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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 therapeutic 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

of headache patients, children/adolescents, healthy participants or participants who had some other dominant physical or mental health issue were not considered for inclusion. Articles were excluded if they described an experimental study that was not designed as a clinical intervention or a non-randomized trial and if they reported on clinical trials of mindfulness alone or otherwise did not explicitly describe the treatment focus as ACT or on psychological flexibility. No restrictions were set on the type of control group used, the method of delivery of the ACT intervention, or the outcomes assessed, as all outcomes were of interest.

2.2. Search strategy

A systematic search was performed in OVID: Embase (1980 to week 14 2014), PsycINFO (1806 to April week 1 2014) and Medline (1946 to March week 4 2014). A further search was carried in EBSCO: CINAHL (January 1999 to April 2014) and The Cochrane Library. All searches were carried out on 5 April 2014. Each search was then limited to include only journal articles published in English in the past 15 years (1999–2014). The reference lists of selected eligible articles were searched to identify any additional relevant studies and the Association for Contextual Behavioral Science website was also searched, as this is known to be a source where most studies of ACT are listed. Unpublished literature was not sought for the review.

The titles, abstracts and keywords were searched for the following terms: "acceptance and commitment therapy", or acceptance, or "acceptance based", or acceptance-based, or ACT; combined with chronic pain, or fibromyalgia, or FM, or "chronic low* back pain", or CLBP, or "whiplash associated disorder", or whiplash, or WAD, or "repetitive strain injury", or RSI, or "complex regional pain syndrome", or CRPS, or "musculoskeletal pain", or osteoarthritis, or OA, or "rheumatoid arthritis", or RA, or neuralgia, or neuropath*, or sciatica; and further combined with "random* control trial", or RCT, or "control* trial", or control. (See Appendix for full search terms.)

2.3. Study selection

Study selection was carried out by the first author and agreed by the second. Fig. 1 shows a flow diagram of the study selection process for the review. The original search returned a total of 1488 articles. After de-duplicating 1034 articles were left to be screened by title and abstract. Eleven articles were identified as being possibly eligible for inclusion, the remaining 1023 articles were irrelevant to the review either because they did not include ACT treatment, did not use a randomized controlled clinical trial design, or the study sample included children/adolescents or headache patients. The full text versions of ten of the selected articles were retrieved and an exclusion/inclusion criteria tool was used to assess whether each study was eligible for inclusion (available from second author). One article was found to be a duplicate published in a different journal. Another article was rejected because it involved an analog experimental design with chronic pain patients rather than a clinical trial (Vowles et al., 2007). The reference lists of the nine eligible studies were searched for any other potentially relevant articles. One trial was identified but was excluded as it involved a sample with work related pain and stress rather than chronic pain (Dahl, Wilson, & Nilsson, 2004). A final article was identified from the Association for Contextual Behavioral Science website and when screened was found to be eligible for inclusion (Steiner, Bogusch, & Bigatti, 2013). After the selection was complete a total of ten studies remained for review. [Note: Two of the studies identified were not fully randomized, as one randomized the first subject and then alternated allocation after that (Johnston, Foster, Shennan, Starkey, & Johnson, 2010), and the other randomized at the level of their nursing home and not individually (Alonso, López, Losada, & González, 2013). Due to the relatively small number of studies identified, these were included in the review.]

2.4. Data extraction

Data were extracted from the selected articles using a data extraction tool devised prior to the search (available from the

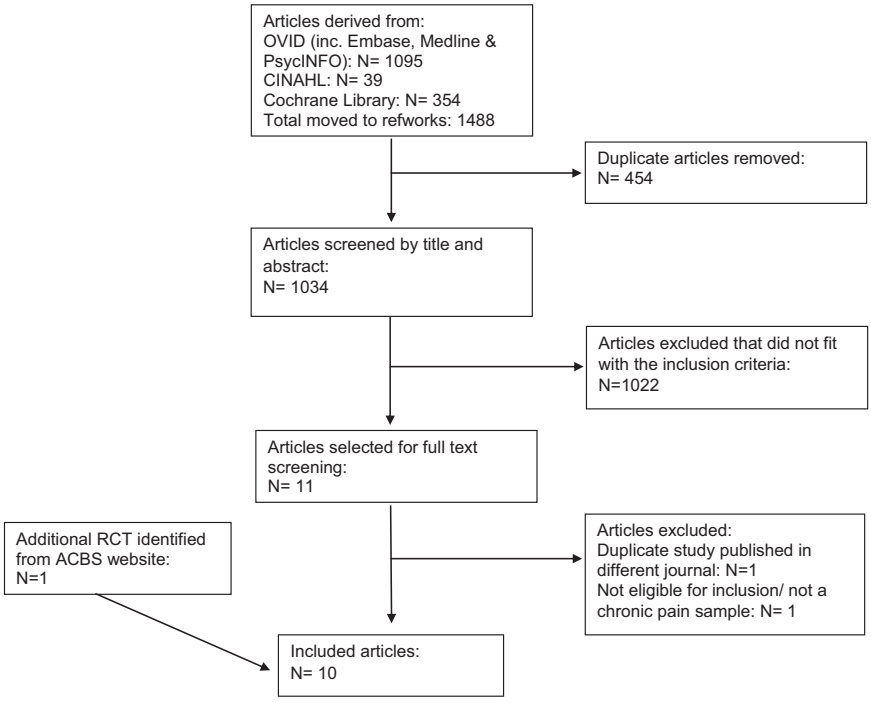

Fig. 1. Flow diagram of study selection.

second author). The data were extracted by the first author and reviewed and agreed by the second. These data included details of the participants' pain condition, average pain duration, the sample size at the start of treatment, mean age of the participants (and range if provided) and the percentage of women, method of treatment delivery, duration or number of sessions, the type of control condition used for comparison, the participant attrition rate, and significant effects. Information on which measures were included in each trial and the results reported from them was extracted for all the primary and secondary outcomes and process variables so that the domains they reflect could be examined. The majority of measures were categorized into domains in-line with the IMMPACT recommendations where possible. In cases where the domain was not clearly given in the article or judged to be an inaccurate description, further literature search on the measure was carried out to establish its best fitting domain.

3. Results

3.1. Study characteristics

Table 1 gives details of the RCTs included in the review. The total number of participants at the start of treatment across the ten trials is 623, with sample sizes at the start of treatment ranging from 16 to 156. The majority of participants were women (around 75%) and the mean age across studies ranged from 45.1 to 85.4 years old. The average length of pain duration ranged from 6.9 to 35 years across the ten trials. The ACT treatment was predominantly provided in groups and follow-up lengths ranged from only a post-treatment assessment to a maximum of 12 months follow up. Control groups included treatment as usual (TAU), wait list control (WLC) and a variety of other active treatments. Nine of the ten trials included reporting of attrition rates.

3.2. Outcome domains

Table 2 shows all the outcomes measured in each study and whether they were categorized as primary, secondary or process outcomes. If measures were not categorized as primary, secondary or process outcomes they were labeled as uncategorized. The review identified 15 outcome domains assessed across the ten trials, these are: physical functioning, emotional functioning, interpersonal functioning, global functioning, pain, life satisfaction, sleep interference, attitudes/beliefs, coping, patient global impression of change/satisfaction, adverse events, health, medication changes/healthcare utilization, aspects of psychological flexibility and 'other'. A total of 39 different tools were used to measure these outcome domains, some of which were used to assess more than one domain. The most frequently measured domains were emotional functioning, which was included in nine trials; pain intensity or severity, measured across eight trials; and physical functioning which was included in seven. Aspects of psychological flexibility were assessed in all ten studies with pain acceptance being assessed in six, values in three trials, and experiential avoidance/general acceptance and psychological inflexibility in two trials each. Life satisfaction was assessed in five trials, global functioning was reported in three, and beliefs/attitudes including pain catastrophizing were assessed in six trials.

Table 1
Characteristics of included trials.

Reference	Pain type/condition	Average pain duration in years (SD)	*N* (at start of treatment)	Mean age in years (range)	Women (%)	Type of ACT intervention	Control group(s)	Treatment duration	Length of follow up	Attrition rate
Wicksell et al. (2008)	WAD	6.9	21	51.5	76.2	IACT	TAU	8 weeks, 10 60 minute sessions	4 and 7 months	4 month: 4.8%
Johnston et al. (2010)	CP		24	Median 43 (20–84)	62.5	ACT SH	WLC	6 weeks	Only post treatment	PT:41.6%
Wetherell et al. (2011)	CP	15 (13.5)	99	54.9 (18–89)	50.9	GACT	GCBT	8, weekly 90 min sessions	6 months	6 month: 14.1%
Thorsell et al. (2011)	CP	_	90	46	64.4	ACT SH	AR SH	7 weeks	6 and 12 months	6 month: 41.1% 12 month: 64.4%
Wicksell et al. (2013)	FM	11.8 (7.2)	40	45.1	100	GACT	WLC	12, weekly 90 min sessions	3–4 months	PT: 10% 3 months: 17.5%
Alonso et al. (2013)	MP	ACT:35 (6.37) WLC:11 (5.65)	16	85.4 (78–91)	80	GACT	WLC	10, 2 hour sessions over 5 weeks	Only post treatment	PT:18.8%
Buhrman et al. (2013)	CP	15.3 (11.7)	76	49.1 (27–69)	59.2	ACT SH	IDF	7 weeks	6 months	PT: 19.7%
McCracken et al. (2013)	CP	10	73	58 (23–86)	68.5	GACT	TAU	4, 4 hour sessions over 2 weeks	3 months	PT: 20.5% 3 months:23.3%
Steiner et al. (2013)	FM	_	28	48.63	100	IACT	IPME	8 weekly 1 hour sessions	3 months	_
Luciano et al. (2014)	FM	13	156	48.31	96.2	GACT	RPT WLC	8, 2.5 hour sessions	3 and 6 months	PT: 9% 6 month:12.8%

ACT SH: Acceptance and Commitment Therapy Self Help, AR SH: Applied Relaxation Self Help, CP: Chronic Pain (variety of pain types), FM: Fibromyalgia, GACT: Group Acceptance and Commitment Therapy, GCBT: Group Cognitive Behavioural Therapy, IACT: Individual Acceptance and Commitment Therapy, ICBT: Individual Cognitive behavioural Therapy, IDF: Internet discussion forum, IPME: Individual Pain Management Education, MP: Musculoskeletal Pain, PT: Post-treatment, RPT: Recommended Pharmacological Treatment, TAU: Treatment as usual, WLC: Wait List Control.

Table 2
Author designated outcome domains and measurement tools.

Reference	Primary outcomes *(Tool)*	Secondary outcomes *(Tool)*	Process measures *(Tool)*	Uncategorised measures *(Tool)*
Wicksell et al. (2008)	Physical functioning *(PDI)* Life satisfaction *(SWLS)*	Attitudes/Beliefs *(TSK)* Emotional functioning *(IES, HADS)* Pain intensity and interference *(VAS)*	Psychological flexibility *(PIPS)*	–
Johnston et al. (2010)	–	–	–	Life satisfaction *(QOLI, SWLS)* Pain *(SF-MPQ)* Emotional functioning *(CMDI, BAI)* Psychological flexibility/Acceptance/ Values *(CPAQ, CPVI)*
Wetherell et al. (2011)	Global functioning *(BPI)* Pain intensity *(BPI)*	Physical Functioning *(SF-12; MPI)* Emotional functioning *(SF-12; BDI; PASS)* Client Satisfaction *(CSQ)*	Psychological flexibility *(CPAQ-R)* Attitudes/beliefs *(SOPA)*	–
Thorsell et al. (2011)	–	–	–	Physical functioning *(OMPQ)* Pain *(OMPQ)* Emotional functioning *(HADS)* Life satisfaction *(SWLS)* Psychological flexibility/Acceptance *(CPAQ)*
Wicksell et al. (2013)	Physical functioning *(PDI)*	Global functioning *(FIQ)* Physical functioning *(SF-36)* Emotional functioning *(SF-36; BDI; STAI)* Pain (NRS) Attitudes/Beliefs (Self-Efficacy Scale)	Psychological flexibility *(PIPS)*	–
Alonso et al. (2013)	–	–	–	Physical functioning *(MHAQ; BPI)* Emotional functioning *(GDS-10)* Interpersonal functioning *(BPI)* Sleep *(BPI)* Life satisfaction *(SWLS)* Attitudes/Beliefs *(SOPA; ATOA, PCS)* Psychological flexibility *(AAQ, CPVI)* Other *(SOC)*
Buhrman et al. (2013).	Psychological flexibility/ Acceptance *(CPAQ)*	Emotional functioning *(HADS, MPI)* Physical functioning *(MPI)* Attitudes/Beliefs *(PAIRS)* Pain severity *(MPI)* Coping *(CSQ)* Life satisfaction *(QOLI)*	–	–
McCracken et al. (2013)	Physical functioning *(RMDQ; SF-36)* Emotional functioning *(PHQ-9)* Pain *(NRS)*	Emotional functioning *(SF-36)* Patient global impression of change Medication changes	Psychological flexibility/Acceptance *(CPAQ; AAQ-II)*	–
Steiner et al. (2013)	Psychological flexibility/Values *(CPVI)*			
Luciano et al. (2014).	Global functioning *(FIQ)*	Emotional functioning *(HADS)* Pain *(PVAS)* Health *(EQ-5D)* Adverse Events Attitudes/Beliefs *(PCS)* Psychological flexibility/ Acceptance *(CPAQ)*	–	–

AAQ: Acceptance and Action Questionnaire, AEs: Adverse Events, ATOA: Attitudes Towards Own Aging, BAI: Beck Anxiety Inventory, BDI: Beck Depression Inventory, BPI: Brief Pain Inventory, CPAQ: Chronic Pain Acceptance Questionnaire, CPVI: Chronic Pain Values Inventory, CSQ: The Coping Strategies Questionnaire, CMDI: Chicago Multi-scale Depression Inventory, CSQ: Client Satisfaction Questionnaire, EQ-5D: EuroQol, FIQ: Fibromyalgia Impact Questionnaire, GDS: Geriatric Depression Scale, HADS: Hospital Anxiety and Depression Scale, IES: Impact of Events Scale, MHAQ: Modified Health Assessment Questionnaire, MPI: Multidimensional Pain Inventory, NRS: Numerical Rating Scale, OMPQ: Orebro Musculoskeletal Pain Questionnaire, PAIRS: Pain And Impairment Relationship Scale, PASS: Pain Anxiety Symptoms Scale – Short-Form, PCS: Pain Catastrophizing Scale, PDI: Pain Disability Index, PGIC: patient global impression of change, PHQ-9: Patient Health Questionnaire-9, PIPS: Psychological Inflexibility in Pain Scale, PVAS: Pain Visual Analog Scale, QOLI: Quality of Life Inventory, RMDQ: Roland Morris Disability Questionnaire, SF-12: Short Form health survey-12, SF-36: Short Form Health Survey, SOC: Selection, Optimization and Compensation questionnaire, SOPA: Survey of Pain Attitudes, STAI: Spielberger Trait-State Inventory, SF-MPQ: Short form-McGill Pain Questionnaire, SWLS: Satisfaction With Life Scale, TSK: Tampa Scale of Kinesiophobia, VAS: Visual analog scale.

Other outcomes such as social functioning, sleep interference, coping, patient global impression of change and client satisfaction, adverse events and medication reduction were included in one study each.

3.3. Primary outcomes

Of the ten articles reviewed seven explicitly identified primary outcome variables (Buhrman et al., 2013; Luciano et al., 2014;

McCracken, Sato, & Taylor, 2013; Steiner et al., 2013; Wetherell et al., 2011; Wicksell et al., 2013; Wicksell, Ahlqvist, Bring, Melin, & Olsson, 2008). The most frequently measured domain reflected in the primary outcomes was physical functioning, assessed in three of the seven trials. Pain intensity/severity was measured as a primary outcome in two trials, as was global functioning. Emotional functioning, life satisfaction, pain acceptance and values were reported as primary outcomes once each.

In total ten different tools were used to assess the primary outcome domains, including four different measures of physical functioning. The Pain Disability Index (PDI; Pollard, 1984) used to assess physical functioning was the only measure used more than once across the primary outcomes.

3.4. Secondary outcomes

Six of the ten RCTs explicitly identified secondary outcomes (Buhrman et al., 2013; Luciano et al., 2014; McCracken et al., 2013; Wetherell et al., 2011; Wicksell et al., 2008, 2013). Twelve domains were measured across the secondary outcomes with the use of 23 different tools. The most consistently measured secondary outcome domain was emotional functioning, included in all six trials. A variety of measures were used to look at this outcome including the Hospital Anxiety and Depression Scale (HADS; Zigmond & Snaith, 1983), included in three trials, and the SF-36 (Ware & Sherbourne, 1992) included in two. Physical functioning was also assessed in three of the six trials' and defined as a secondary outcome, with the use of the Multidimensional Pain Inventory (MPI; Kerns, Turk, & Rudy, 1985) and SF-36. Pain intensity or severity was reported in four trials, measured with a pain visual analog scale by Luciano et al. (2014) and Wicksell et al., (2008), a numerical rating scale by Wicksell et al. (2013) and with the MPI subscale by Buhrman et al. (2013).

Several different pain-related attitudes or beliefs were included as secondary outcomes, assessed with such measures as the Pain and Impairment Relationship Scale (PAIRS; Slater, Hall, Atkinson, & Garfin, 1991), the Pain Catastrophizing Scale (PCS; Sullivan, Bishop, & Pivik, 1995) the Tampa Scale for Kinesiophobia (TSK; Kori, Miller, & Todd, 1990) and a measure of participants' self-efficacy to carry out certain activities (Altmaier, Russell, Kao, Lehmann, & Weinstein, 1993). Other domains were only measured once each within the secondary outcomes, these include global functioning, adverse events, coping, patient global impression of change, client satisfaction, health and life satisfaction. A component of psychological flexibility, chronic pain acceptance, was measured as a secondary outcome by Luciano et al. (2014) using the CPAQ (McCracken, Vowles, & Eccleston, 2004).

3.5. Process measures

Four studies specifically identified process or mediating variables as an explicit focus in their designs (McCracken et al., 2013; Wicksell et al., 2008, 2013; Wetherell et al., 2011). All four studies included some measure of psychological flexibility, the CPAQ, Acceptance and Action Questionnaire (AAQ; Hayes et al., 2004 or AAQ-II; Bond et al., 2011), or the Psychological Inflexibility in Pain Scale (PIPS; Wicksell, Lekander, Sorjonen, & Olsson, 2010) to measure pain and general acceptance and psychological inflexibility. Wetherell et al. (2011) also included a measure of control beliefs using the Survey of Pain Attitudes (SOPA; Jensen, Turner, Romano, & Lawler, 1994) as a mediating variable.

3.6. Uncategorized domains and measures

Three of the ten studies listed a variety of outcomes but did not specify whether any of these were considered primary, secondary, or process variables (Alonso et al., 2013; Johnston et al., 2010; Thorsell et al., 2011). The outcome domains of emotional functioning and life satisfaction were assessed in all three trials using a variety of measures, the most frequently used measure being the Satisfaction with Life Scale (SWLS; Diener, Emmons, Larsen, & Griffin, 1985) used in all three trials. Johnston et al. (2010) report the SWLS and the Quality of life Inventory (QOLI; Frisch, 1994) as measures of global improvement, however they have been re-categorized for the review as measures of life satisfaction as this better aligns with the original design of the measures. Two of the trials included a measure for physical functioning using the Brief Pain Inventory (BPI; Cleeland & Ryan, 1994), the Orebro Musculoskeletal Pain Questionnaire (OMPQ; Linton, 1999) and the Modified Health Assessment Questionnaire (MHAQ; Pincus, Summey, Soraci, Wallston, & Hummon, 1983). Pain was also measured in two of the trials, with the OMPQ and the Short Form-McGill Pain Questionnaire (SF-MPQ; Melzack, 1987).

Components of psychological flexibility were measured in each of the trials, specifically Thorsell et al. (2011) measured pain acceptance with the CPAQ and Alonso et al. (2013) measured general acceptance and values using the AAQ (Hayes et al., 2004) and Chronic Pain Values Inventory (CPVI; McCracken & Yang, 2006). Whilst Johnston et al. (2010) categorized the CPAQ as a measure of physical functioning and the CPVI as a measure of global improvement, they have been re-categorized in this review as measures of psychological flexibility, specifically pain acceptance and values, as this was judged to be the original intended purpose for these measures. Alonso et al. (2013) also included additional outcomes of sleep interference and interpersonal functioning measured with the BPI, attitudes/beliefs (catastrophizing) with the PCS, attitudes towards ageing (ATOA; Liang & Bollen, 1983), and a measure of selection, optimization and compensation (SOCQ; Baltes, Freund, & Lang, 1999) categorized as 'other' in this review.

3.7. Risk of bias within studies

Each study was assessed using an adapted Cochrane Collaboration tool for the risk of bias within randomized trials (Higgins et al., 2011). The tool can be used to assess six areas of potential bias: selection bias, performance bias, detection bias, attrition bias, reporting bias and other bias. Performance bias was omitted from the assessment in this review as it is usually not possible to conceal psychological treatment from participants or the clinicians. Table 3 provides a summary of the risk of bias assessment. The majority of the trials provided sufficient descriptions of participant randomization, which in most cases led to comparable groups. In some cases the method of randomization was not described in sufficient detail (Alonso et al., 2013; Johnston et al., 2010; Thorsell et al., 2011; Steiner et al., 2013) and in other cases randomization it did not lead to completely comparable group (Alonso et al., 2013; Buhrman et al., 2013; Wetherell et al., 2011). Several of the studies reported that researchers collecting data from participants were blinded to the participants' group allocation or were independent, Alonso et al. (2013), Thorsell et al. (2011); and in others this was unclear, Johnston et al. (2010) and Steiner et al. (2013). Data on rates of participant attrition was provided by all the trials other than Steiner et al. (2013) which does not give information on attrition during treatment. Some did not provide sufficient details on the reasons for participants' withdrawals. Perhaps most important for the focus of the current study, only three of the ten study registrations could be found in order to make a clear judgment of reporting bias by comparing the proposed outcomes included in the registration information with the ones included in the published article; therefore the majority of the studies reviewed were judged as having an unclear risk of

Table 3
Risk of bias within studies.

Reference	Selection bias	Detection bias	Attrition bias	Reporting bias	Other bias	Overall assessment of bias
Wicksell et al. (2008)	Low	Low	Unclear	Unclear	Low	**Unclear**
Johnston et al. (2010)	High	Unclear	High	Unclear	Low	**High**
Wetherel et al. (2011)	Unclear	Low	Low	Unclear	Low	**Unclear**
Thorsell et al. (2011)	High	Unclear	Unclear	Unclear	Low	**High**
Wicksell et al. (2013)	Low	Low	Unclear	Unclear	Low	**Unclear**
Alonso et al. (2013)	High	Unclear	Low	High	Low	**High**
Buhrman et al. (2013)	Unclear	Low	Low	Low	Low	**Unclear**
McCracken et al. (2013)	Low	Low	Low	Low	Low	**Low**
Steiner et al. (2013)	High	Unclear	High	High	Low	**High**
Luciano et al. (2014)	Low	Low	Low	Low	Low	**Low**

bias for this criteria. Overall two trials were judged as having a low risk of bias, four were judged to have an unclear risk and four were judged as having a high risk of bias.

3.8. Summary of outcome results

Seven of the ten trials included inactive control conditions (one study, Luciano et al., 2014, provided both inactive and active control conditions). Results across these studies showed a number of beneficial effects of ACT. Here we consider only between group effects from primary analyses. In terms of measures of physical functioning six comparisons showed small to large effects favoring ACT on physical functioning, including one each from the general practice based (McCracken et al., 2013) and fibromyalgia studies (Wicksell et al., 2013), and two from each from the study of whiplash (Wicksell et al., 2008) and the study of online treatment (Buhrman et al., 2013). Two comparisons showed significant medium to large effects favoring ACT on pain global disease impact in fibromyalgia (Luciano et al., 2014; Wicksell et al., 2013). Nine comparisons showed significant small to large effects for measures of anxiety, depression, or general emotional distress (Buhrman et al., 2013; McCracken et al., 2013; Wicksell et al., 2008, 2013). Just one comparison showed a significant large effect favoring ACT for life satisfaction (Wicksell et al., 2008). Three comparisons showed significant small to large effects favoring ACT on relevant measures of facets of psychological flexibility (Buhrman et al., 2013; Wicksell et al., 2008, 2013). In one additional study the effect was not present immediately post treatment but appeared at follow-up (McCracken et al., 2013).

Four of the ten trials included control groups that represented active treatments, in these cases traditional CBT, applied relaxation, education, and recommended medication. The general result was that ACT appeared no more beneficial than the comparison conditions on most outcomes. One comparison showed a large effect size for impact of disease on global functioning in favor of ACT in comparison with recommended medication for fibromyalgia (Luciano et al., 2014). Several comparisons showed significant small to large effects on facets of psychological flexibility favoring ACT, including components of acceptance of pain (Thorsell et al., 2011), and a component of values (Steiner et al., 2013). Another comparison showed higher satisfaction ratings from those who completed the ACT condition compared with those who completed traditional CBT (Whetherell et al., 2011).

3.9. Discussion

Ten RCTs of ACT for chronic pain were identified and included in this review. As a general summary of outcome domains included, measures of emotional functioning, pain, and physical functioning were the most represented outcome domains, included nine, eight, and seven times, respectively. The only domain included in every study was the process domain containing measures of aspects of psychological flexibility. Many of the trials reviewed here are small in size and include significant risks of bias. With this point in mind, based on these trials, ACT appears efficacious as a treatment for chronic pain, particularly with regard to outcomes of physical and emotional functioning. Although, these results emerge almost entirely in comparison to inactive treatment conditions.

The examination of outcome domains and measures used in these RCTs highlights inconsistencies in whether outcomes are categorized by study authors as primary, secondary or process variables, as only six of the ten RCTs reviewed clarified these distinctions. It is arguably important that trials of treatment effectiveness identify primary outcome domains before the trial is started in order to reduce the risk or perception of reporting bias in publications of the results. This risk entails the elevation of significant effects as the primary focus in a selective way after the results are known. Variables of interest that are not the main focus for improvement within the trial, as determined beforehand, obviously should be designated as secondary variables, even if results in these outcomes are found to be more favorable towards the treatment than the primary outcomes. Also, when measures of processes or mediating variables are included in research these should be identified as such in order to make the distinction between these and outcome variables clear to the reader.

A review by Chan, Hróbjartsson, Haahr, Gøtzsche, and Altman (2004) of 122 published articles of clinical trials found that around 50% of efficacy outcomes reported were incomplete, with significant outcomes more likely to be reported in full; and around 62% of articles had changed at least one primary outcome when results were compared to the protocol. Researchers of clinical trials should assure that protocols or trial registrations are easily available to allow others to accurately assess the risk of bias. In the current review it was found that two of the ten trials reported a trial registration code within the article and one other was found despite the code not being supplied in the article. This led to the trials for which registration could not be found to be judged as having an unclear risk of reporting bias.

It was found in the current review that outcome domains covered by the RCTs of ACT for chronic pain were, to a large extent, in-line with those recommended by IMMPACT (Turk et al., 2003). Nine of the trials included a measure assessing emotional functioning, eight included a measure of pain, and seven trials reported physical functioning. Nine of the ten trials also reported attrition rate. This means that the large majority of ACT trials adopted four out of the six recommended core domains from IMMPACT. However, the majority of studies neglected other IMMPACT recommended core outcomes such as adverse events and patient global impression of change/satisfaction, which were only included in the outcomes of one trial each (Luciano et al., 2014; McCracken et al., 2013; Wetherell et al., 2011). It is often presumed that adverse events may be an outcome more suited to pharmaceutical pain management trials as medications are more likely to result in a

variety of negative side effects that psychological treatments are unlikely to produce; however, it is worth showing in evidence whether this is the case or not. Certainly, it is recommended that future RCTs of ACT do include a measure of the participants' global impression of change or satisfaction as such measures are short and easy to administer, can provide useful information on how effective participants found treatment, and could possibly reveal perceived improvements or differences between treatments that other measures are not sensitive enough to reflect (Kamper, Maher, & Mackay, 2009; Turk et al., 2003).

Other IMMPACT recommended supplemental outcomes, such as coping and health care utilization, were infrequently included in the reviewed trials. For the most part measures of coping as such did not appear in the reviewed RCTs, but each one included more precise measures of the treatment processes of interest, including components of psychological flexibility. Measures of patient health care utilization and medications changes could provide useful information on the impact treatment has on the further health care costs and therefore represent an important practical concern.

Results from a focus group and a large online survey showed aspects of daily living that people with chronic pain rated as highly important, including fatigue and sleep related problems, weakness, enjoyment of life, and emotional well-being (Turk et al., 2008). Domains such as life satisfaction, included in five of the trials covered in the review, touches on this set of concerns, and there was some limited inclusion of sleep problems and fatigue (Alonso et al., 2013). Hence, these concerns that people rate very highly are probably not being adequately reflected in the reviewed RCT and certainly warrant consideration in the future.

IMMPACT also provides suggestions on which measures could be used within pain treatment trials (Dworkin et al., 2005). For the measurement of physical functioning IMMPACT recommends the use of condition specific measures where they are available, but also suggest the use of generic measures such as the MPI, BPI or SF-36, in order to facilitate comparisons of treatment effectiveness across studies and pain conditions. For the measurement of emotional functioning IMMPACT recommend the BDI or the Profile of Mood States (POMS; McNair, 1971). The current review found that a variety of measures were used across the ten studies including the MPI, BPI, SF-36 and BDI as recommended. While the remaining range of measures included here, such as FIQ, PDI, HADS and SF-12, has also been found to be valid and reliable measures (Rivera & González, 2004; Bjelland, Dahl, Haug, & Neckelmann, 2002; Gandek et al., 1998), the one limitation in this wide range is the difficulty to combine or compare data across studies.

In their choice and priority of outcomes we rate the ACT RCTs for chronic pain as somewhat better at following the IMMPACT recommendations than in following the psychological flexibility model. The predomination of measures of pain and emotional functioning as outcome variables certainly reflects the mainstream of chronic pain treatment. It does not, however, clearly reflect the focus of ACT, where the emphasis ought to include improving engagement in daily activities. There may have been a time when it was ok to attempt to reflect everyone's priorities, both inside and outside of ACT, defining multiple primary outcomes, including symptoms and functioning. Now, this may be an unnecessary compromise, and for purpose of avoiding contradiction, it seems better to more assertively define outcomes, especially primary outcomes, that do not contradict the therapeutic model.

Levin, Hildebrant, Lillis, and Hayes (2012) argue that in order to increase our understanding of how treatments work, and then to be able to improve treatments, it is important to investigate active therapy processes in relation to effectiveness. In their review of laboratory based experimental studies Levin et al. (2012) found support showing that components of the psychological flexibility model including acceptance, defusion, present moment, values and mindfulness were psychologically active with average small/medium effect sizes across healthy and 'at risk/distressed' participants. A promising finding from the current review was that, whilst not always identified as process variables, all 10 trials included a measurement of some aspect of psychological flexibility. The measurements used in these trials included the AAQ, CPAQ, PIPS and CPVI which were used to measure general acceptance, pain acceptance, psychological inflexibility and values, and have each been found to have at least adequate validity and reliability (Barraca, 2004; McCracken & Yang, 2006; Wicksell et al., 2010; Wicksell, Olsson, & Melin, 2009).

Two studies included in the review categorized measures of psychological flexibility as primary outcomes. Clearly in ACT for chronic pain the primary focus is on increasing treatment participants' psychological flexibility. From here it certainly is tempting to define components of psychological flexibility as outcomes. We feel that is ill-advised.

Within a psychological flexibility model the distinction between outcome and process is not real, it is practical. Values-based action, for example, is neither necessarily true nor untrue as a treatment outcome variable. The "truth" of it depends on the purpose. The purpose of IMMPACT recommendations is to create a quality standard and common currency for RCTs related to pain. We believe it is useful to incorporate this standard and common currency within ACT trials, to the extent possible, because to do so (a) reflects an appreciation of what our wider pain research community and people with chronic pain say is important; (b) provides a basis for comparison between different approaches, (c) allows us to demonstrate our results in terms that have known implications for healthcare need, use, and cost; and (d) because to do so generally improves our ability to communicate and be included. Finally, so far we know from our research that when we enhance psychological flexibility we produce positive changes in more conventionally-conceived outcomes. In this sense, although there may be a more precise and personal quality to values, to enhance values-based action is, to a degree, the same as improving physical and social functioning.

If ACT researchers choose outcome measures that are not familiar or standard in the wider field, this choice may not create progress as well as it could. It seems entirely consistent with the pragmatic philosophy underlying ACT to include variables that need no translation, allow comparison, and improve one's ability to communicate and persuade. There may be a time when recommended outcomes change. In the meantime we recommend adherence to IMMPACT, including a primary focus on physical, social, or general functioning, a secondary focus on pain and emotional functioning, and the addition of global impression of change, and adverse events.

One limitation in the current review and within discussions of outcome is based in how we use terms. For example, it is common to say, as we have said here, that "ACT focuses on behavior change and not on symptoms reduction." Of course this is both accurate, in a sense, and potentially misleading. Conventionally speaking a "symptom" is "a change in the body or mind which indicates that a disease is present…subjective evidence of disease or physical disturbance… [or] something that indicates the existence of something else" (Merriam-Webster, 2014). Indeed ACT does not deem to directly target "evidence of disease or physical disturbance" as these matters are normally conceived. However, one could also use the term symptom in a less conventional way, and more consistent with ACT. Here avoidance and cognitive fusion, for example, might be regarded as "symptoms" of psychological inflexibility. This use of the term "symptoms" blurs the distinction between symptom change versus behavior change. This potential confusion requires that we use care, clarify our terms, and perhaps plan refinements in the future.

Another limitation of the review is that the outcome domains assessed in the trials were not always clearly stated; therefore classification of measures into domains was in some cases carried out by the researcher. The outcome domains presented by IMMPACT were used as a guideline to classify measures, therefore measures of health related quality of life were judged to be assessing physical and emotional functioning and measures of anxiety and depression were classed as emotional functioning. It is acknowledged that certain measures used in the reviewed trials may also include items which assess additional domains such as social or role functioning, however this was not usually clearly stated within the trial articles, so these have not been reported as separate domains. The current review focused on adults and on chronic pain but not headache. Some may regard this as a limitation, however, we believe these are separate populations, including different symptom patterns, treatment methods, and measures, and this increases study heterogeneity and muddies generality. These populations deserve their own separate systematic reviews.

In conclusion, RCTs of ACT for chronic pain do reasonably well in assessing multiple domains deemed important in pain trials, although some consistency with the model underlying ACT is compromised in these choices. There is room for improvement both in following IMMPACT and in remaining true to ACT, and this should help the field progress. Researchers should first designate their primary, secondary, and process measures specifically, and register these choices on one of the widely available trial registration sites. We recommend that those who conduct RCTs of ACT for chronic pain continue to "consider" the six core domains of IMMPACT and customize these as appropriate to ACT. In future these researchers may aim to include measures within domains of physical, social, or more general functioning as primary outcomes. Although pain is of key importance in some treatment approaches, within ACT trials it is probably better conceived as a secondary outcome. Other secondary outcomes could include emotional functioning, global impression of change, adverse events, and healthcare or medication use. It is recommended that trials continue to include measures of psychological flexibility as process measures, and not as outcome, and perhaps broaden the focus of these so that more of the elements of psychological flexibility, such as cognitive defusion or self-related variables in particular (e.g. McCracken, Barker, & Chilcot, 2014) can be tracked.

Appendix

Search terms

OVID, including: Embase (1980 to week 14 2014), PsychINFO (1806 to April week 1 2014), and MEDLINE (1946 to March week 4 2014)

1. Acceptance and Commitment Therapy. ab, kw, ti
2. Acceptance. ab, kw, ti
3. "Acceptance based". ab, kw, ti
4. Acceptance-based. ab, kw, ti
5. ACT. ab, kw, ti
6. 1 or 2 or 3 or 4 or 5
7. Chronic pain. ab, kw, ti
8. Fibromyalgia. ab, kw, ti
9. FM. ab, kw, ti
10. "Chronic Low* Back Pain". ab, kw, ti
11. CLBP. ab, kw, ti
12. Whiplash. ab, kw, ti
13. "Whiplash associated disorder". ab, kw, ti
14. WAD. ab, kw, ti
15. "Repetitive strain injury". ab, kw, ti
16. RSI. ab, kw, ti
17. Dystrophy. ab, kw, ti
18. "Complex Regional Pain Syndrome". ab, kw, ti
19. CRPS. ab, kw, ti
20. "Musculoskeletal pain". ab, kw, ti
21. Osteoarthritis. ab, kw, ti
22. OA ab, kw, ti
23. "Rheumatoid arthritis". ab, kw, ti
24. RA ab, kw, ti
25. Neuralgia. ab, kw, ti
26. Neuropath* ab, kw, ti
27. Sciatica ab, kw, ti
28. 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27
29. RCT. ab, kw, ti
30. "Random* control* trial". ab, kw, ti
31. "Control* trial." ab, kw, ti
32. Control. ab, kw, ti
33. 29 or 30 or 31 or 32
34. 6 and 28 and 33

EBSCO: CINHAL (set to January 1999 to April 2014)

AB ("acceptance and commitment therapy") OR AB Acceptance OR AB Acceptance-based OR AB "Acceptance based" OR AB ACT AND AB chronic pain OR AB fibromyalgia OR AB FM OR AB "chronic low* back pain" OR AB CLBP OR AB whiplash OR AB "whiplash associated disorder" OR AB WAD OR AB "repetitive strain injury" OR AB RSI OR AB "complex regional pain syndrome" OR CRPS OR AB "musculoskeletal pain" OR AB osteoarthritis OR AB OA OR AB "rheumatoid arthritis" OR AB RA OR AB neuralgia OR AB neuropath* OR AB sciatica AND AB "random* control* trial" OR AB RCT OR AB "control* trial" OR AB control

Cochrane Library

#1 "Acceptance and Commitment therapy":ti,ab,kw or Acceptance:ti,ab,kw or Acceptance-based:ti,ab,kw or "Acceptance based":ti,ab,kw or ACT:ti,ab,kw Publication Date from 1999 to 2014 (Word variations have been searched)

#2 Chronic pain:ti,ab,kw or "fibromyalgia":ti,ab,kw or FM:ti,ab,kw or "chronic low* back pain":ti,ab,kw or CLBP:ti,ab,kw Publication Date from 1999 to 2014 (Word variations have been searched)

#3 whiplash:ti,ab,kw or "whiplash associated disorder":ti,ab,kw or WAD:ti,ab,kw or "repetitive strain injury":ti,ab,kw or RSI Publication Date from 1999 to 2014 (Word variations have been searched)

#4 "complex regional pain syndrome":ti,ab,kw or CRPS:ti,ab,kw or "musculoskeletal pain":ti,ab,kw or osteoarthritis:ti,ab,kw or OA:ti,ab,kw Publication Date from 1999 to 2014 (Word variations have been searched)

#5 "rheumatoid arthritis":ti,ab,kw or RA:ti,ab,kw or neuralgia:ti,ab,kw or neuropath*:ti,ab,kw or "sciatica":ti,ab,kw Publication Date from 1999 to 2014 (Word variations have been searched)

#6 RCT:ti,ab,kw or "random* control* trial":ti,ab,kw or "control* trial" or Control Publication Date from 1999 to 2014 (Word variations have been searched)

#7 #2 OR #3 OR #4 OR #5

#8 #1 AND #6 AND #7

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