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Guided cognitive behavioural therapy (CBT) self-help for depression in carers of stroke survivors

Submission date
25/04/2013

Recruitment status
No longer recruiting

Registration date
26/04/2013

Overall study status
Completed

Last Edited
04/10/2018

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
One in three carers of stroke survivors experience depression. Depression both negatively impacts the health and wellbeing of carers and the quality of care and recovery of the person cared for. However, the long term mental health needs of carers of stroke survivors have been neglected. A potential solution is supported cognitive behavioural therapy self-help (CBTsh), which is an evidence based psychological intervention for depression. We have worked closely with carers of stroke survivors to tailor existing treatments to the unique needs and difficulties experienced by carers of stroke survivors.
We want to look at whether this new support will help improve outcomes for relatives and carers of stroke survivors with depression.

Who can participate?
This study is looking to recruit 60 carers of stroke survivors across Dorset and Cornwall. Carers will be aged 16 or over, meeting diagnostic criteria for depression and having been a carer for a minimum of 2 months post home discharge.

What does the study involve?
Taking part in the study involves a number of stages over 6 months. The study team will need to speak with participants over the telephone or face-to-face to confirm suitability for the trial. Participants who are suitable will be randomly allocated to receive either the new CBTsh based support or to remain receiving usual care. We will also need to ask participants further questions at 4 months and 6 months to see how they are doing.
Participants randomly allocated to the new CBTsh based support will meet with a psychological wellbeing practitioner (PWP) face-to-face or speak with them over the telephone. PWPs are workers in the NHS trained to support this type of therapy. Participants will receive regular support sessions over a period of time decided together with their PWP. Usually they will receive up to around 12 sessions over a 4 month period. Each session tends to be up to 40 minutes.
Participants randomly allocated to usual care could receive a number of different things. Participants may receive care from their GP. Their GP may prescribe them with antidepressant

medication if appropriate, or make a referral to a mental health professional. Participants who continue to receive usual care will be given the chance to take part in the CBT based support at the end of the study.

What are the possible benefits and risks of participating?
We hope that either continuing normal care or the CBT based support will help participants depression. CBT based support is recommended for depression by NICE (The National Institute for Clinical Excellence). Continued usual care may include other treatments recommended by NICE. However, we cannot guarantee these treatments will help participants. The information we get from this study will help us to treat future carers of stroke survivors experiencing depression better.
Taking part in this study will involve taking time to talk to the researchers face-to-face or over the telephone about how they are getting on. These questions can be personal and it may be upsetting to discuss these subjects. If randomly allocated to the CBTsh based support participants will have to agree to work through the programme and attend the support sessions. Taking part in the programme does involve time, effort and commitment.

Where is the study run from?
The CEDArS Study is being run by the Mood Disorders Centre, University of Exeter.

When is the study starting and how long is it expected to run for?
The study will be starting in May 2013 and is expected to run for 12 months.

Who is funding the study?
The study is funded by The Dunhill Medical Trust as part of a Research Training Fellowship.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number

14284

Study information

Scientific Title
Feasibility randomised controlled trial of guided cognitive behavioural therapy self-help for informal carers of stroke patients

Acronym
CEDArS

Study objectives
Over 30% of carers of stroke survivors experience depression. Depression both negatively impacts the health and wellbeing of carers and the quality of care and recovery of the person cared for. However, the long term mental health needs of carers of stroke survivors have been neglected resulting in substantial unmet needs for psychological support. A potential solution is supported cognitive behavioural therapy self-help (CBTsh); an evidence based psychological intervention for depression. Supported CBTsh underpins low intensity CBT delivery within the Improving Access to Psychological Therapies (IAPT) Programme and is recommended by NICE (2012). At present, CBTsh interventions used within IAPT are targeted at general mental health populations. However, given demand for psychological therapy amongst physical health patients and their carers there are increasing calls to widen the application of CBTsh to these populations. There is also increasing evidence suggesting for CBTsh interventions for these populations to be effective and acceptable significant adaptations are required to intervention content and method of delivery. A study to gain an appreciation of adaptations required to the content and method of delivery has informed the development of a tailored CBTsh intervention for carers of stroke survivors. This current study seeks to examine the feasibility and acceptability of this intervention.

Participants aged 16 or over, meeting diagnostic criteria for depression and having been a carer for a minimum of 2 months post-home discharge are eligible. 60 participants will be recruited from primary care, specialist stroke settings and community organisations. Participants will be randomised to receive either the new CBTsh intervention, supported by Psychological Wellbeing Practitioners (PWPs) who are paraprofessionals trained to support CBTsh, or treatment-as-usual (which may include medication, other psychological interventions, or no treatment).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Cornwall & Plymouth Research Ethics Committee, 13/SW/0018, 15/02/2013, ref: 13/SW/0018

Study design
Randomised interventional treatment trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Depression in carers of stroke survivors

Interventions
CBT Self-help for Carers, Supported Cognitive Behavioural Therapy (CBT) Self-Help for Carers of Stroke Patients
Participants will receive the CBT self-help written material that was developed in Phase I. Participants will receive up to a maximum of 12 support sessions. The initial assessment session will be up to 35 minutes with subsequent sessions up to 35 minutes each. The number of support sessions received will be decided collaboratively between PWP and patient as per current IAPT protocols.

Treatment-As-Usual, Participants randomised to the control condition will receive usual care delivered by their general practitioner or other healthcare provider. GPs will be able to treat participants as per normal practice and patients will be able to seek any treatment they wish, for example taking antidepressant medication or referral for psychological treatment. Participants use of usual care will be recorded at each follow-up time point to determine the type of care provided.

Follow Up Length: 6 months

Study Entry: Single Randomisation only

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
The primary outcome measurements will mainly pertain to the feasibility aims of the study. Specifically we are interested in testing recruitment methods, study attrition and the variability in the number, length and frequency of support sessions required to bring about recovery. We are also interested in 4 month differences in depression to enable the estimation of sample size for a phase III randomised controlled trial. This will be determined using the Clinical Interview Schedule (CIS-R), a structured diagnostic interview, to reach an ICD-10 diagnosis of depression or anxiety (Lewis et al., 1992).

Key secondary outcome(s))
1. Frequency of depressive symptoms will be measured by the PHQ-9
2. Frequency of anxiety symptoms will be measured by the GAD-7
3. Functional impairment will be measured using the Work & Social Adjustment Scale (WSAS)
4. Stroke patient ability will be measured by the Barthel Index (BI) and the Frenchay Activities Index (FAI)
5. Caregiver burden will be measured by the Caregiver Burden Scale (CBS)
6. Health related quality of life will be measured using the SF-36
7. Quality-adjusted life-years will be measured using the EQ-5D
8. Health and social care service use will be measured by the CSRI adapted for use in a stroke patient carer population

Measured 4 months and 6 months post-randomisation.

Completion date
01/04/2014

Eligibility

Key inclusion criteria
1. Male and female aged 16 years and over
2. Self-identified informal carers of stroke survivors for a minimum of 2 months post home-discharge (relating to the time of the most recent stroke)
3. Currently reaching ICD-10 criteria for major depressive disorder as determined by the Clinical Interview Schedule (CIS-R; Lewis et al. 1992)
4. Score of between 10-23 on the Patient Health Questionnaire (PHQ-9) (Kroenke, Spitzer & Williams, 2001) as a measure of severity of depressive symptoms (moderate depression: PHQ-9 score 10-14; moderately severe depression: PHQ-9 score 15-23)
5. Participants will be eligible whether or not they are receiving antidepressant medication to reflect real-world practice; however dosage must not have been changed during the last month. Participants who have changed their dosage in the last month will be contacted again when they have been on a stable dosage for 1 month

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
16 years

Sex
All

Key exclusion criteria
1. A score of above 21 on the Generalized Anxiety Disorder 7 (GAD-7) (Spitzer, Kroenke, Williams & Löwe, 2006) as a measure of severity of anxiety symptoms
2. Co-morbid diagnosis of post-traumatic stress disorder (PTSD), psychosis, type I and II bipolar disorder, personality disorder
3. Current alcohol abuse
4. Current substance abuse
5. Participants who score 3 on question 9 of the PHQ-9 concerning suicidal ideation or who are determined as acutely suicidal by the Mood Disorders Centre risk protocol and/or a history of persistent self-injury
6. Currently receiving formal psychotherapy
7. A reading impairment which would prevent them from using a CBT self-help intervention

Date of first enrolment
08/04/2013

Date of final enrolment
01/04/2014

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
School of Psychology
Exeter
United Kingdom
EX4 4QG

Sponsor information

Organisation
University of Exeter (UK)

ROR
https://ror.org/03yghzc09

Funder(s)

Funder type
Charity

Funder Name
Dunhill Medical Trust

Alternative Name(s)
The Dunhill Medical Trust, Dunhill Medical Trust, DunhillMedical, DMT

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	06/05/2014		Yes	No
HRA research summary			28/06/2023	No	No