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Individual psychological therapy for bipolar disorder and substance use

Submission date	Recruitment status
28/09/2007	No longer recruiting
Registration date	**Overall study status**
28/09/2007	Completed
Last Edited	**Condition category**
10/09/2012	Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] 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

Protocol serial number
N0133190185

Study information

Scientific Title

Study objectives
Is a psychological treatment comprising motivational interviews and cognitive behaviour therapy feasible in terms of acceptability and retention of participants?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Mental and Behavioural Disorders: Bipolar disorders

Interventions
Purpose:
To explore the feasibility of a psychological treatment, (motivational interviews (MI) and cognitive behaviour therapy (CBT)), on substance use and clinical outcome in bipolar patients. The study aims to establish the feasibility of using the therapeutic integration of MI and CBT for this patient group. Participants with the dual diagnosis of bipolar disorder and substance use will be recruited for this research and form two groups, one group receiving standard psychiatric care and the other psychiatric care and psychological therapy.
Bipolar disorder (BD) is a devastating mental illness characterised by a recurring relapsing course, high risk of self harm and suicide (1-3), and considerable subclinical psychopathology outside full episodes (4, 5). The World Health Organization has identified bipolar disorder as the 6th leading cause of disability adjusted life years in the world among people aged 15-44 years (6), and estimated total costs to the UK per annum
amount to approximately £2 billion (7). Lithium is an effective drug in prophylaxis, but fails to help about 20-40% of bipolar patients (8-11). The disorder is characterised by high rates of substance misuse, with studies in psychiatric and community settings reporting rates of 48-70% (12, 13). Such substance misuse can have profound effects on mood and behaviour which worsen the course, outcome and morbidity of bipolar disorder (14). For example, drugs and alcohol may disrupt sleep and circadian rhythms (15, 16), which can worsen prodromal symptoms and hence increase risk of relapse (17, 18). Furthermore, impulsiveness, which has been shown to be particularly elevated in bipolar patients with co morbid substance abuse (19), has been proposed as a possible factor in the significantly poorer treatment outcome and increased risks of suicide and violence observed in individuals with co morbid substance misuse compared to those bipolar disorder alone (14, 20, 21). Despite the high prevalence of substance use in bipolar disorder and its associated risks for illness complications, it has received very little attention within this diagnostic group.

Design:
As an exploratory study for a future definitive trial, the key questions of this study concern the

feasibility and potential benefits of the new intervention in addition to standard care. Bipolar patients with co morbid substance misuse will receive individual psychological therapy plus standard psychiatric care or standard psychiatric care alone. A placebo control group is neither practical nor appropriate for a study of this scale.
The key issues to be addressed are; whether this intervention can be delivered and assessed appropriately with this group of patients; how outcome might optimally be measured and indicators of the potential benefits and costs of the proposed therapy.

Method:
The recruitment phase will benefit from the patient identification and recruitment systems established by the MIDAS trial (www.midastrial.ac.uk), in conjunction with the Mental Health Research Network. Recruitment will take place during the first nine months of the study. 20 participants, 10 randomised to each arm of the study will be recruited from three mental health trusts in the Manchester area:
1. Pennine Care NHS Trust
2. Bolton, Salford and Trafford Mental Health Partnership Trust
3. Nottinghamshire Healthcare NHS Trust

Identifying potential participants:
All sites within the two trusts will be approached about the trial at the same stage. The research team aim to establish good liaisons with participating sites and services and ensure clinicians are well informed about the study and how to refer potential participants.

Eligible Participants:
Where permission is given eligible participants will be approached and introduced to the study by either the research assistant or care coordinator, depending on the preference of the care coordinator. Each potential participant in the community will be contacted by letter or telephone informing them in brief about the research and to arrange a time for the research assistant to visit them and introduce the study. All written correspondence, including consent forms and information sheets, will be written on headed paper and have contact information for the relevant research assistant. After the initial meeting potential participants will be given at least 24 hours to consider participation and will then be contacted by the research assistant (in a way agreed by the participant) to establish if they wish to take part in the study. The research assistant will visit each Potential participant interested in the study so that written consent can be obtained. Once participants have consented in writing an assessment for inclusion in the trial will be carried out using the SCID (a structured clinical interview) to confirm diagnosis. All potential participants will be assessed according to DSM-IV criteria for bipolar disorder; in addition patients will be interviewed concerning drug and alcohol use on the basis of the relevant SCID screening sections and regarding use in the preceding three months. Participants will be informed about their eligibility for the study and will be randomly allocated to the control group (treatment as usual) or the experimental group which involves treatment as usual plus the additional psychological therapy which is an integration of Motivational Interviews (MI) and Cognitive Behaviour Therapy (CBT). Therapy sessions will be offered in participants preferred location (NHS setting or home) to facilitate attendance. Participants in the experimental group will receive up to 26 therapy sessions over 12 months which will comprise of a one hour session every two weeks. Given the nature of the participants, the trial will be as flexible as time scales permit in offering additional appointments following periods of non-attendance. The follow-up period will be 10 months from initial randomisation into groups (patients will begin treatment within 2 weeks of randomisation). In addition to the therapy sessions participants will have regular assessments to evaluate bipolar relapse and substance use every three months as well as detailed assessment of social rhythms and activity, using the Social rhythm metric which records daily activity patterns over week long periods (22).

Participants will also be asked to wear actiwatches for the initial week of the study and the final week of the study. Actiwatches are a non-invasive objective measure of activity using actigraphy (23, 24). Participants will be asked to complete the Beck depression inventory (BDI) and internal states scale (ISS) which will measure changes in mood. Reduction in impulsivity will be measured with the Barratt impulsiveness scale, a validated self report measure which has identified elevated impulsiveness in bipolar disorder and substance use (19). The additional psychological intervention (MI and CBT) is used to facilitate engagement and explore the role of substance misuse in worsening symptoms of bipolar disorder. Information collected will be used to create an individualised formulation identifying links between substance misuse and destabilisation. This will form the basis of a Cognitive Behaviour Therapy intervention focused on changing drug use behaviour and developing a comprehensive relapse prevention plan.

Treatment Integrity:
Independent evaluation of therapy will be conducted by an independent rater who will listen to 10% of therapy tapes to assess for fidelity and competence. The California Psychotherapy Alliance Scale will be used as a measure of alliance and the Motivational Interviewing Treatment. Integrity code will be used to assess motivational interviewing skills. Treatment dose (frequency and duration) will be closely monitored.

Timetable:
0-4 months: recruit participants, assessment of participants
4-11 months: treatment phase - additional psychological intervention (26 fortnightly sessions) and monthly assessments
12-15 months: collate data, develop and maintain database
15-17 months: follow up assessments, data entry for follow-up
17-24 months: analysis of data, write scientific report

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
The feasibility of a psychological treatment comprising of motivational interviews and cognitive behaviour therapy, in terms of acceptability for this patient group and retention of participants. Effect size for therapy outcomes will be determined to so that a definitive trial can be planned which is appropriately powered with respect to the primary outcome measures. Primary Therapy Outcome Measures: number of bipolar relapses and frequency and severity of substance. misuse.

Key secondary outcome(s)
Measures of bipolar symptomatology and time to relapse will be estimated. Also, in line with the key targets of the planned intervention, we will assess stabilisation of social rhythms and reduction in impulsiveness as a result of treatment. Self report vs collateral outcome measures will be compared for the assessment of time to bipolar relapse, frequency and duration of relapse and severity and frequency of substance misuse. Comparisons will be made with respect to completeness of data sets in each case and will indicate the most appropriate outcome measures to use for a definitive trial.

Completion date

02/01/2009

Eligibility

Key inclusion criteria
1. Bipolar inclusion criteria will be as follows: bipolar disorder I or II according to DSM-IV criteria and not meeting current episode criteria for mania or major depression
2. Substance use inclusion criteria are: alcohol and/or substance abuse or dependence according to DSM-IV criteria, alcohol use exceeding 28 units for males/21 units for females on at least half of the weeks of the previous 3 months and/or use of illicit drugs on at least two days per week in at least half the weeks in the 3 months prior to assessment
3. General inclusion criteria includes: current contact with mental health services, all participants will be 18 years or older, have no evidence of organic brain disease or learning disability, not be currently actively suicidal, they must be able to provide informed consent and having a fixed abode

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
16/01/2007

Date of final enrolment
02/01/2009

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

Academic Division of Clinical Psychology
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Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Funder(s)

Funder type
Government

Funder Name
Bolton, Salford and Trafford Mental Health NHS Trust (UK)

Funder Name
NHS R&D Support Funding

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?
Results article	results	01/09/2011		Yes	No