







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	 Retrospectively registered
Registration date 18/09/2014	Overall study status Completed	 Protocol added
Last Edited 05/01/2021	Condition category Mental and Behavioural Disorders	 SAP not yet added
		 Results added
		 Raw data not yet added
		 Study completed

Plain English Summary

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

Contact name

Dr Jennifer Wenborn

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Protocol/serial number

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 hypothesis

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

Condition

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

Overall study end date

30/06/2018

Eligibility

Participant 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

Participant 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

Recruitment start date

01/09/2014

Recruitment end date

30/06/2017

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

Goodmayes Hospital

Ilford

United Kingdom

IG3 8XJ

Sponsor information

Organisation

North East London NHS Foundation Trust (UK)

Sponsor details

R&D Department
1st Floor Maggie Lilley Suite
Goodmayes Hospital
157 Barley Lane
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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