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Investigating attentional function and cognitive fluctuations in Lewy body disease

Submission date	Recruitment status
21/10/2010	No longer recruiting
Registration date	**Overall study status**
21/10/2010	Completed
Last Edited	**Condition category**
11/05/2018	Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
The two most common forms of memory loss in later life (dementia) are Alzheimer's disease and Lewy body dementia. One big problem for people with Alzheimer's disease and Lewy body dementia is that they often have difficulties with their powers of concentration and attention. In particular, patients with Lewy body dementia tend to fluctuate in their levels of confusion and are often quite drowsy. However, very little is known about what causes these fluctuations in attention and thinking ability and understanding more about them will help with the development of more effective treatments. Two techniques called functional magnetic resonance imaging (fMRI) and electroencephalography (EEG) can be used to try and understand how the brain focuses attention on something. The fMRI involves lying in a scanner while images are taken of the brain showing which bits are active when someone concentrates or focuses their attention. EEG involves attaching special sensors on the head which measure the tiny electrical currents made by the brain when someone is thinking. The aim of this study is to use these techniques in people with Alzheimer's disease and Lewy body dementia to try and understand how attention gets impaired in these conditions.

Who can participate?
Dementia patients and healthy volunteers aged 60 years and over

What does the study involve?
The study involves attending hospital on three occasions. At the first visit there is an assessment of general health and mood, some short memory and vision tests and some attention tests on a computer. This lasts about one and a half hours. At the second visit participants answer some questions about attention and concentration and there is a repeat of the attention tests from visit 1 followed by an fMRI scan during which the attention tests are repeated. This lasts about one and a half hours. At the third visit participants answer some questions about attention and concentration and there is a repeat of the attention tests from visit 1 followed by an EEG and some recordings of the muscle movements in the hands. This lasts about two and a half hours.

What are the possible benefits and risks of participating?
There is no direct benefit in participating. However, the information gathered may help improve the treatment of people with Alzheimer's and Lewy Body Dementia. There are no known risks

with the MRI scan and it is not painful. There is no radiation known to be associated with the scan. The only discomfort some people feel is of claustrophobia while in the scanner but the scan can be stopped at any time. Occasional side effects of the EEG include a headache, slight neck pain which goes when the procedure is complete, or some reddening of the skin on the head where the sensors are attached, which should disappear within half an hour of the sensor mesh being removed.

Where is the study run from?
Wolfson Research Centre (UK)

When is the study starting and how long is it expected to run for?
September 2010 to April 2013

Who is funding the study?
Wellcome Trust (UK)

Who is the main contact?
Dr John-Paul Taylor
John-paul.taylor@ncl.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr John-Paul Taylor

Contact details
Third Floor
Biomedical Research Building
Newcastle University
Campus for Ageing & Vitality
Newcastle upon Tyne
United Kingdom
NE4 5PL
-
John-paul.taylor@ncl.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
8366; 088441

Study information

Scientific Title
Investigating attentional function and cognitive fluctuations in Lewy body disease: a functional magnetic imaging and electrophysiology multicentre non-randomised observational diagnosis cross-sectional study

Acronym
CATFieLD study

Study objectives
Lewy body dementia (LBD) is the second commonest cause of dementia after Alzheimers disease (AD) in older people, and includes dementia with Lewy bodies (DLB) and Parkinsons disease with dementia (PDD). People with LBD suffer considerable disability and distress and can experience problems with movement control, visual hallucinations, and fluctuations in their ability to think clearly. Fluctuations are particularly common in LBD and this study seeks to understand their causes. We will look at changes in brain activity patterns of people with LBD by magnetic resonance (MR) imaging and electrical scalp recordings (encephalography or electroencephalogram [EEG]) while they are doing simple picture tasks. 24 DLB, 24 PDD, 24 AD patients and 24 age-matched controls will be included. These tests will tell us more about the causes of fluctuations in thinking ability and how brain activity goes wrong in LBD. It will also help us diagnose LBD better and earlier, and help develop effective treatments to improve the quality of life for people with LBD.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Newcastle and North Tyneside 1 Research Ethics Committee, 13/05/2010, ref: 10/H0906/19

Study design
Multicentre non-randomised diagnosis cross-sectional study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Diagnostic

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: Dementias and Neurodegenerative Diseases Research Network; Subtopic: Dementia; Disease: Dementia

Interventions
1. Diffusion tensor imaging to assess white matter integrity
2. Functional imaging: functional magnetic resonance imaging (fMRI) BOLD brain scan in response to the attention network task
3. High density electroencephalography while subjects perform attention network task
4. Structural imaging: Structural MR brain scan

Follow up length: 6 months
Study entry: registration only

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Functional MR BOLD activations to attentional network task, measured at end of study

Secondary outcome measures
1. Diffusion tensor measures of white matter, measured at end of study
2. Spatio-temporal EEG activations to attentional network task, measured at end of study

Overall study start date
01/09/2010

Completion date
30/04/2013

Eligibility

Key inclusion criteria
1. For dementia patients: that they meet defined clinical criteria for diagnosis of dementia (dementia with Lewy bodies, Parkinson's disease with dementia, or Alzheimer's dementia) and Mini-Mental State Examination (MMSE) test score of more than 12
2. For healthy controls: No history of psychiatric or neurological brain disease and MMSE score more than 26 and has capacity to consent to participate
3. All aged 60 years and above, either sex

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
Planned sample size: 96; UK sample size: 96

Key exclusion criteria
1. Contraindications for or unwillingness to undergo MR imaging
2. Severe dementia (MMSE score less than 12), as such subjects will have difficulty fully understanding the nature and extent of the proposed research
3. Presence of other severe or unstable medical illnesses
4. Subjects with a history of visual impairment secondary to glaucoma, cataract, or macular degeneration as this could affect the ability of subjects to perform the visual attention task with LBD
5. Medications: subjects on benzodiazepines, antipsychotics or anticonvulsants will not be included as these can effect the EEG activity patterns

Date of first enrolment
01/09/2010

Date of final enrolment
30/04/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Wolfson Research Centre
Third Floor
Biomedical Research Building
Newcastle University
Campus for Ageing & Vitality
Newcastle upon Tyne
United Kingdom
NE4 5PL

Sponsor information

Organisation
Northumbria Tyne and Wear NHS Foundation Trust (UK)

Sponsor details
St Nicholas Hospital
Gosforth

Newcastle upon Tyne
England
United Kingdom
NE3 3XT

Sponsor type
Hospital/treatment centre

Website
http://www.ntw.nhs.uk/

ROR
https://ror.org/01ajv0n48

Funder(s)

Funder type
Charity

Funder Name
Wellcome Trust (grant ref: 088441)

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

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
The datasets generated during and/or analysed during the current study are available upon request from Dr John-Paul Taylor (john-paul.taylor@newcastle.ac.uk). All data is anonymised and identifiable by study number. Consent was obtained from participants for information to be used in anonymised form in similar studies.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2016		Yes	No
HRA research summary			28/06/2023	No	No