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Pilot Trial of "Stop Delirium!"

Submission date
17/05/2012

Recruitment status
No longer recruiting

Registration date
17/05/2012

Overall study status
Completed

Last Edited
04/10/2018

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Delirium (or acute confusion) is a serious illness, common in older people, in which a persons thinking and perceptions may be affected. Reducing delirium is important both because of the considerable distress it causes and poor outcomes associated with it, such as falls, hospital admissions, deaths and costs to the NHS. Preventing delirium is possible; successful interventions in hospitals have reduced it by a third. However, there is little research to guide practice in care homes, where it is likely to be common. In previous research, we developed and tested an intervention, which we called Stop Delirium!. The intervention was based on what is known from the research literature on preventing delirium and on strategies to change professionals practice. We found Stop Delirium! was acceptable to care home staff and had potential to improve care and to improve outcomes for residents. We have yet to find out if it can prevent delirium and whether the additional costs are justified. Before starting on a large (costly) trial to test this, we wish to carry out a pilot study that will test and help improve the design of the main trial. This pilot study will help to address a major gap in the evidence for delirium prevention by providing information that will allow a full trial. It will also help implement recent national (NICE) delirium guidelines, and for intervention homes, increase staff confidence and self-esteem, which is known to be associated with raising quality of care. If shown to be effective in a future trial, Stop Delirium! has the potential to deliver substantial benefits for residents, staff and the NHS.

Who can participate?
All care home residents aged over 60 are eligible unless they are receiving end of life care or have severe communication difficulties. Residents who do not have English as a first language will also be ineligible in this pilot.

What does the study involve?
Twelve care homes (with nursing) will be randomly allocated to receive either Stop Delirium! over 16 months or usual care. We will collect data by administering tests to residents, examining health records and interviewing staff to obtain key information such as how many residents agree to take part and can be followed up and the appropriateness of proposed methods to measure impact and costs.

What are the possible benefits and risks of participating?
Residents may benefit from earlier detection of delirium through the assessments. This would

mean the underlying causes could be treated earlier. If a resident is found to have delirium during the assessments the researcher will, with prior consent, alert the care home manager. It is possible that residents may be distressed by the assessment process. We will not undertake any assessments of individuals where they appear at all reluctant, even if they have formerly consented.

Where is the study run from?
The study is a collaboration between the University of Leeds and Bradford District Care Trust (BDCT) (UK).

When is the study starting and how long is it expected to run for?
The study started in March 2012 and is expected to run until March 2014.

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

Who is the main contact?
Anne Heaven (Research Fellow)
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
12105

Study information

Scientific Title
A cluster randomised controlled pilot trial of 'Stop Delirium!' a complex intervention to prevent delirium in care homes for older people

Acronym
PiTSTOP

Study objectives
Does a multicomponent intervention Stop Delirium!' Prevent Delirium in Care Homes for Older People?

Delirium (or acute confusion) is a serious illness common in older people, in which a persons thinking and perceptions may be affected. Reducing delirium is important because of the considerable distress it causes and the poor outcomes associated with it e.g. falls, hospital admissions, mortality and costs to the NHS. Preventing delirium is possible using multi-component interventions; successful interventions in hospitals have reduced it by one third. However, there is little research to guide practice in care homes.

In previous work we developed a multi-component intervention, called "Stop Delirium!", based on what is already known from the research literature on preventing delirium; and on strategies to change professionals practice. We found Stop Delirium! was acceptable to care home staff and had potential to improve care and to improve outcomes for residents.

We have yet to find out if it can prevent delirium and whether the additional costs are justified. Before starting on a large costly trial of Stop Delirium!, we plan to carry out a pilot that will test and help improve the design of the main trial.

We will select 12 care homes; 6 will be randomised to receive Stop Delirium! over 16 months and 6 to usual care. We will collect data by administering tests to residents, examining their health records and interviewing staff. We will obtain key information e.g rates of recruitment to the study, appropriateness of our proposed methods to measure outcomes, burden of assessments for residents, that will help to plan the main study.

This pilot study will provide information that will allow a full trial. It will also help implement recent national (NICE) delirium guidelines, which recommend multi-component interventions for delirium prevention in care homes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
ref: 12/YH/0018

Study design
Randomised; Interventional; Design type: Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Delirium

Interventions
Input from a Specialist Delirium Practitioner over a 16 month period comprised 3x education sessions and monthly working groups.
Delirium Practitioner work is supported by a Toolkit, Manual and learning resources i.e. 'Delirium box'
The development of a Delirium Champion in the care home.

The methodology for the control arm is care as usual.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Presence of delirium on any day during a 1 month post intervention period. Researchers will examine residents on alternate days (except Sundays).

Secondary outcome measures
Delirium severity (proportion of residents with DRS-R-98 severity scale score >15.25 at any assessment) during the 1 month post intervention period

Overall study start date
26/03/2012

Completion date
31/03/2014

Eligibility

Key inclusion criteria
Care Homes
1. Care homes for older people in Bradford
2. Run by an independent provider (private, voluntary or non profit-making)
3. Managers expressing an interest for their care home to participate in the study

4. Providing nursing care
5. Within catchment area for the City and North Bradford District NHS Care Trust Older Peoples Community Mental Health Teams.

Residents:
1. All people resident in the 12 study care homes during recruitment period recruitment
2. Male and female participants
3. Lower Age Limit 60 years

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
UK Sample Size: 288;

Key exclusion criteria
Care Homes:
1. Local Authority homes
2. Residential homes
3. Specialist homes, except those specialising in providing dementia care
4. Care homes involved in other projects likely to impact on study e.g initiatives to reduce hospital admissions

Residents
1. Unable to participate in assessments because of severe communication difficulties or severe dementia.
2. Receiving end of life care
3. Non-English speakers

Date of first enrolment
26/03/2012

Date of final enrolment
31/03/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

University of Leeds
Leeds
United Kingdom
LS2 9JT

Sponsor information

Organisation
Bradford District Care Trust (UK)

Sponsor details
Lynfield Mount Hospital
Heights Lane
Bradford
England
United Kingdom
BD9 6DP
+44 (0)1274 408600
abc@email.com

Sponsor type
Hospital/treatment centre

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

ROR
https://ror.org/03yzcrs31

Funder(s)

Funder type
Government

Funder Name
Research for Patient Benefit Programme ref: PB-PG-0610-22068

Alternative Name(s)
NIHR Research for Patient Benefit Programme, RfPB

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	05/02/2014		Yes	No
Results article	results	01/09/2016		Yes	No