

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

<b>Submission date</b> 28/03/2011	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 28/03/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 13/03/2020	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<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

**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

## **Study design**

Randomised controlled trial

## **Primary study design**

Interventional

## **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?
<a href="#">Results article</a>	results	15/02/2013		Yes	No