ISRCTN14774583 https://doi.org/10.1186/ISRCTN14774583

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

Registration date
14/03/2011

Overall study status
Completed

Last Edited
18/12/2020

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

Contact name
Miss Nancy Black

Contact details
Zochonis Building
Brunswick Street, Oxford Road
Manchester
United Kingdom
M13 9PL
-
nancy.black@nhs.net

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
Faculty of Medical and Human Sciences
The University of Manchester
Simon Building, Brunswick St
Manchester
England
United Kingdom
M13 9PL

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