

# A randomised controlled study of the effectiveness of a Cognitive Behaviour Therapy (CBT) CD Rom self-help treatment for depression compared with a widely-used Patient Information leaflet when offered to patients on a waiting list for a clinical psychology service

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<b>Registration date</b> 09/09/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 25/05/2018	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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/S0701/77

## **Study information**

### **Scientific Title**

A randomised controlled study of the effectiveness of a Cognitive Behaviour Therapy (CBT) CD Rom self-help treatment for depression compared with a widely-used Patient Information leaflet when offered to patients on a waiting list for a clinical psychology service

### **Study objectives**

1. Patients using the Overcoming Depression CBT CD Rom will:
  - 1.1. Have improved mood measured on the Beck Depression Inventory (BDI-II)
  - 1.2. Have improved symptoms and social functioning measured on the Clinical Outcome Measure in Routine evaluation - Outcome Measure (CORE-OM)
  - 1.3. Have lower health care costs
  - 1.4. Have improved knowledge of the causes and treatment of depression
  - 1.5. Need less subsequent sessions of face to face specialist psychological treatment in the Psychology service compared to the control group receiving the Patient Information leaflet
2. The CD Rom self-help will be more acceptable to patients than the short information leaflet

### **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**

Depression

## **Interventions**

1. In the Patient Information leaflet arm, a short information leaflet (Depression by the British Association for Behavioural and Cognitive Psychotherapies) is given to the patient by the Support Nurse and the content is gone through in a face to face support session lasting 30-40 minutes. A second final support session lasting 20-30 will then be arranged about three weeks later.

2.. In the CBT CD Rom arm, 6 sessions of approximately 45 minutes are delivered by the CD rom. In addition a formal protocol is used to describe the three face to face support sessions that are offered. After the initial session the patient notes their unique user-name and can book in to use the package for up to an hour once a week. After the 3rd and final (session 6) treatment sessions on the computer, a brief review of progress (25-30 minutes) will be offered.

## **Intervention Type**

Other

## **Phase**

Not Specified

## **Primary outcome measure**

Comparison between the Beck Depression Inventory - II scores for the two randomised groups using a 2 sample 2-sided t-test at 2, 4 months and 12 months.

The 4 month outcome is the primary outcome measure.

## **Secondary outcome measures**

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. Secondary analyses will examine the impact of treatment on the total and the four main CORE domains (well-being, symptoms, life functioning and risk), and also patient knowledge, and the cost implications of use, and patient and practitioner perspectives of the effectiveness and acceptability of the treatment approaches. 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**

01/01/2005

## **Completion date**

30/06/2007

## **Eligibility**

### **Key inclusion criteria**

Patients are offered the CD Rom and are eligible for the study when they have symptoms of depression (including depression and anxiety), and are willing and able to use the materials (i.e. have no visual or reading or hearing problems, learning difficulties and are able to read and understand the spoken English language).

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

92 in each arm = 184 in total

**Key exclusion criteria**

Patients who do not wish to use the CD Rom approach, or who have current drug/alcohol abuse /dependency will be excluded from the study. Patients with suicidal intent (score of 2 or more on the BDI-II suicidal thoughts item) and impaired concentration and motivation (as measured by a score of 7 or more on the combined BDI II items for energy, concentration difficulty and tiredness - items 15, 19 and 20 on the BDI-II) will be excluded from the study. In addition, patients with scores lower than 5 or higher than 19 on the Patient Health Questionnaire (PHQ) will not be offered the CD Rom self-help approach and will be excluded from the study.

**Date of first enrolment**

01/01/2005

**Date of final enrolment**

30/06/2007

**Locations****Countries of recruitment**

Scotland

United Kingdom

**Study participating centre**

Psychological Medicine

Glasgow

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**Sponsor information**

**Organisation**

NHS Greater Glasgow (UK)

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**Sponsor type**

Government

**ROR**

<https://ror.org/05kdz4d87>

**Funder(s)****Funder type**

Government

**Funder Name**

Internal NHS Greater Glasgow funding from the SPIRIT project (UK) (code 001 1837)

**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?
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[Results article](#)

results

01/01/2006

Yes

No