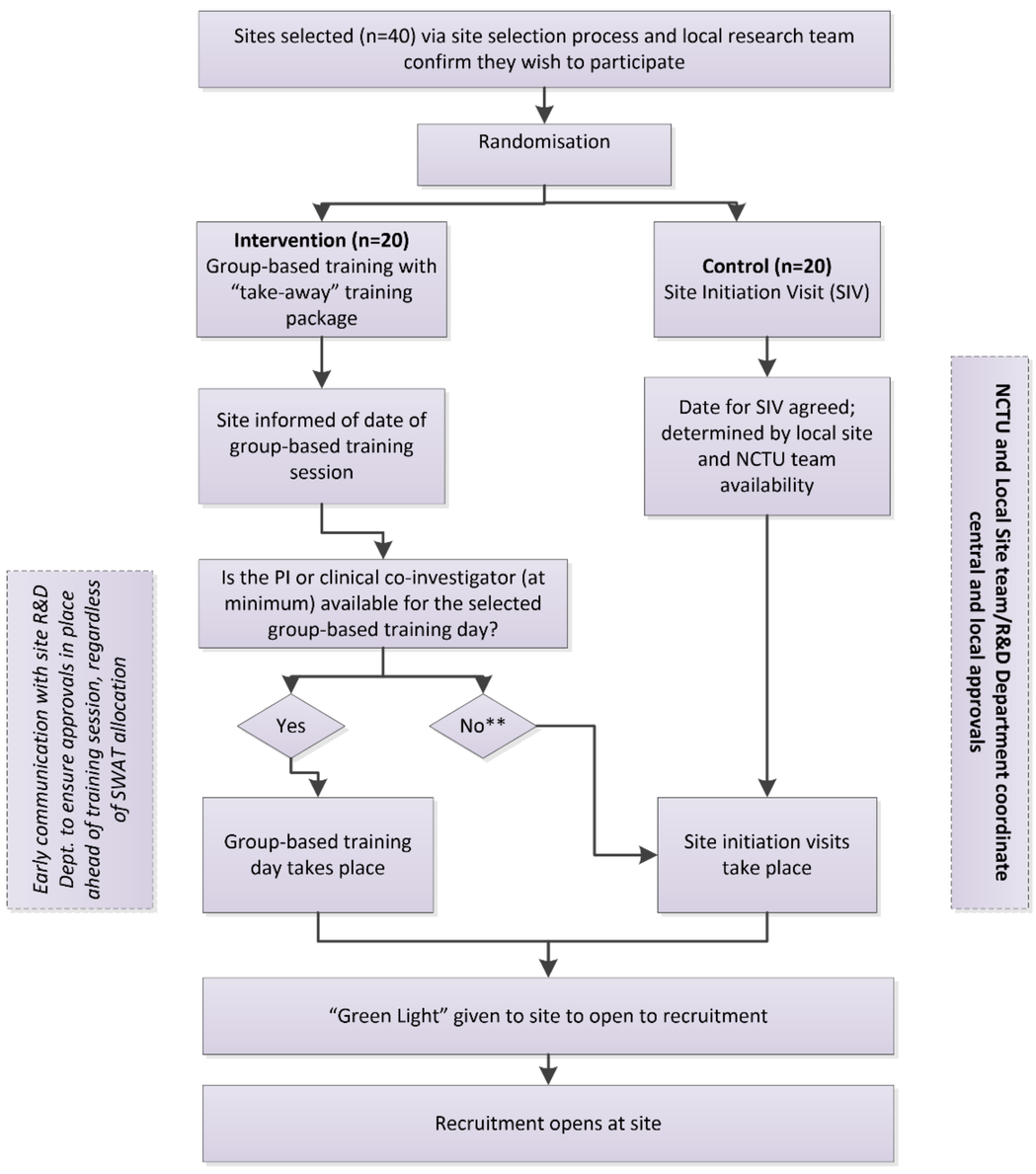
(outcomes assessed at the end of the trial)

We will also explore the views of site staff on training methods by asking them to complete an evaluation form after their training visit

* Outcomes as per key site performance metrics[5]

Methods

FEED1 SWAT Flow Diagram



* if possible, all sites will be randomised in the SWAT following the site selection process. If not possible, two batch randomisations will take place

** every effort will be made to ensure the site is able to attend the group-based training day. If this is not possible for the PI, the site will then have a site initiation visit, organised at a time suitable for the PI and research team. Data will be analysed according to the ITT principle.

Trial status

The FEED1 Trial will open to recruitment in autumn 2019. The results of the clinical trial and embedded SWAT will be available in early 2023.

References

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