

# Cognitive Behavioural Therapy (talking therapy) for Alzheimer's Carers

<b>Submission date</b> 19/03/2008	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 04/04/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 22/10/2012	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Sonja Kruger

**Contact details**  
Towngate House Hospital  
1 Towngate Close  
OFF Queensway  
Guiseley  
Leeds  
United Kingdom  
LS20 9LA

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
N/A

# Study information

## Scientific Title

Cognitive behavioural therapy (CBT) for carers of patients with Alzheimer's disease: a randomised controlled trial

## Acronym

The CBTAC Study

## Study objectives

Many individuals with Alzheimer's disease live in their own homes, cared for by a member of their family. Providing such care can be a source of significant stress. Carers can present with depression, anxiety, loneliness and other psychological strain. The present study seeks to evaluate the efficacy of CBT in treating psychological distress in a group of Alzheimer's carers.

## Hypothesis:

12 sessions of cognitive behavioural therapy (CBT) will significantly reduce the Geriatric Depression Scale scores in carers of patients with Alzheimer's disease, in comparison with a group receiving treatment as usual.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Ethics approval pending from Leeds East Research Ethics Committee as of 19/03/2008. To be submitted April 2008.

## Study design

Prospective, single-centre, unblinded, randomised controlled study

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Not specified

## Study type(s)

Treatment

## Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

## Health condition(s) or problem(s) studied

Psychological distress in Alzheimer's carers

## Interventions

The treatment group will receive between 10 - 12 sessions of weekly CBT over a three-month period. The sessions will last for 50 minutes each, they will see the same therapist every week. Participants will be asked to complete self report questionnaires before treatment starts, after three months of treatment and again after six months of the start of the study. These questionnaires aim to indicate their distress and will be compared to similar measures in the treatment as usual group.

The treatment as usual group (control group), will receive support already offered to Alzheimer's carers in the area. This consist of a carer appointment with nurses, a monthly support group with other carers, and a monthly Forget Me Not Cafe, a support meeting with the person they care for. The participants in the control group will complete the same questionnaires as those in the treatment group, at similar time intervals.

The questionnaires used are:

1. Geriatric Depression Scale
2. Carer Strain Index
3. Carer Burden Inventory score

All participants will also complete a Mini-Mental State Examination to assess their cognition as to be included in the study, as well as a socio-demographic questionnaire at the beginning.

Total duration of follow-up for both treatment and control arm will be six months from start of treatment.

## **Intervention Type**

Other

## **Phase**

Not Specified

## **Primary outcome measure**

12 sessions of CBT will significantly reduce the Geriatric Depression Scale scores in carers of patients with Alzheimer's disease, in comparison with a group receiving treatment as usual. For the Geriatric Depression Rating Scale (GDS) an improvement of a score out of 15 will be measured, where a score greater than 5 indicates probable depression.

These measures will be taken in all participants (treatment and control groups), prior to start of treatment, after 3/12 and again after 6/12 of start of treatment, thus T0, T3 and T6. These scores will then be compared to detect within participant and between group differences at three different time points.

## **Secondary outcome measures**

1. 12 sessions of CBT will significantly reduce the Carer Strain Index scores in carers of patients with Alzheimer's disease, in comparison with a group receiving treatment as usual. For the Carer Strain Index score (CSI) an improvement of a score out of 12 will be measured, where a score greater than 7 indicates a high level of strain.
2. 12 sessions of CBT will significantly reduce the Carer Burden Inventory scores in carers of patients with Alzheimer's disease, in comparison with a group receiving treatment as usual. For the Carer Burden Inventory score (CBI) an improvement of a score out of 88 will be measured, where a score between 61 - 88 indicates severe burden, 41 - 60 moderate to severe burden, 21 - 40 mild to moderate burden and 0 - 20 indicates little or no burden.

These measures will be taken in all participants (treatment and control groups), prior to start of treatment, after 3/12 and again after 6/12 of start of treatment, thus T0, T3 and T6. These scores will then be compared to detect within participant and between group differences at three different time points.

**Overall study start date**

01/07/2008

**Completion date**

01/02/2009

## Eligibility

**Key inclusion criteria**

1. Primary carer of an individual with Alzheimer's disease
2. Willing to engage actively in 10 - 12 weekly therapy sessions, over a three month period
3. Willing to complete self report questionnaires before treatment starts, at three months and six months after entering the study
4. Aged 18 - 90 years, either sex

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Upper age limit**

90 Years

**Sex**

Both

**Target number of participants**

40 participants will be recruited

**Key exclusion criteria**

1. Carers not fluent in English (due to nature of the treatment)
2. Evidence of cognitive impairment, assessed as a Mini-Mental State Examination score of less than 26/30
3. Currently prescribed certain psychotropic medication, i.e., antipsychotics, mood stabilisers, hypnotics and sedatives. Those receiving antidepressants will not be excluded
4. The person they care for with Alzheimer's disease is under 65 (pre-senile dementia)

**Date of first enrolment**

01/07/2008

**Date of final enrolment**

01/02/2009

## Locations

### Countries of recruitment

England

United Kingdom

### Study participating centre

Towngate House Hospital

Leeds

United Kingdom

LS20 9LA

## Sponsor information

### Organisation

Leeds Partnerships NHS Foundation Trust (UK)

### Sponsor details

Twenty One Fifty

Thorpe Park

Leeds

England

United Kingdom

LS15 8ZB

### Sponsor type

Hospital/treatment centre

### Website

<http://www.leedsmentalhealth.nhs.uk/>

### ROR

<https://ror.org/00n635c12>

## Funder(s)

### Funder type

Other

**Funder Name**

Investigator initiated and funded (UK)

**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