ISRCTN27496229 https://doi.org/10.1186/ISRCTN27496229

# A comparison of brief and standard cognitive behavioural therapy (CBT) for patients in palliative care

**Submission date**
18/10/2010

**Recruitment status**
No longer recruiting

**Registration date**
13/01/2011

**Overall study status**
Completed

**Last Edited**
23/05/2016

**Condition category**
Cancer

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

## Plain English summary of protocol

Background and study aims.
Cognitive behaviour therapy (CBT) has been shown to be an effective psychological treatment for distressed patients receiving end of life (palliative) care. But only half of the patients who receive this treatment are well enough to complete treatment which may last 8  12 sessions or more. This study is a randomised controlled trial comparing a specially designed, brief (4 session CBT) with standard CBT (8+ sessions) in people with advanced cancer with anxiety and depression.

Who can participate?
Patients attending St Christophers Hospice who have a diagnosis of advanced cancer and have been referred for psychological therapy because of anxiety or depression will be able to participate.

What does the study involve?
Patients will complete some questionnaires measuring anxiety, depression and coping during an interview with a nurse researcher. After this they will be allocated at random to one of the two treatments. If they receive the brief treatment they will meet a therapist on four occasions and will be helped to work through a self help book that will support the one to one therapy. Their partner will be invited to attend one of the sessions to find out ways they might be able to help. The standard treatment does not use the self help material but focused more on one to one therapy. Both treatments involve cognitive behaviour therapy which is based on the idea that when we become depressed or anxious we focus on the most negative aspects of our situation, become critical of ourselves, and forget our strengths. This unhelpful thinking can make us feel even more hopeless and often leads to withdrawal or avoidance of situations that could make us feel better.

What are the possible benefits and risks of participating?
CBT helps people find more helpful ways of thinking and acting to cope with the stress of life threatening illness. There are no known risks associated with participating in this study.

Where is the study run from?
South London and Maudsley Trust and St Christophers Hospice

When is the study starting and how long is it expected to run for?
April 2010 to April 2012

Who is funding the study?
The Kings Health Partners Biomedical Research Centre (UK)

Who is the main contact?
Dr Stirling Moorey
stirling.moorey@slam.nhs.uk

# Contact information

### Type(s)
Scientific

### Contact name
Dr Stirling Moorey

### Contact details
Maudsley Psychotherapy Service
Maudsley Hospital
Denmark Hill
London
United Kingdom
SE5 8AZ
+44 (0)203 228 2383
stirling.moorey@slam.nhs.uk

# Additional identifiers

### Protocol serial number
CSA/10/022

# Study information

### Scientific Title
A comparison of brief cognitive behavioural therapy (CBT) and standard CBT in patients experiencing anxiety and depression in palliative care: a randomised controlled trial

### Study objectives
A brief cognitive behavioural therapy (CBT) intervention will be as effective as standard CBT in patients attending a CBT outpatients clinic in a palliative care setting. The brief intervention will be as acceptable to patients and their carers as the full standard CBT package.

### Ethics approval required
Old ethics approval format

## Ethics approval(s)
The South East London Research Ethics Committee (REC) 5, 28/05/2008, ref: 10/H0805/25

## Study design
Single centre randomised controlled parallel group trial

## Primary study design
Interventional

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Anxiety and depression in patients with a range of cancers

## Interventions
The standard CBT arm comprises 7 sessions of CBT, plus further sessions if necessary as specified in the CBT clinic operational policy. The brief CBT arm comprises 3 sessions combining assessment and intervention, then a booster session one month later. The extended assessment will consist of a rapid collaborative case conceptualisation, followed by the identification of key targets for rapid change. Brief interventions will be used to break maintaining cycles and regain previous adaptive coping strategies. A blueprint will be developed which will serve as a guide to how the patient, family and palliative care professionals can maintain and continue change. Therapy will be carried out at the hospice. Both therapists have had previous training in CBT and experience of CBT in palliative care. All sessions will be taped and therapists will receive weekly supervision from the Primary Investigator (Dr Moorey). Adherence to the model will be assessed using the Cognitive Therapy First Aid Rating Scale (CFARS).

## Intervention Type
Other

## Phase
Not Applicable

## Primary outcome(s)
Hospital Anxiety and Depression Scale (HADS; Zigmond & Snaith, 1983):
This is a 14-item measure of mood designed for use with patients with physical illness. Seven items measure anxiety and seven depression. Its psychometric properties have been investigated in cancer patients, and it has been used successfully in previous trials in cancer patients.

All outcomes will be assessed at baseline, session 3, then at 10 and 16 weeks.

## Key secondary outcome(s))
1. Impact of Event Scale - Revised (Horowitz 1979, Weiss & Marmar 1997, Mystakidou 2007):
This scale measures symptoms of intrusions and avoidance. A version developed by AJ Mitchell with specific reference to cancer will be used in this study
2. Brief COPE (Carver 1997):
This is a 28-item questionnaire that assesses 14 different ways people respond to stress.
3. Sense of Coherence Scale (Antonovsky 1987):
This scale measures 3 elements hypothesised to keep people well in the face of adversity: the

ability to understand what is happening (comprehensibility), the ability manage the situation alone or with the help of a social network (manageability) and the ability to find meaning in the situation (meaningfulness).
4. Quality of Life Visual Analogue Scale:
Patients are asked to mark on a line how much they are distressed by the following symptoms: nausea, tiredness, pain and appetite problems.
5. The Eastern Cooperative Oncology Group (ECOG) Performance Status Scale (Oken et al. 1982):
The ECOG performance score has been used extensively in oncology research and is one of the most widely accepted measures of functional performance. The score ranges from 0 (fully active, able to carry on all pre-disease performance without restriction) to 5 (dead). At the mid-point, 3, the patient is capable of only limited self-care, confined to bed or chair for more than 50% of waking hours.
6. Cognitive Therapy First Aid Rating Scale (CFARS: Mannix et al 2006):
This is a validated measure of therapist competency and adherence.

All outcomes will be assessed at baseline, session 3, then at 10 and 16 weeks.

### Completion date
01/04/2012

## Eligibility

### Key inclusion criteria
Adult patients (greater than or equal to 18 years) with ongoing and persistent distress /emotional problems (as measured by a Hospital Anxiety and Depression Scale [HADS] score of 8 or more on anxiety or depression) which are directly related to some aspect of the patient's disease/treatment and are not responding to the existing provision of psychological care within the hospice system. This includes:
1. Difficulties making treatment decisions or difficulties adhering to treatment
2. Anticipatory symptoms (e.g. nausea and vomiting)
3. Phobias that are interfering with treatment (e.g. needle or blood phobia)
4. Extreme emotion which appears to be disproportionate to reality
5. Post traumatic symptoms (flashbacks)
6. Body image issues, disfigurement or loss of function
7. Psychosexual problems
8. Extreme fears about the terminal stage of illness
9. Rigid thinking styles (all or nothing, overgeneralisation etc.)

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Sex

All

### Key exclusion criteria
1. Those who do not wish to have CBT
2. Psychosis or personality disorder
3. Very high suicide risk (psychiatric assessment required)
4. Moderate to severe drug and alcohol related problems
5. Patients already receiving psychological therapy or counselling
6. Patients who are not well enough to attend an outpatient clinic (e.g. unable to stay alert /awake for 50 mins, uncontrolled vomiting etc..)
7. Language or communication problems which prevent the patient from engaging in a talking treatment

### Date of first enrolment
01/11/2010

### Date of final enrolment
01/04/2012

## Locations

### Countries of recruitment
United Kingdom

England

### Study participating centre
**Maudsley Hospital**
London
United Kingdom
SE5 8AZ

## Sponsor information

### Organisation
Institute of Psychiatry (UK)

### ROR
https://ror.org/0220mzb33

## Funder(s)

### Funder type

Government

**Funder Name**
National Institute for Health Research (NIHR) (UK) - Biomedical Research Centre for Mental Health: Common Mental and Somatic Disorders Theme

# Results and Publications

## Individual participant data (IPD) sharing plan

**IPD sharing plan summary**
Not provided at time of registration