EnTraP: A Factorial Randomised Controlled Trial embedded within WHiTE 8 COPAL investigating the effect of an **En**hanced **Tra**inee **P**rincipal Investigator Package and Digital Nudge on recruitment rates.

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**ABSTRACT**

**Background**

Studies evaluating interventions to improve recruitment aimed at recruiters to the trial are limited. The primary aim was to evaluate the effectiveness of an educational intervention to Trainee Principal Investigators (TPI) and a positive reinforcement intervention via a digital nudge on recruitment to the WHiTE 8 COPAL trial.

**Design**

This was a multicentre, open, cluster, 2x2 factorial RCT embedded in the WHiTE 8 COPAL RCT, in which research sites were randomised 1:1:1:1 to receive the enhanced TPI package, the digital nudge intervention, both, or neither.

**Results**

1215 patients were recruited to the WHiTE 8 COPAL trial across 20 sites between August 2018 and March 2019. There was a statistically significant interaction between the interventions (IRR 2.09, 95% CI 1.64 to 2.68, p < 0.001). There was a statistically significant benefit on recruitment (IRR 1.23 95% 1.09 to 1.40, p=0.001) from utilizing an enhanced TPI education intervention. The digital nudge intervention had no significant impact on recruitment (IRR 0.89 95% CI 0.79 to 1.01, p=0.07). Within enhanced TPI package sites, the digital nudge had a beneficial effect, while in the standard practice TPI sites it had a detrimental effect.

**Discussion**

An enhanced TPI package involving an education and support programme was effective in increasing recruitment in the first six months of trial commencement. There was no evidence for the effectiveness of the digital nudge intervention in isolation, though our results show that when combined with an education programme it leads to enhanced effectiveness of that programme.

**Background**

Randomised controlled trials (RCTs) are considered the gold standard when evaluating the efficacy and effectiveness of health care interventions. There are an increasing number of UK pragmatic orthopaedic RCTs being conducted investigating treatment options with the aim of determining the most effective and cost-efficient choice for patients and the National Health Service (NHS) respectively.(1–4)

In contrast, there is still only a limited evidence base regarding optimal trial design and trial processes. One method of increasing the evidence base is by embedding a self-contained study in a host trial for the purpose of evaluating or creating new methods of conducting trial processes. This embedded methodology is known as a “study within a trial” (SWAT).(5,6)

RCTs often struggle with various aspects of participant recruitment, including engaging clinicians to get involved effectively in recruitment, and subsequently fail to reach their target sample size. Many trials are forced to extend trial timelines or, due to insufficient funding, either revise their sample size downwards or close trials prematurely.(7–11) Improving recruitment to RCTs is therefore a significant area for efficiency gains. Randomised and quasi-randomised trials that have targeted methods of improving recruitment to RCTs have been evaluated in a Cochrane systematic review.(12) There were limited studies of interventions directed towards healthcare professionals and other persons involved in recruiting participants to clinical trials, thus highlighting a need to evaluate strategies directed towards this cohort.

Clinical trials often recruit participants from multiple research sites. Whilst the trial is overseen by a single (or occasionally two) Chief Investigator (CI), each site has a delegated Principal Investigator (PI), whole role it is to take responsibility for the research activities relating to the trial at that site. The NIHR have seen the benefit of this role and have recently launched the NIHR associate PI programme to formalise this role.(13) Trainee (or Associate) Principal Investigators (TPIs) at a research site can work alongside, and gain experience from, the site PI. Typical responsibilities of a TPI include co-ordination of, and engagement in, the recruitment of patients to the trial at that site. There are no RCTs assessing the effect of a TPI on recruitment rate to a trial. In addition, the evaluation of this TPI role from a trainee perspective has not been undertaken.

The World Hip Trauma Evaluation (WHiTE) is an initiative to rapidly and efficiently investigate interventions to improve the outcomes of patients requiring hip fracture surgery.(14) All hip fracture patients being treated in participating centres are approached for consent to be enrolled in the WHiTE cohort, which collects standardised outcome data from participants. This cohort is a valuable tool in which to embed RCTs to evaluate novel treatment options for hip fracture patients. TPIs, recruited and managed by the local PI, are being employed in some of the RCTs embedded in the WHiTE cohort.(14) A TPI manual is provided by the management team based at Oxford Trauma and Emergency Care, University of Oxford with no further education or support. There is, therefore, the potential to create an enhanced support package for TPIs consisting of formal initial education and ongoing assistance to enhance their knowledge and confidence in undertaking the role. A systematic review of training programmes for recruiters to RCTs found that these programmes were well received and increased recruiters’ self-confidence.(15) There was no definitive conclusion on the impact on recruitment rate and the need for further research in the area, ideally in a randomised evaluation, was highlighted.

An additional method of improving recruitment rates may be through the use of “nudging”. Fundamentally, this is a way of influencing an individual’s behaviour through an intervention without limiting their choice. This concept is used extensively in marketing, economics and healthcare promotion.(16,17)Digital nudging is used regularly in RCTs e.g. emails, recruitment league tables circulated to recruiting sites, and encouragement emails; however, there is limited formal assessment regarding the effect of nudging interventions targeted at recruiters on recruitment rates. In the WHiTE trials, an automated non-specific (generic, non-personalised) email is sent to the research staff at the recruiting centre after each patient randomisation. An additional email sent to the randomising clinician in a timely manner and incorporating features such as personalisation, appreciation for recruitment, and praise may positively reinforce the behaviour of recruiting to a trial. Personalised emails to the recruiting clinician have not been evaluated using an RCT; however, there is evidence that personalised study invites improve patient recruitment in breast cancer survivors(18) and also in invitations for survey research.(19,20) In this paper, we describe a 2x2 factorial, randomised trial evaluating both enhanced training and support for the TPI and personalised, digital nudging to recruiting clinicians to improve recruitment rates.

**Methods**

This SWAT investigated two different methods of enhancing recruitment: introducing a TPI with an enhanced training and support package to a site, and personalised, digital nudge to healthcare professionals involved in patient recruitment. The SWAT was implemented in a large, UK, multicentre orthopaedic RCT, the WHiTE 8 COPAL trial (ISRCTN15606075).

The primary aim is to:

* Assess the effectiveness of an enhanced TPI package, and of a digital nudge, on the total number of patients recruited to the WHITE 8 COPAL trial in the first six months of recruitment at a site.

The secondary aims are to:

* Determine the time taken to implement each intervention from the time recruitment commences at the site.
* Compare the randomisation rate of eligible participants in each of the intervention groups.
* Gain feedback on the trainee perspective of the TPI role via a survey.
* Determine the time needed to conduct the 1:1 educational training session for TPIs.
* Determine the required time and method of additional contact for peer support of the TPIs.

**Design.** This was a multicentre, cluster, 2x2 factorial RCT embedded in the WHiTE 8 COPAL RCT, in which research sites were randomised 1:1:1:1 to receive the enhanced TPI package, the digital nudge intervention, both, or neither. This is an open trial and participating sites, the data analyst and trial team were not blind to allocation. The first site was randomised into the SWAT on 22/08/2018 and follow-up was completed on 20/09/2019. The trial was approved by the NHS Wales Research Ethics Committee and York University Research Governance committee and reported in accordance with the trial protocol and Consolidated Standards of Reporting Trials (CONSORT) statement.

The first 20 WHiTE centres recruiting to the WHiTE 8 COPAL trial were included. The recruitment centre where the CI for the factorial SWAT (author NRA) was based was excluded to prevent bias.

**SWAT interventions.**

The interventions were delivered as described in the published trial protocol,(21) a summary is provided below and in Table 1.

*Standard practice for TPIs:* TPIs were not mandated but were recommended by the trial management team at site initiation visits to the participating site. A TPI manual was made available with specific information regarding the role but no further involvement thereafter.

*Standard practice following successful randomisation of a participant:* An automated email was generated to local research teams after each successful patient randomisation via an online randomisation portal. There were monthly email updates to local research teams regarding trial processes and progress. The usual incentive to randomisers is acknowledgement as a collaborator in the WHiTE 8 COPAL trial publication and trainee orthopaedic surgeons, in addition, receive evidence of randomisation through certification.

*Enhanced TPI Package:* This was a complex intervention involving education, support and supplementary information. A 1:1 telephone training session by the WHiTE 8 surgical research fellow (CI for the SWAT) was conducted along with monthly communication regarding progress and problems via direct messaging/email and/or phone calls if required. A comprehensive package of supplementary information was also provided via email prior to commencing their role.

*Digital Nudging:* A personalised email nudge expressing a combination of appreciation and encouragement from the WHiTE 8 COPAL Research Fellow was sent each time a health care professional randomised a participant to the trial. These were to be sent to the randomiser within 72 hours; where a clinician recruited multiple patients in the period, only one nudge was sent referring to the number recruited in the period.

Table 1: EnTraP intervention summary

|  |  |  |  |
| --- | --- | --- | --- |
| **ACTIVITY** | **STANDARD PRACTICE** | **ENHANCED TPI** | **DIGITAL NUDGE** |
| Identify TPI for the trial | Local Principal Investigator | Local Principal Investigator |  |
| Training of TPI regarding how to perform their role | Local Principal Investigator  TPI Manual | Local Principal Investigator  TPI manual  WHiTE 8 Fellow via 1:1 telephone induction  Induction summary presentation |  |
| Training TPI regarding the WHiTE 8 trial and consenting procedures | Local Principal Investigator | Local Principal Investigator  WHiTE 8 Fellow via 1:1 telephone induction  WHiTE 8 consent flow diagram and protocol provided |  |
| Peer Support of TPI |  | Monthly personal contact by WHiTE 8 fellow  WHiTE 8 Fellow can be contacted by TPI as required by SMS/WhatsApp/Email |  |
| Digital information provided to TPI | TPI Manual | Induction agenda  TPI manual and new TPI checklist  Induction summary presentation  WHiTE 8 consent flow diagram and protocol  TPI contact information consent form |  |
| Identifying patients for the trial | Trauma meeting | Trauma meeting |  |
| Confirmation of randomisation | Automated email to recruiting centre |  | Automated email to recruiting centre  Additional personalised email to randomiser to the trial |

**Outcome assessment.** The primary outcome measure was the total number of patients randomised, from each site, in their first six months of recruitment to the WHiTE 8 COPAL trial. These data are collected by the trial management team on a monthly basis.

Site setup details including activation date, date of first patient recruited, and dates of implementation of each SWAT intervention were recorded on an Excel spreadsheet. This allowed for calculation of time taken to implement each intervention from centres commencing recruitment. Conversion rate from screened population was collected monthly from the main trial database.

The trainee perspective of their role was collected through a TPI Qualtrics survey at the end of the SWAT trial period sent via email. Responses were based on a 5-point Likert scale ranging from “not very satisfied” to “extremely satisfied”. The research fellow maintained a time log for delivering the TPI education intervention and a log of communication for peer support during the period of the SWAT.

**Randomisation.** The WHiTE centres were randomised 1:1:1:1 by minimisation to one of the four groups (Table 2) to balance key baseline characteristics of: cluster size (the expected number of hip fractures requiring hemiarthroplasty in a year at the site; <300/≥300, expected monthly recruitment based on past performance in other WHiTE trials as a recruiting centre (<9/≥9 patients per month), and co-recruitment to the WHiTE 5 trial which is within the same patient population (Y/N). Self-reported site feasibility questionnaires completed by the recruitment centres were used to collate these data. Randomisation was done by specialist computer software MinimPy (Saghaei and Saghaei, 2011) using the “biased coin” method. Randomisation was done on the day that a site recruited their first patient in order to account for the lag from site activation to first recruitment.

**Sample Size.** As in many SWATs, a power calculation was not undertaken as the number of participating sites was fixed and driven by the needs of the host trial. The first 20 WHiTE centres recruiting to the WHiTE 8 COPAL site were included in the SWAT. Further sites were not included due to time constraints (i.e., SWAT CI [lead author NRA] was returning to clinical practice and could no longer manage the SWAT).

**Statistics.** Analysis was conducted in STATA v15 on an intention-to-treat basis. Baseline data relating to the sites (including the minimisation factors) are summarised for the four groups as randomised. No formal statistical comparison of baseline data was undertaken.

The number of participants recruited per site was summarised. A Poisson regression model, containing the two interventions (Enhanced TPI and Digital Nudge) and the three minimisation factors (cluster size and expected number recruited per month were included in their continuous form) was undertaken. Adjusted incidence rate ratios (IRRs) and associated 95% confidence intervals (CIs) and p-values were obtained from this model. We undertook an interaction test between the two interventions.

Feasibility outcomes including time to commence intervention, time required to run the education intervention and communication time and methods used for the peer support aspect of the intervention, were reported descriptively.

**Results**

**Baseline**: The first 20 sites recruiting to the WHiTE 8 COPAL trial opened between 16th August 2018 and 21st February 2019 and were randomised into the SWAT between 22nd August 2018 and 20th March 2019, an average of 14.9 days (SD 17.0) after site activation. Six sites were randomised to usual practice, four to digital nudge only, and five each to TPI only and TPI plus digital nudge. The overall expected mean recruitment rate per site was 8.0 patients per month (SD 3.9) (Table 2). Mean cluster size was 278.5 (SD 113.1) and four sites were co-enrolled into the WHiTE 5 trial.

Table 2: Baseline data for sites involved in EnTraP

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Minimisation factor** | **TPI + DN**  **(n=5)** | **TPI only**  **(n=5)** | **DN only**  **(n=4)** | **UP**  **(n=6)** | **Total**  **(n=20)** |
| **Cluster size** |  |  |  |  |  |
| Mean (SD) | 338.6 (125.0) | 281.6 (118.1) | 233.5 (113.6) | 255.8 (106.5) | 278.5 (113.1) |
| <300, n (%) | 3 (60.0) | 2 (40.0) | 3 (75.0) | 4 (66.7) | 12 (60.0) |
| ≥300, n (%) | 2 (40.0) | 3 (60.0) | 1 (25.0) | 2 (33.3) | 8 (40.0) |
| **Expected monthly recruitment** |  |  |  |  |  |
| Mean (SD) | 9.0 (6.5) | 8.6 (1.9) | 7.0 (2.9) | 7.5 (3.5) | 8.0 (3.9) |
| <9, n (%) | 3 (60.0) | 2 (40.0) | 2 (50.0) | 3 (50.0) | 10 (50.0) |
| ≥9, n (%) | 2 (40.0) | 3 (60.0) | 2 (50.0) | 3 (50.0) | 10 (50.0) |
| **Co-recruitment to the WHiTE 5 trial, n (%)** |  |  |  |  |  |
| Yes | 1 (20.0) | 1 (20.0) | 1 (25.0) | 1 (16.7) | 4 (20.0) |
| No | 4 (80.0) | 4 (80.0) | 3 (75.0) | 5 (83.3) | 16 (80.0) |

TPI = trainee principal investigator; DN = digital nudge; UP = usual practice

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Figure 1: CONSORT flowchart

**Primary outcome**: 1215 patients were recruited to the WHiTE 8 COPAL trial across 20 sites during the SWAT intervention period. The total recruitment figure for each site by group is summarised in Table 3. There were 379, 279, 147 and 410 patients recruited in the 6-month period in the Usual Practice, TPI, Digital Nudge, and, Both TPI and Digital Nudge groups, respectively. The total number of patients recruited over six months in the enhanced TPI package group (10 sites) was 689 (mean 68.9 per site) compared to 526 (mean 52.6 per site) in the 10 centres not allocated to receive this intervention. The total number of patients recruited over six months in the Digital Nudge group (9 sites) was 557 (mean 61.9 per site) compared to 658 (mean 59.8 per site) in the 11 centres not allocated to receive this intervention.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Usual practice | | TPI | | Digital nudge | | Both interventions | |
| Site | Recruited | Site | Recruited | Site | Recruited | Site | Recruited |
| B | 91 | D | 81 | F | 21 | A | 117 |
| C | 46 | H | 51 | I | 65 | G | 98 |
| E | 43 | L | 48 | O | 19 | J | 108 |
| K | 69 | M | 68 | P | 42 | N | 41 |
| R | 100 | S | 31 |  |  | Q | 46 |
| T | 30 |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| TOTAL | 379 |  | 279 |  | 147 |  | 410 |
| Mean (SD) | 63.2 (28.2) |  | 55.8 (19.3) |  | 36.8 (21.5) |  | 82.0 (35.8) |

Table3: Site recruitment as stratified by Group randomisation

From the primary Poisson regression model (no interaction term) the main effect of enhanced TPI intervention was a statistically significant benefit on recruitment (IRR 1.15 95% CI 1.02 to 1.29, p=0.02).

The digital nudge intervention had no significant impact on recruitment (IRR 0.95 95% CI 0.85 to 1.07, p=0.39).

In the Poisson model including an interaction between the two interventions, the main effect of the enhanced TPI intervention was IRR 1.23 (95% CI 1.09 to 1.40, p=0.001) and of the digital nudge intervention was IRR 0.89 (95% CI 0.79 to 1.01, p=0.07). There was a statistically significant interaction (IRR 2.09 95% CI 1.64 to 2.68, p < 0.001). There is a qualitative interaction in that the addition of the digital nudge is beneficial in the enhanced TPI sites (IRR 1.29, 95% CI 1.11 to 1.51, p=0.001) but detrimental in the standard TPI sites (IRR 0.62, 95% CI 0.51 to 0.75, p<0.001).

Table 4: Incidence Rate Ratio between the intervention and participant recruitment to WHiTE 8 COPAL trial

|  |  |  |  |
| --- | --- | --- | --- |
| **Column1** | **IRR** | **95% CI** | **p Value** |
| **Intervention main effects1** |  |  |  |
| Enhanced TPI | 1.15 | 1.02 to 1.29 | 0.02 |
| Digital Nudge | 0.95 | 0.85 to 1.07 | 0.39 |
|  |  |  |  |
| **Intervention main effects2** |  |  |  |
| Enhanced TPI | 1.23 | 1.09 to 1.40 | 0.001 |
| Digital Nudge | 0.89 | 0.79 to 1.01 | 0.07 |
| **Simple effect of DN within TPI sites2** | 1.29 | 1.11 to 1.51 | 0.001 |
| **Simple effect of DN within non-TPI sites2** | 0.62 | 0.51 to 0.75 | <0.001 |

*1Obtained from a Poisson model without the interaction; main effects of each intervention adjusted for the other, and the minimisation factors.*

*2Obtained from a Poisson model with the interaction; main effects of each intervention adjusted for the other, and the minimisation factors.*

**Secondary Outcomes:­­**

From the 557 patients recruited at sites allocated to receive the Digital Nudge intervention, 353 nudges were created for the recruiters. Median time to first nudge from first randomisation at the site was one day (range 0-3). 224 (63.5%) of the nudges were for single randomisations, while 129 (36.5%) were for multiple randomisations conducted over a 72-hour period (relating to 333 randomisations, mean 2.6 per nudge). Seven of the 353 nudges created (2.0%) were unable to be sent due to the lack of an email address despite two follow up emails to local research teams. The average time to construct a nudge, log the activity and then disseminate was 12 minutes. 53 nudges (15.0%) were sent 72 hours after randomisation. Of these late nudges reasons for protocol deviations include: CI on annual leave (n=25, 47.2%); CI clinical commitments (n=17, 32.1%); delay from local centres in retrieving email addresses (n=7, 13.2%), and unknown (n=4, 7.5%).

Nine TPIs were recruited from the ten sites that were randomised to the enhanced TPI package intervention. Median time for identification and induction of TPIs was 17 days (range 9-63). Median induction time for the enhanced TPI was 32 minutes (range 20-50). A log of monthly enhanced TPI follow up (Table 4), showed that out of 45 points of contact across all sites randomised to the intervention, 31 (68.9%) had “no issues”, six (13.3%) received “no response”, four (8.9%) had “clinical issues that were able to be resolved”, three (6.7%) had local research staff issues that could not be solved centrally and one (2.2%) had research issues that could be resolved centrally.

Table 4 Enhanced TPI follow Log of follow up

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **TPI** | **TPI month 1** | **TPI month 2** | **TPI month 3** | **TPI month 4** | **TPI month 5** |
| 1 | Clinical Issues - pending resolution | Clinical Issues - resolved | No issues | No issues | No issues |
| 2 | No issues | No issues | No issues | No issues | No issues |
| 3 | Clinical Issues - resolved | No issues | No issues | Clinical Issues - resolved | No issues |
| 4 | No issues | No issues | No issues | No issues | No issues |
| 5 | No issues | Research process questions - resolved | No issues | No issues | No response |
| 6 | Research Staff sickness - unable to resolve centrally | Research Staff sickness - unable to resolve centrally | Research Staff sickness - unable to resolve centrally | No response | No response |
| 7 | No issues | No issues | No issues | No issues | No issues |
| 8 | No issues | No issues | No response | No response | No response |
| 9 | No issues | No issues | No issues | No issues | No issues |

Among the 20 centres running the WHiTE 8 trial during the intervention period there were 17 TPIs identified from delegation logs. The response rate for the follow up survey was 52.9%. Nine TPIs completed follow up surveys of which seven had received the enhanced TPI intervention (77.7%). All TPIs were very satisfied or extremely satisfied with their inductions in explaining the purpose, consent, role of TPI and benefits of becoming a TPI. Amongst the enhanced TPI group 100% of the responders were extremely satisfied with the induction process and felt “extremely supported” with regards to monthly follow-up. Suggested improvements were generic UK TPI education workshops and e-learning modules to help reinforce and discuss key issues that arise across UK Orthopaedic trials.

The proportion of patients recruited as a percentage of the screened population was not analysed due to inadequate data retrieval from base site screening logs.

**Discussion**

This 2x2 factorial SWAT is the first randomised trial to investigate the effects of an enhanced TPI support package with or without the addition of a personalised digital nudge on recruitment rates; it was embedded within a large orthopedic RCT. The combined use of enhanced TPI and Digital Nudging showed significant interaction (IRR 2.09 95% CI 1.64 to 2.68, p < 0.001) in this trial.

In both Poisson models (without and with intervention interaction), sites that received an enhanced TPI training and support package had a significantly increased rate of patient recruitment to the WHiTE 8 COPAL trial over six months *(*IRR 1.15, 95% 1.02 to 1.29, p=0.02 and IRR 1.23 (95% CI 1.09 to 1.40, p=0.001 respectively). There was excellent engagement with all aspects of the intervention by TPIs; 90.0% participated in the induction activity and 86.7% in the monthly follow up communication indicating that participants were engaged in WHiTE 8 COPAL trial recruitment for the entire six-month duration of the SWAT. The use of increased trial centre coordination through on-site visits has been shown not to impact patient recruitment;(22) however, we have shown that we can deliver a similar educational package more conveniently to both trainer and trainee via off-site methods.

The follow up questionnaire also highlighted no suggested areas for improvements in how the intervention was conducted. The monthly follow-up revealed 5 time points at which CI involvement was needed to address clinical and research issues. Although this represents only 11.1% of the follow up points, all trainees felt “extremely supported” and this may have contributed to the increased recruitment at these sites.

There was no significant difference in six-month total recruitment at sites allocated to the digital nudge intervention in both Poisson models without or with the intervention interaction (IRR 0.95, 95% 0.85 to 1.07, p=0.39 and IRR 0.89 (95% CI 0.79 to 1.01, p=0.07 respectively). In terms of feasibility, the intervention had a median lag set up time of one day from first patient recruitment and delivery of the nudge averaged 12 minutes from construction to dissemination including logging the activity. One other study investigated an additional communication strategy directly to clinical sites compared to usual practice of little communication from central trial co-ordinators and found no difference in the recruitment rates; consistent with our results. (23)

There was a qualitative interaction between the two interventions where the addition of the digital nudge was beneficial in the enhanced TPI sites (IRR 1.29, 95% CI 1.11 to 1.51, p=0.001) but detrimental in the non TPI sites (IRR 0.62, 95% CI 0.51 to 0.75, p<0.001). This may be due to the combined promotion of the host trial at centres by having two interventions directed towards the same recruiting population.

The contact information available from delegation logs and local research nurse input was robust enough to ensure that 98% of nudges were disseminated to the respective trial recruiter. The protocol deviations for nudging beyond 72 hours were relatively high at 15% but 79% (42/53 cases) were due to unavailability of the SWAT CI who delivered the intervention. Therefore, these deviations are potentially avoidable in future trials if the SWAT is conducted by the CTU team managing the host trial with multiple personnel.

The number of sites available to be randomised to interventions in this factorial trial was fixed and thus a low sample size was a limitation. However, 95% of sites randomised were able to run the interventions investigated thus minimising any imprecision in the intention-to-treat analysis. The minimisation factors of cluster size and predicted recruitment could arguably closely correlate thus being considered a single minimisation variable i.e. those centres with higher incidences of hip fractures per year may be better recruiters to this clinical trial due to increased opportunity for recruitment. However, from our experience from previous trials within the WHiTE cohort framework there is no obvious relationship between the size of the recruitment population and performance of the recruiting site and thus having this variable as independent variables ensured balanced randomisation groups.

A weakness of this trial is that there was only one person involved in training and supporting the TPIs and they were also a surgical trainee; thus there is a generalisation issue that others may not be sufficiently motivated or skilled to deliver the training and support or that TPIs may not respond as well to the interventions not being delivered by a peer. Consequently, this intervention ought to be replicated in further trials using different personnel to deliver the training and support.

These results are widely generalisable to UK multicentre surgical trials as the methodology of centralised randomisation and the use of TPIs is becoming the standard operating procedure. This should make the implementation of an Enhanced TPI support package and Digital Nudging relatively straightforward when designing RCTs. These interventions should be evaluated in further trials to achieve a greater sample size for meta-analysis. The costs associated with this intervention have not been formally investigated and a formal cost benefit evaluation would also be a valuable addition. A potential improvement would be assessing further time points to determine the length of time each of these interventions may have an effect for before recruitment fatigue.

**Conclusion**

An education and support programme targeted at surgical TPIs involving a digital education package, 1:1 telephone induction and subsequent support package was effective in increasing recruitment in the first six months of trial commencement. There was no evidence for the effectiveness of the digital nudge intervention in isolation, though, our results show that, when combined with an education programme, it leads to enhanced effectiveness of that programme.

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1. Costa ML, Achten J, Parsons NR, Rangan A, Griffin D, Tubeuf S, et al. Percutaneous fixation with Kirschner wires versus volar locking plate fixation in adults with dorsally displaced fracture of distal radius: Randomised controlled trial. BMJ [Internet]. 2014;349(August):1–10. Available from: http://dx.doi.org/doi:10.1136/bmj.g4807

2. Sims AL, Parsons N, Achten J, Griffin XL, Costa ML, Reed MR. A randomized controlled trial comparing the Thompson hemiarthroplasty with the Exeter polished tapered stem and Unitrax modular head in the treatment of displaced intracapsular fractures of the hip. Bone Jt J. 2018;100B(3):352–60.

3. Handoll H, Brealey S, Rangan A, Keding A, Corbacho B, Jefferson L, et al. The ProFHER (PROximal Fracture of the Humerus: Evaluation by Randomisation) trial - a pragmatic multicentre randomised controlled trial evaluating the clinical effectiveness and cost-effectiveness of surgical compared with non-surgical treatment for proxi. Heal Technol Assess [Internet]. 2015;19(24). Available from: http://journalslibrary.nihr.ac.uk/hta/hta19240

4. Costa ML, Jameson SS, Reed MR. Do large pragmatic randomised trials change clinical practice?: Assesing the impact of the Distal Radius Acute Fracture Fixation Trial (DRAFFT). Bone Jt J. 2016;98B(3):410–3.

5. Treweek S, Bevan S, Bower P, Campbell MK, Christie J, Clarke M, et al. Trial Forge Guidance 1: What is a Study Within A Trial (SWAT)? Trials. 2018;1–5.

6. Clarke M, Savage G, Maguire L, McAneney H. The SWAT (study within a trial) programme; embedding trials to improve the methodological design and conduct of future research. Trials. 2015;16(S2):2015.

7. McDonald AM, Knight RC, Campbell MK, Entwistle VA, Grant AM, Cook JA, et al. What influences recruitment to randomised controlled trials? A review of trials funded by two UK funding agencies. Vol. 7, Trials. 2006.

8. Bower P, Wilson S, Mathers N. Short report: How often do UK primary care trials face recruitment delays? Fam Pract. 2007;24(6):601–3.

9. 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).

10. Walters SJ, Dos Anjos Henriques-Cadby IB, Bortolami O, Flight L, Hind D, Jacques RM, et al. Recruitment and retention of participants in randomised controlled trials: A review of trials funded and published by the United Kingdom Health Technology Assessment Programme. BMJ Open. 2017;

11. Charlson ME, Horwitz RI. Applying results of randomised trials to clinical practice: impact of losses before randomisation. Br Med J (Clin Res Ed) [Internet]. 1984;289(6454):1281–4. Available from: http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=1443545&tool=pmcentrez&rendertype=abstract

12. Treweek S, Pitkethly M, Cook J, Fraser C, Mitchell E, Sullivan F, et al. Strategies to improve recruitment to randomised trials. Cochrane Database of Systematic Reviews. 2018.

13. Associate Principal Investigator (PI) Scheme [Internet]. 2020. Available from: https://www.nihr.ac.uk/documents/associate-principal-investigator-pi-scheme/25040?pr=

14. Costa ML, Griffin XL, Achten J, Metcalfe D, Judge A, Pinedo-Villanueva R, et al. World Hip Trauma Evaluation (WHiTE): Framework for embedded comprehensive cohort studies. BMJ Open. 2016;

15. Townsend D, Mills N, Savović J, Donovan JL. A systematic review of training programmes for recruiters to randomised controlled trials. Trials. 2015;16(1).

16. Thorndike AN, Riis J, Sonnenberg LM, Levy DE. Traffic-light labels and choice architecture: Promoting healthy food choices. Am J Prev Med. 2014;46(2):143–9.

17. Cabinet Office Behavioural Insights Team. Applying Behavioural Insights to Organ Donation: preliminary results from a randomised controlled trial. 2013;1–11. Available from: papers2://publication/uuid/AF229C81-AD21-44D7-851F-CBC015DB96B7

18. Short CE, Rebar AL, Vandelanotte C. Do personalised e-mail invitations increase the response rates of breast cancer survivors invited to participate in a web-based behaviour change intervention? A quasi-randomised 2-arm controlled trial. BMC Med Res Methodol. 2015;

19. Heerwegh D. Effects of personal salutations in e-mail invitations to participate in a web survey. Public Opinion Quarterly. 2005.

20. Muñoz-Leiva F, Sánchez-Fernández J, Montoro-Ríos F, Ibáñez-Zapata JÁ. Improving the response rate and quality in Web-based surveys through the personalization and frequency of reminder mailings. Qual Quant. 2010;

21. 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 [version 1; peer review: 2 approved]. F1000Research. 2019;

22. Liénard J-L, Quinaux E, Fabre-Guillevin E, Piedbois P, Jouhaud a, Decoster G, et al. Impact of on-site initiation visits on patient recruitment and data quality in a randomized trial of adjuvant chemotherapy for breast cancer. Clin Trials. 2006;3:486–92.

23. Monaghan H, Richens A, Colman S, Currie R, Girgis S, Jayne K, et al. A randomised trial of the effects of an additional communication strategy on recruitment into a large-scale, multi-centre trial. Contemp Clin Trials. 2007;28(1):1–5.