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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 non-suicidal 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 self-report 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
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Broadland Business Park Thorpe St Andrew
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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