

An exploratory randomised controlled trial of a CBT-based recovery intervention for early bipolar disorder

Submission date

08/04/2011

Recruitment status

No longer recruiting

☐ Prospectively registered

☒ Protocol

Registration date

08/04/2011

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

26/09/2018

Condition category

Mental and Behavioural Disorders

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

8950

Study information

Scientific Title

An exploratory randomised controlled trial of a CBT-based recovery intervention for early bipolar disorder

Study objectives

A rater blind randomised controlled trial is proposed. As this is an exploratory trial we wish to determine effect sizes for the primary and secondary outcome measures to inform the development of a definitive study. Primary outcomes are time to bipolar relapse and self reported recovery score. Secondary outcomes are levels of affective and psychotic symptoms, level of functioning and levels depressive and hypomanic appraisal style.

Ethics approval required

Old ethics approval format

Ethics approval(s)

10/H1014/60

Study design

Randomised Interventiona; Design type: Treatment

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Bipolar affective disorder

Interventions

1. Recovery focussed CBT
2. The intervention has been developed through collaboration between a multidisciplinary group of mental health professionals and service users with experience of bipolar disorder
3. Focus groups have taken place with individuals who took part in the first phase of the project (the qualitative analysis of recovery themes) to ensure that the intervention is appropriate and acceptable to individuals early in the course of bipolar disorder
4. Furthermore, a service user consultation group have also been provided
5. Follow Up Length: 12 month(s)
6. Study Entry : Single Randomisation only

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

1. Time to bipolar relapse
2. Timepoint(s): assessed every 3 months from baseline

Key secondary outcome(s))

1. Beck Depression Inventory score - Timepoint(s): baseline, 6 months, 12 months, 18 months
2. Hamilton depression rating scale score - Timepoint(s): baseline, 6 months, 12 months, 18 months
3. Hypomanic Interpretations Questionnaire - Timepoint(s): baseline, 6 months, 12 months, 18 months
4. Internal States Scale score - Timepoint(s): baseline, 6 months, 12 months, 18 months
5. Interpretation of Depression Questionnaire - Timepoint(s): baseline, 6 months, 12 months, 18 months
6. Mania Rating Scale - Timepoint(s): baseline, 6 months, 12 months, 18 months
7. Personal and Social Performance Scale - Timepoint(s): baseline, 6 months, 12 months, 18 months;
8. Post Traumatic Growth Inventory - Timepoint(s): baseline, 6 months, 12 months, 18 months
9. Self reported recovery score - Timepoint(s): baseline and every 6 months;
10. Self-Esteem Rating Scale (Short Form) - Timepoint(s): baseline, 6 months, 12 months, 18 months
11. The Brief Quality of Life in Bipolar Disorder - Timepoint(s): baseline, 6 months, 12 months, 18 months

Completion date

30/11/2012

Eligibility

Key inclusion criteria

1. Individuals who have received a clinical diagnosis of bipolar disorder or who have experienced a first episode of mania within the last 5 years
2. Aged between 18-65
3. Can provide written informed consent
4. Can communicate in English
5. Target Gender: Male & Female

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

65 years

Sex

All

Key exclusion criteria

1. Individuals who are currently experiencing or have experienced within the last month, an acute episode of major depression or mania
2. Individuals referred into the study during an acute episode will wait until they have been out of episode for one month before entering the study. Nevertheless, it is expected that most participants will have subsyndromal mood symptoms.

Date of first enrolment

09/02/2011

Date of final enrolment

30/11/2012

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Psychology Department

Manchester

United Kingdom

M25 3BL

Sponsor information

Organisation

Lancaster University (UK)

ROR

<https://ror.org/04f2nsd36>

Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research (NIHR); Grant Codes: RP-PG-0606-1086

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

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	01/01/2015		Yes	No
Protocol article	protocol	21/11/2012		Yes	No