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Evaluating the feasibility and acceptability of a time limited anxiety in bipolar disorder

Submission date	Recruitment status
28/03/2011	No longer recruiting
Registration date	**Overall study status**
28/03/2011	Completed
Last Edited	**Condition category**
13/03/2020	Mental and Behavioural Disorders

[ ] 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

Protocol serial number
9419

Study information

Scientific Title
A randomised controlled trial evaluating the feasibility and acceptability of a time limited anxiety intervention in bipolar disorder

Study objectives
This study aims to evaluate the feasibility and acceptability of a newly adapted, time limited, psychological intervention for anxiety and bipolar disorder. The intervention has been developed in collaboration with service users and health professionals in earlier phases of this research and is based on current, evidence based cognitive behavioural therapy interventions for anxiety and bipolar disorder.

The principle objectives of this study are to evaluate the feasibility of recruiting participants into this study and of delivering this intervention to individuals who experience anxiety and bipolar disorder. The acceptability of the intervention to those who receive it will also be evaluated.

A secondary objective is to assess if the intervention is likely to be clinically effective in reducing anxiety and mood symptoms for individuals with bipolar disorder and concurrent anxiety. These objectives will be evaluated by monitoring recruitment and retention into the study, eliciting feedback from participants in the treatment arm of the trial, and measuring anxiety and mood symptoms at baseline and follow-up time points to evaluate if the intervention is likely to be effective at reducing mood and anxiety symptoms.

Please note that as of 13/11/2012, the anticipated end date of this trial was updated from 30/04/2011 to 24/01/2014.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North West Lancaster Research Ethics Committee ref:10/H1015/83 06/12/2010, amended 21/01/2011

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Bipolar disorder

Interventions
1. PARADES Anxiety, A psychological intervention for the joint treatment of anxiety and bipolar disorder
2. Follow Up Length: 20 month(s); Study Entry : Single Randomisation only
3. Participants who take part in this study will be randomly allocated to receive either the intervention, or their usual treatment.
4. Those in the intervention arm of the study will receive a maximum of 10 therapy sessions over a 4 month period, delivered by a trained psychological therapist, either at home or another place they feel comfortable.

5. All participants who take part in the study will be followed up both in person and over the telephone at regular 4 monthly intervals, over a period of 20 months and all participants will have the chance to share their personal experiences with the research team.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Recruitment & Retention: Timepoint(s): Baseline, 4, 8, 12, 16 and 20 months

Key secondary outcome(s)
Anxiety symptoms; Timepoint(s): Baseline, 4, 8, 12 16 and 20 months; Mood symptoms; Timepoint(s): Baseline, 4, 8, 12, 16 and 20 months.

Completion date
24/01/2014

Eligibility

Key inclusion criteria
1. Primary diagnosis of bipolar I or II disorder
2. Current experience of anxiety evidenced by a HADS-A score > 8
3. Aged 18+
4. Ability to understand spoken and written English to a level where participants are able to provide written informed consent and are able to participate in interviews, questionnaires and therapy sessions, where appropriate.
5. Male or Female

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria

1. Current experience of a manic, hypomanic, depressed or mixed episode, or experience of this in the past four weeks, although it is expected that some subsyndromal symptoms will be present
2. Current suicidal ideation with intent

Date of first enrolment
05/01/2011

Date of final enrolment
24/01/2014

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Spectrum Centre for Mental Health Research
Lancaster
United Kingdom
LA1 4YT

Sponsor information

Organisation
Lancaster University (UK)

ROR
https://ror.org/04f2nsd36

Funder(s)

Funder type
Government

Funder Name
National Institute of Health Research (NIHR) (UK) - Programme for Applied Research

Funder Name
Ref: RP-PG-0407-10389

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	15/02/2013		Yes	No