

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

<b>Submission date</b> 08/10/2010	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 20/10/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 06/03/2017	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> 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  
sg519@york.ac.uk

## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

**Protocol serial number**  
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**

Intentional

### **Study type(s)**

Treatment

### **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(s)**

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

### **Key secondary outcome(s)**

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

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**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

United Kingdom

England

### Study participating centre

**University of York**

York

United Kingdom

YO10 5DD

## Sponsor information

### Organisation

University of York (UK)

### ROR

<https://ror.org/04m01e293>

## Funder(s)

### Funder type

Government

### Funder Name

Health Technology Assessment Programme

### Alternative Name(s)

NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

### Funding Body Type

Government organisation

### Funding Body Subtype

National government

### Location

United Kingdom

# Results and Publications

## 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?
<a href="#">Results article</a>	results	01/11/2016		Yes	No
<a href="#">Results article</a>	results	01/05/2017		Yes	No