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CanTalk : A trial into the benefits of a talking therapy called cognitive behaviour therapy for the treatment of depression in adults with advanced cancer to see whether the intervention is better than treatment as usual

Submission date 15/07/2011	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 20/07/2011	**Overall study status** Completed	
Last Edited 01/10/2019	**Condition category** Cancer	

Plain English summary of protocol
http://www.cancerresearchuk.org/cancer-help/trials/a-study-looking-at-talking-therapy-for-people-with-advanced-cancer-can-talk

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
HTA 09/33/02

Study information

Scientific Title
CanTalk: The clinical and cost effecttiveness of cognitive behaviour therapy (CBT) plus treatment as usual for the treatment of depression in advanced cancer: a randomised controlled trial

Acronym
CanTalk

Study objectives
Cognitive Behavioural Therapy plus treatment as usual is more clinically and cost effective than treatment as usual for major depression in adults with cancer no longer amenable to curative treatment.

Primary objective:
To determine through a randomised controlled trial the clinical effectiveness of Cognitive Behaviour Therapy plus treatment as usual compared to treatment as usual for depression in adults with cancer which is no longer amenable to curative treatment.

Secondary objective:
To determine through a randomised controlled trial the cost effectiveness of Cognitive Behaviour Therapy plus treatment as usual compared to treatment as usual for depression in adults with cancer which is no longer amenable to curative treatment.

More details can be found at http://www.nets.nihr.ac.uk/projects/hta/093302
Protocol can be found at http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0006/54384/PRO-09-33-02.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Research Ethics Service; NRES committee London; Camberwell St Giles, 24/05/2011, REC ref: 11/LO/0376

Study design
Parallel-group single-blind randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Cancer and major depression

Interventions
Intervention group (treatment as usual + CBT) and Control (treatment as usual), 120 patients in each group

Intervention:
The availability of trained psychologists to deliver psychological interventions, such as CBT, to oncology patients in secondary care settings is limited. It is possible to train palliative care practitioners in CBT skills (Mannix et al, 2006), but this does not translate into improved outcomes for depression (Moorey et al, 2009). The Government is developing a roll out programme in a community setting which aims at 'improving access to psychological therapies' (IAPT). These Primary Care Trust funded IAPT centres train, supervise and supply therapists (who come from core professions in nursing, social sciences and psychology) to treat people in primary care with mental health problems. In this study, we propose to train experienced therapists to adapt their skills for treating depression in advanced cancer patients. An overview of the structure and content of sessions (to be manualised), the therapists' experience necessary, the further training which will be offered and how adherence and evaluation of therapy will be undertaken is provided as follows:

Structure of CBT sessions: 16-20 sessions are recommended by NICE for severe depression in secondary care. However, our experience has been that in a primary care setting considerably fewer sessions are taken up in practice. Our patients will have difficulty in coping with longer therapy given their physical limitations. Our intervention will therefore consist of up to 12 sessions of individual CBT delivered face to face or on the telephone over 3 months. Methods developed by Moorey, Mannix (co-applicant) and Serfaty (2008) in which therapists, typical of NHS practice, adapt their work to patients with advanced cancer will be used and the frequency of sessions will be flexible. We anticipate that twice weekly sessions will be offered for the first 2 weeks, weekly sessions for weeks 3 to 9 and then two sessions within weeks 10-12. Although we will aim to offer CBT face to face, telephone CBT is already informally used by IAPT therapists. Mannix and Moorey will teach CBT therapists how to adapt their CBT techniques for telephone counselling using similar methods to Tutty et al, (2000). All patients receiving CBT will be encouraged to complete at least three sessions of face to face CBT before being eligible for telephone CBT.

Content of therapy sessions: IAPT recommends that patients with moderate to severe depression and complex needs receive high intensity (step 3) work. This is consistent with level 4 psychological interventions recommended by NICE (2004) for people with cancer. The CBT intervention will use the following approach:
1. Session 1: assessment of problems, psycho-education about depressive disorder, introduction to the cognitive model
2. Session 2: establishment of the thought-feeling link, identifying unhelpful thinking styles using specific examples from recent events
3. Sessions 3 and 4; reinforcement of cognitive model, activity scheduling, behavioural experiments to test out beliefs. Adaptations of CBT for use in cancer with exploration of patients' beliefs about the negative effects of cancer and their perception of themselves in the context of their illness.
4. Sessions 5-10 will use standard techniques described by Beck (Beck et al, 1979) although techniques which address underlying beliefs ('schema focussed therapy') (Beck and Freeman, 1990) will be used in the latter therapy sessions
5. Sessions 11 and 12: relapse prevention by helping identification of warning signs of depression, how to seek further help and how to address beliefs about termination of therapy.
6. We will also specifically ensure that sessions cover specified components from a checklist which include:
6.1. The effects of physical illness: the impact of the illness, beliefs and expectations about the illness, their plans and hopes for care as the disease advances
6.2. The emotional impact of the disease and coping strategies: the relationship between

emotions, physical symptoms and disability caused by the disease and concerns about the patients ability to cope, their loss of control, and preparedness to accept help and discuss issues around dying.
6.3. The social impact: impact of disease and mood on behaviour and ability to fulfil roles, impact of disease on loved ones
6.4. Spiritual and existential issues: discussion of the meaning of the illness (why me?; it's not fair schema), suicide/euthanasia issues, the potential for spiritual reconciliations, absolutions forgiveness and acceptance of unfinished business.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. The Beck Depression Inventory-II (BDI-II; Beck and Steer, 1996): This is a 21 item self report measure with a maximum score of 63 indicating severe depressive symptoms. It contains few items measuring affective-somatic symptoms, with 15 of the 21 items assessing negative cognitions, a target of cognitive interventions. Its psychometric properties are similar to the BDI (Beck et al, 1961), the most widely used self report instrument for measuring depressive symptoms and which has also been used in trials of psychotherapy for patients with advanced cancer (McLean et al 2008; Savard et al, 2006; Laidlaw et al, 2005).
1.1. We elected not to use the Profile of Mood States (McNair, 1992) which is often used to measure mood in psychological treatments in advanced cancer (Akechi et al 2009) and metastatic breast cancer (Edwards et al, 2009), because it is less sensitive and precise in assessing depressive symptoms and cognitive change when compared to measures solely designed for those purposes (Nezu et al, 2000). The BDI-II also has a number of cognitive elements which are particularly useful for measuring change with CBT. Other rating scales for depression have fewer cognitive elements and scales such as the PHQ-9 have not been used in this sample population and so it would not be possible to generate a suitable power analysis.

Measured at baseline, 6 weeks, 12 weeks (end of intervention), 18 weeks and 24 week follow up

Key secondary outcome(s))
1. Patient Health Questionnaire (PHQ9; Kroenke et al, 2002) screens for depression and is used by IAPT therapists and in primary care. It is a valid measure of severity of depression in primary care and has the advantage that it can be administered over the telephone. Measured at baseline, 12 weeks and 24 weeks follow up.
2. EuroQol (EQ5D; Brooks, 1996; EuroQol Group, 1990) A generic utility measure of quality of life consisting of 5-domains and a visual analogue scale. It will be used in cost-effectiveness analysis. Measured at baseline, 12 weeks and 24 weeks follow up.
3. Satisfaction with care using methods using a visual analogue scale (scored 0 to 10 towards higher satisfaction). Measured at 12 weeks
4. Eastern Cooperative Oncology Group-Performance Status (ECOG-PS; Oken et al, 1982): is a scale to measure physical functioning based on five levels: 0, asymptomatic normal activity; 1, symptomatic but fully ambulatory; 2, symptomatic and in bed less than 50% of time; 3, symptomatic and in bed more than 50% of time; 4, 100% restricted to bed. Measured at baseline, 12 weeks and 24 weeks follow up.

5. Measures of service utilisation: The Client Service Receipt Inventory (CSRI; Beecham and Knapp, 1992). We shall use a short modified version of this measure of service use which collects data directly from patients and their GP. Measured at baseline, 12 weeks and 24 weeks follow up.

Completion date
31/08/2016

Eligibility

Key inclusion criteria
1. A diagnosis of cancer not amenable to curative treatment (this includes patients initially diagnosed with metastatic disease, those at first or subsequent incurable recurrence and who may be receiving palliative treatments including non-curative radiotherapy, chemotherapy, biological therapy or surgery) verified by contacting general practitioners (GPs) or oncologist.
2. A clinical diagnosis of depression through clinical interview on the Mini-International Neuropsychiatric Interview (MINI) (Sheenan et al, 1998)
3. Agreement to be randomised
4. Sufficient understanding of English to be able to engage in CBT
5. The patient is eligible for Improving Access to Psychological Therapies (IAPT) - either they or their GP is in an appropriate catchment area
6. Agreement for GP to be involved so that referral to IAPT can take place through GP

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
230

Key exclusion criteria
1. Clinician estimated survival of less than 4 months (verified by contacting patients' oncologists /GP)
2. Suicidal intent; scoring 3 on question 9 of the Beck Depression Inventory (BDI)-II
3. Currently receiving or having received a psychological intervention recommended by Niational Institute for Health and Clinical Excellence (NICE) aimed at treating depression (e.g. Interpersonal Psychotherapy, CBT etc) in the last 2 months
4. Suspected alcohol dependence using the Alcohol Use disorders Identification Test (AUDIT; Saunders et al, 1993)

Date of first enrolment
19/09/2012

Date of final enrolment
30/11/2015

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Charles Bell House
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Sponsor information

Organisation
University College London (UK)

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (UK) (09/33/02)

Results and Publications

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?
Results article	results	01/05/2019	20/05/2019	Yes	No
Results article	results	01/04/2020	01/10/2019	Yes	No
Protocol article	protocol	29/02/2016		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes