SWAT 214: Effect on recruitment of an Enhanced Associate Principal Investigator Training Package and Additional Digital Nudge delivered by a Trial Coordinator

Objective of this SWAT
This Study Within a Trial (SWAT) will use a 2x2 factorial cluster design and be in the FLARE trial (ISRCTN10918157) to evaluate the effects on recruitment in a secondary care setting of two interventions: Enhanced Associate Principal Investigator (API) Training Package; and Digital Nudging. Due to blinding procedures in the FLARE host trial, for the purpose of this SWAT, consent will be used as a measure of recruitment, and only sites with a surgical trainee API will be randomised into the SWAT. Randomisation is at site level.

The primary objective of this SWAT will be to assess the effects of an Enhanced API training package, a digital nudge, and their combination, compared to standard practice API and/or standard consent processes, on the total number of patients who consent to join the FLARE trial in the 6-month period that the API is in post at a recruiting site. Secondary objectives include assessing the effects of an Enhanced API training package, a digital nudge, and a combined intervention on the total number of patients who consent to join the FLARE trial over 12 months (during the 6 months of an API intervention and 6 months after); comparing the proportion of eligible participants who give consent; determining the time spent by Trial Coordinators to deliver the enhanced API training package and to detail 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 nonfinancial 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 trials have reported 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. An API manual for the trial provided by the associated Clinical Trials Unit (CTU) and the API Toolkit developed by the NIHR serve as resources to guide delivery of their role. 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 a 2x2 factorial cluster SWAT, embedded in the FLARE trial.

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 when a patient consents to join the host trial. This email will incorporate features such as personalisation, appreciation for work done, and praise for the person who obtained the consent in a timely manner. However, this increases the burden of emails received by trained research staff who are experienced in recruitment to trials and may have the unintended effect of causing annoyance and irritation, leading to poorer recruitment.

Results from SWAT 67 [5] suggest a 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 [6]. 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 [6]. Therefore, this SWAT is similar to SWAT 67 [5] and SWAT 140 (API SWAT embedded in SOFFT trial), with the intervention being delivered by a Trial Coordinator, in a further surgical randomised trial (FLARE). The results will be combined in a meta-analysis, increasing the power of the analysis.

Details of the Enhanced API training package:
a) 1:1 telephone or videoconference training (approximately 40 minutes) delivered by a member of the CTU team; covering trial background, API role and benefits, overview of effectively performing the API role, and recruitment and randomisation process in the FLARE trial.
b) Support and advice through follow up emails and telephone calls.
c) Provision of digital supplementary material by email including (1) the FLARE specific API manual containing information on the roles of a PI and API, method of consent and randomisation, benefits to the trainee of participating in the API role, and guidance on mental health and research legislation relevant to recruiting participants; and (2) induction summary presentation.

Details of the digital nudge:
A digital nudge email will be sent by a member of the CTU team when an API obtains consent from a participant to join FLARE and will include personalisation (first name of the person obtaining consent), encouragement through praise to continue seeking consent (drawn from a matrix of statements), and appreciation for obtaining the consent of a patient for FLARE. The aim will be to send this email to the API within 72 hours of obtaining informed consent. Where consent has been obtained from more than one participant in the period (or following a weekend), a single email will be sent referring to the total number. This intervention will be implemented alongside the standard process for obtaining and completing informed consent via REDCap, as detailed in the FLARE Trial protocol and Trial Site Manual.

Interventions and comparators
Intervention 1: Standard consent procedures and Enhanced API Intervention
Intervention 2: Standard consent procedures and Digital Nudge intervention and Enhanced API Intervention
Intervention 3: Standard consent procedures and standard practice API
Intervention 4: Standard consent procedures and Digital Nudge Intervention and standard practice API

Index Type: Method of Recruitment

Method for allocating to intervention or comparator
Randomisation

Outcome measures
Primary: Total number of patients who give their consent to join FLARE at a site in the first six months that the surgical trainee API is in place (data collected from REDCap).
Secondary: 1. Total number of patients who give their consent to join FLARE at a site over 12 months (during 6 months of a surgical trainee API intervention and 6 months thereafter).
2. Proportion of eligible patients who give their consent to join FLARE at a site in the first 6 months that the surgical trainee API is in place, and in months 7 to 12 following this (data collected from REDCap).
3. Time taken (in minutes) by the Trial Coordinator to deliver the enhanced API training package and to detail the methods of additional contact for peer support of the surgical trainee APIs.
4. Estimated cost of implementing the SWAT interventions at a site.

Analysis plans
All analyses will be conducted using the intention to treat principle, where all sites are included in their allocated SWAT group. Statistical significance will be assessed using two-sided statistical tests at the 5% significance level. The trial will be reported in accordance with CONSORT guidelines, and a flow diagram will present the progression of sites through the trial.

Baseline data relating to the sites (including the minimisation factors) will be summarised for the four SWAT groups and for the intervention groups (i.e., Enhanced API (interventions 1 + 2),

standard API (3 + 4), digital nudge (2 + 4) and standard practice (1 + 3)). Continuous data will be presented using descriptive statistics (e.g., mean, standard deviation), 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 who provide consent to join the FLARE trial will be summarised overall and for each SWAT group. A Poisson regression model, containing the two interventions (Enhanced API and Digital Nudge) and the minimisation factors (site size, and number of patients recruited before SWAT implementation will be included in their continuous form) will be performed. Adjusted incidence rate ratios and associated 95% confidence intervals will be obtained from this model. The presence of an interaction between the two SWAT interventions will be tested by re-running this model including an interaction term and this will be assessed at the 10% significance level. The total number of patients who give their consent to join the FLARE trial will be analysed in a similar way. The proportion of eligible patients who give their consent 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.

If possible, an individual participant data meta-analysis will combine the results of this SWAT with the results of the previous SWAT.

Possible problems in implementing this SWAT
To mitigate the problems that might arise if too few APIs join the NIHR API Scheme for the FLARE trial, we will advertise and promote this at the time of initial site set up, at investigators' and research team meetings, and in site newsletters.

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;14:166.
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;16:261.
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, et al. 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. F1000Research 2019;8:1153.
6. Agni NR, Fairhurst C, McDaid C, et al. EnTraP: A factorial randomised controlled trial embedded within world hip trauma evaluation eight COPAL investigating the effect of an enhanced trainee principal investigator package and digital nudge on recruitment rates. Research Methods in Medicine & Health Sciences 2022;3(2):33-41.

Publications or presentations of this SWAT design

Examples of the implementation of this SWAT

People to show as the source of this idea: Joy Adamson, Liz Cook, Michelle Watson, Emma Moatt, Kalpita Baird, Fraser Wiggins
Contact email address: michelle.watson@york.ac.uk
Date of idea: 8/APR/2022
Revisions made by:
Date of revisions: