

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

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

Protocol serial number
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).

Primary study design

Interventional

Study design

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

Study type(s)

Treatment

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(s)

Reaction time standard deviation, measured at intervention.

Key secondary outcome(s)

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

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 equalling 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

Healthy volunteers allowed

No

Age group

Senior

Sex

All

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 of the experimenter 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

United Kingdom

England

Study participating centre

King's College London

London

United Kingdom

SE1 1UL

Sponsor information

Organisation

King's College London (UK)

ROR

<https://ror.org/0220mzb33>

Funder(s)

Funder type

University/education

Funder Name

King's College London (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration