

# Psychotherapy in mild cognitive impairment

<b>Submission date</b> 20/12/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 07/06/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 04/04/2016	<b>Condition category</b> Mental and Behavioural Disorders	<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

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### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

**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 below to request a patient information sheet

**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 re-

examined 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 measure**

Clinical outcomes in routine evaluation

**Secondary outcome measures**

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

**Overall study start date**

01/02/2007

**Completion date**

01/02/2009

**Eligibility****Key inclusion criteria**

Psychotherapy:

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

**Age group**

Adult

**Sex**

Both

**Target number of participants**

40 couples

**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**

01/02/2009

**Locations****Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Wythenshawe Hospital**

Manchester

United Kingdom

M23 9LT

**Sponsor information****Organisation**

Manchester Mental Health and Social Care Trust (UK)

**Sponsor details**

Manchester mental health and social care trust

Second floor

Education Research Centre

Wythenshawe Hospital

Wythenshawe

Manchester

England

United Kingdom  
M23 9LT

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.mhsc.nhs.uk/>

## **Funder(s)**

**Funder type**

Government

**Funder Name**

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

## **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