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Development of a delirium detection tool in hospice patients

Submission date
03/02/2020

Recruitment status
No longer recruiting

Registration date
21/02/2020

Overall study status
Completed

Last Edited
18/06/2024

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[X] 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

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
262658

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Diagnostic

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 a 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(s)
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

Key secondary outcome(s))

There are no secondary outcome measures

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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
United Kingdom

Scotland

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
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Sponsor information

Organisation
University of Edinburgh

ROR
https://ror.org/01nrxwf90

Funder(s)

Funder type
Charity

Funder Name
Marie Curie Cancer Care

Results and Publications

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?
Results article		01/05/2024	18/06/2024	Yes	No
Protocol article		26/04/2021	06/03/2024	Yes	No
Dataset		07/06/2024	18/06/2024	No	No
HRA research summary			28/06/2023	No	No
Other files	Spirit Checklist		11/03/2021	No	No
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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes