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# Improving detection and prevention of cognitive decline in ageing

| Submission date | Recruitment status | [ ] Prospectively registered |
|---|---|---|
| 31/07/2013 | No longer recruiting | [ ] Protocol |
| **Registration date** | **Overall study status** | [ ] Statistical analysis plan |
| 31/07/2013 | Completed | [ ] Results |
| **Last Edited** | **Condition category** | [ ] Individual participant data |
| 12/02/2016 | Mental and Behavioural Disorders | [ ] Record updated in last year |

## Plain English summary of protocol

Background and study aims
The rapid and reliable identification of cognitive (thinking) changes has become more urgent as patients are presenting earlier with subjective memory loss and milder memory impairments. Early detection is therefore increasingly important for planning the clinical management of these diseases along with the use of protective strategies. The influence of early patterns of cognitive deficits and regional brain dysfunction on the development of behavioural symptoms in patients with dementia and stroke hasn't been extensively studied. Early prediction of potential symptoms and their causes will improve the management of such patients. We aim to assess changes in smaller patient groups to find what determines response and non-response to treatment and better inform clinical practice. This study will establish local norms for cognitive tests and compile a database of assessments of patients with degenerative and vascular brain disease

Who can participate?
Volunteers aged over 18 with no history of neurological or psychiatric disorders, and patients aged over 18 who experience cognitive change as a result of neurodegenerative disease, vascular brain disease or dementia due to other causes.

What does the study involve?
The study is undertaken over a 5-year period. Patients are tested every 6 months and the progression of cognitive deficits is monitored to find patterns to identify the different forms of dementia, monitor the formation/development of abnormal beliefs, and assess and monitor the effects of non-drug treatments.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Royal Hallamshire Hospital Neuropsychology Clinic (UK)

When is the study starting and how long is it expected to run for?
February 2013 to February 2018

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Dr Katija Khan
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# Contact information

### Type(s)
Scientific

### Contact name
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# Additional identifiers

### Protocol serial number
14719

# Study information

### Scientific Title
Assessment of age and disease related cognitive impairment in normal volunteers and people with degenerative and vascular brain disease and assessment of the potential neuroplastic effect of non pharmacological treatment

### Study objectives
The rapid and reliable identification of cognitive changes has become more urgent as patients are presenting earlier with subjective memory loss and milder memory impairments. Early detection is therefore increasingly important for planning clinical management of these diseases along with the employment of protective strategies like vascular risk factor and intensive cognitive stimulation which are gaining credibility. Influence of early patterns of cognitive deficits and regional brain dysfunction on the development of behavioural symptoms in patients with dementia and stroke hasnt been extensively studied. Early prediction of potential neuropsychiatric symptoms and their neurological causes will improve management of such patients. Also effects of non-pharmacological treatment for dementia have been studied mostly in large non controllable industry sponsored trials in poorly characterized groups of patients. Our centre aims at detailed assessment of changes in smaller patient groups to identify the determinants of response and non-response and better inform clinical practice. This research

will establish local norms for cognitive tests and compile a database of clinical, neuropsychological and neuroimaging assessments of patients with degenerative and vascular brain disease referred to the Royal Hallamshire Hospital Neuropsychology Clinic. The research will be undertaken longitudinally over a 5yr period. Patients will be tested at 6mnth intervals and progression of deficits will be monitored to identify distinct neuropsychological patterns that permit early differentiation of different forms of dementia, monitor formation /development of abnormal beliefs, assess and monitor effects of non-pharmacological treatments. The data will be used to: establish the earliest cognitive impairments which strongly predict pathological brain aging, establish patterns of impairments after focal brain lesions useful in differential diagnosis, develop models of brain dysfunction.

More details can be found at: http://public.ukcrn.org.uk/search/StudyDetail.aspx?StudyID=14719

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
12_YH_0474

## Study design
Randomised interventional trial; Design type: Screening

## Primary study design
Interventional

## Study type(s)
Screening

## Health condition(s) or problem(s) studied
Topic: Dementias and Neurodegenerative Diseases Research Network; Subtopic: Dementia; Disease: Dementia

## Interventions
Cognitive Stimulation, Face to Face interview and Psychometric tests, administered by experienced research neuropsychologists at Royal Hallamshire Hospital.

## Intervention Type
Other

## Phase
Not Applicable

## Primary outcome(s)
Resting state functional magnetic resonance imaging (fMRI); Timepoints: Baseline and at 6 month intervals

## Key secondary outcome(s))
Not provided at time of registration

## Completion date
01/02/2018

# Eligibility

### Key inclusion criteria
1. Any volunteer with no history of neurological or psychiatric disorders, and fluent in English will be eligible for the study
2. Any patient who experiences cognitive change as a result of neurodegenerative disease, vascular brain disease or dementia due to other causes, and fluent in English may be included
3. Target Gender: Male & Female; Upper Age Limit 100 years ; Lower Age Limit 18 years

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Sex
All

### Key exclusion criteria
1. Any volunteer with history of neurological or psychiatric disorders, substance abuse, persistent use of psychoactive drugs, history of traumatic brain injury with loss of consciousness, or non-fluent in English will not be eligible for inclusion
2. Patients with perceptual deficits or advanced dementia who are unable to complete assessments, or who are non-fluent in English, or patients who clearly lack capacity to give consent will not be eligible for inclusion

### Date of first enrolment
01/02/2013

### Date of final enrolment
01/02/2018

# Locations

### Countries of recruitment
United Kingdom

England

### Study participating centre

**Academic Neurology Unit**
Sheffield
United Kingdom
S10 2RX

# Sponsor information

**Organisation**
Sheffield Teaching Hospitals NHS Trust (UK)

**ROR**
https://ror.org/018hjpz25

# Funder(s)

**Funder type**
Government

**Funder Name**
National Institute for Health Research (NIHR) (UK) Grant Codes: 601055

**Alternative Name(s)**
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

**Funding Body Type**
Government organisation

**Funding Body Subtype**
National government

**Location**
United Kingdom

# Results and Publications

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**
Not provided at time of registration