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Enhancing care for delirium in palliative care units

Submission date
28/03/2025

Registration date
16/04/2025

Last Edited
24/10/2025

Recruitment status
Recruiting

Overall study status
Ongoing

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

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 lives. One-third of people have delirium when they are admitted to a palliative care unit or hospice, and a further one-third develop delirium during their stay. People with delirium may see or hear things that aren't there, say or do things that are out of character, and can't 'think straight'. This can be distressing for the person, their family, and staff. Delirium also causes unnecessary 'downward spirals' in a person's day-to-day abilities. This results in them having increased care needs in the community and unplanned and expensive hospital admissions. There is clear national guidance on the actions needed to prevent, detect, assess, and manage delirium. However, it is difficult for hospices to put this guidance into practice because delirium care is complex and involves lots of different people, including family, friends and health professionals. This study uses a way to help hospices overcome these difficulties and follow delirium guidelines better. These methods have been tested on a small scale, which showed that information can be collected from patients' notes and hospice staff in a reliable and timely way. This study will be a major, national trial to test whether this improves delirium care and reduces delirium in hospices. This will improve the quality of life of the 28,000 people in the UK each year who have delirium whilst in a hospice. The study also wants to improve the well-being of the 112,000 carers (family and friends) who witness the damaging effects of delirium on their loved ones.

Who can participate?
Adult inpatients in a palliative care unit or hospice with capacity to consent

What does the study involve?
1. Compare what happens when 10 hospices test our new approach, alongside 10 hospices who continue their normal ways of working
2. Assess the cost-effectiveness of our approach
3. Look at how our approach works in different hospices and what makes it work well
4. Explore how to adapt our approach for use in different settings, such as care homes and people's own homes

How have people with experience helped?
The original project was supported and guided by four people with personal experience of

caring for a loved one with delirium. People with personal experience, in partnership with hospice staff, also helped to co-design our new approach. In developing this next stage, the researchers reached out to involve new people with different perspectives and backgrounds. They agreed that reducing delirium would make a big difference to distress and could reduce 'downward spirals' in people's day-to-day abilities. They commented on overall design and study materials, e.g. highlighting the importance of including hospices in ethnically-diverse areas and producing study materials in languages other than English. Someone who has a valuable mixture of personal and professional experience of delirium in a hospice setting will join the research team as a public co-applicant. They will chair the public advisory group, help analyse interview data, and help to run our planned workshops.

What are the possible benefits and risks of participating?
Palliative care patients who agree to participate in research can find the opportunity to discuss their care and how it can inform the provision of palliative care in the future helpful. Given this project is about embedding evidence-based guideline-recommended delirium care in practice, patients receiving care after the hospice starts to use CLECC-Pal to help do this may result in better patient care and a reduction in delirium. However, as it is unknown whether CLECC-Pal will be successful in doing this, thus not possible to say for sure that this is the case.

Cluster RCT:
The proposed opt-out process would mean that there would be no study participants in the sense meant by this question, and the intervention does not directly make any changes to patient care. However, processing of patient data introduces a low risk of data breach due to the need to hold identifiable patient information. Steps are being undertaken to mitigate that risk. These steps include the separation of identifiers from study data and the deletion of identifiers when linkage is complete. Further, the technical and operational controls around the environments used to process the data (backed by accreditation) give confidence that risks are minimised.

Process evaluation:
Patients and carers may appreciate the importance of sharing their experiences in an interview as a way of informing improvements in the delivery of care, especially at a stage of life where those experiences are commonly under-researched. Potential risk or burden could occur where symptoms arise (e.g. fatigue, nausea, pain) that make participation in an interview difficult or uncomfortable, but such risks will be minimised by the participation of patients and carers being led by the clinically-informed judgement of the Principal Investigator (or their delegate) at each site regarding the appropriateness or not of approaching patients and/or carers about, or proceeding with, interviews. There will be an ongoing assessment of participants' decision-making capacity, including during the conduct of interviews. Details of how the patient participant identification, screening, consent and interview process will minimise risks and burdens follow below.

Each Site Principal Investigator (PI) will identify staff members who can be approached to participate in interviews with the research team, and inpatients and informal carers who can be approached to participate in interviews with the research team. The Site Pl, in conjunction with relevant clinicians at their PCU, will assess whether patients have capacity to be approached about research, whether they need to be approached while their informal carer is present, and whether they are no longer experiencing delirium. Inpatients and their family member/informal carer will be offered the option of telephone, virtual or in-person interviews while the patient is staying in the PCU. Prior to the interview, both the informal caregiver/and or the patient will be asked about their participation preferences. The informal carer and/or patient will be asked if they wish (i) the carer to join the patient interview to facilitate the patient's participation, (ii) the

carer join the patient interview to offer their own views about the care provided (iii) have separate interviews. They can select any or all of the three options. A Participant Information Sheet (PIS) will be provided to the staff member, inpatient and their informal carer prior to the interview by the site PI or a suitably trained delegate.

Semi-structured interviews will be undertaken in the PCU. Every effort will be made to find a quiet and comfortable room to interview to maintain privacy as much as possible. All interviews will be recorded and transcribed. Interviews may be taken with frequent breaks to ensure that a patient is not fatigued by the process and will be stopped early if necessary or rearranged. However, there is potential that some patients and informal carers feel upset during the interview as a result of talking about their life circumstances, experiences of delirium, and the care they are receiving. The Qualitative Researcher undertaking the interviews will be an experienced palliative care researcher and will listen to patients and informal carers sensitively, and allow breaks or withdrawal from the interview if they wish. It will not be the Qualitative Researcher's role to offer any counselling, but if the Qualitative Researcher is concerned about distress during or after the interview, with the interviewee's permission, the Qualitative Researcher will pass their concerns on to the PCU team. The team will work with the PCUs to ensure that clear safeguarding policies and reporting mechanisms are in place.

Where is the study run from?
University of Hull, UK

When is the study starting and how long is it expected to run for?
October 2024 to September 2028

Who is funding the study?
NIHR, UK

Who is the main contact?
Mr Grant Constable, grant.constable@hyms.ac.uk

Study website
https://hhtu.hull.ac.uk/dampen-d-ll/

Contact information

Type(s)
Scientific, Principal investigator

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Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
351878

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 67161, NIHR161360

Study information

Scientific Title
DAMPen-Delirium II: Improving the detection, assessment, management, and prevention of delirium in palliative care units: a cluster randomised-controlled trial, economic analysis and process evaluation

Acronym
DAMPen-Delirium II

Study objectives
To evaluate the effectiveness and cost-effectiveness of a clinical guideline implementation strategy (CLECC-Pal Delirium) to improve the early detection, management and prevention of delirium among palliative care unit (PCU) in-patients.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 12/03/2025, Yorkshire & The Humber - Bradford Leeds Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, United Kingdom; +44 (0)2071048083; bradfordleeds.rec@hra.nhs.uk), ref: 25/YH/0071

2. Approved 20/05/2025, Confidentiality Advisory Group (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8353; cag@hra.nhs.uk), ref: 25/CAG/0045

Study design
Adaptive implementation-to-target cluster randomized controlled trial with economic evaluation and process evaluation

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Hospice

Study type(s)
Efficacy

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

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

Interventions
The DAMPen-Delirium II study has three work packages:

1. Cluster Randomised Controlled Trial (CRCT)
This work package will evaluate the effectiveness of CLECC-Pal Delirium vs. usual practice on reducing the proportion of in-patient delirium days in palliative care units. The intervention to be tested (a clinical guideline implementation strategy called CLECC-Pal Delirium) comprises five components: training on delirium screening, assessment and management; mid-shift cluster discussions by the professionals delivering care; peer observations of practice; reflective discussions; and action learning sets (all designed to implement changes in delirium screening, assessment and management).

Twenty palliative care units (charitably-funded or NHS) will be randomised (1:1) to the study intervention arm or the usual practice arm. Using an opt-out process, the study will collate approximately 50 sequentially admitted inpatient records from each of the 20 PCU sites at two time points (approximately 1000 records at baseline and approximately 1000 records at follow-up). Based on delirium episodes in our completed feasibility study, it is expected that a minimum of 50 consecutive inpatient records will be required (from each site and at two timepoints) to identify 30 delirium episodes at baseline and 30 episodes at follow-up (total 1200 delirium data records). The study will collate data records from PCU inpatients (stopping record identification

at each site as soon as 30 delirium episodes have been identified) at both timepoints (baseline and follow up) to obtain a total of 1200 episodes of delirium (600 baseline and 600 follow-up,) to achieve a 92.3% power required to detect a 12% reduction of proportion of inpatient days affected by delirium, at 0.05 significance level, assuming an ICC of 0.03. It is expected that there will be a reduced duration of delirium episodes in the follow-up group after the interventions, so adequate consecutive inpatient records will be reviewed during the follow-up period to ensure the data collection of 30 delirium episodes per site.

This study was built on the CAG-approved opt-out process used in the feasibility study (posters and information leaflets in admission packs) through discussion with members of our Public Advisory Group, adding a defined process for the principal investigator at each study site who will have responsibility for ensuring that staff, at a clinically appropriate time, verbally introduce the study to patients and their carers and document this in the patient record.

2. Health Economic Evaluation
This work package will evaluate the cost-effectiveness of CLECC-Pal Delirium vs. usual practice on reducing the proportion of in-patient delirium days in palliative care units (PCU), linking data collection from the cRCT with Hospital Episode Statistics (HES) (for which a separate NHS Data Access Request Service (DARS) application is being prepared). Costs (payer perspective) will be estimated in two settings: palliative care unit (via routine data) and acute hospital (via linked HES data), with all data housed and analysed exclusively in the University of Hull's Data Safe Haven. The cost of a day in PCU will be estimated, stratified by PCU type, using Personal Social Services Research Unit (PSSRU) data, differentiating between staffing costs for patients with and without delirium, based on staff logs and discussions with clinicians and managers. Acute hospital admissions will be identified via linked HES data and estimated associated costs using reference costs adjusted for HRG code, co-occurring conditions including delirium, and length of stay. There will be adjustments for the additional cost associated with an acute hospital admission ending in death.

As this work package will link data collected in the first work package with existing HES data, the only additional ethical considerations are around data governance (as specified in the relevant sections of our CAG application).

3. Process Evaluation
This work package will improve understanding of variations in the implementation of CLECC-Pal-delirium in the Palliative Care Units in the CRCT.

Interviews with patients, carers and staff will be conducted in four out of the ten intervention site PCUs, starting six months after the site commenced the use of CLECC-Pal Delirium. Purposive sampling will be used based on: PCU type, PCU size, diversity of population served, and historical participation with interventional research. In each of the four site PCUs, there will be interviews undertaken with 6-10 staff (total 24-40) and 6-10 inpatients and their informal carers (total 24-40).

The site PI, in conjunction with relevant clinicians at their PCU, will assess whether patients have capacity to be approached about research, whether they need to be approached while their informal carer is present, and whether they are no longer experiencing delirium. Interviews will be arranged for a mutually convenient time and location and will take place in a private room (either face to face or remotely). The Qualitative Researcher undertaking the interviews will be an experienced palliative care researcher and will listen to patients and informal carers sensitively, and allow breaks or withdrawal from the interview if they wish. It will not be the Qualitative Researcher's role to offer any counselling, but if the Qualitative Researcher is

concerned about distress during or after the interview, with the interviewee's permission, the Qualitative Researcher will pass their concerns on to the PCU team. Work will be in conjunction with the PCUs to ensure that clear safeguarding policies and reporting mechanisms are in place.

Note that the aim of the Process Evaluation (to understand variation in the implementation of CLECC-Pal-delirium in Palliative Care Units) means that the focus is on patients' and carers' experiences of the overall care environment rather than their experience of delirium per se. For this reason, the purposive sampling frame will include all PCU inpatients with capacity to consent during the stated timeframe.

Patient and carer participant information sheets have been reviewed by members of our Public Advisory Group, with numerous suggestions for improving clarity of language and presentation incorporated in the final versions.

Intervention Type
Behavioural

Primary outcome measure
Primary outcome measures (clinical):
The proportion of inpatient days affected by delirium for inpatients who experience delirium during PCU admission, calculated as the number of days they experience delirium (as identified with the Inouye tool by HHTU researchers) divided by their total number of inpatient days, measured using data extracted from patient records at one timepoint

Secondary outcome measures
Secondary outcomes (process-related and clinical):
1. Guideline adherence: The number of inpatient records that contain the following evidence of adherence to delirium care guidelines (for the detection, assessment, management and prevention of delirium) at baseline and follow-up:
1.1. Use of 4AT screening tool
1.2. Presence/absence of delirium risk assessment
1.3. Use of Richmond Agitation-Sedation Scale-Pal
1.4. Clinician-documented diagnosis of delirium
1.5. Clinician assessment of cause/reversibility
1.6. Presence/absence of delirium care plan
1.7 Use of antipsychotics in relation to documented harmful/distressing behaviour towards self or others
2. Cost-effectiveness: The incremental cost-effectiveness ratio measures the cost per PCU inpatient day saved by preventing delirium, measured using data collection from the cRCT linked with Hospital Episode Statistics (HES) at the end of the study
3. Inpatient Demographics measured using data extracted from patient records at one timepoint:
3.1. Age
3.2. Sex
3.3. Diagnosis
3.4. Ethnicity
3.5. Postcode (converted to IMD score at data collection)
3.6. Primary Medical Condition
3.7. Date of Death (if applicable)
3.8. Length of stay

Overall study start date

01/10/2024

Completion date
30/09/2028

Eligibility

Key inclusion criteria
Inpatients/Carers Inclusion Criteria:
1. Inpatients with capacity to consent
2. Carers of inpatients with capacity to consent

Participant type(s)
Carer, Patient

Age group
Adult

Sex
All

Target number of participants
2000 datasets (24-40 participants to be interviewed as part of this study)

Key exclusion criteria
Interview: Inpatients/Carers Exclusion Criteria:
1. Patients who do not have capacity at the point of interview will be withdrawn
2. Carers of inpatients without capacity to consent

Date of first enrolment
01/07/2025

Date of final enrolment
30/09/2028

Locations

Countries of recruitment
England

United Kingdom

Wales

Study participating centre
Alice House Hospice
Alice House
Wells Avenue

Hartlepool
United Kingdom
TS24 9DA

Study participating centre
Compton Care
Compton Care Group Ltd
4 Compton Road West
Wolverhampton
United Kingdom
WV3 9DH

Study participating centre
Dorset University Hospitals
Megan Howarth, Macmillan Unit, Christchurch Hospital, Fairmile Road
Christchurch
United Kingdom
BH23 2JX

Study participating centre
Douglas Macmillan Hospice
Barlaston Road
Stoke-on-trent
United Kingdom
ST3 3NZ

Study participating centre
Eden Valley Hospice
Durdar Road
Carlisle
United Kingdom
CA2 4SD

Study participating centre
Gateshead Health NHS Foundation Trust
Queen Elizabeth Hospital
Sheriff Hill
Gateshead
United Kingdom
NE9 6SX

Study participating centre
Havens Hospices
226 Priory Crescent
Southend-on-sea
United Kingdom
SS2 6PR

Study participating centre
Lindsey Lodge Hospice
Burringham Road
Scunthorpe
United Kingdom
DN17 2AA

Study participating centre
Marie Curie Hospice Cardiff and the Vale
Bridgeman Road
Penarth
United Kingdom
CF64 3YR

Study participating centre
Coventry Myton Hospice
Clifford Bridge Road
Walsgrave
Coventry
United Kingdom
CV2 2HJ

Study participating centre
North London Hospice
47 Woodside Avenue
London
United Kingdom
N12 8TT

Study participating centre
Northumbria Palliative Care Unit
Lorelle Dismore

Clinical trials office
Education Centre
North Tyneside General Hospital
Rake Lane
North shields
United Kingdom
NE29 8NH

Study participating centre
Pilgrims Hospice Canterbury
56 London Road
Canterbury
United Kingdom
CT2 8JA

Study participating centre
Sue Ryder Care Home
Leckhampton Court Hospice
Church Road
Leckhampton
Cheltenham
United Kingdom
GL53 0QJ

Study participating centre
St Andrews Hospice
Peaks Lane
Grimsby
United Kingdom
DN32 9RP

Study participating centre
St Christophers Hospice
51-59 Lawrie Park Road
London
United Kingdom
SE26 6DZ

Study participating centre
St Clare Hospice
Stone Barton

Hastingwood Road
Hastingwood
Harlow
United Kingdom
CM17 9JX

Study participating centre
St Lukes the Sheffield Hospice
Little Common Lane
Sheffield
United Kingdom
S11 9NE

Study participating centre
St Margarets Hospice
Heron Drive
Bishops Hull
Taunton
United Kingdom
TA1 5HA

Study participating centre
Walsall Hospice
Goscote Lane
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WS3 1SJ

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Sponsor type
University/education

Website
https://www.hull.ac.uk

ROR
https://ror.org/04nkhwh30

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

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
We will prepare Plain English summaries, Evidence Briefings, and policy papers, as well as presenting evidence to policy makers (including All-Party Parliamentary Groups) and working with the NIHR Palliative Care Policy Research Unit. We will also publish papers in peer-reviewed journals and present our findings at conferences.

Intention to publish date
30/09/2029

Individual participant data (IPD) sharing plan
The datasets generated during and analysed during the current study will be stored in a publicly available repository. All data will be stored and analysed pseudonymised.

IPD sharing plan summary

Stored in publicly available repository