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Integrating Behavioural Activation for Depression into Community Drug and Alcohol Treatment

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ABSTRACT

One in two patients seeking help for substance use disorders (SUDs) have clinically significant depressive symptoms. This comorbidity is associated with poor treatment outcomes, yet the testing and implementation of evidence-based interventions for this group has been slow to occur. Behavioural Activation (BA) is an evidence-based psychological treatment for depression. Emerging evidence suggests that BA holds promise as a treatment for SUD patients with comorbid depressive symptoms, but it is currently unclear whether implementing BA in routine care would improve treatment outcomes. Understanding BA in the context of implementation in SUD treatment may lead to more definitive conclusions regarding the value and adoptability of the intervention, which could help facilitate its translation into practice. Therefore, this thesis sought to conduct a preliminary investigation of the effectiveness and acceptability of integrating BA into community drug and alcohol treatment (CDAT) to treat patients with comorbid SUD-depression. First, a systematic review and meta-analysis (Chapter 2) of randomised controlled trials (RCTs) was conducted to clarify the effectiveness and acceptability of BA for comorbid SUD-depression based on existing evidence. No significant differences were found between BA and controls with regard to depression or substance use outcomes, although BA appeared to be an acceptable treatment option with a comparable dropout rate to controls. Chapter 3 then reports on a pilot RCT of BA facilitated by drug and alcohol treatment workers in CDAT. Compared to Treatment as Usual (TAU), BA was associated with significant improvements in Percent Days Abstinent (PDA) and progress in valued living at 6-week follow-up, along with significant reductions in depressive symptoms and improvements in PDA at 12-week follow-up. However, these effects were not maintained at 24-week follow-up. The BA dropout rate was 59%. Chapter 4 expands on these findings by exploring the experiences of clinical managers, BA therapists (drug and alcohol treatment workers) and BA patients from the pilot trial. Staff and patients discussed the acceptability of delivering evidence-based interventions in CDAT, concerns around patient engagement with BA, challenging yet helpful aspects of BA and the compatibility of BA with routine care. Finally, the overall theoretical, clinical and policy implications of findings from this thesis are discussed in Chapter 5, with recommendations outlined for future research investigating BA as a treatment for comorbid SUD-depression in CDAT.

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Last but not least, I will dedicate this thesis to my grandad, John. He has always believed in me and supported my education, and I know that he will be bursting with pride to finally have a doctor in the family!

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GLOSSARY OF COMMONLY USED TERMS

Behavioural Activation (BA): Psychological therapy aimed at increasing engagement in positively reinforcing activities and reducing avoidance behaviours.

Cognitive Behavioural Therapy (CBT): Psychological therapy aimed at developing coping strategies and changing maladaptive thoughts and behaviours.

Common Mental Disorder (CMD): Term used to refer to depression and anxiety.

Community Drug and Alcohol Treatment (CDAT): Drug and alcohol treatment which is delivered on an outpatient basis.

'Comorbid SUD-depression': Term used in this thesis to refer to comorbid substance use disorder (SUD) and elevated depressive symptoms.

Contingency Management (CM): Behavioural therapy that involves the provision of incentives (e.g. vouchers) as a reward for engaging in desired behaviours.

Life Enhancement Treatment for Substance Use (LETS ACT!): A Behavioural Activation (BA) treatment that has been specifically developed for patients with comorbid substance use disorder (SUD) and elevated depressive symptoms.

Motivational Interviewing (MI): Psychological therapy which aims to increase patient motivation by resolving ambivalence about change.

National Institute for Health and Care Excellence (NICE): Public body that provides guidelines for the provision of healthcare in the UK.

Patient Health Questionnaire-9 (PHQ-9): Brief questionnaire (9 items) used to screen for depressive disorder.

Percent Days Abstinent (PDA): Refers to the percentage of days an individual reports abstinence from substances, typically over the past month. Higher figures indicate lower use of substances.

Substance use disorder (SUD): Problematic drug or alcohol use characterised by loss of control, increased prominence of the substance in a person's life and continuation of use despite negative consequences.

NOTE ON INCLUSION OF PUBLISHED WORK

Work included in two chapters of this thesis have been written up as manuscripts and accepted for publication. The associated thesis chapters and references for the co-authored papers are shown below. Information from the published articles have been presented in the below chapters in a format consistent with the thesis. Therefore, they are not identical to the published papers, but there is some replication.

Chapter 2: Pott, S. L., Delgadillo, J., & Kellett, S. (2022). 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, 132,* 108478. https://doi.org/10.1016/j.jsat.2021.108478

Chapter 3: Pott, S. L., Kellett, S., Green, S., Daughters, S. B., & Delgadillo, J. (2022). Behavioral activation for depression delivered by drug and alcohol treatment workers: A pilot randomized controlled trial. *Journal of Substance Abuse Treatment, 139,* 108769. https://doi.org/10.1016/j.jsat.2022.108769

Chapter 1

Introduction

The aim of this PhD is to explore the effectiveness and acceptability of integrating behavioural activation (BA) into community drug and alcohol treatment (CDAT) for patients with comorbid substance use disorder (SUD) and depression (comorbid SUD-depression). This chapter will introduce the key topics underpinning this area of research. First, the characteristics and treatment of SUDs and depression as specific disorders will be outlined. Second, the symptoms, impact and theoretical explanations of comorbid SUD-depression will be described. Third, key cognitive and behavioural approaches to treating comorbid SUD-depression will be outlined, followed by a detailed examination of the development of BA as a treatment for this comorbidity. Fourth, the SUD treatment context in the UK will be described, including challenges to implementing evidence-based psychological interventions in practice. Finally, the concept of research translation frameworks will be discussed to highlight how the investigation of BA in CDAT can be optimised. The chapter will conclude by bringing all of these topics together to outline the interlinked objectives and methods of the subsequent chapters in this thesis.

1.1 | Substance use disorders (SUDs)

1.1.1 | Prevalence and symptoms

Substance use, including alcohol, illicit drugs and nonmedical use of prescription drugs, is widespread (United Nations Office on Drugs and Crime [UNODC], 2021). Most people use substances recreationally, however, some people are more likely to develop problems with use due to biological and psychosocial vulnerabilities (Grant & Dawson, 1998; Grant et al., 2004). SUDs are characterised by loss of control over drug or alcohol use, increased prominence of the substance in a person's life and continuation of use despite negative consequences (American Psychological Association [APA], 2013). The severity of SUDs can range from mild to severe based on the number of symptoms a person presents with (APA, 2013).

Recent epidemiological data suggest that approximately 271 million people use drugs in a typical year and 35 million have a drug use disorder worldwide (UNODC, 2021). Alcohol use disorders are even more pervasive, with an estimated 100 million cases globally

(Degenhardt et al., 2018). In the US, lifetime prevalence estimates of SUDs range from 3-8% for illicit drugs (Compton et al., 2007) and 13-18% for alcohol (Hasin et al., 2007). Men generally exhibit higher rates of substance use and dependence than women (Substance Abuse and Mental Health Service Administration [SAMHSA], 2016). However, women tend to progress more rapidly from initial use to dependence (Bobzean et al., 2014; Richmond-Rakerd et al., 2016). Biological risk factors for SUDs comprise inherited genetic vulnerabilities and disruption to neuronal pathways in brain areas associated with reward, motivation and learning (Hatoum et al., 2021; Koob & Volkow, 2016). Certain personality traits such as high neuroticism (Terracciano et al., 2008) and impulsivity (Verdejo-García et al., 2008) also appear to increase vulnerability to SUDs. Other psychosocial risk factors include a lack of reward availability in a person's environment (Joyner et al., 2016), high levels of family conflict (Zhou et al., 2006), parental substance use (Mezzich et al., 2007; Buu et al., 2009) and living in an unstable neighbourhood during childhood (Buu et al., 2009). Moreover, there is evidence that having a history of trauma is associated increased risk of developing SUDs (Mills et al., 2006; Stevens et al., 2003), with this particularly being the case for women (Lisa et al., 1997). At a broader societal level, favourable social norms towards substance use may also increase vulnerability to SUDs (UNODC, 2015).

Development of SUDs can occur at any stage in life, although substance use problems typically emerge during late adolescence to early adulthood (Park et al., 2006). Once SUDs have been established, continued use of a problem substance is often, but not always, associated with progression in SUD severity and complexity (Compton et al., 2007; Hasin et al., 2007). For example, some people with alcohol use disorders may be able to attain a level of controlled, moderate drinking, although this is not considered feasible if they have already developed a severe dependence (Babor et al., 2007; Cunningham et al., 2000). It has also been reported that around 60% of people can recover from SUDs without treatment (Moos & Moos, 2006). However, many people with SUDs experience repeated abstinence and relapse cycles that span decades and require multiple treatment episodes (Scott, Foss & Dennis, 2005), with approximately 40% never achieving long-term recovery (Dennis et al., 2005). There are a number of factors associated with increased risk of relapse in people with SUDs, including greater SUD severity (Kopak et al., 2016), low socioeconomic status (Kopak et al., 2016), lack of self-efficacy (Solomon & Annis, 1990) and low levels of social support (Bischof et al., 2001; Hammerbacher & Lyvers, 2006).

1.1.2 | Individual and societal impact

SUDs are a significant risk factor for mortality and disease burden (Whiteford et al., 2013). In a typical year, drug use disorders cause 180 thousand deaths worldwide (World Health Organisation [WHO], 2021[a]) and are the third most common cause of death for people aged 15 to 49 in England (Public Health England, 2017[a]). Moreover, alcohol use contributes to three million deaths every year and it is the leading risk factor for disability and premature mortality in people aged 15 to 49, with current figures indicating that it accounts for 10% of all deaths in this age group (WHO, 2021[b]).

SUDs are associated with various mental and physical health problems, including depression, anxiety, injuries and chronic diseases (Public Health England, 2017[b]). However, the specific health risks associated with different substances and routes of administration vary. For example, smoking drugs such as heroin, crack cocaine and cannabis are primarily associated with an increased risk of lung damage, while injecting drugs such as heroin or amphetamine increases the risk of overdose, vein damage and contracting blood-borne viruses such as HIV and Hepatitis C (Public Health England, 2017[a]). Heroin in particular carries a significant risk of overdose (Gable, 2004), which appears to have been amplified in recent years by increases in poly-drug use (Zambon et al., 2017) and the introduction of synthetic opioids into the illicit drug market (Centers for Disease Control and Prevention [CDC], 2020). Meanwhile, alcohol use disorders are associated with the development of neurological conditions, cancers and liver disease (Public Health England, 2016), the latter of which is the most common cause of death among people with alcohol use disorders in the UK (Office for National Statistics [ONS], 2020).

As well as increasing the risk of adverse health outcomes, SUDs are associated with many other harms to individuals and society. These harms include functional impairment, family breakdown, homelessness and criminal activity (Public Health England, 2017[b]). It has previously been estimated that around 1.5 million people in the UK are affected by a relative's SUD and the resulting harm that they experience alone amounts to approximately £2 billion per year (Davies et al., 2009). Alcohol use is also associated with further risks to the public from violent assaults and traffic accidents caused by driving intoxicated (Public Health England, 2016). Taken together, the financial burden of SUDs in terms of healthcare expenditure and costs related to social welfare and criminal justice is significant, with the

total annual cost of substance-related harms estimated at £36.4 billion in the UK (Public Health England, 2016, 2017[b]).

1.1.3 | Evidence-based treatment of SUDs

The prevalence and impact of SUDs necessitate the development of effective treatments. Yet, the move toward developing and evaluating evidence-based interventions for SUDs has been a relatively recent one. Past treatment approaches were either focused on SUDs as a "moral failing" which led to the delivery of ineffective and punitive interventions (Babor, 1994), or the SUD disease model propagated by 12-step groups (Miller, 2008). There remains some disagreement in the SUD treatment field concerning what evidence is required for an intervention to be considered "evidence-based" (Glasner-Edwards & Rawson, 2010). However, minimum criteria generally include evidence of effectiveness from randomised controlled trials (RCTs) and intervention components that are standardised and replicable (Chambless & Hollon, 1998; Chambless et al., 1996; Miller et al., 2005).

The vast heterogeneity of SUDs means that no single treatment approach is likely to be universally effective. Indeed, SUD presentations vary on several dimensions, including the substance or combination of substances used, severity of dependence and the range of social, physical and psychological problems that may co-occur to various degrees in and across different people (Carroll, 2021). These disparities have led to the development and testing of a wide range of pharmacological and psychosocial treatments for SUDs. In an effort to ensure that only evidence-based interventions are recommended, the WHO have developed a set of international standards for SUD treatment (WHO, 2020). Interventions that are recommended for adult SUD populations are presented in the subsections below.

1.1.3.1 | *Pharmacological Interventions*

Pharmacological approaches to managing SUDs are informed by initial evidence that the neurotransmitters targeted by the intervention are affected by the substance that the person is dependent upon (Koob, 2000; Koob et al., 2004). The aim of these treatments include alleviating withdrawal states, blocking or reducing the reward obtained from a substance and diminishing cravings. Evidence for their effectiveness is largely based on whether they are associated with reductions in substance use or relapse rates (WHO, 2020). However, a key

limitation of pharmacological treatments is that they are mostly substance-specific and there are currently no effective pharmacotherapies available for some SUDs, such as cocaine and cannabis use disorders. According to WHO guidance (2020), recommended pharmacological interventions include:

- *Methadone*; a long-acting opioid receptor agonist that prevents opiate withdrawal, reducing a person's need to use heroin or other non-prescribed opiates. The potential of methadone as a treatment for heroin users was first recognised in the 1960s (Dole et al., 1966) and it remains the most widely adopted (Mattick et al., 2009) and well researched treatment for opiate use disorder. Several systematic reviews of RCTs have been conducted showing that methadone treatment is associated with significant reductions in heroin use and increased treatment retention (Fullerton et al., 2014; Mattick et al., 2009).
- *Buprenorphine;* a long-acting, partial opioid receptor agonist that prevents opiate withdrawal, reduces craving and partly blocks the effects of other opiates. Benefits of buprenorphine compared to methadone include its lower potential for overdose and longer duration of action (Mattick et al., 2014). Meta-analyses of RCTs indicate that medium-high doses of buprenorphine are as effective as methadone for reducing heroin use and may be better tolerated by patients (Thomas et al., 2014; Mattick et al., 2014). However, buprenorphine appears less effective than methadone for retaining patients in treatment (Mattick et al., 2014).
- *Naltrexone*; an opioid receptor antagonist that inhibits the pleasurable effects of opiates (Volavka et al., 1976). Orally administered naltrexone has been established as ineffective for opiate use disorder due to poor patient adherence (Minozzi et al., 2011). However, emerging evidence suggests that injectable naltrexone administered once per month is associated with reduced rates of relapse among formerly opiate-dependent patients (Krupitsky et al., 2013). Naltrexone has also been found to diminish the pleasurable effects of alcohol (Drobes et al., 2004). Several reviews of clinical trial evidence have shown that oral naltrexone is associated with modest, yet significant short-term reductions in drinking days and relapse rates among patients with alcohol use disorders (Srisurapanont & Jarusuraisin, 2005; Streeton & Whelan, 2001).
- *Acamprosate*; a glutamate antagonist purported to alleviate conditioned reactions to alcohol (Cole et al., 2000) and reduce its rewarding effects (McGeehan & Olive,

2003). A review of clinical trial evidence found that acamprosate was associated with significant, albeit modest reductions in relapse rates and increased cumulative abstinence rates compared to placebo in patients with alcohol use disorder (Rösner et al., 2010). Several reviews comparing acamprosate with naltrexone have concluded that both are modestly effective treatments for alcohol dependence. However, acamprosate appears more effective for abstinence-related goals, while naltrexone may be more helpful for achieving controlled drinking (Bouza et al., 2004). The evidence base for both of these approaches is notably based on the provision of adjunctive psychosocial treatment.

1.1.3.2 | *Psychosocial Interventions*

Psychosocial approaches to treating SUDs encompass a broad range of interventions, with varied theoretical backgrounds. These treatments aim to elicit changes in substance use behaviour and improve functioning across key life domains (e.g. relationships, housing, employment). The efficacy of psychosocial interventions is typically based on whether they are associated with reductions in substance use (National Collaborating Centre for Mental Health, 2008). Psychosocial interventions may be used as standalone treatments or in combination with pharmacological treatments. For patients who do not have opiate or alcohol use disorders, psychosocial interventions are currently the only evidence-based treatment option (WHO, 2020).

Several comparatively effective psychosocial interventions have emerged over the past few decades (Carroll & Onken, 2005). A meta-analysis of psychosocial interventions for all SUDs found a moderate effect size for psychosocial treatment overall ($d = 0.45$), with the greatest effect sizes observed for cannabis ($d = 0.81$) and cocaine use disorders ($d = 0.62$), followed by opiate use disorders ($d = 0.39$) and poly-substance use ($d = 0.24$) (Dutra et al., 2008). However, some psychosocial interventions may be more effective for specific SUD treatment presentations than others. According to WHO guidance (2020), recommended psychosocial interventions include:

- *Contingency management (CM);* involves providing patients with vouchers or other incentives as a reward for achieving behavioural goals. CM is based on principles of operant conditioning which is the idea that a behaviour that is rewarded is more likely to be repeated (Skinner, 1953). CM appears to be one of the most effective

psychosocial treatments for SUDs in terms of reducing substance use (Dutra et al., 2008; Lussier et al., 2006). There is also evidence that CM is associated with improved adherence to pharmacological treatment in SUD patients, particularly in patients with opiate use disorders (Petry et al., 2012).

- *Cognitive behavioural therapy (CBT);* a structured intervention targeting cognitive, affective and environmental components of substance use behaviour, including coping skills training to enable patients to achieve and maintain abstinence or reduce substance-related harms. CBT is based on the premise that cognitive processes and behavioural patterns around drug use are learned and can be modified (Moos, 2006). Several meta-analyses have reported small to moderate significant effects of CBT for reducing substance use rates across a range of SUDs (Magill et al., 2019; Dutra et al., 2008; Magill & Ray, 2009), with the strongest effects observed for cannabis and cocaine use disorders (Dutra et al., 2008; Magill & Ray, 2009). A recent Cochrane review of 30 RCTs, mostly involving patients with alcohol use disorders, found that CBT combined with pharmacological treatments was more effective than usual care + pharmacotherapy (Ray et al., 2020).
- *Motivational interviewing (MI)*; a brief (1-4 sessions), client-centred intervention which supports patients to increase their intrinsic motivation to change by exploring and resolving ambivalence (Rollnick & Miller, 1995). MI is aligned with Prochaska and DiClemente's (1983) transtheoretical model of behaviour change and draws on social psychological concepts of cognitive dissonance, causal attribution and self-efficacy (Miller, 1983). Several systematic reviews of RCTs conducted with SUD patients reported that MI was associated with significant reductions in substance use (Burke, Arkowitz & Menchola, 2003; Hettema, Steele & Miller, 2005; Smedslund et al., 2011).
- *Community Reinforcement Approach (CRA);* a behavioural treatment package which supports patients to discover and adopt an enjoyable, healthy lifestyle that is more rewarding than using drugs and alcohol. CRA is primarily based on principles of behavioural economics, which views SUDs as a reinforcement pathology that can be unlearned by increasing access to alternative sources of positive reinforcement (Bickel et al., 2014). A systematic review of 11 RCTs found that CRA was associated with significant reductions in drinking days among patients with alcohol use disorders (Roozen et al., 2004). For patients with drug use disorders, CRA seems to be most

effective when it is combined with CM (De Crescenzo et al., 2018; Roozen et al., 2004)

- *Behavioural Couples Therapy (BCT);* an intervention involving the SUD patient and their partner which aims to resolve difficulties in the relationship that may be caused by and maintaining the SUD. BCT is based on principles of *social learning theory*, which suggest that couples affected by SUDs tend to engage in interactions characterised by punishment rather than positive reinforcement of behaviours that benefit the relationship (Wesley, 2016). A meta-analysis of 12 RCTs including patients with alcohol, opiate and poly-substance use disorders found that BCT was associated with significant reductions in the SUD partner's substance use and improvements in their relationship satisfaction (Powers et al., 2008).
- *Mutual aid;* comprises 12-step therapy (e.g. Narcotics Anonymous [NA]) and other peer-driven, self-help support groups. These groups typically operate on the idea that SUD is a disease and that complete abstinence is the only conceivable treatment goal (Humphreys et al., 2004). A recent Cochrane review of 27 studies found that 12-step therapy was at least as effective as other psychosocial interventions for reducing alcohol use and related problems in patients with alcohol use disorders (Kelly et al., 2020).

1.2 | Depressive disorders

1.2.1 | Prevalence and symptoms

Depression is a common mental disorder (CMD) which affects at least 6% of adults worldwide (Institute of Health Metrics and Evaluation, 2019). Recent estimates indicate that as many as 1 in 6 people will experience depression in their lifetime (Otte et al., 2016), with women almost twice as likely to be affected than men (Seedat et al., 2009). Depression is a debilitating condition characterised by persistent feelings of sadness and loss of interest or pleasure in usual activities (Otte et al., 2016). Other symptoms include feelings of guilt, worthlessness and suicidal ideation, as well as physical symptoms such as appetite problems, sleep disturbances, lack of energy, difficulty concentrating and slowed thoughts or movements (DSM-5; APA, 2013). Depression is associated with considerable functional impairment and it is one of the leading causes of disease burden globally (Vos et al., 2015).

Depression can develop at any stage in life, although data suggests that most people experience their first depressive episode between adolescence and early adulthood (Craighead, Sheets, Brosse & Ilardi, 2007). The severity of depressive disorders can range from mild to severe based on the number and frequency of symptoms a person presents with (DSM-5; APA, 2013). The course of depression also varies; some people experience a time-limited depressive episode that resolves within 12 months of onset. Others experience longer or recurrent episodes of depression (Melartin et al., 2004) that can span up to 20 years (Gilmer et al., 2005). In both men and women, risk factors for depression include the experience of stressful life events (e.g. divorce, illness), financial problems and unemployment (Bromet et al., 2011; Risch et al., 2009). There is also evidence that having a history of childhood trauma is associated with an increased risk of developing depression (Heim & Binder, 2012), particularly in women who have an anxious or avoidant attachment style (Bifulco et al., 2006). Additional risk factors for depression include having any type of insecure attachment style (Bifulco et al., 2002), irrational beliefs about oneself or the world (Vîslă et al., 2016) and a personality profile comprising low extraversion, low conscientiousness and high neuroticism (Allen et al., 2020; Boudouda & Gana, 2020). However, it is generally accepted that depression is the result of a complex combination of biological, psychological and social factors (WHO, 2021[c]).

1.2.2 | Evidence-based treatment of depression

Many treatments have been developed to help alleviate depressive symptoms, informed by various theoretical models of depression. Recommended treatments typically include antidepressant medication, psychological interventions, or a combination of both (NICE, 2009). However, evidence suggests that psychological treatments are equally as effective as antidepressant medication in most cases (Cuijpers, van Straten, van Oppen & Andersson, 2008) and tend be preferred by patients (McHugh, Whitton, Peckham, Welge & Otto, 2013). In the UK, depression treatment is directed by the National Institute for Health and Care Excellence (NICE) to ensure that only the most effective treatments are recommended (NICE, 2016). According to NICE (2016) guidance, recommended psychological treatments for depression include:

- *CBT;* intervention focused on the development of coping skills and changing maladaptive thoughts and behaviours associated with depression.
- *BA;* intervention focused on eliciting behavioural changes to increase a person's access to positive reinforcement and reduce avoidance behaviours associated with depression.
- *Interpersonal psychotherapy (IPT);* intervention focused on identifying and resolving issues with a person's social relationships that may be contributing to depression.
- *Psychodynamic Therapy;* intervention focused on exploring emotions, unresolved conflicts, unconscious motivations and interpersonal patterns that may contribute to depression.
- *Behavioural Couples Therapy (BCT);* intervention that employs behavioural principles to resolve emotional difficulties in relationships that may maintain depression.
- *Person-Centred Experiential Therapy (PCET);* counselling intervention that focuses on exploring emotions and how they impact on thoughts and behaviours that maintain depression.

In 2008, the Improving Access to Psychological Therapy (IAPT) programme was implemented within the National Health Service (NHS) in the UK to increase the availability of evidence-based psychological treatments for depression and anxiety (Clark, 2011). Key principles of IAPT services are that they only deliver NICE-recommended interventions, all therapists are suitably qualified and supervised to ensure adequate treatment fidelity and patient outcomes are assessed at each session (Layard & Clark, 2014). The success of this treatment initiative has been widely reported, with more than 50% of all patients recovering in 2017 (Clark, 2018). Current figures indicate that 56,972 patients completed a course of treatment in 2021, of which 49.9% recovered (NHS Digital, 2021).

1.3 | Comorbidity of SUDs and depressive disorders

1.3.1 | Prevalence and impact

Depression is the most common co-occurring mental health disorder in people with SUDs (Torrens, Mestre-Pintó & Domingo-Salvany, 2015). A systematic review and meta-analysis of 120 epidemiological studies reported the strongest association between illicit SUD and

depressive disorder, followed by alcohol use disorder and depressive disorder, with pooled odds ratios of 5.7 and 2.7, respectively, compared to individuals without SUD (Saha et al., 2021). It has been estimated that approximately one-third of people with depression have a comorbid SUD (Davis, Uezato, Newell & Frazier, 2008). This figure is reported to be even higher in treatment-seeking SUD samples, with data showing that around 1 in 2 SUD patients also has clinically significant depressive symptoms (Johnson, Neal, Brems & Fisher, 2006; McKetin et al., 2011).

The comorbidity of depression and SUDs is associated with increased severity of depressive symptoms, heavier substance use, increased engagement in risky substance use behaviours and poorer physical health outcomes (Erfan, Hashim, Shaheen & Sabry, 2010; Havard, Teesson, Darke & Ross, 2006; Teesson et al., 2008). Patients with comorbid SUD-depression are also more likely to be involved in criminal activity (Teesson et al., 2008). In addition, they tend to require a greater number of treatment episodes (Erfan, Hashim, Shaheen & Sabry, 2010) and are less likely to complete SUD treatment successfully than those without comorbid SUD-depression (Tate et al., 2004). Therefore, effective interventions are needed to improve patient outcomes and minimise the elevated health and social costs associated with this comorbidity.

1.3.2 | Theories of comorbid SUD-depression

The mechanisms underlying the high co-occurrence of SUDs and depressive disorders remains a matter of debate in the field (Volkow, 2004). Several theories have been proposed, which generally align with one of three temporal pathways by which comorbid SUD-depression may develop (see Figure 1.1), and which are explained below. Regardless of how comorbid SUD-depression develops, it is widely acknowledged that SUD and depressive disorders tend to exacerbate each other once they have been established (e.g. Erfan, et al., 2010).

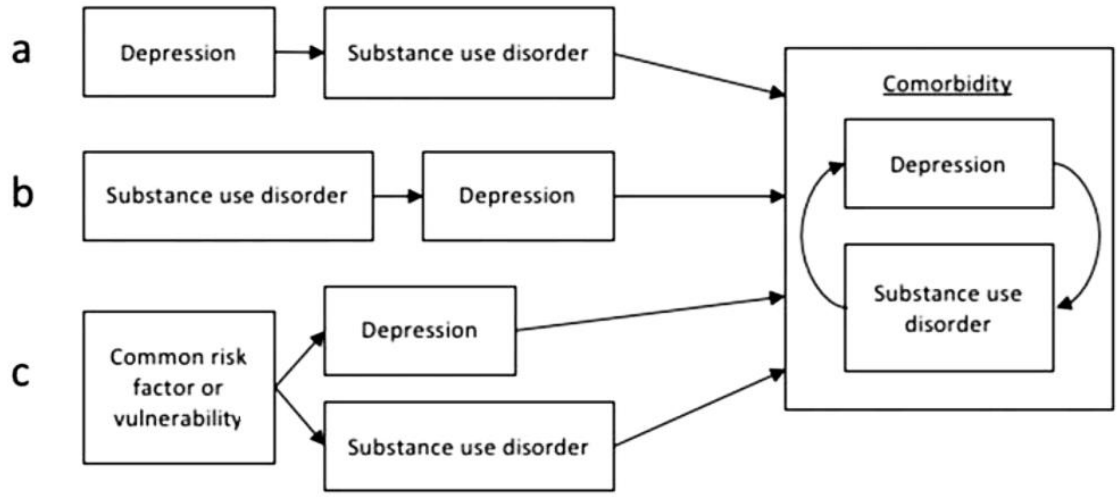


Figure 1.1. Potential pathways to comorbid SUD-depression

1.3.2.1 | *Depression causes SUD*

One possibility is that depression leads people to develop SUDs. According to the self-medication hypothesis, people with depression may become dependent on a particular substance because its effects alleviate their specific negative affective state (Khantzian, 1997). An example would be a person who is depressed repeatedly using cocaine for its uplifting effects and subsequently developing a psychological dependence. The self-medication hypothesis seemingly fits with self-reported reasons for substance use in SUD samples (e.g. Cornford, Umeh & Manshani, 2012). However, there is a lack of evidence that substances reliably improve the symptoms of people who are depressed. For example, acute cocaine intoxication has been found to have unpredictable effects in people with depressed mood, often having no effect and in some cases worsening depressed mood (Gawin & Kleber, 1986; Post, Kotin & Goodwin, 1974).

There is some evidence that depression precedes the onset of SUD in some cases. One study indicated that depression diagnoses tend to precede opiate use disorders in men (Kokkevi & Stefanis, 1995). Two studies also found that depressed mood in adolescence, particularly in females, was predictive of substance use problems in later life (Fleming, Mason, Mazza, Abott & Catalano, 2008; Mason, Hitchings & Spoth, 2007). Conversely, other studies have reported that depression rarely precedes SUD onset (e.g. Hasegawa et al., 1991). However, general limitations of studies in this area include variations in the definition of age of onset and lack of distinction between SUDs and hazardous use.

1.3.2.2 | *SUD causes depression*

Another explanation is that SUDs contribute to the development of depression. Some studies have indicated that the pharmacological effects of a substance can produce depressive symptoms during acute intoxication and withdrawal (Gawin & Kleber, 1986; Markou & Kenny, 2002). With substance-induced depression, patients' depressive symptoms typically resolve within less than a month of abstinence (Nunes & Levin, 2004; Nunes et al., 2004).

It is also possible that SUDs could cause depression indirectly. For example, a person who is alcohol dependent may lose their job due to absenteeism or poor work performance. Unemployment or resulting financial problems could then lead to the development of a depressive disorder. Similarly, people with SUDs tend to be stigmatised by society (Barry, McGinty, Pescosolido & Goldman, 2014; Van Boekel, Brouwers, Van Weeghel & Garretsen, 2013). Resulting self-stigma could then contribute to the development of depressive symptomatology (e.g. Corrigan & Watson, 2002).

1.3.2.3 | *Common risk factors for SUD and depression*

Another potential explanation for the high prevalence of comorbid SUD-depression is that depression and SUDs share common risk factors or vulnerabilities that increase the likelihood they will co-occur. Indeed, accumulating evidence suggests that shared genetic vulnerabilities underpin multiple forms of psychopathology (Carey et al., 2016), including depression and SUDs specifically (e.g. Rask-Andersen et al., 2017). There is also evidence that personality traits such as neuroticism may increase a person's vulnerability to developing both depression (e.g. Allen et al., 2020) and SUDs (e.g. Terracciano et al., 2008). Moreover, psychosocial factors such as lack of reward availability (e.g. Joyner et al., 2016) and history of childhood trauma (e.g. Heim & Binder, 2012; Mills et al., 2006) have been associated with the development of both SUDs and depressive disorders, which could potentially explain their co-occurrence.

1.4 | Integrated cognitive and behavioural treatments for comorbid SUD-depression

Regardless of which disorder came first, integrated treatment is recommended for people with comorbid SUD-depression (WHO, 2020). To date, several integrated cognitive and

behavioural approaches to treating comorbid SUD-depression have been developed and evaluated (Vujavonic et al., 2017). These approaches comprise traditional CBT, in addition to third-wave CBT approaches that focus on the function of problematic thoughts or behaviours rather than their content. An overview of each approach is provided below.

- *CBT* interventions are focused on analysing and changing maladaptive thoughts and behaviours associated with depression and substance use. The evidence base for CBT as a treatment for depression (Cuijpers et al., 2013) and SUDs (McHugh et al., 2010) as individual disorders is well established. Several systematic reviews and meta-analyses have also demonstrated the efficacy of CBT for comorbid depression and alcohol use disorders (Baker, Thornton, et al., 2012; Hides et al., 2010; Riper et al., 2014). However, there is a lack of evidence for CBT to treat comorbid depression and illicit drug use disorders. It is also notable that CBT is associated with moderate-to-large effects on depression outcomes in non-SUD samples (e.g. $g = 0.71$; Cuijpers et al., 2013) and much smaller effects on depression ($g = 0.27$) and substance use ($g = 0.17$) outcomes in SUD samples, even when combined with MI (Riper et al., 2014). One possible explanation for this finding is that the complex cognitive components of CBT may be inappropriate for SUD populations. Indeed, patients accessing SUD treatment are more likely to have cognitive impairments (Bruijnen et al., 2019) and low literacy levels (Beitchmann et al., 2001), which could limit understanding and adherence to CBT treatment concepts in some patients. Therefore, investigating alternative psychological approaches for treating comorbid SUD-depression is warranted.
- *Acceptance and Commitment Therapy (ACT)* is a third-wave CBT intervention emphasising experiential acceptance, psychological flexibility and committed action to reduce psychopathology. Several meta-analyses have reported moderate effects of ACT on depression outcomes in non SUD-samples (Bai et al., 2020; Hacker et al., 2016). A meta-analysis of 10 RCTs comparing ACT to other active treatments in SUD patients also reported small to medium effects favouring ACT (Lee et al., 2015). Moreover, several RCTs have found that ACT was associated with significant reductions in depression and alcohol use in patients with comorbid depression and alcohol use disorders (Petersen & Zettle, 2009; Thekiso et al., 2015).
- *Mindfulness-based interventions* represent a third-wave CBT approach focused on increasing awareness and acceptance of difficult sensations, thoughts, and feelings

associated with depression and SUDs. Several meta-analyses have shown that mindfulness-based cognitive therapy (MBCT) is associated with modest yet significant improvements in depressive symptoms in depressed non-SUD samples (Kuyken et al., 2008; Seshadri et al., 2021). However, a recent Cochrane review found no evidence that mindfulness-based interventions were more effective than no treatment for reducing substance use in SUD samples (Goldberg et al., 2021). The evidence for mindfulness-based interventions for treating comorbid SUD-depression is also limited. One study found that the relationship between substance use craving and depressive symptoms was evident in SUD patients who received usual care, but not in those who received mindfulness-based relapse prevention (MBRP) (Witkiewitz & Bowen, 2010). This finding suggests that MBRP influences SUD patients' cognitive and behavioural responses to depressive symptoms. However, no controlled studies have demonstrated the efficacy of mindfulness-based approaches as a treatment for comorbid SUD-depression.

- *BA* is a behaviour therapy focused on increasing engagement in rewarding activities and reducing engagement in maladaptive (e.g. addictive, avoidance) behaviours. Several meta-analyses have demonstrated that BA is associated with significant reductions in depressive symptoms in depressed non-SUD samples (Cuijpers et al., 2006, 2013; Ekers et al., 2007, 2014; Mazzuchelli et al., 2009; Simmonds-Buckley et al., 2019). Emerging evidence also suggests that BA is a promising treatment for patients with comorbid SUD-depression (Martinez-Vispo et al., 2018).

1.4.1 | BA as a treatment for comorbid SUD-depression

Behavioural activation (BA) is a parsimonious and potentially effective treatment option for comorbid SUD-depression. Compared to CBT, the treatment principles of BA are relatively simple which may facilitate its application to a wider range of patients (e.g. Dimidjian et al., 2011). BA also has a more robust evidence base as a treatment for depression (e.g. Ekers et al., 2014) than ACT and mindfulness-based approaches, in addition to theoretical applicability to SUDs.

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.

Consistent with behavioural theory, SUDs have been associated with a lack of reinforcement for alternative, healthy behaviours (Carroll, 1996; Vuchinich & Tucker, 1988). Additionally, 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). Therefore, the focus of BA treatment for SUD patients with depressive symptomatology is to increase engagement in healthy, positively reinforcing activities and decrease maladaptive behaviours in order to address depressive symptoms and substance use simultaneously (Daughters et al., 2016).

1.5 | SUD treatment context

The purpose of SUD treatment is to support people with SUDs to reduce or stop using substances and improve their overall health, functioning and quality of life (WHO, 2020). SUD treatment services may be delivered on an inpatient or outpatient basis and typically offer a combination of harm reduction (e.g. needle exchange), pharmacological and psychosocial interventions (Department of Health, 2017; WHO, 2020). The benefits of SUD treatment are well-established and include reductions in substance use, risk of overdose and crime (Eastwood et al., 2017). Estimates indicate that for every £1 spent on SUD treatment, £2.50 is saved in associated healthcare, criminal justice and social welfare costs (Davies et al., 2009; Public Health England, 2017[b]).

1.5.1 | SUD treatment provision in the UK

The UK has a public treatment system for SUDs and one of the highest treatment penetration rates in the world (European Monitoring Centre for Drugs and Drug Addiction [EMCDDA], 2020; Public Health England, 2017[b]). Current figures indicate that there are 275,899 adults accessing SUD treatment in England (National Drug Treatment Monitoring System [NDTMS], 2021). Of these patients, 97% receive treatment in a CDAT service and most are accessing treatment for opiate (51%) or alcohol (28%) use disorders. Treatment in CDAT services is delivered on an outpatient basis and typically consists of adjunctive pharmacological and psychosocial interventions to address addiction and associated harms

(Public Health England, 2017[b]). However, the way that SUD treatment services are funded and what is expected of them has changed significantly over the last 40 years.

The 1980s to late 1990s marked the beginning of a united and centrally funded response to problematic substance use in the UK (Public Health England, 2017[b]). During this time, SUD treatment services employed a harm reduction approach which aimed to keep people in treatment and reduce drug-related harm, characterised by needle exchange programs and maintenance prescribing of opiate substitute medication. This approach was adopted in response to the proliferation of injecting heroin use and concerns around HIV transmission (Advisory Council on the Misuse of Drugs [ACMD], 1988), with subsequent evidence indicated that its implementation was successful in reducing blood-borne viruses along with other drug-related problems (Gossop et al., 1997).

In the late 1990s, SUD treatment provision shifted from harm reduction to a criminal justice focus. There was significant government investment in SUD treatment as part of the national drug strategy "tackling drugs to build a better Britain", which aimed to improve the quality and capacity of SUD treatment provision to reduce crime (HM Government, 1998). In 2001, the National Treatment Agency (NTA) and National Drug Treatment Monitoring System (NDTMS) were established to oversee the expansion of SUD treatment provision. Services were commissioned by local Drug and Alcohol Action Teams and there was a guaranteed budget for SUD treatment provision regardless of other public health priorities (ACMD, 2017). The success of SUD treatment services during this time was measured in terms of their ability to engage and retain patients. However, in the mid-2000s, the maintenance approach to SUD treatment was criticised for inhibiting patients from making meaningful changes in their lives and a focus on "full recovery" was called for (Public Health England, 2017[b]).

Consequently, national drug strategies since 2008 have placed a strong emphasis on recovery, with the aim of SUD treatment to help patients achieve abstinence from substances and reintegrate into their communities (HM Government, 2008, 2017). However, this policy change has also coincided with increased austerity (HM Treasury, 2010). Responsibility for commissioning SUD treatment services was transferred from specialised Drug and Alcohol Action Teams to general local authorities in 2012 (Health & Social Care Act, 2012), and funding is no longer protected against other public health priorities (ACMD, 2017). These changes have contributed to sizeable reductions in funding for the SUD treatment sector over

the last ten years (Recovery Partnership, 2017). The NTA was also disbanded in 2013 and merged with Public Health England, which is noted to play more of an advisory role than the quality assurance role afforded by the NTA (ACMD, 2017). Many services are now delivered by voluntary sector organisations instead of the National Health Service (NHS), as these organisations can be delivered at a lower cost employing mostly non-professional staff and volunteers (Recovery Partnership, 2017). The recommissioning of individual services occurs every couple of years in an attempt to ensure the efficiency of services against dwindling local budgets (ACMD, 2017). This competitive tendering process involves SUD treatment providers submitting bids to local commissioners describing how they would deliver a local SUD treatment service against pre-determined specifications, along with how much the provision would cost (NTA, 2010). Therefore, delivering cost-effective services that help patients exit treatment successfully remains a key priority for the SUD treatment sector.

1.5.2 | Delivery of evidence-based interventions in SUD treatment settings

Evidence-based interventions are widely acclaimed for increasing treatment effectiveness (APA Presidential Task Force on Evidence-Based Practice, 2006), establishing accountability of treatment providers (Spring, 2007) and improving the overall cost-effectiveness and quality of treatment (Pope, 2003). Some evidence-based treatments such as medically assisted treatment (MAT) for opiate use (i.e. methadone, buprenorphine) have been widely implemented in SUD treatment (Eastwood et al., 2017). In contrast, the implementation of evidence-based psychosocial interventions has been slow to occur (Carroll & Rounsaville, 2007; Glasner-Edwards & Rawson, 2010).

In the UK, best practice guidelines disseminated by the Department of Health and NICE inform SUD treatment provision. These guidelines extend on WHO (2020) guidance by delineating the scope of service delivery and processes for collaborating with other services, in addition to recommending specific evidence-based interventions and techniques (Department of Health, 2017; NICE, 2007). According to current best practice guidelines, it is recommended that evidence-based pharmacological treatments are provided as appropriate, along with psychosocial interventions for all patients accessing SUD treatment. Recommended psychosocial interventions include brief MI, CM, BCT and mutual aid or self-help (Department of Health, 2017; NICE, 2007).

A survey of 100 SUD treatment practitioners in the UK found that brief MI and CBT-based relapse prevention were the most commonly delivered evidence-based psychosocial interventions in CDAT (Calder, 2019). However, it has also been reported that much of the psychosocial aspect of SUD treatment tends to be based on intuition, practitioner experience and folk wisdom accumulated from peers (Miller et al., 2006). Evidence-based psychosocial interventions are not employed consistently in SUD treatment and providers commonly use practices that have little or no evidence of effectiveness (Carroll & Rounsaville, 2007; Delany et al., 2008; Garner, 2009). For example, Best et al. (2009) found that the majority of treatment sessions in CDAT revolved around case management activities (e.g. discussing prescribing practices and session attendance) and signposting patients to other services (e.g. housing), with evidence-based interventions being offered less frequently. Consequently, there have been calls for more focus on implementing evidence-based interventions in SUD treatment settings (McGovern et al., 2013).

1.5.3 | Lack of access to mental health support for SUD patients

There is a lack of appropriate mental health support available to SUD patients, particularly for common mental health problems like depression and anxiety (Department of Health, 2017; Recovery Partnership, 2017; Turning Point, 2016). In 2020 to 2021, 63% of patients entering SUD treatment in the UK reported an additional mental health treatment need (Public Health England, 2020). Of these patients, 55% were receiving pharmacological treatment from their GP and just 1% reported accessing IAPT for support with depression or anxiety. For patients with comorbid SUD-depression, the benefit of solely pharmacological treatment for depression has been questioned (Lingford-Hughes et al., 2012). Moreover, it has been reported that mental health services such as IAPT tend to exclude SUD patients on the premise that mental health symptoms may cease with abstinence (Recovery Partnership, 2017). When parallel treatment approaches have been attempted to address comorbidity, outcomes have tended to be poor (Kelly & Daley, 2013). The reasons for this may be (a) the complexity for patients of accessing multiple services and/or (b) the staff time required to deliver separate interventions and to liaise between differing services.

Therefore, current UK guidelines recommend integrated approaches addressing SUDs and mental health disorders simultaneously and in the same location where possible (Department of Health, 2017; Hintz et al., 2006). Since many patients receive prescribing

interventions in CDAT (NDTMS, 2021), it seems logical to provide integrated treatment for comorbid SUD-depression in CDAT, rather than mental health services. Furthermore, evidence suggests that patients with comorbid SUD-depression were significantly more likely to access support for CMDs when offered in CDAT, rather than a mental health service (Delgadillo et al., 2015). However, in the UK, only 1% of SUD patients with a mental health treatment need were offered an evidence-based mental health intervention at the start of SUD treatment in 2020 to 2021 (NDTMS, 2021). Likewise, only 14% of UK drug and alcohol treatment workers reported delivering psychological interventions for mental health problems in routine practice (Calder, 2019). Therefore, this data suggests that psychological interventions for mental health problems are seldom delivered in SUD treatment services.

It is widely recognised that there tends to be a delay in translating evidence of effectiveness and efficacy from clinical trials into routine clinical practice (Balas & Boren, 2000) and this issue seems to be especially prominent in SUD treatment (e.g. Carroll & Rounsaville, 2007). The delay in integrating psychological treatments for comorbid SUD-depression into SUD treatment is likely further exacerbated by the general lack of consensus regarding which interventions are effective for this comorbidity and who should deliver them. Indeed, even though current best practice guidelines recommend integrated care for SUD patients with co-occurring mental health problems, they do not specify how this can be achieved (Department of Health, 2017; NICE, 2007; WHO, 2020). Likewise, a previous issue of the Department of Health guidelines stated that treatment for common mental health problems *may* need to be delivered in SUD treatment, but equally emphasised joint working with mental health services and offered no indication of what interventions should be delivered (Department of Health, 2007).

Aside from ambiguous treatment guidelines, many other factors may affect the implementation of evidence-based mental health interventions in routine care. For example, organisational climate, the complexity or relative advantage of an intervention and practitioners' knowledge and beliefs about it (Damschroder & Hagedorn, 2011). Indeed, it may be the case that existing integrated treatments for comorbid SUD-depression (see Section 1.4) are unacceptable or unfeasible for delivery in an SUD treatment context. Even if some are suitable for delivery, there is a lack of evidence regarding how to translate them into routine practice. Therefore, to clarify future recommendations and improve care provision for patients with comorbid SUD-depression, more research is needed to establish both the

effectiveness and acceptability of integrating evidence-based psychological interventions for comorbid SUD-depression into CDAT.

1.6 | Integrating BA into CDAT

BA is a straightforward treatment with a strong evidence base for the treatment of depression (Richards et al., 2016) and theoretical applicability to the treatment of SUDs (e.g. Joyner et al., 2016). Research indicates that BA is equally as effective as CBT for depression (Jacobson et al., 1996) and emerging evidence suggests that it is a promising treatment for patients with comorbid SUD-depression (Martinez-Vispo et al., 2018). The simple treatment principles of BA facilitate its delivery by non-specialist practitioners (e.g. Ekers et al., 2011) and application to a wide range of patients (e.g. Dimidjian et al., 2011; Jahoda et al., 2005), which potentially make it feasible for implementation in busy SUD treatment settings. BA treatment principles are also compatible with recommended SUD treatment approaches that are focused on community integration and recovery (Department of Health, 2017).

Given the gaps between evidence and practice in SUD treatment, it is of paramount importance that BA is investigated in a way that could facilitate future implementation in CDAT if it is found to be effective. A multitude of conceptual frameworks are available to help maximise the use of research resources and address the challenges and delays associated with translating evidence to practice (Milat & Li, 2017). These frameworks offer a broad frame of reference for organising thinking and guiding the overall research process in a systematic way to facilitate implementation (Rycroft-Malone & Bucknall, 2010). A full review of research translation frameworks is beyond the scope of this chapter, however, common elements include critiquing and synthesising evidence for an intervention, evaluating the acceptability (from multiple perspectives) and impact of an intervention in real-world contexts and ultimately integrating effective interventions in to routine practice (for review of research translation frameworks, see Milat & Li, 2017).

1.6.1 | UK Medical Research Council (MRC) framework for developing and evaluating complex interventions

The MRC framework (Craig et al., 2008; Skivington et al., 2021) is a widely used and cited research translation framework that has potential in guiding the evaluation of the introduction

of BA in CDAT. This framework delineates a phased approach to developing and investigating interventions which comprises: (1) development or identification of an intervention based on relevant theory and evidence; (2) feasibility testing to establish acceptability and estimate recruitment and retention rates; (3) testing the effectiveness of the intervention on a larger scale and preferably in different contexts; and finally (4) developing and testing implementation strategies based on knowledge acquired in previous phases to promote adoption of the intervention in routine practice. Sequential progression through these phases is preferable, although it is acknowledged that some phases may need to be repeated or take place simultaneously (Craig et al., 2008; Skivington et al., 2021).

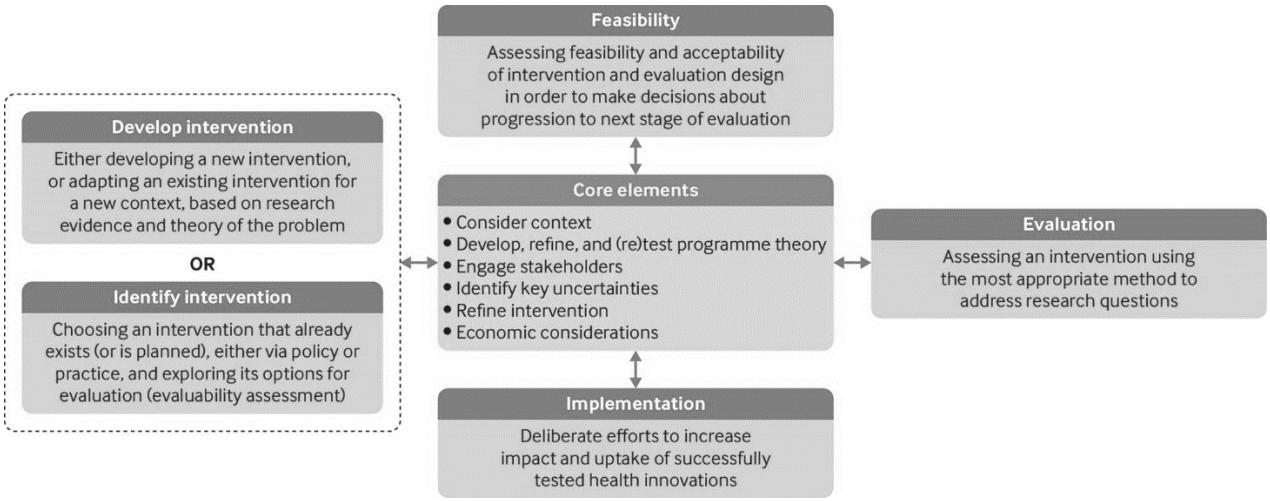


Figure 1.2. MRC framework for developing and evaluation complex interventions
Note. Reprinted from "A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance", by K. Skivington et al., 2021, *BMJ*, *374*(2061), (https://doi.org/10.1136/bmj.n2061)

The MRC framework (Skivington et al., 2021) also clarifies core elements that should be considered from an early stage and continually revisited throughout the research process: (1) appraisal of the social, political and organisational features of the settings in which an intervention is to be implemented; (2) understanding how the intervention produces its effects and under what conditions; (3) involvement of key stakeholders (i.e. patients and treatment providers) in the development of the research and intervention; (4) identification of key uncertainties relating to the intervention or its effects to guide choice of research questions and methodology; (5) refining the intervention based on collected data or the development of

programme theory; and finally , (6) the economic viability and cost-effectiveness of the intervention.

The exact impact of the MRC framework on research efficiency is difficult to gauge. However, several studies have successfully applied the MRC framework to develop and evaluate interventions addressing varied healthcare issues (e.g. Barley et al., 2014; Bobrow et al., 2018), therefore highlighting its flexibility and utility. The framework is also acclaimed for contributing to a broader movement towards strategically phased, pragmatic research which employs a range of research methods to answer research questions more effectively (Craig & Petticrew, 2013). Therefore, drawing on recommendations from the MRC framework should help to guarantee the relevance and impact of research investigating BA delivery in CDAT.

1.7 | Summary

In summary, comorbid SUD-depression is common and associated with poor prognoses in SUD treatment populations. BA is a promising treatment for this comorbidity which could help to address an unmet mental health support need for patients accessing CDAT. However, the efficacy of BA for comorbid SUD-depression remains uncertain and it is unclear whether BA would be feasible or acceptable for implementation in routine CDAT. Applying a research translation framework to the investigation of BA for comorbid SUD-depression may lead to clearer conclusions regarding the value and adoptability of this intervention, which could help to expedite future implementation in routine care. Therefore, this thesis draws on recommendations from the MRC framework (Craig et al., 2008; Skivington et al., 2021) to first establish the evidence base for BA as a treatment for comorbid SUD-depression and then conduct a preliminary exploration of the acceptability and effectiveness of implementing BA in CDAT. The rationale and aims of the following four chapters are now described below:

1.7.1 | Aims of the thesis

- Given the lack of clarity regarding the efficacy of BA for comorbid SUD-depression, Chapter 2 aims to review and synthesise evidence for BA treatments that have been delivered with patients who have comorbid SUD-depression. A meta-analysis is presented on outcomes from randomised controlled trials to

establish how acceptable (via the proxy of dropout rates) and effective (via effect sizes) BA for comorbid SUD-depression is based on the best available evidence. Key uncertainties are highlighted and implications of the findings are discussed in the context of theory, future research and delivery of BA in routine treatment settings.

- Chapter 3 describes a pilot RCT of BA facilitated by drug and alcohol treatment workers in routine CDAT. The effects of the intervention compared to usual care are explored, in addition to identifying the dropout rate (as a proxy of acceptability) and characteristics associated with patient dropout. Key uncertainties are highlighted and the implications of the findings are discussed in the context of theory and future research.
- Chapter 4 consists of a qualitative study nested within the pilot RCT reported in Chapter 3. The perspectives of a sample of clinical managers, BA therapists and BA patients who had been involved in the trial are synthesised to establish the acceptability and perceived value of integrating BA into routine CDAT. Implications of these findings are discussed in the context of theory and directions for future research are provided.
- Finally, Chapter 5 concludes by assimilating the findings from the studies reported in previous chapters guided by recommendations from the MRC framework (Craig et al., 2008; Skivington et al., 2021). The overall implications of the research are discussed in terms of theory regarding the comorbidity of SUD-depression, the effectiveness and potential mechanisms of change associated with BA as a treatment for this comorbidity, what can be concluded regarding the acceptability of integrating BA into routine CDAT, and directions for future research.

Chapter 2

Is Behavioural Activation an acceptable and effective treatment for comorbid SUD-depression? A meta-analysis of randomised controlled trials

In order to explore the possibility of integrating Behavioural Activation (BA) into Community Drug and Alcohol Treatment (CDAT), it is first necessary to gain some clarity on the acceptability and effectiveness of the intervention based on existing research in SUD treatment settings. Therefore, the objective of this empirical chapter is to review and quantitatively synthesise the evidence for BA as a treatment for comorbid SUD-depression in order to establish a combined treatment effect. This chapter reports the findings of a systematic review and meta-analysis of the randomised clinical trial evidence base and acceptability (attendance and dropout rates) of BA for comorbid SUD-depression in comparison to passive and active controls.

2.1 | Introduction

2.1.1 | Behavioural treatment of depression

Reinforcement theory posits that depression occurs when response contingent reinforcement for functional, non-depressive behaviours is low in comparison to reinforcement for depressive behaviours (Ferster, 1973). Increases in maladaptive behavioural responses (e.g. avoidance, inactivity) are common in people with depression and while these behaviours may provide relief from negative stimuli in the short-term, they also reduce access to positive experiences and contribute to the maintenance of low mood in the long-term (Elfrey & Ziegelstein, 2009; Ferster, 1973). The general focus of Behavioural Activation (BA) treatment is therefore to increase access to positive reinforcement and reduce engagement in depressive behaviours.

Central to the BA evidence base is Jacobson's seminal deconstruction trial (Jacobson et al., 1996), which found that activity scheduling alone resulted in similar improvements in depressive symptoms compared to full CBT. Further research has since extended these findings, indicating that there is no difference in efficacy between BA and cognitive therapy (Cuijpers et al., 2006; Ekers et al., 2007; Mazzuchelli et al., 2009). There is also evidence to suggest that BA is economically advantageous, with a large-scale RCT showing that BA produces equivalent outcomes to CBT at a 21% reduced treatment cost (Richards et al.,

2016). Several meta-analyses of the BA trial evidence base have established that BA is an effective standalone treatment for depression. Ekers et al (2014) reported that depression outcomes for BA were superior to controls and medication, while a recent meta-analysis of group BA found that depression outcomes for BA were superior to passive controls and equivalent to active therapies (Simmonds-Buckley et al., 2019).

2.1.1.1 | *Types of BA*

Within the BA evidence base, a number of protocols have been developed and tested, which can be categorised according to five main treatment models: (1) Activity scheduling to support patients to incorporate more pleasant activities into their daily lives (Lewinsohn et al., 1980); (2) *Self-Control Therapy* (SCT), which focuses on activity monitoring, goal-setting and increasing self-reinforcement (Rehm, 1984); (3) *Behavioral Activation Treatment for Depression* (*BATD*; Lejuez et al., 2001), which utilises activity monitoring and additionally enables activity scheduling to be grounded in valued life areas (e.g. family, hobbies); (4) *Contextual Behavioural Activation* (Martell et al., 2001, 2010), which places additional emphasis on functional analysis, skills training and the disruption of rumination; and (5) *Stepped BA* (Kanter et al., 2009), which also incorporates strategies informed by Mindfulness-Based Cognitive Therapy (MBCT; Segal et al., 2002).

Earlier treatment models notably represent simpler forms of BA (Lewinsohn et al., 1980; Rehm, 1984), with treatment comprising only the core behavioural strategies of activity monitoring and scheduling. The more complex forms of BA that have emerged recently are identifiable by their addition of techniques from third-wave therapies and functional analytic psychotherapy which are used to augment behaviour change. For example, BATD (Lejuez et al., 2001), contextual BA (Martell et al., 2001, 2010) and stepped BA (Kanter et al., 2009) variants incorporate values assessments akin to those found in Acceptance and Commitment Therapy (ACT) (Hayes et al., 1999). There is indeed a growing evidence base for the role of values-based interventions in the treatment of depression (Forman et al., 2007; Lappalainen et al., 2007), with research showing that engagement in valued living is associated with reductions in depressive symptoms (Bramwell & Richardson, 2018) and psychological suffering (Gloster et al., 2017) among ACT patients. Contextual BA (Martell et al., 2001, 2010) and Stepped BA (Kanter et al., 2009) variants additionally incorporate enhanced functional analytic techniques such as TRAP (trigger, response, avoidant pattern) and TRAC

(trigger, response, adaptive coping). These approaches place emphasis on the role of the therapist-as-social-reinforcer, whereby the therapist observes and evokes patients' problems with daily functioning and responds contingently to patient improvements in clinically relevant behaviours in order to increase their frequency (Kanter et al., 2017; Kohlenberg & Tsai, 1991). Stepped BA further incorporates mindfulness training to support patients to engage in valued activities despite experiencing difficult thoughts and feelings (Kanter et al., 2009), an approach which is supported by evidence that increased mindfulness is associated with reductions in depressive symptoms among MBCT patients (Kuyken et al., 2010). Regardless of which additional techniques are used in BA therapy, however, the focus of treatment remains on increasing engagement in positively reinforcing activities as opposed to directly modifying cognitions. This makes BA a relatively straightforward treatment which should be suitable for delivery with a wide range of patients (Veale, 2008).

2.1.2 | Behavioural treatment of SUDs

Consistent with reinforcement theory, the development and maintenance of SUDs has been linked to a lack of positive reinforcement for alternative, healthy behaviours (Carroll, 1996; Vuchinich & Tucker, 1988). Research has shown that people with SUDs report less engagement in pleasant activities compared to healthy controls (Roozen et al., 2008) and increasing the availability of alternative sources of drug-free reinforcement has been associated with lower levels of substance use (Correia et al., 2005; Vuchinich & Tucker, 1996). Pure behavioural approaches also notably have some of the most robust evidence for the treatment of SUDs.

A wealth of research has demonstrated that the Community Reinforcement Approach (CRA) is associated with reductions in drinking among patients with alcohol use disorders (Miller & Wilbourne, 2002; Finney & Monahan, 1996; Holder, Longbaugh, Miller & Rubonis, 1991; Roozen et al., 2004). CRA incorporates functional analytic techniques and is similar to BA therapy in that it focuses on exposing patients to positive reinforcement via engagement in rewarding activities (Hunt & Azrin, 1973). In contrast to BA, however, the CRA therapist typically plays a more dynamic role by accompanying patients to access such activities. While the evidence for CRA as a standalone treatment is based on patients with alcohol use disorders, a series of studies combining CRA with contingency management (CM) found that the addition of vouchers as tangible reinforcement was associated with

significant reductions in cocaine (Higgins et al., 2003; Higgins et al., 1993) and opiate use (Bickel et al., 1997). Further, a systematic review of 50 RCTs evaluating 12 psychosocial interventions found that CRA+CM was superior to CBT, CM, CBT+CM and 12-step therapy for patients with cocaine and amphetamine use disorders (De Crescenzo et al., 2018). CM also has some of the strongest evidence in terms of reducing substance use (Dutra et al., 2008; Lussier et al., 2006). Combining CM with usual care and other psychotherapies such as CBT has been associated with improved treatment outcomes in patients with nicotine (Donatell et al., 2004; Higgins et al., 2004), cannabis (Kadden et al., 2007; Budney et al., 2006) and opiate use disorders (Petry et al., 2012).

However, despite clear evidence of efficacy, neither CRA or CM have been widely implemented in SUD treatment. This is likely due to the significant staff time required for CRA delivery and costs associated with CM (Petry & Barry, 2011). Therefore, behavioural approaches appear to be very effective for SUD patients, but it is clear that behavioural interventions need to be cost-effective and simple to deliver if they are to be successfully implemented in SUD treatment settings.

2.3 | BA as a treatment for comorbid SUD-depression

There is considerable evidence that both depression and SUDs are associated with a lack of reinforcement for healthy, functional behaviours in a person's environment (e.g. Carroll, 1996). The focus of BA treatment in an SUD treatment context is to increase engagement in valued, positively reinforcing activities and to decrease engagement in maladaptive (e.g. addictive, avoidance) behaviours, in order to alleviate depression symptoms and dependence on substances simultaneously (Daughters et al., 2016). Given its behavioural focus and parsimonious approach to formulation and intervention, it seems that BA could be a particularly amenable approach for treating comorbid SUD-depression. Yet the focus and evaluation of BA as a treatment for comorbid SUD-depression has so far been limited.

To date, only one systematic review has examined the effectiveness of BA on depression and substance use outcomes in SUD patients (Martínez-Vispo et al., 2018). The review narratively synthesised findings from 6 RCTs and 2 practice-based studies, revealing that BA interventions led to improvements in depression symptoms in 6 studies and reductions in substance use in 7 studies. The authors concluded that BA is a promising treatment for comorbid SUD-depression. However, a key limitation of this review is that they

included samples with subclinical depression (Daughters et al., 2018), which brings into doubt the generalisability of the evidence to clinically depressed substance users treated within routine services. Indeed, the findings from the Daughters et al. (2018) RCT found that BA led to significant improvements in substance use, but not depressive symptoms, which may represent a floor effect due to lower levels of depressive symptoms reported among participants at baseline. Moreover, the BA intervention in one of the included studies (González-Roz et al., 2018) was delivered in combination with CBT, thereby masking the independent effect of either treatment. The inclusion of practice-based studies in this systematic review was not necessarily a limitation, as these studies can be valuable in determining the efficacy of interventions in naturalistic settings (Barkham & Mellor-Clark, 2000). However, evidence from RCTs is generally considered to be more robust and may provide a more reliable estimate of BA's efficacy for this patient population (Hariton & Locascio, 2018). The effectiveness of BA was also not meta-analysed in the previous review, therefore the clinical efficacy of BA for comorbid SUD-depression remains uncertain.

2.4 | Focus of the present meta-analysis

A meta-analysis is a methodologically sound approach that enables the estimation of the overall effects of an intervention across studies, allowing for a thorough assessment of the consistency of effects in order to understand generalisability (Borenstein et al., 2011). It is a statistically rigorous approach to synthesising the best available evidence that is generally considered to be more reliable than qualitative and narrative syntheses (Borenstein et al., 2011; Pettiti, 1999). This systematic review and meta-analysis aimed to address the limitations of the previous narrative review by quantifying the effectiveness of BA as a treatment for comorbid SUD-depression in terms of depression and substance use outcomes, specifically focusing on RCTs that have investigated BA compared to passive and active controls with SUD patients who have clinically significant depression symptoms. A meta-analysis offered the opportunity to critically evaluate and statistically combine results of comparable clinical trials and in doing so increases the number of observations, statistical power and improves the estimates of effect size for BA in this patient group (Walker et al., 2008). Given that there may be distinct benefits of group BA for SUD patients due to factors such as affiliation and strengthening commitment to recovery (Ahmed et al., 2010), the study also sought to examine whether the mode of delivery of BA interventions had any impact on

depression and substance use outcomes. In the sensitivity analyses conducted, the study additionally sought to explore whether the type of substance being used had any effect on treatment outcomes and whether the use of passive controls had an effect, as active controls may be less likely to reveal significant overall effects (Karlsson & Bergmark, 2015). Finally, the study aimed to define the acceptability of BA through reporting the average duration of treatment, number of BA sessions attended and overall dropout rate compared to controls.

2.5 | Objectives of the meta-analysis

To summarise, this systematic review and meta-analysis of BA as a treatment for comorbid SUD-depression had three key objectives:

1. To assess the efficacy of BA compared to passive and active controls in terms of depression and substance use outcomes;
2. To investigate whether mode of BA delivery, type of substance and use of passive or active controls had any impact on depression and substance use outcomes via sensitivity analyses;
3. To define the acceptability of BA by calculating attendance and dropout rates in comparison to passive and active controls.

2.2 | Method

2.2.1 | Study protocol

The systematic review protocol was pre-registered with the International Prospective Register of Systematic Reviews (Protocol ID: PROSPERO 2018: CRD42018112098).

2.2.2 Inclusion and exclusion criteria

Studies were identified as being eligible based on the following five criteria:

2.2.2.1 | *Participants*

Adult substance users aged 18 and over with clinically significant depressive symptoms, as measured using diagnostic interviews or validated case-finding measures were included. Substance users were defined as individuals who met at least one of the following criteria: (i)

enrolled in a community or inpatient addiction treatment programme; (ii) had used substances recently as assessed by a screening questionnaire (e.g. Timeline Follow-Back Method; TLFB; Sobell & Sobell, 1992); and, (iii) met criteria for SUD assessed by a structured clinical interview (e.g. Structured Clinical Interview for DSM-III-R/DSM-IV-SAC; SCID-SAC; Nunes et al., 1996). Substances included alcohol, nicotine, illicit drugs and non-prescription use of legal drugs. There was no limitation in terms of other comorbidities, as long as comorbid SUD-depression was the primary presenting problem. Studies were excluded if they contained child and adolescent samples or participants with subclinical depression.

2.2.2.2 | *Study Design*

RCTs in which participants were randomised to either BA or a passive (i.e. usual care) or active (i.e. alternative psychological treatment) control were included. Uncontrolled (pre-post) studies were excluded. Studies were included if they reported depression outcomes, substance use outcomes, or both.

2.2.2.3 | *BA Interventions*

Studies were included if they involved a BA treatment arm. The methods of studies were analysed and an intervention was labelled as BA when the core focus of treatment was to increase positive interactions between an individual and their environment using at least the following strategies; activity monitoring and activity scheduling. There was no limit on treatment duration, mode of delivery (e.g. group vs. individual) or the setting in which BA was delivered. Studies were included if the BA intervention was combined with an adjunct behavioural treatment such as CM, but excluded if they combined BA with a structured psychotherapy such as CBT.

2.2.2.4 | *Comparators*

Comparators included any passive control or active treatment. Passive control comparators provided participants with either a waitlist period or TAU involving routine care in a clinical practice setting. Active treatment comparators were alternative psychotherapies delivered in an attempt to treat comorbid SUD-depression, including CBT and structured relaxation therapy.

2.2.2.5 | *Accessibility*

All available RCTs, including published studies, unpublished studies and dissertations were included. Studies were excluded if they were not published in the English language or if they did not provide sufficient data for the calculation of effect sizes.

2.2.3 | Search strategy for identification of studies

The following electronic databases were searched from inception to 7th June 2020: PsycINFO, PubMED and the Cochrane Register of Clinical Trials. Searches were conducted with variations (including alternative synonyms and both UK and US spellings) of the following keywords: (a) *behavioural activation* (including *activity scheduling / monitoring*); (b) *depression*; (c) *SUDs* (including various substances such as *alcohol* and *heroin*); and (d) *treatment efficacy* were combined using a mix of MeSH, title, abstract, keywords and text word searches. All searches were limited to human and adult populations and English language (see Appendix A for example search strategy). Further to this, we checked the reference lists of retrieved papers and of a previous review on this topic (Martínez-Vispo et al., 2018) to identify additional RCTs of BA for comorbid SUD-depression.

2.2.4 | Study selection

The search returned 2993 unique titles and abstracts, which were screened for eligibility by the main author (SLP). The corresponding authors of all included papers and relevant study protocols were contacted via email and given four weeks to provide details of any other published studies or unpublished data they were aware of. This generated one new study, though this was a quasi-experimental study and therefore did not meet the inclusion criteria. The most common reasons for exclusion during screening of titles and abstracts were: psychological problems other than depression or SUDs and treatments that were not BA. In total, 23 full-text articles were assessed independently by two reviewers (SLP and JD). Disagreement about the inclusion of studies was resolved by discussion. A total of five studies met eligibility criteria and were included in the review. Figure 2.1 shows the PRISMA diagram (Moher et al., 2009) for the systematic selection of studies.

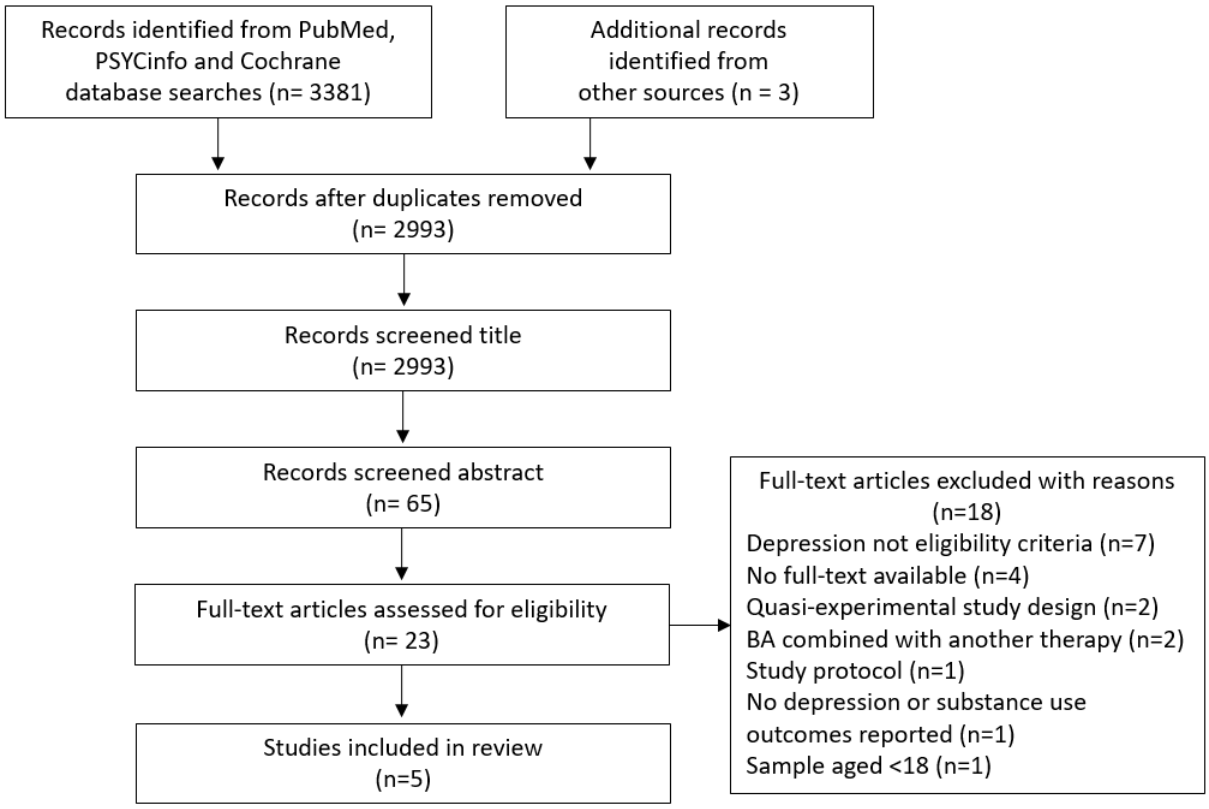


Figure 2.1. PRISMA diagram depicting the process of searching, screening and selecting studies

2.2.5 | Outcome measures

2.2.5.1 | *Primary outcome*

The primary outcome measure was depressive symptomatology as measured using any validated self-report measure (e.g. Patient Health Questionnaire-9; PHQ-9; Kroenke et al., 2003) or clinician-rated (e.g. Hamilton Depression Rating Scale; HAM-D; Hamilton, 1960) presented by means and SDs (continuous data). Psychotherapy trials often report multiple symptom measures and since clinician-rated measures tend to produce larger effect sizes (e.g. Cuijpers et al., 2010), an algorithm was adopted so that self-report measures took precedence over clinician-rated measures. This was in order to create a more conservative estimate of treatment effect (Borenstein et al., 2011). The clinically most commonly used and well validated self-report measure (e.g. Beck Depression Inventory; BDI; Beck et al., 1961, BDI-II; Beck et al., 1996) was selected over other self-report measures.

2.2.5.2 | *Secondary outcomes*

The secondary outcome was substance use as measured using any validated self-report scale (e.g. Severity of Dependence Scale; SDS; Gossop et al., 1995) or assessment (e.g. TLFB; Sobell & Sobell, 1992), presented by means and SDs (continuous data) or abstinent / not abstinent from substances (dichotomous data). The most commonly used substance use outcome (i.e. percent days abstinent; PDA) was selected over self-reported scale measures. For studies that reported the proportion of days that substances were used in the last month, data was converted to PDA rates. Additionally, it was of secondary interest to describe attendance and dropout rates across studies (as defined by the primary study sources). Attendance rates were based on figures reported in the individual studies. Dropout rates were calculated based on the number of patients who were reported to have dropped out of BA and control conditions in proportion to the number of patients who were randomised to each condition in the individual studies.

2.2.6 | Risk of bias

The methodological quality of the RCTs was assessed using the Cochrane Risk of Bias Tool (Higgins et al., 2011). Given the difficulties of blinding staff and participants in psychotherapy trials, studies were assessed using only the following five domains: (1) sequence generation, (2) allocation concealment, (3) blind assessment, (4) data attrition, and (5) selective reporting of outcomes. Each component was rated for high, low or unclear risk of bias and a score was given for each study based on the number of components that met criteria for low risk of bias (higher scores indicate lower risk of bias; maximum score of 5). Studies were assessed independently by the main author and an independent reviewer (PhD student). Interrater reliability was calculated using Cohen's kappa (Cohen, 1960) (whereby .21-.40 = fair agreement, .41-.60 = moderate agreement, .61 to .80 = substantial agreement, .81-1.0 = almost perfect agreement; Landis & Koch, 1977). The kappa was k =.84 indicating almost perfect agreement.

2.2.7 | Quality of evidence

The grading of recommendations assessment, development and evaluation (GRADE; Dijkers, 2013) approach was also used to assess the quality of the included evidence for each meta-analytic comparison. The quality of evidence was assessed using the following six criteria:

(1) study design, (2) risk of bias, (3) inconsistency of results, (4) indirectness of evidence, (5) imprecision, and (6) publication bias. The meta-analysis was graded by three reviewers (SP, SK and JD) and a consensus agreed (rated either high, moderate, low or very low quality).

2.2.8 | Data extraction

Data from included studies were extracted by the main author (SP) using the Cochrane Collaboration Data Collection form (Higgins & Green, 2011) and checked for accuracy by a second author (SK). Data extracted included study population, study setting, participant demographics, details of the intervention and comparators, characteristics of the study methodology, outcomes and times of measurement and attendance and dropout rates. For studies where insufficient data was reported for the calculation of effect sizes, study authors were contacted by e-mail and given four weeks to provide the missing data.

2.2.9 | Calculation of the effect sizes

Effect sizes (ESs) were calculated based on depression and substance use outcomes reported at post-treatment and last available follow-up. Standardised mean differences (SMDs) and standard error (SE) terms were calculated for the difference between BA and each comparator condition. SMDs were calculated by subtracting the mean score of the control group from the mean score of the experimental group and dividing the result by the pooled standard deviations of the experimental and control groups for depression and substance use outcomes reported at post-treatment and last available follow-up. For dichotomous substance use outcomes (i.e. number of participants abstinent vs not abstinent) and dropout rates (i.e. percentage of dropout from BA compared to comparator conditions), the odds ratio was computed and converted to Cohen's *d* using the formula $d = LogOddsRatio \times \frac{\sqrt{3}}{\pi}$ (Borenstein et al., 2011). When a study reported separate outcomes for different substances (i.e. Carpenter et al., 2008), the means of all reported substance use outcomes were averaged for each group and the standard deviations were pooled using the variance pooling formula:

$$S_{pooled} = \sqrt{\frac{\sum_{i=1}^{K}(n_i - 1)S_i^2}{\sum_{i=1}^{K} n_i - K}}$$

Where *K* is the number of outcomes, and n_i, S_i^2 are the sample size and variance corresponding to each outcome. In this particular case, $n_1 = n_2 = \cdots = n_K$ (Borenstein et al., 2011). In order to account for the risk of small-sample bias, the *j* correction was used to convert SMDs to Hedges' *g* (Hedges & Olkin, 1985). Effect sizes were interpreted according to Cohen's criteria, whereby effect sizes of 0.8 and above are considered large, effect sizes of 0.5 are moderate and effect sizes of 0.2 are small (Cohen, 1992).

2.2.10 | Meta-analysis

Data were synthesised using the Cochrane Collaboration RevMan program (Cochrane, 2014). A random effects model was used to account for variance between and within studies. Statistical significance was set at an alpha value of 0.05. Heterogeneity was assessed using the I^2 statistic to indicate percentage of variation. To determine statistical significance, we calculated Cochran's heterogeneity statistic using the following formula:

$$Q = \sum_{i=1}^{k} w_i(d_i - \bar{d})^2$$

Where $w = 1/V_i$ is the weight associated to each studies (i.e. the inverse of the variance V_i), d_i is the effect size for the *i*th study, $\bar{d}$ the summary effect size and k the number of studies. In order to assess the possibility of publication bias, Begg funnel plot graphs were used and inspected for asymmetry (Begg & Mazumdar, 1994). However, the small number of studies in this meta-analysis (<10) limits the accuracy of their interpretation (Higgins & Green, 2011). Due to the small number of studies entered into the meta-analysis (<10), more detailed subgroup or moderator analyses were also not possible (Borenstein et al., 2011).

2.2.11 | Sensitivity analyses

Given that subgroup and moderator analyses were not feasible in this review due to the small number of RCTs available (Borenstein et al., 2011), a series of exploratory random effects meta-analyses were conducted. These aimed to explore the effects of different study characteristics on depression and substance use outcomes. Three sensitivity analyses were conducted: (a) the impact of different substances of dependence on treatment outcomes; (b) the effect of mode of delivery; and (c) the impact of different comparator types on treatment

outcomes. As it has previously been highlighted that active treatment comparators may not be comparable with passive controls (Karlsson & Bergmark, 2015), we only included data from studies that compared BA with TAU in these analyses.

2.2.12 | Within-group analyses

Unbiased within-group ESs were calculated where possible for pre-post and post-treatment to last available follow-up for depression and substance use outcomes to further explore the efficacy and durability of BA. SMDs were calculated for pre-post and post-treatment to follow-up depression and substance use outcomes for BA according to the formula (Minami et al., 2008):

$$d = \left(1 - \frac{3}{4n - 5}\right) \frac{M_{post} - M_{pre}}{SD_{pre}}$$

Where *n* is the number of samples within each group and M_{pre}, M_{post} and M_{endpoint} are the means for the corresponding time points.

2.3 | Results

2.3.1 | Study characteristics

Post-treatment outcomes from N=5 RCTs of BA contributed to the analysis, totalling N=195 participants (1:1 BA *N* =52; Group BA *N*=48; Control *N* =95). Selected characteristics of the included studies are presented in Table 2.1 and details of the interventions are provided in Table 2.2. BA interventions were delivered in group (*N*=2) and individual formats (*N*=3). Treatment duration ranged from 3-24 sessions. BA sessions typically lasted between 30-60 minutes. All BA interventions included activity monitoring and activity scheduling components, some also included values assessments (N=4), behavioural contracting (*N*=2), decisional balance exercises (*N*=2), contingency management (*N*=1) and mindfulness / relaxation exercises (*N*=1).

BA was compared to active treatments in 2 studies and passive controls in 3 studies across 10 comparisons. The active treatment comparisons were structured relaxation therapy (Carpenter et al., 2008) and CBT-based guided self-help (Delgadillo et al., 2015). Structured

relaxation therapy was delivered in a group format, while CBT-based guided self-help was delivered via individual therapy. In the control comparisons, BA was compared with TAU (*N*=3). In studies conducted in outpatient treatment, TAU was contact time matched to the BA interventions during the study period (*N*=2). For inpatient treatment, the BA intervention was delivered in addition to TAU (*N*=1). Participants were recruited from clinical settings in four studies (outpatient *N*=3, inpatient *N*=1) and the community in one study. Substances of dependence included nicotine (*N*=2), illicit drugs (*N*=1) and illicit drugs and alcohol (*N*=2). In all studies and across all conditions, participants had access to pharmacological treatments for substance use (e.g. OST, NRT) and depression. Depression was identified by clinical interview (*N* =4) or self-report (*N* =1). Depression outcomes were measured via self-report in all studies, as well as clinician-rated in two studies. The BDI-II was the most commonly employed self-report outcome measure for depression (*N* =4), and the HAM-D was the most commonly employed clinician-rated measure (*N*=2). Substance use outcomes were measured via self-report using the TLFB in all studies and outcomes were biologically verified in 4/5 studies. Follow-up duration ranged between 4-30 weeks.

2.3.2 | Acceptability of BA

The average session attendance rate for BA was 72% (range 48.3%-100%). The average attendance rate for active comparator conditions was 56% (range 48.1%-100%) and the average attendance rate for passive comparators was 86% (range 75%-100%). Insufficient information was provided to calculate specific attendance rates for BA in Delgadillo et al.'s (2015) study; however, only 34.8% of participants attended at least one session and the average number of sessions attended was 3.13. In the comparator condition the attendance rate was 48.1%. The attendance rate in Bercaw's (2007) study was 100% in both conditions, as failure to attend one session resulted in dropout. In the remaining studies, attendance rates ranged from 48-91% for BA interventions and 64-84% for comparator conditions. The highest attendance rate for BA was reported in the Daughters et al. (2008) inpatient study and this was also the only study in which the BA attendance rate was higher than the comparator (91% versus 84% respectively). An outpatient smoking study reported an equivalent attendance rate of 75% in both arms (MacPherson et al., 2010). The remaining study was conducted in outpatient addictions treatment and reported lower attendance rates in both arms, with a rate of 48% for BA and 64% in the comparator condition (Carpenter et al.,

2008). Overall, the average dropout rate for BA was 35% (range 9-65%), while the average dropout rate for active comparator conditions was 39% (range 25-52%) and the average dropout rate for passive comparators was 32% (range 9-51%). BA dropout rates tended to be lower than comparators, with the lowest BA dropout rate reported in the Daughters et al. (2008) study. The highest dropout rate was reported in Carpenter et al.'s (2008) study which was conducted in outpatient addictions treatment and also reported the lowest attendance rate for BA.

2.3.3 | Risk of bias

Of the *N*=5 studies included, methodological quality ranged from 2-3 quality standards met (maximum was 5); therefore, overall study quality was moderate. Most studies provided sufficient information to assess that there was a low risk of bias from randomisation, however some studies lacked a complete description of randomisation procedures (Daughters et al., 2008; MacPherson et al., 2010). One study reported using an independent administrator to inform researchers of participants' treatment allocation (Delgadillo et al., 2015). However, most studies did not provide sufficient information to assess risk of bias relating to allocation concealment. Some studies reported using research assistants who were blind to the participants' treatment condition when collecting outcome data (Daughters et al., 2008; MacPherson et al., 2010). Other studies either did not provide enough information on the blinding of researchers collecting participant data (Bercaw, 2007; Carpenter et al., 2008), or indicated that researchers collecting data were not blind to participants' treatment condition (Delgadillo et al., 2015). Due to the nature of conducting research in addiction treatment settings, there were high levels of attrition in most studies. One study addressed this by conducting completer analyses (Bercaw, 2007), however most studies either did not provide adequate information on how they addressed missing data (*N*=2), or used methods that carry an increased risk of bias, such as last observation carried forward (Carpenter et al., 2008; Delgadillo et al., 2015). There was no evidence of selective outcome reporting in any of the included studies.

Table 2.1. Study characteristics of the trials treating comorbid SUD-depression

Study	*Clinical setting and country*	*Substance of dependence*	*Aims*	*Inclusion Criteria*	*Exclusion Criteria*	*Sample size (N)*	*Mean age (SD)*	*Sex % Female*	*Measures used (highlighted if meta-analysed)*	*Follow-up (weeks)*	*Risk of bias score (0-5)*
Bercaw et al., (2007)	Clinical (Outpatient), USA	Tobacco	Development and investigation of a brief the BA-based smoking intervention Life Enhancement Treatment for Smoking (LETS-Quit).	(1) Baseline BDI-II score > 12, (2) Regular smoker (10+ cigarettes per day), (3) Aged 18-65, (4) Strong desire to quit smoking (≥7 on 0-10 scale)	(1) Schizophrenia diagnosis, (2) Past-month illicit drug or alcohol abuse	26	48 (SD)	14%	BDI-II, TLFB	5	3
Carpenter et al., (2008)	Clinical (Outpatient), USA	Illicit Drugs	To test the efficacy of BTDD vs. REL for DSM-IV depressive disorders and substance abuse	(1) Current DSM-IV major depression or dysthymic disorder; (2) Stable methadone dose (no changes in prior two weeks) of ≥60 ml.	NR	38	40 (SD)	42.1%	HAM-D, BDI-II, TLFB	24	2
Daughters et al., (2008)	Clinical (Inpatient), USA	Illicit Drugs	To test the efficacy of integrating a brief behavioural	(1) Minimum of 18 years of age, (2) met DSM-IV criteria for substance	(1) Not meeting all inclusion criteria, (2) Taking psychotropic medication for ≤3	44	42.1	37.2%	BDI-II, HAM-D	4	2

			intervention for depression into standard substance abuse treatment	dependence for past year, (3) Completed >= 2 weeks in the inpatient treatment center and detoxification prior to entry into the center, (4) No less than 60 days of treatment, (5) A score at least in the moderate range on the BDI-II, (6) ability to speak and read English sufficiently.	months, (3) Meet criteria for psychotic disorder						
Delgadillo et al., (2015)	Clinical (Outpatient), UK	Illicit Drugs & Alcohol	To examine the feasibility of a 12-session face-to-face BA intervention compared to a CBT-based guided self-help intervention for depression	(1) ≥1 month registered with CDAT service; (2) Clinically significant depression symptoms as defined by the PHQ-9; (3) Mild-to-moderate symptoms of alcohol/drug dependence as defined by SDS	(1) Not meeting all inclusion criteria, (2) Meeting criteria for psychotic, bipolar or severe anxiety disorder, (3) Abstinent from psychoactive substances for at least 4 weeks	50	37.2 (SD)	32%	PHQ-9, TLFB	24	3
MacPherson et al., (2010)	Community, USA	Tobacco	To examine BA as a treatment	(1) Age18–65; (2) current	(1) BDI-II score less than 7, (2)	68	43.8 (SD)	48.5%	BDI-II, TLFB	30	3

	for smoking cessation and depression vs. ST.	regular smoker (≥1 year); (3) Smoking ≥10 cigarettes/day; (4) BDI-II ≥10; (5) No current DSM-IV disorder assessed by the SCID-NP.	Current Axis I disorder as assessed by the SCID-NP, (3) Current use of psychotropic medication, (4) Current participation in psychotherapy, (4) Physical concerns contraindicating the use of nicotine patch, (5) Current use of smoking cessation pharmacotherapy, (6) Current use of smokeless tobacco products

Note: Abbreviations: NR: Not Reported, LETS-QUIT: Life Enhancement Treatment for Substance Use, BDI-II: Beck Depression Inventory-II, TLFB: Timeline Followback Method, BTDD: Behavioral Therapy for Depression in Drug Dependence, REL: Structured Relaxation Intervention, HAM-D: Hamilton Rating Scale for Depression, LETS Act!: Life Enhancement Treatment for Substance Use, BA: Behavioural Activation, CBT: Cognitive Behavioural Therapy, PHQ-9: Patient Health Questionnaire-9, BATS: Behavioral Activation Treatment for Smoking

Table 2.2. Details of BA interventions delivered in the trials, controls used and associated dropout rates

Study	*Type of BA [Complexity]*	*BA treatment*	*Control conditions*	*No. Of sessions (duration in minutes)*	*BA attendance rate vs comparator attendance rate*	*BA dropout rate vs comparator dropout rate*
Bercaw, 2007	BATD [Complex]	LETS-QUIT: (1) Activity Monitoring, (2) Activity Scheduling ,(3) Values Assessment, (4) Behavioural Contracting	ST: (1) Smoking Cessation Advice, (2) Functional Analysis of Thoughts and Behaviour, (3) Progressive Muscle Relaxation Exercises	LETS-QUIT: 3 (180) ST: 3 (180)	100% vs 100%	26.7% vs 9.09%
Carpenter, 2008	BATD [Complex]	BTDD: (1) Activity Monitoring, (2) Life Areas Assessment, (3) Activity Scheduling, (3) Contingency Management	REL: (1) Progressive muscle relaxation exercises, (2) Autogenic relaxation exercises, (3) Visual imagery exercises	BTDD: 24 (NR) REL: 24 (NR)	48.3% vs 63.8%	50% vs 25%
Daughters, 2008	BATD [Complex]	LETS Act!: (1) Activity Monitoring, (2) Activity Scheduling, (3) Values assessments, (4) Behavioural Contracting, (5) Decisional Balance, (6) Mindfulness / Relaxation Exercises	TAU: (1) Relapse prevention, (2) Functional analysis of thoughts and behaviour, (3) Stress management, (4) Anger management, (5) Life skills, (6) AA / NA support groups	BA: 6 (270) TAU: NR	90.91% vs 84.21%	9% vs 36.36%
Delgadillo, 2015	Contextual BA [Complex]	BA: (1) Activity Monitoring, (2) Activity Scheduling, (3) Values Assessments, (4) Decisional Balance	GSH: (1) Guided self-help based on CBT principles	BA: 12 (60) GSH: 1 (60)	NR vs 48.1%	65.2% vs 51.9%
MacPherson, 2010	BATD [Complex]	BATS: (1) Activity Monitoring, (2) Activity Scheduling, (3) Values Assessments	ST: (1) Smoking Cessation Advice, (2) Functional Analysis of Thoughts and Behaviour, (3) Coping Skills, (4) Identifying Social Support, (5) Progressive Muscle Relaxation Exercises	BATS: 8 (480) ST: 8 (480)	75% vs 75%	25.7% vs 51.52%

Note: Abbreviations: NR: Not Reported, LETS-QUIT: Life Enhancement Treatment for Substance Use, BATD: Behavioural Activation Treatment for Depression, BTDD: Behavioral Therapy for Depression in Drug Dependence, LETS Act!: Life Enhancement Treatment for Substance Use, BA: Behavioural Activation, BATS: Behavioral Activation Treatment for Smoking, REL: Structured Relaxation Intervention, CBT: Cognitive Behavioural Therapy, SC: Supportive Counselling

2.3.4 | Meta-analysis of BA versus comparators; GRADE results

Meta-analytic comparisons were performed to examine the aggregated effect of BA versus controls on (1) Depression and (2) Substance use outcomes at post-treatment and last available follow-up. GRADE assessments (Dijkers, 2013) are reported for each comparison to indicate the quality of evidence. All comparisons were based on evidence from RCTs so started as high quality evidence. Across the meta-analyses, few issues were found with heterogeneity or publication bias, but there were some issues with regards to study limitations, indirectness of evidence and imprecision. All comparisons were downgraded two levels due to the small number of studies, risk of bias, differing control groups and differences in follow-up time-points and lengths.

2.3.5 | Effects of BA on depression outcomes

2.3.5.1 | *Post-treatment and follow-up comparisons*

All studies were included in a random effects meta-analysis of BA versus controls for post-treatment depression outcomes (k = 5; N = 195). One of these studies did not assess participants until 12 weeks after BA treatment had finished (Delgadillo et al., 2015; N = 50). The pooled SMD presented in Figure 2 indicated that BA was not associated with differential improvements in post-treatment depression symptoms (Figure 2.2; SMD = 0.19; 95% confidence interval (CI) -0.10 to 0.49; Z = 1.28, p = 0.20; GRADE = Low). Between-study variation was non-significant indicating homogeneity between studies (I^2 = 0%; Q = 2.65, p = 0.61). Inspection of the funnel plot suggested there was some evidence of publication bias for this outcome (see Figure 2.3), however statistical testing using Egger's regression indicated no significant asymmetry in study distribution (B = -3.2, t(4) = -1.23, P = 0.30).

Five treatment arm comparisons evaluated the effects of BA versus controls on depression outcomes at follow-up (k = 5; N = 195), though one of these studies only provided post-treatment data (Carpenter et al., 2008; N = 38). The pooled SMD indicated that BA was not associated with significant improvements in depression symptoms at follow-up when compared to controls (Figure 2.2; SMD = -0.10; 95% confidence interval (CI) -0.51 to 0.30; Z = 0.50; p = 0.62; GRADE = Low). Between-study variation was significant indicating a small to moderate level of heterogeneity between studies (I^2 = 45%; Q = 11.61, $p < 0.05$). Inspection of the funnel plot revealed no evidence of publication bias for this outcome (see

Figure 2.3) and Egger's regression indicated no significant asymmetry in study distribution (B = -3.1, t(4) = -0.62, *P* = 0.58).

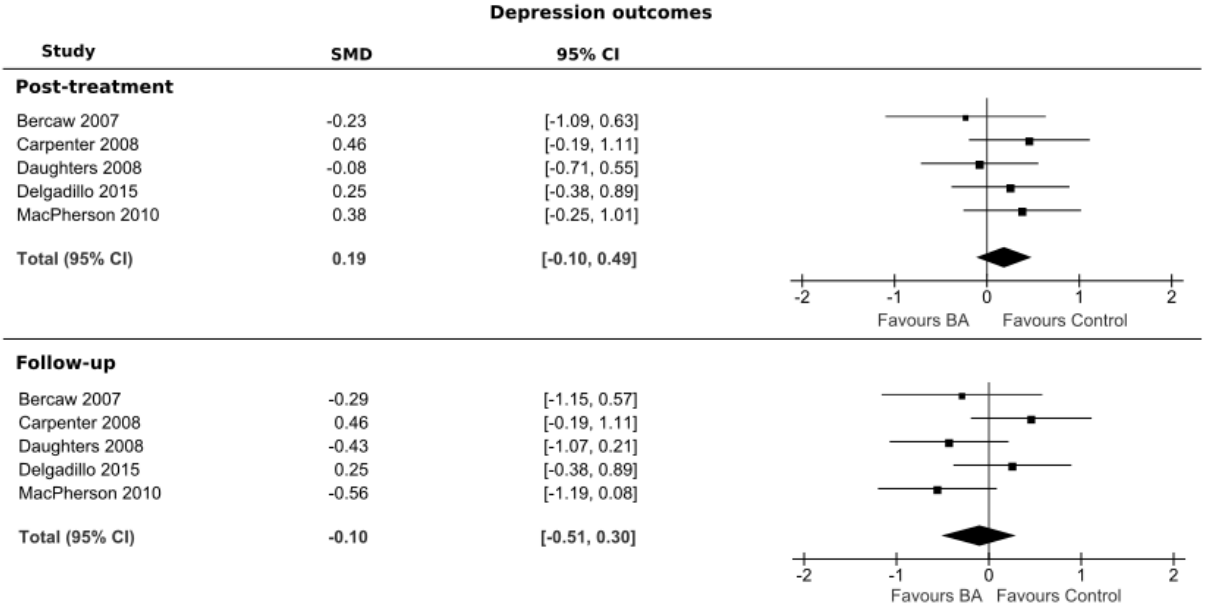


Figure 2.2. Effects of BA versus controls on depression outcomes

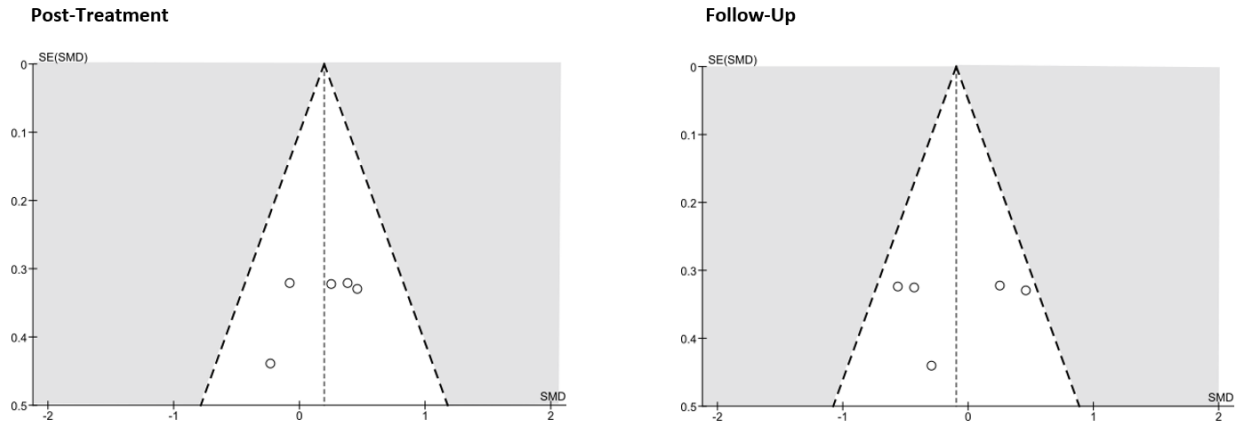


Figure 2.3. Funnel plots for primary random-effects meta-analyses (BA versus controls) – Depression Outcome

2.3.5.2 | *Sensitivity analyses*

For post-treatment depression outcomes, results of sensitivity analyses indicated that neither substance type (*k*=2; *N*=63; SMD = 0.15; 95% confidence interval (CI) -0.44 to 0.73; Z =

0.50; p = 0.62), mode of BA delivery (k=2; N=86; SMD = 0.15; 95% confidence interval (CI) -0.30 to 0.60; Z = 0.66; p = 0.51) nor type of comparator (k=3; N=107; SMD = 0.07; 95% confidence interval (CI) -0.32 to 0.47; Z = 0.35; p = 0.73) affected the size of the effect for post-treatment depression outcomes (see Appendix B).

For follow-up depression outcomes, sensitivity analyses indicated that group BA delivery (k=2, N=86; SMD = -0.49; 95% confidence interval (CI) -0.94 to -0.04; Z = 2.15; p < 0.05) and passive control comparators (k=3; N=107; SMD = -0.45; 95% confidence interval (CI) -0.85 to -0.05; Z = 2.22; p = < 0.05) were associated with significant overall effects in favour of BA. Substance type (Figure 3; k=2; N=63; SMD =- 0.46; 95% confidence interval (CI) -0.97 TO 0.05; Z = 1.78; p = 0.08) did not significantly affect the size of the effect for depression outcomes at follow-up (see Appendix B).

2.3.5.3 | *Within-group Effect Sizes for depression outcomes*

The pre-post standardised mean ES for the full BA sample indicated an overall reduction in depression symptoms from pre-treatment to post-treatment (N = 100; SMD = -0.57; 95% confidence interval (CI) -0.79 TO -0.36). Studies that did not report both post-treatment and follow-up outcomes were excluded from post-treatment to follow-up analyses (Carpenter et al., 2008; Delgadillo et al., 2015). The post-treatment to follow-up standardised mean ES for the remaining BA sample indicated an overall reduction in depression symptoms from post-treatment to last available follow-up (N = 59; SMD = -0.49, confidence interval (CI) -0.76 to -0.22).

2.3.6 | Effects of BA on substance use outcomes

2.3.6.1 | *Post-treatment and follow-up comparisons*

All studies reporting substance use outcomes were included in a random effects meta-analysis of BA versus controls for post-treatment substance use outcomes (k = 4; N = 151). One of these studies did not assess participants until 12 weeks after BA treatment had finished (Delgadillo et al., 2015; N = 50). The pooled SMD indicated that BA was not associated with significant improvements in post-treatment substance use outcomes compared to controls (Figure 2.4; SMD = 0.14; 95% confidence interval (CI) -0.33 to 0.6; Z = 0.57; p = 0.57;

GRADE = Low). Between-study variation was non-significant indicating homogeneity between studies (I^2 = 37%; Q = 5.89, p = 0.12). There was some evidence of publication bias for this outcome based on inspection of the funnel plot (see Figure 2.5), however Egger's regression indicated no significant asymmetry in study distribution (B = -0.67, t(3) = -0.18, P = 0.88).

Four comparisons evaluated the effects of BA versus controls on substance use outcomes at follow-up (k = 5; N = 151). One of these studies only reported post-treatment substance use outcomes (Carpenter et al., 2008; N = 38). The pooled SMD indicated that BA was not associated with significant improvements in follow-up substance use outcomes compared to controls (Figure 2.4; SMD = 0.17; 95% confidence interval (CI) -0.34 to 0.69; Z = 0.65; p = 0.51; GRADE = Low). The studies were homogeneous (I^2 = 35%; Q = 4.81, p = 0.18). There was no evidence of publication bias for this outcome based on inspection of the funnel plot (see Figure 2.5) and Egger's regression indicated no significant asymmetry in study distribution (B = -0.84, t(3) = -0.37, P = 0.75).

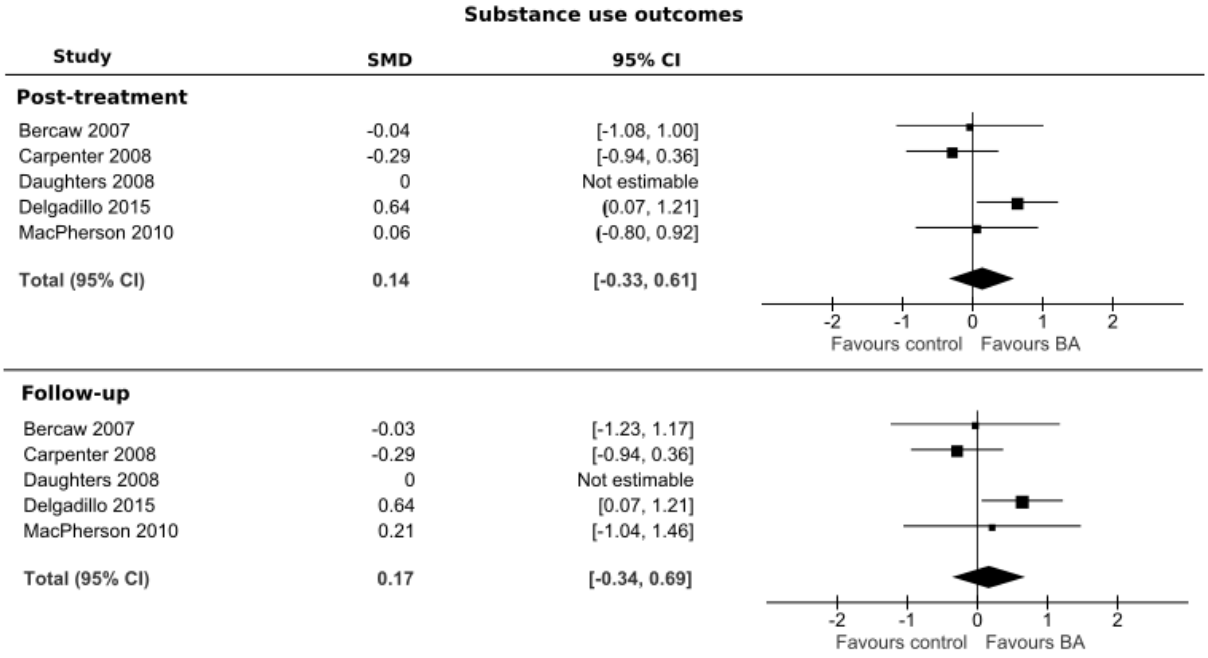


Figure 2.4. Effects of BA versus controls on substance use outcomes

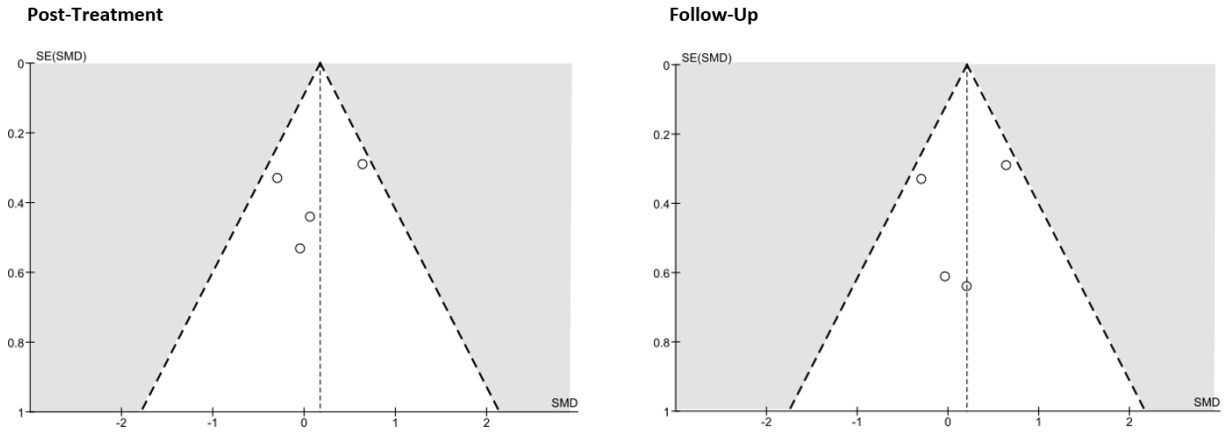


Figure 2.5. Funnel plots for primary random-effects meta-analyses (BA versus controls) – Substance Use Outcome

2.3.6.2 | Sensitivity Analyses

For post-treatment substance use outcomes, results of sensitivity analyses indicated that neither substance type nor type of comparator (*k*=2; *N*=63; SMD = 0.02; 95% confidence interval (CI) -0.64 to 0.68; Z = 0.06; *p* = 0.95) affected the size of the effect for substance use outcomes (see Appendix B). It was not possible to conduct a sensitivity analysis for mode of delivery as one of the two studies that delivered BA in a group format did not report post-treatment substance use outcomes (Daughters et al., 2008).

For substance use outcomes at follow-up, results indicated that neither type of substance nor type of comparator (*k*=2; *N*=63; SMD = 0.08; 95% confidence interval (CI) -0.78 to 0.95; Z = 0.19; *p* = 0.95) affected the size of the effect for substance use outcomes (see Appendix B). It was not possible to conduct a sensitivity analysis for mode of delivery as one of the two studies that delivered BA in a group format did not provide any data on substance use outcomes (Daughters et al., 2008).

2.3.6.3 | *Within-group Effect Sizes*

Studies that did not report substance use outcomes (Daughters et al., 2008) or reported odds ratios for substance use outcomes (Bercaw, 2007; MacPherson et al., 2010) were excluded from pre-post analyses as means and standard deviations were not available to calculate the ES. The pre-post standardised mean ES for the remaining BA sample indicated an overall reduction in substance use from baseline to post-treatment (*N* = 41; SMD = 1.26; 95%

confidence interval (CI) 0.85 to 1.66). Post-treatment to follow-up analyses were not feasible due to studies either not reporting any substance use outcomes (Daughters et al., 2008), reporting only pre-treatment to follow-up data (Delgadillo et al., 2015), or reporting odds ratios for substance use outcomes (Bercaw, 2007; MacPherson et al., 2010).

2.3.7 | *Fail-safe N calculations*

Fail-safe *N* calculations were computed using Rosenthal's *N* (Rosenthal, 1979) to determine the number of RCTs that would need to be conducted to find a significant effect of BA based on the current evidence base. For both depression and substance use outcomes, results indicated that a further 10 trials would need to be conducted in order to find any significant effect of BA in this population.

2.4 | Discussion

This review examined the efficacy of BA for comorbid SUD-depression via a systematic review and meta-analysis of the clinical trial evidence base. Given that there are few evidence-based treatments for co-occurring depression and SUDs (Baker, Thornton, et al., 2012; Hides et al., 2010), the objective of this analysis was to offer a quantitative summary as to the potential efficacy of BA for patients presenting with these comorbid problems. This was the first meta-analysis of BA for comorbid SUD-depression and so complemented and updated a previous systematic review (Martinez-Vispo et al., 2018).

2.4.1 | Summary of BA outcomes

Overall, results did not provide support for the differential effectiveness of BA as a treatment for comorbid SUD-depression. BA had no distinctive significant effects on depression or substance use outcomes compared to passive or active controls at post-treatment or follow-up. The direction of results at post-treatment was in favour of controls rather than BA which is in contrast to the conclusions drawn from a previous narrative review (Martinez-Vispo et al., 2018). However, standardised mean ESs indicated that BA was associated with improvements in depression and substance use outcomes within the pooled BA sample. At follow-up,

For depression and substance use outcomes, studies varied with regards to favouring BA over comparators in the computation of the total effect. For depression outcomes, studies addressing nicotine dependence (Bercaw, 2007; MacPherson et al., 2010) and the study conducted in an inpatient drug and alcohol treatment setting (Daughters et al., 2008) were found to produce the largest ESs in favour of BA at post-treatment and follow-up. These studies were notably conducted with patients who might be expected to have a lower complexity profile in terms of situational and lifestyle factors. Therefore, these findings appear to be consistent with research conducted with non-dependent samples indicating that patients with less complex profiles (in terms of various biological, behavioural and situational factors) tend to exhibit better depression outcomes after psychological treatment compared to those with more complex profiles (Delgadillo et al., 2017). For substance use outcomes, there did not appear to be any distinctive similarities between the two studies with the largest ESs at post-treatment and follow-up (Delgadillo et al., 2015; MacPherson et al., 2010).

For follow-up depression outcomes, ESs in favour of BA were notably larger in studies that delivered group BA and compared against passive comparators for depression outcomes and this observation was supported by evidence from sensitivity analyses. These findings tend to mirror those obtained from reviews of CBT for co-occurring depression and SUDs, which found that although there is support for CBT over passive control conditions, there is little evidence that CBT is superior when compared to other psychotherapies (e.g. Hides et al., 2010). For substance use outcomes, there was no evidence from individual studies or sensitivity analyses that effect sizes in favour of BA were larger in studies that addressed nicotine dependence, delivered BA in a group format or compared against passive controls. The lack of significant findings for substance use outcomes in this review is in contrast to a large RCT of BA conducted with non-depressed SUD patients, which found that BA was associated with a significantly higher likelihood of abstinence up to 12 months' post-treatment compared to an active comparator (Daughters et al., 2018). It seems possible that the small sample sizes of studies included in this review may have reduced their ability to detect any significant effects.

2.4.2 | Acceptability of BA

On average, dropout rates were lower for BA interventions than for comparator conditions, suggesting that BA is an acceptable treatment for patients with co-occurring depression and

SUDs. This finding is consistent with a recent meta-analysis of group BA conducted with non-substance-dependent samples (Simmonds-Buckley et al., 2018). Attendance rates were notably higher in studies addressing nicotine dependence (Bercaw, 2007; MacPherson et al., 2011) and the study conducted in an inpatient SUD treatment centre (Daughters et al., 2008). This may reflect the lower complexity profiles of participants in these studies given that the attendance rate in comparator conditions was also higher compared to studies conducted in outpatient drug and alcohol treatment (Carpenter et al., 2008; Delgadillo et al., 2015). It could also point to the importance of mode of delivery, as attendance rates in BA and comparator conditions were generally higher in studies that delivered treatments in a group format (Daughters et al., 2008; MacPherson et al., 2011). Higher attendance rates for BA were associated with larger ESs for depression outcomes, indicating that treatment engagement is important for reducing depressive pathology in this population.

2.4.3 | The BA approach

Most BA interventions delivered in the included studies were classified as "complex BA" due to their inclusion of treatment components beyond the core BA elements of activity scheduling and monitoring. Three studies (Bercaw, 2007; Daughters et al., 2008; MacPherson et al., 2010) were based on the 'BATD' treatment model (Lejuez et al., 2001) and Delgadillo et al.s' (2015) study was derived from 'contextual BA' (Martell et al., 2001, 2010). Carpenter et al's (2008) study was classified as "simple" BA; employing principles of Rehm's self-control therapy (1984) combined with CM and CRA. This study was associated with the least favourable effects of BA for both depression and substance use outcomes.

There was considerable variability in the length of BA interventions, ranging from 3-24 sessions. The study which delivered the highest number of sessions in this review was found to have the least significant results in favour of BA (Carpenter et al., 2008). This finding is consistent with a previous meta-analysis of CBT for SUDs which found that interventions with a higher number of treatment sessions were associated with lower ESs for substance use outcomes (Magill & Ray, 2009). However, studies that reported the greatest ESs in favour of BA for depression outcomes in this review delivered BA in 8-10 sessions (Daughters et al., 2008' MacPherson et al., 2010) and the study which reported the greatest ES in favour of substance use outcomes delivered BA in 12 sessions (Delgadillo et al., 2015). A previous study of MBCT also found that 10 sessions of therapy were more effective than a

single session for improving substance use outcomes in people with co-occurring depression and alcohol use problems (Baker, Kavanagh et al., 2010). It therefore seems unlikely that number of treatment sessions is the most important factor influencing BA outcomes in this population.

The study that was based exclusively on the BATD treatment model (comprising ≤ 3 treatment components) (Macpherson et al., 2010) notably had greater ESs in favour of BA for both depression and substance use outcomes at follow-up, while the study based on Contextual BA had the greatest ES in favour of BA for substance use outcomes at follow-up (Delgadillo et al., 2015). The former findings are consistent with evidence that more intensive, complicated interventions may be unsuitable for the needs of patients with co-occurring depression and SUDs due to a higher prevalence of cognitive deficits (e.g. Vik et al., 2004) and attention problems (e.g. Kessler et al., 2006). Conversely, the findings from Delgadillo et al.'s (2015) study appear to challenge this idea and are consistent with preliminary evidence suggesting that the use of functional analytic techniques are associated with reductions in substance use (Aranha et al., 2020). However, it is noted that BA participants in Delgadillo et al.'s (2015) study only attended 3/12 sessions on average and it is unclear which aspects of the intervention they actually received. The comparatively low BA attendance rates observed in the two studies conducted in CDAT (Carpenter et al.,2008, Delgadillo et al., 2015) certainly seem to suggest that briefer, more focused forms of BA may be a more suitable option for this specific patient group.

There is also evidence to suggest that BA may be more effective when delivered in a group format. Studies that delivered group BA were found to have higher attendance rates and greater ESs for depression (Daughters et al. 2008; MacPherson et al., 2010) and substance use outcomes (MacPherson et al., 2010). Indeed, previous studies have demonstrated the efficacy of group BA in improving depression outcomes in non-SUD samples (Simmonds-Buckley et al., 2019), as well as substance use outcomes in non-depressed SUD patients (Daughters et al., 2018). Group therapy is widely implemented in routine SUD treatment and the benefits are well-established (Galanter et al., 2005). This mode of delivery may enhance engagement with BA through social processes such as interpersonal learning, peer support and identification (Ahmed et al., 2010). These appear to be the 'common factors' that are present across group based approaches to treatment in complex client groups including feeling connected, communication and a sense of belonging (Bledin et al., 2016). However, there is also some evidence to suggest that group therapy may

be less effective for patients with a higher level of complexity (Moggia et al., 2020). It is therefore unclear whether group BA would be suitable for depressed SUD patients with more complex profiles, such as those who are actively using substances and accessing CDAT.

2.4.4 | Limitations

Results of this review should be interpreted with caution, primarily due to the small number of studies and small sample sizes in the original studies. This may have reduced power to detect a significant effect and impacted on the accuracy of the confidence intervals and heterogeneity tests (Borenstein et al., 2011). None of the included studies reported sample size calculations. Based on the current analyses, an RCT investigating BA as a treatment for co-occurring depression and SUDs would need to recruit at least 786 participants (393 in each group) in order to detect a small effect in favour of BA (Cohen, 1992). This would notably present a considerable challenge to researchers given the difficulties of recruiting SUD participants to trials in addiction treatment centres (e.g. Ashery & McAuliffe, 1992; Melberg & Humphreys, 2010).

Some issues were also noted regarding variability in the measurement and reporting of substance use outcomes. Indeed, in contrast to depression outcomes which were all reported based on standardised self-report measures of recent depressive symptoms, reporting of substance use outcomes varied markedly between studies. Studies addressing nicotine dependence reported point prevalence abstinence (PPA) from 1-week (Bercaw, 2007) up to 30-weeks (MacPherson et al., 2010). Bercaw (2007) also reported continuous abstinence from the quit date. Studies addressing illicit drug and alcohol use reported PDA in the past month (Delgadillo et al., 2015) and the percentage of days that different substances were used in the last month (Carpenter et al., 2008). With regards to the latter, this was somewhat problematic as the separate substance use outcomes had to be pooled in order to calculate the ES for this review. Generally speaking, it can be difficult to reliably measure outcomes for patients who are using illicit drugs and alcohol. Rates of polysubstance use are high (Connor et al., 2013) and PDA (as well as PPA for smoking) does not reflect reductions in the amount of substances used if the patient is still using substances daily.

There was also a lack of consistency with regards to the number and duration of follow-ups which made it somewhat difficult to aggregate and compare findings between studies in this review. Nevertheless, evidence from within-group analyses suggested that BA

led to improvements in depression symptoms both before and after treatment had finished. Indeed, previous research on CBT for substance use has found evidence of "sleeper effects", whereby reductions in substance use continued to increase up to 1-year follow-up (e.g. Carroll et al., 1994). The longest follow-up period of the studies included in this review was 30 weeks, at which point the effects of BA on both depression and smoking outcomes were indeed reported to be superior to standard treatment (MacPherson et al., 2010). In studies addressing illicit drug and alcohol use, there were no significant differences in depression (Carpenter et al., 2008; Delgadillo et al., 2015) or substance use (Carpenter et al., 2008) outcomes reported between BA and comparators at 24-week follow-up, however one of these studies only provided data for post-treatment outcomes (Carpenter et al., 2008). The other study only reported follow-up data for outcomes measured 12 weeks after BA treatment had finished therefore it was not possible to calculate standardised mean ESs from post-treatment to follow-up (Delgadillo, 2015). It is therefore possible that longer follow-ups would reveal significant overall effects of BA that extend beyond those of comparative treatments.

2.4.5 | Future research

Additional RCTs with larger samples and multiple follow-up points over a longer period would allow for a more accurate estimate of the effectiveness and durability of BA for co-occurring depression and SUDs. These studies should compare individual and group BA in different populations of SUD patients to explore the potential influence of patient complexity, as well as any social processes that may contribute to the effectiveness of group BA. It would also be beneficial for studies to compare individual and group BA with other active treatments, particularly emerging third wave therapies such as ACT and MBCT which have received remarkably little attention as a treatment for this comorbidity. This would establish whether there are any distinct benefits of individual and group BA compared to other potentially efficacious treatments. More comprehensive, high-quality studies would also allow for more detailed meta-analyses looking at subgroups and moderators in order to identify specific factors that contribute to the effectiveness of BA. Additionally, future studies of BA for comorbid SUD-depression should conduct multiple follow-ups over longer periods. There is some evidence from studies of CBT that effects emerge over time (e.g. Carroll et al., 1994). Therefore, future studies of BA for comorbid SUD-depression should

conduct multiple follow-ups over a longer period to enable the exploration of possible "sleeper effects".

Due to power analyses not being routinely reported in the trials analysed here, all future trials should report a power analysis in their methods and whether recruitment targets were subsequently achieved in their results. All studies need to routinely report attendance rates for sessions and dropout rates and adverse event rates. Studies also need to be more consistent and specific in how substance use outcomes are reported, particularly in drug and alcohol treatment settings where the substances used varies within samples. Measures of PDA and PPA appear to the most commonly used substance use outcomes and should continue to be reported as standard in order to ensure between-study consistency and associated benchmarking. In drug and alcohol treatment settings, it is important to provide a general measure of PDA based on participants' primary substance, though it may also be useful to report outcomes for different substances individually to allow exploration of BA's effects on the use of different substances (e.g. Carpenter et al., 2008). However, given that PDA and PPA measures may not necessarily reflect the full extent of a patient's progress, it may also be beneficial for studies to additionally report changes in psychological dependence to substances using a standardised self-report measure (e.g. Severity of Dependence scale; Gossop et al., 1995). This could potentially facilitate a more comprehensive view of efficacy in relation to substance use outcomes.

2.4.6 | Conclusion

The current evidence does not support the dissemination of BA to treat comorbid SUD-depression, despite this being an apparently acceptable intervention. BA appears to improve depression and substance use outcomes overall, but there is no evidence that it is more effective compared to other treatments. Preliminary analyses indicate that BA may be more effective for improving depression outcomes when it is compared to passive controls and delivered in a group format. Based on data from the studies included in this review, fail-safe N calculations indicate that a further 10 RCTs would be needed to overturn the above conclusion (Rosenthal, 1979). These additional RCTs would need to recruit a higher volume of participants and adopt multiple follow-ups over longer periods in order to detect any significant effect of BA and then assess its durability. Future RCTs should aim to compare the effectiveness of group and individual BA in different populations of SUD patients, as

well as compare BA with other treatments in order to establish differential effectiveness. BA may still hold promise as a treatment for comorbid SUD-depression. However, there is currently unconvincing evidence that implementing BA in routine practice is associated with distinct improvements in key outcomes for patients with this comorbidity.

Chapter 3

Behavioural Activation delivered by drug and alcohol treatment workers: A pilot randomised controlled trial

The previous chapter demonstrated that BA appears to be an acceptable intervention for patients with comorbid depression and SUDs, but there is currently insufficient evidence that implementing it in routine care would improve treatment outcomes. The two studies conducted with alcohol and illicit drug users in CDAT were associated with the least beneficial effects in favour of BA, but overall, the lack of studies in this area and small sample sizes of many existing studies make it difficult to draw any reliable conclusions regarding the efficacy of BA in this population. A further, more general limitation of intervention studies is that they may not reflect how treatments would be delivered in routine practice, which can contribute to delays in the implementation of evidence-based treatments. This is particularly problematic for CDAT patients who already tend to have limited access to alternative evidence-based psychological interventions for CMDs. Previous trials have investigated BA delivered by qualified mental health therapists, which is unlikely to reflect how BA would be delivered in routine settings with SUD patients. The second empirical study therefore adopts a pragmatic approach to examine the efficacy of BA facilitated by drug and alcohol treatment workers compared to TAU in routine CDAT. This study was originally designed to be a definitive RCT, hence, clinical outcomes are reported in addition to indicators of acceptability that are more consistent with a pilot study. The objectives of this pilot RCT were to extend on previous trials by investigating BA delivery by drug and alcohol treatment workers, establish preliminary effects of BA on depression, substance use, anxiety and valued living outcomes, and to report on the acceptability of this mode of BA delivery in terms of therapist adherence to the BA treatment protocol and patient attendance and dropout rates.

3.1 | Introduction

3.1.1 | Effects of BA for patients with drug or alcohol use disorders

BA is an effective treatment for depression (Ekers et al., 2014) and evidence from recent systematic reviews and meta-analyses suggest that it could be a promising treatment for patients with comorbid SUD-depression (Chapter 2; Martínez-Vispo, 2018). BA is deemed to be an attractive option for delivery with SUD patients due to its cost-effectiveness and

straightforward treatment principles. However, findings from individual studies are varied and few have specifically examined the efficacy of BA for patients with comorbid depression and alcohol or drug use disorders.

3.1.1.1 | *Residential treatment services*

To date, studies conducted in US residential treatment services have reported the most favourable outcomes of BA for patients with alcohol and drug use disorders. The majority of patients in these studies were accessing treatment for crack cocaine or alcohol use and all patients were abstinent at baseline. The BA intervention delivered in these studies was LETS ACT! (Daughters et al., 2016), which has been specifically developed to meet the needs of patients with comorbid SUD-depression who are accessing addictions treatment. The first study was conducted with a sample of patients who were identified as having clinically significant depression symptoms (Daughters et al., 2008). Compared to the TAU group, BA participants reported significantly greater improvements in depression and enjoyment and reward value of activities at post-treatment, as well as significant improvements in depression symptoms at 2-week follow-up and higher treatment satisfaction ratings. Magidson et al (2011) failed to find that BA was associated with improvements in depression symptoms compared to a supportive counselling intervention at 1-month follow-up, but BA participants were significantly less likely to drop out of SUD treatment. A further study conducted with a general sample of patients who were not screened for depression, found that BA was associated with a significantly higher likelihood of abstinence and fewer adverse consequences from substance use up to 12-month follow-up compared to supportive counselling (Daughters et al., 2018). Taken together, the findings from these studies appear to support the application of behavioural theory to SUDs and evidence the benefits and acceptability of providing integrated interventions for SUD-depression in residential treatment settings.

3.1.1.2 | *CDAT services*

Findings from studies conducted in CDAT settings have been less convincing. The majority of patients in these studies were accessing treatment for opiate use. Most reported actively using substances and all were identified as having clinically significant depression symptoms at baseline. A practice-based study in the US found significant within-group improvements in depression symptoms, but not substance use, among patients who were allocated to behavioural therapy (Carpenter et al., 2006). A subsequent RCT of behavioural therapy

combined with contingency management (CM) found no significant differences in depression symptoms, cocaine or benzodiazepine use when BA was compared to a structured relaxation intervention, however, BA participants reported a significant increase in opiate use over time (Carpenter et al., 2008). Meanwhile, a UK study comparing BA to a single session of CBT-based guided self-help found no significant between-group differences in depression or percent days abstinent (PDA), although BA participants reported more improvement in PDA than controls. A notable issue with these studies is that they have all delivered different BA interventions, which makes their findings somewhat difficult to assimilate. Notably, the BA intervention delivered in Carpenter et al.'s (2008) study did not incorporate any values work, even though this is a promising treatment target and key component of the empirically supported LETS ACT! intervention for patients with comorbid depression and alcohol or drug use disorders (Daughters et al., 2016). Overall, the lack of studies conducted with CDAT patients, small sample sizes and heterogeneity of BA interventions delivered in these studies limit conclusions regarding efficacy. BA could still hold promise as a treatment for this population, but more research is needed to determine whether BA is effective for patients who are actively using substances in community settings.

3.1.2 | Improving access to psychological therapy for depression in patients with alcohol or drug use disorders

Integrated treatment is recommended for comorbid SUD-depression (Department of Health, 2017), yet the availability of evidence-based psychological therapies for CMDs remains inconsistent for patients who are accessing treatment for alcohol or drug use disorders (Public Health England, 2017[d]; Recovery Partnership, 2017; Turning Point, 2016). This is likely explained, in part, by the systemic issues associated with mental health and addiction treatment services (Turning Point, 2016). Most services are only equipped to deal with patients' primary need (mental health or substance use) and there tends to be a lack of integration between mental health and addiction treatment teams. This issue may be further compounded by the ambiguity of guidelines on treating patients with comorbid SUD-depression (Department of Health, 2017; Department of Health, 2007) and a lack of consensus on what constitutes evidence-based treatment for patients with drug and alcohol use disorders generally (Glasner-Edwards & Rawson, 2010). Indeed, evidence-based psychological therapies for patients with comorbid SUD-depression have received much less empirical attention than therapies aimed at depressed patients who are not dependent on

drugs or alcohol. This is clear from looking at the BA evidence base. For example, a meta-analysis of BA based on non-dependent samples included 26 RCTs with a total of 1524 participants (Ekers et al., 2014), whereas the meta-analysis of BA for patients with comorbid SUD-depression (Chapter 2) included just five RCTs with a sample of 195 participants. Patients with drug and alcohol use disorders tend to be marginalised and more difficult to recruit to RCTs (Thomson et al., 2008). Nevertheless, the individual and societal costs of not addressing comorbid SUD-depression are significant (e.g. Teesson et al., 2008) and investigating ways of improving access to appropriate psychological treatments remains an important priority for this patient group.

3.1.2.1 | *Narrowing the 'Research-Practice gap'*

RCTs are critical for generating robust evidence on the benefits and harms of psychological interventions. However, a common pitfall of many RCTs is that they do not adequately reflect how an intervention would be delivered in routine care. This may contribute to a research-practice gap which delays the timely implementation of evidence-based interventions in treatment settings. Common barriers to implementing evidence-based psychological interventions tend to centre around lack of resources and practitioner concerns about delivering specific interventions with patients (Amodeo et al., 2011; Bach-Mortensen et al., 2018).

Pragmatic RCTs integrated into treatment services under conditions that are comparable to routine care may lead to a better understanding of the effectiveness and acceptability of implementing an intervention in a real-world setting (Patsopoulos, 2011). This approach could also help to increase the uptake of interventions in practice. Existing trials of BA in CDAT services have notably compared BA to active treatments that are not routinely offered (e.g. structured relaxation; Carpenter et al., 2008). This does not give a true picture of the efficacy of BA in a real-world setting and means that findings may be less relevant to service providers and practitioners, who are likely to be more interested in whether interventions offer an advantage over the care that is usually offered. Likewise, although existing trials of BA for comorbid depression and alcohol or drug use disorders have all been conducted in routine drug treatment settings, they enlisted qualified mental health therapists to deliver BA which is unlikely to be feasible in practice. Therefore, even though some trials have reported beneficial effects of BA for patients with comorbid SUD-depression (e.g. Daughters et al., 2008), there is currently little indication as to how or whether these effects would be replicated in routine settings. Given the established

difficulties in recruiting SUD patients to RCTs, it is vital to maximise the impact of future trials by investigating interventions in a way that is more relevant and translatable to practice, with practitioners who are most likely to be involved in the delivery of interventions in real-world treatment settings.

3.1.2.2 | *Training drug and alcohol treatment workers to deliver evidence-based interventions for comorbid SUD-depression*

Considering that SUD patients are more likely to access mental health support when it is offered as part of routine CDAT (Delgadillo et al., 2015) and these services typically do not have funding to employ specialist mental health practitioners, drug and alcohol treatment workers may be the most appropriate candidates to deliver evidence-based interventions for comorbid SUD-depression. A growing empirical evidence base supports the delivery of CBT and interpersonal interventions by non-specialist practitioners (e.g. peers and community health workers) (Barbui et al., 2020). A series of studies that investigated the delivery of group CBT for depression by drug and alcohol workers in residential treatment found that workers demonstrated good levels of adherence and competence in delivering CBT (Watkins et al., 2011) and patient ratings of the treatment were positive (Hepner et al., 2011). CBT was also associated with significant improvements in depression and substance use outcomes compared to TAU (Watkins et al., 2011). Although CBT may be too costly and time-consuming to implement in routine CDAT settings, these findings suggest that drug and alcohol treatment workers are capable of delivering evidence-based psychological interventions for depression effectively and that patients are receptive to this approach. Considering the current context of service provision for patients with comorbid depression and alcohol or drug use disorders, this is a plausible approach to treatment delivery that deserves continued empirical attention.

3.1.3 | BA delivered by non-specialists

In addition to being a potentially effective treatment for comorbid SUD-depression, BA is a particularly viable option for delivery by drug and alcohol treatment workers. Compared to CBT, the treatment principles of BA are relatively straightforward making it easier to learn, deliver and implement in routine care (Richards et al., 2016). There is also evidence that BA can be delivered effectively with minimal training and supervision by practitioners who have limited psychotherapeutic training and experience (e.g. Ekers et al., 2011). Indeed, several high-quality studies have supported the delivery of BA by non-specialist practitioners (Ekers

et al., 2014). This makes BA an economical option for delivery in resource-limited CDAT settings and suggests that BA would be well-suited to delivery by drug and alcohol treatment workers, who tend to have varied educational backgrounds and often do not possess professional qualifications in delivering psychotherapy (Chapman et al., 2020). Yet there are currently no studies that have explored the effectiveness or acceptability of this approach in an SUD treatment context.

3.1.4 | Aim of the current study

To summarise, despite the health and economic costs of co-occurring SUD-depression, testing and implementation of evidence-based psychological interventions have been slow to occur. BA seems to hold promise as a treatment for patients with comorbid depression and drug or alcohol use disorders, but more research is needed to establish its efficacy with this clinical population. In particular, it remains unclear whether BA is more effective than usual care for depressed patients accessing CDAT. Additionally, no studies have explored the efficacy of BA when it is facilitated by drug and alcohol treatment workers. Given that SUD patients are significantly more likely to access mental health support when it is located in CDAT (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 which could potentially facilitate the translation of BA into real-world practice.

3.1.4.1 | *Objectives and hypotheses*

The broad aim of this study was to test the preliminary effectiveness of a brief, manualised BA intervention facilitated by drug and alcohol treatment workers as part of routine care in CDAT. The study compared the BA intervention with TAU in the CDAT service on depression, substance use, anxiety and valued living outcomes. It was hypothesised that relative to patients in the TAU condition, patients in the BA+TAU condition would demonstrate greater improvements in depression, substance use, anxiety and valued living. An additional objective of the study was to report on the acceptability of BA delivered by drug and alcohol treatment workers in terms of patient attendance and dropout rates.

3.2 | Method

The study was approved by the York research ethics committee and the local NHS research governance department (REC Reference: 247888). Information and evidence of ethical approval can be found in Appendix C (research protocol, ethical approvals and details of amendments). The trial was pre-registered with the Clinicaltrials.gov database prior to commencement of data collection (NCT03661580) and complies with CONSORT recommendations (Grant et al., 2018; see Appendix I for CONSORT checklist).

3.2.1 | Design

This was an open-label, pragmatic, pilot randomised controlled trial of BA facilitated by drug and alcohol treatment workers compared with TAU for CDAT patients with elevated depression symptoms. Primary and secondary outcomes for the trial were assessed at baseline and 6-, 12- and 24-week follow-up. The primary outcome was depression severity 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. The final aim of the study was to evaluate the acceptability of BA delivered by drug and alcohol treatment workers in terms of therapist adherence to the BA treatment protocol and patient attendance and dropout rates.

3.2.2 | Setting

The trial was integrated in to a CDAT service in Doncaster, a large and socioeconomically diverse town in South Yorkshire, United Kingdom. Doncaster is in the 20% most deprived areas in England, with rates of health and life expectancy generally lower than the England average (State of Health, 2019). The CDAT service is staffed by practitioners with diverse experiences and professional backgrounds, including nursing, social work, lived experience of addiction and National Vocational Qualification (NVQ) in SUD treatment.

3.2.3 Participants

3.2.3.1 | *Sample size*

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 $p = .05$ (Cohen, 1992). However, as a pilot trial, the overall goal of this study was to recruit as many participants as possible within a two-year period, and to report preliminary effect sizes and indices of engagement with the BA treatment.

3.2.3.2 | *Eligibility 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 $\geq$ 12 on the PHQ-9 (Kroenke et al., 2001); (4) had mild-to-moderate severity drug dependence, as defined by a score of $\leq$ 10 on the SDS (Gossop et al., 1995); (5) had used alcohol or illicit drugs within the last month and/or were prescribed MAT for opiate use. Patients were excluded from the study if they had a diagnosis of psychotic, bipolar, or severe anxiety disorder, were already accessing psychotherapy or were unable to read and write. These exclusion criteria were selected to be representative of patients who would likely not be offered BA in routine CDAT settings due to complex mental health needs requiring alternative professional treatment, current engagement with mental health services, or not practically being able to engage with the format of the BA intervention delivered in this trial.

3.2.4 | Procedure

The CONSORT diagram in Figure 3.1 summarises the procedures outlined below and illustrates the flow of participants through the study.

3.2.4.1 | *Screening and Recruitment*

Screening and recruitment took place from September 2018 to March 2020, concluding several months earlier than planned due to restrictions imposed by the global COVID-19 pandemic. A stepwise screening and recruitment strategy was applied based on the methods used in a previous trial of BA for depression in UK CDAT (Delgadillo et al., 2015). The approach consisted of the following steps:

(1) All 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 contacted agreeing patients to conduct an eligibility and recruitment interview.
(4) Informed consent was obtained from eligible patients either at the time of the recruitment interview or by post.

The first 2 steps were conducted in routine practice by patients' usual caseworkers and steps 3 and 4 were conducted by the study co-ordinator. In order to minimise selection bias and maximise trial recruitment, the study co-ordinator performed monthly searches of the clinical database to identify patients who were potentially eligible for the trial based on recent TOP item 4a scores. Electronic reminders were sent to caseworkers (via e-mail and online team calendars) on a regular basis to encourage completion of step 2 of the screening method with potential participants. As shown in Figure 1.1, a total of 1271 patients were identified as being potentially eligible for the study based on TOP item 4a scores. Of these patients, 146 were referred for eligibility screening and 110 patients were contacted for screening interviews prior to the COVID-19 pandemic. The most common reasons for exclusion were that patients declined screening (N = 17), had a high severity of psychological dependence to substances (SDS score ≥ 10; N = 12), or were no longer engaging with the CDAT service (N = 10). Out of 44 patients that met eligibility criteria, 34 provided consent to take part in the study and were included in the final sample.

3.2.4.2 | *Randomisation*

Eligible and consenting patients were assigned unique participant codes by the study co-ordinator. These codes were e-mailed to an independent administrator at the University of Sheffield who performed the random allocation. Randomisation was conducted sequentially using a computer-generated random sequence which was concealed from the study co-ordinator. The study co-ordinator was notified of allocations via e-mail and informed participants of their allocation. For participants allocated to BA (N = 17), arrangements were then made for them to commence BA therapy with a trained worker.

3.2.4.3 | *Follow-up*

Follow-up assessments were administered by the study co-ordinator at 6 weeks, 12 weeks and 24 weeks' post-randomisation. The last follow-up contact for this study was in September 2020. As shown in Figure 1.1, there was a minimum 70% follow-up completion rate at each time point in both treatment groups. Only two participants were lost to follow-up, defined as completing no follow-up assessments during the course of the study.

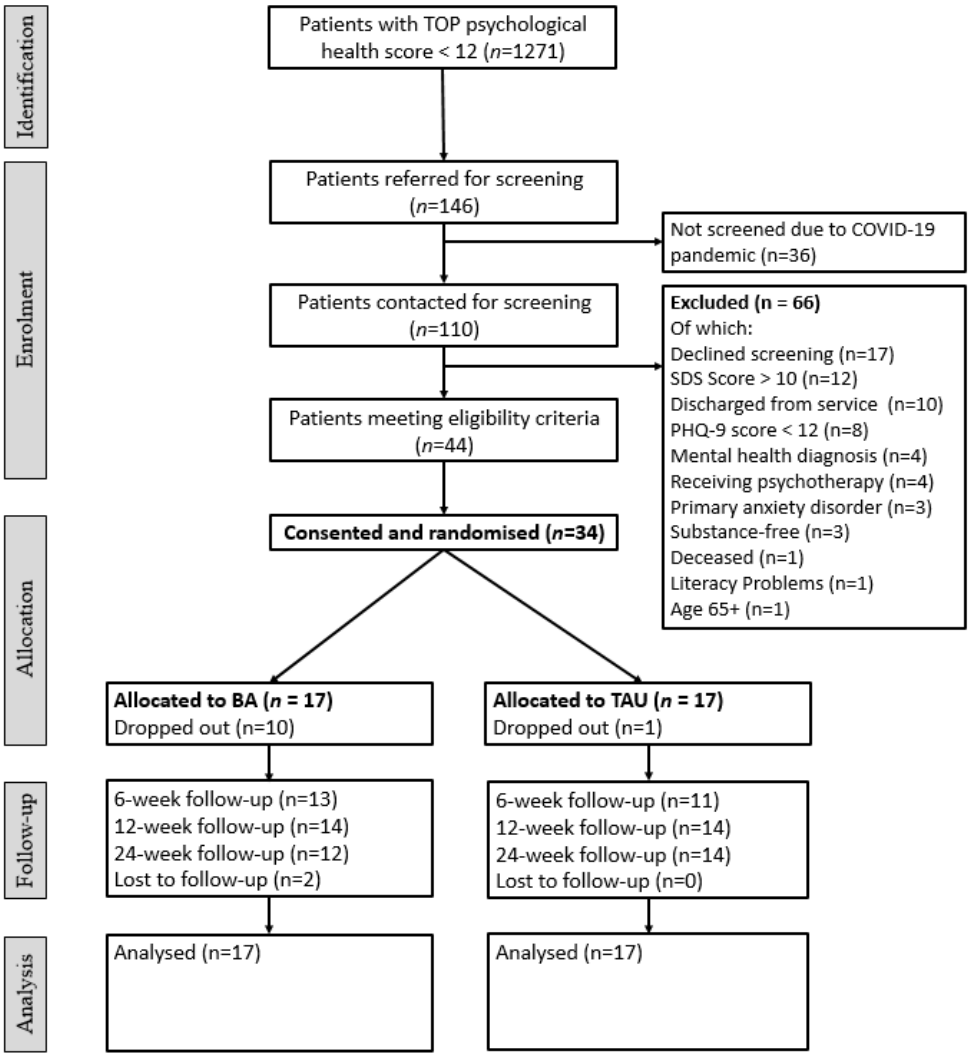


Figure 3.1. CONSORT Diagram

3.2.5 | Treatment as Usual (TAU)

All patients accessing the CDAT service had an initial assessment including a risk management plan, a personalised care plan which lays out a structure of key-working appointments and

prescribing appointments for those who required MAT. All participants in the present study received TAU. This was delivered by drug and alcohol treatment workers and consisted of scheduled 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, 1986), informed by national treatment guidelines which advocate the layering and phasing of interventions according to the stage of change (National Collaborating Centre for Mental Health, 2008). All interventions aimed to enhance patient motivation to reduce harms associated with substance use and to elicit 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 (MI), 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 available to those who chose to engage with this.

3.2.6 | 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 empirically supported 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 6 weeks, followed by 2 optional booster sessions delivered up to 6 weeks' post-treatment. A full outline of session content is provided in Table 1.

Table 3.1. Overview of LETS ACT! treatment protocol.

LETS ACT! Session Outline
Session 1: *Introduction to Treatment Rationale and Activity Monitoring*

- Introduction to comorbid SUD-depression formulation (treatment rationale)
- Introduction to activity monitoring
- Agree on treatment plan
- Assign activity monitoring homework

Session 2: *Introduction to Life Areas, Values and Activities (LAVA)*

- Review comorbid SUD-depression formulation (treatment rationale)
- Review activity monitoring
- Introduce Life Areas, Values and Activities (LAVA)
- Assign activity monitoring and LAVA homework

Session 3: *Selecting Activities and Setting Goals*

- Review comorbid SUD-depression formulation (treatment rationale)
- Review activity monitoring
- Identify activities for goals in corresponding life areas
- Introduce activity scheduling (daily plans)
- Assign activity scheduling and LAVA homework

Session 4: *Monitoring Progress*

- Review comorbid SUD-depression formulation (treatment rationale)
- Review activity scheduling (daily plans)
- Review LAVA
- Assign activity scheduling and LAVA homework

Session 5: *Monitoring and Maintaining Progress*

- Review comorbid SUD-depression formulation (treatment rationale)
- Review activity scheduling (daily plans)
- Identify activities patients can do when they experience urge to use substances
- Introduce behavioural contract (support agreement)
- Assign activity scheduling, LAVA and behavioural contract homework

Session 6: *Staying on track*

- Review comorbid SUD-depression formulation (treatment rationale)
- Review activity scheduling (daily plans)
- Review behavioural contract (support agreement)
- Develop post-treatment plan

Booster Sessions

- Review comorbid SUD-depression formulation (treatment rationale)
- Review activity scheduling (daily plans)
- Review behavioural contracts (support agreement)

3.2.6.1 | *BA Therapists*

BA treatment was provided by five 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 SUD treatment 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. Details of BA therapist characteristics are provided in Table 3.2.

Therapists received a total of 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 two senior clinicians with expertise in BA delivery (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.

Table 3.2. Characteristics of BA therapists

	BA Therapists (*n*=5)
Mean Age (SD)	42.4 (11.5)
Gender (%)	
Male	1 (25)
Female	4 (75)
Education (%)	
Bachelor's degree or equivalent	3 (60)
A-Levels or equivalent	2 (40)
Professional Background (%)	
Nursing	1 (25)
None	4 (75)
Mean number of years employed in SUD treatment (SD)	4.4 (5.41)

3.2.6.2 | *Therapist Adherence to the BA Treatment Protocol*

Therapist adherence to the BA treatment protocol was assessed via self-report checklists highlighting specific session objectives (see Appendix F for session adherence checklists). These checklists were completed by therapists at the end of each session. The average adherence rate for all sessions was 95%, indicating a high level of therapist adherence to the BA treatment protocol. Figures 2.1 and 2.2 show the average adherence ratings for each session and for key treatment components. The highest overall adherence rating was reported for Session 1 (100%) and the lowest overall adherence rating was reported for Session 2 (83.7%). For specific treatment components, the highest adherence rating was reported for

the treatment rationale (100%), while the lowest adherence rating was reported for LAVA (93.4%).

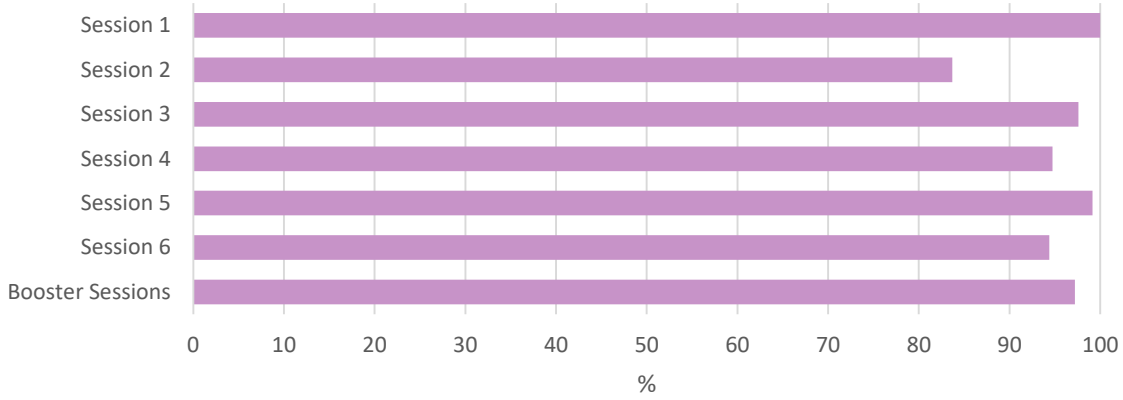


Figure 3.2. Average level of therapist self-rated adherence to the BA treatment protocol for each session (n = 5)

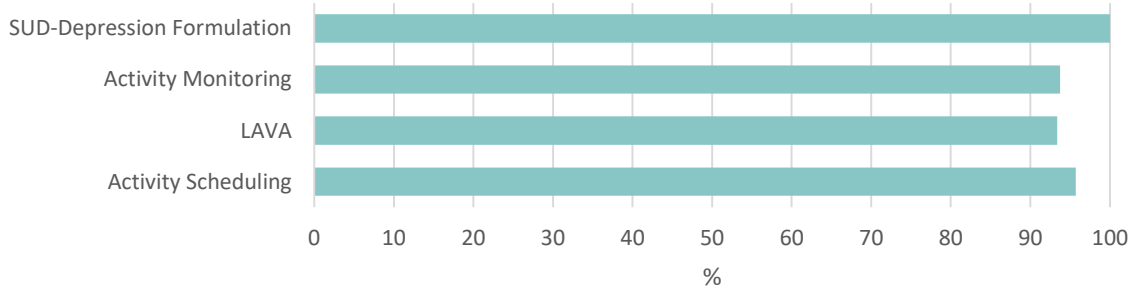


Figure 3.3. Average level of therapist self-rated adherence to key BA treatment components (n = 5)

3.2.6.3 | *Participant Engagement with BA*

BA participants were offered three opportunities to attend their first session of BA. Participants who failed to attend at least three sessions after commencing therapy were classed as having dropped out of BA treatment and were not offered any further sessions. These dropout policies were adopted in order to reduce potential burden on BA therapists in the study. Details of patient engagement with the BA intervention and factors associated with treatment completion are reported in Section 3.3.7.

3.2.7 | Outcome Measures

3.2.7.1 | *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 symptomjs 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 $\geq$ 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 (α = .86)

3.2.7.2 | *Percent Days Abstinent (PDA)*

The Treatment Outcomes Profile (TOP; Marsden et al., 2008) 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, 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.

3.2.7.3 | *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 (α = .80)

3.2.7.4 | *Anxiety*

Given the prevalence of anxiety disorders in patients with comorbid SUD-depression (Delgadillo et al., 2016) and evidence that BA may have a beneficial effect on anxiety symptomatology (e.g. 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, Payne, 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 score indicating greater severity of anxiety. Internal consistency was good in the current study (α = .83)

3.2.7.5 | *Valued Living*

Engaging in valued activities is a core component of modern BA therapies (e.g. Lejuez et al., 2011) and emerging evidence suggests that increases in valued living are associated with reductions in depression symptoms (Bramwell & Richardson, 2018). Given the limitations of domain-specific valued living measures (e.g. VLQ; Wilson, Sandoz, Kitchens & Roberts, 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; Smout et al., 2014). The current study found a moderate negative correlation between the Progress and Obstruction subscales overall (r = -.41, p < .001), although no significant correlation was found between these subscales at baseline assessment (r = .003, p = .990; see Table 6). Overall, internal consistency was good for the Progress subscale (α = .85) and acceptable for the Obstructions subscale (α = .70).

3.2.8 | Statistical Analysis Plan

3.2.8.1 | *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. 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; Gilks et al., 1996) method. Reported results utilise the full imputed dataset and do not differ markedly from the results obtained with missing data (see Appendix H for analyses with missing data).

3.2.8.2 | *Primary outcome*

The primary outcome analysis was conducted using an intention-to-treat (ITT) approach, including those who completed and those who dropped out of treatment. 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).

3.2.8.3 | *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 (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. A series of repeated measures ANOVAs were also conducted with the ITT sample to explore differences in key outcome variables within each treatment group over time. Effect sizes for repeated measures analyses were calculated and reported using Cohen's *d*.

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.

3.3 | Results

3.3.1 | Sample Characteristics

Baseline demographics and clinical characteristics of the overall sample and each treatment group (BA and TAU) are summarised in Table 3.3. 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 ($p = .017$), 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%). The mean intake score on the PHQ-9 was 18.65 (SD = 3.95) which denotes moderately severe depression symptoms (Kroenke, Spitzer & Williams, 2001). The mean score on the GAD-7 was 14.47 (SD = 4.39) representing moderate levels of anxiety (Spitzer, Kroenke, Williams & Lowe, 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).

Table 3.3. Sample characteristics and comparisons between randomly assigned groups

	Full Sample (n=34)	BA (n=17)	TAU (n=17)	Test Statistic	*P*
Mean Age (SD)	42.3 (6.5)	42.18 (7.45)	42.35 (5.53)	$t(32) = -0.08$	.938
Gender (%)					
Male	25 (73.5)	9 (47.1)	16 (94.1)	-	.017[a]
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[a]
Unemployed	29 (85.3)	14 (82.4)	15 (88.2)		
Primary Substance (%)					
Opiates	26 (76.5)	12 (70.6)	14 (82.4)	-	.688[a]
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[a]
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 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)	$t(32) = 0.54$	.592
VQ-Obstruction (SD)	21.03 (4.48)	21.24 (4.51)	20.82 (4.59)	$t(32) = 0.26$	.793

Note: *t* = Student's t-test; χ^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)

[a] *p* value refers to result of Fisher's Exact Test

3.3.2 | Depression Outcome

As shown in Table 3.4, there was a significantly greater reduction in depression (PHQ-9) in BA compared to the TAU group at 12-week follow-up ($F(1,31) = 7.03$, $p = .039$). 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 follow-up points: 6-week, $F(1,31) = 12.62$, $p = .001$; 12-week, $F(1,31) = 6.53$, $p = .016$ and 24-week, $F(1,31) = 11.41$, $p = .002$. 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), $U = 8$, $z = -3.277$, $p = .001$. No significant differences in depression symptoms were found at 6- or 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 6-week follow-up ($U = 29$, $z = -1.949$, $p = .051$). As shown in Figure 3.4, 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 = .007). In the treatment completer sample, five BA participants (71.4%) met criteria for RCSI at 12-week follow-up (p < .001). At 24-week follow-up, three TAU participants (17.7%) and five BA participants (29.4%) met criteria for RCSI (see Figure 3.5), including three BA participants (30%) in the treatment completer sample. Differences between groups were not statistically significant.

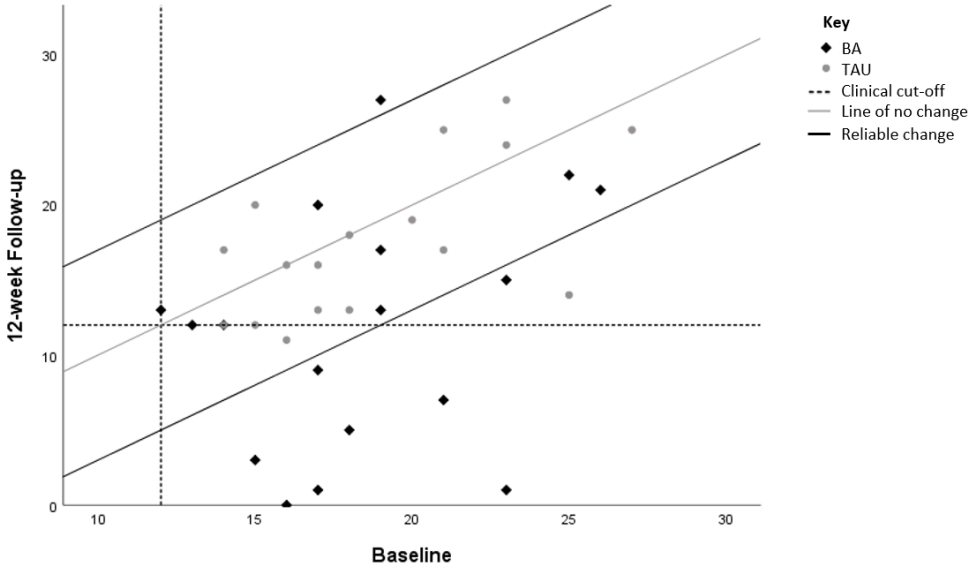


Figure 3.4. Plot of baseline and 12-week PHQ-9 outcomes in BA and TAU conditions

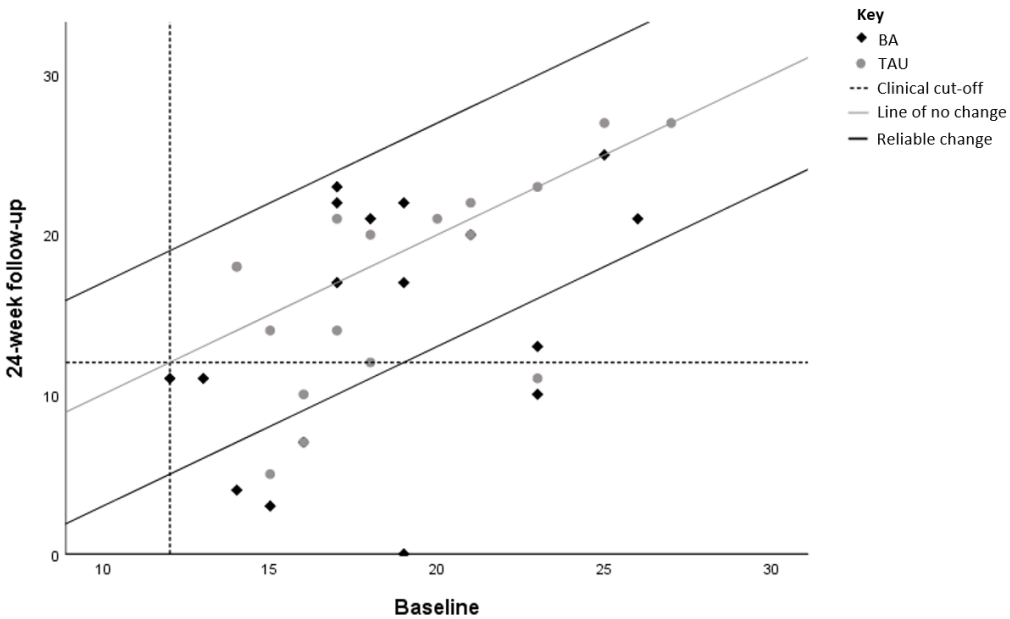


Figure 3.5. Plot of baseline and 24-week PHQ-9 outcomes in BA and TAU conditions

3.3.3 Substance Use Outcomes

3.3.3.1 | *Percent Days Abstinent (PDA)*

The number of days abstinent had differentially increased in the BA group by 6-week ($F(1,31) = 4.66$, $p = .039$) and 12-week follow-up ($F(1,31) = 5.9$, $p = .021$). As shown in Table 3.4, 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, ($F(1,31) = 12.62$, $p = .001$) and 24-week follow-up ($F(1,31) = 11.41$, $p = .007$), 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), $U = 98$, $z = 2.465$, $p = .013$. 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), $U = 98.5$, $z = 2.502$, $p = .011$. No significant difference in PDA was found between BA treatment completers and TAU participants at 24-week follow-up.

3.3.3.2 | *Severity of Dependence (SDS)*

As shown in Table 3.4, 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 ($F(1,31) = 14.22$, $p = .001$), but not at 12- or 24-week follow-up. No significant differences were found between groups using the treatment completer sample.

3.3.4 | 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

($F(1,31) = 11.31$, $p = .002$) and 24-week follow-up ($F(1,31) = 18.17$, $p < .001$), 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 ($U = 29.5$, $z = -1.915$, $p = .055$), suggesting that anxiety symptoms decreased more in BA treatment completers than in the TAU group.

3.3.5 | Valued Living (VQ)

3.3.5.1 | *Progress in Valued Living (VQ-Progress)*

Progress in valued living had differentially increased in the BA group at 6-week follow-up ($F(1,31) = 7.9$, $p = .008$). 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, $F(1,31) = 10.95$, $p = .002$, and 12-week follow-up, $F(1,31) = 35.16$, $p < .001$, 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 ($U = 98.5$, $z = 2.491$, $p = .011$). At 12-week follow-up, VQ-progress scores were again significantly higher ($U = 93$, $z = 2.135$, $p = 034$) in BA treatment completers (mean rank = 17.29) compared to TAU (mean rank = 10.53), $U = 93$, $z = 2.135$, $p = 034$. No significant difference was found between TAU and BA treatment completers at 24-week follow-up.

3.3.5.2 | *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

Table 3.4. Change in primary and secondary outcomes across treatment conditions for randomised sample and treatment completer subsample

Variable and time Point	Randomised Sample (n=34)			Treatment Completers (n=24)	
	TAU (n=17)	BA (n=17)		BA (n=7)	
	Mean (SD)	Mean (SD)	Mean Difference[a] (*p*)	Mean (SD)	Mann-Whitney *U* (*p*)
Depression (PHQ-9)					
6 weeks	17.06 (4.12)	15.94 (7.76)	-0.82 (.655)[b]	11.14 (6.07)	29 (.055)
12 weeks	17.59 (5.09)	11.65 (8.12)	-5.69 (.013)[b]	6.14 (5.61)	8 (.000)
24 weeks	17.06 (6.54)	14.53 (7.82)	-2.20 (.314)[b]	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)[b]	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)	9.12 (4.2)	6.18 (4.85)	-3.06 (.067)[b]	6.14 (5.61)	40.50 (.234)
6 weeks	6.29 (4.3)	6.59 (5)	-0.76 (.583)[b]	4.57 (5.22)	44.50 (.349)
12 weeks	6.65 (4.83)	6.47 (3.94)	-0.75 (.620)	3.57 (3.41)	36.50 (.147)
24 weeks					
Anxiety (GAD-7)	13.47 (4.6)	12.41 (5.06)	-2.28 (.135)	11.14 (4.30)	42.50 (.288)
6 weeks	12.71 (6.07)	9.65 (5.7)	-3.92 (.061)[b]	6.86 (4.45)	29.50 (.055)
12 weeks	11.53 (5.34)	11.59 (6.07)	-1.64 (.322)[b]	9.14 (5.90)	44 (.349)
24 weeks					
Progress in Valued Living (VQ-Progress)	6.29 (3.79)	12.24 (8.1)	5.34 (.008)[b]	13.86 (6.96)	98.50 (.011)
6 weeks	12.53 (7.18)	16 (8.45)	2.41 (.209)[b]	19.14 (5.76)	93 (.034)
12 weeks	11.71 (9.01)	14.41 (8.49)	2.21 (.455)[b]	17.86 (9.49)	83.50 (.130)
24 weeks					
Obstructions to Valued Living (VQ-Obstruction)					
6 weeks	20 (4.82)	18.24 (7.93)	-1.76 (.449)[b]	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)[b]	17 (9.47)	58 (.951)

[a] Mean difference adjusted for baseline scores on corresponding measure

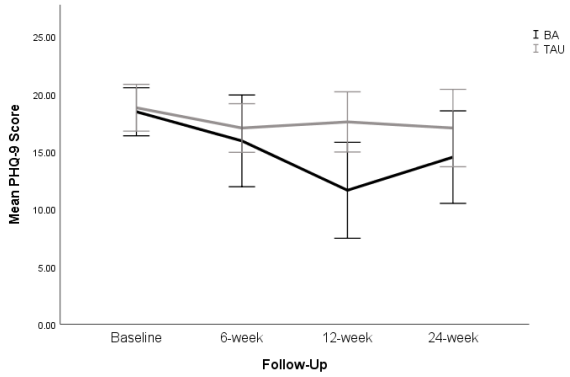
[b] Some assumptions such as homoscedasticity and homogeneity of variance were violated

3.3.6 | Within-group change

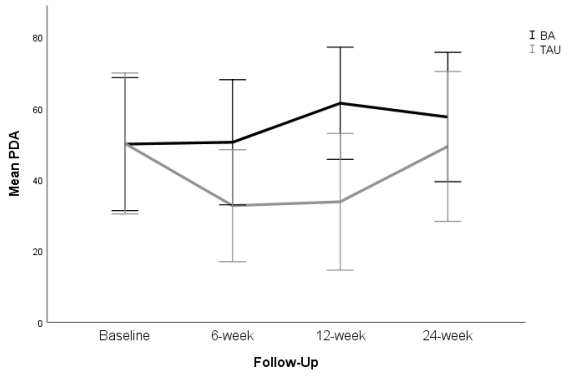
As shown in Figure 3.6A-F, in the BA group there were significant improvements in depression ($F(3,48) = 5.42$, $p = .003$), anxiety ($F(3,48) = 7.04$, $p = .001$) and progress in valued living ($F(3,48) = 5.48$, $p = .003$). Depression decreased significantly from baseline to 12-week follow-up (M = 6.82, 95% CI [1.07 to 12.58], $p = .015$) and from 6-week to 12-week follow-up (M = 4.3, 95% CI [0.88 to 7.7], $p = .01$). Anxiety decreased significantly from baseline to 12-week (M = 5.88, 95% CI [0.53 to 11.23], $p = .027$) and 24-week follow-up (M = 3.94, 95% CI [0.23 to 7.66], $p = .034$). Progress in valued living increased significantly from baseline to 12-week follow-up (M = 6.88, 95% CI [-11.53 to -2.24], $p = .002$) and 6-week to 12-week follow-up (M = 3.77, 95% CI [-7.31 to -0.23], $p = .034$). Obstructions to valued living also increased significantly over time ($F(2.16, 34.58) = 3.2$, $p = .049$), with a significant difference observed from 12-week to 24-week follow-up (M = 5.59, 95% CI [-9.36 to -1.81], $p = .002$). No significant differences were found for PDA or severity of dependence (SDS) at any of the follow-up time points.

In the TAU group, there were no significant changes in depression or anxiety symptoms, PDA or obstructions to valued living at follow-up assessment points. However, there was a significant improvement in progress toward valued living ($F(1.45, 23.18) = 5$, $p < .024$). Progress in valued living increased significantly from baseline to 12-week follow-up (M = 4.59, 95% CI [-7.67 to -1.50], $p = .002$) and from 6-week to 12-week follow-up (M = 6.24, 95% CI [-10.6 to -1.87], $p = .003$). Severity of dependence was also found to increase over time, $F(3,48) = 3.12$, $p < .035$, although a post-hoc analysis revealed no significant differences in SDS scores at any of the follow-up time points.

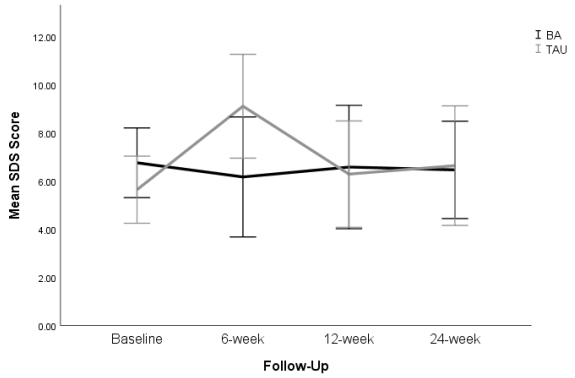
(**a**) PHQ-9 Scores



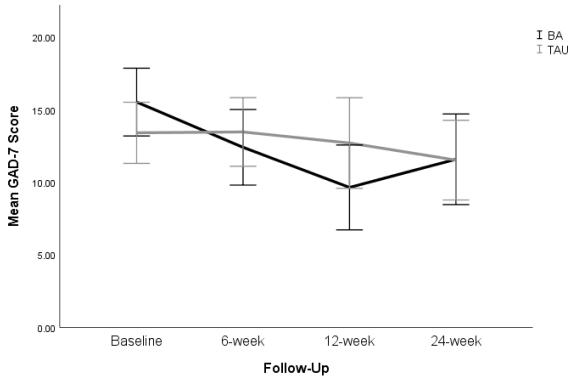
(**b**) PDA



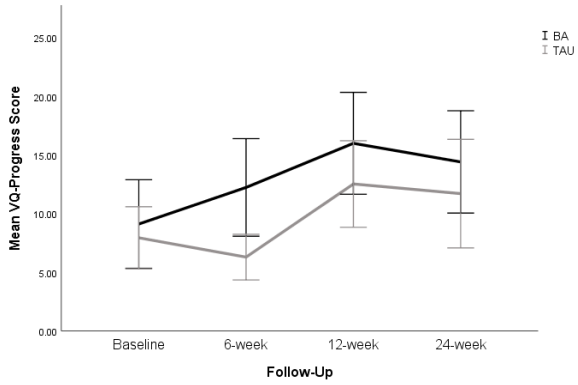
(**c**) SDS Scores



(**d**) GAD-7 Scores



(**e**) VQ-Progress Scores



(**f**) VQ-Obstruction Scores

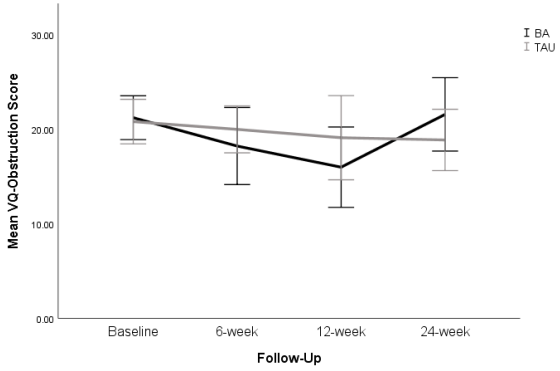


Figure 3.6A-F. Graphs showing changes in primary and secondary outcomes over time (error bars represent 95% confidence intervals)

3.3.7 | Engagement

As shown in Figure 3.1, of the 17 participants randomly assigned to TAU, only one 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 the participants who dropped out of BA treatment (N = 10), the majority had not attended any BA sessions at all (N = 7). As shown in Figure 5, 10 participants (59%) attended at least the first two sessions of BA.

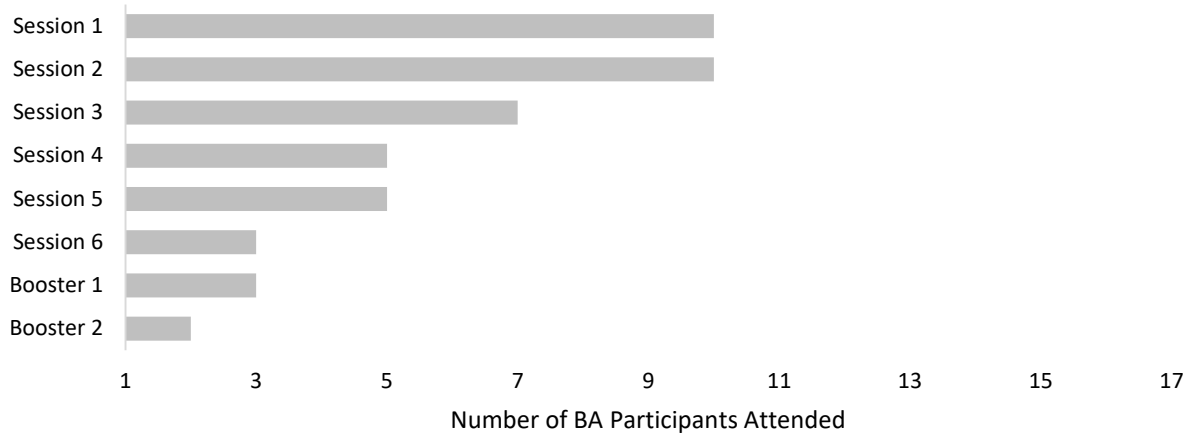


Figure 3.7. Overview of participant attendance in BA treatment

Seven participants (41.2%) completed the BA intervention (defined as attending at least 3 sessions) and those who completed BA attended a mean number of 5.6 sessions (SD = 1.8, mode = 4). As shown in Tables 5 and 6, correlation analyses indicated that participants were more likely to complete BA treatment if they were in employment, $r_s(15) = .55$, $p = .021$, and reported more days abstinent at baseline, $r_{pb}(15) = .53$, $p = .028$. No other demographic or clinical variables at baseline were significantly associated with BA treatment completion.

Table 3.5. Spearman's correlation matrix of BA treatment completion and categorical baseline variables (n = 17)

	1	2	3	4	5	6
1. BA Completion						
2. Gender	-.310					
3. Employment	.553[a]	-.127				
4. Opiate Use	.247	-.091	.378			
5. Polydrug Use	-.029	-.169	.074	-.247		
6. Antidepressant Use	-.310	.292	-.127	-.350	.070	

[a] $p < .05$

Table 3.6. Pearson's correlation matrix of BA treatment completion and continuous baseline variables (n = 17)

	1[a]	2	3	4	5	6	7	8
1. BA Completion								
2. Age	-.186							

3. PHQ-9	-.009	.016					
4. SDS	-.278	.079	.125				
5. PDA	.533[b]	-.286	-.117	-.202			
6. GAD-7	-.290	.250	-.107	-.107	-.358		
7. VQ-Progress	.143	.251	.114	.362	-.175	.227	
8. VQ-Obstruction	.006	.394	-.602[b]	.273	-.290	-.290	.003

[a] Represents point-biserial correlation between BA treatment completion (categorical) and continuous baseline variables
[b] $p < .05$

3.4 | Discussion

This is the first randomised controlled trial examining the effects of BA facilitated by drug and alcohol treatment workers for patients with elevated depression symptoms who are accessing CDAT. The findings indicate that a brief BA intervention (LETS ACT!) delivered in adjunct with usual care had a differentially beneficial effect on depression outcomes at 12-week follow-up. BA was also associated with 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 patients with comorbid SUD-depression (e.g. Martínez-Vispo et al., 2018) and suggest that drug and alcohol treatment workers may be capable of delivering this intervention in routine care.

3.4.1 | Effects of BA

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 a sample of 44 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' (2008) study 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 which focused on trials of integrated CBT and motivational interviewing versus TAU ($g = 0.27$; Riper et al., 2014). In the present study, 41.2% of BA participants demonstrated clinically significant improvement 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).

Consistent with research on the community reinforcement approach (CRA) (e.g. Roozen et al., 2004), PDA outcome in this study supports the application of behaviour therapy principles to the treatment of 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). No significant findings were observed 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 the core treatment principles 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 (Carvalho et al., 2018; Smout et al., 2014). Therefore, closing the values-behaviour gap may be an important treatment target for patients with comorbid depression and SUDs. The finding that TAU participants reported improvements in valued living progress over time is unexpected and difficult to explain, however, especially as these improvements did not appear to correspond with severity of depression symptoms or PDA. Obstructions to valued living is conceptually distinct from progress and refers to the disruption of valued action due to patterns of experiential avoidance (Smout et al., 2014). Interestingly, BA participants reported a significant increase in obstructions to valued living between 12- and 24-week follow-up, which suggests a marked increase in maladaptive cognitions that disrupted engagement in valued activities as the positive effects of BA declined.

Consistent with a previous trial of BA with depressed SUD patients (Daughters et al., 2008), no significant group differences were found for anxiety symptoms, although there was evidence of reductions in anxiety symptoms over time in the BA group. Indeed, it has been suggested that BA may have beneficial effects on anxiety via increasing approach behaviours

(Hopko et al., 2006). 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 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 equally cannot be ruled out.

3.4.2 | 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. Approximately 41% of participants 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. The finding that employment was associated with treatment completion is consistent with research showing that non-SUD patients who are unemployed are less likely to respond to therapy (Delgadillo et al., 2016). There was no evidence that BA 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 (e.g. Cahill et al., 2003).

3.4.3 | 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).

3.4.4 | Strengths and Weaknesses

Major strengths of this study include the randomised controlled design, multiple follow-up assessments and extended follow-up period. The final follow-up assessment in this study was conducted 18 weeks after BA treatment had ended. This permitted a detailed preliminary assessment of the effects and durability of BA in this population. Follow-up rates were relatively high in both treatment groups. The study was also designed to emulate how BA could be integrated into routine care in CDAT setting and therefore it has high external validity. The recruited sample consisted primarily of patients with opiate use disorders, which corresponds with the majority of patients accessing SUD treatment in the UK (Public Health England, 2020). The mean age of participants (M = 42.3, SD = 6.5) and proportion of males (73.5%) to females (26.5%) was also comparable with the SUD treatment population in the UK (NDTMS, 2021).

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 (Thomson et al., 2008), especially when there is a TAU control arm (Howard et

al., 2009). 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 are not fully representative of patients with comorbid SUD-depression accessing CDAT. Due to the small sample size, effect size estimates and other statistical results are likely to be skewed and should be interpreted with caution. It was also not possible to investigate valued living as a mediator of BA treatment effects. A fully powered RCT is indicated to replicate and extend on the findings from this study. Future trials should consider using more direct screening methods (i.e. researchers approaching potential participants directly), changing the inclusion/exclusion criteria and recruiting from multiple sites to address potential recruitment difficulties.

Another potential 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 6 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. Given the nature of busy CDAT services, it may be too burdensome to compare BA with a time-matched TAU control in this setting. It could also be argued that a time-matched TAU control would not give a true reflection of what happens in real practice, where patients are expected to have variable degrees of contact time with services.

Finally, even though this was a novel test of BA delivered by drug and alcohol treatment workers, limited study resources meant that adherence to the BA treatment protocol was assessed via self-report only. Adherence ratings were strikingly high for all sessions and treatment components, yet there is evidence that self-rated adherence may be inflated compared to independent adherence ratings of session content (Hogue et al., 2015). Research has also suggested that therapists can have particular difficulty evaluating their skills when

delivering a new intervention (Miller & Mount, 2001). This means that the adherence reported for BA in the present study may not be a true reflection of the treatment that was actually delivered to participants.

3.4.5 | Implications for Practice and Research

This study provides preliminary evidence that BA facilitated by drug and alcohol treatment workers may be effective for patients with comorbid SUD-depression. 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 particularly promising intervention for patients who exhibit a degree of stability in terms of substance use and employment, but it remains unclear whether all patients can engage successfully in BA treatment. Patients who are in employment and using less substances may have achieved these attributes due to 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 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). Indeed, the study by Carpenter et al. (2008) provided BA participants with vouchers as an incentive for attending BA sessions and completing between-session assignments. Although this study did not find any significant effects of BA, it has so far reported the lowest dropout rate for BA among trials conducted in CDAT (50%). The provision of financial incentives is unlikely to be feasible in routine CDAT due to lack of funding. However, future trials could explore the possibility of combining a more cost-effective CM strategy (e.g. MAT prescription incentives) with the BA intervention delivered in the present study to promote attendance among patients who are otherwise less likely to engage. This approach may be particularly beneficial for patients who have difficulty attending an initial appointment, which was the key reason why most participants dropped out of BA treatment in the present study.

Further research is also needed to refine BA for delivery in an SUD treatment 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 mechanism of change associated with BA for patients with comorbid SUD-depression. Understanding mediators of BA treatment 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 regarding which aspects of BA contribute to significant change in non-dependent samples, although most existing studies have focused on activation and 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 (Smout et al., 2014; Wilson et al., 2010), exploring progress in valued living as a potential mediator of BA for SUD patients could be a promising area of inquiry. Future trials should also conduct more in-depth monitoring of therapist adherence and competency to help establish the level and quality of BA received by participants, as well as a drug and alcohol treatment workers' capabilities in specific areas of BA delivery.

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 depression and SUDs is a pervasive issue associated with significant health and social consequences and reduced rates of SUD treatment completion (Teesson et al., 2008). Therefore, identifying and disseminating treatment approaches that are effective and widely applicable remains an important priority for this patient group.

3.4.6 | Conclusion

This study provides preliminary evidence that BA implemented by drug and alcohol treatment workers is feasible and may add clinical benefit to usual care for patients with co-

occurring depression and SUDs 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. Larger RCTs are warranted to investigate ways of increasing the applicability of BA to patients with more complex profiles, identify mediators of treatment effects and test interventions that support the clinical durability of BA over time.

Chapter 4

Staff and patient experiences of a Behavioural Activation intervention in community drug and alcohol treatment

The previous chapter reported on a pilot RCT of BA facilitated by drug and alcohol treatment workers. Results indicated that implementing BA as part of routine care may be effective for some patients with comorbid SUD-depression who are accessing CDAT in the short-term. RCTs are often hailed as the "gold standard" when it comes to determining the efficacy of psychological interventions, however they do not provide a full picture. It has been argued that psychological therapies cannot be meaningfully evaluated using quantitative data alone and findings from RCTs may be difficult to translate into practice. In contrast, qualitative approaches focus on the perspective of participants to provide "contextual knowledge" which is valuable in defining the acceptability of interventions, how they work and ways in which they could be improved. Several studies have explored the experiences of depressed patients accessing BA which has contributed to an increased understanding of the acceptability of interventions and their effects (e.g. Finning et al., 2017). Studies have also explored staff and patient views of interventions delivered in SUD treatment settings, which has contributed to an increased understanding of barriers and facilitators to implementation (e.g. Amodeo et al., 2011; Gore et al., 2017). However, no studies to date have simultaneously explored staff and patient perspectives of BA therapy in an SUD treatment. Therefore, the third study adopts a qualitative approach to explore the views of clinical managers, BA therapists and BA patients on the implementation of the BA intervention reported in the previous chapter, with the aim of gaining a more comprehensive understanding of the acceptability and perceived value of integrating BA into routine CDAT from key stakeholders at different levels of the organisation.

4.1 | Introduction

4.1.1 | Incorporating qualitative research into RCTs of psychological therapies

Evidence from RCTs is considered the "gold standard" when evaluating the efficacy of psychological interventions. The key advantages of RCTs include randomisation to different treatments, comparison between treatments and the minimisation of bias, meaning that in most cases, the outcomes of RCTs can be confidently attributed to the impact of the

treatments being compared. A well-designed RCT may be appropriate for answering the question “is it effective?”, but there are other questions important for evidence generation that RCTs cannot answer. In particular, RCTs provide little information about the context in which interventions are delivered or how patients experience interventions. Without understanding these contextual factors, findings from RCTs may be difficult to translate into practice (Hollon, 2006).

In order to address the limitations of RCTs as a standalone approach, it has been argued that qualitative approaches should be undertaken alongside RCTs (McLeod, 2011). Qualitative methods are increasingly used to identify the acceptability and feasibility of interventions, provide insights into behaviour change processes and aid understanding of trial findings (Creswell et al., 2009; Richards et al., 2019). Qualitative methods can be adopted as part of a mixed-methods process evaluation (Moore et al., 2015) or as a nested qualitative study alongside a pilot or fully powered RCT (O’Cathain, 2018). These approaches have become a staple of high-quality health research and are increasingly common in healthcare literature (Snowdon, 2015). Given that implementation of evidence-based interventions depends on multiple levels of service delivery (Ferlie & Shortell, 2001), it seems that exploring both staff and patient perspectives could also contribute to a better understanding of interventions and the context of their implementation. The information gained from qualitative approaches can help optimise interventions for delivery in specific contexts, refine and improve treatment protocols and explain null or unexpected trial findings, such as why some patients did not engage with therapy.

4.1.2 | Patient experiences of BA therapy

The burgeoning popularity of BA in recent years has led to increased interest in how the therapy works and how treatment can be optimised for different populations. As a result, several recent qualitative studies have explored patient perspectives of BA therapy. These studies have predominantly explored the helpful and unhelpful aspects of BA, contributing to an increased understanding of effective ingredients of BA in addition to potential barriers to engaging or obtaining benefit from therapy.

Finning et al. (2017) conducted a qualitative process evaluation of a large non-inferiority RCT comparing BA with CBT for depressed patients. They found that therapist support, the opportunity to learn and improved functioning in life were commonly cited by

patients as helpful components of both treatments, while a lack of focus on past problems was perceived to be unhelpful. It was also noted that some BA participants in the study reported specific concerns about the simplicity of the therapy and perceptions that therapists were inexperienced or rigid in their approach. The latter finding is particularly interesting given that BA therapy had been delivered by non-specialist mental health workers in the study, whereas qualified professionals delivered CBT. It suggests that BA delivered by paraprofessionals may be suboptimal and perhaps less acceptable to some patients, even though experimental research has shown that this approach to delivery is generally effective (e.g. Richards et al., 2016).

Other studies focusing on participant experiences of BA therapy have highlighted the importance of common therapeutic factors including therapist support (Lewis-Smith et al., 2021) and peer support in group BA (Stein et al., 2021), in addition to specific characteristics of BA that were perceived to be helpful and unhelpful. For example, Lewis-Smith et al. (2021) interviewed a sample of depressed adolescents who had received brief BA therapy. Participants reported that learning new coping strategies and identifying values and valued activities were beneficial aspects of treatment, however the duration of therapy (6-8 sessions) was perceived to be too brief making it difficult to sustain positive changes. Another study with a sample of depressed adult patients who received group BA found that identifying value-driven activities, goal-setting, activity scheduling, self-monitoring and completing worksheets were helpful aspects of therapy, whereas focusing too much on depression was perceived to be unhelpful. Therefore, findings from these studies suggest that unhelpful aspects of BA may be context-dependent, whereas key BA treatment components, particularly identification of valued activities, are perceived as acceptable and helpful by most patients. However, all of the studies to date have been conducted with non-SUD samples. Given that SUD patients may have different characteristics to non-SUD patients such as reduced cognitive abilities (e.g. Bruijnen et al., 2019; Goldstein et al., 2009; Vik et al., 2004) and increased economic and social deprivation (Shaw et al., 2007), it is generally unclear how existing findings relate to patients with comorbid SUD-depression.

4.1.3 | Staff and patient perspectives of evidence-based interventions in SUD treatment

In addition to aiding understanding of how interventions work, qualitative research is useful for acquiring knowledge of the contexts in which interventions are delivered. Previous

research has indicated that evidence-based interventions are not consistently delivered in SUD treatment settings (Best et al., 2009; Carroll, 2014). There is also evidence to suggest that many SUD patients do not access interventions even when they are implemented (e.g. Delgadillo et al., 2015). Understanding staff and patient perspectives of the barriers and facilitators associated with evidence-based interventions can help to explain these findings, optimise treatments for delivery in this context and reduce gaps between research and practice. Several studies have explored staff and patient perceptions of barriers and facilitators to implementing or engaging with interventions in SUD treatment settings. However, no studies have explored drug and alcohol treatment workers' perspectives on delivering mental health interventions. Few studies have explored patient perspectives of SUD interventions (e.g., Neale et al., 2008) and only one study has explored barriers and facilitators to accessing mental health interventions from the perspective of SUD patients (Gore et al., 2017).

4.1.3.1 | *Staff barriers and facilitators to implementing evidence-based interventions*

Findings from studies of staff-reported barriers and facilitators suggest that four main themes influence the implementation of interventions in SUD treatment settings: (1) organisational issues; (2) staff issues; (3) patient characteristics; and (4) intervention characteristics. Interestingly, these themes are all broadly related to Rogers' (2003) model of diffusion, which suggests that the process of integrating evidence-based interventions into practice is influenced by organisations, people and the characteristics of interventions. Most studies of staff barriers and facilitators have focused on conjectural perceptions of implementing evidence-based SUD interventions. Findings from these studies indicate that lack of staff time (Sondhi & Day, 2015), lack of supervision (Bartholomew et al., 2007), unfavourable staff attitudes and lack of funding (Sinclair et al., 2011) are possible barriers to implementation. One study also explored the experiences of drug and alcohol treatment workers who delivered manualised SUD treatments in an RCT. They found that the structure of manuals helped improve the overall focus of treatment but lack of flexibility to focus on other problems was a barrier in sessions (Godley et al., 2001).

Other studies have explored the experiences of staff delivering SUD interventions in routine care. Amodeo et al. (2011) notably found that drug and alcohol treatment workers' perceptions of barriers varied across different interventions; lack of training and staff resistance were identified as the biggest barriers to implementing Motivational Interviewing

(MI), whereas patient characteristics including motivation, cognitive ability and psychiatric symptoms were identified as the biggest barriers to implementing CBT. Another study identified that broader organisational factors such as service structure, funding priorities and availability of training influenced the provision of evidence-based SUD treatments in the UK (Sheridan et al., 2011). Therefore, it is clear that a combination of factors may affect the implementation of interventions in SUD treatment, which has important implications for future research and implementation efforts. However, BA facilitated by drug and alcohol treatment workers is a novel approach to delivery and research has yet to explore staff's experiences of implementing BA or any other evidence-based mental health interventions in routine CDAT.

4.1.3.2 | *Patient barriers and facilitators to engaging with evidence-based interventions*

Most studies conducted with SUD patients have explored the barriers and facilitators to accessing health and social care services generally and with patients who do not necessarily have comorbid SUD-depression. These studies indicated that difficulties adhering to appointment times (Neale et al., 2008; Riley et al., 2002), poor physical health and travel costs (Neale et al., 2008) were among the most common barriers to accessing services. However, one study has also specifically explored the barriers and facilitators to accessing evidence-based psychological interventions from the perspective of CDAT patients with comorbid SUD-depression (Gore et al., 2017). Patients in this study were recruited from an RCT comparing BA to CBT-based guided self-help in the UK. Findings indicated that the most common barriers to accessing psychological therapy were mental health problems, adverse life situations, memory deficits, avoidance of unfamiliar situations and being overcome with multiple demands and appointments. These findings suggest that patients with comorbid SUD-depression may have particular difficulties accessing mental health support and to encourage attendance, psychological interventions need to be flexible to patient needs and delivered in a familiar environment such as CDAT. Yet research in this area remains scarce and relatively little is known about the needs or preferences of patients with comorbid SUD-depression overall.

4.1.4 | Aim of the current study

Qualitative research can help to explore staff and patient experiences of interventions and provide context to quantitative data, leading to more credible conclusions on the acceptability

of psychological treatments and more comprehensive directions for future experimental research. Several studies have explored the experiences of depressed patients receiving BA, leading to an increased understanding of intervention effects and barriers to patient engagement and benefit from therapy. Studies have also explored staff and patient views of interventions delivered in SUD treatment settings, contributing to an increased understanding of barriers and facilitators to implementation and accessibility for patients. BA facilitated by drug and alcohol treatment workers holds promise as a means to increase patient access to psychological treatment for depression in CDAT and improve treatment outcomes. However, staff and patient perspectives of BA therapy in a SUD treatment context are presently unknown.

The current study was a qualitative follow-up of the pragmatic pilot randomised controlled trial of BA for comorbid SUD-depression described in Chapter 3. Given that barriers to implementation of evidence-based interventions may arise at multiple levels of service delivery (Ferlie & Shortell, 2001), seeking a combination of managerial, therapist and patient views is essential to understand the acceptability of training drug and alcohol treatment workers to deliver BA in routine CDAT. No studies to date have explored staff perspectives of evidence-based mental health interventions delivered in CDAT. Moreover, it is not known how patients with comorbid SUD-depression experience BA treatment or what they find helpful or unhelpful. Therefore, understanding the perspective of clinical managers, BA therapists and BA patients is an innovative area of inquiry that could help refine BA treatment for delivery in this context, direct the focus of further RCTs and potentially facilitate the future implementation of BA in CDAT.

4.1.4.1 | *Objectives*

The current study sought to explore experiences of the BA intervention delivered in the BA trial (Chapter 3) from stakeholders at three organisational levels in CDAT: (1) clinical managers (BA supervisors, CDAT manager); (2) BA therapists (drug and alcohol treatment workers); and, (3) BA patients, to permit a more comprehensive understanding of the acceptability and potential value of implementing BA in CDAT, in addition to identifying any possible areas for improvement of the BA intervention.

4.1.5 | Research questions

This study aimed to explore staff and patient experiences of BA delivered by drug and alcohol treatment workers in CDAT by addressing the following research questions:

1. How did clinical managers and BA therapists experience the delivery of BA in a CDAT setting?
2. How did CDAT patients experience participation in BA treatment?

4.2 | Method

4.2.1 | Design

This was a qualitative study nested within a pilot RCT of BA delivered by drug and alcohol workers in CDAT. Reflexive thematic analysis (Braun & Clarke, 2006, 2019) was conducted on semi-structured interviews with participants representing three organisational levels in the CDAT service: (1) Clinical managers; (2) BA therapists; and (3) BA patients, regarding their experiences of the BA intervention delivered in the trial. Data were compared to identify common and divergent themes between and within these organisational groups.

4.2.2 | Theoretical position

This study was underpinned by a pragmatic epistemology, which is not tied to any specific ontology and simply asserts that knowledge is dependent upon people's actions and experiences (Goldkuhl, 2012; Howe, 1988). Pragmatism promotes a practical, action-oriented method of inquiry and embraces the use of multiple methods to address research questions effectively (Creswell, 2013; Tashakkori & Teddle, 1998). In practice, this meant that the current study was primarily concerned with identifying key benefits, barriers and solutions to delivering BA therapy in CDAT, as opposed to interpreting the meaning of language or generating theories. Multiple methods and sources of data were drawn upon to gain a comprehensive picture of participants' experiences of BA, with consideration of social and environmental factors to aid understanding of these experiences and their interpretations in context (Morgan, 2014),

4.2.3 | Recruitment

All participants had been advised that they may be asked to take part in qualitative interviews when they were recruited to the BA trial. Staff and patient participants provided informed consent before participating in interviews. A convenience sampling strategy was used to recruit clinical managers, BA therapists and BA patients from the BA trial. Convenience sampling was selected for its ease and cost-efficiency (Levy & Lemeshow, 2011), which was deemed necessary to accommodate the time constraints and small sample size of patients in the aforementioned trial. A minimum sample of 6-10 participants is recommended for thematic analysis of interviews (Braun & Clarke, 2013). The aim of the current study was therefore to recruit all clinical managers who had been directly involved in the BA trial (n=3), all BA therapists (n=5), and 6-8 BA patients in order to achieve adequate data saturation for staff and patient perspectives of BA treatment. A summary of participant recruitment is shown in Figure 4.1.

4.2.3.1 | *Clinical managers*

Clinical managers were invited to take part in qualitative interviews following completion of the BA trial. This ensured that they could offer a comprehensive view of their experience of BA treatment delivery in the CDAT service.

4.2.3.2 | *BA therapists*

Drug and alcohol treatment workers who delivered BA in the trial were invited to take part in qualitative interviews sequentially once they had delivered BA treatment with at least 2 patients. This ensured that they had experience of delivering BA with different patients. One BA therapist left employment at the CDAT service during the trial and was not contactable for interview.

4.2.3.3 | *BA patients*

BA patients were invited to take part in qualitative interviews if they had attended at least one session of BA therapy in the trial. Interviews were arranged within six weeks of the last attended session. Four patients who would have been eligible for interview were not contacted due to a delay in the initiation of the current study. Two patients who were eligible for interview and given information about the study did not respond.

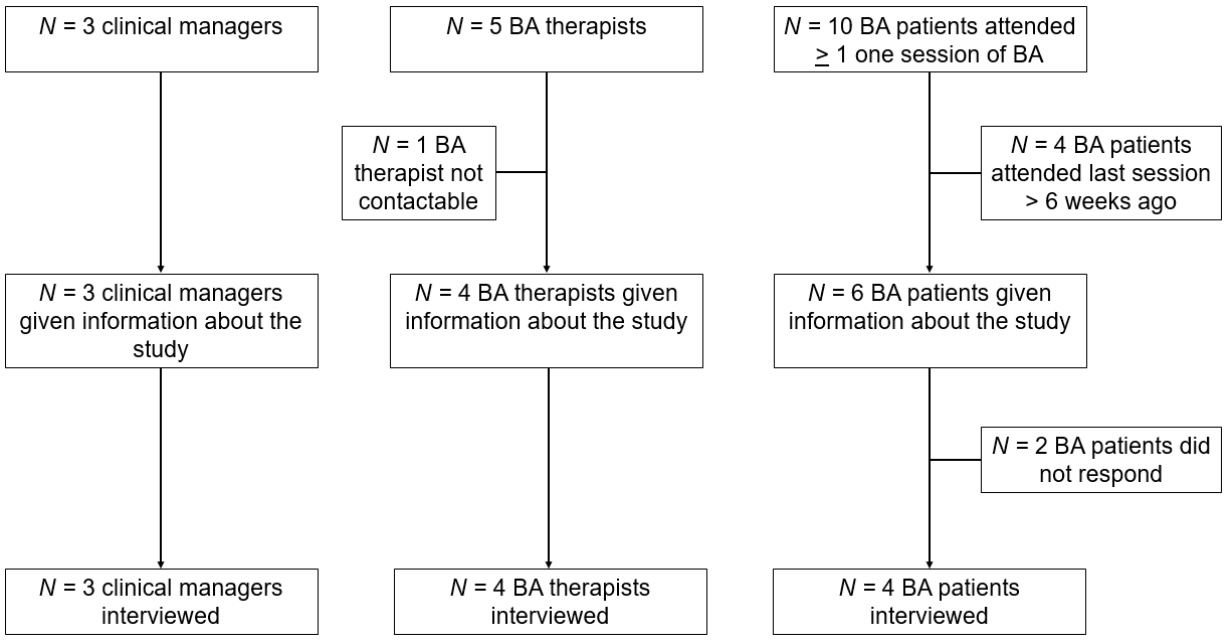


Figure 4.1. Recruitment process

4.2.4 | Sample

A total of eleven (Clinical managers = 3; BA therapists = 4; BA patients = 4) consenting participants who had been involved in the BA trial were included. Their characteristics are summarised in *Table 4.1*. All clinical managers in the current study were involved in the BA trial through being approached by the study team and willingly agreeing to support its implementation in the CDAT service. Drug and alcohol treatment workers elected to take part in the trial voluntarily following a recruitment presentation delivered by the study coordinator. The only inclusion criteria for BA therapists in the trial were: (1) current employment as a drug and alcohol treatment worker on a permanent full-time contract in the CDAT service; (2) ability and willingness to attend BA training and monthly clinical supervision; and, (3) ability and willingness to allocate up to 3 hours per week to delivering BA. All patients in the BA trial were recruited via a stepwise screening method detailed in the previous chapter (section 3.2.4.1). The main inclusion criteria for BA patients were: (1) clinically significant depression symptoms; (2) mild to moderate psychological dependence on substances; (3) absence of psychotic, bipolar or severe anxiety disorder; and, (4) ability to read and write. Full details of inclusion and exclusion criteria for the trial are reported in the previous chapter (section 3.2.3.2).

Table 4.1. Characteristics of clinical managers, BA therapists and BA patients

Clinical Managers (*N* = 3)	
Gender, *N* (%)	
Female	2 (67)
Male	1 (33)
Ethnicity *N* (%)	
White	3 (100)
Job Role *N* (%)	
CBT Psychotherapist	2 (67)
CDAT Service Manager	1 (33)
BA Therapists (*N* = 4)	
Gender, *N* (%)	
Female	3 (75)
Male	1 (25)
Age (y)	
Range	28-55
Mean (SD)	40 (11.75)
Ethnicity *N* (%)	
White	4 (100)
Education *N* (%)	
Bachelor's degree or equivalent	2 (50)
A-Levels or equivalent	2 (50)
Professional Background *N* (%)	
None	4 (100)
Years worked in SUD treatment	
Range	1-3
Mean (SD)	2 (0.81)
Number of BA patients allocated	
Range	3-5
Mean	3.5 (1.00)
Number of BA sessions delivered	
Range	7-16

Mean (SD)	10.5 (3.87)
BA Patients (*N* = 4)	
Gender, *N* (%)	
Male	3 (75)
Female	1 (25)
Age (y)	
Range	34-48
Mean (SD)	39.25 (6.7)
Ethnicity, *N* (%)	
White	4 (100)
Education, *N* (%)	
A-Levels or equivalent	2 (50)
School-leaving qualifications	1 (25)
None	1 (25)
Employment, *N* (%)	
Employed	2 (50)
Unemployed	2 (50)
Primary Substance, *N* (%)	
Alcohol	2 (50)
Opiates	2 (50)
Number of BA sessions attended	
Range	4-8
Mean (SD)	6 (2.31)
BA Treatment Outcome[a], *N* (%)	
Clinically significant improvement	4 (100)
In depressive symptoms	
Abstinent	2 (50)

[a] Based on outcome assessments at 12-week follow-up in the BA trial

4.2.5 | Setting

Participants in the current study were recruited from the BA trial at a CDAT service in Doncaster, United Kingdom. This CDAT service offers SUD treatment to adults across

Doncaster and primarily operates on an outpatient basis, offering access to prescribing, detox, structured care coordination and psychosocial interventions consistent with national treatment guidelines (Department of Health, 2017). Further details of this CDAT service can be found in the previous chapter (sections 3.2.2 and 3.2.5).

4.2.6 | BA treatment under investigation

The BA intervention delivered in the trial was an outpatient version of the Life Enhancement Treatment for Substance Use (*LETS ACT*; Daughters et al., 2016), which had been amended for delivery on a 1:1 basis in the trial. This brief, manualised intervention was specifically developed to meet the needs of patients with comorbid SUD-depression in drug and alcohol treatment settings. Sessions focus on the link between mood, substance use and behaviour, in addition to identifying and increasing rewarding, substance-free activities that are grounded in patients' values. BA therapists were drug and alcohol treatment workers with no prior psychotherapeutic training or experience, who voluntarily completed 3 days of training to deliver the intervention with patients who were allocated to BA in the trial. Group clinical supervision was provided by two qualified CBT therapists who were employed in specialist mental health services and did not have direct experience of working with SUD patients in CDAT. A more detailed description of the BA intervention, training and supervision received by BA therapists is reported in the previous chapter (section 3.2.6).

4.2.7 | Data collection

Semi-structured interviews with participants were conducted 1:1 in person or over the telephone by the lead researcher who was also the study coordinator of the BA trial (SP). The lead researcher was enrolled in a PhD Psychology programme and had previous experience of employment in a CDAT service. All participants in the current study had a prior relationship with the interviewer through their involvement in the trial. Interviews were audio recorded and transcribed verbatim. Member checking was not completed for transcripts due to limited study resources and doubts regarding the value of this practice with regards to verifying the collection of qualitative data (Thomas, 2017).

4.2.8 | Interview topic guides

Interview topic guides were used in semi-structured interviews to ensure that key themes were covered while also allowing for further probing to illuminate areas of interest. Different topic guides were employed for participants from different organisational levels in order to ensure that questions were relevant to understanding their experiences. (See Appendix J for interview topic guides).

4.2.8.1 | Clinical managers

The interview topic guide for clinical managers was specifically developed for this study. Questions asked about their views on BA therapy and treating patients with comorbid SUD-depression, the barriers and facilitators to BA delivery in CDAT and perceptions of BA therapists' experiences of training and delivering BA. BA supervisors were also specifically asked about their experiences of delivering supervision with BA therapists.

4.2.8.2 | BA therapists

The interview topic guide for BA therapists was specifically developed for this study. Questions covered their experiences of training, supervision and delivering BA, as well as their perceptions of what was helpful and unhelpful for patients and views on how comorbid SUD-depression should be addressed in CDAT.

4.2.8.3 | BA patients

The Client Change Interview (CCI; Elliot & Rodgers, 2008) was used for BA patients. This topic guide has been specifically developed to elicit patient perceptions of changes experienced during interventions. Questions asked whether patients had made any changes as a result of the BA intervention, what they attributed these changes (or lack of change) to, and what they found helpful and unhelpful about the intervention.

4.2.9 | Data analysis

Anonymised interview transcripts were analysed by the lead researcher and an independent coder. Transcripts were coded with the aid of NVivo qualitative data analysis software (QSR International, 2021) and analysed according to the six phases of reflexive thematic analysis (Braun & Clark, 2019). Phase 1 involved familiarisation with the data, followed by Phase 2 which involved sorting codes into preliminary themes for each data source (clinical

managers, BA therapists and BA patients). Coding schemes were generated both deductively and inductively, based on the research questions, interview transcripts and discussion between the researchers. Phase 3 involved generating themes within each data source and refining them to maximise internal homogeneity and external heterogeneity. Phase 4 consisted of comparing the themes to identify similarities and contrasts between the three sources of data (Farmer, Robinson, Elliot & Eyles, 2006). In Phase 5, themes were assimilated where appropriate, before being further examined, refined into sub-themes and named. The final phase involved assimilating the analytic narrative and data extracts into a coherent story for each theme. Phases 1-4 were conducted independently by the lead researcher and independent coder, phase 5 was conducted collaboratively between the lead research and independent coder, phase 6 was conducted independently by the lead researcher and checked for agreement with the independent coder.

4.2.10 | Reflexivity

The lead researcher was a PhD Psychology student and coordinator of the BA trial, who had prior experience of working with SUD patients as a drug and alcohol treatment worker in CDAT. Their interpretation of the findings may have been impacted by prior relationships with the trial participants and pre-existing assumptions about the treatment of addiction and delivery of BA in a CDAT setting. The independent coder was a PhD Business student with an academic background in psychology, qualitative methods and lived experience of receiving BA therapy for depression, but no experience of working with patients with SUDs. Their experiential knowledge of BA therapy was valuable in ensuring that the service-user perspective, as opposed to professional or academic assumptions, was emphasised in interpreting the meaning and implications of the data, although it may also have raised potential issues with over-identification (Hofmann & Barker, 2016). Their lack of experience in working on the BA trial or in CDAT nonetheless allowed for a more objective view of the data, which was not tied to any prior relationships with participants or assumptions about delivering BA therapy in this context. The researchers used a collaborative approach to maintain awareness and "bracket" any prior assumptions, utilising reflective journaling and discussion to reflect on the influence that their beliefs, knowledge and experience may have had on their perception of the data and to encourage consideration of alternative perspectives (Dodgson, 2019).

4.3 | Results

Several themes emerged from the thematic analysis of interviews with staff and patients, organised within four superordinate categories: (1) Addressing mental health in CDAT; (2) The right patient at the right time; (3) Challenging yet helpful aspects of BA; and, (4) Barriers to BA implementation. Figure 2 provides a map of the themes and sub-themes identified. A selection of illustrative quotes supports the narrative summary of thematic analysis results that follows. Some quotes have been edited where appropriate to improve readability, but no changes have been made to their original meaning. Each quote is linked to an anonymous citation code which denotes a participant number (e.g. M1), along with a code to specify the organisational category of each participant and their gender: CM = Clinical manager, T = BA therapist, P = BA patient, M = Male, F = Female.

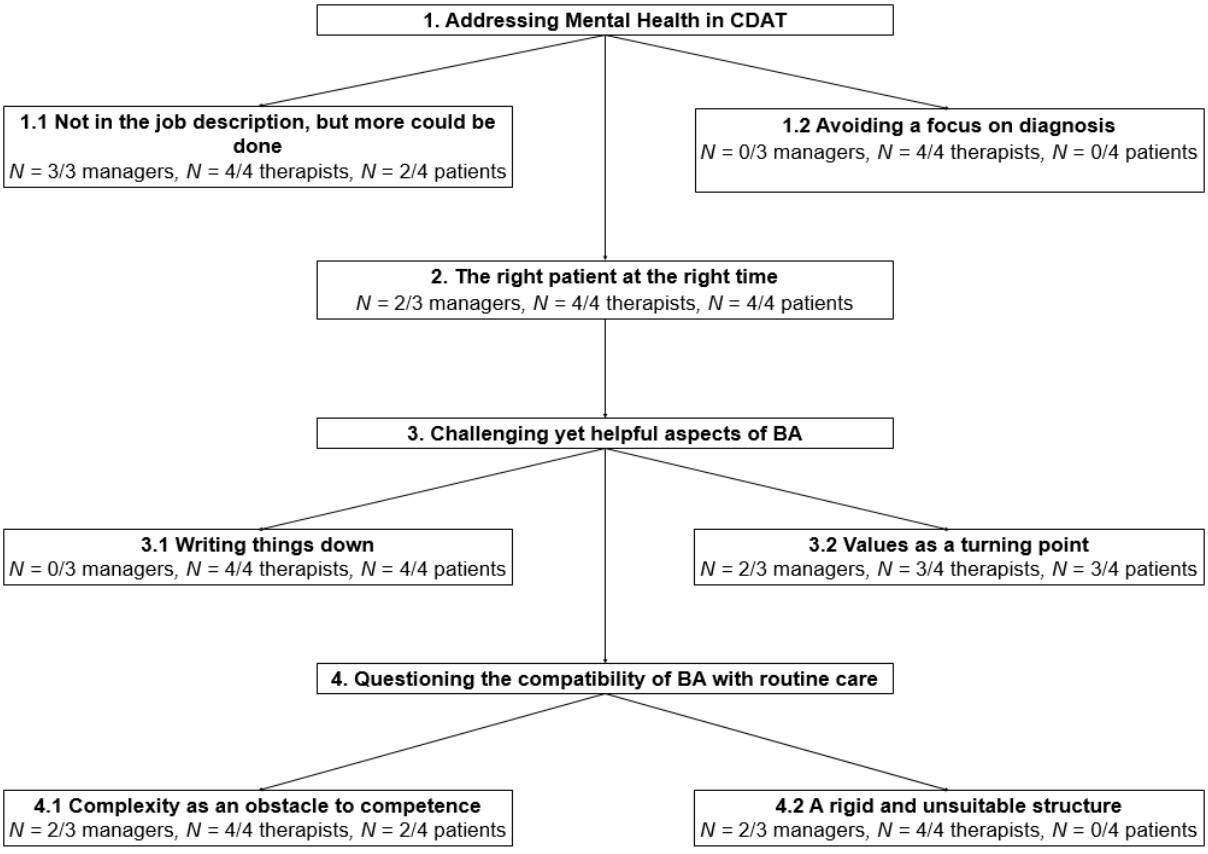


Figure 4.2. Themes derived from analysis

4.3.1 | Theme 1: Addressing mental health in CDAT

Clinical managers and BA therapists described their personal views, as well as organisational conventions and constraints regarding the treatment of patients with mental health problems in CDAT. It was widely agreed that mental health services were absent and needed to be more involved in the care of CDAT patients. Some identified that drug and alcohol treatment workers also had a role to play in managing patients' mental health issues, while others felt that they were not equipped to treat mental health. Therapists also questioned the legitimacy of mental health diagnoses and emphasised the influence of substance use on depressive symptoms, which appeared to contribute to inconsistencies in the way that depression was addressed as part of usual care in CDAT.

4.3.1.1 | *Sub-theme 1.1: Not in the job description, but more could be done*
(*N*= 3/3 Clinical managers, *N* = 4/4 BA therapists, 2/4 BA patients)

Managers and therapists agreed that there was lack of mental health support available for patients in CDAT. All staff held the view that more collaboration was needed between CDAT and mental health services. One patient described how they had previously been turned away from mental health services because they were using alcohol. Managers and therapists explained that this was a common predicament for CDAT patients, with mental health services often advising patients to address their substance use before they were able to access specialist mental health support.

> *"Co-working between our service and theirs, very rarely happens because they argue, you know what came first the chicken or the egg, is it the drugs that are making the mental health even be there in the first place?"* T1-F

Half of therapists felt that brief psychological interventions such as BA, delivered by drug and alcohol treatment workers in CDAT, could be useful to help patients reach a point where they are able to engage with specialist mental health support. "*I do think that this therapy would have its place as a, a bridge. But, we should still be co-working people with mental health services."* T1-F

In contrast, other therapists felt that delivering psychological interventions for mental health

problems was not part of their role, that it fell beyond their area of expertise and that it should be the responsibility of mental health professionals. *"That's like asking mental health services to reduce them off drugs and alcohol isn't it?"* T4-F

One manager also suggested that drug and alcohol treatment workers may lack the skills to deliver psychological interventions effectively.

> *"I definitely think in the drug and alcohol services they are missing, or it appears to be that they're missing.. people with qualified, formalised therapy qualifications working alongside staff in the team. To help with all of their psychological mindedness skills. And I think if that was embedded. That would really make the team more robust, more psychologically minded."* M3-F (BA supervisor)

Other managers felt that drug and alcohol treatment workers were capable of delivering psychological interventions, although one manager acknowledged that there was a lack of evidence-based psychosocial treatments currently being delivered in CDAT generally. They described how CDAT was overly focused on clinical prescribing and that this tended to dominate the interventions delivered in usual care.

> *"When you look at it you've got biopsychosocial drug treatment. The bio part plays a significant part both in funding, occupying people's time, conversations, everything. And. The rest feels. A bit of a poor relation to the prescribing… A dispensing machine could dispense methadone. [Yet] we end up in a whole circus of conversations with patients around the prescribing practices, the drugs.. you know"* M1-M (CDAT manager)

Patients reinforced this view, describing usual care in CDAT as consisting predominantly of drug testing and talking about their drug use. One patient described how this put them "on edge" when they attended usual care appointments. Another patient described how they felt that drug treatment had become less responsive to patients over the years, which they perceived to be due to funding cuts. These patients felt that BA was different to what was

currently offered in usual care and that it was beneficial to be able to explore their emotions and mental health instead of focusing solely on their drug use.

> *"I found it better you could, I don't know it were just… Different. You're not there just thinking about "right I've just got to do me urine sample", do this, tell them that I've not been doing- do you know not done drugs I've not done this it were… more expressing how you are, how you feel, how I were coping with things more"* P2-M

4.3.1.2 | Sub-theme 1.2: Avoiding a focus on diagnosis

(*N*= 1/3 Clinical managers, *N* = 4/4 BA therapists, 0/4 BA patients)

Therapists indicated that the majority of patients in CDAT report having mental health disorders such as depression and anxiety. They reported that patients were either diagnosed by their GP or in many cases that they diagnosed themselves. One therapist explained that prior to the BA trial, staff did not use formal screening measures to identify patients with clinically significant depression or anxiety symptoms.

> *"We just took people, I guess at their word. I mean we did the TOPS with people. Erm. And we took their word if they said that they were.. feeling depressed and the terms got thrown around quite a bit for depression and anxiety. And not necessarily having a formal diagnosis from a GP of that."* T1-F

Some therapists suggested that mental health diagnoses contributed to a lack of insight and accountability from patients, which was perceived as being a barrier to their engagement in CDAT.

> *"it's not their fault. It's just that.. they've never looked further than, beyond somebody telling them that yeah you've got depression, you've got PTSD, you've got this you've got that, you're OCD.. and before you know it, that person can tell you everything they're diagnosed with [and] what medication they're on, but can't tell you nowt else. And. You know it's difficult.. because it becomes.. sometimes.. it's their, I shouldn't say an excuse, it's their.. barrier, you know." T3-F*

Therapists also questioned the legitimacy of patients' depression and anxiety diagnoses. One manager suggested that many patients in CDAT likely have a "depressive position" as opposed to a diagnosable depressive disorder. Most therapists agreed that patients had a poor understanding of mental health and felt that depression and anxiety symptoms were often tied to their substance use. One therapist suggested that patients confused common mental health symptoms with substance withdrawal.

> *"I think.. in substance misuse nearly every, everybody you speak to on my caseload, will say "oh I've got depression"... "I've got anxiety".. "I have panic attacks". But when you ask them to explain it.. no. It's more like withdrawals. It's so confusing for them," T3-F*

Another therapist described avoiding focusing on patients' mental health in usual care and instead asking about what was happening in their life and focusing on distraction techniques, as they felt that drawing attention to patients' mental health could potentially make it more of an issue for them. *"the more you address it, the more they think about it. So it's looking at like, "what's going off, how're you feeling" like "why don't you do this", you know looking at distractions."* T4-F

In contrast, other therapists identified that it was useful to explore patients' mental health by asking open questions to explore their understanding of depression and anxiety. Half of therapists felt that it was particularly important to increase patients' awareness of the influence that substances may be having on their mental health.

"Making them aware. Because, you know a lot of clients don't know, don't know that alcohol's a depressant they don't know that heroin's a depressant they just think that I'll deal this way and that's me and I've always been this way and I use to cope and.. it's bringing that awareness of it, you know, you don't need to feel like this you know there is another way." T2-M

4.3.2 | Theme 2: The right patient at the right time

(*N*= 2/3 Clinical managers, *N* = 4/4 BA therapists, *N* = 4/4 BA patients)

Most BA therapists described some difficulties with engaging patients in BA treatment. Patient motivation, stability and the timing of intervention delivery were emphasised by clinical managers, BA therapists and BA patients as important predictors of patient engagement. Poor mental health was viewed by many therapists as a barrier to attendance and patients with comorbid SUD-depression were described by some therapists as being particularly difficult to engage in CDAT. Correspondingly, half of patients in the current study reported that depression or anxiety symptoms had made it difficult for them to attend and engage in BA therapy at times. *"I didn't really have any get up and go or.. Any motivation or anything"* P1-M

Managers and therapists also identified ongoing substance use as a significant barrier to attendance and engagement in BA sessions. Managers suggested that while abstinence did not need to be a precursor to BA therapy, there was no benefit in delivering BA with patients if they were under the influence of drugs or alcohol. Half of the therapists described how some patients either did not attend any sessions or attended under the influence. Therapists found it frustrating when patients did not attend BA sessions, but one therapist also described the challenge of working with a patient who consistently attended under the influence.

> *"I found it quite difficult. Because.. He was using heroin and he was also drinking a lot of alcohol… he couldn't point a lot out when we tried to talk about values and where he was and… he came back with his book all in bits and then he was giving excuses that he needed to leave early to meet his son. When I challenged him on different things do you know.. "well what have you done this week?", "can you tell me and we'll try to write it down together?". He couldn't be bothered then because he'd had a drink. And it were "I'll fetch it to you next time". It was always an excuse. And I knew he couldn't fetch it because half the book were in bits… I would say, because he was under the influence he wasn't really getting much from it. Even though he were attending"* T3-F

Most managers and therapists identified motivation as a key facilitator of engagement. Motivation was described as something that had to come from patients and could not be coerced via the provision of incentives.

> *"Clients will take what they can, they'll take a bus ticket, they'll take food bank, they'll take, whatever they can because it's, it's the same behaviour in drugs. If you're getting something for nothing.. you're going to take it. But once you've got it.. you're not working on anything because, you haven't respected it and you haven't worked hard for it."* T3-F

Most therapists described patients' motivation resulting from either "hitting rock bottom" or otherwise being tired or dissatisfied with their lifestyle in some way. All patients in the current study substantiated this view. However, most managers and therapists also described patient motivation as being highly changeable. It was suggested that patients could attend a session and talk in great detail about all the changes they wanted to make, but then not follow through with any of them. This was assumed to be due to substance use, mental health, other life pressures or lack of self-belief. For this reason, one therapist suggested that it was

important to capitalise on motivation and encourage patients to engage or make changes as soon as possible after they have expressed the intention.

> *"it only takes for that… that lightbulb moment that, you know "I've had enough of all of this lifestyle now I want to, I do really want to, genuinely want to move forward", it only takes for that to happen to somebody. And it's being opportunistic about it. And just, you know, going with it when that time is right for that person if you get them.. if you get them there and then."* T1-F

Most therapists also emphasised the importance of patients' life situation on their ability to change at any given time, particularly with regards to the suitability of their housing, the quality of their social support network and whether they were experiencing any significant life events such as an illness or bereavement. Practical considerations such as being able to afford transport to appointments was also mentioned by some therapists and patients. The majority of patients in the current study notably reported having a stable life situation and support from family or peers prior to commencing BA therapy, which they felt had facilitated their engagement in BA treatment. One patient had recently completed an alcohol detox and was attending AA meetings.

> *"my new group of friends. They've definitely had an impact like, I've now got a team that, what I would consider a team behind me, that want me to succeed rather than my old friends who, erm… want me to drink 'cause that's all they do. Or smoke drugs"* P3-M

One therapist felt that there was no "ideal client" for BA and that patients would need to be assessed for suitability on a case by case basis. However, in order to target treatment more effectively in CDAT, most managers and therapists agreed that BA would be most appropriate for patients with less complex needs who have achieved a certain degree of stability in their life.

> *"I suppose it depends on what people's level of difficulty is… if their difficulties in the grand scheme of things are kind of relatively mild to moderate then BA could be implemented straight away… for people who have maybe more long-standing, complex difficulties I think there would have to be a period of stabilisation before being able to implement it."* M2-F (BA supervisor)

4.3.3 | Theme 3: Challenging yet helpful aspects of BA

Clinical managers, BA therapists and BA patients described several helpful aspects of the BA intervention that contributed to patients making positive changes, although in many cases the helpful aspects of treatment were found to be challenging at first. The process of writing things down was viewed by patients as being difficult at the beginning, but many therapists and patients described how it facilitated understanding, self-awareness and accountability which contributed to using less substances and engaging in more activities outside of sessions. Managers and therapists also viewed values work as a useful tool, which helped patients to make sense of BA therapy and enable positive changes once they understood the concept of values.

4.3.3.1 | *Sub-theme 3.1: Writing things down*

(*N*= 0/3 Clinical managers, *N* = 4/4 BA therapists, *N* = 4/4 BA patients)

Most patients described how they had initially felt that writing was hard work. In particular, writing down their activities for the daily monitoring component of BA therapy was perceived as tedious and unhelpful. This was primarily due to a lack of variation in the activities they had been doing, difficulty remembering what they had done or uncertainty about what they should be writing. However, patients also described it as being helpful to look back on their activities once they were written down.

> *"it was a chore writing it down, but it was helpful to look at it and see… what you've been doing with yourself. 'Cause half the time you don't realise do you, sit watching telly all day.. er… and you know, I've not moved."* P1-M

Patients described how reviewing their daily monitoring logs had helped them to reflect on what they had been doing, or not doing, in addition to how they had been feeling. One therapist reported that it was helpful to be able to review patients' daily monitoring logs with them in sessions to see what they had been doing, rather than relying on patients to recall activities from memory. Some patients also talked about how the enjoyment and importance ratings had encouraged them to reflect and start focusing on doing more activities that could bring them a sense of pleasure or accomplishment.

> *"Like looking and thinking "oh that were a good one I'll try doing that again". Obviously, once you've written down what you've done like you've got your little rating system on there and you think, what was enjoyable or, the importance of the actual activity to you"* P3-M

Therapists and patients also talked about the benefits of drawing the cycle to look at the link between mood and behaviour. Therapists described how repeatedly drawing this cycle in sessions and walking patients through it had helped them to understand the link between their mood and urges to use drugs or alcohol, in addition to identifying how they could break that cycle.

> *"It's being able to work with clients, looking at, positive thoughts and positive emotions and, you know, how negative ones lead to [drug use], and try to get them to break that cycle. So being able to like get them to write down, write things down.. and getting them to then look at things, BEFORE they got to certain points in that cycle."* T4-F

Patients also reported that they found it helpful to see the cycle written down and felt that this had contributed to them thinking more and using less substances. *"it made me think about it more writing stuff down made me think about… what I needed to do rather than just reacting straight away to drugs"* P2-M

Writing plans was also described by patients as helping them to remember what activities they wanted to do. Therapists felt that writing plans gave patients a sense of responsibility which in many cases contributed to increased engagement in activities outside of sessions. Some patients reported that writing plans gave them a sense of purpose or something to look forward to and many felt that it contributed to them following through with activities.

> *"I mean if you think you're gonna do things then you go to sleep and you wake up and things go out the window or, whatever… but I always wrote it down the day before, night before, what I were gonna do the next day… er, had me breakfast then I'd go straight to it. So it were, yeah it had a massive impact writing it, writing everything down."* P1-M

4.3.3.2 | *Sub-theme 3.2: Values as a turning point*
(*N*= 2/3 Clinical managers, *N* = 3/4 BA therapists, *N* = 3/4 BA patients)

Many managers and therapists viewed values work as an important part of BA treatment, describing how patients in CDAT have often lost touch with their values due to drug use and other problems. However, values work was considered by the majority of patients to be difficult to understand at first. Patients explained that it was difficult to think about what a value was and what their own values were generally or in certain life areas.

> *"It's hard to, it's hard to think what you value in yourself and what… do you know it's not something you ever think about, it's just. 'cause at the time when I were on drugs and stuff it wasn't, do you know I didn't value meself at all it were just a, an escape route."* P2-M

Therapists described offering a lot of clarification and support to help patients understand and identify their values. However, patients explained that once they understood what was meant by values and started to identify their own values in different life areas, everything became

clearer and the purpose of BA treatment made more sense to them. Some therapists also perceived patients' understanding and identification of values to be a pivotal point in their BA treatment journey.

> *"it were good to see little lightbulb moments and little, you know just like a light switched on in certain sessions. When we were going through explaining the daily activities and then going into the LAVA (life areas and values assessment), and kind of matching that up with the, you know doing activities alongside the values is key and I think.. one client in particular, once she bought into that her whole demeanour lifted.. face lifted, body language lifted, and you could see she really tapped into it."* T2-M

Managers and therapists viewed values as being particularly helpful for directing activities. They described how values enhanced activity scheduling by encouraging patients to engage in meaningful activities that could lift their mood both in the short-term and the long-term. One therapist also perceived that patients may be less likely to use drugs or alcohol if they were engaging in activities that were more important to them. *"it's likely that if they do more of the things that are actually important to them, they're less likely to, to go out and use substances because they're going to be.. experiencing more joy in the day"* T1-F

All patients described thinking about their values more and increasing engagement in activities that moved them closer to their values. Half of the patients described reconnecting with family, one patient had started exercising regularly and one patient described re-engaging in activities that they used to do before using drugs.

> *"spending time with me wife watching films spending time with the kids.. going shopping just general, general everyday stuff what I'd.. got out of do you know what I mean through doing drug use I wasn't doing things like, well I should have been at home. Do you know so just fetching me out meself a bit more you know back to normal."* P2-M

4.3.4 | Theme 4: Questioning the compatibility of BA with routine care

(*N*= 2/3 Clinical managers, *N* = 4/4 BA therapists, *N* = 2/4 BA patients)

Clinical managers, BA therapists and BA patients described some specific limitations of the BA intervention, which were viewed by many therapists as being likely to impede its implementation in routine CDAT. Some clinical managers and all BA therapists felt that the treatment manual and patient workbooks were too complex and required simplification. Some clinical managers and most BA therapists also viewed the structure of the BA intervention as problematic for patients in CDAT. Supervision was viewed as important, both for helping therapists to simplify the treatment and to work with difficult patients. However, the requirement of monthly supervision was viewed as unfeasible for some therapists. Organisational factors (e.g. recommissioning, increased caseloads) contributing to therapist stress and lack of time were highlighted as a possible barrier to BA implementation by clinical managers.

4.3.4.1 | *Sub-theme 4.1: Complexity as an obstacle to competence*

(*N*= 2/3 Clinical managers, *N* = 4/4 BA therapists, *N* = 2/4 BA patients)

Most therapists reported anxiety around delivering BA in the trial, particularly at the beginning. Managers and therapists attributed this to lack of understanding of the session content, as well as a large gap between training and delivery. Most therapists reported that training had been helpful, however, many patients who were allocated to BA in the trial did not attend any sessions, meaning that most staff had limited experience of delivering BA consistently with patients. Half of the therapists described how putting BA into practice had facilitated their understanding of the treatment and one felt that their confidence had been increased by working with BA patients who attended sessions consistently.

> *"I've had a couple of people who've made it all the way through and I've really seen some success from it. But I know other people have really struggled with their clients, they've struggled with confidence and being able to deliver it."* T1-F

Many managers and therapists felt that the BA treatment manual was too complex, which had contributed to difficulties with therapists' understanding of session content and ability to

deliver sessions effectively with patients. One manager described the treatment manual as "overwhelming" and "wordy". All therapists emphasised that supervision had been important for helping them to simplify treatment. In particular, managers and therapists reported that summarising each session in bullet points had facilitated understanding of session content and improved therapists' confidence in delivering BA.

> *"that for me just reinforced what I needed to be doing really. 'cause sometimes you can get confused going through the book and then going back here, or reading it all out and, kind of losing me own, slant on it and me own personality on it, so to actually go through bullet points... simplifying it, just made things a lot simpler"* T2-M

The concept of patient workbooks was generally viewed as helpful, but some managers, therapists and patients commented that the workbook in the trial was disorganised and difficult to understand. One therapist felt that the worksheets were too complex for CDAT patients and suggested simplifying them with more visual material. *"some visual.. you know. Even if it's a little stick man… I think that helps when they, are, in substance misuse… not everybody's really educated in reading and understanding."* T3-F

4.3.4.2 | *Sub-theme 4.2: A rigid and unsuitable structure*
(*N*= 2/3 Clinical managers, *N* = 3/4 BA therapists, *N* = 0/4 BA patients)

The structure of the BA intervention was viewed by many therapists as problematic for patients. Some felt that it was difficult for most CDAT patients to commit to 6 weeks of BA sessions and to make changes within that timeframe. *"I think just with our client group, for them to commit to 6 sessions, each week, it is a challenge."* T2-M

Most of the therapists also talked about difficulties with the structure of BA sessions, which were perceived to be inflexible to the needs of patients and the problems that they brought to therapy. One manager agreed that there was not a lot of room to explore other problems within BA sessions. Half of the therapists described difficulties with keeping patients focused on session content and one therapist specifically talked about the difficulty of managing a patient who had disclosed an experience of trauma.

> *"So somebody had opened up that the reason that they'd got into substance misuse was because they were abused as a child. You know, it's a case of, you can't shut somebody down when they're saying things like that."* T4-F

All therapists reported that group supervision had been helpful with regards to identifying strategies for managing difficult patients or problems that patients brought to sessions. They reported that supervision had been used as a form of training and that group supervision was helpful for discussing their practice with peers. However, one manager identified that attendance at supervision had been inconsistent and felt that it was not a priority for therapists. Some therapists reinforced this view and identified that it was not always feasible to attend supervision regularly due to other work commitments. *"If I've got things booked in… then I can not change an 8 hour day where I'm not even in the office… for an hour's supervision. So it's not, it weren't practical for me"* T4-F

Managers also identified that organisational factors such as recommissioning, staff turnover and increasing caseloads had caused some therapists to feel stressed and have less time available. One manager described how work pressures had affected therapists' ability to commit to the structure of supervision and delivering BA during the trial.

> *"the work pressures. Because obviously, you know there was a lot of discussion within the supervision around kind of... other staff leaving and their workloads increasing and things, and it being kind of quite difficult quite stressful at the best of times let alone them trying to do this"* M2-F (BA Supervisor)

Another manager indicated that staff may not have the capacity to deliver BA in routine care, *"I think having the correct size caseloads and the capacity to deliver it is the challenge."* M1-M (CDAT Manager).

4.4 | Discussion

The current study explored staff and patient experiences of BA for comorbid SUD-depression delivered by drug and alcohol treatment workers in CDAT. Four themes were generated from thematic analysis of clinical manager, BA therapist and BA patient accounts. Theme 1 characterised views on the acceptability of addressing patients' mental health in CDAT. A need for evidence-based mental health support was identified, but views were divided on whether this support should be offered by drug and alcohol treatment workers, with some staff feeling that it was beyond their remit. Therapists reported concerns around identifying patients with depression and disparities in the way that they typically approached mental health problems with patients in usual care. Theme 2 characterised the difficulties of engaging patients in BA treatment and emphasised the importance of motivation and stability as necessary precursors to engagement with the intervention. Theme 3 characterised challenging but helpful aspects of the BA intervention, with writing and values work identified as being instrumental in supporting patients to make positive changes. Finally, Theme 4 reflected specific limitations of the BA intervention, with issues relating to the complexity and structure of BA highlighted as potential barriers to implementation in routine CDAT.

4.4.1 | Main findings

4.4.1.1 | *Acceptability of delivering evidence-based psychological interventions in CDAT*

Staff identified a mental health treatment need for patients and described a lack of co-operation from mental health services consistent with previous research (Sheridan et al., 2011). However, attitudes regarding addressing mental health in CDAT were varied. Depression screening was not routinely implemented which is consistent with previous findings (Weaver et al., 2003) and some staff also suggested that identifying patients with depression may be detrimental. Most staff felt that patients had a limited understanding of depression and emphasised that substance use played a central role in maintaining depressive symptoms. This finding converges with a previous study in which SUD patients described various thoughts and emotions as 'depression' and mainly talked about depression in the context of drug-taking (Cornford et al., 2012). Substance use is hypothesised to contribute to depressive symptoms both indirectly via adverse consequences caused by problematic substance use and directly due to the neurobiological effects of substance withdrawal, and

substances may equally be used to medicate depressive symptoms (Nunes & Levin, 2008). Current treatment guidelines recommend integrated treatment of comorbid SUD-depression (Department of Health, 2017), yet some staff were more receptive to this approach than others.

Staff appeared to vary in their endorsement of delivering evidence-based psychological interventions generally, with managers endorsing evidence-based practice to a greater degree than therapists. This finding may correspond with research showing that evidence-based psychosocial interventions are not consistently delivered in CDAT (Best et al., 2009). The delivery of evidence-based interventions in this context is likely influenced to some extent by broader organisational factors such as funding and the structure of services (Sheridan et al., 2011). However, staff endorsement is certainly a requisite for implementing evidence-based interventions in routine care (e.g. Garner, 2009). Evidence suggests that staff with higher levels of education and experience working in SUD treatment may be most likely to support the use of evidence-based practice in general (Aletraris et al., 2015; Rash et al., 2012). Yet research has also shown that drug and alcohol treatment workers may be resistant to evidence-based interventions that do not align with their own views or treatment philosophies (e.g. Amodeo et al., 2011; Guydish et al., 2007). Given that some therapists questioned the benefit of addressing depressive symptoms and felt that delivering evidence-based mental health treatment was not part of their job role, it seems that staff ideologies regarding the delivery of psychological treatments for patients with depression are mixed and could be a potential barrier to BA implementation in CDAT.

4.4.1.2 | *Patient engagement*

Lack of patient engagement in BA was identified by staff as problematic, which corresponds with the high dropout rate in the BA trial (Chapter 3) and other trials of BA conducted with patients with comorbid SUD-depression in CDAT (e.g. Delgadillo et al., 2015). In the current study, staff emphasised that mental health symptoms made it difficult for patients to engage and that patients with chaotic or adverse life situations were unlikely to engage in BA. This finding is consistent with the results of dropout analyses in the BA trial, which showed that patients who were not in employment and using more substances at baseline were more likely to drop out of BA treatment (Chapter 3). It also mirrors findings from Gore et al.'s (2017) study, whereby CDAT patients cited poor mental health and life problems as critical barriers to their engagement in psychological interventions.

In addition to a stable life situation, staff and patients in the current study indicated that motivation was crucial for engagement. This finding converges with a core component of the Transtheoretical Model (TTM; DiClemente et al., 1991; Prochaska & DiClemente, 1983), which suggests that motivation lies on a continuum of five stages (pre-contemplation, contemplation, preparation, action, maintenance) and that interventions targeted to patients' stage of change are more likely to be acceptable and effective. Motivational interventions are indicated for patients in the pre-contemplation or contemplation stages of change, whereas action-oriented interventions such as BA are deemed more suitable for patients in the preparation or action stage of change (Prochaska, Redding & Evers, 2008). Stages of change are widely recognised in SUD treatment and reportedly guided the provision of usual care in the CDAT service in the BA trial (see section 3.2.5). Previous research has indicated that there may be benefits of targeting interventions to patients' stage of change (e.g. Dijkstra, Conijin & De Vries, 2006), yet no previous trials of BA for comorbid SUD-depression have explored the possibility of targeting treatment in this way.

4.4.1.3 | *Helpful aspects of BA therapy*

Consistent with previous qualitative analyses in non-SUD samples (e.g. Stein et al., 2021), patients generally perceived core elements of BA treatment (Daughters et al., 2016; Lejuez et al., 2001) as helpful, particularly values-driven activities and activity scheduling. Treatment components were reported to be somewhat challenging for patients to understand at first, but this might be expected given that SUD patients may be more likely to have cognitive impairment (e.g. Bruijnen et al., 2019; Goldstein et al., 2009; Vik et al., 2004). One of the most prominent findings regarding the helpfulness of BA treatment components in this study was the impact of writing things down. Therapists and patients reported that writing facilitated a number of positive therapeutic processes, including patient understanding of BA treatment, self-reflection, therapeutic rapport, memory for completing activities and engagement in planned activities. This finding is consistent with previous qualitative analyses of BA which indicated that patients found completing worksheets and practicing BA skills helpful (e.g. Finning et al., 2017; Stein et al., 2021).

The finding that writing was perceived as helpful appears to relate to the large body of research that has been conducted on node-link mapping in SUD treatment populations. Node-link mapping is a cognitive enhancement technique which involves writing down treatment-related information (e.g. personal issues, action plans) and making links between these

concepts to explore issues in more detail (Czuchry & Dansereau, 2003). A wealth of research conducted with SUD patients indicates that node-link mapping facilitates patient engagement (Czuchry et al., 1995; Dansereau et al., 1996), therapeutic rapport (Dansereau et al., 1996; Dansereau et al., 1993) self-discovery (Newbern et al., 1997) and memory for session content (Boatler et al., 1994). From a cognitive standpoint, the 'generation effect' also suggests that the process of writing facilitates memory (Jacoby, 1978) and this theory is well-supported by empirical evidence (Bertsch et al., 2007). Therefore, given that psychoactive drug use may impair memory (e.g. Solowji et al., 2011) and memory deficits are also a common feature of depression (Christopher & MacDonald, 2005; Porter et al., 2003), it makes sense that writing would be a particularly useful therapeutic tool for patients with comorbid SUD-depression.

Patients and staff perceived values work to be another pivotal component of BA treatment in this study, which is consistent with previous qualitative results (Lewis-Smith, Pass, Jones & Reynolds, 2021; Stein et al., 2021). It also appears to correspond with the finding that BA participants demonstrated significant within-group improvements in valued living from baseline to 12-week follow-up in the BA trial (Chapter 3). Previous research has suggested that both SUDs (Copeland et al., 2020) and depression (Smout et al., 2014; Wilson et al., 2010) may be associated with a lack of values identification or engagement in values-driven activities. Indeed, psychological treatments that emphasise engagement in values-driven activities such as Acceptance and Commitment Therapy (ACT) are associated with improved depression (Folke et al., 2012; Pots et al., 2016) and substance use outcomes (e.g. Lee et al., 2015). Valued living has also been found to mediate the effects of ACT on depressive symptoms (Bramwell & Richardson, 2018). The emphasis on values-driven activities in BA therapy emerged with the BATD (Lejuez et al., 2001) and contextual BA (Martell et al., 2001) protocols 20 years ago. Yet, despite considerable efforts to identify mediators of BA treatment effects in recent years (e.g. Janssen et al., 2021), valued living appears to have been overlooked as a possible BA change mechanism in the depression and comorbid SUD-depression literature.

4.4.1.4 | *Barriers to BA implementation*

Staff identified some key barriers relating to the characteristics of the intervention that could impede the implementation of BA in routine care. In particular, staff perceived the complexity and structure of the BA treatment protocol to be problematic. These concerns appear related to the literature on barriers and facilitators to delivering manualised therapies

generally. Manualised treatments are argued to be a valuable means of transporting evidence-based treatments in to practice (Addis, 1997). However, they can also be perceived as inflexible and therapist concerns around their impact on the therapeutic relationship and ability to address individual patient needs are common (Addis et al., 1999). In the BA trial, sessions in the therapist treatment manual were scripted word for word, which was perceived by staff as overly detailed and mechanistic. This appeared to detract from therapists' understanding of the core treatment components of BA and led to concerns that the manual did not allow them to address patient needs effectively. It has been suggested that too much specificity may lead practitioners to be more concerned with adhering to technical requirements rather than ongoing interaction with a patient, which clearly has implications for therapist competence in delivering the therapy (Binder, 1993; Waltz et al., 1993). However, treatment manuals do not necessarily need to be highly structured and devoting more space to common treatment factors (e.g. therapeutic relationship) may help to improve their overall utility for therapists (Addis, 1997; Addis et al., 1997). Training should also address therapist attitudes towards manualised treatments generally and incorporate examples of alliance-building strategies (Addis et al., 1997), which was included in the training that therapists received. However, a significant issue highlighted by therapists was the large gap between training and delivery, contributing to a lack of confidence in delivering the treatment. Previous research has indeed shown that although training can improve practitioner knowledge and skills, these gains may be inconsistent (Sondhi & Day, 2015) and tend to diminish quickly over time (Walters et al., 2005).

Therapists in the current study identified that supervision was critical for helping them to deliver BA treatment, particularly with regards to understanding the treatment, implementing manual procedures and using the manual flexibly with difficult patients. This finding corresponds with a previous study exploring the delivery of manualised treatments by drug and alcohol treatment workers (Godley et al., 2001). Regular clinical supervision appears to be vital for maintaining therapist knowledge (Carroll et al., 2010) and implementing evidence-based treatments in SUD settings (Sondhi & Day, 2015). However, staff in the current study reported difficulties attending supervision due to organisational pressures, including increased work demands due to service restructuring and staff turnover. This finding is consistent with previous research indicating that organisational constraints are common and may be a key barrier to implementing evidence-based interventions in CDAT (Sheridan, Barnard, & Webster, 2011).

4.4.2 | Reflexivity considerations

Reading and interpretation of the interview data was likely influenced to some degree by the researchers' experiences and philosophical orientations. The lead researcher had experience of working with patients in CDAT services and held a realist orientation to understanding and explaining participant experiences, which was predominantly grounded in experimental and correlational research paradigms. Meanwhile, the independent reviewer had lived experience of BA therapy and innately held a more idealist philosophical orientation to understanding and interpreting the data, contributing important insights into the possible meanings behind what participants said. These differences in experience and philosophical orientations prompted in-depth discussions between the researchers about how to interpret the interview data. As this was a pragmatically oriented study which aimed to reveal implications for real-world practice, it was decided that it was most important to focus on describing patterns in participant experiences as they appeared, rather than inferring the underlying meaning behind what was said. Descriptions of participant experiences were discussed in the context of relevant literature to support their interpretation.

4.4.3 | Strengths, limitations and contextual factors

This is the first study to explore staff and patient perspectives of BA delivered by drug and alcohol treatment workers in an SUD treatment context. The simultaneous exploration of clinical manager, BA therapist and BA patient perspectives permitted a more comprehensive exploration of BA delivery in this context than would be afforded by focusing on the accounts of one group of stakeholders alone. Additionally, given that participants may vary in their ability to understand and articulate their perspectives, triangulation of findings between and within organisational groups makes the findings of this study more credible (Spencer & Ritchie, 2002). Consistent with the TACT (Trustworthiness, Auditability, Credibility, Transferability) framework for ensuring rigour and credibility in qualitative research (Daniel, 2019), researchers also reflected on how their beliefs, knowledge and experience may have affected their interpretation of the data and engaged in a systematic data analysis process, thereby enhancing the trustworthiness and auditability of this study. The researchers also initially coded all data independently and later refined the analysis through consensus and peer review. This strategy ensured that analysis and interpretation was not unduly influenced by one researcher's understanding of the data, which further enhances credibility.

However, several limitations affect the transferability and interpretation of findings. Some methodological choices in this study were influenced by the small sample size in the BA trial, time pressures and restrictions imposed by the COVID-19 pandemic. Convenience sampling was generally appropriate for recruiting the clinical managers and BA therapists involved in the trial. However, it led to a pool of participants who were not representative of all patients who attended BA sessions and this clearly limits transferability. Indeed, all BA patients interviewed in the current study had completed BA therapy (attended at least 3 sessions) and reported clinically significant improvements in depressive symptoms at 12-week follow-up in the trial. The views of patients who dropped out after one or two sessions, or did not report clinically significant improvements in depressive symptoms, appeared to be less likely to participate in interviews within the required timeframe and their views were not represented in the current study. These patients may have experienced adverse life situations or low motivation that also precluded them from engaging or making changes during therapy, therefore it is likely that their views may have been different to other patients. Despite aiming to recruit 6-8 BA patients in the current study, only four patients participated in interviews which suggests that adequate data saturation was not achieved for participant perspectives overall (Braun & Clark, 2013). Additionally, most interviews were completed over the telephone due to the COVID-19 pandemic. Some researchers have suggested that telephone interviews may be less effective than face-to-face (Shuy, 2011), although others have indicated that telephone interviewing yields equivalent amounts and quality of data (Sturges et al., 2004).

Nevertheless, several contextual factors may have affected participants' recall. Firstly, BA training took place 2 years before the interviews and most therapists reported difficulties remembering details about the content of the training. Secondly, therapists' opinions on the acceptability of BA may have been influenced by their views on the RCT generally. Although the aims of this qualitative study did not focus on participants' perceptions of the research aspect of the BA trial, many therapists described negative aspects of the research and were sometimes observed to confound clinical concerns with research concerns in interviews. Several emerging issues appeared to be related to necessary constraints of the research protocol (e.g. randomisation, treatment adherence) rather than BA itself. Some therapists referred to BA treatment as "the study" and described BA supervision as separate from their "actual job", which implies that they did not equate BA delivery with routine treatment provision. Contrary to expectation, it is also noted that patients in the current study

did not describe many unhelpful aspects of therapy, except for stating that some aspects were tedious or difficult to understand at first. This finding could be explained by self-selection bias, with patients who had positive experiences of therapy being more likely to take part in interviews in the first place. It is also possible that they felt unable to disclose negative therapy experiences to the interviewer, perhaps perceiving the interviewer to be in a position of power through affiliation with therapists or the CDAT service. Moreover, is notable that all participants in the current study had a prior relationship with the interviewer via their involvement in the trial. Therefore, participant recall was likely influenced to some extent by their existing rapport with the interviewer or assumptions about what the interviewer expected them to say.

Finally, no personal and public involvement (PPI) work was carried out with CDAT staff or patients to assess and provide feedback on the suitability of the BA treatment manuals prior to trialling the intervention in this context. PPI approaches such as co-production emphasise the needs and knowledge of participants at all stages of the research process (National Institute for Health Research [NIHR], 2021) and can help to ensure that study materials are acceptable and relevant for their intended purpose prior to testing. The LETS ACT treatment (Daughters et al., 2008) was co-produced in collaboration with drug treatment stakeholders and beneficiaries in the USA, yet this does not guarantee that the intervention translates equally well to other social and geographical contexts. Therefore, the lack of PPI work prior to the BA trial could help to explain why staff placed greater emphasis on the unsuitability of the treatment manuals in this study.

4.4.4 | Implications for practice and future research

Evidence-based treatments for common mental health problems were not reported to be routinely available to patients accessing CDAT, which is consistent with previous reports (Public Health England, 2017[d]; Turning Point, 2016) and highlights the importance of investigating ways to improve patient access to psychological interventions for depression. However, staff are likely to vary with regards to their endorsement and adoption of evidence-based interventions in CDAT. Drug and alcohol treatment workers may also have specific concerns about identifying and treating patients with CMDs. These findings suggest that a greater focus on training may be necessary to improve staff attitudes towards addressing mental health and implementing BA in CDAT. Previous research has shown that pre-

implementation training focused on education, clinical case studies and pragmatic group discussions was associated with significant improvements in clinicians' attitudes towards buprenorphine treatment (McCarty et al., 2004). This broadly reflects the training that was delivered to therapists in the BA trial, however it is not known how therapists perceived the BA training. Future research should measure pre- and post-training attitudes and overall satisfaction with training to determine its suitability and impact, which could then be used to refine and implement further training if necessary. Research has previously demonstrated that mental health screening is acceptable to CDAT patients (Delgadillo Gore, et al., 2012) and patients in the current study expressed a preference for addressing their mental health symptoms and substance use simultaneously. This preference does not necessarily reflect the views of all patients with comorbid SUD-depression and future studies should explore the acceptability of integrated treatment with CDAT patients in more detail. Nevertheless, findings from the current study suggest that there may be a gap between the needs of depressed patients and the care currently offered in CDAT which warrants continued research and implementation efforts.

Drug and alcohol treatment workers perceived lack of patient engagement as pervasive and problematic. Previous research suggests that this perception could contribute to staff resisting the adoption of BA in routine practice (e.g. Amodeo et al., 2011). Patients with comorbid SUD-depression may be more difficult to engage than other patients due to the impairing influence of comorbid mental health symptoms and substance use. However, evidence from the BA trial suggested that some patients with this comorbidity can engage well with BA and this finding was supported in the current study. Patients appear to be more likely to engage in BA provided that their life situation is stable and they are motivated to make changes. The BA trial excluded patients who were perceived to be less likely to engage based on the severity of their psychological dependence to substances and self-reported diagnoses of severe mental health disorders such as psychosis. However, it is clear that these exclusion criteria alone did not result in a pool of participants that were sufficiently able to engage in BA. Based on comments from drug and alcohol treatment workers in the current study and previous research (e.g. Sinclair et al., 2011), contingency management strategies to promote engagement may be unlikely to be adopted by staff in CDAT settings. Therefore, future trials could consider combining BA with motivational interviewing (MI) to see if this helps to improve engagement. Previous research has shown that MI pre-treatment increased

the likelihood that patients with comorbid SUD and severe mental health disorders would attend an initial psychiatric appointment (e.g. Zanjani et al. 2008).

There is currently a lack of evidence that BA could be implemented in routine CDAT in its current format. However, key BA treatment components including activity monitoring, values assessments, and activity scheduling appear acceptable and helpful for some patients with comorbid SUD-depression. Encouraging patients to draw their mood and behaviour cycles or write logs of their daily activities may augment self-reflection and motivate behaviour change. Likewise, encouraging patients to write their own goals and plans may facilitate increased goal accomplishment. Values work was identified as a pivotal component of BA treatment for patients with comorbid SUD-depression. Future trials should therefore explore meaning in life or valued living as a potential mediator of BA treatment effects. An increased understanding of BA's effective ingredients could help to refine and improve on the current treatment protocol.

It is clear that future trials of BA implementation in CDAT need to address issues relating to the complexity and structure of intervention delivery. Firstly, simplification of the therapist manuals and patient workbooks is warranted, which could be achieved by utilising a co-production approach with staff and patients prior to testing (e.g. Hales & Fossey, 2018). Secondly, it may be beneficial for future trials to explore BA delivered in a group format. Group BA is reported to be effective (Simmonds-Buckley et al., 2019) and may be more acceptable for patients with comorbid SUD-depression compared to individual delivery (Chapter 2). In addition to being more cost-effective by reducing staff time required per patient, group delivery capitalises on social processes such as interpersonal learning and peer support that could facilitate participant engagement in BA sessions (Ahmed et al., 2010). In future trials, dropout criteria should also be relaxed and core BA treatment extended to 8 weeks as per Daughters et al.'s (2018) study. This would allow for minor variations in engagement and increased time for patients to make behavioural changes. Moreover, training and treatment protocols should include clear guidelines for managing difficult patients and handling sensitive patient disclosures. Clinical supervision is essential, however, it also needs to be flexible to the needs of drug and alcohol treatment workers in busy CDAT services.

4.4.4 Conclusion

This study explored staff and patient perspectives of BA delivered by drug and alcohol treatment workers in CDAT. Although a mental health support need was identified for patients accessing CDAT, staff opinions were varied with regards to the delivery of psychological interventions for depression by drug and alcohol treatment workers. In addition to the disparities in staff attitudes towards addressing patients' mental health, specific factors relating to the structure and complexity of intervention delivery were identified as potential barriers to BA implementation in CDAT. Lack of patient engagement appeared to be another potential deterrent to BA delivery, although patient stability and motivation were identified as facilitators of engagement that should be explored further in future trials. The writing and valued living aspects of BA were perceived by staff and patients to be particularly helpful for facilitating behaviour change in patients. Fully powered effectiveness trials are warranted to address limitations of the previous BA trial, with particular focus on increasing patient motivation to engage, reducing the complexity of BA treatment materials and trialling alternative, more flexible approaches to the mode of BA delivery and supervision.

Chapter 5

Integrative Discussion

The final chapter aims to integrate findings from the three empirical studies presented in this thesis and consider their overall theoretical, clinical and organisational implications. First, the thesis aims will be summarised and an overview of results from each chapter provided. Second, findings will be discussed in the context of implementation theories with regard to: (1) understanding of comorbid SUD-depression; (2) acceptability of behavioural activation (BA) as a treatment for comorbid SUD-depression; (3) effectiveness of BA as a treatment for comorbid SUD-depression; and (4) possible BA treatment mechanisms. Third, the implications of the findings will be discussed in terms of recommendations for policy, practice, and theory. Fourth, the overall strengths and limitations of the thesis will be discussed. Finally, directions for further research will be provided before closing with the thesis conclusion.

5.1 | Summary of thesis aims

The principal aim of this thesis was to explore the effectiveness and acceptability of integrating BA into community drug and alcohol treatment (CDAT) to treat patients with comorbid SUD-depression. The programme of interrelated studies presented in this thesis was guided by the Medical Research Council (MRC) framework for developing and evaluating complex interventions (Craig et al., 2008; Skivington et al., 2021). First, a meta-analysis of randomised controlled trials (RCTs) was conducted to examine the current evidence base for BA as a treatment for comorbid SUD-depression (Chapter 2). Second, a pragmatic pilot RCT of BA implemented by drug and alcohol treatment workers was conducted to examine the effects of BA on key outcomes in patients with comorbid SUD-depression accessing CDAT (Chapter 3). Finally, a qualitative process evaluation of the pilot RCT was conducted. This study integrated perspectives of multiple stakeholders (clinical managers, BA therapists and BA patients) to explore the acceptability and perceived value of integrating BA into routine CDAT (Chapter 4).

5.2 | Summary of thesis findings

The first empirical study (Chapter 2) was a systematic review and meta-analysis. This review found no significant differences between BA and controls with regard to depression (Post-treatment: k = 5; N = 195; SMD: 0.19, CI -0.10 to 0.49; p = 0.20; GRADE = Low; Follow-up: k = 5; N = 195; SMD: -0.10, CI -0.51 to -0.30; p = 0.62; GRADE = Low) or substance use (Post-treatment: k = 4; N = 151; SMD: 0.14, CI -0.33 to -0.6; p = 0.57, GRADE = Low; Follow-up: k = 4; N = 151; SMD: 0.17, CI -0.34 to 0.69; p = 0.51, GRADE = Low). The average session attendance rate for BA was 72%. The BA dropout rate was 26% compared to an average of 29% for controls. Overall, BA did not emerge as a differentially efficacious treatment for comorbid SUD-depression, but it appeared to be an acceptable treatment option.

A pilot RCT of BA facilitated by drug and alcohol treatment workers (Chapter 3) revealed that BA was associated with significantly greater reductions in depressive symptoms (PHQ-9 mean difference -5.69, 95% CI -10.07 to -1.31) at 12-week follow-up compared to Treatment as Usual (TAU). Additionally, BA participants had significantly greater improvements in Percent Days Abstinent (PDA) (mean difference 17.9, 95% CI 0.99 to 34.82) and progress in valued living (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. The BA dropout rate was 59%. This study provided preliminary evidence that BA implemented by drug and alcohol treatment workers may add clinical benefit to usual care for patients with comorbid SUD-depression, although the maintenance of these treatment effects seems limited and the BA intervention appeared to be more suitable for patients who were more stable in terms of substance use and everyday functioning.

The final empirical study (Chapter 4) explored staff and patients' perspectives of BA facilitated by drug and alcohol treatment workers in CDAT. Four main themes were identified based on clinical manager, BA therapist (drug and alcohol treatment workers) and BA patient accounts. (1) *Acceptability of delivering evidence-based psychological interventions in CDAT*. Staff views were divided on whether mental health support should be offered by drug and alcohol treatment workers in CDAT. Drug and alcohol treatment workers reported concerns about addressing patients' mental health and varied in how they usually discussed and approached mental health with patients. (2) *Patient engagement*. Staff and patients emphasised the importance of stability and motivation for successful engagement in

BA. (3) *Challenging yet helpful aspects of BA.* Staff and patients identified writing and values work as helping patients to make positive changes. (4) *Questioning the compatibility of BA with routine care.* Staff talked about specific limitations of the BA intervention. Issues relating to the complexity and structure of BA were highlighted as potential barriers to implementation in routine CDAT.

5.3 | Interpretation of results

The findings from this thesis will be discussed and interpreted in the context of BA implementation with regard to: (1) how the findings contribute to understanding comorbid SUD-depression; (2) what the findings show about the acceptability of integrating BA into CDAT; (3) what results show about the effectiveness of BA for comorbid SUD-depression; and (4) how the findings contribute to understanding how BA works.

5.3.1 | Understanding of comorbid SUD-depression

A fundamental aspect of intervention development is establishing the nature of the problem that needs to be addressed and assessing the theoretical applicability of an intervention to solving that problem (Craig et al., 2008). Overall, findings from this thesis suggest that relationships between SUDs, depression and deficits in value-driven activation are apparent, but they are complex. There was some evidence to support the role of deficits in value-driven activation in maintaining depressive symptoms in patients with comorbid SUD-depression. Depressive symptoms significantly decreased over time among BA patients (Chapter 2), and engaging in more valued activities corresponded with improvements in depressive symptoms over time (Chapter 3). This finding is consistent with learning theory, suggesting that depression is maintained by a lack of positive reinforcement for healthy, non-depressive behaviours (Lewinsohn & Graf, 1973). It also corresponds with the *learned helplessness* theory of depression, which posits that depression is shaped by a person's environment, in circumstances where an individual perceives that they are powerless to control or mitigate aversive experiences, and which results in the extinction of adaptive behaviours (Seligman, 1973). Findings from Chapter 3 suggest that increasing engagement in adaptive behaviours helped BA patients to take control of their lives and access greater reward from the environment.

However, increased engagement in valued activities did not correspond with improvements in depressive symptoms over time in the usual care group, suggesting that increasing access to positive reinforcement alone is insufficient to improve depressive symptoms for patients with comorbid SUD-depression (Chapter 3). Given that TAU participants generally reported higher substance use levels than BA patients, it may be the case that negatively reinforcing behaviours (i.e. substance use) also need to be lower for reductions in depressive symptoms to be observed in this population. This finding is consistent with the theory that depression is not a unitary phenomenon that can simply be explained by lack of positive reinforcement, high levels of negative reinforcement or punishment; it is a complex and diverse set of co-occurring operant and respondent behaviours (Kanter et al., 2011), which highlights the importance of functional analysis in BA treatment.

There was some evidence to suggest that SUDs are associated with lack of access to environmental reward. Non-significant decreases in substance use were observed over time in Chapter 2 and Chapter 3. BA was also associated with significant reductions in substance use compared to TAU (Chapter 3). This finding lends support to the behavioural economic theory of SUDs, which suggests that SUDs are maintained and exacerbated by a lack of reinforcement for alternative rewarding behaviours (Bickel & Vuchinich, 2000; Hogarth & Field, 2020). However, reductions in substance use did not always appear related to increased engagement in valued activities. This could be because the relative value of substance use was greater than that of engaging in valued activities for some patients (Hogarth & Field, 2020), suggesting that other theories may need to be drawn upon to explain and treat substance use behaviour in patients with comorbid SUD-depression. For example, stress and coping theory posits that self-efficacy is necessary for patients to change their substance use (Kaplan, 1996), while social control theory also highlights the role of the quality of patients' social support network in facilitating changes in substance use (Hirschi, 1969). Theoretically, BA could help patients to increase their self-efficacy via understanding links between their mood and behaviour and learning behavioural coping skills, or by increasing access to social support, but the extent to which treatment addresses these goals remains unclear.

The empirical studies covered in this thesis also found no evidence that variability in substance use was related to the severity of depressive symptoms, a finding consistent with the contemporary Hierarchical Taxonomy of Psychopathology (HiTOP; Ruggero et al., 2019). The HiTOP model has been developed to address the limitations of commonly used

categorical classification systems for psychiatric diagnoses (e.g. DSM-V; APA, 2013), which tend to lack clinical utility (Chmielewski et al., 2015; First et al., 2018) and fail to account for the excessive co-occurrence of disorders (Clark et al., 2017) and within-diagnosis heterogeneity of symptoms (Galatzer-Levy & Bryant, 2013). The HiTOP model posits that psychopathology cannot be understood in terms of discrete, neatly defined disorders, but rather a continuum of psychopathological spectrums that comprise commonly co-occurring symptoms (Kotov et al., 2017). Depressive symptoms are conceptualised as part of the internalising spectrum, often co-occurring with anxiety symptoms, compulsive behaviours and PTSD symptoms. Consistent with this model and previous research (e.g. Delgadillo, Godfrey, Gilbody & Payne, 2013), participants in Chapter 3 were found to have moderate levels of comorbid anxiety. Meanwhile, SUDs are hypothesised to be part of the externalising spectrum, characterised by components such as problematic substance use, impulsivity and inattention. The HiTOP model suggests that patients typically present with varying degrees of symptoms and problems that may span different spectra (e.g. depressive symptoms and problematic substance use), warranting integrated, nuanced treatment approaches to address specific symptom clusters and levels of difficulty in different areas (Ruggero et al., 2019). For example, treatment for a patient with comorbid SUD-depression who presents with severe internalising spectrum symptoms and mild externalising spectrum symptoms should focus more broadly on addressing depression, with a narrower focus on specific techniques to address substance use.

Therefore, from the perspective of the HiTOP model, depression and SUDs may co-occur and influence each other in complex ways, but ultimately they are distinctive psychopathological domains and there is little evidence to suggest that solving one problem will automatically solve the other. Given that BA has so far been offered as a "one-size-fits all" approach with limited understanding of how specific components affect different outcomes, this could certainly help to explain some of the variability in findings for depression and substance use outcomes in this thesis, particularly within individual studies. It could also explain the small effect sizes observed in RCTs of psychological treatments for comorbid SUD-depression generally (e.g. Magill & Ray, 2009). Nevertheless, this thesis provides preliminary evidence that behavioural theory is applicable to comorbid SUD-depression and that integrated BA is more effective than usual care alone for this comorbidity, which extends on previous research on integrated treatments (e.g. Hesse, 2009) and warrants continued investigation.

5.3.2 | Acceptability of BA as a treatment for comorbid SUD-depression

The successful implementation of interventions relies on end-user acceptability. A lack of patient acceptability can limit evidence of efficacy, diminishing the likelihood that an intervention would be recommended for implementation (Damschroder & Hagedorn, 2011). Equally, even the most effective interventions are unlikely to be adopted in practice if they are perceived as offering limited advantage, or if they are incompatible with the values, experiences, and needs of treatment practitioners and service providers (Damschroder & Hagedorn, 2011; Rogers et al., 2003). Therefore, understanding intervention acceptability is a critical component of developing and evaluating interventions that can help guide future research and implementation efforts (Craig et al., 2008). In this thesis, BA acceptability was assessed from patients' perspective in terms of BA attendance and dropout rates and their experiences of receiving BA treatment, as well as staff's perspective regarding their experiences of implementing BA in CDAT.

5.3.2.1 | *SUD Patients*

Patient dropout rates for BA (9-65%) and active treatments (25-52%) generally appear to be higher in studies conducted with SUD patients than dropout rates reported in studies conducted with non-SUD samples (14-17%; Simmonds-Buckley et al., 2019). This finding appears to reflect the established difficulties in engaging SUD patients in treatment (McCarty et al., 2007), particularly those who have comorbid mental health disorders (e.g. Teesson et al., 2008).

However, it seems that the acceptability of BA for patients with comorbid SUD-depression in drug and alcohol treatment is largely influenced by patient characteristics and to some extent, treatment setting. BA delivered in residential SUD treatment was associated with the lowest dropout (9%) and highest attendance rate (91%) (Daughters et al., 2008). This finding could be expected given that patients in residential treatment are usually abstinent and likely experience fewer practical barriers to engaging in therapy than patients accessing outpatient SUD treatment. For example, patients in residential treatment have all of their basic needs met and therapy appointments are delivered onsite. In contrast, dropout rates were much higher (50-65%) and attendance rates much lower (38-48%) for BA delivered in outpatient SUD treatment (Chapter 3; Carpenter et al., 2008; Delgadillo et al., 2015). Previous research has indicated that CDAT patients with comorbid SUD-depression face multiple barriers to accessing mental health support, including travel costs, fears around

attending and being overwhelmed with multiple appointments (Gore et al., 2017). Therefore, increased barriers could help explain the higher dropout rates and lower attendance rates observed in BA trials conducted in outpatient settings generally.

There was no evidence that patient demographics such as age or gender were associated with engagement in BA. However, patients who were using less substances and were more stable in terms of everyday functioning notably attended more BA sessions and were less likely to drop out of BA treatment in CDAT (Chapter 3; Delgadillo et al., 2015). This finding is consistent with evidence from non-SUD samples indicating that patients who have higher levels of functioning and less complex clinical profiles are more likely to respond to psychological interventions in outpatient settings (Delgadillo et al., 2016).

However, stability is not the only factor affecting the acceptability of BA for CDAT patients; motivation also appears to be important for BA engagement. This finding corresponds with guidance on phased intervention delivery in SUD treatment (Department of Health, 2017) and the Transtheoretical Model (TTM; Prochaska & DiClemente, 1983). According to these models, structured psychological interventions are unsuitable for patients who are not yet sufficiently motivated to change, although motivational interventions may help patients reach a stage where they can engage. For example, there is evidence to suggest that combining motivational and psychological interventions can enhance engagement. The highest dropout rate reported in a meta-analysis of 12 RCTs that combined motivational interviewing (MI) with CBT for patients with comorbid AUD-depression was 40% (Riper et al., 2014), which is considerably lower than the 59% BA dropout rate reported in the study conducted in CDAT (Chapter 3). It is also much lower than the 52% dropout rate reported for CBT-based guided self-help in CDAT patients with comorbid SUD-depression (Delgadillo et al., 2015). Lack of motivation is a key characteristic of depression that could inhibit patients from engaging with BA therapy, especially in an outpatient setting where there are likely to be other obstacles to engagement (e.g. Gore et al., 2017). Yet previous trials of BA for comorbid SUD-depression have not accounted for nor addressed patient motivation in any specific way, which could explain the high BA dropout rates observed in outpatient SUD treatment settings.

Regarding the content of BA treatment, the LETS ACT! treatment protocol (Daughters et al., 2016) generally appears to be acceptable for patients with comorbid SUD-depression who are ready to engage, although patients may have difficulty understanding

treatment concepts initially. This finding is in contrast to previous research conducted with non-SUD patients, which found that BA was sometimes perceived as overly simplistic (Finning et al., 2017). Therefore, comprehension difficulties could be explained by lower levels of literacy (Degan et al., 2019) and higher rates of cognitive impairment in SUD patients (Bruijnen et al., 2019). However, they may also be related to factors that are more amenable to change, such as therapist understanding and confidence in delivering the therapy, or intervention characteristics such as the complexity of the BA patient workbook. An initial lack of understanding did not seem to preclude positive treatment outcomes for the patients interviewed in Chapter 4, although it is not known how it may have affected other BA patients.

5.3.2.2 | *SUD Treatment Staff*

Evidence from this thesis suggests that drug and alcohol treatment workers can deliver BA. However, staff held mixed views on implementing BA in CDAT (Chapter 4). Research has shown that staff may vary in their views on the acceptability of evidence-based interventions generally based on their educational background and experience (Aletraris et al., 2015; Haug et al., 2008; Rash et al., 2012), and whether they have an intuitive or analytical decision-making style (Seligman et al., 2016). Staff may also resist interventions that do not align with their own treatment ideologies (e.g. Aarons, 2005; Amodeo et al., 2011). Indeed, a critical issue that appeared to colour drug and alcohol treatment workers' perceptions of BA was frustration about the lack of cooperation from mental health services and reservations about their role in identifying and treating depressed patients in CDAT (Chapter 4). Lack of access to mental health services is a widespread issue for SUD patients (Hamilton & Holland, 2017) and the ambiguity of treatment guidelines for patients with comorbid SUD-depression leaves them open to staff interpretation (Department of Health, 2017). Given that signposting patients to other services for specialist support (e.g. housing, employment services) is a standard principle of SUD treatment (Department of Health, 2017), it is comprehensible that staff might question their responsibility regarding the delivery of psychological interventions for depression, especially when the efficacy of this approach to treatment delivery has not yet been established (Damschroder & Hagedorn, 2011).

Staff also indicated that specific characteristics of the BA intervention might be incompatible with routine care in CDAT. These concerns were primarily related to the treatment being manualised. In particular, the complexity of the manual was reported to limit staff understanding and confidence in BA delivery, while the structure was perceived to be

incompatible with the needs of patients. These findings are consistent with previous research conducted with SUD treatment workers (Autrique et al., 2009; Rieckmann et al., 2011) and some would argue that they represent a fundamental mismatch between the needs of researchers and those of treatment staff (e.g. Shedler, 2018). Indeed, researchers require standardised, measurable treatments delivered with fidelity so that effects can be directly attributed to the intervention, whereas SUD treatment workers require interventions that are flexible and can be delivered according to patients' individual needs and circumstances.

Consequently, some researchers have called for the implementation of evidence-based techniques in SUD treatment rather than structured, manualised interventions (Glasner-Edwards & Rawson, 2010). More specifically, it has been suggested that CM techniques, motivational techniques, CBT coping skills/relapse prevention strategies and family/relationship counselling skills represent core skill sets that should be disseminated and widely diffused in SUD treatment settings (Glasner-Edwards & Rawson, 2010). However, from a research perspective, it would be difficult to reliably assess the efficacy of these techniques on clinical outcomes without the structure afforded by manualised interventions that have a clear beginning and end. Moreover, drug and alcohol treatment workers are typically not expert psychotherapists and they may lack understanding of the nuances of different therapeutic techniques and their application in different circumstances. Therefore, implementing "evidence-based techniques" could lead to inconsistent, subpar delivery of empirically supported treatments, akin to what currently seems to be happening in practice in SUD treatment in any case (e.g. Best et al., 2009).

Moreover, the argument that manuals are inflexible is a common misconception, as manualised interventions are not designed to be delivered to the letter and certainly not to the detriment of the therapeutic relationship (Addis, 1997; Addis et al., 1997). When properly used, manuals help ensure the quality of treatment delivery (Addis, 1997) and there is a solid evidence base for the delivery of manualised cognitive and behavioural interventions with non-SUD samples in real-world clinical settings (Clark, 2018). Therefore, it is clear that providing appropriate training (e.g. Addis et al., 1997) and clinical supervision (e.g. Godley et al., 2001) may be necessary to mitigate staff concerns about manualised treatment and ensure that manuals are used efficaciously in SUD treatment settings.

Nevertheless, organisational constraints such as large caseload sizes, lack of time and organisational restructuring mean that staff may lack the capacity to learn and deliver BA in

any case. This finding is consistent with reports indicating that persistent funding cuts to the SUD treatment sector have led to a reduced workforce and increased caseload sizes in recent years (Black, 2021; Recovery Partnership, 2017). Lack of funding has also led to a less qualified workforce and reduced opportunities for staff training and development (Black, 2021; Recovery Partnership, 2017). Given that higher levels of education and training are associated with increased support for evidence-based interventions generally (Haug et al., 2008; Rieckmann et al., 2011), an overall lack of access to training could help explain why drug and alcohol treatment workers were found to place less emphasis on evidence-based practice in Chapter 4. Likewise, the frequent re-tendering of services is disruptive and may generally impact staff's enthusiasm and ability to adopt innovations (e.g. Advisory Council on the Misuse of Drugs [ACMD], 2017; Hall et al., 2016; Sheridan et al., 2011). Taken together, it is clear that staff attitudes and organisational issues influenced by funding constraints and recommissioning may be key barriers to BA implementation and the overall quality of SUD treatment provision in the UK.

Perhaps the key overarching issue is that evidence-based psychosocial interventions are not prioritised for implementation in SUD treatment at a systemic level. Current implementation strategies for psychosocial interventions in SUD treatment appear to consist only of providing best practice guidelines (Department of Health, 2017). Yet, guidelines alone are not sufficient to facilitate the real-world application of evidence-based practice (Lomas et al., 1989; Toman et al., 2001). Training and competency frameworks are important for supporting the implementation of evidence-based practice and fostering a culture of clinical effectiveness (e.g. Lehane et al., 2020), they define the roles and skills required of professionals and facilitate appropriate training to attain those skills. These frameworks are strongly embedded in IAPT service delivery and may help to explain the overall success of the initiative (Clark, 2018). However, no such framework has existed for drug and alcohol treatment workers in the UK since the disbanding of the National Occupational Standards for Drug and Alcohol Workers (DANOS; Skills for Health, 2008) over ten years ago. A lack of applied quality standards may imply to SUD treatment providers that evidence-based practice is optional and not necessary to achieve good outcomes. Therefore, overall, a greater emphasis on implementing existing evidence-based psychosocial interventions may be needed to lay the foundation for effective implementation of new innovations in SUD treatment.

5.3.3 | Effectiveness of BA as a treatment for comorbid SUD-depression

Without robust and observable evidence of effectiveness, it is unlikely that BA would be recommended as a treatment for comorbid SUD-depression (Craig et al., 2008; Rycroft-Malone et al., 2002). Findings from this thesis suggest that overall, evidence is mixed regarding the efficacy of BA for patients with comorbid SUD-depression; the quality of evidence is generally low and there is a considerable degree of heterogeneity between individual studies. As discussed in Section 5.3.1, variability in patient symptom presentations may influence the rate at which different outcomes improve. However, based on the patterns of results observed in existing studies, it seems that certain general factors may also influence the overall efficacy of BA in SUD treatment populations. A greater understanding of these factors could help direct future research efforts and potentially increase the strength of evidence for BA as a treatment for comorbid SUD-depression.

5.3.3.1 | *BA Engagement*

The most convincing evidence for BA in SUD populations currently comes from RCTs conducted in residential SUD treatment (Daughters et al., 2018, 2008). Although one of these studies included patients who did not have clinically significant depressive symptoms (Daughters et al., 2018) so it is unclear whether the findings are generalizable to patients with comorbid SUD-depression. Nevertheless, the finding that BA was generally more effective for patients in residential treatment may be due to higher patient engagement with BA in this setting. Indeed, studies reporting higher levels of BA dropout tended to report the least favourable effects of BA (Carpenter et al., 2008; Delgadillo et al., 2015). Even when the dropout rate did not appear to be associated with BA effects, patients with comorbid SUD-depression who attended more BA sessions reported more clinically significant improvement in depressive symptoms in CDAT (Chapter 3). It is widely acknowledged that patient engagement is necessary to improve treatment outcomes (Cahill et al., 2003) and patients with comorbid SUD-depression tend to exhibit poorer engagement with treatment than those without co-occurring disorders (Teesson et al., 2008). Therefore, reducing barriers to BA attendance (e.g. increasing motivation) and adherence (e.g. simplifying treatment) may be essential to improve the effectiveness of BA for a broader range of patients with comorbid SUD-depression, particularly those accessing outpatient drug and alcohol treatment settings where engagement already tends to be lower.

5.3.3.2 | *Type of comparator*

Findings from this thesis suggest that BA is more effective than usual care than it is compared to other active treatments for patients with comorbid SUD-depression. This finding is consistent with evidence from non-SUD samples indicating that of the many psychotherapies available for depression, no single intervention appears to be vastly superior in efficacy, commonly referred to as the dodo bird verdict (Cuijpers, 2017). Therefore, the main priority of research should be to identify acceptable treatments and optimise them for delivery in specific contexts. Also, since psychological interventions for mental health problems are not routinely delivered in CDAT (e.g. NDTMS, 2021; Recovery Partnership, 2017), generating evidence for BA based on comparisons to other active treatments is likely to be irrelevant to commissioners and treatment providers. Therefore, the benefits of comparing BA to usual care in CDAT are twofold; the likelihood of a significant BA treatment effect increases, and the findings are more relevant to current practice.

5.3.3.3 | *Type of BA*

Evidence presented in this thesis suggests that BA interventions based on the BATD model (Lejuez et al., 2001, 2011) may be most effective for patients with comorbid SUD-depression. In particular, studies that employed the LETS ACT! treatment protocol (Daughters et al., 2016) were associated with significant reductions in depressive symptoms in patients accessing residential treatment (Daughters et al., 2008) and significant improvements in depression and substance use outcomes in patients accessing CDAT (Chapter 3). The BATD model expands on simpler forms of BA (e.g. Rehm, 1984) by grounding activation in valued life areas, but includes fewer treatment components than Contextual (Martell, Addis & Jacobson, 2001, 2010) and Stepped BA approaches (Kanters et al., 2009). However, it is also notable that the original LETS ACT! treatment protocol (Daughters et al., 2016) employed in Daughters et al.'s (2018; 2008) studies is not a pure BATD approach as it includes mindfulness training, characteristic of Stepped BA (Kanter et al., 2009). The BA trial in Chapter 3 omitted mindfulness training from the LETS ACT! protocol to be more consistent with BATD and still found significant BA treatment effects up to 12-week follow-up, suggesting that mindfulness is not necessary for improving outcomes in patients with comorbid SUD-depression, at least not in the short term.

However, treatment effects were not maintained at 24-week follow-up, even though two booster sessions were added to the end of treatment to reinforce learning and behaviours adopted in core sessions (Chapter 3). The finding that treatment effects were not maintained over time contrasts with Daughters et al.'s (2018) study, which reported a higher likelihood

of abstinence and reduced adverse consequences from substance use following LETS ACT! up to 1-year follow-up. This discrepancy in findings could be explained by the inclusion of patients with subclinical depression in Daughters et al.'s (2018) study, or the fact that patients in this study were already abstinent at baseline. However, it could also be the case that mindfulness is a critical component of the LETS ACT! treatment for SUD patients when it comes to maintaining treatment effects longer term.

Indeed, research has shown that Mindfulness-Based Cognitive Therapy (MBCT) is associated with a reduced risk of relapse in patients with recurrent depression (Chiesa & Serretti, 2011) and reduced depressive symptoms up to 1-year follow-up in depressed patients (van Aalderen, Donders, Peffer & Speckens, 2015). A recent systematic review of 30 RCTs also found that mindfulness-based interventions were associated with significant improvements in rates of abstinence and reductions in frequency of substance use and craving for substances in SUD patients (Korecki, Schwebel, Votaw & Witkiewitz, 2020). The rationale for incorporating "mindful valued action" into Stepped BA (Kanter, Busch & Rusch, 2009) is to encourage patients to develop non-judgemental awareness of their thoughts and feelings so that negative affectivity does not interfere with their engagement in valued activities. Consistent with this rationale, mindful attention has been identified as a mechanism of change in mindfulness-based interventions for depression (McKim, 2008; Shahar et al., 2010). Improving mindful attention could be particularly beneficial for patients with comorbid SUD-depression, as SUDs are associated with impulsivity and inattention (Ruggero et al., 2019). Therefore, overall, mindfulness techniques appear to complement BA for patients with comorbid SUD-depression and may contribute to improved maintenance of treatment effects over time.

5.3.4 | Possible BA Treatment Mechanisms

Understanding the mechanisms of change associated with BA for patients with comorbid SUD-depression can help refine and advance BA treatment protocols for this comorbidity (Craig et al., 2008). Further development of BA for this population could contribute to bigger BA treatment effects, improved maintenance of effects over time and ultimately a stronger evidence base that could facilitate future implementation. Unfortunately, due to the small sample size of the study in Chapter 3, it was impossible to quantify moderators or mediators

of BA treatment effects. However, evidence from this thesis provides insight into some potential mechanisms of change in this patient population.

BA patients in Chapter 4 reported doing more as a result of engaging in BA. Indeed, the central aim of BA treatment is to reduce avoidance behaviours and increase engagement in alternative, functional behaviours (Lejuez et al., 2001). Several studies have shown that BA is associated with improvements in activation and that activation mediates the effects of BA on depressive symptoms (e.g. Dimidjian et al., 2017; Nasrin et al., 2017). However, a recent systematic review of studies conducted with non-SUD samples found only weak evidence for activation as a mediator of BA effects overall (Janssen et al., 2021). Therefore, perhaps it would be helpful to consider activation in more specific terms. BA patients in Chapter 4 reported that reconnecting with their values was helpful. There was also quantitative evidence that progress in valued living was related to BA and reductions in depressive symptoms among BA patients (Chapter 3). Values work is a core component of modern BA therapies (e.g. BATD; Lejuez et al., 2001), including LETS ACT! (Daughters et al., 2016), and previous studies have suggested that lack of engagement in valued living is associated with both depressive symptoms (Smout et al., 2014) and problematic substance use (Copeland et al., 2020). Therefore, it is plausible that activation and more specifically, engagement in valued activities, are potential mediators of BA treatment effects.

5.4 | General strengths and limitations

5.4.1 | Strengths

This thesis addressed key recommendations from the MRC framework for developing and evaluating complex interventions (Craig et al., 2008; Skivington et al., 2021); the evidence base for BA as a treatment for comorbid SUD-depression was established, a pilot trial of BA facilitated by drug and alcohol treatment workers was conducted to determine the effectiveness of this approach and a qualitative process evaluation helped to establish the context of implementation. Additionally, robust methodologies were used to address each of these recommendations. Meta-analysis is a statistically rigorous approach that permits a detailed assessment of the effects of an intervention across different studies to establish overall efficacy (Borenstein et al., 2011). Including only RCTs in the meta-analysis ensured that results were based on the best available evidence. Meanwhile, the use of a pragmatic RCT encompassed the rigour of randomising patients to an intervention or control, with the

added benefit of ensuring that trial findings were more relevant to practice (Patsopoulos, 2011). The acceptability of BA was also assessed quantitatively and qualitatively and the process evaluation included views of key stakeholders from different organisational levels, contributing to a comprehensive view of the acceptability of BA in a CDAT context. Overall, this thesis extends on previous research investigating BA as a treatment for comorbid SUD-depression. It has explored how BA could be transported into routine practice, effectively laying the groundwork for future effectiveness-implementation trials to continue closing the gap between research and practice in CDAT.

5.4.2 | Limitations

The findings from this thesis should also be considered in the context of its limitations. These limitations are discussed below.

All of the studies in this thesis had smaller than expected samples. Regarding the meta-analysis (Chapter 2), the small number of eligible studies and small sample sizes of studies could have reduced the likelihood of finding significant effects for depression or substance use outcomes. Conversely, the small sample size in the pilot RCT (Chapter 3) may have skewed the results and resulted in a Type I error. Additionally, the RCT was only conducted at one site due to limited study resources, yet multi-site studies often show a site effect (Nunes et al., 2010). Therefore, it is unclear whether the same results would have been obtained in different CDAT services and the broader generalisability of findings from Chapters 3 and 4 remains questionable.

The qualitative study (Chapter 4) did not achieve adequate data saturation for patient perspectives. The views of patients who dropped out of BA treatment or did not experience clinically significant change were not represented, perhaps because they had negative experiences and were less likely to agree to interview. The small sample sizes of the studies in Chapters 2 and 3 also meant that it was impossible to explore moderators or mediators of BA treatment effects. It was also not possible to conduct regression analyses to explore predictors of treatment dropout in Chapter 3. Therefore, overall, the results of this thesis may be somewhat skewed and do not necessarily generalise to all patients with comorbid SUD-depression, nor all drug and alcohol treatment workers who may deliver BA in CDAT settings. Accordingly, the findings from this thesis should be interpreted with caution. This

thesis also does not provide the level of detail about the efficacy and acceptability of BA that could have been afforded with larger samples.

The difficulties of recruiting SUD patients to RCTs are widely acknowledged (Melberg & Humphreys, 2010; Thomson et al., 2008). Indeed, a considerable proportion of patients referred to the study in Chapter 3 declined screening because they did not want to take part in a trial. It was also noted that there was a large disparity between potentially eligible patients and patients who were referred to the study by CDAT staff (Chapter 3). This could suggest several things: (1) potentially eligible patients did not want to be referred to the study due to lack of interest; (2) potentially eligible patients did not attend CDAT regularly enough to be informed about the study; (3) staff forgot to inform patients about the study; (4) staff were not fully on board with the research and chose not to inform patients about the study; and (5) staff "cherry-picked" patients whom they thought would be most suitable. It is likely that a combination of these factors contributed to the disparity in potentially eligible participants and study referrals. These issues could have been addressed by minimising exclusion criteria, recruiting patients from multiple sites and providing more frequent training to staff on how to discuss the study with patients, or by having researchers approach patients about the study to reduce burden on staff and the potential for selection bias.

Further methodological limitations that were apparent in this thesis include a reliance on self-report measures, lack of rigorous competency and adherence monitoring and no broader measures of functioning. The majority of studies included in the meta-analysis (Chapter 2) and the RCT (Chapter 3) used self-report measures of substance use, which is likely to be subject to recall bias (e.g. Cherpitel et al., 2018). However, the use of objective measures such as urine drug screening may be too expensive and could be perceived as invasive, especially if not already routinely implemented in SUD treatment settings. The use of self-report measures of adherence for BA therapists in Chapter 3 was due to limited study resources. However, reliance on this method was particularly problematic as there is evidence to suggest that staff may overestimate their adherence (Hogue, Dauber, Lichvar, Bobek & Henderson, 2015). Moreover, the lack of competency assessments means that it is unclear whether staff were proficient in delivering BA. Questions relating to staff competency and adherence in delivering BA would be resolved by recording treatment sessions and completing independent adherence and competency ratings. The extent to which BA patients engaged with the session content was also unclear across all of the studies in this thesis. Therefore, it may be beneficial for future studies to record patient engagement in elements of

BA, such as their understanding of various treatment components and whether homework assignments were completed. A further limitation is that measures of functioning (e.g. healthcare utilisation) were not included in any of the studies, meaning that no conclusions can be made about the cost-effectiveness of BA for this population.

There was also a lack of blinding in several studies included in the meta-analysis (Chapter 2) and the study conducted in Chapter 3. It is often impractical to blind patients to treatment condition in RCTs of interventions in any case. However, it would have been preferable for researchers who were blinded to participant allocation to conduct outcome assessments in order to minimise the risk of bias. This was not possible in Chapter 3 due to limited study resources. Likewise, qualitative interviews were conducted by a researcher who had pre-existing relationships with study participants as part of their study coordinator role, which may have affected participant responses in Chapter 4.

Finally, a substantial proportion of the 24-week follow-up data (Chapter 3) and qualitative interview data (Chapter 4) was collected during the first six months of the COVID-19 pandemic, when restrictions were most stringent. It has been widely documented that the initial phase of the pandemic was associated with deteriorations in mental health (O'Connor et al., 2021) and increases in substance use (Jacob et al., 2021) among people in the general population, in addition to creating more vulnerabilities for the physical and psychological health of SUD patients specifically (Volkow, 2020). Therefore, it is plausible that some of the findings in this thesis may have been impacted by the wider context of the COVID-19 pandemic and should be interpreted with caution.

5.5 | Implications

5.5.1 | Policy implications

In terms of implications for policy, brief, manualised BA interventions such as LETS ACT! (Daughters, Magidson, Lejuez & Chen, 2016) appear to be safe and potentially effective for patients with comorbid SUD-depression. However, for an intervention to be considered "evidence-based", it must be compatible with the needs of practitioners and patients (Sackett et al., 1996). Also, a general parameter is that evidence of effectiveness needs to be replicated across multiple studies with adequately large sample sizes to ensure the consistency and generalisability of findings (Chambless & Hollon, 1998). Therefore, more work is needed to

establish the compatibility of BA with routine care in CDAT and additional, fully powered RCTs are required to strengthen the evidence base for BA before it could be recommended as an evidence-based intervention for implementation in this setting.

Consistent with previous reports, mental health interventions did not seem to be routinely available to patients accessing CDAT (Recovery Partnership, 2017; Turning Point, 2016). It is plausible that the ambiguity of current treatment guidelines (Department of Health, 2017) has contributed to a lack of consensus regarding who is responsible for treating SUD patients with comorbid common mental health disorders (CMDs), leaving an increasing number with unmet mental health needs. In addition, mental health screening for CMDs was not routinely implemented in the CDAT service despite evidence that it is feasible (Delgadillo et al., 2011) and acceptable to patients (Delgadillo, Gore, et al., 2012), suggesting that many patients with comorbid SUD-depression may also remain unidentified in routine CDAT. If this information was routinely recorded and made publicly available as part of the National Drug Treatment Monitoring System (NDTMS), it would help clarify the extent of the problem and could be used as a call to action. Failing to identify and address the needs of patients with comorbid SUD-depression seems counterintuitive at any rate, potentially heightening the strain on drug and alcohol treatment workers with patients who cannot progress and exit treatment successfully under usual care conditions. Given that patients are more likely to access mental health support located in CDAT (Delgadillo et al., 2015) and these services typically do not have funding to employ specialist mental health practitioners, it seems drug and alcohol treatment workers are the most appropriate candidates for treating patients with comorbid SUD-depression. This approach to treatment delivery has also been recommended in a recent independent review of drug treatment directed at UK government policy makers (Black, 2021).

However, findings from this thesis suggest that drug and alcohol treatment workers may hold conflicted views about their role in delivering psychological interventions for patients with mental health problems and vary in their support for evidence-based interventions generally. Staff attitudes toward the delivery of psychological interventions for comorbid SUD-depression may be amenable to change through effective training (e.g. Addis et al., 1997) and social reinforcement, such as exposure to positive subjective opinions about delivering psychological interventions from peers (Rogers, 2003). Issues relating to the delivery of manualised treatments may also be alleviated through training (e.g. Addis et al., 1997) and clinical supervision (e.g. Godley et al., 2001. Yet the impact of these strategies

alone may be limited when staff also face considerable organisational constraints and pressures related to caseload sizes, lack of training and lack of time, that make it difficult for them to deliver structured interventions generally (e.g. Black, 2021; Recovery Partnership, 2017). Likewise, the frequent recommissioning of services appears to be of limited overall benefit and may be particularly detrimental to research, staff morale and patient outcomes (ACMD, 2017).

Findings from this thesis also suggest that even if BA were implemented in CDAT, it may only be effective for some patients with comorbid SUD-depression. For SUD patients who are not ready to engage with structured psychological interventions, treatment guidelines recommend delivering contingency management (CM) or motivational interventions to facilitate engagement (Department for Health, 2017). CM interventions are effective and straightforward to deliver, but they tend to be expensive and may be perceived by staff as coercive and at odds with the SUD treatment principle of increasing patient autonomy (Sinclair et al., 2011). On the other hand, MI appears to be a more widely accepted and adopted evidence-based intervention in SUD treatment generally (Best et al., 2009; Calder, 2019; Carroll, 2014). Combining MI with BA could help improve BA engagement and contribute to better treatment outcomes. However, there is equally little evidence that MI is delivered with adequate fidelity in CDAT (e.g. Best et al., 2009), or that drug and alcohol treatment workers have the capacity to do so. Like BA, MI requires considerable training and clinical supervision for staff to be competent and deliver the treatment effectively (Schwalbe et al., 2014), which is clearly challenging in the current context of service provision (e.g. ACMD, 2017; Black, 2021).

Therefore, in light of increased funding planned for the SUD treatment sector in the UK over the next couple of years (Black, 2021), the following systemic changes are suggested to better facilitate evidence-based practice generally and create a more favourable milieu for the investigation and diffusion of manualised treatment approaches for comorbid SUD-depression and other CMDs in CDAT: (1) a reduction in the frequency of service recommissioning to stabilise the SUD treatment workforce, improve staff morale and facilitate high-quality research; (2) more investment in the training and development of the SUD treatment workforce, reinforced by a core competency and training framework for drug and alcohol treatment workers; (3) implementation of routine screening for CMDs (e.g. PHQ-9; Kroenke, Spitzer & Williams, 2001), recorded at initial assessment and reviewed at regular intervals throughout treatment alongside the Treatment Outcomes Profile (TOP;); and (4)

allocation of funding for research on integrating psychological interventions for comorbid SUD-depression into CDAT to clarify treatment guidelines and establish specific implementation strategies.

5.5.2 | Practice implications

Even if the above systemic changes are realised, CDAT services are still likely to require parsimonious treatment approaches that make the best use of available resources. If manualised interventions are to be implemented, group delivery is likely to be a more cost-effective option than individual delivery. Fewer staff would need to be trained to deliver the intervention and multiple patients could receive treatment at the same time. Research in SUD (Daughters et al., 2008) and non-SUD samples (Simmonds-Buckley et al., 2019) have shown that group BA is acceptable and effective. Group delivery could also potentially enhance the efficacy of BA via common therapeutic factors associated with group interventions such as peer identification and support (Ahmed et al., 2010).

Although it tends to be underutilised, clinical supervision is essential for drug and alcohol treatment workers to develop and maintain their skills (e.g. Roche et al., 2007). Group supervision may be more cost-effective than individual supervision and evidence from this thesis indicates that it is generally acceptable and helpful for supporting drug and alcohol treatment workers to deliver psychological interventions. Inevitably there tends to be more logistical constraints associated with group supervision (e.g. timing; Enyedy et al., 2003), but overall there does not appear to be any difference in effectiveness between the two modalities (Livni et al., 2012; Ray & Altekruse, 2000). Therefore, group supervision could be a valuable means of increasing drug and alcohol treatment workers' competency and facilitating the implementation of evidence-based interventions in routine care.

It is also essential to recognise that patients with comorbid SUD-depression may be less likely to attend appointments in SUD treatment (e.g. Delgadillo et al., 2015) and they could also have more difficulties engaging with session content. Failing to attend appointments could be due to a range of barriers, including lack of motivation and substance use (Chapter 4), as well as memory problems, fears around attending and struggling with the demands of daily life (Gore et al., 2017). Therefore, practitioners need to consistently employ strategies to promote attendance with patients who have comorbid SUD-depression, such as providing multiple reminders of appointments and if missed appointments need to be

rebooked, scheduling them as soon as possible after contact with the patient (e.g. DeMarce et al., 2008). Motivational techniques may also be useful for improving engagement (e.g. Carroll et al., 2006), but the importance of person-centred care cannot be underestimated (Stanhope et al., 2013). Drug and alcohol treatment workers should seek to understand all patients as individuals and incorporate their background, preferences and immediate goals into treatment planning. Helping patients to address immediate concerns such as housing and finances may be necessary to facilitate engagement and this work can also be incorporated into therapies such as BA. For example, living in suitable housing could be framed as a value within a particular life area, while activities to secure a housing tenancy could be discussed and scheduled as part of the therapy. Indeed, manualised treatments need not be the enemy, if employed flexibly they have the potential to greatly improve treatment delivery and clinical outcomes in routine care (e.g. Addis, 1997). Moreover, flexible approaches to treatment provision may be helpful for this patient group, including home visits or delivering sessions over the telephone rather than face to face. Writing things down in sessions could also help patients to engage with session content and follow through with planned activities or goals.

5.5.3 | Theory and research implications

While preliminary, findings from this thesis generally support a behavioural model of comorbid SUD-depression. There was also evidence that BA based on the BATD model facilitates increased engagement in valued activities. However, increasing engagement in valued activities did not seem to correspond with significant changes in substance use; therefore, more research is needed to clarify which components of BA are effective for improving substance use outcomes. There was also evidence that increasing engagement in valued activities alone was insufficient to improve depressive symptoms. Variability in the symptom profiles of patients may influence the rate at which depressive symptoms and substance use improve during BA treatment. Increased individualisation of BA treatment may be necessary to achieve larger and more consistent treatment effects, although standardised treatments may still offer benefits over usual care.

In order to influence policy and facilitate the delivery of evidence-based interventions and practices in SUD treatment generally, it is clear that more research is also needed to establish the relative efficacy and cost-effectiveness of different approaches compared with usual care. BA appears to be a promising, economical treatment for patients with comorbid

SUD-depression, but further research is needed to explore ways of improving maintenance of BA effects over time. One option could be to offer a rolling "BA maintenance group" after core BA treatment has finished. This approach would be consistent with popular mutual aid approaches in SUD treatment settings (Department of Health, 2017; Galanter et al., 2005). It would allow patients to access continuous booster sessions for as long as needed whilst minimising costs. Another option would be to explore computer-assisted BA therapy. Indeed, emerging evidence suggests that computer-assisted CBT is effective for SUD patients (Kiluk, 2019) with effects extending to 6-month follow-up (Carroll et al., 2008). Computer-assisted BA would notably place less burden on staff compared to traditional individual and group delivery approaches. However, research conducted with non-SUD samples suggests that guided self-help treatment formats may be less acceptable to patients and unguided self-help is no more effective than usual care (Cuijpers et al., 2019).

Regardless of which approach to BA delivery is tested, future trials should continue to adopt research designs relevant to implementation to ensure that findings can be more readily translated to SUD treatment settings. Curran et al.'s (2012) framework may be particularly beneficial for guiding future research in this area. They suggest that intervention research should begin with Type I effectiveness-implementation trials, which primarily emphasise establishing the effectiveness of an intervention using an experimental design and secondarily, understanding the context of implementation using a qualitative process evaluation. This stage of the research process is essentially represented in Chapters 3 and 4 of this thesis. Type II effectiveness-implementation trials are then warranted once enough information about intervention barriers and facilitators is obtained to inform implementation strategies. These trials place dual focus on testing the effectiveness of an intervention and exploring the feasibility and utility of implementation strategies. For example, based on findings from this thesis, potential implementation strategies for BA could include training staff to improve their attitudes towards the delivery of mental health interventions in SUD treatment. It may also be necessary to explore ways of training SUD treatment workers to deliver BA supervision to staff, as it would unlikely be feasible for qualified mental health professionals to provide supervision in routine care. Once viable implementation strategies have been identified, the final stage in the effectiveness-implementation framework is to conduct Type III trials. These trials primarily focus on comparing the effectiveness of different implementation strategies and secondarily, assessing clinical outcomes associated with implementation. According to Curran et al. (2012), systematically exploring

effectiveness and implementation outcomes simultaneously is expected to minimise the research-practice gap and have a more significant public health impact.

Consistent with recommendations in the MRC framework (Craig et al., 2008; Skivington et al., 2021), future trials should also investigate mediators of BA treatment effects. Some potential mechanisms of change include self-efficacy (with regards to reducing substance use or managing depressive symptoms), mindful attention and activity engagement. Engagement in valued activities appears to be particularly important and could be a potential mechanism of change in BA. However, the VQ questionnaire (Smout et al., 2014) used in Chapter 3 is a relatively new measure and it has not been validated with SUD populations. An unexpected finding in Chapter 3 was that progress in valued living increased over time in the usual care group, even though they had not received any specific intervention aimed at improving valued living. Therefore, it may be beneficial for research to explore the reliability and validity of this measure with SUD patients in more detail before it is explored as a mediator of BA treatment effects.

This project also found that the severity of dependence scale (Gossop et al., 1995) may be somewhat useful for identifying the initial severity of psychological dependence. However, it does not appear to be useful for measuring changes over time, especially if patients with severe dependence are excluded from RCTs. Therefore, it may be more useful for future trials to include negative consequences of substance use as a secondary substance use outcome instead. For example, the Short Inventory of Problems – Alcohol and Drugs (SIP-AD; Blanchard et al., 2003) assesses the occurrence and frequency of various personal, social and physical health consequences of alcohol and drug use. This measure was used in Daughters et al.'s (2018) study, with results indicating that BA was associated with significant reductions in negative consequences from substance use at 1-year follow-up compared to supportive counselling.

5.6 | Recommendations for future research

More RCTs are warranted to extend on the preliminary findings from this thesis and investigate the effectiveness of BA for SUD patients with comorbid depression. To begin with, fully powered RCTs following the Type I hybrid effectiveness-implementation format should be conducted (e.g. Curran et al, 2012). These trials should be designed to extend on the pilot trial reported in Chapter 3 and compare BA to TAU or a minimally active control

(e.g. signposting to self-help resources). An outpatient version of the LETS ACT! protocol (Daughters, Magidson, Lejuez & Chen, 2016) should be used as it currently has the most evidence for the treatment of this comorbidity, with the mindfulness component included to see if this is associated with increased maintenance of BA effects over time. BA treatment manuals and patient workbooks should be co-produced with CDAT staff and patients to help ensure their acceptability prior to testing. In addition to teaching drug and alcohol treatment workers BA theory, training may seek to address the comorbidity of depression and SUDs, reasons for providing integrated treatment and how to use BA manuals flexibly. It may be helpful to assess staff attitudes and self-efficacy pre- and post-training to establish the impact of training and identify any areas for improvement. Clinical supervision should be provided to BA therapists every 4-6 weeks in a group format. It may also be preferable for manualised BA to be delivered in a group format as this seems more likely to be suitable for eventual implementation, although it may also be useful to compare individual and group BA delivery to investigate whether there are any differences in efficacy and patient acceptability. Independent and self-reported adherence and competency ratings should be conducted for any BA interventions delivered.

Future trials should aim to include longer-term follow-ups and investigate ways of improving the maintenance of BA effects over time. For example, incorporating mindfulness and switching to group delivery of BA could potentially enhance maintenance of effects. Further options include offering a rolling "BA maintenance group" after core BA therapy has finished or exploring computer-assisted BA therapy, which could permit the flexible provision of BA treatment with minimal burden on staff (e.g. Caroll, 2021).

An additional priority for future Type I trials could be to investigate whether MI improves engagement with BA treatment. MI could be provided as a pre-treatment prior to commencing BA and delivered over the telephone (e.g. Zanjani et al. 2008) to reduce potential patient engagement issues and staff burden. Independent adherence and competency ratings should be completed for MI. Patient motivation to change and motivation to engage in BA should be assessed before and after MI pre-treatment. Detailed exploration is also needed into the characteristics of patients who drop out of MI pre-treatment and the BA intervention via regression analyses.

To address potential recruitment difficulties, studies should be conducted across multiple sites. Exclusion criteria should also be minimised and researchers may need to

approach potential participants directly. To minimise the possibility of research concerns affecting study recruitment or staff views on the acceptability of BA, extensive effort needs to be made to support SUD treatment staff to become accustomed to the research before and during participant recruitment. It may also be helpful for research to be co-produced with CDAT staff and patients where possible to promote a sense of ownership and ensure that the study design and materials are acceptable prior to trial implementation.

To ensure consistency and generalisability, all RCTs of BA for comorbid SUD-depression should use similar measures and report outcomes across a similar number and duration of follow-ups. Depression outcome should be measured using the PHQ-9 (Kroenke et al., 2001) or BDI-II (Beck et al., 1996) to be consistent with previous research on BA for comorbid SUD-depression. The primary substance use outcome should be Percent Days Abstinent (PDA) and a secondary substance use outcome could be negative consequences of substance use (SIP-AD; Blanchard et al., 2003). Studies should also continue to assess whether BA has any effect on anxiety symptoms (GAD-7; Spitzer et al., 2006). It would be preferable for outcomes to be assessed blindly to minimise potential bias. There should be multiple follow-up assessment points leading up to at least 6-month follow-up to assess the effects of BA over time. A follow-up that extends to one year would be particularly beneficial to assess longer term effects and permit comparability with Daughter et al.'s (2018) study. Studies should also include measures of functioning (e.g. hospital utilisation) to allow for assessments of the cost-effectiveness of BA for this population (Skivington et al., 2021).

All Type I effectiveness-implementation RCTs should include a qualitative process evaluation (Curran et al., 2012). These qualitative studies should include the experiences of BA staff and BA patients. Researchers should especially seek to interview patients who dropped out of BA treatment or did not demonstrate clinically significant change following the intervention. In order to recruit an adequate number of patients, qualitative studies should recruit throughout the trial. Qualitative interviews should preferably be conducted by an independent interviewer who does not have a prior relationship with staff or patients involved in the study. Information from qualitative interviews, along with recommendations in the Theoretical Domains Framework (TDF; Atkins et al., 2017) and Consolidated Framework for Implementation Research (CFIR; Damschroder & Hagedorn, 2011), can then be used to develop BA implementation strategies for Type II effectiveness-implementation RCTs. For example, if concern about drug and alcohol treatment workers' role in delivering mental health interventions continues to be identified as a barrier to BA implementation, Type II

trials could seek to test an implementation intervention that involves the modelling of BA delivery by a drug and alcohol treatment worker.

Qualitative data can also be used to inform mediation analyses of BA effects. Mediation studies should be conducted alongside all RCTs to establish the effective ingredients of BA for patients with comorbid SUD-depression. Potential mechanisms of change that currently warrant investigation include activation and progress in valued living. It would also be interesting to look at whether self-efficacy (with regard to reducing substance use or managing depressive symptoms), social impairment or support and mindful attention can help to explain BA effects on depression and substance use outcomes. Successful identification of mechanisms of change can then be used to refine the BA treatment protocol for testing in further trials.

5.7 | Conclusion

This thesis has examined the effectiveness and acceptability of BA for comorbid SUD-depression. The resulting findings have expanded the understanding of BA as a treatment for this comorbidity and provided novel insights into the potential value and challenges of integrating this intervention into routine CDAT settings.

Overall, the preliminary findings presented in this thesis demonstrate the utility of behavioural principles in the treatment of comorbid SUD-depression. However, effects were not maintained over time and certain factors were noted to impact the efficacy of BA in this patient group. Firstly, there was evidence that depression and substance use outcomes tended to improve independently in response to BA treatment, which may be due to variability in the symptom profiles of different patients. It was also evident that patient engagement with BA was necessary to achieve positive outcomes and that patients who were relatively stable and motivated were more likely to engage. The most favourable evidence for BA was based on studies that employed the LETS ACT! protocol (Daughters et al., 2016), with writing things down and activating values appearing to be particularly beneficial aspects of therapy for this patient group. BA did not appear to be more effective than other active treatments, but BA may still be a more attractive option than other psychotherapies due to its relative simplicity.

However, in terms of implementing BA in routine CDAT settings, findings suggest there may still be considerable challenges to overcome. Specifically, the low rate of patient

engagement with BA reduced its perceived efficacy and would likely deter staff from delivering the intervention in routine care. Also, evidence-based practice did not appear to be a priority for CDAT staff and they generally held unfavourable opinions of manualised treatments and delivery of mental health interventions by drug and alcohol treatment workers. These attitudes may reflect some of the broader issues afflicting the SUD treatment sector, such as lack of funding, unclear treatment guidelines and inadequate training provision.

Nevertheless, findings from this thesis provide preliminary evidence that brief, manualised BA can be effective for patients with comorbid SUD-depression who are ready to engage. Drug and alcohol treatment workers also appear to possess the requisite skills to learn and effectively deliver BA with this patient group. Therefore, further research is needed to investigate ways of improving patient engagement, in addition to extending the durability of BA effects over time. Research should also continue investigating BA implemented by drug and alcohol treatment workers and specifically explore strategies to facilitate BA delivery in routine care. More generally, systemic changes to the SUD treatment sector are warranted to facilitate research and help improve the implementation of evidence-based interventions in CDAT.

In conclusion, BA is a promising treatment for comorbid SUD-depression and delivery by drug and alcohol treatment workers could help to address an unmet mental health support need for patients accessing CDAT. The widespread implementation of BA in routine care may be unlikely in the near future, but the findings from this thesis are encouraging and insightful, laying the foundation for continued research exploring BA delivery in this context.

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APPENDICES

Appendix A. Meta-analysis search strategy (PubMed & PSYCinfo)

PubMed			
Behavioural Activation	**Depression**	**Addiction**	**Efficacy**
Behavior Therapy [mh:NoExp] Behavioural Activation*[tiab] Behavioral Activation*[tiab] Rewarding Activities [tw] Valued Activities [tw] Activity Scheduling [tw] Behavioural Intervention*[tiab] Behavioral Intervention*[tiab] Behavioural Therap*[tiab] Behavioral Therap*[tiab]	Depression [mh] Depressive disorder [mh] Depression*[tiab] Depressive*[tiab] Depressed*[tiab] Mood Disorder*[tiab] Depressive Disorder*[tiab] Depressive Symptoms*[tiab]	Substance-Related Disorders [mh] Alcoholism [mh] Heroin Dependence [mh] Opium Dependence [mh] Opioid-Related Disorders [mh] Marijuana Abuse [mh] Cocaine-Related Disorders [mh] Amphetamine-Related Disorders [mh] Tobacco Use Disorder [mh] Smoking Cessation [mh] Substance-Related Disorder*[tiab] Alcoholism*[tiab] Heroin Dependenc*[tiab] Opium Dependenc*[tiab] Opioid-Related Disorder*[tiab] Benzodiazepine*[tw] Tobacco*[tw] Methamphetamine* [tw] Substance Use Disorder*[tiab] Substance Abuse*[tiab] Drug Addiction*[tiab] Alcohol Use Disorder*[tiab]	Treatment Outcome [mh:NoExp] Clinical Study [mh] Effectiv* [tiab] Efficac* [tiab]

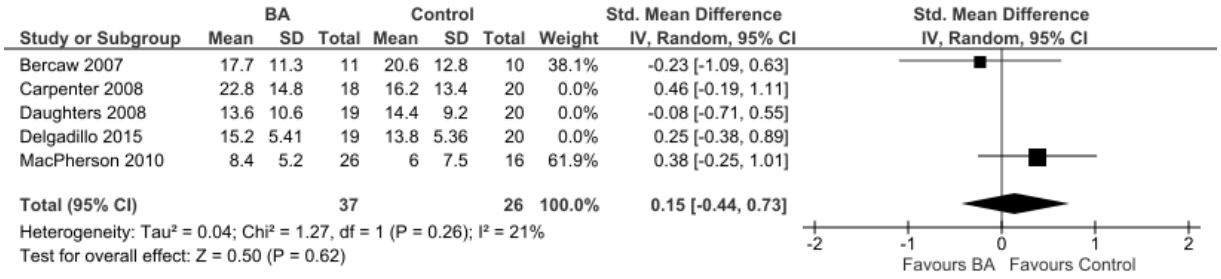
PSYCinfo			
Behavioural Activation	**Depression**	**Addiction**	**Efficacy**
Behavior Therapy/ Behavioural adj Activation.ti,ab Behavioral adj Activation.ti,ab Rewarding Activit*.tw Valued Activit.tw Activity Schedul*.tw Behavioural Intervention*.ti,ab Behavioral Intervention*.ti,ab Behavioural Therap*.ti,ab Behavioral Therap*.ti,ab	Exp Depression (emotion) Exp Major Depression Depression.ti,ab Depressive.ti,ab Depressed.ti,ab Mood Disorder.ti,ab Depressive Disorder.ti,ab Depressive Symptoms.ti,ab	Exp Drug Abuse Exp Drug Usage Exp Alcoholism Exp Heroin Addiction Tobacco Smoking/ Smoking Cessation/ Marijuana Abuse.tw Cannabis Use.tw Cocaine Use.tw Cocaine Addiction.ti,ab Substance Use Disorder*.ti,ab Alcoholism.ti,ab Heroin Dependenc*.ti,ab Opium Dependenc*.ti,ab Opioid-Related Disorder*.ti,ab Benzodiazepine*.tw Tobacco.tw Methamphetamine*.tw Substance Abuse.ti,ab Drug Addiction.ti,ab Alcohol Use Disorder*.ti,ab	Psychotherapeutic Outcomes/ Treatment effectiveness evaluation/ Clinical Trials/ Effectiv*.ti,ab Efficac*.ti,ab

Appendix B. Sensitivity analyses.

Depression Outcome

1. Comparisons of studies conducted with nicotine dependent samples only

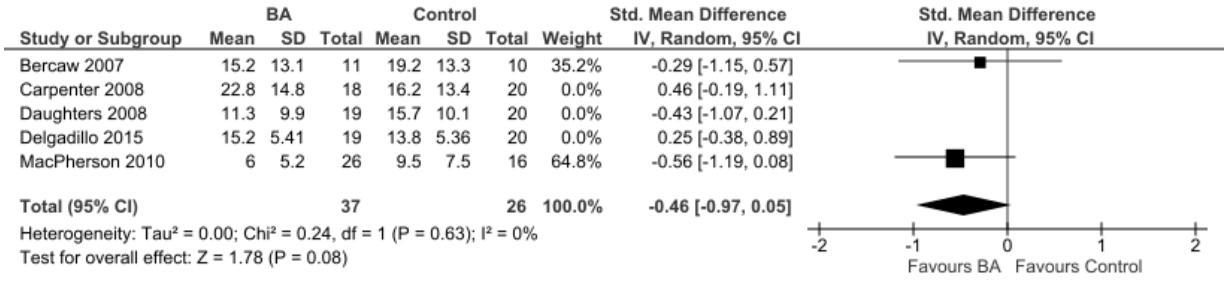
Post-Treatment Depression



Study or Subgroup	BA Mean	BA SD	BA Total	Control Mean	Control SD	Control Total	Weight	Std. Mean Difference IV, Random, 95% CI
Bercaw 2007	17.7	11.3	11	20.6	12.8	10	38.1%	-0.23 [-1.09, 0.63]
Carpenter 2008	22.8	14.8	18	16.2	13.4	20	0.0%	0.46 [-0.19, 1.11]
Daughters 2008	13.6	10.6	19	14.4	9.2	20	0.0%	-0.08 [-0.71, 0.55]
Delgadillo 2015	15.2	5.41	19	13.8	5.36	20	0.0%	0.25 [-0.38, 0.89]
MacPherson 2010	8.4	5.2	26	6	7.5	16	61.9%	0.38 [-0.25, 1.01]
Total (95% CI)			**37**			**26**	**100.0%**	**0.15 [-0.44, 0.73]**

Heterogeneity: Tau² = 0.04; Chi² = 1.27, df = 1 (P = 0.26); I² = 21%
Test for overall effect: Z = 0.50 (P = 0.62)

Follow-Up Depression

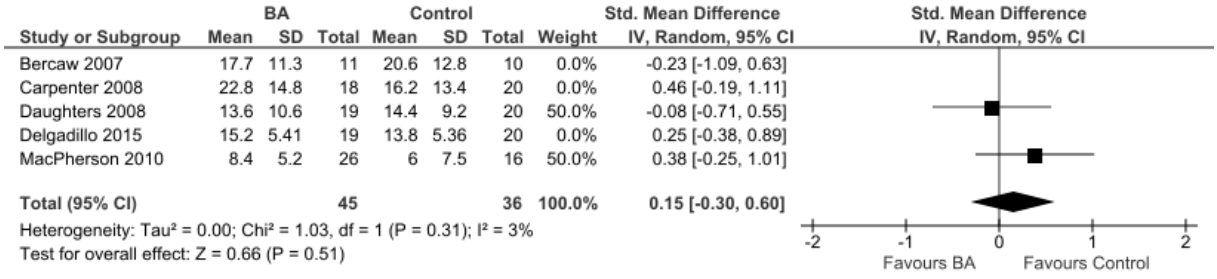


Study or Subgroup	BA Mean	BA SD	BA Total	Control Mean	Control SD	Control Total	Weight	Std. Mean Difference IV, Random, 95% CI
Bercaw 2007	15.2	13.1	11	19.2	13.3	10	35.2%	-0.29 [-1.15, 0.57]
Carpenter 2008	22.8	14.8	18	16.2	13.4	20	0.0%	0.46 [-0.19, 1.11]
Daughters 2008	11.3	9.9	19	15.7	10.1	20	0.0%	-0.43 [-1.07, 0.21]
Delgadillo 2015	15.2	5.41	19	13.8	5.36	20	0.0%	0.25 [-0.38, 0.89]
MacPherson 2010	6	5.2	26	9.5	7.5	16	64.8%	-0.56 [-1.19, 0.08]
Total (95% CI)			**37**			**26**	**100.0%**	**-0.46 [-0.97, 0.05]**

Heterogeneity: Tau² = 0.00; Chi² = 0.24, df = 1 (P = 0.63); I² = 0%
Test for overall effect: Z = 1.78 (P = 0.08)

2. Comparisons of studies that delivered group BA

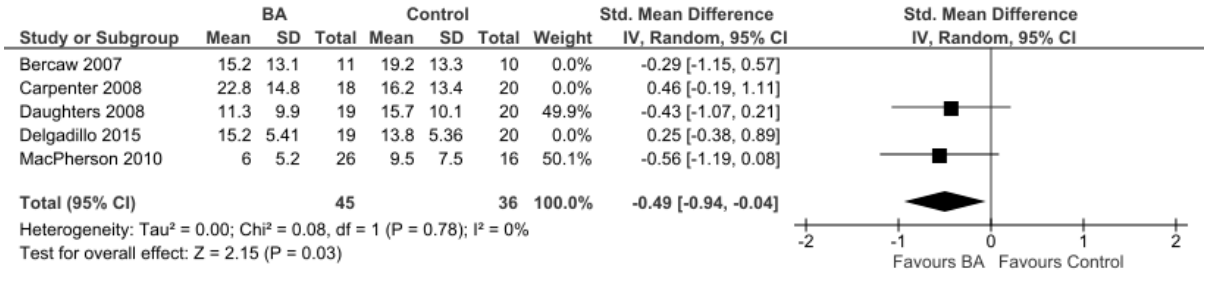
Post-Treatment Depression



Study or Subgroup	BA Mean	BA SD	BA Total	Control Mean	Control SD	Control Total	Weight	Std. Mean Difference IV, Random, 95% CI
Bercaw 2007	17.7	11.3	11	20.6	12.8	10	0.0%	-0.23 [-1.09, 0.63]
Carpenter 2008	22.8	14.8	18	16.2	13.4	20	0.0%	0.46 [-0.19, 1.11]
Daughters 2008	13.6	10.6	19	14.4	9.2	20	50.0%	-0.08 [-0.71, 0.55]
Delgadillo 2015	15.2	5.41	19	13.8	5.36	20	0.0%	0.25 [-0.38, 0.89]
MacPherson 2010	8.4	5.2	26	6	7.5	16	50.0%	0.38 [-0.25, 1.01]
Total (95% CI)			**45**			**36**	**100.0%**	**0.15 [-0.30, 0.60]**

Heterogeneity: Tau² = 0.00; Chi² = 1.03, df = 1 (P = 0.31); I² = 3%
Test for overall effect: Z = 0.66 (P = 0.51)

Follow-up Depression



Study or Subgroup	BA Mean	BA SD	BA Total	Control Mean	Control SD	Control Total	Weight	Std. Mean Difference IV, Random, 95% CI
Bercaw 2007	15.2	13.1	11	19.2	13.3	10	0.0%	-0.29 [-1.15, 0.57]
Carpenter 2008	22.8	14.8	18	16.2	13.4	20	0.0%	0.46 [-0.19, 1.11]
Daughters 2008	11.3	9.9	19	15.7	10.1	20	49.9%	-0.43 [-1.07, 0.21]
Delgadillo 2015	15.2	5.41	19	13.8	5.36	20	0.0%	0.25 [-0.38, 0.89]
MacPherson 2010	6	5.2	26	9.5	7.5	16	50.1%	-0.56 [-1.19, 0.08]
Total (95% CI)			**45**			**36**	**100.0%**	**-0.49 [-0.94, -0.04]**

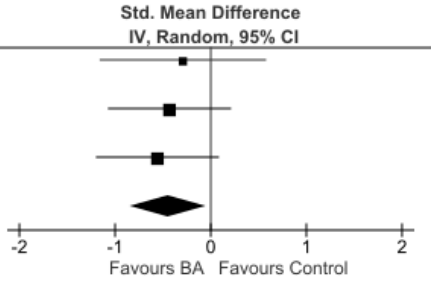
Heterogeneity: Tau² = 0.00; Chi² = 0.08, df = 1 (P = 0.78); I² = 0%
Test for overall effect: Z = 2.15 (P = 0.03)

3. Comparisons of studies that employed passive controls

Post-Treatment Depression

Study or Subgroup	BA Mean	BA SD	BA Total	Control Mean	Control SD	Control Total	Weight	Std. Mean Difference IV, Random, 95% CI
Bercaw 2007	15.2	13.1	11	19.2	13.3	10	21.4%	-0.29 [-1.15, 0.57]
Carpenter 2008	22.8	14.8	18	16.2	13.4	20	0.0%	0.46 [-0.19, 1.11]
Daughters 2008	11.3	9.9	19	15.7	10.1	20	39.3%	-0.43 [-1.07, 0.21]
Delgadillo 2015	15.2	5.41	19	13.8	5.36	20	0.0%	0.25 [-0.38, 0.89]
MacPherson 2010	6	5.2	26	9.5	7.5	16	39.4%	-0.56 [-1.19, 0.08]
Total (95% CI)			**56**			**46**	**100.0%**	**-0.45 [-0.85, -0.05]**

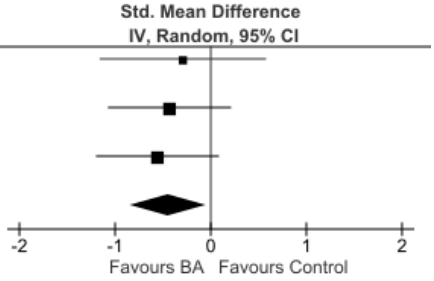
Heterogeneity: Tau² = 0.00; Chi² = 0.24, df = 2 (P = 0.89); I² = 0%
Test for overall effect: Z = 2.22 (P = 0.03)



Follow-up Depression

Study or Subgroup	BA Mean	BA SD	BA Total	Control Mean	Control SD	Control Total	Weight	Std. Mean Difference IV, Random, 95% CI
Bercaw 2007	15.2	13.1	11	19.2	13.3	10	21.4%	-0.29 [-1.15, 0.57]
Carpenter 2008	22.8	14.8	18	16.2	13.4	20	0.0%	0.46 [-0.19, 1.11]
Daughters 2008	11.3	9.9	19	15.7	10.1	20	39.3%	-0.43 [-1.07, 0.21]
Delgadillo 2015	15.2	5.41	19	13.8	5.36	20	0.0%	0.25 [-0.38, 0.89]
MacPherson 2010	6	5.2	26	9.5	7.5	16	39.4%	-0.56 [-1.19, 0.08]
Total (95% CI)			**56**			**46**	**100.0%**	**-0.45 [-0.85, -0.05]**

Heterogeneity: Tau² = 0.00; Chi² = 0.24, df = 2 (P = 0.89); I² = 0%
Test for overall effect: Z = 2.22 (P = 0.03)



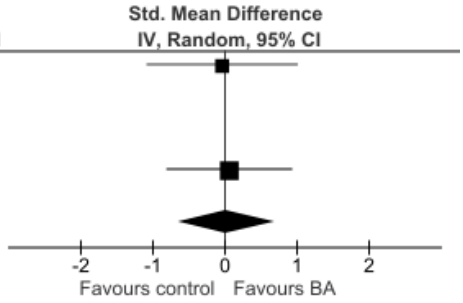
Substance Use Outcome

1. Comparisons of studies conducted with nicotine dependent samples and passive control comparators only (same sample)

Post-Treatment Substance Use

Study or Subgroup	Std. Mean Difference	SE	Weight	Std. Mean Difference IV, Random, 95% CI
Bercaw 2007	-0.04	0.53	40.8%	-0.04 [-1.08, 1.00]
Carpenter 2008	-0.29	0.33	0.0%	-0.29 [-0.94, 0.36]
Daughters 2008	0	0		Not estimable
Delgadillo 2015	0.64	0.29	0.0%	0.64 [0.07, 1.21]
MacPherson 2010	0.06	0.44	59.2%	0.06 [-0.80, 0.92]
Total (95% CI)			**100.0%**	**0.02 [-0.64, 0.68]**

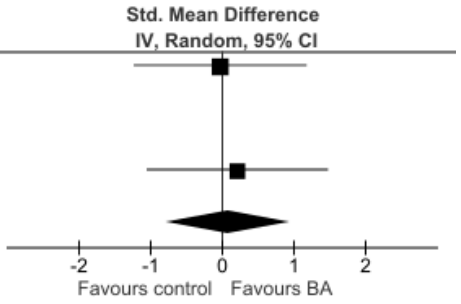
Heterogeneity: Tau² = 0.00; Chi² = 0.02, df = 1 (P = 0.88); I² = 0%
Test for overall effect: Z = 0.06 (P = 0.95)



Follow-up Substance Use

Study or Subgroup	Std. Mean Difference	SE	Weight	Std. Mean Difference IV, Random, 95% CI
Bercaw 2007	-0.03	0.61	52.4%	-0.03 [-1.23, 1.17]
Carpenter 2008	-0.29	0.33	0.0%	-0.29 [-0.94, 0.36]
Daughters 2008	0	0		Not estimable
Delgadillo 2015	0.64	0.29	0.0%	0.64 [0.07, 1.21]
MacPherson 2010	0.21	0.64	47.6%	0.21 [-1.04, 1.46]
Total (95% CI)			**100.0%**	**0.08 [-0.78, 0.95]**

Heterogeneity: Tau² = 0.00; Chi² = 0.07, df = 1 (P = 0.79); I² = 0%
Test for overall effect: Z = 0.19 (P = 0.85)



Appendix C. Evidence of ethical approval for two empirical studies in Chapters 3 & 4 (letter confirming ethical approval, amendment documentation).

Health Research Authority letter confirming ethical approval for studies conducted in Chapter 3 & 4.

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

NHS
Health Research Authority

Dr Jaime Delgadillo
University of Sheffield, Department of Psychology
Floor F, Cathedral Court, 1 Vicar Lane
Sheffield
S1 2LT

Email: hra.approval@nhs.net
Research-permissions@wales.nhs.uk

07 September 2018

Dear Dr Delgadillo

HRA and Health and Care Research Wales (HCRW) Approval Letter

Study title:	**Integrating Behavioural Activation for Depression into Community Drugs and Alcohol Treatment: A Mixed-Methods Randomised Controlled Trial**
IRAS project ID:	**247888**
Protocol number:	**URMS no: 157527**
REC reference:	**18/NE/0222**
Sponsor	**University of Sheffield**

I am pleased to confirm that **HRA and Health and Care Research Wales (HCRW) Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

How should I continue to work with participating NHS organisations in England and Wales?
You should now provide a copy of this letter to all participating NHS organisations in England and Wales, as well as any documentation that has been updated as a result of the assessment.

Following the arranging of capacity and capability, participating NHS organisations should **formally confirm** their capacity and capability to undertake the study. How this will be confirmed is detailed in the "*summary of assessment*" section towards the end of this letter.

You should provide, if you have not already done so, detailed instructions to each organisation as to how you will notify them that research activities may commence at site following their confirmation of capacity and capability (e.g. provision by you of a 'green light' email, formal notification following a site initiation visit, activities may commence immediately following confirmation by participating organisation, etc.).

It is important that you involve both the research management function (e.g. R&D office) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details of the research management function for each organisation can be accessed here.

How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?
HRA and HCRW Approval does not apply to NHS/HSC organisations within the devolved administrations of Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report (including this letter) has been sent to the coordinating centre of each participating nation. You should work with the relevant national coordinating functions to ensure any nation specific checks are complete, and with each site so that they are able to give management permission for the study to begin.

Please see IRAS Help for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

How should I work with participating non-NHS organisations?
HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to obtain local agreement in accordance with their procedures.

What are my notification responsibilities during the study?
The document "*After Ethical Review – guidance for sponsors and investigators*", issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

I am a participating NHS organisation in England or Wales. What should I do once I receive this letter?
You should work with the applicant and sponsor to complete any outstanding arrangements so you are able to confirm capacity and capability in line with the information provided in this letter.

The sponsor contact for this application is as follows:

Name: Dr Thomas Webb
Tel: (0)114 222 4705
Email: T.Webb@sheffield.ac.uk

Who should I contact for further information?
Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is **247888**. Please quote this on all correspondence.

IRAS project ID	247888

Yours sincerely

Aliki Sifostratoudaki
Assessor

Email: hra.approval@nhs.net

Copy to: *Dr Thomas Webb, University of Sheffield, Sponsor Contact*
Ms Jeannie McKie, Rotherham Doncaster & South Humber NHS Trust, R&D Contact

Notification of substantial amendment to research protocol

The University Of Sheffield.

Department Of Psychology
Clinical Psychology Unit

Clinical Psychology Unit
Department of Psychology
University of Sheffield
Floor F, Cathedral Court
1 Vicar Lane
Sheffield S1 2LT

13th March 2019

Mr Chris Turnock, Chair of REC
North East - York Research Ethics Committee
NHSBT Newcastle Blood Donor Centre
Holland Drive
Newcastle upon Tyne
NE2 4NQ

Study Title: Integrating Behavioural Activation for Depression into Community Drugs and Alcohol Treatment: A Mixed-Methods Randomised Controlled Trial
REC reference: 18/NE/0222
Protocol number: URMS no: 157527
IRAS project ID: 247888

Mr Turnock

Since the above study commenced on 12th September 2018 we have had some issues with recruitment as shown in the CONSORT diagram attached. Following feedback from staff and service users at Aspire drugs and alcohol service we have agreed that the following changes, which are described in the IRAS amendment dated 06/03/19, will help to improve recruitment and strengthen the methodology of the study:

1. Inclusion of OST clients who are not using illicit substances
There are a large number of clients in treatment at Aspire who have been identified as having low mood and are receiving opiate substitution therapy (OST) but no longer use illicit substances. We are currently excluding these clients from the study; however, research has indicated that BA may be of particular benefit to clients who are maintained on OST (e.g. Carpenter et al., 2004) and given that these clients are still dependent on a substance there is no reason not to include them in the study. We are therefore proposing to expand the eligibility criteria to include OST clients who have not used illicitly in the past month. This will increase the number of potential participants who can take part in the study which is expected to improve recruitment.

2. Inclusion of 'Percent Dose Reduction' as an additional outcome measure
Since we are planning to include OST clients who are not using illicitly in the study, we would like to measure substance use in terms of Percent Dose Reduction as well as Percent Days Abstinent for all participants who are on OST (whether using illicitly or not). If participants report being prescribed OST medication during the baseline assessment their dose will continue to be recorded at every follow-up. Percent dose reduction will be calculated based on the dose the participant was prescribed at baseline. This will allow us to measure the effectiveness of the BA intervention in terms of another important goal of addictions treatment, which is to reduce people's reliance on OST with the aim of completing a detox and re-integrating into the community.

3. Participant incentives for screening
In order to mitigate any potential burden on clients and to improve screening rates, we would like to offer a financial incentive to all participants who complete eligibility screening. The proposed incentive will be a community leisure pass voucher worth approximately £8. We have chosen to offer a leisure pass voucher rather than shopping vouchers to better fit with the study's aim of improving people's health and wellbeing.

4. Participant incentives for study completion
In order to improve follow-up rates, we are also proposing to offer an incentive to participants who complete all follow-up assessments in the study. The proposed incentive will be that participants in both treatment conditions are entered into a prize draw to win a bike worth approximately £100 once they have completed their final follow-up assessment at 24 weeks post-randomisation. Again, we selected a bike as the prize to fit with the overall aims of the study.

5. Staff Incentives
To mitigate any burden that staff may feel from being involved in the study and to encourage staff to screen clients and make referrals, we are proposing to offer an incentive up to the value of £25 (chocolates or high street shopping vouchers) to staff members who have made the most referrals to the study each month.

6. Strategy for identifying potential participants
Instead of the study co-ordinator completing regular clinical audits to identify potential participants and then notifying staff to screen these clients with the PHQ-9, which staff at Aspire have reported is burdensome and inefficient, we are proposing to embed the stepwise mental health screening strategy into routine practice. Staff will complete the TOP measure as usual with clients every 3 months, if a client scores < 12 they will be screened with the PHQ-9, if the client scores > 12 on the PHQ-9 they will be approached about the study. The study co-ordinator will continue to complete regular database audits to ensure that all potentially eligible clients are being screened to reduce the possibility of selection bias. This strategy is expected to improve recruitment by reducing the chance that staff will forget to screen a client with the PHQ-9 due to clients not attending appointments regularly etc.

7. Recruitment Poster / Flyer
In order to facilitate clients' awareness of the study and to help remind staff to screen and refer clients, we are proposing to advertise the study in the service via posters and flyers. We expect that this will improve recruitment by reminding staff about the study and making it easier for them to approach clients about the study.

8. Participant Engagement Questionnaire
In addition to BA case managers completing the Session Adherence Monitoring forms after each BA session, we would like to include a therapist-rated participant engagement questionnaire. Staff delivering the BA intervention will complete a questionnaire at the end of each session indicating how well the participant engaged in the session, with the questions for each session highlighting specific session objectives (e.g. completion of assignments), comprehension of session content and participation in the session. This measure has been specifically developed for the project and will allow us to evaluate how well participants engaged in the BA sessions. This will be relevant to our interpretation of the results and determining the overall efficacy of the intervention.

9. Participant Information Sheet
Finally, we have edited the Participant Information sheet to make it clearer that participants are required to complete eligibility screening to confirm if they are eligible to take part in the study. This point was not clearly explained on the information sheet previously. The participant information sheet (V10, 12/03/19) has also been updated to include information about screening and study completion incentives. The Participant consent form has been updated to reflect the new Version number of the revised PIS.

The full list of updated documents that have been attached in the IRAS checklist is described below. Please let us know if you require any further information. We look forward to hearing from you soon regarding your decision.

Kind Regards,

Jaime Delgadillo, PhD
(Chief Investigator)

Clinical Psychology Unit
University of Sheffield

New documents attached to IRAS project checklist:

Trial Protocol (V10, 11/02/19)
Participant Information Sheet (V10, 12/03/19)
Participant Consent Form (V10, 12/03/19)
Recruitment Poster / Flyer (V1, 11/02/19)
Therapist-Rated Participant Engagement (V1, 11/02/19)

Confirmation of HRA approval for substantial amendment

From: "YORK, Nrescommitteenortheast- (HEALTH RESEARCH AUTHORITY)" <nrescommittee.northeast-york@nhs.net>
To: "j.delgadillo@sheffield.ac.uk" <j.delgadillo@sheffield.ac.uk>, "T.Webb@sheffield.ac.uk" <T.Webb@sheffield.ac.uk>
Cc:
Bcc:
Date: Thu, 18 Apr 2019 09:25:00 +0000
Subject: IRAS Project ID 247888. HRA Approval for the Amendment

Dear Dr Delgadillo,

IRAS Project ID:	247888
Short Study Title:	BA Trial for Co-occurring Depression and Substance Use
Amendment No./Sponsor Ref:	Substantial Amendment 1, 06/03/2019
Amendment Date:	21 March 2019
Amendment Type:	Substantial Non-CTIMP

I am pleased to confirm **HRA and HCRW Approval** for the above referenced amendment.

You should implement this amendment at NHS organisations in England and Wales, in line with the conditions outlined in your categorisation email.

Please contact hra.amendments@nhs.net for any queries relating to the assessment of this amendment.

Kind regards

Mr Michael Higgs

Approvals Specialist

Health Research Authority

Ground Floor | Skipton House | 80 London Road | London | SE1 6LH

E.hra.amendments@nhs.net

Notification of non-substantial amendment to research protocol (NSA2)

Partner Organisations:
Health Research Authority, England
NIHR Clinical Research Network, England
NHS Research Scotland
NISCHR Permissions Co-ordinating Unit, Wales
HSC Research & Development, Public Health Agency, Northern Ireland

Notification of Non-Substantial/Minor Amendments(s) for NHS Studies

This template **must only** be used to notify NHS/HSC R&D office(s) of amendments, which are **NOT** categorised as Substantial Amendments.
If you need to notify a Substantial Amendment to your study then you MUST use the appropriate Substantial Amendment form in IRAS.

Instructions for using this template

- For guidance on amendments refer to http://www.hra.nhs.uk/research-community/during-your-research-project/amendments/
- This template should be completed by the CI and optionally authorised by Sponsor, if required by sponsor guidelines.
- This form should be submitted according to the instructions provided for NHS/HSC R&D at http://www.hra.nhs.uk/research-community/during-your-research-project/amendments/which-review-bodies-need-to-approve-or-be-notified-of-which-types-of-amendments/ . If you do not submit your notification in accordance with these instructions then processing of your submission may be significantly delayed.

1. Study Information

Full title of study:	Integrating Behavioural Activation for Depression into Community Drugs and Alcohol Treatment: A Mixed-Methods Randomised Controlled Trial
IRAS Project ID:	247888
Sponsor Amendment Notification number:	NSA2
Sponsor Amendment Notification date:	27/07/2019
Details of Chief Investigator:	
Name [first name and surname]	Jaime Delgadillo
Address:	University of Sheffield, Department of Psychology, Cathedral Court, 1 Vicar Lane, Sheffield
Postcode:	S1 2LT
Contact telephone number:	0114 2226614
Email address:	j.delgadillo@sheffield.ac.uk
Details of Lead Sponsor:	
Name:	Thomas Webb
Contact email address:	t.webb@sheffield.ac.uk
Details of Lead Nation:	
Name of lead nation *delete as appropriate*	England
If England led is the study going through CSP? *delete as appropriate*	No
Name of lead R&D office:	RDaSH Grounded Research

2. Summary of amendment(s)

This template **must only** be used to notify NHS/HSC R&D office(s) of amendments, which are **NOT** categorised as Substantial Amendments.
If you need to notify a Substantial Amendment to your study then you MUST use the appropriate Substantial Amendment form in IRAS.

No.	Brief description of amendment *(please enter each separate amendment in a new row)*	Amendment applies to *(delete/ list as appropriate)*		List relevant supporting document(s), including version numbers *(please ensure all referenced supporting documents are submitted with this form)*		R&D category of amendment *(category A, B, C) For office use only*
		Nation	**Sites**	**Document**	**Version**	
1	The study coordinator will contact clients within 21 days instead of one week for eligibility screening, and this will be conducted in person or over the phone. This change is necessary to make the best use of the research team's time. Trial protocol and PIS have been amended to reflect this change. Participants will receive a bus pass worth approx. £5 upon completion of eligibility screening instead of a leisure voucher. This is because the leisure voucher was not suitable for many participants. Trial protocol, PIS and Recruitment Poster have been amended to reflect this. The consent form has been updated to correspond with the date on the new PIS.	England	All sites or list affected sites	Trial Protocol Participant Information Sheet Recruitment Poster – Flyer Participant Consent Form	11 12 3 12	
		Northern Ireland	All sites or list affected sites			
		Scotland	All sites or list affected sites			
		Wales	All sites or list affected sites			
2						
3						
4						
5						

[Add further rows as required]

Confirmation of HRA approval for non-substantial amendment (NSA2)

Amendment Categorisation and Implementation Information

Dear Dr Delgadillo,

IRAS Project ID:	247888
Short Study Title:	BA Trial for Co-occurring Depression and Substance Use
Date complete amendment submission received:	5 December 2019
Amendment No./ Sponsor Ref:	Non-Substantial Amendment 2, 24/11/2019
Amendment Date:	25 November 2019
Amendment Type:	Non-substantial
Outcome of HRA and HCRW Assessment	**This email also constitutes HRA and HCRW Approval for the amendment,** and you should not expect anything further.
Implementation date in NHS organisations in England and Wales	35 days from date amendment information together with this email, is supplied to participating organisations **(providing conditions are met)**
For NHS/HSC R&D Office information	
Amendment Category	**A**

Thank you for submitting an amendment to your project. We have now categorised your amendment and please find this, as well as other relevant information, in the table above.

Please do not hesitate to contact me if you require further information.

Kind regards

Miss Donna Bennett

Approvals Administrator

Health Research Authority

Notification of non-substantial amendment to research protocol (NSA3)

Notification of Non-Substantial/Minor Amendments(s) for NHS Studies

This template **must only** be used to notify NHS/HSC R&D office(s) of amendments, which are **NOT** categorised as Substantial Amendments.
If you need to notify a Substantial Amendment to your study then you MUST use the appropriate Substantial Amendment form in IRAS.

Instructions for using this template

- For guidance on amendments refer to http://www.hra.nhs.uk/research-community/during-your-research-project/amendments/
- This template should be completed by the CI and optionally authorised by Sponsor, if required by sponsor guidelines.
- This form should be submitted according to the instructions provided for NHS/HSC R&D at http://www.hra.nhs.uk/research-community/during-your-research-project/amendments/which-review-bodies-need-to-approve-or-be-notified-of-which-types-of-amendments/ . If you do not submit your notification in accordance with these instructions then processing of your submission may be significantly delayed.

1. Study Information

Full title of study:	Integrating Behavioural Activation for Depression into Community Drugs and Alcohol Treatment: A Mixed-Methods Randomised Controlled Trial
IRAS Project ID:	247888
Sponsor Amendment Notification number:	NSA3
Sponsor Amendment Notification date:	26/03/20
Details of Chief Investigator:	
Name [first name and surname]	Jaime Delgadillo
Address:	University of Sheffield, Department of Psychology, Cathedral Court, 1 Vicar Lane, Sheffield
Postcode:	S1 2LT
Contact telephone number:	0114 2226614
Email address:	j.delgadillo@sheffield.ac.uk
Details of Lead Sponsor:	
Name:	Thomas Webb
Contact email address:	t.webb@sheffield.ac.uk
Details of Lead Nation:	
Name of lead nation *delete as appropriate*	England
If England led is the study going through CSP? *delete as appropriate*	No
Name of lead R&D office:	RDaSH Grounded Research

Partner Organisations:
Health Research Authority, England NIHR Clinical Research Network, England
NHS Research Scotland NISCHR Permissions Co-ordinating Unit, Wales
HSC Research & Development, Public Health Agency, Northern Ireland

2. Summary of amendment(s)

This template **must only** be used to notify NHS/HSC R&D office(s) of amendments, which are **NOT** categorised as Substantial Amendments.
If you need to notify a Substantial Amendment to your study then you MUST use the appropriate Substantial Amendment form in IRAS.

No.	Brief description of amendment *(please enter each separate amendment in a new row)*	Amendment applies to *(delete/ list as appropriate)*		List relevant supporting document(s), including version numbers *(please ensure all referenced supporting documents are submitted with this form)*		R&D category of amendment *(category A, B, C) For office use only*
		Nation	**Sites**	**Document**	**Version**	
1	BA treatment may be delivered in person or over the phone Trial Protocol has been updated to reflect this change	England	All sites or list affected sites	Trial Protocol	13	
		Northern Ireland	All sites or list affected sites			
		Scotland	All sites or list affected sites			
		Wales	All sites or list affected sites			
2						
3						
4						

[Add further rows as required]

Confirmation of HRA approval for non-substantial amendment (NSA3)

MCKIE, Jeannie (ROTHERHAM DONCASTER AND SOUTH HUMBER NHS FOUNDATION TRUST 2 Apr 2020, 12:55

to me, Jaime, Thomas

Dear Sophie,

Study Title: Integrating Behavioural Activation for Depression into Community Drugs and Alcohol Treatment: A Mixed-Methods Randomised Controlled Trial

REC Reference: 18/NE/0222

IRAS ID: 247888

Amendment description: Protocol v13, to allow telephone and face to face BA treatment

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This email confirms that **Rotherham Doncaster & South Humber NHS Trust** (RDaSH) has completed a review of this amendment to the above study.

I confirm continued capacity and capability for the study to be undertaken within the Trust.

Please ensure a copy of this letter is filed in the Master Study File.

I would like to take this opportunity to wish you well with your project. If you have any questions or we can be of any further assistance to you, do not hesitate to contact Grounded Research.

Kinds regards
Jeannie

Jeannie McKie

Research Governance Manger

Grounded Research Team, Community Research Hub, RDaSH NHS FT

Notification of non-substantial amendment to research protocol (NSA4)

Amendment Tool
v1.1 22 May 2020

For office use
QC: No

Section 1: Project information

Short project title*:	BA Trial for Co-Occurring Depression and Substance Use
IRAS project ID* (or REC reference if no IRAS project ID is available):	247888
Sponsor amendment reference number*:	NSA 4
Sponsor amendment date* (enter as DD/MM/YY):	11 June 2020
Summary of amendment including justification*:	We are amending the qualitative component of the study to include interviews with BA supervisors, the drugs and alcohol service manager and the developer of the BA treatment manual in order to gain a more comprehensive understanding of the acceptability and feasibility of the treatment and training protocol.

Project type:	◉ Specific study ○ Research tissue bank ○ Research database	
Has the study been reviewed by a UKECA-recognised Research Ethics Committee (REC) prior to this amendment?:	◉ Yes	○ No
What type of UKECA-recognised Research Ethics Committee (REC) review is applicable?:	◉ NHS/HSC REC ○ Ministry of Defence (MoDREC)	
Is all or part of this amendment being resubmitted to the Research Ethics Committee (REC) as a modified amendment?:	○ Yes	◉ No

Where is the NHS/HSC Research Ethics Committee (REC) that reviewed the study based?:	England	Wales	Scotland	Northern Ireland
	◉	○	○	○

Was the study a clinical trial of an investigational medicinal product (CTIMP) OR does the amendment make it one?:	○ Yes	◉ No
Was the study a clinical investigation or other study of a medical device OR does the amendment make it one?:	○ Yes	◉ No
Did the study involve the administration of radioactive substances, therefore requiring ARSAC review, OR does the amendment introduce this?:	○ Yes	◉ No
Did the study involve the use of research exposures to ionising radiation (not involving the administration of radioactive substances) OR does the amendment introduce this?:	○ Yes	◉ No
Did the study involve adults lacking capacity OR does the amendment introduce this?:	○ Yes	◉ No
Did the study involve access to confidential patient information without consent OR does the amendment introduce this?:	○ Yes	◉ No
Did the study involve prisoners OR does the amendment introduce this?:	○ Yes	◉ No
Did the study involve NHS/HSC organisations prior to this amendment?:	◉ Yes	○ No
Did the study involve non-NHS/HSC organisations OR does the amendment introduce them?:	○ Yes	◉ No

	England	Wales	Scotland	Northern Ireland
Lead nation for the study:	◉	○	○	○
Which nations had participating NHS/HSC organisations prior to this amendment?	☐	☐	☐	☐
Which nations will have participating NHS/HSC organisations after this amendment?	☐	☐	☐	☐

Section 2: Summary of change(s)

Please note: Each change being made as part of the amendment must be entered separately. For example, if an amendment to a clinical trial of an investigational medicinal product (CTIMP) involves an update to the Investigator's Brochure (IB), affecting the Reference Safety Information (RSI) and so the information documents to be given to participants, these should be entered into the amendment tool as three separate changes. A list of all possible changes is available on the "Glossary of Changes" tab. To add another change, tick the "Add another change" box.

Change 1	
Area of change (select)*:	Study Documents
Specific change (select - only available when area of change is selected first)*:	Other minor document change that can be implemented within existing resource in place at participating organisations - Please specify in the free text below
Further information (free text):	Staff PIS for interview updated to include BA supervisors, CDAT service manager and developer of treatment manual. Consent form updated to reflect new version/date of PIS. All changes highlighted.

Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	☑	☐	☐	☐
Will all participating NHS/HSC organisations be affected by this change, or only some?:	◉ All		○ Some	

Add another change: ☑

Change 2	
Area of change (select)*:	Study Documents
Specific change (select - only available when area of change is selected first)*:	Other minor document change that can be implemented within existing resource in place at participating organisations - Please specify in the free text below
Further information (free text):	Trial protocol updated to reflect change to qualitative component of study

Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	☑	☐	☐	☐
Will all participating NHS/HSC organisations be affected by this change, or only some?:	◉ All		○ Some	

Add another change: ☐

Section 3: Declaration(s) and look for submission

Declaration by the Sponsor or authorised delegate

- I confirm that the Sponsor takes responsibility for the completed amendment tool
- I confirm that I have been formally authorised by the Sponsor to complete the amendment tool on their behalf

Name [first name and surname]:*	Jaime Delgadillo
*Email address**:	j.delgadillo@sheffield.ac.uk

Look for submission

Please note: This button will only become available when all mandatory (*) fields have been completed. When the button is available, clicking it will generate a PDF copy of the completed amendment tool that can be included in the amendment submission. Please ensure that the amendment tool is completed correctly before locking it for submission.

Look for submission

Section 4: Review bodies for the amendment

Please note: This section is for **information only**. Details in this section will complete automatically based on the options selected in Sections 1 and 2.

	Review bodies																	
	UK wide:						England and Wales:				Scotland:				Northern Ireland:				
	REC	Competent Authority MHRA - Medicines	Competent Authority MHRA - Devices	ARSAC	Radiation Assurance	UKSW Governance	REC (MCA)	CAG	RMPPS	HRA and HCRW Approval	REC (AWA)	PBPP	SPS (RAEC)	National coordinating function	HSC REC	HSC Data Guardians	Prisons	National coordinating function	Category:
Change 1:						(Y)				(Y)									C
Change 2:						(Y)				(Y)									C
Overall reviews for the amendment:																			
Full review:						N				N									
Notification only:						Y				Y									
Overall amendment type:	Non-substantial, no study-wide review required																		
Overall Category:	C																		

Notification of non-substantial amendment to research protocol (NSA5)

Amendment Tool
v1.1 22 May 2020

For office use
QC: No

Section 1: Project information

Short project title*:	BA trial for co-occurring depression and substance use			
IRAS project ID* (or REC reference if no IRAS project ID is available):	247888			
Sponsor amendment reference number*:	NSA 5			
Sponsor amendment date* (enter as DD/MM/YY):	30 September 2020			
Summary of amendment including justification*:	Due to COVID-19, trial participants will only be required to provide verbal consent to take part in the interview substudy and will not be asked to return signed consent forms.			
Project type:	● Specific study ○ Research tissue bank ○ Research database			
Has the study been reviewed by a UKECA-recognised Research Ethics Committee (REC) prior to this amendment?:	● Yes	○ No		
What type of UKECA-recognised Research Ethics Committee (REC) review is applicable?:	● NHS/HSC REC ○ Ministry of Defence (MoDREC)			
Is all or part of this amendment being resubmitted to the Research Ethics Committee (REC) as a modified amendment?	○ Yes	● No		
Where is the NHS/HSC Research Ethics Committee (REC) that reviewed the study based?:	England: ●	Wales: ○	Scotland: ○	Northern Ireland: ○
Was the study a clinicial trial of an investigational medicinal product (CTIMP) OR does the amendment make it one?:	○ Yes	● No		
Was the study a clinical investigation or other study of a medical device OR does the amendment make it one?:	○ Yes	● No		
Did the study involve the administration of radioactive substances, therefore requiring ARSAC review, OR does the amendment introduce this?:	○ Yes	● No		
Did the study involve the use of research exposures to ionising radiation (not involving the administration of radioactive substances) OR does the amendment introduce this?:	○ Yes	● No		
Did the study involve adults lacking capacity OR does the amendment introduce this?:	○ Yes	● No		
Did the study involve access to confidential patient information without consent OR does the amendment introduce this?:	○ Yes	● No		
Did the study involve prisoners OR does the amendment introduce this?:	○ Yes	● No		
Did the study involve NHS/HSC organisations prior to this amendment?:	● Yes	○ No		
Did the study involve non-NHS/HSC organisations OR does the amendment introduce them?:	○ Yes	● No		
	England	Wales	Scotland	Northern Ireland
Lead nation for the study:	●	○	○	○
Which nations had participating NHS/HSC organisations prior to this amendment?	☐	☐	☐	☐
Which nations will have participating NHS/HSC organisations after this amendment?	☐	☐	☐	☐

Section 2: Summary of change(s)

Please note: Each change being made as part of the amendment must be entered separately. For example, if an amendment to a clinical trial of an investigational medicinal product (CTIMP) involves an update to the Investigator's Brochure (IB), affecting the Reference Safety Information (RSI) and so the information documents to be given to participants, these should be entered into the amendment tool as three separate changes. A list of all possible changes is available on the "Glossary of Changes" tab. To add another change, tick the "Add another change" box.

Change 1					
Area of change (select)*:	Participant Procedures				
Specific change (select - only available when area of change is selected first)*:	Procedures - Change to the procedures undertaken by participants where there is no increased risk to the participant (e.g. changing site visits to phone calls or postal questionnaires)				
Further information (free text):	Due to the Covid-19 pandemic recruitment to this study stopped and contact with participants was conducted by telephone. As it was not possible meet face to face, for the interview subgroup, consent was obtained verbally. They were sent the PIS and ICF beforehand and had the opportunity to ask questions before giving consent.				
Applicability:		**England**	**Wales**	**Scotland**	**Northern Ireland**
Where are the participating NHS/HSC organisations located that will be affected by this change?*:		☒	☐	☐	☐

Will all participating NHS/HSC organisations be affected by this change, or only some?:	● All	○ Some

Add another change: ☐

Section 3: Declaration(s) and lock for submission

Declaration by the Sponsor or authorised delegate

- I confirm that the Sponsor takes responsibility for the completed amendment tool
- I confirm that I have been formally authorised by the Sponsor to complete the amendment tool on their behalf

*Name [first name and surname]**:	Sophie Pott
*Email address**:	slpott1@sheffield.ac.uk

Lock for submission

Please note: This button will only become available when all mandatory (*) fields have been completed. When the button is available, clicking it will generate a PDF copy of the completed amendment tool that can be included in the amendment submission. Please ensure that the amendment tool is completed correctly before locking it for submission.

Lock for submission

Section 4: Review bodies for the amendment

Please note: This section is for **information only**. Details in this section will complete automatically based on the options selected in Sections 1 and 2.

	Review bodies																	
	UK wide:						England and Wales:				Scotland:				Northern Ireland:			
	REC	Competent Authority MHRA - Medicines	Competent Authority MHRA - Devices	ARSAC	Radiation Assurance	UKSW Governance	REC (MCA)	CAG	HMPPS	HRA and HCRW Approval	REC (AWIA)	PBPP	SPS (RAEC)	National coordinating function	HSC REC	HSC Data Guardians	Prisons	National coordinating function	Category:
Change 1:	(Y)																		C
Overall reviews for the amendment:																			
Full review:	N																		
Notification only:	Y																		
Overall amendment type:	Non-substantial																		
Overall Category:	C																		

Confirmation of HRA approval for non-substantial amendment (NSA5)

noreply@harp.org.uk

16 Oct 2020, 14:33

to j.delgadillo, T.Webb, me

Dear Dr Delgadillo,

IRAS Project ID:	247888
Short Study Title:	BA Trial for Co-occurring Depression and Substance Use
Amendment No./Sponsor Ref:	NSA 5
Amendment Date:	30 September 2020
Amendment Type:	Non Substantial Non-CTIMP

I am pleased to confirm **HRA and HCRW Approval** for the above referenced amendment.

You should implement this amendment at NHS organisations in England and Wales, in line with the guidance in the amendment tool.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/.

Please contact amendments@hra.nhs.uk for any queries relating to the assessment of this amendment.

Kind regards

Miss Donna Bennett

Approvals Administrator

Health Research Authority

Appendix D. Questionnaires, Screening and Outcome Measures

Demographic Questionnaire - Staff

IRAS ID: 247888 Date and Version: 03/05/18 (V1)

BA Trial for Co-occurring Depression and Substance Use

STAFF ENROLMENT QUESTIONNAIRE

Date:

CONTACT DETAILS			
STUDY ID:			
TEAM:			
PHONE:		WORK E-MAIL:	

PERSONAL INFORMATION			
DATE OF BIRTH:		GENDER:	Male ☐ Female ☐
ETHNICITY:	White ☐ Mixed ☐ Asian ☐ Black ☐ Other ☐ If 'other' please specify: ……		

EDUCATION AND EMPLOYMENT	
Current job title	……
What is the highest level of education you have completed to date?	☐ School-leaving qualifications (e.g. GCSEs) ☐ A-Levels or equivalent professional/vocational qualification (e.g. NVQ) ☐ Bachelor's degree or equivalent professional / vocational qualification ☐ Postgraduate degree or equivalent professional qualification (e.g. PGDip)
What is your professional background?	☐ None ☐ Social worker ☐ Nurse ☐ Accredited counsellor (BACP / BABCP) ☐ Other, please specify……
How many years in total have you been working in drug treatment services?	..... Years ..... Months
How many clients do you currently have on your caseload?	……

Demographic Questionnaire - Patients

PARTICIPANT ENROLMENT QUESTIONNAIRE

Date:	Participant No.:

CONTACT DETAILS

NAME			
ADDRESS			
PHONE		E-MAIL	
PREFERRED CONTACT METHOD	Phone ☐ Post ☐ Email ☐		

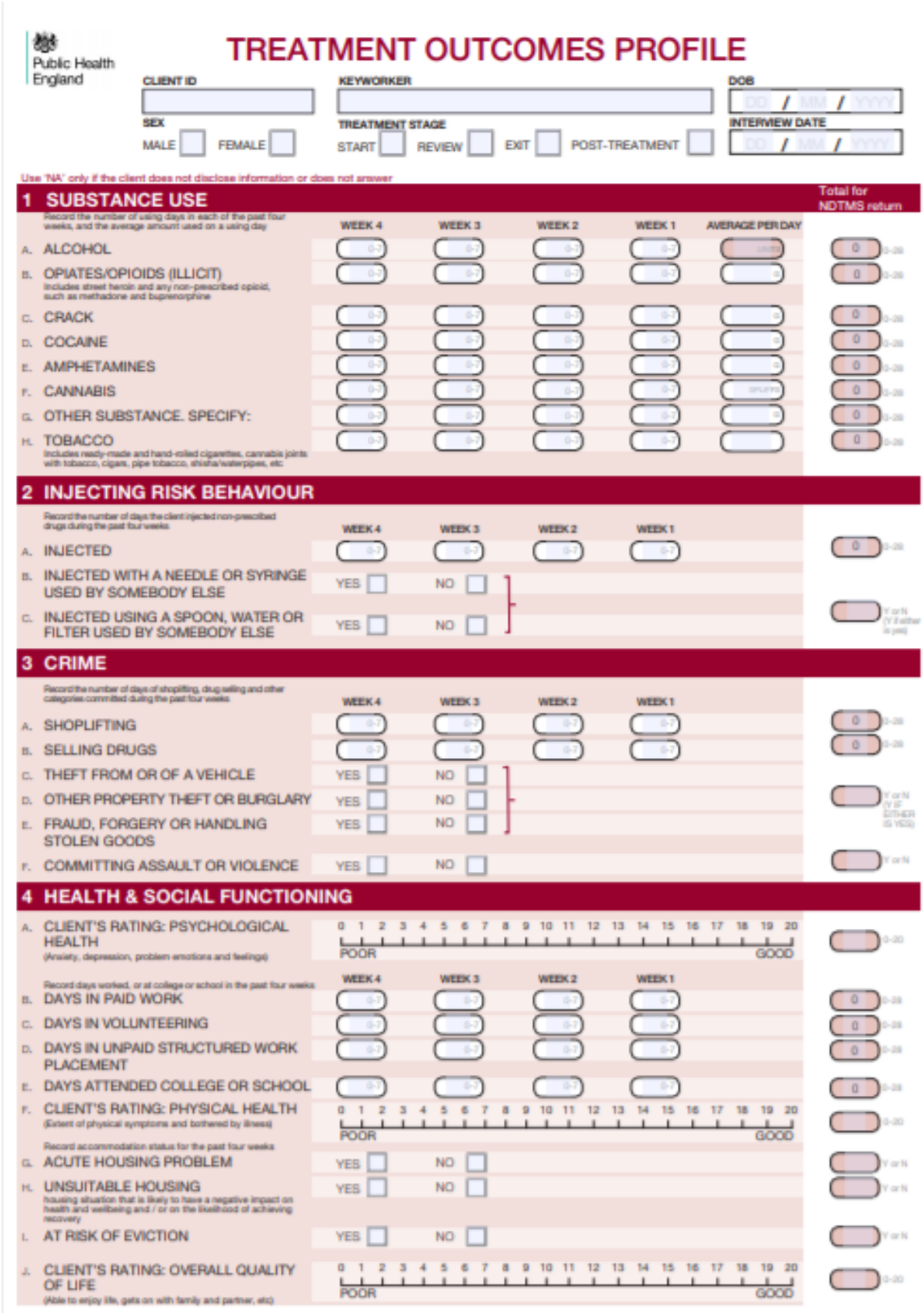
SOCIODEMOGRAPHICS

AGE		GENDER	Male ☐ Female ☐
ETHNICITY	White ☐ Mixed ☐ Asian ☐ Black ☐ Other ☐ If 'other' please specify:		
MARITAL STATUS	Single ☐ Married ☐ Cohabiting ☐		
EMPLOYMENT STATUS	☐ Currently employed ☐ Unemployed and seeking work ☐ Unemployed and not seeking work (e.g. due to ill-health) ☐ Student ☐ Retired		
HIGHEST LEVEL OF EDUCATION COMPLETED	☐ No qualifications ☐ School-leaving qualifications (e.g. GCSE's) ☐ Further education qualifications (e.g. A-Levels / vocational qualifications) ☐ Higher education qualifications (e.g. university degree or equivalent)		

MEDICAL INFORMATION

Are you prescribed any medication as part of your drugs and alcohol treatment?	☐ No medication ☐ Methadone ☐ Buprenorphine ☐ Acamprosate	☐ Naltrexone ☐ Nalmefene ☐ Disulfiram		
Has there been any change to your dose recently?	Not on medication ☐	My dose stayed the same ☐	My dose increased ☐	My dose reduced ☐
Are you taking prescribed antidepressants?	Yes ☐	No ☐		
CONSENT GIVEN TO INFORM GP OF TRIAL PARTICIPATION?	Yes ☐	No ☐		

Treatment Outcomes Profile (TOP)



Public Health England

TREATMENT OUTCOMES PROFILE

CLIENT ID | KEYWORKER | DOB (DD / MM / YYYY)

SEX: MALE ☐ FEMALE ☐

TREATMENT STAGE: START ☐ REVIEW ☐ EXIT ☐ POST-TREATMENT ☐

INTERVIEW DATE (DD / MM / YYYY)

Use 'NA' only if the client does not disclose information or does not answer

1 SUBSTANCE USE

Total for NDTMS return

Record the number of using days in each of the past four weeks, and the average amount used on a using day

	WEEK 4	WEEK 3	WEEK 2	WEEK 1	AVERAGE PER DAY	Total for NDTMS return
A. ALCOHOL	0-7	0-7	0-7	0-7	UNITS	0 0-28
B. OPIATES/OPIOIDS (ILLICIT) Includes street heroin and any non-prescribed opioid, such as methadone and buprenorphine	0-7	0-7	0-7	0-7	£	0 0-28
C. CRACK	0-7	0-7	0-7	0-7	£	0 0-28
D. COCAINE	0-7	0-7	0-7	0-7	£	0 0-28
E. AMPHETAMINES	0-7	0-7	0-7	0-7	£	0 0-28
F. CANNABIS	0-7	0-7	0-7	0-7	SPLIFFS	0 0-28
G. OTHER SUBSTANCE. SPECIFY:	0-7	0-7	0-7	0-7	£	0 0-28
H. TOBACCO Includes ready-made and hand-rolled cigarettes, cannabis joints with tobacco, cigars, pipe tobacco, shisha/waterpipes, etc	0-7	0-7	0-7	0-7	£	0 0-28

2 INJECTING RISK BEHAVIOUR

Record the number of days the client injected non-prescribed drugs during the past four weeks

	WEEK 4	WEEK 3	WEEK 2	WEEK 1	
A. INJECTED	0-7	0-7	0-7	0-7	0 0-28
B. INJECTED WITH A NEEDLE OR SYRINGE USED BY SOMEBODY ELSE	YES ☐	NO ☐			Y or N (Y if either is yes)
C. INJECTED USING A SPOON, WATER OR FILTER USED BY SOMEBODY ELSE	YES ☐	NO ☐			

3 CRIME

Record the number of days of shoplifting, drug selling and other categories committed during the past four weeks

	WEEK 4	WEEK 3	WEEK 2	WEEK 1	
A. SHOPLIFTING	0-7	0-7	0-7	0-7	0 0-28
B. SELLING DRUGS	0-7	0-7	0-7	0-7	0 0-28
C. THEFT FROM OR OF A VEHICLE	YES ☐	NO ☐			Y or N (Y if EITHER IS YES)
D. OTHER PROPERTY THEFT OR BURGLARY	YES ☐	NO ☐			
E. FRAUD, FORGERY OR HANDLING STOLEN GOODS	YES ☐	NO ☐			
F. COMMITTING ASSAULT OR VIOLENCE	YES ☐	NO ☐			Y or N

4 HEALTH & SOCIAL FUNCTIONING

A. CLIENT'S RATING: PSYCHOLOGICAL HEALTH (Anxiety, depression, problem emotions and feelings)

0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20

POOR — GOOD

0-20

Record days worked, or at college or school in the past four weeks

	WEEK 4	WEEK 3	WEEK 2	WEEK 1	
B. DAYS IN PAID WORK	0-7	0-7	0-7	0-7	0 0-28
C. DAYS IN VOLUNTEERING	0-7	0-7	0-7	0-7	0 0-28
D. DAYS IN UNPAID STRUCTURED WORK PLACEMENT	0-7	0-7	0-7	0-7	0 0-28
E. DAYS ATTENDED COLLEGE OR SCHOOL	0-7	0-7	0-7	0-7	0 0-28

F. CLIENT'S RATING: PHYSICAL HEALTH (Extent of physical symptoms and bothered by illness)

0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20

POOR — GOOD

0-20

Record accommodation status for the past four weeks

G. ACUTE HOUSING PROBLEM YES ☐ NO ☐ Y or N

H. UNSUITABLE HOUSING housing situation that is likely to have a negative impact on health and wellbeing and / or on the likelihood of achieving recovery YES ☐ NO ☐ Y or N

I. AT RISK OF EVICTION YES ☐ NO ☐ Y or N

J. CLIENT'S RATING: OVERALL QUALITY OF LIFE (Able to enjoy life, gets on with family and partner, etc)

0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20

POOR — GOOD

0-20

PHQ-9, GAD-7, SDS

MENTAL HEALTH AND SUBSTANCE USE QUESTIONNAIRE

Client ID: _____ **Date:** _____

In the last 2 weeks, how often have you been bothered by any of the following problems?

		YOUR ANSWER			
		Never, not at all	Sometimes, several days	Often, more than half the days	Always, or nearly every day
1	Little interest or pleasure in doing things?	☐	☐	☐	☐
2	Feeling down, depressed, or hopeless?	☐	☐	☐	☐
3	Trouble falling or staying asleep, or sleeping too much?	☐	☐	☐	☐
4	Feeling tired or having little energy?	☐	☐	☐	☐
5	Poor appetite or overeating?	☐	☐	☐	☐
6	Feeling bad about yourself - or that you are a failure or have let yourself or your family down?	☐	☐	☐	☐
7	Trouble concentrating on things, such as reading the newspaper or watching television?	☐	☐	☐	☐
8	Moving or speaking so slowly that other people could have noticed? Or the opposite - being so fidgety or restless that you have been moving around a lot more than usual?	☐	☐	☐	☐
9	Thoughts that you would be better off dead, or of hurting yourself in some way?	☐	☐	☐	☐
10	Feeling nervous, anxious or on edge?	☐	☐	☐	☐
11	Not being able to stop or control worrying?	☐	☐	☐	☐
12	Worrying too much about different things?	☐	☐	☐	☐
13	Trouble relaxing?	☐	☐	☐	☐
14	Being so restless that it is hard to sit still?	☐	☐	☐	☐
15	Becoming easily annoyed or irritable?	☐	☐	☐	☐
16	Feeling afraid as if something awful might happen?	☐	☐	☐	☐
17	Do you think your drug or alcohol use was out of control?	☐	☐	☐	☐
18	Did the prospect of missing a fix (or dose) make you anxious or worried?	☐	☐	☐	☐
19	Did you worry about your drug or alcohol use?	☐	☐	☐	☐
20	Did you wish you could stop using drugs or alcohol?	☐	☐	☐	☐
21	How difficult did you find it to stop or go without using drugs or alcohol?	Not difficult ☐	Quite difficult ☐	Very difficult ☐	Impossible ☐

To be completed by staff:

PHQ-9 _____ **GAD-7** _____ **SDS** _____

Valuing Questionnaire

Valuing Questionnaire

Client ID: _____ **Date:** _____

Instructions:
Please consider each statement carefully and then select which option best describes how much the statement was for you in the PAST WEEK, INCLUDING TODAY

Below each statement there is a 7-point scale:

0	1	2	3	4	5	6
Not at all True	Rarely True	Occasionally True	Sometimes True	Often True	Very Often True	Always True

1. I spent a lot of time thinking about the past or future, rather than being engaged in activities that matter to me

0	1	2	3	4	5	6
Never	Rarely	Occasionally	Sometimes	Often	Very Often	Always

2. I was basically on "auto-pilot" most of the time

0	1	2	3	4	5	6
Never	Rarely	Occasionally	Sometimes	Often	Very Often	Always

3. I worked towards my goals even if I didn't feel motivated to

0	1	2	3	4	5	6
Never	Rarely	Occasionally	Sometimes	Often	Very Often	Always

4. I was proud about how I lived my life

0	1	2	3	4	5	6
Never	Rarely	Occasionally	Sometimes	Often	Very Often	Always

5. **I made progress in the areas of my life I care most about**

0	1	2	3	4	5	6
Never	Rarely	Occasionally	Sometimes	Often	Very Often	Always

6. **Difficult thoughts, feelings or memories got in the way of what I really wanted to do**

0	1	2	3	4	5	6
Never	Rarely	Occasionally	Sometimes	Often	Very Often	Always

7. **I continued to get better at being the kind of person I want to be**

0	1	2	3	4	5	6
Never	Rarely	Occasionally	Sometimes	Often	Very Often	Always

8. **When things didn't go according to plan, I gave up easily**

0	1	2	3	4	5	6
Never	Rarely	Occasionally	Sometimes	Often	Very Often	Always

9. **I felt like I had a purpose in life**

0	1	2	3	4	5	6
Never	Rarely	Occasionally	Sometimes	Often	Very Often	Always

10. **It seemed like I was just "going through the motions" rather than focusing on what was important to me**

0	1	2	3	4	5	6
Never	Rarely	Occasionally	Sometimes	Often	Very Often	Always

Appendix E. BA Therapist Manual (Session 3).

SESSION THREE
Reducing Depression and Living a Substance-Free, Enjoyable and Rewarding Life: Selecting Activities

Overview of Session Three (Total Time: 45 Minutes)

- Welcome/Check-In (~5 Minutes)
- Review Treatment Rationale (10 Minutes)
- Brief review of **Daily Activities** (10 Minutes)
- Review and continue working on **LAVA** (15 Minutes)
- Keeping Track of Progress – **Daily Plans** (10 Minutes)
- Wrap-Up (~5 Minutes)

Welcome/Check-In (~5 Minutes)

Procedure: Welcome the client, go through the agenda for today and elicit any questions. Check **Daily Activities** for homework completion.

Text: *Now is a good time to talk about any questions or concerns you have about the treatment* (Answer any questions/address comments and discuss how Monitoring Daily Activities is working for the client). *We are going to discuss your Daily Activities, but let's start by reviewing the treatment rationale that we talked about last session.*

Review Treatment Rationale (10 Minutes)

Procedure: Ask the client to turn to the treatment rationale work sheet on page 87 in their workbook. Lead the discussion of the treatment rationale while also asking for input from the client to demonstrate comprehension. Ensure that the client understands the rationale before proceeding. If the client is doing well and cannot identify any negative activity to complete the negative circle, ask him/her to write down what he/she did in the past.

If a client reports using drugs or alcohol as a negative behaviour, it would be a good opportunity to explore this experience within the framework of the treatment rationale.

Text: *Now if you turn to page 87 in your workbook, together we are going to review the treatment rationale again. Based on your experience since the last session, please fill out the sheet as we go along with information that is specific to experiences you've had in the past week. If you have been doing well since the last session and have not engaged in any negative behaviors, it would be helpful to think about some of the negative behaviors you've done in the past.*

Review of Daily Activities (10 Minutes)

Procedure: Review **Daily Activities** with the client. First ask what he/she learned about himself/herself as a result of completing the exercise. Give the client time to discuss their experience. Try to determine whether particular patterns of behaviourr are evident. Are they

engaging in enough Activities that they WANT to do? Which Activities were more enjoyable than others? Why? Again write down the most enjoyable Activities on a piece of paper for the client. In addition to enjoyment, also discuss Activities the client found important to them, beyond whether they found those Activities enjoyable. Verbally praise the client for completing a very challenging exercise and reiterate the importance of the exercise as it relates to future Values of the treatment (that is, this exercise helps you learn about what kinds of activities are important/ enjoyable so that you can plan to do more of them going forward).

If the client was unable to complete the exercise, address why and help them to problem solve. Emphasise the importance of support, encourage the client to ask their peer mentor for help with homework if it is unclear, and repeat the treatment rationale to increase motivation.

Text: *I am curious to learn what types of Activities you have engaged in since our last session. What Activities, if any, have you found to be particularly enjoyable? Are any of them you found particularly not enjoyable? What about importance? Were there any activities that were important, but not necessarily enjoyable? Let's discuss as a group.*

Note: At this stage, this exercise should serve as a quick and general check-in about participants' experience of a few Activities that stood out for them.

Life Areas: Values and Activities (15 Minutes)

Procedure: First start by reviewing the Activities and Values that the client completed for homework for the Life Areas identified at the last session. If they did not finish completing these forms then spend time in the session filling them out. Have the client be as specific as possible in generating Values and Activities and make sure that they understand the difference between a Value and an Activity.

Text: *Let's start by reviewing the Values and Activities you identified for homework. Did you talk to anyone for ideas of new Activities? If you need help thinking of some more ideas, try looking at the Activity Form again.*

Remember that the activities must be observable by others and they must be measurable (i.e. you have to specify the "what", "when", "how long" etc). For example, "feeling better" is not what we mean by activity but "eating dinner with my mother twice a week" would be appropriate.

Another tip is that activities are far easier to accomplish if they are broken into the smallest pieces possible. Sometimes we might have the tendency to select very difficult activities for which the benefits are in the future and not a guarantee. For example, getting a college degree is a long-term goal that may take some time to achieve. It is important to have these types of goals, but it is even more important to be clear about the rewarding activities that are a part of achieving that long-term goal. This might include activities that get you to the goal but are important and/or enjoyable on a daily basis such as studying a topic you enjoy or discussing something you learned in a class.

If these three conditions (observable, measurable, and smallest piece possible) are met, you have identified an acceptable activity.

Procedure: Start completing the Values and Activities forms for another Life area in addition to the 3 they started working on last session. Generate discussion with the client about the importance of being specific, and how they can be specific about their Activities.

Text: *Today we are going to continue to establish different Values and Activities for you in other areas of your life. Apart from the 3 Life areas you have already focused on, what are the other important Life areas to you? It's ok if you haven't thought about them yet, we are going to start with the next most important Life Area to you [Based on what Life areas are left from the previous sessions that have not yet been discussed in session] in your workbook. Which life area do you want to start with? Can you think of any values you would add to this area? What activities can you think of to act consistently with your values in this area?*

Procedure: Ask the client to write any additional values plus activities for all values in this area in their workbook. Probe them on their Values if any of the Values are sounding more like Activities. The client should only write down additional Values when they truly are in the form of Values and not Activities. Once the client has provided Values for this Life Area, ask them to identify Activities that they can do to achieve this Value.

If the client demonstrates understanding of the difference between a Value and an Activity, support them to complete two more Life areas (Values and Activities) in their workbook during the session, and then complete the remaining Life Areas for homework. If the client does not want to focus on one of the Life areas, that is OK. Move on and try to have them focus on Values in other Life Areas later in the session.

Keeping Track of Progress: Daily Plan (20 Minutes)

Text: *Okay, so now that you have decided which Activities and Life Areas you want to work on, the next step is to start scheduling some of these activities into your plan for the days to come. So now we are going to introduce a new exercise which helps you plan these activities and track them in coming days. This* ***Daily Plan*** *exercise is meant to help you stay in the positive cycle. And remember, that is the best way to break the negative cycle.*

In this exercise, you will be setting Values for each day, as well as Activities that will help you achieve these Values. Having a ***Daily Plan*** *will help you stay focused on doing your Activities. It is easier to remember to do an Activity each day if you decide ahead of time what you want to do and the specific details about the activity (e.g. how long you will be doing it for). In your book, you will write down which Value(s) you want to focus on each day, what Life Area(s) these fall under, and what Activities you can do to achieve these Value(s).*

Procedure: Explain the rationale for Plan Ahead – i.e. if you wake up and see activities already planned for the day, it makes it more likely that you will do them. Also, this way, the decision to schedule an activity is not dependent on your mood at the time.
Explain in detail the **Daily Plan** in the participant booklet, making sure participants know where to write their Values/Activities/Life Areas. Values are set for the following day up until, and including, the day of the next session.

Text: *At the start of all future sessions, we will start with a review of your progress towards Values in the previous days and then discuss new Values and Activities for upcoming days. So, here is what you will do:*

Procedure: Start with Life Areas, Values and Activities for today using the client's most important life areas.

Text: *In your workbook you will fill out a* ***Daily Plan*** *page for each day until our next session. For each page, you will list your Values and Life areas in the top box, and then list the Activities you plan to do on that day to meet those Values. You can one or more life areas and values to work on any given day.*

Let's start with today. Think about at least one life area and value that you would like to work on today. Write down at least one activity that helps you get closer to that value and schedule it for some time today after leaving this session.

Procedure: If it is easier to first identify an activity they plan to do today and then work backwards to identify the life area and value it comes under, that is okay. Just make sure that they understand the importance of knowing the value behind the activity.

Ok, now we are going to set daily Life Areas, Values and Activities for all of the days until our next session. It is important to do this beforehand so that when you wake up each day you will already have a set plan for what you want to do that day. Keep in mind that you cannot erase what you write down here today, but you can always add to it.

Procedure: Once today's daily Life Areas, Values and Activities are set, move on to the next day, and complete each day's Values & Activities up until the day of the next session (set Values for the actual day of your next session).

Text: *When you wake up each day, you should look at your workbook and turn to the page for that day to see which Activities you are going to complete. To fill this form out, circle "Y" if you were able to do that Activity, and circle "N" if you were not able to complete that Activity. Finally, add up the number of Activities you circled "Y" and list that number at the bottom of the page. During the day you can take notes on the side of the page or in the Notes page at the end of the note book about how you are feeling about your Values or any other issues you may want to bring up in our next session. You should fill out these pages every day, and bring it back to next session so we can go over it together.*

Procedure: Ask the client if any obstacles may get in the way of their scheduling activities each day. Ask them to decide ahead of time when is a good time in the day to devote to scheduling activities for the next day.

Wrap Up (~5 Minutes)

Procedure: Offer positive feedback on the client's engagement in the session today and ensure that they are booked in for their next session in a week's time. Set the homework assignments between now and next session and ask the client to write this in the appointments page in their

workbook. Emphasise the importance of regular attendance and of completing homework assignments as part of this treatment. Briefly explain what will be covered next session and remind the client to bring their booklet to the next session.

Text: *So that's it for today's session. I think you've done really well today by…. Talking openly about things you've been struggling with / Asking questions / Exploring the difficult emotions you've been experiencing etc. (Arrange session for next week). Remember, if something comes up and you can't make the appointment let me or the study coordinator know as soon as possible and we can try and reschedule so you don't end up missing a week.*

Your assignment between now and next session is to monitor your engagement in the activities you have set for each day in your Daily Plans. Feel free to come up with more activities for each day if you want to but remember they should be related to the values you have chosen for that day. You can also continue to think about the other life areas we talked about today and whether you have any values and activities you want to add to these areas – but we won't focus on including these life areas in your daily plans until later on in treatment. (Give the client a moment to write these assignments down in their workbook). If you need help with any of this then you can ask your peer mentor. In the next session, we will continue to work on your Daily Plans and setting Values and Activities for any remaining Life Areas. Remember to bring your booklet with you when you come next week.

Homework:

- **Do the activities you identified for each day between now and next session and record this using your Daily Plan in your workbook. Add any additional activities for these values if you would like to.**
- **Continue identifying values and activities in the life areas that have been discussed during today's session, until there is at least one activity identified for each value within each life area (excluding any life areas that they have chosen to skip completely).**

Note: If the client is confused about completing the **Daily Plans** or completing the Life Areas exercise for homework, spend a few minutes at the end of the session explaining this and discussing again the difference between Values and Activities.

Appendix F. BA Session Adherence Checklist (Session 3)

Date: _____ Client ID: _____ Therapist ID: _____

THERAPIST ADHERENCE CHECKLIST
SESSION 3

Welcome/Check in? ☐ Yes ☐ No _____

Review treatment rationale? ☐ Yes ☐ No If no, elaborate on omission below: _____

Draw model in workbook? ☐ Omitted _____

QUICK check Activity Monitoring? ☐ Yes ☐ No If no, elaborate on omission below: _____

What client learned? ☐ Omitted _____
List most enjoyable? ☐ Omitted _____
Enjoyable AND important? ☐ Omitted _____

Discuss Activity Monitoring? ☐ Yes ☐ No _____

Complete Values and Activities Form for remaining Life Areas? ☐ Yes ☐ No If no, elaborate on omission below: _____

Differentiate Value/Activity? ☐ Omitted _____
List 2 columns on paper? ☐ Omitted _____
I.D. 1 activity for during Tx? ☐ Omitted _____

Introduce Daily Plan? ☐ Yes ☐ No If no, elaborate on omission below: _____

Provide rationale? ☐ Omitted _____
Explain Daily Plan procedure using workbook? ☐ Omitted _____
Complete up to next session? ☐ Omitted _____

Remind what HW is assigned? ☐ Yes ☐ No If no, elaborate on omission below: _____

Complete all Daily Plans? ☐ Omitted _____

Remind to bring booklet to next session? ☐ Yes ☐ No _____

Appendix G. Patient Workbook (Daily Monitoring, LAVA, Daily Scheduling)

Daily Monitoring

Daily Activity Form

Circle the day & insert the date: _____

M T W T F S S

Time	Activity	E (0-10)	I (0-10)
5-6am			
6-7am			
7-8am			
8-9am			
9-10am			
10-11am			
11-12pm			
12-1pm			
1-2pm			
2-3pm			
3-4pm			
4-5pm			

5-6pm			
6-7pm			
7-8pm			
8-9pm			
9-10pm			
10-11pm			
11-12am			
12-1am			
1-2am			
2-3am			
3-4am			
4-5am			
E= Enjoyment, I = Importance			

Number of Enjoyable activities I did today _____

Number of Important activities I did today _____

Overall mood (0/10) _____

LAVA

LAVA

RELATIONSHIPS 
My Values
It is important to me....
My Activities

Daily Scheduling

Daily Plan

Circle the day & insert the date: _____

M T W T F S S

Life Areas

The values I am working from

1.

2.

3.

Time	Activity	C
		Y / N
		Y / N
		Y / N
		Y / N
		Y / N
		Y / N
		Y / N

C = Completed? (Circle Y / N)

Total Activities Completed Today _____

Appendix H. CONSORT checklist.

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	p.68
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	pp. 73-101
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	pp.68-73
	2b	Specific objectives or hypotheses	p.73
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	p.74, CONSORT diagram
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	Appendices
Participants	4a	Eligibility criteria for participants	p.75
	4b	Settings and locations where the data were collected	p.74, p.76
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	pp.77-79

Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	p.5-7, P.9-11
	6b	Any changes to trial outcomes after the trial commenced, with reasons	N/A
Sample size	7a	How sample size was determined	p.74
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	p.76
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	p.76
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	p.76
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	p.76
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	N/A
	11b	If relevant, description of the similarity of interventions	pp. 77-79
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	pp.83-84
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	p. 84

Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	CONSORT Diagram
	13b	For each group, losses and exclusions after randomisation, together with reasons	p.96
Recruitment	14a	Dates defining the periods of recruitment and follow-up	p.75
	14b	Why the trial ended or was stopped	p.75
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 3.3
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	CONSORT diagram, Table 3.4
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Table 3.4
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	N/A
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	Pp.88-94, Appendix
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	See figure 3.4 and 3.5
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	p.21-22

Generalisability	21	Generalisability (external validity, applicability) of the trial findings	p.94-101
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	p.94-101
Other information			
Registration	23	Registration number and name of trial registry	p.74
Protocol	24	Where the full trial protocol can be accessed, if available	p.74
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	N/A

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Appendix I. ANCOVA analyses with missing data.

Variable and time point	Randomised Sample (n=34)		Mean Difference[a]	*p*	ES[b]
	TAU (n=17)	BA (n=17)			
	Mean (SD)	Mean (SD)			
Depression (PHQ-9)					
6 weeks	18.73 (3.90)	14.62 (7.59)	-3.80	.081	0.8
12 weeks	17.29 (5.58)	10.43 (7.82)	-6.58	.008	1.1
24 weeks	17.43 (6.71)	15.69 (6.93)	-2.29	.292	0.4
Percent Days Abstinent (PDA)					
6 weeks	26.54 (31.64)	52.31 (37.59)	23.51	.040	1
12 weeks	38.21 (39.82)	62.43 (31.89)	20.58	.127	0.6
24 weeks	46.43 (44.46)	65.38 (36.27)	13.52	.486	0.4
Severity of Dependence (SDS)					
6 weeks	8.18 (4.31)	6.38 (4.86)	-2.30	.224	0.6
12 weeks	6.50 (4.57)	6.64 (4.99)	-0.90	.579	0.2
24 weeks	5.71 (4.73)	5.67 (3.99)	-0.35	.849	0.1
Anxiety (GAD-7)					
6 weeks	12.72 (5.44)	12.46 (4.50)	-1.47	.416	0.4
12 weeks	12.93 (5.86)	8.79 (5.62)	-4.71	.037	0.9
24 weeks	10.57 (5.39)	12.00 (5.74)	-0.25	.899	0.1
Progress in Valued Living (VQ-Progress)					
6 weeks	6.45 (3.96)	12.38 (9.07)	-7.00	.032	1
12 weeks	11.62 (7.19)	15.71 (9.09)	-3.35	.150	0.6
24 weeks	11.14 (8.72)	15.64 (9.37)	-5.09	.136	0.7
Obstructions to Valued Living (VQ-Obstruction)					
6 weeks	20.09 (4.25)	19.38 (7.05)	-0.86	.730	0.2
12 weeks	19.62 (9.25)	14.64 (8.43)	-4.79	.164	0.6
24 weeks	18.29 (6.75)	20.73 (7.54)	-1.82	.529	0.3

[a] Mean difference adjusted for baseline scores on corresponding measure
[b] ES = Cohen's *d*

Appendix J. Interview Topic Guides (clinical managers, BA therapists, BA patients).

Clinical managers

Questions for Managers

1. What made you decide to be involved in the study?
2. What was your experience of delivering supervision with BA staff?
3. How do you think staff found delivering the BA intervention?

   (Prompts: what was difficult? what did you do to try to address difficulties? what worked?)
4. Why do you think some patients did not engage, even though they signed up to the study?
5. How effective do you think this type of intervention will be with this patient group?

   (Prompt: what makes it effective? what would help to make it more effective?)
6. Having taken part in the study, what's your view about how services should identify and address these clients' mental health needs?

BA Therapists

Questions for Staff

1. What made you decide to take part in the study?
2. What did you think about the training and supervision you've had as part of the study?
3. What was it like to try and get participants to attend appointments?

   (Prompts: what was difficult? what did you do to try to address difficulties? what worked?)
4. Why do you think some participants did not engage, even though they signed up to the study?
5. What was it like to deliver the intervention with study participants who attended sessions?

   (Prompts: what was difficult? What worked well? What worked less well?)
6. Did you mostly stick to the BA protocol or did you have to change or adapt the way in which you delivered the intervention?

   (Prompt: What did you change? Why?)
7. How effective do you think the type of intervention you delivered will be with this patient group?

   (Prompt: what would help to make it more effective?)
8. Having taken part in the study, what's your view about how services should identify and address these clients' mental health needs?

BA Patients

Client Change Interview Schedule

At the end of the intervention period, clients are asked to come in for an hour-long semi-structured interview. The major topics of this interview are any changes you have noticed since therapy began, what you believe may have brought about these changes, and helpful and unhelpful aspects of the therapy. The main purpose of this interview is to allow you to tell us about the therapy and the research in your own words. This information will help us to understand better how the therapy works; it will also help us to improve the therapy.

This interview is recorded for later transcription. Please provide as much detail as possible.

1. General Questions: [about 5 min]

1a. How are you doing now in general?

1b. What has therapy been like for you so far? How has it felt to be in therapy?

1c. What medications are you currently on? (interviewer: record on form, including dose, how long, last adjustment)

2. Changes: [about 10 min]

2a. What changes, if any, have you noticed in yourself since therapy started? (Interviewer: Reflect back change to client and write down brief versions of the changes for later. If it is helpful, you can use some of these follow-up questions: For example, Are you doing, feeling, or thinking differently from the way you did before? What specific ideas, if any, have you gotten from therapy so far, including ideas about yourself or other people? Have any changes been brought to your attention by other people?)

2b. Has anything changed for the worse for you since therapy started?

2c. Is there anything that you wanted to change that hasn't since therapy started?

3. Change Ratings: [about 10 min] (Go through each change and rate it on the following three scales:)

3a. For each change, please rate how much you expected it vs. were surprised by it? (Use this rating scale:)

(1) Very much expected it

(2) Somewhat expected it

(3) Neither expected nor surprised by the change

(4) Somewhat surprised by it

(5) Very much surprised by it

3b. For each change, please rate how likely you think it would have been if you hadn't been in BA treatment? (Use this rating scale:)

(1) Very unlikely without BA (clearly would not have happened)

(2) Somewhat unlikely without BA (probably would not have happened)

(3) Neither likely nor unlikely (no way of telling)

(4) Somewhat likely without BA (probably would have happened)

(5) Very likely without BA (clearly would have happened anyway)

3c. How important or significant to you personally do you consider this change to be? (Use this rating scale:)

(1) Not at all important

(2) Slightly important

(3) Moderately important

(4) Very important

(5) Extremely important

Client Change Interview, p. 2

4. Attributions: [about 5 min] In general, what do you think has caused the various changes you described? In other words, what do you think might have brought them about? (Including things both outside of therapy and in therapy)

5. Resources: [about 5 min]

5a. What personal strengths do you think have helped you make use of BA to deal with your problems? (what you're good at, personal qualities)

5b. What things in your current life situation have helped you make use of BA to deal with your problems? (family, job, relationships, living arrangements)

6. Limitations: [about 5 min]

6a. What things about you do you think have made it harder for you to use BA to deal with your problems? (things about you as a person)

6b. What things in your life situation have made it harder for you to use BA to deal with your problems? (family, job, relationships, living arrangements)

7. Helpful Aspects: [about 10 min] Can you sum up what has been helpful about your therapy so far? Please give examples. (For example, general aspects, specific events)

8. Problematic Aspects: [about 5 min]

8a. What kinds of things about BA have been hindering, unhelpful, negative or disappointing for you? (For example, general aspects. specific events)

8b. Were there things in the BA treatment which were difficult or painful but still OK or perhaps helpful? What were they?

8c. Has anything been missing from your treatment? (What would make/have made your therapy more effective or helpful?)

9. The Research [about 10 min]

9a. What has it been like to be involved in this research? (Initial screening, research interviews, completing questionnaires etc)

9b. Can you sum up what has been helpful about the research so far? Please give examples.

9c. What kinds of things about the research have been hindering, unhelpful, negative or have got in the way of BA? Please give examples.

10. Suggestions: [about 5 min] Do you have any suggestions for us, regarding the research or the BA treatment? Do you have anything else that you want to tell me?

Appendix K. Coding framework.

Themes (final coding framework)	Initial Coding Framework (SP)	Initial Coding Framework (LRDB)
1. Addressing Mental Health in CDAT 1.1. Not in the job description but more could be done 1.2. Avoiding a focus on diagnosis	• **Lack of effective mental health interventions delivered in CDAT** • **Barriers to delivering mental health interventions in CDAT** (Categories: staff ambivalence, "not our job", time constraints) • **Mental health services need to be more involved** • **BA as bridge to mental health** • **Patient expectations of CDAT** (Category: Prescribing, drug testing) • **Usual care is service-driven** • **Exploring mental health in CDAT** (Category: positive, negative) • **Patient misdiagnosis**	• **Avoiding over-reliance on diagnostic labels** (Categories: dual diagnosis, label as justification for drug use, misdiagnosis, withdrawal or depression) • **Focus on individual meaning of mental health** • **Understanding of the links between substance use and depression** • **Accountability versus self-accountability** (Categories: existing practice – patients accountable to staff, with BA – patients accountable for themselves) • **BA as staff professional development** • **Lack of effective interventions in existing practice in CDAT** (Categories: barriers, staff capable, staff keen or interested) • **Mental health services need to be more involved** (Category: BA as a bridge)
2. The right patient at the right time	• **Barriers to engagement** (Categories: life events, mental health, practical barriers, chaotic lifestyle) • **Facilitators of engagement** (Categories: stability, commitment, life situation, motivation, personal attributes, support, previous therapy experience)	• **Barriers to engagement** (Category: Chaotic lifestyles) • **Facilitators of engagement** (Categories: Commitment, consistency, motivation, stability, readiness) • **Reasons to engage** (Categories: Convinced by staff, desire for change or being sick of lifestyle, improving mood, social reasons, trying something new, using less)
3. Challenging yet helpful aspects of BA therapy 3.1. Writing things down 3.2. Values as a turning point	• **Helpful aspects of BA** (Categories: daily monitoring, planning, LAVA, structure, support agreement, treatment rationale, workbook)	• **Planning and writing things down** (Categories: Helped to think and do, focus, mindset) • **Explaining the rationale** • **Values work** (Categories: Feels right, gives meaning to planned activities, lightbulb moments)

	• **Difficult aspects of BA** (Categories: acknowledging progress, daily monitoring, engaging in activities, LAVA, structure of therapy, support agreement) • **Positive changes** (Categories: back to self, better coping skills, doing more, feel happier, more focused, more positive, reconnecting, talking more, thinking about the future, more mindful, using less)	• **Re-connecting with values and with self** • **Shortfall between quitting drug use and BA helping mental health**
4. Barriers to BA Implementation 4.1. Complexity: an obstacle to confidence and understanding 4.2. A rigid and incompatible structure	• **Structure as a barrier** (Category: sessions) • **Complexity as a barrier** (Category: difficult to understand, difficult to deliver) • **Patients not engaging with BA** • **Issues relating to the CDAT service** (Categories: lack of time, other responsibilities service restructure)	• **Structural issues due to errors in implementation** • **Sessions** (Categories: Number, duration, length) • **Program complexity as a barrier** (Categories: Affected engagement, difficult to understand and/or deliver, supervision used as training to aid understanding)