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'I can't forget to worry': cognitive behavioural therapy (CBT) for anxiety in people with dementia

Submission date
21/06/2011

Recruitment status
No longer recruiting

Registration date
21/06/2011

Overall study status
Completed

Last Edited
19/11/2018

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims?
There are about 700,000 people with dementia in the UK and up to two thirds of them also have anxiety. This can worsen their cognitive (e.g. memory and language) and behavioural problems. It can also lead to relationship difficulties, physical dependency and increase the risk of being admitted to a care home. The Department of Health's first ever 'National Dementia Strategy' sets standards for best care for people with dementia, including ensuring early treatment. Cognitive Behavioural Therapy (CBT) is a person-centred talking therapy that addresses the thoughts and feelings associated with anxiety and teaches people new skills to manage it. It is the treatment of choice for anxiety in other groups, including older people in general. There is some evidence from research with individual cases that CBT has great potential to help reduce anxiety and improve mood in people with dementia. This study will test whether CBT reduces anxiety in people with dementia and whether it improves their cognitive problems, everyday behaviour and quality of life. We will also test if it improves relationships with carers, as they develop new skills to help support their relative. The study will be an initial study: 50 people with mild to moderate dementia and anxiety (and their carer) will be randomly allocated to receive either CBT or treatment as usual (typically medication or no treatment). For the NHS, this method of treatment may reduce costs e.g. through reductions in GP visits, use of medication and admission to care homes. If the results of the trial are positive, we will apply for funding for a full-scale clinical trial. We also aim to produce a CBT training manual for dementia health professionals (e.g. Psychologists and Nurses) that will be freely available online. This study is important because anxiety increases disability in dementia and treatment options are limited, often leading to unnecessary use of medication which can have serious side-effects.

Who can participate?
To take part you need to have a diagnosis of dementia, experience regular feelings of worry or anxiety, and have a family member/carer who would be interested in taking part in the study.

What does the study involve?
Before deciding to take part, you will have an opportunity to discuss any questions you may have about the study with a researcher. If you decide to take part, you and your friend/relative will be

asked to complete some questionnaires covering your quality of life, memory and mood. You and your friend/relative may take as many breaks as you want or feel necessary, and even complete the process over two sessions if preferred. We would like to meet with everyone involved in the study three times over a period of six months.
If you are eligible to take part you will have a 50:50 chance of receiving Cognitive Behaviour Therapy (CBT). The decision is made completely at random by a computer, which will not have any identifying information about you or your relative/friend. CBT involves identifying and understanding the relationship between your thoughts, feelings and behaviour. Goals will be identified and strategies and skills learnt in order to reduce anxiety. Each session will last approximately 60 minutes and will take place once a week for 10 weeks. These will be with a clinical psychologist and can take place in your home, or elsewhere if you prefer, such as at a day centre, day hospital or GP surgery. Your friend/relative may be invited in to some sessions, but this decision will be made by you. Whether or not you are offered CBT, there will be no changes made by service providers to the services you normally receive.

What are the possible benefits and risks of participating?
Previous research on CBT for people who have anxiety but do not have dementia has shown many benefits, including reduced anxiety, improved mood and increased participation in pleasurable activities. There has been a small amount of research also showing that CBT is beneficial for people who have anxiety and a diagnosis of dementia. The information we get from all participants in the study may help us to confirm these findings, and treat people with memory problems and anxiety better in the future.
CBT sessions involve discussing and understanding the relationship between thoughts, feelings and behaviour and the risks of taking part are minimal. If the therapy really does not suit you, for example if you find it distressing, you are free to withdraw at any point.

Where is the study run from?
It is being organised by North East London (NHS) Foundation Trust and UCL. There are four boroughs from which participants are being recruited: Barking & Dagenham, Havering, Redbridge, Waltham Forest.

When is the study starting and how long is it expected to run for?
The study will be running from 01/02/2011 until 01/01/2013 and will be open to new participants, from June 2011 until June 2012.

Who is funding the study?
The National Institute for Health Research (NIHR) (UK) - Research for Patient Benefit (RfPB) programme,

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
9365

Study information

Scientific Title
A pilot randomised controlled trial of cognitive behavioural therapy (CBT) for anxiety in people with dementia

Study objectives
There are about 700,000 people with dementia in the UK and up to two thirds of them also have anxiety. This can worsen their cognitive (e.g. memory and language) and behavioural problems. It can also lead to relationship difficulties, physical dependency and increase the risk of being admitted to a care home. The Department of Health's first ever 'National Dementia Strategy' sets standards for best care for people with dementia, including ensuring early treatment (DoH, 2009). Cognitive Behavioural Therapy (CBT) is a person-centred talking therapy that addresses the thoughts and feelings associated with anxiety and teaches people new skills to manage it. It is the treatment of choice for anxiety in other groups, including older people in general. There is some evidence from research with individual cases that CBT has great potential to help reduce anxiety and improve mood in people with dementia.

This project will test whether CBT reduces anxiety in people with dementia and whether it improves their cognitive problems, everyday behaviour and quality of life. We will also test if it improves relationships with carers, as they develop new skills to help support their relative. The study will be a pilot trial. 50 people with mild to moderate dementia and anxiety (and their carer) will be randomly allocated to receive either CBT or treatment as usual (typically medication or no treatment). For the NHS, this method of treatment may reduce costs e.g. through reductions in GP visits, use of medication and admission to care homes. If the results of the trial are positive, we will apply for funding for a full-scale clinical trial. We also aim to produce a CBT training manual for dementia health professionals (e.g. Psychologists and Nurses) that will be freely available online. This study is important because anxiety increases disability in dementia and treatment options are limited, often leading to unnecessary use of medication which can have serious side-effects.

1. How effective are psychosocial interventions for anxiety in dementia, as identified from past research?
2. What are the key features (identified from research evidence and by service-users) that can contribute to a cognitive behavioural therapy (CBT) for anxiety programme for people with dementia?
3. Is CBT more effective in reducing anxiety and improving quality of life (QoL), cognitive function, mood, carer relationship and behavioural function than treatment as usual?

The primary hypothesis is that CBT will lead to reduced anxiety for people with dementia, when compared to treatment as usual.

Ethics approval required
Old ethics approval format

Ethics approval(s)
East London REC 3, 27/01/2011, ref: 10/H0701/124

Study design
Randomised interventional Design type: Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Dementias and Neurodegenerative Diseases Research Network; Subtopic: Dementia

Interventions
1. Cognitve behaviour therapy (CBT) for people with anxiety and dementia
2. 25 will be randomised to the treatment group and 25 to the control group

Intervention Type
Behavioural

Primary outcome measure
Rating Anxiety in Dementia (RAID). This rates signs and symptoms of anxiety using interviews with carers and people with dementia. There are 18 questions in various categories: worry, apprehension, vigilance, motor tension and autonomic hypersensitivity. A score of 11 or above indicates significant clinical anxiety. It has good inter-rater and test-retest reliability, is sensitive to change and correlates with quality of life.

Measured at baseline, 12 weeks and 6 months.

Secondary outcome measures
1. Cornell Scale for Depression in Dementia at 1, 12 and 24 weeks
2. Hospital Anxiety and Depression Scale (HADS) at 1, 12 and 24 weeks
3. Mini Mental State Examination (MMSE) at 1, 12 and 24 weeks
4. Quality of Caregiver and Patient Relationship (QCPR) at 1, 12 and 24 weeks
5. Quality of Life in Alzheimer's Disease (QOLAD) at 1, 12 and 24 weeks

Overall study start date
01/02/2011

Completion date
01/01/2013

Eligibility

Key inclusion criteria
1. Meet DSMIV criteria for dementia in mild to moderate range
2. Clinical Dementia Rating score of 0.5, 1 or 2
3. Clinical anxiety, as determined by a score of 11 or above on the RAID (Rating Anxiety in Dementia)
4. Living in the community
5. The presence of a carer, who is willing to participate in the therapy
6. An ability to understand and communicate in English
7. Willing to engage in therapy involving discussion of thoughts and feelings
8. Male or female

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
UK Sample Size: 50; Description: 25 will be randomised to the treatment group and 25 to the control group.

Key exclusion criteria
1. Co-morbid psychiatric disorder (e.g. psychosis) or challenging behaviour (e.g. severe agitation) likely to prevent engagement in therapy, not including anxiety or depression
2. Presence of a learning disability or severe physical illness, which could impact on participation, involving discussions of thoughts and feelings

Date of first enrolment
01/06/2011

Date of final enrolment
01/06/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University College London
London
United Kingdom
WC1E 7HB

Sponsor information

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

Sponsor details
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United Kingdom
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Sponsor type
University/education

Website
http://www.ucl.ac.uk/

ROR
https://ror.org/023e5m798

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Research for Patient Benefit (RfPB) programme, ref: PB PG 0609-182 30(1)

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	23/10/2012		Yes	No
Results article	results	01/06/2015		Yes	No