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## A systematic review of randomized controlled trials of Acceptance and Commitment Therapy for adults with chronic pain: Outcome domains, design quality, and efficacy



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#### ABSTRACT

Acceptance and Commitment Therapy (ACT) is a form of Cognitive Behavioral Therapy that includes a specific therapeutic process, "psychological flexibility," and focuses on behavior change rather than symptom reduction. One relatively well-developed research area includes ACT applied to chronic pain. The current systematic review examines outcome domains included as primary, secondary and process variables in controlled trials of ACT-based pain treatment studies, and also summarizes evidence for efficacy. The review of outcome domains is to establish whether these are in-line with recommendations, consistent with the theory underlying ACT, and optimal for further development. A systematic search identified 1034 articles and ten studies were selected as eligible for review. Overall, 15 outcome domains were assessed using 39 different measurement tools across the ten RCTs. The outcome domains assessed in the reviewed trials were, to an extent, in-line with recognized guidelines. Six of the ten studies identified primary and secondary outcomes; one included just one outcome and three did not categorize outcomes. All ten trials included a measure of some aspect of psychological flexibility; however these were not always formally identified as process variables. Pain and emotional functioning were the most frequently measured outcome domains. A review of outcome results suggests that ACT is efficacious particularly for enhancing general, mostly physical functioning, and for decreasing distress, in comparison to inactive treatment comparisons. It is recommended that future RCTs (a) formally define outcomes as primary, secondary and process variables, (b) consider including measures of physical or social functioning, rather than pain and emotional functioning, as primary outcomes, (c) address existing risks of bias, such as reporting bias, and (d) include more components of psychological flexibility, such as cognitive defusion and self-related variables.

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#### 1. Introduction

Chronic pain is a major problem with estimated prevalence rates around 10–30% of the adult population (Reid et al., 2011). Chronic pain can have serious implications for patients' general health, everyday functioning, and quality of life, and incurs significant economic impacts, in healthcare use and time off from work (Reid et al., 2011). Medical treatments, including the use of analgesics, surgical interventions, spinal cord stimulators and implantable drug delivery systems have limited success in reducing chronic pain, and some can be costly (Turk & Burwinkle, 2005). On the other hand psychological interventions can have beneficial effects for people with chronic pain, particularly on their daily functioning and health related quality of life (Hoffman, Papas, Chatkoff, & Kerns, 2007).

Acceptance and Commitment Therapy (ACT; Hayes, Strosahl, & Wilson, 1999) is a rapidly developing psychological treatment approach applicable to a wide range of physical and mental health issues, including chronic pain (McCracken & Morley, 2014; McCracken & Vowles, 2014). The psychological model on which ACT is based is called the psychological flexibility model (Hayes, Luoma, Bond, Masuda, & Lillis, 2006; McCracken & Morley, 2014; McCracken & Vowles, 2014). There are six core processes involved in psychological flexibility: acceptance, cognitive defusion, present-focused attention, self-as-context, values, and committed action. These can also be summarized as openness, awareness, and engagement (Hayes, Villatte, Levin, & Hildebrandt, 2011). ACT is different from traditional CBT because, rather than focusing on change in the content of patients' maladaptive thoughts and beliefs, ACT uses predominantly acceptance, mindfulness, and activation methods, to change their impact. Hence, the strategic focus within ACT in pain management is not to reduce patients' pain, negative automatic thoughts, or uncomfortable emotions, but to improve daily functioning by building more successful patterns of behavioral performance (outcome) explicitly through enhanced psychological flexibility (process).

Previous systematic reviews have provided support for the efficacy and effectiveness of ACT across a range of conditions and via different methods of delivery, including group therapy and self-help (Cavanagh, Strauss, Forder, & Jones, 2014; Ost, 2008; Powers, Zum Vörde Sive Vörding, & Emmelkamp, 2009; Ruiz, 2010, 2012). Whilst there has been some dispute over whether ACT is more effective than other active treatments, it has been suggested that further RCTs making such comparisons would be needed (Levin & Hayes, 2009; Powers & Emmelkamp, 2009). In the area of pain, a systematic review by Veehof, Oskam, Schreurs, and Bohlmeijer's (2011) that included acceptance-based treatments found moderate within group effect sizes for pain, depression, anxiety, physical well-being and quality of life. Analyses of controlled trials within this review revealed significant small to medium effects for the reduction of pain and depression compared to control groups. At some point an updated systematic review and meta-analysis on the efficacy of ACT for chronic pain will be needed. In the meantime there are other questions to review.

There are now widely disseminated guidelines for measuring outcomes in chronic pain treatment trials that emerge from what is

called the Initiative on Methods, Measurement, and Pain Assessment in Clinical trials (IMMPACT; Turk et al., 2003). This initiative is meant to aid comparison and pooling of data, to encourage a more complete assessment of outcomes, and support clinicians in making more informed choices of treatment, based on a clearer view of risks and benefits. The IMMPACT recommendations for core outcome domains that should be *considered* when evaluating treatments for pain include pain, physical functioning, emotional functioning, patient rating of global improvement, adverse events and participant disposition (such as premature withdrawal) (Turk et al., 2003). Potential supplemental outcomes domains include role and interpersonal functioning, healthcare utilization and coping. These guidelines are not meant to be rigid but are meant to allow customizing based on the particular needs of the trial

Once again the philosophy and theory underling ACT are clear on outcomes and process and these include differences from IMMPACT. In ACT pain and emotional functioning (certainly in the form of mood symptoms) would not be regarded as core or primary outcome domains. On the other hand, physical functioning and social or role performance would be primary, particularly when these aspects are attuned to patient values and goals. Secondary outcomes for ACT certainly can include pain, emotional functioning, and healthcare utilization. Whether ratings of global improvement are pertinent would lie with how this item is understood, as a reflection of symptoms or functioning. Finally, processes of change within ACT trials ought to include measures of psychological flexibility in order to assess whether treatment is working as the theory suggests. "Coping" as identified in IMMPACT might be too loosely conceived to necessarily address the specific therapeutic focus within ACT. Just as with the wider world of chronic pain treatment trials, the choices made in ACT trials are important so that data can be compared and synthesized. It is also important that outcomes are broad and inclusive enough to inform treatment choices, and to test and develop underlying theraneutic models.

The purpose of the current study is to systematically review assessment approaches used in randomized controlled trials (RCTs) of ACT for chronic pain in adults. The specific objectives are to (a) identify the outcome domains assessed, including those defined as primary and secondary, (b) determine the degree to which these domains reflect IMMPACT versus the model underlying ACT, (c) examine current approaches to treatment process assessment in these studies, and (d) provide a brief narrative review of treatment efficacy. A secondary objective was to consider the quality of current RCTs of the ACT-based treatments for chronic pain identified.

#### 2. Method

#### 2.1. Eligibility criteria

This review only includes published journal articles describing RCTs of ACT for adults with chronic pain. Trials that included samples

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