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Valuing Active Life in Dementia: a trial to assess the effectiveness of community occupational therapy for people with dementia

Submission date
18/09/2014

Recruitment status
No longer recruiting

Registration date
18/09/2014

Overall study status
Completed

Last Edited
05/01/2021

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Occupational therapists are health and social care professionals who help people to live life their way - helping people to keep up their everyday activities and remain independent for as long as possible after they develop dementia. Researchers in The Netherlands developed a Community Occupational Therapy in Dementia programme (COTiD) for people with mild to moderate dementia and their family carers. The programme showed benefits to the person with dementia in terms of their ability to carry out activities, quality of life and mood. Family carers' quality of life, mood and sense of competence also improved and the programme was cost effective. We have developed a similar programme to meet the needs of the UK population, known as COTiD-UK. The next phase is to test whether this helps people or not.

Who can participate?
People with mild to moderate dementia who have a family carer willing to participate may be involved in the study. Participants need to be over the age of 18.

What does the study involve?
Participants will be randomly allocated to receive either the COTiD-UK intervention (ten 1-hour occupational therapy sessions delivered in the person with dementia's home), or to continue with their usual care. Outcome measures will be completed at the start, then at 12, 26 and 52 weeks, with the first half of the participants also completing a 78-week follow-up.

What are the possible benefits and risks of participating?
COTiD-UK offers more intensive occupational therapy input at an earlier stage than is currently provided in the UK, which has potential benefits to the participants. Participants may find talking about the experience of having dementia or caring for a person with dementia upsetting. Research staff will be trained and experienced in conducting interviews of this nature and to respond sensitively and appropriately. Participants may reveal circumstances that have or may place them at risk of harm or neglect. Research staff will be trained to recognise these risks and where appropriate to take action.

Where is the study run from?
This study has been set up in North East London NHS Foundation Trust, UK. There are two other research centres in Sheffield and Hull (UK).

When is the study starting and how long is it expected to run for?
September 2014 to September 2017.

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

Who is the main contact?
Dr Jennifer Wenborn
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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
17304

Study information

Scientific Title
Valuing Active Life in Dementia (VALID) Work Packages 3/4: a pilot trial and randomised controlled trial of Community Occupational Therapy in Dementia (COTiD-UK)

Acronym
VALID

Study objectives
It is hypothesised that in comparison to 'treatment as usual', COTiD-UK will:
1. Significantly improve ADL abilities in people with dementia
2. Significantly improve quality of life of the people with dementia and their family carers
3. Demonstrate cost effectiveness

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee London - Camberwell St Giles, 14/07/2014 (minor amendment approved: 25/07/2014), ref: 14/LO/0736

Study design
Randomised; Interventional and Observational; Design type: Treatment, Qualitative

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
Topic: Dementias and neurodegeneration; Subtopic: Dementia; Disease: Dementia

Interventions
In total, 480 dyads (a person with dementia and their family carer) will be recruited and randomly allocated to EITHER receive the COTiD-UK intervention (ten 1-hour occupational therapy sessions delivered in the person with dementia's home) OR to continue with their usual care (TAU). Qualitative data will also be collected through interviews and observation of COTiD-UK sessions.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Activities of Daily Living Scale - Bristol Activities of Daily Living Scale. Outcome measures will be completed at baseline, then at: 12, 26 and 52 weeks, with the first 40% of the participants also completing a 78-week follow-up

Secondary outcome measures
1. Canadian Occupational Performance Measure (COPM)
2. Client Service Receipt Inventory (CSRI)
3. Mini Mental State Examination (MMSE)
4. Interview of Deterioration in Daily activities in Dementia (IDDD)
5. Dementia Quality of Life Scale (DEMQOL)
6. European Quality of Life - Five Dimensions (EQ-5D) 5 Level
7. Cornell Scale for Depression in Dementia (CSDD)
8. Serious adverse events
9. Use of psychotropic drugs
10. Sense of Competence Questionnaire (SCQ)
11. Hospital Anxiety and Depression Scale (HADS)

Overall study start date
01/09/2014

Completion date
30/06/2018

Eligibility

Key inclusion criteria
Inclusion criteria for people with dementia:
1. Living in the community in own home (includes sheltered accommodation)
2. Identified family carer who provides at least four hours support per week
3. Has a diagnosis of dementia, as defined by the DSM-IV and scores between 0.5 and 2 on the Clinical Dementia
Rating Scale
4. Able to converse in English
5. Able and willing to participate in the COTiD-UK intervention in partnership with their family carer, i.e., ten 1-hour sessions of home-based occupational therapy
6. Has capacity to provide his/her consent

Inclusion criteria for family caregivers:
1. Aged 18 or over
2. Is currently providing practical support with domestic and/or personal activities to the person with dementia for a
minimum of 4 hours per week
3. Able to converse in English
4. Able and willing to participate in the COTiD-UK intervention in partnership with the person with dementia that
they support, i.e., ten 1-hour sessions of home-based occupational therapy
5. Has capacity to provide his/her consent

Inclusion criteria for occupational therapist participants:
1. Be registered as an occupational therapist with the Health and Care Professions Council

2. Have experience of working in the community and/or with people who have dementia and their family carers
3. Have completed the COTi-DUK training and achieved fidelity with COTi-DUK implementation

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 985; UK Sample Size: 985

Total final enrolment
936

Key exclusion criteria
Exclusion criteria for people with dementia:
1. Participating in another intervention research study
2. Currently in hospital or living in a care home

Exclusion criteria for family carers:
1. Participating in another intervention research study

Date of first enrolment
01/09/2014

Date of final enrolment
30/06/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Goodmayes Hospital
Ilford
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Sponsor information

Organisation
North East London NHS Foundation Trust (UK)

Sponsor details
R&D Department
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/023e5m798

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK); Grant Codes: RP-PG-0610-10108

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
30/06/2020

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	03/02/2016		Yes	No
Results article	results	04/01/2021	05/01/2021	Yes	No
HRA research summary			28/06/2023	No	No