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Effects of an enhanced trainee principal investigator package and digital nudging on recruitment rates

Submission date
20/08/2018

Recruitment status
No longer recruiting

Registration date
29/10/2018

Overall study status
Completed

Last Edited
25/04/2022

Condition category
Other

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Randomised control trials (RCTs) are considered the gold standard when evaluating the efficacy and effectiveness of health care interventions. Unfortunately, a significant number of well-designed RCTs struggle with the recruitment of clinicians and patients, subsequentl leading to a failure to reach their target sample size. In the UK, 55% of NIHR (National Institute for Health Research) trials between 2002 and 2008 met recruitment targets, but 45% of all trials needed funding extensions to meet their recruitment target. Studies within a trial (SWATs) are used to investigate ways of improving the conduct of RCTs. This study is a SWAT, embedded in the WHiTE 8 COPAL trial (a trial of two antibiotic regimens for hip fracture patients) to evaluate whether two interventions; Enhanced Trainee Principal Investigator (TPI) Package and/or an Additional Post Recruitment Email effects patient recruitment rates to the COPAL trial. These interventions have not been formally tested before in a RCT or in a hypothetical setting. The results of this SWAT will be used to inform the design of future RCTs to increase the recruitment rates of patients to multicentre trials in orthopaedics. The data will also inform future decisions regarding how best to deliver TPI training and improve trainee satisfaction during his/her period in the role.

Who can participate?
Trial centres participating in the WHiTE 8 COPAL RCT

What does the study involve?
Centres involved in the WHiTE 8 COPAL trial will be randomly allocated to one of four groups. Group A will receive the enhanced TPI intervention, group B will receive the enhanced TPI and digital nudge intervention, group C will receive standard practice and group D will receive the digital nudge intervention only. Groups receiving the enhanced TPI intervention (A and C) will receive education via telephone training, peer support through texting and WhatsApp and digital information. Groups receiving the digital nudge intervention will receive emails each time a new participant joins the WHiTE 8 COPAL trial, which will encourage and thank them for recruiting participants to the trial.

What are the possible benefits and risks of participating?
The benefit in participating is to contribute to a study where positive results may be used to influence the methodology of future RCTs to improve patient recruitment. There are no known risks to participants taking part in this study.

Where is the study run from?
Trial and Statistics Department, University of York (as part of a PhD project) (UK)

When is the study starting and how long is it expected to run for?
October 2017 to March 2020

Who is funding the study?
This research is not directly funded, but it is embedded in a RCT which is industry funded by Heraeus Medical GmbH (Germany)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Swat repository store - Swat 67

Study information

Scientific Title
A factorial randomised controlled trial embedded within WHiTE 8 COPAL looking at the effect of an Enhanced Trainee Principal investigator package and additional digital nudge on recruitment rates.

Acronym
EnTraP

Study objectives
The use of an enhanced trainee principal investigator package and/or digital nudge will increase the recruitment rate to a randomised controlled trial

Ethics approval required
Old ethics approval format

Ethics approval(s)
The University of York Health Sciences Ethics Committee, 16/03/2018, Ethics Approval ID: HSRGC /2018/266/C

Study design
Interventional multi-centre 2x2 factorial randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Recruitment to trials

Interventions
All centres recruiting to the WHiTE 8 randomised controlled trial will be included, with the exception of the recruitment centre that the Chief Investigator (CI) for this factorial trial is based at. There will be a minimum of 20 centres involved with the trial and any additional sites brought online will also be included in this embedded study. The interventions will run for 6 months in each recruitment centre. We anticipate 2-3 centres opening to recruitment per month, therefore, we anticipate that this trial will run for 16 months in total. The factorial design will allow for the evaluation of two interventions in one trial thus presents a more cost-effective option than running two separate trials.

There will be four groups created through randomisation:
Group A – Enhanced TPI (trained principal investigator) Intervention only
Group B – Enhanced TPI and Digital Nudge intervention
Group C – Standard practice
Group D – Digital Nudge Intervention only
All groups will receive automatic emails when they randomise a patient to the WHiTE 8 trial as outlined in standard practice. There will be no interference with Group C to identify TPIs if the centres allocated to this group are unable to recruit to this role.
The WHiTE centres will be randomised 1:1:1:1 by minimisation to one of the four groups to balance key baseline characteristics. Self-reported site feasibility questionnaires completed by the recruitment centres will be used as information for minimisation. Minimisation will be based on the following factors:
1. Cluster size (Number of intracapsular hip fractures presenting per year, cut at median <300 or 300)
2. High vs Low recruiting centres (<9 or >9 per month)
3. Co-Recruitment to WHiTE 5 (yes/no)
This randomisation will be done by a specialist computer software MinimPy.
The enhanced TPI intervention involves education, peer support and digital supplementary information. This can be broken down into the following:
1. Education - one-to-one telephone training by the WHiTE 8 research follow to the TPI, covering:
1.1. Background to the WHiTE 8 trial
1.2. TPI role and benefits of participating
1.3. How to effectively perform the TPI role
1.4. How to recruit and randomise to the WHiTE 8 trial
2. Peer support - support and advice through SMS/WhatsApp messaging, with follow-up emails and telephone calls if required for problems related to carrying out the role
3. Digital supplementary information - provision of the following supplementary material by email, including:
3.1. Induction agenda
3.2. TPI manual and new TPI checklist
3.3. Induction summary presentation
3.4. WHiTE 8 consent flow diagram and protocol
3.5. TPI contact information consent form
The Digital Nudge intervention will be an email from the WHiTE 8 Copal Research Fellow each time a health care professional randomises to the trial. Each email will include these nudges:
1. Personalisation (clinician is named)
2. Encouragement through praise to continue recruiting
3. Statement of appreciation for recruiting a patient to the WHiTE 8 COPAL trial
4. Digital nudge within 72 hours after recruitment
The aim will be to email the recruiter within 72 hours and where a clinician has recruited multiple patients in the period, only one email will be sent referring to the number recruited in the period.

Intervention Type
Mixed

Primary outcome measure
The total number of patients recruited in 6 months to the WHiTE 8 COPAL trial, which is routinely collected for the Oxford CTU on a monthly basis for all WHiTE trials. Data will be collated on an Excel spreadsheet for each trial centre on a monthly basis until 6 months in total.

Secondary outcome measures

1. Time taken to begin each intervention from centre activation, taken from Oxford CTU records at the time of interventions commencing at each trial centre
2. Feasibility of delivering both interventions, determined from a logbook of data collected by the CI at 6 months
3. Conversion rate to recruitment from the proportion of those screened to be eligible in each of the intervention groups, taken from Oxford CTU records on a monthly basis
4. Feedback on the trainee perspective of the TPI role via a survey completed by the TPI in the last 2 weeks of their role
5. Time needed to conduct the 1:1 educational training session for TPIs, determined from a logbook of data collected by the CI at 6 months
6. Required time and method of additional contact for peer support of the TPIs, determined from a logbook of data collected by the CI at 6 months

Overall study start date
01/10/2017

Completion date
01/03/2020

Eligibility

Key inclusion criteria
All hospitals running the WHiTE 8 COPAL RCT

Participant type(s)
Health professional

Age group
Adult

Sex
Both

Target number of participants
A minimum of 20 trial centres

Total final enrolment
20

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
22/08/2018

Date of final enrolment
01/01/2020

Locations

Countries of recruitment
England

United Kingdom

Wales

Study participating centre
John Radcliffe Hospital
Oxford
United Kingdom
OX3 9DU

Study participating centre
Leicester Royal Infirmary
Leicester
United Kingdom
LE1 5WW

Study participating centre
Poole Hospital
Poole
United Kingdom
BH15 2JB

Study participating centre
Queen Alexandra Hospital
Portsmouth
United Kingdom
PO6 3LY

Study participating centre
Queen Elizabeth Hospital
Birmingham
United Kingdom
B15 2TH

Study participating centre

Royal Berkshire Hospital
Reading
United Kingdom
RG1 5AN

Study participating centre
Princess Royal Hospital
Haywards Heath
United Kingdom
RH16 4EX

Study participating centre
Royal Victoria Infirmary
Newcastle Upon Tyne
United Kingdom
NE1 4LP

Study participating centre
Southmead Hospital
Bristol
United Kingdom
BS10 5NB

Study participating centre
University Hospital Coventry
Coventry
United Kingdom
CV2 2DX

Study participating centre
Queens Medical Centre
Nottingham
United Kingdom
NG7 2UH

Study participating centre

University Hospital Wales
Cardiff
United Kingdom
CF64 2XX

Sponsor information

Organisation
University of York

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Sponsor type
University/education

ROR
https://ror.org/04m01e293

Funder(s)

Funder type
Other

Funder Name
investigator initiated and funded

Results and Publications

Publication and dissemination plan
The aim is to publish the results of the study in a peer reviewed journal and present at conferences to the wider orthopaedic community. The study will also form as part of a PhD thesis chapter

Intention to publish date

01/04/2020

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available as all data analysed will be available in the final peer publication and there will be no benefit to accessing raw data.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	22/07/2019	25/09/2019	Yes	No
Results article		02/01/2022	25/04/2022	Yes	No