ISRCTN01187372 https://doi.org/10.1186/ISRCTN01187372

Prevention of Delirium (POD) for older people in hospital - a feasibility study

Submission date
13/03/2014

Recruitment status
No longer recruiting

Registration date
13/03/2014

Overall study status
Completed

Last Edited
28/10/2022

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Delirium is also known as acute confusion. Someone with delirium can become confused, have difficulty understanding things, and have poor concentration and memory. These problems can come and go throughout the day. Delirium can last for a short time but it can be a serious illness. Although delirium cannot always be prevented, much can be done to reduce the possibility of it happening in hospitalised older patients. The best way is by making sure patients: have enough food and fluid, keep as mentally and physically active as possible, wear their glasses and hearing aids (if they have them), get enough sleep, do not have infections or low oxygen in their blood, are not on too many medications, and are not in pain. We have designed a system of care to help staff to be able to do this. We have called this the Prevention of Delirium (POD) Programme. We don't yet know if using the POD Programme will help staff to stop their patients getting delirium. In order to find this out, we are doing this study. At the end of the study the results will be compared to see if one way of caring for patients is better than the other at preventing delirium.

Who can participate?
All patients aged 65 years or older who do not have delirium when admitted to elderly care /geriatric medicine or orthopaedic trauma/orthopaedic surgery wards.

What does the study involve?
Sixteen wards in eight hospitals across the UK are taking part in this study. Each ward has been put into a group randomly selected by a computer. Eight wards will use the POD Programme system of care and eight will continue to provide their usual care. Recruited patients will have a delirium test daily for up to 10 days, and then at 30 days. Each test will take less than 10 minutes. Patients will also be asked to complete some questionnaires about their general health, what they are able to do and their thoughts on their experience of hospital care. All these questions should take less than 30 minutes each to complete. There will be three questionnaires in total to be completed when they are asked to join the study, and then at 30 days and 3 months after admission. In addition, the study team will also review hospital and social records of recruited patients to work out how much it costs to stop delirium for patients in hospital. Patients will be involved in the study for around 3 months.

What are the possible benefits and risks of participating?
The benefit of taking part would be the early detection and monitoring of delirium and speedier treatment of the causes. As patients' treatment will be the same whether they take part or not there are no extra risks. The daily visits from the researcher and completion of questions may be a little inconvenient.

Where is the study run from?
Sixteen wards in eight hospitals across the UK are taking part in this study:
University Hospitals South Manchester, Nottingham University Hospitals NHS Trust, Poole Hospital NHS Foundation Trust, St Helens & Knowsley NHS Teaching Hospitals Trust - Whiston Hospital, Queen Elizabeth Hospital, University Hospitals Birmingham, York Teaching Hospitals NHS Foundation Trust, Wales (Bangor) and Ipswich Hospital NHS Trust.

When is the study starting and how long is it expected to run for?
The study started in October 2013 and will run for two years.

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

Who is the main contact?
1. Dr Shamaila Anwar (s.t.anwar@leeds.ac.uk)
2. Dr John Green (john.green@bthft.nhs.uk)

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

16222

Study information

Scientific Title
A cluster randomised feasibility study evaluating the Effectiveness and Cost effectiveness of the System of Care versus standard care practice in older patients at risk of developing delirium who are admitted to hospital

Acronym
POD

Study objectives
POD is a cluster randomised feasibility study which seeks to explore the potential clinical and cost-effectiveness of the POD System of Care versus standard care practice in older patients at risk of developing delirium who are admitted to hospital, and to gather data to inform a future larger study. It is the third and final project of a programme of interlinked studies that aims to improve delirium prevention for older people in hospital and reduce the burden of delirium for the NHS through the development of a multi-component delirium prevention system of care (the Prevention of Delirium [POD] Programme).

The primary objectives are to:
1. Provide a preliminary estimate of the effectiveness of POD compared to standard care. as measured by the incidence of new onset delirium within 10 days of hospital admission (anticipated primary outcome for definitive trial)
2. Assess the variability of the incidence of new onset delirium within 10 days of hospital admission in both treatment groups
3. Estimate the Intracluster Correlation Coefficient and likely cluster size
4. Assess barriers to the delivery of the POD system of care (e.g. because of changes to service configuration)
5. Assess compliance with the POD system of care
6. Estimate recruitment and follow-up rates at both patient and cluster levels
7. Assess the degree of contamination at ward level
8. Investigate differences in financial costs and benefits between the POD Programme and standard care practice

Secondary objectives are to: investigate differences in the number, severity and length of delirium episodes (including the presence of persistent delirium [at 30 days post admission to the ward]), length of stay in hospital, in-hospital mortality, destination at discharge, health outcome, physical and social independence, anxiety and depression and patient experience. At 3 months post admission we will also investigate health outcome, physical and social independence and health and social care economic resource use.

Ethics approval required
Old ethics approval format

Ethics approval(s)
First MREC approval date 22/01/2014, 13/YH/0400

Study design
Randomised; Interventional; Design type: Prevention, Process of Care

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

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

Interventions
Participants are randomised to two groups:
1. POD System of Care: The POD System of Care is a quality improvement, multi-component delirium prevention intervention which will be delivered by ward staff and volunteers. It targets modifiable clinical risk factors for delirium (such as immobility, sleep deprivation, dehydration and pain) in vulnerable patients
2. Control group: Usual care
Follow Up Length: 3 month(s); Study Entry: Registration only

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Estimate effectiveness through calculating incidence of delirium within 10 days of hospital admission
2. Estimate cost-effectiveness
3. Assess intervention delivery
4. Estimate recruitment uptake and follow-up rates
5. Assess completeness of follow-up data collection
6. Assess degree of contamination
7. Estimate cost-effectiveness

Secondary outcome measures
1. Number, severity and length of delirium episodes (including persistent delirium at 30 days post admission)
2. Length of stay
3. Death

4. Discharge destination
5. Health outcome as measured by the EQ5D at baseline, 30 days and 3 months
6. Physical and social independence as measured by the NEADL at baseline and 3 months
7. Depression as measured by the Geriatric Depression Scale at 30 days
8. Anxiety as measured by the Clincial Anxiety Scale at 30 days
9. Patient experience as measured by the Patient Reported Experience Measure from the National Audit of Intermediate Care at 30 days
10. Health and social care economic resource as measured by the trial-specific Health Economic resource use questionnaire at 30 days

Overall study start date
10/02/2014

Completion date
03/07/2015

Eligibility

Key inclusion criteria
All patients aged 65 years or older who do not have delirium when admitted to any elderly care /geriatric medicine or orthopaedic trauma/orthopaedic surgery wards taking part in the study will be assessed and given the opportunity to join.

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
Planned Sample Size: 720; UK Sample Size: 720

Total final enrolment
714

Key exclusion criteria
1. Patients with prevalent delirium diagnosed by completion of the Confusion Assessment Method
2. Patients with a planned discharged from hospital within 48 hours of admission (established from information provided by the ward staff)
3. Patients where a delirium assessment (i.e. CAM) has not been performed within 24 hours of admission to the ward (for elderly care patients) or pre-operatively (e.g. fracture patients)
4. Patients who have not provided consent or consultee declaration for trial participation within 48 hours of admission to the ward
5. Patients receiving end of life care (because it is unlikely follow-up data will be available for these patients)

Date of first enrolment
01/08/2014

Date of final enrolment
28/02/2015

Locations

Countries of recruitment
England

United Kingdom

Wales

Study participating centre
University Hospitals South Manchester
Manchester
United Kingdom
M23 9LT

Study participating centre
Nottingham University Hospitals NHS Trust
Nottingham
United Kingdom
NG5 1PB

Study participating centre
Poole Hospital NHS Foundation Trust
Poole
United Kingdom
BH15 2JB

Study participating centre
St Helens & Knowsley NHS Teaching Hospitals Trust - Whiston Hospital
Prescot
United Kingdom
L35 5DR

Study participating centre

Queen Elizabeth Hospital, University Hospitals Birmingham
Birmingham
United Kingdom
B15 2GW

Study participating centre
York Teaching Hospitals NHS Foundation Trust
York
United Kingdom
YO31 8HE

Study participating centre
Ysbyty Gwynedd
Bangor
United Kingdom
LL57 2PW

Study participating centre
Ipswich Hospital NHS Trust
Ipswich
United Kingdom
IP4 5PD

Sponsor information

Organisation
Bradford Institute for Health Research (UK)

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Sponsor type
Research organisation

ROR
https://ror.org/05gekvn04

Funder(s)

Funder type
Government

Funder Name
NIHR Programme Grants for Applied Research; Grant Codes: RP-PG-0108-10037

Results and Publications

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available

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	08/08/2015		Yes	No
Results article	results	15/04/2019		Yes	No
Results article	results	01/07/2020	21/04/2020	Yes	No
Results article		01/03/2021	28/10/2022	Yes	No
HRA research summary			28/06/2023	No	No