

# Integrated psychological therapy for people with bipolar disorder (BD) and co-morbid alcohol use: a feasibility randomised trial

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<b>Registration date</b> 14/03/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 18/12/2020	<b>Condition category</b> Mental and Behavioural Disorders	<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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
9418

# Study information

## Scientific Title

Integrated psychological therapy for people with bipolar disorder (BD) and co-morbid alcohol use: a feasibility randomised trial

## Study objectives

This study is part of the NIHR funded PARADES programme (Psychoeducation Anxiety Relapse Advance Directives Evaluation & Suicidality). The PARADES programme runs over 5 years in collaboration with Manchester Mental Health and Social Care Trust, Nottingham and Manchester Universities and aims to investigate bipolar disorder and its associated problems and comorbidities. The programme consists of 5 separate studies running in parallel, of which this project is one. This study is the final phase of a treatment development study which aims to evaluate the potential benefits of a time limited psychological intervention for alcohol use in bipolar disorder. The intervention was developed in earlier work by the group including phase 1 (an investigation of the reasons for substance use in bipolar individuals; phase 2 (focus group sessions with service users and mental health professionals to develop and finalise the intervention) and a pilot study of the MICBT intervention with 5 service users (Jones et al in press).

More details can be found here: <http://public.ukcrn.org.uk/Search/StudyDetail.aspx?StudyID=9418>

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

North West 9 REC - Greater Manchester West (10/H1014/75) approved on 11/11/2010

## 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 the contact details below to request a patient information sheet

## Health condition(s) or problem(s) studied

Topic: Mental Health Research Network; Subtopic: Bipolar affective disorder; Disease: Bipolar affective disorder

## **Interventions**

MI-CBT, The intervention is a time limited, psychological intervention incorporating Motivational interviewing (MI) and Cognitive Behaviour Therapy (CBT) for alcohol use in bipolar disorder. The intervention was developed by a Manchester based group headed by CB for people with substance abuse and psychosis (Barrowclough et al, 2005). Initial sessions will focus on engagement and use motivational interviewing to develop a shared understanding of the clients key life goals and concerns; to elicit and select; Follow Up Length: 12 month(s); Study Entry : Single Randomisation only

## **Intervention Type**

Other

## **Phase**

Not Applicable

## **Primary outcome measure**

Bipolar relapse; Timepoint(s): Baseline, 3, 6, 9 and 12 months

## **Secondary outcome measures**

Alcohol Use and other substance use; Timepoint(s): Baseline, 3, 6, 9 and 12 months

## **Overall study start date**

04/01/2011

## **Completion date**

06/06/2012

# **Eligibility**

## **Key inclusion criteria**

1. Primary Diagnosis of Bipolar disorder I or II
2. Current alcohol use (a score of 8 or more on the Alcohol Use Disorders Identification Test, AUDIT)
3. In current contact with mental health services
4. Age 18 years or older
5. An ability to provide informed consent
6. Having a fixed abode.; Target Gender: Male & Female ; lower age limit 18 years

## **Participant type(s)**

Patient

## **Age group**

Adult

## **Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

Planned Sample Size: 48; UK Sample Size: 48

**Key exclusion criteria**

1. Evidence of organic brain disease, significant concurrent physical illness or learning disability
2. Presence of current manic, hypomanic, mixed affective or major depressive episode currently or within 4 weeks of initial assessment
3. An inability to communicate in written and verbal English

**Date of first enrolment**

04/01/2011

**Date of final enrolment**

06/06/2012

**Locations****Countries of recruitment**

England

United Kingdom

**Study participating centre**

University of Manchester

Manchester

United Kingdom

M13 9PL

**Sponsor information****Organisation**

University of Manchester (UK)

**Sponsor details**

c/o Mohammed Zubair

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England

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**Sponsor type**

University/education

**ROR**

<https://ror.org/027m9bs27>

## Funder(s)

**Funder type**

Government

**Funder Name**

National Institutes of Health Research (NIHR) (UK) - Programme for Applied Research; (ref: grant codes: RP-PG-0407-10389)

## 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?
<a href="#">Protocol article</a>	protocol	08/05/2018	18/12/2020	Yes	No
<a href="#">Results article</a>	results	01/09/2018	18/12/2020	Yes	No