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Computerised cognitive behavioural therapy (CBT) for common mental disorders

Submission date	Recruitment status
12/05/2010	No longer recruiting
Registration date	**Overall study status**
12/05/2010	Completed
Last Edited	**Condition category**
01/04/2014	Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

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
6027

Study information

Scientific Title

Computerised cognitive behavioural therapy (CBT) for common mental disorders: a randomised controlled trial (RCT) of a workplace intervention

Study objectives
Primary hypothesis:
To test the impact of MoodGYM on employess work related performance and psychological well-being.

Secondary hypotheses:
1. To assess the cost effectivenss of MoodGYM in a workplace context
2. To evaluate the acceptability of the intervention and mode delivery

Ethics approval required
Old ethics approval format

Ethics approval(s)
Derbyshire Research Ethics Committee approved on the 6th January 2009 (ref: 08/H0401/91)

Study design
Multicentre randomised interventional treatment trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please contact selfhelp@nottingham.ac.uk or Justine.Schneider@nottingham.ac.uk to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Mental Health Research Network; Subtopic: Anxiety, Depression; Disease: Depression

Interventions
MoodGYM is a modularised course, designed to last 6 weeks, which participants will follow at their own pace. Weekly, brief (10-minute) calls will be made to check on use of MoodGYM or other services (e.g., health care, counselling, medication) used by by the intervention group and any services which the control group uses over the first 6 weeks in the study.

Study entry: registration and one or more randomisations

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Patient Health Questionnaire (PHQ9)
2. Work Limitations Questionnaire, WLQ
3. Generalised Anxiety Disorder Assessment (GAD7)

Measured at baseline, 6 weeks and 12 weeks.

Secondary outcome measures
1. Clinical Outcomes in Routine Evaluation (CORE10)
2. Work and Social Attitudes Scale (WSAS)

Measured at baseline, 6 weeks and 12 weeks.

Overall study start date
26/06/2009

Completion date
15/11/2010

Eligibility

Key inclusion criteria
1. A positive response to any of the questions 1 - 3 of the Brief Patient Health Questionnaire (PHQ-Brief), indicating:
1.1. Major depression
1.2. Other depressive syndromes (2 - 5 symptoms more than half the days over 2 weeks affecting function at home, work or socially), or
1.3. Panic syndrome (at least one panic in the last 4 weeks affecting function at home, work or socially)
Mood Gym is supposed to manage all these problems and any of them is likely to lead to problems at work.

OR

2. On Patient Health Questionnaire-9 (PHQ-9), employee scores 2 or more on 5 of the 9 items including 2 on item 1 or 2 and "somewhat difficult" on item 10 (function). These scores are equivalent symptomatically to a diagnosis of major depression

AND

3. Age over 18 years and under 65 years, either sex

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned sample size: 535

Key exclusion criteria
1. Has a primary alcohol or drug use problem
2. Depression secondary to organic brain disease, e.g., stroke
3. Bipolar disorder or other serious mental illness apart from unipolar depression
4. Is already receiving cognitive behaviour therapy
5. Has current suicide plans requiring emergency psychiatric treatment
6. Does not or cannot give written informed consent to the study

Date of first enrolment
26/06/2009

Date of final enrolment
15/11/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
School of Sociology and Social Policy
Nottingham
United Kingdom
NG7 2RD

Sponsor information

Organisation
The Institute of Mental Health (UK)

Sponsor details
Sir Colin Campbell Building
University of Nottingham Innovation Park
Triumph Road

Nottingham
United Kingdom
NG7 2TU

Sponsor type
Research organisation

Website
http://www.institutemh.org.uk/

ROR
https://ror.org/015dvxx67

Funder(s)

Funder type
Charity

Funder Name
British Occupational Health Research Foundation (BOHRF) (UK)

Alternative Name(s)
BOHRF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

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?
Results article	results	01/03/2014		Yes	No
Results article	results	28/03/2014		Yes	No