

This is a repository copy of *Behavioral activation for depression delivered by drug and alcohol treatment workers : a pilot randomized controlled trial.* 

White Rose Research Online URL for this paper: <u>https://eprints.whiterose.ac.uk/185460/</u>

Version: Accepted Version

#### Article:

Pott, S.L., Kellett, S.C., Green, S. et al. (2 more authors) (2022) Behavioral activation for depression delivered by drug and alcohol treatment workers : a pilot randomized controlled trial. Journal of Substance Abuse Treatment, 139. 108769. ISSN 0740-5472

https://doi.org/10.1016/j.jsat.2022.108769

© 2022 Elsevier Inc. This is an author produced version of a paper subsequently published in Journal of Substance Abuse Treatment. Uploaded in accordance with the publisher's self-archiving policy. Article available under the terms of the CC-BY-NC-ND licence (https://creativecommons.org/licenses/by-nc-nd/4.0/).

#### Reuse

This article is distributed under the terms of the Creative Commons Attribution-NonCommercial-NoDerivs (CC BY-NC-ND) licence. This licence only allows you to download this work and share it with others as long as you credit the authors, but you can't change the article in any way or use it commercially. More information and the full terms of the licence here: https://creativecommons.org/licenses/

#### Takedown

If you consider content in White Rose Research Online to be in breach of UK law, please notify us by emailing eprints@whiterose.ac.uk including the URL of the record and the reason for the withdrawal request.



eprints@whiterose.ac.uk https://eprints.whiterose.ac.uk/

### Author's Manuscript

**Note:** This is a pre-print peer reviewed article, accepted for publication on 12.03.22. Please do not copy or share without the author's permission.

**Citation:** Pott, S.L., Kellett, S., Green, S., Daughters, S., & Delgadillo, J. (*in press*). Behavioral activation delivered by drug and alcohol treatment workers: A pilot randomized controlled trial. *Journal of Substance Abuse Treatment*.

### Behavioral activation delivered by drug and alcohol treatment workers: A pilot

## randomized controlled trial

Sophie L. Pott<sup>1</sup>, Stephen Kellett<sup>1,2</sup>, Stuart Green<sup>2</sup>,

Stacey Daughters<sup>3</sup>, & Jaime Delgadillo<sup>1,2</sup>

- 1. Department of Psychology, University of Sheffield, UK
- 2. Rotherham Doncaster and South Humber NHS Foundation Trust, UK
- Department of Psychology and Neuroscience, University of North Carolina at Chapel Hill, USA

*Correspondence:* Sophie L. Pott, Department of Psychology, University of Sheffield, Cathedral Court, Sheffield S1 2LT, United Kingdom

### Abstract

*Background.* One in two patients seeking help for substance use disorders (SUDs) have clinically significant depression symptoms. This co-occurrence impairs treatment outcomes, but there has been limited evaluation of the implementation of evidence-based interventions. *Methods.* This pilot randomised controlled trial (RCT) assessed the feasibility and potential efficacy of a brief, protocol-driven behavioural activation (BA) intervention delivered by drug and alcohol workers in a community drug and alcohol treatment (CDAT) service. Eligible participants (n=34) were randomly allocated to either BA (n = 17) or treatment as usual (n = 17) and assessed at baseline and 6, 12 and 24-week follow-up. Feasibility outcomes were participant engagement and worker protocol adherence. The primary pilot outcome was severity of depression symptoms (PHQ-9) at 12-week follow-up. Secondary outcomes included percent days abstinent (PDA) in the past month, severity of dependence (SDS), anxiety symptoms (GAD-7) and valued living (VQ) at all follow-up points. *Results.* 59% of BA participants attended at least one session and there was 95% adherence to the treatment protocol. BA was associated with significantly reduced depression at 12-week follow-up (PHQ-9 mean difference -5.69, 95% CI -10.07 to -1.31). BA participants had significantly greater improvements in PDA (mean difference 17.9, 95% CI 0.99 to 34.82) and VQ-Progress (mean difference 5.34, 95% CI 1.47 to 9.22) at 6-week follow-up and PDA (mean difference 27.69, 95% CI 4.44 o 50.95) at 12-week follow-up. No significant between-group differences were found at 24-week follow-up. *Conclusion*. BA implemented by drug and alcohol treatment workers in CDAT appears feasible and may add clinical benefit to usual care for SUD patients with elevated depressive symptoms accessing CDAT. Fully powered RCTs are warranted to better investigate the replicability of these preliminary findings. Methodological limitations are discussed and suggestions for future research are provided.

**Keywords:** Behavioral Activation; Depression; Substance Use Disorder; Alcohol; Drugs; Treatment

#### 1. Introduction

Up to 55% of patients accessing treatment for SUDs have clinically significant depression symptoms (Johnson et al., 2006; McKetin et al., 2011) and this comorbidity tends to suppress treatment outcomes (Najt et al., 2011). SUD patients with elevated depressive symptoms often have greater social and functional impairment, poorer physical health, engage in riskier substance use behaviours and are less likely to adhere to interventions offered (Havard et al., 2006; Teesson et al., 2008). Although treatment guidelines recommend treating both problems concurrently (Public Health England, 2017), testing and implementation of evidence-based psychological interventions have been slow to occur (Clark et al., 2008; Recovery Partnership, 2017). In the UK, systemic constraints mean that most treatment services are only equipped to manage patients' primary need and there tends to be a lack of mental health support available to patients who are accessing drug and alcohol treatment (Turning Point, 2016). Investigating ways of improving access to appropriate psychological therapies is therefore an important priority for this patient group.

Cognitive behaviour therapy (CBT) is the most commonly delivered and empirically supported psychological treatment for both depression (Cuijpers et al., 2016; David et al., 2018) and SUDs (Carroll & Kiluk, 2017), but there is limited evidence for the effectiveness of CBT when SUD co-occurs with depression (Vujanovic et al., 2017). Given that SUD patients are more likely to present with cognitive impairments (Bruijnen et al., 2019) and low literacy (Degan et al., 2019), the complex cognitive components of CBT may be inappropriate for some patients. Moreover, CBT requires a considerable degree of therapist competency (Easden & Fletcher, 2020) and the costs associated with training and employing therapists may limit widespread implementation in drug and alcohol treatment. Indeed, many extant evidence-based interventions are delivered sub-optimally in SUD treatment (e.g. Best et al., 2009) and this has been attributed to organisational constraints such as lack of funding and high staff caseloads (Black, 2021). Therefore, investigation of alternative psychological approaches that are less complicated to deliver and for patients to engage with is warranted, as such treatments are likely to be more easily disseminated in routine services.

A potentially viable psychological treatment option when SUD co-occurs with depression is behavioural activation (BA). BA is based on behavioural theory (Ferster, 1973; Lewinsohn, 1974), which posits that depression occurs when response-contingent reinforcement for healthy non-depressive behaviours is low, in comparison to reinforcement for maladaptive, depressive behaviours. Treatment has evolved from earlier activity scheduling formats (Rehm, 1984), to later versions of contextual BA (Martell, Addis & Jacobson, 2001) and BA treatment for depression (BATD; Lejuez et al., 2011) which place greater emphasis on value-driven behaviour change. Several meta-analyses have established that BA is an effective standalone treatment for depression [Cuijpers et al., 2007; Dimidjian & Davis, 2009; Ekers et al., 2014; Simmonds-Buckley et al., 2019). The simple treatment principles of BA also facilitate application across a wide range of patients (e.g. Dimidjian et al., 2011; Jahoda et al., 2005) again potentially making it feasible for implementation in busy SUD treatment settings.

Consistent with behavioural theory, SUDs have been associated with a lack of reinforcement for alternative, healthy behaviours (Carroll, 1996; Vuchinich & Tucker, 1988). Both depression and SUDs are associated with health and social problems and these may increase the frequency of negative experiences and reduce the availability of alternative sources of reward, leading to the repetition of maladaptive (e.g. addictive, avoidance) behaviours, as well as increases in depressive symptoms (Carvahlo & Hopko, 2011). The focus of BA treatment for SUD patients with depressive symptomatology is therefore to increase engagement in healthy, positively reinforcing activities and decrease maladaptive behaviours, in order to address depression symptoms and substance use simultaneously (Daughters et al., 2016). Key treatment components typically include self-monitoring of mood and behaviours followed by identification and continued activation of valued activities.

Activation of valued activities is a core component of modern BA therapies (Lejuez et al., 2011; Martell et al., 2001) and emerging evidence suggests that increases in valued living are associated with reductions in depression symptoms (Bramwell & Richardson, 2019). Problematic substance use is associated with a lack of meaning in life (Copeland et al., 2020). Therefore, an intervention focused on increasing and sustaining engagement in valued activities could contribute to reductions in both depression and substance use in patients with co-occurring SUDs

and elevated depressive symptoms. Research has also indicated that BA may contribute to reductions in anxiety symptoms (Hopko et al., 2016), which commonly co-occur and complicate treatment in depressed SUD patients (Delgadillo et al., 2013).

Results of recent systematic reviews and meta-analyses have suggested that BA holds promise as a treatment for SUD patients with elevated depression symptoms (Martínez-Vispo et al., 2018; Pott et al., 2021). A narrative review by Martínez-Vispo et al. (2018) compiled evidence from six RCTs and two practicebased studies and found that BA led to improvements in depression symptoms in six studies and reductions in substance use in seven studies. A recent meta-analysis of five RCTs found no significant differences between BA and comparator conditions, although BA was found to be an acceptable treatment and the direction of results favoured BA at follow-up (Pott et al., 2021). Both of these reviews have called for more controlled research. Yet a key issue with existing RCTs of BA for SUD patients is that they have not adequately reflected the conditions under which the intervention might be delivered in routine care. For example, BA has been compared to active treatments that are not routinely offered (e.g. structured relaxation, CBT-based guided self-help; Carpenter et al., 2008; Delgadillo et al., 2015) and gualified mental health therapists have been enlisted to deliver BA (Carpenter et al., 2008; Daughters et al., 2018; Daughters et al., 2008; Delgadillo et al., 2015), which as previously noted is unlikely to be feasible in routine treatment. This may contribute to a research-practice gap which further delays the timely implementation of evidencebased interventions for SUD patients. The potential impact of future trials would be maximized by investigating BA in the closest possible manner to an SUD treatment context with those practitioners most likely to be involved in the delivery of BA in real-world service settings. This would balance internal validity (well controlled studies) with external validity (studies conducted in routine settings).

SUD patients are more likely to access mental health support when it is integrated into routine addictions treatment (Delgadillo et al., 2015) and drug and alcohol treatment workers are capable of delivering evidence-based mental health interventions effectively (Hepner et al., 2011). In addition to being a potentially effective treatment for SUD patients with comorbid depression symptoms, BA appears to be well-suited for delivery by non-specialist practitioners in resource-

limited settings such as Community Drug and Alcohol Treatment (CDAT). Minimal training and supervision is required to deliver BA (Ekers et al., 2011) and several high-quality studies evidence effective delivery by non-specialist practitioners (Ekers et al., 2014). Training drug and alcohol treatment workers to deliver BA is therefore a valuable means of testing the feasibility of this therapy for SUD patients.

To summarise, despite the health and economic costs of co-occurring depression and SUDs, testing and implementation of evidence-based psychological interventions for this group have been limited. No previous studies have explored the feasibility and potential clinical utility of BA when delivered by drug and alcohol workers in a CDAT setting. Given that patients are more likely to access mental health support when it is delivered in drug and alcohol treatment services (Delgadillo et al., 2015), along with evidence that BA can be delivered effectively with minimal training and supervision (Ekers et al., 2011), this represents a novel and clinically relevant area of inquiry. The present study therefore aimed to test the feasibility and pilot the potential efficacy of a brief, protocol-driven BA intervention facilitated by drug and alcohol treatment workers as part of routine care in CDAT. This study used a randomised controlled trial method that compared BA to treatment as usual (TAU). The clinical value of pilot trials is widely recognised (Leon et al., 2011). In terms of feasibility outcomes, we report on therapist adherence to the BA protocol and the acceptability of BA delivered by drug and alcohol treatment workers in terms of patient attendance and dropout rates. In terms of pilot outcomes, we report on clinical outcomes. We hypothesised that relative to patients accessing TAU, the BA + TAU group would demonstrate greater improvements in depression (primary outcome), substance use, anxiety and valued living outcomes (secondary outcomes).

#### 2. Methods

#### 2.1. Design and Setting

This was an open-label, two-arm (BA versus TAU), pragmatic, pilot randomised controlled trial that complied with CONSORT recommendations (Grant et al., 2018) (see supplemental file for CONSORT checklist). The study was approved by York research ethics committee (REC Reference: 247888) and the trial protocol pre-

registered with the Clinicaltrials.gov database (NCT03661580). The study was embedded within a CDAT service in Doncaster, a large and socioeconomically diverse town in South Yorkshire, United Kingdom. Doncaster is one of the most deprived districts in England, with rates of health and life expectancy generally lower than the England average (State of Health, 2019). The CDAT is staffed by professionals with diverse experiences and professional backgrounds, including nursing, social work, lived experience of addiction and national vocational qualification (NVQ) in SUD treatment. The primary feasibility outcomes were attendance and protocol adherence. The primary clinical outcome was severity of depression symptoms at 12-week follow-up. Secondary objectives of the study were to investigate the effects of BA on depression, substance use, anxiety and valued living outcomes at all follow-up points. Primary and secondary clinical outcomes for the trial were assessed at baseline and 6-, 12- and 24-week follow-up.

#### 2.2. Inclusion Criteria

Patients accessing the CDAT service were screened for eligibility and included if they were; (1) aged 18-65; (2) currently registered with the CDAT service and had engaged with the service within the last month; (3) screened positive for clinically significant depression symptoms as defined by a score of > 12 on the PHQ-9 (Kroenke et al., 2001); (4) had mild-to-moderate severity drug dependence, as defined by a score of < 10 on the SDS (Gossop et al., 1995); (5) had used alcohol or illicit drugs within the last month and/or were prescribed medically-assisted treatment (MAT) for opiate use. Patients were excluded from the study if they reported active suicidality, had a diagnosis of a psychotic, bipolar, or severe anxiety disorder, were already accessing psychotherapy or were unable to read and write. Details of all measures used for screening and follow-up are provided in section 2.7.

#### 2.3. Screening, recruitment, randomisation and follow-up

Screening and recruitment took place from September 2018 to March 2020. The stepwise screening and recruitment strategy employed was based on the methods used in a previous trial of BA for depression in UK CDAT services (Delgadillo et al.,

2015). The approach consisted of the following steps: (1) patients accessing the CDAT service completed the Treatment Outcomes Profile (TOP) questionnaire as part of routine outcome monitoring; (2) patients that screened positive for a possible mental health problem using the TOP psychological health scale (score < 12 on TOP item 4a) were informed about the study by their drug and alcohol treatment worker, and asked for permission to pass their details to the study co-ordinator; (3) the study co-ordinator then contacted consenting patients to conduct an eligibility and recruitment interview and (4) eligible participants provided informed consent either at the time of the recruitment interview or by post. Eligible and consenting patients were assigned unique participant codes by the study co-ordinator and randomised by an independent administrator at the University of Sheffield. Randomisation was conducted sequentially using a computer-generated random sequence concealed from the study co-ordinator who conducted the screening interviews. The study coordinator notified participants of their treatment allocation and administered all followup assessments. The CONSORT diagram (Figure 1) summaries the procedures outlined above and illustrates the flow of participants throughout the study.

### 2.4. Adverse Events

An adverse event reporting procedure was in place such that patients who reported any intention to harm themselves or others at screening, follow-up assessments or during treatment would be promptly referred for appropriate support via the normal CDAT service risk management protocol.

### 2.5. Treatment as Usual (TAU)

All patients accessing the service had an initial assessment including a risk management plan, a personalised care plan which lays out a structure of keyworking appointments and prescribing appointments for those who required MAT. All participants received TAU and this was delivered by drug and alcohol treatment workers and consisted of scheduled, structured 60-minute one-to-one key-working sessions every 2-4 weeks. TAU was delivered by 55 drug and alcohol treatment workers (65% female) for the duration of the study. Patients in the CDAT service were assigned to drug and alcohol treatment workers based on worker availability and patient complexity, with patients who had a higher degree of complexity being assigned to more experienced workers. TAU was based on the cycle of change model (Prochaska & DiClemente, 1983), informed by national treatment guidelines which advocate the layering and phasing of interventions according to the stage of change (Department of Health, 2017). All interventions aimed to enhance patient motivation to reduce harms associated with substance use and to create change. Key-working sessions generally covered: current drug or alcohol use, screening, harm reduction or relapse prevention. Workers conducting these sessions drew upon a number of theoretical frameworks, including node-link mapping, social identity mapping, motivational interviewing, and the identification of support networks to support recovery using the CHIME (connection, hope, identity, meaning, empowerment) process (Leamy et al., 2011). Structured group-work focusing on several aspects of health (substance use, mood) and lifestyle (employment, hobbies, social networks) were also made available to those who chose to engage with this.

#### 2.6. BA Intervention

BA is a structured, activity-scheduling intervention designed to increase engagement in rewarding activities. The BA protocol used in this study was an outpatient version of the LETS ACT protocol (Daughters et al., 2016) modified for delivery on a 1:1 basis. Key treatment strategies include psychoeducation, self-monitoring of mood and daily activities, identifying and scheduling valued activities and problem-solving around implementing scheduled activities. BA treatment consisted of weekly 1-hour sessions for six weeks, followed by two optional booster sessions delivered up to six weeks' post-treatment (see supplemental file for full outline of session content).

#### 2.6.1. BA Therapists

BA treatment was provided by drug and alcohol treatment workers (1 male, 4 females) with no formal psychotherapeutic qualifications or experience. Workers were aged between 28-55 (M= 42.4, SD= 11.5) and had worked in CDAT services for 1-15 years (M= 4.4, SD= 5.41). All workers had completed at least further education (A-levels or equivalent) and one was a registered nurse. Therapists received three days of face-to-face training in BA, comprising 20 hours in total.

Training was focused on the rationale and skills required to deliver the 8-session BA treatment protocol (LETS ACT). It included sections on behavioural learning theory and its application to depression and substance use and the development of specific techniques used in sessions. Training was delivered by the developer of the LETS ACT protocol (SD) and authors (JD & SK) utilising a combination of didactic teaching, demonstration and role-playing exercises. Each therapist attended one hour of monthly clinical group supervision facilitated by a BABCP accredited cognitive behavioural psychotherapist.

### 2.6.2. BA Therapist Adherence

Therapist adherence to the BA treatment protocol was assessed via checklists highlighting specific session objectives (see supplemental file). Checklists were completed by therapists at the end of each session.

## 2.6.3. Participant Engagement with BA

Participants who failed to attend at least three BA sessions were classified as having dropped out of treatment and were not offered any further sessions. This approach was primarily chosen to minimise burden on therapists and also ensured that BA participants who completed treatment had received core components of the BA therapy; activity monitoring, values assessments and activity scheduling.

# 2.7. Measures

# 2.7.1. Depression

The Patient Health Questionnaire (PHQ-9) (Kroenke et al., 2001) was used to screen for depression symptoms and as a primary outcome measure. This 9-item self-report questionnaire is based on the Diagnostic and Statistical Manual (DSM-IV) diagnostic criteria for major depressive disorder. Each item is rated on a 0 to 3 scale relating to the frequency of depressive symptoms over the past 2 weeks (0 = "not at all", 3 = "nearly every day"). Scores range from 0 to 27 with higher scores indicating greater severity of depression. A cut-off score of > 12 has been found to reliably detect the presence of a current depressive episode in patients accessing treatment for SUDs (Delgadillo et al., 2011). The current study found good internal consistency ( $\alpha$  = 0.86)

### 2.7.2. Percent Days Abstinent (PDA)

The Treatment Outcomes Profile (TOP) is a validated questionnaire that is routinely used for outcome monitoring in UK CDAT services (Public Health England, 2019). It contains a brief psychological health scale (TOP item 4a) which has been established as a valid and reliable case-finding measure for common mental health disorders in patients accessing treatment for SUDs (Delgadillo et al., 2012). The TOP also captures information about substance use during the last 4-week period using the timeline follow-back method (Sobell & Sobell, 1992), which was used to calculate Percent Days Abstinent (PDA) in the past month.

### 2.7.3. Severity of Dependence

The Severity of Dependence Scale (SDS) (Gossop et al., 1995) was used to screen for psychological dependence and as a secondary outcome measure for substance use. This 5-item scale has been widely validated as a case-finding measure for SUDs (Castillo et al., 2010; Lawrinson et al., 2007). Scores range from 0-15, with a score of 0 to 10 indicating mild-to-moderate psychological dependence. The current study found good internal consistency for this scale ( $\alpha = 0.80$ )

# 2.7.4. Anxiety

Given the prevalence of anxiety disorders in patients with comorbid depression and SUDs (Delgadillo et al., 2016) and evidence that BA may have a beneficial effect on anxiety symptomatology (Hopko et al., 2004), anxiety symptoms were monitored using the GAD-7 questionnaire (Spitzer et al., 2006). This 7-item self-report questionnaire has been established as a valid and reliable case-finding measure for anxiety disorders in patients accessing treatment for SUDs (Delgadillo et al., 2012). Each item is rated on a 0 to 3 scale representing the frequency of anxiety symptoms over the past 2 weeks (0 = "not at all", 3 = "nearly every day"). Scores range from 0 to 21 with higher scores indicating greater severity of anxiety. Internal consistency was good in the current study ( $\alpha$  = 0.83)

# 2.7.5. Valued Living

Engaging in valued activities is a core component of modern BA therapies (Lejuez et al., 2011; Martell et al., 2001) and emerging evidence suggests that increases in valued living are associated with reductions in depression symptoms (Bramwell &

Richardson, 2019). Given the limitations of domain-specific valued living measures (e.g. VLQ; Wilson et al., 2010), valued living was measured in the present study using the recently developed Valuing Questionnaire (VQ; Smout et al., 2014). This domain-general, 10-item self-report measure consists of two subscales assessing progress in valued living and obstructions to valued living in the past 2 weeks. Each item is rated on a 0 to 6 scale (0 = "not at all true", 6 = "completely true") and scores for each subscale range from 0 to 30, with higher scores indicating greater progress or greater obstructions to valued living respectively. This measure has demonstrated good validity and reliability in clinical samples (Carvalho et al., 2018). The current study found a moderate negative correlation between the Progress and Obstruction subscales (r = -.41, p < 0.001). Internal consistency was good for the Progress subscale ( $\alpha = 0.85$ ) and acceptable for the Obstructions subscale ( $\alpha = 0.70$ ).

### 2.8. Power analysis

An *a priori* power analysis indicated that a sample of 128 patients (64 per group) would provide 80% power to detect a medium effect size (d = 0.5) using independent groups ANOVA with a significance level of p = 0.05 (Cohen, 1992). However, as a pilot trial, the overall goal of this study was to recruit as many participants as viable within a two-year period, and to report preliminary effect sizes and indices of engagement with the BA treatment.

#### 2.9. Statistical analysis

### 2.9.1. Data pre-processing and preliminary analyses

Baseline differences between treatment groups were assessed using t-tests for continuous variables and chi-square tests for categorical variables. Regression analyses to explore predictors of BA treatment completion were not feasible due to small sample size. Spearman's and point-biserial correlation analyses were used to examine relationships between baseline scores and demographics and BA treatment completion. Missing values constituted 18% of the dataset and analyses indicated that these values were missing completely at random (MCAR; Little, 1988). Data were imputed in IBM SPSS statistics 26 using the Monte Carlo Markov Chain

(MCMC) method (Gilks et al., 1996). Reported results utilise the full imputed dataset and do not differ markedly from the results obtained with missing data (see supplemental file for analyses with missing data).

#### 2.9.2. Primary analysis

Primary analysis was conducted using an intention-to-treat (ITT) approach. An independent-groups analysis of covariance (ANCOVA) was used to compare group differences in post-treatment depression (PHQ-9), controlling for baseline severity, at the 12-week follow-up point which constituted the end of acute-phase treatment (6 sessions) and any additional booster sessions (up to 2).

#### 2.9.3. Secondary analyses

Further ITT ANCOVAs were applied to compare between-group differences in all measures (PHQ-9, PDA, SDS, GAD-7 and VQ subscales) at 6-, 12- and 24-week follow-up points. Scores on the outcome measure were taken as the dependent variable in ANCOVA models, with group entered as the fixed factor and baseline scores on the corresponding measure entered as the covariate. Conventional assumptions for ANCOVA analyses were established using formal tests of homogeneity of variance and inspection of residual plots. Effect sizes were calculated and reported using Cohen's d, where 0.2 indicates a small effect, 0.5 indicates a medium effect and 0.8 represents a large effect (Cohen, 1988). Secondary analyses were conducted with a treatment completer sample. For treatment completer analyses, non-parametric Mann Whitney U tests were conducted to account for the small sample size. Reliable and clinically significant improvement (RCSI) rates were calculated for PHQ-9 scores at 12-week follow-up using Jacobson and Truax's (Jacobson & Truax, 1991) method. RCSI rates were based on a PHQ-9 reliable change index of >7 and cut-off of <12 appropriate for clinical samples of drug and alcohol users (Delgadillo, 2012). Chi-square analysis was used to compare between-group RCSI rates.

#### 3. Results

As shown in Figure 1, a total of 1271 patients were identified as being potentially eligible to participate in the trial based on TOP psychological health scores (<12). Of

these patients, 146 were referred for study screening and 34 eligible participants consented to take part in the trial.

#### 3.1. Sample Characteristics

Baseline demographics and clinical characteristics of the overall sample and each treatment group (BA and TAU) are summarised in Table 1. Mean age was 42.3 (SD = 6.5) and the majority were White British (97.1%), male (73.5%) and unemployed (85.3%). A higher proportion of females were allocated to BA than TAU (p = 0.017), but no other significant differences were found between the treatment groups for any of the demographic or clinical variables. Most participants were accessing treatment for opiate dependence (76.5%) and more than half reported poly-drug use (61.8%). The most commonly used substances in the past month were heroin (50%), crack cocaine (47.1%) and alcohol (32.4%). Most participants were prescribed MAT for opiate use (76.5%) and almost half of the sample reported taking prescribed antidepressant medication (47.1%). No adverse events were reported during the course of the study. Mean intake score on the PHQ-9 was 18.65 (SD = 3.95) which denotes moderately severe depression symptoms (Kroenke et al., 2001). The mean score on the GAD-7 was 14.47 (SD = 4.39) representing moderate levels of anxiety (Spitzer et al., 2006). Mean SDS score at baseline was 6.21 (SD = 2.78), indicating a moderate degree of psychological dependence (Gossop et al., 1995). Mean PDA at baseline was 50.01 (SD = 36.83).

#### 3.1. Feasibility; Participant Engagement

As shown in Figure 1, of the 17 participants randomly assigned to TAU, only 1 dropped out of treatment in the CDAT service. None of the 17 participants in the BA condition dropped out of CDAT during their involvement in the study. Of those randomised to the BA group, 10 participants (59%) attended at least one session, and 7 participants (41.2%) completed the intervention (defined as attending at least 3 sessions). Those who completed BA attended a mean number of 5.6 sessions (SD = 1.8, mode = 4). Correlation analyses indicated that participants were more likely to complete BA treatment if they were in employment,  $r_s(15) = 0.55$ , p = 0.021, and reported more days abstinent at baseline,  $r_{pb}(15) = 0.53$ , p = 0.028. No other

demographic or clinical variables were significantly associated with BA treatment completion.

#### 3.2. Feasibility; BA Therapist Adherence

The average adherence rate to the BA treatment protocol was 95% (range 83.7%-100%), indicating a high level of therapist adherence to the BA treatment protocol.

#### 3.3. Primary Depression Outcome

As shown in Table 2, there was a significantly greater reduction in depression (PHQ-9) in the BA condition compared to TAU at 12-week follow-up (F(1,31) = 7.03, p =0.039). The mean difference of -5.69 (95% CI -10.07 to -1.31) at this time point reflects a large between-groups effect size (d = 0.95) favouring BA. There were no significant differences between BA and TAU at 6- or 24-week follow-up. Baseline PHQ-9 scores significantly predicted changes in depression symptoms at all followup points: 6-week, F(1,31) = 12.62, p = 0.001; 12-week, F(1,31) = 6.53, p = 0.016and 24-week, F(1,31) = 11.41, p = 0.002. Between-group analyses conducted with the treatment completer sample were consistent with results obtained from ITT analyses. At 12-week follow-up, PHQ-9 scores in BA treatment completers (mean rank = 5.14) were significantly lower than in TAU (mean rank = 15.53), U = 8, z = -1003.277, p = 0.001. No significant differences in depression symptoms were found at 6or 24-week follow-up, although group differences between BA treatment completers (mean rank = 8.14) and TAU (mean rank = 14.29) did approach significance at 6week follow-up (U = 29, z = -1.949, p = 0.051). As shown in Figure 2, no TAU participants and seven BA participants (41.2%) met criteria for RCSI at 12-week follow-up and this difference was statistically significant according to Fisher's exact test (p = 0.007). In the treatment completer sample, five BA participants (71.4%) met criteria for RCSI at 12-week follow-up (p < 0.001). At 24-week follow-up, three TAU participants (17.7%) and five BA participants (29.4%) met criteria for RCSI (see figure 3), including three BA participants (30%) in the treatment completer sample. Differences between groups were not statistically significant.

#### 3.4. Secondary Substance Use Outcomes

### 3.4.1. Percent Days Abstinent (PDA)

The number of days abstinent had differentially increased in the BA group by 6-week (F(1,31) = 4.66, p = 0.039) and 12-week follow-up (F(1,31) = 5.9, p = 0.021). As shown in Table 2, the mean difference of 17.9 (95% CI 0.99 to 34.82) at 6-week follow-up reflects a large between-groups effect size (d = 0.78) favouring BA. The mean difference of 27.69 represents a large effect size of d = 0.87 in favour of BA at 12-week follow-up. No significant main effects were found for treatment group at 24-week follow-up. Baseline PDA significantly predicted changes in PDA at 6-week, (F(1,31) = 12.62, p = 0.001) and 24-week follow-up (F(1,31) = 11.41, p = 0.007), but not at 12-week follow-up. Analyses with the treatment completer sample produced similar results. At 6-week follow-up, PDA was significantly higher in BA treatment completers (mean rank = 18) compared to TAU (mean rank = 10.24), U = 98, z = 2.465, p = 0.013. At 12-week follow-up, PDA was significantly higher in the BA treatment completers (mean rank = 18.07) compared to TAU (mean rank = 10.21), U = 98.5, z = 2.502, p = 0.011. No significant difference in PDA was found between BA treatment completers and TAU participants at 24-week follow-up.

#### 3.4.2. Severity of Dependence (SDS)

No significant differences were found in severity of dependence between BA and TAU after controlling for baseline SDS scores using ITT ANCOVAs. Baseline SDS scores significantly predicted changes in severity of dependence at 12-week follow-up (F(1,31) = 14.22, p = 0.001), but not at 12- or 24-week follow-up. No significant differences were found between groups using the treatment completer sample.

### 3.5. Anxiety (GAD-7)

There were no significant differences between BA and TAU on anxiety outcomes at any time point. Baseline GAD-7 scores significantly predicted changes in anxiety symptoms at 6-week (F(1,31) = 11.31, p = 0.002) and 24-week follow-up (F(1,31) =18.17, p < 0.001), but not at 12-week follow-up. No significant differences were found between groups using the treatment completer sample, although group differences in anxiety symptoms between BA (mean rank = 8.21) and TAU (mean rank = 14.26) did approach significance at 12-week follow-up (U = 29.5, z = -1.915, p = 0.055), suggesting that anxiety symptoms decreased more in BA treatment completers than in the TAU group.

### 3.6. Valued Living (VQ)

#### 3.6.1. Progress in Valued Living (VQ-Progress)

Progress in valued living had differentially increased in the BA group at 6-week follow-up (F(1,31) = 7.9, p = 0.008). The mean difference of 5.34 (95% CI 1.47 to 9.22) represents a large between-groups effect size of d = 1.0 favouring BA. No significant main effects were found at 12 or 24-week follow-up. Baseline VQ-Progress scores significantly predicted changes in valued living progress at 6-week, F(1,31) = 10.95, p = 0.002, and 12-week follow-up, F(1,31) = 35.16, p < 0.001, but not at 24-week follow-up. Between-group analyses with the treatment completer sample indicated that VQ-Progress scores were significantly higher in BA treatment completers (mean rank = 18.07) compared to TAU (mean rank = 10.21) at 6-week follow-up (U = 98.5, z = 2.491, p = 0.011). At 12-week follow-up, VQ-progress scores were again significantly higher (U = 93, z = 2.135, p = 0.34) in BA treatment completers (mean rank = 17.29) compared to TAU (mean rank = 10.53), U = 93, z = 2.135, p = 0.34. No significant difference was found between TAU and BA treatment completers at 24-week follow-up.

#### 3.6.2. Obstructions to Valued Living (VQ-Obstruction)

ITT analyses found no significant differences between treatment groups and baseline VQ-Obstruction scores did not significantly predict changes in obstructions to valued living at any of the follow-up points. No significant differences were found between groups using the treatment completer sample.

#### 4. Discussion

This pragmatic pilot randomised controlled trial examined the feasibility and clinical outcomes of BA facilitated by drug and alcohol treatment workers for patients with elevated depression symptoms who are accessing CDAT. The findings indicate that

drug and alcohol treatment workers may be capable of delivering a brief BA intervention (LETS ACT!) in routine care, although BA appears to be less suitable for patients who exhibit a higher degree of clinical complexity. In terms of the primary outcome, BA delivered in adjunct with usual care had a differentially beneficial effect on depression symptoms at 12-week follow-up. BA was also associated with differentially significant improvements in PDA and progress in valued living at 6-week follow-up and significant improvements in PDA at 12-week follow-up compared with TAU participants. Group differences were no longer evident by 24-week follow-up and BA had no significant effects on anxiety symptoms or severity of dependence. These findings add to the growing body of evidence regarding the potential efficacy of BA for SUD patients with elevated depressive symptoms (Martínez-Vispo et al., 2018; Pott et al., 2021) and suggest that BA is a transferable therapy in this context.

### 4.1. Therapist Adherence to BA

Therapist adherence to the BA protocol was high. This finding is consistent with studies showing that drug and alcohol treatment workers in residential treatment can generate good levels of adherence and competence when delivering CBT for patients with depression (Watkins et al., 2011). It also adds to the growing empirical evidence base which supports the dissemination of evidenced based psychological therapies by non-specialist practitioners (Barbui et al., 2020; Ekers et al., 2014).

### 4.2. Acceptability of BA

There was a high level of attrition in the BA group. The observed dropout rate of 59% is similar to previous trials of BA in CDAT settings. A study by Carpenter et al. (2008) reported a dropout rate of 50% and Delgadillo et al. (2015) reported a dropout rate of 65% for BA. However, these studies notably implemented less stringent criteria in terms of excluding patients who did not engage. In order to minimise burden on therapists, patients in the present study were only offered up to three opportunities to attend their first BA appointment and were not offered any further sessions if they missed a total of three treatment sessions. 41% of participants in the present study never attended any BA sessions, but the majority of patients who attended at least

one session went on to complete BA treatment (i.e. attended at least three sessions).

Patients were more likely to complete treatment if they were in employment and reported lower frequency of substance use at baseline. There was no evidence that engagement was associated with poly-drug use as reported in a previous study in this setting (Delgadillo et al., 2015). However, it is likely that being in employment and using a lower level of substances are similar markers of stability. Patients who are using less substances may be leading less chaotic lifestyles as a result of engaging in lower drug-seeking behaviours and spending less time intoxicated. Likewise, those who are in employment would be expected to have an existing degree of routine and stability in their lives which may facilitate engagement with structured interventions like BA.

Attendance was relatively high among patients who completed BA treatment, indicating that BA delivered by drug and alcohol workers was acceptable to the patients who were ready to engage. Analyses with 'treatment completers' did not change the pattern of results. However, 'treatment completers' were more likely to demonstrate clinically significant changes in depression symptoms (74%), which is consistent with previous research highlighting the importance of engagement for improving treatment outcomes (Cahill et al., 2003).

#### 4.3. Contextualising the clinical outcomes

BA participants reported lower depression symptoms compared to TAU participants across all follow-up points. This finding is comparable with a previous trial of the LETS ACT protocol with depressed patients in residential treatment (Daughters et al., 2008). The between-group effect size at 12-week follow-up (d = 0.95) was large and consistent with the effect size reported in Daughters' et al.'s (2008) study of 44 patients at 2-week follow-up (d = 0.91). It is also much larger than the aggregated effect size for depression symptoms reported in a meta-analysis of 1271 patients which focused on trials of integrated CBT and motivational interviewing versus TAU (g = 0.27) (Riper et al., 2014). Moreover, 41.2% of BA participants in the present study demonstrated clinically significant improvements in depression symptoms, which is substantially higher than the recovery rates reported for BA (11.8%) in a

similar trial conducted in CDAT with a sample of 48 participants (Delgadillo et al., 2015).

PDA outcome in this study provides preliminary support for the application of behavioural theory to SUDs. BA participants reported higher PDA, indicating a lower frequency of substance use compared to TAU participants at all follow-ups. Previous research has demonstrated that SUD patients who receive BA are more likely to report abstinence and a reduction in negative consequences from substance use up to 1-year post treatment (Daughters et al., 2018). Consistent with the expected association between substance use and depression, PDA appeared to correspond with severity of depression symptoms in both treatment groups. No significant results were found for severity of dependence in the present study. However, participants with severe psychological dependence were excluded from participation which likely explains the lack of significant effects for this outcome.

The finding that BA was associated with increases in valued living is consistent with core treatment components of LETS ACT (Daughters et al., 2016) and other contemporary BA therapies, which focus on identifying and increasing engagement in valued activities. Lack of meaning in life has been associated with problematic substance use (Copeland et al., 2020; Csabonyi & Phillips, 2020) and depressive symptoms are negatively related to progress in valued living (Bramwell & Richardson, 2019; Smout et al., 2014). These findings, along with the preliminary results from the present study, suggest that closing the values-behaviour gap may be an important treatment target for patients with comorbid depression and SUDs.

Consistent with a previous trial of BA with depressed SUD patients (Daughters et al., 2008), no significant group differences were found for anxiety symptoms. It has been suggested that BA may have beneficial effects on anxiety via increasing approach behaviours (Hopko et al., 2006). However, some studies have reported a significant effect of BA on anxiety symptoms (Hopko et al., 2016), while others have failed to find an effect (Hopko et al., 2005). Therapists in the current study were not experienced in delivering psychotherapy and had not been specifically trained to target and change behaviours relevant to anxiety (e.g. exposure and habituation), which may explain the lack of significant effects for this outcome. The small sample size of this study could also have limited the ability to

observe any significant effects of BA on anxiety. However, the possibility that BA is not associated with any effects on anxiety for this patient group cannot be ruled out.

#### 4.4. Strengths, Weaknesses and Methodological Indications

A key strength of this study is that it has been specifically designed to emulate how BA could be implemented in routine care in CDAT and therefore has high external validity. The recruited sample consisted primarily of patients with opiate use disorders, which corresponds with the majority of patients accessing CDAT in the UK (Public Health England, 2020). Further strengths of this study include the randomised controlled design, multiple follow-up assessments and extended followup period. The final follow-up assessment in this study was conducted 18 weeks after BA treatment had ended. This permitted a preliminary assessment of the durability of BA in this population. Follow-up rates were relatively high in both treatment groups.

A major limitation of this study is the small sample size. The difficulties of recruiting participants to RCTs are well established in clinical (McDonald et al., 2006) and SUD populations [78], especially when there is a TAU control arm (Thomson et al., 2008). In the present study, drug and alcohol treatment workers in the CDAT service were prompted to refer potentially eligible patients for screening in accordance with a stepwise method employed in a previous study (Delgadillo et al., 2015). However, of the 1271 potentially eligible patients identified, only 146 (11.5%) were referred for screening over the course of the study. Additionally, the majority of patients who were screened but excluded from the study were found to have declined participation. Participants primarily declined participation due to not wanting to take part in a trial, which may mean that the findings from this study may not be fully representative of patients with co-occurring depression and SUDs accessing CDAT. Due to the small sample size, effect size estimates and other statistical results are likely to be skewed and so should be interpreted with caution.

A further limitation of this study is the lack of contact time-matched control. Patients in the TAU condition had variable contact time with the CDAT service, although standard practice was a 1-hour key-working appointment every 2-4 weeks. In contrast, patients in the BA condition were offered weekly one-hour sessions of

BA for six weeks. It is therefore possible that the significant effects found for BA in this study are a result of increased contact time among BA participants, rather than the BA treatment components specifically. Although this seems unlikely given that only a minority of BA participants attended all of their allocated sessions. This was an open-label study and therefore participants' questionnaire responses may have been influenced by the knowledge of their treatment allocation. A way to overcome this issue would be to compare BA with another structured intervention and blind participants to their allocation. However, given that structured interventions for depression are not typically offered in routine CDAT (Recovery Partnership, 2017; Turning Point, 2016), this approach would not provide an accurate representation of the potential benefits of implementing BA in routine care which was a key focus of this pilot trial.

Further limitations of this study include the reliance on self-report for screening of severe mental health disorders and assessing PDA outcome. Future studies could consider conducting formal assessments of severe mental health diagnoses and biochemically measuring abstinence. However, such approaches risk being invasive and inconsistent with the conventions of routine practice in CDAT services in the UK.

Finally, even though this was a novel test of BA delivered by drug and alcohol treatment workers, adherence to the BA treatment protocol was assessed via self-report only. Research has suggested that therapists may have particular difficulty in evaluating their skills when delivering a new intervention (Miller & Mount, 2001). Therefore, future trials should consider the use of formal fidelity checks (i.e. independent adherence ratings of session content) to monitor therapist adherence to BA treatment. A fully powered RCT is indicated to replicate and extend on the findings. Future trials should consider using more direct screening methods (e.g. researchers approaching potential participants directly), changing the inclusion/exclusion criteria and recruiting from multiple sites in order to address potential recruitment difficulties.

#### 4.5. Implications for Practice and Research

This study provides preliminary evidence that BA facilitated by drug and alcohol treatment workers is feasible and may be effective for SUD patients with elevated depression symptoms. The lack of any adverse events during the trial suggests that BA may be a safe option for delivery in CDAT settings. Fully powered RCTs are warranted to clarify and extend on the findings from this pilot trial and to explore this approach to BA delivery further. Based on the current findings, BA appears to be a promising intervention for patients who exhibit a degree of stability in terms of substance use and employment, but it remains unclear whether all patients are capable of engaging successfully in BA treatment. Patients who are in employment and using less substances may have achieved these attributes as a result of the beneficial effects of accessing CDAT and being motivated to change their lifestyle. Alternatively, these patients may possess personal traits or qualities that allow them to maintain a degree of stability in their lives, which other patients do not have. Further research is therefore needed to explore whether engagement can be improved in patients who exhibit more complex profiles. There is substantial evidence that contingency management (CM) strategies are effective for increasing treatment adherence in SUD populations (Davis et al., 2016). The provision of financial incentives is unlikely to be feasible in routine CDAT. However, future trials could explore the possibility of combining cost-effective CM strategies (i.e. MAT prescription incentives) with BA to promote attendance among patients who are otherwise less likely to engage. This approach may be particularly useful for patients who have difficulty attending an initial appointment, which was the key point at which most BA participants dropped out of the present study.

Further research is also needed to refine BA for delivery in an SUD context and investigate how effects can be maintained over time. Despite significant improvements in key outcomes at 12-week follow-up, these effects were not maintained at 24-week follow-up in the present study. It may be that 6-8 sessions of BA are simply insufficient to bring about sustainable change for patients accessing CDAT. However, it is also notable that few treatment completers attended all of their allocated sessions. Future trials should aim to identify mechanisms of change associated with BA for SUD patients with elevated depression symptoms. Understanding mediators of BA's effects could be used to enhance the content of individual sessions, improve overall engagement with the therapy and contribute to

improved maintenance of effects over time. There is currently a lack of consensus on which aspects of BA contribute to significant change in non-dependent samples, although most existing mediation studies have only focused on activation or environmental reward (Janssen et al., 2021). Increasing engagement in valued activities is a core component of contemporary BA therapy which appears to have been overlooked as a potential mechanism of change. Given that valued living appears to be associated with both SUDs (Copeland et al., 2020; Csabonyi & Phillips, 2020) and depressive symptomatology (Bramwell & Richardson, 2019; Smout et al., 2014), exploring progress in valued living as a potential mediator of BA for SUD patients could be a promising area of inquiry.

Another potential means of addressing engagement and durability of BA's effects may be to investigate group BA delivery in CDAT settings. A recent metaanalysis has shown that group BA is effective at improving depression outcomes in non-dependent samples (Simmonds-Buckley et al., 2019) and trials of BA delivered in a small group format have reported beneficial outcomes in residential SUD treatment settings (Daughters et al., 2018, 2008). Group therapy may improve engagement with BA treatment components via social processes such as interpersonal learning, peer support and accountability (Ahmed et al., 2010; Bledin et al., 2016), which could potentially contribute to increased engagement and maintenance of improvements over time. Moreover, group therapy is widely adopted in SUD treatment settings and associated with reduced treatment costs. Delivering BA in a group format may therefore be a more parsimonious approach than individual delivery that would better meet the needs of resource-limited CDAT services. A trial of individual versus group BA in CDAT would therefore add value.

A prominent finding in the current study is that depression symptoms in the TAU group remained moderately severe across all follow-up points. This highlights the durability of depressive symptomatology in this population and the potential clinical implications of not delivering appropriate evidence-based treatments. Comorbidity of SUDs and depression is a pervasive issue associated with significant health and social consequences and reduced rates of SUD treatment completion (Havard et al., 2006; Najt et al., 2011; Teesson et al., 2008). Identifying and disseminating treatment approaches that are effective and widely applicable remains an important priority for this patient group.

### 5. Conclusions

This study provides preliminary evidence that BA implemented by drug and alcohol workers is feasible and may add clinical benefit to usual care for SUD patients with elevated depressive symptoms accessing CDAT. In its' current format, BA appears to be suitable for patients who are more stable in terms of substance use and everyday functioning. Fully powered RCTs are warranted to investigate the replicability of these findings. Future trials should also investigate ways of increasing the applicability of BA to patients with more complex profiles, identify mediators of treatment effects and test interventions that better support the clinical durability of BA over time.

### 6. References

- Ahmed, S., Abolmagd, S., Rakhawy, M., Erfan, S., & Mamdouh, R. (2010). Therapeutic factors in group psychotherapy: a study of Egyptian drug addicts. *Journal of Groups in Addiction & Recovery*, *5*(3-4), 194-213. https://doi.org/10.1080/1556035X.2010.523345
- Best, D., Day, E., Morgan, B., Oza, T., Copello, A., & Gossop, M. (2009). What treatment means in practice: An analysis of the delivery of evidence-based interventions in criminal justice drug treatment services in Birmingham, England. *Addiction Research & Theory*, *17*(6), 678-687. <a href="https://doi.org/10.3109/16066350802447090">https://doi.org/10.3109/16066350802447090</a>
- Black, C. (2021). *Review of drugs part two: prevention, treatment and recovery.* Department of Health and Social Care. <u>https://www.gov.uk/government/publications/review-of-drugs-phase-two-</u> report/review-of-drugs-part-two-prevention-treatment-and-recovery
- Bledin, K., Loat, M., Caffrey, A., Evans, K. B., Taylor, B., & Nitsun, M. (2016). 'Most important events' and therapeutic factors: An evaluation of inpatient groups for people with severe and enduring mental health difficulties. *Group Analysis*, 49(4), 398-413. https://doi.org/10.1177/0533316416675442
- Bramwell, K., & Richardson, T. (2018). Improvements in depression and mental health after acceptance and commitment therapy are related to changes in defusion and values-based action. *Journal of Contemporary Psychotherapy*, *48*(1), 9-14. https://doi.org/10.1007/s10879-017-9367-6
- Bruijnen, C. J., Dijkstra, B. A., Walvoort, S. J., Markus, W., VanDerNagel, J. E., Kessels, R. P., & De Jong, C. A. (2019). Prevalence of cognitive impairment in patients with substance use disorder. *Drug and Alcohol Review*, *38*(4), 435-442. <u>https://doi.org/10.1111/dar.12922</u>
- Cahill, M. A., Adinoff, B., Hosig, H., Muller, K., & Pulliam, C. (2003). Motivation for treatment preceding and following a substance abuse program. *Addictive Behaviors*, *28*(1), 67-79. <u>https://doi.org/10.1016/s0306-4603(01)00217-9</u>
- Carpenter, K. M., Smith, J. L., Aharonovich, E., & Nunes, E. V. (2008). Developing therapies for depression in drug dependence: results of a stage 1 therapy study. *The American Journal of Drug and Alcohol Abuse, 34*, 642-652. <u>https://doi.org/10.1080/00952990802308171</u>
- Carpenter, K. M., Aharonovich, E., Smith, J. L., Iguchi, M. Y., & Nunes, E. V. (2006).
   Behavior therapy for depression in drug dependence (BTDD): Results of a stage la therapy development pilot. *The American Journal of Drug and Alcohol Abuse*, *32*(4), 541-548. <u>https://doi.org/10.1080/00952990600919450</u>
- Carroll, K. M., & Kiluk, B. D. (2017). Cognitive behavioral interventions for alcohol and drug use disorders: Through the stage model and back again. *Psychology* of Addictive Behaviors, 31(8), 847. <u>https://doi.org/10.1037/adb0000311</u>
- Carroll, M. E. (1996). Reducing drug abuse by enriching the environment with alternative nondrug reinforcers. In L. Green & J. H. Kagel (Eds.), *Advances in*

behavioral economics. Advances in behavioral economics, Vol. 3. Substance use and abuse (pp. 37-68). Westport, CT, US: Ablex Publishing

- Carvalho, S. A., Palmeira, L., Pinto-Gouveia, J., Gillanders, D., & Castilho, P. (2018). The utility of the valuing questionnaire in chronic pain. *Journal of Contextual Behavioral Science*, *9*, 21-29. <u>https://doi.org/10.1016/j.jcbs.2018.06.002</u>
- Carvalho, J. P., & Hopko, D. R. (2011). Behavioral theory of depression: Reinforcement as a mediating variable between avoidance and depression. *Journal of Behavior Therapy and Experimental Psychiatry*, *42*(2), 154-162. <u>https://doi.org/10.1016/j.jbtep.2010.10.001</u>
- Castillo, I., Vázquez, L., & JM, J. L. (2010). Estimation of cutoff for the Severity of Dependence Scale (SDS) for opiate dependence by ROC analysis. *Actas Espanolas de Psiquiatria*, *38*(5), 270-277. <u>https://doi.org/10.1046/j.1360-</u> 0443.2002.00121.x
- Clinical Guidelines on Drug Misuse and Dependence (2017) *Drug misuse and dependence: UK guidelines on clinical management*. London: Department of Health
- Cohen, J. (1992). A power primer. *Psychological Bulletin*, *112*(1), 155. <u>https://doi.org/10.1037/0033-2909.112.1.155</u>
- Cohen, J. (1988). *Statistical Power Analysis for the Behavioral Sciences*. New York, NY: Routledge Academic.
- Copeland, A., Jones, A., & Field, M. (2020). The association between meaning in life and harmful drinking is mediated by individual differences in self-control and alcohol value. *Addictive Behaviors Reports*, *100258.* https://doi.org/10.1016/j.abrep.2020.100258
- Csabonyi, M., & Phillips, L. J. (2020). Meaning in life and substance use. *Journal of Humanistic Psychology*, *60*(1), 3-19. https://doi.org/10.1177/0022167816687674
- Cuijpers, P., Cristea, I. A., Karyotaki, E., Reijnders, M., & Huibers, M. J. (2016). How effective are cognitive behavior therapies for major depression and anxiety disorders? A meta-analytic update of the evidence. *World Psychiatry*, *15*(3), 245-258. <u>https://doi.org/10.1002/wps.20346</u>
- Cuijpers, P., Van Straten, A., & Warmerdam, L. (2007). Behavioral activation treatments of depression: A meta-analysis. *Clinical Psychology Review*, *27*, 318-326. <u>https://doi.org/10.1016/j.cpr.2006.11.001</u>
- Daughters, S. B., Magidson, J. F., Anand, D., Seitz-Brown, C. J., Chen, Y., & Baker, S. (2018). The effect of a behavioral activation treatment for substance use on post-treatment abstinence: A randomized controlled trial. *Addiction*, *113*(3), 535-544. <u>https://doi.org/10.1111/add.14049</u>
- Daughters, S. B., Magidson, J. F., Lejuez, C. W., & Chen, Y. (2016). LETS ACT: A behavioral activation treatment for substance use and depression. *Advances in Dual Diagnosis*. <u>https://doi.org/10.1108/add-02-2016-0006</u>
- Daughters, S. B., Braun, A. R., Sargeant, M. N., Reynolds, E. K., Hopko, D. R.,
   Blanco, C., & Lejuez, C. W. (2008). Effectiveness of a brief behavioral
   treatment for inner-city illicit drug users with elevated depressive symptoms: the

life enhancement treatment for substance use (LETS Act!). *Journal of Clinical Psychiatry*, *69*, 122-129. <u>https://doi.org/10.4088/jcp.v69n0116</u>

- David, D., Cristea, I., & Hofmann, S. G. (2018). Why cognitive behavioral therapy is the current gold standard of psychotherapy. *Frontiers in Psychiatry*, *9*, 4. <u>https://doi.org/10.3389/fpsyt.2018.00004</u>
- Davis, D. R., Kurti, A. N., Skelly, J. M., Redner, R., White, T. J., & Higgins, S. T. (2016). A review of the literature on contingency management in the treatment of substance use disorders, 2009–2014. *Preventive Medicine*, *92*, 36-46. <u>https://doi.org/10.1016/j.ypmed.2016.08.008</u>
- Degan, T. J., Kelly, P. J., Robinson, L. D., & Deane, F. P. (2019). Health literacy in substance use disorder treatment: A latent profile analysis. *Journal of Substance Abuse Treatment*, 96, 46-52. https://doi.org/10.1016/j.jsat.2018.10.009
- Delgadillo, J., Böhnke, J. R., Hughes, E., & Gilbody, S. (2016). Disentangling psychopathology, substance use and dependence: a factor analysis. *BMC Psychiatry*, *16*(1), 1-10. <u>https://doi.org/10.1186/s12888-016-0988-1</u>
- Delgadillo, J., Gore, S., Ali, S., Ekers, D., Gilbody, S., Gilchrist, G., McMillan, D., & Hughes, E. (2015). Feasibility randomized controlled trial of cognitive and behavioral interventions for depression symptoms in patients accessing drug and alcohol treatment. *Journal of Substance Abuse Treatment, 55*, 6-14. <u>https://doi.org/10.1016/j.jsat.2015.02.008</u>
- Delgadillo, J., Godfrey, C., Gilbody, S., & Payne, S. (2013). Depression, anxiety and comorbid substance use: association patterns in outpatient addictions treatment. *Mental Health and Substance Use*, *6*(1), 59-75.
- Delgadillo, J., Payne, S., Gilbody, S., Godfrey, C., Gore, S., Jessop, D., & Dale, V. (2012). Brief case finding tools for anxiety disorders: Validation of GAD-7 and GAD-2 in addictions treatment. *Drug and Alcohol Dependence*, *125*(1-2), 37-42. <u>https://doi.org/10.1016/j.drugalcdep.2012.03.011</u>
- Delgadillo, J. (2012). Depression and anxiety symptoms: measuring reliable change in alcohol and drug users. *Advances in Dual Diagnosis 5*(3), 102-114. <u>https://doi.org/10.1108/17570971211253685</u>\_
- Dimidjian, S., Barrera Jr, M., Martell, C., Munoz, R. F., & Lewinsohn, P. M. (2011). The origins and current status of behavioral activation treatments for depression. *Annual Review of Clinical Psychology*, *7*, 1-38. <u>https://doi.org/10.1146/annurev-clinpsy-032210-104535</u>
- Dimidjian, S., & Davis, K. J. (2009). Newer variations of cognitive-behavioral therapy: behavioral activation and mindfulness-based cognitive therapy. *Current Psychiatry Reports*, *11*(6), 453-458. <u>https://doi.org/10.1007/s11920-009-0069-</u> <u>y</u>\_
- Easden, M. H., & Fletcher, R. B. (2020). Therapist competence in case conceptualization and outcome in CBT for depression. *Psychotherapy Research*, *30*(2), 151-169. <u>https://doi.org/10.1080/10503307.2018.1540895</u>
- Ekers, D., Webster, L., Van Straten, A., Cuijpers, P., Richards, D., & Gilbody, S. (2014). Behavioural activation for depression; an update of meta-analysis of

effectiveness and sub group analysis. *PloS One*, *9*(6), e100100. https://doi.org/10.1371/journal.pone.0100100\_

- Ekers, D., Richards, D., McMillan, D., Bland, J. M., & Gilbody, S. (2011). Behavioural activation delivered by the non-specialist: phase II randomised controlled trial. *The British Journal of Psychiatry*, *198*(1), 66-72. <u>https://doi.org/10.1192/bjp.bp.110.079111</u>
- Ferster, C. B. (1973). A functional analysis of depression. *American Psychologist*, *28*(10), 857-870. <u>https://doi.org/10.1037/h0035605</u>
- Gossop, M., Darke, S., Griffiths, P., Hando, J., Powis, B., Hall, W., & Strang, J. (1995). The Severity of Dependence Scale (SDS): psychometric properties of the SDS in English and Australian samples of heroin, cocaine and amphetamine users. *Addiction*, *90*, 607-614. <u>https://doi.org/10.1046/j.1360-0443.1995.9056072.x</u>
- Gilks, W. R., Richardson, S., & Spiegelhalter, D. J. (1996). *Introducing Markov chain Monte Carlo*. In: W.R. Gilks, S. Richardson, and D.J. Spiegelhalter (eds.), Markov chain Monte Carlo in practise, pp. 1–19, Chapman and Hall: London
- Grant, S., Mayo-Wilson, E., Montgomery, P., Macdonald, G., Michie, S., Hopewell, S., & Moher, D. (2018). CONSORT-SPI 2018 explanation and elaboration: guidance for reporting social and psychological intervention trials. *Trials*, *19*(1), 1-18. https://doi.org/10.1186/s13063-018-2735-z
- Havard, A., Teesson, M., Darke, S., & Ross, J. (2006). Depression among heroin users: 12-Month outcomes from the Australian Treatment Outcome Study (ATOS). *Journal of Substance Abuse Treatment*, *30*(4), 355-362. <a href="https://doi.org/10.1016/j.jsat.2006.03.012">https://doi.org/10.1016/j.jsat.2006.03.012</a>
- Hepner, K. A., Hunter, S. B., Paddock, S. M., Zhou, A. J., & Watkins, K. E. (2011).
  Training addiction counselors to implement CBT for depression. *Administration* and Policy in Mental Health and Mental Health Services Research, 38(4), 313-323. <u>https://doi.org/10.1007/s10488-011-0359-7</u>
- Hopko, D. R., Robertson, S., & Lejuez, C. W. (2006). Behavioral activation for anxiety disorders. *The Behavior Analyst Today*, 7(2), 212-232. <u>https://doi.org/10.1037/h0100084</u>
- Hopko, D. R., Bell, J. L., Armento, M. E. A., Hunt, M. K., & Lejuez, C. W. (2005). Behavior Therapy for Depressed Cancer Patients in Primary Care. *Psychotherapy: Theory, Research, Practice, Training*, 42(2), 236-243. <u>https://doi.org/10.1037/0033-3204.42.2.236</u>
- Hopko, D. R., Lejuez, C. W., & Hopko, S. D. (2004). Behavioral activation as an intervention for coexistent depressive and anxiety symptoms. *Clinical Case Studies*, *3*(1), 37-48. <u>https://doi.org/10.1177/1534650103258969</u>
- Howard, L., de Salis, I., Tomlin, Z., Thornicroft, G., & Donovan, J. (2009). Why is recruitment to trials difficult? An investigation into recruitment difficulties in an RCT of supported employment in patients with severe mental illness. *Contemporary Clinical Trials*, *30*(1), 40-46. <u>https://doi.org/10.1016/j.cct.2008.07.007</u>

- Jacobson, N.S., Dobson, K.S., Truax, P.A., Addis, M.E., Koerner, K., Gollan, J.K., Gortner, E. and Prince, S.E. (1996). A component analysis of cognitivebehavioral treatment for depression. *Journal of Consulting and Clinical Psychology, 64*, 295-304. <u>https://doi.org/10.1037/0022-006x.64.2.295</u>
- Jacobson, N., & Truax, P. (1991). Clinical significance: a statistical approach to defining meaningful change in psychotherapy research. *Journal of Consulting Clinical Psychology, 59,* 12–19. <u>https://doi.org/10.1037/0022-006x.59.1.12</u>
- Jahoda, A., Melville, C. A., Pert, C., Cooper, S. A., Lynn, H., Williams, C., & Davidson, C. (2015). A feasibility study of behavioural activation for depressive symptoms in adults with intellectual disabilities. *Journal of Intellectual Disability Research*, *59*, 1010-1021. https://doi.org/10.1111/jir.12175
- Johnson, M. E., Neal, D. B., Brems, C., & Fisher, D. G. (2006). Depression among out of treatment injecting drug users as measured by the Beck Depression Inventory–II. *Assessment, 13*, 168-177. https://doi.org/10.1177/1073191106286951
- Kroenke, K., Spitzer, R. L., & Williams, J. B. (2001). The PHQ-9: validity of a brief depression severity measure. *Journal of General Internal Medicine*, *16*(9), 606-613. <u>https://doi.org/10.1046/j.1525-1497.2001.016009606.x</u>
- Lawrinson, P., Copeland, J., Gerber, S., & Gilmour, S. (2007). Determining a cut-off on the Severity of Dependence Scale (SDS) for alcohol dependence. *Addictive Behaviors*, *32*(7), 1474-1479. <u>https://doi.org/10.1016/j.addbeh.2006.09.005</u>
- Leamy, M., Bird, V., Le Boutillier, C., Williams, J., & Slade, M. (2011). Conceptual framework for personal recovery in mental health: systematic review and narrative synthesis. *The British Journal of Psychiatry*, *199*(6), 445-452. <u>https://doi.org/10.1192/bjp.bp.110.083733</u>
- Lejuez, C. W., Hopko, D. R., Acierno, R., Daughters, S. B., & Pagoto, S. L. (2011). Ten year revision of the brief behavioral activation treatment for depression: Revised treatment manual. *Behavior Modification*, *35*, 111-161. https://doi.org/10.1177/0145445510390929
- Leon, A. C., Davis, L. L., & Kraemer, H. C. (2011). The role and interpretation of pilot studies in clinical research. *Journal of Psychiatric Research*, *45*(5), 626-629. <u>https://doi.org/10.1016/j.jpsychires.2010.10.008</u>
- Lewinsohn, P. M. (1974). A behavioral approach to depression. *Essential Papers on Depression*, 150-172. <u>https://doi.org/10.1007/978-1-4684-4958-7\_11\_</u>
- Little, R. J. (1988). A test of missing completely at random for multivariate data with missing values. *Journal of the American Statistical Association*, *83*(404), 1198-1202. <u>https://doi.org/10.1080/01621459.1988.10478722</u>
- Magill, M., Ray, L., Kiluk, B., Hoadley, A., Bernstein, M., Tonigan, J. S., & Carroll, K. (2019). A meta-analysis of cognitive-behavioral therapy for alcohol or other drug use disorders: Treatment efficacy by contrast condition. *Journal of Consulting and Clinical Psychology*, *87*(12), 1093-1105. <u>https://doi.org/10.1037/ccp0000447</u>
- Marsden, J., Farrell, M., Bradbury, C., Dale-Perera, A., Eastwood, B., Roxburgh, M., & Taylor, S. (2008). Development of the treatment outcomes

profile. *Addiction*, *103*(9), 1450-1460. <u>https://doi.org/10.1111/j.1360-0443.2008.02284.x</u>

- Martínez-Vispo, C., Martínez, Ú., López-Durán, A., del Río, E. F., & Becoña, E. (2018). Effects of behavioural activation on substance use and depression: a systematic review. Substance Abuse Treatment, Prevention and Policy, 13: 36. <u>https://doi.org/10.1186/s13011-018-0173-2</u>
- Martell, C. R., Addis, M. E., & Jacobson, N. S. (2001). *Depression in context: Strategies for guided action*. WW Norton & Co: New York. <u>https://doi.org/10.1017/s1352465803272118</u>
- McDonald, A. M., Knight, R. C., Campbell, M. K., Entwistle, V. A., Grant, A. M., Cook, J. A., ... & Snowdon, C. (2006). What influences recruitment to randomised controlled trials? A review of trials funded by two UK funding agencies. *Trials*, 7(1), 1-8. <u>https://doi.org/10.1186/1745-6215-7-9</u>
- McKetin, R., Lubman, D. I., Lee, N. M., Ross, J. E., & Slade, T. N. (2011). Major depression among methamphetamine users entering drug treatment programs. *Medical Journal of Australia*, *195*, S51-S55. <u>https://doi.org/10.5694/j.1326-5377.2011.tb03266.x</u>
- Najt, P., Fusar-Poli, P., & Brambilla, P. (2011). Co-occurring mental and substance abuse disorders: a review on the potential predictors and clinical outcomes. *Psychiatry Research*, *186*(2-3), 159-164. <u>https://doi.org/10.1016/j.psychres.2010.07.042</u>
- Pickard, H. (2016). Denial in addiction. *Mind and Language, 31*, 277-299. https://doi.org/10.1111/mila.12106
- Pott, S. L., Delgadillo, J., & Kellett, S. C. (2021). Is behavioral activation an effective and acceptable treatment for co-occurring depression and substance use disorders? A meta-analysis of randomized controlled trials. *Journal of Substance Abuse Treatment*, 108478. https://doi.org/10.1016/j.jsat.2021.108478
- Prochaska, J. O., & DiClemente, C. C. (1983). Stages and processes of self-change of smoking: toward an integrative model of change. *Journal of consulting and clinical psychology*, *51*(3), 390-395. <u>https://doi.org/10.1037/0022-</u> <u>006x.51.3.390</u>
- Public Health England (2020). Adult substance misuse treatment statistics 2019 to 2020: Report. Retrieved from: <u>https://www.gov.uk/government/statistics/substance-misuse-treatment-for-adults-statistics-2019-to-2020/adult-substance-misuse-treatment-statistics-2019-to-2020/adult-substance-misuse-treatment-statistics-2019-to-2020-report</u>
- Public Health England (2019). *Treatment outcomes profile*. Retrieved from: <u>https://assets.publishing.service.gov.uk/government/uploads/system/uploads/atta</u> <u>chment\_data/file/786739/TOP\_form\_v2\_July\_2018.pdf</u>
- Public Health England (2017). *Better care for people co-occurring mental health and alcohol/drug use conditions: A guide for commissioners and service providers.* Retrieved from:

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/atta chment\_data/file/625809/Co-

occurring mental health and alcohol drug use conditions.pdf

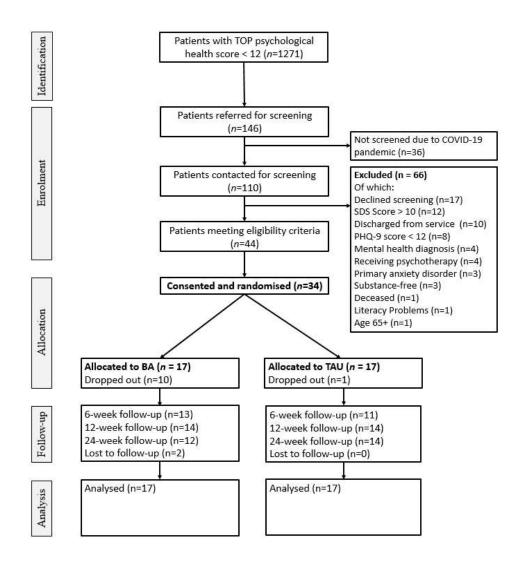
- Recovery Partnership (2017). *State of the sector 2017: Beyond the tipping point.* Retrieved from: <u>http://www.recovery-</u> <u>partnership.org/uploads/5/1/8/2/51822429/state of the sector 2017 -</u> \_\_beyond the tipping point.pdf
- Rehm, L. P. (1984). A self-management therapy program for depression. *International Journal of Mental Health*, *13*, 34-53. <u>https://doi.org/10.1080/00207411.1984.11448975</u>
- Richards, D. A., Ekers, D., McMillan, D., Taylor, R. S., Byford, S., Warren, F. C., ... & Finning, K. (2016). Cost and Outcome of Behavioural Activation versus Cognitive Behavioural Therapy for Depression (COBRA): a randomised, controlled, non-inferiority trial. *The Lancet*, *388*(10047), 871-880. <u>https://doi.org/10.1016/s0140-6736(16)31140-0</u>
- Riper, H., Andersson, G., Hunter, S. B., de Wit, J., Berking, M., & Cuijpers, P. (2014). Treatment of comorbid alcohol use disorders and depression with cognitive-behavioural therapy and motivational interviewing: A meta-analysis. *Addiction*, *109*, 394-406. <u>https://doi.org/10.1111/add.12441</u>
- Simmonds-Buckley, M., Kellett, S., & Waller, G. (2019). Acceptability and efficacy of group behavioral activation for depression among adults: a metaanalysis. *Behavior Therapy*, 50(5), 864-885. https://doi.org/10.1016/j.beth.2019.01.003
- Smout, M., Davies, M., Burns, N., & Christie, A. (2014). Development of the valuing questionnaire (VQ). *Journal of Contextual Behavioral Science*, *3*(3), 164-172. <u>https://doi.org/10.1016/j.jcbs.2014.06.001</u>
- Sobell, L. C., & Sobell, M. B. (1992). Timeline follow-back. In *Measuring alcohol consumption: Psychosocial and biochemical methods* (pp. 41-72). Humana Press: Totowa, New Jersey. <u>https://doi.org/10.1007/978-1-4612-0357-5\_3</u>
- Spitzer, R. L., Kroenke, K., Williams, J. B., & Löwe, B. (2006). A brief measure for assessing generalized anxiety disorder: the GAD-7. *Archives of internal medicine*, *166*(10), 1092-1097. <u>https://doi.org/10.1001/archinte.166.10.1092</u>
- Teesson, M., Mills, K., Ross, J., Darke, S., Williamson, A., & Havard, A. (2008). The impact of treatment on 3 years' outcome for heroin dependence: findings from the Australian Treatment Outcome Study (ATOS). *Addiction*, *103*(1), 80-88. <u>https://doi.org/10.1111/j.1360-0443.2007.02029.x</u>
- Thomson, C. L., Morley, K. C., Teesson, M., Sannibale, C., & Haber, P. S. (2008). Issues with recruitment to randomised controlled trials in the drug and alcohol field: a literature review and Australian case study. *Drug and Alcohol Review*, 27(2), 115-122. <u>https://doi.org/10.1080/09595230701829561</u>

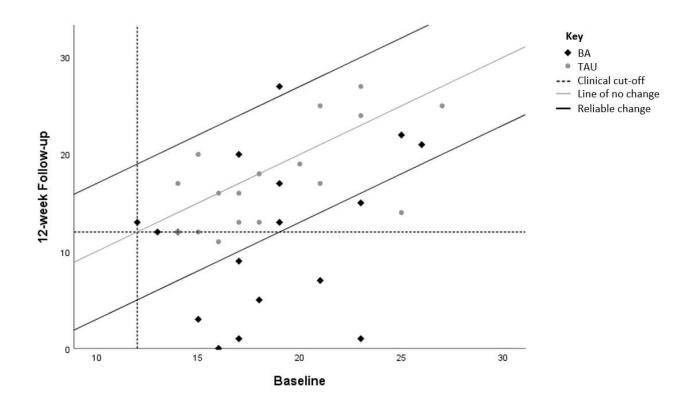
- Torrens, M., Mestre-Pintó, J. I., & Domingo-Salvany, A. (2015). Comorbidity of substance use and mental disorders in Europe. Retrieved from: https://www.emcdda.europa.eu/system/files/publications/1988/TDXD15019ENN .pdf
- Vuchinich, R. E., & Tucker, J. A. (1988). Contributions from behavioral theories of choice to an analysis of alcohol abuse. *Journal of Abnormal Psychology*, 97(2), 181. <u>https://doi.org/10.1037/0021-843x.97.2.181</u>
- Vujanovic, A. A., Meyer, T. D., Heads, A. M., Stotts, A. L., Villarreal, Y. R., & Schmitz, J. M. (2017). Cognitive-behavioral therapies for depression and substance use disorders: An overview of traditional, third-wave, and transdiagnostic approaches. *The American Journal of Drug and Alcohol Abuse*, 43(4), 402-415. <u>https://doi.org/10.1080/00952990.2016.1199697</u>
- Wilson, K. G., Sandoz, E. K., Kitchens, J., & Roberts, M. (2010). The Valued Living Questionnaire: Defining and measuring valued action within a behavioral framework. *The Psychological Record*, 60(2), 249-272. <u>https://doi.org/10.1007/bf03395706</u>

# **Appendices**

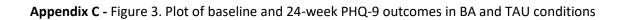
Appendix A - Figure 1. CONSORT Diagram	p.34
<b>Appendix B -</b> Figure 2. Plot of baseline and 12-week PHQ-9 outcomes in the arms of the trial	p.35
<b>Appendix C</b> - Figure 3. Plot of baseline and 24-week PHQ-9 outcomes in the arms of the trial	p36
<b>Appendix D -</b> Table 1. Sample characteristics and comparisons between randomly assigned groups	p.37
<b>Appendix E -</b> Table 2. Change in primary and secondary outcomes across treatment conditions for randomised sample and treatment completer subsample.	p.38

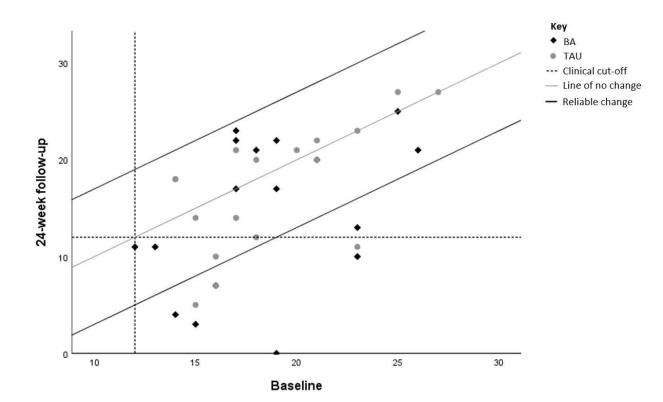
#### Appendix A - Figure 1. CONSORT Diagram.





Appendix B - Figure 2. Plot of baseline and 12-week PHQ-9 outcomes in BA and TAU conditions





	Full Sample (n=34)	BA (n=17)	TAU (n=17)	Test Statistic	Ρ
Mean Age (SD)	42.3 (6.5)	42.18 (7.45)	42.35 (5.53)	<i>t</i> (32) = -0.08	.938
Gender (%)					
Male	25 (73.5)	9 (47.1)	16 (94.1)	-	.017ª
Female	9 (26.5)	8 (52.9)	1 (5.9)		
Ethnicity (%)					
White British	33 (97.1)	16 (94.1)	17 (100)	-	-
Other	1 (2.9)	1 (5.9)	0 (0)		
Employment (%)					
Employed	5 (14.7)	3 (17.6)	2 (11.8)	-	1.00 <sup>a</sup>
Unemployed	29 (85.3)	14 (82.4)	15 (88.2)		
Primary Substance (%)					
Opiates	26 (76.5)	12 (70.6)	14 (82.4)	-	.688ª
Alcohol	8 (23.5)	5 (29.4)	3 (17.6)		
Substances used in last month					
Heroin	17 (50)	7 (41.2)	10 (58.8)	$\chi^{2}(1) = 1.06$	.303
Crack	16 (47.1)	6 (35.3)	10 (58.8)	$\chi^2(1) = 1.89$	.169
Alcohol	11 (32.4)	7 (41.2)	4 (36.4)	$\chi_{2}(1) = 1.21$	.271
Other	10 (29.4)	6 (35.3)	4 (11.8)	-	1.00 <sup>a</sup>
Polydrug Use (%)	21 (61.8)	10 (58.8)	11 (64.7)	$\chi^{2}(1) = 0.13$	.724
Abstinent (%)	2 (5.9)	1 (5.9)	1 (5.9)	-	-
Prescribed MAT for					
opiate use	26 (76.5)	12 (70.6)	14 (82.4)	$\chi^{2}(1) = 0.65$	.419
Prescribed		- / >		<i>.</i>	
antidepressants	16 (47.1)	8 (50)	8 (50)	$\chi^{2}(1) = 0.00$	1.00
Baseline Scores on Outcome Measures					
PHQ-9 (SD)	18.65 (3.95)	18.47 (4.06)	18.82 (4.00)	t(32) = 0.26	.799
PDA (SD)	50.01 (36.83)	50 (36.29)	50.18 (38.74)	t(32) = 0.01	.989
SDS (SD)	6.21 (2.78)	6.76 (2.81)	5.65 (2.71)	t(32) = -1.18	.248
GAD-7 (SD)	14.47 (4.39)	15.53 (4.54)	13.41 (4.09)	t(32) =-1.43	.163
VQ-Progress (SD)	8.53 (6.27)	9.12 (7.34)	7.94 (5.15)	<i>t</i> (32) = 0.54	.592
VQ-Obstruction (SD)	21.03 (4.48)	21.24 (4.51)	20.82 (4.59)	<i>t</i> (32) = 0.26	.793

Appendix D - Table 1. Sample characteristics and comparisons between randomly assigned groups

**Note:** t = Student's t-test;  $\chi^2$  = Chi-square test; - denotes missing estimates due to violation of test assumptions; Abbreviations: MAT: Medically Assisted Treatment; PHQ-9: Patient Health Questionnaire-9; PDA: Percent Days Abstinent; SDS: Severity of Dependence Scale; GAD-7: General Anxiety Disorder-7; VQ-Progress: Valuing Questionnaire (Progress Subscale); VQ-Obstruction: Valuing Questionnaire (Obstructions Subscale)

<sup>a</sup> p value refers to result of Fisher's Exact Test

· .		· · · ·				
	Randomised Sample (n=34)			Treatment Completers (n=24)		
	TAU (n=17)	BA (n=17)		BA (n=7)		
Variable and time Point	Mean (SD)	Mean (SD)	Mean Difference <sup>a</sup> (p)	Mean (SD)	Mann- Whitney <i>U</i> (p)	
Depression						
(PHQ-9)						
6 weeks	17.06 (4.12)	15.94 (7.76)	-0.82 (.655) <sup>b</sup>	11.14 (6.07)	29 (.055)	
12 weeks	17.59 (5.09)	11.65 (8.12)	-5.69 (.013) <sup>b</sup>	6.14 (5.61)	8 (.000)	
24 weeks	17.06 (6.54)	14.53 (7.82)	-2.20 (.314) <sup>b</sup>	12.14 (6.54)	34.50 (.111)	
Percent Days Abstinent (PDA)						
6 weeks	32.73 (30.54)	50.53 (34.15)	17.9 (.039)	71.23 (20.43)	98 (.013)	
12 weeks	33.82 (37.31)	61.46 (30.63)	27.69 (.021) <sup>b</sup>	78.43 (20.67)	98.50 (.011)	
24 weeks	49.36 (40.9)	57.6 (35.32)	8.33 (.486)	74.43 (35)	80.50 (.187)	
Severity of Dependence (SDS)						
6 weeks	9.12 (4.2)	6.18 (4.85)	-3.06 (.067) <sup>b</sup>	6.14 (5.61)	40.50 (.234)	
12 weeks	6.29 (4.3)	6.59 (5)	-0.76 (.583) <sup>b</sup>	4.57 (5.22)	44.50 (.349)	
24 weeks	6.65 (4.83)	6.47 (3.94)	-0.75 (.620)	3.57 (3.41)	36.50 (.147)	
Anxiety (GAD-7)						
6 weeks	13.47 (4.6)	12.41 (5.06)	-2.28 (.135)	11.14 (4.30)	42.50 (.288)	
12 weeks	12.71 (6.07)	9.65 (5.7)	-3.92 (.061) <sup>b</sup>	6.86 (4.45)	29.50 (.055)	
24 weeks	11.53 (5.34)	11.59 (6.07)	-1.64 (.322) <sup>b</sup>	9.14 (5.90)	44 (.349)	
Progress in Valued Living (VQ-Progress)						
6 weeks	6.29 (3.79)	12.24 (8.1)	5.34 (.008) <sup>b</sup>	13.86 (6.96)	98.50 (.011)	
12 weeks	12.53 (7.18)	16 (8.45)	2.41 (.209) <sup>b</sup>	19.14 (5.76)	93 (.034)	
24 weeks	11.71 (9.01)	14.41 (8.49)	2.21 (.455) <sup>b</sup>	17.86 (9.49)	83.50 (.130)	
Obstructions to Valued Living (VQ-Obstruction)						
6 weeks	20 (4.82)	18.24 (7.93)	-1.76 (.449) <sup>b</sup>	17 (8.27)	46.50 (.418)	
12 weeks	19.12 (8.67)	16 (8.27)	-3.29 (.261)	10.71 (9.2)	29 (.055)	
24 weeks	18.90 (6.31)	21.60 (7.56)	2.49 (.284) <sup>b</sup>	17 (9.47)	58 (.951)	

**Appendix E** - Table 2. Change in primary and secondary outcomes across treatment conditions for randomised sample and treatment completer subsample

<sup>a</sup> Mean difference adjusted for baseline scores on corresponding measure

<sup>b</sup> Some assumptions such as homoscedasticity and homogeneity of variance were violated