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Clinical and cost effectiveness of cognitive behaviour therapy for depressed older people in primary care

Submission date
14/09/2005

Recruitment status
No longer recruiting

Registration date
09/02/2006

Overall study status
Completed

Last Edited
13/06/2014

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Study objectives
To determine the clinical and cost effectiveness of Cognitive Behaviour Therapy (CBT)
Primary hypothesis: CBT plus Treatment As Usual (TAU) is more clinically and cost effective than TAU
Secondary hypothesis: AC plus TAU is more clinically and cost effective than TAU

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

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
Depressive disorder

Interventions
1. CBT plus TAU: up to twelve 50-minute sessions of CBT will be offered
2. AC plus TAU: up to twelve 50-minute sessions of non-specific talking to control for attention will be offered - this is to match the time spent face to face in the CBT group
3. TAU only: general practitioners will provide usual treatment but will be asked not to refer patients for CBT or other brief talking therapies

Intervention Type
Other

Phase

Not Applicable

Primary outcome measure
Beck Depression Inventory

Secondary outcome measures
Patient completes:
1. EuroQuol (EQ-5D)
2. Social functioning questionnaire
3. Patient satisfaction with treatment
4. Credibility of treatments

Researcher completes:
1. Practice record data
2. Resource use and costs - the trial will measure all the costs of participants in the trial regardless of why costs were incurred, starting prior to randomisation and continuing for the duration of follow-up. Data on services used will be collected using a modified version of the Client Service Receipt Inventory (CSRI) developed specifically for the study from pilot work. Questions will be retrospective, covering the previous 6 months. This will include examination of the general practitioners records for consultation rates (at home or the practice) and other treatments received throughout the trial.
3. Rate of non-attendance to therapy sessions
4. Therapists expectation of outcome
5. Assessment of blindness by rater

Overall study start date
01/04/2004

Completion date
31/03/2007

Eligibility

Key inclusion criteria
1. Diagnosis of depressive disorder according to the Geriatric Mental State and History and Aetiology Schedule (GMS-HAS) to confirm a primary diagnosis of depression. This uses a computer-based, semi-structured interview, which has been well validated in the community and used in international comparisons of depression.
2. Severity of depression score on the Beck Depression Inventory (BDI) of 14 or more than 25; this threshold is to include people with the less severe levels of mixed anxiety and depression frequently seen in primary care which may respond to CBT
3. Sufficient command of English to use CBT techniques
4. If taking an antidepressant, this must have been at a stable dose for at least 8 weeks prior to randomisation

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
198

Key exclusion criteria
1. Intense suicidal intent requiring in-patient admission
2. A GMS-HAS diagnosis of alcohol misuse or drug dependence
3. History of bipolar affective disorder
4. Presence of hallucinations or delusions
5. Cognitive deficits judged by a score of less than 24 on the Mini-Mental State Examination (MMSE), which means that the participant may have difficulty with cognitive techniques
6. People who have received cognitive therapy within the last year
7. Having received Electro-Convulsive Therapy (ECT) within the last 6 months as this may have a residual effect on cognition (it also implies recent, severe disorder)

Date of first enrolment
01/04/2004

Date of final enrolment
31/03/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Mental Health Sciences
London
United Kingdom
NW3 2PF

Sponsor information

Organisation
Health Foundation (UK)

Sponsor details

90 Long Acre
London
United Kingdom
WC2E 9RA

Sponsor type
Charity

Website
http://www.health.org.uk

ROR
https://ror.org/02bzj4420

Funder(s)

Funder type
Not defined

Funder Name
Not provided at time of registration

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2009		Yes	No
Results article	cost-effectiveness results	11/02/2011		Yes	No