

Computerised cognitive behavioural therapy (CBT) for common mental disorders

Submission date 12/05/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 12/05/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 01/04/2014	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Pooria Sarrami Foroushani

Contact details
School of Sociology and Social Policy
University Park
Nottingham
United Kingdom
NG7 2RD

Additional identifiers

Protocol serial number
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 employees work related performance and psychological well-being.

Secondary hypotheses:

1. To assess the cost effectiveness 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

Study type(s)

Treatment

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 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(s)

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

Measured at baseline, 6 weeks and 12 weeks.

Key secondary outcome(s)

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

Measured at baseline, 6 weeks and 12 weeks.

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

United Kingdom

England

Study participating centre

School of Sociology and Social Policy

Nottingham

United Kingdom

NG7 2RD

Sponsor information

Organisation

The Institute of Mental Health (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

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