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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

Submission date
01/09/2005

Recruitment status
No longer recruiting

Registration date
09/09/2005

Overall study status
Completed

Last Edited
25/05/2018

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/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

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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?

Results article	results	01/01/2006	Yes	No