MINDFULESS-BASED STRESS REDUCTION ALLEVIATES STRESS AND DEPRESSION IN ADULTS WITH CHRONIC PAIN: A RANDOMIZED CONTROLLED TRIAL

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Abstract

The primary aim of this study was to evaluate the effectiveness of Mindfulness-Based Stress Reduction (MBSR) in improving attention and pain-related outcomes, using a randomized controlled trial. Secondary aims included evaluating changes in mindfulness and pain acceptance following MBSR training and their role in improving outcomes, exploring the role of homework adherence in enhanced outcomes, and assessing stability of improvements long-term at 3-months follow up. Forty-nine adults with chronic pain between 18 and 80 years of age were randomized to an 8-week MBSR group or a Waitlist Control (WC) group that was then crossed over into the MBSR treatment. Outcome measures included pain intensity, pain disability, depression, anxiety, stress, mindfulness, pain acceptance, and performance on a change blindness task. Measures were administered prior to treatment, following the wait period for the WC group, following MBSR treatment, and 3-months subsequent to MBSR treatment completion. It was hypothesized that the MBSR group would demonstrate significant improvements in these outcomes, with the exception of pain severity, following treatment relative to the waitlist control group and that these benefits would be maintained at follow up. Linear regression analyses using changes scores of the outcomes revealed significantly greater reductions from pre-to-post treatment in the MBSR group compared to the WC group in depression and stress ($ps < .05$), and increases in mindfulness ($p < .01$). Multiple linear regression analyses using the entire sample demonstrated that increases in mindfulness significantly predicted decreases in depression ($p < .05$) and stress ($p < .01$) and increases in pain acceptance was significantly predictive of decreases in pain disability ($p < .05$). Significant correlations were obtained between the number of days engaging in practice and stress, pain acceptance, and attention. Benefits observed at post-treatment were maintained at 3-months follow up. Results suggest that mindfulness-based approaches can be integrated in pain clinics to facilitate patient recovery by reducing emotional distress.

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Chapter 1: Introduction

Chronic pain (CP) is defined as an emotional and sensory experience that continues for at least 3 months following its onset. CP is a subjective experience, may be sporadic or ongoing, and usually begins as a result of injury (Merskey, & Bogduk, 1994; Turk & Okifuji, 2001). Research reports that approximately 1 in 5 Canadian adults (20%) suffer with CP (Moulin, Clark, Speechley, & Morley-Forster, 2002; Schopflocher, Taenzer, & Jovey, 2011) and this estimate markedly increases to a range of 25% to 65% amongst older adults living in the community and then to a surprising 80% among those living in long-term care facilities (Hadjistavropoulos et al., 2009; Gibson, 2003). In comparison to other chronic diseases such as lung or heart disease when these are not accompanied by CP, individuals with CP experience the poorest quality of life (Choinière et al., 2010) and face a host of physical, psychological, social, and financial challenges including interferences in daily activities (Choinière et al., 2010), higher prevalence of mood disorders (McWilliams, Goodwin, & Cox, 2004), disrupted relationships with family and friends (Breivik, Collett, Ventafridda, Cohen, & Gallacher, 2006), and an increase in sick days and job losses resulting in economic burden (Choinière et al., 2010). Not only is the individual economic burden devastating, but the societal costs are alarming with the annual direct and indirect Canadian health care costs associated with managing CP and reduced productivity estimated at $43 billion (Schopflocher & Harstall, 2008). Despite the high number of Canadians experiencing CP and the significant burden on the health care system, pain research receives less than 1% of funding awarded by the Canadian Institutes of Health Research and 0.25% of total health research funding (Lynch, Schopflocher, Taenzer, & Sinclair, 2009).

Given the variety of domains impacted by this condition, a multidisciplinary approach for managing CP is important for improving health. Pharmacotherapy, including opioid prescriptions, is most commonly used by health care practitioners to manage CP (Aloysi & Bryson, 2012). In isolation, a pharmacological approach is often inadequate, and a combination of treatment modalities are frequently employed such as individual psychotherapy, injection treatments, nerve blocks, physiotherapy, sex therapy, acupuncture, and group therapy. Models of CP emphasize the interactive nature of biological, psychological, and social influences on the pain experience, which overshadow traditional biomedical and psychogenic views (Gatchel, Peng, Peters, Fuchs, & Turk, 2007; Turk & Okifuji, 2002). This progress in understanding the pain experience as a complex interactive biopsychosocial system, as well as the urgent need for effective pain management treatments, has elicited investigation of a variety of psychosocial treatment approaches for CP.

Management of Chronic Pain

Much research has focused on evaluating the effectiveness of psychosocial based approaches for improving pain management outcomes. A treatment modality that is often implemented and evaluated is Cognitive Behaviour Therapy (CBT). CBT involves a variety of techniques including psychoeducation (e.g., teaching patients about CP), operant treatment (i.e., behavioural reinforcement), coping skills training, relaxing strategies, and activity scheduling (e.g., exercise, pleasant tasks). Several meta-analyses conclude that CBT results in small to moderate effects for pain and psychological health outcomes among adults with CP (Astin, Beckner, Soeken, Hochberg, & Berman, 2002; Dixon, Keefe, Scipio, Perri, & Abernethy, 2007; Morley, 1999). CBT focuses on teaching individuals to take control of their thoughts and emotions by increasing awareness through self-monitoring exercises, relabeling thoughts, and restructuring behaviours to lead to more adaptive pain coping (Jensen, 2011; Skinner, Wilson, & Turk, 2012).

Researchers have directed attention towards evaluating acceptance-based approaches that emphasize surrendering control over physical, emotional, cognitive and social obstacles associated with pain, and accepting experience as it is (McCracken & Vowles, 2014). One of the most well known acceptance-based therapeutic approaches is Mindfulness-Based Stress Reduction (MBSR; Kabit-Zinn, 1982). The MBSR program was originally developed to help patients with CP and stress-related conditions such as anxiety, depression, and panic disorders (Kabat-Zinn, 1990) cultivate mindfulness via regular meditation practice. The standard MBSR treatment group consists of 8 consecutive weekly 2.5 hr sessions, with an additional all day retreat session during the 6th week. This program teaches a variety of mindfulness meditation exercises combined with group discussions regarding participant experiences. Participants are encouraged to commit 45 minutes daily to formal mindful meditation homework (e.g., sitting meditation and body scan) as well as informal mindful meditation (e.g., eating mindfully). During all mindfulness meditation exercises participants are taught to bring their attention to an object of awareness (e.g., breathing or eating) and notice any thoughts, emotions, or sensations that arise in a non-judgmental and non-elaborative way.

Definition of Mindfulness

Most researchers agree that mindfulness is an experiential process in which “awareness emerges through paying attention on purpose, in the present moment, and non-judgmentally to the unfolding of experience, moment to moment” (Kabit-Zinn, 2003, p. 145). There are two primary types of meditation practice including concentration meditation and mindfulness meditation (Kabit-Zinn, 1982). Concentration meditation involves focusing attention on one stimulus such as an object, a mantra, or the breath and holding this in focus for 20 minutes or longer. Mindfulness meditation, on the other hand, begins with focusing attention on one main object, usually the sensation of the breath, but then progresses to focus attention on all stimuli within the internal and external field of awareness such as thoughts, emotions, memories, sound and physical sensations. Mindfulness is rooted in Theravada Buddhism and is also referred to as vipassana or insight meditation, and the core goal is to cultivate insight into one's mental processes with a quality of nonjudgement and detached self-observation (Kabit-Zinn, 1982). In order to better understand the concept of mindfulness, several theoretical models have attempted to describe the mechanisms involved during this experiential process (Bishop et al., 2004; Brown & Ryan, 2003; Lutz, Slagter, Dunne, & Davidson, 2008; Roemer & Orsillo, 2003; Shapiro, Carlson, Astin, & Freedman, 2006; Wallace & Shapiro, 2006).

Theories of Mindfulness

Bishop et al.'s (2004) two-component mindfulness model is often used as a catalyst to formulate predictions about the effects of mindfulness training. These researchers suggest that mindfulness facilitates *self-regulation of attention* and a greater focal *orientation to experience*. Regarding attention self-regulation, mindfulness is predicted to improve *sustained attention* (maintaining attention to present-moment experience), *attention switching* (shifting the focus of attention back to an anchor, usually the breath, when thoughts, emotions, sensations or external stimuli create interference), *inhibition of elaborative processing* (avoidance of ruminating on thoughts, emotions and sensations that arise in the field of awareness) and *non-directed attention* (greater awareness to the present moment, without limiting biases interfering with the experience; Anderson, Lau, Segal, & Bishop, 2007). The second component of mindfulness, orientation to experience, emphasizes perceiving each moment-to-moment experience as it enters into the field of awareness in an open, accepting manner, without trying to evaluate or alter it in any way.

Lutz et al. (2008) put forth a mindfulness model emphasizing that focused attention and open monitoring are the primary styles of meditation trained in MBSR. Focused attention is described as cultivating three qualities to enhance attention regulation including: 1) monitoring and detecting distractions (e.g., mind wandering, pain, sounds), 2) disengaging focus from distractions without elaboration, and 3) redirecting focus of attention back to the intended object. These qualities of attention parallel those identified by Bishop et al. 2004 including sustained attention, inhibition of elaborative processing, and attention switching. Once these skills are advanced, the next skill of open monitoring can be practiced, which involves expanding attention to all stimuli that enter into the field of awareness with no selected object of focus and reducing reaction to cognitive and affective interpretations of the mind. The goal of continued mindfulness practice is to sustain attention with less effort. The parallels between open monitoring discussed by Lutz et al. and orientation to experience put forth by Bishop et al. are clear. Although there are differences in theoretical models and terminology used to describe the process of mindfulness training, the general conceptualization is that mindfulness meditation involves learning how to regulate attention and emotion with greater ease by training the mind to engage, disengage, and eventually accept as much as possible into the field of awareness with minimal elaboration of the experience.

Mindfulness and Attention

In an effort to investigate the validity of mindfulness theories, researchers have administered a range of objective cognitive tasks thought to tap these specific attention regulatory skills and have obtained conflicting results. Some researchers report improved attentional abilities (e.g., sustained attention, orienting, conflict monitoring and inhibitory control) in individuals after mindfulness training (Chambers, Lo, & Allen, 2008; Jha, Krompinger, & Baime, 2007; Moore & Malinowski, 2009; Tang et al., 2007; Valentine & Sweet, 1999; Wenk-Sormaz, 2005), while others found no significant change in these skills (Anderson, et al., 2007; Cusens, Duggan, Thorne, & Burch, 2010; MacCoon, Maclean, Davidson, Saron, & Lutz, 2014; McMillan, Robertson, Brock, & Chorlton, 2002; Ornter, Kilner, & Zelazo, 2007). The majority of these studies used healthy samples with the exception of two studies conducted by McMilan et al. and Cusens et al. which used a patient sample of traumatic brain injury and CP, respectively. The lack of observed attentional change may reflect deviations in the standardized mindfulness intervention, quantity of mindfulness meditation experience or other methodological variations.

Another potential explanation for failures to find attentional benefits is that mindfulness meditation might operate only on specific features of attention. Findings from recent studies suggest that this might be the case. For example, Anderson et al. (2007) included measures of sustained attention, attention switching, inhibition of elaborative processing, and non-directed attention. Thirty-nine participants were randomly assigned to the MBSR condition and 33 participants were assigned to a waitlist control group. Although no significant differences were reported between the groups on any of the attention tasks, they did find that an increase in mindfulness predicted improvements on the object detection task, a measure of non-directed attention, for the MBSR group but not the controls. These researchers suggest that the object detection task requires present moment awareness, which is associated with Bishop et al.'s (2004) second construct of orientation to experience more so than the first construct of attention regulation.

In line with these findings, Cusens et al. (2010) found no significant improvement in sustained attention in a CP patient sample receiving the Breathworks Mindfulness-Based Pain

Management Programme (n = 33). Implicit affect was measured by administering a version of the Implicit Association Test (IAT), which assesses associations between self and affective states. The IAT effect is the bias that occurs for categorizing self and positive words more quickly than self and negative words. A larger IAT effect represents a more positive self-concept. Explicit affect was also measured by asking participants to what degree they were experiencing each of the emotions used in the IAT test. The question of interest was the degree to which mindfulness training improved awareness of affect, which they examined by the correlation between the IAT effect and corresponding explicit measure. It was hypothesized that after mindfulness training patients would have greater awareness of pleasant stimuli rather than unpleasant stimuli. Consistent with this prediction, a significant negative correlation between implicit and explicit affect for pleasant words at Time 1 and a positive significant correlation for pleasant words at Time 2 was found. No significant correlation was obtained for unpleasant words in the intervention group, or for either pleasant or unpleasant words in the control group. These findings suggest that mindfulness helps patients disengage from focusing on emotionally salient stimuli such as negative affect or pain, and allows a broader awareness of their environment. Therefore, commonly used attention tasks in the literature may not tap the specific attention processes altered by mindfulness training. Given these findings, utilizing alternative tasks that measure one's ability to maintain awareness in the present moment and detect objects without allowing biases or expectations to limit perception would be valuable. The current study evaluated performance on a change blindness task to capture this attention process.

Change blindness is the failure to notice modifications to objects or scenes (Simons & Levin, 1998). It is commonly measured using two static images that contain an item of distinction between them, and these two images flicker, separated by a blank screen that prevents purely perceptual detection of the scene change (Koivisto & Revonsuo, 2008). In order to detect object changes in scenes, attention must be directed by motion signals, or guided by preference or interest. Since the flicker delocalizes the motion signals required to easily detect the change, viewers must guide attention by interest in particular aspects of the scene or scan the scene feature-by-feature (Rensink, O'Regan, & Clark, 1997). In light of Bishop et al.'s (2004) prediction that mindfulness training facilitates object detection in unexpected situations because it allows for greater awareness to the present moment as well as Cusens et al.'s (2010) findings with CP patients, it is reasonable to expect improvement in a change blindness task after participation in a MBSR program. Indeed, Hodgins and Adair (2010) found that individuals with greater meditation experience (n = 51; practiced 3 times per week) detected significantly more changes in flickering scenes and identified the changes more quickly compared to individuals with little or no meditation practice (n = 45).

Moreover, the fear-avoidance model of CP suggests that individuals living with CP are more primed to interpret noxious and non-noxious stimuli as threatening and are hypervigilant to potential causes of pain in order to help them avoid painful experiences (Vlaeyen & Linton, 2000). In other words, CP patients may narrowly direct their focus of attention to pain-related potential of stimuli in an effort to avoid triggers or exacerbations of their pain to the detriment of their ability to spend attentional resources to a broader range of stimuli in their environment. Therefore, since MBSR training teaches individuals to accept thoughts, emotions, and sensations as they are experienced without further processing and reduces expectations about the pain experience, CP patients can learn to disengage from perceived pain-relevant stimuli more quickly and allocate resources to other aspects of their environment. The current study will be the first to examine the effects of MBSR training on change blindness in a CP population using a randomized controlled trial. It is hypothesized that CP patients will show significant improvements in identifying changes in scenes and do so more quickly compared to a waitlist control group (WC).

General Effects of MBSR

Studies examining MBSR training benefits on objective measures of attention is limited and the results to date have been inconsistent, however, research assessing psychological and physical health in a wide range of clinical and non-clinical samples is abundant and findings are more congruent. Three meta-analytic summaries of the effects of MBSR on physical and mental health in clinical and non-clinical samples suggest positive outcomes. Grossman, Niemann, Schmidt and Walach (2004) and Baer (2003) included both controlled and uncontrolled studies and reported moderate to large effect sizes. Specifically, Grossman and colleagues obtained an effect size of $d = 0.54$ for mental health and $d = 0.53$ for physical health. Baer (2003) reported effect sizes of $d = 0.70$ for anxiety and $d = 0.84$ for depression across a variety of populations. Effect sizes for medical and psychological outcomes for CP patients was lower at $d = 0.37$. Bohlmeijer Prenger, Taal, and Cuijpers (2010) used a more conservative approach and only included 8 randomized controlled trials of MBSR on depression, psychological distress, and anxiety for chronic somatic conditions and found an effect size of $d = 0.26$, $d = 0.47$, and $d = 0.32$, respectively, for these variables. Generally, mindfulness training has demonstrated benefits for improving health in a variety of populations including CP patients.

Effects of MBSR on CP

Jon Kabat-Zinn (1982) conducted the first study assessing the capacity for MBSR to reduce CP. The rationale set forth for using mindfulness training to regulate the experience of CP was that with continued practice an uncoupling between the sensation of pain and the negative cognitive, interpretative, and affective elements associated with pain (e.g., this pain is unbearable and will never go away) might occur by observing these components as separate and disconnected. Significant reductions in pain ratings and mood disturbance for a heterogeneous group of 51 CP patients were obtained; however, no control group was implemented for between-group comparison purposes. A later study compared CP patients receiving 10 weeks of mindfulness training with a group receiving treatment as usual including medication and nerve blocks (Kabat-Zinn, Lipworth, & Burney, 1985). Reductions in anxiety, depression, pain intensity, perceptions of negative body image, and medication use occurred in the mindfulness group but not in the control group. Results remained the same at 15 months follow up with the exception of pain intensity, which returned to baseline levels. These positive findings initiated an increase of research examining the effects of MBSR to ameliorate symptoms in CP sufferers. Therefore, a review of the controlled literature examining the effects of MBSR on physical and psychological symptoms in CP patients is warranted.

Researchers have used randomized controlled trials to examine the effects of MBSR in various CP samples including fibromyalgia, rheumatoid arthritis, migraine, mixed pain samples, and back pain. Astin, Shapiro, Eisenberg, and Forys (2003) randomized 128 fibromyalgia patients (*Mean age* = 47.7± 10.6*)* to an 8-week MBSR program with Qigong movement (*n* = 64) or an 8-week education control group (*n* = 64). Assessments were conducted at baseline, 8, 14 and 24 weeks. Forty-nine % of the sample dropped out by 24 weeks, which as highlighted by the authors can introduce bias to the results. The intervention group received standard MBSR for the initial 1.5 hours and Qigong for the last hour. Pain was measured with the number and severity of tender points and the pain subscale from the Medical Outcome Study Short Form (SF-36). Depression, functioning and coping were measured using the Beck Depression Inventory (BDI), Fibromyalgia Impact Questionnaire (FIQ), and Coping Strategies Questionnaire (CSQ), respectively. There were no between group differences for any outcomes. However, analysis of within-group effects showed statistically significant improvements from baseline to post-treatment in both groups in the severity of tender points, pain severity as measured with SF-36, functioning, depression, and the catastrophizing subscale from the CSQ. These improvements maintained at 14 and 24 weeks follow up.

In a 3-armed randomized controlled trial, 177 middle-aged adults (*Mean age* = 52.9 ± 9.6) diagnosed with fibromyalgia were allocated to a MBSR group (n = 59), an active education and relaxation control group (n = 59), or waitlist control group (n = 59; Schmidt et al., 2011). The number of participants that completed the study for each group was 45, 51 and 52, respectively, resulting in an 84% completion rate. Pain was measured with the FIQ, affective and sensory pain subscales from the Pain Perception Scale (PPS), and the 24-item general complaint subscale derived from the Giessen Complaint Questionnaire (GCQ). Other measures included the Quality of Life Profile for the Chronically Ill (PLC), Pittsburg Sleep Quality Index (PSQI), Center for Epidemiological Studies Depression Inventory (CES-D), trait subscale from the State-Trait Anxiety Inventory (STAI) and Frieburg Mindfulness Inventory (FMI). Participants in the MBSR group and active control group demonstrated significant reductions in trait anxiety at 16 weeks compared to waitlist controls. Also, patients in the MBSR group reported higher mindfulness at 16 weeks compared to patients in the active control group. No other significant group differences were obtained. Post-hoc analyses comparing within-group effects between baseline and 16-weeks follow up demonstrated significant improvements in the impact of fibromyalgia, quality of life, depression, and trait anxiety in the MBSR group but not the active or waitlist control groups. Sleep quality significantly improved from baseline to 16 weeks follow up in the MBSR and active control groups but not the waitlist control group. Sensory pain marginally improved in the MBSR group and waitlist control groups, but not in the active control group. Improvements in affective pain and general physical complaints improved in all three groups from baseline to 16 weeks. There were no significant within-group effects found for mindfulness.

Sephton et al. (2007) randomized 91 females diagnosed with fibromyalgia (*Mean age* = 48.2 ± 10.6) to MBSR (*n* = 51) or a waitlist control group (*n* = 40) and assessed functional impairment and symptom severity with the FIQ, pain severity with a 4-item visual analog scale (VAS), sleep quality with the Stanford Sleep Questionnaire (SSQ), and depression with the BDI at 3 timepoints: prior to treatment, at 8-weeks post-treatment and at 16-weeks follow up. Ten participants dropped out of the MBSR group and 13 dropped out of the waitlist control group, leaving a completion rate of 75%. An intent-to-treat approach was used as the primary analysis and baseline scores were inserted in place of missing data at post-treatment and 16 weeks follow up. Secondary analyses used only participants who completed at least baseline and post-treatment assessments. Both primary and secondary analyses revealed significant reductions in depression in the MBSR group versus the control group at post-treatment and the effect persisted at 16-weeks follow up. Results for the remaining outcomes were not reported in this study.

Cash and colleagues (2015) used the same sample of 91 women diagnosed with fibromyalgia in Septhon et al.'s study (2007) and reported on the remaining outcomes including: functional impairment and symptom severity (FIQ), pain severity (4-item VAS), and sleep quality (SSQ), and also reported on two additional outcomes not mentioned in the previous study: perceived stress (Perceived Stress Scale), and neuroendocrine function (salivary cortisol levels at waking, 45 minutes after waking, bedtime, noon, 4pm and 7pm). Compared to controls, significant improvements in the severity of fibromyalgia symptoms measured with the FIQ and perceived stress were found in the MBSR group, while no significant improvements were observed in functional impairment (FIQ), pain severity (VAS), sleep quality, or cortisol levels. Furthermore, Weissbecker et al. (2002) used the same sample of 91 fibromyalgia patients in the two aforementioned studies and reported that sense of coherence, that is, viewing the world as meaningful, manageable, and understandable, significantly improved 2 months following MBSR, while this change was not observed for waitlist controls.

Selective reporting is a concern for these RCTs and results should be interpreted with caution. Few between group differences were observed when comparing MBSR to active control groups rather than waitlist control groups, and all five studies relied on self-report measures, with the exception of cortisol levels reported in Cash et al. (2015). This raises the concern that social desirability is a potential explanation for the findings, that is, the tendency for patients to respond favourably or according to preferences of the researcher when they are aware they are being observed. Incorporating objective measures such as the computerized change blindness task in the current study helps to address this gap in the literature. Other explanations for the lack of group differences include limited power to detect effects, modifications of the MBSR program, or selection of assessment tools. A recent systematic review and meta-analysis of 6 controlled studies examined MBSR for 674 individuals with fibromyalgia (Lauche, Cramer, Dobos, Langhorst, & Schmidt, 2013) and concluded that there is weak evidence for pain reduction and increase in quality of life. The paucity of controlled studies assessing sleep quality, fatigue, and depression prevented recommendations regarding the utility of MBSR to improve these outcomes. It was highlighted that future RCTs are needed to make conclusions and recommendations regarding the utility of MBSR for fibromyalgia.

Randomized controlled trials assessing MBSR in individuals with arthritis, migraines, mixed CP and back pain highlight the potential for emotional and physical improvements following treatment, however, contradictory findings across trials further support the need for the current study. For example, Pradhan and colleagues (2007) randomized 31 patients diagnosed with rheumatoid arthritis to MBSR (*Mean age* = 56 ± 9) and 32 patients to a waitlist control group (*Mean age* = 53 ± 11) and assessed the following outcomes at baseline, 2 months and 6 months: 1) Depression and psychological distress were measured with the depression subscale and General Severity Index (GSI) from the Symptom Checklist-90-Revised (SCL-90-R), 2) RA disease status was assessed using the Disease Activity Score in 28 joints (DAS28), which provides an indication of the number of swollen and tender joints, and patients' perception of disease status on a 100-mm VAS scale, 3) Well-being was measured with the total summary score from the Psychological Well-Being Scale and, 4) Mindfulness was assessed using the Mindfulness Attention Awareness Scale (MAAS). No significant group differences were obtained at post-treatment for any of these outcomes. Significant reductions in psychological distress and improvements in well-being at 6-months follow up were observed as well as marginally significant decreases in depression and increases in mindfulness, suggesting that assessing outcomes beyond post-treatment is an important consideration in order to track changes over time.

Wells et al. (2014) conducted a pilot RCT to assess the safety, feasibility and effectiveness of MBSR in adults with migraines. Ten patients were assigned to 8-week MBSR (*Mean age* = 45.9 ± 17) and 9 continued with standard care (*Mean age* = 45.2 ± 12). Participants were asked to report the frequency, duration and severity of migraines over 28 days prior to treatment (baseline), the last 28 days of the MBSR intervention (first follow up), and 28 days following end of treatment (final follow up). Migraine-related disability was measured with the Headache Impact Test-6 (HIT-6) and the 1-month Migraine Disability Assessment (MIDAS). Self-efficacy (Self-Efficacy Scale), mindfulness (Five-Facet Mindfulness Questionnaire), perceived stress (Perceived Stress Scale-10), anxiety (State-Trait Anxiety Inventory), depression (PRIME-MD Patient Health Questionnaire-depression module; PHQ-9), and quality of life (Migraine Specific Quality of Life) were also assessed. No adverse events were reported and there were no dropouts suggesting that MBSR is a safe and feasible therapeutic approach with migraineurs. Significant reductions were obtained in the MBSR group relative to the control group from baseline to post-treatment in migraine pain-related disability, self-efficacy and mindfulness, and these effects were maintained at 1-month follow up. No significant group differences were obtained in headache frequency, severity and duration, quality of life, depression, anxiety, and perceived stress.

Plews-Ogan, Owens, Goodman, Wolfe and Schorling (2005) conducted a randomized controlled pilot study to assess the feasibility and effectiveness of using MBSR and massage for treating patients who have chronic musculoskeletal (MSK) pain and have predominately low socioeconomic status (*Mean income* = $23,500). Thirty patients (*Mean age* = 46.5 years) were assigned to 8-week MBSR, 1-hour weekly massages or usual standard care (*n* = 10 for each group) and assessed at baseline, 4, 8, and 12 weeks. Four patients dropped from the MBSR group, 1 from the massage group and 2 from the usual standard care group, for a total completion rate of 77%. Pain sensation (i.e., the intensity of pain) and pain unpleasantness (i.e., how annoying the pain is) were each rated on a 10-point scale. Physical and mental health was assessed using the 12-item Short Form Health Survey (SF-12). Significant improvements in mental health were obtained in the MBSR group but not the standard care group at 8 weeks and 12 weeks, while no differences in pain sensation or unpleasantness were observed. Mental health significantly improved in the massage group relative to the standard care group at 8 weeks, but scores returned to baseline at week 12. Pain unpleasantness significantly decreased in the massage group compared to the standard care group at week 8, but no differences were obtained between groups at week 12.

Wong et al. (2011) compared 8-week MBSR (*Mean age* = 48.7 ± 7.8) to a multidisciplinary psychoeducation group (MPI; *Mean age* = 47.1 ± 7.8) in a sample of predominately low-income adults living in Hong Kong with various CP conditions who did not have comorbid depression. The MPI active control group was designed to match the duration of treatment in the MBSR group and covered educational topics on understanding CP, while no mind-body or cognitive techniques were included to prevent content overlap from MBSR. Ninety-nine participants were randomly assigned to the MBSR group (n = 51) and MPI group (n = 49) and assessed at baseline, immediately following intervention, 3-months, and 6-months follow up. Primary outcomes were pain intensity and pain-related distress measured each on an 11-point numerical rating scale. Secondary outcomes included mood assessed with the Chinese version of Profile of Mood States (POMS), depression, assessed with the Chinese Centre for Epidemiological Studies-Depression Scale (CES-D), anxiety, assessed with the Chinese Version State-Trait Anxiety Inventory (STAI), physical functioning and mental health, assessed with the Chinese version Medical Outcomes Study Short-Form Health Survey (SF-12), and reported number of sick days, which served as a proxy for pain disability. The MPI group had significantly greater improvements from baseline to post-treatment in pain-related distress, and vigor (POMS), compared to the MBSR group. Significant within-group differences were found for both groups in pain intensity and pain-related distress when comparing scores from baseline to post-treatment. Physical functioning significantly improved at 3 months and 6 months compared to baseline scores for the MBSR and MPI groups. No between or within-group differences were found for pain disability (number of sick days), depression, anxiety, and mental health.

In a recent evaluation of 109 individuals with various pain conditions in Denmark, participants were assigned to standard 8-week MBSR with a shorter retreat day (*Mean age* = 46 ± 12*; n = 54)* or a waitlist control group (*Mean age* = 46 ± 12; *n* = 55; La Cour & Peterson, 2015. Significant improvements were observed post-treatment in the MBSR relative to control group in vitality (SF-36), anxiety and depression (Hospital Anxiety and Depression Scale), psychological well-being (SF-36), and perceived control over pain (CSQ) with medium effect sizes (*d* = .37 to .55). Significant group differences with larger effects were observed for the activity engagement subscale and total pain acceptance scores from the Chronic Pain Acceptance Questionnaire (*d* = .60 and *d* = .71, respectively) in the MBSR group compared to the control group at post-treatment. Completion rates were 83% (*n* = 90/109) for comparing outcomes at post-intervention, and 67% at 6-months follow up (73/109). No significant group differences were obtained in the pain willingness subscale of the CPAQ, pain severity (Brief Pain Inventory and SF-36 pain subscale), physical functioning (SF-36), catastrophic thinking and minimizing pain (CSQ), or mental and physical health (SF-36). Among those in the intervention group, no significant changes in outcomes were observed from post-treatment to 6-months follow up suggesting long-term maintenance of effects.

Morone and colleagues have conducted a series of RCTs with adults older than 65 years of age with chronic low back pain (Morone et al., 2016; Morone, Greco & Weiner, 2008; Morone, Rollman, Moore, Li, & Weiner, 2009). The first pilot study involved randomly assigning 19 participants to MBSR and 18 participants to a waitlist control group (Morone, et al., 2008). Significant group differences were obtained in CP acceptance and physical functioning with improvements observed in the MBSR group compared to the control group at post-treatment, measured with the CPAQ and SF-36, respectively (d = .83 and d = .46). These improvements were maintained at 3-months follow up. No significant group differences were obtained in pain severity (Short-Form McGill Pain Questionnaire; SF-MPQ and SF-36 pain scale), pain disability, (Roland Disability Questionnaire; RMDQ), or quality of life (physical, mental and global health composites from the SF-36).

A later study conducted by Morone and colleagues (2009) compared MBSR to an active education control group (n = 20 per group) to account for duration of treatment, group size and facilitator attention and reported improvements in both groups from baseline to post-treatment and 4 months follow up in pain disability (RMDQ), pain severity (SF-MPQ) and pain self-efficacy (Chronic Pain Self-Efficacy Scale) while no changes in levels of mindfulness (FFMQ and MAAS) or quality of life (role limitations due to emotional problems scale from SF-36) were found. Morone et al.'s most recent work (2016) involved a large and adequately powered RCT with 140 and 142 individuals assigned to MBSR and education control groups. Significant improvements in physical function and pain self-efficacy were found in the MBSR group relative to controls at post-treatment but these effects did not persist at 6-months follow up. Current and most severe pain (over the past week) significantly decreased at 6 months assessed with a Numeric Pain Rating Scale (NRS) for the MBSR group but not controls. No differences were found in levels of mindfulness (MAAS) or depression (Geriatric Depression Scale), and improvements in quality of life (global and physical health composites SF-36) and pain catastrophizing (PCS) did not reach significance.

Interpretation of findings across RCTs examining the effectiveness of MBSR for CP is complicated by variation in sample characteristics such as pain condition (single disease vs. mixed pain conditions), socioeconomic status (low vs. middle income), age (middle-aged vs. older adults), exclusion criteria that impact the level of disability among the sample (e.g., excluding patients with co-morbid depression), and cultural differences inherent in the study sample based on location (U.S., Hong Kong, and Denmark). Methodological variations are also prevalent across studies including modifications to the standard MBSR program (e.g., shorter retreat day or varying amounts of homework assigned), differences in selected control group (waitlist control versus active control group), level of facilitator training and personal practice, and differences in the selected questionnaires to assess outcomes.

Out of the 13 RCTs reviewed, the most common outcomes assessed were pain severity (n = 11) and pain disability/physical functioning (n = 9). Of the 11 studies that assessed pain severity, only 2 found significant improvements in the MBSR group when compared to a waitlist control group (Cash et al., 2015) or education control group (Morone et al., 2016), using the FIQ and VAS, respectively. Five studies found no group differences in pain severity when comparing MBSR to a waitlist control group (La Cour & Peterson, 2015; Pradhan et al., 2007; Wells et al., 2014; Morone, et al., 2008) or standard care (Plews-Ogan et al., 2005), and 4 revealed within group improvements in pain severity over time for both MBSR and education control groups (Astin et al., 2003; Morone et al., 2009; Schmidt et al., 2011; Wong et al., 2011). Significant between group differences in physical functioning or disability, assessed with the SF-36, HIT-6, MIDAS, and FIQ, were found in 4 of 9 studies (Morone, et al., 2008; Morone et al., 2016; Schmidt et al., 2011; Wells et al., 2014), while no differences were found in 2 studies using a waitlist control group (Cash et al., 2015, La Cour & Peterson, 2015), and 3 studies found improvements in both MBSR and active education control groups (Astin et al., 2003; Morone et al., 2009; Wong et al., 2011).

All of the reviewed RCTs included assessment of non-pain outcomes including depression (*n* = 8), quality of life (*n* = 6), coping (*n* = 5), anxiety (*n* = 3), and stress (*n* = 2). Depression significantly improved following MBSR relative to controls for 3 studies, of which 2 compared scores on the BDI and HADS, respectively, to a waitlist control group (La Cour & Peterson, 2015; Sephton et al., 2007), and 1 study compared scores on the CES-D inventory to an active control group (Schmidt et al., 2011), while no differences were found in 4 studies (Morone et al., 2016; Pradhan et al., 2007; Wells et al., 2014; Wong et al., 2011) and 1 study found improvements for both MBSR and an education control group (Astin et al., 2003).

Quality of life was assessed using various indices including well-being (Psychological Well-Being Scale), mental, physical, and global health (SF-12 or SF-36), vitality (SF-36), and vigor (POMS). Between group differences were obtained in some measures of quality of life in 2 studies which compared MBSR to a waitlist control group (La Cour & Peterson, 2015) and standard care (Plews-Ogan et al., 2005), while no differences were obtained for quality of life in 4 studies which compared MBSR to standard care (Wells et al., 2014), waitlist controls (Morone, et al., 2008), or active controls (Morone et al., 2009; Morone et al., 2016).

Coping with pain was assessed with measures of self-efficacy (chronic pain self-efficacy scale; CSQ), sense of coherence (SOC), and pain catastrophizing (PCS; CSQ). Sense of coherence and control over pain significantly improved in MBSR participants relative to waitlist controls in 2 studies (La Cour & Peterson, 2015; Weissbecker et al., 2002). Two studies reported improvements in self-efficacy and catastrophizing in both MBSR and active educational control groups, respectively (Astin et al., 2003; Morone et al., 2009), and Morone et al. (2016) found greater self-efficacy but no improvements in pain catastrophizing when comparing MBSR to an education control group.

Anxiety and stress were only examined in a few of the RCTs reviewed. Anxiety significantly improved in 2 of 3 studies when comparing MBSR to waitlist controls with the HADS in a MSK pain sample (La Cour & Peterson, 2015), and when comparing MBSR and an education control group to waitlist controls with the STAI in a fibromyalgia sample (Schmidt et al., 2011), but no differences in scores were found on the STAI when comparing MBSR to standard care in migraineurs (Wells et al., 2014). Stress significantly improved in MBSR versus waitlist controls in fibromyalgia patients (Cash et al., 2015), but no effects were observed when comparing MBSR to standard care in migraineurs (Wells et al., 2014), and both of these studies used the PSS.

In addition to these outcomes, mindfulness was measured in 5 studies and pain acceptance was measured in 2 studies. Two of 5 studies found significant increases in mindfulness when comparing MBSR to an education control group on the FMI (Schmidt et al., 2011) and when comparing MBSR to standard care on the FFMQ (Wells et al., 2014). Two studies found no significant differences on the FFMQ between MBSR and education controls (Morone et al., 2009; Morone et al., 2016), and 1 study found a marginally significant improvement on the MAAS in the MBSR group compared to a waitlist control group at 6-months follow up (Pradhan et al., 2007). In the 2 studies that assessed changes in pain acceptance, both reported significant improvements in the MBSR group relative to the waitlist control group using the CPAQ (La Cour & Peterson, 2015, Morone et al., 2008).

Systematic and meta-analytic reviews have been conducted to summarize the experimental (i.e., RCTs, non-randomized controlled trials) and non-experimental (i.e., no control group, cohort study, case series) literature examining the impact of MBSR, or modified mindfulness interventions, for heterogenous CP samples. Teixeira (2008) conducted an integrative review on 10 studies of which 6 were RCTs/quasi-experimental and 4 were non-experimental to address gaps in the literature and provide direction for future research. Recommendations include larger sample sizes, randomization procedures, and inclusion of other CP conditions like neuropathic pain, greater representation of demographic characteristics, more qualitative research, and use of objective measures. Chiesa and Serretti (2011) reviewed 6 RCTs and 4 non-randomized controlled studies that examined the effectiveness of standard MBSR or close variants of MBSR (e.g., addition of qigong or removal of yoga), and concluded that there is evidence to support non-specific effects for reducing symptoms of pain and depression but no evidence to support specific effects due to the absence of active comparator groups to rule out factors such as group support or facilitator attention. Similar limitations to those identified by Teixeira (2008) were noted including small sample size, lack of demographic representation and reliance on subjective self-report measures, in addition to deviations in the mindfulness intervention employed.

Garmon et al. (2014) conducted a systematic review of 13 RCTs, 6 case series, and 4 cohort studies and concluded that there is not sufficient evidence in support of MBSR to reduce pain severity, but the lack of power to detect an effect is a potential explanation. The greater number of positive findings in at least 1 non-pain outcome for the majority of studies led the authors to suggest that MBSR may help individuals manage pain, rather than reduce the degree of pain, through improvements in coping skills, anxiety, depression and well-being, but cautioned that these effects may be due type 1 error given the high number of outcomes evaluated in each study.

The most recent meta-analytic review selected broader criteria for the type of intervention included and summarized findings from 25 RCTs that compared MBSR (*n* = 11), Acceptance and Commitment Therapy (ACT; *n* = 9), Mindfulness-Based Cognitive Therapy (MBCT; *n* = 2), MBSR plus MBCT (*n* = 1), or other mindfulness-based intervention variants (*n* = 3) to waitlist control groups, education/support control groups or treatment as usual (Veehof, Trompetter, Bohlmeijer, & Schreurs, 2016). Pooled standardized mean differences revealed small post-treatment effects for pain severity, depression, disability, and quality of life (.24, .43, .40, .44, respectively), while moderate effects were found for anxiety and pain interference (.51 and .62). Analysis of follow up ranging between 2 and 6 months revealed that these effects at minimum were maintained, except that the effects for pain interference increased from moderate to large (1.05), and the effects for depression and quality of life increased from small to moderate (.53 and .66). They concluded that overall mindfulness- and acceptance-based approaches have moderate effectiveness for several pain-related outcomes particularly when examined long-term, however, future research should incorporate larger sample sizes, assessment of mechanisms of change over time, and adequate reporting on randomization procedures and expertise of therapists.

Although reviews and meta-analytic studies varied regarding the selection criteria for inclusion of the intervention type, primary outcomes, and quality of methodological design, the general consensus is that more high quality trials using a randomized design are needed to determine the effects of mindfulness-based interventions for CP. The current study will address some of the aforementioned limitations by: 1) implementing a randomized cross-over design in a mixed CP sample, 2) including an objective measure of attention 3) reporting specific randomization procedures, 4) describing the competency of the group facilitator, and 5) assessing potential mechanisms of change attributable to MBSR at short and long-term follow up. Given the few studies that reported improvements in pain severity, the small effect sizes, and the complex and often refractory pain conditions individuals present with at the pain clinic where this work was completed, differences between groups were not expected in the current study. Greater consistency in effects for pain disability and non-pain outcomes across studies suggest that managing the symptoms associated with pain are more amenable to change.

Pain disability is described as the degree to which pain interferes with individuals' ability to engage in rudimentary and meaningful activities. Although the severity of pain may remain unchanged, it is possible that MBSR can help individuals better identify and manage distressing emotions, cognitive interpretations, and experiences associated with pain, which will result in reduced interference of pain. Moreover, given the comprehensive pain models which recognize psychological and social processes as important parts of the pain experience (Melzack, 2004; Turk & Okifuji, 2002), the high rates of co-occurring depression and anxiety reported among patients with CP (Asmundson, & Katz, 2009; Dworkin & Gitlin, 1991), and theories of mindfulness proposing that continued practice permits greater capacity to regulate stress and emotions by viewing cognitive interpretations and emotional responses as separate from pain sensation (Kabit-Zinn, 1982), evaluating changes in symptoms of depression, anxiety, and stress following MBSR training is an important avenue to investigate. Therefore, in the current randomized controlled trial of MBSR, it is expected that CP patients will experience significant reductions in depression, anxiety, stress, and pain disability, while no significant differences are expected in pain severity.

Mechanisms of Mindfulness

Two important areas of research surrounding mindfulness training are critical to understanding how MBSR operates to improve pain management. The first is determining the areas of functioning in which mindfulness confers benefits. The present study addresses this question by investigating whether MBSR training influences change blindness, pain severity, pain disability, depression, anxiety, and stress in CP patients. The second area of research involves understanding the mechanisms by which these benefits occur. As previously mentioned, theoretical models have been put forth in an attempt to understand the experiential process of mindfulness, and researchers are urged to include measures that assess specific aspects of MBSR that are thought to induce improvements to better evaluate its unique contribution (e.g., Chiesa & Serretti, 2011; Veehof et al., 2016). Several measures have been developed to assess levels of mindfulness, which is a core component of MBSR. Common scales used in the literature include the *Freiburg Mindfulness Inventory* (Buchheld, Grossman, & Walach, 2001), the *Kentucky Inventory of Mindfulness Skills* (Baer, Smith, & Allan, 2004), the *Cognitive and Affective Mindfulness Scale* (Feldman, Hayes, Kumar, Greeson, & Laurenceau, 2007), the *Five Facet Mindfulness Questionnaire* (Baer, Smith, Hopkins, Krietemeyer, & Toney, 2006) and the *Mindful Attention Awareness Scale* (Brown & Ryan, 2003).

For the current study, both the FFMQ and MAAS were administered as these scales have revealed changes in mindfulness in the randomized controlled trials conducted to date with CP and have adequate reliability. The combined evidence from randomized and non-randomized studies suggests that mindfulness may be a significant contributor to positive outcomes. A fraction of RCTs examining the effects of MBSR in CP samples have revealed significant pre-to-post changes in mindfulness when compared to control groups which were maintained at follow up (Schmidt et al., 2011; Wells et al., 2014), while other studies have not (Morone et al., 2009; Morone et al., 2016). Non-randomized studies have demonstrated an increase in mindfulness scores post-training and significant associations between mindfulness and a variety of cognitive tasks in healthy populations (Anderson et al., 2007; Chambers et al., 2008; Moore & Malinowski, 2009; Ortner et al., 2007; Schmertz, Anderson, & Robins, 2009) as well as psychological outcomes in distressed patients (Nyklicek & Kuijpers, 2008). Studies have also shown the importance of mindfulness for improving functioning in CP patients (McCracken, Gauntlett-Gilbert, & Vowles, 2007; McCracken & Thompson, 2009).

A second construct deemed important for psychological improvement and functioning in CP patients is acceptance of pain. Acceptance is part of the definition of mindfulness and is viewed as a process that evolves during mindfulness training. Two RCTs demonstrated pre-to-post improvements in pain acceptance following MBSR compared to controls which were maintained at follow up (La Cour & Peterson, 2015; Morone et al., 2008) and pain acceptance has been highlighted as an important component for reducing pain-related symptoms (Mason, Mathias, & Skevington, 2008; McCracken, 1998; McCracken et al., 2007; Viane et al., 2003; Vowles & McCracken, 2008). Given that mindfulness and pain acceptance are core principles of MBSR, the current study will evaluate changes in these outcomes from pre-MBSR to post-MBSR, and 3 months follow up, and examine their predictive role in leading to improved outcomes which will add a novel dimension to the literature. Therefore, it is expected that MBSR training will lead to an increase in mindfulness and acceptance of pain at post-treatment and that both of these constructs will be significantly associated with improvement on the change blindness task as well as the psychological and physical pain indices (i.e., depression, anxiety, stress, pain intensity, and pain disability).

The extent to which acceptance of pain and mindfulness induces improved outcomes may be dependent on the amount of meditation homework employed by MBSR participants. Indeed, between-session mindfulness homework is viewed as crucial to optimizing treatment outcomes and facilitators of MBSR programs are informed to encourage patients to incorporate mindfulness meditation into their daily routines. A review of studies examining the relationship between homework and program outcomes has highlighted a discrepancy in the literature (Vettese, Toneatto, Stea, Nguyen, & Wang, 2009). Some research has found a significant association between homework and program outcomes (Carlson, Ursuliak, Goodey, Angen, & Speca, 2001; Carlson, Speca, Faris, & Patel, 2007; Carmody & Baer, 2008; Carmody, Crawford, & Churchill, 2006), whereas other studies found no relationship (Anderson et al., 2007; Carlson, Speca, Patel, & Goodey, 2004; Davidson et al., 2003). Following the MBSR intervention, participants will be asked to indicate the quantity of formal and informal meditation practices they engaged in. A significant association between amount of homework and all outcomes is expected.

Research suggests mindfulness training produces benefits long-term. Of the RCTs that demonstrated between group benefits post-MBSR, all effects were maintained at follow up, with the exception of Morone et al.'s (2016) study which found that physical functioning and self-efficacy did not sustain at 6 months in a large sample of older adults with low back pain. Significant improvements in depression, sense of coherence, severity of fibromyalgia symptoms and perceived stress among middle-aged adults with fibromyalgia maintained at 2 months follow up (Cash et al., 2015; Sephton et al., 2007, Weissbecker et al., 2002). In addition, migraine disability, self-efficacy and mindfulness improvements maintained at 1-month follow up in middle-aged adult migraineurs compared to standard care (Wells et al., 2014), improved mental health maintained at 1-month follow up in middle-aged low SES individuals with MSK pain compared to standard care (Plews-Ogan et al., 2005), improved vitality, anxiety, depression, psychological well-being, control over pain, and pain acceptance maintained at 6-months follow up in a middle-aged mixed CP sample compared to waitlist controls (La Cour & Peterson, 2005), and CP acceptance maintained at 3-months follow up in older adults with low back pain compared to waitlist controls (Morone et al., 2008). The majority of research that has examined and observed benefits in attention immediately following MBSR training has not evaluated maintenance of effects (Chambers et al., 2008; Jha et al., 2007; Moore & Malinowski, 2009; Tang et al., 2007; Valentine & Sweet, 1999; Wenk-Sormaz, 2005). This is the first study to examine the effects of MBSR on attention, as measured with change blindness long-term. Taken together, it is expected that the significant benefits hypothesized in pain-related health outcomes post-treatment in the current study will be maintained at 3-months follow up.

Summary of Goals and Hypotheses

There are two primary goals and four secondary goals for the current study.

Primary Objective 1. To evaluate the effectiveness of MBSR compared with a WC group in improving pain-related symptoms using a randomized controlled trial. The primary outcome measures include depression, anxiety, stress, pain intensity and pain disability.

Hypothesis. It is hypothesized that patients assigned to the MBSR group will have significantly decreased depression, anxiety, stress, and pain disability at post-treatment compared to patients assigned to the WC group. Pain intensity is expected to reduce, although this finding may not reach statistical significance.

Primary Objective 2. To examine the effects of MBSR on attention, assessed with a computerized change blindness task.

Hypothesis. It is hypothesized that patients in the MBSR group will show significant speed and accuracy improvements in a change blindness task, compared to the WC group.

Secondary Objective 1. To determine if MBSR training leads to significant increases in mindfulness and pain acceptance.

Hypothesis. It is expected that participants in the MBSR group will demonstrate significantly greater mindfulness and pain acceptance compared to the WC group.

Secondary Objective 2. To determine if changes in mindfulness and pain acceptance are associated with changes in attention and pain-related symptoms.

Hypothesis**.** A significant association between mindfulness and change blindness as well as mindfulness and pain-related symptoms is expected such that patients with greater mindfulness will have an improved ability to detect changes in scenes (i.e., faster reaction times and greater accuracy), and fewer symptoms of depression, anxiety, stress, pain intensity and disability. The same pattern is expected with pain acceptance.

Secondary Objective 3. To explore associations between quantity of homework completion and changes in pain-related symptoms and attention.

Hypothesis. A significant negative association is expected such that patients who report completing more meditation homework will have greater improvement in pain intensity, pain disability, depression, anxiety, stress, and faster reaction times and greater accuracy on the change blindness task.

Secondary Objective 4. To explore whether benefits observed following MBSR treatment are maintained at 3-months follow up.

Hypothesis. Benefits observed post-treatment are expected to maintain at 3-months follow up.

Chapter 2: Methods

Design

A 2-armed single centre, single blind, prospective randomized crossover trial was conducted in which participants were randomly assigned to a (1) MBSR group (n = 25) or (2) WC group (n = 24). The primary outcome measures were changes in pain disability, pain intensity, depression, anxiety, stress and attention, as measured by a computerized and adapted version of the change blindness task. Secondary outcomes were changes in mindfulness and pain acceptance. Based on an effect size of 0.5, derived from reviews of the effects of mindfulness on mental and physical health (Baer, 2003; Grossman, 2004), and power of .80, power analyses calculated using G*Power software determined the optimal sample size is 64 per group.

Participants

Forty-nine adult patients with chronic non-cancer pain between 18 and 80 years of age were recruited from a multidisciplinary pain management centre in a Toronto academic hospital and participated in this study over 2 years. Additional inclusion criteria were proficiency in the English language, capability of interacting with others in a group setting and basic computer skills. Demographic data are provided in the results section.

Exclusion criteria were based on considerations of severity that interfere with participants' capacity to engage in the group treatment process. These include: 1) alcohol or drug abuse (past history was acceptable as long as their situation was stable for a minimum of 3 months), 2) psychiatric psychosis (past history of schizophrenia was acceptable as long as currently stable), 3) current major depressive disorder, 4) current severe social phobia, 5) at immediate risk for suicide, 6) cerebral lesions or tumors (unless medically and cognitively stable), 7) neurological disease, 8) medically or cognitively unstable as determined by a family physician. Individuals who previously participated in a mindfulness meditation program were also excluded. Examining the effects of the MBSR program among patients with a diverse range of CP conditions (i.e., chronic pelvic pain, facial pain, back pain, headaches, fibromyalgia, and arthritis rather than a single condition was chosen since the program was originally developed and evaluated for a heterogeneous group of CP patients (Kabit-Zinn, 1982) and this is the current delivery format at the pain centre where this research was conducted. The purpose was to evaluate the MBSR program and limit modification to the current delivery permitting increased generalizability of the intervention effects.

Procedure

Upon approval from the Research Ethics Board, patients were recruited based on referral by staff members from the pain management center or by responding to a study poster located in the clinic. A recruitment email including inclusion and exclusion criteria was sent to all staff requesting referrals to be sent to the nurse clinician. The nurse clinician briefly described the study either in person or by telephone and conducted an initial screening for eligibility. Screening involved asking patients if they had previously participated in mindfulness programs and if the MBSR program schedule was feasible for them. The researcher contacted the participants via telephone and provided further details if they were initially screened as eligible and expressed interest in participating. The researcher confirmed initial screening and patients were informed that they had the option of participating in a randomized controlled trail of a group pain management program and would be randomized to a MBSR program or a WC group, in which case, they were required to wait for 3 months before participating in the MBSR program. Details of the consent form were reviewed and any questions were answered. If patients agreed to participate, they were scheduled for their first study visit.

At the first visit, the consent form was reviewed in further detail and written informed consent was obtained. Participants completed the computerized cognitive task followed by the self-report questionnaires during all testing sessions to reduce the possibility of fatigue hindering performance on the cognitive task. The group schedules for both the MBSR and WC groups were provided to all participants. Immediately following data collection at the first visit, the group facilitator conducted a 45 to 60 minute standard of care assessment, which involved screening patients to ensure eligibility for participation in the MBSR treatment. The assessment was chosen to follow data collection since the researcher was not clinically trained and we deemed it important for participants to have an opportunity to discuss any concerns that arose during questionnaire completion with a physician. In addition, given that information regarding mindfulness would be shared with patients during the assessment, this may have impacted patient responses to the questionnaires. Alternative treatment recommendations according to usual standard of care were planned if patients were ineligible to participate in the group; however, all patients who agreed to participate and completed the 1st set of questionnaires were eligible to take part in the MBSR program.

Randomization and Blindness

Simple randomization procedures were followed using a computerized random generator by one of the investigators not involved with recruitment or data collection after informed consent and measures were completed by all patients at study visit 1 for each year of recruitment (n = 22 for year 1 and n = 27 for year 2). A research volunteer uninvolved in the study was provided with the 1:1 ratio allocation sequence to give to the nurse clinician and was concealed from the researcher conducting data collection. The nurse clinician contacted patients via telephone 1 day following the last day of study visit 1 assessments to inform them which group they were randomly assigned to. This ensured the researcher remained blind to treatment allocation. Patients were reminded and encouraged at the beginning of each telephone call for scheduling of visits and in person at the study visits to not disclose their group assignment to the researcher, however, despite these attempts, 4 out of 49 (8.2%) patients volunteered this information unintentionally.

The MBSR and WC group received the same treatment, by the same group facilitator in the same hospital setting over 2 years of data collection (referred to herein as wave 1 and wave 2). The WC group waited for 12 weeks following the first assessment before crossing over to receive the MBSR treatment. Patients in both groups continued standard of care treatments as usual, including but not limited to, pharmacotherapy, individual psychotherapy, injection treatments, sex therapy, physiotherapy, acupuncture, and referrals to other physicians. Measures were administered and standard of care assessment was conducted prior to randomization and allocation to 1 of the 2 study groups (T1). Patients in the WC group came in for 1 additional study visit to complete measures following the wait period before crossing over into the MBSR treatment (T2). Patients in the MBSR and WC groups completed measures following participation in the MBSR treatment (T2 for MBSR group and T3 for WC group). Both groups completed measures 3-months following completion of the MBSR treatment (T3 for MBSR group and T4 for WC group) to explore maintenance of effects. Figure 1 provides an illustration of assessment and program delivery time points. Recruitment and data collection occurred between January 2012 and November 2013. Assessments and treatment delivery were scheduled for the same timeframe across wave 1 and wave 2 as much as possible to preserve consistency. In order to increase sample size during the second wave, assessments began earlier and occurred over a longer duration (47 versus 24 days). Time of MBSR treatment delivery was consistent across waves and the remaining assessment durations for T2, T3 and T4 varied slightly across waves (range = 2 to 10 days).

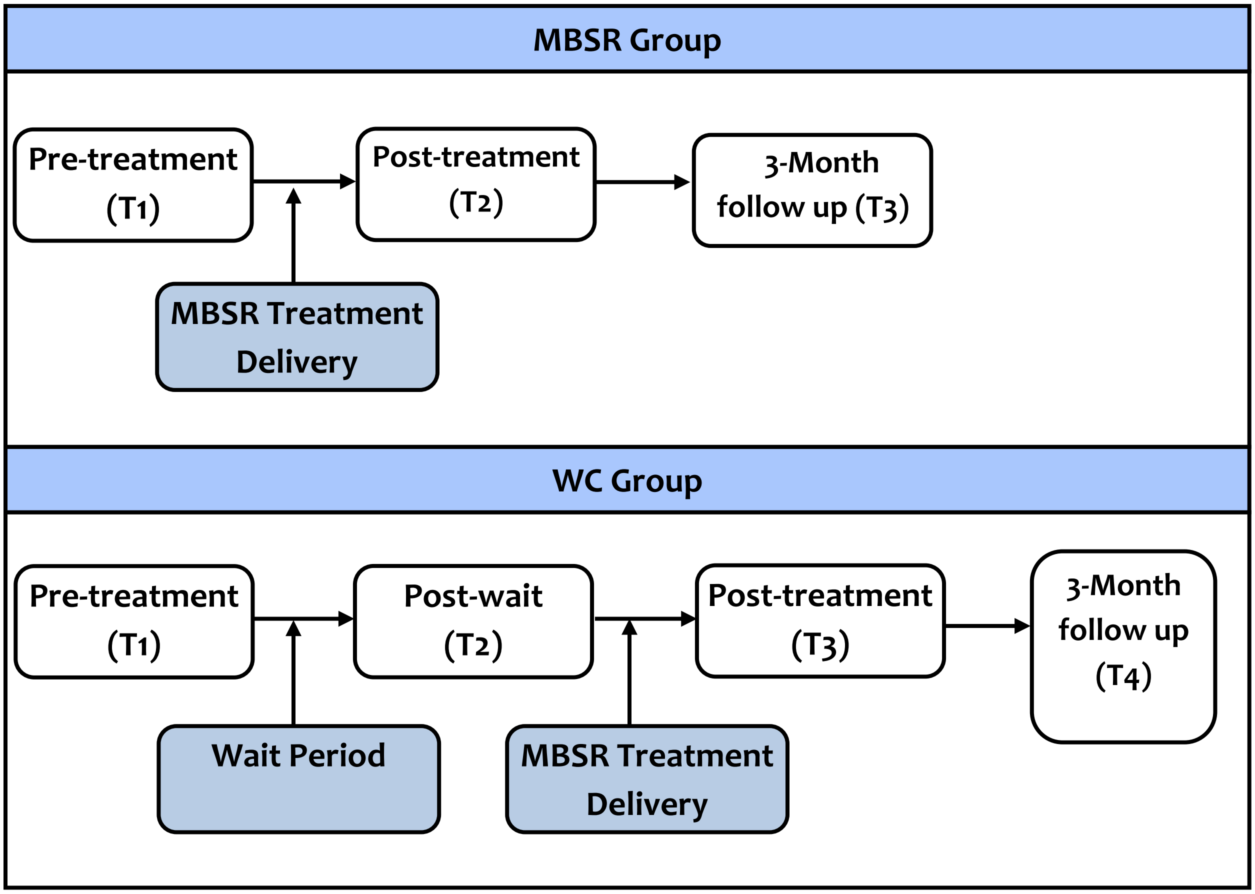

Figure 1. Assessment and Program Delivery Time points for MBSR and WC Groups.

Logistical and Ethical Considerations

Sample size was lower than expected for wave 1 of data collection. Patients were informed on numerous occasions that should they choose not to participate or withdraw from the study at any time their care would not be impacted. Patients who chose not to participate in the study were offered the opportunity to take part in a parallel CBT group program or a MBSR program held later in the year by the same facilitator, and in the same location, as for the study groups. Three MBSR groups are offered yearly as part of standard care. The first 2 groups were reserved for the MBSR treatment group and waitlist group, respectively, and the 3rd group was not part of the study and offered to patients that chose not to participate in the study or could not due to scheduling difficulties. By reserving the first 2 groups for study participants only, this prevented study group contamination by having a mixed MBSR group composed of study and non-study participants.

The number of measures was minimized to reduce patient burden, and the researcher scheduled 1.5 hours for each patient to provide ample time for completion and permit breaks as needed. Extra assistance was provided to patients who had difficulty completing the questionnaires independently and this happened on several occasions, particularly for older patients or individuals with migraines. One researcher scheduled all study visits including the physician standard care assessment at the first study visit, and collected data for all patients over the 2 waves to limit potential biases from introducing additional researchers into the study protocol. The researcher was no longer blinded to treatment group following T3 for the WC group in order to allow for scheduling of T4 assessments for the remaining participants. Patients were required to pay standard group fees for materials associated with the program ($100), but this cost was partially reduced by an honorarium of $20 provided at each study visit (i.e., 3 study visits for the MBSR group = $60, and 4 study visits for the WC group = $80). Participants were offered the opportunity to pay in installments if they indicated financial difficulties.

Intervention

Frequency, setting and facilitator experience. The MBSR program consisted of 3-hour weekly group sessions for 8 consecutive weeks with an additional all day 6-hour session during the 6th week. Daily homework was assigned and attendance was recorded for each session. Patients engaged in various meditation exercises and didactic group discussions in a hospital setting. Group sessions were facilitated by a medical physician with over 30 years of experience working with CP patients, a personal meditation practice for 8 years, and MBSR teacher training received at the Center for Mindfulness with Jon Kabit-Zinn and Saki Santorelli. The group facilitator was blind to study hypotheses.

Intervention techniques. The MBSR program offered at the pain centre closely adheres to the original MBSR 8-week standard program developed by Jon Kabit-Zinn at the University of Massachusetts Medical Centre. The program teaches patients to focus their attention to the breath without judgment of any internal (e.g., thoughts, emotions or painful sensations) or external (e.g., sounds) distractions that may arise. A variety of meditation techniques including sitting meditation, body scan, walking meditation, and mindful movement are introduced over the course of the program (Kabit-Zinn, 1990). Prior to designing the study, the researcher observed the 8-week MBSR program offered at the pain centre to assist in selection of appropriate outcome measures and to acquire knowledge regarding the common challenges faced by individuals experiencing pain. A detailed session-by-session outline of the MBSR intervention follows.

Session 1. Group guidelines are provided including importance of homework, confidentiality, and attendance. Group members pair up with another participant and discuss why they are in the program and what they hope to gain from the program. Participant introductions are followed by the ‘raisin exercise,’ which allows for exploration of sensations (e.g., touch, smell and taste), emotions, and thoughts (Kabit-Zinn, 1990). Patients are then guided through a mindful breathing exercise while lying supine on yoga mats, and their attention is brought to the feeling of the abdomen rising and falling with the in-breath and out-breath. The body scan is the final meditation introduced during this session and allows patients the opportunity to focus on each individual body part, bringing full awareness to any thought, emotion, or sensation that arises. Homework is assigned including daily body scan, informal practices such as performing a routine daily activity in a mindful way (e.g., brushing teeth with awareness), and eating mindfully at least once during the week.

Session 2. This session begins with a body scan and is followed by discussion of homework. The importance of homework is emphasized and the group discusses barriers to practicing on a daily basis such as finding the time or increased pain. All remaining sessions begin with a meditation and discussion of homework. A visualization exercise is used to highlight the relationship between thoughts, emotions, and sensations. Patients are taught that the breath is used during meditation because it facilitates awareness to present moment experience and can be used during pain to soften its intensity by focusing on the breath as it moves into the painful region and visualizing the pain diminishing during exhalations. Patients are asked to note a pleasant event they experience during the following week as well as any associated thoughts, emotions, or sensations. Participants are instructed to continue with the same homework.

Session 3. Mindful movement, or gentle yoga, is introduced in a lying down position and patients are reminded that they can prevent flare-ups by moving with awareness and listening to their bodily sensations. The importance of stretching and movement for reducing pain is emphasized. The relationship between thoughts, emotions and sensations are explored by providing patients an opportunity to share a pleasant event they experienced during the past week. Assigned homework includes alternating between mindful movement and body scan, daily sitting meditation and noting an unpleasant event that occurs during the week.

Session 4. Awareness to all internal and external stimuli is emphasized during sitting and mindful walking meditations. Patients are guided to open up their awareness to anything that arises and be open to new experiences. A definition of stress is provided and an explanation of its influence on the mind, body and health is highlighted. Patients are taught the distinction between reacting and responding with awareness to stressful circumstances. They are taught how irrational thoughts can influence the experience of pain and how to practice identifying and challenging limiting thoughts in an accepting way. Assigned homework is the same as the previous week, with the exception of asking patients to note an unpleasant event.

Session 5. Continued mindful walking practice and mindful movement takes place, however, the concept of acceptance is highlighted. Patients are taught that acceptance involves noticing all thoughts, emotions, and sensations that occur within or outside of the body without judging the experience or trying to alter it in any way. For instance, if a patient experiences pain in their knee, a typical reaction might be to engage in another task as a distraction from the pain. Acceptance encourages non-judgmental openness to the experience of pain without trying to change it. Participants are instructed to continue with the same homework.

Session 6. This session focuses on stressful communications and how to identify one's patterns during social interactions such as passiveness, aggressiveness, or assertiveness. The importance of mindful listening and responding is discussed and patients are provided an opportunity to communicate with another member of the group and reflect on their level of mindfulness during the interaction. Mindful sitting and movement exercises are performed, patients are assigned the same homework, and a discussion of the upcoming all day retreat takes place.

Session 7. This session allows an opportunity for patients to deepen their practice with a longer 6-hour retreat day. Participants are instructed that the session will be in silence and to refrain from communicating with other members of the group. Patients' work through a series of meditation exercises including those previously learned (i.e., sitting meditation, mindful movement, walking meditation, and body scan) as well as new mindful exercises such as imagery and loving-kindness meditations. Poems are read throughout the day and the session closes with an opportunity for members to share their thoughts, feelings and experiences.

Session 8. Visualization and imagery are taught as tools to deepen meditation practice. Further opportunity is provided to share experiences of the all-day retreat as well as homework practice. The connection between mindfulness and consumption is drawn. Patients are taught that mindfulness techniques can be applied during consumption of food and exposure to advertising and technological devices. Patients are encouraged to attend mindfully to their internal and external experiences and vary their home practice among the various techniques taught throughout the program.

Session 9. Material that was learned during the program is discussed as well as strategies for overcoming obstacles to continued meditation practice. The notion that this session marks the beginning of their ongoing practice is reinforced. Community resources to continue their practice are provided and patients are encouraged to set goals for maintaining a daily practice.

Additional sessions. In addition to the standard 8-week program, there are two additional 3-hour sessions; an orientation and 3-month follow up. The orientation session occurred prior to the first standard session and involved watching a video by Jon Kabit-Zinn and discussing participant questions. Program logistics are discussed and materials are distributed. Participants not able to attend the orientation session were offered an opportunity to visit the clinic and watch a video providing information on the MBSR program. The 3-month follow up session is held to allow the group to reconnect and share their experiences and obstacles since the end of the program and discuss resources to encourage continued practice.

Measures

Primary and secondary outcome measures were administered at all study visits for both groups (T1-T3 for MBSR group and T1-T4 for the WC group). Total scores for each standardized measure were used for analyses.

Primary Outcomes

Pain Intensity. The Short-Form McGill Pain Questionnaire (SF-MPQ-2; Dworkin et al., 2009) was used to measure pain severity. Participants rate the intensity of their pain on a numerical scale from 0 (representing none) to 10 (representing worst possible) for 22 pain qualities and symptoms. Higher scores indicate greater pain intensity (range 0 – 220). The reliability, validity, and subscale structure of the SF-MPQ-2 were examined using responses from 882 individuals with diverse CP syndromes and 226 patients with painful diabetic peripheral neuropathy (Dworkin et al., 2009). The data suggest that the SF-MPQ-2 has excellent reliability and validity. Chronbach's alpha ranged from .83 to .87 for the subscales and was .95 for the total score. Results from both exploratory and confirmatory factor analyses provide support for four subscales: 1) continuous pain, 2) intermittent pain, 3) predominantly neuropathic pain, and 4) affective descriptors.

Pain Disability. The Pain Disability Index (PDI; Pollard, 1984) assesses the extent to which pain interferes with functioning in seven areas including family/home responsibilities, recreation, social activity, occupation, sexual behaviour, self-care, and life-support activities. Respondents are asked to indicate their perceived level of disability from 0 (no disability) to 10 (worst disability), with higher scores indicating greater disability (range 0 – 70). The PDI has been shown to be internally consistent, with 0.85 reliability reported for the three pain intensity indicators (Tait & Chibnall, 2005), and associated with restriction of activities (Tait, Chibnall, & Krause, 1990) and other disability indices (Gauthier, Sullivan, Adams, Stanish, & Thibault, 2006).

Depression, Anxiety and Stress. The Depression, Anxiety, and Stress Scale-21 (DASS-21) consists of 21-items assessing levels of depression, stress and anxiety. Each subscale consists of 7 items ranging from 0 (did not apply to me at all) to 3 (applied to me very much, or most of the time) and has good reliability (Taylor, Lovibond, Nicholas, Cayley, & Wilson, 2005). Severity on each scale ranges from normal, mild, moderate, severe to extremely severe. Higher scores indicate greater emotional distress for each subscale (range 0 – 21). Coefficient alpha was reported to be .96, .90, and .94 for depression, anxiety, and stress, respectively, among a sample of CP patients. The DASS does not rely on somatic items, and therefore, is less likely to be overestimated in a CP sample. The DASS has been found to have the best psychometric properties in CP patients compared with other measures of depression (Taylor et al., 2005).

Attention. A version of the change blindness flickering task (Rensink et al., 1997) was administered on a MacBook Pro laptop computer with a high-resolution 15” monitor to assess attention. The task was programmed and presented using PsychoPy software package (v1.71.01; Jonathan Pierce University of Nottingham). Six image pairs were presented during each testing session. Each image pair flickered (500 ms image 1 on; 200 ms off; 500 ms image 2 on; 200 ms off; repeat cycle) on the screen for a maximum of 2 minutes or until the participant indicated they detected the change by pressing enter. Blur, brightness and contrast were set to 0, 50, and 100, respectively, uniformly across the image. Since there were three testing sessions for the MBSR group and four testing sessions for the WC group, a total of 24 different image pairs were selected (8.2 by 11.0 cm). Each session’s images were equally difficult, as determined through pilot testing and subsequent assignment of image to session based on observed difficulty. Each image within a pair was identical except that the second image consisted of one deviation. Practice trials included 3 image pairs not used during testing sessions. The same 3 practice image pairs were presented prior to each testing session at each time point. All stimuli were presented against a grey background at a viewing distance of approximately 12 cm. Participants were asked to detect the change in each scene as quickly as possible by pressing enter followed by indicating the location of the change that occurred by pointing and clicking the right mouse button as close to the change as possible. Changes in the images included objects moving, objects appearing and objects disappearing and the number of each was equal across testing sessions. Accuracy in identifying the change and reaction time (in milliseconds) were recorded.

Secondary Outcomes

Mindfulness. The Five-Facet Mindfulness Questionnaire (FFMQ; Baer et al., 2006) is based on a factor analytic study of five independently developed mindfulness questionnaires. This scale consists of 39 items assessing five facets of mindfulness on a 5-item likert scale ranging from 1 (never or very rarely true) to 5 (very often or always true). Higher scores indicate greater mindfulness (range 39 - 195). Coefficient alphas for each aspect of mindfulness is as follows: Nonreactivity to Experience (7 items, $\alpha = .75$; e.g., "I perceive my feelings and emotions without having to react to them"), Acting with Awareness (8 items, $\alpha = .87$; e.g., "I find it difficult to stay focused on what's happening in the present"; reverse scored), Describing with Words (8 items, $\alpha = .87$; e.g., "I'm good at finding words to describe my feelings"), Nonjudging of Experience (8 items, $\alpha = .88$; e.g., "I criticize myself for having irrational or inappropriate emotions"; reverse scored), and Observation of Experience (8 items, $\alpha = .84$; e.g., "I pay attention to how my emotions affect my thoughts and behavior").

Mindful Attention Awareness Scale (MAAS; Brown & Ryan, 2003): The MAAS is an 11-item scale designed to assess a core characteristic of dispositional mindfulness, namely, open or receptive awareness of and attention to what is taking place in the present. For example, "I could be experiencing some emotion and not be conscious of it until some later time." Statements are rated on a 6-point scale, ranging from 1 (almost always) to 6 (almost never). Higher scores indicate greater mindfulness (range 6 – 66). The MAAS has demonstrated adequate internal reliability, with Cronbach alpha coefficients reported to be .82 - .89 (Baer et al., 2006; Brown & Ryan, 2003; MacKillop & Anderson, 2007).

Acceptance. The Chronic Pain Acceptance Questionnaire (CPAQ; McCracken, Carson, Eccleston, & Keefe, 2004) is a 20-item inventory designed to measure acceptance of pain and includes two subscales: 1) Activity engagement assesses the degree to which patients perform activities when pain is present, and 2) Pain willingness measures the absence of attempts to control or avoid pain. Patients rate each item on a scale of 0 (never true) to 6 (always true) with higher scores indicating greater acceptance (range 0 – 120). Good internal consistency has been reported for the activity engagement subscale (>.80) and acceptable consistency for the pain willingness domain (>.70) (Bernini, Pennato, Cosci, & Berrocal, 2010).

Non-Standardized Measures

Three questionnaires were developed by the investigators and can be found in Appendix A, B, and C.

Appendix A. The first questionnaire was administered during participants' first study visit prior to receiving treatment (T1). Participants were asked to report demographic information, medical history, current pain condition, current pain intensity, previous treatments for managing pain, medication use, previous meditation experience, expectations for treatment, motivation, sleep quantity, and difficulty focusing attention.

Appendix B. The second questionnaire was a 9-item survey administered at T2, T3 and T4. Participants' current medication use, current pain intensity, changes in treatment/exercise routine, change in life events, sleep quantity, difficulty in focusing attention, and difficulty in schedule organization was assessed.

Appendix C. The third questionnaire was completed following the MBSR intervention and used to assess adherence to mindfulness homework. Patients were asked how much of the formal and informal meditation practices they completed on a scale from 0 (none of the homework) to 10 (all of the homework). Participants were also asked to report the average amount of time they spent engaging in formal and informal meditation practices. Formal practices include body scan, mindful yoga, sitting meditation, and walking meditation. Informal meditation practices include engaging in daily activities mindfully (e.g., eating or taking a shower mindfully). These questions were used to explore the association between adherence to homework and change in outcomes. Blindness of the researcher was maintained by distributing this questionnaire to all participants regardless if they were in the MBSR group or WC group. Participants were asked to complete all questionnaires and place them in a sealed envelope and return them to the researcher. All standardized and non-standardized questionnaires were administered subsequent to completing the cognitive task. No data were entered until completion of all study visits. Table 1 provides a summary of the measures administered at each time point for the MBSR and WC groups.

Table 1.

Measures Administered Over Time for MBSR and WC Groups

Timeline for Treatment and Control Groups								
Measures/Assessment	MBSR Group			WC Group				Duration
	T1	T2	T3	T1	T2	T3	T4	

Cognitive Task	X	X	X	X	X	X	X	10 min
Standardized Questionnaires	X	X	X	X	X	X	X	60 min
Standard of Care Assessment	X			X				45-60 min
Appendix A	X			X				10 min
Appendix B		X	X		X	X	X	5 min
Appendix C		X			X	X		5 min

Note: For the MBSR group: (T1) = pre-treatment, (T2) = post-treatment, (T3) = 3-month follow up. For the WC group: (T1) = pre-treatment, (T2) = post-wait, (T3) = post-treatment, (T4) = 3-month follow up

Statistical Analyses

All statistical analyses were performed using SPSS (version 22.0). Descriptive analyses were used to report the sample size (%) and Mean (±*SD*) for all variables. Chi-square tests of independence (χ^2) and 1-way analysis of variance (ANOVA) were used to compare the MBSR and WC groups on socio-demographic variables and outcome measures at T1 for categorical and continuous variables, respectively. The same analyses were used to compare study dropouts and completers for the same variables at T1.

To examine changes in outcomes between the MBSR and WC groups (*n* = 21 per group; 7 participants excluded) for primary objectives 1 and 2, and secondary objective 1, change scores were calculated for each of the 9 outcome variables (T2 – T1) and entered into separate linear regression models for each outcome with treatment group as the predictor (i.e., MBSR vs. WC). Analysis of Covariance using pre-treatment score and treatment group as covariates and post-test score as the outcome variable demonstrated similar results as the change score approach. The change score approach was chosen in favour of ANCOVA to maintain consistency across analyses.

To examine the predictive role of mindfulness and pain acceptance in improving attention and health outcomes for secondary objective 2, both the MBSR and WC group once crossed over into the MBSR arm were included in the analysis (*n* = 33; 16 participants excluded). Change scores were obtained for all outcome variables (i.e., combined scores: T2-T1 for MBSR group and T3-T2 for WC group) and entered into separate simultaneous multiple regressions with mindfulness and pain acceptance as predictors and change scores of the 7 primary variables as outcomes (pain severity, pain disability, depression, anxiety, stress, change blindness RT and change blindness accuracy).

The relationship between adherence to homework and improved outcomes for secondary objective 3 was explored using Pearson product moment correlations by including both the MBSR and WC group once crossed over into the MBSR arm in the analysis (*n* = 33; 16 participants excluded). The same change scores computed for secondary objective 2 were used for this analysis.

Maintenance of outcome benefits at 3-month follow up was explored for secondary objective 4 by comparing post-test scores and 3-month follow up scores for the entire sample using paired t-tests (*n* = 29; 20 participants excluded).

Chapter 3: Results

Participant Study Flow

Overall, 96 patients underwent initial telephone or in person screening by the nurse clinician. Eight-five of these patients expressed interest in the study (wave 1: *n* = 39 and wave 2: *n* = 46). Thirty-six patients were excluded because they did not meet inclusion criteria (*n* = 1), were not interested in participating (*n* = 5), cancelled their first study visit/did not show up (*n* = 8), indicated a scheduling conflict (*n* = 14), reported illness (*n* = 2), or were unreachable (*n* = 6). Therefore, 49 patients were included and allocated to the MBSR (*n* = 25) or WC group (*n* = 24).

Three out of 25 patients dropped out of the study prior to T2 assessment for the MBSR group and 3 out of 24 patients dropped out of the WC group prior to T2 assessment. Therefore, the overall completion rate was 88% (43/49). To allow comparisons in outcomes between the MBSR and WC groups for objectives 1 to 3, 1 participant was excluded due to insufficient MBSR session attendance (< 18 hours), leaving a sample of 42/49. Fifteen out of 24 patients in the WC group completed T3 assessments; therefore, the completion rate for the WC group after they crossed over to the MBSR treatment was 63%. Nineteen out of 25 (76%) patients provided 3-month follow up data for the MBSR group (T3) and 13 out of 24 (54%) patients provided 3-month follow up data for the WC group (T4). The dropout rate is comparable to reports from a review of RCTs in the MBSR and CP literature indicating a dropout range of 5% to 49% with a median of 17% (Garmon et al., 2014). Figure 2 shows participant flow and completion rates according to CONSORT statement guidelines (Moher, Schulz, & Altman, 2001).

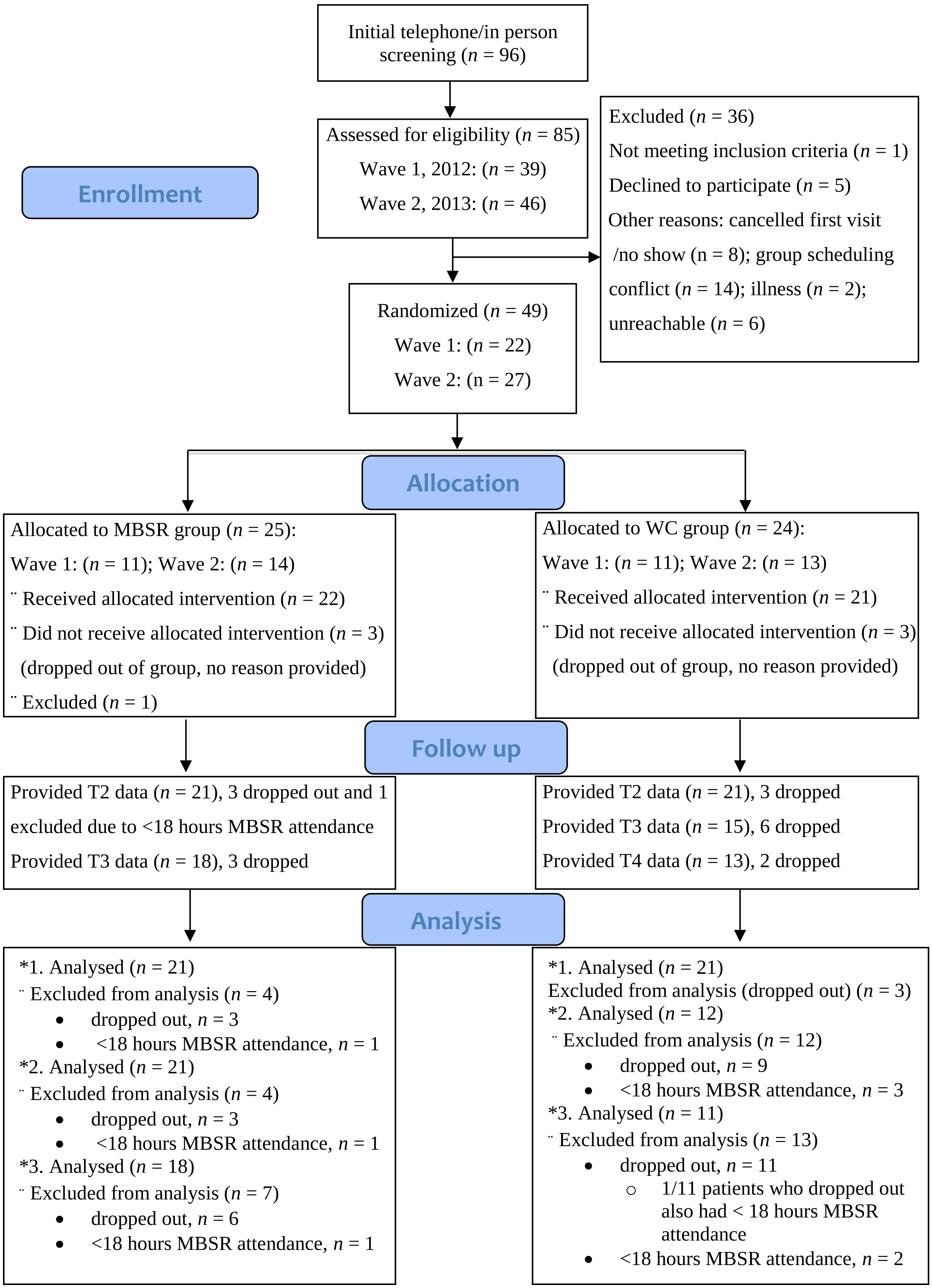
Initial telephone/in person screening (n = 96)
Assessed for eligibility (n = 85)
Wave 1, 2012: (n = 39)
Wave 2, 2013: (n = 46)
Enrollment
Excluded (n = 36)
Not meeting inclusion criteria (n = 1)
Declined to participate (n = 5)
Other reasons: cancelled first visit /no show (n = 8); group scheduling conflict (n = 14); illness (n = 2); unreachable (n = 6)
Randomized (n = 49)
Wave 1: (n = 22)
Wave 2: (n = 27)
Allocation
Allocated to MBSR group (n = 25):
Wave 1: (n = 11); Wave 2: (n = 14)
¨ Received allocated intervention (n = 22)
¨ Did not receive allocated intervention (n = 3)
(dropped out of group, no reason provided)
¨ Excluded (n = 1)
Allocated to WC group (n = 24):
Wave 1: (n = 11); Wave 2: (n = 13)
¨ Received allocated intervention (n = 21)
¨ Did not receive allocated intervention (n = 3)
(dropped out of group, no reason provided)
Follow up
Provided T2 data (n = 21), 3 dropped out and 1 excluded due to <18 hours MBSR attendance
Provided T3 data (n = 18), 3 dropped
Provided T2 data (n = 21), 3 dropped
Provided T3 data (n = 15), 6 dropped
Provided T4 data (n = 13), 2 dropped
Analysis
*1. Analysed (n = 21)
¨ Excluded from analysis (n = 4)
• dropped out, n = 3
• <18 hours MBSR attendance, n = 1
*2. Analysed (n = 21)
¨ Excluded from analysis (n = 4)
• dropped out, n = 3
• <18 hours MBSR attendance, n = 1
*3. Analysed (n = 18)
¨ Excluded from analysis (n = 7)
• dropped out, n = 6
• <18 hours MBSR attendance, n = 1
*1. Analysed (n = 21)
Excluded from analysis (dropped out) (n = 3)
*2. Analysed (n = 12)
¨ Excluded from analysis (n = 12)
• dropped out, n = 9
• <18 hours MBSR attendance, n = 3
*3. Analysed (n = 11)
¨ Excluded from analysis (n = 13)
• dropped out, n = 11
○ 1/11 patients who dropped out also had < 18 hours MBSR attendance
• <18 hours MBSR attendance, n = 2

Figure 2. Participant Flow Diagram According to Revised CONSORT Statement Guidelines.
Note: *1 represents the number of participants included in the analyses for primary objectives 1 and 2, and secondary objective 1 (*n* = 42, 21 from each group); *2 represents the number of participants included in the analyses for secondary objectives 2 and 3 (*n* = 33; 21 from MBSR group + 12 from WC group); *3 represents the number of participants included for secondary objective 4 (*n* = 29; 18 from MBSR group + 11 from WC group).

Socio-Demographic and Pain Characteristics at T1

The average age for the final sample was 49.61 (±*SD* = 14.38; range = 19 to 82). The majority of participants were female (*n* = 30; 61.2%) and married (*n* = 28; 57.1%). Twenty-one (42.9%) participants completed college or a bachelor's degree, and 23 (46.9%) participants reported an income of $60,000 or greater. The majority of participants reported past medical history of chronic back pain (59%), chronic headache (53%), anxiety (57%) and depression (51%), and fewer patients reported histories of chronic facial pain (37%) chronic pelvic pain (31%), irritable bowel syndrome (24%), fibromyalgia (24%) and substance abuse and/or dependence (18%). Demographic information is presented separately for the MBSR and WC groups in Table 2. There were no significant baseline differences (T1) for age, gender, marital status, and education, *ps* > .05. There were no significant differences at T1 for participants' treatment expectations regarding improved pain symptoms or any of the primary outcomes, *ps* >.05. Motivation and income was marginally higher in the WC group.

Table 2.

Comparison of Socio-Demographic and Primary Outcome Variables of the 2 study arms at T1

Variable	Treatment Condition		*p* value
	MBSR group (*n* = 25)	WC group (*n* = 24)	
Mean age (±SD)	46 (12.20)	52.52 (15.14)	.64
Gender *n* (%)			.545
Female	15 (60%)	15 (63%)	

Male	9 (36%)	10 (42%)	
Marital Status			.68
Single	6 (24%)	6 (25%)	
Common law	3 (12%)	3 (13%)	
Married	15 (60%)	13 (54%)	
Separated/divorced	0	2 (8%)	
Widowed	0	1 (4%)	
Education			.60
No high school diploma	2 (8%)	4 (17%)	
High school diploma	5 (25%)	8 (33%)	
College diploma/Bachelor’s degree	12 (48%)	9 (37%)	
Master’s/Doctorate degree	5 (20%)	4 (17%)	
Income			.09
≤ $14,999	5 (20%)	2 (8%)	
$15,000-$29,999	2 (8%)	1 (4%)	
$30,000-$44,999	2 (8%)	2 (8%)	
$45,000-$59,999	1 (4%)	2 (8%)	
$60,000-$79,999	2 (8%)	2 (8%)	
$80,000-$99,999	0	4 (17%)	
$100,000-$129,999	8 (32%)	3 (13%)	
$130,000+	0	4 (17%)	
Missing data	*4 (16%)*	*5 (21%)*	
Mean Treatment Expectancy (±*SD*)	5.17 (2.59)	6.08 (2.28)	.195
Mean Motivation (±*SD*)	7.83 (2.48)	8.92 (1.91)	.09
Primary Outcomes *Mean* (±*SD*)			
Pain severity (SF-MPQ-2)	102.89 (49.2)	93.82 (42.84)	.49
Pain disability (PDI)*	49.25 (13.34)	43.0 (14)	.12

Depression (DASS)	11.42 (6.35)	11.46 (5.83)	.98
Anxiety (DASS)	8.67 (5.68)	7.08 (5.24)	.31
Stress (DASS)	12.13 (5.63)	10.78 (5.56)	.40
Change blindness (median RT)	39.39 (35.67)	31.68 (30.07)	.42
Change blindness (% Accuracy)	.73 (.27)	.77 (.27)	.69

Note: * denotes 1 missing data point

Completers vs. Dropouts

Patients who completed (*n* = 33) MBSR training versus those who dropped prior to completion (*n* = 16) were similar on sociodemographic (age, marital status, education, income, motivation and treatment expectations) and outcome variables (pain severity, pain disability, depression, anxiety, stress, change blindness measures, and mindfulness) at T1, *ps* > .05. The 16 participants considered dropouts either dropped out of the study (*n* = 12; 3 from MBSR group and 9 from WC group) or did not complete at least 18 hours of MBSR session attendance (*n* = 4; 1 from MBSR group and 3 from WC group). There were 2 exceptions; first there was a significant association between gender and study completion as well as pain acceptance and study completion, such that significantly more males dropped the study (*n* = 10/19 = 52.6%) compared to females (*n* = 6/30 = 20%), χ^2 (1, *N* = 20) =5.63, *p* = .02, and patients who dropped the study had significantly lower pain acceptance (*M* = 35.95, ±*SD* = 17.26) compared to completers (*M* = 46.82, ±*SD* = 17.14), *F*(1, 47) = 4.32, *p* = .04, η_p^2 = .08.

Previous Meditation Experience and Adherence to MBSR

Patients were excluded at the start of the study if they previously participated in a MBSR program (*n* = 1). To further assess the degree of naivety to meditation prior to the study, patients were asked to report any previous meditation experience. The majority of the sample reported no previous meditation experience (*n* = 35/49; 71%). Of the remaining patients who indicated they had engaged in previous meditation (*n* = 14), a variety of meditation practices were noted including visualization or imagery (*n* = 3), yoga (*n* = 2), informal mindful practices (*n* = 2), prayer (*n* = 4), and relaxation exercises (*n* = 3).

Patients who participated in less than 18 hours of the total 30 hours of standard MBSR treatment in this study (i.e., fewer than 6 MBSR sessions or 4 sessions + 6-hour retreat day) were excluded from analyses (*n* = 4). Three of these patients completed all assessments (1 in the MBSR group and 2 in the WC group) and the remaining patient dropped out and did not complete T4 assessments in the WC group. There was no significant difference in the number of MBSR session hours attended by the MBSR group (*M* = 25.25, ±*SD* = 10.35) or WC group once crossed over to the MBSR treatment (*M* = 23.14, ±*SD* = 10.95), *F*(1, 43) = .44, *p* = .511.

Post-Treatment Outcome Comparisons

Seven patients were excluded due to not completing the MBSR treatment or assessments (*n* = 6), or insufficient MBSR attendance (*n* = 1), resulting in a sample size of 21 per group for the linear regression analyses conducted to examine differences in mean change scores between MBSR and WC groups (T2 for the MBSR group and T3 for the WC group). The MBSR group demonstrated a significantly greater mean decrease in depression change scores (*M* = -3.79, *SE* = 1.06) compared to the WC group (*M* = -.30, *SE* = 1.06), *b* = -3.49, *t* = -2.33, *p* = .025. A significant proportion of the variability in depression mean change scores was explained by treatment group (R^2 = .12), *F*(1, 39) = 5.41, *p* = .025. The MBSR group also demonstrated significantly greater decreases in mean stress change scores (*M* = -3.12, *SE* = .93) compared to the WC group (*M* = .29, *SE* = 1.12), *b* = -3.40, *t* = -2.34, *p* = .025, and increases in mean mindfulness change scores, as measured with the FFMQ, (*M* = 12.93, *SE* = 3.22) compared to the WC group (*M* = .14, *SE* = 1.60), *b* = 12.79, *t* = 3.56, *p* = .001. There was no significant difference in total mindfulness change scores, as measured with the MAAS, in the MBSR group (*M* = 1.18, *SE* = 2.22) compared to the WC group (*M* = 1.00, *SE* = 1.38), *b* = -.17, *t* = -.07, *p* = .946. Treatment group accounted for a significant proportion of the variability in mean stress change scores (R^2 = .12) and mean mindfulness (FFMQ) change scores (R^2 = .24), [*F*(1, 40) = 5.45, *p* = .025; *F*(1, 40) = 12.65, *p* = .001, respectively]. Figures 3 to 6 illustrate the significant differences in mean change scores between MBSR and WC groups for depression, stress and mindfulness (FFMQ), respectively.

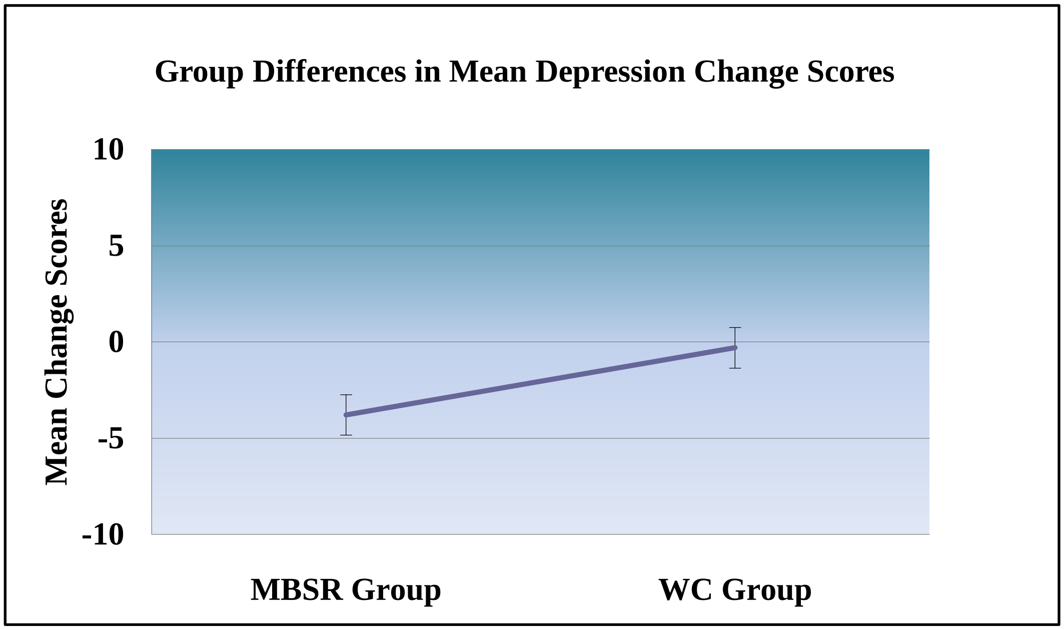

Figure 3. Mean Change Scores in Depression for the MBSR and WC Groups.
Note: Mean scores lower than 0 represent a decrease in levels of depression from T1 to T2. Bars represent error of the mean for each group.

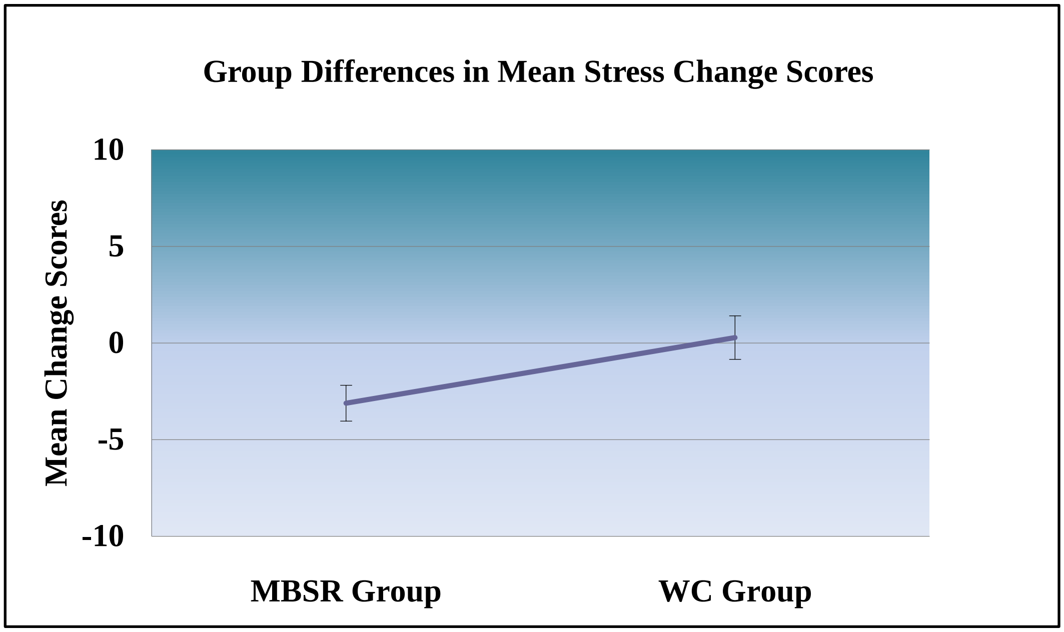

Figure 4. Mean Change Scores in Stress for the MBSR and WC Groups.
Note: Mean scores lower than 0 represent a decrease in levels of stress from T1 to T2. Bars represent error of the mean for each group.

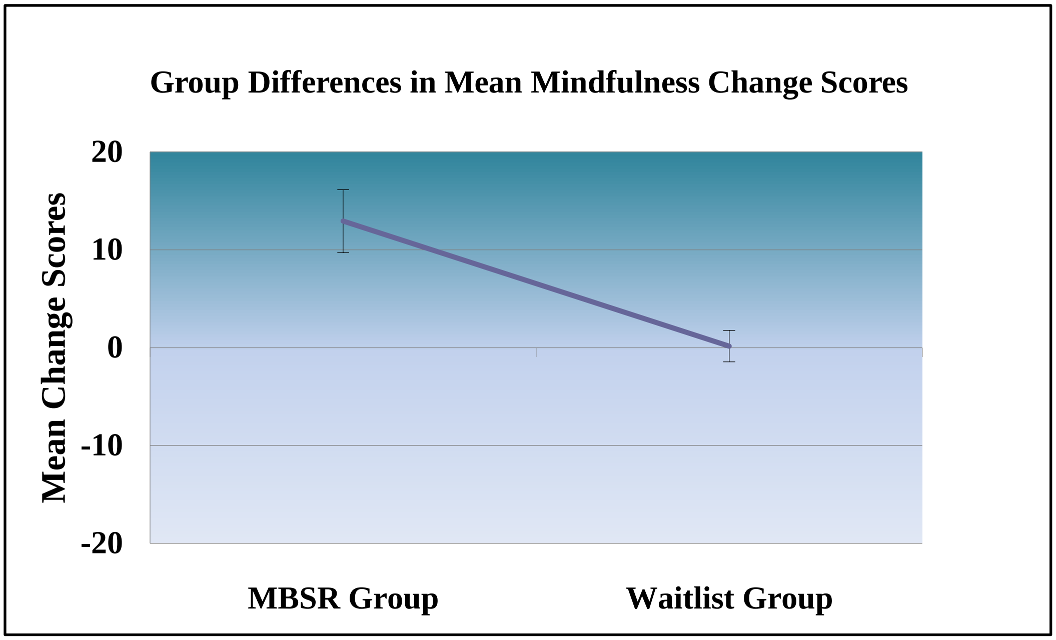

Figure 5. Mean Change Scores in Mindfulness for the MBSR and WC Groups.
Note: Mean scores greater than 0 represent an increase in mindfulness levels from T1 to T2. Bars represent error of the mean for each group.

No significant differences were found between groups on the remaining outcomes including pain severity, pain disability, anxiety, attention (as measured by change blindness accuracy and RT), and CP acceptance, *ps* > .05. Table 3 summarizes the mean change scores (T2-T1), standard errors and associated significance tests for all outcomes for the MBSR vs. WC group.

Table 3.

Comparison of the Mean Outcome Change Scores for MBSR and WC Groups

Outcomes	**MBSR Group** Mean change score (*SE*)	**WC Group** Mean change score (*SE*)	***B***	**t**	***p* value**
Pain severity	-11.69 (5.75)	.48 (5.99)	-12.17	-1.47	.15
Pain disability	-1.35 (1.73)	-3.7 (1.41)	2.36	1.06	.29
Depression	-3.79 (1.06)	-.30 (1.06)	-3.49	-2.33	.025*
Anxiety	-.52 (.93)	1.05 (1.13)	-1.57	-1.07	.29
Stress	-3.12 (.93)	.29 (1.12)	-3.40	-2.34	.025*
Change blindness (accuracy)	.033 (.04)	.07 (.04)	-.044	-.61	.546
Change blindness (RT)	-1.06 (1.13)	-2.34 (1.28)	3.34	.60	.549
Mindfulness (FFMQ)	12.93 (3.22)	.14 (1.60)	12.79	3.56	.001**
Mindfulness (MAAS)	1.18 (2.22)	1.00 (1.38)	-.17	-.07	.946
Pain acceptance	3.52 (2.72)	6.43 (1.79)	-2.91	-.89	.378

Note: Mean change score is calculated for each outcome by taking the average T2 scores – T1 scores (i.e., change score = T2 post-treatment – T1 pre-treatment assessments for MBSR group and T2 post-wait – T1 pre-treatment assessments for WC group); *SEM* = standard error; *B* = mean parameter estimate (i.e., difference between mean MBSR group change score and mean WC group change score); *P* value is associated with the mean parameter estimate; R^2= the total variance in outcome accounted for by treatment group. *p < .05, **p < .01.

Role of Mindfulness and Chronic Pain Acceptance in Attention and Health outcomes

Simultaneous multiple regressions using the entire sample (N = 33; 16 excluded) revealed that changes in mindfulness (assessed with the FFMQ) and chronic pain acceptance were associated with changes in health outcomes and specifically accounted for a significant proportion of the variability in pain disability [(R^2 = .20), $F(2, 29) = 3.70$, $p = .037$)], depression [(R^2 = .26), $F(2, 30) = 5.25$, $p = .011$)], and stress [(R^2 = .25), $F(2, 30) = 5.08$, $p = .013$)]. The role of mindfulness and pain acceptance in predicting anxiety approached significance, [(R^2 = .17), $F(2, 30) = 3.07$, $p = .061$)]. Taken together change in mindfulness and pain acceptance (i.e., increase) explained 20%, 26%, 25%, and 17% of the variation in mean change scores of pain disability, depression, stress, and anxiety, respectively.

Specifically, results showed that increases in levels of mindfulness significantly predicted decreases in depression scores, $b = -0.13$, $t = -2.56$, $p = .016$, 95% CI = (-.23, -.03), stress scores, $b = -0.13$, $t = -2.8$, $p = .008$, 95% CI = (-.22, -.04), and marginally predicted decreases in anxiety scores, $b = -0.09$, $t = -2.04$, $p = .05$, 95% CI = (-.18, .00), while pain acceptance was not a significant unique predictor of these outcomes, *ps* < .05. Mindfulness uniquely predicted 16%, 12%, and 20% of the variability in depression, anxiety and stress, respectively, while controlling for pain acceptance. Increases in levels of pain acceptance predicted decreases in pain disability, $b = -0.31$, $t = -2.72$, $p = .011$, 95% CI = (-.54, -.07), while mindfulness was not a significant unique predictor of pain disability, $p > .05$. The unique amount of variation in pain disability scores that was accounted for by pain acceptance, while controlling for mindfulness, was 20%.

Mindfulness and CP acceptance were not significant predictors of the remaining outcomes including pain severity [(R^2 = .07), F(2, 30) = 1.09, p = .347)], change blindness RT [(R^2 = .03), F(2, 29) = .435, p = .651)], or change blindness accuracy [(R^2 = .06), F(2, 29) = .988, p = .385)]. The partial regression coefficients for each predictor (mindfulness and pain acceptance) and associated significance test results for all outcomes are provided in Table 4. When mindfulness, was assessed by the MAAS and entered into the model with chronic pain acceptance, this measure did not contribute significant variance to any of the health or attention outcomes, *ps* > .05

Table 4.

Predictive Role of Mindfulness and Pain Acceptance in Outcomes

Outcome	**Predictor**	***b* (CI)**	***t***	***P* value**	**Semi-Partial Correlation**
Pain severity	Mindfulness	-.23 (-.93, .47)	-.68	.50	.01
	Pain Acceptance	-.50 (-1.40, .39)	-1.14	.26	.04
Pain Disability	Mindfulness	.06 (-.13, .24)	.62	.53	.01
	Pain Acceptance	-.31 (-.54, -.07)	-2.72	.011*	.20
Depression	Mindfulness	-.13 (-.23, -.03)	-2.56	.016*	.16
	Pain Acceptance	-.09 (-.22, .04)	-1.40	.172	.05
Anxiety	Mindfulness	-.09 (-.18, .00)	-2.04	.05*	.12
	Pain Acceptance	-.05 (-.17, .06)	-.94	.35	.03

Stress	Mindfulness	-.13 (-.22, -.04)	-2.8	.008**	.20
	Pain acceptance	-.05 (-.16, .07)	-.81	.422	-.02
Change Blindness (RT)	Mindfulness	.13 (-.30, .55)	.62	.543	.01
	Pain acceptance	.15 (-.40, .70)	.56	.583	.01
Change Blindness (accuracy)	Mindfulness	-.00 (-.01, .00)	-1.32	.198	-.06
	Pain acceptance	.00 (-.00, .00)	.75	.457	.02

Note: Mean change scores were calculated for each outcome (i.e., change score = T2 post-treatment – T1 pre-treatment assessments for MBSR group and T3 post-treatment assessment – T2 post-wait assessment for WC group); *b* = partial regression coefficient; CI = confidence interval for regression coefficient. *t* = test statistic and corresponding *p* value associated with partial regression coefficient; Semi-partial correlation is the unique amount of variation explained in the outcome by 1 predictor while controlling for the second predictor in the model. *p < .05, **p < .01.

Relationship Between Homework Adherence and Outcomes

Patients were asked following MBSR treatment (T2 for MBSR and T3 for WC group) how much of the formal and informal meditation practices they completed on a scale from 0 (none of the homework) to 10 (all of the homework). There were no significant relationships between the amount of *formal or informal* meditation reported and mean change scores of pain severity, pain disability, depression, anxiety, stress, mindfulness, pain acceptance, change blindness RT, and change blindness accuracy, *ps* < .05.

To further explore the relationship between meditation homework and outcomes, correlations were conducted between participant reports of the average number of days engaging in specific formal (i.e., body scan, mindful yoga, sitting and walking meditations) and informal meditation practices and changes in outcomes. There was a positive and significant correlation between walking meditation and pain acceptance, *r* (23) = .47, *p* = .02, and significant negative correlations between informal mindfulness practice (days) and stress, *r* (22) = -.57, *p* = .006, informal mindfulness practice and change blindness accuracy, *r* (22) = -.44, *p* = .042, as well as body scan (days) and difficulty focusing attention, *r* (27) = -.50, *p* = .011. No other correlations were obtained, *ps* > .05. Table 5 presents correlations between homework and primary outcomes, secondary outcomes, difficulty in focusing attention and difficulty in organizing schedule.

Table 5.

Correlations Between Amount of Meditation Homework and Outcomes

	Pain Sev.	Pain Dis.	Dep.	Anxiety	Stress	Mind.	Accep.	CB (RT)	CB (Accu.)	Diff. Foc. Atten.	Diff. Organ. Sched.
Informal Practice (total)	.22	-.06	-.06	-.08	-.02	.04	.06	.14	.03	.30	-.04
Formal Practice (total)	.31	.08	-.06	-.15	-.19	.16	.11	.05	.18	-.25	-.15
Body Scan (days)	-.26	.01	-.12	.18	.09	.21	.16	.17	-.09	**-.50***	-.14
Yoga (days)	-.05	-.22	-.22	-.20	-.16	.37	.15	.37	-.23	-.32	-.11
Sitting Practice (days)	.07	-.03	.01	-.17	-.13	.15	.23	.22	-.16	-.24	-.24
Walking Practice (days)	-.14	-.17	-.28	-.37	-.20	.37	**.47***	.33	-.22	-.03	-.19
Informal Practice (days)	-.11	-.17	-.16	-.39	**-.57****	.42	.14	0.29	**-.44***	.16	.04

Note: *p < .05, **p < .01. Pain Sev. = Pain Severity; Pain Dis. = Pain Disability; Dep. = Depression; Mind. = Mindfulness (FFMQ); Accep. = Pain Acceptance; CB (RT) = Change Blindness Reaction Time; CB (Accu.) = Change Blindness Accuracy; Diff. Foc. Atten. = Difficulty in Focusing Attention; Diff. Organ. Sched. = Difficulty in Organizing Schedule

Maintenance of Improved Health Outcomes at 3-month Follow Up

Paired t-tests revealed no significant differences from post-test to follow up for pain severity, pain disability, depression, anxiety, stress, mindfulness and change blindness accuracy scores *ps* >.05, suggesting that any benefits observed were maintained at least 3 months following MBSR treatment. Pain acceptance significantly increased from post-test to follow up, and speed to detect changes on the attention task improved (i.e., RT decreased) from post-test to follow up, *ps* < .05. Table 6 presents Mean scores *(±SD*) for post-treatment and follow up using the entire sample (i.e., combined scores for the MBSR group and WC group once crossed over into the treatment arm; *n* = 29).

Table 6.

Maintenance of Outcome Benefits at 3-month Follow Up

Variable	Time		*p* value
	Post-test	3-month follow up	
Primary Outcomes *Mean* (±*SD*)			
Pain severity (SF-MPQ-2)	88.86 (55.85)	85.02 (56.76)	.549
Pain disability (PDI)	41.11 (17.44)	37.44 (20.8)	.121
Depression (DASS)	6.89 (6.07)	7.16 (5.92)	.729
Anxiety (DASS)	6.93 (5.7)	5.82 (5.15)	.104
Stress (DASS)	9.0 (6.03)	9.05 (5.7)	.933
Change blindness (RT ms)	28.47 (29.4)	21.61 (23.91)	.019*
Change blindness (% Accuracy)	.87 (.2)	.87 (.2)	1.00
Secondary Outcomes *Mean* (±*SD*)			
Mindfulness (FFMQ)	131.91 (22.4)	132.31 (21.5)	.840
Mindfulness (MAAS)	41.85 (9.6)	43.15 (11.7)	.335
Pain Acceptance	53.29 (21.9)	56.75 (21.68)	.048*

Note: Post-treatment data combines scores from T2 for the MBSR group and T3 for the WC group and 3-month follow up data combines scores from T3 for the MBSR group and T4 for the WC group. *$p < .05$, **$p < .01$.

Chapter 4: Discussion

Effects of MBSR on Physical and Psychological health

The primary goal of this study was to evaluate the effectiveness of MBSR compared to a WC group in improving pain severity, pain disability, depression, anxiety, stress, and attention, as measured by a computerized change blindness task. Levels of depression and stress significantly decreased following mindfulness training in the MBSR group compared to the WC group, while no significant group differences were observed for anxiety, pain severity and pain disability. This study strengthens evidence suggesting that Mindfulness-Based Stress Reduction can improve emotional difficulties commonly experienced by individuals with chronic physical conditions such as pain.

Twelve of 13 RCTs in Garmon et al.'s (2014) systematic review of MBSR for CP did not show improvements in pain severity, while 6 of the 10 observational studies demonstrated reduced pain severity from pre-to-post treatment. Of the 13 RCTs, 6 included an active control group such as education or relaxation techniques and benefits in pain severity were observed for both groups. Of the remaining 7 RCTs, MBSR was compared to waitlist or treatment as usual controls and only 1 demonstrated significant improvement in pain severity, 2 did not measure pain, 1 found improvement in both groups, and 3 found no benefit in either group. The researchers indicated that they could not conclude MBSR produced benefits in pain severity.

The primary goal of mindfulness training is not to reduce or change symptoms directly but rather to increase awareness of experience and modify the relationship between mental processes and physical sensations (Chiesa & Serretti, 2011; Kabit-Zinn, 1982). Research comparing focused attention and open monitoring forms of meditation among novices and long-term meditators demonstrate no analgesic effects of meditation in novices, but reductions in pain severity and unpleasantness among expert meditators (Grant & Rainville, 2009; Perlman, Salomons, Davidson, & Lutz, 2010). This helps shed light on the lack of improvement in pain severity in the current study, as patients had no previous MBSR training. Research also demonstrates that individuals who have CP and are trained to bring the focus of attention into painful regions during mindfulness training experience an increase in pain intensity (Grant & Rainville, 2009). Therefore, it is not surprising that the primary sensation of pain was unchanged.

On the other hand, Garmon and colleagues reported in their review that 10 of 13 RCTs and all 10 observational studies demonstrated improvements in one or more of the other health measures including anxiety, depression, well-being, sense of coherence, sleep quality, and mental health. The present study's findings are in line with this review and suggest that 8-weeks of MBSR may not be sufficient to reduce the sensory experience of pain, but can help individuals manage their pain. Specifically, MBSR training led to decreased depression and stress but not anxiety. One potential explanation for the lack of benefits observed for anxiety is that the physiological responses often experienced during anxious states (e.g., sweaty palms or increased heart rate) have strong biological and evolutionary roots and may be more challenging to regulate upon initiation, particularly when anxiety has been experienced for prolonged periods of time.

Mindfulness training teaches increased awareness and nonjudgement and may help individuals to identify and observe physiological responses (e.g., sweaty palms), and cognitive interpretations (e.g., "I can't believe this is happening to me") associated with stressful experiences permitting time to respond adaptively rather than reactively (Bishop et al., 2004). Indeed, in a healthy community sample of university students and experienced Vipassana and

Zen meditators, the nonjudgement subscale of the FFMQ predicted lower levels of depression, anxiety and stress, as measured with the DASS, while the act with awareness subscale predicted less depression (Cash & Wittingham, 2010). Self-reports of nonreactivity to inner experience significantly decrease following MBSR and are related to improvements in perceived stress, depression and anxiety (Carmody & Baer, 2008).

Moreover, changes in physiological responses associated with stress have also been shown to decrease following mindfulness training including decreased cortisol levels (Carlson, Speca, Faris, & Patel, 2007) and decreased heart rate (Zeidan, Johnson, Gordon, & Goolkasian, 2010). Researchers suggest that mindfulness may operate to reduce stress via down-regulation of the limbic system and hypothalamic pituitary axis (Garmon et al., 2014). Neuroimaging research supports the notion that mindfulness training modifies the function of brain regions associated with emotion such as decreased activity in the amygdala (Holzel et al., 2011). A large prospective study of 339 participants taking part in a Mindfulness-Based Stress and Pain Management Program tested a theoretical model proposing that mindfulness training impacts stress via cognitive-emotional coping processes. Results showed that significant increases in mindfulness predicted decreases in stress and this was partially mediated by increases in positive reappraisal, defined as the process by which stressful circumstances are viewed as beneficial, meaningful, and positive rather than negative and unmanageable (Garland, Gaylord, & Fredrickson, 2011). Therefore, the ability to observe, monitor and prevent escalation of thoughts, intensity of emotions, and physiological sensations, and reappraise a negative event as helpful or positive, may be critical to changing the perception of distressing experiences associated with pain.

Effects of MBSR on Attention

This was the first study to examine the effects of MBSR on change blindness in a CP sample. Hypervigilance to pain-laden cues, sensations and experiences is documented in individuals with CP (Vlaeyen & Linton, 2000), and it was predicted that MBSR training would modify this narrowed focus of attention and increase patients' ability to open awareness to broader experience and detect unexpected changes to scenes. There were no significant improvements in RT or accuracy from pre-treatment to post-treatment on the change blindness task in the MBSR group which is inconsistent with our prediction and Hodgins and Adair's (2010) findings that healthy individuals with greater meditation practice detected a greater number of changes in flickering scenes and with greater speed. There are several potential explanations for the lack of attention benefits observed.

First, the 8-week dose of mindfulness practice in the MBSR program may not be sufficient to modify the attention skills required to improve performance in change blindness, rather assessment of experienced meditators may be needed to observe benefits. Indeed, studies suggest that intensive mindfulness training is associated with enhanced cognitive task performance. For instance, Slagter and colleagues (2007) evaluated the performance of 17 healthy participants on an attentional blink task prior to and following an intensive 3-month vipassana meditation training involving 10 to 12 hours of meditation per day compared to 23 participants who took part in a 1-hour meditation class and meditated only 20 minutes daily for 1 week. The 3 month mindfulness training began with focused meditation followed by open monitoring with the goal of cultivating awareness of broader experience with minimal elaboration. Participants were required to identify two numerical targets embedded within a rapid stream of distracters. Only participants with intensive training showed reduced elaborative processing of the first of two targets, that is, a smaller attentional blink and a reduced brain potential index of resource allocation to the first target, indicated by a smaller T1-elicted P3b.

Another significant study supports the idea that greater mindfulness experience is required to improve attention skills. When comparing performance in alerting, orienting and conflict monitoring, as measured by an attention network task, healthy individuals with greater meditation exposure participating in a 1-month intensive retreat group (with previous concentration meditation experience) showed improved alerting compared to individuals in a standard MBSR group or control group with no meditation experience. Also, the amount of meditation experience for those in the retreat group was associated with performance in the alerting component of attention. In contrast, individuals participating in the MBSR program performed better in orienting compared to individuals in the intensive retreat or control group. No differences in conflict monitoring were observed following training (Jha et al., 2007).

The researchers suggest that individuals with less exposure to mindfulness training, as experienced in the MBSR group, may develop the focused attention skills necessary for improved performance in orienting attention to the breath and disengaging from distracters, but not the open receptive attention skills which may explain superior performance in alerting. Successful performance in the alerting component requires the ability to detect unexpected targets without temporal and spatial information, similar to the skills required in the change blindness task. It was highlighted that receptive attention or the ability to be ready and open to experience may develop with greater mindfulness training. These findings may help explain the lack of change blindness benefits in the current study. It may be the case that an 8-week MBSR program begins to train participants to focus on the breath and start to identify when they experience a distraction but the capacity to open attention to all experience, as required in detecting unexpected changes to scenes, may require more extensive training. This also makes sense given the improvements in speed to detect changes in scenes obtained from post-treatment to 3-months follow up in the current study. Continued practice following MBSR treatment may explain this improvement, however, given that we did not specifically ask patients the amount of continued mindfulness practice they engaged in following treatment, this could not be further assessed.

A second potential explanation for the lack of attention benefits may relate to the level of pain disability in the current sample and attentional biases observed among individuals with chronic pain. Because levels of pain severity and pain disability were moderate to high in the current sample and did not significantly improve following MBSR training, it is possible that the sensory pain experience was too salient to disengage from in order to allow greater allocation of attentional resources to improve accuracy and speed in detecting scene changes. Individuals with pain often self-report cognitive difficulties such as forgetfulness and difficulty with attention (McCracken & Iverson, 2001), and research continues to document that pain severity is associated with poorer performance on a range of objective cognitive tasks. Patients with fibromyalgia, for instance, obtained lower scores on a cued recall task compared to patients with localized pain or no pain (Grisart, Van der Linden, & Masquelier, 2002), as well as immediate and delayed recall and sustained auditory concentration as measured with the Wechsler Memory Scale-Revised and the Paced Auditory Serial Additions Test, respectively, compared to matched healthy controls (Grace, Nielson, Hopkins, & Berg, 1999). Moreover, performance in working memory, assessed with the reading span test, auditory verbal working memory, attention, and dual task performance, measured with the auditory consonant trigram, was worse among fibromyalgia patients compared to healthy matched controls (Dick, Verrier, Harker, & Rashiq, 2008).

Cognitive deficits have been reported among older adult samples with diverse CP conditions in immediate and delayed reproduction of visuospatial information, as measured with the Wechsler Memory Scale-Revised (Iezzi, Duckworth, Vuong, Archibald, & Klinck, 2004), and cognitive flexibility, assessed with the Number-Letter-Switching subtest from the Delis-Kaplan Executive Function System (D-KEFS; Karp et al., 2006). Impaired selective attention as indexed by increased reaction time on the colour-word stroop task in adults with mixed CP conditions versus no-pain controls has also been observed (Grisart & Plaghki, 1999). Furthermore, Söderfjell, Molander, Johansson, Barnekow-Bergkvist, and Nilsson (2006) studied a large population-based sample of 929 individuals with pain (back; or shoulder, arm, and leg pain) versus pain-free controls and reported worse performance on a vocabulary test of semantic memory and visuospatial block design task.

It is not surprising that pain places demands on attention and interferes with successful cognitive task performance (Eccleston & Crombez, 1999) as exemplified by these findings. In an effort to investigate how pain impacts attention processes, a large body of evidence has explored attentional biases to pain-related stimuli. It is postulated that attentional bias in individuals with CP may play a role in either the onset or maintenance of the condition (Schoth, Nunes, & Lossi, 2012). Specifically, those in pain may be preoccupied with their pain experience or circumstances that may worsen their state resulting in avoidance behaviours. Continued avoidance of potentially exacerbating circumstances or activities may lead to social isolation and reduced physical activity, thereby perpetuation the pain condition. To assess attention biases, these elements of the fear-avoidance model of pain (Vlaeyen & Linton, 2000), that is, hypervigilance towards – and avoidance of – pain cues have been investigated using modified versions of the dot-probe task (Macleod, Matthews, & Tata, 1986) in CP samples (Asmundson, Carleton, & Ekong, 2005; Asmundson & Hadjistavropoulos, 2007; Asmundson, Wright, & Hadjistavropoulos, 2005; Dehghani, Sharpe, & Nicholas, 2003; Keogh, Ellery, Hunt, & Hannent, 2001; Schoth, Nunes, & Lossi, 2012; Sharpe, Dear, & Schrieber, 2009; Sharpe et al., 2012; Vago & Nakamura, 2011). Hypervigilance refers to the ongoing monitoring, quick identification and fixation of pain-related cues, while avoidance involves reducing the threat of pain-related cues by engaging in habitual and purposeful forms of emotion regulation (Vago & Nakamura, 2011).

The typical dot probe task used in the CP literature (Schoth et al., 2012) presents a fixation point in the middle of the screen for 500 ms and is replaced by pairs of pain-related and neutral words (e.g., “stabbing” and “door”) or images (e.g., grimacing facial expression and neutral facial expression) located above and below the initial fixation stimulus. The pair of stimuli is then replaced with a probe in one of these locations and participants are required to indicate the location of the probe as accurately and efficiently as possible. It is assumed that faster detection of probes presented in the same location as pain-related stimuli (congruent trials) versus the neutral stimuli location (incongruent trials) is an index of attentional biases towards pain-related stimuli.

A recent meta-analysis of controlled studies examining attention bias (Schoth et al., 2012) reported significantly greater biases towards pain-related stimuli with a small to medium effect size of .36 in individuals with CP compared to healthy controls. Given the accumulating evidence demonstrating attentional biases to pain related cues in individuals with CP and the severity of pain in the current sample, it is certainly possible that the physical experience of pain placed to significant a load on attentional processes thereby disrupting participants’ ability to allocate sufficient resources to scan features in the change blindness task and improve accuracy or efficiency. It is also possible, as mentioned by Schoth and colleagues that attention bias to pain is not only associated with cognitive interference but likely impacts negatively upon other domains of patient health resulting in greater health care seeking, use of analgesics, and maladaptive coping strategies such as recreational substance use. They highlight the clinical usefulness of using dot probe paradigms to detect patients with greater attention biases so appropriate treatments can be recommended. In fact, the potential role of attention bias in perpetuating the pain cycle has recently elicited the development and evaluation of treatments specifically tailored to reduce these biases in individuals with CP and preliminary results suggest promise for improvement in clinical outcomes (Sharpe et al., 2012). As other researches have noted, increased mindfulness may play a critical role in reducing maladaptive coping responses including hypervigilance to pain-related stimuli and catastrophizing (Garland et al., 2012).

A third explanation for the lack of attention benefits in the current study is the possibility that MBSR training does not improve attention skills directly but rather enhances moment to moment awareness regarding the relationship between thoughts, emotions, and sensations permitting greater acceptance of the experience and an improved ability to detect and respond to stressors more adaptively, which may then free up attention resources. A secondary objective of this study was to examine if levels of mindfulness and pain acceptance improved following MBSR training. Only a few randomized controlled trials have examined changes in self-reported mindfulness skills among individuals with CP. Three randomized controlled trials did not observe significant changes in mindfulness (FFMQ and MAAS) pre-to-post MBSR treatment among a community sample of low back pain compared to an education active control group (Morone et al., 2009; Morone et al., 2016), and a group of patients with rheumatoid arthritis compared to waitlist controls (Pradhan et al., 2007).

Effects of MBSR on Levels of Mindfulness and Pain Acceptance

The current study demonstrated significant increases in mindfulness in the MBSR group compared to the WC group and is consistent with three randomized controlled trials that reported greater mindfulness post-MBSR in individuals with fibromyalgia compared to an active relaxation control and WC group (Schmidt et al., 2011), among migraineurs when compared to standard care (Wells et al., 2014), and among healthy adults when compared to a WC group (Anderson et al., 2007). Non-randomized designs found increases in self-reported mindfulness in non-clinical samples following modified mindfulness interventions (Chambers et al., 2008) and in experienced Buddhist meditators compared to non-meditation controls (Moore & Malinowski, 2009). This study, therefore, provides further support that MBSR enhances patients' capacity for mindfulness in a heterogeneous CP sample presenting to a tertiary pain management centre.

With respect to evaluating levels of pain acceptance following MBSR training in CP, few controlled studies have been conducted. Two randomized controlled trials comparing MBSR to a WC group found greater pain acceptance scores in the MBSR group in a sample of patients with low back pain (Morone, 2008) and a mixed pain sample (La Cour & Peterson, 2015). Following participation in a variant of MBSR: Breathworks Mindfulness-Based Pain Management, Cusens and colleagues (2010) found significant increases in the total score of pain acceptance and the activity engagement subscale score in a heterogeneous sample of individuals with low back pain, arthritis, sciatic injury, and fibromyalgia compared to a treatment as usual control group.

Other research has typically recruited community and clinic pain samples and administered self-report measures of pain acceptance and pain-related outcomes at one time point and conducted regression analysis to determine the association between pain acceptance and outcomes. Pain acceptance has been found to significantly and uniquely predict mental health in a mixed sample of 120 CP patients, as measured by the SF-36, over and above pain severity and pain catastrophizing (Viane et al., 2003), as well as quality of life, assessed with the World Health Organization Quality of Life Assessment, in a sample of 86 low back pain patients (Mason et al., 2008). Pain acceptance has also been found to significantly contribute to lower levels of depression (measured with the Beck Depression Inventory), anxiety (measured with the Pain Anxiety Symptoms Scale) and disability (measured with the Sickness Impact Profile), after controlling for pain severity and demographic variables, in a mixed sample of 160 CP patients (McCracken, 1998).

Pain acceptance did not significantly increase immediately following MBSR treatment in the current study, contrary to expectations and the aforementioned findings. One explanation for the lack of pre-post treatment effect is that by the time patients arrive at the pain centre their condition is often refractory in nature and they have visited dozens of health care practitioners with little avail and express worry and fear that the pain will never go away. Acceptance of CP has been described as the acknowledgement of the pain condition, reducing strategies aimed at controlling or changing pain, and living an adequate quality of life in the face of pain (McCracken, 1998). It is possible that the 8-week MBSR program is more likely to open awareness to the present experience and encourage individuals to recognize how their thoughts and emotions are connected to their physical pain, that is, increased mindfulness, but the acceptance of the continued presence of pain in their lives likely requires more effort and time to unfold.

In fact, many patients expressed frustration when completing the Chronic Pain Acceptance Questionnaire due to the sensitive nature and wording of the statements. For instance, the following items appeared to induce the most frustration: “it’s not necessary for me to control my pain in order to handle my life well"; "it's a relief to realize that I don't have to change my pain to get on with my life"; "I will have better control over my life if I can control my negative thoughts about pain". It is not surprising that individuals who have been suffering with pain for a long time with little or no relief are focused on reducing the sensory experience of pain and are looking for health care practitioners to provide them with a quick solution. Self-pain management programs such as MBSR require patients to make a concerted effort to reflect introspectively and observe thoughts, emotions, and sensations that may be exacerbating their pain experience. This encourages the realization that elements of the "self" may be contributing to the chronicity of the condition rather than solely an external explanation. Also, given that the concept of accepting pain is introduced later in the group at week 5, it is possible that these patients need more time to process the meaning of acceptance and begin to incorporate it into their lives. Consistent with this notion, levels of pain acceptance did significantly increase from post-treatment to 3-months follow up.

Role of Mindfulness and Pain Acceptance in Outcomes

Another secondary objective of this study was to examine the predictive role of mindfulness and pain acceptance for improving pain-related outcomes. Multiple regression analyses using the entire sample showed that changes (i.e., increases) in mindfulness significantly predicted changes (i.e., decreases) in emotional distress including stress and depression and marginal decreases in anxiety, but did not play a role in pain severity, pain disability or performance on the change blindness task. These findings are in line with cross-sectional studies demonstrating that self-reported mindfulness is significantly associated with patient distress and functioning in individuals suffering with CP. For example, McCracken et al. (2007) administered take home questionnaires to a sample of 105 patients seeking treatment in a pain centre in the UK and found that the total score of mindfulness, as measured with the MAAS, was a significant unique predictor of depression (measured with the British Columbia-Major Depression Inventory), anxiety (measured with the Pain Anxiety Symptoms Scale), and physical, psychosocial and other types of disability (measured with the Sickness Impact Profile), over and above background variables (i.e., pain severity, pain distress, amount of daily activity and medication use) and pain acceptance.

A later study by McCracken and Thompson (2009) used the same sample of 105 patients and an additional 45 patients and conducted exploratory factor analysis of the MAAS items which revealed four factors termed: Acting with Awareness (e.g., “I break or spill things because of carelessness, not paying attention, or thinking of something else”), Present Focus (e.g., “I snack without being aware of what I am eating”), Responsiveness (e.g., “I get so focused on the goal I want to achieve I lose touch with what I’m doing right now to get there”), and Social Awareness (e.g., “I forget a person’s name almost as soon as I’ve been told it for the first time”). These components were entered into hierarchical multiple regression analyses controlling for pain severity and background variables. *Present focus* was the most significant predictor for all 8 outcomes including pain-related distress, physical disability and psychosocial disability, depression, pain-related anxiety, number of pain-related medications, number of general practitioner visits and daily activity. *Acting with awareness* significantly predicted 3 of these outcomes including psychosocial disability, depression, and pain-related anxiety. It was concluded that maintaining contact to present experience is particularly important for patient functioning. Interestingly, in the current study there were no significant differences in total MAAS mean change scores between the MBSR and WC groups, in contrast with the significant increases in total FFMQ mean change scores. Future researchers should consider the relevance and appropriateness of standardized mindfulness questionnaire items for their sample. The MAAS scale assesses levels of mindfulness by using statements that reflect mindlessness, which is not ideal. Also, the MAAS includes items that likely do not reflect mindfulness in a CP sample ("I tend not to notice feelings of physical tension or discomfort until they really grab my attention"). It is expected that most patients with debilitating pain will notice feelings of physical tension - and given evidence suggestive of attention biases towards pain - this likely has very little to do with an improved capacity for moment-to-moment awareness in the sense that researchers hope to capture. Regardless, the current study provides evidence to suggest that cultivating mindfulness is a skill or state of mind that can be trained and helps patients manage emotional distress associated with their pain condition.

This is the first randomized controlled trial to assess the predictive role of pain acceptance following MBSR among a heterogenous CP sample. There is some evidence to suggest that pain acceptance is related to functioning. Specifically, using multiple regression analyses change in pain acceptance was found to be predictive of pain disability in the entire sample but did not significantly contribute any variance to the remaining outcomes of pain severity, depression, anxiety, stress, and change blindness performance. Other research has demonstrated the predictive role of pain acceptance among a mixed sample of CP patients in physical disability and psychosocial disability (measured with Sickness impact profile), and other health outcomes over and above pain severity following participation in cognitive-behavioural therapy (Vowles, McCracken, & Eccleston, 2007). Research has also demonstrated the predictive role of pain acceptance in pain disability and depression among individuals with pain secondary to neurological disorders who present with marked physical disability including multiple sclerosis, muscular dystrophy, post-polio syndrome and spinal cord injury (Kratz, Hirsh, Ehde, & Jensen, 2013). Longitudinal research is needed to further explore the predictive role of pain acceptance, mindfulness and other important variables that likely play a role in the development and maintenance of CP, including pain severity, pain-related fear, pain-related anxiety, and pain catastrophizing. It seems to be the case that the cognitive and affective components are more important than the sensory experience of pain in patients' functioning (Crombez, Vlaeyen, Heuts, & Lysens, 1999; McCracken, 1998; Swinkels-Meewisse, Roelofs, Oostendorp, Verbeek, & Vlaeyen, 2006; Viane et al., 2003; Vowles, McCracken, & Eccleston, 2007).

Acceptance is one of seven core attitudes important for successful mindfulness practice, in addition to non-judgment, patience, beginner's mind, trust, non-striving, and letting go (Kabit-Zinn, 1990). Kabit-Zinn (1982) eloquently described how consistent mindfulness practice might operate to reduce suffering in individuals with CP. He suggests that mindfulness training can assist in managing the experience of CP via an uncoupling between the sensation of pain and the cognitive, interpretative and affective elements (e.g., this pain is unbearable and will never go away) associated with pain. This process can unfold by continuously observing these components as separate and altering the view that they have any more veracity or significance than other mental events passing through the mind. Therefore, with continued practice the cognitive-affective part of pain could subside even if the specific sensory aspects of pain are unchanged. Further work is needed to untangle these components of mindfulness and determine how initial levels of mindfulness impact patient functioning over time and how the capacity for mindfulness changes during and subsequent to mindfulness training. Qualitative analyses such as semi-structured interviews are particularly lacking in this line of work. Simply asking patients their views of mindfulness over the course of MBSR could help shed light on this introspective process.

Although the concept of mindfulness is abstract and difficult to measure, evidence continues to document the health benefits of being aware of thoughts, emotions, and behaviours as they occur. Training individuals to value the importance of identifying and separating the negative or hurtful thoughts and emotions tied to any experience is challenging. This is particularly the case when the perception of pain as simply a sensory experience is common and ingrained within public views of pain and traditional medical models. Understanding pain as a physical, psychological, cognitive, and social experience, which is unique to each individual, has certainly contributed to the successful integration of mindfulness- and acceptance-based approaches within multidisciplinary pain clinics. A recent theoretical model put forth by Teper, Segal and Inzlicht (2013) suggests that mindfulness promotes executive control through greater awareness and acceptance of experience. Specifically, mindfulness encourages greater sensitivity and ability to detect subtle variations in affect and sensations in the body, which is critical for recognizing and implementing goal oriented behaviours when required to successfully regulate emotional reactivity. Acceptance is also viewed as crucial for improved executive control and emotion regulation since it reduces the tendency to elaborate or ruminate on any affective cues and permits the opportunity to implement strategies to reduce negative affect. Managing anger was used to illustrate that individuals who practice mindfulness and acceptance and are open to changes in affect will quickly notice increases in heartbeat and are able to recruit resources to regulate this experience prior to escalation. Individuals with pain face an array of emotional and physical challenges that can contribute to increased pain including, anger, fear, anxiety, worry, catastrophizing, depression, stress, muscle tension, inflammation, and inactivity (Garmen, 2014). It is not difficult to envision how the ability to efficiently identify and allocate appropriate resources during fluctuations in these experiences can change the way pain is experienced and ultimately reduce suffering.

Functional and structural neuroimaging research is underway to better understand the specific mechanisms by which mindfulness operates and produces benefits. A comprehensive theoretical review (Holzel et al., 2011) highlighted the neuroplastic changes associated with 4 main components of mindfulness meditation including: 1) attention regulation, 2) body awareness, 3) emotion regulation, and 4) change in self-perspective. Increased activity in the anterior cingulate cortex is implicated during attention regulation, described as the ability to detect conflict and distractors during meditation and return attention to the object of choice. Increased insula activation and increased gray matter concentration in the temporo-parietal junction are associated with an enhanced awareness of the sensation of stimuli and perspective of bodily states, respectively. Improved emotion regulation in meditators, that is the ability to approach affect with acceptance and reduce reactivity to affect, is supported by increased activation in the dorsal and ventro-medial prefrontal cortex and reduced activity in the amygdala and hippocampus. Change in the perspective of the self and viewing oneself and one's thoughts as transient, dynamic, and separate from the self is associated with decreased brain activity in areas of the default mode network, including the medial prefrontal cortex and posterior cingulated cortex, which are typically highly active during rest or mind wandering. Neuroimaging research is an exciting avenue for future research to better understand the processes of mindfulness meditation and studies would do well to incorporate both behavioural and neuroimaging methodologies in naïve meditators over several years of mindfulness practice to further understand the distinctiveness and coordination of these processes and how they contribute to improved well-being.

Relationship Between Homework and Outcomes

The current study provided support for the importance of mindfulness practice in improved health outcomes indicated by moderate to strong correlations between the amount of self-reported informal meditation practice and stress, walking meditation and pain acceptance, and correlations between the body scan and ability to focus attention. This is in line with previous research demonstrating a link between mindfulness homework and outcomes (Carlson et al., 2001; Carlson et al., 2004; Carmody & Baer, 2008; Carmody et al., 2006). These findings combined with the significant improvements in mindfulness in the MBSR group compared to WC group in the current study provides further support that mindfulness is a unique skill that transforms with practice and helps individuals better cope with negative affect and the pain experience. The importance of continued mindfulness practice should be further investigated by monitoring daily or weekly homework over the progression of the MBSR course and long-term.

Maintenance of Effects at 3-Month Follow Up

The last goal was to explore whether changes observed following MBSR training maintained at 3-month follow up assessment. Observed effects remained relatively unchanged with the exception of significant improvements in pain acceptance and reaction time to detect changes in the change blindness task, from post-treatment to 3-month follow up. Although we did not directly measure the amount of mindfulness practice following the completion of MBSR training, these findings are encouraging and suggest that mindfulness may be an adaptive coping resource for individuals to draw from when faced with stressful and/or painful experiences. The standard MBSR program does not include an additional 3-month session as currently delivered at our pain centre. The group facilitator offers additional resources at the end of the standard 8-week group to encourage continued mindfulness practice. The 3-month follow up meeting may provide an additional motivation booster to encourage continued practice, as participants are aware they will have an opportunity to re-connect with the group and discuss barriers to practice. Exploratory correlation analyses revealed that motivation prior to MBSR treatment was significantly associated with increased self-reports of informal and formal at-home meditation during training. As with any skill requiring continued practice, motivation may be targeted to enhance outcomes. A recent cluster randomized controlled trial of 87 participants participating in cognitive-behavioural therapy at our pain centre demonstrated that a one-time 60 minute session of motivational interviewing prior to cognitive-behavioural therapy compared to a pain information control group significantly increased the number of attendees at the 3-month follow up session (Fuss et al., 2016).

Strengths

There are several notable strengths including the use of a randomized controlled trial and assessment of long-term benefits at 3-months follow up. Second, treatment fidelity was strong given that one instructor with ample experience working with individuals with CP and mindfulness training facilitated all 4 MBSR groups across waves. Third, given that the MBSR program was delivered to mixed CP populations, the results can be generalized to individuals suffering from several CP conditions rather than a single diagnosis. Fourth, participants in the sample were novice meditators reducing the possibility that variation in previous formal meditation experience confounded the results. Fifth, we demonstrate evidence to support that mindfulness is a skill that can be trained in patients with debilitating CP through a group-administered 8-week MBSR program and improves affect regulation.

Limitations

There are several limitations of the current study. First, the use of a waitlist control group instead of an active control group limits our ability to conclude the benefits observed are a result of MBSR treatment rather than nonspecific factors such as group support or therapist contact. The use of a waitlist control group was the most feasible option as resources were not in place to support a new active treatment and there was already a waitlist at the clinic for the MBSR program. Second, there were a limited number of image pairs presented in the change blindness task at each testing session, which may have reduced our possibility to detect group differences in attention. Third, all outcomes with the exception of attention were assessed using self-report measures which are subject to social desirability bias and based on recall. For instance, patients may have reported what they thought was preferred by the researcher rather than their true symptoms and experiences. To limit this possibility, the researcher always premised questionnaire completion with a statement indicating the importance that patients respond as truthfully as possible. In order to address recall biases, future research could incorporate weekly or daily monitoring of primary outcome variables to better assess patients' cognitive, affective and behavioural patterns surrounding the pain experience. Fourth, the sample size is small and results should be interpreted with caution given the number of analyses conducted. Finally, there is no control group to allow comparison for the 3-month follow up data; however, it is promising that scores did not return to baseline.

Implications

Mindfulness training has the potential to increase awareness of internal experiences, acceptance of pain, and improve abilities to regulate affect and reactions to stress. If individuals with pain begin to recognize how their thoughts, emotions, memories, and experiences shape the chronicity of their condition, this has the potential to reduce the suffering experienced and the burden and responsibility often placed on health care providers. Furthermore, MBSR is a nonpharmacological treatment option with few or no side effects and could be incorporated as part of comprehensive treatment plans at pain centres to complement standard pain management approaches. It is a relatively inexpensive option to implement in tertiary pain clinics and is capable of transforming traditional pain management models. Given the potential for mindfulness training to regulate affective processes, it can be used for a diverse range of clinical pediatric and adult populations who suffer significant emotional distress including individuals with cancer, diabetes, attention-deficit hyperactivity disorder, borderline personality disorder, substance use disorder, anxiety disorders, post-traumatic stress disorders, and eating disorders. Since the introduction of MBSR there has been an exponential increase in research investigating its usefulness in these conditions and others. With the burgeoning of research demonstrating its benefits in a multitude of conditions, mindfulness training is gaining momentum and program evaluations directed at teachers and students are underway in primary and secondary educational institutions in Europe (Gold et al., 2010), Canada, and the United States (for a recent review see Meiklejohn et al., 2012). This work shows tremendous promise for a range of benefits including increased well-being and reduced stress for teachers, and improved working memory, attention, social skills, and emotion regulation skills for students. This line of work is particularly encouraged because early learning of cognitive and emotion regulatory processes can shift the way members of society deal with everyday stressors and more severe clinical issues, and ultimately reduce the economic burden on the health care system.

Conclusion

Pre-post treatment improvements were found in depression, stress, and mindfulness following MBSR training in a randomized controlled trial of a heterogeneous CP sample, while no benefits were observed for pain severity, pain disability, anxiety, or attention, as measured with a change blindness task. Mindfulness and pain acceptance significantly contributed to emotional distress and pain disability, respectively. Self-reported between session mindfulness homework was associated with decreased stress, increased pain acceptance, and ability to focus attention. Benefits observed at post-treatment were maintained at 3-months follow up. The current findings contribute to our understanding of the mechanisms important for improved emotion regulation. Given previous research demonstrating the negative effects of stress and depression on physical health as well as the challenges health care practitioners face in managing and treating complex pain conditions, mindfulness-based approaches can be integrated in pain clinics to facilitate patient recovery via reduced psychological distress.

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Appendix A: Pre-Treatment Questionnaire

ID Number (Completed by Researcher): ____________ Date (DD/MM/YY): ____________

Date of birth (DD/MM/YY): ____________ Gender: ______ Country of birth: ____________

1. What is your marital status? Please circle one:

   Single Common Law Married Separated/Divorced Widowed Other

2. Education:

   ______ Without high school diploma
   ______ High school diploma, no college
   ______ College diploma/Bachelor's degree
   ______ Master's/Doctorate degree

3. Current Employment

   ______ Looking for work
   ______ Part-time work
   ______ Full-time work
   ______ Unemployed because of my health
   ______ Retired because of my health
   ______ Retired for some other reason
   ______ Student
   ______ Other (Please Specify: __________
   ____

4. Occupation: ____

5. What is your average annual household income?

   ______ Under $14,999
   ______ $15,000 - $29,999
   ______ $30,000 - $44,999
   ______ $45,000 - $59,999
   ______ $60,000 - $79,999
   ______ $80,000 - $99,999
   ______ $100,000 - $129,999
   ______ $130,000 +

6. Are you currently receiving disability? Please circle one: Yes No

7. If yes, please check which type of disability

   ______ Employer
   ______ WSIB
   ______ Provincial (ODSP)
   ______ Other (please specify: ___________
   ____

8. Personal past history of (please check all that apply):

_______ Headache condition
_______ Chronic facial pain
_______ Chronic pelvic pain
_______ Chronic back pain
_______ Depression
_______ Anxiety
_______ IBS (Irritable Bowel Syndrome)
_______ Fibromyalgia
_______ Substance abuse or dependence

9. Please list all the medications that you are CURRENTLY taking:

Medication Name	Dose of Each Tablet (e.g. Number of mg)	Daily Frequency (e.g. 3 times per day)	Length of Time Taking Medication (e.g. 2 Months or 1 Year)

10. Please describe your current pain problem.

____
____
____
____
____
____
____

11. Please rate your pain by circling the one number that best describes how much pain you have RIGHT NOW.

0 1 2 3 4 5 6 7 8 9 10

No pain — Pain as bad as I can imagine

12. Have you attended any other GROUP THERAPY before to treat your specific chronic pain condition? Please circle one: Yes No

If you responded yes to this question, please complete (a), (b) & (c) below

(a) Please specify the name of the treatment below

____

(b) Please specify the duration of the treatment below

____

(c) Please indicate when you began this treatment (please indicate the month and year)

____

13. Have you practiced meditation before? Please circle one: Yes No

If yes, please describe the **type** of meditation and **how often** you practice (e.g. 20 min/day or 1x a week)

____
____
____
____

14. On a scale of 0 – 10, what level of improvement do you expect from this program in your pain symptoms, with 0 representing no improvement, and 10 representing highest improvement?

0 1 2 3 4 5 6 7 8 9 10

No improvement | Highest improvement

15. On a scale of 0 – 10, how motivated are you to take part in the program, with 0 representing not at all motivated, and 10 representing highly motivated?

0 1 2 3 4 5 6 7 8 9 10

Not at all motivated | Highly motivated

16. On average, how many hours of sleep do you get per night? _______

17. How many hours of sleep did you get last night? _______

18. On a scale of 0 – 10, how much difficulty do you have in focusing your attention on daily tasks, with 0 representing no difficulty, and 10 representing as much difficulty as you can imagine?

0	1	2	3	4	5	6	7	8	9	10

No difficulty

As much difficulty as I can imagine

19. On a scale of 0 – 10, how much difficulty do you have in organizing your schedule, such as doctor's appointments, social events, and family events, with 0 representing no difficulty, and 10 representing as much difficulty as you can imagine?

0	1	2	3	4	5	6	7	8	9	10

No difficulty

As much difficulty as I can imagine

Appendix B: Post-treatment Questionnaire

1. Please list all the medications that you are CURRENTLY taking:

Medication Name	Dose of Each Tablet (e.g. Number of mg)	Daily Frequency (e.g. 3 Times Per Day)	Length of Time Taking Medication (e.g. 2 Months or 1 Year)

2. Please rate your pain by circling the one number that best describes how much pain you have right now.

0 1 2 3 4 5 6 7 8 9 10

No pain — Pain as bad as I can imagine

3. Are there any new treatments/exercise programs you have begun for your chronic pain condition since your last study visit? Yes No (If not, please skip to question 5)

   If yes, please indicate the NAME of the treatment/program and the START DATE (DD/MM/YY)

   ____

4. On a scale from 0 – 10, how helpful has this treatment/program **listed above** been in reducing your chronic pain?

0 1 2 3 4 5 6 7 8 9 10

Not helpful at all — Extremely helpful

5. Has anything significant happened in your life/or anything changed related to your work, family, or health since your last visit? Please indicate your response below

   ____
   ____
   ____
   ____

6. On average, how many hours of sleep do you get per night? _______

7. How many hours of sleep did you get last night? _______

8. On a scale of 0 – 10, how much difficulty do you have in focusing your attention on daily tasks, with 0 representing no difficulty, and 10 representing as much difficulty as you can imagine?

0	1	2	3	4	5	6	7	8	9	10
No difficulty									As much difficulty as I can imagine	

9. On a scale of 0 – 10, how much difficulty do you have in organizing your schedule, such as doctor's appointments, social events, and family events, with 0 representing no difficulty, and 10 representing as much difficulty as you can imagine?

0	1	2	3	4	5	6	7	8	9	10
No difficulty									As much difficulty as I can imagine	

Appendix C: Post-Treatment Questionnaire following MBSR

If you participated in the Mindfulness-Based Stress Reduction program, please answer all questions below, if not, you have completed filling out the questionnaires. Thank-you!

1. On a scale of 0 – 10, how helpful would you say the group program has been in helping you manage your chronic pain, with 0 representing not helpful at all, and 10 representing extremely helpful?

0	1	2	3	4	5	6	7	8	9	10
Not helpful at all										Extremely helpful

2. On a scale of 0 – 10, how much of the AT-HOME **FORMAL** meditation practices did you complete, with 0 representing none of the homework, and 10 representing all of the homework?

0	1	2	3	4	5	6	7	8	9	10
No homework										All of the homework

3. Outside of the weekly sessions, how much of the AT-HOME **INFORMAL** meditation practices did you complete? (Incorporating mindfulness in daily activities)?

0	1	2	3	4	5	6	7	8	9	10
No homework										All of the homework

4. How long did you engage in the following meditation practices **on average per week**?

Body Scan:	______ Hours	______ Minutes
Mindful Yoga:	______ Hours	______ Minutes
Sitting Meditation:	______ Hours	______ Minutes
Walking Meditation:	______ Hours	______ Minutes
Informal Meditation (e.g. Eating Mindfully):	______ Hours	______ Minutes
Other (Please Specify): ________________	______ Hours	______ Minutes

5. **On average,** how many days per week did you engage in these practices?

Body Scan:	______ Days per week
Mindful Yoga:	______ Days per week
Sitting Meditation:	______ Days per week
Walking Meditation:	______ Days per week
Informal Meditation (e.g. Eating Mindfully):	______ Days per week
Other (Please Specify): __________________	______ Days per week