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Behavioural therapy of depression: a randomised controlled trial of behavioural therapy of depression delivered by specifically trained generic mental health staff

Submission date
02/11/2007

Recruitment status
No longer recruiting

Registration date
30/11/2007

Overall study status
Completed

Last Edited
01/02/2012

Condition category
Mental and Behavioural Disorders

[X] 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
N/A

Study information

Scientific Title

Study objectives
1. After 12 weeks of treatment, depressed patients in the Behavioural Therapy (BT) group will have superior clinical outcomes (measured by Beck Depression Inventory) compared to those in the monitoring control arm
2. Patient satisfaction will be superior in BT than in monitoring control arm
3. BT will be a cost effective intervention

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Northumberland Research Ethics Committee on the 4th April 2008 (ref: 08/H0902/26).

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

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
Depression

Interventions
Please note that the interventions section of this trial has been updated as of 29/04/2008 to the following:
BT: Patients will receive a 45 minute assessment and up to twelve 30 - 45 minute BT therapy sessions from a mental health worker using structured materials following a BT protocol. BT consists of a structured programme of reducing the frequency of negatively reinforced avoidant

behaviours in parallel with increasing the frequency of positively reinforcing behaviours to improve functioning and raise mood.

Usual GP care (Delayed BT): Treatment in this arm of the study will be delivered by participant's GP as per usual practise. In addition participants will be contacted for 15-20 minutes via phone monthly by research staff. During this call depression symptom level will be assessed using the PHQ9 (Koneke et al 2001) and participants will be
advised to contact their GP should information be elicited that requires further clinical intervention (such as increased risk, significant deterioration in depression symptom level).

Previous interventions:
BT: Patients will receive a 45 minute assessment and up to twelve 30 - 45 minute BT therapy sessions from a mental health worker using structured materials following a BT protocol. BT consists of a structured programme of reducing the frequency of negatively reinforced avoidant behaviours in parallel with increasing the frequency of positively reinforcing behaviours to improve functioning and raise mood.

The control group is a monitoring control arm. Participants will be placed on a 12 week monitoring control group. They will be contacted fortnightly by phone for approximately 10 minutes. Depression severity will be assesed via the Patient Health Questionaire. Should clinical indications suggest further intervention is required, patients will be asked to contact their GP. At 12 weeks participants in this arm will be offered intervention as per BT treatment arm.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Assessments will be conducted by a research worker blind to treatment allocation at pre-treatment and 12 weeks follow up. The primary clinical outcome will be depression symptom level as measured by the Beck Depression inventory.

Secondary outcome measures
Secondary outcome measures include:
1. The Social Adjustment Scale
2. Measures of treatment satisfaction, assessed using the 8-item Client Satisfaction Questionnaire (CSQ8)
3. Service utilisation data collected on frequency of primary, secondary and tertiary service use via patient diaries and questionnaires
4. Health utility data, measured by the Euroqol

All measurements will be collected pre treatment and at 12 weeks.

Overall study start date
01/04/2008

Completion date
01/04/2009

Eligibility

Key inclusion criteria
1. Patients aged 18+
2. A General Practitioner (GP) diagnosis of depression
3. On no antidepressant medication or have been on a stable dose for at least 6 weeks
4. Consent to take part in the study

Eligibility will be assessed by trained research interviewer using the Clinical Interview Schedule Revised (CSIR) prior to randomisation.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60 (70 as of 29/04/2008)

Key exclusion criteria
1. Currently actively suicidal
2. Have psychosis, diagnosis of bi-polar disorder or organic brain disease
3. Use alcohol or non prescription drugs requiring a primary clinical intervention

Date of first enrolment
01/04/2008

Date of final enrolment
01/04/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Health Centre
County Durham
United Kingdom
DH3 3UR

Sponsor information

Organisation
Tees Esk & Wear Valleys NHS Trust (UK)

Sponsor details
Research and Development Office
TAD Centre
Ormesby Road
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Sponsor type
Hospital/treatment centre

Website
http://www.tewv.nhs.uk/

ROR
https://ror.org/04s03zf45

Funder(s)

Funder type
Government

Funder Name
Tees Esk & Wear Valleys NHS Trust (UK)

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	01/01/2011		Yes	No
Results article	cost-effectiveness results	01/12/2011		Yes	No