ISRCTN53388093 https://doi.org/10.1186/ISRCTN53388093

Development and validation of the 4AT: a new rapid screening tool for delirium

Submission date
30/05/2014

Recruitment status
No longer recruiting

Registration date
02/06/2014

Overall study status
Completed

Last Edited
12/08/2019

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Delirium (acute confusion) affects more than 15% of acute hospital patients. It is commonly due to acute illness, trauma or the side effects of drugs and can be very distressing for the patient and their families. Rapid detection of delirium is vital so that the patient can receive the appropriate treatment and support. Currently doctors use screening tools to help them assess whether a patient has delirium. However these are not suitable for all patients and can be time consuming to use. As a result it is estimated that two-thirds of acute hospital patients with delirium are not being diagnosed. A new quick, easy to use screening tool for delirium and cognitive impairment called the 4AT has been developed to help doctors diagnose delirium. It has 4 parts and is very quick to complete. In this study we compare the new 4AT screening tool against a reference standard assessment to show that it can be used to accurately diagnose delirium. The 4AT is compared with one of the most commonly used screening tools, the CAM (Confusion Assessment Method) to find out if it performs similarly whilst being potentially quicker to use. The study also includes a cost evaluation. The study's findings will improve the diagnosis of delirium allowing better management by the clinical team thereby improving both patient care and outcomes.

Who can participate?
Patients who are admitted to hospital via the emergency department or through acute general medical or geriatric units will be eligible. The 4AT study aims to recruit 900 patients over 70 years old from the 3 hospitals involved in the study.

What does the study involve?
Patients on the study are split into one of two groups at random. One group is screened for delirium using the 4AT screening tool while the other group is screened using the CAM screening tool. All patients on the study are screened using the reference standard assessment. Patients are screened within the first two days following admission. Information about their subsequent hospital stay will be collected from their medical records.

What are the possible benefits and risks of participating?
Patients on this study will be screened twice for delirium. There are no known risks to these assessments. A possible benefit of participation is that patients on this study in either group

may be diagnosed with delirium more frequently which will mean that more can receive more appropriate care.

Where is the study run from?
The University of Edinburgh and NHS Lothian (UK)

When is study starting and how long is it expected to run for?
March 2015 to end of May 2017

Who is funding the study?
National Institute for Health Research; Health Technology Assessment Programme (UK)

Who is the main contact?
Professor Alasdair MacLullich
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Study website
http://www.the4at.com

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

HTA 11/143/01

Study information

Scientific Title
Development and validation of the 4AT- a new rapid screening tool for delirium: a multicentre randomised controlled trial

Acronym
4AT

Study objectives
The diagnostic screening performance of 4AT will be assessed by comparing the diagnostic accuracy of the 4AT with the reference standard (Delirium Rating Scale-Revised-98) using the positive and negative predictive values, sensitivity and specificity.
In addition
1. The 4AT will be compared with one of the most commonly used screening tools, the short CAM (Confusion Assessment Method)
2. Performance of the 4AT cognitive screening assessment will be evaluated
3. Performance of the 4AT in predicting clinical outcomes will be evaluated

More details can be found at http://www.nets.nihr.ac.uk/projects/hta/1114301
Protocol can be found at http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0009/113949/PRO-11-143-01.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Scotland A REC, 03/07/2015, ref: 15/SS/0071
2. Yorkshire & The Humber – Bradford Leeds REC, 16/09/2015, ref: 15/YH/0317

Study design
Multicentre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Screening

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

Health condition(s) or problem(s) studied
Delirium/geriatric/acute admissions

Interventions
Patients on the study will be randomised into one of 2 groups. One group will be screened for delirium using the 4AT screening tool while the other group will be screened using the CAM (Confusion Assessment Method) screening tool. All patients on the study will also be screened using the reference standard assessment (Delirium Rating Scale-Revised-98). Patients will be screened within the first two days following admission. Information about their subsequent hospital stay will be collected from their medical records.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Primary objective: 4AT vs reference standard (binary): the diagnostic screening performance of 4AT versus the reference standard will be assessed using the positive and negative predictive values, sensitivity and specificity. The exact binomial 95% confidence interval will be reported for each measure. An ROC curve will be constructed to verify that the proposed cut point on the 4AT score is appropriate. The area under the ROC curve and its 95% confidence interval will be reported.

Secondary outcome measures
1. 4AT vs short CAM: differences in each of sensitivity, specificity, positive and negative predictive values between 4AT and short CAM will be tested by Fisher's exact test and quantified by the difference in the two proportions (4AT-CAM) and its 95% confidence interval. To aid comparison of 4AT and CAM, the overall performance of each will also be summarised using Youden's Index (sensitivity minus false positive rate) and the odds ratio of sensitivity to specificity.
2. Performance of the 4AT cognitive screening items: is the 4AT an adequately sensitive tool for detecting general cognitive impairment as judged against a documented history of dementia and /or the Informant Questionnaire for Cognitive Decline in the Elderly? Methods as per primary objective.
3. 4AT vs clinical outcomes: as assessment of criterion validity, the performance of the 4AT in predicting length of stay, institutionalisation, and mortality, up to 12 weeks. Descriptive statistics of clinical outcomes (continuous variables: mean, median, standard deviation, minimum, maximum; categorical variables, number and percentage of participants) will be presented for the groups with and without 4AT scores above the cut point of 3.

Overall study start date
01/03/2015

Completion date
30/05/2017

Eligibility

Key inclusion criteria
1. Subject > 70 years old
2. Subject admitted to hospital via:
2.1. Emergency Department (ED)
2.2. Acute general medical and geriatric unit

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
900

Total final enrolment
843

Key exclusion criteria
1. Acute life-threatening illness
2. Communication difficulties

Date of first enrolment
01/04/2015

Date of final enrolment
31/12/2016

Locations

Countries of recruitment
England

Scotland

United Kingdom

Study participating centre
NHS Lothian
Royal Infirmary of Edinburgh
Little France
Edinburgh
Edinburgh
United Kingdom
EH16 4SA

Study participating centre
Sheffield Teaching Hospitals NHS Foundation Trust
Weston Park Hospital
Whitham Road
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S10 2SJ

Study participating centre
Bradford Teaching Hospitals NHS Foundation Trust
Bradford Royal Infirmary
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Sponsor information

Organisation
University of Edinburgh and NHS Lothian - co-sponsors (UK)

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Sponsor type
Other

Website
http://www.accord.ed.ac.uk

ROR
https://ror.org/03q82t418

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme Ref. 11/143/01

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	10/02/2018		Yes	No
Results article	results	24/07/2019	25/07/2019	Yes	No
Results article	results	01/08/2019	12/08/2019	Yes	No
HRA research summary			28/06/2023	No	No
HRA research summary			28/06/2023	No	No