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Individual Cognitive Stimulation Therapy for dementia

Submission date	Recruitment status	[X] Prospectively registered
30/04/2010	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
05/05/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
30/03/2017	Mental and Behavioural Disorders	

Plain English summary of protocol

Background and study aims
In the UK, over 700,000 older people have dementia. This leads to progressive intellectual deterioration, problems carrying out daily activities such as self-care, social isolation, and increasing difficulty interacting and communicating. Dementia also has an immense social and economic impact on health and social care services, and on family carers. Drug treatments have an important role in dementia care but in the UK they are limited to people with Alzheimer's disease with moderately severe dementia, have a limited impact on the illness, and are not suitable for all patients. Psychological treatments for dementia such as reality orientation are widely used in the UK and internationally for several decades, but there has been little high quality research on their effectiveness. There is an urgent need to find useful interventions to help reduce the impact of dementia on people with dementia, carers and society. In the UK there is increasing recognition that psychological therapies for dementia should be made more available and the National Institute of Clinical Excellence has recommended that cognitive stimulation approaches should be made widely available for people with mild to moderate dementia. A new approach known as Cognitive Stimulation Therapy (CST) has been developed and has been found to improve memory, quality of life, and cognition. CST may also potentially reduce costs of care, for example by delaying institutionalisation. We have spoken to people with dementia and their carers who are keen on having a version of CST which can be delivered by the carer, particularly for people who are unable or unwilling to go out of the house and/or to attend groups. They also felt it could help the relationship between the carer and the person with dementia. Previous research has also shown that involving carers in delivering interventions can be beneficial for both. The aim of this study is to find out whether individual home-based CST improves cognition and quality of life in people with dementia.

Who can participate?
Patients with dementia

What does the study involve?
Participants are randomly allocated to receive either usual care or individual CST sessions delivered by their caregiver. Individual CST sessions last for 30 minutes each and take place three times a week over 25 weeks. We then assess cognition, quality of life, and costs of care in both groups.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
University College London (UCL) (UK)

When is the study starting and how long is it expected to run for?
July 2010 to June 2014

Who is funding the study?
NIHR Health Technology Assessment Programme - HTA (UK)

Who is the main contact?
Prof Martin Orrell
m.orrell@ucl.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof Martin Orrell

Contact details
Department of Mental Health Sciences
UCL
Charles Bell House
67-73 Riding House Street
London
United Kingdom
W1W 7EJ
-
m.orrell@ucl.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 08/116/06

Study information

Scientific Title

Individual Cognitive Stimulation Therapy vs treatment as usual for dementia: a multicentre, single-blind, randomised controlled trial

Acronym
iCST

Study objectives
1. Individual home-based CST (iCST) will benefit cognition and quality of life in people with dementia over six months relative to a control (treatment as usual) group
2. iCST will be cost-effective relative to treatment as usual

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Multicentre pragmatic single-blind two-arm randomised controlled clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Dementia

Interventions
Individualised CST vs no treatment (control)
iCST sessions will last for 30 minutes and take place 3 times a week for 25 weeks.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure

1. Alzheimer's Disease Assessment Scale - Cognitive subscale (ADAS-Cog) (Rosen et al., 1984)
2. Quality of Life-Alzheimer's disease Scale (QoL-AD) (Logsdon et al., 1999)
3. Short Form-12 (SF-12) (Ware, Kosinski, and Keller, 1996)
Assessments will take place at baseline (pre iCST), 13 weeks (to safeguard loss to follow-up) and 26 weeks.

Secondary outcome measures
1. Client Service Receipt Inventory (Beecham & Knapp, 1992)
2. Dementia-related Quality of Life (DEMQOL) (Smith et al., 2005)
3. Behaviour
4. Neuropsychiatric Inventory (NPI) (Cummings et al. 1994)
5. Bristol Activities of Daily Living Scale (BADLS) (Bucks et al, 1996)
6. Hospital Anxiety and Depression Scale (HADS) (Zigmond and Snaith, 1983)
7. EQ-5D (EuroQol group, 1990)
Assessments will take place at baseline, 13 and 26 weeks.

Overall study start date
01/07/2010

Completion date
30/06/2014

Eligibility

Key inclusion criteria
1. Meet Diagnostic and Statistical Manual of Mental Disorders 4th edition (DSM IV) criteria for dementia
2. Score 10 or above on the Mini Mental State Examination (MMSE)
3. Some ability to communicate and understand
4. See/hear well enough to participate
5. No major physical illness or disability affecting their participation
6. Male or female, no age restrictions

Additional criteria will include living in the community and regular availability of a carer (or friend or befriender) to participate in the sessions.

Participant type(s)
Patient

Age group
All

Sex
Both

Target number of participants
306

Key exclusion criteria

People with dementia not meeting the criteria for individual work (living in a care home, no available family carer) but who are eligible for group CST will be linked up with the trial of maintenance group CST (NIHR programme).

Date of first enrolment
01/07/2010

Date of final enrolment
30/06/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University College London (UCL) (UK)
London
United Kingdom
W1W 7EJ

Sponsor information

Organisation
University College London (UCL) (UK)

Sponsor details
Gower Street
London
England
United Kingdom
WC1E 6BT
-
CTIMPS@ucl.ac.uk

Sponsor type
University/education

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	22/09/2012		Yes	No
Results article	results	06/02/2015		Yes	No
Results article	results	01/08/2015		Yes	No
Results article	results	28/03/2017		Yes	No