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Implementation and evaluation of two different cognitive stimulation therapy training approaches

Submission date
26/11/2010

Recruitment status
No longer recruiting

Registration date
10/03/2011

Overall study status
Completed

Last Edited
11/12/2018

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Dementia is a common condition in the aging population. People with dementia have difficulties with mental processes such as memory, language, reasoning and identifying people and objects, which become progressively worst over time (cognitive function). This can make it very difficult to deal with daily life and so many sufferers are eventually placed in nursing homes so that they can receive round-the-clock care. Cognitive Stimulation Therapy (CST) is a treatment for people suffering from mild to moderate dementia. CST involves group-sessions run by specially trained staff to help to stimulate and engage people with dementia, helping them to improve their memory and communication skills. The aim of this study is to look at the training and outreach support offered to staff providing CST, as well as the benefits to people with dementia who are taking part in CST groups.

Who can participate?
Adults with mild to moderate dementia and the staff members looking after them.

What does the study involve?
Staff members are randomly allocated to one of two groups. Participants in both groups receive their usual training, as well as the 1-day CST training, training DVD and two manuals containing information of training and maintaining the skills they learn. For those in the first group, outreach support is also provided, which consists of online forum, email support, telephone conferences and local supervision, available over 12 months. For those in the second group, no additional support is provided. At the start of the study, and then again after 6 and 12 months, participants in both groups complete three questionnaires designed to find out their thoughts on the programme, the knowledge they have gained, and if the training has changed the way they work. In a second aspect of the trial, the participants are contacted in order to find out whether staff members have been running the CST groups after purchasing the manual and/or attending the training day. For those who are given access to outreach support (providing extra support that is not usually offered), the amount that they have used it is recorded. In a third aspect of the trial, people with dementia who are taking part in the CST programme undergo additional tests to find out if the CST has had any effect on their cognitive function and quality of life.

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

Where is the study run from?
North East London NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
February 2011 to August 2012

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

Who is the main contact?
Professor Martin Orrell

Contact information

Type(s)
Scientific

Contact name
Prof Martin Orrell

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
An evaluation and comparison of the effectiveness of two different cognitive stimulation therapy (CST) approaches and their implementation in practice

Study objectives
The level of adherence to cognitive stimulation therapy (CST) will increase in relation to the degree of support that the site receives.

The null hypothesis is that training alone would not be sufficient knowledge to run groups.

Ethics approval required
Old ethics approval format

Ethics approval(s)
East London REC3 pending approval as of 26/11/2010

Study design
Multicentre randomised controlled trial with a monitoring 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 below to request a patient information sheet

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

Interventions
Randomised controlled trial (RCT):
In the RCT all staff members will be expected to attend training and will receive two manuals, workbook and DVD. They will then be randomised to receive outreach support or no outreach support. The outreach support consists of online forum, email support, telephone conferences and local supervision, these will be offered over a twelve month period.

All of the people with dementia will receive CST and maintenance CST therapy sessions and half of the people with dementia will be randomised to complete minimal outcome measures, relating to their cognition and quality of life.

Monitoring trial:
The members of staff will be recruited if they have independently bought the training manual and/or attended the training day. So this will not be offered to them. They will then be split in to which one they apply to and half from each group will be offered outreach support linked in to the RCT.

All of the people with dementia will receive CST and maintenance CST therapy sessions and half of the people with dementia will be randomised to complete minimal outcome measures, relating to their cognition and quality of life.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Number of attendees to the CST groups
2. Level of adherence
3. Competency of staff member

For staff the measures will be completed at baseline, 6 and 12 months. For the people with dementia they will be measured at baseline, 7 and 31 weeks.

Secondary outcome measures
1. Minimal outcome measures with person with dementia (cognition and quality of life)
2. Job satisfaction
3. Approaches to dementia
4. Dementia knowledge
5. Learning transfer system inventory
6. Barriers to change

For staff the measures will be completed at baseline, 6 and 12 months. For the people with dementia they will be measured at baseline, 7 and 31 weeks.

Overall study start date
01/02/2011

Completion date
31/08/2012

Eligibility

Key inclusion criteria
Staff:
1. Staff members' working directly for people with dementia
2. Willingness to self complete three sets of questionnaires within a year time frame
3. Adequate written and spoken comprehension of the English language
4. Opportunity to recruit five to eight suitable people in the mild to moderate stages of dementia
5. Access to a computer and an adequate level of competency to complete questionnaires online
6. Each centre will contribute three or more staff members who will intend to run CST groups
7. Agreement with management to have two hours, set aside, each week to run CST sessions and one hour a week, set aside, for the following 24 weeks of maintenance CST groups

Person with dementia:
1. Previous diagnosis of mild to moderate dementia, with a score of between 0.5 and 2 on the

Clinical Dementia Rating
2. Adequate spoken and written English
3. Ability to participate in a 'meaningful' conversation
4. Good eyesight and hearing
5. Level of comprehension to willingly give informed consent to take part in groups
6. Ability to partake in a group for 45 minutes
7. Willingness to complete the QoL-AD and Mini-Mental State Examination (MMSE) at three intervals over a year time frame
8. Do not have a major physical illness or disability which could affect participation
9. Do not have a diagnosis of a learning disability

Both:
10. Male and female, aged between 18 - 99 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
240

Key exclusion criteria
Staff:
1. Not having direct access to people with dementia
2. Not being able to recruit between five to eight people with dementia
3. Unable to complete self-completing questionnaires
4. Inability to access or use a computer
5. Unable to write or speak fluently in English
6. Inability to provide three staff members to take part in the the trial
7. No consent from management

Person with dementia:
1. No diagnosis of dementia
2. Inability to write or speak fluently in English
3. Unable to enagage in a conversation
4. Unable to stay in a group for 45 minutes
5. Bad eyesight or hearing
6. Unable to give informed consent
7. Not willing to complete minimal outcome measures

Date of first enrolment
01/02/2011

Date of final enrolment
31/08/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
North East London NHS Foundation Trust (NELFT)
Essex
United Kingdom
IG3 8XJ

Sponsor information

Organisation
North East London NHS Foundation Trust (NELFT) (UK)

Sponsor details
c/o John Brouder, Chief Executive
Goodmayes Hospital
Ilford
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Sponsor type
Hospital/treatment centre

Website
http://www.nelft.nhs.uk/

ROR
https://ror.org/023e5m798

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

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	26/06/2012		Yes	No
Results article	results	01/02/2017		Yes	No