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The Randomised Evaluation of the Effectiveness and Acceptability of Computerised Therapy (REEACT) Trial

Submission date
23/08/2007

Recruitment status
No longer recruiting

Registration date
24/08/2007

Overall study status
Completed

Last Edited
02/09/2016

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Many people with depression would like to receive a 'talking treatment' (counselling or psychotherapy). The form of talking treatment that is supported by the greatest amount of evidence is Cognitive Behaviour Therapy (CBT). At the present time, there are too few therapists to treat people with depression. Recently, a form of CBT has been developed that can be delivered by computer. Computerised CBT can be delivered in the patient's own time (and potentially in their own home) and does not require waiting for a therapist. Several computer packages of CBT have been developed. Some of these are free to use and are available over the internet, whilst some are commercial products and have to be purchased at substantial cost to the NHS. We need more information about the effectiveness of these packages and we need to know whether the additional cost of purchasing commercially available products is a sensible use of limited NHS funds. The aim of this study is to compare two CBT packages to usual GP care.

Who can participate?
Patients aged 18 and over with depression

What does the study involve?
Participants are randomly allocated into three groups. The first group receives usual GP care plus "Beating the Blues", a computerised CBT package. The second group receives usual GP care plus "MoodGYM", a free to use web-based CBT programme for depression. The third group receives usual GP care. We examine whether computerised forms of CBT are effective at reducing the symptoms of depression and at improving quality of life and helping people with depression to resume work or caring. We also examine whether expensive commercial products are any better than freely available programmes, and whether the extra cost is justified. Computerised CBT involves interaction with a computer rather than a trained therapist. Although computers have increasingly become part of modern life, it remains unclear how acceptable this form of treatment is for people with depression. We examine whether people with little or no experience of computers find this form of treatment acceptable, and whether the treatment can be realistically offered in the patient's own home or in a GP surgery.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
University of York (UK)

When is the study starting and how long is it expected to run for?
May 2009 to October 2013

Who is funding the study?
NIHR Health Technology Assessment Programme - HTA (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 06/43/05

Study information

Scientific Title
The Randomised Evaluation of the Effectiveness and Acceptability of Computerised Therapy (REEACT) Trial

Acronym
REEACT

Study objectives
Amended as of 08/10/2008:
1. To establish the clinical and cost effectiveness of the addition of computerised cognitive behavioural therapy (CBT) to usual General Practitioner (GP) care over a two year follow-up period
2. To establish the acceptability (to patients and clinicians) of computerised CBT
3. To establish the differential clinical and cost effectiveness of a free-to-use computerised package, in comparison to a commercial pay-to-use computerised CBT package over a two year and longer-term time horizon

Initial information at time of registration:
Our objectives are:
1. To establish the clinical and cost effectiveness of computerised Cognitive Behavioural Therapy (CBT) in comparison with anti-depressant medication over a two year follow-up period
2. To establish the acceptability (to patients and clinicians) of computerised CBT in comparison with anti-depressant medication
3. To establish the differential clinical and cost effectiveness of a free-to-use computerised package, in comparison to a commercial computerised CBT package over a two year and longer-term time horizon
4. To establish the impact of initial patient preference for computerised CBT on clinical and cost effectiveness of computerised CBT

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/064305
Protocol can be found at: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0003/51438/PRO-06-43-05.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Research Ethics Service, 10/07/2008

Study design
Fully randomised controlled multicentre study including a concurrent economic and qualitative evaluation

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Internet/virtual

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
Amended as of 08/10/2008:
Experimental Group 1: usual GP care plus "Beating the Blues", a computerised cognitive behavioural therapy package
Experimental Group 2: usual GP care plus "MoodGYM", a free to use web-based CBT programme for depression
Control Intervention: usual GP care

Initial information at time of registration:
Experimental Group 1: "Beating the Blues", a computerised cognitive behavioural therapy package
Experimental Group 2: "MoodGYM", a free-to use web-based CBT programme for depression
Control Intervention: Anti-depressants prescribed by patient's general practitioner in line with normal GP practice

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Depression severity and symptomatology as measured by a validated self-report measure (the Patient Health Questionnaire [PHQ-9]) and the International Classification of Diseases (ICD-10) depression score at four months.

Secondary outcome measures
1. PHQ-9 at 12 and 24 months
2. Generic and global mental health (Clinical Outcomes in Routine Evaluation-Outcome Measure [CORE-OM]) at 4, 12 and 24 months
3. Health related quality of life (the Short-Form 36 [SF-36] v2) at 4, 12 and 24 months
4. Health state utility (EuroQol [EQ5D]) at 4, 12 and 24 months

Overall study start date
01/05/2009

Completion date
31/10/2013

Eligibility

Key inclusion criteria

Amended as of 08/10/2008:
Adult patients, aged 18 years and above with depression who are not currently in receipt of computerised CBT or specialist psychological therapy. Our inclusion threshold will be a score of greater than or equal to 10 on the PHQ9 depression severity instrument. We will also include patients with either co-morbid physical illness or co-morbid non-psychotic functional disorders, such as anxiety. We will include both incident and prevalent cases. In line with the pragmatic nature of this trial, we will reflect usual GP care and participants will be eligible to participate whether they are in receipt of antidepressant medication or not. Patients with previous treatment experience of CBT will not be excluded.

Initial information at time of registration:
Adult patients aged 18 and above with depression who are being considered for anti-depressant drug treatment and for whom computerised therapy represents a non-drug alternative (within a stepped care framework). We will also include patients with either co-morbid physical illness or co-morbid non-psychotic functional disorders, such as anxiety.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
600

Key exclusion criteria
Amended as of 08/10/2008:
1. Actively suicidal
2. Suffering psychotic symptoms
3. Depressed in the post-natal period
4. Have recently suffered bereavement
5. Cases of psychotic depression; since computerised therapy is not recommended within NICE guidance, and are also unlikely to be recruited or randomised by general practitioners to receive computerised CBT, since they are unlikely to have sufficient equipoise in this case

Initial information at time of registration:
1. Actively suicidal
2. Suffering psychotic symptoms
3. Depressed in the post-natal period
4. Have recently suffered bereavement
5. Patients already in receipt of anti-depressants
6. Women who are pregnant, or planning to become pregnant (added as of 29/04/2008)

Date of first enrolment
01/05/2009

Date of final enrolment
31/10/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of York
York
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YO10 5DD

Sponsor information

Organisation
University of York (UK)

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Sponsor type
University/education

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ROR
https://ror.org/04m01e293

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (UK)

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	11/11/2015		Yes	No
Results article	results	30/11/2015		Yes	No
Results article	results	01/12/2015		Yes	No