

Telephone-administered cognitive behavioural therapy (CBT) for working adults

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|--|---|--|
| Submission date 31/07/2009 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| | | <input type="checkbox"/> Protocol |
| Registration date 19/11/2009 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan |
| | | <input checked="" type="checkbox"/> Results |
| Last Edited 07/02/2013 | Condition category Mental and Behavioural Disorders | <input type="checkbox"/> 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
N/A

Study information

Scientific Title

Improving health and productivity: an exploratory randomised controlled trial (RCT) of delivery in an occupational setting

Study objectives

Telephone-based cognitive behavioural therapy is likely to represent a feasible and clinically effective service for working adults with mild/moderate mental health problems.

Ethics approval required

Old ethics approval format

Ethics approval(s)

University of Manchester Research Ethics Committee approved in October 2007 (ref: 07/1012 /NMSW)

Study design

Pilot single centre randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Quality of life

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Mild/moderate mental health difficulties

Interventions

1. Usual care with 6-month follow-up
2. Usual care plus 12 sessions of telephone T-CBT delivered by graduate mental health workers, with 6-month follow-up

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Mental health symptom severity quantified by the 34-item Clinical Outcomes in Routine Evaluation Outcome Measure (CORE-OM) at baseline, 3 months and 6 months follow-up.

Secondary outcome measures

1. Presence of anxiety and depressive-related symptoms quantified by the 14-item Hospital Anxiety and Depression Scale (HADS)
2. Self-rated functioning quantified by the Work and Social Adjustment Scale (WSAS)
3. Self-rated work productivity measured by the World Health Organization (WHO) Health and Work Performance Questionnaire

Measured at baseline, 3 months and 6 months follow-up.

Overall study start date

01/02/2008

Completion date

01/10/2009

Eligibility**Key inclusion criteria**

1. Working adults aged 18 years and greater, either sex
2. Employed by a large UK communications company
3. Registered as absent from work due to mild/moderate mental health difficulties
4. Currently on sick leave of between 8 and 90 days as authorised by GP certificate

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

60

Key exclusion criteria

1. Severe or complex mental health problems (i.e. psychosis, post-traumatic stress disorder [PTSD], co-morbid personality disorder)
2. Degenerative cognitive disorders
3. Substance misuse
4. Active suicidal ideation or self-harm

Date of first enrolment

01/02/2008

Date of final enrolment

01/10/2009

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

School of Nursing, Midwifery & Social Work

Manchester

United Kingdom

M13 9PL

Sponsor information

Organisation

University of Manchester (UK)

Sponsor details

Oxford Road

Manchester

England

United Kingdom

M13 9PL

Sponsor type

University/education

Website

<http://www.manchester.ac.uk/>

ROR

<https://ror.org/027m9bs27>

Funder(s)

Funder type

University/education

Funder Name

University of Manchester (UK) - School of Nursing, Midwifery and Social Work

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 | 01/05/2010 | | Yes | No |