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A feasibility study of an implementation strategy to improve the detection, assessment, management and prevention of delirium in hospices

Submission date
22/06/2021

Recruitment status
No longer recruiting

Registration date
30/06/2021

Overall study status
Completed

Last Edited
30/09/2024

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
It is common for people to suffer from acute confusion (delirium) towards the end of their life. People with delirium may see or hear things that aren't there and say or do things that are out of character. This is distressing for them, their family, carers and friends. It's important to improve how we assess, prevent, and manage delirium in hospices.
Guidelines for improving delirium care have been issued by, amongst others, the National Institute for Health & Care Excellence. These guidelines clearly state the role of doctors, nurses, and other staff in assessing (using validated questions), preventing (by enabling daily activities of living and symptom management), and managing delirium (by minimising distress). However, in a national UK survey, 38% of palliative care physicians never used delirium guidelines and only 10% of hospices used a delirium screening tool.
The aim of this study is to underpin a future study that tests whether the use of an implementation strategy (the intervention) designed to improve guideline-adherent delirium care in palliative care settings is associated with improved patient outcomes (reduced number of days with delirium).

Who can participate?
Members of the public and hospice volunteers, staff, and management.

What does this study involve?
This study addresses the guideline implementation challenge of how to bring together practical support (e.g. screening tools and clinical pathways) and communication between family, friends, volunteers, and health professionals to support hospice teams to deliver guideline-adherent delirium care in everyday practice. At three Yorkshire hospices, the researchers will:
1. Run workshops with members of the public and hospice volunteers, staff, and management to adapt an existing implementation plan for hospices
2. Test the potential for a future national study to see if better implemented guideline-adherent care benefits patients (reduces delirium) by studying the feasibility of using clinical record

entries to diagnose delirium, study participation, and the extent to which the implementation plan was used
3. Assess the acceptability and flexibility of the implementation plan in hospice volunteers, staff, and management using surveys and interviews about their experiences of implementing delirium guidelines

What are the possible benefits and risks of participating?
This research will address the Department of Health and Social Care's recommendation of ensuring equal access to high-quality palliative care through symptom assessment, management, and prevention, and the NHS Long Term Plan priority area of providing 'out of hospital' care within Integrated Care Systems. The researchers do not anticipate any risk in this study to staff, patients, or carers.

Where is the study run from?
University of Hull (UK)

When is the study starting and how long is it expected to run for?
February 2021 to February 2023

Who is funding the study?
Yorkshire Cancer Research (UK)

Who is the main contact?
Dr Mark Pearson
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Study website
https://www.hyms.ac.uk/research/research-centres-and-groups/wolfson/delirium

Contact information

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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
299277

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 299277

Study information

Scientific Title
The DAMPen-D study - improving the Detection, Assessment, Management, and Prevention of Delirium in hospices: co-design and feasibility study of a flexible and scalable implementation strategy to deliver guideline-adherent delirium care

Acronym
DAMPen-D

Study objectives
To underpin a future national quasi-experimental study that tests whether the use of an implementation strategy (the intervention) designed to improve guideline-adherent delirium care in palliative care settings is associated with improved patient outcomes (reduced number of days with delirium), this study will demonstrate if it is possible to:
1. Co-adapt an implementation strategy (Creating Learning Environments for Compassionate Care (CLECC)) for use in hospices (Work Package 1)
2. Systematically and reliably collect data (including delirium diagnosis) from clinical records in a way that minimises burden for patients, families, and staff (Work Package 2)
3. Collect measures of staff engagement with the implementation strategy, delivery of guideline-adherent delirium care, and the costs of staff involvement (Work Packages 2 and 3)
4. Collect explanatory process data about staff use of the implementation strategy (Work Package 3)
5. Estimate the number of palliative care sites and in-patient episodes needed for the planned national quasi-experimental study

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 15/04/2021, Hull York Medical School Ethics Committee (University of Hull, Cottingham Road, Hull HU6 7RX, UK; +44 (0)870 1245500; info@hyms.ac.uk), ref: 21/23
2. Approved 28/05/2021, Health Research Authority (HRA) Research Ethics Committee, Wales REC 7 (Public Health Wales Meeting Room, Building 1, St. David's Park, Carmarthen, SA31 3HB, UK; +44 (0)29 2023 0457; Wales.REC7@wales.nhs.uk), ref: 21/WA/0180
3. Approved 14/06/2021, Health Research Authority (HRA) Confidentiality Advisory Group (CAG) (2 Redman Place, Stratford, London, E20 1JQ, UK; +44 (0)20 7104 8100, cag@hra.nhs.uk), ref: 21/CAG/0070

Study design
Multi-centre co-design and feasibility study

Primary study design
Observational

Secondary study design
Feasibility study and process evaluation

Study setting(s)
Other

Study type(s)
Quality of life

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Detection, assessment, management and prevention of delirium in hospice in-patients

Interventions
Each hospice will be supported by the study team to use the CLECC-Pal plan to implement guideline-adherent delirium care over a minimum 12-week period. Hospices who wish to continue following this period (e.g. if they find it helpful) would be encouraged to do so. A hospice lead clinician has been identified and the following CLECC-Pal activities will be put in place (NB these may be subject to change depending on Work Package 1: co-design workshops)
1. A team study session in which CLECC-Pal is introduced and training given regarding guideline-adherent delirium care, including use of screening tools, patient care plans and computer- or paper-based templates for clinical record keeping (as relevant). Teaching materials and IT templates for SystOne are already prepared during our previous work
2. Ward manager action learning sets, mid-shift 'cluster discussions' and twice-weekly reflective discussions regarding the use of guideline-adherent delirium care, and peer observations of practice

Intervention Type
Behavioural

Primary outcome measure
Feasibility will be assessed by:
1. Number of relevant hospice staff engaging and maintaining engagement with CLECC-Pal during the 12-week intervention period
2. Ability to collect high validity, anonymised delirium outcome data from clinical records using an expanded version of a chart based tool developed by Inouye et al. at baseline and 12 weeks
3. Cost data in relation to the number of staff hours engaged in CLECC-Pal activities during the 12-week intervention period
4. Variability in delirium day measures (to calculate sample size for a subsequent national study) at baseline and at 12 weeks

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
15/02/2021

Completion date
14/02/2023

Eligibility

Key inclusion criteria
Work package 1 (co-design):
Not applicable

Work package 2 (feasibility study):
In-patients admitted to study hospices

Work package 3 (process evaluation):
Hospice staff (healthcare assistants, nurses, allied health professionals, doctors, volunteers, care managers and executive board members) and volunteers directly and/or indirectly involved with the delivery of care

Participant type(s)
Patient, Health professional

Age group
Adult

Sex
Both

Target number of participants
Work package 1: Not applicable; Work package 2: 300 case records; Work package 3: 30 survey responses, 15 interviews

Total final enrolment
425

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
05/07/2021

Date of final enrolment
31/01/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Dove House Hospice
Chamberlain Road
Hull
United Kingdom
HU8 8DH

Study participating centre
St Leonard’s Hospice
185 Tadcaster Road
York
United Kingdom
YO24 1GL

Study participating centre
Marie Curie Hospice
Maudsley Street
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United Kingdom
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Study participating centre
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Sponsor type
University/education

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ROR
https://ror.org/04nkhwh30

Funder(s)

Funder type
Charity

Funder Name
Yorkshire Cancer Research

Alternative Name(s)
YCR

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
A full report of the study's methods and findings will be prepared for the funder (Yorkshire Cancer Research) and a manuscript reporting the findings submitted to a peer-reviewed journal. The study's findings will be submitted for oral presentation at one national health services research conference and one international palliative care conference.

A plain English summary of study findings will be prepared for distribution through palliative care clinical networks (including Hospice UK) and public involvement groups.

Consistent with our application to Health Research Authority Confidentiality Advisory Group, participant-level data will not be shared.

Intention to publish date
15/02/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available. Whilst the data is completely anonymous and would be suitable for sharing, following discussion with Patient & Public Involvement Group members who expressed some concern, the researchers felt it was more appropriate to uphold their wishes to not share the data. The data will be preserved for 5 years after the research has taken place in the Hull Health Trials Unit Box (a cloud-based storage system that uses AES-256 encryption in transit and at rest). Once the 5 years is complete, the data will be destroyed.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version V1.0		08/07/2021	No	Yes
Protocol article		13/07/2022	14/07/2022	Yes	No
HRA research summary			28/06/2023	No	No
Results article		01/04/2024	30/09/2024	Yes	No