Pilot implementation of a delirium prevention system of care

Submission date 05/04/2012	Recruitment status No longer recruiting	 Prospectively registered Protocol
Registration date 29/06/2012	Overall study status Completed	 Statistical analysis plan [X] Results
Last Edited 28/10/2022	Condition category Signs and Symptoms	Individual participant data

Plain English summary of protocol

Background and study aims

Delirium, or acute confusional illness, is common in older people. As many as a third of older people who have been admitted into hospital can develop delirium and many people do not fully recover. However, although evidence has shown that there is much that could be done to prevent delirium, the United Kingdom National Health Service does not have routine care systems capable of minimising the impact of this condition. We are undertaking a series of interlinked studies to investigate delirium prevention for older people in hospital. In the first study we worked closely with staff, volunteers and patient and carer representatives from three NHS Trusts to develop a delirium prevention system of care for use in National Health Service hospital wards. We have called this the Prevention of Delirium Programme. The Prevention of Delirium Programme is based on the evidence for delirium prevention and learning from our research partners in the previous study. It involves ward staff and volunteers addressing known modifiable risk factors for delirium (including, for example, infection, pain, poor mobility and sleep disturbance). The basis for this intervention is not a novel treatment approach but attempts to provide a comprehensive system of care that reliably and routinely drives up the standard of general care for vulnerable older patients at risk of delirium on general medical and surgical wards.

The aim of the present study, which is the second in our programme of research to investigate delirium prevention for older people in hospital, is to test the Prevention of Delirium Programme system of care in hospital wards to see how well it works and how acceptable it is to patients, carers, volunteers and staff.

Who can participate?

Managers, staff and volunteers in participating wards and hospitals. Patients who have been admitted to participating wards and their carers.

What does the study involve?

We will introduce the Prevention of Delirium Programme on at least one ward in each of three hospitals over six months and implement it for a further six months. We will undertake an audit before and after implementation of the Prevention of Delirium Programme to see what impact it has on staff workload. We will assess the impact of the Prevention of Delirium Programme on patients satisfaction with care using questions from the national in-patient questionnaire survey. We will interview patients, carers, staff and hospital volunteers to see how acceptable the Prevention of Delirium Programme has been. We will collect data to assess how well the Prevention of Delirium Programme has been used in practice. We will analyse all the data to see how feasible and acceptable the Prevention of Delirium Programme has been and whether we need to alter it. If we find it has been successful, we plan to test the delirium prevention system of care in a future study to see if it reduces delirium.

What are the possible benefits and risks of participating?

There will be heightened awareness and knowledge of delirium prevention among the staff in the participating wards. The participating wards will be implementing a delirium prevention system of care with potential benefits to patients admitted to those wards a particularly vulnerable group of patients susceptible to delirium.

The Prevention of Delirium Programme is a ward-based quality-improvement programme with minimal associated risk for patients. There are no risks involved to staff and hospital volunteers over and above those associated with their usual ward-based activities.

Where is the study run from?

The Academic Unit of Elderly Care and Rehabilitation, Institute of Health Sciences, University of Leeds, UK.

When is the study starting and how long is it expected to run? The study started in June 2011 and is scheduled to run for 18 months until November 2012.

Who is funding the study?

Funding has been obtained from the National Institute for Health Research as a Programme Grant for Applied Research.

Who is the main contact? Chief Investigator: Professor John Young (john.young@bthft.nhs.uk) Programme Manager: Dr John Green (john.green@bthft.nhs.uk)

Contact information

Type(s) Scientific

Contact name Prof John Young

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers 10652

Study information

Scientific Title

Pilot to test implementation feasibility and acceptability of a delirium prevention system of care

Study objectives

Delirium, or acute confusional illness, is common in older people: as many as a third of hospitalised older people can develop delirium and many people do not fully recover. However, although there is much that could be done to prevent delirium, the NHS does not have routine care systems capable of minimising the impact of this condition.

In an ongoing study, we are developing a delirium prevention system of care for use in NHS hospital wards. We now want to test this delirium prevention system of care in hospital wards to see how well it works and how acceptable it is to patients, carers, volunteers and staff.

To do this, in cooperation with managers, staff and hospital volunteers, we will introduce the delirium prevention system of care on at least one ward in each of three hospitals over six months and implement it for a further six months. We will undertake an audit before and after implementation of the delirium prevention system of care to see what impact it had on staff workload. We will assess the impact of the delirium prevention system of care on patients satisfaction with care using questions from the national inpatient questionnaire survey. We will interview patients, carers, staff and hospital volunteers to see how acceptable the delirium prevention system of care has been. We will collect data to assess how well the delirium prevention system of care has been used in practice.

We will analyse all the data to see how feasible and acceptable the delirium prevention system of care has been and whether we need to alter it. If we find it has been successful, we plan to test the delirium prevention system of care in a future study to see if it reduces delirium.

Ethics approval required Old ethics approval format

Ethics approval(s) Bradford Research Ethics Committee, 25/10/010, ref: 10/H1302/66

Study design Pilot observational qualitative trial

Primary study design

Observational

Secondary study design Other

Study setting(s) Hospital

Study type(s) Quality of life

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Generic Health Relevance: Age and ageing

Interventions

The intervention is a delirium prevention system of care the Prevention of Delirium (POD) Programme. The POD Programme is a ward-based, quality improvement programme which will be embedded in usual ward practice. The POD Programme will consist of a multicomponent intervention targeting ten modifiable delirium risk factors in older people in hospital: cognitive impairment / disorientation, dehydration and/or constipation, hypoxia, infection, limited mobility or immobility, pain, polypharmacy.

Intervention Type

Other

Phase Not Applicable

Primary outcome measure

We will undertake a before and after study in each of the case study sites.

Secondary outcome measures

No secondary outcome measures

Overall study start date 01/06/2011

Completion date 30/11/2012

Eligibility

Key inclusion criteria

Hospital staff and volunteers: 1. Introductory workshop and associated follow-up interviews Workshop participants will include patient and carer representatives, hospital managers, clinical and voluntary service managers, volunteers, senior clinicians, nurses and therapists. We will arrange individual followup interviews with purposefully selected staff.

2. Delirium Prevention System of Care Implementation Teams

Team members will consist of staff having a potential interest/role in the delirium prevention system of care, e.g. senior manager, senior doctor, matron, nurse consultant and/or specialist nurse, staff nurse, therapist, manager of the volunteer service, volunteer, patient representative, care assistant and ward clerk or housekeeper.

3. Audit of the impact of the intervention on staff workload

All members of the participating ward team and volunteers involved in the delirium prevention intervention present on the participating wards during the audit which will occur over six shifts on each participating ward.

4. Acceptability to staff and volunteers

Interviews and focus groups with a sample of service managers, staff and volunteers from participating wards.

Patients and carers:

1. Patient satisfaction questionnaire

Consecutive patients about to be discharged from the participating wards at the start of the implementation phase and during the delivery phase of the intervention.

2. Patient description

All patients admitted to the participating wards over the six months of the delivery of the delirium prevention system of care intervention.

3. Audit of the impact of the intervention on staff workload

Patients present on the ward at the time of the audit which will occur over six shifts on each participating ward.

4. Acceptability to patients and carers

Interviews with a purposeful sample of patients discharged from participating wards and their carers with differing, positive and negative perceptions of care experiences identified through the satisfaction questionnaire

5. Male and femal participants

6. Aged 65 years and over

Participant type(s)

Patient

Age group

Senior

Sex

Both

Target number of participants

Planned Sample Size: 500; UK Sample Size: 500

Key exclusion criteria

1. Patients in a terminal phase of their illness

2. Does not meet inclusion criteria

Date of first enrolment

01/06/2011

Date of final enrolment 30/11/2012

Locations

Countries of recruitment England

United Kingdom

Study participating centre The Academic Unit of Elderly Care and Rehabilitation Bradford United Kingdom BD9 6RJ

Sponsor information

Organisation Bradford Institute for Health Research (UK)

Sponsor details

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Sponsor type Research organisation

Website http://www.bradfordresearch.nhs.uk/

ROR https://ror.org/05gekvn04

Funder(s)

Funder type

Government

Funder Name National Institute for Health Research (NIHR) (UK)

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

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

Not provided at time of registration

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<u>Results article</u>	results	03/09/2013		Yes	No
<u>Results article</u>		01/03/2021	28/10/2022	Yes	No