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Bipolar at risk trial

Submission date	Recruitment status	[ ] Prospectively registered
26/08/2015	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
26/08/2015	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
29/10/2021	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol
Plain English summary under review

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
19040

Study information

Scientific Title
Cognitive behavioural therapy in comparison to treatment as usual in adults at high risk of developing bipolar disorder (Bipolar At Risk): a feasibility study

Acronym
BART

Study objectives
Bipolar Disorder (BD) affects around 1% of the population. 1.14 million people met criteria for this condition in 2007. The World Health Organisation has identified BD as one of the main reasons for loss of life and health in 15–44 year olds, with a diagnosis of BD increasing the rate of suicide above the general population rate by 20-30 times. There is poor recognition of the disorder, especially in the early stages. People often experience misdiagnosis which causes frustration and disenchantment with services. Misdiagnosis can also lead to incorrect treatment which can make people's difficulties worse. BD also has financial costs; it is thought that the cost of BD in the UK for 2007 was £5.2 billion and likely to rise to £8.2 billion per year by 2026. People who experience symptoms of high and low mood and meet criteria for Bipolar At Risk (BAR) are considered to be at high risk of developing a full episode of BD. If these individuals are detected then interventions aimed at reducing these symptoms and associated distress may reduce the chance of a future full blown episode of BD. Early intervention for psychosis services have been successfully established throughout England. Extending early intervention to other mental health problems such as BD would be a major step forward in preventing long term problems and their associated distress, disability and financial burden. The importance of developing interventions with a focus on health promotion and preventative interventions has long been recognised. However, evidence is required to test what treatments might best help this group. This study provides an investigation of a specific psychological intervention. This work fits with recent policy developments such as the Improving Access to Psychological Therapies Programme for those with severe and enduring mental illness.

Ethics approval required
Old ethics approval format

Ethics approval(s)
15/NW/0336

Study design
Randomised; Interventional; Design type: Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

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

Interventions
The Cognitive Behavioural Therapy (CBT) intervention will use a specific cognitive model of mood swings. The model proposes that people hold a range of extreme and contradictory beliefs concerning their mood and other internal states (e.g. energy levels). The specific interventions are dependent on the individual formulation, but the range of permissible interventions will be described in our manual. Up to 25 sessions will be delivered over the 6 month treatment envelope.
Follow Up Length: 12 month(s); Study Entry : Single Randomisation only

Intervention Type
Other

Primary outcome measure
Conversion to mania (SCID); Timepoint(s): 6 months, 12 months

Secondary outcome measures
1. Beck Depression Inventory; Timepoint(s): 6 months,12 months
2. EPQ adapted; Timepoint(s): 6 months, 12 months
3. Global Assessment of Functioning scale; Timepoint(s): 6 months, 12 months
4. Health Status (EQ-5D); Timepoint(s): 6 months, 12 months
5. Hypomanic Attitudes and Positive Predictions Inventory; Timepoint(s): 6 months, 12 months
6. Internal States Scale; Timepoint(s): 6 months, 12 months
7. World Health Organisation Quality of Life; Timepoint(s): 6 months,12 months
8. Young Mania Rating Scale; Timepoint(s): 6 months,12 months

Overall study start date
01/06/2015

Completion date
01/12/2016

Eligibility

Key inclusion criteria
1. Age 16-25 years old
2. Meet criteria for one of the following Bipolar At Risk (BAR) criteria:
2.1. Group I: Subthreshold mania (Young Mania Rating Scale total score between 5 and 15 + elevated mood = 2 + irritability = 2 for at least 4 days)
2.2. Group II: Depression + Cyclothymia: mild depressive symptoms (BDI-II >20 for at least 1 week) + diagnosis of cyclothymic disorder or bipolar disorder NOS as assessed by SCID I
2.3. Group III: Depression + genetic risk: mild depressive symptoms (BDI-II >20 for at least 1 week) + genetic risk (first degree relative with bipolar disorder)
3. Help seeking
4. Competent and willing to provide written, informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 76; UK Sample Size: 76; Description: A target recruitment of 76 (38 per condition) would allow for a drop out rate of 20%.

Total final enrolment
76

Key exclusion criteria
1. Past history of a treated or untreated manic episode or psychosis of one week duration or longer
2. Past treatment with a mood stabiliser for longer than 6 weeks or antipsychotic for 3 weeks (equals 15 mg per week of haloperidol or equivalent)
3. Moderate to severe learning disability
4. Organic brain disorder
5. Non-english speaking (this would prevent the use of standardised assessment instruments) .
6. Inpatient/acute psychiatric care needed
7. Substance dependency

Date of first enrolment
01/06/2015

Date of final enrolment
01/12/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Greater Manchester West Mental Health NHS Foundation Trust
Psychology Department
Prestwich Hospital
Bury New Road
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Manchester

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Sponsor information

Organisation
Greater Manchester West Mental Health NHS Foundation Trust

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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

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
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications	qualitative investigation of participant experiences	16/10/2021	29/10/2021	Yes	No
HRA research summary			28/06/2023	No	No