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	[X] Prospectively registered		
		Protocol Statistical applying plan		
Registration date 20/10/2010	Overall study status Completed	 Statistical analysis plan [X] Results 		
Last Edited	Condition category	 Individual participant data 		
06/03/2017	Mental and Behavioural Disorders			

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 webbased 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 sg519@york.ac.uk

Contact information

Type(s) Scientific

Contact name Prof Simon Gilbody

Contact details

Department of Health Sciences Seebohm Rowntrees Building (area 4) University of York Heslington York United Kingdom YO10 5DD

sg519@york.ac.uk

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

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 United Kingdom YO10 5DD **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