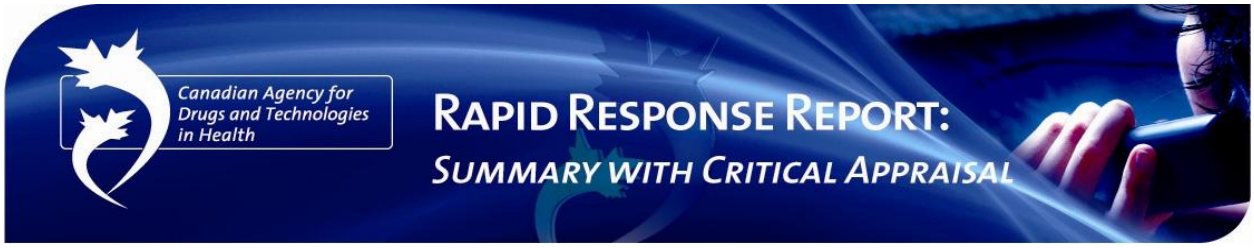

TITLE: Mindfulness Training for Chronic Pain Management: A Review of the Clinical Evidence and Guidelines

DATE: 12 January 2012

CONTEXT AND POLICY ISSUES

Chronic pain has been defined as persistent pain, which can be either continuous or recurrent and of sufficient duration and intensity to adversely affect a patient's well-being, level of function, and quality of life.[1] Common, non-cancer related, types of chronic pain include: low back pain, osteoarthritis, fibromyalgia, neuropathy, and headaches.[2] The prevalence of chronic pain in Canada has been estimated to be 16% in people aged 14 to 64 and 27% in people age 65 or older.[3] Chronic pain has substantial economic implications and has been estimated to cost the United States $61 billion/year in lost productivity.[2] A variety of treatments can be used to manage chronic pain including: prescription and nonprescription medications, physical therapy, surgery, cognitive behavioral therapy, exercise, and various complementary and alternative therapies.[1,2]

It has been suggested that psychosocial and behavioural factors may play an important role in managing chronic pain and that mind-body therapies may be useful for some patients. The National Center for Complementary and Alternative Medicine in the United States describes mind-body therapies as interventions which focus on the brain, mind, body, and behaviours with the intent to use the mind to affect physical function and promote health.[2] A 2007 survey reported that the back pain was by far the most common reason individuals in the United States had sought complementary and alternative medicines such as mind-body therapies.[2] The objective of this review is to summarize the clinical effectiveness and guidelines for the use of mindfulness training for the treatment of chronic non-cancer pain.

RESEARCH QUESTIONS

1. What is the clinical effectiveness of mindfulness training for chronic pain management in adults?

2. What are the evidence-based guidelines regarding the use of mindfulness training for chronic pain management in adults?

KEY MESSAGE

Regarding the effectiveness of mindfulness-training in the treatment of chronic pain, the systematic reviews included in this review concluded the following: insufficient evidence to draw conclusions (three reviews); preliminary evidence supporting the use mindfulness-training (two studies); and good evidence that cognitive behavioral therapy and progressive relaxation are effective for chronic low back pain (one study). Ten RCTs failed to consistently demonstrate statistically significant improvements with various forms of mindfulness training in patients with chronic pain. One evidence-based guideline suggested that cognitive behavioral therapy, mindfulness-based stress reduction, and biofeedback may be useful in the treatment of chronic pain.

METHODS

Literature Search Strategy

A limited literature search was conducted on key resources including PubMed, Medline, EMBASE, The Cochrane Library (2011, Issue 11), University of York Centre for Reviews and Dissemination (CRD) databases, Canadian and abbreviated list of major international health technology agencies, as well as a focused Internet search. No filters were applied to limit the retrieval by study type. The search was also limited to English language documents published between Jan 1, 2006 and Nov 30, 2011.

Selection Criteria and Methods

One reviewer screened the titles and abstracts of the retrieved publications and evaluated the full-text publications for the final article selection according to criteria presented in Table 1.

Table 1: Selection Criteria

Population	Adults with chronic non-malignant pain
Intervention	Mindfulness training
Comparator	Any
Outcomes	Pain management Reduction in pain medication use Return to work Quality of life Clinical practice guidelines
Study Designs	Health technology assessments, systematic reviews and meta-analyses, randomized controlled trials, evidence based guidelines

Exclusion Criteria

Studies meeting any of the following criteria were excluded: studies that were addressed in one or more of the included systematic reviews, non-randomized primary studies, case series, case reports, non-English language publications.

Critical Appraisal of Individual Studies

Critical appraisal of the included studies was performed according to study design. Appraisal of full-text publications for primary studies was performed using the criteria described by Downs and Black.[4] One of the included RCTs[5] was reported in two papers, one of which was published outside the date range for the literature search.[6] This publication was reviewed and used to assist in the critical appraisal of the study. Systematic reviews and clinical practice guidelines were assessed using the Assessment of Multiple Systematic Reviews (AMSTAR)[7] criteria and the Appraisal of Guidelines for Research and Evaluation (AGREE)[8] criteria, respectively. Numeric scores were not calculated. Instead, the strengths and limitations of each included study were described.

SUMMARY OF EVIDENCE

Quantity of Research Available

A total of 340 citations were retrieved from the literature search. The abstracts for these reports were reviewed and 36 studies that could potentially fulfill the selection criteria were identified for further screening. One additional reference was retrieved from the grey literature. The screening process resulted in the selection of 17 reports for inclusion in the present review. A summary of the screening results is provided in Appendix 1. The 17 articles reported the results of six systematic reviews,[9-14] 10 RCTs,[5,13,15-22] and one evidenced-based clinical practice guideline.[1]

Summary of Study Characteristics

A summary of the characteristics of the included studies is provided in Table 16 for systematic reviews and Table 17 for randomized controlled trials (Appendix 2).

Systematic reviews

There were six systematic reviews included in this review.[9-14] Three of the reviews included a meta-analysis of primary studies[9,10,12] and one was a review of existing systematic reviews.[14] The populations of interest for the reviews were as follows: patients with chronic pain,[9,11-13] patients with chronic musculoskeletal pain,[10] and patients with chronic low back pain.[14] Two of the reviews were focused on elderly patients.[12,13] The interventions of interest were mindfulness-based stress reduction (MBSR),[9,11,12] acceptance and commitment therapy (ACT),[9] mindfulness-based meditation,[11-13] self-management,[10,12] cognitive behavioural therapy (CBT),[11,12,14] progressive relaxation,[11-14] biofeedback,[12-14] and guided imagery.[13] Comparator groups included usual care,[10,14] waiting list,[10,11,14] support groups,[11] education controls,[12] and exercise.[14] The number of included studies ranged from 10[11] to 46.[10]

Randomized controlled trials

Ten RCTs,[5,13,15-22] with sample sizes ranging from 36[5] to 177,[17] were included in this review. The patient populations were diverse and included the following: non-specific chronic pain,[15,16,20] chronic back pain,[5,13,19] chronic neck pain,[21] chronic musculoskeletal pain,[22] fibromyalgia,[17] and failed back surgery syndrome.[18] The trials involved a variety of mind-body therapies including: applied relaxation,[15,21] ACT,[15] MBSR,[16-18] multidisciplinary pain intervention,[16] progressive muscle relaxation,[17] mindfulness meditation,[13] CBT,[19] and breath therapy.[5] Commonly used control groups were waiting list,[17,19,20] education control,[13] and treatment as usual.[18,21] All RCTs were single centered, unblinded, and used a parallel-group design. The majority of RCTs were conducted in the United States,[5,13,18,20,22] two were in Germany,[17,19] two were in Sweden,[15,21] and one was in Hong Kong.[16]

Evidence-based guidelines

One clinical practice guideline, published by the Institute for Clinical Systems Improvement, was identified regarding assessment and treatment of chronic pain.[1] The report provided commentary on the use of cognitive behavioural therapy, mindfulness-based stress reduction, and biofeedback. Specific types of chronic pain were not considered. The guidelines were developed based on a literature review. Recommendations for clinical practice were not provided.

Summary of Critical Appraisal

A detailed summary of the critical appraisal is provided in Table 18 for systematic reviews, Table 19 for RCTs, and Table 20 for evidence-based guidelines (Appendix 3).

Systematic reviews

All of the systematic reviews included comprehensive literature searches involving multiple databases and articles were selected with clearly stated eligibility criteria. None of the literature searches included grey literature and all were restricted to English-language publications. Five reviews reported a well-documented article selection process.[9-11,13,14] All of the reviews provided a list of the included studies and all reported key characteristics of the included studies.[9-14] Only two reviews provided a list of excluded studies.[9,14] All but one of the reviews[12] included a formal risk of bias assessment. Three reviews[9,11,14] specified some form of duplicate study selection, data extraction, and/or risk of bias assessment; however, it was not always clear which steps were performed in duplicate. Two of the meta-analyses investigated the possibility of publication bias using funnel plots.[9,10]

Randomized controlled trials

All of the included RCTs provided a clear statement of the study object and provided an adequate description of the study protocol. Common limitations were poor reporting of methods for allocation concealment[13,15,17-20,22] and failure to conduct an intention-to-treat (ITT) analysis using all randomized patients.[5,13,17-22] The interventions were unblinded in all studies and only three RCTs made an effort to blind study personnel such as the statisticians.[17,18,22] Given the complexity of the interventions in these studies, blinding of participants and clinical staff would likely be unfeasible; however, the lack of blinding remains an important source of potential bias for the included studies. The majority of RCTs reported baseline characteristics which were

similar between the treatment groups.[5,13,15-17,20,22] One study[21] had differences between the groups at baseline for important variables and two studies failed to properly report the baseline characteristics of participants.[18,19] Four RCTs[5,15,18,21] had a high proportion of participants who were lost to follow-up (range: 22% to 70%) and two studies showed large differences in loss to follow-up between the treatment groups (40% vs. 22%[5] and 20% vs. 5%[13]). Women were more commonly enrolled in the included RCTs which may limit the generalizability of the results to men. Four RCTs[17,20-22] ranged from 87% to 100% women, two RCTs[5,13] included approximately 60% women, and one indicated that a majority were women but failed to provide the exact proportion.[16]

Evidence-based guidelines

The objectives, target population, and target users of the ICSI guideline were well-described. Individuals from relevant professional groups were included in development of the guideline group and the methods used for formulating the recommendations were clearly described. The research questions, methods, and search results for the systematic review(s) were not reported and there was a lack of clarity regarding the involvement of patient input in the development process. The guideline described a systematic process for grading the strength and level of evidence associated with recommendations; however, these elements were not clearly reported for the recommendations and commentary relevant to this review.

Summary of Findings

Systematic reviews

Veehof *et al* (2011)[9] conducted a systematic review and meta-analysis to investigate the effects of MBSR or ACT on patients with chronic pain or conditions related to chronic pain. The review included a total of 22 studies with nine RCTs, five controlled clinical trials, and eight uncontrolled trials. Fifteen studies evaluated MBSR and seven investigated ACT. There were a total of 1295 patients in the 22 studies (range: 6 to 171). The key outcomes were pain intensity, depression, anxiety, physical well-being, and quality of life. Nine studies were described as involving patients with chronic pain (no additional details) and the others included a variety of different patient populations including: fibromyalgia (N = 4); rheumatoid arthritis (N = 2); chronic fatigue syndrome (N = 4); chronic low back pain (N = 1); whiplash-associated disorder (N = 1); chronic headache (N = 1).

The authors conducted meta-analyses based on study design and studies were pooled regardless of interventions and comparators (Table 2). Meta-analyses including both controlled and uncontrolled studies were based on the outcome measures before and after the intervention and showed moderate, statistically-significant improvements in pain, depression, anxiety, physical well-being, quality of life (all $P < 0.01$). Meta-analyses including only on controlled studies (i.e., RCTs and controlled clinical trials) demonstrated similar results; however, when the analysis was restricted to RCTs only the results for pain, depression, and physical well-being were statistically significant. Overall, the authors concluded that acceptance-based therapies appear to have small to medium effects on the physical and mental health of chronic pain patients and suggest that more high quality evidence is required to confirm these findings.

Table 2: Results of Meta-Analyses for MBSR and ACT

Outcomes	Pre and Post*		RCTs		RCTs and CCTs	
	N	SMD (95% CI)	N	SMD (95% CI)	N	SMD (95% CI)
Pain	14	0.43 (0.22, 0.64)	7	0.25 (0.01, 0.49)	10	0.37 (0.20, 0.53)
Depression	17	0.69 (0.47, 0.92)	6	0.26 (0.05, 0.47)	9	0.32 (0.13, 0.50)
Anxiety	13	0.69 (0.51, 0.88)	2	0.55 (-0.09, 1.18)	5	0.40 (0.07, 0.73)
Physical well-being	13	0.48 (0.27, 0.68)	4	0.43 (0.04, 0.82)	6	0.35 (0.10, 0.59)
Quality of Life	5	0.63 (0.28, 0.98)	4	0.25 (-0.10, 0.59)	6	0.41 (0.16, 0.65)

CCT=controlled clinical trial; **CI**=confidence interval; **N**=number of pooled studies; **RCT**=randomized controlled trial; **SMD**=standardized mean difference

*Measure of the effect size based on the outcome measure before and after the intervention. This analysis includes both controlled and uncontrolled studies.

Carnes *et al* (2011)[10] conducted a systematic review and meta-analysis to evaluate the effect of self-management interventions against usual care or waiting-list control groups for patients with chronic musculoskeletal pain. The authors defined self-management interventions as structured, taught, or self-taught courses aimed improving the participants' health status or quality of life. To be eligible for inclusion, the interventions were required to contain at least two of the following components: psychological (e.g., CBT), mind-body therapies (e.g., relaxation or meditation), physical activity, life-style (e.g., dietary advice), and pain education. The review included 46 RCTs involving a total of 8539 patients (range: 50 to 855). Key outcomes were pain intensity, depression, physical function, self-efficacy, and global health. Seventeen studies involved patients with mixed chronic pain conditions and the others included patients with osteoarthritis (N = 13), low back pain (N = 12), and fibromyalgia (N = 5). The included studies included a variety of self-management components including: psychological (N = 38); life-style (N = 39); pain education (N = 35); physical activity (N = 40); and mind-body therapies (N = 26).

A number of meta-analyses were conducted by pooling studies according self-management components, duration, and delivery mode, and setting. Standardized mean differences were calculated for the intervention versus the control in the presence and absence of a particular characteristic (e.g., with and without mind-body therapy). The authors reported that the majority of comparisons demonstrated either no statistically significant difference or a small difference between self-management courses with and without a mind-body therapy component. They concluded that more evidence is required to substantiate their findings.

Table 3: Results of Meta-Analyses for Interventions With and Without MBT

Outcomes	Pooled Effect Sizes for Mind-body Therapies - SMD (95% CI)			
	Medium-term (4-8 months)		Longer-term (>4 months)	
	With MBT	Without MBT	With MBT	Without MBT
Pain intensity	< 0.2	0.30 (0.05, 0.55)	NS	0.20 (0.07, 0.34)
Physical function	< 0.2	< 0.2	< 0.2	NS
Self-efficacy	NS	0.36 (0.17, 0.55)	0.23 (0.13, 0.33)	0.47 (0.13, 0.81)
Global health	0.33 (0.01, 0.65)	0.67 (0.26, 1.09)	NS	NS
Depression	NS	NS	NS	NS

CI=confidence interval; **MBT**=mind-body therapies; **NS**=not significant; **SMD**=standardized mean difference

Lunde *et al* (2009)[12] conducted a systematic review and meta-analysis to evaluate the effectiveness of cognitive and behavioral interventions for the treatment of chronic pain in elderly patients. Outcomes of interest were pain experience, depression, physical function, and medication use. The review included 12 studies (controlled and uncontrolled) with a total of 614 patients (range: 14 to 256). The individual studies investigated the use of CBT, mindfulness-based meditation, MBSR, progressive relaxation, self-management groups, and biofeedback.

The authors calculated effect sizes using the difference between the pre- and post-intervention measures for each of the individual studies and meta-analyses were conducted for each of the outcome measures. The results of the meta-analysis suggest that the cognitive and behavioural interventions included in the review resulted in statistically significant improvement in self-reported pain ($P < 0.01$) and physical functioning ($P < 0.05$) with no statistically significant improvements in depression or medication use (both $P > 0.05$). However, these results should be interpreted with caution as the studies were pooled regardless of study design (e.g., controlled and uncontrolled), intervention (e.g., CBT and MBSR), or comparator. In addition, there was no measure of statistical heterogeneity presented with the pooled effect sizes. Overall, the authors concluded that their meta-analysis provides some evidence for the effectiveness of cognitive and behavioural treatment for chronic pain in the elderly.

Table 4: Results of Meta-Analyses for Cognitive and Behavioural Interventions

Outcome	N	Effect Size (95% CI)*	P value
Pain Experience	16	0.47 (0.34, 0.60)	< 0.01
Depression	8	0.08 (-0.08, 0.24)	> 0.05
Physical Functioning	8	0.15 (0.01, 0.30)	< 0.05
Medication use	8	0.05 (-0.12, 0.22)	> 0.05

CI=confidence interval; **N**=number of studies

*Pooled results for pre-intervention versus post-intervention

Chiesa *et al* (2011)[11] conducted a systematic review to investigate the efficacy of mindfulness-based interventions for patients with chronic pain. The outcomes of interest were pain reduction, depression, physical function, stress reduction, and quality of life. The review included a total of ten studies (six RCTs and four controlled clinical trials) involving a total of 921 patients (range: 30 to 213). The interventions included mindfulness-based meditation, MBSR, CBT, and progressive relaxation. Control groups included patients on a waiting list and patients in a support group. Three studies included patients with a variety of chronic pain and the remaining studies included patient with the following: fibromyalgia (N = 4), rheumatoid arthritis (N = 2), and chronic low back pain (N =1). The primary outcomes of the review were pain and depression (results summarized in Table 5). Overall, the authors concluded that there is insufficient evidence to determine if mindfulness-based interventions are more efficacious than non-specific interventions for the reduction of pain and depressive symptoms in patients with chronic pain.

Table 5: Summary of Findings for Pain and Depression from Chiesa 2011[11]

Outcome	Summary of Findings
Pain symptoms **(7 studies)**	• Significantly greater improvement in pain perception in the MBI groups relative to the following comparators: waiting list (three studies); educational control (one study); progressive muscle relaxation (one study) • No significant difference between MBI with qigong and an educational control (one study) • No significant difference between MBI, massage, or a waiting list (one study)
Depression **(6 studies)**	• Significant improvement in depressive symptoms in the MBI groups relative to the following comparators: waiting list (three studies); and progressive muscle relaxation (one study) • No significant difference between MBI with qigong and an educational control (one study) • No significant difference between MBI, CBT, or an educational control (one study)

CBT=cognitive behavioral therapy; **MBI**=mindfulness-based interventions

Morone and Greco (2007)[23] conducted a systematic review to evaluate the safety and efficacy of mind-body interventions for the treatment of chronic pain in older adults. The review included twenty studies with 12 RCTs, five uncontrolled trials, and two retrospective clinical chart reviews. The following types of mind-body therapies were addressed in the included studies: relaxation-based (four studies), biofeedback (four studies), meditation (two studies), guided

imagery (two studies), hypnosis (one study), tai chi (three studies), and yoga (four studies). The outcomes of interest were pain, physical function, mobility, and quality of life. The authors concluded that there is some evidence for the efficacy of progressive muscle relaxation plus guided imagery for the treatment of osteoarthritis pain and that there is limited support for the use of meditation, and tai chi for improving function and coping with pain for older adults with osteoarthritis or low back pain. The results of this review should be interpreted with caution as the majority of evidence was derived from low quality studies with small sample sizes and short durations. There were no adverse events reported in any of the trials included in this review.

Chou *et al* (2007)[14] conducted a systematic review of RCTs and existing systematic reviews to evaluate the use of non-pharmacologic therapies in the treatment of acute and chronic low back pain. The non-pharmacological therapies of interest included psychological therapies (defined as biofeedback, progressive relaxation, and CBT). Outcomes of interest included pain intensity, functional status, short-term pain, and behavioral outcomes. The authors stated that due to the large amount of literature for therapies for low back pain, the primary source of information was systematic reviews. The review included a total of 40 systematic reviews and 19 RCTs. Two of the systematic reviews investigated the use of psychological therapies. One was a meta-analysis of 22 RCTs (Hoffman *et al*, 2007)[24] and the other a Cochrane review of 21 studies (Ostelo *et al*, 2005).[25] Key findings from the meta-analyses by Ostelo *et al* (2005) were reported and are summarized in Table 6. Overall, the authors concluded that there is good evidence that psychological interventions (CBT and progressive relaxation) are effective for chronic low back pain.

Table 6: Results of Meta-Analyses for Pain Intensity from Ostelo 2005[25]

Comparison	Studies	SMD (95% CI)
Cognitive behavioural therapy vs. Waiting list	4	0.59 (0.10, 1.09)
Progressive muscle relaxation vs. Waiting list	2	1.16 (0.47, 1.85)
Biofeedback vs. Waiting list	3	0.84 (0.32, 1.35)*

CI=confidence interval; **SMD**=standardized mean difference

*Meta-analysis included 3 studies that showed a beneficial effect; however, another study which was not pooled failed to show that biofeedback was superior to waiting list

Randomized controlled trials

Mindfulness-based stress reduction

Schmidt (2011)[17] conducted an open-label, three-arm, parallel-group RCT comparing an eight-week MBSR program, progressive muscle relaxation, and a waiting list control for the treatment of patients with fibromyalgia (n = 177). The primary outcome was health-related quality of life measured two months post-treatment using the Quality of Life Profile for the Chronically Ill inventory. Secondary outcomes were depression, pain, anxiety, somatic complaints, and mindfulness. The authors reported that there were no statistically significant differences between the three groups for health-related quality of life. The two active groups (MBSR and PMR) demonstrated a statistically significant improvement in anxiety compared with the wait-list control group. The results (change from baseline) for each of the individual groups are shown in Table 7.

Table 7: Within-group Results from Schmidt 2011[17]

Outcome	Wait-list (N = 59)		PMR (N = 56)		MBSR (N = 53)	
	Mean ∆BL	P value	Mean ∆BL	P value	Mean ∆BL	P value
QoL	0.19	0.11	0.13	0.34	0.39	0.017
FIQ	0.19	0.10	0.10	0.49	0.45	0.021
CES-D	0.15	0.18	0.04	0.79	0.36	0.012
STAI	-0.05	0.63	0.12	0.17	0.41	0.003
PSQI	0.17	0.17	0.27	0.015	0.38	0.004
PPS affective	0.25	0.026	0.30	0.027	0.50	<0.001

∆**BL**=change from baseline; **CES-D**=Center for Epidemiologic Studies Depression Scale; **FIQ**=Fibromyalgia Impact Questionnaire; **MBSR**=mindfulness-based stressed reduction; **PPS**=Pain Perception Scale; **PMR**=progressive muscle relaxation; **PSQI**=Pittsburgh Sleep Quality Index; **QoL**=quality of life; **STAI**=State-Trait Anxiety Inventory

Esmer *et al* (2010)[18] conducted an RCT to evaluate the addition of an eight-week MBSR program to the usual treatment for patients with failed back surgery syndrome (N = 42). The authors defined failed back surgery syndrome as back or leg pain which persisted or recurred after one or more surgical procedures on the lumbosacral spine. The MBSR intervention involved the following components: 1) weekly classroom learning for 1.5 to 2.5 hours for eight weeks; 2) a six hour session at week six; and 3) patients were encouraged to meditate for 45 minutes per day through the study. Participants randomized to the control group received treatment as usual (specific details were not provided). Follow-up was conducted at 12 weeks and the authors reported statistically significant improvements in the following outcome measures (Table 8): chronic pain acceptance (P < 0.014); pain measured by visual analogue scale (P < 0.021); sleep quality (P < 0.047); analgesic use (P < 0.001); and low back pain-related functional disability (P < 0.005). These results should be interpreted with caution as the analysis presented in the report only included 60% of participants. The authors concluded that the results suggest that MBSR may be useful for patients with failed back surgery syndrome; however, they caution that more evidence is required to confirm these findings.

Table 8: Summary of Findings from Esmer 2010[18]

Outcome	Change from Baseline		P value
	MBSR + TAU (n = 15)	TAU (n = 10)	
Pain acceptance (CPAQ)	7.0 (13.5)	-6.7 (11.0)	<0.014
Disability (RMDQ)	-3.6 (3.4)	0.1 (1.9)	<0.005
Pain (VAS)	-6.9 (6.9)	-0.2 (6.0)	<0.021
Sleep quality (PSQI)	2.0 (3.5)	-0.2 (1.7)	<0.047
Analgesic use	-1.5 (1.8)	0.4 (1.1)	<0.001

CPAQ=chronic pain acceptance questionnaire; **MBSR**=mindfulness-based stress reduction; **RMDQ**=Roland Morris Disability Questionnaire; **PSQI**=Pittsburgh Sleep Quality Index; **TAU**=treatment as usual; **VAS**=visual analog scale

Wong et al (2011)[16] conducted an RCT to compare the clinical effectiveness of an eight-week MBSR program against a multidisciplinary pain intervention (MPI) in patients with chronic pain (N = 99). Both group groups received eight 2.5 hour group sessions (one per week) and one seven hour session. The key components of the MBSR program were mindfulness, relaxation, meditation, yoga, and the body-mind connection. The MPI program focussed on basic understanding of chronic pain, factors that may increase or decrease chronic pain, and methods for signalling chronic pain to others. Outcomes were assessed immediately after the interventions (i.e., eight weeks) and at three and six month follow-up (Table 9). There were no statistically significant differences between the two groups in any of the following outcomes: pain intensity, health-related quality of life (SF-12), depression, anxiety, and number of sick days. The only statistically significant difference between the groups was in pain-related distress at the eight-week time point and favoured MPI over MBSR (-1.08 vs. -0.37; P = 0.046). Both

groups showed statistically significant improvements from baseline in both pain intensity and pain-related distress at all time points; however, the authors concluded that the effects were small and of questionable clinical relevance.

Table 9: Summary of Pain-related Outcomes from Wong 2011[16]

Outcome	Δ from BL to 6 months – Mean (SE)		MBSR vs. MPI P value
	MBSR (n = 51)	MPI (n = 48)	
Pain intensity*			
Post-intervention	-0.57 (0.16)	-0.61 (0.22)	0.882
3 months	-0.71 (0.22)	-0.91 (0.27)	0.517
6 months	-1.15 (0.30)	-1.19 (0.31)	0.910
Pain-related distress*			
Post-intervention	-0.37 (0.23)	-1.08 (0.25)	0.046
3 months	-0.79 (0.24)	-1.15 (0.31)	0.324
6 months	-1.02 (0.23)	-0.97 (0.29)	0.869

Δ=change; **BL**=baseline; **MBSR**=mindfulness-based stress reduction; **MPI=**multidisciplinary pain intervention; **SE**=standard error

*measured using an 11-point numerical rating scale

Mindfulness meditation

Morone *et al* (2009)[13] conducted an RCT to compare an eight-week mindfulness meditation program against an education control program for older adults (≥ 65 years) with chronic low back pain (N = 40). The intervention consisted of 1.5 hour classes once per week for eight weeks where participants were given instruction on three methods of mindfulness meditation (body scan, sitting practice, and walking mediation). The control group received the equivalent number of instructional sessions with a focus on aging and non-meditation based treatments for back pain. Follow-up was conducted after four months and there were no statistically significant differences between the two groups for the following outcomes: pain, disability, and self-efficacy (effect sizes were not reported). No adverse events occurred during the study.

Breath Therapy

Mehling *et al* (2006)[5] conducted an RCT to compare the efficacy of breath therapy against physical therapy for patients with chronic low back pain (N = 36). The breath therapy intervention sought to teach the participants a "meditative kind of awareness" through the use of verbal intervention and skillful touch. Both groups received a total of 13 sessions over a period of six to eight weeks. Measurements at baseline were compared to those obtained post-intervention (six to eight weeks) and at a six month follow-up. At both post-intervention time points, there were no statistically significant differences between the two groups for any of the following outcomes: pain intensity; health-related quality of life (SF-36); low back pain-related functional disability (Roland Morris scale); or the proportion of patients with improvement in pain or functional disability. Within each treatment group, participants undergoing breath therapy improved significantly in low back pain-related functional disability and in the physical and emotional components of the SF-36, participants in the physical therapy group improved significantly in the vitality component of the SF-36, and participants in both groups had statistically significant improvements in pain intensity and overall SF-36. The authors reported that there were no significant adverse events reported in either group.

Online Mind-Body Intervention

Berman *et al* (2009)[20] conducted an RCT to evaluate the feasibility and efficacy of an online mind-body intervention for the treatment of older adults (≥ 55 years) with chronic pain. The online intervention involved the following mind-body exercises: abdominal breathing, relaxation, writing about both positive and difficult experiences, creative visual expression, and positive thinking. Participants in the intervention group were instructed to use the online intervention at least once a week for six weeks. The median number of visits was 22.5 over the course of the six week trial. Participants in the control group were randomized to a waiting-list. After six weeks, there were no statistically significant differences between the two groups for any of the following outcomes: pain intensity, pain interference, self-efficacy, depression, or anxiety (within group comparisons are summarized in Table 10).

Table 10: Summary of Pain-related Outcomes from Berman 2009[20]

Outcome	Change from BL at 6 weeks Mean (SD)		Within Group Comparison P value	
	MBI	Control	MBI	Control
Worst pain (BPI)	-1.27 (2.88)	-0.94 (2.04)	< 0.01	< 0.01
Least pain (BPI)	-1.05 (2.81)	-0.95 (2.05)	< 0.05	< 0.01
Average pain (BPI)	-0.64 (1.48)	-0.70 (1.82)	< 0.01	< 0.05
Pain interference (BPI)	-1.21 (2.44)	-0.88 (2.08)	< 0.01	< 0.01

BL=baseline; **BPI**=Brief Pain Inventory; **MBI**=mind-body intervention; **NS**=not significant; **SD**=standard deviation

Acceptance and Commitment Therapy Versus Applied Relaxation

Thorsell *et al* (2011)[15] conducted an RCT to compare ACT against applied relaxation for the treatment of chronic pain (N = 90). Participants in both groups received a seven week self-help intervention. The ACT intervention involved identifying the participants' values, cognitive defusion, mindfulness, acceptance, and committed actions. The applied relaxation intervention involved progressive relaxation, cue-controlled relaxation, differential relaxation, and rapid relaxation. Outcomes were assessed at the end of the intervention (i.e., seven weeks) and at 6 and 12 months follow-up. The authors reported that, in comparison with applied relaxation group, the ACT group showed increases in acceptance of chronic pain, satisfaction with life, and level of function and a decrease in pain intensity (within group comparisons are summarized in Table 11). Both groups showed improvements in depression and anxiety.

Table 11: Summary of Pain-related Outcomes from Thorsell 2011[15]

Outcome	Change from Baseline - MD (95% CI)			Within Group Comparisons - P Value		
	7 weeks	6 months	12 months	7 weeks	6 months	12 months
Pain Acceptance						
ACT	14.8 (9.9,19.6)	10.5 (4.9,16.2)	13.0 (5.7,20.2)	<0.005	<0.005	0.001
AR	NR	NR	NR	NS	NS	NS
Pain Intensity						
ACT	-0.8 (-1.5,-0.0)	NR	-1.1 (-2.0,-0.2)	0.045	NS	0.023
AR	NR	NR	NR	NS	NS	NS

ACT=acceptance and commitment therapy; **AR**=applied relaxation; **CI**=confidence interval; **MD**=mean difference; **NR**=not reported; **NS**=not significant

Cognitive Behavioural Therapy

Glombiewski *et al* (2010)[19] conducted a three arm RCT comparing the efficacy of CBT with and without biofeedback (CBT and CBT-B) against a waiting list control group in severely disabled

patients with chronic back pain (N = 128). The CBT and CBT-B groups both received 25 one hour sessions with information regarding the biopsychosocial aspects of pain, goal setting, progressive muscle relaxation, activity scheduling, restructuring pain cognitions and avoidance beliefs, breathing exercises, attention diversion, and stress-coping skills. In addition to this material, the CBT-B group received additional support in the form of biofeedback with the goal of reducing tension, increasing relaxation, and increasing self-efficacy. Outcomes were assessed at the end of the intervention and at six months follow-up.

The authors conducted two types of analysis: a comparison between the two active treatment groups (i.e., CBT vs. CBT-B); and a pooled comparison of the two active groups against the wait list control group (i.e., CBT + CBT-B vs. waiting list). The pooled analysis demonstrated statistically significant differences favouring the CBT and CBT-B groups over the control group for pain intensity, pain diary, number of pain drugs taken, pain disability, health-related life satisfaction scale, and depression (all $P < 0.05$). In contrast, the only statistically significant difference between the CBT and CBT-B groups was a lower number of doctor visits at six months in the CBT-B group ($P = 0.024$); there were no differences in any outcomes related to pain (Table 12).

Table 12: Summary of Pain-related Outcomes from Glombiewski 2010[19]

Outcome	Change from Baseline - MD (95% CI)			
	CBT-B (n = 62)		CBT (n = 54)	
	Post	6 months	Post	6 months
Pain intensity	0.67 (0.39, 0.95)	0.6 (0.33, 0.87)	0.47 (0.19, 0.75)	0.47 (0.19, 0.75)
Pain diary	0.33 (0.07, 0.59)	0.33 (0.07, 0.59)	0.21 (-0.06, 0.48)	0.21 (-0.06, 0.48)
Number of pain drugs	0.31 (0.06, 0.56)	0.31 (0.06, 0.56)	0.46 (0.18, 0.74)	0.42 (0.14, 0.70)
Pain disability	0.44 (0.18, 0.70)	0.44 (0.18, 0.70)	0.38 (0.10, 0.66)	0.29 (0.02, 0.56)

CBT=cognitive behavioural therapy without biofeedback; **CBT**=cognitive behavioural therapy with biofeedback; **CI**=confidence interval; **MD**=mean difference

Applied Relaxation

Gustavsson and von Koch (2006)[21] conducted an RCT to compare the efficacy of an intervention involving a pain and stress management group with applied relaxation against treatment as usual (i.e., physiotherapy) for patients with chronic neck pain (N = 37). The applied relaxation group received seven sessions over a period of seven weeks. The physiotherapy group received an average of eleven non-standardized sessions over a period of 20 weeks. Outcomes were measured at seven and 20 weeks and were compared against baseline measurements. There were no statistically significant differences between the applied relaxation and physiotherapy groups for any of the following outcomes: pain, analgesic usage, healthcare utilization, disability, pattern of coping strategies, fear and avoidance, or sleep (Table 13). Both groups demonstrated statistically significant improvements in the use of analgesics due to neck pain. The applied relaxation group also had a statistically significant reduction in the number of healthcare visits reported during the follow-up period compared with the pre-trial period.

Table 13: Summary of Pain-related Outcomes from Gustavsson 2006[21]

Outcomes	7 weeks – Median (IQR)			20 weeks - Median (IQR)		
	AR	PT	P value	AR	PT	P value
Healthcare visits due to pain	NR	NR	NR	2 (0, 5)	5 (1, 10)	0.101
Perceived pain (0 to 10)	6 (2, 8)	6 (3, 7)	0.506	5 (2, 8)	7 (4, 8)	0.255
Analgesics (0 to 4)	1 (1, 3)	1 (1, 2)	0.439	1 (1, 2)	2 (1, 2)	0.153
Pain behaviors (CSQ)	24 (17, 25)	21 (15, 25)	0.628	22 (13, 31)	24 (9, 29)	0.792
Pain control (CSQ)	4 (3, 5)	3 (2, 4)	0.148	4 (3, 5)	2 (2, 3)	0.003
Ability to reduce pain (CSR)	3 (3, 4)	3 (2, 4)	0.333	4 (3, 4)	2 (2, 3)	0.003

AR=applied relaxation; **CSQ**=Coping Strategies Questionnaire; **HAD**=Hospital Anxiety and Depression Scale; **IQR**=interquartile range; **NR**=not reported; **PT**=physiotherapy

Mind-body Approach for Chiropractic Care

Hawk *et al* (2006)[22] conducted an RCT to compare the clinical effectiveness of chiropractic spinal manipulation against a non-manipulative mind-body approach for treating adults with chronic musculoskeletal pain (N = 91). The mind-body intervention was called Bioenergetic Synchronization Technique and consisted of light touch, verbal suggestions, group lectures on self-empowerment and lifestyle, and provision of nutritional supplements. The comparator group received spinal manipulation using the diversified technique. The treatment period for both groups was four weeks and outcomes were assessed at seven weeks. The authors reported that there was no statistically significant difference between the groups for scores on the Pain Disability Index (Table 14). There were no adverse events reported during the study.

Table 14: Summary of Pain-related Outcome from Hawk 2006[22]

Outcome	Mean Change from BL to 7 weeks		MBI vs. SM
	MBI (n = 40)	SM (n = 38)	MD (95% CI)
Pain disability (PDI)	6.9	6.4	0.6 (-4.7, 5.8)

BL=baseline; **CI**=confidence interval; **MBI**=mind-body intervention; **MD**=mean difference; **PDI**=Pain Disability Index; **SM**=spinal manipulation

Evidence based guidelines

The Institute for Clinical Systems Improvement (ICSI) has published an evidence-based guideline regarding the assessment and management of chronic pain.[1] The guideline comments on the use of cognitive and behavioural therapies and addresses the evidence for the use of MBSR and biofeedback in the treatment of chronic pain (summarized in Table 15). There was no evidence cited in favour or against any of the other mind-body therapies.

Table 15: ICSI Commentary on Mind-Body Therapies for Chronic Pain[1]

Intervention	Summary of Findings*
CBT	• Clinicians may consider a CBT approach with functional restoration to help reduce pain and improve function *(evidence not cited)* • Significant literature exists that supports positive outcomes for CBT, and these strategies are considered to be among the most effective for the treatment of chronic pain. Specific outcomes have been noted in RCTs and other treatment evaluation studies and include evidence for the efficacy of CBT in improving function and mood, and in reducing pain and disability-related behaviour, particularly in low back pain *(systematic review and meta-analysis)*
MBSR	• Training in mindfulness meditation, in the context of MBSR, has been shown to be effective in the regulation of chronic pain *(low quality evidence)* • Mindfulness is becoming a mainstream practice in assisting patients in pain programs *(evidence not cited)*
Biofeedback	• Biofeedback has been found to be effective in headache management *(meta-analysis),* temperomandibular disorders *(meta-analysis)*, and other recurrent pain conditions *(low quality evidence)*

CBT=cognitive behavioral therapy; **MBSR**=mindfulness-based stress reduction

*Information regarding the evidence used to formulate the recommendation is provided in parentheses.

Limitations

The evidence included in this review has important limitations that restrict the ability to draw conclusions regarding the safety and effectiveness of mind-body therapies in the treatment of chronic pain. The study populations were composed of patients with a variety of different forms of chronic pain making it difficult to determine if any one particular intervention is more or less effective in a particular patient population. In addition, there was extensive heterogeneity

between the different studies with respect to the duration of interventions, the choice of comparators, the number of treatment sessions, and the time between follow-up periods. Therefore, despite the large amount of evidence included in this review, there were no studies similar enough to convincingly demonstrate reproducible results. Women were more commonly enrolled in the included RCTs which may limit the generalizability of the results to men with chronic pain. All of the included studies were limited by small sample sizes and lack blinding. In general, there was poor reporting of adverse events in the studies which makes it difficult to make a balanced assessment of safety and effectiveness.

CONCLUSIONS AND IMPLICATIONS FOR DECISION OR POLICY MAKING

The six systematic reviews included in this review were predominantly composed of low quality primary studies and the conclusions of three stated that there is insufficient evidence to accurately assess the effectiveness of mindfulness interventions in chronic pain. One review of existing systematic reviews concluded that there is good evidence that CBT and progressive relaxation are effective in the treatment for chronic low back pain. The RCTs identified in this review failed to consistently demonstrate statistically significant improvements with various forms of mindfulness training in patients with chronic pain. One evidence-based guideline suggested that CBT, MBSR, and biofeedback may be useful in the treatment in the treatment of various chronic pain conditions.

Overall, the evidence identified in this rapid review is insufficient to draw conclusions regarding the effectiveness of mindfulness training in the treatment of chronic pain. Larger, well-conducted, studies with a longer duration would be required to accurately determine the place in therapy for the different forms of mindfulness interventions in the treatment of chronic pain.

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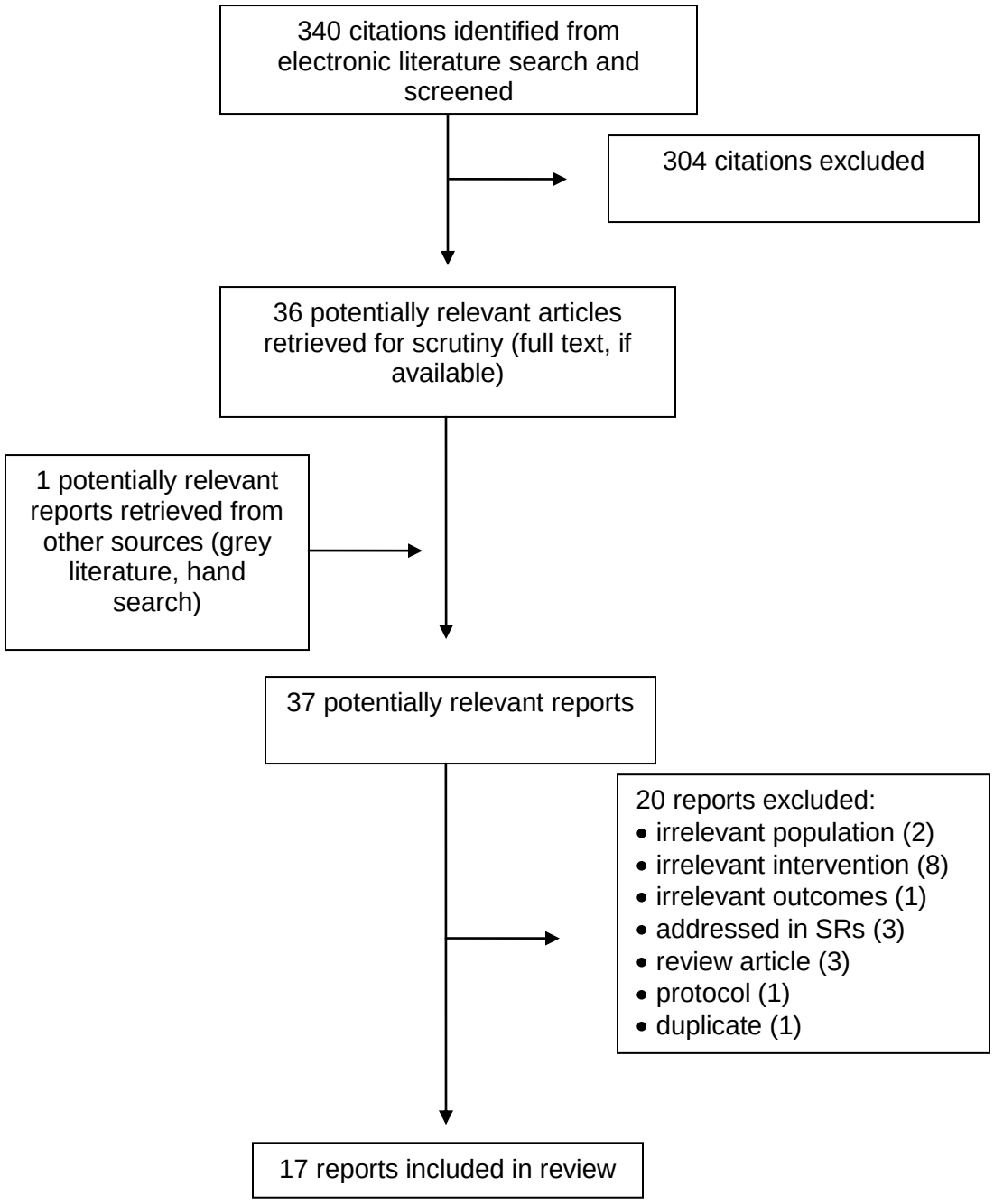
Appendix 1: Selection of Included Studies



Appendix 2: Summary of Study Characteristics

Table 16: Characteristics of Included Systematic Reviews

Author	Description	Comparators	Outcomes	Population
Veehof 2011[9]	• Systematic review and meta-analysis • 22 studies (9 RCTs, 5 CCT, 8 UCT)	• MBSR • ACT	• Pain intensity • Depression • Anxiety • Physical well-being • Quality of life	• Patients with chronic pain or conditions related to chronic pain
Carnes 2011[10]	• Systematic review and meta-analysis • 46 RCTs included	• Self-management • Usual care • Waiting list	• Pain intensity • Physical function • Self-efficacy • Global health • Depression	• Patients with chronic musculoskeletal pain
Chiesa 2011[11]	• Systematic review • 6 RCTs and 4 CCTs included	• MBM • MBSR • CBT • Support group • Progressive relaxation • Waiting list	• Pain reduction • Coping with pain • Depression • Physical function • Stress reduction • Quality of life	• Patients with chronic pain
Lunde 2009[12]	• Systematic review and meta-analysis • 12 studies	• CBT • MBM • MBSR • Progressive relaxation • Biofeedback • Education control • Self-management	• Pain experience • Depression • Physical function • Medication use	• Elderly patients with chronic pain
Morone 2007[13]	• Systematic review	• Meditation • Biofeedback • Progressive relaxation • Guided imagery	• Pain • Physical function • Mobility • Quality of life	• Older adults with chronic pain
Chou 2007[14]	• Systematic review of RCTs and existing SRs • 40 SRs and 19 RCTs included • 2 SRs on psychological therapies	• CBT • Progressive relaxation • Biofeedback • Exercise • Waiting list • Usual care	• Pain intensity • Functional status • Short-term pain • Behavioral outcomes	• Patients with chronic low back pain

ACT=acceptance and commitment therapy; **CBT**=cognitive behavioural therapy; **CCT**=controlled clinical trial; **MA**=meta-analysis; **MBM**=mindfulness-based meditation ; **MBSR**=mindfulness-based stress reduction; **SR**=systematic review; **RCT**=randomized controlled trial; **UCT**=uncontrolled trials

Table 17: Summary of Included Clinical Trials

Author/Trial ID	Description	Comparators	Endpoints	Population
Thorsell 2011[15] Sweden	• 14 months • Open-label • Parallel-group • N = 90	• Applied relaxation • Acceptance and commitment therapy	• Pain intensity • Quality of life • Depression • Anxiety • Acceptance of pain • Level of function	• Patients with chronic pain
Wong 2011[16] Hong Kong	• F/U 6 months • Open label • Parallel-group • N = 99	• MBSR • Multidisciplinary pain intervention	• Pain intensity • Mood status • Symptoms • Quality of life	• Patients with chronic pain
Schmidt 2011[17] Germany	• 16 weeks • Open label • Three-arm • Parallel-group • N = 177	• MBSR • PMR • Wait list control	• Quality of life • Depression • Pain • Anxiety • Somatic complaints	• Females with fibromyalgia
Esmer 2010[18] USA	• F/U 12 weeks • Open label • Parallel-group • N = 42	• MBSR (8 weeks) + Treatment as usual • Treatment as usual	• Pain • Quality of life • Sleep quality	• Patients with failed back surgery syndrome
Glombiewski 2010[19] Germany	• 6 months • Open label • Single center • Parallel-group • N = 128	• CBT • CBT with biofeedback • Wait list control	• Pain • Physical functioning • Emotional functioning • Coping strategies • Health care utilization	• Severely disabled chronic back pain patients
Berman 2009[20] USA	• 6 weeks • Open-label • Parallel-group • N = 89	• Mind-body intervention (online) • Wait list (control)	• Pain • Self-efficacy • Depression • Anxiety • Self-care • Satisfaction	• Patients aged 55 or older with chronic pain
Morone 2009[13] USA	• 4 months • Open label • Single center • Parallel-group • N = 40	• 8 week mindfulness meditation • Education control	• Disability • Psychological function • Pain severity	• Older adults with chronic low back pain
Gustavsson 2006[21] Sweden	• 20 weeks • Open label • Single center • Parallel-group • N = 37	• Applied relaxation • Treatment as usual	• Pain and analgesics • Health care utilization • Coping strategies • Fear of injury • Depression/anxiety	• Patients with neck pain for ≥3 months
Hawk 2006[22] USA	• 7 weeks • Open label • Single center • Parallel-group • N = 81	• Spinal manipulation • Non-manipulative mind-body approach	• Pain disability index • Depression	• Older adults with chronic musculoskeletal pain
Mehling 2006[5] USA	• F/U 6 months • Single center • Parallel-group • N = 36	• Breath therapy • Physical therapy	• Pain • Function • Overall health	• Patients with chronic low back pain

CBT=cognitive behavioural therapy; **F/U**=follow-up; **PTSD**=post-traumatic stress disorder; **MBSR**=mindfulness-based stress reduction; **PMR**=progressive muscle relaxation

Appendix 3: Summary of Critical Appraisal

Table 18: Critical Appraisal of Systematic Reviews

Author, Year	Strengths	Limitations
Veehof 2011[9]	• Comprehensive literature search involving multiple databases • Literature search methods were well reported • Eligibility criteria was clearly stated • Review contained a formal risk of bias assessment • Study selection was performed in duplicate by two independent reviewers • Data extraction was performed by one reviewer and checked by another reviewer • Study characteristics were reported • Methods of pooling studies were appropriate and well reported • Article selection process was well documented including a list of included and excluded studies. • Publication bias assessed with a funnel plot	• Search restricted to English language articles • Unclear if grey literature was included in the literature search • Unclear if the risk of bias assessment was performed in duplicate
Carnes 2011[10]	• Comprehensive literature search involving multiple databases • Literature search methods were well reported • Eligibility criteria was clearly stated • Review contained a formal risk of bias assessment • Article selection was well documented and a list of included studies provided • Characteristics of the included studies were well reported • Publication bias was assessed using a funnel plot • Methods of pooling studies were appropriate	• Search restricted to English language articles • Unclear if grey literature was included in the literature search • Two reviewers selected the articles; however, it was not performed in duplicate • Unclear if data extraction was performed in duplicate • List of excluded studies was not provided • No conflict of interest statements
Chiesa 2011[11]	• Comprehensive literature search involving multiple databases • Eligibility criteria was clearly stated • Review contained a formal risk of bias assessment • Data extraction and risk of bias assessment was performed in duplicate • Characteristics of the included studies were well reported • Article selection was well documented • A list of included studies and excluded studies was provided • Conflict of interest statement provided	• Search restricted to English language articles • Unclear if grey literature was included in the literature search • Unclear of publication bias was assessed

Author, Year	Strengths	Limitations
Lunde 2009[12]	• Comprehensive literature search involving multiple databases • Eligibility criteria was clearly stated • A list of included studies was provided • Characteristics of the included studies were reported	• Article selection process was poorly documented • List of excluded studies was not provided • No risk of bias assessment • Methods for study selection and data extraction were not reported (e.g., unclear if this was performed independently or in duplicate) • No conflict of interest statements
Morone 2007[13]	• Comprehensive literature search involving multiple databases • Literature search methods were well reported • Eligibility criteria was clearly stated • Review contained a formal risk of bias assessment • Article selection was well documented • A list of included studies was provided • Characteristics of the included studies were well reported	• Search restricted to English language articles • Grey literature was not included in the literature search • Methods for data extraction were not reported • Unclear if risk of bias assessment was performed in duplicate • No conflict of interest statements • List of excluded studies was not provided • Unclear of publication bias was assessed
Chou 2007[14]	• Comprehensive literature search involving multiple databases • Literature search methods were well reported • Eligibility criteria was clearly stated • Review contained a formal risk of bias assessment which was performed by two independent reviewers • Article selection was well documented • A list of included and excluded studies was provided • Characteristics of the included studies were well reported • Conflict of interest statement provided	• Non-english language articles were only included if they were included in systematic reviews • Unclear if study selection and data extraction were performed in duplicate • Publication bias was not assessed; however, this was due to a limited number of studies

Table 19: Critical Appraisal of Randomized Controlled Trials

Author, Year	Strengths	Limitations
Schmidt 2011[17]	• Objective and methods were clearly stated • Eligibility criteria was clearly stated • Interventions were well described • Sample size calculation provided • Methods of randomization were provided; however, it is unclear if there was an appropriate form of allocation concealment (study manager was responsible for randomization) • Baseline characteristics were similar between the three groups • Patient disposition was well reported • Authors reported that adherence to the trial protocol was high and comparable between the groups	• Treatments were open-label (attempts were made to blind study personnel, but allocation was known for at least 20% of the sample) • 100% of participants were women (limited generalizability for men) • Did not conduct an ITT analysis based on all randomized patients. The authors defined an ITT data set that included 95% of patients
Thorsell 2011[15]	• Objective and methods were clearly stated • Interventions were well described • Eligibility criteria was clearly stated • Sample size calculation provided • Method of randomization was stated; however, it is unclear if allocation was properly concealed from the investigators • Patient disposition was well reported • Baseline characteristics were similar between the three groups • ITT analysis included all randomized patients (MMRM used for imputation)	• Treatments were open-label • Compliance data was not collected in a structured manner • Approximately 50% of participants failed to complete the randomized treatment and less than 30% completed the 12 month follow-up.
Wong 2011[16]	• Objective and methods were clearly stated • Interventions were well described • Eligibility criteria was clearly stated • Randomization methods were reported • Authors report that allocation was concealed • Sample size calculation provided • Patient disposition was well reported • Baseline characteristics were similar between the three groups • ITT analysis included all randomized patients (LOCF used for imputation)	• Treatments were open-label • Adherence to the protocol was better in the MPI group (90%) compared with the MBSR group (76%) • Authors noted that the majority of participants were women (limited generalizability for men)
Glombiewski 2010[19]	• Objective and methods were clearly stated • Sample size calculation provided • Eligibility criteria was clearly stated • Method of randomization was stated; however, it is unclear if allocation was properly concealed from the investigators • Compliance was reported and overall adherence to the protocol was high • Authors report that the treatment and control groups were similar at baseline	• Treatments were open-label • Patient disposition was reported; however, the reasons for withdrawal were not clearly stated • Baseline characteristics not reported for the wait list control group • Patient outcomes and withdrawals were similar across each of the four therapists in the study • Did not conduct an ITT analysis based on all randomized patients. The authors defined an ITT data set that included 91% of patients

Author, Year	Strengths	Limitations
Esmer 2010[18]	• Objective and methods were clearly stated • Eligibility criteria was clearly stated • Patient disposition was well reported	• Treatments were open-label; however, the statistician was blinded • Poor description of methods for randomization and allocation concealment • The MBSR interventions was well described; however, there was little information regarding the treatment as usual component of the study • No sample size calculations provided • Pilot study with a limited sample size (N = 42) • Baseline characteristics were poorly reported (only for 60% of participants) • 26% of participants were lost to follow-up • Did not conduct an ITT analysis using all randomized patients (only included 60% of participants)
Berman 2009[20]	• Objective and methods were clearly stated • Patient disposition was well reported • Baseline characteristics were similar between the three groups	• Treatments were open label • No sample size calculations provided • Inclusion criteria was stated but there was no mention of any exclusion criteria • 87% of participants were women (limited generalizability for men) • Patients were randomized by a coin-toss which may be subject to selection bias due to limited allocation concealment. • No sample size calculation provide • Loss to follow-up was not equal between the MBI group (20%) and the control group (0%) • Did not conduct an ITT analysis using all randomized patients
Morone 2009[13]	• Objective and methods were clearly stated • Eligibility criteria was clearly stated • Method of randomization was stated; however, it is unclear if allocation was properly concealed from the investigators • Baseline characteristics were generally similar between the two groups. The only exception was patient age which was adjusted in all analyses • Patient disposition was well reported • Adverse events were reported	• Treatments were open-label • No sample size calculations provided • Pilot study with a limited sample size (N = 40) • Greater proportion of patients withdrew from the meditation group (20% vs. 5%) • Did not conduct an ITT analysis using all randomized patients
Gustavsson 2006[21]	• Objective and methods were clearly stated • Randomization was concealed • Eligibility criteria was clearly stated • Patient disposition was well reported • Compliance was reported • Results were clearly stated in the report	• Treatments were open-label • No sample size calculations provided • Limited sample size (N = 34) • 92% of participants were women (limited generalizability for men) • Baseline characteristics were different between the two groups for important variables (e.g., duration of neck pain and analgesic usage) • 22% of participants withdrew early (including those with the most severe depression) • Did not conduct an ITT analysis

Author, Year	Strengths	Limitations
Hawk 2006[22]	• Objective and methods were clearly stated • Eligibility criteria was clearly stated • Method of randomization was reported • Sample size calculation provided • Baseline characteristics were similar between the two groups • Patient disposition was well-reported • 86% of participants completed the trial • Compliance was reported and overall adherence to the protocol was high	• Treatments were open-label; however, the primary investigator and the statistician were blinded throughout the data analysis. • Unclear if randomization was adequately concealed • 91% of participants were women (limited generalizability for men) • Did not conduct an ITT analysis using all randomized patients
Mehling 2006[5]	• Objective and methods were clearly stated • Eligibility criteria was clearly stated • Methods for randomization were appropriate and well-reported • Randomization was concealed using opaque envelopes • Interventions were well described • Baseline characteristics were similar between the two groups • Compliance was reported	• Treatments were open-label • No sample size calculations provided • Limited sample size (N = 36) • 22% of participants did not receive any intervention • A greater proportion of participants in the control group were lost to follow-up (40% vs. 22%) • Did not conduct an ITT analysis using all randomized patients (only 69% included)

ITT=intention to treat; **LOCF**=last observation carried forward ; **MBSR**=mindfulness based stress reduction ; **MMRM**=mixed-effect model repeated measure ; **MPI**=multidisciplinary pain intervention; **PP**=per protocol

Table 20: Critical Appraisal of Evidence-based Guidelines

Publisher, Year	Strengths	Limitations
ICSI[1]	• The objectives of the guideline are specifically described • The population to whom the guideline is meant to apply is specifically described • Individuals from relevant professional groups were included in development of the guideline group • The target users of the guideline were clearly defined • The methods used for formulating the recommendations were clearly described	• Unclear if patient input was considered in the development process • Research questions were not clearly stated • Methods and search results for the systematic review were not reported • The strength of evidence for the recommendations and commentary relevant to this review were not clearly described

Appendix 4: Detailed Description of Study Interventions

Author, Year	Description of the Interventions	Key Findings
Schmidt 2011[17]	**Mindfulness-based stress reduction** "The intervention comprised an 8-week structured program with groups of up to 12 patients, taught by a single instructor. Participants took part in one 2.5 hour session every week, and an additional 7 hour all-day session on a weekend day. Each session covered specific exercises and topics within the context of mindfulness practice and training. These included various types of formal mindfulness practice, mindful awareness of dynamic yoga postures, and mindfulness during stressful situations, and social interactions. The all-day retreat included a combination of previously used and newly introduced mindfulness exercises. Upon enrollment, participants were asked to commit themselves to daily homework assignments of 45 to 60 minutes." (page 362-636) **Progressive muscle relaxation (active control group)** "The active control intervention was planned to control for the nonspecific aspects of the MBSR curriculum. It comprised an 8-week group of size and weekly format similar to that of the MBSR program. In addition, equivalent amounts of social support and weekly topical educational discussions were provided. Use of Jacobson Progressive Muscle Relaxation training (PMR), and fibromyalgia-specific gentle stretching exercises served as counterparts for mindfulness and yoga elements of the MBSR curriculum. Homework assignments were similar in duration and intensity to those in the MBSR group. Patients received instructions for daily exercises" (page 362-636) **Waiting-list (control group)** No active treatment but participants were offered their choice of either intervention at conclusion of the short-term follow-up period.	No statistically significant differences between the three groups for HRQoL MBSR and PMR groups showed statistically significant improvements in anxiety compared with the wait-list control group
Thorsell 2011[15]	**Acceptance and commitment therapy** "An initial 90-minute face-to-face session consisted of identification of the short and long-term effects of previously used pain control strategies, identification of the participant's valued direction in life, and identification of patterns of avoidance and degree of fusion with verbal obstacles. The Bull's Eye Values Survey was used to illustrate personal values and measure value attainment and the degree to which obstacles prevent valued action. Participants describe their values in 4 domains (work, leisure, relationships, and health) and rate to what extent they live in accordance with those values. At the end of this session, participants received instructions for supplementary exercises. Participants worked independently in their homes for 7 weeks using the self-help manual with 30 minutes of weekly telephone support. A final 90-minute session was aimed at discussing the participant's impediments to engaging in meaningful life activities." (page 718) **Applied relaxation** "An initial 90-minute face-to-face session was to sample challenging pain situations and show how AR is practiced by carrying out the first part of the intervention, Progressive Relaxation long version, in session. Focus in this module is on learning to differentiate between tension and relaxation and to start the process of learning to relax. The session also included a discussion of AR as a coping strategy that can be used both in difficult situations and as a preventive strategy. Participants were provided with instructions for supplementary exercises. Participants worked independently for 7 weeks using the self-help manual with 30 minutes of weekly telephone support. A final 90-minute face-to-face session was aimed at establishing a maintenance program for the AR skills learned." (page 718)	In comparison with applied relaxation group, the ACT group showed increases in acceptance of chronic pain, satisfaction with life, and level of function and a decrease in pain intensity

Author, Year	Description of the Interventions	Key Findings
Wong 2011[16]	**Mindfulness-based stress reduction** "The intervention comprised 8 weekly 2.5 hours group sessions and a 7-hour "retreat" session. Instructive, inductive, and experiential modes of learning were used to carry out the intervention and to convey the information content. The 3 primary elements of the intervention were as follows: 1) theoretical material related to mindfulness, relaxation, meditation, yoga, and the body-mind connection; 2) experiential practice of meditation and yoga, both during the group meetings and at home; and 3) group activities that focused on removing impediments to effective practice, practical day-to-day applications of mindfulness, and supportive intervention between group members. Participants were given a booklet on the MBSR program and CDs that guided them through the mindfulness meditation exercises, which they were instructed to practice daily." (page 725) **Multidisciplinary pain intervention (active control)** "The intervention included a set of educational instructions on management of chronic pain, based on a book, "Managing Pain Before It Manages You." The aims of the treatment group were to act as a control for therapists' attention and contact time, and for any unmeasured effects of taking part in a group intervention. To avoid overlap between what is taught in the two groups, any information in the self-help book concerning mind-body connection and cognitive techniques introduced were not taught to the control group. Participants in this group met with a nurse coordinator for 8 weekly 2.5 hour group sessions. These sessions took the form of instructional lectures on basic understanding of chronic pain, factors that increase or decrease chronic pain, and effective ways for participants to signal their chronic pain to others." (page 725)	No statistically significant differences between the two groups in any of the following outcomes: pain intensity, health-related quality of life, depression, anxiety, and number of sick days.
Glombiewski 2010[19]	**Cognitive-behavioural therapy (CBT)** "The intervention included information about biopsychosocial aspects of pain, goal setting, progressive muscle relaxation, activity scheduling, cognitive therapy for restructuring pain cognitions, restructuring of fear avoidance beliefs, breathing exercises and further progressive muscle relaxation training, attention diversion, relapse prevention strategies and stress-coping skills." (page 100) **Cognitive-behavioural therapy and biofeedback (CBT-B)** "The intervention was identical to CBT, but many of the interventions were supported by biofeedback (40% of treatment time), mainly EMG biofeedback. The aims of the biofeedback intervention were as follows: (a) to reduce tension in specific muscles, (b) to increase generalised relaxation and (c) to increase self-efficacy. Skin-conductance-level biofeedback and respiratory biofeedback were also occasionally offered for demonstration purposes, but the main goal for every patient was to achieve self-control by learning muscle self-control." (page 100) **Waiting-list (control)** The control group did not receive the cognitive behavioral treatments.	Statistically significant differences favouring the pooled CBT and CBT-B groups over the control group for pain intensity, pain diary, number of pain drugs taken, pain disability, health-related life satisfaction scale, and depression. No statistically significant differences between the CBT and CBT-B groups in any outcomes related to pain

Author, Year	Description of the Interventions	Key Findings
Esmer 2010[18]	**Mindfulness-based stress reduction** "Participants had classroom learning once per week for 1.5 to 2.5 hours for 8 weeks. During the other 6 days of each week they were encouraged to meditate for 45 minutes per day with the aid of guided meditation audiotapes. A series of required homework assignments also underscored mindfulness and its incorporation into daily living. The sixth week of training included a 6-hour session that was in addition to the weekly session. The course educated participants on the physiology of stress and stress hardiness and provided participants with strategies for coping with stressful life experiences using their mindfulness skills. The primary strategy for coping with pain was to develop and refine the capacity to be mindful. Participants were encouraged to be present with their experience of pain and stress in particular. Participants were taught to perform daily mindfulness practices (i.e., gentle yoga, walking, and seated meditation)." (page 647) **Waiting-list (control)** Participants were given access to usual medical care (unspecified).	Statistically significant improvements favouring MBSR in chronic pain acceptance; pain measured by VAS; sleep quality; analgesic use; and low back pain-related functional disability.
Berman 2009[20]	**Mindfulness Intervention** "Participants were instructed to use the online intervention at least once a week for 6 weeks. They were able to access the web site on their own schedule and use the intervention at their own pace, at a location of their choice. Participants were asked to first visit an introductory module describing a problem-solving approach to planning for change and were also asked to try each of 6 modules at least once. The modules were purposefully designed to be generic for a variety of chronic pain conditions, and we expected that participants would find some exercises more helpful than others. The self-care modules included a selection of several exercises in each of the following areas: 1) abdominal breathing; 2) relaxation; 3) writing about positive experiences; 4) writing about difficult experiences; 5) creative visual expression; and 6) positive thinking. The online materials included audio, visual, and textual components." (page 70) **Waiting-list (control)** Participants were given access to the online intervention after completing the follow-up assessment at 6 weeks.	No statistically significant differences between the two groups for any of the following outcomes: pain intensity, pain interference, self-efficacy, depression, or anxiety
Morone 2009[13]	**Mindfulness meditation** "Classes met weekly for 8 weeks, and sessions lasted 90 minutes. Three methods of mindfulness meditation were taught. These techniques take regular activities like sitting, walking, and lying down and transform them into a meditation through directed breathing and mindful awareness of thoughts and sensations. The methods used were 1) the body scan; 2) sitting practice; and 3) walking meditation." (page 1398) **Heath education (control)** "8-week health education program on a successful aging curriculum that has been used in other trials. The health education curriculum involved lectures, group discussion, and homework assignments based on the health topics discussed. Additionally, a general theme of "brain health" was emphasized for the 8 weeks. Session topics were 1) pain medications, 2) complementary treatments for back pain, 3) types of back pain, 4) role of physical therapist in treating back pain, 5) eating and health, and 6) Alzheimer's. Additionally, subjects were given materials to promote participation and retention in the program. They were given the use of a Nintendo DS "Brain Age" game and encouraged to do this as daily homework, as well as homework assignments from the book *Keep Your Brain Alive*." (page 1399)	No statistically significant differences between the two groups for the following outcomes: pain, disability, and self-efficacy

Author, Year	Description of the Interventions	Key Findings
Gustavsson 2006[21]	**Applied relaxation** "The intervention consisted of an information and training program involving seven 1.5-hour sessions, over a period of 7 weeks. The sessions consisted of applied relaxation training, body awareness exercises, and information about pain and stress management. Participants were taught the following: to relax using progressive and autogenic relaxation methods; conditioned relaxation exercises; how to identify stimuli believed to cause pain, and to apply the relaxation in these real-life stressful situations. The participants were instructed to practise relaxation exercises twice a day at home between sessions in addition to applying new relaxation skills in everyday situations. The sessions also consisted of theoretical information about anatomy, aetiology, physiology of pain and stress, and pain and stress management." (page 101) **Physiotherapy (active control)** "Individual physiotherapy sessions according to current practise (not a standardized treatment procedure). The type of treatment, frequency of visits and duration of contact were left to the discretion of the physiotherapists and their patients. The participants were not to receive relaxation training of any kind." (page 101)	No statistically significant differences between the applied relaxation and physiotherapy groups for any of the following outcomes: pain, analgesic usage, healthcare utilization, disability, pattern of coping strategies, fear and avoidance, or sleep
Hawk 2006[22]	**Mindfulness intervention** The mind-body approach (bioenergetic synchronization technique) included light touch, verbal suggestions on positive thinking, group lectures on self-empowerment, lifestyle and nutrition, and provision of specific nutritional supplements. **Usual chiropractic care (control)** "The intervention in this group was designed to represent the customary procedures used by most chiropractors. The primary procedure was spinal manipulation using diversified technique; ancillary procedures permitted were soft tissue treatment, heat, ultrasound, and/or interferential current, as well as advice on exercise and/or nutrition. Areas of the spine manipulated and use of ancillary procedures were determined by this group's clinician's judgment on the basis of the physical examination and history, x-rays, and static and motion palpation." (page 542)	No statistically significant difference between the groups for scores on the Pain Disability Index
Mehling 2006[5]	**Breath therapy** "The intervention involved a 1 hour introductory evaluation session and 12 individual therapy sessions of 45 minutes over 6 to 8 weeks. Through verbal intervention and skillful touch, the breath therapist guided the participant's awareness to the subtle physical sensations of breath movements in the patient's back. Skillful touch involved touching the patient with gentle pressure, holding, or gentle stretching at the back, neck, and legs with the goal of enhancing attention allocation. The therapist provided verbal and non-verbal cues to allow for less restricted breath movements in the body regions where breathing was restricted in conjunction with the patient's experience of low back pain. Patients were instructed in daily exercises to do at home." (page 46)[6] **Physiotherapy** "The intervention involved a 1 hour introductory evaluation session and 12 individual therapy sessions of 45 minutes over 6 to 8 weeks. Physical therapists followed a study protocol recommended by an experienced physical therapist clinician and educator. The intervention began after a thorough evaluation of the patient and consisted of individualized strategies, including soft-tissue mobilization; joint mobilization; and exercises for postural righting, flexibility, pain relief, stabilization, strengthening, functional task performance, and back-related education. The physical therapy sessions used the same structure as usual practice but had a longer duration to match the breath therapy intervention. Patients were instructed in daily exercises to do at home." (page 46)	No statistically significant differences between the two groups for any of the following outcomes, pain intensity, HRQoL, low back pain-related functional disability, pain or functional disability

ACT=acceptance and commitment therapy; **CBT**=cognitive behavior therapy; **CBT-B**=cognitive behavior therapy with biofeedback; **HRQoL**=health-related quality of life; **MBSR**=mindfulness-based stress reduction; **PMR**=progressive muscle relaxation; **VAS**=visual analogue scale