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Can a new talking therapy for people with bipolar disorders lead to improvements that are better than their usual treatment?

Submission date
25/07/2014

Recruitment status
No longer recruiting

Registration date
25/07/2014

Overall study status
Completed

Last Edited
18/10/2018

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
About 2 in 100 of the UK population are diagnosed with bipolar disorders, although some argue that this figure is more like 1 in 20 people if you include individuals experiencing mood swings that cause them significant distress and impact negatively on their daily lives. The most common problems for which people with bipolar disorders seek help are their persistent symptoms that interfere with their lives even when outside an episode - such as depression and anxiety. TEAMS (Think Effectively About Mood Swings) is a talking therapy based on a scientific model of mood swings and bipolar disorders and consultations with patients and service user organisations since 2003. It is a form of Cognitive Behaviour Therapy (CBT), designed to help a therapist and client to work together on current problems such as depression, anxiety, high moods, relationships, and functioning. The model proposes that these difficulties are made worse by the beliefs that people with bipolar disorders hold about mood states and how to manage them. For example, a person may be driven to avoid seeing other people for fear of embarrassing themselves when in a high mood. Using TEAMS, they may learn that they can manage to see other people and not feel embarrassed. So, the TEAMS intervention involves helping patients reclaim their lives from an existence that is driven by their mood, and helps them to learn to work out what moods are acceptable and which require some effective action. The next stage of our research is to test whether it is feasible to provide the TEAMS approach to people with bipolar disorder, and get their views on the approach. We are also planning to see whether TEAMS leads to people having less symptoms, and managing better, than the treatment people currently receive. We aim to develop therapist and client manuals for the approach, and improve it using the comments we receive from the clients in the study.

Who can participate?
Anyone over 16 who fits the criteria for a diagnosis of a bipolar disorder can participate in the study, subject to some exclusion criteria.

What does the study involve?
The study involves completing a number of questionnaires and interviews on several occasions: baseline, and then 3, 6, 12 and 18 months afterwards. Each participant will be allocated at

random to either TEAMS plus their treatment-as-usual or to treatment-as-usual. In addition, all participants will have the opportunity to talk about their difficulties in confidence with the research assistants on several occasions, and receive expenses for the follow-up visits.

What are the possible benefits and risks of participating?
Participants will have a 50% chance of receiving a new therapy that is designed to benefit people with bipolar disorders.

Where is the study run from?
The study is being led by Greater Manchester West Mental Health NHS Foundation Trust, and is also being conducted at other Trusts in Greater Manchester, including Pennine, Lancashire and Five Boroughs.

When is the study starting and how long is it expected to run for?
The study begins in October 2011 and continues recruiting until the start of January 2014.

Who is funding the study?
The trial is funded by the NIHR Research for Patient Benefit Scheme (UK).

Who is the main contact?
Dr Warren Mansell
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Study website
http://teamstrial.net/

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
11119

Study information

Scientific Title
A pilot randomised controlled trial of CBT for people with bipolar disorders and current symptoms: Think Effectively About Mood Swings (TEAMS)

Acronym
TEAMS

Study objectives
The main hypothesis is that TEAMS will reduce depression in comparison to treatment as usual at 6 and 12 months post-randomisation.
The secondary hypotheses are that TEAMS will:
1. Reduce the severity of hypomanic symptoms and anxiety
2. Reduce thinking styles responsible for maintaining symptoms which will be targeted by the therapy,
3. Improve social functioning and promote recovery compared to treatment as usual at post-treatment and follow-up.
These effects are predicted to be strongest in those patients whose therapy is assessed as reflecting the closest adherence to the TEAMS approach and who show the greatest shifts in a measure of the thinking style targeted by TEAMS.
The trial will also explore the relative costs and outcomes of the TEAMS intervention in comparison to treatment as usual and whether the incremental cost per quality adjusted life year (QALY) gained by the intervention is acceptable to UK policy makers (e.g. NICE) and commissioners.
The second objective is to obtain in depth feedback from service users and front line clinical staff, through the use of qualitative methodology (thematic analysis) about their preferences regarding psychological treatment prior to the trial, feedback on the features of the treatment they found helpful and unhelpful, and their constructive suggestions for future interventions.

Ethics approval required
Old ethics approval format

Ethics approval(s)
11/LO/1326; First MREC approval date 21/09/2011

Study design
Randomised; Interventional; Design type: Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
http://teamstrial.net/what-does-our-cbt-research-involve/we-need-participants/

Health condition(s) or problem(s) studied
Topic: Mental Health; Subtopic: Bipolar affective disorder; Disease: Bipolar affective disorder

Interventions
TEAMS, Think Effectively About Mood Swings - a novel cognitive therapy based on an integrative cognitive model (Mansell et al., 2007).; Follow Up Length: 18 month(s); Study Entry : Single Randomisation only

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Beck Depression Inventory (Beck et al., 1961); Timepoint(s): self-report scale administered at baseline, and 3, 6, 12, and 18 months post randomization.

Secondary outcome measures
1. Anxiety (GAD-7; Spitzer et al., 2006); Timepoint(s): 0, 3, 6, 12, 18 months 2. Composite internal state scale score (ISS; Bauer et al., 1991); Timepoint(s): 0, 3, 6, 12, 18 months
3. Hamilton (1960) Depression; Timepoint(s): 0, 3, 6, 9, 12, 18 months
4. Health status (EQ-5D/Euroqol, Kind et al 1996).; Timepoint(s): 0, 3, 6, 12, 18 months
5. Hypomanic Attitudes and Positive Predictions Inventory; Dodd et al., 2009; Mansell, 2006; Timepoint(s): 0, 3, 6, 12, 18 months
6. Measure of manic symptoms (Bech-Rafaelson; Bech et al., 1978); Timepoint(s): 0, 3, 6, 12, 18
7. Recovery measure (Pitt et al., in press); Timepoint(s): 0, 3, 6, 12, 18 months
8. SCID-LIFE interview for episodes of mania or depression (Paykel et al., 2006); Timepoint(s): 0, 3, 6, 12, 18 months

Overall study start date
21/10/2011

Completion date
13/01/2014

Eligibility

Key inclusion criteria
1. Meet DSM-IV criteria for bipolar I or II disorder, or bipolar disorder not otherwise specified, characterised by a past major depressive episode and DSM-IV hypomania of two days or more (Akiskal et al., 2006).
2. Complete baseline assessment sessions in an outpatient setting
3. A baseline score of at least 15 on the Beck Depression Inventory that is maintained over two

consecutive weeks
prior to the study (to ensure presence of significant current distress as targeted in the trial)
4. Aged 16 and above

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 82; UK Sample Size: 82

Key exclusion criteria
1. A diagnosis of a non-affective psychotic disorder according to DSM-IV
2. Current mania or mixed episode according to DSM-IV
3. A primary substance use disorder according to DSM-IV
4. Moderate to severe learning disability
5. Organic impairment that accounts for mental health problem
6. Non-English speaking (owing to the standardised assessment measures)

Date of first enrolment
21/10/2011

Date of final enrolment
13/01/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
School of Psychological Sciences
Manchester
United Kingdom
M13 9PL

Sponsor information

Organisation
University of Manchester (UK)

Sponsor details
Oxford Road
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Sponsor type
University/education

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Government

Funder Name
NIHR Research for Patient Benefit (RfPB); Grant Codes: PB-PG-0110-21087

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?
Protocol article	protocol	24/10/2014		Yes	No
Results article	results	01/05/2017		Yes	No