ISRCTN26286067 https://doi.org/10.1186/ISRCTN26286067

Maintenance Cognitive Stimulation Therapy groups for dementia

Submission date
26/08/2008

Recruitment status
No longer recruiting

Registration date
12/11/2008

Overall study status
Completed

Last Edited
13/03/2018

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The population is rapidly ageing and with this syndromes such as dementia are on the increase. The symptoms of dementia include memory loss and difficulties with thinking, problem-solving and language. Treatments such as Cognitive Stimulation Therapy (CST) have been developed to help people with dementia. CST is a 45-minute group therapy running twice weekly over 7 weeks that has been shown to improve cognition and quality of life for people with mild to moderate dementia. The aim of this study is to see whether an additional 24 weeks of maintenance CST sessions improves cognition in people with dementia .

Who can participate?
Patients with mild to moderate dementia

What does the study involve?
All participants will receive the initial CST programme consisting of 14, 45-minute twice weekly sessions. Participants will then be randomly allocated either to receive treatment as usual for 24 weeks or to attend weekly maintenance CST sessions for 24 weeks.

What are the potential benefits and risks of participating?
Reported benefits include feelings of validation, self worth and overall enjoyment of the sessions. There are no known risks to participants.

Where is the study run?
The study will take place in a variety of dementia care settings and NHS Trusts in the UK

When is the study starting and how long is it expected to run for?
Participants have been in the study since August 2011 and recruitment is expected to continue up until July 2012. Follow-up examinations will continue until July 2013.

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
RP-PG-0606-1083

Study information

Scientific Title
A multicentre randomised control trial of Maintenance Cognitive Stimulation Therapy (CST) vs CST only for dementia

Acronym
MCST, SHIELD

Study objectives
Maintenance Cognitive Stimulation Therapy (CST) groups for dementia will be more effective in the long-term than CST only groups.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Barking and Havering Research Ethics Committee, 14/10/2008, ref: 08/H0702/68

Study design
Multicentre single-blind randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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

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

Interventions
Although the first phase of the trial consists of identifying people with dementia that are taking cholinesterase inhibitors and the potential candidates suitable for taking cholinesterase inhibitor, only part of the trial consists of referring people to the appropriate health care teams in order to prescribe and monitor the medication. This randomised control trial is not a drug trial therefore all clinical responsibilities remain within the clinical team in charge of prescribing and monitoring medication.

All participants received the initial CST programme. The CST programme aims to create an environment where people learn and strengthen their existing resources, hence functioning at their maximum capacity. This is achieved through implicit learning rather than explicit teaching. For example, people are asked of their opinions rather than to provide factual answers; and multi-sensory stimulation is used to stimulate all the senses. Reminiscence is integrated into the programme, partly used as a means to orientate to the here and now.

The programme consisted of 14, 45-minute sessions which ran twice weekly for groups of approximately 5 people. Topics of the 14 sessions are as follows:

1. Physical games
2. Sound
3. Childhood
4. Food
5. Current affairs
6. Faces/scenes
7. Word association

8. Being creative
9. Categorising objects
10. Orientation
11. Using money
12. Number games
13. Word games
14. Team quiz

The programme included an 'RO board', displaying both personal and orientation information, including the group name (chosen by participants). The guiding principles of CST are the principles of person-centred care, treating people as unique individuals with their own personality and preferences. This is an essential aspect when delivering CST therapy for people with dementia. For this reason, group members are often assigned a role within the group, according to their interests and abilities.

After completion of the initial CST programme participants will be randomised into either the CST only control group (treatment as usual for 24 weeks) or maintenance CST group (Maintenance CST weekly for 24 weeks). The original maintenance CST of 16 sessions described in the pilot study (http://www.ncbi.nlm.nih.gov/pubmed/15852436) will be revised and further developed for this trial. The topics of the 16 sessions of the maintenance CST in the pilot study were as follows:

1. Childhood
2. Current affairs
3. Current affairs
4. Using objects
5. Number Games
6. Quiz
7. Music session
8. Physical games
9. Categorizing objects
10. Using objects
11. Useful tips
12. Discussion topics
13. Discussion topics
14. Discussion topics
15. Famous faces
16. Word completion

The participants randomly allocated to the control group will receive treatment as usual and will naturally vary between and within centres and may change over time. In general, the interventions that could possibly been offered to this group will also be available to those in the active treatment groups, so that we will be examining the additional effects of maintenance CST. The only exception to this would be where the active treatment is scheduled at the same time as an alternative intervention. Our approach to costing the services and interventions received should allow us to monitor whether the usual treatment group is receiving alternative interventions in this way.

Changes and developments in the availability of medications for Alzheimer's and other dementias will affect both groups equally, and will be recorded as part of the costing information collected. It is entirely feasible that participants in the usual treatment group may be involved in some form of cognitive stimulation work during the 24 weeks of the study period.

It is a popular approach in day-care centres. However, it is very unlikely that, in our experience, such a structured approach to CST will be offered in any of the centres. It is this systematic group-based approach, rather than a general exhortation to cognitive stimulation activity to improve cognition and quality of life, that is the concern of this evaluation.

Intervention Type
Behavioural

Primary outcome measure
The following will be assessed at baseline, after CST (7 weeks), after 3 and 6 months from the beginning of the maintenance sessions:
1. Cognition, assessed by the Alzheimer's Disease Assessment Scale - Cognitive Subscale (ADAS-Cog)
2. Quality of Life: Alzheimer's disease Scale (QoL-AD), EQ-5D, Dementia Quality of Life (DemQol)

Secondary outcome measures
The following will be assessed at baseline, after CST (7 weeks), after 3 and 6 months from the beginning of the maintenance sessions:
1. Communication, assessed by the Holden Communication Scale
2. Severity of dementia, assessed by the Clinical Dementia Rating (CDR)
3. Depression, assessed by the Cornell Scale for Depression in Dementia
4. Anxiety, assessed by the Rating Anxiety in Dementia (RAID) tool
5. Behaviour, assessed by the Neuropsychiatric Inventory (NPI)
6. Activities of daily living, assessed by Alzheimer's Disease Co-operative Study - Activities of Daily Living Inventory (ADCS-ADL)
7. Short Form-12 Health Survey (SF-12)

Overall study start date
01/11/2008

Completion date
01/11/2012

Eligibility

Key inclusion criteria
Both males and females are eligible, and there is no age limit for participation in this trial. People will be considered suitable for full assessment and participation if they:
1. Meet the Diagnostic and Statistical Manual of Mental Disorders, fourth edition (DSM-IV) criteria for dementia
2. Score between 0.5 and 2 on the Clinical Dementia Rating (CDR)
3. Have some ability to communicate and understand communication - a score of 1 or 0 in questions 12 and 13 of the Clifton Assessment Procedures for the Elderly - Behaviour Rating Scale (CAPE-BRS)
4. Are able to see and hear well enough to participate in the group and make use of most of the material in the programme, as determined by the researcher
5. Do not have major physical illness or disability which could affect participation
6. Do not have a diagnosis of a learning disability
7. Are able to communicate in English

Participant type(s)

Patient

Age group
Senior

Sex
Both

Target number of participants
230

Key exclusion criteria
Participants not meeting the inclusion criteria

Date of first enrolment
01/08/2011

Date of final enrolment
01/07/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University College London
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Sponsor information

Organisation
National Institute for Health Research (NIHR) (UK)

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Sponsor type
Government

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ROR
https://ror.org/0187kwz08

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) (ref: RP-PG-0606-1083)

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

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?

Protocol article	protocol	28/04/2010	Yes	No
Results article	results	14/03/2014	Yes	No
Results article	results	01/06/2014	Yes	No
Other publications	economic evaluation	01/01/2015	Yes	No
Other publications	cost effectiveness analysis	01/05/2019	Yes	No