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Rehabilitation of Memory in Neurological Disabilities - Pilot study

Submission date	Recruitment status	[ ] Prospectively registered
30/09/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
30/09/2005	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
21/02/2018	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

N0192147133

Study information

Scientific Title
A comparison of the effectiveness of two types of neuropsychological rehabilitation for memory deficits following brain damage: A single blind randomised controlled trial

Acronym
ReMIND - Pilot study

Study objectives
The aim of this study is to compare the effectiveness of two types of cognitive rehabilitation techniques (ie restitution and compensation) in reducing memory deficits following brain damage.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical approval obtained from Central Office for Research Ethics Committees, Nottingham Research Ethics Committee 1 (12 May 2004)

Study design
Single blind randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

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
Stroke, Traumatic Brain Injury (TBI), Multiple Sclerosis (MS) / memory deficits

Interventions
1. Restitution group
2. Compensation group
3. Attention placebo group

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Prior to July 2008:
To assess memory functions, disability, psychological adjustment.

Modified July 2008:
To assess everyday memory functions, based on the Everyday Memory Questionnaire.

Secondary outcome measures
Added July 2008:
Objective measures of memory (RBMTE, Doors & People, Memory Aids Questionnaire), mood (GHQ12, Wimbledon Self Report Scale), psychological adjustment (Mental Adjustment to Brain Damage), and extended activities of daily living (Nottingham EADL).

Overall study start date
24/05/2004

Completion date
31/01/2009

Eligibility

Key inclusion criteria
Prior to July 2008:
Participants having sustained a brain damage, verified by hospital or GP records, should have a memory deficit, defined as overall profile score of 1 (poor memory) or 0 (impaired) on the Rivermead Behavioural memory Test (RBMT), over 18 years of age, living in or around Nottingham (within 50 miles radius), having at least one identified individual who will supervise homework assignments, they give informed consent, they are not blind or deaf, should speak English, should have been diagnosed at least one month prior to recruitment to the study, should be more than one month post injury and or diagnosis, no previous diagnosis of brain damage or other severe disability.

Modified July 2008:
Participants with a stroke, TBI, or MS, verified by hospital or GP records, should have a memory deficit, defined as overall profile score of 2 (average memory) to 0 (impaired) on the Rivermead Behavioural memory Test-extended version (RBMTE), over 18 years of age, living in or around Nottingham or Derby (within 50 miles radius), having at least one identified individual who will supervise homework assignments, they give informed consent, should speak English, and should be more than one month post injury and or diagnosis.

Participant type(s)
Patient

Age group

Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
At least 60 patients in each group (restitution group, compensation group, attention placebo group) = 180.

Key exclusion criteria
Added July 2008:
Those who are blind or deaf, have previous diagnosis of brain damage or dementia, have severe activity limitations which would restrict them from taking part in assessments or intervention, current psychiatric/mental health problems, and language problems (defined as a score of less than 15 on the Sheffield Screening Test for Acquired Language Disorders).

Date of first enrolment
24/05/2004

Date of final enrolment
31/01/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Nottingham
Nottingham
United Kingdom
NG7 2RQ

Sponsor information

Organisation
Department of Health

Sponsor details

Richmond House
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Sponsor type
Government

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

Funder(s)

Funder type
Government

Funder Name
Queen's Medical Centre University Hospital NHS Trust (UK) NHS R&D Support Funding

Funder Name
Added July 2008:

Funder Name
Stroke Association (UK) (AHP Research Bursary)

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United Kingdom

Funder Name
Remedi (UK)

Alternative Name(s)
Remedi UK, Remedi, UK, RemediRj

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

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	01/10/2012		Yes	No
Results article	results	19/09/2016		Yes	No