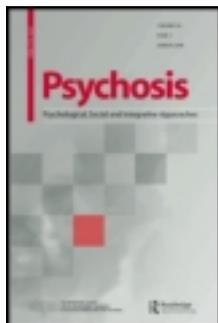


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Acceptance and commitment therapy for psychosis: intent to treat, hospitalization outcome and mediation by believability

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Cognitive behavior therapy (CBT) has been shown to be efficacious when used as an adjunct to pharmacotherapy for psychotic disorders. Acceptance and Commitment Therapy (ACT) is a contextual form of CBT that attempts to alter one's relationship to symptoms of psychosis rather than attempting to reduce or control them. Two previously published randomized trials of ACT for symptoms of psychosis have found evidence for decreased believability of symptoms and decreased hospitalization, among other outcomes. Using the combined dataset from these trials, the impact of ACT on intent to treat analyses of hospitalization outcomes and the mediating role of symptom believability on hospitalization outcomes were examined. Results showed reduction of rehospitalization at the 4-month follow-up, mediated by symptom believability but not symptom-related distress. The current study provides incremental support for the impact and putative processes of ACT for psychosis.

Keywords: psychosis; acceptance and commitment therapy; mediation; cognitive behavior therapy; defusion; hospitalization; believability

Although medications are by far the most widely used interventions for patients with psychotic disorders, there is a growing role for psychosocial interventions, particularly cognitive behavior therapy (CBT; e.g., Beck, Rector, Stolar, & Grant, 2009). In addition to more traditional forms of CBT, researchers are increasingly investigating modern contextual forms of CBT for psychosis that emphasize acceptance and mindfulness strategies (Tai & Turkington, 2009). These include mindfulness-based group interventions (e.g., Chadwick, Hughes, Russell, Russell, & Dagnan, 2009) and Acceptance and Commitment Therapy (ACT; Hayes, Strosahl, & Wilson, 2011).

ACT uses mindfulness and behavior change methods to produce greater psychological flexibility. Psychological flexibility is defined as contacting the present moment fully as a conscious human being, and based on what the situation affords, changing or persisting in behavior in the service of chosen values (Hayes et al., 2011). In contrast to traditional approaches to the treatment of psychosis that emphasize symptom reduction or elimination, the emphasis is on changing one's relationship to symptoms. For example, when experiencing voices patients are encouraged to accept

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their presence and the emotions they produce; to be aware of them as a psychological experience without treating them literally (cognitive defusion), and to shift attention toward values-based actions.

There is correlational evidence for the role of such processes in psychosis (e.g., Udachina et al., 2009) and there have been three randomized clinical trials (RCTs) of ACT for psychosis (Bach & Hayes, 2002; Gaudiano & Herbert, 2006; White et al., 2011). Bach and Hayes (2002) found in a sample of 80 inpatients reporting hallucinations or delusional beliefs that a brief 4-session intervention reduced rehospitalization over 4 months post-discharge compared to a treatment-as-usual (TAU) control condition; differences were maintained 1 year post release (Bach, Hayes, & Gallop, 2012). Gaudiano and Herbert (2006) replicated this study with controls for therapist contact. With a smaller sample ($n = 40$) the ACT group showed significantly greater reduction of symptom severity. Rehospitalization differences were similar to those in original study but that failed to reach significance in this smaller study. In a study of emotional upheaval following a psychotic break, White et al. (2011) found lower rates of depression and fewer crisis calls in the 3 months following 10 sessions of ACT.

There are limitations. In the initial two RCTs, no full intent-to-treat (ITT) analyses were conducted on the 4-month hospitalization outcomes. Hospitalization rate is a broadly used outcome (Pfammatter, Junghan, & Brenner, 2006), with high costs (Knapp, 2005), so the lack of ITT analyses is a significant weakness that needs correction.

In ACT for psychosis, mindfulness is known to change (White et al., 2011) and believability of hallucinations mediates the effect of ACT versus TAU on hallucination-related distress (Gaudiano, Herbert, & Hayes, 2010). The processes accounting for rehospitalization outcomes have also not yet been examined, however. Bach and Hayes (2002; the “Reno Study”) and Gaudiano and Herbert (2006; the “Philadelphia Study”) used the same protocol and primary outcome measure, thus ITT outcome analyses and mediation were examined in the combined dataset to afford more statistical power.

Method

Given limited space and published descriptions (Bach & Hayes, 2002; Bach et al., 2012; Gaudiano & Herbert, 2006; Gaudiano et al., 2010), methodological details of the trials, such as sample details, inclusion and exclusion criteria, and intervention details will not be covered in the current report. Both studies focused on patients currently experiencing hallucinations or delusions not due to dementia, delirium, substance-induced psychosis, or medical conditions.

Participants: Reno study

Inpatients at a Nevada state psychiatric facility based in Reno, Nevada were recruited for the study. Seven participants were discharged before they could be randomized, leaving 80 who were randomized to receive the ACT intervention ($n = 40$), or TAU ($n = 40$). Average length of stay on the unit was 52 days ($SD = 72$). Average age of participants was 39 ($SD = 9$), and the sample was predominantly male (64%) and White (80%). The majority of participants carried a primary diagnosis of a psychotic disorder (86%) and 79% a schizophrenia spectrum disorder (APA, 2000). Approximately equal numbers reported primarily hallucinations (49%) versus primarily delusions (51%).

Participants: Philadelphia study

Forty patients (ACT = 19; TAU = 21) were recruited from a university-affiliated, tertiary-care psychiatric inpatient unit in the center city area of Philadelphia. The average length of stay on the unit was 10.7 days ($SD = 11.5$). Average age of participants was 40 days ($SD = 10$), and the sample was predominantly male (64%) and African-American (88%). The majority of participants carried a primary diagnosis of a psychotic disorder (58%), with the remaining diagnosed with a primary mood disorder with psychotic symptoms (APA, 2000).

Missing data

In the original report of the Reno study, 10 of the 80 randomized participants were not included in the results. One participant in each arm of the study was incarcerated in correctional facilities for minor offenses, which due to ethical concerns removed them from the study; one TAU participant shot himself, one ACT participant was hit by a vehicle on the freeway and killed (it was not known if it was a suicide); three ACT participants and two TAU participants relocated out of the area; and one TAU participant was in town but no longer willing to be in contact with the hospital (hospitalization data were available, however, and were included in the present analysis). In the original report of the Philadelphia study, 2 (1 in each condition) of the 40 randomized participants were not included in the results due to drop out during the acute hospitalization phase.

Procedure: Reno study

All participants received medication and generally participated in three or more psychoeducational groups that met weekly or twice weekly and weekly individual psychotherapy sessions with a psychologist or psychology trainee. After discharge, TAU generally consisted of case management services, and monthly medication management meeting. Somewhat less than half of the participants ($n = 21$ TAU and 20 ACT, respectively) participated in post-discharge psychosocial rehabilitation and/or assertive community treatment.

In addition ACT participants received four 45-minute sessions of individual ACT intervention provided by one of the authors (PB). The four sessions focused on acceptance, defusion, and values, using standard ACT methods (see Bach & Hayes, 2002; Bach et al., 2012).

Procedure: Philadelphia study

All patients received antipsychotic medication and participated in daily group therapy; unstructured individual therapy and case management was also provided based on need and availability. Patients were referred to appropriate community services upon discharge. To control for increased individual attention, patients assigned to TAU also met with the study therapist daily (approximately 15 min). TAU participants received equal amounts of formal therapy compared to ACT participants, as standard unit therapy was conducted concurrently with the ACT sessions. The ACT treatment protocol was modeled after the Reno study.

Rehospitalization data

The outcome data in the present report consist of system records regarding rehospitalization. In the Reno study, since the nearest alternative public hospital is over 100 miles away, data were collected monthly beginning at 60 days post discharge from patient charts in the facility and was double checked against weekly reports of new admissions. In the Philadelphia study, rehospitalization data were collected at the end of 120 days from the agency that administered Medicaid funds for the state and held data on all services used by patients. Additional data were also obtained from the hospital records of patients who were rehospitalized at the recruitment site.

Assessments

Participants in both studies completed measures assessing the frequency of their symptoms, the distress they experienced with regard to such symptoms, and the believability of these specific symptoms. Questions were presented orally during an assessment meeting with the participant. Baseline measures were collected immediately after the participant agreed to participate in the study. In the Reno study follow-up measures were collected by the participant's case manager or by one of the investigators (PB) 4 months after discharge from the hospital; in Philadelphia study these measures were taken prior to discharge by one of the investigators (BG) or a research assistant. To simplify the language, hereafter these post or follow-up scores will be termed "post scores" but it should be remembered that in the Reno dataset the scores were collected at follow-up.

In addition to conducting an ITT analysis a focus of the present report is on the mediational role of the frequency, distress, and believability reports of positive symptoms. In both studies participants were asked how frequently they experience symptoms of psychosis in the past month on a 7 point Likert-type scale (1 = never/no symptoms; 4 = several times a week; 7 = almost constant). For the distress measure, participants in Reno were asked, "On a scale of zero to 100, how distressed are you when you [the patient's primary symptom was described; for example, 'hear voices']. Zero means not distressed at all, and 100 is the most distressed you've ever been". For the believability measure, participants were asked, "On a scale of zero to 100, to what degree do you believe _____ (e.g., 'that gang members are stalking you,' or 'the voices telling you that you are a bad person') is true. Zero means you are certain it is not real or true, and 100 means you are absolutely certain that it is real or true." Identical self-report ratings were taken in the Philadelphia study but the scale for distress and believability was zero to ten. Symptom ratings assessed delusions or hallucinations in Reno; it was limited to hallucinations in Philadelphia. Philadelphia distress and believability scores were multiplied by 10 to make the scales comparable (all participants in the Reno study provided data evenly divisible by 10, also supporting their comparability).

In Reno distress and believability were not taken if participants said they were experiencing no symptoms (a frequency rating of zero; this did not happen at baseline because it was an inclusion criterion). In the Philadelphia study ratings were taken regardless, since participants were asked to provide distress and believability ratings were the baseline symptom to occur.

Patients in the Philadelphia study were also administered the Brief Psychiatric Rating Scale (BPRS): an 18-item semi-structured clinical interview used to assess a variety of psychiatric symptoms (Lukoff, Nuechterlein, & Ventura, 1986). The

validated subscales (Long & Brekke, 1999) of thought disorder (positive symptoms) and affect (depression, anxiety, hostility) were used in the present study. Raters were not blind to condition but were trained to proficiency (use the manual of Ventura et al., 1993). Interrater-rater reliability alpha was .90.

Statistical approach to mediation analysis

Mediation refers to the statistical difference between the impact of treatment on outcome (the “*c* path”) and the impact of treatment on outcome accounting for the mediator (the “*c*’ path”). Mediation analysis is in a period of flux conceptually, following the weakening of support for the traditional causal steps approach (Baron & Kenny, 1986). A recent review (MacKinnon, Fairchild, & Fritz, 2007) of available methods suggested testing the cross-product of the coefficients for differential impact of treatment condition on the mediator, and the relation of the mediator to outcome, controlling for treatment condition (MacKinnon, Lockwood, Hoffman, West, & Sheets, 2002), since this is statistically identical to the difference between the *c* and *c*’ paths. The distribution of the cross product cannot be assumed to be normal (Preacher & Hayes, 2008), so non-parametric bootstrapping has been recommended (MacKinnon et al., 2007). Other new approaches to mediation include structural mean models (Emsley, Dunn, & White, 2010), and principle stratification (Emsley et al., 2010; Gallop et al., 2009), but these are more complex, require more participants, and are currently less mainstream procedures. Mediation was tested in the current study using the bootstrapped cross product test (Preacher & Hayes, 2008). From the original dataset, 3000 identically sized datasets were created using random selection with replacement, and a cross product test was calculated in each sample. If the confidence intervals of the distribution of cross-products do not contain zero, the point estimate is significant at the level indicated.

The present set of mediation analyses examined post scores of believability, distress, or frequency of psychotic symptoms, as mediators of rehospitalization at 4 months post discharge, controlling for baseline values of all three self-report measures. In order to conduct such analyses across the two datasets, the present study proceeded on the assumption in the Reno dataset that if symptoms were totally denied at follow-up no change should be assumed in the reaction to symptoms where they are likely to occur. The assumption of no change in the absence of evidence of change is a common analytic tactic, but it also seems empirically reasonable in this case. Under-reporting of hallucinations is common due to stigma and negative treatment implications (Waters, 2010); rates of 33–50% underreporting of command hallucinations have been reported in the literature (e.g., Zisook, Byrd, Kuck, & Jeste, 1995). Furthermore, in the original Reno study, rehospitalization rates in the ACT condition were unchanged as compared to treatment as usual among those who denied symptoms, suggesting an absence of substantial psychological change.

Results

Hospitalization outcomes

Hospitalization outcomes were examined in several ways to ensure that they were reliable and similar in the two datasets.

Raw rates of hospitalization: ITT analysis. Neither of the original studies tested differences in the raw rates of rehospitalization between conditions, but their

combination provided additional power to examine the question. Participants who had committed suicide, died, or been jailed were counted as hospitalized ($n = 4$ of 120); those with missing data were assumed not to be hospitalized ($n = 7$ of 120; 3 in TAU, 4 in ACT). Twenty-six of the 61 TAU participants were hospitalized (42.6%) versus 14 of the 59 ACT participants (23.7%): a significant difference ($\chi^2(1) = 4.82, p < .03, d = .41$) and a 44.4% decrease in the rate of hospitalization for those receiving the ACT intervention.

Survival analysis. A full ITT Kaplan-Meier survival analysis was conducted on 4-month hospitalization outcomes on the combined dataset. Dates of deaths were treated as dates of hospitalization; missing data were imputed. Results showed a significant difference in survival rates between the two conditions (pooled Generalized Wilcoxon $\chi^2(1) = 5.10, p \leq .025, d = .42$). On average, ACT participants stayed out of the hospital for 104.2 days ($SE = 4.48$), whereas TAU participants stayed out of the hospital for 87.7 days ($SE = 5.56$).

Because the mediation analyses described below examined distress, believability, and frequency ratings as mediators of outcomes, the survival analysis was repeated using pre-scores of these ratings to ensure that outcome differences remained. Use of pre-treatment covariates helps increase the power of between-group comparisons by reducing variance within groups due to pre-existing subject characteristics (Miller & Chapman, 2001). This analysis was significant ($b = .748, SE = .369, Wald = 4.10, p = .043$); there was a nearly identical 133% and 132% increased hazard rate in the Reno and Philadelphia samples, respectively, in TAU as compared to ACT condition, as derived from the $\text{Exp}(b)$ values.

The use of the BPRS in the Philadelphia study enabled a more sophisticated control for psychopathology at baseline. A Cox regression analysis on hospitalization using the baseline BPRS thought disorder and affect subscales as covariates showed a significant effect for treatment condition ($b = 1.481, SE = .738, Wald = 4.033, p = .045, \text{Exp}(b) = 4.40$), with a 340% higher hazard rate for those in the enhanced TAU condition as compared to ACT participants.

Mediation

The mediation analysis entered baseline self-reports of distress, frequency, and believability as covariates, and the post score for believability was entered as the mediator of treatment condition on hospitalization outcomes. Because mediation is highly sensitive to covariance among measures, which is difficult to model precisely, experts recommend that mediation analyses be conducted on completers only (Kraemer, Wilson, Fairburn, & Agras, 2002). Thus, participants without available hospitalization data ($n = 11$ of 120) were not included in the mediation analysis; additional analyses with complete imputed datasets showed the same pattern of results as those reported here, however.

In the combined dataset, the difference between conditions in days to rehospitalization at 4 months post discharge was significantly mediated ($p < .01$) by the post scores of believability of psychotic symptoms (bootstrapped point estimate = 4.81; $SE = 2.16$; 99% $CI = .62, 11.79$). The significantly better impact of ACT on rehospitalization, $t(110) = 2.18; p < .032$, was no longer significant after adjusting for the mediator, $t(110) = 1.54; p > .12$ (proportion of effect mediated = 28.3%). This same analysis for the distress produced by positive symptoms and for the frequency of positive symptoms was not significant ($p > .10$).

In the Reno study believability ratings were taken at the 4-month follow-up, after outcomes were already different (Bach & Hayes, 2002), which violates the temporal order desired in mediation. Temporal order was not violated in the Philadelphia study, however, and thus a final mediation analysis was conducted separately on both datasets to see if the mediation pattern differed in the two datasets. It did not. The effect was significant at $p < .01$ in the Reno dataset and marginally significant ($p = .07$) in the smaller Philadelphia dataset. The magnitude of the meditational effect was highly similar in both (Reno bootstrapped point estimate = 4.37; $SE = 2.37$; 95% $CI = .33, 14.55$; proportion of effect mediated = 19.6%; Philadelphia bootstrapped point estimate = 5.04; $SE = 4.67$; 93% $CI = .02, 18.02$; proportion of effect mediated = 38.8%). This suggests that violation of temporal order was not responsible for the mediation effect.

Discussion

Based on a recent meta-analysis (Lynch, Laws, & McKenna, 2010) the combined sample examined in the present study represents one of the larger trials of CBT for psychosis. The present study confirms and extends previous findings that ACT reduced hospitalization and extends the finding (Gaudiano et al., 2010) that reduced symptom believability-mediated changes in the symptom distress to rehospitalization itself. The two datasets differed in investigators, the race and ethnicity of participants, and in the cultural and systemic features of a large Eastern urban area versus a smaller and more isolated Western city. Nevertheless, the strength and pattern of effects was virtually identical across the two studies.

Using conservative assumptions and a full ITT analysis, hospitalization rates were improved for ACT in the combined dataset regardless of the analytic method used: raw tests of hospitalization versus non-hospitalization, simple survival analysis, and forms of survival analyses that attempted to adjust for baseline levels of pathology. The mediation analysis provided evidence that decreased believability in the literal content of symptoms was functionally related to rehospitalization. This was true in both datasets and thus cannot be readily explained by a violation of temporal order. Reduced believability as a measure of cognitive defusion has successfully mediated ACT outcomes in other populations as well (e.g., Zettle, Rains, & Hayes, 2011).

There are other measures of ACT processes in psychosis that might be examined in the future such as the Voices Acceptance and Action Scale (Shawyer et al., 2007). Believability of thoughts as distinct from the occurrence of thoughts has been used to measure defusion since the first ACT study (Zettle & Hayes, 1986) but it should be noted that other CBT approaches to psychosis might also target symptom believability including metacognitive approaches (Lysaker, Glynn, Wilkniss, & Silverstein, 2010), and cognitive reappraisal methods (Kuipers et al., 2006). It is important to note, however, that the present protocols included none of the CBT methods commonly used to reduce conviction in a belief (e.g., evaluation of evidence for a belief or behavioral experiments to test them). Thus, whether the present meditational results would apply to other forms of CBT is not yet known.

The present study has limitations. Neither study measured treatment integrity. Other than hospitalization and the BPRS, the measures used in both studies were developed specifically for these studies and their validity has not been assessed. Believability measures were not taken in the Reno study if patients denied symptoms, and in Reno all self-report measures were collected at follow-up rather

than at post-treatment. The studies were diagnostically heterogeneous and lacked power to compare results across different disorders. All of these weaknesses need to be corrected in future research.

The present study provides incremental evidence that a very brief ACT intervention reduces hospitalization and does so through processes hypothesized to mediate ACT outcomes. Further investigation is warranted to replicate the present findings, to explore them in more extensive and integrative psychosocial packages, as well as to extend them to outcomes (e.g., well-being, independent living, treatment participation) key to the lives of those suffering from psychosis.

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