

SWAT 134: Impact of an enhanced education and training package on protocol adherence and staff confidence

Objective of this SWAT

To evaluate the impact of an additional training package on top of a standard site initiation visit on protocol adherence and staff confidence in recruitment, consent procedures and trial delivery within the Oxy-PICU study.

Study area: Recruitment, Randomisation

Sample type: Healthcare Professionals

Estimated funding level needed: Medium

Background

We recently completed the NIHR-funded FEVER Feasibility Study (HTA Project: 15/44/01) [1]. Results from the mixed-methods integrated perspective part of this study (which sought site staff views on the study procedures) revealed that site staff who received study training from the Chief Investigator (CI) felt more prepared for recruitment and consent procedures, and had greater 'buy-in' to both the trial protocol and intervention, which ultimately may have impacted on adherence to the study protocol and procedures. Consequently, reviewers identified the need to explore good practice education and training modules to promote engagement with research and protocol adherence as a future research recommendation in line with the findings of this project.

Therefore, we propose to conduct this SWAT within the Oxy-PICU trial (ISRCTN92103439) to evaluate the impact of an enhanced education and training package on protocol adherence and staff confidence in recruitment and consent procedures. We will randomise sites at a cluster level (1:1) to intervention (site initiation training plus education and training package) or control (site initiation training and materials alone). Intervention sites will receive an enhanced training and education package in addition to a site initiation visit conducted by the CI, while control sites will receive a site initiation visit alone.

Interventions and comparators

Intervention 1: Clinical teams will be given an education and training package in addition to a standard site initiation visit.

Intervention 2: Standard site initiation visit alone.

Index Type: Staff training

Method for allocating to intervention or comparator

Randomisation

Outcome measures

Primary: Change in rates of protocol adherence in intervention group compared to control group; change in levels of staff confidence with recruitment and consent procedures in intervention group compared to control group (measured by questionnaire)

Secondary:

Analysis plans

Analysis will compare protocol adherence and staff confidence in recruitment and consent procedures between intervention group sites and control group sites.

Possible problems in implementing this SWAT

Additional education and training package must be created and delivered consistently across all intervention group sites.

References

1. Peters MJ, Khan I, Woolfall K, Deja E, Mouncey PR, Wulff J, et al. Different temperature thresholds for antipyretic intervention in critically ill children with fever due to infection: the FEVER feasibility RCT. *Health Technology Assessment* 2019;23(5). doi: 10.3310/hta23050

Publications or presentations of this SWAT design

Examples of the implementation of this SWAT

People to show as the source of this idea: Paul Mouncey

Contact email address: oxypicu@icnarc.org

Date of idea: 1/SEP/2019

Revisions made by: Daisy Wiley, Doug Gould, Sam Peters

Date of revisions: 1/NOV/2019