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# Identifying depression in older patients in the emergency department

**Submission date**
27/03/2017

**Recruitment status**
Stopped

**Registration date**
28/03/2017

**Overall study status**
Stopped

**Last Edited**
24/10/2017

**Condition category**
Mental and Behavioural Disorders

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

## Plain English summary of protocol

Background and study aims
Depression is one of the most common mental health conditions worldwide. The symptoms of depression can vary greatly from person to person, but generally include low mood, problems with sleeping and/or eating, and loss of interest in life. As many as one in four older patients presenting to emergency departments are affected, however it can be hard to diagnose and so is often missed. There is a need for a simple, reliable clinical assessment questionnaire to help detect depression in older patients presenting to the emergency department. The aim of this study is to test the ability of a two stage questionnaire to identify patients with depression in the emergency department compared with an assessment by a specialist psychiatrist.

Who can participate?
Patients aged 65 and over presenting at the emergency department of Salford Royal Hospital.

What does the study involve?
All participants are interviewed by two doctors or nurse practitioners from the Emergency Department using a short questionnaire to determine whether they are suffering from depression. Each of the Emergency Department staff asks participants a series of questions aimed at finding out whether they may be suffering from low mood. Each interview takes about 5 minutes. Within 12 hours, participants are assessed by a psychiatric (mental health) nurse. The psychiatric nurse also assesses whether participants might have a problem with low mood. This final assessment is a bit more detailed and may take up to 45 minutes. The accuracy of the questionnaire is then compared to the results of the assessment with the psychiatric nurse in order to find out if the results of the assessments are the same.

What are the possible benefits and risks of participating?
Participants benefit from being able to see a psychiatric (mental health) nurse and if they are found have low mood then they can be referred for treatment. There are no risks involved with taking part in this study.

Where is the study run from?
Salford Royal Hospital (UK)

When is the study starting and how long is it expected to run for?
July 2015 to December 2017

Who is funding the study?
Royal College of Emergency Medicine (UK)

Who is the main contact?
Dr Ian Sammy
ian.sammy@sheffield.ac.uk

# Contact information

### Type(s)
Public

### Contact name
Dr Ian Sammy

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# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
31516

# Study information

### Scientific Title
Identifying depression in older patients in the emergency department – assessing the efficacy of a two-stage screening tool: A diagnostic accuracy study

### Study objectives

The overall aim of this study is to test the accuracy of a questionnaire designed to and identify older patient who have depression in older patients in the emergency department.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
South West - Cornwall & Plymouth Research Ethics Committee, 14/03/2016, ref: 16/SW/0068

## Study design
Non-randomised; Interventional; Design type: Screening, Diagnosis, Psychological & Behavioural; Diagnostic accuracy

## Primary study design
Interventional

## Secondary study design
Non randomised study

## Study setting(s)
Hospital

## Study type(s)
Treatment

## Participant information sheet
See additional files

## Health condition(s) or problem(s) studied
Specialty: Injuries and emergencies, Primary sub-specialty: Pre-hospital and Emergency Department Care; UKCRC code/ Disease: Mental Health/ Mood [affective] disorders

## Interventions
This is a phase 3 diagnostic accuracy study assessing the diagnostic accuracy, inter-rater reliability, internal validity and acceptability of a two-stage screening tool for the identification of depression in older patients presenting to the Emergency Department. A convenience sample of patients is used for this study. This study will be performed on patients with normal cognitive function. All patients will be assessed for capacity prior to consent, by the experienced research nurses that have undergone NIHR Mental Capacity Training

The first stage of this new clinical assessment is a three-question screening tool (first described by Fabacher et al in 2002). Patients with positive results from this screening tool will be assessed in more detail using the 15-item short form of the Geriatric Depression Score GDS (mini-GDS), the second stage of the new assessment tool. Appendices 1 & 2 are examples of the three-question geriatric screening tool and the mini-GDS respectively.

A single centre diagnostic study will be performed in the Emergency Department of Salford Royal NHS Foundation Trust, to assess the diagnostic accuracy, inter-rater reliability, internal validity and acceptability of this screening tool. Older patients (65 years and older) will be administered the screening tools by two independent emergency clinicians and /or research

nurses and the results compared, to assess inter-rater reliability. In addition, all participating clinicians will be asked to fill out a short questionnaire on the ease of use of the screening tools, including the time taken to fill out each phase (the 3-question screening tool and the mini-GDS). Cohen's kappa will be calculated from the results of this study to determine the inter-rater reliability of the screening method. Finally, once patients have been assessed, they will be asked to complete a short (2 item) questionnaire assessing the relevance and acceptability of the questionnaire to them. In addition a screening log will be kept of all patients identified as eligible for the study, to determine the conversion rate from initial identification through recruitment to completion of the study.

The diagnostic accuracy of the screening tool will be validated against the assessment of an experienced psychiatric clinician. Study subjects will be assessed by an experienced community psychiatric nurse (CPN) using the ICD10 criteria for depression, within 12 hours of the initial assessment and the results of the screening assessment will be validated against this 'gold standard'. This assessment will be recorded on a standardized Trust clerking proforma currently used by psychiatric liaison service when assessing patients in the ED. The psychiatric nurses conducting this assessment will not be using structured proformas. The diagnostic end point, which will be recorded on the research datasheet, will consist of a simple 'Yes/No' answer to the question 'Do you think that this patient is suffering from depression?', as well as an opinion on the most appropriate management plan for the patient.

### Intervention Type
Other

### Primary outcome measure
Sensitivity and specificity of the diagnostic questionnaire compared to the assessment of a CPN, using the ICD10 criteria for clinical depression is assessed on the study visit.

### Secondary outcome measures
Clinical depression is measured against the DSM10 criteria, when patients are assessed by a psychiatric liaison nurse (trained CPN) within 12 hours of the patient's initial assessment by the research team.

### Overall study start date
07/07/2015

### Completion date
31/12/2017

### Reason abandoned (if study stopped)
Participant recruitment issue

## Eligibility

### Key inclusion criteria
All patients 65 years and older presenting to the Emergency Department during the study period.

### Participant type(s)
Patient

### Age group
Senior

### Sex
Both

### Target number of participants
Planned Sample Size: 200; UK Sample Size: 200

### Key exclusion criteria
1. Patients in whom the clinical severity of the illness, or the treatments being administered preclude assessment for depression, in the judgement of the clinician providing care for that patient
2. Patients who refuse to, or cannot provide informed consent to enter into the study
3. Patients whose mental status precludes inclusion into the study due to inability to cooperate with or understand the assessment process, in the judgement of the clinician providing care for that patient
4. Patients less than 65 years old

### Date of first enrolment
11/07/2016

### Date of final enrolment
31/07/2017

## Locations

### Countries of recruitment
England

United Kingdom

### Study participating centre
**Salford Royal Hospital**
Stott Lane
Salford
United Kingdom
M6 8HD

## Sponsor information

### Organisation
Salford Royal NHS Foundation Trust

### Sponsor details

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**Sponsor type**
Hospital/treatment centre

**ROR**
https://ror.org/019j78370

# Funder(s)

**Funder type**
University/education

**Funder Name**
Royal College of Emergency Medicine

**Alternative Name(s)**
RCEM

**Funding Body Type**
Private sector organisation

**Funding Body Subtype**
Universities (academic only)

**Location**
United Kingdom

# Results and Publications

**Publication and dissemination plan**
1. Planned presentation at a future Royal College of Emergency Medicine Annual Scientific Meeting
2. Planned publication in a high impact peer reviewed journal such as the Emergency Medicine Journal

**Intention to publish date**
01/01/2018

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Ian Sammy (ian.sammy@sheffield.ac.uk)

## IPD sharing plan summary

Available on request

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Participant information sheet | version V3 | 31/10/2016 | 28/03/2017 | No | Yes |
| HRA research summary | | | 28/06/2023 | No | No |