Volume One

Research Component

Shame, mental health and substance use: an exploration of psychological processes and interventions.

by

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Doctor of clinical psychology

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The University of Birmingham

May 2017

Thesis overview

This thesis is presented in two volumes; the research component (Volume One) and the clinical component (Volume Two).

Volume One presents three research papers focusing on understanding interventions and change processes for people with severe and enduring mental health problems. The first paper is a meta-analysis evaluating the use of Acceptance and Commitment Therapy for people with severe and enduring mental health problems. The second is an empirical study examining the role of shame and psychological flexibility in the relationship between mental health and substance use in people with severe and enduring mental health problems. The third is a report written to disseminate the research findings to the research participants and health care professionals.

Volume Two consists of five clinical practice reports (CPRs). CPR one presents two formulations (using cognitive-behavioural and psychodynamic models) of a 71-year-old lady presenting with symptoms of obsessive-compulsive disorder. CPR two is a service evaluation examining how an older adult community mental health team worked with behaviour that challenges in care homes. CPR three describes a single case experiment evaluating a cognitive-behavioural intervention for a 43-year-old man diagnosed with obsessive-compulsive disorder. CPR four presents a case study of a compassion-focused intervention with a 25-year-old man presenting with shame and self-criticism within a community forensic learning disability service. The abstract of CPR five, an oral case presentation of a 40-year-

old man presenting with psychosis within an adult acute inpatient service, is also included.

Acknowledgements

I would like to thank all of the men and women who kindly agreed to take part in my research project and the ward staff who were enormously helpful throughout the recruitment process. Without your participation and support this research project would not have been possible.

I would also like to thank Alex, for taking a chance on me seven years ago, and for supporting and encouraging me ever since. I would not have made it without you, and I am eternally grateful.

Thank you to Chris, for bestowing upon me a little bit of your knowledge and enthusiasm for statistics.

Thank you to my clinical placement supervisors, Mike, Liz, Morna, Cressida and Paige. I have learned so much from each of you and will be taking a little bit of you all forward with me as I embark on the next stage of my journey.

Thank you to Oli, for always being there for me, for putting up with my stress and exhaustion, and for building a study for me to write this thesis in.

Thank you to my awesome cohort of fellow trainees, I could not have asked for a better bunch to spend the past three years with.

And finally, thank you to Claire, for being a reminder of the light at the end of the tunnel.

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Chapter I: Literature Review

Acceptance and Commitment Therapy (ACT) for people with severe and enduring mental health problems: A meta-analysis

1. Abstract

Background: People with severe and enduring mental health problems (SMI; psychotic disorders, bipolar affective disorder and major depressive disorder) experience poorer outcomes across a range of psychological, social and physical domains. The current review aimed to establish whether Acceptance and Commitment Therapy (ACT) can improve outcomes for this client group.

Method: Twelve randomised controlled trials including participants (N=470) with SMI were included in the review. Trials were assessed for methodological quality using Down's and Black's Quality Index. Data relating to four outcomes (psychotic symptoms, depression, psychological flexibility and rehospitalisation rate) were extracted and analysed using the "Meta" package from the R programme. Standardised mean differences were calculated for continuous outcomes and a relative risk ratio for incidence data.

Results: Regarding depression outcomes, ACT significantly outperformed control conditions at both post-intervention (*d*=0.39) and follow-up (*d*=0.43). There was no significant difference in psychotic symptoms between ACT and control groups at either time point (*d*=-0.02 and *d*=0.16 respectively). A significant effect favouring ACT was observed for the psychological flexibility outcome at post intervention (*d*=0.33) but this was not maintained at follow-up (*d*=0.13). ACT did not significantly reduce the risk or rehospitalisation in comparison to control (RR=-0.36).

Conclusion: The number of trials included in the review was small and the evidence base has limitations. Despite this, the review provides preliminary evidence that ACT may be useful in decreasing depressive symptoms amongst people with

SMI and that this is maintained over time. It also suggested that ACT increases psychological flexibility in the short term. The results suggested that ACT did not improve symptoms of psychosis or reduce the risk of rehospitalisation compared to control groups.

2. Introduction

2.1 Evidence-based interventions for severe and enduring mental health problems

People who receive mental health services over long periods often present with a complex mix of psychological and social difficulties that can have significant and enduring negative impacts. People within this population often receive a diagnosis of 'schizophrenia-related disorders', 'bipolar affective disorder' and 'major depressive disorder'. There is much debate in the literature about the value of diagnosis or labels such as 'lifelong illness', as well as the potential negative contribution of such diagnoses and labels to the continued difficulties (BPS, 2013). Whether or not a diagnosis is present, there is evidence that the difficulties experienced by this group can lead to substantial and sustained impairment in a person's functioning (Charlwood, Mason, Goldacre et al., 1999).

There is evidence to suggest that people with severe and enduring mental health problems (SMI) experience poorer outcomes across a range of psychological, social and physical domains. For example, people with SMI have an increased risk of suicide (Osborn, Levy, Nazareth & King, 2008) and an increased risk of symptom reoccurrence and rehospitalisation, often associated with poor treatment engagement (Higashi, Medic, Littlewood et al., 2013). They may also be socially excluded and experience discrimination and loneliness (Fleischhacker, Arango, Arteel et al., 2014; Perese & Wolf, 2005). Research suggests that people with SMI have a reduced life expectancy of up to 25 years compared to the general population (Chang, Hayes, Perera et al., 2011; Everett, Mahler, Biblin et al., 2008). This is largely due to poorer physical health (in part associated with the side effects of anti-

psychotic mediations, such as weight gain), an increased risk of suicide and inadequate management or treatment (Fleischhacker et al., 2014).

In order to improve outcomes for people with severe and enduring mental health problems, evidence-based interventions must be made available. Medication is often the first line of treatment for this population (British Medical Journal, 2017) and a combination of pharmacological and psychological treatment is recommended over either intervention in isolation (NICE, 2014b). When psychological interventions are offered, cognitive-behavioural therapy (CBT) is recommended (NICE, 2009; NICE, 2014a; NICE, 2014b).

Although CBT is recommended within clinical guidelines, there has been growing debate about the endorsement of CBT as an evidence-based approach (Thomas, 2015). This is primarily due to criticisms of the quality of research and claims that the evidence in favour of CBT has been "oversold" (McKenna & Kingdon, 2014). For example, a meta-analysis of 'well-controlled' trials reported that CBT was ineffective at reducing symptoms or reoccurrence in schizophrenia, or at preventing reoccurrence in bipolar disorder (Lynch, Laws & McKenna, 2010). A Cochrane Review (Jones, Hacker, Cormack et al., 2012; pg. 2) evaluating CBT for schizophrenia concluded that there is "no clear and convincing advantage for cognitive behavioural therapy over other - and sometime much less sophisticated - therapies for people with schizophrenia."

Potentially as a result of concerns such as these, over recent years there has been growing interest in alternative treatment options for this client group. One such approach that has attracted attention is Acceptance and Commitment Therapy (ACT).

2.2 What is Acceptance and Commitment Therapy?

Acceptance and commitment therapy uses a combination of acceptance, mindfulness and values-based therapeutic processes with the overall aim of increasing a person's psychological flexibility and enabling them to engage in value-driven activity (Hayes & Levin, 2012). Psychological flexibility is a process whereby an individual is able to mindfully observe inner and private experiences, such as thoughts, emotions and bodily experiences, and accept these as they are rather than attempting to change them (Hayes et al., 2013). It is understood that if an individual becomes 'fused' with such experiences and attempts to change or avoid them, their inward focus is increased and this can often prevent them from engaging in activities or pursuing goals that may be important to them (experiential avoidance; Pankey & Hayes, 2003). ACT first aims to clarify a person's values and identify activities or behaviours that are in accordance with such values. Second, it promotes defusion from the inner experiences (i.e. observing a thought as just a product of our busy mind) to enable the individual to reduce avoidance and engage in value-driven activity. Although a reduction in symptoms or a change in cognition may occur throughout an ACT intervention, symptom reduction is not the primary goal. ACT attempts to change a person's relationship with their inner experience, rather than changing the experience itself (Pankey & Hayes, 2003).

2.3 Acceptance and Commitment therapy with severe and enduring mental health problems

ACT has been applied when working with people presenting with a range of physical and mental health problems, including stress, depression, anxiety, smoking, , pain, cancer, eating disorders, epilepsy, diabetes, tinnitus, trichotillomania, OCD and substance use (Association for Contextual Behavioural Science, 2015). Research

has also begun to emerge evaluating ACT for people with severe and enduring mental health problems.

When working with people with severe and enduring mental health problems, it has been argued that attempting to reduce or modify private events may increase an already excessive inward focus; and that targeting symptoms directly may produce paradoxical effects (Pankey & Hayes, 2003). ACT instead aims to alter the 'believability' or behavioural impact of problematic cognitions; in essence the person's relationship with a private event rather than the private event per se (Bach & Hayes, 2002). As the symptoms of people with severe and enduring mental health problems are likely to persist, ACT seems well suited for this client group and could enable individuals to live more value-driven lives, even if unpleasant private events continue at some frequency (Pankey & Hayes, 2003).

2.4 Published reviews of Acceptance and Commitment Therapy

Several systematic reviews and meta-analyses have attempted to evaluate the effectiveness of ACT interventions. These have focussed on ACT for broad categories of physical disorders (Ost, 2014; Veehof, Oskam, Schreurs & Bohlmeijer, 2011) or mental health problems (Bluett, Homan, Morrison et al., 2014; Hacker, Stone & MacBeth, 2015; Ost, 2014; Swain, Hancock, Hainsworth & Bowman, 2013), as well as work stress (Ost, 2014) and substance use (Lee, An, Levin & Twohig, 2015). Regarding mental health problems, reviews have focussed either specifically on anxiety (Swain et al., 2013), anxiety and Obsessive Compulsive Disorder (OCD; Bluett et al., 2014), anxiety and depression (A-Tjak, Davis, Morina et al., 2015; Hacker et al., 2015) or more generally on 'any' mental health presentation (A-Tjak et al., 2015; Ost, 2014).

These reviews have found significant small to medium effect sizes for ACT in comparison to control conditions. For a small effect size (d=0.2), there is a 56% chance that a person picked at random from the treatment group will have an improved outcome compared to a person picked at random from the control group, whereas for a medium effect size (d=0.5) this probability of superiority is 64% (Magnusson, 2017). Hedges' g effect size corrects for the slight overestimation of Cohen's d (Borenstein et al., 2009) but can be interpreted using the same rule of thumb (i.e. for a small, medium and large effect size).

In the largest meta-analysis for ACT to date, Ost (2014) reported an overall effect size of g=0.42 (p<.001) when combining 60 RCT's (N=4234) evaluating ACT for people with somatic disorders, psychiatric disorders and work stress; however such a broad focus may have masked subgroup differences. Similar effect sizes have been reported in smaller meta-analyses evaluating ACT for substance use (g=0.43, p<.001; Lee et al., 2015), mental and somatic disorders (g=0.57, p<.001; A-Tjak et al., 2015) and anxiety and OCD spectrum diagnoses (g=0.40, p=.16; Bluett et al., 2014).

There are however differences in reported effect sizes between presenting problems, for example Ost (2014) reported that the type of disorder significantly mediated the overall effect size (p=.04), with the effect size higher for work stress (g=0.45) and somatic disorders (g=0.43) compared to mental health problems (g=0.27). Although the number of studies within specific mental health problem categories was too small for meta-analysis, Ost (2014) summarised the data for specific mental health presentations and attempted to categorise the efficacy of ACT for each in line with APA criteria for evidence-based treatments (i.e. well-established

treatment, probably efficacious, possibly efficacious or experimental). Differences were observed across presenting problems, with ACT identified as ‘probably efficacious’ for only generalised anxiety disorder, ‘possibly efficacious’ for depression, social anxiety disorder and psychotic symptoms, and experimental for borderline personality disorder (Ost, 2014).

2.5 Limitations of previous reviews

The reviews to date have captured a broad range of both mental health and physical health problems to varying degrees of severity, making it difficult to evaluate ACT for a specific, more circumscribed presenting problem. When a specific problem has been targeted, variation in the sample of studies has made it difficult to establish whether the results are representative of a particular population. For example, in an evaluation of ACT for depression (Hacker, Stone & MacBeth, 2015), samples included university students with low self-esteem, older adults with chronic pain and individuals with treatment resistant mental health problems within a specialist personality disorder clinic. When both the presenting problem and the population are narrowed the number of trials is reduced; for example, Lee et al., (2015) focussed on treatment seeking people with substance use problems and found only 10 RCT’s. It could be argued however that these results are more representative of the population of interest. Finally, individual trials and reviews tend to evaluate the effectiveness of ACT based on an improvement in symptoms. As discussed above, symptom reduction is not the primary target for an ACT intervention and perhaps process of change data (e.g. changes in psychological flexibility) should be given a greater focus in order to understand how ACT improves outcomes over time (Lee et al., 2015).

2.6 Aim of the current review

To date no review has evaluated whether Acceptance and Commitment Therapy can improve outcomes for people with severe and enduring mental health problems. The current review aims to fill this gap, whilst also attempting to address some of the limitations of previous reviews. For example, the present review focuses on a specific presenting problem (severe and enduing mental health problems, defined as psychotic disorders, bipolar affective disorder and major depressive disorders), therefore increasing the reliability of the findings for this particular population. Process of change measures relating to the targets of an ACT intervention, such as measures of psychological flexibility, will be considered in addition to symptom reduction data in an attempt to better understand study findings. Rehospitalisation outcomes will also be considered as a more objective outcome measure alongside participant rating scales; particularly as this client group has an increased risk of admission to hospital as previously discussed.

3. Method

3.1 Search strategy

Empirical studies that evaluated the effectiveness of an ACT intervention for people with severe and enduring mental health problems were identified through a search of three electronic databases; PsychInfo, MedLine and Web of Science. A keyword search strategy was used for two topic areas (ACT and severe and enduring mental health problems) which were then combined. Search terms are presented in Table 1.

It was anticipated that the ACT search terms would not identify compound therapies (i.e. therapies with an active component of ACT but in conjunction with other therapeutic systems), that are often given alternative intervention names. However the current review aimed to identify the efficacy of ACT in its purest form at this stage.

Table 1. Database search terms

Search	Topic	Keywords
1	Acceptance and Commitment Therapy	acceptance-based
		acceptance based
		acceptance and commitment
		ACT
2	Severe and enduring mental health problems	SCHIZOPHRENIA
		PSYCHOSIS
		schizo*
		psychotic
		BIPOLAR
		DEPRESSION
		SEVERE near2 MENTAL
		ENDURING near2 MENTAL
		MAJOR near2 MENTAL

The initial database search was completed during April 2016. Search alerts were created for the databases to highlight any new publications that satisfied the search criteria between April 2016 and December 2016. Following the electronic database search, the reference lists of suitable articles were screened to identify additional papers. The Association for Contextual Behavioural Science (2015) website produces a list of ACT publications and this was also consulted. The authors of papers identified through the database search were approached via Email to identify any potential publications that were under review or in press.

3.2 Inclusion and exclusion criteria

In addition to peer-reviewed studies, 'grey literature' (e.g. unpublished doctoral theses) was included to reduce the impact of publication bias (Higgins & Green, 2011). Randomised controlled trials (RCT's) are considered to be the most rigorous study design (NICE, 2012), whilst non-randomised trials introduce a risk of bias (Higgins & Green, 2011). For this reason, only RCT's that allocated participants to an ACT intervention plus at least one additional treatment arm were eligible for inclusion in the meta-analysis. Additional inclusion criteria were that the study was 1) published in English language and 2) recruited participants with a diagnosed severe and enduring mental health problem (defined as a psychotic or schizophrenia related disorder, bipolar disorder or major depressive disorder).

Studies were excluded from the meta-analysis if only qualitative results were reported, if they replicated data previously published and included, or if the paper was unable to be retrieved through internet and library searches and attempts to contact the author. Where overlap of reported data were identified between peer-reviewed journal articles and unpublished theses, the thesis was excluded.

3.3 Study Selection

Figure 1 presents the process of identifying articles for the review. The electronic database search identified 220 articles once duplicates (n=65) were removed. Three additional articles were identified through email correspondence with authors and each of these was screened for eligibility. No additional articles were identified through inspection of reference lists or through the Association for Contextual Behavioural Science website.

Of the 223 records screened, 175 were excluded due to either the topic area being not relevant (n=83) or the article being a non-intervention paper (n=92; i.e. book chapter, review paper, treatment manual). Forty-eight intervention papers were assessed using the inclusion and exclusion criteria and a further 35 papers were excluded for the reasons presented in Figure 1. Thirteen papers satisfied the criteria for the meta-analysis and were included. Twelve of these were original papers, whilst one reported a follow-up of a sample previously reported. Twelve articles were published within a peer-reviewed journal, whilst one was a thesis identified through a dissertation publication website. The study characteristics of the included papers are presented in Table 2 and further described under the results sections.

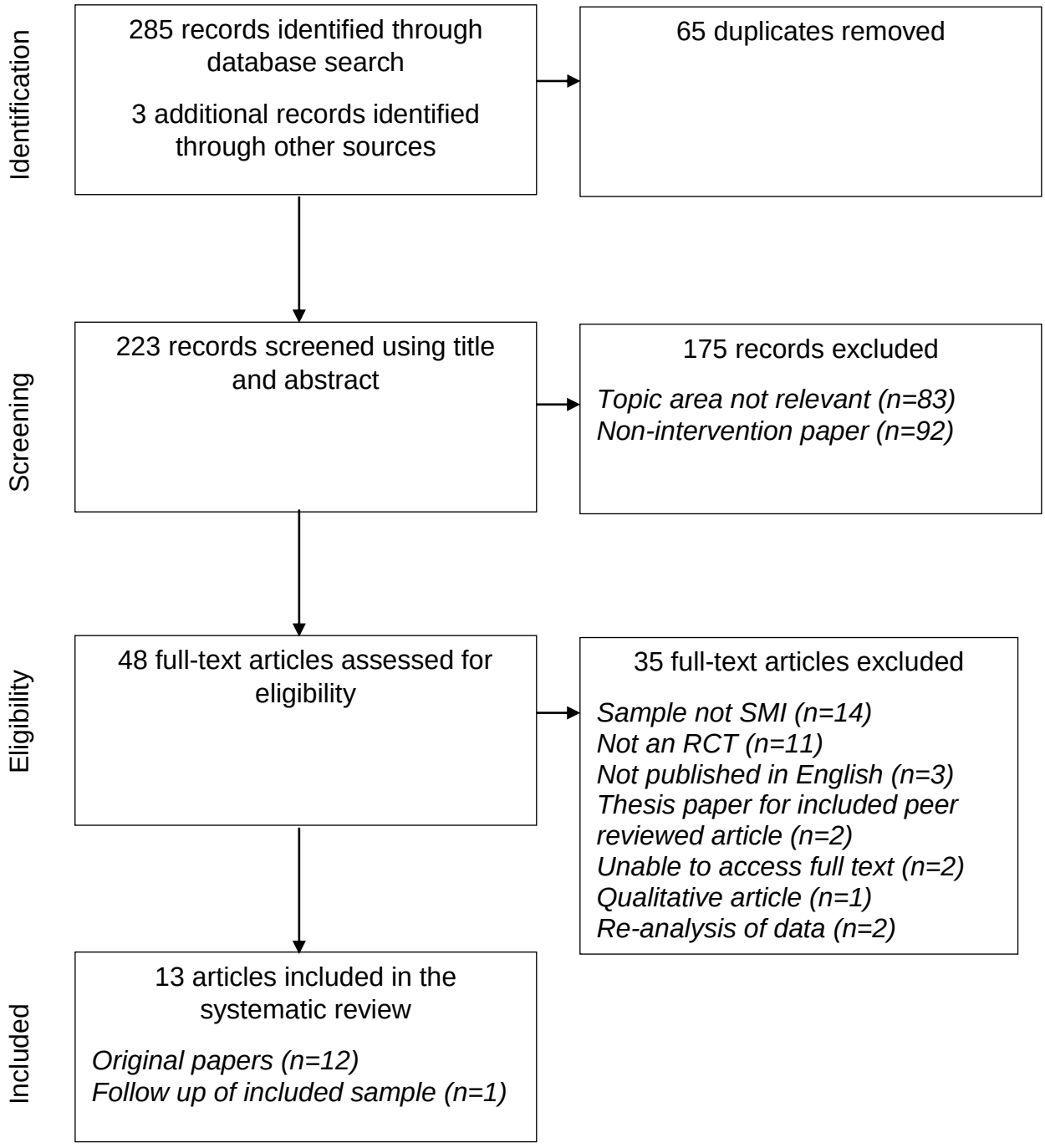


Figure 1. Identification of articles for review

Table 2. Study characteristics

Study	Sample						Intervention		
	N	% male[1]	Mean age[1]	% Caucasian[1]	Population	Country	Mental Health diagnosis	Control group[2]	Intervention exposure	Follow-up length
Bach & Hayes (2002); Bach, Hayes & Gallop (2012)[3]	80	I:68 C:60	I:39 C:40	I: 80 C: 70	Inpatient	USA	Psychotic Disorders	TAU	4 x 45-minute individual sessions	4 months, 12 months
Gaudiano & Herbert (2006)	40	I:37 C:86	40	I: 9 C: 5	Inpatient	USA	Psychotic Disorders	TAU	3 x 1hour individual sessions	Post-intervention; 4 months
Petersen & Zettle (2009)	29	I:58 C:42	I:37 C:39	I: 67 C:58	Inpatient	USA	Major Depressive Disorder	TAU	5 x 30mins individual sessions	Post-intervention
White et al (2011)	27	I: 71 C:85	I:34 C:35	I: 100 C:92	Inpatient and community	UK	Psychotic Disorders	TAU	10 x 1h individual sessions	3 months
Folke et al (2012)	35	I: 6 C: 19	I: 41 C: 46	I: 100 C: 100	Community	Sweden	Major Depressive Disorder	TAU	1 individual session and 5 group sessions	Post-intervention, 18 months
Shawyer et al (2012)	43	I:71 C: 41	I:40 C: 40	Not reported	Inpatient and community	Australia	Psychotic Disorders	Befriending	15x 50-minute individual sessions plus 2 follow up sessions	Post-intervention, 6 months
Broten (2013)	39	I:43 C: 40	I:48 C: 39	I: 64 C: 80	Inpatient	USA	Major Depressive Disorder and Bipolar Disorder	TAU	6 individual sessions	Post-intervention; 3 months

Gaudiano et al (2015)	13	I:13 C: 57	I:45 C:55	Not reported	Inpatient and community	USA	Psychotic Disorders	TAU	11 individual sessions	Post-intervention; 3 months
Tyrberg et al., (2016)	21	I:45 C:80	I: 43 C: 39	Not reported	Inpatient	Sweden	Psychotic Disorders	TAU	2 x 45-minute individual sessions	Post-intervention; 4 months
Shawyer et al., (2016)	96	I: 59 C: 64	I:36 C: 33	Not reported	Inpatient and community	Australia	Psychotic Disorders	Befriending	8 x 50-minute individual sessions	Post-intervention; 6 months
Boden et al., (2016)	18	I: 100 C:100	I: 52 C: 56	I: 40 C: 33	Inpatient	USA	Psychotic disorders	TAU	3 individual sessions	Post-intervention
Gumley et al., (2016)	29	I: 67 C:64	I: 47 C:46	I: 100 C:86	Inpatient and community	UK	Schizophrenia and Major Depressive Disorder	TAU	15 individual sessions	Post-intervention; 10 months

[1]I = intervention group, C = control group
[2]TAU = Treatment as usual
[3]The follow-up paper (Bach, Hayes & Gallop, 2012) and its original paper (Bach & Hayes, 2002) will be referenced as Bach and Hayes (2002) throughout the review.

3.4 Data extraction and coding

Studies were coded for outcomes by the review author. Outcome measures were assigned to one of four outcome categories in line with the aims of the review; 1) mental health (psychotic symptoms), 2) mental health (depression), 3) ACT related outcomes and 4) rehospitalisation. The outcome measures extracted from each study are presented in Table 3.

End-of-intervention data (means, standard deviations and sample sizes for intervention and control groups) were favoured over change data. Where change data were reported, the author was contacted for end-of-intervention data and the latter was included where available. Intention-to-treat data are considered the least biased way to estimate intervention effects (Higgins & Green, 2011) and so this was favoured over completer-data when both were reported. Non-parametric data were not included in the analysis as violating parametric assumptions may lead to biased estimates and inappropriate standard errors (Van den Noortgate & Ongnena, 2005).

Where multiple outcome measures of the same domain of functioning were reported within an outcome category, a decision was made to either select the more reliable outcome measure or to aggregate the effect sizes (Borenstein, Hedges, Higgins & Rothstein, 2009) to produce one effect size per outcome category. Validated measures were selected over more subjective participant self-ratings, with participant self-ratings utilised only if no validated measure of a construct was employed. Complete measures were favoured over subscales of incomplete measures as a more reliable measure of the complete construct (i.e. psychotic symptoms). Where all subscales of a measure were reported with no total score, the subscales were aggregated. Where two validated measures of the same construct were reported, the effect size was aggregated to produce a single effect size using

the correlation between measures as reported in the literature. Where no correlation was available within the literature, effect sizes were calculated using three correlation coefficients (0.3, 0.5 and 0.7) and if no difference in the effect size was observed this effect size was utilised. All outcomes within each category that were not selected are included in Appendix 1 and correlation coefficients between aggregated outcomes in Appendix 2. If two measures were reported within an outcome category that were not considered to measure the same construct (e.g. an acceptance measure and a mindfulness measure within the ACT outcome category), the most consistent measure across studies within that category was selected.

Table 3. Extracted outcome data

Study	Mental Health: Psychotic symptoms	Mental Health: Depression	ACT related outcomes	Rehospitalisation
Bach & Hayes (2002)	Aggregated effect size of self-ratings of psychotic symptoms (frequency, believability, and distress)	None	None	Number re-hospitalised
Gaudiano & Herbert (2006)	BPRS[1]	None	None	Number re-hospitalised
Petersen & Zettle (2009)	None	Aggregated effects size of HRS[2] and BDI[3]	AAQ-II[4]	None
White et al (2011)	Aggregated ES of PANSS[5] Positive Subscale and PANSS[5] Negative Subscale	HADS[6]	AAQ-II[4]	None
Folke et al (2012)	None	BDI[3]		None
Shawyer et al (2012)	PANSS[5] Total	None	Aggregated ES of VAAS[7]-Subscale A and B	None
Broten (2013)	None	MADRS[8]	AAQ-II[4]	Number re-hospitalised
Gaudiano et al (2015)	BPRS[1] Psychosis Subscale	QIDS-C[9]	AAQ-II[4]	
Tyrberg et al., (2016)	None	None	None	Number re-hospitalised
Shawyer et al., (2016)	PANSS[5] Total	None	AAQ-II[4]	None
Boden et al., (2016)	BPRS[1]	PANAS[10]	AAQ-II[4]	None
Gumley et al., (2016)	None	BDI[3]	AAQ-II[4]	None

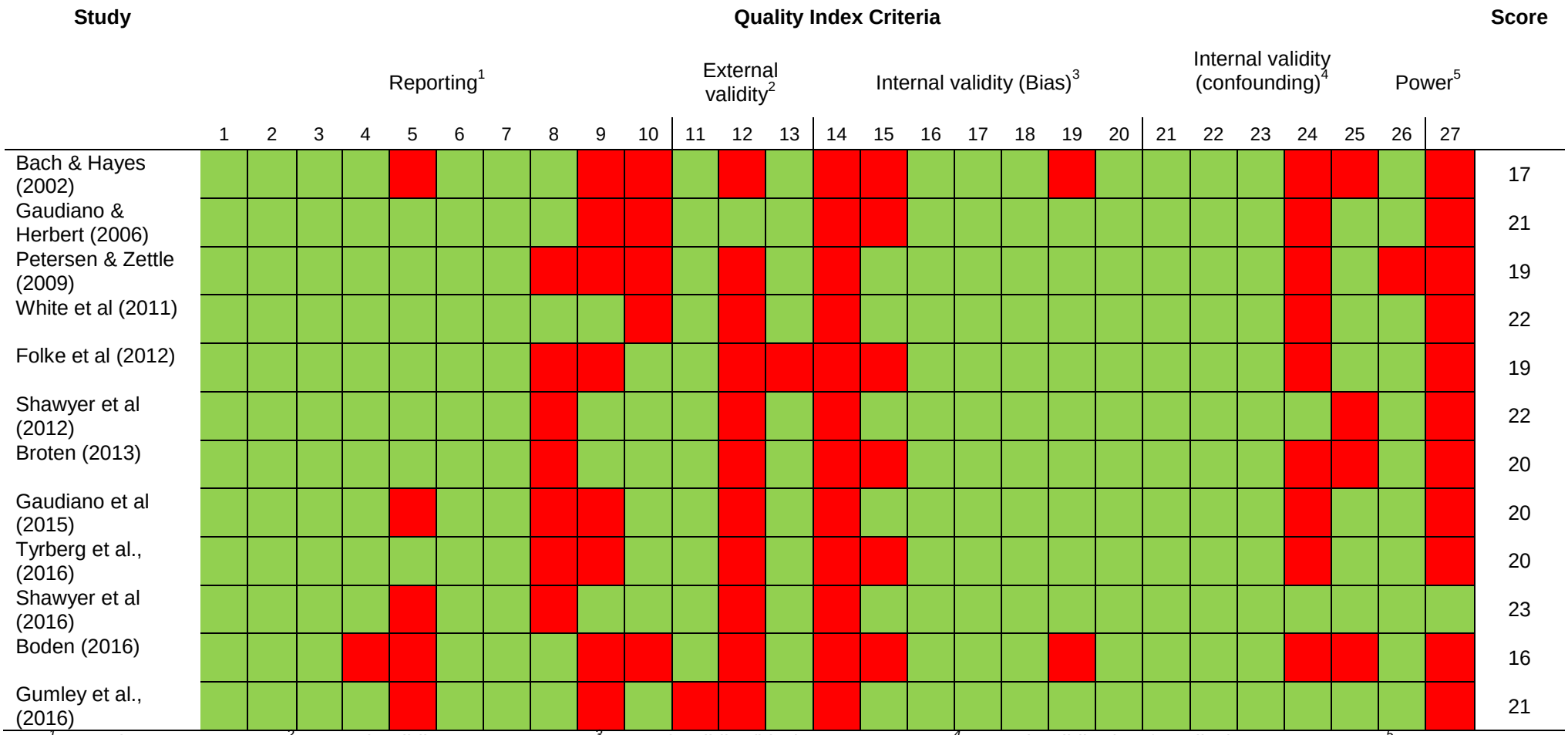
[1]Brief Psychiatric Rating Scale; [2]Hamilton Rating Scale; [3]Beck Depression Inventory; [4]Acceptance and Action Questionnaire; [5]Positive and Negative Syndrome Scale; [6]Hospital Anxiety and Depression Scale; [7]Voices Acceptance and Action Questionnaire; [8]Montgomery Asberg Depression Rating Scale; [11]Automatic Thoughts Questionnaire; [9]Quick Inventory of Depressive Symptomology-Clinician; [10]Positive and Negative affect Scale

3.5 Quality assessment

The quality of each study was assessed using Down's and Black's (1998) Quality Index (see Appendix 3). The Quality Index assesses important features of both internal and external validity as well as reporting standards and power calculations. Each of the 27 items was scored as either present or absent, yielding a Quality Index score for each study between 0 and 27.

A subsample of studies was selected at random and these were scored by a second rater to assess reliability of the ratings. Interrater reliability analysis was conducted by calculating the Kappa statistic. Kappa ranges from -1 to +1; with 1 indicating perfect agreement between raters (McHugh, 2012). Reliability of the quality assessment was good (Kappa = 0.81), and would be considered to be within the category of 'almost perfect agreement' (McHugh, 2012). Discrepancies were resolved through discussion between the raters. The quality assessment of each study is presented in Table 4.

Table 4. Quality Index assessment



[1]*Reporting: Items 1 to 10;* [2]*External Validity: Items 11 to 13;* [3]*Internal Validity (bias): Items 14 to 20;* [4]*Internal Validity (confounding): Items 21 to 26;* [5]*Power: Item 27*

3.6 Quality review

The overall score for the studies ranged from 16 to 22 (out of 27). Studies generally provided good descriptions of study aims, measurement (using reliable and valid measures), interventions and results. Samples were generally well described, were recruited from and received interventions where they would routinely receive treatment and were recruited from the same population across treatment arms (i.e. both the intervention group and the control group were recruited from the same hospital).

Although studies often reported the number of participants lost to follow-up there was rarely a description of those lost or a comparison of completers and non-completers. Furthermore, studies reported the number of participants who agreed to participate and often the number of refusers; however there was a limited number of comparisons between those who consented and those who refused, or a comparison of consenters with the population for the sample. Bach and Hayes (2002) compared consenters with the sample population and identified that consenters were less likely to have a secondary substance abuse diagnosis and were more likely to have had a previous hospital admission. Only one study (Gaudiano & Herbert, 2006) reported no significant differences between consenters and refusers across demographic variables. Each of these limitations raises questions about the representativeness of the samples.

Only two studies (Shawyer et al., 2012; Shawyer et al., 2016) reported a power analysis calculation and one of these (Shawyer et al., 2012) was underpowered. The presence or absence of any adverse events was also often omitted from reports. In terms of blinding, it is often not possible to blind participants

in psychological intervention studies to their treatment condition, which resulted in studies losing quality points. Blind assessment of outcome measures occurred in only six of the 12 studies, raising questions about possible assessment bias.

3.7 Data analysis

A separate meta-analysis was conducted for each outcome (psychotic symptoms, depression, ACT related outcomes and rehospitalisation) using the "Meta" package from the R programme (R Core Team, 2015; Schwarzer, 2007; Schwarzer, Carpenter & Rucker, 2015). As studies often reported both post-intervention and follow-up outcomes, separate analyses were conducted for both categories to identify any differences in effect over time. Summary effect sizes using standardised mean differences and 95% confidence intervals (CI) were calculated for each outcome category that used continuous outcomes (psychotic symptoms, depression and ACT outcomes). The standardised mean difference transforms all effect sizes to a common metric, and therefore allows the inclusion, within the same analysis, of similar outcomes that were measured using a range of different scales (Borenstein et al., 2009). As Cohen's *d* has been shown to slightly overestimate the true effect, particularly in small samples, all calculations were undertaken on the Hedges' *g* transformed standardised mean difference score, which contains a correction for this slight overestimation (Borenstein et al., 2009). However, Hedges' *g* was back-transformed to the more familiar Cohen's *d* for presentation in summary tables and forest plots. The summary effects were interpreted using Cohen's rule of thumb for a small (0.2), medium (0.5) and large (0.8) effect (Cohen, 1988). For outcomes that used frequency data (i.e. rehospitalisation rate), the relative risk ratio was calculated.

A fixed-effects model assumes that the individual trial perfectly measures (i.e., without error) the outcome of interest and the only source of between group heterogeneity is sampling variation. This assumption is, quite obviously, inappropriate for the evaluation of psychological constructs which are often measured with considerable error and may be moderated by methodologically uncontrolled factors. In contrast, the random effects model accommodates such methodological and measurement error. In the current review, it was assumed that the studies were not functionally identical and varied in terms of the quality of outcome measurement, the way that treatment was implemented, trial methodology and population characteristics (among other features). Accordingly, in line with recommendations (Hak, Van Rhee & Suurmond, 2016), the random-effects model was employed in the meta-analysis of all outcomes, even when significant heterogeneity was not identified.

Sensitivity analyses were conducted in order to test the validity and robustness of the results. Firstly, the quality effects model was reported in addition to the random effects model. The quality effects model is a measure of attenuation of effect due to methodological variation and is equivalent to the effect size that may be obtained if all of the studies were of the same methodological standard as the best study in the group. Secondly, the impact of any individual influential study was assessed using a “one left out” procedure, where each study was omitted from the meta-analysis in turn (Dias, Sutton, Welton & Ades, 2011). If the results of the meta-analysis with a study omitted are consistent with the overall results of the meta-analysis then there is confidence that the overall meta-analysis is robust to the over-influence of individual studies.

Heterogeneity in the study effects was quantified using Higgins' I^2. This statistic indicates the proportion of heterogeneity reflecting real variation in true effect size relative to within-study error. Value ranges of 0-50%, 50-75% and 75-100% have been suggested to signify low, medium and high levels of heterogeneity respectively (Higgins, Thompson, Deeks & Altman, 2003). As all of the studies within the current review were randomised controlled trials, a more rigorous research design is implied and therefore a lower level of heterogeneity due to methodological variation was expected. With this is mind, a more stringent acceptability level of Higgins I^2 (0-50%) was utilised.

Publication bias was identified using a combination of Egger's statistic (Egger, Smith, Schneider & Minder, 1997) and examination of funnel plots. If publication bias was suggested then a trim and fill procedure (Duval & Tweedie 2000a; Duval & Tweedie, 2000b) was used to estimate attenuation of the meta-analytic effect and the fail-safe number was calculated (Borenstein et al., 2009). Trim and fill uses an iterative procedure to remove the most extreme small studies from the positive side of the funnel plot and add studies to the area associated with publication bias. The effect size is recomputed at each iteration until the funnel plot is symmetric about the attenuated effect size. The effect attenuated for publication bias can then be compared to the effect that was calculated for the published studies.

4. Results

4.1 Participant characteristics

The total sample size across the 12 trials was 470, with a range across studies from 18 to 96 participants. The proportion of males and females varied greatly across studies. Participants were typically aged in their thirties or forties and were recruited primarily from inpatient or mixed (inpatient and community) samples. Where ethnicity was reported, the participants were predominantly Caucasian, except for one study in which participants were predominantly African-American (Gaudiano & Hebert, 2006). Approximately half of the studies (n=6) recruited participants from the USA, with other studies recruiting from either Australia (n=2), Sweden (n=2) or the UK (n=2). Eight studies recruited participants with a psychotic disorder, two with a major depressive disorder and two with a combination of diagnoses (either major depression and bipolar affective disorder, or schizophrenia and major depressive disorder).

4.2 Intervention characteristics

Number of intervention sessions varied across studies from two sessions (Tyrberg et al., 2016) to 15 sessions in addition to two follow-up sessions (Shawyer et al., 2012). The majority of studies (n=11) delivered one-to-one intervention sessions with only one study evaluating group therapy (Folke et al., 2012). Ten studies compared the ACT intervention to treatment as usual and two studies compared ACT to an active intervention (befriending).

4.3 Meta-analysis

Results of the meta-analysis are presented for each of the four outcome categories in turn; psychotic symptoms, depression, ACT related outcomes and

rehospitalisation rate. Within the first three outcome categories, post-intervention outcomes are presented first followed by follow-up outcomes. For the fourth outcome (rehospitalisation rate), only follow-up data are presented.

4.3.1 Psychotic symptoms

Seven studies (n=317) reported outcomes related to psychotic symptoms. Five of these (n=210) reported post-intervention outcomes and six (n=299) reported follow-up outcomes. The mean length of follow up was 4.3 months (range 3 to 6 months).

Post-intervention results

Figure 2 displays the forest plot with the effect size and 95% confidence interval (CI) for each individual study and the omnibus test of the combined effect. Two studies favoured the intervention, whilst three studies favoured the control group. Confidence intervals for all studies included zero, indicating that no individual study showed a significant effect.

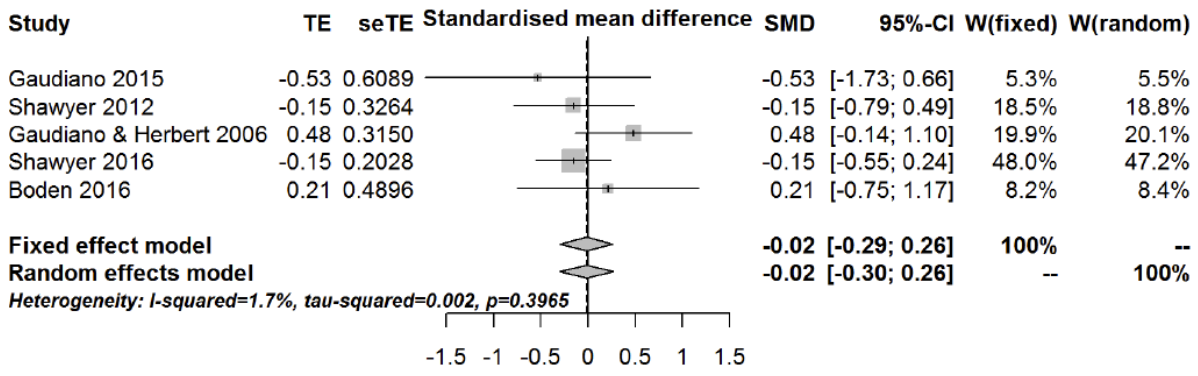


Figure 2. Forest plot for psychotic symptoms post-intervention

The random effects model revealed a no significant difference between treatment and control groups at the post-intervention time point (SMD=-0.02, 95% CI [-0.30-0.26], *p*=0.91). Weighting studies by their quality in the quality effects model did not influence the effect (WMD=-0.04, 95% CI [-0.39-0.31], *p*=0.82). The results remained non-significant when the "one left out" procedure was applied. Heterogeneity within the sample was low (I^2=1.73%).

Regarding publication bias, Egger's statistic showed no significant bias (*p*=0.91). This was confirmed using trim and fill procedures where the corrected estimate (SMD=-0.02, 95% CI [-0.30-0.26], *p*=0.91) remained the same as the uncorrected estimate. The failsafe number was unattainable as no significant effect was observed.

Follow-up results

The forest plot at follow-up (Figure 3) shows that three studies favoured the intervention, whilst two studies favoured the control group. Four studies showed no significant effect, whilst one study showed a significant effect in favour of the intervention.

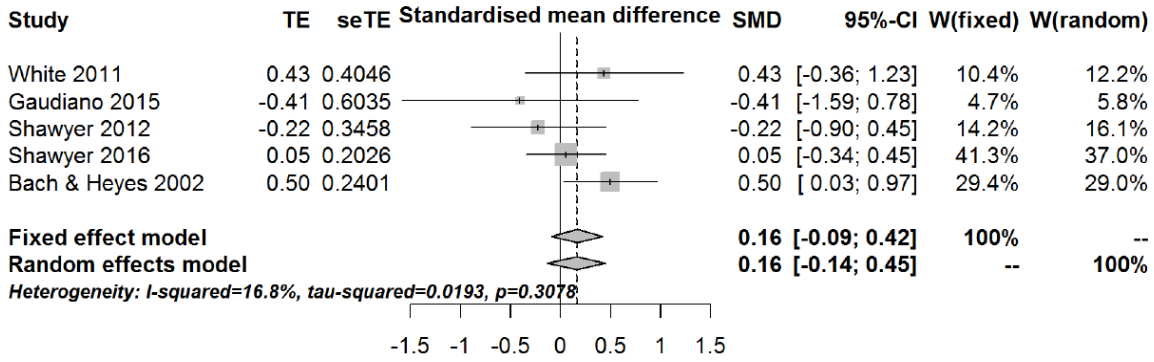


Figure 3. Forest plot for psychotic symptoms at follow-up

The random effects model showed no significant difference between treatment and control groups at the post-intervention time point (SMD=0.16, 95% CI [-0.14-0.45], *p*=0.30). Weighting studies by their quality in the quality effects model slightly reduced the effect (WMD=0.06, 95% CI [-0.30-0.42], *p*=0.75). The results remained non-significant when the "one left out" procedure was applied. Heterogeneity within the sample was low (I^2=16.8%).

Egger's statistic showed no significant bias (*p*=0.60). This was confirmed using trim and fill procedures where the corrected estimate (SMD=0.19, 95% CI [-0.09-0.47]) showed trivial correction to the uncorrected estimate (SMD=0.16, 95% CI [-0.14-0.45]). The failsafe number was not calculated as no significant effect was observed.

4.3.2 Depression outcomes

Seven studies (n=190) reported depression outcomes. Six of these (n=161) reported post-intervention outcomes and five (n=143) reported follow-up outcomes. The mean length of follow up was 7.4 months (range 3 to 18 months).

Post-intervention results

Figure 4 displays the forest plot with the effect size and 95% CI interval for each individual study and the omnibus meta-analytic result. Five studies favoured the intervention, whilst one study favoured the control group. Confidence intervals for all studies included zero, indicating no significant effect in any individual study.

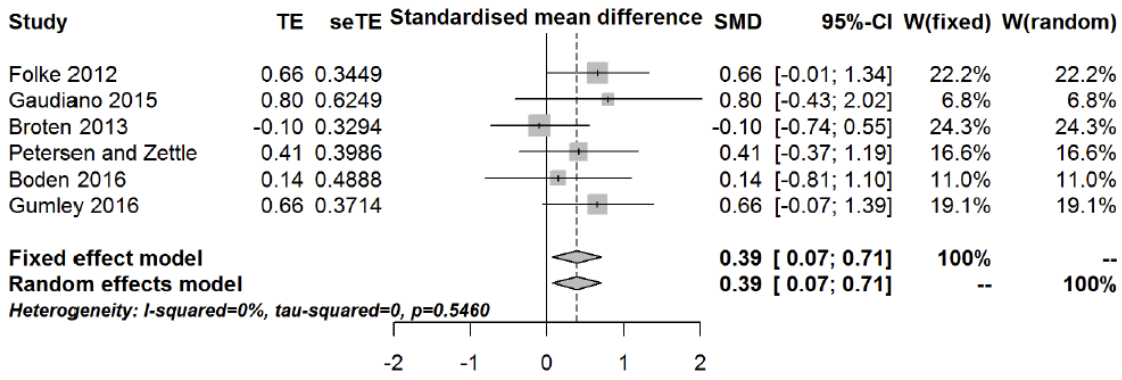


Figure 4. Forest plot for depression outcomes post-intervention

The random effects model revealed a significant difference between treatment and control groups at the post-intervention time point (SMD=0.39, 95% CI [0.07-0.71], *p*=0.02). Weighting studies by their quality in the quality effects model showed trivial correction to the model (WMD=0.44, 95% CI [0.09-0.79], *p*=0.01). Using the "one left out" procedure, the effect was no longer significant when the study by Folke et al., (2012) was omitted (SMD=0.31, 95% CI [-0.05-0.67], *p*=0.09) or when the study by Gumley et al., (2016) was omitted (SMD=0.32, 95% CI [-0.03-0.68], *p*=0.07). This suggests that the conclusion is sensitively dependent upon the inclusion of these two studies. Heterogeneity within the sample was low (I^2=0.0%).

Egger's statistic showed no significant publication bias (*p*=0.58). The funnel plots (Figure 5) suggest that a study with a relatively low effect size is missing. Using the trim and fill method the corrected estimate (SMD=0.36, 95% CI [0.05-0.67]) showed trivial correction to the uncorrected estimate (SMD=0.39, 95% CI [0.07-0.71]).

Using the Rosenthal (1979) algorithm, 14 (233%) unpublished null studies are required to reduce the six observed meta-analytic effect to non-significance. As the

failsafe number is twice that of the included it would be safe to assume that this conclusion should be robust to effects of unpublished null studies.

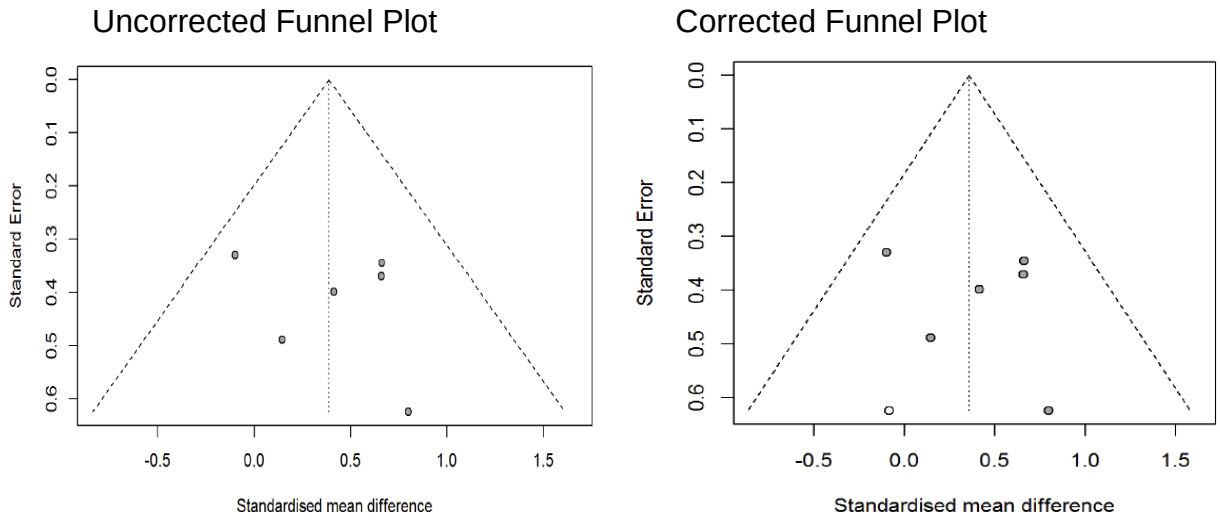


Figure 5. Funnel Plots for depression outcomes post-intervention

Follow-up results

Figure 6 displays the forest plot with the effect size and 95% CI for each individual study and the combined meta-analytic result. All five studies favoured the intervention, however no significant effect was observed for an individual study.

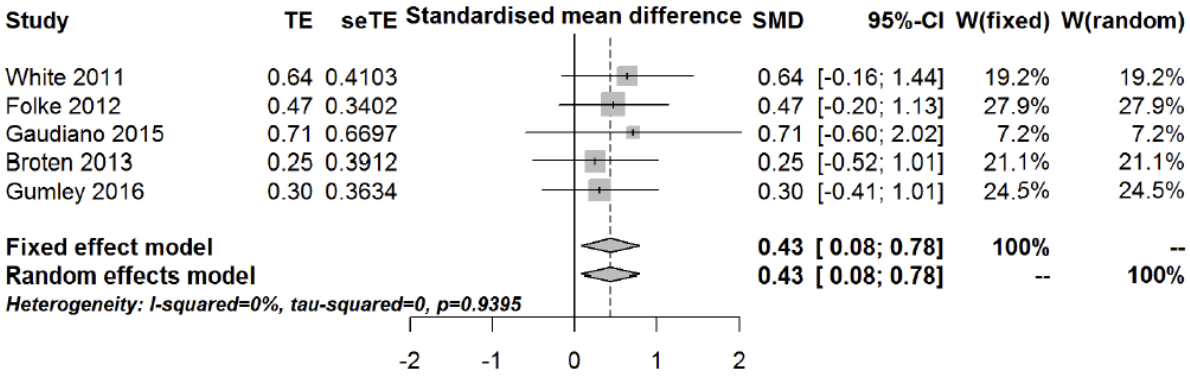


Figure 6. Forest plot for depression outcomes at follow-up

The random effects model revealed a significant difference between treatment and control groups at the post-intervention time point (SMD=0.43, 95% CI [0.08-0.78], *p*=0.02). Weighting studies by their quality in the quality effects model showed trivial correction to the model (WMD=0.48, 95% CI [0.08-0.87], *p*=0.02). The effect did not remain significant when the study by White et al., (2011) was omitted (SMD=0.38, 95% CI [-0.01-0.77], *p*=0.06). Heterogeneity within the sample was low (I^2=0.0%).

Egger's statistic showed no significant publication bias (*p*=0.37). The funnel plots (Figure 7) suggest that a study with a relatively low effect size is missing. Using the trim and fill method the corrected estimate (SMD=0.41, 95% CI [0.07-0.75]) showed trivial correction to the uncorrected estimate (SMD=0.43, 95% CI [0.08-0.78]). Using the Rosenthal (1979) algorithm, 10 (200%) unpublished null studies are required to reduce the five observed meta-analytic effect to non-significance. Again, it would be safe to assume that this conclusion should be robust to effects of unpublished null studies.

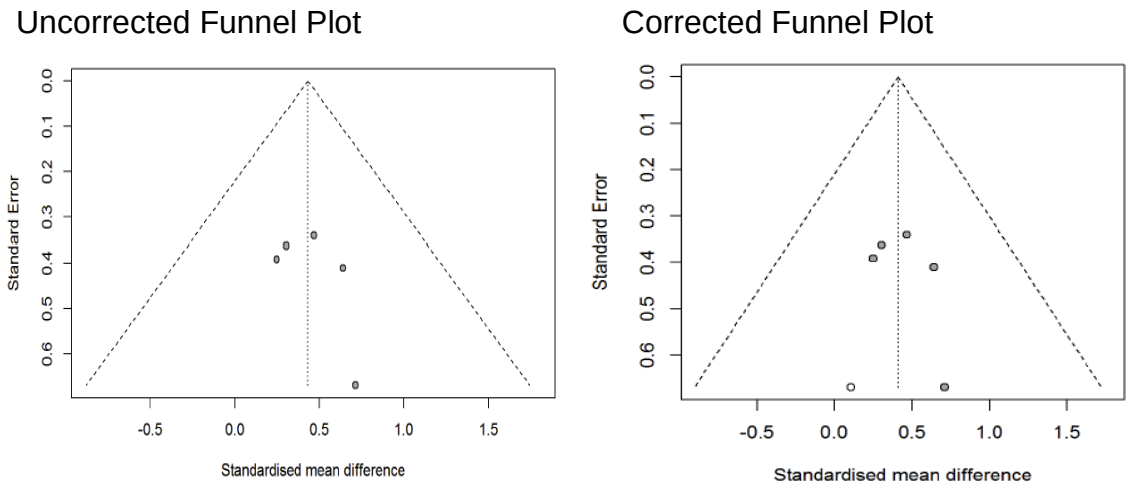


Figure 7. Funnel Plots for depression outcomes at follow-up

4.3.3 ACT specific outcomes

Eight studies (n=294) reported ACT related outcomes. Seven of these (n=267) reported post-intervention outcomes and five (n=208) reported follow-up outcomes. The mean length of follow up was 6.8 months (range 3 to 10 months). Data from one additional study (n=21) were not included as non-parametric data were reported.

Post-intervention results

Figure 8 displays the forest plot with the effect size and 95% CI for each individual study and the omnibus meta-analytic result. Five studies favoured the intervention, whilst two studies favoured the control group. Two studies independently indicated a significant effect in favour of the intervention (Petersen & Zettle, 2009; Gumley et al., 2016).

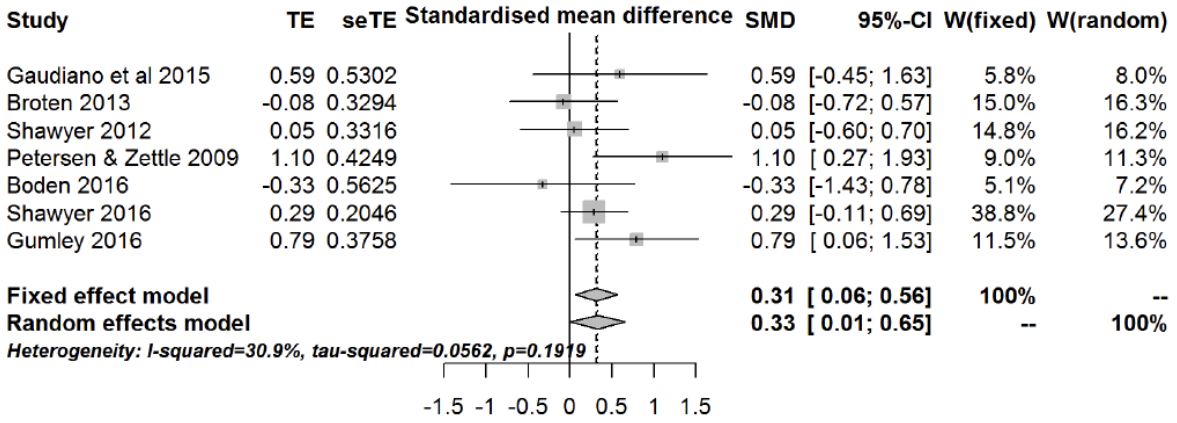


Figure 8. Forest plot for ACT outcomes post-intervention

The random effects model showed a significant difference between treatment and control groups at the post-intervention time point (SMD=0.33, 95% CI [0.01-0.65], *p*=0.04). Weighting studies by their quality in the quality effects model showed trivial correction to the model (WMD=0.36, 95% CI [0.02-0.70], *p*=0.04). Heterogeneity

within the sample was low (I^2=30.9%). Using the “one left out” procedure”, the results were no longer significant when one of four studies were omitted; Gaudiano et al., (2015; *p*=0.09), Petersen and Zettle (2009, *p*=0.07), Shawyer et al., (2016, *p*=0.11) and Gumley et al., (2016, *p*=0.13).

Egger’s statistic showed no significant bias (*p*=0.75). This was confirmed using trim and fill procedures where no missing studies were identified using funnel plots and the corrected estimate (SMD=0.33, 95% CI [0.01-0.65]) remained the same as the uncorrected estimate. Using the Rosenthal (1979) algorithm, 3 (43%) unpublished null studies are required to reduce the four observed meta-analytic effect to non-significance. This suggests that this result is not robust to publication bias and may lose significance with the publication of only a few null studies.

Follow-up results

Figure 9 displays the forest plot with the effect size and 95% CI for each individual study and the omnibus meta-analytic result. Four studies favoured the intervention whilst one favoured the control group. No study independently showed a significant effect.

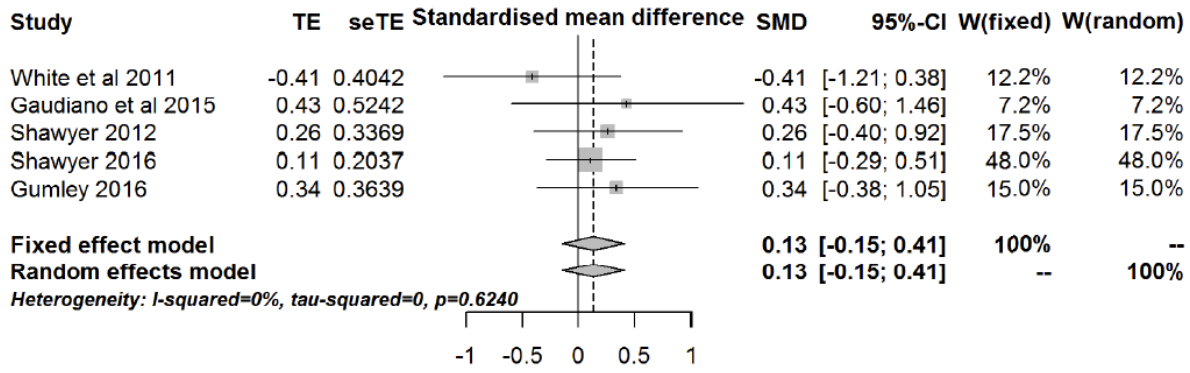


Figure 9. Forest plot for ACT outcomes at follow-up

The random effects model revealed no significant difference between treatment and control groups (SMD=0.13, 95% CI [-0.15-0.41], p=0.36). Weighting studies by their quality in the quality effects model showed trivial correction to the model (WMD=0.14, 95% CI [-0.19-0.46], p=0.41). Heterogeneity within the sample was low (I^2=0.0%). The results remained non-significant when the "one left out" procedure was applied.

Egger's statistic showed no significant publication bias (p=0.91). Trim and fill procedures indicated that one study with relatively low effect size was missing. The corrected model (SMD=0.11, 95% CI [-0.16-0.37]) showed trivial correction to the uncorrected model. The failsafe number was not calculated as no significant effect was observed.

4.3.4 Rehospitalisation

Four studies (n=180) reported rehospitalisation rates. The mean length of follow up was 4.5 months (range 4 to 6 months). Figure 10 displays the forest plot with the relative risk and 95% CI for each individual study and the omnibus meta-analytic result. Three studies favoured the intervention, whilst one study favoured the control group. No study independently indicated a significant effect in favour of the intervention.

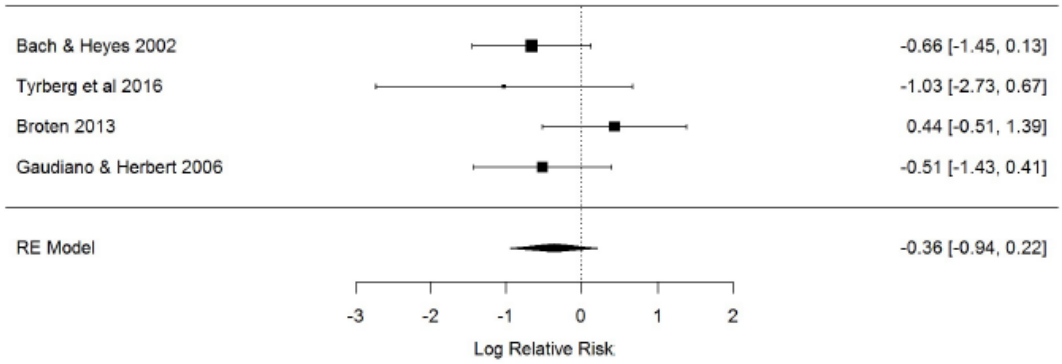


Figure 10. Forest plot for rehospitalisation rate

The random effects model revealed no significant difference between treatment and control groups (RR=-0.36, 95% CI [-0.94-0.22], *p*=0.22). Weighting studies by their quality in the quality effects model showed trivial correction to the model (RR=-0.43, 95% CI [-1.09-0.22], *p*=0.19). Heterogeneity within the sample was low (I^2=26.0%).

5. Discussion

5.1 Summary of findings

The current review aimed to evaluate whether Acceptance and Commitment Therapy (ACT) improves outcomes for people with severe and enduring mental health problems. Reviews to date have focused on whether ACT is an effective intervention for mental health problems more generally, combining both clinical and sub-clinical presentations across a wide range demographics and treatment settings (e.g. schools, prisons, physical health settings). In contrast to previous reviews, a strength of the current review is that it focused on a specific clinical population (those with severe and enduing mental health problems), making the results more reliable for this particular population. Furthermore, while previous reviews primarily reported outcomes related to mental health symptoms, the current review also examined outcomes specifically related to ACT processes as well as the more objective outcome of rehospitalisation.

Twelve quantitative studies met the inclusion criteria and were included in the meta-analysis. Seven of the 12 studies measured psychotic symptoms, using either the Positive and Negative Syndrome Scale (PANSS), the Brief Psychiatric Rating Scale (BPRS) or self-ratings of psychotic symptoms (frequency, believability, and distress). The results suggest that ACT did not improve psychotic symptoms compared to the control group either at post-intervention or follow-up time points. Tests of sensitivity, heterogeneity and publication bias indicated that this result was robust to publication bias and the publication of null studies in the future.

Regarding depressive symptoms, seven of the 12 studies reported outcomes, using a range of six different outcome measures. The Beck Depression Inventory

was the most consistent measure of depression, employed across three of the studies. The results suggested that those who received ACT exhibited fewer symptoms of depression after the intervention than those who received the control condition; and this improvement was maintained at follow-up. At both time points, a large number of null studies would be required to reduce the effect to non-significance, although sensitivity analyses suggested that the results were potentially being influenced by individual studies. The effect size reported here for depression outcomes (0.42) was larger than the effect size reported for mood outcomes in similar samples that received CBT; an effect size of *d*=0.29 in people with a diagnosis of bipolar disorder (Gregory, 2010) and of *d*=0.36 in people with a diagnosis of psychosis (Wykes, Steel, Everitt & Tarrier, 2008).

The analysis for ACT specific outcomes focused on psychological flexibility measured primarily by the Acceptance and Action Questionnaire (AAQ; 7 studies) with one study using the Voices Acceptance and Action Questionnaire (VAAS). The results suggested that the intervention significantly increased psychological flexibility compared to the control group post-intervention, however this was not maintained at follow-up. The robustness of the result is questionable, with a relatively small amount of null results required to reduce the significant post-intervention result to non-significance, and sensitivity analyses suggesting that this result was potentially being driven by individual studies.

ACT did not significantly reduce the risk of rehospitalisation compared to controls. Only four studies measured rehospitalisation; three of these showed that ACT reduced the risk of rehospitalisation compared to controls, whereas one showed the opposite.

5.2 Potential mediators of effect size

Examining the impact of study level co-variates on the effect sizes using meta-regression was not possible within the current review due to the small number of studies in each analysis. For this procedure, the ratio of studies to covariates needs to be large, with a recommendation of 10 studies per co-variate as a minimum (Borenstein et al., 2009). Heterogeneity (assessed using Higgin's I^2) was low across the analyses, which may be a result of the analyses focusing on a specific intervention for a specific client group and conducting a separate meta-analysis for each outcome category. Furthermore, the potential influence of studies based on their methodological quality was controlled for by including the quality effects model. However two important factors were not considered independently within the analyses. First, the within-study approach to statistical analysis (i.e. the use of intention-to-treat versus completer-data), and second, the type of control group used (i.e. active treatment control versus 'treatment as usual').

Several meta-analyses have compared effect sizes between studies that reported completer-data and those that reported intention-to-treat data. Hans and Hiller (2013) reported a significantly larger effect size when completer-data were reported compared to intention-to-treat data; a trend that has also been observed by others (A-Tjak et al., 2016; Johnsen & Friborg, 2015). Within the current review, five studies reported intention-to-treat data (Folke et al., 2012; Gaudiano & Herbert, 2006; Gaudiano et al., 2015; Gumley et al., 2016; Shawyer et al., 2016), whilst the remaining studies reported completer-data. Although not statistically analysed, visual inspection of the forest plots does not appear to indicate a bias whereby completer-data produces larger effect sizes. In fact, in the analysis for depression outcomes at

post-intervention, the three studies with the larger effect sizes are all based on intention-to-treat analyses. This would suggest that the results of the current review are not being driven by larger effect sizes generated using completer-data, thereby increasing the validity of the findings.

The second area was associated with the control group used as a comparison to the ACT intervention. Previous meta-analyses have suggested that larger effect sizes are observed when ACT is compared to 'treatment as usual' than other active comparison groups (e.g. A-Tjak et al., 2015; Ost, 2014). Within the current review two studies used an active, manualised treatment as the comparison condition ('befriending'; Shawyer et al., 2012; Shawyer et al., 2016), whilst the remaining studies compared ACT to treatment as usual. Again, no statistical comparison of studies based on control group was undertaken due to the small number of studies; however visual inspection of the forest plot does not suggest that those studies with active treatment comparisons produced smaller effect sizes in relation to the remaining studies.

5.3 Fidelity to the key ingredients of the ACT intervention

It is surprising that, as increasing psychological flexibility is the primary target of ACT, the results for the process outcome were not more robust and maintained over time. This leads to two important questions; (1) how is ACT delivered in the trials, and (2) are ACT outcomes measured in a reliable and valid way.

Fidelity assessments are often used to measure adherence to the treatment manual or protocol. Within the current review six studies reported a fidelity assessment and where results were reported fidelity ratings were high. Within the ACT outcome analysis, at both time points (post-intervention and follow-up),

outcomes in favour of the ACT intervention were observed for studies that reported fidelity assessments, and outcomes in favour of the control group were observed for studies that reported no fidelity assessments. Although the suggestion can only be tentative at this point without further exploration and statistical analyses, it seems possible that studies with high levels of adherence to the ACT protocol or manual were more likely to result in increased psychological flexibility within the treatment condition.

ACT utilises a range of methods to promote psychological flexibility, including mindfulness, defusion and values-based living. The current analysis focused on a general measure of psychological flexibility (i.e. the AAQ) to evaluate ACT related outcomes; as this was consistently reported by the majority of studies. This is also a reliable and valid measure of the construct (Bond, Hayes, Baer et al., 2011). This meant, however, that additional outcomes of important ACT processes were not evaluated. Only three studies measured additional ACT processes, including mindfulness (Gumley et al., 2016; White et al., 2011) and values-based living (Tyrberg, et al., 2016). These studies showed that ACT significantly increased mindfulness (Gumley et al., 2016; White et al., 2011) but not values-based living (Tyrberg et al., 2016) compared to the control. Although the number of studies measuring these constructs was too small to be subjected to meta-analysis, it is important to highlight this area.

When evaluating treatment approaches it is important to not only determine whether an intervention can improve broad outcomes, but to also consider which aspect or aspects of the intervention promote what predicted change to what specific outcomes. The evidence base for ACT for people with severe and enduring mental

health problems is still in its infancy, and it is difficult therefore to statistically explore the different concepts at this stage. Qualitative interviews with participants from a trial included in the meta-analysis (Shawyer et al., 2016) reinforce the importance of this; suggesting that the different components of ACT are received differently by individuals. For example, eight out of nine participants interviewed stated that mindfulness was helpful to them, whilst only two found the concept of acceptance beneficial (Bacon, Farhall & Fossey, 2014).

5.4 Limitations of the research literature

There are several limitations to the existing literature that make it difficult to draw firm conclusions from the present data. Although the number of trials evaluating ACT has been increasing in recent years, the evidence base evaluating ACT for people with severe and enduring mental health problems is still in its infancy, and it is difficult to generate reliable findings based on a small number of studies with a relatively small number of participants. More studies would allow for more robust meta-analytical conclusions. Available studies measure different outcomes; which reduces the number of studies within the meta-analysis further, and raises questions about the type of outcomes that trials should be reporting. When an outcome is consistently reported across studies, a range of different measures is used, again raising questions about which measure is the most reliable and valid measure of a particular construct for a particular client group.

Ten of the 12 studies in the review compared ACT to ‘treatment as usual’, and as a result it is difficult to attribute effects to a specific intervention. It is possible that other non-specific intervention factors, such as increased contact time or the therapeutic alliance, were responsible for the observed intervention effects. One

study demonstrated statistical mediation of the intervention effect by changes on the Acceptance and Action Questionnaire (AAQ; Gumley et al., 2016); suggesting that within-study effects were attributable to the intervention components rather than the non-specific factors. Future research should consider using an active control group, such as CBT, and be able to demonstrate mechanisms of change (i.e changes in acceptance, mindfulness or values-based living, for example). This would allow for refinement of the intervention and consideration of which components of an intervention promote change.

5.5 Convergence with other reviews

During the course of this review, a meta-analysis of four randomised controlled trials comparing ACT to treatment as usual for people with psychosis was published (Tonarelli, Pasillas, Alvarado et al., 2016). They reported that, based on two studies, ACT significantly improved negative symptoms of psychosis but had no effect on positive symptoms. They also reported that, based on two studies, those who received ACT had significantly lower risk of rehospitalisation compared to those who received 'treatment as usual'. The results of the current review differ from the results of Tonarelli et al., (2016), with the current review reporting no effect on either psychotic symptoms or rehospitalisation rate. The primary limitation of the Tonarelli et al., (2016) review was the sample size. Only four studies were included in the review; and only two studies were included in each of the analyses. This number is very small and brings into question the reliability of the findings. The current review included each of the four studies selected for Tonarelli et al., (2016) review, with an additional eight studies included. This would suggest that the results and conclusions of the current review are more robust and reliable.

5.6 Clinical implications

The finding that ACT improves depression for this client group, and that this improvement is maintained over time, is an important one. The experience of psychosis is associated with increased risk of depression (Birchwood, Iqbal, Chadwicjk & Trower, 2000), and depression in this context has been identified as a major factor contributing to poorer quality of life (Meijer, Koeter, Sprangers & Schene, 2009; Saarni et al., 2010) and increased levels of hopelessness and suicide (White, McCreery, Gumley & Mulholland, 2007). Reducing depression amongst this client group is therefore a primary target for psychological interventions, and the results of the current review, although tentative at this stage, suggest that ACT may be an appropriate intervention and is worthy of further study.

In terms of attempting to explain how ACT is an effective treatment for depression, it has been proposed that depression in the context of psychosis is associated with lower psychological flexibility (White, Gumley, McTaggart et al., 2013), and therefore changes in psychological flexibility will in turn lead to changes in depression. Some studies have begun to explore the change mechanisms in this relationship. For example, Gumley et al., (2016) found a significant correlation between changes in BDI scores and changes in AAQ scores, suggesting that as flexibility increased, depression decreased. The same study reported the same significant correlation between BDI scores and KIMS (Kentucky Inventory of Mindfulness Skills; Baer, Smith & Allen, 2004) scores. Finally, Shawyer (2007) reported that greater psychological flexibility in relation to hallucinatory voices was associated with lower depression.

The results of the current review found no change in psychotic symptoms following an ACT intervention; however, it is often highlighted that the target of ACT is not symptom reduction, but rather increase in psychological flexibility. It is recognised that this change in psychological flexibility may in turn reduce or improve symptoms over time. Follow-up lengths of studies in the review that measured psychotic symptoms were short (mean follow up of 4.3 months), and so it would be important for studies to assess psychotic symptoms longer term in order to understand whether or not changes in psychological flexibility correlate to changes in psychotic symptoms over time.

5.7 Conclusion

The question of whether or not ACT is an effective treatment for people with severe and enduring mental health problems is a difficult one to answer with certainty at this current stage of evidence. The answer, in part, depends on what one perceives constitutes a successful intervention. If symptom reduction is the aim, then the current review suggests that ACT is useful in decreasing depressive symptoms, but not psychotic ones, amongst this client group. If the target of the intervention is to increase psychological flexibility, then the current review provides preliminary evidence that ACT can increase psychological flexibility in the short term for this client group, but that these changes are not maintained in the longer term. If the target of an intervention is to attempt to reduce reoccurrence of symptoms and keep people out of hospital, an important consideration for this group, then the results suggest that ACT is no more successful than treatment as usual.

All of these treatment aims are important, and moving forward future research should consider each of them. Of particular importance is determining why

interventions work, not just if they do, and measurement of additional processes of change, rather than reliance solely on the AAQ, may help to do this. Mindfulness and values work are two core concepts to ACT and their role in the effectiveness of the intervention should be considered.

6. References

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Chapter II: Empirical Paper

An exploration of shame, psychological flexibility and the use of alcohol or drugs in people with mental health problems.

1. Abstract

Introduction: Substance use is prevalent amongst people with severe and enduring mental health problems and is associated with negative outcomes and high levels of resource use. The role of shame in the development and maintenance of both substance use and mental health problems independently has been demonstrated; however research is yet to explore the role of shame in the relationship between mental health and substance use in this complex client group. Similarly, the role of psychological flexibility has been explored in both individual research fields but not in co-existing presentations.

Method: A cross-sectional questionnaire study was used to explore the relationships between mental health, substance use, shame and psychological flexibility in people with severe mental health problems admitted to inpatient units. Planned analyses included correlational as well as exploratory mediation and moderation analyses.

Results: Forty-nine participants consented to the study. Participants were typically male (73.5%), white British (53.1%) and had an average age of 39 years. Results showed a significant relationship between psychological distress and substance use. This relationship was fully mediated by shame. Psychological flexibility did not moderate the effect of shame on substance use.

Conclusion: When working with this client group, targeting shame may be an important focus for psychological interventions. Acceptance and Commitment Therapy is presented as a therapeutic framework working with shame. The role of

psychological flexibility in the relationship between psychological distress, shame and substance use requires further exploration.

2. Introduction

2.1 Rationale

Substance use, particularly alcohol and cannabis use, is highly prevalent amongst people with severe and enduring mental health problems (Graham, Copello, Griffith et al., 2016; NICE, 2011). Co-existing substance use and mental health problems are increasingly recognised problems that have been associated with poorer outcomes and high levels of resource use when compared to either problem on its own (Banjaree, Clancy & Crome, 2002; NICE, 2011). As a result, people with these co-occurring problems are often perceived as difficult to engage in treatment and as 'lacking motivation to change' (van Boekel, Brouwers, van Weeghel & Garretsen, 2013). This is compounded by intervention trials that show mixed results and are plagued with recruitment and retention difficulties (Barrowclough, Haddock, Wykes, Beardmore et al., 2010).

The main focus to date has been on intervention techniques (mostly behavioural or motivational based) that may improve outcomes for individuals with co-existing mental health and substance use problems, with less attention being paid to potential core psychological factors that may underlie and be associated with the development and severity of these combined problems (Levin, Lillis, Seeley, Hayes et al., 2012). Two such factors that have been shown to be important in both conditions independently include the experience of shame and the presence and extent of psychological flexibility as an adaptive response. The lack of focus on underlying psychological factors as possible mechanisms of change may limit the future development of potential intervention strategies that could be used for this complex group.

2.2 The experience of shame

Shame has been described as a powerful self-conscious emotion involving a global negative feeling about the self that can lead to a desire to hide or escape (Scheel, Bender, Tuschen-Caffier, Brodführer et al., 2014; Wiklander, Samuelsson, Jokinen, Nilsonne et al., 2012). Shame is elicited when one percieves their personal attributes or actions as unattractive or worthless, consequently leading to anticipation of rejection from others or loss of social status (Gilbert, 1998; Gilbert, 2000; Gilbert, 2003). In some cases, shame can be adaptive as it can help to inhibit further threats to the self (Michail & Birchwood, 2013), however high levels of persistent shame are associated with a range of negative internalising and externalising symptoms or behaviours, including mental health problems and substance use. In light of this, there has been increasing interest in the relationship between the experience of shame and psychological difficulties (Dinis, Carvalho, Gouveia & Estanqueiro, 2015).

Michail and Birchwood (2013) have argued that stigma acts as a catalyst for people who are vulnerable to experience shame, for example those who developed early maladaptive attachment styles or experienced dysfunctional parenting. Therefore, an important contributor to the experience of shame is the societal devaluation of stigmatized identities (Luoma & Platt, 2015). Strong, negative stigmatizing atttudes towards people with mental health problems and people who use substances are prevalent amongst both the general population and healthcare professionals (Barry, McGinty, Pescosolido & Goldman, 2014; Phillips & Shaw, 2013; Stuber, Rocha, Christian & Link, 2014; van Boekel et al., 2013). Both problems are more stigmatized than physical health problems (Ahmedani, Kubiak, Kessler, de Graaf et al., 2013; Corrigan, Lurie, Goldman, Slopen et al., 2005), and there is

evidence to suggest that substance use is more stigmatized than mental health (Barry et al., 2014; Corrigan et al., 2005;; van Boekel et al., 2013).

Negative judgements are held not only by society but can be internalised by those who themselves use substances or experience mental health problems (self-stigma). Shame has been described as the “emotional core of self-stigma” (Luoma, Kohlenberg, Hayes & Fletcher, 2012; p. 43). When a person identifies with more than one socially stigmatised group, it is hypothesised that the self-stigma and shame from one identity “layers” on top of that related to another identiy, creating a “dense web of ideas about the self that must be managed and responded to” (Luoma, 2010; p. 1202). It can therefore be hypothesised that those who have both co-existing mental health and substance use problems have the potential to experience higher and more problematic, more distressing levels of shame leading to a greater impact than that of either problem in isolation.

2.3 The relationship between shame and mental health problems

High levels of shame have been positivley correlated with a range of mental health problems, including depression (Cheung, Gilbert, & Irons, 2004; Kim, Thibodeau & Jorgensen, 2011), social anxiety disorder (Michail & Birchwood, 2013) and eating disorders (Troop & Redshaw, 2012).

Compared to controls, higher levels of shame have been found in individuals with anhedonic schizophrenia (Suslow, Roestel,Ohrmann & Arolt, 2003) and in people with first-episode psychosis who were also experiencing social anxiety (Michail & Birchwood, 2013). Positive correlational relationships have been observed between shame and 1) post-psychotic depression in first episode psychosis (Upthegrove, Ross, Brunet, McCollum & Jones, 2014), 2) paranoia, depression and

anxiety in a clinical sample of young people at risk of developing psychosis (Johnson, Jones, Lin, Wood et al., 2014), and 3) delusional beliefs in a clinical sample of people with psychosis-related disorders (Barratt, 2015).

Furthermore, there is emerging evidence that shame may have a mediating or moderating role in psychological difficulties (Hasson-Ohayon et al., 2012; Johnson et al., 2014; Rice & Fallon, 2012). For example, in a clinical sample of young people at risk of psychosis, shame moderated the the association between stress and paranoia. For high shame individuals, shame amplified the association between stress and paranoia, but for individuals who scored low on shame, the association between stress and paranoia was no longer significant (Johnson et al., 2014).

In addition to the potential consequences of shame on psychological outcomes, shame also plays a role in delaying help-seeking. When shame is evoked in those seeking help for illness, potentially through the mechanisms of self-stigma or fear of enacted stigma, it is likley to motivate self-concealment (Jones & Crossley, 2008). Forsell (2006) found shame to be the most common reason for not seeking help for psychiatric problems, and higher levels of shame have been associated with more negative views of help-seeking (Rusch, Müller, Ajdacic-Gross, Rodgers et al., 2013). With potential for shame to lead to poorer psychological outcomes and possible reluctance to seek help, it is important to consider the role of shame in the context of co-exsiting mental health and substance use problems; which is currently a gap in the literature.

2.4 The relationship between shame and substance use

The literature examining the role of shame within the field of substance use is less extensive than the mental health focused literature; however there is some evidence to suggest that shame is also positively associated with problematic substance use. In a sample of college students, higher levels of shame have been associated with problematic alcohol use (Dearing, Stuewig & Price-Tangney, 2005). In the same study, amongst prison inmates shame was positively correlated with alcohol and drug problems, alcohol and drug dependence, and frequency of cocaine use (but not with frequency of alcohol or cannabis use). Treeby and Bruno (2012) found that shame-prone university students were more likely to experience alcohol related problems and were more motivated to use alcohol to cope with depression and anxiety.

The relationship between shame and substance use is clinically controversial, and whether shame is an antecedent to substance use or consequence of use is unclear from current evidence. Many people with substance use disorders experience shame as a result of behaviours associated with their use; however there is also evidence to suggest that shame evokes substance use, as a possible method of regulating the negative affect associated with shame (Luoma, 2010). It is possible that there is a synergistic relationship whereby shame and substance use lead to a vicious cycle (Dearing et al., 2005). For example, substance use may begin as an attempt to suppress negative emotions (such as shame), however the substance use itself may create more shame and self-stigma, resulting in the person using more substances to supress these feelings. Additionally the shame and stigma of being a 'substance user' may lead people to avoid applying for jobs or avoid intimate social

relationships because, as a result of self-stigma, people no longer trust themselves to fulfill these roles or fear rejection based on their substance-using identity (Luoma, 2010). Opportunities to disprove their beliefs or elicit compassion within others may become limited, further maintaining their experience of shame and in turn their substance use.

Whilst shame has been shown to be an important factor in the experience of both mental health and substance use problems, on the other hand the concept of psychological flexibility has been postulated as a mechanism that allows individuals to respond adaptively to unpleasant and unwanted feelings, for example shame, in the context of both mental health and substance use.

2.5 Psychological flexibility in mental health and substance use problems

Psychological flexibility is defined as the tendency to respond to unwanted internal experiences (thoughts, emotions, memories) in an accepting, mindful, defused manner, which allows for engagement in behaviour that serves chosen goals (Hayes, Luoma, Bond, Masuda, & Lillis, 2006). The postulated opposite state, experiential avoidance (or low psychological flexibility), is therefore an unwillingness to experience these unwanted internal experiences in the present moment, resulting in the person taking steps to attempt to suppress or control such states (Dinis et al., 2015). These attempts often include various forms of avoidance, and do not only paradoxically increase the occurrence of such events over time, but result in the person sacrificing opportunities to work towards their values or goals.

Low psychological flexibility (or experiential avoidance) has been implicated in both mental health and substance use problems. A significant positive correlation between experiential avoidance and symptoms of depression has been

demonstrated within a general population sample (Dinis et al., 2015) and within a clinical sample of people with psychosis (White, Gumley, McTaggart, Rattrie et al., 2012). Research has highlighted a mediating role of experiential avoidance, for example between childhood psychological abuse and current mental health symptoms (Reddy, Pickett & Orcull, 2006), and between shame memories and depression (Dinis et al., 2015). Psychological flexibility has also moderated treatment effects; with higher levels of psychological flexibility leading to enhanced intervention outcomes in a workplace intervention (Bond, Flaxman & Bunce, 2008) and in an intervention targeting stigma in students (Masuda, Hayes, Fletcher, Seignourel et al., 2007). Within clinical samples, psychological flexibility has been found to moderate a mediated relationship between negative schemas and delusional ideation via mood (Oliver, O'Connor, Jose, McLachlan & Peters, 2011).

Experiential avoidance has also been proposed as a risk and maintenance factor for substance use, whereby individuals with low psychological flexibility may use substances to avoid and suppress shame and other negative emotions. Levin et al., (2012) found a significant difference in experiential avoidance between students who used alcohol problematically and those who did not. Within a regression model, experiential avoidance was related to more alcohol-related problems. Furthermore, psychological distress was initially a significant predictor of alcohol problems, however once experiential avoidance was added to the model the relationship between distress and alcohol problems was no longer significant. This suggests that the relationship between psychological distress and problematic alcohol use can be accounted for by experiential avoidance.

Not only does psychological flexibility have a potential role in the development and maintainence of both mental health and substance use problems, it may also have an impact on treatment engagment and oucome. For example, Stotts, Vujanovic, Heads, Suchting et al., (2015) compared people within addiction treatment services who had responded to a contingency management programme with those who had not responded to treatment. The two groups reported similar levels of negative affect, impulsivity and cravings; however, those who did not respond to treatment displayed higher levels of experiential avoidance.

2.6 Limitations of current research

The literature to date indicates that both shame and psychological flexibility play a role in the development and maintainence of mental health and substance use problems independently, and that both of these concepts may impact on treatment engagmement or outcome. There are two important limitations to the current evidence base.

First, the research is limited by use of general population or student samples (Dearing, Stuewig & Price-Tangney, 2005; Dinis et al., 2015; Levin et al., 2012; Reddy, Pickett & Orcutt, 2006Treeby & Bruno, 2012). Within these samples the severity of mental health or substance use problems are generally below that seen within clincial samples and participants often fail to meet diagnostic levels. Dearing, Stuewig & Price-Tangney (2005) demonstrated that shame had a different role in a student and a prison sample, highlighting the importance of studying this relationship across different populations.

Second, the literature on substance use within clinical samples often fails to consider mental health problems, and vice versa, despite high levels of co-

occurrence and the complex nature of the relationship between these two problems, particulalry within secondary services. For example, in the study by Johnson et al., (2014), the authors made no reference to substance use in a sample where the use of substances, particularly cannabis, was likely to be prevalent (e.g. Patel, Wilson, Jackson, Ball et al., 2016). Based on the literature reviewed, it is possible that adding substance use to the model may have affected the nature of the relationship between shame, stress and paranoia.

2.7 Aims and hypotheses of the current study

Despite the emerging evidence on shame for people with either mental health or substance use problems, there is to date limited research on the experience of shame in those with co-occurring substance use and severe mental health problems. This includes an exploration of not only a general or global sense of shame, but also an exploration of shame specific to the person's substance use. Shame may potentially play a role in the development and maintenance of these complex problems and needs to be further understood in this client group. Furthermore, how individual levels of psychological flexibility may impact on the relationship between psychological problems, shame and substance use also needs to be explored in order to establish whether it is an important factor in the potential improvement or resolution of negative consequences.

With these points in mind, the current study had two broad aims; 1) to explore the role of shame in people with severe mental health problems who also use substances, and 2) to explore the potential role of psychological flexibility/experiential avoidance in the relationship between severe mental health problems, shame and

substance use. Three more specific hypotheses were formulated based on previous literature and tested:

Hypothesis 1: There will be a positive correlation between psychological distress and substance use.

Hypothesis 2: The relationship between psychological distress and substance use will be mediated by shame (both a global sense of shame and shame in relation to substance use).

Hypothesis 3: The mediated effect of shame on the relationship between psychological distress and substance use will be moderated by psychological flexibility (representing a moderated mediation effect).

3. Method

3.1 Design

A cross-sectional questionnaire study was used to explore the associations between mental health, substance use, shame and psychological flexibility in people with severe mental health problems admitted to inpatient units. Planned analyses included correlational as well as exploratory mediation and moderation analyses. The study was reviewed and given ethical approval by the UK South Birmingham Research Ethics Committee on 01.12.15 (reference: 15/WM/0416; see Appendix 4).

3.2 Participants

The sample size was calculated with reference to the mediation analysis. Using the bias-corrected and accelerated bootstrap method for a mediation analysis (Preacher, Rucker & Hayes, 2007) a sample size of 71 is needed to identify a medium effect size on the mediated pathway (Fritz & MacKinnon, 2007).

Participants were recruited from adult acute inpatient wards within an NHS Trust in England. Recruitment took place across four acute wards. Participants were eligible for the study if they:

1) were admitted to an acute inpatient ward and had been on the ward for at least one week,

2) had a diagnosis of a severe mental health problem (schizophenia or psychosis related disorder, bipolar disorder or major depressive disorder) according to ICD-10 criteria,

3) had used either alcohol or cannabis on at least one occasion in the 30 days prior to their admission, and

4) were aged 18 or above.

Alcohol and cannabis were used as the inclusion criteria for substance use as these are the two most commonly used substances amongst this client group (Graham, Copello, Griffiths et al., 2016; NICE, 2011). The frequency of substance use was set to be at least once in the 30 days prior to admission in order to ensure that participants experienced recent use, and to yield a sample with varying degrees of alcohol and cannabis use.

Participants were excluded from the study if they:

1) did not have capacity to consent to a research study, and

2) required an interpreter (as no funding resources were available for interpreters within the study).

Participants were not excluded from the research based on disability, gender, race or nationality, religion or belief, or sexual orientation.

3.3 Data collection

Recruitment took place on the acute inpatient ward where the participant was receiving treatment. Potential participants were identified from their clinical records and new admissions to the wards were screened using the inclusion criteria. If a potential participant met all inclusion criteria the ward manager was contacted to establish whether or not the exclusion criteria should be applied. If the potential participant met all criteria, they were approached by a member of the clinical team on the ward and asked if they were willing to meet with the researcher to discuss participation in a research project. Participants who agreed were given the information sheet (see Appendix 5) and given the opportunity to ask any questions

about the research. Potential participants were given at least twenty-four hours to consider particpation and they were then visited a second time to establish whether or not they wanted to take part in the research. Participants who agreed to take part were asked to provide written consent (see Appendix 6) and then took part in the assessment process.

The assessment involved completion of up to seven questionnaires and took approximately 45 minutes to complete with the participant.

3.4 Measures

A battery of well established and validiated questionnaires was used to measure mental health symptoms, shame, psychological flexibility and substance use.

Mental health symptoms

The Brief Symptom Inventory (BSI; Derogatis & Melisaratos, 1983; see Appendix 7) was used to assess mental health symptoms. The BSI is a 53-item measure of psychological symptoms and has nine subscales (somatization, obsession-compulsion, interpersonal sensitivity, depression, anxiety, hostility, phobic anxiety, paranoid ideation and psychoticism). The BSI also includes three indices of global distress. The Global Severity Index (GSI) measures the overall distress level and is calculated by dividing the summed total by the number of responses. The Positive Symptom Total (PST) measures the number of self-reported symptoms and is derived from counting the number of items endorsed with a positive response. The Positive Symptom Distress Index (PDSI) measures the intensity of the symptoms and is calculated by dividing the sum of the item values by the PST. The BSI has strong

internal consistency (α=.97) and there is normative data for adult psychiatric inpatients; the GSI mean score and standard deviation for adult psychiatric inpatients are 1.19 and 0.86 respectivley (Derogatis & Melisaratos, 1983).

Shame

General experience of shame: The Experience of Shame Scale (ESS; Andrews, Qian & Valentine, 2002; see Appendix 8) is a 25-item measure that assesses three aspects of shame; characterological shame, behavioural shame and bodily shame. Total possible scores range from 25 to 100. The measure has good internal consistency (α=.92) and test-retest reliability over 11 weeks ($r_{1,2}$=.83; Andrews et al., 2002).

Substance use related experience of shame: The Substance Abuse Self-Stigma Scale (SASSS; Luoma, Nobles, Drake, Hayes et al., 2013; see Appendix 9) is a 40-item measure of self-stigma and shame in relation to substance abuse. There are 3 subscales; self-devaluation, fear of enacted stigma and stigma avoidance/ values disengagement. Total scores range from 0 to 200. The overall internal consistency is good (α=.86). The original measure was amended slightly for the study with permission of the scale author. To make the measure more appropriate for the client group, in two items ‘substance abuse’ was amended to ‘substance use’, and for 4 of the items, the terms ‘substance use problems’ or ‘problems with substances’ were amended to ‘substance use’. It is acknowledged that these amendments will change the psychometric properties of the measure.

Psychological Flexibility

The Acceptance and Action Questionniare II (AAQ-II; Bond, Hayes, Baer, Carpenter et al., 2011; see Appendix 10) is a 7-item, 1-factor measure of psychological flexibility or experiential avoidance. Items responses are summed to produce a total score of between 0 and 49; with higher scores suggesting greater levels of experiential avoidance (and therefore lower levels of psychological flexibility). The mean alpha coefficient (from 6 studies including 2,816 participants) is .84 (.78 - .88), and the 3 and 12 month test-retest reliability is .81 and .79, respectively (Bond et al., 2011).

Substance Use

Two measures of substance use were administered that focused on consumption and level of problems. The Maudsley Addiction Profile, section B (MAP; Marsden, Gossop, Stewart, Best et al., 1998; see Appendix 11) was used to measure 1) the type of substances used over the past 30 days, 2) the total number of days that each substance was used on, 3) the amount used on a typical day, and 4) the route of administration. Test-retest reliability for all substances is high, averaging .94 (Marsden et al., 1998).

The Alcohol Use Disorder Identification Test (AUDIT; Saunders, Aasland, Babor, de la Fuente & Grant, 1993; see Appendix 12) and the The Cannabis Use Disorder Identification Test –Revised (CUDIT-R; Adamson, Kay-Lambkin, Baker, Lewin et al., 2010; see Appendix 13) were used to assess the level of alcohol and cannabis related problems. If the participant had used both alcohol and cannabis in the 30 days prior to admission, both of these measures were completed but the

participant was asked to identify their primary substance which was then recorded and used in further analyses. If the participant had used just one of these substances within the time frame, only the applicable measure was completed. The AUDIT is a 10-item scale measuring recent alcohol use, alcohol dependence symptoms, and alcohol-related problems. Total scores range from 0 to 40, with scores of greater than 8 indicating hazardous or harmful use. The AUDIT is a widely used measure with good reliability and validity across a range of settings and populations (Babor, Higgins-Biddle, Saunders & Monteiro, 2001). The CUDIT-R is an 8-item scale developed along the same principles of the AUDIT and measuring cannabis consumption, abuse, dependence and psychological features. Total scores range from 0 to 32, again with a score of 8 or above indicating hazardous or harmful use. The CUDIT-R was validated within a clinical sample of people with depression and co-occuring substance use (Kay-Lambkin, Baker, Lewin & Carr, 2008). It has high sensitivity (91%), specificity (90%) and internal consistency (α=.91).

3.5 Analysis plan

Data were analysed using SPSS version 23 (IBM Corp, 2014). Data screening procedures (Tabachnick & Fidell, 2006) were followed to ensure that the data met parametric assumptions for analysis. Univariate and multivariate outliers were screened for through calculation of z-scores, examination of box-plots and calculation of Malhanobis Distance. Normality of distribution was explored through calculation of skewness and kurtosis values, visual inspection of histograms and completion of the Shapiro-Wilks test. Homoscedacity was evaluated through visual inspection of scatter-plots, and multicollinearity through inspection of bivariate correlations between variables.

Descriptive statistics (mean, standard deviation, minimum and maximum values) were computed for each outcome measure. A new variable, labelled “level of substance use” was computed for each participant using their z-score for the AUDIT or CUDIT depending on which substance (alcohol or cannabis) they identified as their primary substance. This was done in order to ensure that each participant was given a score from either the AUDIT or the CUDIT depending on the main substance of use and that scores were comparable across the two measures and on the same scale. This variable provided a score for each participant representing the same information as both the AUDIT and the CUDIT, i.e. recent use (i.e. frequency and amount), dependence symptoms, substance-related problems and psychological features associated with use.

Potential confounding variables including age, gender and ethnicity were explored using a series of Pearson’s correlation analyses, t-tests and ANOVAs. Representativeness of the sample was considered in two ways; comparison of consenters and refusers on demographic variables (age, gender, ethnicity and diagnosis), and comparison of consenters to the population as a whole (i.e. all inpatient admissions screened) on demographic variables (age, gender and ethnicity).

Pearson’s correlations were initially calculated to assess the zero-order associations between variables of interest (psychological distress, shame, psychological flexibility and level of substance use) and to test hypothesis 1.

Shame was measured in two ways; using the ESS as a global measure of shame, and the SASSS as a measure of shame and self-stigma associated with substance use. The current evidence base has not explored the correlation between

these two measures; and as a result, it is currently difficult to determine whether it is reliably possible to examine them as two distinct components of shame, and whether or not they are conceptually different from one another. With this in mind, prior to conducting the mediation analysis, a variance components analysis was planned to explore the degree to which the two variables (general shame and substance use related shame) contribute a unique source of variance to the outcome (i.e. level of substance use).

A simple mediation model was used to test hypothesis 2 (Figure 1). This model aimed to test the extent to which shame (M) accounts for the relationship between psychological distress (X) and level of substance use (Y). Shame would be considered a mediator if 1) psychological distress significnatly predicted level of substance use, 2) psychological distress significantly predicted shame, and 3) shame significantly predicted level of substance use controlling for psychological distress (Preacher & Hayes, 2004). When the effect of X on Y decreases to zero with the inclusion of M, perfect of full mediation is said to have occurred; when the effect decreases but not to zero, partial mediation has occurred (Preacher & Hayes, 2004).

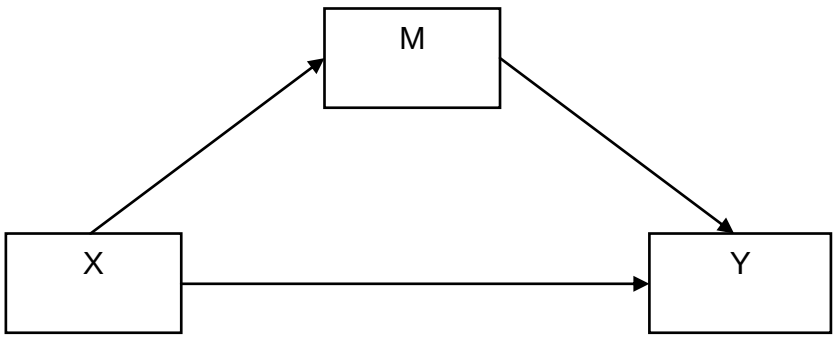

Figure 1. Simple Mediation Model

To test hypothesis 3, a moderated mediation analysis was used to establish whether psychological flexibility (V) moderated the relationship between shame and substance use in this participant group, as presented in Figure 2. This model proposes that the indirect effect of the mediated model may vary depending on the level of the moderator variable (psychological flexibility).

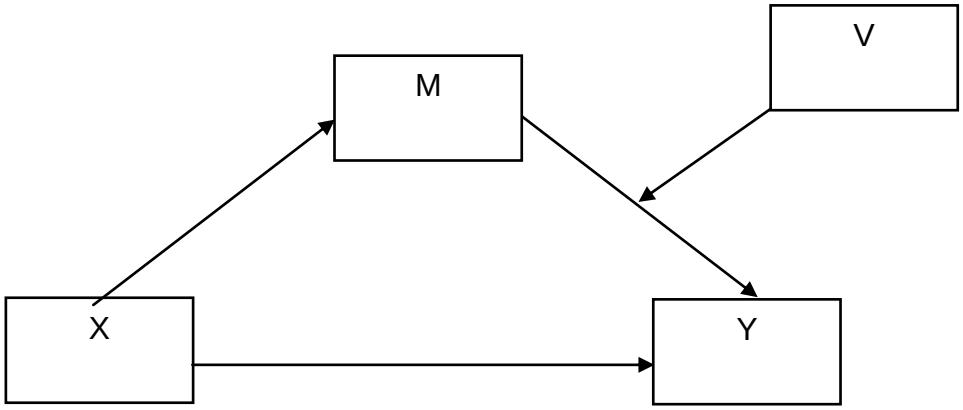

Figure 2. Moderated Mediation Model

4. Results

4.1 Recruitment to the study

A total of 49 participants were recruited between April 2016 and March 2017. Figure 3 shows the consort diagram for recruitment to the study. Four-hundred and forty-two admissions to four wards were screened during the study time frame and 112 (25%) of these met the study inclusion criteria. Of those who met the criteria, 37 were discharged before they could be approached to be seen, 26 refused to take part and the remaining 49 consented (65% of participants approached). Participants refused to take part for several reasons; the most common reasons were that the research involved too much work (n=5) or that the participant felt it was not an appropriate time for them to take part in a research project (n=5). No participant withdrew from the study following consent.

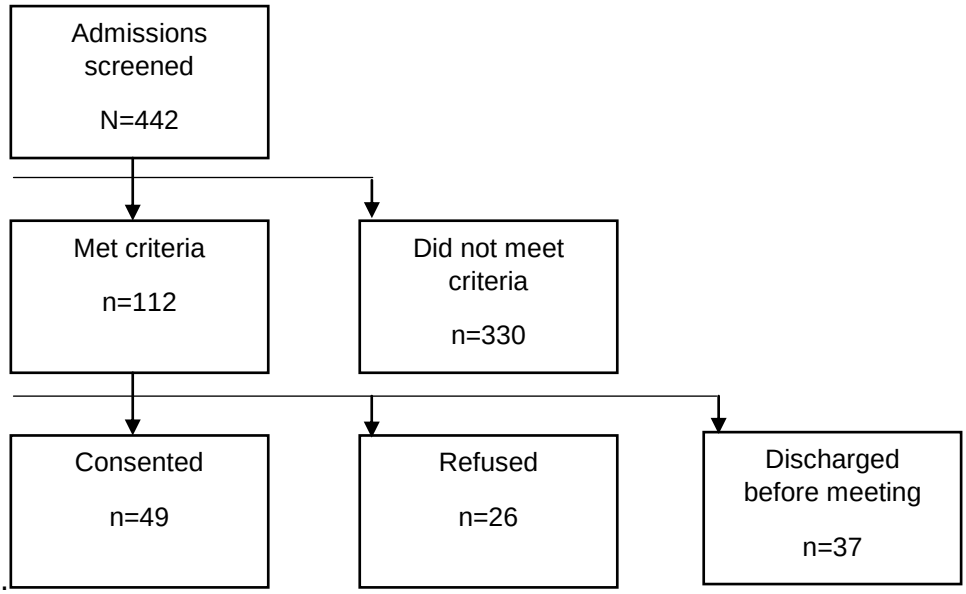

Figure 3. Recruitment to the study

4.2 Participant characteristics

Demographic details of the participants recruited are displayed in Table 1. The participants were typically male (n=36, 73.5%) with a mean age of 39 (SD=10.34; range 21 to 61). Approximately half of the sample were white British (n=26, 53.1%). The most frequent diagnosis within the sample was schizophrenia (n=18, 36.7%). Eighty-eight percent of the sample had used alcohol in the 30 days prior to admission to hospital and 36.7% had used cannabis.

4.3 Representativeness of the sample

There was no significant difference between those who consented and those who refused to participate in terms of their age (t=-.96, p=.34), gender (x^2=.54, p=.46), ethnicity (x^2=2.90, p=.57) or mental health diagnosis (x^2=4.95, p=.22). Those who consented to the study did not differ from the population they were recruited from in terms of their age (t=.93, p=.35) or their ethnicity (x^2=4.37, p=.50). There was a significant difference in terms of gender (x^2=12.52, p<.001), with a higher proportion of males amongst consenters (73.5%) compared to the whole population (46.8%).

Table 1. Demographic characteristics of the sample (N=49)

	N	%
Gender		
Male	36	73.5
Female	13	26.5
Ethnicity		
White	26	53.1
Asian / Asian British	10	20.4
Black / Black British	8	16.3
Mixed	5	10.2
Mental health diagnosis		
Schizophrenia	18	36.7
Bipolar Affective Disorder	14	28.6
Other psychotic disorder	7	14.3
Schizoaffective Disorder	5	10.2
Major Depressive Disorder	5	10.2
Substance use[1]		
Alcohol	43	87.8
Cannabis	18	36.7
Cocaine	6	12.2
Crack cocaine	4	8.2
New Psychoactive Substances	4	8.2
Heroin	2	4.1
Amphetamine	1	2.0
Primary substance		
Alcohol	38	77.6
Cannabis	11	22.4

[1]*Participants may have used more than one substance within the 30 days prior to admission to hospital*

4.4 Data screening

Data screening procedures were conducted on the total score for each measure employed (BSI, ESS, AAQ, AUDIT, CUDIT, SASSS) and the computed "level of substance use" variable. Data met the assumptions for parametric analysis.

4.5 Descriptive statistics

Table 2 displays the mean score, the standard deviation and the minimum and maximum scores for each of the measures completed. The mean score for the sample on the BSI Global Severity Index (GSI) was slightly higher than the normative score for psychiatric inpatients (1.19; Derogatis & Melisaratos, 1983); however was more comparable to other research studies for psychiatric inpatients that reported mean scores of between 1.23 and 1.66 (Kohler, Hoffman, Fydrich et al., 2013; Piersma, Reaume & Bues, 1994). The mean score on the ESS was comparable to the mean score in a similar sample of people with psychosis (56.87; Barratt, 2015) and higher than the mean score reported in a general population sample (47.52; Matos, Pinto-Gouveia & Gilbert, 2013). The mean AAQ score was lower than mean scores (33.3 to 45.5) previously reported in similar samples (Broten, 2013; Gaudiano, Busch, Wenze, Nowlan, et al., 2015; Gumley, White, Briggs, Ford et al., 2016; Petersen & Zettle, 2009; White, Gumley, McTaggart, Rattrie et al., 2011;). The mean score on the AUDIT was slightly lower than in a similar sample (Graham et al., 2016); however this was to be expected as the inclusion criteria in Graham et al., (2016) study was for 'problematic substance use', as opposed to any level of use within the previous month as was defined within the current study. To date, a mean score of the CUDIT-R in a similar sample to the current one is not available; however the mean score in the current sample is higher than the mean score within a non-treatment

seeking sample of cannabis users (9.6; Bruno, Marshall & Adamson, 2013). Although the current study did not aim to recruit only participants with "problematic" levels of substance use, on average, the mean scores for both the AUDIT and CUDIT would fall within this category (Adamson et al., 2010; Saunders et al., 1993).

Table 2. Descriptive statistics for outcome variables

Measure	N	Mean	SD	Min	Max
Brief Symptom Inventory (BSI) Global Severity Index (GSI)	49	1.34	.769	0	3
Experience of Shame Scale (ESS)	49	58.06	18.93	25	97
Acceptance and Action Questionnaire	49	27.65	11.63	7	49
Maudsley Addiction Profile (MAP)					
Number of days used alcohol	43	17.40	11.31	1	30
Alcohol units consumed per day	43	16.30	19.17	1	90
Number of days used cannabis	18	12.56	11.81	1	30
Cost of cannabis per day (£)	17	11.71	8.11	2	35
Alcohol Use Disorders Identification Test (AUDIT)	42	16.31	9.94	1	35
Cannabis Use Disorders Identification Test (CUDIT)	18	13.72	7.27	4	31
Level of substance use (Z score)	49	.19	.974	-1	2
Substance Abuse Self Stigma Scale	48	102.39	29.23	50	161

4.6 Confounding variables

There was no significant correlation between age and any of the total scores on the outcome measures. There were also no significant differences between ethnicities on any of the outcomes. There was a significant gender difference on the AAQ ($t(47)=-2.181$; $p=.03$), with females scoring significantly higher scores

(mean=33.46, SD=11.87) compared to males (mean=25.56, SD=10.97). No other significant gender differences were observed.

4.7 Pearson's correlations

Pearson's correlations (Table 3) were used to examine the relationships between the variables. The relationships between psychological distress (BSI), shame (ESS), experiential avoidance (AAQ), level of substance use (computed z score of AUDIT and CUDIT scores) and substance use related shame (SASSS) were all positive and all significant; suggesting that an increase on one of these measures correlates to an increase on another.

Table 3. Pearson's correlations

	BSI (GSI)	ESS	AAQ	Substance Use	SASSS
BSI (GSI)	1	.679**	.723**	.513**	.529**
ESS		1	.663**	.611**	.701**
AAQ			1	.554**	.656**
Substance use				1	.715**
SASSS					1

. Correlation is significant at the 0.01 level (2-tailed). *. Correlation is significant at the 0.05 level (2-tailed).

4.7 Hypothesis 1: **There will be a positive correlation between psychological distress and level of substance use.**

As presented in Table 3, Pearson's *r* indicates that there was a significant and positive correlation between psychological distress and level of substance use (r=.513; p<.001). This suggests that an increase in psychological distress is associated with an increase in substance use.

4.8 Hypothesis 2: **The relationship between psychological distress and substance use will be mediated by shame (both a global sense of shame and shame in relation to substance use).**

4.8.1 Variance components analysis

As described in the method section, prior to conducting the mediation analysis, a variance components analysis was planned to explore the degree to which the two shame variables (general shame measured by the ESS and substance use related shame and self-stigma measured by the SASSS) contributed a unique source of variance to the outcome (i.e. level of substance use) and, therefore, represent orthogonal dimensions of shame.

A linear regression model confirmed that each predictor variable (ESS and SASSS) was independently contributing to explaining the variance in substance use; with the SASSS explaining 51% of the variance (R^2=.51, F(1,46)=48.24, p<.001) and the ESS explaining 37% of the variance (R^2=.37, F(1,47)=28.07, p<.001) when each variable was independently regressed to substance use.

A hierarchical regression model was used to assess the unique contribution of each predictor (ESS and SASSS) to substance use over and above the variance shared between the two measures of shame. The SASSS was entered into the model on step 1 as it had the strongest relationship with the outcome variable and explained more of the variance in the previous model, followed by the ESS in step 2. The results of the hierarchical regression (Table 4) suggest that step 1 accounted for 51% of the variance in substance use (R^2=.51, f(1,46)=48.24, p<.001), whilst step 2 accounted for 54% of the variance (R^2=.54, f(2,45)=27.05, p<.001); an increase of

3%. The ESS is therefore providing 3% of unique variance. The regression was repeated with the ESS entered at step 1 and the SASSS at step 2 to determine the unique contribution of the SASSS.

Table 4. Hierarchical regression model to substance use

	b	SE b	B
Step 1			
Constant	-2.272	.369	
SASSS	.024	.003	.715**
Step 2			
Constant	-2.430	.370	
SASSS	.018	.005	.534**
ESS	.014	.007	.259

R^2 = 0.51 for step 1; R^2 = 0.54 for step 2.

The Venn diagram (Figure 4) shows the amount of variance in substance use explained by substance use related shame independently (SASSS; A), by global shame independently (ESS; C) and by the shared variance between the SASSS and the ESS (B). As shown in Figure 4, a large part of the variance in substance use explained by the hierarchical regression model is shared between the contributions of general shame and substance related shame (37%), with both constructs contributing only a small amount independently of one another. With this is mind, it cannot be concluded that the ESS and the SASSS are measuring two unique and distinct concepts and therefore, as they cannot be assumed to be conceptually different from one another, they cannot be entered into the mediation analysis as two separate measures. At this stage, both measures of shame (ESS and SASSS) were combined by adding the total score of each together for each participant; therefore,

producing a single measurement of the construct, which was then labelled as “shame”. This measure was used in the following mediation analysis.

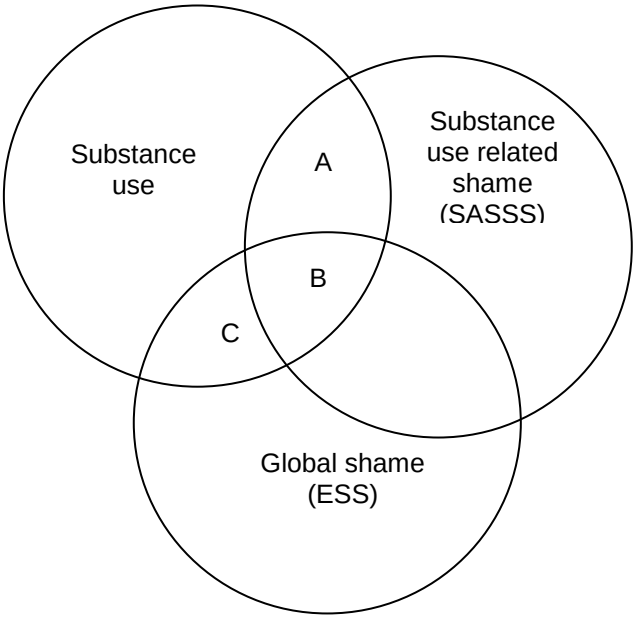

Figure 4. Venn diagram of shared variance

4.8.2 Mediation analysis

Regression analysis was used to investigate the hypothesis that shame mediates the effect of psychological distress on substance use (Figure 5). The total effect model (c; in the absence of the mediator) indicated that psychological distress was a significant predictor of substance use (b=.755, SE=.165, p<.001), with psychological distress accounting for 31% of the variance in level of substance use.

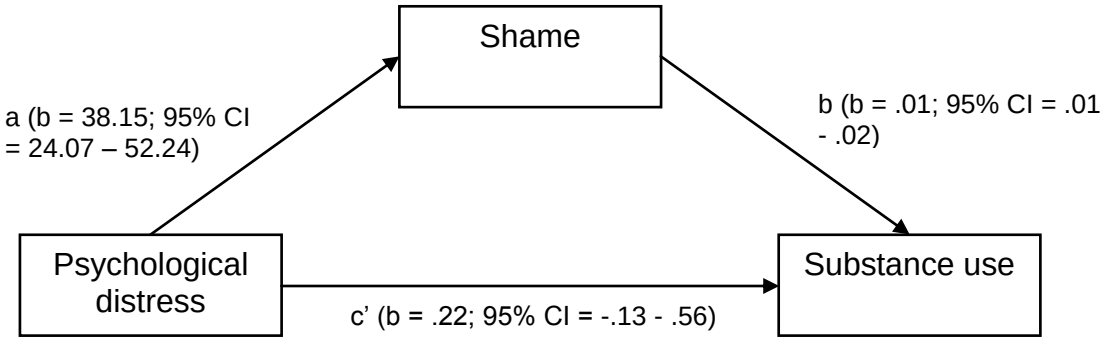

Figure 5. *The mediating effect of shame*

When the mediator variable (shame) was added to the model, the results indicated that psychological distress was a significant predictor of shame (b=38.158, SE=6.996, *p*<.001), and that shame was a significant predictor of substance use (b=.014, SE=.003, *p*< .001). These results support the mediational hypothesis. The variance in substance use explained by the total effects model fell by 71% when controlling for shame; from 31% to 9%. Although this did not reach zero; psychological distress was no longer a significant predictor of substance use after controlling for shame (the mediator; b=.215, SE=.171, *p*=.215), consistent with full mediation. In other words, the effect of psychological distress on substance use is fully mediated by shame. The mediated model accounted for 56% of the variation in substance use, an increase of 25% compared to the total effect model.

4.9 Hypothesis 3: The mediated effect of shame on the relationship between psychological distress and substance use, will be moderated by psychological flexibility (representing a moderated mediation effect).

In order to test this hypothesis, the conditional indirect effect of psychological distress on substance use via shame was examined at different levels of

psychological flexibility using the PROCESS macro on SPSS (Preacher, Rucker & Hayes, 2007). Psychological flexibility did not significantly moderate the association between shame and substance misuse, implying that the indirect effect of shame on level of substance use was not higher or lower depending on psychological flexibility (b=.0003, SE=.0002, *p*=.201)

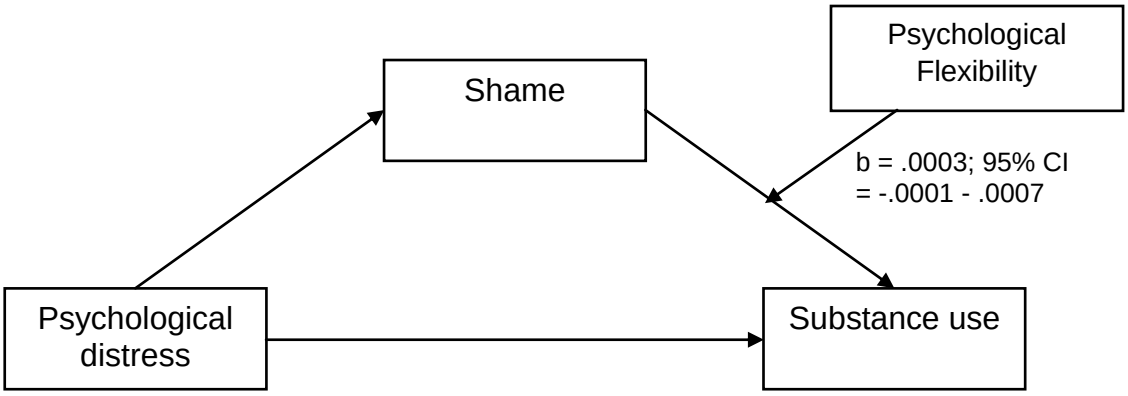

Figure 6. Moderated mediation model

5. Discussion

5.1 Summary of study results

The current study aimed to explore the role of the experience of shame and psychological flexibility in the relationship between psychological distress and substance use amongst a clinical sample of people with severe and enduring mental health problems (psychotic disorders, bipolar affective disorder and major depressive disorders). Based on previous research, it was hypothesised that there would be a relationship between psychological distress and substance use, and that this relationship would be mediated by shame. Furthermore, it was hypothesised that this mediated relationship would be moderated by psychological flexibility.

The results highlighted that there was a significant and positive relationship between psychological distress and substance use in line with the predicted hypothesis, showing that an increase in psychological distress was associated with an increase in substance use. When hypothesis two was explored, it was found that this relationship was mediated by shame, instead suggesting a different path through which increased psychological distress was associated with increased shame, which in turn was associated with increased substance use. Psychological flexibility was not found to moderate this mediated relationship, suggesting that higher levels of psychological flexibility did not reduce the impact of shame on substance use; the third hypothesis was therefore not supported within this study. The results are further discussed below, starting with consideration of the study sample.

5.2 Representativeness of the sample

The participants recruited to the study were typically male, approximately half were white British and the most common diagnosis was schizophrenia. A comparison across demographic variables of both those who consented to those who refused, as well as those who consented to the entire population from which participants were recruited, suggested that the sample was, on the whole, representative of both those eligible and the wider population of inpatient admissions. Although there was no significant gender difference between those who consented and those who refused, there was a gender difference between those who consented (the sample) and the entire population of admissions screened. This is unsurprising when considering the inclusion criteria for the study, as there is evidence to suggest that males are more likely than females to have a diagnosis of schizophrenia (Iacono & Beiser, 1992; Ochoa, Usall, Cobo, Labad & Kulkarni, 2012) and also to use alcohol and drugs (Substance Abuse and Mental Health Services Administration, 2014). Although this gender difference could potentially introduce bias to the results, the finding that there was no significant gender difference between those who consented and those who refused implies that, of those meeting the inclusion criteria for the study, the results were representative in terms of gender. This therefore increases the external validity of the study and makes the results more generalizable to this particular client group.

Previous research had shown that females report higher levels of shame than males across different populations (Wiklander et al., 2012); this finding was not replicated within this sample, where males expressed comparable levels of shame to females. Previous research has also shown a negative correlation between shame and age (Wiklander et al., 2012), again a finding that was not replicated within this

study sample. It is important to acknowledge that, based on these findings, high levels of shame can be experienced by people within this client group regardless of their age, gender or ethnicity. Whilst levels of psychological flexibility did not differ across age or ethnicity, females scored significantly higher on the AAQ than males, suggesting lower levels of psychological flexibility (or higher levels of experiential avoidance) amongst females. This is in contrast to previous findings (Bond et al., 2011; Dinis et al., 2015) that reported no gender difference in experiential avoidance within samples recruited from the general population, student populations and a treatment seeking population of substance users. The present results suggest a gender difference in this complex population and therefore psychological flexibility amongst people with co-existing mental health problems and substance use requires further exploration.

5.3 Shame and Psychological Flexibility

As discussed in the introduction, the present study aimed to focus on a group of people with complex and co-existing needs related to mental health and substance use, and therefore makes a contribution to this area that has tended to be overlooked in previous research literature. One of the original aims, having established from previous evidence that the experience of shame was relevant to both mental health and substance use separately, was to explore the contribution of a global sense of shame as well as a more specific substance use related shame within a group with co-existing problems. The two originally identified measures of shame (Andrews, Qian & Valentine, 2002; Luoma et al., 2013) were therefore selected from the research literature on the assumption that they would each tap into distinctive aspects of the shame experience; either adding different variance in the test or one

being more important than the other within this population. Once the data were collected however and subjected to the initial analyses, it was found that there was a highly significant level of correlation between the two separate shame measures with only a very small amount of variance explained by each separately. This suggests that even though the two measures are presented as being empirically different, we may conclude from the present study that the experience of both a global sense of shame and shame in relation to substance use as currently measured, share more commonality than difference and that our ability to empirically separate the two experiences of shame is limited at present.

Whist the separation of two conceptually distinct experiences of shame proved to be not possible, the findings through combining both measures suggested nevertheless that the overall experience of shame was a significant factor in the relationship between psychological distress and substance use. Whist the precise mechanism is difficult to ascertain from the present findings, it remains an important area for both future research and practical treatment focus that may benefit from further exploration with, for example, longitudinal designs. The extent to which substance use adds to the overall experience of shame that has been documented in mental health samples, remains unclear.

An additional aim of the study was to explore the potential moderating effect of psychological flexibility on the relationship between shame and substance use, which was not supported. One possible explanation for this is a lack of power to detect an effect due to the relatively small sample size, as a moderated-mediation model requires a larger number of participants given the increased number of paths tested. An alternative interpretation is that psychologically flexibility within this sample was

higher than what has been reported in similar samples, and there is evidence to suggest that psychological flexibility may be more influential at lower levels. For example, Masuda et al., (2007) reported that Acceptance and Commitment Therapy had superior outcomes compared to a control intervention for people with lower levels of psychological flexibility, but there was no difference in outcomes between groups for those with higher levels of psychological flexibility.

5.4 Limitations

Potential limitations of the current research relate to study design, sample size and measurement. The study utilised a cross-sectional design, which limits the extent to which causal interpretations can be made regarding the study findings. The initial power calculation indicated that 71 participants were required to detect a medium effect using the bias-corrected bootstrap mediation model when both paths (psychological distress to shame, and shame to substance use) produced a medium effect size (Fritz & MacKinnon, 2007). Recruitment of this sample proved challenging given the fact that the study group involved those admitted to acute inpatient services where typically the admission period was brief, and so often potential participants were discharged before being seen by the researcher. A number of potential participants also refused to take part, for example if they felt that the research involved too much work, further limiting the sample size. The expected sample size was therefore not fully achieved. However, given the finding of significance in the mediation analysis, it is possible to propose that the sample obtained was adequate to test the mediation model. In comparison to the mediation model, the moderated mediation model included several additional regression paths; indicating a need for a larger sample size to detect an effect within this model. With this is mind, the

moderated mediation analysis might have been considerably underpowered within the current study.

Measurement of shame and substance use posed some challenges that need to be considered in future studies. Those related to the specificity and measurement of shame have been already discussed. The measurement of substance use and related problems also posed some challenges. Despite the conceptual and theoretical ways in which various substances, or indeed substance and non-substance related addictions, have been seen as having clear commonalities (e.g. Orford, 2001), measurement appears to lag behind with most existing questionnaires focused on a single, specific substance (i.e. alcohol or cannabis). Whilst generic measures of serious dependence are available and can be completed irrespective the specific substance (e.g. Severity of Dependence Scale; Gossop, Darke, Griffiths, Hando, Powis, et al., 1995), when attempting to measure infrequent and lower levels of use as well as higher, more dependent levels of use, such as those displayed in this sample, this becomes a challenge. Given that alcohol and cannabis are the most common substances used by this population, and that the current study therefore aimed to include both, the only alternative measure that could have been considered was the ASSIST (Humeniuk, Ali, Babor, Farrell, Formigoni, et al., 2008). This measure however was developed for young people and was considered less relevant and reliable for the current sample than the AUDIT and the CUDIT. The strategy adopted in this study to be able to equate one substance with another (i.e. alcohol with cannabis) was to use standardised z-scores from the AUDIT and CUDIT in order to make them comparable across both substances, and to use the relevant score depending on which was the main substance used as reported by the participant.

5.5 Clinical and future research implications

The present results suggest that, when working with those experiencing combined mental health problems and substance use, targeting shame constitutes an important focus for psychological interventions. Targeting shame therapeutically may contribute towards breaking or at least impacting on the relationship between mental health and substance use.

Acceptance and Commitment therapy (ACT) is a psychological approach that can help people to become more mindful of stigmatizing and shaming thoughts and evaluations (Luoma, 2010), and to develop strategies to increase acceptance of them. ACT postulates that by developing an ability to "defuse" from such evaluations (i.e. to see a thought as just a product of our busy minds), the individual increases their psychological flexibility and is more able to engage in value-driven activity, rather than getting caught-up in and attempting to suppress or avoid such evaluations or emotional states (for example through the use of substances).

Luoma et al., (2012) reported a randomised controlled trial that compared an ACT intervention specifically targeting shame to treatment as usual in a residential substance use treatment centre. At follow-up those who received the ACT intervention showed significantly lower levels of shame, and were also less likely to have used substances during the follow-up period. As previously highlighted, the evidence base examining the role of shame substance use often fails to consider the role of mental health, and vice versa. It is unclear in the study by Luoma et al., (2012) how many participants within this sample had a mental health diagnosis or what the possible diagnoses were. There is also to date an absence of evidence evaluating ACT for shame within mental health populations or importantly for people

with co-existing mental health and substance use problems. A prospective longitudinal intervention study evaluating ACT for this client group is recommended. It would be important to measure shame at pre-intervention, post-intervention and longer-term follow-up. The intervention could be compared to 'treatment as usual' or an active intervention condition, such as CBT, or ideally both.

This research would be an important next step, and with the mediation model presented in the current study in mind, it would be not only important to evaluate such an intervention in terms of its impact on shame, but also to consider and draw attention to the processes of change during such interventions (i.e. do changes in shame correlate to changes in substance use?). It has been suggested that mixed results in treatment trials are potentially caused by the presence of unrecognised mediating or moderating factors (Johnson et al., 2014). Shame may fit into this category, and it is imporant to consider this when evaluating interventions for this client group.

Whilst the current paper focused on substance use as the outcome, it is also important to consider the evidence base more broadly and think about the clinical implications of the research in terms of additional outcomes for this client group. For example, it is well documented that this client group experience higher rates of reoccurrence of problems, increased rates of hospitalisation and are often less engaged in treatment programmes. The shame literature highlights that a fear of help-seeking due to feelings of shame or anticipation of enacted stigma may decrease motivation to ask for help, and therefore contribute to the above outcomes (Luoma, 2010). Reducing shame through psychological interventions may enable

people to seek help at an earlier stage, become more engaged in the treatment process and maybe even avoid admission to hospital.

5.6 Conclusion

Substance use, particularly use of alcohol, is prevalent amongst people with severe and enduring mental health problems admitted to acute inpatient wards. Shame is an important factor to consider when working with people with severe and enduring mental health problems who are also using substances and may influence the relationship between psychological distress and substance use. When working with this client group, targeting shame may therefore be an important goal for psychological interventions. The role of psychological flexibility in the relationship between psychological distress, shame and substance use requires further exploration.

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Chapter III: Public Dissemination Document

Shame, mental health and substance use: an exploration of psychological processes and interventions.

1. Introduction

Serious and persistent mental health problems, also described as severe and enduring, are long-lasting mental health problems that can have a very large impact on a person's life. They usually include diagnoses such as schizophrenia and psychosis-related diagnoses, bipolar affective disorder and major depression. Severe and enduring mental health problems can increase the risk of poor outcomes such as mental health relapses and admission to hospital, social exclusion, discrimination and loneliness, all shown in previous research studies. The prevalence of alcohol and drug use amongst this client group is high (NICE, 2011), which also increases some of these risks.

It is therefore extremely important that effective psychological interventions are available for this group of people. Currently, Cognitive-Behavioural Therapy (CBT) is the psychological intervention that is recommended by the National Institute of Clinical Excellence (e.g. NICE, 2014), however, some suggest that the evidence for CBT has been "oversold" (e.g. Jones, Hacker, Cormack et al, 2012) and that perhaps alternative therapies should be explored.

The present thesis attempts to contribute to the evidence in two ways. First, it considers one of these alternative therapies for people with severe and enduring mental health problems. It does this by reviewing published research to date that has evaluated a specific therapy, Acceptance and Commitment Therapy (ACT), for this client group. Second, it reports an original empirical research paper that considers *why* change may occur for people with severe and enduring mental health problems who also use substances (alcohol or cannabis). It does this by looking at two

important factors that might influence the relationship between psychological distress and substance use (and therefore be important targets for psychological interventions); shame and psychological flexibility.

2. Chapter I: Literature review

Title: Acceptance and Commitment Therapy (ACT) for people with severe and enduring mental health problems: A meta-analysis

Introduction: Acceptance and Commitment Therapy (ACT) is a therapeutic approach that aims to help people to increase their “psychological flexibility”. Psychological flexibility has been defined as a process whereby an individual is able to notice and observe inner and private experiences, such as thoughts or emotions, and accept these as they are rather than attempting to change them. A reduction in mental health symptoms is not the primary goal of ACT, instead, ACT attempts to change a person’s relationship with their inner experience, rather than changing the experience itself.

Research trials have found that ACT can be helpful for people with a range of physical and mental health problems, for example stress, anxiety, smoking, weight loss and pain (Association for Contextual Behavioural Science, 2015). Research has also begun to evaluate ACT for severe and enduring mental health problems. The current literature review aimed to bring together the research on ACT for this client group and evaluate whether or not it might be a helpful therapeutic intervention.

Method: A search for relevant research was conducted using electronic databases and by contacting key authors in the ACT field. Twelve research trials that evaluated ACT for people with severe and enduring mental health problems were identified. These trials were then combined using a technique called meta-analysis; a statistical procedure that allows information from different trials to be combined to reach a single conclusion. The review explored four different outcomes and looked at

whether ACT, in comparison to a person's usual care or another intervention (i.e. the control condition), had an impact on 1) symptoms of psychosis, 2) symptoms of depression, 3) psychological flexibility and 4) admission to hospital.

Main results: The results suggested that ACT had no beneficial effect on symptoms of psychosis compared to the control group either immediately after the intervention or at follow-up a few months later. The results suggested that those who received ACT reported fewer symptoms of depression after the intervention than those who received the control condition; and this improvement was maintained at follow-up. Regarding psychological flexibility, the results suggested that the intervention increased psychological flexibility compared to the control group immediately after therapy, however this had decreased again by follow-up. Finally, ACT did not significantly reduce the risk of admission to hospital compared to the control group.

Conclusion: The question of whether or not ACT is an effective treatment for people with severe and enduring mental health problems is a difficult one to answer with certainty at this current stage of evidence. The answer, in part, depends on what indicates that an intervention is successful. If a reduction in symptoms is the aim, then the current review suggests that ACT is useful in decreasing symptoms of depression, but not symptoms of psychosis. If the target of the intervention is to increase psychological flexibility, then the current review provides some evidence that ACT can increase psychological flexibility in the short term. If the target of an intervention is to attempt to reduce reoccurrence of symptoms and keep people out of hospital, an important consideration for this group, then the present results suggest that ACT is no more successful than treatment as usual.

3. Chapter II: Empirical paper

Title: An exploration of shame, psychological flexibility and the use of alcohol or drugs in people with mental health problems.

Background: Shame is defined as a powerful self-conscious emotion that often leads to a desire to hide or escape. Research has shown that high levels of persistent shame are associated with a range of mental health problems and also with increased substance use. Research to date however has looked at the role of shame in mental health and the role of shame in substance use separately, and has not investigated the specific role of shame in people with co-existing mental health problems and substance use. This study predicted that shame would help to explain the relationship between mental health and substance use. The study also wanted to investigate the role of psychological flexibility within this relationship. Previous research has suggested that lower levels of psychological flexibility may be associated with mental health problems and also with substance use. With this in mind, the current study predicted that higher levels of psychological flexibility would protect those taking part against the impact of shame.

Method: People who had been admitted to an inpatient unit were asked to take part in the research if they had a mental health diagnosis (bipolar disorder, major depression or a psychosis-related diagnosis) and if they had used alcohol or cannabis in the month before their admission to hospital. If they agreed to take part in the research, the participant completed questionnaires with the researcher. The questionnaires asked questions about psychological distress, shame, psychological flexibility and alcohol and drug use.

Main results: Forty-nine people took part in the research project and completed the questionnaires. Participants were typically male (74%), had an average age of 37 years and approximately half were white British (53%). The results suggested that there is a positive relationship between psychological distress and substance use; meaning that typically as psychological distress increases, so does substance use. When we think about how shame fits into this relationship, the results suggest that high levels of psychological distress lead to high levels of shame, and shame can then lead to substance use. The results also suggested that psychological flexibility did not influence this relationship, so people with higher levels of psychological flexibility were not protected against the impact of shame as it was hypothesised.

Conclusions: Shame is an important factor to consider when working with people with severe and enduring mental health problems who also use substances. When working with this client group, targeting shame may be an important goal for psychological interventions. The role of psychological flexibility in the relationship between psychological distress, shame and substance use requires further exploration.

4. Overall Summary

There is preliminary evidence that shame plays a role in the relationship between psychological distress and substance use amongst people with severe and enduring mental health problems. There is some evidence that Acceptance and Commitment Therapy (ACT) may be a helpful therapeutic approach for people with severe mental health problems in terms of increasing psychological flexibility and reducing depression. Research trials are yet to evaluate whether ACT can reduce feelings of shame amongst people with severe and enduring mental health problems who are also using substances.

5. References

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NICE, (2014). *Psychosis and schizophrenia in adults: prevention and management (CG178).* Retrieved from: https://www.nice.org.uk/guidance/cg178/resources/psychosis-and-schizophrenia-in-adults-prevention-and-management-35109758952133

Appendix 1: Outcomes excluded from the analysis

Study	Outcome excluded	Reason for exclusion
Bach & Heyes (2002)	Rehospitalisation rate at 12 months	N's not reported
Gaudino & Herbert (2006)	Self-ratings of psychotic symptoms (frequency, believability, and distress)	Validated measure of psychotic symptoms included
Petersen & Zettle (2009)	None	
White et al (2011)	Kentucky Inventory of Mindfulness Skills	Measure of acceptance selected to increase consistency within the outcome category
Folke et al (2012)	None	
Shawyer et al (2012)	Self-ratings of psychotic symptoms (compliance, confidence resisting, distress, preoccupation)	Validated measure of psychotic symptoms included
	BAVQ[1] - Resistance Subscale BAVQ[1] – Engagement Subscale	Complete measure of the construct included over subscales
Broten (2013)	Beck Depression Inventory (BDI)	Not reported at final follow up point
	Automatic Thoughts Questionnaire	Not reported at final follow up point
Gaudiano et al (2015)	None	
Tyrberg et al., (2016)	Bulls-Eye Values Survey	Non-parametric data reported
Shawyer et al (2016)	PSYRATS[2]-AH subscale PSYRATS[2]-D Subscale	Complete measure of the construct included over subscales
Boden (2016)	PANSS[3] Positive Subscale PANSS[3] Negative Subscale	Data not reported
	Self-ratings of psychotic symptoms (frequency, believability, and distress)	Validated measure of psychotic symptoms included
Gumley et al., (2016)	PANSS[3]	Data not reported
	Kentucky Inventory of Mindfulness Skills	Measure of acceptance selected to increase consistency within the outcome category
	Calgary Depression Scale	BDI selected as measure of depression to increase consistency within the outcome category

[1]Beliefs about Voices Questionnaire; [2]Psychotic Symptom Rating Scale; [3]Positive and Negative Syndrome Scale

Appendix 2: Correlation co-efficient used to aggregate outcomes

Study	Aggregated Outcomes	Correlation co-efficient between measures	Reference
Bach & Heyes (2002)	Self-ratings of psychotic symptoms (frequency, believability, distress)	0.3, 0.5, 0.7	None available within the literature
Gaudino & Herbert (2006)	None		
Petersen & Zettle (2009)	Hamilton Rating Scale Beck Depression Inventory	0.73	Beck, (1988)
White et al (2011)	PANSS[1] Positive Subscale PANSS[1] Negative Subscale	0.32 0.19	Van Erp, (2014) Fulford et al., (2014)
Folke et al (2012)	None		
Shawyer et al (2012)	VAAS[2] Subscale A VAAS[2] Subscale B	0.3, 0.5, 0.7	None available within the literature
Broten (2013)	None		
Gaudiano et al (2015)	None		
Tyrberg et al., (2016)	None		
Shawyer et al., (2016)	None		
Boden et al., (2016)	None		
Gumley et al., (2016)	PANAS[3]- positive scale PANAS[3]- negative scale	-0.17	Watson & Clark, (1988)

[1]Positive and Negative Syndrome Scale; [2]Voices Acceptance and Action Questionnaire; [3]Positive and Negative Affect Scale

Appendix 3: The Quality Index (Downs and Black, 1998)

Checklist for measuring study quality

Reporting

1. Is the hypothesis/aim/objective of the study clearly described?

2. *Are the main outcomes to be measured clearly described in the Introduction or Methods section?*
If the main outcomes are first mentioned in the Results section, the question should be answered no.

3. *Are the characteristics of the patients included in the study clearly described?*
In cohort studies and trials, inclusion and/or exclusion criteria should be given. In case-control studies, a case-definition and
the source for controls should be given.

4. *Are the interventions of interest clearly described?*
Treatments and placebo (where relevant) that are to be compared should be clearly described.

5. *Are the distributions of principal confounders in each group of subjects to be compared clearly described?*
A list of principal confounders is provided.

6. *Are the main findings of the study clearly described?*
Simple outcome data (including denominators and numerators) should be reported for all major findings so that the reader can check the major analyses and conclusions.
(This question does not cover statistical tests which are considered below).

7. *Does the study provide estimates of the random variability in the data for the main outcomes?*
In non-normally distributed data the inter-quartile range of results should be reported. In normally distributed data the standard error, standard deviation or confidence intervals should be reported. If the distribution of the data is not described, it must be assumed that the estimates used were appropriate and the question should be answered yes.

8. *Have all important adverse events that may be a consequence of the intervention been reported?*
This should be answered yes if the study demonstrates that there was a comprehensive attempt to measure adverse events. (A list of possible adverse events is provided).

9. *Have the characteristics of patients lost to follow-up been described?*

This should be answered yes where there were no losses to follow-up or where losses to follow-up were so small that findings would be unaffected by their inclusion. This should be answered no where a study does not report the number of patients lost to follow-up.

10. *Have actual probability values been reported (e.g. 0.035 rather than <0.05) for the main outcomes except where the probability value is less than 0.001?*

External validity

All the following criteria attempt to address the representativeness of the findings of the study and whether they may be generalised to the population from which the study subjects were derived.

11. *Were the subjects asked to participate in the study representative of the entire population from which they were recruited?*
The study must identify the source population for patients and describe how the patients were selected. Patients would be representative if they comprised the entire source population, an unselected sample of consecutive patients, or a random sample. Random sampling is only feasible where a list of all members of the relevant population exists. Where a study does not report the proportion of the source population from which the patients are derived, the question should be answered as unable to determine.

12. *Were those subjects who were prepared to participate representative of the entire population from which they were recruited?*
The proportion of those asked who agreed should be stated. Validation that the sample was representative would include
demonstrating that the distribution of the main confounding factors was the same in the study sample and the source population.

13. *Were the staff, places, and facilities where the patients were treated, representative of the treatment the majority of patients receive?*
For the question to be answered yes the study should demonstrate that the intervention was representative of that in use in
the source population. The question should be answered no if, for example, the intervention was undertaken in a specialist
centre unrepresentative of the hospitals most of the source population would attend.

Internal validity – bias

14. *Was an attempt made to blind study subjects to the intervention they have received?*
For studies where the patients would have no way of knowing which intervention they received, this should be answered yes.

15. Was an attempt made to blind those measuring the main outcomes of the intervention?

16. *If any of the results of the study were based on "data dredging", was this made clear?*
Any analyses that had not been planned at the outset of the study should be clearly indicated. If no retrospective unplanned subgroup analyses were reported, then answer yes.

17. *In trials and cohort studies, do the analyses adjust for different lengths of follow-up of patients, or in case-control studies, is the time period between the intervention and outcome the same for cases and controls?*
Where follow-up was the same for all study patients the answer should yes. If different lengths of follow-up were adjusted for by, for example, survival analysis the answer should be yes. Studies where differences in follow-up are ignored should be answered no.

18. *Were the statistical tests used to assess the main outcomes appropriate?*
The statistical techniques used must be appropriate to the data. For example nonparametric methods should be used for
small sample sizes. Where little statistical analysis has been undertaken but where there is no evidence of bias, the question
should be answered yes. If the distribution of the data (normal or not) is not described it must be assumed that the estimates used were appropriate and the question should be answered yes.

19. *Was compliance with the intervention/s reliable?*
Where there was non-compliance with the allocated treatment or where there was contamination of one group, the question
should be answered no. For studies where the effect of any misclassification was likely to bias any association to the null, the
question should be answered yes.

20. *Were the main outcome measures used accurate (valid and reliable)?*
For studies where the outcome measures are clearly described, the question should be answered yes. For studies which refer to other work or that demonstrates the outcome measures are accurate, the question should be answered as yes.

Internal validity - confounding (selection bias)

21. *Were the patients in different intervention groups (trials and cohort studies) or were the cases and controls (case-control studies) recruited from the same population?*
For example, patients for all comparison groups should be selected from the same hospital. The question should be answered
unable to determine for cohort and case control studies where there is no information concerning the source of patients included in the study.

22. *Were study subjects in different intervention groups (trials and cohort studies) or were the cases and controls (case-control studies) recruited over the same period of time?*
For a study which does not specify the time period over which patients were recruited, the question should be answered as unable to determine.

23. *Were study subjects randomised to intervention groups?*
Studies which state that subjects were randomised should be answered yes except where method of randomisation would not
ensure random allocation. For example alternate allocation would score no because it is predictable.

24. *Was the randomised intervention assignment concealed from both patients and health care staff until recruitment was complete and irrevocable?*
All non-randomised studies should be answered no. If assignment was concealed from patients but not from staff, it should
be answered no.

25. *Was there adequate adjustment for confounding in the analyses from which the main findings were drawn?*
This question should be answered no for trials if: the main conclusions of the study were based on analyses of treatment rather than intention to treat; the distribution of known confounders in the different treatment groups was not described; or the distribution of known confounders differed between the treatment groups but was not taken into account in the analyses. In nonrandomised studies if the effect of the main confounders was not investigated or confounding was demonstrated but no adjustment was made in the final analyses the question should be answered as no.

26. *Were losses of patients to follow-up taken into account?*
If the numbers of patients lost to follow-up are not reported, the question should be answered as unable to determine. If the
proportion lost to follow-up was too small to affect the main findings, the question should be answered yes.

Power

27. *Did the study have sufficient power to detect a clinically important effect where the probability value for a difference being due to chance is less than 5%?*
Sample sizes have been calculated to detect a difference of x% and y%.

Appendix 4: REC approval letter

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Appendix 5: Participant Information Sheet

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Appendix 6: Participant Consent Form

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Appendix 7: Brief Symptom Inventory

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Appendix 8: Experience of Shame Scale

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Appendix 9: Substance Abuse Self-Stigma Scale

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Appendix 10: Acceptance and Action Questionnaire

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Appendix 11: Maudsley Addiction Profile

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Appendix 12: Alcohol Use Disorders Identification Test

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Appendix 13: Cannabis Use Disorders Identification Test

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