Psychotherapy in mild cognitive impairment

Submission date	Recruitment status No longer recruiting	Prospectively registered	
20/12/2006		Protocol	
Registration date	Overall study status	Statistical analysis plan	
07/06/2007	Completed	Results	
Last Edited	Condition category	Individual participant data	
04/04/2016	Mental and Behavioural Disorders	Record updated in last year	

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number 1234

Study information

Scientific Title

Psychotherapy in mild cognitive impairment

Acronym

PICT-MCI

Study objectives

- 1. The hypothesis is that, structured psychotherapeutic intervention, based on Psychodynamic Interpersonal Therapy principles, directed at sufferers of MCI and their partners/spouses will result in improved well being of sufferers [as assessed by measures of cognitive function, mood, psychological distress, interpersonal functioning and quality of life] and lowered psychological distress in their partners/ spouses, in comparison with controls.
- 2. The improved well being of sufferers of MCI, as a result of successful Psychodynamic Interpersonal Therapy would result in changes in task induced Blood Oxygenation Level Dependant (BOLD) signal of functional Magnetic Resonance Imaging (fMRI).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Being reviewed by South Manchester Research Ethics Committee as of 20/12/2006 – approval pending

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Mild cognitive impairment

Interventions

Baseline fMRI measures will be obtained before a course of psychotherapy in patients in the experimental group receiving psychotherapy, and patients in the control group receiving standard care. After which patients are classified as responders or non-responders in both groups based on symptom improvement or other clinical outcome measures and they will be reexamined with the same imaging protocol. This technique allows for the assessment of psychotherapy related changes in brain activation and their specificity for successful outcome.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Clinical outcomes in routine evaluation

Key secondary outcome(s))

- 1. Geriatric Depression Scale [GDS]
- 2. Becks Anxiety Inventory

- 3. Marital Intimacy Scale in Dementia
- 4. MMSE
- 5. QUAL-AD
- 6. RSQ and RQ-Attachment

Completion date

01/02/2009

Eligibility

Key inclusion criteria

Psvchotherapv:

- 1. Diagnosis of MCI according to the criteria suggested by the International Psychogeriatric Association expert conference on mild cognitive impairment
- 2. Living with a spouse or partner
- 3. Ability to create of a conversation in English aiming to develop a mutual feeling language based on psychodynamic interpersonal concepts
- 4. Mini Mental State Examination (MMSE) above 26

Imaging:

5. Fifteen patients with MCI from the intervention arm and 15 patients with MCI from the control arm as described in inclusion criteria above without any standard contraindications to MR imaging

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

Psychotherapy:

- 1. People not meeting the inclusion criteria
- 2. Patients/spouses suffering from serious physical conditions

Imaging:

- 1. Patients with standard contraindications to MR imaging, including patients with metal implants, or cardiac pacemakers
- 2. Patients with psychological distress (e.g. phobias) associated with MR imaging

Date of first enrolment

01/02/2007

Date of final enrolment

Locations

Countries of recruitment

United Kingdom

England

Study participating centre **Wythenshawe Hospital** Manchester United Kingdom M23 9LT

Sponsor information

Organisation

Manchester Mental Health and Social Care Trust (UK)

Funder(s)

Funder type

Government

Funder Name

Wythenshawe Hospital (the academic division of old age psychiatry, Education Research Centre) (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type

Details