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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

**Protocol serial number**
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

## Primary study design
Interventional

## Study design
Randomised controlled trial

## Study type(s)
Treatment

## 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(s)
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.

## Key secondary outcome(s)

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.

### 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

### Healthy volunteers allowed
No

### Age group
Adult

### Sex
All

### 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
United Kingdom

Scotland

### Study participating centre
**Psychological Medicine**
Glasgow
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# Sponsor information

### Organisation
NHS Greater Glasgow (UK)

### 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

### 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 | | | | |

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|---|---|---|---|
| Results article | 01/09/2013 | Yes | No |