SWAT 67: Effects of an enhanced trainee Principal Investigator package and digital nudging on monthly recruitment rates

Objective of this SWAT
The primary objective of this SWAT is to assess the effects of an enhanced trainee principal investigator (TPI) package, a digital nudge, and a combined intervention on the rate of recruitment to a randomised trial. Secondary objectives include comparing the conversion rate to recruitment from the proportion of those found to be eligible on screening across the intervention groups; gaining feedback on the trainee perspective of the TPI role via a survey; determining the time needed to conduct the 1:1 educational training session for TPIs; and determining the required time and method of additional contact for peer support of the TPIs. We will also determine the feasibility of delivering both interventions in the setting of a large-scale randomised trial.

Study area: Recruitment
Sample type: Healthcare professionals
Estimated funding level needed: Low

Background
Recruitment remains one of the major challenges for randomised trials and researchers have tried many different ways to overcome the problems of slow recruitment [1]. This SWAT will test two different approaches in a factorial, cluster randomised design: introducing an enhanced trainee principal investigator's package and email digital nudges to healthcare professionals involved in the trial. The SWAT will be implemented in the WHiTE 8 COPAL trial, which is a large multicentre trial in orthopaedics starting in 2018 (www.octru.ox.ac.uk/trials/trials-in-set-up/WHiTE-8-COPAL). The interventions have both been used in current orthopaedic trials, but their effects on recruitment have not been investigated.

Interventions and comparators
Intervention 1: Deliver an enhanced TPI package (induction & training, trial education, peer support)
Intervention 2: Use of a personalised, timely email nudge to express gratitude and encourage further recruitment to each successful healthcare recruiter
Intervention 3: Deliver an enhanced TPI intervention (induction, trial education, peer support) and use of a personalised, timely email nudge to express gratitude and encourage further recruitment to each successful healthcare recruiter
Intervention 4: Usual practice without TPI education package or nudge (comparator)

Index Type: Recruitment, Monitoring

Method for allocating to intervention or comparator
Randomisation

Outcome measures
Primary: Total number of patients recruited in 6 months to the WHiTE 8 COPAL trial.
Secondary: Conversion rate from screened population, collected monthly from the central Oxford database (coordinated by the Oxford Clinical Trials Research Unit, OCTRU).
The trainee perspective of their role will be collected through the TPI survey in the last 2 weeks of the SWAT period. The research fellow will keep a time log for delivering the TPI education intervention and a log of communication for peer support during the period of the SWAT

Analysis plans
Analysis will be conducted on an intention to treat basis including all sites in the group they were originally allocated to regardless of deviations based on non-compliance. Statistical significance will be assessed using two-sided statistical tests at the 5% significance level. Baseline data relating to the sites (including the minimisation factors) will be summarised for the four groups, as randomised and as analysed to assess whether possible loss-to-follow-up has introduced selection bias. Continuous data will be presented using descriptive statistics (e.g., mean, standard deviation, median, minimum, maximum), while categorical data will be given as counts and percentages. No formal statistical comparison of baseline data will be undertaken between the four groups.

The number of participants recruited per site will be summarised. A Poisson regression model, containing the two interventions (Enhanced TPI and Digital Nudge) and the minimisation factors (cluster size, and number recruited per month will be included in their continuous form) will be performed. Adjusted incidence rate ratios (IRRs) and associated 95% confidence intervals (CIs) will be obtained from this model. The presence of an interaction between the two interventions will also be tested by including an interaction term in the model.

Feasibility outcomes, such as the time required to run the education intervention and communication time and methods used for the peer support aspect of the intervention, will be reported descriptively.

Possible problems in implementing this SWAT

The fixed number of clusters in the host trial (WHiTE 8 COPAL) is too small to provide sufficient power for this SWAT in that trial alone. However, this first implementation will show if it is feasible to run these interventions in factorial trial and if they could be included as part of a much larger cluster study.

References

1. Treweek S, Pitkethly M, Cook J, et al. Strategies to improve recruitment to randomised trials. Cochrane Database of Systematic Reviews 2018; (2): MR000013.

Publications or presentations of this SWAT design

Examples of the implementation of this SWAT

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Date of idea: 1/OCT/2017
Revisions made by: Nickil Agni
Date of revisions: 19/AUG/2018