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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

Registration date
08/04/2011

Overall study status
Completed

Last Edited
26/09/2018

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[X] 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
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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

Secondary outcome measures
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

Overall study start date
09/02/2011

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
Planned Sample Size: 72; UK Sample Size: 72

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
England

United Kingdom

Study participating centre
Psychology Department
Manchester
United Kingdom
M25 3BL

Sponsor information

Organisation
Lancaster University (UK)

Sponsor details
Bailrigg
Lancaster
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United Kingdom
LA1 4YB

Sponsor type
University/education

Website
http://www.physics.lancs.ac.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

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	21/11/2012		Yes	No
Results article	results	01/01/2015		Yes	No