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Patient Reporting and Action for a Safe Environment (PRASE) intervention: a multi-centred evaluation

Submission date
15/08/2013

Recruitment status
No longer recruiting

Registration date
16/08/2013

Overall study status
Completed

Last Edited
19/03/2018

Condition category
Other

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

Plain English summary of protocol

Background and aim
Reports show that as many as one in ten patients are harmed while receiving hospital care. The recent NHS Mandate lists one of its core themes as: "treating and caring for people in a safe environment and protecting them from avoidable harm, with the objective of reducing avoidable harm and embedding a culture of patient safety in the NHS by 2015. Strategies to improve safety have focused on developing incident reporting systems and changing systems of care and professional behaviour, with little involvement of patients. However, there has recently been a growing interest in involving patients in safety initiatives. Over the past three years, our research team at the Bradford Institute for Health Research have developed, tested and refined the PRASE (Patient Reporting and Action for a Safe
Environment) intervention, which collects patient feedback about the safety and quality of care on hospital wards, and then uses this information as the basis for structured feedback to ward teams. The intervention has two related components a survey of patients views of organisational safety (Patient Measure of Organisational Safety - PMOS) and a patient incident reporting tool (PIRT) for any immediate concerns or comments. The aim of study is to assess the effectiveness of the PRASE intervention at achieving patient safety improvements over a 12-month period.

Who can participate?
All patients aged 16 and over spending a minimum of two hours on the wards.

What does the study involve?
Hospital wards are randomly allocated to either the standard care or the intervention group. In this study we aim to recruit 2400 patients - over three time points, 800 at each time point - to give their feedback on the safety and quality of the hospital ward to which they have been admitted. Patient feedback about their experience of safety on the ward will be given to ward staff at the end of each time point through the format of a feedback report. Ward staff will then meet to consider the feedback in an Action Planning Meeting and make safety improvements or changes, as appropriate to the patient feedback received. Staff on intervention wards will be participants in a process evaluation - using qualitative methodology to assess the fidelity of the

intervention and to understand the experience of ward teams allocated to be in the intervention group.

What are the possible benefits and risks of participating?
The initially small study for PRASE has shown that patients value having their voices and experiences listened to and are pleased to be invited to take part in the research. Moreover, previous studies and our own pilot work have demonstrated that patients wish to discuss incidents, events and concerns. It is therefore anticipated this current project will be a positive experience for patients as it has been previously. In addition, patients involved in this project will be helping to inform the testing of a patient safety intervention which will most likely bring about local positive changes to the safety and quality of care delivered in the hospital wards in the intervention group. It is very unlikely that any significant risks or burdens should arise from participating in this research. The questionnaire tools used in this study are not onerous, taking on average 15 minutes of a patients time. For the staff involvement, we are asking staff to meet twice during a 16-month period, in a meeting which should last less than an hour each time. All participants will be advised that they can withdraw from the study at any time and decline to answer any questions they are uncomfortable with. Researchers will emphasise the strict confidentiality and voluntary nature of the research to all potential participants. As the nature of this research centres on patients' perceptions of the safety of their care, it is possible that some patients might raise issues regarding current unsafe or inappropriate practices that constitute an immediate safety concern for their care or that of others. The research team have developed a 'safety net' system that allows us to feedback important information to the ward if the patient has not already made the ward aware allowing them to act on the information in a timely and appropriate manner. The researcher will encourage the patient to inform a senior member of staff on the ward, or offer to inform a member of staff on behalf of the patient. Under our professional duty of care, if the researcher feels there is an immediate threat to the safety of the patient or others, the researcher we will be required to inform a senior member of ward staff.

Where is the study run from?
33 hospital wards across three NHS hospital trusts in Yorkshire, England. The study is being led by senior researchers based at Bradford Teaching Hospitals NHS Foundation Trust (UK).

When is the study starting and how long is it expected to run for?
May 2013 to September 2014

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
14478

Study information

Scientific Title
A multi-centre, single-blind, cluster randomised controlled trial, with a wait list design, of a patient safety intervention with a qualitative process evaluation

Acronym
PRASE

Study objectives
Does the PRASE intervention achieve measured improvements in patient safety and quality outcomes on hospital wards over a 12-month period?

Estimates show that as many as one in ten patients are harmed while receiving hospital care. The recent NHS Mandate lists one of its core themes as: "treating and caring for people in a safe environment and protecting them from avoidable harm, with the objective of reducing avoidable harm and embedding a culture of patient safety in the NHS by 2015. Strategies to improve safety have focused on developing incident reporting systems and changing systems of care and professional behaviour, with little involvement of patients. However, there has recently been a growing interest in involving patients in safety initiatives. Over the past three years, our research team at the Bradford Institute for Health Research have developed, tested and refined the PRASE (Patient Reporting and Action for a Safe Environment) intervention, which gains patient feedback about the safety of care on hospital wards. The proposed study will test the PRASE intervention further in a multi-centre, cluster randomised controlled trial, employing a wait list design. It comprises two tools: i) a 44-item questionnaire which asks patients about safety issues and failures and ii) a pro-forma for patients to report a) any specific patient safety incidents they have been involved in or witnessed b) any positive experiences patients wish to report. These two tools then provide data which is fed back to wards in a structured feedback report, which is used as a means of galvanising ward staff to make targeted changes with a view to improving patient safety and the patient experience. Using this report, ward staff are then asked to formally action plan, implement and monitor changes in line with the issues raised by patients. PRASE has already been piloted in a trial of over 300 patients which has allowed the research team to test key feasibility, usability and logistic issues.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES South Yorkshire, 15/03/2013, ref: 13/YH/077

Study design
Interventional multi-centre cluster randomised controlled single-blind list trial

Primary study design
Interventional

Study type(s)
Treatment

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
The three key stages of the process are:

1. Measurement
Over a 2-3 week period, 25 patients will be asked to participate in the measurement phase on each ward. Each patient (deemed to have capacity to consent) will be approached, the study explained, and informed consent taken. Following this, and using a computer tablet, the researcher or research nurse will ask the patient to complete the 49-item PMOS questionnaire, and report any safety concerns (or specific positive experiences of care) using the PIRT incident reporting tool. Patients will be given a choice of whether they would prefer to self-complete the questionnaire or have it facilitated by the researcher. There are three outcome measurement periods at baseline, at 6 months, and a final measurement at 12 months.

2. Feedback
Following the measurement period, the information for each ward is collated and presented to the ward in the form of a Feedback Report. This report provides a variety of different qualitative and quantitative information for staff, and has been designed and piloted by a team of patients, academics and health professionals to be as user friendly as possible.

The report provides an overall ward safety profile which summarises scores and number of reports (concerns or positive experiences) relating to each domain of the PMOS questionnaire (domains are aligned with contributory factors specific to organisational safety), as well as providing a breakdown of how these scores and reports relate to specific questions. PMOS questionnaire scores are shown graphically using a traffic light system to allow staff to see easily which areas they are performing in well, and those areas perhaps in need of improvement.

No recommendations for areas of action are suggested by the research team. The feedback report is simply a reflection of the patients perspective of the safety of their care. It is then up to ward staff to identify areas to target for improvement within the next phase of the intervention.

3. Action planning and change
The next phase of the intervention is for action planning, followed by implementing and monitoring changes, based on the areas identified for action in the feedback report. To undertake the action planning, we will ask participating wards to identify an Action Planning Team (APT). This team will comprise a minimum of four people who work on the ward, and

ideally include both senior and more junior staff, from different professional groups. The APT will be responsible for receiving the feedback report, considering which areas should be targeted, and agreeing an action plan for improvement. In addition, the team will need to monitor the implementation of the plan. Following the initial action planning meeting, we will advise wards that the APT should try and meet every two months to review action plans and monitor progress. A nominated person within the APT takes responsibility for delivering the action plan. Resources on strategies for safety improvement, mapped onto each of the PMOS domains will also be made available to participants via a website and manual.

Management of the intervention
Within each participating trust, we will run a series of three 2-hour group trust briefing sessions with the identified APTs from the trust. The first will be a start-up session, which will run before the study begins, and will provide information about the PRASE intervention, its conceptual basis, how it will work, and what is required of the APTs. The aim of this meeting will also be to bring together all of the teams, to identify potential barriers to the intervention and share ideas about how best to manage them. The second meeting will be at 6 months. At this meeting, teams will be to receive updates from each of the APTs about progress, share their success as well as troubleshoot any problems, and generally try to maintain motivation for the intervention and the study. The final meeting will be for the APTs to share their experience of PRASE, discuss changes they have implemented, and allow the research team to elicit contextual information about the ward that may affect the outcome measures.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Patient Safety Thermometer data; This is routinely collected ward level data which includes information on:
1.1. Pressure ulcers
1.2. Venous thromboembolism (VTE)
1.3. Catheter associated Urinary Tract Infections
1.4. Falls
Timepoints: 6 month and 12 months post baseline
2. Patient Measure of Organisational Safety (PMOS) questionnaire domain scores
Measured at baseline, 6 months, 12 months

Key secondary outcome(s))
1. Three CQUIN questions (from patients, at the end of the questionnaire) measured at baseline, six months, twelve months
2. Family & Friends question, which is: How likely are you to recommend this ward to friends and family if they needed similar care or treatment? (from patients, at the beginning of the questionnaire)
3. Staff patient safety culture, including:
3.1. Questions from national staff survey
3.2. Staff satisfaction/morale
Measured at baseline, 6 months, 12 months

The trialists will also seek to access some routinely collected ward-level data from participating wards:
1. Patient safety incidents for the study period (as a secondary outcome)
2. Staff absence/sickness rates (as a covariate)
3. Patient acuity/dependency scores (as a covariate)
4. Nurse/patient ratios (as a covariate)
Measured at baseline and 12 months

Completion date
30/09/2014

Eligibility

Key inclusion criteria
1. Male or female
2. Aged 16 or over, upper age limit 99 years
3. Able to give informed consent
4. Minimum period of two hours on the ward before questionnaire administered
5. Parents or carers of child patients in paediatric wards

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Does not have capacity to consent
2. Children under the age of 16
3. Has capacity but is too ill or distressed to take part e.g. breathlessness, pain, bleeding, immediately post-op etc
4. Has taken part in the study within the previous month

Date of first enrolment
06/05/2013

Date of final enrolment
30/09/2014

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Bradford Institute for Health Research
Bradford
United Kingdom
BD9 6RJ

Sponsor information

Organisation
Bradford Institute for Health Research (UK)

ROR
https://ror.org/05gekvn04

Funder(s)

Funder type
Government

Funder Name
NIHR Programme Grants for Applied Research (UK) Grant Codes: RP-PG-0108-10049

Results and Publications

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?
Results article	results	01/06/2015		Yes	No
Results article	results	01/10/2016		Yes	No
Results article	results	01/08/2017		Yes	No

Results article	results	01/09/2018	Yes	No
Protocol article	protocol	29/10/2014	Yes	No