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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?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet

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 measure
Resting state functional magnetic resonance imaging (fMRI); Timepoints: Baseline and at 6 month intervals

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/02/2013

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
UK Sample Size: 500

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
England

United Kingdom

Study participating centre
Academic Neurology Unit
Sheffield
United Kingdom
S10 2RX

Sponsor information

Organisation
Sheffield Teaching Hospitals NHS Trust (UK)

Sponsor details
South Yorkshire Cardiothoracic Unit
Northern General Hospital
Sheffield
England
United Kingdom
S5 7AU

Sponsor type
Hospital/treatment centre

Website
http://www.sth.nhs.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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration