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The second Randomised Evaluation of the Effectiveness and Acceptability of Computerised Therapy (REEACT-2) Trial

Submission date
08/10/2010

Recruitment status
No longer recruiting

Registration date
20/10/2010

Overall study status
Completed

Last Edited
06/03/2017

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. As part of a study comparing two CBT packages with usual GP care, we wish to assess the clinical and cost effectiveness of the addition of regular telephone support to computerised CBT.

Who can participate?
Patients with depression, aged 18 and over

What does the study involve?
All participants receive usual GP care and computerised CBT (MoodGYM - a free-to use web-based CBT programme for depression). In addition participants are randomly allocated to receive either weekly telephone support calls or no telephone support calls. We examine whether this is effective at reducing the symptoms of depression over a 12-month follow-up period.

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?
January 2011 to May 2015

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

Who is the main contact?
Prof. Simon Gilbody
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 06/43/504

Study information

Scientific Title
Does the provision of telephone support enhance the effectiveness of therapy? A randomised controlled trial and economic evaluation

Acronym
REEACT-2

Study objectives

To establish the clinical and cost effectiveness of the addition of regular telephone support to computerised CBT over a four and 12 month follow-up period.

This trial is a sub-study of the REEACT trial. More details may be found at:
1. http://www.isrctn.com/ISRCTN91947481
2. http://www.nets.nihr.ac.uk/projects/hta/064305

Ethics approval required
Old ethics approval format

Ethics approval(s)
Bradford Research Ethics Committee, 20/12/2010, ref: 10/H1302/95

Study design
Randomised controlled multicentre study including concurrent economic evaluation

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Not available in web format, please contact Sally Brabyn [sally.brabyn@york.ac.uk] to request a patient information sheet

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

Interventions
Experimental intervention: Usual GP care PLUS computerised CBT (MoodGYM - a free-to use web-based CBT programme for depression) PLUS weekly telephone support calls.

Control intervention: Usual GP care PLUS computerised CBT (MoodGYM)

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Depression severity and symptomatology (PHQ-9 >=10), measured by a validated self-report measure (the Patient Health Questionnaire [PHQ-9]) depression score at four months.

Secondary outcome measures
Outcome measures as of 01/04/2016:
1. Self-reported depression severity, measured by the 9-item Patient Health Questionnaire (PHQ-9) at four and 12 months as a continuous measure
2. Anxiety, measured using the Generalised Anxiety Disorder Assessment (GAD-7) at 4 and 12 months
3. Somatoform complaints, measured using the Patient Health Questionnaire 15 (PHQ-15) at 4 and 12 months
4. Health state utility, measured using EuroQol (EQ5D) at 4 and 12 months

Original secondary outcome measures:
1. PHQ-9 measured at 12 months
And the following outcome measures at both 4 and 12 months:
2. Anxiety, measured using the Generalised Anxiety Disorder Assessment (GAD-7)
3. Somatoform complaints, measured using the Patient Health Questionnaire 15 (PHQ-15)
4. Health-related quality of life, measured using the Short-Form 12 (SF-12)
5. Health state utility, measured using EuroQol (EQ5D) at 4, 12 and 24 months

Overall study start date
04/01/2011

Completion date
31/05/2015

Eligibility

Key inclusion criteria
1. Adult patients, aged 18 years and above
2. Depression defined as a score of greater than or equal to 10 on the PHQ9 depression severity instrument
3. Not currently in receipt of computerised CBT or specialist psychological therapy
4. Patients may be with or without either co-morbid physical illness or co-morbid non-psychotic functional disorders, such as anxiety
5. Both incident and prevalent cases
6. 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
7. Patients with previous treatment experience of CBT will not be excluded

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
350, 175 per study arm

Key exclusion criteria
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.

Date of first enrolment
04/01/2011

Date of final enrolment
05/04/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of York
York
United Kingdom
YO10 5DD

Sponsor information

Organisation
University of York (UK)

Sponsor details
c/o Sue Final
University of York
Research Innovation Office
Innovation Centre
York Science Park
York
England
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Sponsor type
University/education

ROR
https://ror.org/04m01e293

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication of study results in a peer reviewed journal and as a HTA monograph.

Intention to publish date
31/12/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2016		Yes	No
Results article	results	01/05/2017		Yes	No