

# The Delirium Observation Screening Scale (DOSS) study

<b>Submission date</b> 13/02/2015	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 12/03/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 09/04/2021	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data

## 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?
<a href="#">Protocol article</a>	protocol	20/06/2016		Yes	No
<a href="#">Results article</a>		01/01/2018	09/04/2021	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No