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

Submission date 22/06/2021	<b>Recruitment status</b> No longer recruiting	[X] Prospectively registered		
		[X] Protocol		
Registration date	Overall study status Completed	Statistical analysis plan		
30/06/2021		[X] Results		
<b>Last Edited</b> 30/09/2024	Condition category  Mental and Behavioural Disorders	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 Mark.pearson@hyms.ac.uk

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### Additional identifiers

#### Clinical Trials Information System (CTIS)

Nil known

#### Integrated Research Application System (IRAS)

299277

#### ClinicalTrials.gov (NCT)

Nil known

#### Protocol serial number

**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

#### Study type(s)

Quality of life

#### 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(s)

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

#### Key secondary outcome(s))

There are no secondary outcome measures

#### 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

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Sex

All

#### 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

**United Kingdom** 

England

#### 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

Bradford United Kingdom BD3 9LE

Study participating centre St Catherine's Hospice Throxenby Lane

Scarborough United Kingdom YO12 5RE

# Sponsor information

#### Organisation

University of Hull

#### **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**

#### 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?
Results article		01/04/2024	30/09/2024	Yes	No
<u>Protocol article</u>		13/07/2022	14/07/2022	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	version V1.0		08/07/2021	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes