ISRCTN43516338 https://doi.org/10.1186/ISRCTN43516338

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	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 29/09/2006	**Overall study status** Completed	
Last Edited 07/06/2017	**Condition category** Nervous System Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
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 measure
Change in cognition and/or behaviour following treatment.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/10/2005

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

Age group
Senior

Sex
Both

Target number of participants
75

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
England

United Kingdom

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

Sponsor details
The Department of Health
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

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

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