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A neurophysiological study of near infrared spectroscopy haemoencephalography neurofeedback treatment in Alzheimer's disease and related cognitive impairments

Submission date
29/09/2006

Recruitment status
No longer recruiting

Registration date
29/09/2006

Overall study status
Completed

Last Edited
07/06/2017

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] 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

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Additional identifiers

Protocol serial number
N0151176859

Study information

Scientific Title
A neurophysiological study of near infrared spectroscopy haemoencephalography neurofeedback treatment in Alzheimer's disease and related cognitive impairments

Study objectives
Can the memory and attention difficulties seen in Alzheimer's disease (AD) and its preclinical stages be treated with a biofeedback procedure that allows you to voluntarily increase blood flow and activation in specific parts of the brain?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Essex 1 Research Committee, 20/12/2005, ref: 05/Q0301/38

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Nervous System Diseases: Alzheimer's disease

Interventions
Phase 1 - establish the neurofeedback protocols, monitor treatment effects and side effects and confirm the number of participants required for Phase 2.

Phase 2 - baseline and post treatment fMRI on five groups of patients AMCI treated with NIRS-HEG biofeedback, AMCI treated with placebo NIRS-HEG biofeedback, elderly controls treated with NIRS-HEG biofeedback, mild AD treated with NIRS-HEG and mild AD treated with placebo NIRS-HEG biofeedback.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Change in cognition and/or behaviour following treatment.

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

Completion date
01/10/2008

Eligibility

Key inclusion criteria
Phase 1: 10 patients with AMCI and 10 with mild AD
Phase 2: 12-15 patients in each group depending upon the results of phase 1 of the study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Sex
All

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/10/2005

Date of final enrolment
01/10/2008

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
St Margaret's Hospital
Epping
United Kingdom
CM16 6TN

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
North Essex Mental Health Partnership NHS Trust (UK)

Funder Name
NHS R&D Support Funding

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes