

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

Submission date

14/03/2011

Recruitment status

No longer recruiting

☐ Prospectively registered

☒ Protocol

Registration date

14/03/2011

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

18/12/2020

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

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Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Randomised; Interventional; Design type: Treatment

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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

United Kingdom

England

Study participating centre

University of Manchester

Manchester

United Kingdom

M13 9PL

Sponsor information

Organisation

University of Manchester (UK)

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

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?
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Results article	results	01/09/2018	18/12/2020	Yes	No
Protocol article	protocol	08/05/2018	18/12/2020	Yes	No