

Integrated psychological therapy for people with bipolar disorder and co-morbid alcohol use: A feasibility and acceptability randomised controlled trial

Steven Jones^{a,*}, Heather Robinson^a, Lisa Riste^b, Chris Roberts^c, Sarah Peters^b, Lucy Bateman^b, Emma Weymouth^b, Christine Barrowclough^b

^a Spectrum Centre for Mental Health Research, Faculty of Health and Medicine, Lancaster University, United Kingdom

^b Division of Psychology and Mental Health, Faculty of Biology, Medicine and Health, University of Manchester, Manchester, United Kingdom

^c Centre for Biostatistics Research, University of Manchester, Manchester, United Kingdom

ARTICLE INFO

Keywords:

Bipolar
Alcohol
Substance
Motivational interviewing
Trial registration
number:
ISRCTN14774583

ABSTRACT

Background: Co-morbid substance misuse, particularly alcohol, is common in bipolar disorder (BD) and associated with worse treatment outcomes. Research into psychological interventions for substance misuse in BD is at an early stage and no studies have specifically targeted problematic alcohol use. This paper describes the context and protocol for a feasibility and acceptability randomised controlled trial (RCT) evaluating a novel intervention combining motivational interviewing and cognitive behavioural therapy (MI-CBT) for participants with BD and problematic alcohol use, developed in collaboration with people with lived experience of both issues.

Methods and design: An RCT will assess the feasibility and acceptability of MI-CBT in addition to treatment as usual (TAU) compared with TAU alone. Participants will be recruited from across the North West of England through NHS services and self-referral. The primary outcomes will be the feasibility and acceptability of the intervention assessed by recruitment to target, adherence to intervention, retention rate at follow-up, absence of adverse events and qualitative analysis of participants' reported experiences of intervention. The effect size of the impact of the intervention on alcohol use and mood outcomes will also be estimated. In addition, we will explore a number of potential process variables in therapy.

Discussion: This is the first RCT evaluating MI-CBT for BD and problematic alcohol use. Given the prevalence and impact of alcohol problems in BD this novel integrated intervention may have potential to offer important improvements in clinical and functional outcomes.

1. Introduction

Bipolar disorder (BD) has a prevalence rate of 1–2% [1] and is the sixth leading cause of disability [2], estimated cost to the English economy in excess of £5 billion per annum [3]. BD is likely to be comorbid with alcohol or substance misuse [4], and even at more moderate levels, alcohol use is associated with poorer prognosis and more severe mood disturbance [5]. Whilst psychological treatments for relapse in BD are shown to be effective, cost effective and popular with services users [6], there is no established treatment to address alcohol use in BD.

Intervention research for substance use in BD is at an early stage and to our knowledge there are only three published RCTs (and a single open trial) evaluating approaches targeted at this client group [7–10]. Schmitz et al. [7] compared 16 sessions of CBT for BD and substance use with 4 medication monitoring assessments over 3 months. No

differences were observed in substance use but participants in the CBT group experienced fewer days with depression or mania symptoms. Three other published studies from Weiss and colleagues [8–10], report the development and evaluation of an integrated group therapy (IGT) for people with BD and substance use. They found that 20 sessions of IGT led to better substance use outcomes but worse mood outcomes whereas a 12 session version of IGT led to both better substance use and mood outcomes (both compared with group drug counselling) [9] [10].

Although promising, Weiss's [8–10] research only included individuals who were treatment seeking for both BD and substance use. As ambivalence is common in BD and linked to substance use, this approach risks excluding individuals most in need of help [11,12]. Motivational interviewing (MI) offers an established approach to engaging individuals with substance use issues [13,14] and reducing

* Corresponding author. Spectrum Centre for Mental Health Research, Faculty of Health and Medicine, Lancaster University, United Kingdom.
E-mail address: s.jones7@lancaster.ac.uk (S. Jones).

<https://doi.org/10.1016/j.conctc.2018.05.001>

Received 13 September 2017; Received in revised form 5 April 2018; Accepted 2 May 2018

Available online 08 May 2018

2451-8654/ © 2018 Published by Elsevier Inc. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

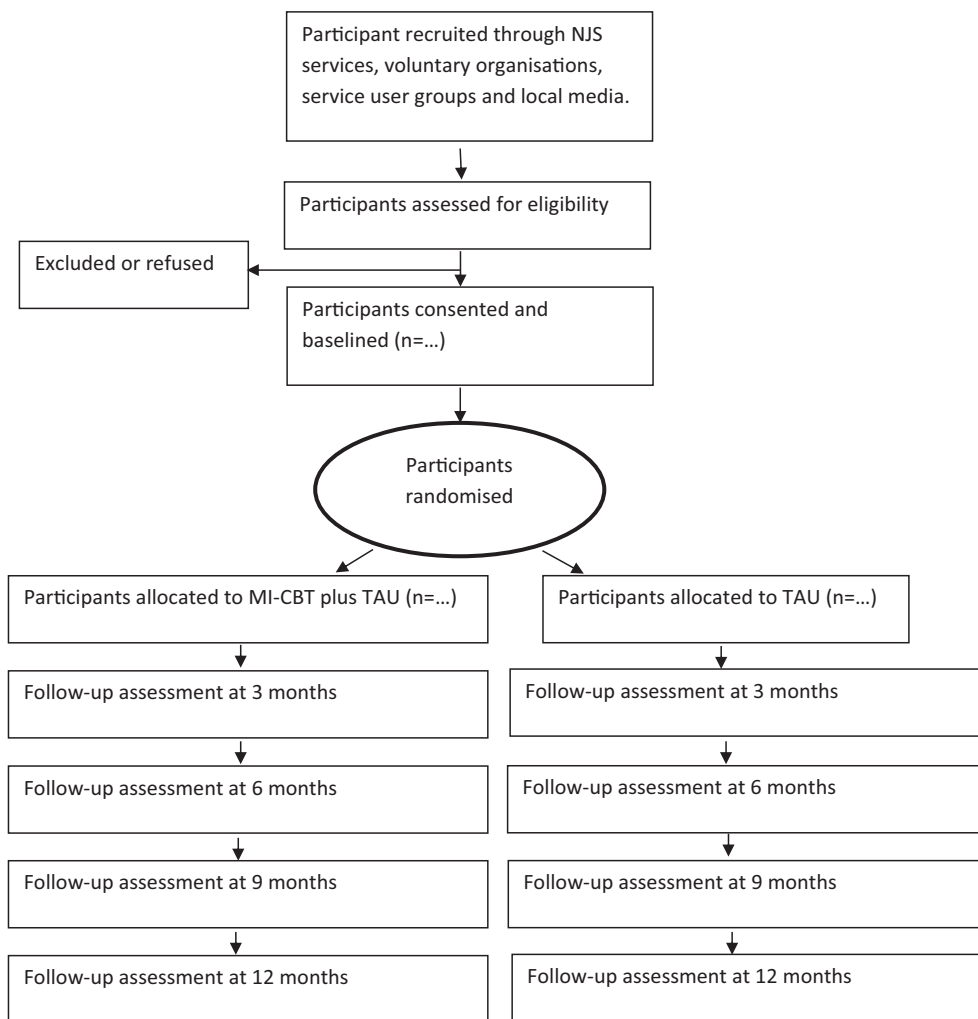


Fig. 1. Diagram showing the design of the study.

treatment ambivalence [15].

This protocol paper describes an RCT to evaluate the feasibility and acceptability of delivering an integrated MI-CBT intervention to individuals with BD who use alcohol. The focus is on BD with comorbid alcohol misuse as it is the most common substance of abuse and research indicates more positive psychological treatment outcomes for alcohol than other substances [9]. The intervention, individually tailored to address idiosyncratic reasons for alcohol use and relationships to mood symptoms in BD [16,17], has been successfully employed in a previous case series study [18].

MI-CBT was developed with the help of individuals with lived experience of both BD and alcohol use issues consistent with the growing recognition of the importance of involving service users in treatment development [19]. As a feasibility and acceptability study the primary outcomes are recruitment to target, adherence to intervention, retention rate at follow-up, absence of adverse events and qualitative analysis of participant experiences of intervention. In addition, the study will provide preliminary evidence of the impact of the intervention with respect to alcohol use and bipolar mood symptoms and relapse as potential primary outcomes for a future definitive RCT.

2. Methods

This RCT is conducted by a multidisciplinary team of researchers, clinicians, statisticians and therapists from academic institutions and NHS trusts in the North West of England. The study was approved by

the UK NHS Ethics Committee process (REC ref: 10/H1014/75).

2.1. Objective

To determine the feasibility and acceptability of an integrated motivational interviewing and cognitive behaviour therapy (MI-CBT) intervention for alcohol use in the context of bipolar disorder compared with treatment as usual.

Main research aims:

- To explore feasibility of recruitment and consenting procedures, adherence to treatment protocol and retention to both arms of the trial across assessment, intervention and follow-up periods. Specific targets are specified in the outcome section below.
- To provide initial parameter estimates of clinical outcomes including alcohol use (both frequency and severity of use), bipolar relapse, mood, social functioning, medication adherence and cost effectiveness.
- To systematically examine acceptability of the intervention from the perspective of service users.

2.2. Trial design

A rater-blind randomised controlled trial which compares up to 20 sessions of integrated MI-CBT for alcohol use in the context of bipolar disorder plus treatment as usual with TAU alone. The trial is based in

Download English Version:

<https://daneshyari.com/en/article/8519315>

Download Persian Version:

<https://daneshyari.com/article/8519315>

[Daneshyari.com](https://daneshyari.com)