Patient involvement in education and training: a randomised cluster trial of a patient-led training programme to improve patient safety

Submission date 21/10/2010	Recruitment status No longer recruiting	 Prospectively registered [X] Protocol
Registration date 21/10/2010	Overall study status Completed	 [] Statistical analysis plan [X] Results
Last Edited 11/02/2019	Condition category Other	Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s) Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers 8835

Study information

Scientific Title

Patient involvement in education and training: a randomised cluster trial of a patient-led training programme to improve patient safety

Study objectives

The study is a randomised cluster trial with control conducted in the former Yorkshire Deanery. In North and East Yorkshire and Northern Lincolnshire (NEYNL) Foundation school the intervention and control arm will run in parallel sessions, trainees and participants will be randomly assigned to either group on the day of teaching. In the West Yorkshire Foundation School, teaching takes place on two sites, one site will receive the intervention (Harrogate) and a second site will receive the control (Airedale). Participants will be allocated to either site preintervention based on their on-call rota.

Ethics approval required

Old ethics approval format

Ethics approval(s) MREC approved (ref: 10/H1302/6)

Study design

Multicentre non-randomised observational prevention qualitative study

Primary study design Observational

Secondary study design Cohort study

Study setting(s) Hospital

Study type(s) Prevention

Participant information sheet

Health condition(s) or problem(s) studied

Topic: Generic Health Relevance and Cross Cutting Themes; Subtopic: Generic Health Relevance (all Subtopics); Disease: Health Services Research

Interventions

Control: Foundation Year 1 junior doctors will receive their standard mandatory patient safety training

Intervention: Foundation Year 1 junior doctors will listen to two patients talk about their experiences of a patient safety incident as part of their mandatory patient safety training

Intervention Type

Other

Phase Not Applicable

Primary outcome measure

Change attitudes and culture among the doctors, measured with the Attitudes to Patient Safety Questionnaire (APSQ)

Secondary outcome measures

In depth interviews with a purposive sample of ten trainees from each group, at 4 - 6 weeks following the teaching session

Overall study start date 01/01/2010

Completion date 30/11/2012

Eligibility

Key inclusion criteria

1. Foundation year one trainee doctors undertaking the patient safety module as part of their mandatory training in East and West Yorkshire.

2. Patients that have been involved in a patient safety incident in the NHS

3. Aged 18 years or older, either sex

Participant type(s) Mixed

Age group Adult

Lower age limit 18 Years

Sex Both

Target number of participants Planned sample size: 438

Key exclusion criteria

 Trainee doctors - we anticipate that all those enrolled on the safety training module will be eligible to take part in the research study
 Patients under the age of 18 years

3. Unable to give consent to participate

Date of first enrolment

01/01/2010

Date of final enrolment 30/11/2012

Locations

Countries of recruitment England

United Kingdom

Study participating centre Bradford Hospitals NHS Trust Bradford United Kingdom BD9 6RJ

Sponsor information

Organisation NHS Bradford and Airedale (UK)

Sponsor details Douglas Mill

Bowling Old Lane Bradford United Kingdom BD5 7JR

Sponsor type Government

Website http://www.bradfordairedale-pct.nhs.uk

Funder(s)

Funder type Government

Funder Name Programme Grants for Applied Research Alternative Name(s) NIHR Programme Grants for Applied Research, PGfAR

Funding Body Type Government organisation

Funding Body Subtype National government

Location United Kingdom

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	03/12/2010		Yes	No
<u>Results article</u>	results	01/09/2013	11/02/2019	Yes	No