ACCEPTANCE-BASED INTERVENTIONS FOR THE TREATMENT OF CHRONIC PAIN. A SYSTEMATIC REVIEW AND META-ANALYSIS.

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ABSTRACT

Acceptance-based interventions such as Mindfulness-Based Stress Reduction program (MBSR), and Acceptance and Commitment Therapy (ACT) are alternative therapies for Cognitive-Behavioural Therapy (CBT) for treating chronic pain patients. The aim of this review was to analyze the overall effects of acceptance-based interventions on patients with pain. We undertook a systematic review and meta-analysis of controlled, uncontrolled, and unpublished studies from four databases from inception to January 2009 which reported on an effect study with an acceptance-based intervention with pain patients. Methodological quality was assessed, and data extraction undertaken by one reviewer with a second reviewer checking for accuracy. The fixed-effects model to estimate the intervention effect among controlled studies was used, and the random-effects model to calculate an average effect among all studies. Main outcome measures were pain intensity and depression. Anxiety, physical wellbeing and quality of life were also extracted. Twenty-two studies (9 RCT's, 15 controlled, 7 uncontrolled) totalling 1511 patients met inclusion. An effect on pain of 0.37 was found for the controlled studies. The effect on depression was 0.32. When comparing directly, a small effect (0.36) was found for acceptance-based interventions compared to CBT for depression. This data suggests that acceptance-based interventions are at least as effective as CBT for chronic pain patients.

INTRODUCTION

Chronic pain is a major health problem, and has high comorbidity with depression (35%) and other psychological problems [39]. The cognitive-behavioural perspective introduced in 1983 [59] emphasized the role of attributions, efficacy expectations, personal control, and problem solving. Cognitive-Behavioural Therapy (CBT) became the standard treatment intervention for chronic pain patients, with an emphasis on individual information processing. It assumes that thoughts and beliefs may alter behaviour by their direct influence on emotional and physiological responses. There is good evidence that active psychological treatments based on the principle of CBT are effective, with moderate effect-sizes ranging from 0.5 [41] to 0.62 [26]. Although CBT is considered evidence-based, effects for CBT are not very large. The main reason is that not all patients benefit from CBT [57, 60].

Alternative therapies have developed in the last years, their central focus is not on fighting pain, but on acceptance of pain. One of those programs is the Mindfulness-Based Stress Reduction program (MBSR) [29]. Mindfulness consists of the practice of being aware of thoughts, actions and existence in the present moment, non-judgmentally. It teaches skills that facilitate detached observation and reduce the experience of suffering via cognitive re-appraisal. Participants take part in an 8-week group program with groups of 10-15 participants, with sessions of 2.5 hours each week. Additionally there is an 7-hour session after the 5th week. Excercises include different types of formal mindfulness practice, mindful awareness during yoga postures, and mindfulness during stressful situations and social interactions. Mindfulness-based cognitive therapy (MBCT) [52] is based on Kabat-Zinn's [29] MBSR program, but incorporates elements of cognitive therapy, and was designed to prevent depressive relapse.

Another acceptance-based intervention is Acceptance and Commitment Therapy (ACT) [22]. ACT targets ineffective control strategies and experiential avoidance. The main difference with CBT is the use of negative thoughts associated with pain as targets for exposure rather than attempting to change their irrational content (13). ACT uses mindfulness excercises, but goes further than accepting thoughts and emotions. ACT increases participants' ability to act on their values rather than on other private experiences such as thoughts and feelings [35].

The aim of this study was to analyze the overall effects of acceptance-based interventions on patients with pain, and the influence on these effects of possible moderating factors. To our knowledge there is no systematic review which measures the effects of acceptance-based studies, such as ACT and Mindfulness, on pain patients. Teixeira [55] studied the effects of meditation on pain, and suggests that meditation programs may help ease the burden of chronic pain on short- and long-term. However, she did not perform a meta-analysis, nor assessed the quality of the included studies. Baer [3] also conducted a meta-analysis on mindfulness, and found significant improvements in ratings on pain (0.31) and depression (0.86). She did not include ACT, nor assessed the quality of the included studies. Moreover, this study is dated and only includes four studies examining chronic pain.

METHODS

Search strategy

A systematic search was performed in four electronic databases: PubMed (1966 – January 2009), EMBASE (- to January 2009), PsycInfo (1960 - January 2009) and the Cochrane Central Register of Controlled Trials (1800 – January 2009). The databases were searched for English language studies using the following terms: 'mindfulness' or 'vipassana' or 'meditation' or 'mindfulness-based stress reduction' or 'MBSR' or 'mindfulness-based cognitive therapy' or 'MBCT' or 'acceptance-based' or 'acceptance

based' or 'acceptance and commitment', in combination with 'chronic pain' or specific chronic pain conditions including 'fibromyalgia' or 'chronic fatigue syndrome' or 'chronic low back pain' or 'whiplash associated disorder' or 'WAD' or 'repetitive strain injury' or 'RSI' or 'dystrophy'. Furthermore, the reference lists of included studies were examined for additional potentially eligible studies.

Selection of studies

Two reviewers (MO and MV) independently selected potentially eligible studies on the basis of title and abstract. The inter-rater reliability was 80% and most of the inconsistencies in the judgements were due to conservative scoring. Disagreements were resolved by consensus. Studies were included if they reported on the effectiveness of a standardized acceptance- or mindfulness based treatment program in patients with chronic pain or chronic pain related conditions. Both controlled (randomized controlled studies and quasi-experimental studies) and uncontrolled were included to estimate within-groups changes, as well as published and unpublished (e.g., dissertations) studies. Studies were excluded if (1) mindfulness or acceptance was just one of several modalities provided simultaneously to the treatment group, (2) the intervention consisted of a single treatment session, (3) no abstract was available, or (4) insufficient data was reported to calculate standardised mean differences. We have requested the full text articles whereupon the definitive selection was made by two reviewers (MO and MV). The inter-rater reliability was 93%.

Data extraction

Data extraction and study quality assessment was performed by one reviewer (MO) and checked by a second reviewer (MV) using a standardized data abstraction form created for the study. Disagreements were resolved, if possible, by consensus and otherwise by consultations with a third reviewer (EB). Data were extracted on design, country, characteristics of participants, intervention type, control or comparison group and attrition rate. The primary outcome of our review was pain intensity. Depression was a secondary outcome. We also recorded outcome data on anxiety, quality of life and physical wellbeing. When a study included a comparison group (e.g., CBT) these data were analyzed seperately and were not included in the pooled estimate for control groups.

Quality Assessment

Methodological quality of included studies was assessed using a 9-point scale, based on criteria by the Cochrane Collaboration [24] and the validated Jadad scale [27] tailored for the included studies (displayed on the next page). Disagreements were resolved by discussion, and each study was assigned a quality score. The quality of the study was assesed as high when 7 or more criteria were met, medium when 4,5 or 6 criteria were met, and low when 3 or less criteria were met.

Data analysis

For this meta-analysis, Hedges'g effect sizes were calculated using Microsoft Excel with the following formula: $g = M_1 - M_2 / S_{pooled}$, where $S = \sqrt{[\Sigma(X - M)^2 / N-1]}$, and $S_{pooled} = \sqrt{}$Mswithin. Cohen [8] has described effect sizes 0.2, 0.5, and 0.8 as small, medium, and large, respectively. If no means and standard deviations were reported, other test statistics (*p, t*, confidence intervals) were converted into Hedges' g [23]. We compared posttest scores from the control group and experimental group to calculate Hedges' g. We also included non-controlled studies, therefore we calculated Hedges' g based on pretest and posttest scores from the intervention group for all studies. Note that we calculated two estimates for controlled studies: one compared posttest scores between control and experimental group, the other compared pretest and posttest results from the experimental group.

We used RevMan software version 5.0.18 for calculating pooled standardized mean

Quality criteria

A	Allocation to conditions was based on randomization according to the text.	1/0
B	The randomization scheme was described and appropriate, e.g. using a computer, random number table.	1/0
C	Study reported that participants were blinded for the treatment they received and were not aware of all the present groups.	1
	No control group, or a waitlist control group, or blinding not mentioned.	0
D	A drop-out analysis was conducted, or there were no drop-outs.	1
	Reasons of attrition were reported, but no analysis was conducted.	0
E	Intention to treat analysis was performed, or there were no drop-outs.	1/0
F	At least one of the trainers was experienced or trained in teaching Mindfulness or ACT	1
	Specific experience or training was not reported.	0
G	Patient's pain was diagnosed by a physician or rheumatologist, or patients were referred from a pain clinic were diagnosis is prior to admission.	1
	Recruitment through media, or diagnosis based on a scale and self-report, or diagnosis not mentioned.	0
H	The study had a minimal level of statistical power to find significant effects of the treatment, and included 50 or more persons in the comparison between treatment and control group (this allows the study to find standardized effect sizes of 0.80 and larger, assuming a statistical power of 0.80 and alpha of 0.05)	1
	Sample smaller than 50, or the total the sample was bigger than 50, but the results were only reported divided by different studies.	0
I	Treatment integrity was checked during the study by supervision of the therapists during treatment, or by recording the treatment sessions, or by systematic screening of protocol adherence by a standardized measurement instrument.	1
	Treatment integrity was not checken, or integrity was supervised by one of the therapists, or they tried to keep the intervention sound by intensive consultation.	0

differences (SMD), to test heterogeneity and to perform subgroup analyses. Pooled SMD's for the controlled studies, and comparison with CBT were calculated using the fixed-effects model, since we observed minimal clinical and methodological diversity between the controlled studies. By using the fixed-effects model it is assumed that the observed differences among study results are due solely to the play of chance [14].

When non-controlled studies were included, pooled SMD's were calculated using the random-effects model, also known as the DerSimonian and Laird model [15]. Since there is a major methodological diversity between controlled and non-controlled studies (e.g. risk of bias and study design) we consider studies to be heterogenous. When using the random-

effects model, an average intervention effect is calculated instead of an estimate of the intervention effect.

The chi-square test was used to measure significant statistical heterogeneity. Statistical heterogeniety is an indicator of clinical and methodological heterogeneity. The I2-statistic was calculated for indication of the heterogeneity in percentages [14, 25]. A value of 0% indicates no observed heterogeneity, and larger show increasing heterogeneity. 0-40% is considered as low heterogeneity, 30-60% may represent moderate heterogeneity, 50-90% may represent substantial heterogeneity and 75-100% is considerable heterogeneity. When using the random-effects model, Tau2-statistic was calculated, which is an estimate of the between-study variance.

Subgroup analyses were performed by testing pooled SMD's for significant differences between subgroups in RevMan. Analyses were only performed for the controlled studies, and by the following subdivision: (1) Quality score divided by low, medium and high quality as mentioned earlier, (2) subgroups for control group. Included studies used waitlist controls, education/support groups, or Treatment As Usual (TAU). One study [20] included waitlist and no interest controls, but data was nog presented seperately. These data were scored as waitlist controls. One study [65] placed participants on a waiting list, but offered them treatment as usual as well, and were scored in this study as waitlist controls, (3) intervention type; ACT-based or MBSR-based, (4) type of pain in four subgroups; mixed chronic pain populations, fybromyalgia combined with Chronic Fatigue Syndrome (CFS), rheumatoid arthritis, and special site pain populations (e.g. chronic low back pain, chronic headache), (5) attrition rate higher or lower than 25%.

To assess for publication bias, we performed a funnel plot [14] for the controlled studies by plotting the pooled SMD against study size. When publication bias is absent, the studies can be expected to be distributed symmetrically around the pooled effect size. Bias can be expected when the plot shows a higher concentration of studies on one side of the pooled SMD than on the other.

RESULTS

Initially 1121 titles were retrieved from the databases (PubMed 894, PsycInfo 89, Cochrane 32, Embase 106). After review of title and abstract and removal of duplicates, 40 studies were identified as being potentially eligible for inclusion in the study. Full-text versions of these papers were obtained and independently assessed by two reviewers (MO and MV). 18 of the 40 articles were excluded for the following reasons: no acceptance-based intervention [7, 10, 17, 34, 36, 38, 56], insufficient data [30, 32, 40, 46, 48, 63], sample contained other than pain patients [1, 6, 9], same used in two publications [51], and inconsistencies in the intervention protocol [64]. Therefore 22 were included in this systematic review, 15 controlled [2, 5, 13, 18, 20, 21, 42, 43, 47, 50, 53, 54, 61, 65, 66], and 7 uncontrolled [28, 31, 36, 37, 44, 49, 62], from which 9 RCT's [2, 5, 13, 42, 43, 47, 53, 65, 66]. Some controlled studies also included a non-controlled sub-study, which we also included [54, 61].

Characteristics of Included Studies

Characteristics of the selected studies are presented in Table 1. The 22 studies included in the analysis evaluated 1511 subjects. In general, the participants were adults with a mean age between 40 and 60. In all studies, except 2 [32, 62] the majority of the participants was female. In 7 studies the attrition rate was higher than 25%. 18 studies measured pain, 21 depression, 13 anxiety, 13 physical wellbeing, and 5 quality of life. All instruments had good psychometric properties. Study size ranged from a small pilot study of 17 subjects [55] to a large-scale study involving 156 subjects [19]. 16 studies used a MBSR(-based) program, and 6 studies ACT(-based). Most studies held 8 weekly sessions in a range from 1 hour to 2.5 hours, a minority treated their patients full time for 3 or 4 weeks.

TABLE 1 - STUDY CHARACTERISTICS

Controlled trials	Study Design	Country	Pain	Mean age (SD or range)	% Male	Intervention type	Group size	sessions, duration	Control group	n	Attrition rate	Outcome measures
Astin (2003)	RCT	USA	Fibromyalgia	T: 47.7 (10.6)	T: 0.8% I: 1.6% C: 0%	MBSR + Qigong	10-20	8, 2.5h	Education/support	I: 32 C: 33	39%	Pain: SF-36 Depression: BDI QoL: FIQ
Bruckstein (1999)	RCT	USA	Chronic pain	T: 56.4 (13.7)	T: 26.6% I: 22.7% C: 38.9%	MBSR		8, 1.5h	Education/support CBT group	I: 15 C: 7 CBT: 17	T: 39.1 I: (n=7) C: (n=11)	Pain: VAS Depression: BDI Anxiety: SCL-90 Physical: SIP
Dahl (2004)	RCT	USA	Chronic pain	T: 40 (13.2) I: 36.7 (12.5) C: 44.4 (13.6)	10.5%	ACT	Individual	4, 1h	TAU	I: 11 C: 8	0%	Pain QoL: LSQ
Gardner-Nix 2008	CCT	Canada	Chronic pain	I: 51 C: 52	I: 20%, C: 25%	MBSR	10-20	10, 2h	Waitlist	I: 99 C: 57	I: 49% C: 10%	Pain Physical: SF-36
Goldenberg (1994)	CCT	USA	Fibromyalgia	I: 46 (9.9) C: 47.2 (11.8)	I: 10% C: 3%)	MBSR	7-12	10, 2h	Waitlist (n=18) No interest (n=24)	I: 79 C: 42	I: 9.2%	Pain: VAS QoL: FIQ
Grossman (2007)	CCT	Zwitser-land	Fibromyalgia	T: 52 (8) I: 54.4 (8.3) C: 48.8 (9.1)	0%	MBSR	10-15	8, 2.5h	Education/support	I: 39 C: 13	T: 10.3% I: 9.3% C: 13.3%	Pain: VAS Depression: HADS Anxiety: HADS Coping: IPR QoL
Morone (2008)	RCT	USA	Chronic Low Back Pain	T: 74.9 (65-84)	43%	MBSR		8, 1.5h	Waitlist	I: 19 C: 18	T: 19% I: 32% C: 6%	Pain: MPQ-SF Coping: CPAQ Physical: SF-36 QoL
Nash-Mc Feron (2006)	RCT	USA	Chronic headache	I: 50 (14.6) C: 51 (12.2)	I: 0% C: 35%	MBSR	20	8, 1.5h	TAU	I: 20 C: 20	I: 5% C:10%	Pain: SF-36 Physical: SF-36
Pradhan (2007)	RCT	USA	Rheumatoid Arthritis	I: 56 (9) C: 53 (11)	I: 16% C: 9%	MBSR	Cohort I: 18 Cohort II:13	8, 2.5h	Waitlist	I: 32 C: 32		Depression: SCL-90
Sagula (2004)	CCT	USA	Chronic pain		23.9	MBSR	7-10	8, 1.5h	TAU	I: 39 C: 18	T: 19.7% I: 20.4% C:18.2%	Depression: BDI Anxiety Coping
Sephton (2007)	RCT	USA	Fibromyalgia	T: 48.2 (10.6) I: 48.4 (8.9) C:47.6 (11.5)	0%	MBSR	25	8, 2.5h	Waitlist	I: 51 C: 39	25,3%	Depression: BDI
Surawy (2005) study 1	CCT	UK	Chronic Fatigue Syndrome	(18-65)	44.4%	MBSR	9	8	Waitlist	I: 9 C: 8	T: 6%	Depression: HADS Anxiety: HADS Physical: SF-36
Vowles (2009) study 2	CCT	USA	Chronic pain	T: 50.4 (17.8)	82%	ACT	2-3	4, 1.5h	CBT	I: 11 C: 11		Pain: MPQ Depression: CES-D Anxiety: PASS Coping: CPAQ Physical: PDI
Wicksell (2008)	RCT	zweden	Whiplash-associated disorders	I: 48.2 (7.8) C: 55.1 (11.2)	38.5%	ACT	individueel	10, 1h	Waitlist + TAU	I: 11 C: 9	T: 4.8% I: 0% C: 10%	Pain Depression: HADS Anxiety: HADS Physical: PDI QoL: SWLS
Zautra (2008)	RCT	USA	Rheumatoid Arthritis	I: 57.3 (15.3) C: 52.4 (13.0)	31.9%	MBSR	6-10	8	Education/support CBT groep	I: 47 C: 44 CBT: 52	T: 3.5-4.3%	Pain Depression Coping

TABLE 1 - CONTINUED

Uncontrolled Trials	Study Design	Country	Pain	Mean age (SD or range)	% male	Intervention type	Group size	sessions, duration	Control group	n	Attrition rate	Outcome measures
Kabat-Zinn(1982) Study 2	OD	USA	Chronic pain	45.9 (22-67)	35.3%	MBSR	15-20	10, 2h	-	16	12,1%	Pain: MPQ Depression: POMS
Kabat-Zinn (1982) Study 3	OD	USA	Chronic pain	47.2 (29-75)	37.5%	MBSR	15-20	10, 2h	-	24		Pain: MPQ Depression: POMS
Kabat-Zinn (1985)	OD	USA	Chronic pain	48	62%	MBSR	15-20	10, 2h	TAU (unused)	73	10 - 20%	Pain: MPQ Depression: POMS
McCracken (2007)	OD	UK	Highly diasabled chronic pain patients	47.6 (11.6)	35.8%	ACT		3 weeks full time, 80h	-	53	0%	Pain Depression: BDI Anxiety: PASS Coping: CPAQ Physical: SIP
McCracken (2005)	OD	UK	Complex chronic pain	44.4 (10.7)	35.8%	ACT		3 or 4 weeks full time	-	108	23,9%	Pain Depression: BDI Anxiety: PASS Coping: CPAQ Physical: SIP
Pauzano-Slamm (2005)	OD	USA	Chronic Fatigue Syndrome	52.4 (14.2)	23.6%	MBSR	4-5	8, 1.5h	-	16	17,7%	Depression: BDI Anxiety: BSI-18
Randolph (1999)	OD	USA	Chronic pain	49.7	31%	MBSR	9	8, 2h	-	78		Pain: VAS Depression: POMS
Surawy (2005) study 2	OD	UK	Chronic Fatigue Syndrome	(18-65)	25%	MBSR	12	8	-	10	18%	Depression: HADS Anxiety: HADS Physical: SF-36
Surawy (2005) study 3	OD	UK	Chronic Fatigue Syndrome	(18-65)	36%	MBSR	11		-	9	18%	Depression: HADS Anxiety: HADS Physical: SF-36
Vowles (2009) study 1	OD	USA	Chronic pain	49.5 (6.9)	36.4%	ACT	6	8, 1.5h	-	11	31,3%	Pain: MPQ Depression CES-D Anxiety: PASS Coping: CPAQ Physical: PDI
Vowles (2008)	OD	UK	Chronic pain	47.3 (11.4)	35.8%	ACT		3 or 4 weeks full time	-	171	8,6%	Pain Depression: BCMDI Anxiety: PASS Coping: CPAQ Physical: SIP

Note.
RCT: Randomised Controlled Trial, CCT: Clinical Controlled Trial, OD: Other Design (pre-posttest)
T: Total sample, I: Intervention group, C: Control group, CBT: Cognitive Behavioural Therapy

TABLE 1 - CONTINUED

Controlled trials	A	B	C	D	E	F	G	H	I	Score
Astin (2003)	1	1	0	1	0	0	1	1	0	**5**
Bruckstein (1999)	1	0	1	1	1	1	1	1	1	**8**
Dahl (2004)	1	0	1	1	1	1	0	0	0	**5**
Gardner-Nix 2008	0	0	0	0	0	0	0	1	0	**1**
Goldenberg (1994)	0	0	0	1	0	0	1	1	0	**3**
Grossman (2007)	0	0	0	0	0	1	1	1	0	**3**
Morone (2008)	1	1	0	1	1	1	0	0	0	**5**
Nash-Mc Feron (2006)	1	0	0	1	1	1	1	0	0	**5**
Pradhan (2007)	1	1	0	1	0	1	1	1	0	**6**
Sagula (2004)	0	0	0	1	0	1	1	1	0	**4**
Sephton (2007)	1	0	0	1	1	1	1	1	0	**6**
Surawy (2005) study 1	1	0	0	0	0	0	1	0	0	**2**
Vowles (2009) study 2	0	0	0	0	0	1	0	0	0	**1**
Wicksell (2008)	1	1	0	1	1	1	0	0	0	**5**
Zautra (2008)	1	1	1	1	1	0	1	1	1	**8**
Uncontrolled Trials										
Kabat-Zinn(1982)	0	0	0	0	0	0	1	0	0	**1**
Kabat-Zinn (1985)	0	0	0	0	0	1	1	1	0	**3**
McCracken (2007)	0	0	0	1	1	0	0	1	0	**3**
McCracken (2005)	0	0	0	1	0	0	0	1	0	**2**
Pauzano-Slamm (2005)	0	0	0	0	0	1	1	0	1	**3**
Randolph (1999)	0	0	0	0	0	1	0	1	0	**2**
Surawy (2005) study 2	1	0	0	0	0	0	1	0	0	**2**
Vowles (2009) study 1	0	0	0	0	0	1	0	0	0	**1**
Vowles (2008)	0	0	0	1	0	0	1	1	0	**3**

TABLE 2 - EFFECTS

	n	**Pooled standardized mean difference [Confidence Interval]**	**Heterogeneity**	**Test for overall effect**
RCT's				
Pain	7	0.25 [0.01, 0.49]	Chi^2 = 8.46, df = 6 (P = 0.21); I^2 = 29%	Z = 2.06 (P = 0.04)
Depression	6	0.26 [0.05, 0.47]	Chi^2 = 6.46, df = 5 (P = 0.26); I^2 = 23%	Z = 2.39 (P = 0.02)
Anxiety	3	0.54 [0.12, 0.97]	Chi^2 = 0.05, df = 2 (P = 0.97); I^2 = 0%	Z = 2.50 (P = 0.01)
Physical wellbeing	4	0.43 [0.04, 0.82]	Chi^2 = 2.06, df = 3 (P = 0.56); I^2 = 0%	Z = 2.16 (P = 0.03)
Quality of life	4	0.25 [-0.10, 0.59]	Chi^2 = 3.02, df = 3 (P = 0.39); I^2 = 1%	Z = 1.41 (P = 0.16)
All controlled trials				
Pain	10	0.37 [0.20, 0.53]	Chi^2 = 10.41, df = 9 (P = 0.32); I^2 = 14%	Z = 4.36 (P < 0.01)
Depression	9	0.32 [0.13, 0.50]	Chi^2 = 7.75, df = 8 (P = 0.46); I^2 = 0%	Z = 3.32 (P = 0.01)
Anxiety	5	0.40 [0.07, 0.73]	Chi^2 = 1.21, df = 4 (P = 0.88); I^2 = 0%	Z = 2.36 (P = 0.02)
Physical wellbeing	6	0.35 [0.10, 0.59]	Chi^2 = 2.44, df = 5 (P = 0.79); I^2 = 0%	Z = 2.78 (P < 0.01)
Quality of life	6	0.41 [0.16, 0.65]	Chi^2 = 4.68, df = 5 (P = 0.46); I^2 = 0%	Z = 3.25 (P < 0.01)
Effect size based on pre- and posttest scores: all studies included				
Pain	17	0.47 [0.28, 0.66]	Tau^2 = 0.08; Chi^2 = 40.90, df = 16 (P = 0.0006); I^2 = 61%	Z = 4.89 (P < 0.01)
Depression	21	0.64 [0.43, 0.85]	Tau^2 = 0.16; Chi^2 = 77.19, df = 20 (P < 0.00001); I^2 = 74%	Z = 5.92 (P < 0.01)
Anxiety	13	0.69 [0.51, 0.88]	Tau^2 = 0.03; Chi^2 = 18.24, df = 12 (P = 0.11); I^2 = 34%	Z = 7.39 (P < 0.01)
Physical wellbeing	13	0.48 [0.27, 0.68]	Tau^2 = 0.06; Chi^2 = 24.66, df = 12 (P = 0.02); I^2 = 51%	Z = 4.48 (P < 0.01)
Quality of life	5	0.63 [0.28, 0.98]	Tau^2 = 0.05; Chi^2 = 5.78, df = 4 (P = 0.22); I^2 = 31%	Z = 3.58 (P < 0.01)
Effect size comparison acceptance-based and CBT interventions				
Pain	3	0.22 [-0.09, 0.54]	Chi^2 = 0.24, df = 2 (P = 0.89); I^2 = 0%	Z = 1.37 (P = 0.17)
Depression	3	0.36 [0.04, 0.68]	Chi^2 = 5.08, df = 2 (P = 0.08); I^2 = 61%	Z = 2.20 (P = 0.03)

Note.
RCT: Randomized Controlled Trial, CBT: Cognitive-Behavioural Therapy.

In general, group sizes ranged from 6 persons to 25. Some studies used smaller groups [45, 62], or even did individual sessions [13, 66]. 13 studies included patients with some sort of chronic pain, 4 with Fybromyalgia, 2 with Rheumatoïd Arthritis, 4 with Chronic Fatigue Syndrome, and three studies included patients with special site pain (e.g. chronic low back pain). From the controlled studies 7 used a waitlist control, 4 used Treatment as Usual (TAU), 4 used an education/support group, and 3 used a CBT group as comparison group. Scores on extracted outcome measures were nog significantly different between groups in any study at baseline. 2 studies scored 'high' on the quality criteria, 8 scored medium, and 12 scored low (Table 1). None of the studies met all quality criteria.

Effects for the controlled studies

Calculated effects, their confidence intervals, heterogeneity tests and tests for the effects are presented in Table 2. The pooled SMD for all controlled studies on pain was 0.37 [0.20, 0.53]. Heterogeneity tests indicates no heterogeneity (Chi^2 = 10.41, df = 9, P = 0.32, I^2 = 14%). For depression the pooled SMD is 0.32 [0.13, 0.50], and there is no heterogeneity (Chi^2 = 7.75, df = 8, P = 0.46, I^2 = 0%). The Pooled SMD for controlled studies on anxiety was 0.40 [0.07, 0.73], on physical wellbeing 0.35 [0.10, 0.59], and quality of life 0.41 [0.16, 0.65]. The results on these outcome measures were all homogenous (I^2 = 0%), and significant (p< 0.03). When including solely RCT's, the effects for pain and depression drop to 0.25 and 0.26 respectively. Effects for anxiety (0.54) and physical wellbeing (0.43) slightly rise, and for quality of life a smaller effect is found (0.25). When excluding studies scored as low quality, and calculate a pooled SMD for pain and depression based on studies with medium and high quality, the SMD for pain drops to 0.25 [0.01, 0.49], and to 0.30 [0.10, 0.49] for depression.

Effects based on pretest and posttest including noncontrolled studies

When including non-controlled studies the pooled SMD for pain slightly rises to 0.47 [0.28, 0.66], heterogeneity is substantial and significant (Tau^2 = 0.08; Chi^2 = 40.90, df = 16, P < 0.01, I^2 = 61%), therefore a random-effects analysis is used. This effect is statistically significant (Z = 4.89, P < 0.01). When including non-controlled studies the pooled SMD for depression rises to 0.64 [0.43, 0.85], heterogeneity is substantial, and significant (Tau^2 = 0.16; Chi^2 = 77.19, df = 20, P < 0.01, I^2 = 74%). This effect is statistically significant (Z = 5.92, p < 0.01).

Effects for comparison CBT directly

Acceptance-based interventions have a small effect on chronic pain patients compared to CBT. A pooled SMD on pain of 0.22 [-0.09, 0.54] was found, but the SMD was non-significant (P=0.17) For depression the pooled SMD was 0.36 [0.04, 0.68], and significant (P=0.03). Heterogeneity for pain (P = 0.89, I^2 = 0%) and depression (P=0.08, I^2 = 61%) was non-significant.

Subgroup analyses

There are no significant differences between subgroups in the effects on pain or depression (p>0.05) between the different subgroups, except pulication status. Unpublished studies reported higher effects (0.90) than published studies (0.32), but note that only two unpublished studies were included in this subgroup analysis. Subgroup analyses are presented in Table 3.

Publication bias

Some indications for publications bias were found for the funnel plot for outcome measure depression. The funnel plot for pain was symmetrically distributed around the pooled SMD, which is an indication for the absence of publication bias. The funnel plot for depression is presented in Fig. 1, and shows asymmetrically distributed studies in the bottom of the figure. In the presence of bias, it can be expected

TABLE 3 - SUBGROUP ANALYSES OF ALL CONTROLLED STUDIES ON PAIN AND DEPRESSION

Outcome measure	Criteria	Subgroup	*n*	SMD [95% CI]	Test for subgroup differences
Pain	Quality	Low Quality	4	0.48 [0.25, 0.71]	Chi² = 1.85, df = 2 (P = 0.40)
		Medium Quality	5	0.24 [-0.07, 0.54]	
		High Quality	2	0.27 [-0.11, 0.65]	
	Intervention	ACT (-based)	2	0.29 [-0.35, 0.94]	Chi² = 0.06, df = 1 (P = 0.81)
		MBSR (-based)	8	0.37 [0.20, 0.54]	
	Control group	Education/support	4	0.20 [-0.07, 0.47]	Chi² = 2.32, df = 2 (P = 0.31)
		TAU	2	0.51 [-0.03, 1.05]	
		Waitlist	4	0.46 [0.23, 0.69]	
	Pain type	Chronic Pain	3	0.49 [0.19, 0.79]	Chi² = 2.76, df = 3 (P = 0.43)
		Fybromyalgia	3	0.34 [0.07, 0.61]	
		Special site pain	3	0.49 [0.06, 0.92]	
		Rheumatoid Arthritis	1	0.09 [-0.32, 0.50]	
	Attrition rate	<25%	6	0.38 [0.16, 0.61]	Chi² = 0.04, df = 1 (P = 0.83)
		>25%	4	0.35 [0.10, 0.60]	
	Publish status	Unpublished studies	2	0.90 [0.35, 1.45]	Chi² = 3.89, df = 1 (P = 0.05)
		Published studies	8	0.32 [0.14, 0.49]	
Depression	Quality	Low Quality	2	0.45 [-0.07, 0.98]	Chi² = 0.31, df = 2 (P = 0.86)
		Medium Quality	5	0.30 [0.06, 0.53]	
		High Quality	2	0.29 [-0.08, 0.67]	
	Intervention	MBSR	8	0.28 [0.09, 0.47]	Chi² = 2.71, df = 1 (P = 0.10)
		ACT	1	1.09 [0.15, 2.03]	
	Control group	Education/support	4	0.29 [0.02, 0.56]	Chi² = 0.79, df = 2 (P = 0.67)
		Waitlist	4	0.29 [-0.00, 0.58]	
		TAU	1	0.56 [-0.01, 1.13]	
	Pain type	Chronic Pain	2	0.63 [0.15, 1.11]	Chi² = 6.17, df = 3 (P = 0.10)
		Fybromyalgie + CFS	4	0.32 [0.05, 0.59]	
		Rheumatoid Arthritis	2	0.09 [-0.23, 0.41]	
		Special site pain	1	1.09 [0.15, 2.03]	
	Attrition rate	<25%	6	0.31 [0.07, 0.55]	Chi² = 0.01, df = 1 (P = 0.94)
		>25%	3	0.32 [0.03, 0.62]	
	Publish status	Unpublished studies	1	0.81 [-0.11, 1.73]	Chi² = 1.15, df = 1 (P = 0.28)
		Published studies	8	0.29 [0.10, 0.48]	

Note.

ACT: Acceptance and Commitment Therapy, MBSR: Mindfulness-Based Stress Reduction program, TAU: Treatment As Usual, CFS: Chronic Fatigue Syndrome.

that the bottom of the plot, which displays smaller studies, shows a higher concentration of studies on one side of the pooled SMD than on the other. This is due to the fact that smaller studies are more likely to be published if they have larger than average effects [4].

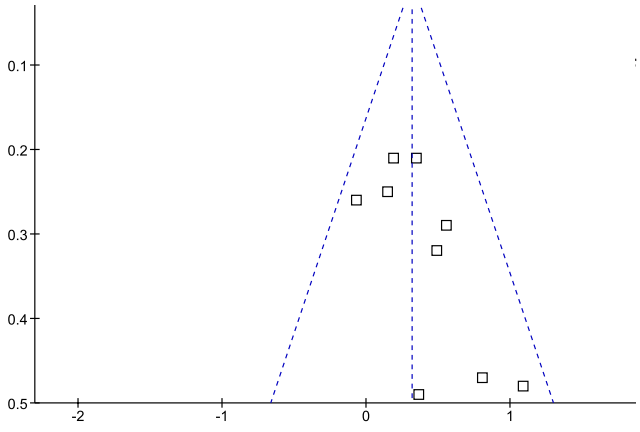

Figure 1: Funnel plot for depression

DISCUSSION

Main Findings

We found indications that acceptance-based therapies are a good alternative for CBT for people with chronic pain. When all studies focusing on change score before and after treatment were included in the meta-analysis we found a medium effect-size for pain intensity, depression, anxiety, physical wellbeing and quality of life. This finding shows that in general patients with chronic pain respond well to acceptance based therapies.

On the basis of 10 controlled studies it was found that MBSR and ACT have small effects (0.37) on pain intensity. In other meta-analyses comparable effects were found for CBT [17, 27, 42]. Some other results underscore the robustness of this finding. When only randomized controlled studies were included, a small effect size was found as well (0.25). Also, within this sample of controlled studies no heterogeneity was found. Furthermore, when excluding low quality studies in this meta-analysis, a small effect size is found as well. In three studies acceptance based interventions were directly compared to CBT and an effect-size of 0.22 was found, in favor of acceptance based therapy. In an earlier meta-analysis, Baer [3] found a smaller effect-size for mindfulness interventions on pain intensity. This may be explained by the fact that in this former meta-analysis studies with mixed populations were included. Smaller effects on pain can be expected when participants do not have high levels of pain.

In a similar way it was found that MBSR and ACT have small effects (0.32) on depression. No indication for heterogeneity was found in this cluster of studies as well. These effects are comparable with the effect-size (0.34) found in studies of CBT. In three studies acceptance based interventions were directly compared to CBT and a small effect-size (0.36) was found in favor of acceptance based interventions. Acceptance-based interventions may be especially indicated for people with chronic pain and recurrent depression. One study of high quality included Rheumatoid Arthritis patients [67] and the authors ascribed a key-role for recurrent depression. Patients with recurrent depression benefited more from mindfulness across several measures compared to patients with no recurrent depression. Zautra et al. conclude that CBT provides better cognitive control, and mindfulness provides better emotion regulation. Recurrent depression is one important factor for referring patients to acceptance based interventions. More research is needed to find other characteristics that seem important in referring patients to either CBT or mindfulness or ACT as has been recommended by several scientists [58, 61]. It is important to note that neither CBT nor an acceptance-based intervention is the golden standard, since chronic pain patients do not respond to an intervention the same way.

Fewer studies reported the effects of ACT and MBSR on anxiety, physical well-being and quality of life. On the basis of the included randomized controlled trials it can be concluded that acceptance based interventions are possibly moderately effective for anxiety and physical wellbeing. A small effect-size was

found for quality of life.

With respect to the quality of the studies it was found that the quality of the studies did not moderate the effects of acceptance based interventions. This result is somewhat surprising. In several recent, large meta-analyses on the effects of psychotherapy and pharmacotherapy it has been found that lower effects were found in higher quality studies [11, 12, 20, 34]. However only two high quality studies were included in this study so these findings have to be interpreted with caution. Other factors were not found to significantly moderate the effects of acceptance-based therapy with chronic pain patients, except for publication status, with unpublished studies reporting higher effects on pain.

For the studies on pain intensity and depression funnel plots were conducted to check the possibility of publication bias. A symmetrical funnel plot was found for pain intensity, suggesting the absence of publication bias. For depression in the left lower side of funnel plot studies are lacking. This may be an indication of publication bias, as studies with small samples that found no or small effects may be underrepresented in the published articles [4]. In contrast with this is the finding that the two unpublished study that were included in the meta-analysis reported a significant higher effect size than the published studies. However we did not systematically search for unpublished studies in european dissertation databases. Future meta-analyses may shed more light on this issue.

Limitations

This study has several limitations. First of all, we found only two studies that met 7, 8 or 9 quality criteria and no study that met all criteria. This is probably an underestimation, because quality criteria were scored conservatively. When a criterion was not reported in the paper, we coded this criterion as negative. It is very plausible that authors chose to leave certain study characteristics out because there was a lack of space in the journal. Clearly more high quality studies are needed to the reported results with regard to effectiveness and quality as a moderating factor. A second limitation was that insufficient data were reported to conduct a meta-analysis of the long-term effects of acceptance-based interventions. Third, PsycINFO solely retrieves unpublished dissertations from North America. Excluding non-american dissertation could lead to bias. A final limitation of this study is the small number of studies in many subgroups. E.g. only two small studies on the effects of ACT on pain intensity were found and one study on the effects on depression. So more studies are needed to allow more solid conclusions about most moderating factors.

Implications

To assess the efficacy and effectiveness of treatments, we recommend to use at least the six core outcome measures selected by the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) in future research [58]. These six outcome measures are: (1) pain, (2) physical phunctioning, (3) emotional functioning, (4) participant ratings of improvement and satisfaction with treatment, (5) symptoms and adverse events, and (6) participant disposition. In 2005 IMMPACT presented recommendations for specific measures of each of the IMMPACT core outcome measures [16]. We support these recommendations and encourage to use these specific measures in future research. For example, it is recommended to use numerical rating scales for pain intensity, usage of rescue analgesics, and categorical rating of pain intensity. Furthermore, they recommended the use of Beck Depression Inventory (BDI) or the Profile of Mood States (POMS) for measuring emotional functioning.

More high quality studies are needed, and future studies should bear in mind some quality criteria. We especially advise to evaluate treatment integrity in future effect studies. Currently, treatment integrity is adequately addressed for only 3.50% in studies

for psychosocial interventions [45]. To our knowledge, there is no effect study evaluating the influence of treatment inconsistencies, but the four domains of treatment integrity are considered important: (1) establishing, (2) assessing, (3) evaluating, and (4) reporting integrity. Treatment integrity is not only realized by protocol adherence, but by trainer competence as well. Not every clinical psychologist can provide acceptance-based interventions, and clinical experience is less important than experience or training in mindfulness or ACT. Furthermore, participants can easily be blinded for the intervention in an effect study when allocation concealment is appropriate. This can be done by concealing allocation by sequentially numbered, opaque, sealed envelopes, and by separating the randomization office from the patient recruitment centres [24]. We would like to conclude with stressing the importance of reporting these quality criteria. Without reporting relevant quality criteria, quality assessments lead to unjustful lower quality scoring in reviews.

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