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Original Article

A systematic review of randomised controlled trials using Acceptance and commitment therapy as an intervention in the management of non-malignant, chronic pain in adults

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ABSTRACT

Context: Acceptance and Commitment Therapy (ACT) is a psychological, behavioural based intervention used in the management of chronic pain (CP). CP represents a significant challenge for health care professionals including osteopaths. Whilst support for ACT's effectiveness is present in peer reviewed literature, the validity and generalisability of reported findings is negatively affected by methodological flaws and trial heterogeneity. A systematic review of randomised controlled trials (RCTs) of ACT as an intervention in the management of non-malignant, CP in adults was conducted to evaluate the effectiveness of ACT.
Method: Systematic online searches for RCTs and evaluation using methodological quality criteria.
Literature search: 110 trials were identified of which 93 were duplicates, 17 were assessed for eligibility, 4 were excluded according to criteria and 3 for high risk of bias. 10 trials were reviewed.
Results: Evidence exists in support of the effectiveness of ACT in managing CP. Evidence regarding process mediators of behavioural change in ACT is insufficient and conflicting. Meta-analysis was precluded due to heterogeneity in the sample.
Conclusions: ACT demonstrates promise as a therapeutic intervention for non-malignant, CP populations. Evidence regarding mediation of behavioural change is conflicting. Heterogeneity in the sample precludes meta-analysis. Generalisability was supported by corroborating evidence across numbers of trials. Further research is indicated to develop the utilisation of ACT in conjunction with manual therapies as an intervention for CP.

Implications for Practice

- Introduces Acceptance and commitment therapy (ACT), a developing approach in chronic pain, to Osteopaths.
- Evaluates ACT effectiveness in a review of Randomised Controlled Trials of ACT as an intervention for chronic pain (CP).
- Draws attention to conflicting evidence relative to the ACT model's theoretical mechanisms of change.
- Presents evidence in support of ACT as a therapeutic intervention for CP.

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Legend of acronyms of outcome measures

AAQ II	Acceptance Action Questionnaire II
AEs	Assessment of adverse events
BAI	Beck Anxiety Inventory
BDI	Beck Depression Inventory-II
BPI	Brief Pain Inventory Short Form Interference Subscale
CPAQ	Chronic pain acceptance questionnaire
CPVI	Chronic pain values inventory
CSQ[1]	Client Satisfaction Questionnaire
CSQ[2]	Coping strategies questionnaire
ELS	Engaged Living Scale
FIQ	Fibromyalgia Impact questionnaire
FFMQ-SF	Five Facet Mindfulness Questionnaire—Short Form
HRQL	Health related quality of life
HADS	Hospital and anxiety depression scale
IES	Impact of Event Scale
LSQ	Life Satisfaction Questionnaire
LSP	Linton screening for pain (1998)
MU	Medical utilisation
MHC-SF	Mental Health Continuum-Short Form
MPI	Multidimensional pain inventory
OMPQ	Orebro MSK Pain Questionnaire
PAIRS	Pain and impairment relationship scale
PASS	Pain Anxiety Symptoms Scale
PCS	Pain catastrophising scale
PDI	Pain Disability Index
PI	Pain Intensity
NRS	Pain intensity numeric rating scale
EQ-5D	Pain VAS of EuroQol
VAS	Pain visual analogue scale
PGIC	Patient global impression of change
PHQ9	Patient health questionnaire 9
PIPS	Psychological Inflexibility in Pain Scale
QOLI	Quality of life Inventory
RMDQ	Roland Morris disability questionnaire
SWLS	Satisfaction with life scale
SES	Self-Efficacy Scale
SF-12	Short Form Health Survey
SF36	Short-form Health Survey 36
SLU	Sick leave utilisation
STAI	State-trait Anxiety Inventory
SOPA	Survey of Pain Attitudes
TSK	Tampa Scale of Kinesiophobia
TCS	Treatment Credibility Scale
TIC-P	Trimbos and Institute of Medical Technology Assessment Cost Questionnaire for Psychiatry
VLQ	Valued living questionnaire

1. Introduction

Chronic pain is pain that lasts for more than 3–6 months [1] and affects an estimated 7.8 million people in the UK [2], 1 in 5 of the European population [3,4] and 1 in 5 adults in Australia [5], and 11.2% of adults in the U.S.A. [6,7].

Care of people with chronic musculoskeletal (MSK) pain remains a significant challenge for osteopaths and other health practitioners. Evidence for the treatment of chronic low back pain (CLBP) with manipulative therapy is conflicting in that osteopathic manual treatment (OMT) is reported as providing short-term relief [8] and small, yet clinically important, changes in functional status [9] and, conversely, whilst reducing pain, does not improve function and appears to be no better or worse than other existing therapies [10,11].

Chronic pain conditions, with associated neural changes such as central sensitisation and associated cognitive and non-cognitive factors require further strategies to enhance patient care. Emotions and emotional processes, along with beliefs and actions, are vital parts of human pain experience [12]. Perceived pain is not an accurate indicator of tissue damage and structural approaches alone fail to address maladaptive behavioural changes aimed at reducing pain [12,13].

Osteopaths focusing on the biomedical model for chronic musculoskeletal pain need to be aware of the likelihood of a poorer treatment outcome [14], as interventions based on OMT alone are unlikely to address psychosocial or other factors that may contribute to disability [10]. Recent evidence suggests that multidisciplinary biopsychosocial rehabilitation interventions are more effective than usual care in decreasing pain and disability in people with CLBP [15].

Acceptance and commitment therapy (ACT), a developing management approach in chronic pain, is a mindfulness-based, process focussed [16] behaviour therapy facilitating committed action and psychological flexibility [17]. Psychological flexibility is the ability, of the person experiencing chronic pain, to act effectively in accordance with personal values and goals in the presence of interfering pain and distress [18]. ACT conceptualises psychological suffering as being largely caused by cognitive entanglement, experiential avoidance and the resulting psychological rigidity that impedes a person's ability to take behavioural steps that are consistent with their core values [19].

Randomised Controlled Trials (RCTs) using ACT as an intervention for chronic pain report significant improvements across a wide range of outcomes including the processes of pain acceptance [20,21], values based action [22] and psychological inflexibility [23,24]. Medium to large effect sizes were demonstrated in improved quality [21] and satisfaction with life [25], decreased pain intensity [25], pain related disability, affective distress [26], fibromyalgia (FM) impact [27], self-efficacy and depression [24]. Collectively these findings indicate support for ACT as an intervention for management of chronic pain.

Whilst the focus of ACT is not specifically directed toward symptom reduction but psychological flexibility [28], outcomes reporting reductions in pain and depression, greater self-efficacy, quality of life and physical activity may be attractive to osteopaths managing patients experiencing chronic pain.

Evident across these RCTs are variations in the frequency, duration and format of the ACT interventions [20–27,29,30]. This may be reflective of the fact that in ACT the 'ultimate goal' of psychological flexibility [31] using mindfulness, itself a process of awareness, openness and curiosity [32], is not a structured process and, as such, procedural variations are inevitable.

Methodological flaws are evident, too, in the lack of participant randomisation [21,27], inadequate blinding of study personnel [21,22,29,30] and pragmatic allocation [27] affecting the internal validity [33] of several of the studies.

While the findings for ACT are promising in terms of significance and medium to large effect sizes, small purposive chronic pain populations [20,21,23,24,26], heterogeneity, procedural variations and methodological flaws may negatively impact on their validity and generalisability.

Therefore the aim of this systematic review was to evaluate the clinical effectiveness of ACT as an intervention for adults with chronic pain.

2. Methods

The systematic review protocol was formulated in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) checklist [34,35].

2.1. Literature search

A systematic search of English language publications was undertaken using the following search syntax: (“Acceptance and commitment therapy"[MeSH] OR “Acceptance and commitment therapy”) AND (“Chronic pain"[MeSH] OR “Pain, Intractable"[MeSH] OR “persistent pain” OR “pain” OR “Pain"[MeSH]) AND (“Controlled Clinical Trial” [Publication Type] OR “Randomised Controlled Trial” [Publication Type]) in 15 databases (PubMed, PsycINFO, PsycARTICLES, Cochrane Database, AMED, ASSIA, CINAHL, Medline, Embase, Directory of Open Access Journals (DOAJ), Wiley Online Library, SAGE Premier, Database of Abstracts of Reviews of Effects (DARE), Mednar and Scopus) from the date of their inception to September 2015:

2.2. Study selection, methodological quality control and data collection

To minimise reviewer bias in inclusion, exclusion, risk of bias (ROB) assessment and data extraction processes, trials identified from the literature search were manually blinded for author, publication, date, sponsor, institution [36] and assigned an identification number [37]. A master list of the numbered trials was compiled by the first author. Trials were evaluated in random order using a computerised random number generator [38]. A second reviewer was co-opted [39] to conduct inclusion, exclusion, ROB assessment and data extraction [37,40] on the 17 identified trials. The level of inter-rater agreement was calculated using the kappa statistic [33,41,42] for the inclusion process and intra-class correlation coefficient (ICC) [43] for the ROB assessment.

2.3. Inclusion and exclusion criteria

Inclusion criteria were: Randomised controlled trials (RCTs), controlled clinical trials (CCTs) and cohort trials with comparison groups reported in English language peer-reviewed literature, focusing on chronic, persistent or intractable pain using ACT as an intervention in adult populations.

Exclusion: Trials involving acute pain. Trials involving the pain of malignancy since osteopaths are more likely to encounter non-malignant, chronic musculoskeletal pain such as nonspecific chronic low back pain (CLBP) [8] in the clinical setting. Paediatric chronic pain studies because prevalence is low, less than 5% of cases in the UK [44], and less likely to present to osteopathic practice.

Case series, case–control trials, and case reports were also excluded owing to the high potential for bias in these designs [37]. Non- ACT interventions e.g., Cognitive behavioural therapy (CBT) were excluded since this review aimed to evaluate ACT only. A trial eligibility form based on the Cochrane version [33] was used for the inclusion, exclusion process.

2.4. Methodological quality- risk of bias assessment (ROB)

Methodological quality was evaluated using the 12 criteria of the Cochrane ROB assessment tool [33,39,45]. The ROB tool covers six domains of bias: selection bias, performance bias, detection bias, attrition bias, reporting bias, and other bias [46,47]. Within each domain, assessments were made for one or more items, which may cover different aspects of the domain, or different outcomes [46]. Trials meeting fewer than 6 of the 12 criteria i.e. less than 50% were rated as having a high ROB [33,39].

Reviewer disagreements regarding ROB evaluations were discussed and a consensus reached. The level of inter-rater agreement was calculated using the intra-class correlation coefficient (ICC) [43,48].

2.5. Data extraction

A customised data extraction tool based on standardised methodological quality criteria [37,39] was used. Data were stored in word processor software and later converted into tabulated form [40].

2.6. Quality of evidence

The Cochrane Handbook GRADE approach was used to evaluate quality of evidence in this review [49].

3. Results

3.1. Literature search

A total of 110 trials were identified from 15 databases. 93 were duplicates. 17 trials were selected for eligibility assessment (Fig. 1).

3.2. Inclusion and exclusion criteria

Consensus was achieved between the first and second reviewer, who was blinded to the first reviewer's findings regarding the 17 identified trials.

The level of inter-rater agreement for trial inclusion and exclusion calculated prior to inclusion using a kappa statistic [33,41,42] was considered ‘perfect’ [50] with a value of $k = 1.0$.

3.3. Methodological quality- risk of bias (ROB) assessment

Included trials (n = 13) were evaluated for ROB (Table 1). Analysis of agreement between reviewers for ROB was ‘perfect’ (ICC 2, 1 = 0.88) [51].

Three trials were excluded due to high ROB [33,52].

3.4. Trial characteristics

Trial characteristics and ROB scores are summarised in Table 1.

3.5. Sample characteristics

Sample size ranged from 238 [31] to 19 [53].

Mean ages of the trial samples ranged between 40.0 (SD 13.2) to 58.0 (SD 12.8) years.

The sample in one trial was all female [24], four had a pronounced female majority [23,31,53,54], and the remainder had a larger female to male ratio.

Participant characteristics varied from those experiencing functional impairment caused by chronic pain [29], chronic pain [16,25,30,31], chronic pain and whiplash associated disorders [23],

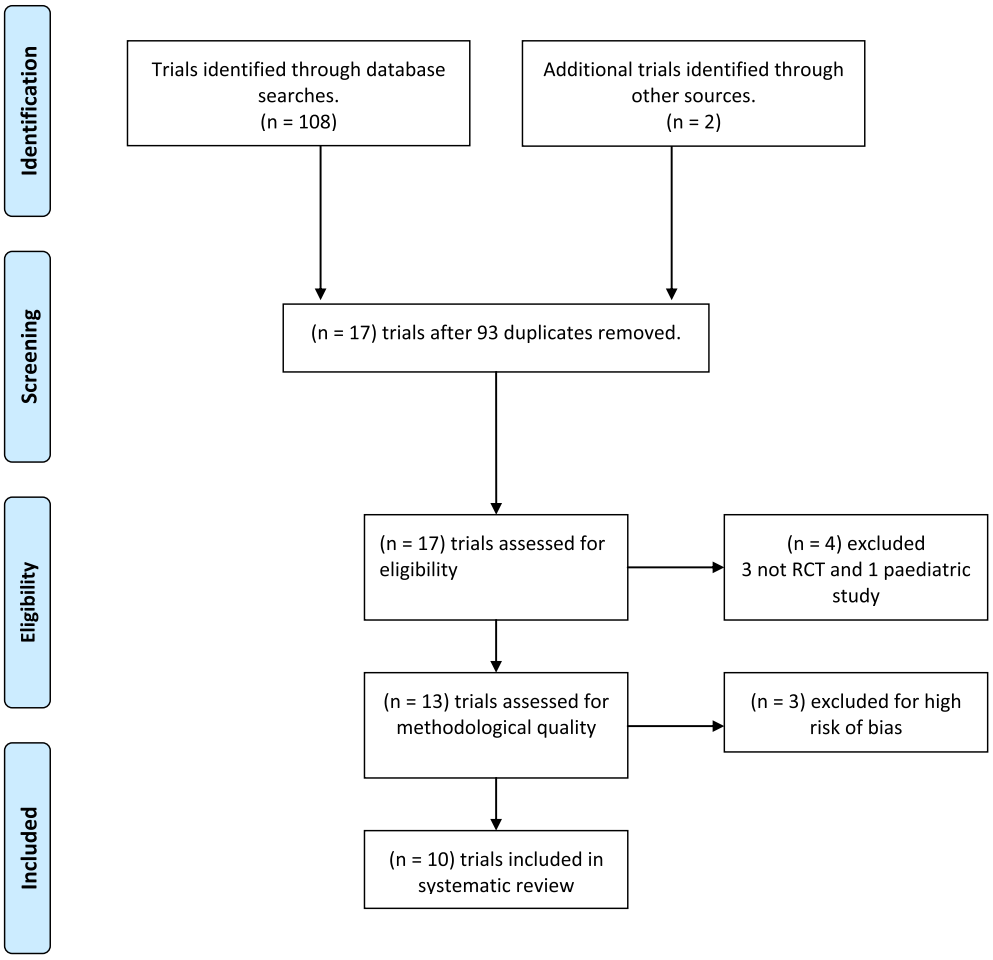

Fig. 1. PRISMA 2009 flow Diagram.

fibromyalgia [24,54], longstanding pain [18] and those at risk of increasing workplace related stress, pain and sick leave utilisation [53].

ACT interventions were trialled against a variety of comparison and control groups (Table 1).

There was no consistent ACT intervention across the 10 appraised trials (Table 2). ACT was administered to individuals, to groups of varying size, for varying lengths of time per session and over varying numbers of weeks. Three studies investigated ACT delivered by self-administered programs using either a written workbook [25], or accessed online [29,31].

Fifteen primary outcome measures were used across the 10 reviewed RCTs. In total, 44 primary and secondary outcome measures were used. No one primary outcome measure was used consistently across reviewed trials. The most frequently used primary outcome measure, the Chronic Pain Acceptance Questionnaire (CPAQ) [55], was used in three trials as a primary outcome measure [18,25,29], and in three as a secondary outcome measure [16,30,54]. The Hospital and Anxiety Depression Scale (HADS), a reliable instrument for detecting states of depression and anxiety [56], was used by two trials as a primary outcome measure [18,25], and four trials as a secondary outcome measure [23,29,31,54].

3.6. Results of outcome measures

44 primary and secondary outcome measures used across 10 trials yielded a large volume of pain related data including pain interference, pain disability, pain catastrophising, pain intensity, fibromyalgia impact, anxiety, depression, pain willingness, activities engagement, pain acceptance, psychological inflexibility, psychological fusion, pain avoidance, increase in physical health, level of function, satisfaction with life, sick leave and medical utilisation, subjective pain, praying and hoping and affective distress, patient's global impression of change, kinesiophobia, mental health quality of life and self-efficacy (Tables 1, 3 and 4).

3.6.1. Pain interference

Four trials measured pain interference, the degree to which pain interferes with mobility and social activity. The Brief Pain Inventory (BPI) used by Wetherell et al. [30], and the Multidimensional Pain Inventory (MPI) used by Trompetter et al. [31] and Buhrman et al. [29] each have subscales to evaluate the construct of pain interference. Wicksell et al. [23] used a Pain Interference Visual Analogue Scale (PVAS) on which participants were requested to indicate how much their pain “prevented them from doing things”.

In a moderate-quality non-controlled randomised trial of 114 participants, Wetherell et al. [30] found significant post treatment reductions in pain interference, using the BPI, in the ACT and the CBT group. In a low quality RCT of 238 participants, Trompetter et al. [31] found a small magnitude but significant 3 and 6 months post treatment reduction in pain interference, using the MPI, in the internet delivered ACT group compared with the expressive writing (EW) and the wait list (WL) control group.

In a low quality, small sample RCT of participants with chronic

Table 1
Trial Characteristics: Trials ranked for ROB.

Author	Study Population and number	Mean Age years	Gender	Study Design	ACT intervention	1° outcome measures	2° outcome measures	Timing of measures	Cochrane ROB. Score out of 12 criteria	Sources of bias	Quality of evidence
Wetherell et al. [30]	Chronic pain N = 114 N = 57 each to ACT and CBT	54.9 SD 12.5	Mixed F 50.9%	RCT: ACT vs CBT	8 × 90 min weekly group ACT sessions	BPI	SF-12 MPI BDI PASS CSQ[1] CPAQ SOPA	Pre and post intervention and at 6 month follow up	10/12	Performance bias: Lack of blinding of participants and care providers. Some care providers delivered interventions in both groups.	Moderate
Luciano et al. [54]	Fibromyalgia N = 156 Group ACT 51 RPT 52 WL 53	48.88 SD 5.94, 47.77 SD 5.87 48.28 SD 5.71	Mixed F150 M6	RCT: ACT vs recommended pharmacological treatment RPT vs wait list WL	8 × 2.5 h sessions in groups of 10–15.	FIQ	PCS HADS CPAQ VAS EQ-5D	Pre and post intervention plus 3/12 and 6/12 post intervention	10/12	Selection bias: Educational status of the intervention groups differed at baseline. Performance bias: Lack of blinding of participants and care providers.	Moderate
McCracken et al. [16]	Chronic pain N = 73 37 ACT + TAU 36 TAU	58.0 SD 12.8	Mixed F68.5%	RCT: ACT + TAU vs TAU	Group ACT 12 or 13 per group. 4 × 4 h sessions over 2 weeks.	RMDQ PHQ9 SF36	SF-36 CPAQ AAQ II	Pre and within 2 weeks of intervention completion and 3/12 follow up	9/12	Selection bias: lack of treatment allocation concealment. Performance bias: Lack of blinding of participants and care providers.	Low
Wicksell et al. [24]	Fibromyalgia N = 40 23 ACT 17 WL	45.1 SD 6.6	All female	RCT: ACT vs TAU vs wait list control	12, weekly 90 min group ACT sessions with 6 persons per group.	PDI	FIQ SF36 SES BDI STAIT PIPS	Pre, post-intervention and 3/12 follow up measures.	9/12	Performance bias: Lack of blinding of participants and care providers. Reporting bias: Treatment allocation concealment was unreported.	Low
Kemani et al. [18]	Longstanding pain N = 60 30 Group ACT 30 AR	40.3 SD 11.3	Mixed 80% female ACT 66.7% in AR	RCT: ACT vs Applied relaxation AR.	12 weekly group sessions 6 per group for 1.5 h 18 h total. 10 sessions with pain psychologists and 2 (sessions 2 and 8) with pain physicians trained in ACT	PDI PI SF12 HADS CPAQ TIC-P	N/A	Pre, mid and post intervention, 3/12 and 6/12 follow up.	9/12	Selection bias: More females in the ACT group. Greater mean pain duration in the applied relaxation group. Performance bias: lack of blinding of care providers. One care provider delivered interventions in both groups. Detection bias: lack of blinding of outcome assessors.	Low
Dahl et al. [53]	At risk of increasing stress, pain and sick leave utilisation from the workplace N = 19 11 ACT	40.0 SD 13.2	Mixed F17 > M2	RCT: ACT + MTAU vs MTAU	Weekly 1 h individual sessions for 4 weeks using VLQ as a clinical tool	SLU	MU LSQ	Pre and post intervention and monthly for 6/12 post intervention	8/12	Selection bias: Inadequate reporting of randomisation. Performance bias: Lack of blinding of care providers Detection bias: lack of blinding of outcome assessors.	Low

Wicksell et al. [23]	Chronic pain and whiplash associated disorders N = 22 11 ACT + TAU 11 WL + TAU	48.2 SD 7.8 55.1 SD 11.2	Mixed F 76%	RCT: ACT + TAU vs waiting list control and TAU	10 × 60 min individual sessions over an 8 week period.	PDI SWLS	TSK IES HADS PIPS Pain VAS	Pre, post-intervention and 4/12 and 7/12 (ACT group only) follow up measures.	8/12	Selection bias: lack of treatment allocation concealment. Performance bias: Lack of blinding of participants and care providers. Reporting bias: Outcome assessor blinding not reported.	Low
Trompetter et al. [31]	Chronic pain N = 238 82 Internet ACT 79 Expressive writing 77 Wait list control	ACT 52.9 (SD 13.3) EW 52.3 (SD 11.8) WL 53.2 (SD 12.0)	Mixed ACT 76.8% female EW 75.9% WL 75.3%	RCT: ACT Internet vs Expressive writing vs Wait list control.	9 internet-based modules in 9–12 weeks. Daily mindfulness exercises 10 –15 min. Reading, keeping a personal diary. 3 h per week.	MPI-interference	HADS NRS PDI MHC-SF PIPS FFMQ-SF ELS PCS	Pre, post intervention, 3/12 and 6/12 follow up.	8/12	Selection bias: Lack of allocation concealment. Performance bias: Lack of blinding of participants and care providers. Reporting bias: Outcome assessment blinding was unreported.	Low
Thorsell et al. [25]	Chronic pain N = 115 61 Self Help ACT 54 Applied relaxation	46.0 SD 12.3	Mixed F 64.4%	RCT: ACT vs Applied relaxation	Individual 90 min introductory and concluding sessions and 7 weeks of self-help ACT with 30 min phone support per week	SWLS HADS OMPQ CPAQ	TCS	Pre and post intervention and at 6/12 and 12/12 follow up.	7/12	Selection bias: Lack of treatment allocation concealment. Performance bias: Lack of blinding of participants and care providers. Reporting bias: Outcome assessor blinding was not reported. Attrition bias: Attrition post intervention was 46% in the ACT group and 42% in the AR group.	Low
Buhrman et al. [29]	Functional impairment caused by chronic pain N = 76 38 Internet ACT 38 WL	49.1 SD 10.34	Mixed F45 > M31	RCT: ACT v Active wait list control	7 × Internet delivered, individual weekly sessions	CPAQ	HADS CSQ[2] MPI PAIRS QOLI	Pre and post intervention and for 6/12 post intervention in ACT group only	6/12	Selection bias: Educational status of groups differed at baseline. Lack of treatment allocation concealment. Performance bias: Lack of, blinding of participants and care providers. Detection bias: Lack of blinding of outcome assessors.	Low

Table 2
ACT interventions.

Author	ACT intervention administration	Number of sessions per week	Number weeks	Session length per week in hours	Total ACT exposure in hours
Wetherell et al. [30]	Group	1	8	1.5	12
Luciano et al. [54]	Group 10 to 15 persons per group.	1	8	2.5	20
McCracken et al. [16]	Group 12 or 13 persons per group.	2	2	4	16
Wicksell et al. [24]	Group sessions 6 persons per group	1	12	1.5	18
Kemani et al. [18]	Group sessions. 6 persons per group	1	12	1.5	18
Dahl et al. [53]	Individual	1	4	1	4
Wicksell et al. [23]	Individual	10 sessions in total	8	1	10
Trompetter et al. [31]	Individual self-help internet-based modules.	1–2	9–12 weeks	3 per week expected	27
Thorsell et al. [25]	Individual Self- help manual	1	7	1.5 h introductory and concluding sessions. 0.5 h telephone support per week	6.5 Does not include individuals time spent on tasks.
Buhrman et al. [29]	Individual Self-help Internet delivered	1	7		No data for individual's time spent on tasks.

pain and whiplash associated disorders (WAD), Wicksell et al. [23] found significant post treatment reductions in pain interference in the ACT group compared to treatment as usual (TAU) WL control with a large effect size using a PVAS. In a low quality RCT of 76 participants with functional impairment caused by chronic pain, Buhrman et al. [29] found a significant post treatment and 6 month follow up reduction in pain interference in the internet guided ACT group compared to an active WL control using the MPI with medium and small effect sizes respectively.

3.6.2. Pain disability

Four trials measured pain disability, the degree to which chronic pain interferes with daily activities, using the Pain Disability Index (PDI).

In a low quality RCT of 40 female participants with fibromyalgia, Wicksell et al. [24] found significant post treatment and 3 month follow up reductions in pain disability in the ACT group compared to the WL control with medium to large effect sizes. In a low quality non-controlled randomised trial of 60 participants with long-standing pain, Kemani et al. [18] found significant post treatment reductions in pain disability in the ACT group compared to the Applied Relaxation (AR) group with medium effect size.

Wicksell et al. [23] found significant post treatment reductions in pain disability in the ACT group compared to the TAU WL group with large effect size. Trompetter et al. [31] reported a significant, 6 month follow up, reduction in pain disability in the ACT group compared with EW and WL controls with small effect size.

3.6.3. Pain catastrophising

Three trials measured pain catastrophising, the exaggerated negative mental set brought to bear during actual or anticipated painful experience [57].

In a moderate quality RCT of 156 participants diagnosed with fibromyalgia, Luciano et al. [54] found significant post treatment and 6 month follow up reductions in pain catastrophising in the ACT group compared with recommended pharmacological treatment (RPT) and WL control using the Pain Catastrophising Scale (PCS) with medium effect sizes.

In a low quality RCT of 238 participants, Trompetter et al. [31] reported a significant 3 month follow up reduction in pain catastrophising compared with WL controls with a small effect size using the PCS.

In a low quality RCT of 76 participants with functional impairment caused by chronic pain, Buhrman et al. [29] reported a significant post treatment reduction in pain catastrophising compared to WL with medium effect size using the Coping strategies questionnaire (CSQ).

3.6.4. Pain intensity

Three trials measured pain intensity each with a different outcome measure.

In a low quality non-controlled randomised trial, Kemani et al. [18] found significant post treatment reductions in pain intensity in the ACT group compared to pre-treatment scores (PTS) using the Pain Intensity (PI) outcome measure with a small effect size.

Thorsell et al. [25], in a low quality non-controlled randomised trial of 115 participants experiencing chronic pain, reported significant post treatment and 12 month follow up reductions in pain intensity in the self-help, manual based ACT group compared to PTS using the Orebro Musculoskeletal Pain Questionnaire (OMPQ) with small effect sizes.

In their low quality RCT of 238 participants, Trompetter et al. [31] reported a significant 3 month follow up reduction in pain intensity in the ACT group compared to the EW group using the Pain Intensity Numeric Rating Scale (NRS) with a small effect size.

3.6.5. Fibromyalgia impact

Two trials measured the impact of diagnosed fibromyalgia on participant's daily lives using the Fibromyalgia Impact Questionnaire (FIQ).

In a moderate quality RCT of 156 participants, Luciano et al. [54] found significant post treatment and 6 month follow up reductions in fibromyalgia impact in the ACT group compared with RPT group and WL controls all with large effect sizes.

In a low quality, small RCT, Wicksell et al. [24] reported significant post treatment and 3 month follow up reductions in fibromyalgia impact in the ACT group compared with the WL control with small effect size.

3.6.6. Anxiety

Five trials measured anxiety levels of participants. Luciano et al. [54], Kemani et al. [18], Thorsell et al. [25] and Buhrman et al. [29] used the anxiety subscale of the Hospital and Anxiety Depression Scale (HADS) which evaluates current anxiety. Wicksell et al. [24]

Table 3
Trial results: Primary outcome measures.

Author	1° outcome measures	Statistical analysis	Results of 1° outcome measures
Wetherell et al. [30]	BPI administered weekly before during and after intervention	Intention to treat (ITT). Linear mixed effects models. *t* and chi squared tests.	ACT: Significant post treatment reduction pain interference compared with pre-treatment scores (PTS) β = −0.06; SE 0.02; P = 0.02
Luciano et al. [54]	FIQ	ITT. Linear mixed effects models. Bonferroni corrections	ACT: Significant post treatment reduction in fibromyalgia impact d = 1.43 (1.12; 1.75) compared with RPT (large effect) and WL d = 2.35 (1.98; 2.72) (large effect). ACT: Significant 6 month follow up reduction in fibromyalgia impact d = 1.43 (1.08; 1.78) compared with RPT (large effect) and WL d = 2.11 (1.69; 2.54) (large effect).
McCracken et al. [16]	RMDQ SF36 PHQ9	ITT. ANOVA using baseline characteristics as covariates. Cohen's d for effect size.	ACT: Significant post treatment and 3 month f/u reduction in depression compared to TAU Cohen's d = 0.46 (small effect) and Cohen's d = 0.58 (medium effect) respectively.
Wicksell et al. [24]	PDI	ANOVA Linear mixed effects models Cohen's d for effect size.	ACT: Significant post treatment and 3 month f/u reduction in pain disability compared to WL F (1, 67) = 16.59, *p* = < 0.001 Cohen's d 0.75 (medium effect) and Cohen's d = 0.73 (medium to large effect) respectively. Mediation analysis: A reduction in psychological inflexibility from pre to post assessments significantly mediated increases in pain disability.
Kemani et al. [18]	PDI PI SF12 HADS CPAQ TIC-P	Latent growth curve modelling (LGM), ITT, ANOVA, within and between group effect sizes. PDI for clinically significant change.	ACT: Significant post treatment reduction in: Pain disability compared to the active relaxation (AR) group (B = −8.30, SE = 2.94, p < 0.01) Cohen's d = 0.61 (medium effect) Pain disability compared to PTS (B = −5.17, SE = 1.47 p = < 0.01) Cohen's d = 0.54 (medium effect); Pain intensity compared to PTS (B = −0.45, SE = 0.17 p = < 0.01) Cohen's d = 0.34 (small effect) Anxiety compared to PTS (B = −1.42, SE = 0.64 p = 0.03) Cohen's d = 0.33 (small effect) Depression compared to PTS (B = −1.89, SE = 0.54 p = < 0.01) Cohen's d = 0.41 (small effect). Significant post treatment increase in: Pain acceptance compared to AR (B = 14.84, SE = 5.34 p = < 0.01) Cohen's d = 0.90 (large effect). Pain acceptance compared to PTS (B = 8.26, SE = 2.71, p = < 0.01) and 3/12 f/u (B = 3.15, SE = 0.87, p < 0.01) Physical health compared to PTS (B = 3.19, SE = 0.95 p = 0.01) Cohen's d 0.79 (medium effect). Marginally significant difference in clinically significant change.
Dahl et al. [53]	SLU	General linear model repeated measures. ANOVA. t tests. Partial eta for effect size.	ACT: Significant post treatment reduction in sick leave utilisation compared to medical treatment as usual (MTAU) F (12, 204) = 3.34, p = 0.002, partial eta sq. = 0.16 (medium effect). Maintained at f/u.
Wicksell et al. [23]	PDI SWLS	ITT t and chi squared tests ANCOVA with pre TTT as covariate Partial eta for effect size.	ACT: Significant post treatment reduction in pain disability compared with TAU F (1, 16) = 12.6, p = 0.003 partial eta squared = 0.44 (large effect). ACT: Significant post treatment increase in satisfaction with life compared to TAU F (3, 30) = 11.1, p = 0.001 Partial eta Squared 0.53 (large effect) and compared to PTS F (1, 16) = 10.1, p = 0.006 Partial eta Squared 0.40 (large effect).
Trompetter et al. [31]	MPI- interference	ITT, ANOVA, Little's MCAR, using the general linear mixed model (GLMM), estimation methods restricted to maximum likelihood (REML), Cohen's D.	ACT Significant 3 and 6 month f/u reduction in pain interference compared to Expressive Writing (EW) Treatment effect (95%CI) 4.1 (1.1–7.1), p = 0.008, Cohen's d = 0.33; (small effect) and Treatment effect (95%CI) 5.6 (2.7–8.7), p < 0.001, Cohen's d = 0.47 (small effect) respectively.
Thorsell et al. [25]	SWLS HADS OMPQ CPAQ	ITT t and chi squared tests and Mixed Model Repeated Measures Cohen's d	Significant post treatment increase in: Activities engagement compared to PTS [estimate = 10.06, standard error (SE) = 1.60, t (121.52) = 6.28, P < 0.005, 95% (CI) = 6.88, 13.23, large effect = 1.14] Pain willingness compared to PTS [estimate = 5.81, standard error (SE) = 1.33, t (118.46) = 4.38, P < 0.005, 95% (CI) = 3.19, 8.44, medium effect = 0.79]; Pain acceptance compared to PTS [estimate = 14.76, standard error (SE) = 2.44, t (121.50) = 6.05, P < 0.005, 95% (CI) = 9.93, 19.59, large effect = 1.10] Satisfaction with life (SWL) compared to PTS [estimate = 4.29, standard error (SE) = 1.03, t (150.0) = 4.17, P < 0.005, 95%(CI) = 2.25, 6.32, medium effect = 0.75] Level of function compared to PTS [estimate = 0.83, standard error (SE) = 0.32, t (60.41) = 2.58, P < 0.012, 95% (CI) = 0.19, 1.47, small effect = 0.46]. Significant 6 month f/u increase in: Activities engagement compared to PTS [estimate = 6.16, standard error (SE) = 1.86, t (108.3) = 3.14, P < 0.002, 95% (CI) = 2.27, 10.04, medium effect = 0.55] Pain willingness compared to PTS [estimate = 4.41, standard error (SE) = 1.50, t (104.86) = 2.94, P < 0.004, 95% (CI) = 1.44, 7.38, medium effect = 0.52]. Pain acceptance compared to PTS [estimate = 10.54, standard error (SE) = 2.83, t (102.56) = 3.72, P < 0.005, 95% (CI) = 4.92, 16.16, medium effect = 0.65] Satisfaction with life compared to PTS [estimate = 2.15, standard error (SE) = 1.03, t (149.95) = 2.09, P < 0.038, 95%(CI) = 0.12, 4.18, small effect = 0.38] Level of function compared to PTS [estimate = 0.67, standard error (SE) = 0.29, t (64.14) = 2.27, P < 0.026, 95% (CI) = 0.08, 1.26, small effect = 0.47]. Significant 12 month f/u increase in: Activities engagement compared to PTS [estimate = 6.99, standard error (SE) = 2.44, t (67.6) = 2.86, P < 0.006, 95% (CI) = 2.11, 11.87, medium effect = 0.58]. Pain willingness compared to PTS [estimate = 6.75, standard error (SE) = 1.92, t

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Table 3 (*continued*)

Author	1° outcome measures	Statistical analysis	Results of 1° outcome measures
			(76.76) = 3.52, P < 0.001, 95% (CI) = 2.93, 10.56, medium effect = 0.72]. Pain acceptance compared to PTS [estimate = 12.96, standard error (SE) = 3.61, t (50.05) = 3.59, P < 0.001, 95% (CI) = 5.72, 20.20, medium effect = 0.74] Satisfaction with life compared to PTS [estimate = 3.10, standard error (SE) = 1.24, t (150.72) = 2.51, P < 0.013, 95%(CI) = 0.66, 5.54, medium effect = 0.54] Significant post treatment reduction in: Depression compared to PTS [estimate = −2.14, standard error (SE) = 0.61, t (104.37) = −3.52, P < 0.001, 95% (CI) = −3.34, −0.93, medium effect = 0.63]. Anxiety compared to PTS [estimate = −1.77, standard error (SE) = 0.52, t (110.75) = −3.43, P < 0.001, 95% (CI) = −2.79, −0.74, medium effect = 0.62]. Pain intensity compared to PTS [estimate = −0.78, standard error (SE) = 0.38, t (61.11) = −2.05, P < 0.045, 95% (CI) = −1.54, −0.02, small effect = 0.37]. Significant 6 month f/u reduction in: Depression compared to PTS [estimate = −1.39, standard error (SE) = 0.63, t (100.90) = −2.20, P < 0.030, 95% (CI) = −2.65, −0.14, small effect = 0.40]. Significant 12 month f/u reduction in: Depression compared to PTS [estimate = −1.75, standard error (SE) = 0.83, t (80.17) = −2.11, P < 0.038, 95% (CI) = −3.40, −0.95, small effect = 0.44]. Anxiety compared to PTS [estimate = −2.65, standard error (SE) = 0.75, t (54.94) = −3.56, P < 0.001, 95% (CI) = −4.14, −1.16, medium effect = 0.75]. Pain intensity compared to PTS [estimate = −1.09, standard error (SE) = 0.46, t (43.84) = −2.36, P < 0.023, 95% (CI) = −2.03, −0.16, small effect = 0.47].
Buhrman et al. [29]	CPAQ	ITT ANCOVA P < 0.05 Cohen's D	ACT: Significant post treatment increase in activity engagement compared to the WL [F (1, 73) = 4.36, p = 0.04] Cohen's d = 0.6 (CI 95% = 0.11, 1.03) medium effect. Significant post treatment increase in pain willingness compared to WL [F (1, 73) = 6.69, p = 0.012] Cohen's d = 0.49 (CI 95% = 0.04, 0.94) small effect. Significant post treatment increase in pain acceptance compared to WL [F (1, 73) = 6.0, p = 0.017] Cohen's d = 0.41 (CI 95% = 0.0, 0.86) small effect.

BPI Brief Pain Inventory, CPAQ Chronic pain acceptance questionnaire, FIQ Fibromyalgia Impact questionnaire, HADS Hospital and anxiety depression scale, MPI Multidimensional pain inventory, OMPQ Orebro MSK Pain, Questionnaire, PDI Pain Disability Index, PHQ9 Patient health questionnaire 9, PI Pain Inventory, RMDQ Roland Morris disability questionnaire, SF12 Short-form Health Survey, SF36 Short-form Health Survey 36, SLU Sick leave utilisation, SWLS Satisfaction with life scale, TIC-P Trimbos and Institute of Medical Technology Assessment Cost Questionnaire for Psychiatry.

used the State-trait Anxiety Inventory (STAI) which evaluates state anxiety, a short-term, temporary condition in response to some perceived threat, and trait anxiety, a non-temporary personality characteristic.

In a moderate quality RCT involving participants with fibromyalgia, Luciano et al. [54] found significant post treatment and 6 month follow up reductions in anxiety in the ACT group compared to RPT group and WL controls with small and medium effect size.

Of the remaining four low quality trials, Kemani et al. [18] found a significant post treatment reduction in anxiety in the ACT group compared to PTS with small effect size. Thorsell et al. [25] reported significant post treatment and 12 month follow up reductions in anxiety in the ACT group compared to PTS with medium effect sizes. Buhrman et al. [29] reported a significant post treatment reduction in anxiety in the ACT group compared with active WL control with small effect size. In a small RCT of female participants with fibromyalgia, Wicksell et al. [24] found significant post treatment reductions in state and trait anxieties in the ACT group compared with WL control using the State-trait Anxiety Inventory (STAI) with medium effect sizes.

3.6.7. Depression

Eight trials evaluated depression. McCracken et al. [16] used the Patient health questionnaire (PHQ9). Kemani et al. [18], Thorsell et al. [25], Luciano et al. [54], Wicksell et al. [23] and Buhrman et al. [29] used the HADS outcome measure. Wetherell et al. [30] and Wicksell et al. [24] used the Beck Depression Inventory (BDI).

In a low quality RCT of 73 participants with chronic pain, McCracken et al. [16] found significant post treatment and 3 month follow up reductions in depression in the ACT group compared to the TAU control with a small and medium effect sizes respectively.

Using the HADS outcome measure, Luciano et al. [54], in their moderate quality RCT of participants with fibromyalgia, reported significant post treatment and 6 month follow up reductions in depression in the ACT group compared to the RPT group and WL controls with small, small, large and medium effect sizes respectively. In the remaining four low quality trials using the HADS, Kemani et al. [18] reported a significant post treatment reduction in depression in the ACT group compared to PTS with small effect size. Thorsell et al. [25] reported significant post treatment, 6 and 12 month follow up reductions in depression in the ACT group compared to PTS with medium, small and small effect sizes respectively.

Wicksell et al. [23] reported significant post treatment reductions in depression in the ACT group compared with the TAU control and PTS with large effect sizes and Buhrman et al. [29] found a significant post treatment reduction in depression in the ACT group compared with active WL control with a small effect size.

In a moderate quality non-controlled randomised trial of 114 participants experiencing chronic pain, Wetherell et al. [30] found significant post-treatment reductions in depression in the ACT group compared to PTS using the Beck Depression Inventory (BDI). Using the same outcome measure in their low quality RCT of females with fibromyalgia, Wicksell et al. [24] found a significant post treatment reduction in depression in the ACT group compared with the WL control with a small effect size.

3.6.8. Pain willingness

Two trials, Thorsell et al. [25] and Buhrman et al. [29], measured pain willingness (the degree to which a person is willing to experience pain) using the Chronic Pain Acceptance Questionnaire (CPAQ).

In their low quality non-controlled randomised trial, Thorsell et al. [25] report significant post treatment, 6 and 12 month follow-

Table 4
Trial results: 2° outcome measures.

Author	2° outcome measures	Results from 2° outcome measures
Wetherell et al. [30]	SF-12 MPI BDI PASS CSQ[1] CPAQ SOPA	ACT Significant post- treatment reductions in depression compared to pre-treatment scores (PTS) ΔM = −2.32, t (56) = −2.98, P = 0.004 Significant post- treatment reductions in pain related anxiety compared to PTS ΔM = −4.51, t (56) = −3.74, P = 0.001. Mediation analysis indicated that pain acceptance did not mediate treatment response in the ACT group.
Luciano et al. [54]	PCS HADS CPAQ VAS EQ-5D	ACT: Significant post treatment reduction in: Subjective pain compared to recommended pharmaceutical treatment (RPT) d = 0.62 (0.42; 0.83) (medium effect) and wait list (WL) d = 0.93 (0.74; 1.12) (medium effect). Pain catastrophising compared to RPT d = 0.76 (0.60; 0.93) (medium effect) and WL d = 0.89 (0.73; 1.06) (medium effect). Anxiety compared to RPT d = 0.36 (0.15; 0.57) (small effect) and WL d = 0.77 (0.57; 0.96) (medium effect). Depression compared to RPT d = 0.43 (0.21; 0.65) (small effect) and WL d = 1.01 (0.80; 1.23) (large effect). Significant 6 month f/u reduction in: Subjective pain compared to RPT (VAS) d = 0.47 (0.26; 0.68) (small effect) and WL 0.80 (0.6170; 0.99) (medium effect). Pain catastrophising compared to RPT d = 0.69 (0.53; 0.84) (medium effect) and WL 0.72 (0.57; 0.88) (medium effect). Anxiety compared to RPT d = 0.39 (0.17; 0.61) (small effect) and WL 0.85 (0.65; 1.06) (medium effect) Depression compared to RPT d = 0.37 (0.19; 0.54) (small effect) and WL 0.88 (0.70; 1.06) (medium effect). Significant post treatment increase: Pain acceptance compared to RPT d = 1.05 (0.85; 1.25) (large effect) and WL 1.21 (1.03; 1.40) (large effect). Significant 6 month f/u increase in: Pain acceptance compared to RPT d = 1.01 (0.81; 1.20) (large effect) and WL 1.14 (0.95; 1.33) (Large effect). Longitudinal mediation analysis: No support for pain acceptance change as a mediator of change in functional status, pain catastrophizing, subjective pain, anxiety and depression.
McCracken et al. [16]	SF-36 CPAQ AAQ II	Significant 3 month f/u improvement in pain acceptance compared to TAU Cohen's d = 0.64 (medium effect) No significant group difference for psychological acceptance at 3 month follow up. Significant post treatment improvement in patient's global impression of change (PGIC) 53.3% ACT vs 25% TAU ($\chi 2 = 4.43$ P = < 0.05).
Wicksell et al. [24]	FIQ SF36 SES BDI STAIT PIPS	ACT: Significant post treatment reduction in: Fibromyalgia impact compared with WL F (1, 68) = 4.09, p = 0.047) Cohen's d = 0.41 (small effect) Depression compared with WL F (1, 63) = 8.32, p = 0.005) d = 0.44 (small effect) State anxieties compared with WL F (1, 66) = 5.56, p = 0.021) d = 0.51 (medium effect) Trait anxieties compared with WL F (1, 66) = 9.31, p = 0.003) d = 0.73 (medium effect) Psychological inflexibility F (1, 69) = 7.40, p = 0.008) d = 1.05 (large effect). Significant post treatment increase in mental health quality of life compared with WL F (1, 64) = 4.92, p = 0.030) d = 0.84 (medium effect) Self- efficacy compared with WL F (1, 67) = 4.03, p = 0.049) d = 0.74 (medium effect). Mediation analysis: Decreased psychological inflexibility significantly mediated improvements in FM impact, self-efficacy, depression, state anxiety and trait anxiety.
Kemani et al. [18]	N/A	N/A
Dahl et al. [53]	MU LSQ	ACT: Significant post treatment reduction in medical utilisation compared with MTAU F (1.15, 19.55) = 4.77, p = 0.037 partial eta squared = 0.22 (medium effect).
Wicksell et al. [23]	TSK IES HADS PIPS Pain VAS for pain Pain VAS for interference	ACT: Significant post treatment reduction in: Kinesiophobia compared with TAU F (1, 16) = 10.8, p = 0.005 partial eta squared = 0.40 (large effect) Depression compared with TAU F (1, 16) = 22.8, p < 0.001 partial eta squared = 0.60 (large effect) Depression compared to pre-treatment scores (PTS) F (3, 30) = 7.2, p = 0.001 partial eta squared = 0.44 (large effect) Pain interference compared to PTS F (1, 16) = 7.3, p = 0.016 partial eta squared = 0.31 (large effect) Pain avoidance compared with TAU F (1, 16) = 24.6, p < 0.001 partial eta squared = 0.61 (large effect). Pain avoidance compared to PTS F (3, 30) = 27.5, p < 0.001 partial eta squared = 0.73 (large effect) Psychological fusion compared with TAU F (1, 16) = 8.2, p < 0.011 partial eta squared = 0.34 (large effect) Psychological fusion compared to PTS F (3, 30) = 7.3, p = 0.007 partial eta squared = 0.42 (large effect)
Trompetter et al. [31]	HADS NRS PDI MHC-SF PIPS FFMQ-SF ELS PCS	ACT: Significant 3 month f/u reduction in: Pain intensity compared with expressive writing (EW) [treatment effect (95 %CI) 0.73 (0.0–1.4), p = 0.04, Cohen's d = 0.23 small effect]. Psychological Inflexibility compared with EW [treatment effect (95 %CI) 5.4 (1.3–9.6), p = 0.011, d = 0.4 small effect]. Psychological Inflexibility compared with WL [treatment effect (95 %CI) 8.6 (4.6–12.6), p < 0.001, d = 0.6 medium effect]. Pain catastrophising compared with WL [treatment effect (95 %CI) 3.7 (0.8–6.6), p = 0.013, d = 0.39 small effect]. Significant 6 month f/u reduction: Pain disability compared with EW [treatment effect (95 %CI) 5.6 (1.4–9.9), p = 0.011, d = 0.4 small effect].
Thorsell et al. [25]	TCS	Mean Treatment Credibility rating 33.4/50 (SD = 7.8). No significant differences across conditions.
Buhrman et al. [29]	HADS CSQ[2] MPI PAIRS QOLI	ACT: Significant post treatment reduction in: Anxiety compared with active WL [F (1, 73) = 5.88, p = 0.018] Cohen's d = 0.18 (CI 95% = −0.27–0.63) (small effect) Depression compared with active WL [F (1, 73) = 6.87, p = 0.01] d = 0.44 (CI 95% = −0.02–0.89) (small effect). No improvements or deterioration at 6 month follow up. Pain catastrophising compared with active WL [F (1, 73) = 6.10, p = 0.016] Cohen's d = 0.51 (CI 95% = −0.05–0.96) (medium effect)

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Table 4 (*continued*)

Author	2° outcome measures	Results from 2° outcome measures
		Praying and hoping compared with active WL [F (1, 73) = 9.46, $p = 0.003$] d = 0.28 (CI 95% = −0.02–0.89) (small effect). No improvements or deterioration at 6 month follow up. Pain interference compared with active WL [F (1, 73) = 9.49, p = 0.003] Cohen's d = 0.56 (CI 95% = −0.10–1.02) (medium effect) Affective distress compared with active WL [F (1, 73) = 5.08, p = 0.027] d = 0.30 (CI 95% = −0.12–0.78) (small effect) Significant 6 month f/u reduction in: Pain interference compared with active WL t (28) = 3.22, p = 0.003] Cohen's d = 0.32 (CI 95% = −0.13–0.77) (small effect)

AAQ II Acceptance Action Questionnaire II, BDI Beck Depression Inventory-II, CPAQ Chronic pain acceptance questionnaire, CSQ[1] Client Satisfaction Questionnaire, CSQ[2] Coping strategies questionnaire, ELS Engaged Living Scale, EQ-5D Pain VAS of EuroQol, FFMQ-SF Five Facet Mindfulness Questionnaire—Short Form, FIQ Fibromyalgia Impact questionnaire, HADS Hospital and anxiety depression scale, IES Impact of Event Scale, LSQ Life Satisfaction Questionnaire, MHC-SF Mental Health Continuum-Short Form, MPI Multidimensional pain inventory, MU Medical utilisation, NRS Pain intensity numeric rating scale, PAIRS Pain and impairment relationship scale, PASS Pain Anxiety Symptoms Scale, PCS Pain catastrophising scale, PDI Pain Disability Index, PIPS Psychological Inflexibility in Pain Scale, QOLI Quality of life Inventory, SES Self-Efficacy Scale, SF-12 Short-form Health Survey, SF-36 Short-form Health Survey 36, SOPA Survey of Pain Attitudes, STAIT State-trait Anxiety Inventory, TCS Treatment Credibility Scale, TSK Tampa Scale of Kinesiophobia and VAS Pain visual analogue scale.

up increases in pain willingness in the ACT group compared to PTS with medium effect sizes. Buhrman et al.'s [29] low quality RCT found significant post treatment increases in pain willingness in the ACT group compared to WL control with a small effect size.

3.6.9. Activities engagement

Two trials, Thorsell et al. [25] and Buhrman et al. [29] measured activities engagement using the CPAQ.

Thorsell et al. [25] reported significant post treatment, 6 and 12 month follow-up increases in activities engagement in the ACT group compared to PTS with large, medium and medium effect sizes respectively. Buhrman et al. [29] found significant post treatment increases in activities engagement in the ACT group compared to WL control with medium effect size.

3.6.10. Pain acceptance

Four trials measured pain acceptance using the CPAQ.

Luciano et al. [54], in their moderate quality RCT of participants with fibromyalgia, reported significant post treatment and 6 month follow up increases in pain acceptance in the ACT group compared to the RPT group and WL controls all with large effect sizes.

In a low quality RCT of 73 participants with chronic pain, McCracken et al. [16] found a significant 3 month follow up increase in pain acceptance in the ACT group compared to the TAU control group with medium effect size.

Kemani et al.'s [18] low quality non-controlled randomised RCT of 60 participants with longstanding pain reported a significant post treatment increase in pain acceptance in the ACT group compared to the applied relaxation (AR) group and PTS with large and small effect sizes respectively.

Thorsell et al.'s [25] low quality non-controlled randomised trial reported significant post treatment, 6 and 12 month follow up increase in pain acceptance in the ACT group compared to PTS with large, medium and medium effect sizes respectively.

3.6.11. Psychological inflexibility

Two trials measured psychological inflexibility using the Psychological Inflexibility in Pain Scale (PIPS).

In a low quality RCT of 40 female participants with fibromyalgia, Wicksell et al. [24] found a significant post treatment reduction in psychological inflexibility in the ACT group compared to the WL control with large effect size.

Trompetter et al.'s [31] low quality RCT of 238 participants reported a significant 3 month follow up reduction in psychological inflexibility in the ACT group compared with the expressive writing EW and WL controls with small and medium effect sizes respectively.

3.6.12. Psychological fusion

The Psychological Inflexibility in Pain Scale (PIPS) assesses psychological inflexibility, a central construct in ACT, in relation to chronic pain. The scale contains a 6 item 'fusion with pain' subscale.

In a low quality, small sample RCT of participants with chronic pain and WAD, Wicksell et al. [23] found significant post treatment reductions in psychological fusion in the ACT compared with the TAU group and PTS with large effect sizes.

3.6.13. Pain avoidance

In a low quality, small sample RCT, Wicksell et al. [23] found significant post treatment reductions in pain avoidance in the ACT group compared to the TAU group and PTS with large effect sizes using the PIPS.

3.6.14. Increase in physical health

Kemani et al.'s [18] low quality non-controlled randomised trial found significant post treatment increase in physical health in the ACT group compared to PTS with medium to large effect size using the Short Form Health Survey (SF12).

3.6.15. Level of function

In a low quality non-controlled randomised trial of 115 chronic pain participants, Thorsell et al. [25] found significant post treatment and 6 month follow up increases in level of function in the ACT group compared to PTS with small effect sizes using the OMPQ.

3.6.16. Satisfaction with life

Two trials measured satisfaction with life. Wicksell et al. [23] used the Satisfaction with Life Scale (SWLS) and Thorsell et al. [25] used the OMPQ.

Wicksell et al.'s [23] small sample RCT reports significant post treatment increase in satisfaction with life in the ACT group compared to TAU and to PTS with large effect sizes.

In their low quality non-controlled randomised trial, Thorsell et al. [25] report significant post treatment increases in satisfaction with life in the ACT group compared to the WL control and PTS (medium and large effects).

3.6.17. Sick leave utilisation and medical utilisation

In a small, low quality RCT of 19 participants confirmed at risk of increasing stress, pain and sick leave utilisation from the workplace, Dahl et al. [53] found a significant post treatment reduction in sick leave utilisation and medical utilisation in the ACT group compared to medical treatment as usual (MTAU) with medium effect sizes.

3.6.18. Subjective pain

In a moderate quality RCT of 156 participants, Luciano et al. [54] found significant post treatment and 6 month follow up reduction in subjective pain in the ACT group compared to the RPT group and WL control with medium, small, medium and medium effect sizes respectively using the Pain visual analogue scale (VAS).

3.6.19. Praying and hoping and affective distress

Buhrman et al.'s [29] low quality RCT found significant post treatment reduction in praying and hoping and affective distress in the ACT group compared with the WL control with small effect sizes using the CSQ and the Pain and Impairment Relationship Scale (PAIRS) outcome measures respectively.

3.6.20. Patient's global impression of change

In a low quality RCT of 73 participants with chronic pain, McCracken et al. [16] found a significantly greater number of participants reporting post treatment improvement in global impression of change in the ACT group when compared to TAU using the Short-form Health Survey 36 (SF-36).

3.6.21. Kinesiophobia

Wicksell et al. [23] report a significant post treatment reduction in kinesiophobia in the ACT group when compared to TAU with large effect size using the Tampa Scale of Kinesiophobia (TSK).

3.6.22. Mental health quality of life and self-efficacy

In a low quality RCT of 40 female participants with fibromyalgia, Wicksell et al. [24] found a significant post treatment increase in mental health quality of life and self-efficacy in the ACT group compared to the WL control with medium effect sizes using the SF36 and Self-Efficacy Scale (SES) outcome measures respectively.

3.7. Mediation analysis

In a low quality RCT of 40 female participants with fibromyalgia using the PDI, Wicksell et al. [24] reported that a decrease in psychological inflexibility from pre to post assessment significantly mediated improvements in pain disability, FM impact, self-efficacy, depression, state anxiety and trait anxiety.

Wetherell et al. [30], in their moderate-quality non-controlled randomised trial of 114 participants, found that pain acceptance did not mediate treatment response in the ACT group and Luciano et al. [54], in a moderate quality RCT involving participants with fibromyalgia, found that pain acceptance did not mediate change in functional status, pain catastrophizing, subjective pain, anxiety or depression.

4. Discussion

ACT aims to increase pain acceptance and reduce psychological inflexibility which, theoretically, act to mediate behavioural change in response to chronic pain [16,25].

Moderate and low quality evidence indicates that ACT appears to have a significant effect upon improving pain willingness [25,29], activities engagement [25,29] and pain acceptance [16,18,25,54].

However, determining pain acceptance, by combining scores from the two CPAQ subscales of pain willingness and activities engagement, may be unreliable or misleading. Whilst a higher combined score might suggest a higher level of pain acceptance [25], the identification of a distinct subgroup in chronic pain populations with high activities engagement and low pain willingness scores [58] indicates that this may not always be the case.

Wetherell et al. [30] and Luciano et al.'s [54] moderate quality evidence show that increases in pain acceptance did not mediate treatment responses, changes in functional status, pain catastrophizing, subjective pain, anxiety or depression indicating that evidence for the theoretical mechanisms of change underpinning the six core processes of ACT [19,59] is conflicting. However, Wetherell et al. [30] report the difficulties encountered in their analysis of mediation when comparing ACT to CBT interventions without a control group.

Wicksell et al.'s [24] results provide low quality evidence suggesting that reductions in psychological inflexibility did significantly mediate improvements in pain disability, FM impact, self-efficacy, depression, state anxiety and trait anxiety.

Low quality evidence suggests that ACT appears to have a significant effect upon reducing psychological inflexibility [24,31] and psychological fusion [23]. Effect sizes varied from large [23,25] to small and medium [31] using the same outcome measure, PIP. These results, in contrast to those of Wetherell et al. [30] and Luciano et al.'s [54], indicate support for the theoretical mechanisms of change in ACT [19,52], the aim of which is to modify ongoing behaviours [16] associated with chronic pain rather than alleviation of symptoms.

Evidence from the 10 reviewed trials, incorporating 44 primary and secondary outcome measures, suggests support for the effectiveness of ACT and reflects the large numbers of outcome measures used.

Moderate and low quality evidence suggests that ACT had a significant effect in reducing pain interference [23,29–31], pain disability [18,23,24,31], pain catastrophising [29,31,54], pain intensity [18,25,31], fibromyalgia impact [24,54], anxiety [18,24,25,29,54] and depression [16,18,23–25,29,30,54]. Magnitude of effect sizes for reductions in pain interference were large [23], medium [29] and small [31]; pain disability, large [23], medium [18,24] and small [31]; pain catastrophising, medium [29,54] and small [31]; pain intensity, small [18,25,31]; fibromyalgia impact, small [24] and very large [54]; anxiety, small [18,29,54], medium [24,25,54]; depression, small [16,18,24,25,29,54], medium [25,54] and large [23].

Evidence also suggests that ACT had a significant effect in reducing subjective pain [54], pain avoidance [23], sick leave and medical utilisation [53], praying and hoping, affective distress [29], and kinesiophobia [23]. Magnitude of effect sizes for reductions in subjective pain were medium [54]; pain avoidance, large [23]; sick leave and medical utilisation, medium [53]; praying and hoping and, affective distress, small [29], and kinesiophobia, large [23].

Evidence further suggested that ACT had a significant effect in increasing physical health [18], level of function [25] satisfaction with life [23,25], patient's global impression of change [16], and mental health quality of life and self-efficacy [24]. Magnitude of effect sizes for increases in physical health were medium [18]; level of function, small [25]; satisfaction with life, small, medium [25] and large [23]; mental health quality of life and self-efficacy, medium [24].

Heterogeneity across sample populations, ACT interventions, outcome measures and risk of bias ratings [33] precluded opportunities for meta-analysis. For example, of the eight trials measuring depression, five trials used HADS, two BDI and one PHQ9. Those measuring with HADS used four different ACT interventions. Two trials with similar ACT interventions used different sample populations.

Two further opportunities were identified to combine data using meta-analysis. Firstly, we considered combining data from two trials indicating significant reductions in pain interference [29,31]; both trials were internet based ACT interventions utilising the MPI outcome measure. However, sample numbers were small, there was a borderline rating of high ROB and differences existed in the format of the ACT intervention. Secondly, we

considered combining data indicating significant reductions in the impact of fibromyalgia [24,54]. Both trials investigated group administered ACT interventions utilising the FIQ outcome measure and were similarly rated in terms of ROB. However, sample populations in both trials were small, mixed in one trial [54] and all female in the other [24]. There were marked differences in the number and length of time of ACT interventions and the sizes of the groups receiving ACT.

Trials meeting the eligibility criteria for inclusion in this systematic review were predominantly effectiveness or 'pragmatic' trials [33,47] investigating the degree of beneficial effect under "real world" clinical settings [54]. They are not consistent with the criteria of efficacy trials wherein there is high internal validity [60] with potentially low generalisability. According to Gartlehner et al. [60], the sample size of an effectiveness trial should be sufficient to detect at least a minimally important difference [61] on a health-related quality of life scale. Minimally important difference is defined as the smallest difference in score in the domain of interest, which patients perceive as beneficial and which would mandate, in the absence of troublesome side effects and excessive cost, a change in the patient's management [62,63]. Gartlehner et al. [60] propose a minimum starting sample size of n = 75 participants per treatment arm to factor in a possible attrition of 15 percent i.e. n = 63 to detect a minimally important difference. One of the 10 included trials meets this particular criterion [31]. Only one trial reports on sample size calculation [54]. It is unclear whether sample numbers in the remaining included trials are sufficient for detection of a minimally important difference.

Whilst mindfulness is implicit in ACT, four of the methodologically stronger RCTs make no specific mention of it [16,18,23,30]. Only one trial measures and reports on mindfulness utilising the Five Facet Mindfulness Questionnaire [31].

Mindfulness and acceptance practice involves development of present moment awareness [19,53]. Whilst practicing present moment awareness, the potential exists for participants' post ACT intervention scores e.g., of anxiety or depression, to remain erroneously high, since they are more aware of those experiences, thereby masking potential positive behavioural changes. Whilst it may be argued that participants' developing acceptance may mitigate this effect, it serves to emphasise the need to develop a consensus for measuring appropriate functional, contextual and behavioural outcomes from ACT, rather than changes in levels of symptoms.

5. Limitations

This study reviewed English language papers only and is therefore likely to be subject to publication bias. No grey literature was included in the search.

The first author conducted all levels of the literature search, title and abstract screening, full-test screening and data extraction, and acknowledges the likelihood of selection bias. Issues pertaining to internal and external validity are present in all primary sources, meaning, that having been selected for inclusion, they are necessarily present in this review.

The inability to statistically pool data rendered qualitative synthesis the only option in this review.

6. Conclusion

The aim of this systematic review was to evaluate the effectiveness of ACT as an intervention for patients experiencing chronic pain.

Moderate and low quality evidence suggests that ACT demonstrates promise as a therapeutic intervention for non-malignant, chronic pain populations with significant effects across a number of pain, anxiety and depression related outcomes.

However, conflicting evidence exists for the theoretical mechanisms of change underpinning ACT. Moderate quality evidence does not appear to provide support for pain acceptance as a mediator of change whereas low quality evidence suggests that reductions in psychological inflexibility mediate change in pain, depression and anxiety related outcomes.

Osteopaths should consider the role of ACT as an adjunct to treatment for patients with chronic MSK pain. However, the findings should be interpreted judiciously due to the low to moderate quality of evidence, heterogeneity of trials, conflicting findings and inability to conduct meta-analysis.

Further high quality research is warranted to evaluate ACT's effectiveness as an intervention for chronic MSK pain in conjunction with other therapies including manual therapy and lifestyle interventions. The utilisation of less disparate outcome measures would likely enhance data pooling and increase generalisability.

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