

Psychotherapy in mild cognitive impairment

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