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

Submission date	Recruitment status	[X] Prospectively registered
19/03/2008	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
04/04/2008	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
22/10/2012	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s))
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.

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
90 years

Sex
All

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
United Kingdom

England

Study participating centre
Towngate House Hospital
Leeds
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LS20 9LA

Sponsor information

Organisation
Leeds Partnerships NHS Foundation Trust (UK)

ROR
https://ror.org/00n635c12

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded (UK)

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes