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Psychological and Electrophysiological Correlates of dementia with Lewy bodies and Parkinson's disease dementia

Submission date	Recruitment status	[ ] Prospectively registered
02/06/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
15/09/2006	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
25/05/2018	Nervous System Diseases	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Clive Ballard

Contact details
King's College London
Wolfson CARD
Guy's Campus
London
United Kingdom
SE1 1UL

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
10/10/2005

Study information

Scientific Title
A randomised, repeated measures investigation of rhythmic auditory cues as a potential intervention for attentional fluctuations in dementia with Lewy bodies (DLB)/Parkinson's disease dementia (PDD)

Acronym
PECFC

Study objectives
Dementia with Lewy bodies (DLB) accounts for 15% - 20% of late onset dementia whilst Parkinson's disease occurs in 1% of individuals over the age of 65; with at least 50% of these individuals developing symptoms of dementia (Parkinson's disease dementia - PDD). In addition to memory problems, people with these conditions experience persistent hallucinations, parkinsonian symptoms, marked problems with attention and fluctuating consciousness. Other symptoms that occur commonly include repeated falls, faints, temporary loss of consciousness, delusions and Rapid Eye Movement (REM) sleep behaviour disorder.

Rhythmic auditory cues can regulate attentional processes and fluctuating cognition in patients suffering from DLB or Parkinson's Disease Dementia (PDD) as reflected by a decrease in reaction time standard deviation variability in attentional tasks.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South London and Maudsley NHS trust approved of protocol on 22 November 2005 (ref. no.: 05 /Q0706/264).

Study design
Within-subjects comparison design testing a possible healthcare intervention where the sequence in which the different forms of care received are randomised.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Dementia

Interventions
Baseline versus rhythmic auditory cue versus rhythmic auditory cue at increased volume - a one-off assessment comparing patients baseline performance with performance under different experimental conditions.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Reaction time standard deviation, measured at intervention.

Secondary outcome measures
Measured at intervention:
1. Attentional performance
2. Reaction time
3. Tapping speed
4. Tracking precision
5. Electroencephalogram (EEG) mean frequency variability
6. Frequency of occurrence of stimulus independent thoughts

Overall study start date
01/07/2006

Completion date
01/10/2008

Eligibility

Key inclusion criteria
1. Operationalised diagnosis of Dementia with Lewy Bodies (DLB), Parkinsons Disease with Dementia (PDD), mild possible or probable Alzheimers Disease (AD), or Parkinsons Disease (PD)
2. DLB and PDD patients must show clear signs of fluctuating cognition as indicated by a score eqaulling six on the One Day Fluctuation Assessment
3. Severity of dementia must be mild to moderate (Mini Mental State Examination [MMSE] greater than 14)
4. Capacity to give informed consent for participating in the study or Assent from Next of Kin (NOK)
5. Able to complete computerised test battery and understand instructions
6. Good hearing
7. Aged 63 - 89 years, either sex

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
64

Key exclusion criteria
1. Symptoms or disabilities that would result in difficulties fulfilling the test requirements
2. Any diagnosis of another medical condition that in the eyes or the experimentor or investigator would prohibit partaking in the study
3. Ability to undergo 12 hour washout period from anti-parkinsonian medication before cognitive testing

Date of first enrolment
01/07/2006

Date of final enrolment
01/10/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
King's College London
London
United Kingdom
SE1 1UL

Sponsor information

Organisation
King's College London (UK)

Sponsor details
Guy's Campus
London
England
United Kingdom
SE1 1UL

Sponsor type

University/education

Website
http://www.kcl.ac.uk/

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
University/education

Funder Name
King's College London (UK)

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