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An evaluation of the effectiveness of structured Cognitive Behaviour Therapy (CBT) self-help materials delivered by a self-help support worker within primary care

Submission date
30/08/2005

Recruitment status
No longer recruiting

Registration date
09/09/2005

Overall study status
Completed

Last Edited
21/01/2013

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
04 AMO6

Study information

Scientific Title

Study objectives
1. Patients using the CBT self-help materials will have:
1.1. Improved mood measured on the Beck Depression Inventory (BDI-II)
1.2. Improved social functioning measured on the Clinical Outcome Measure in Routine evaluation - Outcome Measure (CORE-OM)
1.3. Lower health care costs
1.4. Improved knowledge of the causes and treatment of depression compared to the control group receiving treatment as usual
2. Written self-help will be acceptable to both patients and staff within a primary care setting

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

Health condition(s) or problem(s) studied
Depressive symptoms

Interventions
We are evaluating a structured self-help workbook treatment for mild to moderate depression called Overcoming Depression: A Five Areas Approach. A randomised controlled study design comparing treatment as usual as a control (arm 1); and supported self-help via three 40-minute appointments at week 1, 2 and one month (the '2 + 1' model, Barkham et al, 1996) comprising the second arm of the study.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Comparison between the Beck Depression Inventory -II scores for the two randomised groups (self help plus treatment as usual versus TAU) using a 2 sample 2-sided t-test at 4 months.

Secondary outcome measures
Psychological symptoms, well-being, risk and social functioning (using the CORE-OM scale), and acceptability of the intervention (using the Client Satisfaction Questionnaire- CSQ) compared to treatment as usual. In addition, the health care costs of both arms are being evaluated and the Euroquol (European Quality of Life measure) used to record health status and health-related quality of life change. Secondary analyses will also examine the impact of treatment patient knowledge. Further analyses that adjust the treatment effect for a pre-specified set of baseline covariates thought to be of influence on the treatment effect such as use of antidepressants, other self-help materials, and the chronicity of depression using Normal Linear models, will be considered. The approach by Jacobson et al, (1991) to present change in the group under study at the level of the individual will also be used. Categorical data will be compared between the two groups using chi-squared tests and logistic regression to adjust for covariates.

Overall study start date
01/04/2004

Completion date
30/06/2007

Eligibility

Key inclusion criteria
1. Patients presenting in a primary care/General Practice setting with symptoms of depression
2. Beck Depression Inventory -II score of 14 or more
3. Aged eighteen or above
4. Able to use the materials (i.e. have no visual or reading problems, learning difficulties or dementia)
Any member of the primary care team including GPs, practice or district nurses and health visitors will be able to refer to the study.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
100 evaluable patients in each arm i.e. 200 evaluable patients

Key exclusion criteria
1, Suicidal intent (score of 2 or more on the BDI-II suicidal thoughts item)
2. Impaired concentration and motivation (as measured by a score of 7 or more on the combined BDI II items for energy [item 15], concentration difficulty [item 19] and tiredness [item 20])

Date of first enrolment
01/04/2004

Date of final enrolment
30/06/2007

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Psychological Medicine
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Sponsor information

Organisation
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Sponsor type
Government

ROR
https://ror.org/05kdz4d87

Funder(s)

Funder type
Government

Funder Name
Chief Scientists Office Scottish Executive Health Department (UK) (ref: CZH/4/61)

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	01/09/2013		Yes	No