

Development of a delirium detection tool in hospice patients

Submission date 03/02/2020	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 21/02/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 18/06/2024	Condition category Mental and Behavioural Disorders	<input checked="" type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Delirium is one of the most common and serious neuropsychiatric conditions affecting specialist palliative care (hospice) inpatients. Delirium is associated with increased morbidity and mortality. Patients' ability to communicate may be impaired, as may their decision-making ability and quality of life. If delirium is detected earlier or more accurately, it can result in better treatment for patients. However, delirium often goes unrecognised because of the lack of quick and simple ways to detect it. The '4AT' is a short and simple bedside test for detecting delirium. Previous research studies have shown it to be an effective test in hospitalised patients. The 4AT is already used in hospices, however, it has not been proven in this setting. The aim of this study is to explore how accurately the 4AT can diagnose delirium in hospice inpatients.

Who can participate?

Patients aged 18 and over who are admitted to hospice inpatient units

What does the study involve?

Two sets of tests of thinking, memory and concentration will be done by the participant's bedside by two different healthcare professionals (a nurse or a doctor). One set of tests will last around 2 minutes (the 4AT), and the other set (the reference standard delirium assessment) lasts up to 15-20 minutes. There are no treatments or invasive investigations. The researcher will also seek the participant's permission to examine their medical notes, and speak to the hospice team looking after them and/or someone who knows them well.

What are the possible benefits and risks of participating?

The hospice team looking after the patient will be informed of the results of the assessments. It may help the patient's care if they have this information. It is hoped that the results of the study will help nurses and doctors decide if they should use the 4AT test in hospice settings. The only disadvantage of taking part in the study is that the participant might find the questions irritating – however, the participant can choose to stop at any point if they wish. There are no significant risks in this study.

Where is the study run from?

The study is being held at Marie Curie Hospices in Edinburgh and Glasgow (UK)

When is the study starting and how long is it expected to run for?
January 2019 to March 2022

Who is funding the study?
Marie Curie (UK)

Who is the main contact?
Dr Elizabeth Arnold
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
262658

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
AC19073, IRAS 262658

Study information

Scientific Title
Preliminary validation study of the 4AT delirium assessment tool in specialist palliative care inpatients

Study objectives

To determine the validity or accuracy of the 4AT for delirium detection versus a reference standard delirium assessment in specialist palliative care inpatient (hospice) populations.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 15/10/2019, Scotland A Research Ethics Committee (Scotland A REC) (2nd Floor Waverley Gate, 2-4 Waterloo Place, Edinburgh, EH1 3EG, UK; +44 (0)131 465 5680; Manx.neill@nhslothian.scot.nhs.uk), ref: 19/SS/0091

Study design

Multicentre randomized cross over trial

Primary study design

Interventional

Secondary study design

Randomised cross over trial

Study setting(s)

Other

Study type(s)

Diagnostic

Participant information sheet

See study outputs table

Health condition(s) or problem(s) studied

Delirium

Interventions

Participants will undergo two assessments for detecting delirium:

1. The 4AT, a quick, easy to use test, which takes around 2 min to complete
2. A reference standard delirium assessment, which takes up to 15-20 min to complete. The reference standard delirium assessment will be based on the core diagnostic criteria for delirium as documented in the fifth edition of the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders.

The two assessments will be completed independently by two clinicians. The order of the tests will be randomised in a 1:1 ratio. The randomisation process will occur immediately after consent is obtained. During the assessment period, there will be no direct communication about the participant between the two clinicians, until both assessments are completed (other than to schedule the order of the tests). This is to ensure blinding of the assessment results. Given the fluctuating nature of delirium, the assessments will be completed within a maximum time period of 3 h, with a target time interval of 15 min.

Intervention Type

Behavioural

Primary outcome measure

1. The accuracy of the 4AT in detecting delirium amongst hospice inpatients compared to the reference standard assessment centred on the DSM-5 criteria for delirium
 2. The diagnostic accuracy of the 4AT assessed using specificity, sensitivity, positive and negative predictive values
- Measured at a single study visit

Secondary outcome measures

There are no secondary outcome measures

Overall study start date

01/01/2019

Completion date

31/03/2022

Eligibility**Key inclusion criteria**

1. Aged 18 years or over
2. Acutely admitted to a specialist palliative care inpatient unit

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

200-240 participants: the researchers are aiming to recruit 240 participants, across the 3 sites, allowing for two hundred participants with complete data suitable for analysis.

Key exclusion criteria

1. Acute life-threatening illness requiring time-critical intervention
2. Coma
3. Unable to communicate in English. (The cognitive tests used have not been validated in non-English speakers, hence the study only includes patients who can communicate fluently in English.)
4. Severe dysphasia
5. Combined severe hearing and visual impairment, which would limit participation in the study's tests
6. High level of patient and family distress, as judged by the clinical team

Date of first enrolment

17/10/2019

Date of final enrolment

31/03/2022

Locations

Countries of recruitment

Scotland

United Kingdom

Study participating centre**Marie Curie Hospice Edinburgh**

45 Frogston Road West

Edinburgh

United Kingdom

EH10 7DR

Study participating centre**Marie Curie Hospice Glasgow**

Balornock Road

Glasgow

United Kingdom

G21 3US

Sponsor information

Organisation

University of Edinburgh

Sponsor details

ACCORD

The Queen's Medical Research Institute

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EH16 4TJ

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resgov@accord.scot

Sponsor type

University/education

Website

<http://www.accord.scot>

ROR

<https://ror.org/01nrxf90>

Funder(s)

Funder type

Charity

Funder Name

Marie Curie Cancer Care

Results and Publications

Publication and dissemination plan

The researchers plan to submit the protocol for publication and plan to publish information from the study in a peer-reviewed medical journal and/or present at a conference.

Intention to publish date

20/05/2024

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in the publically available repository at Edinburgh Datashare; <https://datashare.ed.ac.uk/handle/10283/8794>.

The SPIRIT checklist has been uploaded as an additional file. (added 11/03/2021)

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version V4	14/08/2019	09/03/2021	No	Yes
Participant information sheet	version V4	14/08/2019	09/03/2021	No	Yes
Participant information sheet	version V4	14/08/2019	09/03/2021	No	Yes
Other files	Spirit Checklist		11/03/2021	No	No

HRA research summary		28/06/2023	No	No
Protocol article	26/04/2021	06/03/2024	Yes	No
Dataset	07/06/2024	18/06/2024	No	No
Results article	01/05/2024	18/06/2024	Yes	No