Citation for published version:

DOI:
10.1016/j.brat.2011.08.002

Publication date:
2011

Document Version
Peer reviewed version

Link to publication

NOTICE: this is the author's version of a work that was accepted for publication in Behaviour Research and Therapy. Changes resulting from the publishing process, such as peer review, editing, corrections, structural formatting, and other quality control mechanisms may not be reflected in this document. Changes may have been made to this work since it was submitted for publication. A definitive version was subsequently published in Behaviour Research and Therapy, vol 49, issue 11, 2011, DOI 10.1016/j.brat.2011.08.002

University of Bath

General rights
Copyright and moral rights for the publications made accessible in the public portal are retained by the authors and/or other copyright owners and it is a condition of accessing publications that users recognise and abide by the legal requirements associated with these rights.

Take down policy
If you believe that this document breaches copyright please contact us providing details, and we will remove access to the work immediately and investigate your claim.
Acceptance and Values-Based Action in Chronic Pain:
A Three Year Follow-up Analysis of Treatment Effectiveness and Process

Kevin E. Vowles¹,², Lance M. McCracken², & Jane Zhao O’Brien²,³

¹ Interdisciplinary Musculoskeletal Pain Assessment and Community Treatment Service
Haywood Hospital, Stoke-on-Trent PCT & Primary Care Sciences Research Centre, Keele University

² Bath Centre for Pain Services, Royal National Hospital for Rheumatic Diseases
NHS Foundation Trust & Centre for Pain Research, University of Bath

³ School of Psychology, University of Newcastle Upon Tyne

25 July 2011

Correspondence to: Kevin E. Vowles, Ph.D., Interdisciplinary Musculoskeletal Pain Assessment and Community Treatment (IMPACT) Service, Haywood Hospital, Burslem, Stoke-on-Trent ST2 8BY, United Kingdom, +44 (0)1782 673751 (phone), Kevin.Vowles@stokepct.nhs.uk (e-mail)
Abstract

Recent developments in CBT emphasize the promotion of psychological flexibility to improve daily functioning for people with a wide range of health conditions. In particular, one of these approaches, Acceptance and Commitment Therapy (ACT), has been studied for treatment of chronic pain. While trials have provided good support for treatment effectiveness through follow-ups of as long as seven months, the longer term impact is not known. The present study of 108 participants with chronic pain examined outcomes three years after treatment completion and included analyses of two key treatment processes, acceptance of pain and values-based action. Overall, results indicated significant improvements in emotional and physical functioning relative to the start of treatment, as well as good maintenance of treatment gains relative to an earlier follow-up assessment. Effect size statistics were generally medium or large. At the three year follow-up, 64.8% of patients had reliably improved in at least one key domain. Improvements in acceptance of pain and values-based action were associated with improvements in outcome measures. A “treatment responder” analysis, using variables collected at pre-treatment and shorter term follow-up, failed to identify any salient predictors of response. This study adds to the growing literature supporting the effectiveness of ACT for chronic pain and yields evidence for both statistical and clinical significance of improvements over a three-year period.

Keywords: Acceptance, Values, Chronic Pain, Contextual Cognitive-Behavioral Treatment; Acceptance and Commitment Therapy
Acceptance and Values Three Year Follow-up

Introduction

Cognitive Behavioral Therapy (CBT) has a significant record of success in the treatment of chronic pain (e.g., Hoffman, Papas, Chatkoff, & Kerns, 2007; Morley, Eccleston, & Williams, 1999). Nevertheless there are calls to improve upon the current standard treatments, such as by focusing greater attention on therapeutic processes, by selecting processes and methods known to produce improvements, and by considering treatment integrity (Eccleston, Morley, & Williams, 2009). There are approaches within CBT that are attempting to meet these challenges. Some of these are referred to as contextual forms of CBT and include Acceptance and Commitment Therapy (ACT; Hayes, Strosahl, & Wilson, 1999).

Currently there are at least eleven trials that provide evidence for the efficacy or effectiveness of ACT for chronic pain (see Vowles & Thompson, 2011 for a review). The majority of these studies include follow-up assessment, the longest of which has been a seven month interval (Wicksell, Ahlqvist, Bring, Melin, & Olsson, 2008). These follow-up assessments suggest good maintenance of treatment effects achieved in ACT. The longer term effects of treatment, however, are not yet known. This issue is of particular relevance in chronic pain, where pain intensity, as well as other symptoms, are likely to persist after treatment, and there is a need for consistent engagement in new patterns of behavior over the long term, patterns that may be in some ways unnatural given the persistence of pain.

The purpose of the present study was to extend the results from previous studies of ACT for chronic pain by examining outcomes in a cohort of patients three years after treatment completion. Outcomes through a three-month follow-up for these patients were previously reported by Vowles & McCracken (2008). Three specific objectives were identified for the longer term outcome data presented here. The first was to perform a rigorous analysis of longer term treatment outcomes, including significance testing, calculation of treatment effect sizes, and analyses of reliable change on key measures of functioning (Jacobson, Roberts, Berns, & McGlinchey, 1999). The second objective was to investigate how changes in treatment process
variables, in this case acceptance of pain and values-based action, related to changes in
treatment outcomes through the three year follow-up. Finally, we sought to perform an analysis
of three-year “treatment responders”. Specifically, pre-treatment and treatment response
variables were examined to determine if they could reliably predict who had maintained
treatment benefits at the three year follow-up.

Method

All patients who had completed treatment between January 2005 and August 2006 were
contacted three years following the end of treatment and asked to complete a questionnaire
pack assessing physical and psychosocial functioning in relation to pain. In order to maximize
response rates, a £10.00 gift card was included with the original mailing, patients were
contacted by telephone on the day the questionnaires were sent out, and a reminder telephone
call and letter were sent two and four weeks, respectively, after initial invitation was sent out.
The study was approved by the local ethics board.

Participants

In total, there were 171 individuals who had completed treatment during the selected
study period. There was a small proportion of these who were not contactable, either because
they were deceased (n = 3) or had moved house and no address was traceable through the
National Health Service database or through the Post Office (n = 2). Of the remaining 166
patients, 108 completed the questionnaires, yielding an overall response rate of 65.1% of
patients who were contactable.

The majority of individuals who provided three year follow-up data were female (62.0%),
White European (96.3%), and married or co-habitating (72.8%; divorced: 13.2%; single: 10.4;
widowed: 3.8%). Demographic and pain characteristics were collected at treatment onset. At
this initial point of contact, participants were on average 47.1 years of age (SD = 10.7) and had
13.2 years of formal education (SD = 2.8). Most were unemployed (70.4%) and receiving some
type of disability or wage replacement (72.0%). Median pain duration was 96 months (range: 13
to 360). The most frequently identified site of pain was low back (46.3%), followed by shoulder/arms (18.6%), full body (15.8%), legs/pelvic region (9.2%), neck (3.7%), mid-back (3.7%), and other (e.g., head, abdominal; 2.7%). Most patients also identified one or more additional pain sites (57.4%).

Measures

The questionnaire set completed at the three year follow-up was essentially identical to the sets completed at treatment onset, conclusion, and three month follow-up. A brief background inventory asked patients to report on usual pain intensity over the past week using a 0 (none) to 10 (worst imaginable) numeric rating scale, work status, and the number of pain-related medical appointments that had occurred in the preceding six months, including primary care, specialist, and emergency department visits.

Missing responses were rare and occurred for less than 5% of items across all assessment points. For completion of all measures through the three month follow-up, a research assistant was available to assist patients with questionnaires and ensure completed responses. Rates of missing responses were similar for the three year follow-up data in comparison to for data collected at other time periods.

Chronic Pain Acceptance Questionnaire (CPAQ)

Acceptance of pain was assessed using the 20-item CPAQ (McCracken, Vowles, & Eccleston, 2004). A total score and two subscale scores can be calculated. The first subscale, Activity Engagement, assesses the degree to which effective functioning occurs in a way that is not markedly restricted by pain and the second, Pain Willingness, assesses the extent to which respondents are willing to have pain without engaging in attempts to control it. The total score was used within most analyses in the present study; scores range from 0-120. The total and subscale scores of the CPAQ have demonstrated psychometric properties and the factor structure has been supported via confirmatory factor analysis (McCracken et al., 2004;
Reneman, Kijkstra, Geertzen, & Kijkstra, 2010; Vowles, McCracken, McLeod, & Eccleston, 2008; Wicksell, Olsson, & Melin, 2009).

*Chronic Pain Values Inventory (CPVI)*

The ACT model places particular importance on values-based action as a focus of treatment. Values are directions or qualities of action in domains of functioning. They are personally important and, when values-based actions are engaged in, they bring meaning and vitality to daily functioning. The CPVI (McCracken & Yang, 2006) measures values in six domains, including family, intimate/close interpersonal relationships, friends, work, and growth or learning. The importance of values held in each domain and success in following them are assessed on 0 (not at all important/successful) to 5 (extremely important/successful) scales. Three scores can be calculated: average importance; average success; and average discrepancy between importance and success. To date, the values success score has been most widely used in research as a reflection of values-based action, and there is evidence that greater success scores are associated with better concurrent and future functioning (McCracken & Yang, 2006; McCracken & Vowles, 2008) and greater levels of improvement following treatment (Vowles & McCracken, 2008). Within the present study, we report on all three CPVI scores.

*British Columbia Major Depression Inventory (BCMDI)*

The BCMDI (Iverson & Remick, 2004) is a 20 item measure of depression modeled after the Diagnostic and Statistical Manual of Mental Disorders criteria for Major Depressive Disorder (4th ed.; American Psychiatric Association, 1994). The first 16 items assess symptom severity and each symptom present is rated on a zero (symptom is absent) to five (very severe symptom) scale. The final four items evaluate the impact of symptoms on areas of work/school, family, and social activities. The symptom score was used in the present study; scores range from 0-80. Good evidence of psychometric properties has been demonstrated, as has good
sensitivity and specificity for a diagnosis of Major Depressive Disorder (Iverson & Remick, 2004).

Pain Anxiety Symptoms Scale-20 (PASS)

The total score of the 20-item PASS (McCracken & Dhingra, 2002) was used as a measure of pain-related fear and avoidance. The PASS has demonstrated a stable factor structure and good psychometric properties (McCracken & Dhingra, 2002; Roelofs et al., 2004), as well as strong correlations with the original 40-item PASS (McCracken, Zayfert, & Gross, 1992). Scores range from 0-100.

Sickness Impact Profile (SIP)

The SIP (Bergner, Bobbitt, Carter, & Gilson, 1981) is a 136-item measure of the effects of health on daily functioning. The measure includes twelve subscales that are combined to form a total score and three composite scores: physical disability, psychosocial disability, and “other” disability; scores range from 0-1. The SIP has been widely used in health care settings (Battié & May, 2001). The present analyses used the total score, physical and psychosocial disability composite scores, and the work disability subscale score.

Treatment Program

McCracken (2005) and Hayes et al. (1999) provide detailed information on the theoretical and practical aspects of the treatment model and methods. The treatment attended by patients was a form of ACT specifically designed for use with chronic pain patients being treated by an interdisciplinary team consisting of clinical psychology, physical therapy, occupational therapy, nursing, and medicine. Patients were treated on a three or four week course of treatment. While in treatment, patients lived independently in apartments adjacent to the hospital. Treatment sessions were provided five days per week for 6.5 hours daily. Each day included approximately 2.25 hours of physical conditioning, one hour of psychological methods, 30 minutes of mindfulness training, and the remaining time was devoted to skills training or health/medical education. Treatment was primarily provided in a group format, although
individual sessions were also delivered approximately once per week. The fidelity of the treatment was maintained by appropriately designed treatment guides, supervision, three hours of clinical team meetings per week, and a once weekly hour long clinical seminar.

**Analyses**

In addition to the primary assessment points of pre-treatment and three-year follow-up, a number of analyses included outcomes at a three month follow-up appointment. Three month follow-up data were available for 81 (75%) of the individuals who had provided three year follow-up data. While our earlier report on this cohort (Vowles & McCracken, 2008) detailed these three month outcomes, we felt that their inclusion within the present report allowed for comparisons at the different follow-up intervals and an examination of whether treatment gains had been maintained.

Initially, a series of Analyses of Variance (ANOVAs) were performed to examine potential differences between participants who provided three year follow-up data and those who did not. These analyses were performed using both pre-treatment and three month follow-up data.

Second, treatment outcomes across the pre-treatment, three month follow-up, and three year follow-up were assessed. Repeated measures ANOVAs were used for all variables with the exception of the work status variable for which a Wilcoxon signed ranks test was performed. Pairwise comparisons for the ANOVA’s used a Bonferroni-corrected alpha of .004.

Given the number of nonresponders at the three year follow-up, a second set of ANOVA’s was also performed on the pre-treatment to three year follow-up data using an Intent-to-Treat analysis. In this analysis, baseline scores were carried forward and used to replace missing three year follow-up data. While there are limitations to this approach to missing data (e.g., Beunckens, Molenberghs, & Kenward, 2005; Streiner, 2008), we felt it appropriately conservative to assume that all individuals who had not provided three year data were
continuing to function at baseline levels and that treatment was essentially ineffective at changing measures of outcome.

Third, within-subjects effect sizes (Cohen’s $d$), corrected for correlated data, were calculated using the formula of Dunlap et al. (1996).\(^1\) Confidence intervals (95%) for each effect size were also calculated using Becker’s (1998) formula to determine the standard error for repeated measures analyses. Supplementary Table S1 displays all formulae used (see also Nakagawa & Cuthill, 2007). Cohen (1988) suggested that effect sizes be interpreted as small when above 0.2, medium when above 0.5, and large when above 0.8. Absolute values are reported for all effect sizes such that greater values are associated with better treatment outcomes.

Fourth, we calculated reliable change between pre-treatment and both follow-up periods using the reliable change formulae of Jacobson and colleagues (1999). Reliable change is one aspect of clinical significance that identifies the amount of change required on a specific measure to exceed change that could be accounted for by measurement error. It uses temporal stability data for the measures (i.e., test-retest reliability) and $SD$’s at each time point to determine a standard error of the difference between assessment points. Using this value, a change score can be determined. If the change score of a particular patient exceeds the cut-score, then that patient’s score can be classified as reliably changed. Jacobson et al. (1999) describe the formulae used in detail. Consistent with previous analyses of this cohort of patients, reliable change analyses for three outcomes were performed including depression (BCMDI), disability (SIP), and pain-related anxiety and avoidance (PASS). These domains have been recommended as core outcomes by recent consensus panels (e.g. Dworkin et al., 2005).

Fifth, we examined how changes in two process measures, values-based action and acceptance of pain, related to changes in outcomes from pre-treatment through the three year follow-up. Residualized change scores for all measures were initially computed and correlations among process and outcome measures examined. Next, multiple regression analyses were
conducted to determine the amount of variance in residualized change in outcomes accounted for by residualized change in acceptance and values-based action, when considered together. Relevant background variables, including age, gender, education, and pain duration, were also tested for entry in the regressions.

A final set of analyses examined whether particular patient characteristics or patterns of treatment response could reliably predict treatment response at the three year follow-up. Using the three year follow-up reliable change data, participants were coded as either improved in at least one measure or not. Then two stepwise discriminant analyses were performed to determine if there were differences in pre-treatment or treatment response data among these two groups. The first included pre-treatment variables, including demographic information and questionnaire scores at treatment onset. The second included residualized changes in functioning from pre-treatment through three month follow-up.²

Results

Preliminary Analyses

There were only two differences between those who provided three year follow-up data and those who did not. Specifically, compared to those who did not provide data at the three-month follow-up appointment, those who did provide data reported lower levels of physical disability, $M = 0.09$ ($SD = 0.09$) and $M = 0.15$ ($SD = 0.13$), $F(1, 107) = 11.24$, $p < .001$, and psychosocial disability $M = 0.15$ ($SD = 0.14$) and $M = 0.22$ ($SD = 0.19$), $F(1, 107) = 5.35$, $p < .02$. There were no other differences indicated at either of the assessment points, including age, gender, marital status, work status, pain duration, pain intensity, pain-related surgeries, pain-related medical visits over the preceding six months, or any of the self-report measures.

Significance Testing

All descriptive information is displayed in Table 1. For the pre-treatment to three month follow-up interval, significant improvement was indicated across all measures, all $F$s $> 21.89$, all $p$'s $< .001$. For the pre-treatment to three year follow-up interval, significant improvements were
indicated across all measures with the exception of usual pain intensity, for which change was non-significant, $F(1, 107) = 5.52, p = .021$. All other $F$'s $\geq 8.29$, all other $p$'s $\leq .004$. Finally, for the interval between the three month and three year follow-up assessments, there was evidence of a significant decrease in two measures only, values-based action, $F(1, 71) = 13.65, p < .001$, and physical disability, $F(1, 80) = 24.53, p < .001$.

As noted, for the 58 individuals who did not respond, we replaced missing three-year data with pre-treatment scores for each individual, essentially assuming that these individuals had failed to derive benefit from treatment. We then performed a second set of repeated measures ANOVA’s integrating these replaced data. Again, a Bonferroni-controlled alpha of $p = .004$ was used. The results were almost identical to the ANOVA’s using complete cases only. Specifically, with one exception, significant improvements matched the results from the complete cases ANOVA’s, all $F$’s $> 21.33$, all $p$’s $< .001$. The sole exception was for the CPVI Values Success subscale, where the alpha fell just short of our required Bonferroni-controlled alpha, $F(1, 165) = 8.30, p = .005$. Change in usual pain intensity remained non-significant, $F(1, 165) = 5.63, p = .019$. The results of these analyses are displayed in Supplementary Table S2.

For work status, the Wilcoxin Signed Ranks Test of change from pre-treatment to three year follow-up was non-significant, $z = .13, p = .18$. In the three years from treatment onset to follow-up, 17 individuals had returned to work, 11 had discontinued work, and the work status of the remaining individuals was unchanged. Descriptively, 29.6% of patients were working at pretreatment and 36.4% were working at three year follow-up. For those who were working at three-year follow-up, a repeated measures ANOVA was performed using the work disability subscale of the SIP. The results of this analysis indicated that disability for work significantly decreased from 0.36 ($SD = 0.26$) to 0.12 ($SD = 0.15$), $F(1, 38) = 21.63, p < .001$. 
Effect Size Calculations

Effect sizes and 95% confidence intervals for all measures are displayed in Figure 1. The average effect size for the pre-treatment to three-month follow-up period was 0.76 (range: 0.42 for pain intensity to 1.28 for acceptance of pain). Using the guidelines of Cohen (1988) with regard to effect size interpretation, effect sizes were large for acceptance of pain, depression, and pain-related anxiety, small for pain intensity, and medium for all other variables.

The average effect size in the pre-treatment to three-year follow-up period was 0.57 (range: 0.28 for pain intensity to 0.85 for acceptance). Effect size was large for acceptance, medium for values discrepancy, depression, pain-related anxiety, psychosocial disability, and medical visits, and small for values success, pain intensity, and physical disability.

Reliable Change Analyses

The results of the reliable change analyses at the 90% confidence interval for depression, pain-related anxiety, and disability are displayed in Table 2. In our previous report (Vowles & McCracken, 2008), we performed reliable change analyses using the total score of the SIP as we were unable to find individual test-retest data for the physical and psychosocial disability subscales. Given the divergence of SIP subscale scores observed in our analyses, with physical disability scores significantly worsening relative to three month follow-up while psychosocial disability scores did not, we felt it appropriate to perform separate reliable change analyses for the subscales using the test-retest estimate for the total score.

Rates of reliable improvement were similar across all measures, averaging 46.2% (range: 45.0% – 46.9%) at the three month follow-up and 35.8% (range: 29.1% - 38.0%) at three year follow-up. When cases were evaluated on an individual basis, at the three month follow-up, 81.4% (n = 66) had reliably improved since treatment onset on one or more measure, 53.1% (n = 43) on two or more, 33.3% (n = 27) on three or more, and 11.1% (n = 9) on all four. At the three year follow-up, 64.8% (n = 70) had improved on one or more measure, 36.1% (n = 39) on two or more, 19.4% (n = 21) on three or more, and 9.3% (n = 10) on all four.
At three months, reliable decline occurred only for the Psychosocial Disability subscale of the SIP and only for 1.2% of individuals. At three years, rates of reliable decline averaged 5.9% across the four measures (range: 4.7% to 6.9%). Individually, 13.0% (n = 14) had reliably declined since treatment onset on one or more measure, 4.6% (n = 5) on two or more, 2.8% (n = 3) on three or more, and 0.9% (n = 1) on all four.

_Treatment Process Analyses_

Correlations among residualized change scores for acceptance and values-based action with residualized change scores in outcome measures are displayed in Table 3. These changes in the two treatment process measures were significantly correlated with changes in all except one measure of outcome, \( r \) range = 0.32, \( p < .005 \), to -0.75, \( p < .001 \). The sole exception was change in values-based action and change in pain-related medical visits, \( r = -.13, p = .20 \). Changes in acceptance and values-based action was also significantly correlated, \( r = 0.71, p < .001 \).

Multiple regressions were then performed for all outcome variables except pain intensity as there was no evidence of significant improvement at the three-year follow-up on that measure. Estimates of variance (\( \Delta r^2 \)) and standardized regression coefficients (\( \beta \)) are displayed in Table 4.

Initially, demographic factors, including age, gender, education, and pain duration were statistically tested for entry. These variables did not enter as significant predictors in any of the equations.

When residualized changes in acceptance and values-based action were entered simultaneously, they accounted for significant variance in each of the five equations (range \( \Delta r^2 \) = .11 to .61, average = .37). Significant regression coefficients were achieved across all equations as well. The coefficient for change in acceptance was significant in four of five equations, including change in depression, pain-related anxiety, physical disability, and medical
visits. The coefficient for change in values-based action was significant in three of five equations, including depression, pain-related anxiety, and psychosocial disability.

Identification of Potential Predictors of Treatment Response

Two discriminant analyses were performed to determine if characteristics of treatment responders could be identified. As noted, treatment “response” was defined as having reliably improved in depression, pain-related anxiety, physical disability, or psychosocial disability at the three year follow-up. All variables were tested for entry in a statistical fashion.

The first analysis examined pre-treatment characteristics of patients, including demographic factors (i.e., gender, age, education, pain duration), and measures of treatment process (i.e., acceptance and values-based action) and outcome (i.e., pain intensity, depression, pain-related anxiety, physical and psychosocial disability, and medical visits). A significant discriminant function was not identified as none of the included variables was able to reliably discriminate between those who had reliably changed and those who had not.

The second analysis examined residualized change through three month follow-up and included residualized change in process and outcome measures as predictor variables. Only residualized change in psychosocial disability emerged as a significant predictor of treatment response, Wilks’ $\lambda = 0.88$, $F (1, 55) = 7.51$, $p = .008$. The ability of residualized change in this variable to reliably classify individuals was modest however, 65.4%, which is only marginally greater than chance. In particular, the function was poor at accurately classifying those who had not reliably changed, 35.3%, although it was better in the classification of those who had, 70.5%.

Discussion

The primary purpose of the present analyses was to determine longer term outcomes in a sample of individuals with chronic pain following a programme of interdisciplinary ACT. In brief, the results indicate that the functioning of patients was substantially improved three years following treatment completion relative to the start of treatment and that there was good
maintenance of gains relative to a follow-up conducted three months after treatment completion. To our knowledge, this study is the first to report long term outcomes of ACT for chronic pain. These data provide additional supportive evidence for the treatment approach as applied to chronic pain and for the overall theoretical and clinical model.

In addition to evidence regarding the statistically significant improvements achieved following treatment, we believe that there is a reasonable argument to be made for the clinical significance of the results, particularly given the complexity of the problems with pain experienced by this patient group. Effect sizes for outcome measures were medium at the three year follow-up for the majority of measures, including depression, pain-related anxiety, psychosocial disability, and pain-related healthcare visits, while they were small for physical disability. Further, the intent to treat analysis indicated significant change across all measures of outcome and all but one measure of treatment process. In brief, these analyses indicate that even when a “worst case” analysis was performed, assuming no improvement for those with missing data, there was still evidence of significant change across most measures.

The effect size for reduction in pain was of a small size. Given that pain reduction is not an intended goal of the ACT-based treatment studied here, the lack of long-term pain reduction is not particularly surprising. One could interpret the improvements in pain intensity that have resulted from ACT for pain (e.g., Vowles & McCracken, 2008) as reflecting a reduction in pain-related distress and interference with functioning, rather than a reduction in pain sensations per se. Regardless of the accuracy of this perspective, the present data support the contention that effective functioning is possible in a context of continuing pain.

The results of the reliable change analyses indicate that almost two-thirds of treatment completers experienced a reliable improvement in depression, pain-related anxiety, psychosocial disability, or physical disability three years following treatment, while just over one-third experienced a reliable improvement in two of these measures. A simple algebraic calculation of the proportion reliably improved relative to number needed to treat to see reliable
improvement in one individual would suggest that 1.5 individuals would need to be treated to see reliable improvement in one individual on at least one measure (i.e., 0.648/1.00 = 1/x) and 2.8 individuals would need to be treated to see reliable improvement in one individual on at least two measures (i.e., 0.361/1.00 = 1/x). Using the same calculation with regard to reliable decline, 7.7 individuals would need to be treated to see reliable decline in at least one measure (i.e., 0.130/1.00 = 1/x) and 21.7 to see reliable decline in at least two measures (i.e., 0.046/1.00 = 1/x). Given the initial complexity of the pain experience and significant amount of time that had passed since treatment completion, the fact that so many individuals had reliably improved, while only a minority had reliably worsened, provides added support for the durability of improvement following the treatment that was provided.

Furthermore, as previously described (Vowles & McCracken, 2008), the calculation of reliable change is one of two components of the clinically significant change approach proposed by Jacobson and colleagues (1999). The second component involves a determination of whether scores for each individual case move from a “clinical” to a “recovered” distribution and ideally this requires normative data from the latter distribution, which to our knowledge is not available for chronic pain. While there are other methods that have been used to determine this second aspect of clinically significant change (e.g., a shift of 2 or more standard deviations; Jacobson et al., 1999), we would argue that these are not particularly appropriate for chronic conditions where “recovery” is not synonymous with an absence of symptoms as can be the observed in conditions where symptom remission is possible (e.g., major depressive disorder; see Jacobson et al. for an example). Therefore, it seems necessary for the field to collect data from a larger sample of “recovered” individuals with chronic pain in order to provide a more robust and appropriate normative sample. Until such time as a large sample can be collected, we suggest that the present data can serve as at least a preliminary sample of such individuals, meaning that, on the whole, the three year responders appear to be functioning effectively within a context of continuing pain and could reasonably be considered as recovered.
There were two variables for which there was seemingly a loss of treatment effect, as a
significant worsening of scores was observed between the three month and three year follow-up
assessments even though both remained improved relative to treatment onset. An extended
discussion for both variables seems warranted.

For physical disability, just under half of the improvements were lost at the three-year
follow-up in comparison to improvements seen at the three month follow-up. While this
decrease in treatment effect is obviously substantial, when one evaluates it in relation to the
maintenance of treatment gains across all other measures of outcome, the magnitude of the
decline in physical disability seems inconsistent. If gains in physical disability were lost within a
context of worsening scores in all other measures of outcome, then perhaps there would be a
stronger case against long-term benefit of the treatment overall. This specific loss of some
improvements in physical disability clearly is not uniform in the sample but rather happens to a
greater degree is some people compared to others. It could be useful to further explore the
roots of this reduction in physical functioning in some of these individuals.

The second variable for which there was evidence for a loss of treatment effect was for
values-based action. Given the prominence of the focus on values clarity and values-based
action within the ACT treatment model, this could point to a weakness in the methods being
used. It is curious, however, that values success decreases between the two follow-up periods,
while the discrepancy between values importance and values success does not. The
interpretation of these two seemingly divergent results is obviously complex, although it can be
explained at a statistical level by the reduction in values importance scores between pre-
treatment and the three year follow-up. One possibility is that values-related methods are more
vulnerable to a loss of effect and are more likely to need some type of reinforcement during
follow-up intervals.

Results of treatment process analyses are similar to those from previous studies
(McCracken, Vowles, & Eccleston, 2005; Vowles, McCracken, & Eccleston, 2007; Vowles &
McCracken, 2008) in that changes in pain acceptance and values-based action through the three year follow-up accounted for significant variance in changes in overall functioning over the same interval. In some of these analyses, the percentage of variance that was accounted for is substantial. For example, improvements in these two measures accounted for 53% of the variance in improvements in depression, 61% of the variance in improvements for pain-related anxiety, and 37% of the variance in improvements in psychosocial disability, in addition to the lesser amounts of the variance accounted for in improvements in physical disability and reductions in pain-related healthcare visits, 22% and 11%, respectively. The larger magnitudes here are substantial and provide additional support for this process-oriented treatment provided, in that two of the key treatment processes targeted are strongly related to overall levels of improvement.

It is worth noting that the regression analyses do not allow any conclusions regarding causality. Instead, they only allow us to draw conclusions with regard to patterns of change across variables; in this case, change in our process variables accounted for significant change in our outcome measures. True tests of causality in research such as this are difficult to carry out. As an alternative, researchers often look for a pattern of findings across different studies and different approaches to help bolster the strength with which causal conclusions can be drawn. At the present time, there is relatively broad support for the relevance of the processes studied here on patient outcomes. In particular, there are data available which parallel these findings in measures of chronic pain “coping” behaviors (McCracken & Vowles, 2007; Vowles & McCracken, 2010) and experimental settings with chronic pain patients (Vowles et al., 2007).

Further, there is now evidence that these processes have a mediating effect on chronic pain treatment outcomes (Wicksell, Olsson, & Hayes, 2010). Regardless, continued work in this area is a priority to allow a more clear understanding of active treatment processes, as well as how these processes serve to influence treatment outcomes.
In the discriminant analyses examining whether pre-treatment or change through three-month follow-up data could be used to reliably predict treatment response, only a single variable emerged as a significant predictor and its value was marginal overall and fairly poor at predicting an absence of reliable change. One the one hand, these results simply add to a larger pool of analyses that have generally failed to find reliable predictors of treatment response (e.g., see the review of McCracken & Turk, 2002). It is interesting that changes in our processes measures were related to changes in outcome within the regression analyses, but changes in these same variables were not able to predict the frequency of reliable change. This lack of prediction could be due to a number of factors, including the long interval between follow-up and the last clinical contact (2.75 years), differences in the statistical methodologies used in the regression and discriminant analyses, or perhaps the difficulty inherent in measuring complex human behavior using a self-report questionnaire. It is also possible that further refinement is needed in our definition and measurement of hypothesized “active” treatment processes in order to derive more accurate predictive models of longer term functioning with chronic pain. On the other hand, it may be that these results suggest that ACT for chronic pain may be of use to patients presenting with a variety of demographic, psychosocial, and physical characteristics. Obviously, this conclusion cannot be drawn with certainty and further data are needed.

There are limitations to acknowledge. First, the overall response rate was a relatively modest 65.1%, although it fell only slightly short of the 70% cut point recommended by Peat et al. (2001) following a UK national survey of interdisciplinary pain programmes and the follow-up period used here was considerably longer than the survey period of less than one year used by Peat and colleagues to identify that cut-point. The severity of this limitation is perhaps diminished by the last observation carried forward algorithm that we used for missing data; nonetheless, it may be that the overall pattern of results would have been different if response rates had been higher.
Second, there was no control group used. While this does mean that we are not able to draw any firm conclusions with regard to longer term functioning in the absence of treatment, the magnitude of this limitation is attenuated to some extent by a number of considerations. For example, these patients had complex, disabling, and longstanding pain at treatment onset and were, on the whole, functioning much better three years following treatment conclusion across multiple domains of functioning, a pattern of results that would seem highly unlikely in the absence of some type of treatment effect. Furthermore, the treatment provided took place within an existing clinical service, as opposed to being part of a tightly controlled clinical trial, and therefore included a broad mix of relatively unselected patients suffering significantly as a result of pain.

Finally, assessment measures were entirely self-report and it may be that method variance accounted for some proportion of the pattern of findings. The collection of measures of observed physical, vocational, or social functioning would have provided a potentially fuller understanding of longer-term functioning.

The effectiveness of ACT for chronic pain is increasingly well-established. It has recently been added as an intervention with modest support to the empirically supported treatment list maintained by the American Psychological Association’s Division of Clinical Psychology (see http://www.div12.org/PsychologicalTreatments/disorders/pain_general.php). Interest and empirical work in this area has advanced fairly rapidly since the first published study in this area (McCracken, 1998) and the first published trial (Dahl, Wilson, & Nilsson, 2004). It now seems reasonable to conclude that individuals with chronic pain can approach their pain, and the suffering naturally occasioned by it, in a manner that more flexibly entails willingness to have pain, openness to experience, clarity in values, and with an allegiance between behavior and these values. Further, it seems that responding to pain in this way is related to improvements in functioning not only over the months immediately following treatment, but over the longer term as well.
Footnotes

1 While the calculation of effect size used here differs from our previous report (Vowles & McCracken, 2008), controlling for correlated data appears the more conservative estimate and was therefore used.

2 We also performed a discriminant analyses using residualized change in process and outcome data from pre to post-treatment in this cohort. As post-treatment data are not detailed within this report and a significant discriminant function was not identified using these data, these results are not reported here.
References


Wicksell, R. K., Olsson, G. L., & Hayes, S. C. (2010). Psychological flexibility as a mediator...
Acknowledgements

The authors have no conflicts of interest to declare.
Figure Caption

Within-subjects effect size statistics (Cohen’s $d$), controlled for within participant correlations, with 95% Confidence Intervals. Vertical reference lines in the figure represent small (0.2), medium (0.5), and large (0.8) effect sizes.