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Functional anatomy and impact of cognitive training on chunking within working memory in early Alzheimer's disease

Submission date	Recruitment status	[ ] Prospectively registered
10/12/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
07/02/2011	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
24/10/2016	Nervous System Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Jonathan Huntley

Contact details
Institute of Psychiatry
De Crespigny Park
London
United Kingdom
SE5 8AZ

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Version 1 (13.7.10); G0901982

Study information

Scientific Title
Functional anatomy and impact of cognitive training on chunking within working memory in early Alzheimer's disease: a randomised controlled trial

Study objectives
1. Training individuals with early Alzheimer's disease (AD) in the use of chunking strategies will improve their working memory (WM) capacity
2. Use of chunking strategies in early AD will correlate with significantly increased activity in the prefrontal cortex (PFC) and posterior parietal cortex (PPC)
3. Following training in chunking, improvement in WM capacity will generalise across different modalities of WM tasks and measures of general cognitive functioning
4. Improvements in WM following cognitive training will be associated with structural and functional re-organisation of brain activity

Ethics approval required
Old ethics approval format

Ethics approval(s)
Cambridgeshire 1 Research Ethics Committee, 21/10/2010, ref: 10/H0304/68

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Early Alzheimer's disease

Interventions
Subjects will be randomly allocated to either a cognitive training group or control group. The cognitive training group will undergo 18 days of training over 6 weeks for approximately 45 minutes/day. Each training session will consist of 30 trials of structured span tasks. The length of span will be adjusted after each trial depending on whether it is correctly recalled. Each subject will therefore be continually tested at their span limit, which can adjust both within and across

sessions. The control group will perform 30 trials of a 2 span unstructured task over the same time period. After 6 weeks of training, subjects will be reassessed using the baseline battery of tasks, and re-imaged with functional magnetic resonance imaging (fMRI) performing the same verbal chunking task protocol.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Scores on verbal working memory task
2. Cerebral blood flow in the prefrontal and parietal cortices as measured using fMRI
Measured at baseline and after 8 weeks (following the 6 week cognitive training intervention).

Secondary outcome measures
Scores on:
1. Spatial working memory task
2. Sustained attention, reasoning and episodic memory tasks
3. Artificial grammar task
4. Instrumental activities of daily living (ADL) task
Measured at baseline and after 8 weeks (following the 6 week cognitive training intervention).

Overall study start date
20/12/2010

Completion date
05/08/2014

Eligibility

Key inclusion criteria
1. Aged greater than 60 years, either sex
2. Diagnosis of probable Alzheimer's disease according to National Institute of Neurological and Communicative Disorders and Stroke and the Alzheimer's Disease and Related Disorders Association (NINCDS-ADRDA) criteria
3. Mini-Mental State Examination (MMSE) score greater than 23/30
4. All subjects will be required to provide informed consent to participate in the study

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants

Key exclusion criteria
1. Co-existent neurological or psychiatric disease
2. Substance misuse
3. Significant auditory or visual impairment

Date of first enrolment
20/12/2010

Date of final enrolment
05/08/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Institute of Psychiatry
London
United Kingdom
SE5 8AZ

Sponsor information

Organisation
Institute of Psychiatry (UK)

Sponsor details
c/o Professor Robert Howard
Kings College London
De Crespigny Park
London
England
United Kingdom
SE5 8AF

Sponsor type
University/education

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

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) (UK) (ref: G0901982/ ID 93849)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2017		Yes	No