SWAT 140: A factorial, cluster randomised trial of an enhanced associate principal investigator (API) training package and an additional digital nudge delivered by a trial coordinator

Objective of this SWAT
The primary objective is to assess the effects of an enhanced API package, a digital nudge, and a combination of the two compared to standard practice API and/or standard email alone on the number of patients recruited to the host trial during the six months that the API is in post at a recruiting site. Secondary objectives include assessing the effects of the enhanced API package, digital nudge, and combination of the two on the number of patients recruited to the host trial over 12 months (six months of the enhanced API training package/standard practice API /digital email nudge/standard email only and six months after this) at a recruiting site; determining the time taken to implement each intervention; comparing the proportion of eligible participants who are recruited; determining the amount of time taken by the trial coordinators to deliver the enhanced API package and describing the methods of additional contact for peer support of the APIs.

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

Background
The challenges of recruitment to randomised trials are well documented [1,2,3]. Many interventions to improve recruitment at sites, such as site champions and incentivising clinicians with non-financial benefits are routinely used but do not have any evidence of their effectiveness [4]. The NIHR supported Associate Principal Investigators (API) scheme aims to integrate clinical research as part of routine clinical training by developing a structure for APIs to work alongside the local Principal Investigator (PI) to gain experience in local leadership of clinical trials, supported by mentors. Several multicentre orthopaedic trials have reported anecdotal success with improved recruitment when using APIs but there are also possible detrimental effects from the use of APIs, such as replacement or dilution of trained research nurses, increased protocol deviations and slower recruitment. In normal practice, an API is recruited and managed locally and by the PI, and an API manual for the trial is provided by the associated Clinical Trials Unit (CTU) with no further education given. We have sought to improve on this by creating an enhanced API training and support package where formal initial education and ongoing support can be used to support the API with a view to enhancing their knowledge and confidence in undertaking their role. We will test this in this SWAT.

The behavioural concept of nudge theory is a way of influencing an individual's behaviour through an intervention without limiting their choice. Digital nudging is used regularly in randomised trials (e.g. emails, recruitment league tables sent to recruiting sites, and encouragement emails), but there is limited evidence on the effects on recruitment. This SWAT will test an additional email communication to recruiting staff following a successful recruitment to a trial incorporating features such as personalisation, appreciation for work done, and praise sent to the recruiter in a timely manner. However, this increases the burden of emails sent to trained research staff who are experienced in recruitment to trials and may have the unintended effect of annoyance and irritation leading to poorer recruitment.

A recent SWAT (SWAT 67) suggests that there is a statistically significant benefit to trial recruitment of an enhanced training and support package for APIs delivered by a surgical trainee, but no evidence of benefit from a digital nudge intervention (Agni et al, in preparation). This led to a recommendation that the intervention be evaluated in a SWAT with a CTU team member delivering the intervention, because this is more likely to be deliverable at scale than delivery by a surgical trainee (Agni et al, in preparation). Therefore, this SWAT is a repeat of SWAT 67 [5], with the intervention being delivered by a Trial Coordinator, in a further surgical randomised trial (SOFFT, ISRCTN87904264). The results will be combined in a meta-analysis increasing the power of the analysis.

Interventions and comparators
Intervention 1: 1) Enhanced API intervention involving: a) Education (1:1 telephone or video conference training by a member of the CTU team to the API covering background to SOFFT, API role and benefits of participating, how to effectively perform the API role, and how to recruit and randomise to SOFFT); b) Support and advice through follow up emails and telephone calls to a member of the CTU team if required for problems related to carrying out the role; and c) Digital supplementary information by email including induction agenda, SOFFT specific API manual (containing information on the roles of a PI and API, method of randomisation, benefits to the trainee of participating in the role, and relevant guidance on mental health and research legislation relevant to recruiting participants, induction summary presentation, SOFFT consent flow diagram and protocol and API contact information consent form). 2) The educational session will be an induction into the API role run by a member of the CTU team. This will be an approximately 40-minute telephone/videoconference session covering all aspects of the role outlined in an agenda emailed to trainees with additional supplementary material one week beforehand. The APIs will be emailed monthly to ask if there are any problems with recruitment that they need support with and a record of these communications will be kept by CTU.
Intervention 2: Digital Nudge email from a member of the CTU team to the site SOFFT team members who routinely receive the standard randomisation notification emails. This email will be sent each time an API recruits a participant to SOFFT (when a copy of a completed consent form signed by the API is received at the CTU).and will include personalisation (site team members' names), encouragement through praise to continue recruiting drawn from a matrix of statements, and statement of appreciation for recruiting a patient to SOFFT. The aim will be to send this email to the site team within 72 hours of the randomisation and, where multiple participants have been recruited in the period (or following a weekend), a single email will be sent referring to the number recruited in the period. This intervention will be implemented alongside the standard practice of a generic notification of randomisation email which will continue to be automatically sent to the site's research team following a randomisation.
Intervention 3: Both the enhanced API package and the digital nudge.
Intervention 4: Usual practice, without the enhanced API package or the digital nudge.

Index Type: Recruitment

Method for allocating to intervention or comparator
Randomisation

Outcome measures
Primary: Total number of patients recruited to SOFFT by a site in the six months that the API is in place (from the SOFFT randomisation database).
Secondary: Total number of patients recruited to SOFFT by a site in the 12 months following the API being in place (from the SOFFT randomisation database); proportion of eligible screened patients recruited to the trial (from the screening logs provided by the sites and number of randomisations recorded at the CTU); estimated cost of implementing the interventions at a site.

Analysis plans
All analysis will be conducted on an ITT (intention to treat) basis where all sites are included in the group they were allocated. 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 groups. The number of participants recruited will be summarised by site, as well as for each arm of the SWAT. A Poisson regression model, containing the two interventions (Enhanced API and Digital Nudge) and the minimisation factors (site size, and number recruited prior to SWAT implementation 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 be tested by re-running this model including an interaction term; this will be assessed at 10% significance level. The total number of recruits will be analysed in a similar way. The proportion of eligible patients recruited will be analysed using a logistic model, adjusting for the same factors as in the primary analysis. 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
To mitigate the problems that might arise if too few APIs join the NIHR API Scheme, we will advertise and promote this through SOFFT.

References
1. Puffer S, Torgerson D, Watson J. Evidence for risk of bias in cluster randomised trials: review of recent trials published in three general medical journals. BMJ 2003;327(7418):785-9.
2. Sully BGO, Julious SA, Nicholl J. A reinvestigation of recruitment to randomised, controlled, multicenter trials: A review of trials funded by two UK funding agencies. Trials 2013;14(1):166.
3. Treweek S, Altman DG, Bower P, et al. Making randomised trials more efficient: report of the first meeting to discuss the Trial Forge platform. Trials 2015;16(1):261.
4. Treweek S, Pitkethly M, Cook J, et al. Strategies to improve recruitment to randomised trials. Cochrane Database of Systematic Reviews 2018;(2):MR000013.
5. Agni N, Fairhurst C, McDaid C, Reed M, Torgerson D. Protocol for a factorial randomised controlled trial, embedded within WHiTE 8 COPAL, of an Enhanced Trainee Principal Investigator Package and Additional Digital Nudge to increase recruitment rates. F1000Res 2019;8:1153.

Publications or presentations of this SWAT design

Examples of the implementation of this SWAT

People to show as the source of this idea: Catriona McDaid, Liz Cook, Sophie James, Zohaib Ahkter, Danielle Podmore, Izzy Coleman
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