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Feasibility randomized controlled trial of cognitive and behavioral interventions for depression symptoms in patients accessing drug and alcohol treatment $\stackrel{\text{trial}}{\xrightarrow{}}, \stackrel{\text{trial}}{\xrightarrow{}}$

Jaime Delgadillo, Ph.D.^{a,*}, Stuart Gore, M.A.^b, Shehzad Ali, Ph.D.^c, David Ekers, Ph.D.^{d,1},

Simon Gilbody, F.R.C.Psych., Ph.D.^e, Gail Gilchrist, Ph.D.^f, Dean McMillan, D.Clin.Psych., Ph.D.^e, Elizabeth Hughes, Ph.D.^g

^a Leeds Community Healthcare NHS Trust, Leeds, United Kingdom

^b St. Anne's Community Services, Leeds, United Kingdom

^c Department of Health Sciences and Centre for Health Economics, University of York, York, United Kingdom

^d Wolfson Research Institute for Health and Wellbeing, Durham University, Stockton on Tees, United Kingdom

^e Hull York Medical School and Department of Health Sciences, University of York, York, United Kingdom

^f Institute of Psychiatry, King's College London, London, United Kingdom

^g University of Huddersfield and South West Yorkshire Partnership NHS Foundation Trust, Huddersfield, United Kingdom

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ABSTRACT

Depressed mood often co-exists with frequent drug and alcohol use. This trial examined the feasibility of screening, recruitment, randomization and engagement of drug and alcohol users in psychological interventions for depression symptoms. A total of 50 patients involved in community drugs and alcohol treatment (CDAT) were randomly allocated to behavioral activation delivered by psychological therapists (n = 23) or to cognitive behavioral therapy based self-help introduced by CDAT workers (n = 27). We examined recruitment and engagement rates, as well as changes in depression (PHQ-9) symptoms and changes in percent days abstinent (PDA within last month) at 24 weeks follow-up. The ratio of screened to recruited participants was 4 to 1, and the randomization schedule successfully generated 2 groups with comparable characteristics. Follow-up was possible with 78% of participants post-treatment. Overall engagement in psychological interventions was low; only 42% of randomized participants attended at least 1 therapy session. Patients offered therapy appointments co-located in CDAT clinics were more likely to engage with treatment (odds ratio = 7.14, p = .04) compared to those offered appointments in community psychological care clinics. Intention-to-treat analyses indicated no significant between-group differences at follow-up in mean PHQ-9 change scores (p = .59) or in PDA (p =.08). Overall, it was feasible to conduct a pragmatic trial within busy CDAT services, maximizing external validity of study results. Moderate and comparable improvements in depression symptoms over time were observed for participants in both treatment groups.

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1. Introduction

There is considerable evidence that common mental health problems like depression and anxiety often co-occur with problematic alcohol and drug use (Marsden, Gossop, Stewart, Rolfe, & Farrell, 2000; Strathdee et al., 2002; Weaver et al., 2003). People who frequently use substances are 2 times at greater risk of having a comorbid depression or anxiety disorder, and this increases to 5 times greater risk for dependent

¹ Requests for a BA treatment manual can be made to: D. Ekers.

http://dx.doi.org/10.1016/j.jsat.2015.02.008 0740-5472/© 2015 Elsevier Inc. All rights reserved. substance users (Merikangas et al., 1998). This combination of problems often complicates treatment and can result in greater functional impairment (Johnson et al., 1995), reduced treatment adherence (Carroll, Power, Bryant, & Rounsaville, 1993; Ford, Snowden, & Walser, 1991), poor health outcomes (Hasin et al., 2002; McKay et al., 2002) and increased risk of suicide (Harris & Barraclough, 1997).

The detection of such comorbid disorders has historically been inconsistent in routine treatment in the United Kingdom (Weaver et al., 2003). Consequently, it has been estimated that only 1 in 5 people (20%) involved with community drugs services tend to access mental health treatment (Marsden et al., 2000). Even if comorbid mental health problems are adequately detected, treatment options for this client group seem to have fairly modest benefits. Pharmacological treatments for depression in alcohol and drug users appear to have mixed evidence, with some reviews that indicate a beneficial effect (Iovieno, Tedeschini, Bentley, Evins, & Papakostas, 2011; Nunes & Levin, 2004) and other reviews that question their efficacy (Lingford-Hughes, Welch, & Nutt,

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^{*} Corresponding author at: LCH NHS Trust, The Reginald Centre, Second Floor, 263 Chapeltown Road, Leeds LS7 3EX, United Kingdom. Tel.:+44 113 843 4388;

fax: +44 113 843 4448.

E-mail addresses: jaime.delgadillo@nhs.net (J. Delgadillo), david.ekers@durham.ac.uk (D. Ekers).

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2012; Pedrelli et al., 2011; Torrens, Fonseca, Mateu, & Farré, 2005). In view of such evidence, exploring the potential of psychological treatments may be a fruitful avenue for research and practice.

Published trials of psychological treatments for depression and anxiety in substance users suggest that cognitive behavioral therapy (CBT) may be an effective treatment (Baillie & Sannibale, 2007; Baker et al., 2010; Brown et al., 2006; Brown, Evans, Miller, Burgess & Mueller, 1997; Hides, Samet, & Lubman, 2010; Hunter et al., 2012; Kay-Lambkin, Baker, Lewin, & Carr, 2009; Kay-Lambkin, Baker, Kelly, & Lewin, 2011; Watkins, Paddock, Zhang, & Wells, 2006; Watkins et al., 2011). There is, however, scarce research on the application of contemporary behavioral activation (BA) models of treatment in clinical populations of substance users. BA is an intervention that alleviates depression by focusing primarily on changing maladaptive behaviors (such as avoidance, rumination, coping strategies that have unintended negative consequences) that are posited to maintain a cycle of low mood (Martell, Addis, & Jacobson, 2001). BA shares some conceptual underpinnings with CBT such as behavior modification and learning theories, but it does not emphasize the direct modification of thoughts and beliefs as in CBT. The efficacy of BA for the treatment of depression in adults has been endorsed by several meta-analyses of clinical trials (Cuijpers, van Straten, & Warmerdam, 2007; Ekers, Richards, & Gilbody, 2008; Ekers et al., 2014; Mazzucchelli, Kane, & Rees, 2009). However, to our knowledge, only one published controlled trial has tested the efficacy of BA with a clinical sample of dependent substance users (Daughters et al., 2008). This trial concluded that augmenting inpatient addiction treatment with BA leads to greater reductions in depression symptoms compared to usual inpatient care.

Considering the prevalence and impact of common mental health problems in drug and alcohol users, and the emerging evidence-base for cognitive and behavioral interventions, we conducted a trial to investigate the feasibility of delivering BA and CBT based guided selfhelp for depression as part of routine community drugs and alcohol treatment (CDAT). Given our focus on feasibility, the study design also aimed to assess whether co-locating BA within CDAT clinics may enhance engagement with therapy, by comparison to offering this intervention in external mental health clinics as in usual practice. This aspect of the trial was informed by policy guidelines (Department of Health, 2002) that promote integration and close partnership work between substance use and mental health professionals. Although this seems like a sensible policy, we are not aware of empirical evidence specifically supporting the co-location of psychological interventions within CDAT settings and we therefore considered it worthy of further investigation.

2. Methods

2.1. Study design

This was a phase I feasibility randomized controlled trial embedded within CDAT services in Leeds, United Kingdom. Consistent with the medical research council (MRC) guidelines for the development of complex interventions (Craig et al., 2008), the central objective was to examine the feasibility of screening, recruitment, randomization and engagement of patients in psychological interventions for depression symptoms. In this context, we defined engagement as having attended at least one therapy session post-randomization. As part of the design, half of the patients assigned to BA were offered appointments in clinics co-located in CDAT services, and the other half were offered appointments in external clinics—which we refer to as 'parallel' care. A secondary objective was to compare the proportion of cases that engaged with treatment in the co-located versus parallel clinics. Finally, we also aimed to estimate comparative effect sizes to inform the sample size calculation for a fully powered efficacy trial.

Ethical approval for this trial was granted by a National Health Service research ethics committee (REC Reference: 12/YH/0096, Registration: ISRCTN26937594).

2.2. Inclusion criteria

Outpatients accessing five CDAT teams were screened for eligibility to take part in the trial. Patients were included if (a) they were currently registered with CDAT and engaged with these services within the last month; (b) they screened positive for clinically significant depression symptoms as defined by the Patient Health Questionnaire (PHQ-9); (c) they had mild-to-moderate symptoms of alcohol or drug dependence as defined by the Severity of Dependence Scale (SDS). Patients who did not meet the above criteria were excluded from the study, as were those who had a current diagnosis of a psychotic, bipolar, or severe anxiety disorder (this was established based on clinical records, screening tools and interview). People who were in treatment but were free from psychoactive substances (abstinent for at least 4 weeks) were excluded as we were interested in assessing how feasible it may be to recruit and to provide psychological treatment to those who were current and recent substance users.

2.3. Screening, recruitment and randomization

A stepwise screening and recruitment method was applied for 18 months, using the following steps:

- (1) All patients currently in treatment in the participating services completed the Treatment Outcomes Profile (TOP) questionnaire as part of regular outcome monitoring.
- (2) Those that screened positive for a possible common mental health problem using the TOP psychological health scale (TOP item 4a) were then immediately screened with more specific depression (PHQ-9), anxiety (GAD-7) and severity of dependence (SDS) questionnaires by their case managers.
- (3) Those who met inclusion criteria based on step 2 were informed about the study by their case manager and consent to be contacted by the study co-ordinator was obtained.
- (4) The contact details of consenting patients were passed on to the study co-ordinator who contacted them to conduct an eligibility and recruitment interview. Informed consent was obtained for participation in the trial at the time of these interviews.

The first 3 steps were conducted in routine practice by the usual case managers and support workers, and step 4 was conducted by the study co-ordinator. The co-ordinator was a researcher with experience in screening and diagnostic assessment, who was not involved in the direct delivery of the trial interventions. In order to minimize the chances that case managers in CDAT teams may be selective about the patients they approached for mental health screening, the study co-ordinator performed regular searches in the clinical database to identify potential participants who had recently completed a TOP questionnaire and who screened positive on TOP item 4a. Electronic reminders were sent (via email and online team calendar) on a weekly basis to case managers to undertake step 2 of the screening method.

Eligible and consenting patients were assigned unique participant codes by the co-ordinator and these codes were then emailed to an independent assistant employed by the National Health Service who performed the random allocation. Randomization was conducted using a computer generated random sequence which was concealed from the clinical teams and the study co-ordinator who undertook recruitment interviews. Participants were either randomized to receive BA or CBT based guided self-help, and this outcome was communicated to clinical administrators who then made contact with participants to offer them a treatment appointment. Outcomes data were collected by the study co-ordinator at 6, 12 and 24 week follow-up to maximize data completeness. This follow-up method ensured that posttreatment outcomes were not collected by the therapists who delivered the intervention. The CONSORT diagram in Fig. 1 summarizes all of the above steps and illustrates the flow of participants through the screening, randomization, treatment and follow-up phases.

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