Empirical Research

Acceptance and Commitment Therapy group for treatment-resistant participants: A randomized controlled trial

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A B S T R A C T

Acceptance and Commitment Therapy (ACT) is a theoretically coherent approach addressing common processes across a range of disorders. The aim of this study was to investigate the effectiveness of a group-based ACT intervention for “treatment-resistant” participants with various diagnoses, who had already completed at least one psychosocial intervention. Of 61 individuals randomized into a service-based trial comparing ACT and Treatment as Usual based on Cognitive Behavior Therapy (TAU-CBT), 45 provided data (ACT n=26; TAU-CBT n=19). Primary outcomes were measures of psychological symptoms. All participants showed reduced symptoms immediately after intervention but improvements were more completely sustained in the ACT group at 6-month follow-up. More elaborate and more fully controlled evaluations are required to confirm the findings, improve understanding of ACT processes and assess health economic benefits.

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1. Introduction

Despite considerable advances in psychotherapy for individuals struggling with acute psychological disorders, numerous outcome studies indicate that a substantial proportion of clients respond poorly, even to well-validated interventions. For example, between 30 and 60% of clients fail to make clinically meaningful improvements following Cognitive Behavioral Therapy (CBT), Interpersonal Therapy, or Psychodynamic Therapy across a range of difficulties, including Generalized Anxiety Disorder (Borkovec, Newman, Pincus, & Lytle, 2002), Bulimia Nervosa (Agras, Walsh, Fairburn, Wilson, & Kraemer, 2000; Wilson, Fairburn, & Agras, 1997) Anorexia Nervosa (Dare, Eiser, Russell, Treasure, & Dodge, 2001), and Depression (DeRubeis et al., 2005; Dimidjian et al., 2006; Elkin et al., 1989; Leichsenring, 2001). CBT has been shown to be relatively ineffective in treating depression when clients present with more chronic, co-morbid, and personality disordered symptoms (Fournier et al., 2008).

Clients with these multi-diagnostic presentations may also be categorized as “treatment-resistant” if they meet certain criteria for relapse or chronicity. For example, Kenny and Williams (2007) defined treatment resistance in relation to depression as having had three or more previous episodes, or one chronic episode lasting 1 year or more. Such clients consume a disproportionate amount of clinical resources (Amsterdam, Horning, & Nierenberg, 2001; Crown et al., 2002; Russell et al., 2004) but, ironically, they are sometimes excluded from clinical trials to reduce variability and thus increase internal validity (Persons & Silberschatz, 1998; Westen, Novotny, & Thompson-Brenner, 2004; Zarin, Young, & West, 2005).

Fortunately, there is some evidence that “third wave” (Hayes, 2004) forms of behavior therapy incorporating principles of mindfulness can successfully treat complex and intransigent clinical problems such as chronic or recurrent depression and personality disorder (e.g., Lynch, Trost, Salsman, & Linehan, 2007; Ma & Teasdale, 2004; Segal, Williams & Teasdale, 2002). Acceptance and Commitment Therapy (ACT; Hayes, Strosahl & Wilson, 1999) has figured prominently amongst these new forms. ACT’s central focus, distinguishing it from other psychotherapies, is the notion that a broad range of psychological difficulties, typically viewed as distinct under DSM-IV, emerges from our capacity for human language (Hayes et al., 2004a; Wilson, Hayes, Gregg, & Zettle, 2001). ACT uses several therapeutic techniques to increase psychological flexibility by undermining unhelpful verbal representations of experience, encouraging a present moment focus, and promoting action consistent with long-term values (Hayes, Luoma, Bond, Masuda, & Lillis, 2006). Because ACT aims to teach generic positive psychological skills, rather than targeting specific unwanted experiences and feelings (Lundgren, Dahl, & Hayes,
it is inherently transdiagnostic (Hayes et al., 2006). The central role that ACT accords to values may facilitate motivation in treatment-resistant clients with long-standing problems. This shift in focus may be especially salient to clients more familiar with forms of therapy that emphasize symptomatic relief.

Following Hayes et al. (2006), some recent studies have attempted to evaluate ACT with heterogeneous client groups. For example, Fledderus, Bohlmeijer, Pieterse, and Schreurs (2012) compared two versions of an ACT self-help intervention (minimal vs. substantive email support) with a waiting list control, using a sample of individuals experiencing depression and/or anxiety. Improvements in each experimental condition exceeded those for controls, and were sustained at 3 month follow-up. Forman, Herbert, Moitra, Yeomans, and Geller (2007) also compared ACT with Cognitive Therapy for individuals with severe anxiety and/or depression. They kept their “exclusion criteria purposefully broad for maximum external validity” (p. 8). Both groups improved on a range of measures, but the mechanisms of action appeared to differ in ways consistent with the underlying therapeutic models. Finally, Lang et al. (2012) have described a protocol for an ongoing randomized controlled trial designed to compare ACT with psychotherapy for military veterans exhibiting high levels of comorbidity.

We recently conducted a treatment development trial to test the utility of ACT with a heterogeneous group of clients in a naturalistic clinical setting (Clarke, Kingston, Wilson, Bolderston, & Remington, 2012). Ten participants presented: All had clinical disorders (Axis I diagnoses), and half met criteria for co-morbid personality disorders (Axis II diagnoses). The inclusion criteria specified that participants had “already received at least one previous episode of therapy, for which they attended at least eight sessions, and ... were being re-referred with significant residual mental health concerns” (p. 562; emphasis in the original). This criterion for treatment resistance differs from that of Kenny and Williams (2007) because (a) it is not specific to depression, and (b) it requires the client to have had psychological treatment. In fact, group members had on average attended a mean of 3.5 previous psychological interventions. After 16 ACT-based group sessions using a protocol adapted from Hayes and Smith (2005), the group showed significant improvements in self-reported depression, overall symptomatology and quality of life, with medium to large effect sizes on all measures. Individual analyses showed clinically significant and reliable change in up to 70% of participants. Moreover, significant improvements over baseline were maintained at 6 and 12 month follow-up. These findings, although promising, are tentative because the study was uncontrolled and the small sample of clients limited the power to detect differences. To increase external validity, replication using a randomized controlled trial (RCT) design is required.

Thus, building on previous research, the aim of the present study was to assess the effectiveness of ACT for a heterogeneous group of treatment-resistant clients. Following the recommendations of Smout, Hayes, Atkins, Klausen, and Duguid (2012), we used an active CBT-based control group for comparison purposes. We designated this control condition as Treatment as Usual based on CB (TAU-CBTT) because CBT is the most widely utilized and researched psychotherapy (Norcross, Hedges, & Castle, 2002). Although most CBT research is disorder-specific, the use of unified treatment protocols for mood and anxiety disorders is now being explored by some investigators (McEvoy, Nathan, & Norton, 2009). CBT-based TAU was therefore considered an appropriate active comparison condition against which to evaluate ACT.

In keeping with previous ACT research, we chose to conduct a small-scale RCT utilizing a pragmatically acquired sample. We chose our primary outcome measures to reflect the heterogeneous and treatment-resistant characteristics of this sample, and the goals of ACT-based intervention. Because our selection criterion did not specify any diagnosis, we assessed participants’ overall symptomatology. Because treatment resistance is strongly associated with depression (Blom et al., 2007; Fournier et al., 2009; Joyce et al., 2002; Sotsky et al., 1991), we used a robust measure of depressive symptomatology. Our secondary outcome measures were chosen to monitor changes in complex personality disorder symptomatology and quality of life; the latter is a non-symptomatic measure expected to vary with personal adjustment. Assessments were made post-therapy and at 6 month follow-up, to assess whether any benefits had been sustained. Furthermore, because inappropriate care can worsen symptoms and personality pathology for treatment-resistant clients (Clarke, Thomas, & James, 2013; Tyrer & Simmonds, 2003), we assessed changes in participant functioning on both an individual and a group basis. We further assessed preliminary theory-driven process variables for both conditions.

We hypothesized that participants receiving ACT would show greater improvements in primary outcome measures across time than those receiving TAU-CBTT. We also predicted that a greater proportion of ACT participants would improve and that less would deteriorate than CBT-based TAU participants.

2. Method

2.1. Design

We used an RCT to compare the effectiveness of a 16 week, group-based ACT intervention with a group-based TAU-CBT intervention of the same duration at a specialist personality disorder clinic in a public health setting (ISRCTN17801606). The Dorset Research and Development Support Unit assigned participants to treatments using block randomization (block sizes 2–4) to ensure the numbers allocated to each intervention were always closely balanced. Outcome and process measures were obtained at baseline, post-therapy and follow-up. The protocol was approved by the UK National Health Service Research Ethics Committee (Dorset: 06/Q2201/170).

2.2. Participants

Participants were recruited from referrals to a Community Mental Health Team and a specialist outpatient service for people with a personality disorder. Consistent with our earlier definition of treatment resistance (Clarke et al., 2012), eligible participants had received at least one previous 8-session episode of psychological therapy and had been re-referred. No independent data were available on the quality or fidelity of previous treatments. Owing to the group-based nature of the intervention, and the relative vulnerability of the client group, exclusion criteria (based on DSM-IV, 1994), were intellectual disability, schizophrenia or other psychotic illness, or any of the following high risk behaviors: (a) current drug or alcohol dependency; (b) a current eating disorder and a BMI of <16; and (c) deliberate self-harm in the past 6 months (defined using Kreitman’s (1977) criteria). In keeping with the service protocol, clients who engaged in self-harming behavior monthly or more were referred directly to an established Dialectical Behavior Therapy program.

2.3. Measures

2.3.1. Primary outcome measures

The Symptom Check List-90 Revised (SCL-90-R; Derogatis, 1993), a 90-item self-report measure, was used to measure psychiatric distress. Given the symptomatic heterogeneity of the conditions, we...
used the Global Severity Index to evaluate a broad range of psychological problems and symptoms of psychopathology, providing scores on nine primary symptom dimensions and three global indices. A higher GSI score indicates greater psychiatric distress. Internal consistency and test–retest reliability for the GSI are excellent ($\alpha = .90, r = .91$, respectively; Derogatis, 1993; Derogatis & Spencer, 1982). We used the Beck Depression Inventory-II (BDI-II; Beck, Steer, & Brown, 1996b) to assess depression: Higher scores indicate greater depressive severity. Internal consistency and test–retest reliability are excellent for this measure ($\alpha = .91, r = .93$, respectively; Beck, Steer, Ball & Ranieri, 1996a; Beck et al., 1996b).

### 2.3.2. Secondary outcome measures

We used the Structured Clinical Interview for DSM-IV Axis II Disorders (SCID-II; First, Gibbon, Spitzer, & Williams, 1996) to assess symptomatology of 10 personality disorders. This measure has good to excellent interrater reliability (Lobbestael, Leurgans, & Arntz, 2011), and acceptable to good internal consistency and test–retest reliability ($\alpha = .71–.94$, kappa $=.61–.68$; Maffei et al., 1997; Williams et al., 1992; respectively). The SCID was used to index “presence” (symptoms reach diagnostic threshold) versus “absence” (symptoms, if present, do not reach diagnostic threshold) of a personality disorder diagnosis. We used the World Health Organization Quality of Life (WHOQOL; Skevington, Lofty, & O’Connell, 2004) to assess quality of life across four domains (physical health, psychological health, social relationships, and environment). Higher scores indicate higher quality of life. This measure has acceptable to good internal consistency and test–retest reliability ($\alpha = .55–.87, r = .71–.91$, respectively; Skevington et al., 2004; Taylor, Myers, Simpson, McPherson, & Weatherall, 2004).

### 2.3.3. Process measures

We used the Acceptance and Action Questionnaire (AAQ, 9-item; Hayes et al., 2004a), a measure designed to examine ACT-theory consistent changes in psychological flexibility during treatment, with higher scores indicating less flexibility. Internal consistency and test–retest reliability are adequate for this measure ($\alpha = .77, r = .64$, respectively; Hayes et al., 2004a). The 15-item Mindful Attention Awareness Scale (MAAS; Brown & Ryan, 2003) was selected to assess the frequency of mindful states, with higher scores indicating greater mindfulness. Internal consistency and test–retest reliability are good for this measure ($\alpha = .86, r = .81$, respectively; Brown & Ryan, 2003). Finally, we used the Automatic Thoughts Questionnaire/Thought Believability and Frequency (ATQ/TBF; Bach & Hayes, 2002), a modified version of the 30-item intrusive thoughts measure, to assess thought believability and frequency. Using a 5-point scale, participants rated how frequently they had experienced unwanted/intrusive thoughts and emotions in the past week, and how believable and meaningful these experiences were. Internal consistency and test–retest reliability data are not available for this measure.

### 2.3.4. Treatment integrity measure

In keeping with previous research (Forman et al., 2007), the Drexel University CT/ACT Therapist Adherence and Competence Rating Scale (DUAACRS) was used to rate treatment integrity in both conditions. The scale comprises six subscales: ACT-Specific Behavior; CBT-Specific Behavior; and four generic measures (Therapist Competence; Relationship-Building; Treatment Implementation; Miscellaneous Therapist Behaviors). Reported inter-reliability (intra-class correlation coefficient $= .95$) and internal consistency ($\alpha = .92$) are excellent (Forman et al., 2007).

### 2.4. Interventions

Participants in both conditions attended weekly sessions lasting 2 h, with a 10 min break and ending with a homework task. Although neither treatment was fully manualized, the content of each closely followed client-oriented self-help manuals (Greenberg & Padesky, 1995; Hayes & Smith, 2005).

#### 2.4.1. Acceptance and Commitment Therapy

ACT groups were run by a consultant clinical psychologist and a clinical psychologist (mean post-qualification experience=19 years). Both were ACT-trained and under supervision of an ACT originator (Dr. Kelly Wilson). All sessions began with a brief mindfulness exercise and a homework review. The remainder of the time was spent in didactic and experiential learning using pre-planned materials and exercises. These were chosen to enable clients to both understand ACT processes and perspectives and to experience their impact. Each session addressed a specific theme taken from Hayes and Smith (2005): These included experiential avoidance, cognitive fusion, willingness, and values. Homework was set at the end of each session, often in the form of behavioral practices and experiments. Despite the structured nature of the intervention, the therapists made in-the-moment decisions with regard to the intensity with which particular topics were explored. A more detailed account of the intervention appears in Clarke et al. (2012).

#### 2.4.2. Treatment-as-usual based on Cognitive Behavior Therapy

TAU-CBT groups were run by either a clinical psychologist and a counselor (mean post-qualification experience=9 years), or by a nurse specialist in CBT and a counselor (mean post-qualification experience=18 years). All TAU-CBT therapists were CBT-trained and under the supervision of the local service lead CBT practitioner (19 years post-qualification experience). TAU-CBT contained no mindfulness components. Early sessions introduced the model. Later sessions reviewed participants’ negative automatic thoughts and thinking biases, identified their core schemas and discussed the relationship between early experiences and long-standing beliefs. CBT skills, such as challenging thoughts and conducting behavioral experiments, were taught. The final sessions focused on relapse prevention.

### 2.5. Procedure

On referral, clients meeting inclusion and exclusion criteria were sent a letter informing them about the trial and inviting them to an assessment session. Those that attended and gave written informed consent were then screened before completing all baseline measures. A SCID-II was used to assess personality disorder symptomatology. This was administered by one of two postgraduate level psychologists, a psychiatrist, or a clinical psychologist, all of whom were trained to a level of 80% concordance with other SCID-II-trained clinicians. Consistent with previous research (e.g., Clarke et al., 2012; Emmelkamp, Benner, Kuipers, Feiertag, & Koster, 2006) participants were asked to report symptoms since early adolescence (diagnostic criterion) and in the last year (symptomatic criterion). Details of previous treatment episodes were also obtained and subsequently verified from NHS clinical files. When baseline data had been obtained, participants were randomly assigned to conditions. The groups were run in each condition, with a maximum of 11 participants per group.

Psychometric assessment to obtain process and outcome data was repeated 1–3 weeks after therapy termination (post-therapy) and again at 6-month follow-up. At follow-up, a post-intervention
SCID-II was administered to assess symptoms in the interval since baseline assessment (symptomatic criterion).

### 2.5.1. SCID reliability

All SCID-II interviews were audio-taped and a random sample (25%) was rated by three experienced independent assessors (a clinical psychologist and two psychiatrists), who were naive to the treatment allocation. Inter-rater reliability for “PD present versus absent” was high (Kappa = .84; 95% agreement).

### 2.5.2. Treatment integrity

At the end of the study, an independent assessor (a psychiatrist with specialist interest in psychotherapy including ACT and CBT) rated audio-recordings of a randomly selected 15% of ACT and TAU-CBT group sessions using the DUACRS. Half of these sessions were then rated by another independent assessor (a CBT- and ACT-trained consultant clinical psychologist). Both raters were able successfully to differentiate the treatment conditions for all sessions coded. Therapists spent an average of 68.2% of sessions on treatment-specific components and only 3.4% on components specific to the non-assigned condition. Inter-rater reliability across the five relevant adherence sub-scales was acceptable (kappa = .62, range 50–78). Therapist competence was judged to be “good”, “very good”, or “excellent” for 78.6% of rated sessions. Data from both raters indicated that there was no significant difference between ACT and TAU-CBT sessions in terms of score on the relationship-building subscale of the DUACRS (Rater 1: U = 14.00, p = .21; Rater 2: U = 8.00, p = 1.00).

### 2.6. Overview of statistical methods

To assess group change, a series of mixed-design Analyses of Variance (ANOVA) was used to establish the impact of treatment on all outcome and process measures. Further analyses were conducted with post hoc repeated measures ANOVA. Separate analyses were based on (a) data from participants who completed treatment and provided follow-up data; that is, on treatment administered basis; and (b) data from all recruited participants who completed pre- and post-assessments, regardless of whether they completed treatment (i.e., intention-to-treat; Ost, 2008). Intention-to-treat analyses assessed group change on a more conservative basis. Like previous trials with relatively small sample sizes (Morton, Snowdon, Gopold, & Guymer, 2012), Cohen’s $d$ between-group effect sizes were calculated by dividing the mean differences by the baseline pooled standard deviations (Cohen, 1988), even when no significant group effects had been obtained at post-test. Using Cohen’s (1988) guidelines, the following conventions were used: “small” ($d$ = .2), “medium” ($d$ = .5) and “large” ($d$ = .8).

Because the SCID-II is a nominal variable, the data were dichotomized into two categories (“personality disorder” or “no personality disorder”) and the Fisher’s Exact Test was used to compare the distribution of scores between the two study groups.

We used Jacobson and Truax’s (1991) criteria for reliable and clinically significant change to assess whether group differences were reflected in outcomes for individual participants. Statistics were computed for changes (a) between baseline and post-therapy and (b) between baseline and follow-up, using the published normative values for the GSI and BDI-II and test–retest reliability values stated in Section 2.

Finally, analyses assessing whether changes in theoretically relevant process measures during treatment predicted outcomes at follow-up were conducted to explore ACT theory-consistent processes of change. Separate multiple regressions for ACT and TAU-CBT were computed using residual gain scores (Stekete & Chambless, 1992) to index pre- to post-therapy change, adjusted for repeated testing.

### 3. Results

#### 3.1. Participant recruitment

Fig. 1 shows the participant flow throughout the trial. Of 140 participants assessed for eligibility, 50 did not respond to the written invitation. Of the remaining 90, 25 did not, on closer examination, meet the inclusion criteria, two met the exclusion criteria (eating disorder and deliberate self-harm), and two were excluded for other reasons (e.g. left the area). This yielded a sample size of 61 participants randomized between the two conditions (ACT: $n = 30$; TAU-CBT: $n = 31$), a figure compatible with that reported in previous ACT research involving participants with complex problems (Gratz & Gunderson, 2006; Hayes et al., 2004b).

#### 3.2. Baseline data

The final sample consisted of 41 women (67.21%) and 20 men, with a mean age of 43.46 (s.d. = 12.35). Table 1 provides demographic information on the full sample, and baseline psychometric data. Clinical norms for the GSI indicated that 44 participants (72%) had psychiatric symptoms within the clinical range and 45 (76% of those who returned their questionnaires) were experiencing moderate to severe levels of depression, as assessed with the BDI-II. Other diagnoses included anxiety disorders (e.g. agoraphobia and social phobia), eating disorders (e.g. bulimia), and adjustment disorders. Participants also presented with a range of personality disorders: 31 (51%) met criteria for at least one personality disorder and 19 (31%) met criteria for two or more co-morbid disorders. A broad range of personality disorders were represented, with the exception of schizoid, schizotypal, and histrionic. A third of participants met the diagnostic criteria for depressive personality disorder. Avoidant, obsessive-compulsive, paranoid and borderline personality disorders were each seen in 20–30% of the sample. There were no significant between-group differences on demographic or baseline characteristics.

#### 3.3. Attrition

Fig. 1 shows that between the baseline and post-therapy assessments, 12 participants (39%) dropped out of the TAU-CBT group (five did not attend any sessions and seven dropped out during treatment); and four started but discontinued in the ACT group (13%). A further two participants from the TAU-CBT group and one participant from the ACT group dropped out between the post-therapy and follow-up assessments. Ten of the 16 participants (63%) who discontinued treatment met diagnostic and symptomatic criteria for a personality disorder. Because differences in attrition between conditions during active therapy were significant ($\chi^2 = 5.074, p = .024$), comparisons of completers’ versus non-completers’ baseline data were conducted. These indicated that non-completers had higher baseline GSI scores ($t(59) = 1.926, p = .059$) and lower WHOQOL scores ($t(59) = 2.531, p = .014$).

#### 3.4. Outcomes

Descriptive analyses confirmed that the data for all continuous study variables were normally distributed.

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1 The residual gain score was computed by standardizing pre- and post-treatment means and subtracts the T1 score, multiplied by the correlation between T1 and T2 scores, from T2 (i.e., $RG = Z_{T2} - (Z_{T1} \times r_{T1,T2})$).
3.4.1. Analysis of participants who completed treatment

3.4.1.1. Primary outcome measures. Table 2 shows that groups did not differ significantly in terms of the two primary outcome measures, but that there were significant overall improvements over time on both measures. Post hoc analyses (adjusted $p < .01$) revealed significant reductions in scores from baseline to post-therapy (GSI: $F(1, 40) = 9.096, p = .004$; BDI-II: $F(1, 38) = 37.128, p < .001$) and baseline to follow-up (GSI: $F(1, 41) = 16.115, p < .001$; BDI-II: $F(1, 39) = 27.049, p < .001$).

Examination of means (see Fig. 2) suggested a differential effect of the two interventions on general symptom severity and depression. The Group × Time interaction for GSI was not significant, however Fig. 2 shows that GSI scores followed a similar pattern to the BDI-II scores. For BDI-II scores, a significant Group × Time interaction was observed (adjusted $p < .01$).
3.4.1.2. Secondary outcome measures. Twelve participants completing the ACT group and seven participants completing the TAU-CBT group met SCID-II diagnostic and symptomatic criteria for at least one personality disorder at baseline. Of those who received ACT, eight no longer met symptomatic criteria at follow-up, three remained symptomatic and one did not complete the full SCID-II assessment. Of those who received TAU-CBT, three no longer met symptomatic criteria at follow-up, three continued to be symptomatic and one dropped out before assessment. These between group differences were not significant (Fisher’s Exact Test: \( p < .05 \)).

Analyses showed a significant time effect for the WHOQOL, but no between-group differences (Table 2). Post hoc analyses (adjusted \( p < .01 \)) revealed a significant increase in WHOQOL scores from baseline to post-therapy (\( F(1, 38) = 19.195, p < .001 \)) and baseline to follow-up (\( F(1, 38) = 18.964, p < .001 \)). Between-group comparisons of WHOQOL scores yielded small effect sizes, favoring TAU-CBT at post-therapy (\( d = .13 \)) and ACT at follow-up (\( d = .33 \)).

3.4.1.3. Intention-to-treat analysis. Because attrition was selective, ANOVAs were re-run on an intention-to-treat basis, meaning that comparisons included all clients who consented to the trial, regardless of amount of treatment received. Missing data was managed using the last observation carried forward method (Spokas, Rodebaugh, & Heinberg, 2008). The results of these analyses were akin to those for treatment completers. No group differences were observed but significant effects of time were
again apparent for all outcome measures (GSI: F(2, 118)=13.782, p < .001; BDI-II: F(2, 112)=24.991, p < .001; and WHOQOL: F(2, 118)=17.012, p < .001). Post hoc pairwise comparisons revealed significant reductions in GSI scores from baseline to post-therapy (F(1, 60)=11.526, p < .001) and baseline to follow-up (F(1, 60)=17.172, p < .001). BDI-II scores significantly improved from baseline to post-therapy (F(1, 58)=34.056, p < .001) and baseline to follow-up (F(1, 57)=25.506, p < .001). WHOQOL scores significantly improved from baseline to post-therapy (F(1, 60)=21.191, p < .001) and baseline to follow-up (F(1, 60)=21.755, p < .001).

The BDI-II Group × Time interaction approached significance (F(1, 59)=3.324, p = .073) and post hoc analysis showed the same pattern as that observed for the treatment completers. Significant baseline to post-therapy reductions in BDI-II occurred for both groups (ACT: F(1, 28)=28.114, p < .001; CBT: F(1, 29)=9.394, p = .005) but change from baseline to follow-up was significant only for the ACT group (ACT: F(1, 28)=25.122, p < .001; TAU-CBT: F(1, 28)=4.790, p = .037). Because broadly similar outcomes were obtained from treatment-completers and intention-to-treat analyses, subsequent discussion will rely on the latter.

### 3.5. Clinically significant individual change

Norms used for change calculations were drawn from published psychometric data (Beck et al., 1996b; Derogatis, 1993; Dozois, Dobson, & Ahnberg, 1998). Based on the recommendations of Thomas and Truax (2008), the following categories of change were calculated: recovered (reliable and significant clinical change), improved (reliable change, without significant clinical change), same (no change) and deteriorated (reliable change in direction of worsening symptoms). Next, Chi-square analyses comparing “Recovered or Improved” and “Same or Deteriorated” participants were computed to compare individual patterns of change between conditions. The percentage of ACT and TAU-CBT participants, who reliably recovered, improved, remained the same or deteriorated at post-therapy and follow-up is shown in Table 3. These analyses suggest that, in comparison with TAU-CBT participants, a significantly greater number of ACT participants made reliable and clinically significant improvements according to scores on the GSI and BDI-II at both post-therapy (respectively, $\chi^2=4.471$, p = .034; $\chi^2=4.127$, p = .042) and follow-up (respectively, $\chi^2=7.412$, p = .006; $\chi^2=7.519$, p = .006).

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<th>GSI</th>
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<td>ACT TAU-CBT</td>
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<tr>
<td>Recovered (%)</td>
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<td>44 12</td>
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<td>Deteriorated (%)</td>
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Note: GSI: Global Severity Index; BDI-II, Beck’s Depression Inventory.
* p < .05.
** p < .01.

In the ACT group, AAQ residual gain pre-post scores were significantly predictive of both GSI and BDI-II at follow-up (respectively, $\beta=.615$, p = .001; $\beta=.599$, p = .003) and approached, but did not reach significance for, follow-up WHOQOL ($\beta=.293$, p = .057) scores. For the TAU-CBT group, AAQ residual gain scores were not significantly related to any outcome measures at follow-up.

Multiple regression analyses were also computed to test whether baseline to post-intervention changes in ATQ-TB scores were associated with follow-up outcomes for the ACT group, but not CBT group. In keeping with our expectation, the ACT group, ATQ-TB residual gain scores were significantly predictive of GSI and BDI-II at follow-up (respectively, $p=.490$, p = .020; $\beta=.506$, p = .022). However, ATQ-TB residual gain scores were not predictive of WHOQOL at follow-up. For the TAU-CBT group, ATQ-TB residual gain scores were not related to any follow-up outcome measures. Contrary to our expectation, ATQ-TF residual gain scores were not significantly predictive of outcome in the TAU-CBT group, but they were in the ACT group. Specifically, ATQ-TF residual gain scores were significantly predictive of GSI and BDI-II at follow-up (GSI: $\beta=-.737$, p < .001; BDI-II: $\beta=-.570$, p = .007), and approached, but did not reach significance for, WHOQOL scores ($\beta=-.287$, p = .070).

Finally, to assess for dormant effects of previous therapies, non-parametric correlations were used to assess the relationship between the previous number of therapeutic sessions and pre-post change in outcome measures. These correlations were not significant (all p > .05).

### 4. Discussion

Our results indicate that group-based intervention for a heterogeneous group of treatment-resistant participants produced substantial improvements. Group analyses showed that mean levels of deleterious psychological symptoms and baseline depression were significantly reduced after intervention and at follow-up, and quality of life improved, regardless of whether participants received ACT or TAU-CBT. A similar pattern of results also emerged from more conservative intention-to-treat analyses. There was no relationship between the previous number of therapeutic sessions and pre-post change in outcome measures, suggesting that improvements were unlikely to be related to the dormant effects of previous therapies.

Although no main effects of therapy (group) on depressive symptoms were observed, Group × Time interaction effects and effect size analyses indicated that the improvements following ACT exceeded those for TAU-CBT. Within-group post hoc analyses showed that, unlike TAU-CBT participants, ACT participants continued to show significantly reduced depression at 6-month
follow-up, with large effect sizes favoring ACT. Similarly, despite the absence of significant Group × Time interactions, medium and small effect sizes in favor of ACT were observed for reductions of overall psychological symptoms and quality of life at 6-month follow-up.

Group analyses were supported by assessment of changes on an individual basis, both immediately post-therapy and at follow-up. In each case, a significantly greater proportion of ACT participants were classified as “recovered” or “improved” on primary outcome measures; in contrast, a significantly greater proportion of TAU-CBT participants were categorized as the “same” or “deteriorated”.

Overall, these findings suggest that participants who received ACT maintained their post-treatment gains on primary outcome measures (GSI; BDI-II) at follow-up, whereas those who received TAU-CBT showed weaker maintenance. These outcomes parallel the results of previous ACT research (Clarke et al., 2012; Gifford et al., 2004; Hayes et al., 2004b; Lundgren, Dahl, Melin, & Kies, 2006) suggesting an “incubation effect”, whereby improvement is maintained after ACT treatment ceases. Hollon, Stewart, and Strunk (2006) distinguish between interventions that produce palliative effects that “suppress the expression of the disorder so long as they are applied” (p. 287) and those that are enduring and curative (i.e., those that “reverse[d] processes that would otherwise lead to the continuation of the disorder”; p. 287). ACT may achieve enduring effects because interventions focus on increasing psychological flexibility in the service of engaging in more valued, meaningful activities, even if these may occasionally expose clients to aversive experiences. To the extent that exposure is a useful therapeutic tool, behaviors that produce repeated self-initiated exposure might be expected to produce continuing gains. This interpretation is supported by the AAQ process data. These showed that, for the ACT group alone, residual gains at post-test were significantly predictive of improved GSI and BDI-II scores at follow-up.

Our data support the view that the core theoretical principles of ACT can be applied across diagnoses, suggesting ACT may be a second-line approach for individuals who have not benefitted from previous first-line interventions, including CBT. Moreover, the application of ACT as a group-based approach also has practical and economic implications for service delivery.

Using an RCT design in a naturalistic setting created some tensions between research and practice which contributed to both the strengths and limitations of the study. For example, both interventions were consistent with clinical practice in the real world public sector service providing treatment to a heterogeneous group of "treatment-resistant" clients. Such clients, highly prevalent in clinical practice (Fournier et al., 2008), are sometimes excluded from outcome research (Persons & Silberschatz, 1998; Westen et al., 2004; Zarin et al., 2005). The ecological validity of the study was, however, limited because clients displaying risky behavior were excluded, so the sample may not be fully representative of the treatment-resistant population.

Although in keeping with previous ACT research in terms of methodology, a significant limitation of the study was its relatively small sample size, and the fact that markedly more participants dropped out from TAU-CBT than ACT. This differential attrition may, however, be of some clinical significance. Perhaps ACT is more acceptable to treatment-resistant clients either because of its novelty and/or previous unsuccessful experiences with CBT-based interventions. In future research, it would be possible to test these admittedly post hoc hypotheses using structured interviews to follow-up participants who dropped out. A second concern is that differential attrition may have affected our comparisons. Fortunately, however, intention-to-treat analyses produced findings that were broadly in line with the treatment-completers analyses. Although non-treatment specific factors—such as therapeutic alliance or quality of supervision—were not assessed and may have contributed to change, most therapeutic time was spent on treatment-specific components. Moreover, most rated sessions (79%) were judged “good” to “excellent” and there was no difference between the two conditions on the relationship-building subscale of the DUACRS.

Finally, the SCID measure was rated by assessors who were not blind to group assignment, but there was good inter-rater reliability with second raters naive to treatment allocation. All other key measures were self-report questionnaires completed privately by participants.

In conclusion, our findings provide evidence that group-based ACT is more effective than CBT-based TAU in maintaining outcomes for a group of treatment-resistant participants experiencing a range of heterogeneous difficulties. ACT may also be more acceptable to treatment-resistant participants, possibly by virtue of their previous experiences of CBT. Future research building on these findings would benefit from a fully powered evaluation of ACT for treatment-resistant participants, again in comparison with an evidence-based intervention. Given the increased potential for relapse amongst treatment-resistant participants, longer-term follow-ups (e.g., 12- or 18-months) would be valuable. Such comparisons would also benefit from a formal assessment of process variables and a cost-effectiveness evaluation.

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