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An observational study to assess the performance of the 4AT tool for measuring recovery from delirium in hospitalised older people

Submission date
11/02/2022

Recruitment status
No longer recruiting

Registration date
22/02/2022

Overall study status
Completed

Last Edited
10/03/2022

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
People who are in hospital can develop short-term problems with memory, thinking and concentration, or become drowsy as a result of their condition. This problem is called 'delirium'. Delirium can be very distressing. However, delirium is often not recognised in hospital.
The ‘4AT’ is a short and simple test of thinking and memory. The test is routinely used in many hospitals in the UK and across the world to detect delirium.
Delirium usually lasts for a few days but it may continue for weeks or months. It is important for staff to know if a person is recovering from delirium, or if the delirium is ongoing, because this may help them manage and treat these patients better. However, there are currently no tests to accurately measure recovery from delirium. This is an important gap in medical practice.
The aim of this study is to assess how accurate the 4AT is in checking if a person has recovered from delirium. Better assessment of delirium over time may result in better care and treatment of patients with delirium.

Who can participate?
Older people who are in hospital and are having some acute problems with thinking and memory, which we call delirium.

What does the study involve?
Patients will be seen by two different researchers in the hospital. Each researcher will ask them to do short tests of thinking, memory and concentration. The tests last between 10 and 25 minutes in total. They can do the tasks in their bed or bedside seat. There will be a break of between 15 minutes to 3 hours between the two visits. These tests will be carried out on 2-3 more days during their stay in hospital; this is so we can see what happens to the test performance over time.

What are the possible benefits and risks of participating?
We will inform the healthcare team in hospital about the results of the tests. We will also inform

each patient's GP of the results of the tests. We hope the results of this study will help doctors and nurses decide if they should use the 4AT test to check if a person has recovered from delirium. It may lead to improved treatment and care of affected patients.
The only disadvantage is that patients might find the test questions irritating. However, they can choose to stop at any point if they wish.

Where is the study run from?
The Royal Infirmary of Edinburgh (UK)

When is the study starting and ending?
December 2021 to July 2022.

Who is funding the study?
The study is funded by the Dunhill Medical Trust (independently endowed charity). The University of Edinburgh and NHS Lothian Health Board are co-sponsoring the research (UK)

Who is the main contact?
Prof Alasdair MacLullich, a.maclullich@ed.ac.uk
Dr Zoë Tieges, zoe.tieges@ed.ac.uk

Contact information

Type(s)
Principal Investigator

Contact name
Prof Alasdair MacLullich

Contact details
51 Little France Crescent
Edinburgh
United Kingdom
EH16 4SA
+44 131 242 6481
a.maclullich@ed.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
273848

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
AC19145. IRAS 273848, CPMS 49506

Study information

Scientific Title
Assessing recovery from delirium in older hospitalised people: optimisation and validation of the 4AT

Study objectives
The 4AT is a rapid clinical assessment tool for delirium detection. The 4AT is sometimes used to assess for delirium recovery using repeated administration but it has not been validated for this purpose.

The aim of this research study is to validate the 4AT as a tool for assessment of delirium recovery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 10/03/2020, Scotland A Research Ethics Committee (Research Ethics Service, 2nd Floor Waverley Gate, 2-4 Waterloo Place, Edinburgh, EH1 3EG; UK; +44 131 465 5680; manx.neill@nhslothian.scot.nhs.uk), ref: 20/SS/0010

Study design
Single-centre longitudinal prospective observational cohort study

Primary study design
Observational

Secondary study design
Longitudinal study

Study setting(s)
Hospital

Study type(s)
Screening

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

Health condition(s) or problem(s) studied
Assessing delirium in older hospitalised patients - a severe and distressing neuropsychiatric syndrome which is characterised by acute deterioration in attention and other mental functions.

Interventions
Reference standard assessment including three-item recall (short- and long-term memory), orientation questions, attention tasks (20 to 1, Vigilance A and DelApp), DRS-R98, OSLA and RASS. Index assessment including 4AT, Days of the Week Backwards, psychotic features, arousal and an observational distress measure.

The delirium reference standard assessment and index assessment (including the 4AT) are carried out on the same day (between 15 minutes and 3 hours apart) by different researchers. These assessments are then repeated on up to 3 days during the patient's hospital stay.

Intervention Type
Other

Primary outcome measure
Delirium recovery measured using brief questionnaires and observational scales (reference and index assessments). The index assessment consists of the 4AT test plus brief supplementary tests, specifically the Days of the Week Backwards test. This will be compared against a more comprehensive reference assessment (including Vigilance A test, DelApp, 20 to 1, DRS-R98) to assess attentional function, orientation, memory, psychotic features, etc. at baseline and up to 3 further assessment days in hospital.

Secondary outcome measures
1. Demographic and baseline variables such as age, medications, body measurements (height, weight, BMI), main reason for hospital admission, social history (including alcohol misuse and tobacco use) and health status (including dementia diagnosis or psychiatric/developmental condition), extracted from NHS electronic patient medical records at baseline.
2. Length of stay, institutionalisation, discharge location and mortality will be assessed at 12 weeks post-recruitment, also from NHS electronic patient medical records.

Overall study start date
06/12/2021

Completion date
31/07/2022

Eligibility

Key inclusion criteria
1. Surgical (cardiac and hip fracture) and medical patients with current delirium
2. Aged 70 years or older
3. Capacity to provide written, informed consent or the availability of a suitable relative or welfare guardian/attorney who is able to provide informed consent on behalf of the patient

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
150

Key exclusion criteria

1. Unable to communicate in English (some of the cognitive tests used have not been validated in non-English speakers, hence the study only includes patients who can normally communicate fluently in English), including severe dysphasia.
2. Acute life-threatening illness requiring time-critical intervention.
3. Coma.
4. Vision or hearing impairment severe enough to preclude testing or interview.
5. Photosensitive epilepsy.
6. High level of patient and family distress, as judged by the clinical team.

Date of first enrolment
06/12/2021

Date of final enrolment
31/07/2022

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Royal Infirmary of Edinburgh at Little France
51 Little France Crescent
Old Dalkeith Road
Edinburgh
Lothian
United Kingdom
EH16 4SA

Sponsor information

Organisation
University of Edinburgh and NHS Lothian Health Board

Sponsor details
The Queen's Medical Research Institute
47 Little France Crescent
Edinburgh
England
United Kingdom
EH16 4TJ
+44 131 2423326
resgov@accord.scot

Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Charity

Funder Name
Dunhill Medical Trust

Alternative Name(s)
The Dunhill Medical Trust, DMT

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
31/12/2022

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 2.0	19/03/2021	21/02/2022	No	No