# Computerised cognitive behavioural therapy (CBT) for common mental disorders

| <b>Submission date</b><br>12/05/2010 | <b>Recruitment status</b><br>No longer recruiting             | <ul> <li>Prospectively registered</li> <li>Protocol</li> </ul>     |
|--------------------------------------|---|--|
| <b>Registration date</b> 12/05/2010  | <b>Overall study status</b><br>Completed                      | <ul> <li>Statistical analysis plan</li> <li>[X] Results</li> </ul> |
| Last Edited<br>01/04/2014            | <b>Condition category</b><br>Mental and Behavioural Disorders | 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**

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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 wellbeing.

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