# Individualised patient support as an adjunct to computerised selfhelp for depression: factorial randomised controlled trial of brief vs. extended support given by clinicians vs. assistants

Submission date	Recruitment status	Prospectively registered		
26/07/2011	No longer recruiting	[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
26/07/2011	Completed	Results		
Last Edited	Condition category	Individual participant data		
26/09/2018	Mental and Behavioural Disorders	Record updated in last year		

# 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 8014

# Study information

#### Scientific Title

Individualised patient support as an adjunct to computerised selfhelp for depression: factorial randomised controlled trial of brief vs. extended support given by clinicians vs. assistants

#### **Study objectives**

The study aims to determine the effectiveness, cost-effectiveness and cost implications of brief vs. extended support given by clinicians vs. assistants as an adjunct to computerised Cognitive Behavioural Therapy (cCBT). It will also examine if such support could be tailored to suit different patients needs and preferences in order to achieve optimal clinical outcomes with cCBT within the budget constraints of the NHS. The sample will include 300 patients with nonsuicidal depression who are 18 years old or above, are registered with a GP within NHS Norfolk. Suitable patients who agree to participate in the study will be randomly allocated in a 1:1 ratio to an 8-session cCBT programme, called Beating the Blues, which can be accessed via the internet from patients homes or at public venues (e.g. libraries, internet cafes). Patients will receive phone support as an adjunct to cCBT either by a clinician (CBT-trained health professional with an active registration) or by an assistant (graduate mental health worker with no clinical qualifications. Support will be provided once a week for the first 6 weeks, once a fortnight for the following 6 weeks and once a month for the following 3 months (a total of 12 phone support sessions over 6 months). The clinician-vs. assistant-supported groups will be further randomised in a 1:1 ratio to receive sessions that are either brief (5-10 min per session) or extended (20-10 min per session). Patients will have a total of 1-2 hrs brief support or 4-6 hrs extended support over 6 months. Data on clinical outcomes (depression and anxiety symptoms, functioning, quality of life) and on healthcare resource and service use will be collected with selfreport standardised measures which will be posted to the patients for completion at baseline (week 0) and then at two follow-up points (approx. at weeks 12 and 24 post-randomisation). Interviews will be carried out about patient experiences at approx. 12 weeks post-randomisation.

# Ethics approval required

Old ethics approval format

# Ethics approval(s)

09/H0311/98

# Study design

Randomised; Interventional; Design type: Process of Care, Screening, Treatment

# Primary study design

Interventional

## Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

#### Study type(s)

Treatment

#### Participant information sheet

#### Health condition(s) or problem(s) studied

Topic: Mental Health Research Network, Primary Care Research Network for England; Subtopic: Depression, Not Assigned; Disease: Depression

#### **Interventions**

cCBT + phone support, The computerised cCBT system used in this study is Beating the Blues (BtB). During eight 50-minute sessions, BtB teaches patients how to identify unhelpful thoughts and come up with helpful alternatives, and how to do activity scheduling, problem-solving and other relevant homework tasks between their computer sessions. Patients are also offered individual support as a single, scheduled, telephone call once a week for the first 6 weeks, then once a fortnight for a subsequent 6 weeks; Follow Up Length: 6 month(s); Study Entry: Single Randomisation only

#### Intervention Type

Other

#### Phase

Phase IV

#### Primary outcome measure

Work & Social Adjustment Scale (WSAS); Timepoint(s): Baseline, 12-weeks, 24-weeks (post-randomisation)

#### Secondary outcome measures

- 1. Beck Anxiety Inventory (BAI); Timepoint(s): Baseline, 12-weeks, 24-weeks (post-randomisation)
- 2. Beck Depression Inventory (BDI); Timepoint(s): Baseline, 12-weeks, 24-weeks (post-randomisation)
- 3. Baeting the Blue (BtB) individual problem scores; Timepoint(s): At the beginning of every cCBT module
- 4. BtB single-item anxiety scores; Timepoint(s): At the beginning of every cCBT module
- 5. BtB single-item depression score; Timepoint(s): At the beginning of every cCBT module
- 6. BtB suicide scores; Timepoint(s): At the beginning of every cCBT module
- 7. cCBT system relevance, usefulness and ease of use scores; Timepoint(s): At the end of every cCBT module
- 8. Computer-Patient Alliance Scale (C-PAS); Timepoint(s): 12 weeks and 24 weeks post-randomisation
- 9. Generalised Anxiety Disorder-7 item (GAD-7); Timepoint(s): Baseline, 12-weeks, 24-weeks (post-randomisation)
- 10. BtB versions at beginning of every cCBT module
- 10.1. Health-Related Quality of Life EQ-5D; Timepoint(s): Baseline, 12-weeks, 24-weeks (post-randomisation)
- 10.2. Patient Experience Interview (PEI); Timepoint(s): 12 weeks post randomisation
- 10.3. Patient Health Questionnaire (PHQ); Timepoint(s): Baseline, 12-weeks, 24-weeks (post-randomisation)

- 10.4. Depression-9 item (PHQ-9); Timepoint(s): Baseline, 12-weeks, 24-weeks (post-randomisation)
- 11. BtB versions at beginning of every cCBT module
- 11.1. Resource & Service Use Questionnaire (RSUQ); Timepoint(s): Baseline, 12 week and 24 week post randomisation
- 11.2. Therapist-Patient Alliance Scale (T-PAS); Timepoint(s): 12 weeks and 24 weeks post-randomisation

#### Overall study start date

01/05/2010

#### Completion date

30/09/2012

# **Eligibility**

#### Key inclusion criteria

The main criterion for patients to be included in the study is that their primary problem is:

1. Nonsuicidal, nonpsychotic, unipolar mood disorder, such as depression or dysthymia: the key features are low mood, loss of interest/pleasure and/or increased fatigue/low energy for more than 2 weeks. Secondary features can be: feelings of guilt and self-reproach, emotional blunting, loss of confidence, psychomotor retardation or agitation, problems with memory or concentration, changes in weight & appetite, sleep problems, irritability, loss of libido

2. Mixed anxiety and depressive disorder: this condition is very common in primary care and shares key features of both depression (as above) and generalised anxiety (key features: 6 months of tension, worry, apprehension paniclike physical symptoms) but neither cluster of symptoms is clearly predominant and present to the extent that justifies separate diagnoses of a depressive episode or generalised anxiety disorder.

- 3. Additional inclusion criteria that need to be met so that patients can participate in the study are:
- 3.1. Signing a written consent form for screening & treatment
- 3.2. Having a general practitioner (GP) within NHS Norfolk (which does not include Great Yarmouth & Waveney) or being cared for by a service/facility commissioned by NHS Norfolk. In case of University of East Anglia (UEA) students, they would need to have a temporary GP within NHS Norfolk.
- 3.3. Being 18 years old or above.; Target Gender: Male & Female; Lower Age Limit 18 years

#### Participant type(s)

Patient

#### Age group

Adult

#### Lower age limit

18 Years

#### Sex

Both

## Target number of participants

Planned Sample Size: 300; UK Sample Size: 300

#### Key exclusion criteria

- 1. High current risk of suicide (current suicide plans and intent to harm oneself). In this case, referral to a community mental health or crisis team should be a priority
- 2. Current psychotic symptoms (due to schizophrenia or bipolar affective disorder or severe depression with psychotic features)
- 3. Current substance abuse/misuse (alcohol, illicit drugs, tranquilisers) which needs to be addressed as a priority
- 4. Cognitive impairment which makes difficult the use of a computer, doing homework, etc.
- 5. Any other primary problem (e.g. posttraumaticstress disorder, obsessive compulsive disorder) which needs to be treated as a priority but which may have depression as a comorbid feature

#### Date of first enrolment

01/05/2010

#### Date of final enrolment

30/09/2012

# Locations

#### Countries of recruitment

England

**United Kingdom** 

### Study participating centre School of Medicine

Norwich United Kingdom NR4 7TJ

# Sponsor information

#### Organisation

NHS Norfolk (UK)

#### Sponsor details

Lakeside 400
Old Chapel Way
Broadland Business Park Thorpe St Andrew
Norwich
England
United Kingdom
NR7 0WG

#### Sponsor type

Hospital/treatment centre

#### **ROR**

https://ror.org/01wspv808

# Funder(s)

## Funder type

Government

#### **Funder Name**

National Institute for Health Research (NIHR) (UK) - Research for Patient Benefit (RfPB) programme

# **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?
Protocol article	protocol	27/08/2012		Yes	No