ISRCTN14608554 https://doi.org/10.1186/ISRCTN14608554

The Delirium Observation Screening Scale (DOSS) study

Submission date	Recruitment status	[_] Prospectively registered
13/02/2015	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/03/2015	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
09/04/2021	Other	

Plain English summary of protocol

Background and study aims
Delirium is a state of mental confusion that can happen if you become medically unwell. The aim of this study is to investigate whether a simple screening tool for delirium, which has been shown to be reliable in the detection of delirium in the hospital setting, might be useful for detecting delirium as part of routine care in (UK) care homes, and whether it can be used to assess delirium severity.

Who can participate?
All individuals aged over 65 resident in participating care homes

What does the study involve?
Participating care home residents from four care homes in Leeds/Bradford will be assessed daily for delirium with the Delirium Observation Screening Scale (DOSS). The diagnostic accuracy of the DOSS for the detection of delirium will be tested against the Confusion Assessment Method completed by trained research assistants. Data collection will occur over nine months.

What are the possible benefits and risks of participating?
A reliable method of routine delirium detection in care homes may reduce the impact of an episode of delirium on individuals, their families, and care home staff, offering substantial benefits for the health economy and the wider NHS. Reliable detection of delirium in long-term care settings could form the basis for future delirium research and make delirium a feasible outcome measure for frail older people in this setting.

Where is the study run from?
Bradford Royal Infirmary (UK)

When is the study starting and how long is it expected to run for?
February 2015 to April 2016

Who is funding the study?
Bradford Teaching Hospitals NHS Foundation Trust (UK)

Who is the main contact?
Satti Saggu

Contact information

Type(s)
Scientific

Contact name
Mr Satti Saggu

Contact details
Bradford Royal Infirmary
Duckworth Lane
Bradford
West Yorkshire
United Kingdom
BD9 6RJ

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
18279

Study information

Scientific Title
Investigation of the Delirium Observation Screening Scale (DOSS) for the routine detection of delirium in the Care Home Setting: the DOSS study

Study objectives
The aim of this study is to investigate whether a simple screening tool for delirium, that has been shown to be reliable in the detection of delirium in the hospital setting, might have utility in the detection of delirium as part of routine care in (UK) care homes, and whether it can be used to assess delirium severity.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee Yorkshire & The Humber - Leeds West, 31/10/2014, ref: 14/YH/1174

Study design

Non-randomised; Observational; Design type: Qualitative

Primary study design
Observational

Secondary study design
Qualitative

Study setting(s)
Other

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
Topic: Ageing; Subtopic: Ageing; Disease: All Ageing

Interventions
Participating care home residents from four care homes in Leeds/Bradford will be assessed daily for delirium with the DOSS. Diagnostic accuracy of the DOSS for the detection of delirium will be tested against the Confusion Assessment Method completed by trained research assistants. Data collection will occur over 9 months.

Intervention Type
Other

Primary outcome measure
To determine how the DOSS performs as a screening instrument for delirium when administered by care home staff as part of routine care in UK care homes in comparison to the research standard the CAM (Confusion Assessment Method)

Secondary outcome measures
1. To investigate the feasibility of routine daily administration of a delirium screening tool by care home staff in the long-term care setting
2. To determine whether the DOSS may be used as a measure of delirium severity
3. To examine, through item response theory, the psychometric properties and scalability of the 25-item DOSS and to determine whether a shorter, care home specific DOSS may be identified

Overall study start date
23/02/2015

Completion date
29/04/2016

Eligibility

Key inclusion criteria
All individuals aged over 65 resident in participating care homes
Target Gender: Male & Female; Lower Age Limit 65 years

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
Planned Sample Size: 258; UK Sample Size: 258

Total final enrolment
216

Key exclusion criteria
1. Residents approaching end of life (within three months) or in receipt of palliative care (as advised by care home staff)
2. Residents unwilling to provide informed consent
3. Residents lacking capacity to consent to recruitment, for whom a consultee declaration for participation cannot be obtained
4. Residents with an advance decision or statement against participation in research

Date of first enrolment
23/02/2015

Date of final enrolment
15/05/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Bradford Royal Infirmary
Duckworth Lane
Bradford
United Kingdom
BD9 6RJ

Sponsor information

Organisation
Bradford Teaching Hospitals NHS Foundation Trust

Sponsor details
Duckworth Lane
Bradford
England
United Kingdom
BD9 6RJ

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05gekvn04

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research Central Commissioning Facility

Results and Publications

Publication and dissemination plan
Pending publications:
1. Teale EA, Young J, Siddiqi N, Munyombwe T, Schuurmans M. Feasibility and diagnostic test accuracy of the Delirium Observation Screening Scale for routine detection of delirium in UK care homes
2. Teale EA, Young J, Siddiqi N, Munyombwe T, Harrison J, Schuurmans M. Scaling properties of the Delirium Observation Screening Scale in UK care-homes: development of the Care Home-DOSS (CH-DOSS)
3. Teale EA, Munyombwe T. Measuring delirium severity with the CH-DOSS: a latent profile analysis

Intention to publish date
30/04/2017

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study is not expected to be made available because the trialists do not have participant consent for the sharing of the data outside the research team, and receiving the regulatory approvals and retrospective consent would be difficult with this particular cohort of patients

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	20/06/2016		Yes	No
Results article		01/01/2018	09/04/2021	Yes	No
HRA research summary			28/06/2023	No	No