

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	<input type="checkbox"/> Prospectively registered
Registration date 29/09/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 07/06/2017	Condition category Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Thomas Dannhauser

Contact details

The Mental Health Unit

St Margaret's Hospital

Epping

United Kingdom

CM16 6TN

+44 (0)7971 096 766

tom.dannhauser@nemhpt.nhs.uk

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