The effectiveness of a mindfulness based stress reduction (MBSR) program in a mixed chronic pain population

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DECLARATION

Name of candidate: Leigh Townsend


Candidate’s declaration

I confirm that:

- This Thesis/Dissertation/Research Project represents my own work;
- The contribution of supervisors and others to this work was consistent with the Unitec Regulations and Policies.

- Research for this work has been conducted in accordance with the Unitec Research Ethics Committee Policy and Procedures, and has fulfilled any requirements set for this project by the Unitec Research Ethics Committee.

- Research Ethics Committee Approval Number: 2011-1194

Candidate Signature: …………………………………………. Date:

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<td>HRQoL</td>
<td>Health related quality of life</td>
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<td>SF-MPQ</td>
<td>Short form McGill Pain Rating Questionnaire</td>
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<td>CPAQ</td>
<td>Chronic Pain Acceptance Questionnaire</td>
</tr>
<tr>
<td>SF-36</td>
<td>Short-form 36 Health Survey version 2.0</td>
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Structure of the literature review

This review will be divided into two sections. The first section is a background of the historical and scientific aspects of pain and the implications of pain on individuals and wider society. The theory of mindfulness and its neuroscience correlates, application and benefits in healthcare are also explored in this section. The second section will be a review of the key salient and seminal studies investigating mindfulness and its effects on pain, and the mental and physical symptoms related to disease. This review is a collection of seminal and salient works rather than a comprehensive review due to the requirements of the course this review pertains too and the lack of high quality studies pertaining to this field of study.
Introduction

Pain is one of the most common reasons for individuals to seek healthcare, self medicate, and withdraw from social and economic activities (International Association for the Study of Pain, 2012; Loeser & Melzack, 1999; Waddell, 2004). Pain is a burden not only to the individual but to their wider family and community, due to the financial, emotional and psychological factors that are associated with long term pain conditions. Despite substantial investments in research and technology to improve our understanding of pain, the management of chronic pain remains less than optimal. Moreover, current treatment models are expensive to access, with long waiting periods (Loeser & Melzack, 1999; Moseley & Butler, 2003; Waddell, 2004). The intention of this literature review is to provide a context for why pain is an issue and to illustrate how a low-technology, low-cost mindfulness based stress reduction program may be an intervention that requires investigation to determine it’s effectiveness in people experiencing chronic pain.

Background to understanding pain

Pain – A personal, social, local and global economic burden

Pain is succinctly defined by the International Association for the Study of Pain (IASP) as “an unpleasant sensory and emotional experience associated with actual or potential tissue damage” (International Association for the Study of Pain, 2012). Pain is the most frequently reported cause of suffering and disability that seriously impairs the quality of life for millions of people throughout the world (International Association for the Study of Pain, 2012; Loeser, 2001). Pain is well known to be a conscious response to potential tissue damaging stimuli (Loeser & Melzack, 1999; Moseley & Butler, 2003; Waddell, 2004), with disease, trauma and medical treatments being identified as common causes (International Association for the Study of Pain, 2012; Lakke, Soer, Takken, & Reneman, 2009; Loeser & Melzack, 1999). The nature of pain may be transient, acute or chronic and may lead an individual to seek medical care, however transient pain can be experienced on a daily basis (e.g. falling and suffering a bruise), yet the body’s intrinsic healing mechanisms are usually able to resolve the issue quickly and efficiently without the need for external care (Loeser & Melzack, 1999). In contrast, acute pain is usually related to significant tissue damage that may or may not be able to be resolved by the body (Loeser, 2001; Loeser & Melzack, 1999) requiring external intervention and a period of recovery. In some cases, acute pain may transition to chronic pain, defined “as pain without apparent biological value that has persisted beyond the normal tissue healing time” (often described in a research context as being 3 months) (International Association for the Study of Pain, 2012, p.1). Chronic pain may be perpetuated by an increased activation of the central nervous system (plasticity) once tissue damage has healed, which is a characteristic of chronic not acute pain (Bogduk & McGuirk, 2002; Loeser, 2001; Loeser & Melzack, 1999; Moseley & Butler, 2003). Additionally
negative psychological factors can perpetuate the physical symptomatology of pain (Bogduk, 2006; Keefe, Rumble, Scipio, Giordano, & Perri, 2004; Loeser, 2001). The mechanisms and science of pain is not well understood by healthcare practitioners and as a result pain is often treated inappropriately and inadequately (International Association for the Study of Pain, 2012; Loeser, 2001).

The literature on chronic pain has identified a strong association between psychosocial prognostic factors and the progression from acute into chronic pain. Psychosocial prognostic factors have been identified as significant barriers to recovery and socialisation (Accident Compensation Corporation, 2004; Bogduk, 2006; Innes, 2005; International Association for the Study of Pain, 2012; Waddell, 2004) yet no individual factor nor specific cluster of factors has a complete role in predicting chronicity (Bogduk, 2006). However, it has been identified that when a greater number of factors from within the psychological and occupational domains present, there is a stronger possibility of chronicity compared to when fewer factors are present (Bogduk, 2006; E-Thomas et al., 1999). The cardinal psychological prognostic factors are consistently identified in the literature as psychological distress - depression and anxiety; somatisation (presence of pain without an identifiable cause) and catastrophisation (exaggeration of the effects of pain) (Accident Compensation Corporation, 2004; Bogduk, 2006; Pincus, Vogel, Burton, Santos, & Field, 2006; E-Thomas et al., 1999).

A series of psychosocial prognostic factors have been identified in the literature, that if present simultaneously predict a poor treatment outcome (Accident Compensation Corporation, 2004; Bogduk, 2006; Waddell, 2004) including: job dissatisfaction with either the status, role or work relationships (Accident Compensation Corporation, 2004; Bogduk, 2006; Lakke et al., 2009; E-Thomas et al., 1999) a negative emotional appraisal of pain (Accident Compensation Corporation, 2004; Brown & Jones, 2010) delay in seeking treatment (Accident Compensation Corporation, 2004; E. Thomas et al., 1999) a history of multiple episodes of pain (E-Thomas et al., 1999) and emotional or financial stress (Lakke et al., 2009). There is contradictory evidence about the role of fear related behaviours and related reduction in work capacity in the progression of acute into chronic pain. Some authors suggest fear related behaviours are a behavioural trait that presents early in the onset of pain (Accident Compensation Corporation, 2004; Bogduk, 2006; E-Thomas et al., 1999) while others suggest that these develop later in the process (Pincus et al., 2006). However there appears to be consensus, that if multiple prognostic factors are present, there is a higher probability an individual will quit full time work, decrease social and familial activities and reduce their cognitive acceptance of recovering (Accident Compensation Corporation, 2004; Bogduk, 2006; Lakke et al., 2009; Pincus et al., 2006).

The effects of chronic pain are not only contained to the individual but are also apparent within the local and national economies, with an increasing volume of research dedicated to the social and economic impact of poor adjustment to pain (Accident Compensation Corporation, 1997, 2004; Bossley & Miles, 2009; Dunn, Jordan, & Croft, 2011; International Association for the Study of Pain, 2012; Lakke et al., 2009). The prevalence of chronic pain, in the New Zealand context, is currently
reported as 1 in 8 people (Pfizer New Zealand, 2012) but has been reported as high as 1 in 4 people when considering musculoskeletal pain (Bossley & Miles, 2009). The economic costs associated with the treatment and care of musculoskeletal pain contributes to approximately 25% of the total annual health costs and is estimated to cost New Zealand more than $5.57 million (NZD) per annum (Bossley & Miles, 2009, p.1). Similarly, the economic cost of living with osteoarthritis, identified as one of the most significant causes of chronic pain in NZ in 2010, was approximated at $3.2 million (NZD) (Bossley & Miles, 2009; Pfizer New Zealand, 2012), with the bulk of this spent on direct health care costs, indirect lifestyle aids and modifications, time off work and continuing care (Pfizer New Zealand, 2012). A similar report into chronic pain (of any origins) in Australia showed the total cost to the community as $10.847 per person (living with chronic pain) and a total cost of approximately $33.4 billion (AUD) (Pfizer New Zealand, 2012). The financial costs associated with chronic pain are estimated to continue growing, most likely due to the increase in age and size of the population, lack of continuity of care (including poor inter-professional communication and moderate efficacy of treatments for relieving chronic pain) (Bossley & Miles, 2009; Pfizer New Zealand, 2012), under utilisation of multidisciplinary treatment protocols across the healthcare sector as well as a poor understanding of the mechanisms of pain within health professions (Loeser, 2001).

**Pain – A proposed mechanism of pain**

Pain science studies have identified and corroborated that pain is not, by definition, considered pain unless it is consciously recognised (Bogduk & McGuirk, 2002; Loeser, 2001; Loeser & Treede, 2008; Moseley & Butler, 2003; Waddell, 2004; Zeidan et al., 2011). The neural pathways of pain can be considered as four processes: transduction, peripheral transmission, central transmission and modulation (Holdcroft & Jagger, 2005; Loeser, 2001). Transduction occurs when noxious stimuli are transduced into electrochemical signals, a process known as nociception. Nociception may be generated by mechanical, chemical or electrical stimuli (Bogduk, 2002; Moseley & Butler, 2003; Siddall & Cousins, 1997) of sensory neural structures, located in all innervated tissues including the majority of the musculoskeletal and visceral systems. Once a nociceptive signal is generated in the periphery it undertakes a journey into the central nervous system. Firstly the signal is conveyed from the site of nociception along a peripheral neural fibre to the dorsal root ganglion and into the spinal cord (Loeser & Melzack, 1999; Siddall & Cousins, 1997) in the process of peripheral transmission. At this stage, nociception is not pain but merely an unconscious signal (Loeser & Treede, 2008; Waddell, 2004). The next stage is called central transmission where nociceptive signals from the spinal cord are conveyed to the brain stem and then into the higher brain centres i.e. somatosensory cortex for further multidimensional processing and overlaying of affective-motivational, sensory-discriminative, emotional and behavioural factors (A.A. Grant, Courtemanche, & Rainville, 2011; Zeidan, Grant, Brown, McHaffie, & Coghill, 2012). Throughout nociception pathways, there is the possibility for the signal to undergo modulation from various chemical mediators located in the spinal cord and in the
tissues in the periphery (Waddell, 2004). Modulation can either inhibit or elevate the strength of the signal.

It is important to understand that pain is a conscious recognition of a stimulus (actual, or potential) that creates not only a physical sensation but has emotional effects (Waddell, 2004). The emotional aspects of pain are integrated once nociception reaches the higher levels of the CNS due to the close anatomical and physiological links between brain regions which deal with sensations and emotions (Waddell, 2004; Zeidan et al., 2011). The sensory and emotional aspects of pain have been identified to occur simultaneously and to also influence each other (Melzack, Gatchel, & Turk, 1999; Waddell, 2004). Additionally, the observed effects of pain-related behaviours in acute pain have also been shown to occur without conscious recognition of pain, due to the connection of the sensory and motor pathways throughout the central nervous system. Nociceptive stimuli have been demonstrated to reduce the motor activity of muscles involved in injury through motor inhibition within the spinal cord (Nijs et al., 2012; Waddell, 2004). Therefore pain involves a number of complex interactions in the peripheral and central nervous systems and incorporates emotional, sensory, cognitive and behavioural information into the pain experience (Bogduk, 2002; Loeser & Melzack, 1999; Waddell, 2004)

**Sustained Nociception – incriminated in the continuation of pain**

Nociception is a part of the unconscious generation of pain but has been implicated as a potential factor in the maintenance of chronic pain alongside the sympathetic nervous system. The sympathetic nervous system functions as the ‘fight or flight’ survival mechanism in the body that enables rapid reaction and response to potential stressors that may result in injury or death (Holdcroft & Jagger, 2005; Loeser & Melzack, 1999). The sympathetic nervous system can be stimulated through both external and internal factors including nociception, inflammation and mental or emotional stress. This stimulation can occur through the chemical interactions taking place at the neural synapses along the peripheral and central pathways (Holdcroft & Jagger, 2005; Loeser & Treede, 2008; Zeidan et al., 2011). The sympathetic nervous system responds to chronic nociception with enhanced activation causing increased chemical pain mediators in the affected area, as well as delaying tissue healing and promoting underuse. The effect of sustained nociceptive input is not only limited to the motor and sympathetic nervous system pathways but can also involve the afferent mechano-sensory pathways that relay information regarding proprioception and tactile discrimination (Holdcroft & Jagger, 2005; Loeser, 2001; Nijs et al., 2012) from the periphery to the central nervous system.

Loeser & Melzack (1999) and Waddell (2004) suggest that sustained nociceptive input causes changes in sensitization in the peripheral and the central neural structures. Sensitization allows for normal stimuli to produce pain where it normally would not. These changes are hypothesized to be an important factor in the maintenance of pain sensations once the peripheral tissue damage and
inflammation has subsided, and as such is implicated as a principle maintaining factor in chronic pain (Holdcroft & Jagger, 2005; Loeser, 2001; Loeser & Melzack, 1999).

**The Neuromatrix – the integrated network**

Pain as defined by the IASP “is a complex and unpleasant sensory and emotional experience derived from actual or potential tissue damage, or described in terms of such damage” (International Association for the Study of Pain, 2012, p.1). The IASP definition proposes a deeper origin of pain than peripheral nociception and subsequent central nervous system processing. A proposed complex, integrated neural network or neuromatrix is a concept of pain generation and maintenance that has formed the basis of modern pain science (Melzack, 2001; Waddell, 2004). The neuromatrix theory is a conceptual framework aimed at assisting the understanding of pain in the presence and absence of physical tissue injury or pathology and for the development of acute pain into chronic pain. The neuromatrix provides a perspective that pain is a “multidimensional experience produced by multiple influences” (Melzack, 2001, p.4). The neuromatrix theory has been touted as a very plausible mechanism for the generation of pain in populations where tissue injury is no longer the source of the problem i.e. chronic pain populations, people with severed spinal cords and amputees experiencing phantom limb pain. Studies into these and other pain populations have identified that the notion of “pain as a reliable informant of what is actually happening in the tissues is no longer tenable” (Moseley, 2003, p. 130), suggesting a broader influence in the sensory experience of pain.

The neuromatrix is proposed to consist of a network of cells that are architecturally structured by genetics and modified by sensory information gained from our environments and early experiences (Melzack, 2001; Moseley, 2003; Waddell, 2004). Research utilising functional MRI into the neurophysiology of pain has demonstrated that multiple brain regions are activated with the pain experience, with no one ‘pain centre’ identified (Moseley, 2003; Waddell, 2004; Zeidan et al., 2011). Collectively these studies support the theoretical basis of a neuromatrix that incorporates multiple sources of input including stress, the endocrine, autonomic and immune systems as well as emotional and sensory input when interacting and modulating pain (Melzack, 2001; Waddell, 2004). The neuromatrix theory suggests that the large integrated neural network forms a virtual representation of the body that with continual input is able to reproduce all of the normal sensations felt on the body, including pain, even in the absence of any sensory input from the body (Melzack, 2001). Stimuli including stress, memories, smells or anticipation of an event may all be enough to trigger a motor or sensory response including pain, which may also occur in the absence of stimuli (Moseley, 2003).

Moseley (2003) suggests that continued input of any origin into the neuromatrix can result in an intractable modification of the sensory outputs from the neuromatrix called ‘neurosignatures’, and that if appropriate interventions are not applied i.e. development of central and peripheral sensitisation due to continued nociception. Where the acute phase of pain may have involved nociception, if central sensitisation has occurred, pain may still persist despite the initial tissue damage having resolved.
Sensitisation is proposed to be due to the continual neuronal feedback from the periphery to the spinal cord and brain resulting in a pain neuromatrix output from the cortex involving motor, sensory and emotional components. Additionally the more sensitised the central and peripheral tissues become, a greater intensity is likely for self-generating pain and fear related pain behaviours (from the neuromatrix) (Melzack, 2001; Moseley, 2003). The neuromatrix theory presents a plausible rationale to explain the persistence of pain in the absence of clinical tissue or pathology. Cognitive interventions such as mindfulness meditation which are theorised to effect the sensory and cognitive processing centres of the brain may potentially be a method of addressing the functional units of the neuromatrix, modulating the perpetuation of aberrant sensory neurosignatures.

**Pain – the psychological influence**

The recognition of the role of the personality traits, behaviours, beliefs and thoughts in the role of pain have been acknowledged since the mid twentieth century in the multi-factorial cognitive-behavioural (CB) models of pain. The CB models are a combination of cognitive, behavioural and mechanical models of pain, that identify interactions between the psyche and behaviour that may contribute to the development of chronic pain. This concept was not previously addressed in early medical models of pain that primarily focused on the physical issue. It was noted in research utilising these pain models that acute pain showed a somatic response that had “physiologic symptoms which were associated with anxiety attacks” (Innes, 2005, p.2). In chronic pain, however, the somatic structure showed a “habituation of autonomic responses and a pattern of vegetative signs similar to those seen in depressive disorders” (Innes, 2005, p.2). The recognition of psychosocial elements in the generation and maintenance of pain has demonstrated that not all pain is organic, therefore cannot always be treated with a biomedical approach as it can be more complex than previously acknowledged in the earlier biomedical models (Innes, 2005; Main & Watson, 1999). Waddell (2004) states that neurophysiology and psychology are not alternatives but are linked together to influence the pain, behaviour and suffering that result within the pain process (p.32).

Related research has highlighted that fear of pain and subsequent pain beliefs can be more disabling than the pain itself (Innes, 2005; Waddell, 2004) and fear appears to be one of the strongest predictors of disability and poor prognosis in chronic pain populations (Bogduk, 2006; Pincus et al., 2006). Bogduk, (2006); Pincus et al (2006); Innes, (2005); Keefe et al, (2004) & Waddell (2004) all found that a strong correlation existed between specific pain related beliefs and increased levels of physical disability, emotional feelings of helplessness and catastrophising, time off work, and withdrawal from social pursuits in chronic pain populations. In addition it was found that the transition of pain from acute to chronic was escalated through the reinforcement of behaviours by others (family, friends and healthcare workers) while in the acute phase through allowing the individual to avoiding chores, undertake a limited role in daily living and avoid actions/movements that anticipated the onset of pain (Innes, 2005). Alongside fear avoidance beliefs, distress and depression plays an
important role at early stages of pain and it has been recommended in the literature that clinicians focus on these factors (Pincus et al., 2006; Waddell, Newton, Henderson, Somerville, & Main, 1993) in all medical management. Innes (2005) suggests that the biopsychosocial model is a potentially useful clinical tool to assess the cognitive, affective and behavioural influences in low back pain and disability that may arise within social, familial and/or work cultures.

Biopsychosocial Model—multifactorial approach to the patient and pain

The biopsychosocial (BPS) model as proposed by Engel (1977) integrates biological (disease, health, pathogens), psychological (thoughts, emotions and behaviours) and social factors (family, work, friends) into the clinical approach to the patient. The model reflects the multi faceted aspect of human nature and how this may influence or interact with a presenting physical complaint as well as impacting the recovery. The BPS differs from the biomedical model of patient care, in that the biomedical model views the disease process as an alteration of normal function due to organic factors such as pathogens, injury, genetic variance (Engel, 1977). The biomedical approach has attracted heavy criticism for “basically ignore(ing) the fact that human beings are human and doesn’t adequately explain pain behaviour” (Loeser, 2001, p. 2).

Engel (1977) proposed the need for the BPS model of disease to address the determinants of disease and the steps required for a rationale treatment protocol, not previously considered within the biomedical model. Engel (1977) highlighted the interactions between the psyche and the development of mental health disease as well as the maintenance of physical disease, a concept not previously considered as a factor in physical disease. One of the earliest reported uses of a BPS model in practice is from 1985, in the United States where Robert Gatchel, a specialist in psychophysiology (addressing the physical pain and stress related to injury) treated patients in a biophysical approach to “functionally restore them to health” (Martinsons, 2009, p. 1). Gatchel utilised an interdisciplinary team including a physician/nurse team, a physical therapist, an occupational therapist, a psychologist, and a psychiatrist to focus on every aspect of an individual with pain—not only the pain itself.

The BPS model can be utilised as a screening and intervention model for a wide variety of healthcare practitioners. Some of the additional uses of a biopsychosocial model are Waddell’s neurophysiologic and physiological dysfunction and Kasarek’s work-related model which focuses on job control and demands in the work place (Lakke et al., 2009). In the New Zealand context, the Accident Compensation Corporation (ACC) has adopted the biopsychosocial model as seen in the Guidelines for the Management of Low Back Pain (2004) and guide to assessing psychosocial yellow flags (1997). ACC guidelines have become a benchmark document in the New Zealand healthcare environment for the screening and management of the patient in relation to their physical, mental, environmental, emotional and social context.
The biopsychosocial model in practice

ACC defines psychosocial as the “interaction between the person and their social environment, and the ensuing influence on their behaviour” (2004, p.51) The importance of identifying yellow flags is in identifying “factors that increase the risk of developing, or perpetuating long-term disability and work loss” (ACC, 1997, p.1) associated with an injury. The guidelines incorporate a series of variables that (represent the BPS focus of the whole patient) have an impact on patient behaviour and pain exacerbation such as; attitudes, beliefs, mood state, social factors and work factors which are collectively termed ‘psycho-social yellow flags’. ACC has provided clinicians with a clear direction as to the importance of identifying risk factors and simple tools through which to achieve this. The tools, which include prompting questions and questionnaires, are intended to aid the patient recovery as well as steering their management plan to the areas of greatest concern. The yellow flags were developed through extensive research, that demonstrated evidence that the flags were valid and reliable indicators of a progression from acute to chronic pain (Accident Compensation Corporation, 1997; Waddell, 2004). However current thinking in this field suggests that the yellow flags be primarily used for the identification of psychological risk factors to avoid confusion with other social and environmental factors (Nicholas, Linton, Watson, & Main, 2011).

Although models are useful in conceptualising pain and suggesting potential treatment and attitudes for both practitioners and patients, it is also important for healthcare practitioners and support staff to understand the neurophysiologic process of pain and the internal mechanisms which account for the continuation of pain in the absence of physical signs i.e. nociception and central and peripheral sensitisation in context of a dynamic interaction between psychological, social, emotional and biological variables (Loeser, 2001).

Pain Assessment – reliability of subjective reporting of the pain experience

Due to the heavily subjective nature of the pain experience, there is great difficulty in acquiring precise measurements of the severity of pain (Melzack, 2005; Moseley & Butler, 2003; Waddell, 2004). Subjectivity suggests that patient oriented subjective pain questionnaires may not be a reliable source of gauging pain information (Coghill, McHaffie, & Yen, 2003) and if so may lead to unfavourable clinical decisions due to a misrepresentation of pain. Routine clinical patient assessment utilises patient self-reporting of pain to assist the diagnosis, treatment and management of patients. This method may be influenced by a number of factors including: the individual differences in pain tolerance; the context within which pain was experienced (e.g. at work); and the origin of pain (e.g. trauma or disease related) (Moseley & Butler, 2003; Waddell, 2004). Moseley (2003) suggests that subjective reports of pain (particularly in chronic patients) may not be a reliable indication of the degree of nociception or tissue damage, due to the potential presence and complexity of central nervous system interactions (modulation and integration) that distort the original nociceptive
signalling, particularly if pain has persisted after the original tissue damage has healed. Moseley also suggests that the notion of “pain as a reliable informant of what is actually happening in the tissues is no longer tenable” (2003, p. 130).

Neural correlates of the inter-individual difference in the subjective experience of pain

A study by Coghill, McHaffie & Yen (2003) utilised subjective reporting measures to assess pain sensitivity as well as functional MRI (fMRI) to assess brain activity while participants received an experimental pain stimulus. Healthy subjects ($n = 17$) were firstly asked to use a 10 point visual analogue scale (VAS) to rate 32 stimuli ranging in heat temperature from $35^\circ$ – $49^\circ$ of 5s duration. Subjects were also asked to identify the duration of pain intensity while receiving the stimulus. The subjects were then classified into 3 pain groups: high, medium and low sensitivity to pain. Participants were then subjected to thermal stimuli of the same temperature range over a 5min 30s duration, whilst undergoing functional imaging. Subjects provided VAS ratings after each stimulus. Brain activation was compared between the three groups by subtracting the frequency of activation map of the low sensitivity group from the high and medium sensitivity groups. Brain activation was then correlated with VAS scores to identify a concurrence of pain sensitivity and cortical activation. In concordance with more recent neurological pain studies (Creswell, Way, Eisenberger, & Lieberman, 2007; Grant & Rainville, 2009), the authors identified more frequent and robust activation of superior cortical regions known to be important in the pain experience in individuals highly sensitive to pain compared to the individuals with low sensitivity. Additionally, individuals experiencing similar patterns of cortical activation also provided similar subjective pain reports. The study highlights that although there are unique patterns of activity within the cortex during a pain state, a person’s ability to introspect and verbally quantify the intensity of the pain, is a reliable indicator of the pain severity (Coghill et al., 2003; Koyama, McHaffie, Laurienti, & Coghill, 2005). The authors state that the study validates the subjective reporting and utilisation of psychophysical ratings (VAS) as a means of assessing the conscious pain experience.

The thalamus is considered in many pain studies as a critical site of processing and transmission of nociceptive signals to the CNS. The thalamus is therefore implicated as a site of particular interest in understanding the inter-individual differences in conscious pain recognition. Cresswell et al (2007) & Zeidan et al. (2011) have both reported that the thalamus is highly active on MRI during pain studies where experimental thermal stimuli were administered to participants. However Coghll et al., (2003) noted that there was no statistical difference between the activation of the thalamus between high and low sensitivity groups, “…the absence of detectable functional MRI differences in the thalamus (in combination with robust differences in the other components of the pain matrix) suggests that generally similar incoming (afferent) signals were conveyed to the thalamus in both high and low sensitivity individuals” (p.2), Studies by Coghll et al.,(2003), Brown & Jones (2010), and Zeidan et al. (2011), concurrently reported that after passing the thalamus, nociceptive information was transmitted to cortical regions associated with more ‘executive’ level cognitive and sensory evaluation. These
regions displayed large differences in activation between high and low pain sensitivity groups (Coghill et al., 2003), indicating alongside various reports on the quality of pain, that each cortical region beyond the thalamus "may make a differential contribution to various aspects of the pain experience" (Coghill et al., 2003, p.3). The Coghill, McHaffie & Yen study highlights that the cortical processing of nociceptive signals beyond the thalamus has a greater role to play in the inter-individual difference of the pain experience as opposed to the intensity of incoming (afferent) nociceptive signals. Awareness of cortical involvement in the pain experience provides insight into the mechanisms of cognitive interventions aimed at attenuating the sensory response to pain. This will be discussed further in the mechanism of mindfulness section.

**Recommendations for future pain related interventions**

The International Association for the Study of Pain (IASP) (N.D) and the European Federation of IASP chapters (2012) declare that chronic unrelieved pain is a major healthcare problem, and should be considered as a disease in its own right (European Federation of International Association for the Study of Pain Chapters, 2012, p.1) and that is a global burden with social, economic and financial implications for individuals and their communities (International Association for the Study of Pain, N.D.). The IASP (N.D) state that “addressing the global burden of pain does not require high-tech costly interventions but requires global education of healthcare providers, people and their families of the best applications of low-cost yet effective therapies” (European Federation of International Association for the Study of Pain Chapters, 2012; International Association for the Study of Pain, N.D.). The mindfulness-based stress reduction (MBSR) program is one example of a low cost intervention that has shown some utility in reducing the effects of chronic pain.

**Pain interventions**

As highlighted within this literature review, pain is a multifactorial experience that has origins in different domains other than the physical, as represented within the biopsychosocial model of health, disease and treatment. Therapeutic options depend on many factors including: the duration, quality and level of urgency, recommended treatment protocols for specific conditions, the healthcare provider being consulted and the values of the patient. Clinical interventions may originate from a range of fields including: psychological, physical therapy, surgical, technological, biomedical and pharmaceutical. Consistent with the way complex multifactorial way that pain is experienced, there is no single solution to treating and managing pain (Moseley & Butler, 2003). However with continued development and incorporation of the biopsychosocial model into healthcare there is a growing understanding of the nature of pain. For the purpose of this review, psychological interventions will be discussed.
Psychological interventions

The discipline of psychology explores the way the human mind acts, reacts and interacts with others and their environment (Sheldon, 2011). There are many divisions of psychology that examine the various aspects of the human mind and its subsequent intricacies. In regards to healthcare, the combined cognitive-behavioural and social branches of psychology are often utilised, as they investigate the characteristic patterns of individual thoughts, feelings and behaviours that make a person unique, as well as inter-individual similarities which make us alike (cognition/personality psychology). The social and cognitive branches are an attempt "to understand and explain how the thought(s), feeling(s) and behaviour(s) of individuals are influenced by the actual, imagined or implied presence of other human beings" (Gilbert, Fiske, & Lindzey, 1998, p. 165).

Cognitive behavioural therapy

The cognitive branch of psychology is based on the tenet that behaviours and emotions are learned phenomena, resulting from cognitive processing, and can therefore be altered (Froggatt, 2006; Sheldon, 2011). American psychologist Aaron T Beck believed that the client’s perception, interpretation of matters and the meaning of these to the individual’s life, held greater therapeutic value than the dominant psychodynamic theories prior to the 1960s (Sheldon, 2011). The psychodynamic theories focused on gaining insight into the unconscious mental processing of emotions and desires of patients. In contrast the cognitive model assists the individual to overcome their difficulties by changing their thinking, behaviour, and emotional responses (Froggatt, 2006; Sheldon, 2011) as opposed to internally analysing and hoping for change. The behaviourism school of psychology holds the central belief that all behaviour is a response to an environmental stimulus, to which we respond in particular ways. The behaviourists believe that when explaining behaviour: it is simply enough to know which stimuli elicit which responses in order to be able to decrease reactivity (Sammons, 2008). Therefore by combining the two approaches a person’s thoughts, behaviour and emotional responses are altered through re-education and awareness of the cues to which they are produced.

The aim of cognitive behavioural therapy (CBT) is the deconstruction of negative emotions and problematic dysfunctional behaviours, which give an individual, skills to appraise environmental stimuli and decrease the reactivity related to learned and conditioned behaviours (Sheldon, 2011). This form of psychological therapy has been widely utilised in health and in the late 1990s was integrated with aspects of mindfulness meditation within the Mindfulness Based Cognitive Therapy (MBCT) program. Mindfulness Based Cognitive Therapy aims to address the negative emotional cycles that persist with chronic illness, in particular depression. The construction of MBCT places little emphasis on changing the content of thoughts as in CBT; rather, the emphasis is on changing awareness of and relationship to thoughts (Kabat-Zinn et al., 1992; Teasdale et al., 2000). A large
randomized controlled trial over a 60-week period, demonstrated that this approach can significantly reduce the rate of relapse in recurrent major depression (Teasdale et al., 2000). Early studies by Kabat-Zinn and colleagues demonstrated preliminary evidence that mindfulness has a positive effect in the treatment of generalized anxiety disorder and panic (Kabat-Zinn et al., 1992).

Aspects of CBT included in MBCT are primarily those designed to facilitate “decentred” views, a concept best illustrated through considering these statements: “thoughts are not facts” and “I am not my thoughts.” (Teasdale et al., 2000, p.2). Mindfulness Based Cognitive Therapy addresses the recurrence of depression through teaching participants, what depression is, how they become vulnerable to downward mood spirals, and why it is difficult to remove themselves from the spiral. The course also highlights the connections between the downward spirals and the associated emotional responses which drive the behaviour of depression and keep the individual in the depressive cycle.

**Acceptance**

Acceptance is a construct of behavioural psychology and has emerged as a valuable concept in contemporary theories of chronic pain that evaluate the reactivity and adaptation to chronic pain (Baer, 2003; McCracken & Eccleston, 2005). Acceptance can be defined as willingness to experience pain, thoughts, feelings, urges, or other bodily, cognitive, and emotional phenomena, without trying to change, escape, or avoid them (Baer, 2003; McCracken & Zhao-O'Brien, 2010). Keeffe et al., (2004) and McCracken & Zhao-O'Brien (2010) report that individuals with higher acceptance of chronic pain report decreased pain; psychological distress; physical and psychological disability and greater daily activity. Additionally, individuals who demonstrate higher levels of pain acceptance are more likely to adaptively respond to pain, above and beyond the influences of depression, pain intensity, or pain-related anxiety (McCracken & Eccleston, 2005). Acceptance is one of several foundations of mindfulness practice (Baer, 2003; Kabat-Zinn, 1982) and is a core component in several mindfulness techniques taught within Dialectical Behavioural Training a sub-therapy of behavioural psychology. The emphasis placed on the acceptance of reality, as it is, within mindfulness meditation related interventions, suggests that mindfulness may provide a method for teaching acceptance skills (Baer, 2003).

**Background to meditation and mindfulness**

**Meditation**

Meditation is described as a collective term of “self-regulation practices that focus on training attention and awareness in order to bring mental processes under greater voluntary control” (Bishop et al.,
Many forms of meditation have been described, however, there are two main categories that western meditation practices fall under: concentration and mindfulness.

**Concentration**

Concentration also known as Transcendental Meditation, is a mantra meditation, where the mental focus of a practitioner is to a particular mantra, either a sound, image or word which is unique to the individual and to be reverted back to when the mind wanders (Baer, 2003; Kabat-Zinn et al., 1984; Mars & Abbey, 2009; Ospina et al., 2007). It is not a central tenet of this form of meditation to reserve judgement on arising emotional, sensory or cognitive events, making it difficult to ascertain if cognitive reappraisal occurs within a sustained practise. Research into the benefits of Transcendental Meditation have reported positive effects on cardiovascular disease risk factors, and mortality (Barnes & Orme-Johnson, 2012; Schneider et al., 2012) as well as decreasing stress and increasing relaxation of participants (Baer, 2003; Mars & Abbey, 2009; Ospina et al., 2007).

**Mindfulness**

Mindfulness meditation techniques are considered a form of mental training, aimed at reducing cognitive sensitivity to stressors and reactive mindsets that may potentially perpetuate any psychopathology (Bishop et al., 2003) as opposed to a relaxation or mood altering technique. Mindfulness is difficult to define due to the various interpretations of its inherent form and function, “its diversity of cultural traditions from which the concept originates, the difficulty with which it is measured, and its distinction from its common usage” (Vago & Silbersweig, 2012). However the following description by Kabat-Zinn (1990) provides a simple insight into what mindfulness is and is not:

> “Mindfulness is basically just a particular way of paying attention. It is a way of looking deeply into oneself in the spirit of self-inquiry and self-understanding. For this reason it can be learned and practiced... without appealing to Oriental culture or Buddhist authority to enrich it or authenticate it. Mindfulness stands on its own as a powerful vehicle for self-understanding and healing. In fact one of its major strengths is that it is not dependent on any belief system or ideology, so that its benefits are therefore accessible for anyone to test himself or herself. Yet it is no accident that mindfulness comes out of Buddhism, which has as its overriding concerns the relief of suffering and the dispelling of illusions” (Kabat-Zinn, 1990, p. 12-13).

Mindfulness derives from ancient writings known as “The Noble eightfold pathway”, by Siddhārtha Gautama (563 BC to 483 BC). The Noble eightfold pathway is a practical 8 step guideline for living
an ethical and moral life including the relinquishment to attachments and delusions that arise from daily living which Goenka describes as conspiring to cause emotional and mental suffering (Goenka, 2006). Mindfulness is considered under the eightfold pathway to be a means of taking control of the conscious mind, which when coupled with regular practice and sustained concentration allows reality to be seen as it is, with a clear consciousness, not as we want it to be (Goenka, 2006). A developed base in mindfulness can result in a non-judgmental, non-reactive form of awareness, which is a central tenet of mindfulness meditation (Baer, 2003; Kabat-Zinn, Lipworth, & Burney, 1985; Mars & Abbey, 2009; Perlman, Salomons, Davidson, & Lutz, 2010), and is key to taking control of the conscious mind, interrupting the often inappropriate interpretation of thoughts and sensations (Knierim, 2012).

Mindfulness meditation as taught in the MBSR program, embraces the historical Buddhist origins of mindfulness, however, as per the previous definition, the MBSR program is non-secular in its teachings, increasing its potential appeal to a wider audience. The development of mindfulness at all levels of experience requires a sustained cognitive attention and conscious monitoring of bodily sensations and thoughts as they arise from moment to moment (Baer, 2003; Kabat-Zinn et al., 1984; Mars & Abbey, 2009). With regular practise and application of a non-judgemental and non-reactory mindset, the conscious mind "emphasises a detached observation" (Kabat-Zinn, & Chapman-Waldrop, 1987, p.1.). A result of increased mindfulness is a cognitive reappraisal and stability of the emotional and cognitive mind that leads to a ‘richer and more vital sense of life (Grossman, Niemann, Schmidt & Walach, 2004, p.2.) with health benefits such as: decreased anxiety (Goldin & Gross, 2010; Kabat-Zinn et al., 1992); depression (Ma & Teasdale, 2004; Teasdale et al., 2000); and stress (Carlson, Speca, Patel, & Goodey, 2003).

Mindfulness meditation practises

There is considerable ambiguity in the literature when defining and operationalising “mindfulness” in the context of investigations meditation related pain changes. Because the specific mechanisms for meditation-induced pain changes may be dependent on the specific technique being employed, Zeidan et al., (2012) states that it is essential to define and characterise the practise being taught. There are two main modes of mindfulness, focused attention and open monitoring (Zeidan et al., 2012).

Focused attention is similar to concentration meditation mode described earlier, in that the focus is maintained on a specific object either internal (the breath) or external (object). In contrast to concentration meditation, when the attention is distracted by arising cognitive, sensory or emotional events, the practitioner is taught to “acknowledge the event and to disengage from it, by gently returning to the object of meditation” (Zeidan et al., 2012, p.166). There is little emphasis placed on
avoidance of judgement or appraisal of arising events or thoughts in this mode.

Open monitoring meditation (also known as Vipassana) is characterised by a "non-directed acknowledgement of any arising cognitive, sensory or emotional events" (Zeidan et al., 2012, p.166). In contrast to focused attention, there is a strong emphasis placed on the non-evaluation, interpretation or preference for any arising events or thoughts and to view each one as transitory without any defining characteristics. Zen Buddhism is a commonly recognisable form of open monitoring, which describes the process of sitting (meditation) as a slowing down of the surface activity of the mind, which brings clarity and allows the reality of a moment to be seen (Grant et al., 2011). Grant & Rainville (2009) & Zeidan et al (2011) suggest that people who regularly practice meditation require a shorter time to access this mental clarity compared with non-meditators or short term meditators, although short term meditators have shown changes in cognitive patterning with only 3 days of mindfulness training (in pain studies) (Zeidan, Gordon, Merchant, & Goolkasian, 2009).

**Mindfulness based stress reduction**

Jon Kabat-Zinn, a molecular biologist and emeritus professor of medicine at The University of Massachusetts Medical School, utilised the theoretical underpinnings of Buddhism and pain science to develop the mindfulness based stress reduction (MBSR) program in 1979 (University of Massachusetts Worcester Campus Center for Mindfulness, N.D). The program is intended as a self-regulation method for chronic pain patients who have been taught to "live with the pain"(Kabat-Zinn, 1982, p.1). Kabat-Zinn's focus for MBSR was addressing the social, physical and emotional cost of uncontrolled stress that exists with chronic conditions and has been identified as a factor in the progression from acute to chronic pain (Baer, 2003; Kabat-Zinn, 1982). The program is secular in its development and application but does draw on various aspects of the joint philosophies and practice of Theravada Buddhism, Soto Zen practices, Mahayana Buddhism and the yogic traditions (Kabat-Zinn, 1982). Mindfulness as a tool has been described by Kabat-Zinn as

> "Mindfulness practice provides an opportunity to walk along the path of your own life with your eyes open, awake instead of half unconscious, responding consciously in the world instead of reacting automatically, mindlessly" (Kabat-Zinn, 1982).

The MBSR course is characterised by the development of a non-judgemental attitude toward arising sensations, thoughts, urges and emotions (Kabat-Zinn, 1982). Participants are encouraged to remain mindful at all times including when they perceive that they cannot reasonably stay still and have the urge to move, they are to be mindful of their arising and changing sensations, not attaching nor avoiding whatever may arise (Baer, 2003; Kabat-Zinn, 1990). The skill of "observing pain sensations non-judgementally is believed to reduce the distress associated with pain" (Baer, 2003, p.6). Kabat-
Zinn (1982) hypothesises that with prolonged exposure to mindfulness through non-judgmental observation, individuals can experience pain sensations without "excessive emotional reactivity" (Baer, 2003, p.6) and even if pain sensations were not reduced, suffering and distress might be alleviated (Baer, 2003; Kabat-Zinn et al., 1985; Mars & Abbey, 2009).

**Stress**

Since the 1950s, prolonged physical and psychological stress has been implicated as a precipitating factor to illness, disease and maintenance of chronic somatic pain (Kabat-Zinn, 1982; Melzack et al., 1999; Selye, 1956). Biological stress can be described as the process by which the body responds to external demands labelled as "stressors" (McGrath, 1982). The "general adaptation syndrome" (GAS), an early model of biological stress by Hans Selye (1956), describes stress as an internal process the body undergoes in response to "stressors", which may result in adaptation within the body or tissue damage/death under prolonged or severe stress. The general adaptation syndrome is a three phase conceptual framework for understanding the somatic response to prolonged and unrelenting stress. Phase one (the alarm reaction) describes the activation of the autonomic nervous system in response to stress. If the stress overwhelms the nervous systems capacity to adapt, then physiological change occurs and may be associated with pathology e.g. gastrointestinal ulcers form, the adrenal glands become enlarged, and the thymus begins wasting away (Selye, 1956). During phase two (the resistance phase), the organic tissue of the body continues to adapt or damage occurs as a result of stress. The final phase, exhaustion, is characterised by the death or irreversible damage of the organism as a result of ongoing stress. Studies investigating the effects of physical and/or psychological stress on the healing times for experimentally induced wounds showed that healing takes longer in populations with high levels of perceived stress than those with lower levels (Gouina & Kiecolt-Glaser, 2011).

Kabat-Zinn (1982) noted the presence of uncontrolled psychological and physical stress in the maintenance of chronic pain in his early research studies of pain populations. In the field of psychology, it is suggested that the way an individual cognitively appraises an environmental situation determines whether or not they will show a physiological stress response (Lazarus, 1966). Lazarus (1966) theorised that a person experiences the effects of stress when they perceive the demands of a situation to be beyond their perceived resources. Several psychological studies have been conducted investigating this relationship and the majority concluded that perceived stress is a better predictor of poorer health outcomes than exposure to particular stressors (Brosschot et al., 1998; Lazarus & Folkman, 1984)

**Mindfulness based stress reduction in clinical settings**

The MBSR program as designed by Kabat-Zinn has been operating in private and public clinical settings across the United States and Canada for more than 30 years. In the United States, over 200
clinics are reporting use of the MBSR program after various research studies have shown the efficacy of MBSR on pain indices, medical symptoms (Baer, 2003; Grossman et al., 2004; Rosenzweig et al., 2010) and psychological measures (Rosenzweig et al., 2010; Thomas et al., 1999; Young, 2011) as well as the emotional state, immune system (Carlson et al., 2003) and neural processing of pain populations. The utility of MBSR is still being explored but the preliminary evidence to date suggests that it could provide the low cost therapy to combat the growing burden of chronic pain as outlined by the IASP (N.D).

**Mindfulness based stress reduction program - typical format**

The MBSR program is typically run within a private clinical setting over 8-weeks and includes teacher guided group and individual meditation. Participants are required to attend a 1.5 – 2.25 hour group session once a week, which is led by a qualified MBSR teacher. Group sessions involve instruction and practice in mindfulness meditation skills, along with discussions about personal experiences with the practice, coping, and home practice assignments. Home practice assignments are recommended to be a minimum of 60 minutes, six days per week. Audiotapes, a daily diary and reading materials are provided to support home practice. It is intended that participants attend all group classes and undertake as much of the daily practice as possible in order to have completed the course. The programme is summarised in Appendix A.

**Neurological studies in Mindfulness based stress reduction**

Studies investigating the neurological processes of meditation and pain suggest that meditation has the capacity to attenuate the subjective response to pain (Brown & Jones, 2010; Grant & Rainville, 2009; Zeidan et al., 2009). Sustained meditation is theorised to create an uncoupling mechanism between the sensory and affective processes involved in the subjective experience of pain (Brown & Jones, 2010; Grant et al., 2011; Kabat-Zinn, 1982; Zeidan et al., 2011). A combination of physiological and neurophysiologic interactions (Melzack, 2001; Zeidan et al., 2011) are known to occur in the peripheral and central nervous system when nociception occurs, which result in sensory, affective and cognitive signals being sent to ‘executive’ cortical regions for processing (Brown & Jones, 2010; Grant et al., 2011; Melzack, 2001; Zeidan et al., 2011). Individuals undertaking mindfulness meditation of a short duration have shown greater cognitive control and regulation of the cognitive reaction to sensory, affective and cognitive signals thereby reducing subjective pain sensations (Grant et al., 2011; Zeidan et al., 2011). Additionally people who meditate over longer periods of time have demonstrated cortical adaptations (in the central nervous system) in the regions associated with the processing and modification of nociceptive signals and evaluation of sensory events therefore resulting in a decreased perception of pain. However, the literature states that the
specific brain mechanisms related to mindfulness meditation remain poorly characterised (Zeidan et al., 2011).

**Neuroscience mechanism of mindfulness**

Current neuroscience research has clearly indicated that the mechanism for meditation related pain reduction lies in the prefrontal pathways of the cortex that are associated with perception, memory, processing, and modulation of nociception and the subjective pain experience (Grant et al., 2011; Zeidan et al., 2011). Zeidan et al., (2011); Grant, Courtemanche & Rainville (2011) and Brown & Jones (2010) suggest that the regions of the brain involved in meditation, interact with the regions associated with pain and nociceptive processing. Grant et al., (2011), investigated the mechanisms of mindfulness-related pain reduction utilising functional magnetic resonance imaging (fMRI) in Zen meditators. It was shown that long term meditators demonstrated reduced activation in the prefrontal cortices associated with affective processing and modulation of nociceptive signals (Brown & Jones, 2010; Grant et al., 2011) compared with non-meditative controls. It was identified that those with a longer history of mediation experience utilising a form of non-evaluative form of meditation, demonstrated the largest reductions in cortical activation and subsequent reductions in pain. The cognitive modulation of pain has been shown to be a multi-factorial process involving, but not limited to, increased attentional control of the frontal cortex and increased activation of a meditation related gating mechanism at the emotional processing level (limbic-thalamic axis) that decreases the transmission of nociceptive sensory information to the higher cortical levels for cognitive evaluation (Zeidan et al., 2011). This mechanism has informed the theory that meditation related pain reductions may occur as a result of functional uncoupling of the cognitive-evaluative and sensory-discriminative dimensions of pain resulting in decreased emotional evaluation of pain and physical perception (Grant et al., 2011, p.1).

Brown & Jones (2010) and Grant, Courtemanche & Rainville (2011) demonstrated that long term mindfulness meditators, experienced decreased activation of cortices associated with memory and anticipation of events when compared to non-meditating control groups. These decreases were demonstrated to result in less anticipation of painful stimuli and reductions in perceived pain in comparison to non-meditators (Brown & Jones, 2010). This finding may indicate that chronic pain sufferers who demonstrate high levels of fear related pain behaviours may benefit from an MBSR intervention as these behaviours are believed to be perpetuated by the memory of painful events.
Clinical studies of effectiveness

Studies examining the effects of Mindfulness based stress reduction program on chronic pain populations

Search strategies

An extensive electronic literature search between the period 1980 – 2012 was conducted utilising the following databases: Academic OneFile, Pubmed (Medline), CINAHL with Full Text (EBSCO) and Science Direct. Online searches utilising Google scholar and open access journals were also used to find relevant articles unattainable through the databases. Literature pertaining to mindfulness based stress reduction programs in health were retrieved using the keywords Adult; Female; Meditation course; Meditation/methods; Meditation/psychology; Mindfulness; mindfulness/therapy; Pain; Psychological/therapy; Psychological/pain; Rheumatoid arthritis; Single systems anywhere in the record. The search resulted in a variety of review studies, randomised controlled trials and studies of various designs. The reviews were assessed for their quality and then cross-referenced to identify individual studies that were reliable, demonstrated quality reporting, were methodologically similar and investigating similar populations to the study within the enclosed manuscript.

Mindfulness based stress reduction literature

Literature investigating the effects of the 8-week MBSR program has been conducted on various medical and psychological conditions including: chronic pain (Kabat-Zinn, 1982; Kabat-Zinn et al., 1985; Morone, Greco, & Weiner, 2008; Rosenzweig et al., 2010); rheumatoid arthritis (Pradhan et al., 2007); cancer (Carlson et al., 2003); fibromyalgia (Lush et al., 2009; Schmidt et al., 2011); anxiety and depression (Kabat-Zinn et al., 1992; Ma & Teasdale, 2004; Teasdale et al., 2000). Reported health benefits include improvements in pain, pain sensitivity, disordered eating, mood, sleep quality, fatigue, psychological distress, overall quality of life, and reduced stress levels (Baer, 2003; Bohlmeijer, Prenger, Taal, & Cuypers, 2010; Grossman et al., 2004; Morone et al., 2008; Pradhan et al., 2007; Rosenzweig et al., 2010; Schmidt et al., 2011). For the purpose of this review four salient works will be reviewed that were critically reviewed within two systematic literature reviews (Bohlmeijer et al., 2010; Merkes, 2010) and one meta-analysis (Grossman et al., 2004) investigating the effect of MBSR on chronic pain and disease conditions. The studies identified examine the effect of MBSR on different sample populations: 1. Chronic low back pain in the elderly (Morone et al., 2008), 2. A mixed cohort of chronic pain conditions including chronic headaches/migraines, arthritis and fibromyalgia (Rosenzweig et al., 2010), 3. Rheumatoid arthritis (Pradhan et al., 2007); and 4. Fibromyalgia (Schmidt et al., 2011)
Overview of reviewed studies

The literature search revealed that in general, studies in MBSR are methodologically weak and the quality of reporting is poor. The four studies reviewed within this part of the review, have been identified as moderate to high quality methodology (Bohlmeijer et al., 2010; Grossman et al., 2004; Merkes, 2010), adequate quality of reporting and represent the chronic pain conditions presented within the main study reported in Section II of this thesis. The four studies utilised measures of physical and mental health to gauge the effects of MBSR with all four studies measuring depression with specific standardised outcomes for depression - Symptom Checklist 90 Revised (SCL-90-R) (Morone et al., 2008; Pradhan et al., 2007; Rosenzweig et al., 2010; Schmidt et al., 2011) and/or measures that contained depression as a subscale – Medical Outcomes Study 36 Item Short-Form (SF-36) (Morone et al., 2008; Rosenzweig et al., 2010). Additionally primary outcomes for the studies were measured with the following measures: Quality of life - Medical Outcomes Study 36 Item Short-Form (SF-36) (Morone et al., 2008); acceptance – chronic pain acceptance questionnaire (CPAQ) and disability (Morone et al., 2008); mindfulness – mindfulness attention awareness scale (MAAS) (Pradhan et al., 2007); and home practise diaries (Rosenzweig et al., 2010; Schmidt et al., 2011) were all measured outcomes. The four studies utilised the 8-week MBSR program as designed by Kabat-Zinn (1982) [see Appendix A], with an adapted version being utilised by Morone et al., (2008).

Study 1.


Morone, Greco and Weiner (2008) in a randomised controlled trial utilised an adapted version of the MBSR program in a population of 37 community dwelling older adults with low back pain. The adapted version did not contain a yoga component or a full day silent retreat as outlined in the typical format. The aim of the study by Morone et al., (2008) was to investigate the treatment effect of MBSR in people with chronic low back pain and to review the feasibility of this intervention in this population. The majority of the participants were female and Caucasian. Participants were randomised into an 8-week MBSR program or a wait-list control group. Significant improvements were reported in pain acceptance (CPAQ) and physical function (SF-36) in the MBSR group compared with the wait-list control at the post intervention measures. Additionally improvements were reported in mean pain scores (short form McGill pain questionnaire), disability and quality of life (SF-36) subscales although they were not clinically or statistically significant improvements. The 3-month follow-up did not identify any significant differences between the 8-week post intervention scores and the 3-month follow up, which may be accounted for by the majority of participants (76%) adherence to continued meditation at follow up. Participants reported improvements in concentration and decreased use of medications for pain and/or sleep with continued incorporation of meditation into their daily lives. Limitations of the study were observed to be a lack of intra-group reporting, which does not enable the reader to establish if MBSR has the ability to create change as the study only reported comparisons between the control and meditation groups. Therefore it appears that this paper is reporting conclusions that
are not fully supported by the results. Additionally, the authors of the study were also directly involved in the delivery of the MBSR program and were therefore not blinded to which participants were in the control and MBSR groups. This involvement by the authors may represent a potential conflict of interest between the delivery, treatment and outcomes assessment as completed by the same personnel.

Study 2.


Rosenzweig, Greeson, Reibel, Green, Jasser and Beasley, (2010) conducted a longitudinal study of the MBSR program (n=133) in a mixed cohort experiencing one or more chronic medical conditions including chronic headaches/migraines, arthritis and fibromyalgia. The authors were interested in not only the treatment effects of MBSR but also identifying if the role of home practise contributes to the effect. Within the sample population, there were a number of participants (n= 52) who experienced two or more co-morbidities (diseases). The sample population was predominantly female, Caucasian and middle class which is a common feature in MBSR related research such as those conducted by Baer (2003); Bohlmeijer et al., (2010); Grossman et al., (2004); and Merkes (2010). The studies of Morone et al., (2008) and Rosenzweig et al., (2010) also reported similar populations and demographics. The primary outcomes of the study were quality of life (SF-36) and psychological distress (SCL-90-R). The authors reported that the total sample experienced beneficial improvements in quality of life and decreased psychological distress. However, inspection of the results revealed that specific groups demonstrated more consistency and change than others. The arthritis subgroup demonstrated the largest improvements on both measures. The subgroups of people experiencing chronic neck/back pain and two or more other co-morbidities reported significant improvements in health related quality of life including pain severity and functional limitations due to pain. These findings are similar to that of Morone et al., (2008). The fibromyalgia subgroup reported the smallest changes in health related quality of life including pain, and did not show any significant improvements in distress. The literature on the effects of MBSR on fibromyalgia is generally lacking in control groups and has demonstrated inconsistent results in regards to beneficial changes in pain (Astin et al., 2003; Kaplan, Goldenberg, & Galvin-Nadeau, 1993; Sephton et al., 2007) however improvements in psychological and psychosocial factors were more consistent as demonstrated in the studies by Astin, Berman, Bausell, Lee, Hochberg and Forys (2003); Kaplan, Goldenberg, and Galvin-Nadeau (1993); Schmidt, Grossman, Schwarzer, Jena, Naumann, and Walach (2011); Sephton, Salmon, Weissbecker, Ulmer, Floyd, Hoover and Studts (2007). Therefore the pain findings are not unexpected. The long term effects of the intervention are unable to be determined due to lack of a follow-up which is consistent with other many studies of MBSR that do not contain follow up periods. Where follow up periods do exist in the research, they range from 3 – 12 months (Toneatto & Nguyen, 2007).
Daily home meditation practice diaries were correlated with the treatment effects. Not all of the participants completed the diaries (40% completed diaries). The low completion rate may have been due to the introduction of diaries midway through the 8-week course (Rosenzweig et al., 2010). However, correlation analyses determined that participants with a greater average weekly home practice, experienced greater reductions in psychological distress ($r=.40$, $P<.05$, $n=31$), somatisation symptoms ($r=.50$, $P<.05$, $n=29$), general overall health ($r=.42$, $P<.01$, $n=35$), role limitations due to emotional problems ($r=.30$, $P=.08$, $n=36$) and social functioning ($r=.42$, $P=.07$, $n=36$) (Rosenzweig et al., 2010). Low correlation factors were detected across the sample between home practice and beneficial changes in anxiety ($r=-.14$, $P=.46$, $n=31$), depression ($r=.18$, $P=.12$, $n=29$) or bodily pain ($r=.18$, $P=.29$, $n=36$). The 3-month follow-up findings of Morone et al (2008) identified maintenance of the beneficial changes in bodily pain observed post intervention which is not supported by the correlation analysis of Rosenzweig et al., (2010). However Rosenstein’s findings do provide support for the mechanism of MBSR attenuating the emotional response to “distressing thoughts and feelings that accompany and amplify the pain experience” (Kabat-Zinn, 1982, p.35)

**Study 3.**


Schmidt, Grossman, Schwarzer, Jena, Naumann and Walach (2011) attempted to replicate an earlier study investigating the effects of MBSR on female fibromyalgia sufferers by Grossman, Tiefenthaler-Gilmerb, Rayszc, and Kespe (2007). The two studies utilised a quasi-randomised design with the current study employing a 3-armed randomised trial consisting of 1. An 8-week MBSR group, 2. Active control group designed to match for non-specific effects of MBSR and 3. A wait list control group. The aim of the study was to gauge the efficacy of both MBSR and active controls compared to doing nothing as an effective treatment for fibromyalgia. The primary outcome measure was quality of life as measured by the Quality of Life Profile for the Chronically ill (PLC). Grossman et al., (2007) identified that the MBSR group in comparison to an active control group (designed to match for non-specific effects of MBSR) demonstrated strong effects and significantly greater improvement on health related quality of life, pain, depression, anxiety and coping ability scales (Schmidt et al., 2011). The results were maintained at a 3 year observational follow up at the conclusion of the study.

Schmidt et al., (2011) were unable to replicate the positive findings of Grossman et al., (2007) in any of the pre-post inter-group contrasts of the PLC, with no significant statistical or clinical changes detected. One reason may be due to the lack of a control used in the earlier study. The within group analysis demonstrated small improvements, with the MBSR group demonstrating the largest improvement in all scales utilised, however any differential benefits of MBSR on the quality of life of fibromyalgia sufferers was undetectable. However, psychological stress and negative emotions (a
component of fibromyalgia pain) have been identified in triggering and amplifying pain (Kabat-Zinn, 1982; Waddell, 2004). The positive improvements in quality of life of fibromyalgia subgroups in the Rosenzweig et al., (2010) study and the long term positive effect demonstrated by Grossman et al (2007) suggests that further research in this population should be undertaken to identify the within group effect of MBSR on fibromyalgia. Additionally, as the intention of MBSR is to attenuate the perception of pain through the acquisition of an open minded, non-judgemental awareness and acceptance of sensations, it could be argued that the PLC or other quality of life measures are not specific enough for this population or that they are not the most suitable measure with which to detect the efficacy of MBSR. Furthermore, the nature of mindfulness skills is that they improve over time (Goenka, 2006), perhaps the effects are more likely to be detectable after a longer period of practise and greater understanding of the technique. This concept may be supported by the maintenance and improvement of physical and psychological effects at 3 – 36 months post intervention (Bohlmeijer et al., 2010; Grossman et al., 2007; Merkes, 2010; Morone et al., 2008; Pradhan et al., 2007; Toneatto & Nguyen, 2007), however, is a potential limitation to assessing the immediate post treatment efficacy of mindfulness based therapies.

Similar to the study by Rosenzweig et al., (2010) participants in the Schmidt et al., (2011) study were also required to complete home practice diaries at four time points throughout the 8-week intervention. Participants were required to note for an entire week (at week 3 and again at week 7), the duration and type of practice undertaken, as well as to record all medications taken during that week. Participants in the MBSR group reported having greater mindfulness which when compared with some of the secondary measures of the study related to a decrease in anxiety and depression symptoms and a perceived increase in quality of life. The active control group demonstrated a similar pattern compared to the wait-list control group. Although the associations between mindfulness and a decrease in anxiety and depressive symptoms were detected they were not significant therefore the results are similar to those of Rosenzweig et al., (2010). However Schmidt et al., (2011) did not report a correlation between the frequency of home practice and the observed benefits. This may have been difficult to ascertain due to the intermittent completion requirements of the diaries.

**Study 4.**


Pradhan, Baumgarten, Langenberg, Handwerger, Gilpin, Magyari, Hochberg, and Berman (2007) evaluated the effects of MBSR on people with rheumatoid arthritis (n=62) using a wait listed randomised controlled trial. Like the previous studies the sample population was predominantly female, Caucasian, educated and middle class. The authors employed disease specific biological parameters in addition to 4 outcome measures relating to psychological distress and depressive
symptoms, psychological wellbeing and mindfulness. At the 8-week post intervention measure, positive but not significant changes were reported in all measures. However it was not until the 16-week follow-up that statistically significant changes were identified in psychological distress \((P=.04)\) and well-being \((P=.03)\). At the same time point, no significant findings were reported in depression symptoms and mindfulness \((P=.09)\). In contrast to the psychological measures, the biological parameters consisting of a blood test for inflammatory markers (erythrocyte sedimentation rate) and regular clinical assessment by a rheumatologist demonstrated no clinical or statistical significance at any time points \((P=.48)\). The improvements reported in the psychological measures corroborates the results of Rosenzweig et al., (2010); Morone et al., (2008) and Schmidt et al (2011) in regards to the relationship between practising mindfulness and reports of decreased psychological symptoms. It may be inferred from this study that MBSR may not alter disease activity (as observed by no change in biological parameters) however, mindfulness did appear to assist in the psychological adjustment to the disease.

The authors did not measure the connection between frequency, duration and type of home practice however; the observed sustained effect of MBSR on the variable measures was associated with 86% of the responders verbally reporting a continuation of MBSR practice. The findings of Pradhan et al (2007) provide evidence for the concept that a longer exposure to MBSR practice may be a factor in the continued improvements observed in psychological and physical measures (Bohlmeijer et al., 2010; Grossman et al., 2007; Merkes, 2010; Morone et al., 2008).

**Mindfulness based stress reduction literature limitations**

Limitations identified within the studies reviewed, are outlined below. It is important to note that these limitations are also synonymous with the majority of meditation in health related research (e.g. as demonstrated in meditation related reviews between 2003-2012). Generally, the studies critiqued lacked clarity on the following areas: 1. The content of the MBSR program undertaken (notation of any adaptations to the original MBSR format), 2. Detail of methodological process including inclusion/exclusion criteria, withdrawals and levels of expertise of participants (short or long term experienced meditators or meditation naïve) and 3. Information pertaining to teacher training, researcher bias and participant bias was absent from all of the individual studies and not reported within the reviews.

The following is a summary of the limitations detected in the aforementioned studies in this literature review, that were synonymous with more than one article and that are worthy of being reported separately as they reflect many of the limitations in the wider field of meditation related research.

- The burden of participation (scheduling, time commitment, home practice requirements) was noted as a deterrent in many studies. The ability to generalise the findings is therefore
decreased as the sample may not be representative of the overall population of specific disease conditions (Bohlmeijer et al., 2010; Merkes, 2010; Pradhan et al., 2007; Schmidt et al., 2011; Simpson & Mapel, 2011; Thomas, Tuck, Shennan, Conaglen, & Bell, 2009);

- Furthermore, participant willingness and openness to the concept of meditation has been identified as a barrier to participation (Bohlmeijer et al., 2010; Merkes, 2010). This feature alone limits the extent to which the effects of MBSR can be generalised to wider populations, as by its nature the program requires active engagement and regular practice in order to develop alterations in cognitive processing (Zeidan et al., 2011);

- The majority of participants within MBSR studies are female, middle aged, middle class women with chronic pain (Bohlmeijer et al., 2010; Morone et al., 2008; Pradhan et al., 2007; Rosenzweig et al., 2010; Schmidt et al., 2011). There is very little data to support the efficacy of MBSR in other demographics particularly male and younger populations;

- The broad utilisation of subjective data measures, presents the studies with an element of participant over reporting and an expectation of meeting the researchers needs. Therefore a truly objective analysis take this factor into account and allow some degree of variance from the truth in the reporting of such factors as pain and quality of life;

- The use of different measures in different studies for the assessment of the same outcome (e.g. Pain) makes a comparison of effects difficult. Within the studies investigating the effects on fibromyalgia, quality of life was measured in two studies with the quality of life profile for the chronically ill (PLC) (Grossman et al., 2007; Schmidt et al., 2011) and in another with the short form 36 Medical Outcomes survey (SF-36) (Rosenzweig et al., 2010);

- The investigation of the relationship between the duration and frequency of home practice does not yet enable a dose-effect relationship to be identified (Bohlmeijer et al., 2010; Pradhan et al., 2007; Schmidt et al., 2011) as the use of home diaries to record practice is under utilised;

- Many MBSR related studies do not contain a follow up period to assess the long term efficacy of MBSR (Bohlmeijer et al., 2010; Merkes, 2010; Toneatto & Nguyen, 2007). In the studies employing this design feature the time periods range from 3-12 months (Toneatto & Nguyen, 2007) and in a small selection of studies a 3 year (Grossman et al., 2007) and 4 year time period (Kabat-Zinn et al., 1984) has been utilised. The results of studies with follow-ups have reflected that physical and mental health related benefits can be observed and shown to improve after a significant time period post exposure to a mindfulness intervention (Grossman et al., 2007; Kabat-Zinn et al., 1984).
Generalizing the clinical effectiveness in the New Zealand context

The majority of research into the efficacy of the MBSR program has been conducted in the United States of America with the recruitment of participants from within local communities. The utility of MBSR within the New Zealand and Australian healthcare context has been investigated in a number of small studies (Simpson & Mapel, 2011; Thomas et al., 2009). The studies identified similar positive results in relation to quality of life and pain perception (Simpson & Mapel, 2011; Thomas et al., 2009) as reported in the larger US studies of Morone et al., (2008); Pradhan et al., (2007) and the study of Schmidt et al., (2011) set in Germany. The quality of the New Zealand based studies is moderate with many of the same limitations as other studies. Further research into the MBSR within a different demographic profile, different ethnicities and varying education levels would indicate if there is relevance of MBSR in other communities. Thomas et al., (2009) states that although there are limitations to their New Zealand based study, the results are in standing with overseas studies however more extensive investigation into the effectiveness of the MBSR program should be conducted in primary and secondary healthcare settings within the New Zealand context.

Conclusion

Since 1982, the Mindfulness Based Stress Reduction program has been researched in a broad range of clinical and non-clinical populations, to assess both efficacy and effectiveness as a method of treatment for both psychological and physical conditions. According to a review by Bogduk (2006) the cardinal risk factors for the persistence of pain and its progression from acute to sub acute to chronic are psychosocial factors that include the individuals’ attitudes, cognitions, fear-avoidance beliefs, levels of depression, anxiety, and distress. Additionally the factors which have been identified as limiting the success of pain related treatments and return to ‘normal’ are also based in the psychological field and include decreased acceptance, mental distress, somatisation, and catastrophising behaviour (Bogduk, 2006; Keefe et al., 2004). Baer’s 2003 narrative style literature review on mindfulness as a clinical intervention, highlighted that although the majority of studies contained methodological flaws, the findings for chronic pain patients showed statistically significant improvements in self rated pain, physical and psychological symptoms. Bohlmeijer et al., (2010) surmises the literature on mindfulness-based interventions with the conclusion that MBSR is helpful in the treatment of various medical and psychological conditions including depression and anxiety.

The mechanism of Mindfulness and its effect on reducing physical and psychological features of pain is considered to be the inhibition or down regulation of central nervous system pain pathways (Rosenzweig et al., 2010; Zeidan et al., 2012). Some aspects of meditation induced pain reduction is hypothesised to be due to the engagement of brain mechanisms that may be specific to meditation like states and not the traditional cognitive factors known to modulate pain (Zeidan et al., 2012). The
The outcome of mindfulness training on psychology is a reduced emotional reactivity to stressful thoughts and feelings that accompany the pain experience (Baer, 2003; Kabat-Zinn, 1982; Rosenzweig et al., 2010). Through a decreased reactivity individuals may develop a means of propagating greater attention, awareness and acceptance through meditation practice (Baer, 2003; Bohlmeijer et al., 2010; Grossman et al., 2004; Kabat-Zinn, 1982) which allows the attenuation of the pain experience. The associated benefits of an increase in mindfulness are lower levels of psychological distress, including less anxiety, depression, anger, and somatic pain (Baer, 2003; Carmody & Baer, 2008; Grossman et al., 2004; Rosenzweig et al., 2010). Additionally, studies employing measures of mindfulness indicate that persons with an increased level of mindfulness report higher levels of wellbeing including joy, inspiration, gratefulness, hope, contentedness, vitality, and satisfaction with life (Baer, 2003; Cardaciotto, Herbert, Forman, Moitra, & Farrow, 2008; Carlson et al., 2003; Carmody & Baer, 2008). Therefore the aim of this study is to investigate the effectiveness of a mindfulness based stress reduction (MBSR) program on self-reported pain, quality of life, acceptance, and resilience and in a mixed chronic pain population.

References


SECTION II: MANUSCRIPT

Note: The following manuscript was prepared in accordance with the Instructions for Authors for the International Journal of Osteopathic Medicine [see Appendix I]. The required word limit and references have been exceeded in order for full evaluation and discussion of the results in this thesis.
The effectiveness of a mindfulness based stress reduction (MBSR) program in a mixed chronic pain population

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Objective: To investigate the effectiveness of a mindfulness based stress reduction (MBSR) program on self reported pain, acceptance, resilience and quality of life in a mixed chronic pain population.

Design: A single cohort observational study with pre-post measures.

Setting: Community based program located in the Sunshine Coast, Queensland, Australia.

Participants: Fifteen volunteers (1 male, 14 female; mean age=52.9y) with a history of chronic musculoskeletal pain referred from local healthcare providers.

Methods: People who experienced chronic pain of a musculoskeletal origin and/or mild to moderate rheumatoid arthritis and who were interested in exploring the potential health benefits of mindfulness meditation were enrolled in the study. Participants were enrolled in an 8-week program of Mindfulness Based Stress Reduction (MBSR). Participants were required to attend a 2-hour group session once a week led by a qualified MBSR teacher and complete home practice in addition to daily mindfulness. Participants completed electronic questionnaires for each of the outcome measures at baseline, post intervention and 1, 2, and 3 months post intervention.

Results: Perceived pain intensity: Clinically significant changes (>5 points) in the median MPQ score was observed at pre – post, 1 and 3 month contrasts. A 60% reduction in pain intensity scores was observed in pre and post measures. SF-36: The physical health subcategories improved in 4 out of 5 subcategories. Similarly the mental health subcategories demonstrated change in the anticipated direction on 3 out of 5 subcategories, with 2 significant changes being observed in 2 out of the 3 subcategories. The SF-36 total component scores (combined physical and mental health sub-scales) increased between the pre intervention median (Mdn=45) to the immediate 8-week post-intervention follow-up (Mdn=67.5) (difference in Mdn 22.5-points; z=1.99, p=.046, r=.63). Improvement in pre and post intervention medians was maintained at 1-month (Mdn=60, z=1.57, p=.116, r=.52) and 2-months (Mdn=53, z=1.60, p=.109, r=.66). A significant difference was observed between the pre and 3-month comparison (Mdn=68.5, z=-2.19, p=.026, r=.70). There was no substantial change in the chronic pain acceptance or resilience scores between pre-intervention and all post-intervention time points.

Conclusion: The findings of this study indicate that the mindfulness based stress reduction program has potential health benefits on a mixed chronic pain population. Moderate to large effect sizes were observed on the health related quality of life, and large effect sizes were observed on the perceived pain levels in this mixed cohort of people experiencing chronic pain. The beneficial effects were maintained at 3-month follow up for the majority of participants in both quality of life and pain. No change in acceptance and resilience was detected. Further research in a specific New Zealand health care environment should be undertaken, due to the unique differences in the prevalence and management of chronic pain in different cultures and health care models.

MeSH Keywords:
Adult; Female; Meditation course; Meditation/methods; Meditation/psychology; Mindfulness; mindfulness/therapy; Pain; Psychological/therapy; Psychological/pain; Rheumatoid arthritis; Single systems.
Introduction

Pain is a widely studied subject and globally is one of the most common reasons for individuals to seek healthcare, self medicate, and withdraw from social and economic activities. Pain is a burden not only to the individual but to their wider family and community, due to the financial, emotional and psychological factors that are associated with long term pain conditions. Despite large investments into research and technology, the management of chronic pain remains less than optimal. Moreover, current treatment models are expensive to access, with long waiting periods. The International association for the study of pain (IASP) has called for greater education of the effects and processes of pain amongst health professionals, patients and support persons to increase the awareness of what is and is not pain. Additionally due to the increasing financial and personal burden of pain, the IASP suggests that ‘addressing the global burden of pain does not require high-tech costly interventions but requires global education of healthcare providers, people and their families of the best applications of low-cost yet effective therapies.

The mindfulness based stress reduction program (MBSR) is one option of a low cost program that has shown preliminary evidence of its effectiveness. The MBSR program was created with the intention of combating the uncontrolled stress that co-existed with many chronic illnesses. Kabat-Zinn states that the MBSR course is characterised by the development of a non-judgemental attitude toward arising sensations, thoughts, urges and emotions. Baer states that the skill of “observing pain sensations non-judgementally is believed to reduce the distress associated with pain” (p.6). Kabat-Zinn hypothesises that with prolonged exposure to mindfulness through non-judgmental observation, individuals can experience pain sensations without “excessive emotional reactivity” and even if pain sensations are not reduced, suffering and distress might be alleviated.

Previous research into the 8-week MBSR program has demonstrated evidence of its efficacy in various medical and psychological conditions including; chronic pain, rheumatoid arthritis, cancer, fibromyalgia and anxiety and depression. Reported health benefits include improvements in pain, pain sensitivity, disordered eating, mood, sleep quality, fatigue, psychological distress, overall quality of life, and reduced stress levels. A short term exposure (20min-d over a 3day period) to mindfulness mediation has been shown to be long enough to learn and incorporate the technique to reduce pain and anxiety therefore with the structure of the 8-week MBSR program incorporating 2hr weekly group sessions and daily home practice of up to 60mins, the accumulative effect on physical and psychological symptoms could be suggested to be very effective in the symptoms of chronic illness. However despite the growing volumes of research into the MBSR program, there remain many methodological flaws and weaknesses which could be attributed to investigating the intangible field of the psyche and spirituality. There exists a need to continue investigating the potential for this program as it may provide a useful key to increased functioning for those who suffer with chronic pain. Therefore the intention of this research project is to ascertain the...
effectiveness of a low cost mindfulness based stress reduction program in a mixed chronic pain population to add to the growing data providing support for its utility in a health populations.
Methods

Design and Procedure

This study utilised a single cohort design with pre-post measures to assess the change in bodily pain, acceptance, psychological resilience and health related quality of life (HRQoL) factors during a community based Mindfulness Based Stress Reduction (MBSR) program. The MBSR program was similar to the seminal MBSR study undertaken by Kabat-Zinn. The study was conducted in Maroochydore, Queensland, Australia. The weekly group sessions were conducted in a private function room. Participants were recruited through advertising placed in the Sunshine Coast branch of the Arthritis and Rheumatism Council; and notice boards of local general practitioners and rheumatologists. Word of mouth and verbal advertisements of the program was given to prospective participants who were patients of the MBSR therapist.

Recruitment of Participants

Participation in the MBSR program was open to people experiencing chronic pain of musculoskeletal origin and/or mild to moderate rheumatoid arthritis who were interested in exploring the potential health benefits of mindfulness meditation. The inclusion criteria were: 1. diagnosis of rheumatoid arthritis; or 2. reported musculoskeletal pain for a period longer than 6 months. All prospective participants were interviewed by telephone to determine eligibility prior to enrolment in the study. All participants gave written informed consent prior to participating in the study associated with the program. The study protocol was approved by the Unitec Research Ethics Committee (UREC Approval No.: 2011-1194). (See figure 1 for participant flow diagram).

Concurrent therapies

All participants were encouraged to continue with their current treatment plan (if any) while participating in the study.

Mindfulness Based Stress Reduction Intervention

Participants were enrolled in an 8-week program of Mindfulness Based Stress Reduction (MBSR). Participants were required to attend a 2-hour group session once a week led by a qualified MBSR teacher. Group sessions were divided into instruction and practice in mindfulness meditation skills; discussions about stress, coping, home practice assignments and mindfulness skill building activities. Home practice assignments were set at a minimum of 20-25min of formal meditation, on at least six days of the week. This formal meditation practice was in addition to the informal practice of being mindful in everyday activities. Audiotapes, a daily diary and reading materials were provided to
support home practice. Participants were encouraged to attend all group classes and undertake daily practice. Further details of the MBSR programme are summarised in Appendix X.

Therapist

The MBSR therapist was a registered and experienced MBSR therapist, completing MBSR training in 2009 and at the time of the program had co-taught two, 8-week MBSR programs for people suffering from chronic pain. The therapist was also a practising osteopath with a doctoral qualification in musculoskeletal medicine. The therapist has a personal 5-year history of mindful-meditation practice.

Outcome Measures

Assessment of the broad range of MBSR effects was undertaken using 4 standardised assessment measures, none of these were considered as a primary measure. The Brief Resilience Scale was included in this study as a pilot because it is a new measure that has shown preliminary positive utility in measuring the construct of resilience.  

Table 1. Outcome Measures

<table>
<thead>
<tr>
<th>Name</th>
<th>Author</th>
<th>Acronym</th>
<th>Variable</th>
<th>Improvement</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Short form McGill Pain Rating Questionnaire</td>
<td>Melzack, (1975)</td>
<td>(SF-MPQ)</td>
<td>Perceived pain</td>
<td>Higher scores indicate increased pain</td>
</tr>
<tr>
<td>2 Chronic Pain Acceptance Questionnaire</td>
<td>McCracken, Vowles &amp; Eccleston, (1998)</td>
<td>(CPAQ)</td>
<td>Pain Acceptance</td>
<td>Higher scores signify increased acceptance</td>
</tr>
<tr>
<td>3 Short-form 36 Health Survey version 2.0</td>
<td>Ware, Kosinsky &amp; Gandek (1993)</td>
<td>(SF-36)</td>
<td>Physical and mental functioning and wellbeing</td>
<td>Higher scores indicate increased functioning and quality of life</td>
</tr>
<tr>
<td>4 Brief Resilience Scale</td>
<td>Smith, Dalen, Wiggins, Tooley, Christopher, Paulette &amp; Bernard, (2008)</td>
<td>(BRS)</td>
<td>Psychological resilience (ability to bounce back)</td>
<td>Higher mean scores indicate increased resilience</td>
</tr>
</tbody>
</table>
1) Short form McGill Pain Rating Questionnaire (SF-MPQ)

The short form McGill Pain Rating Questionnaire (SF-MPQ) consists of 15 descriptors (11 sensory; 4 affective) which are rated on an intensity scale as 0 = none, 1 = mild, 2 = moderate or 3 = severe. Three pain scores are derived from the sum of the intensity rank values of the words chosen for sensory, affective and total descriptors. The higher the score the higher the perceived pain. Melzack\textsuperscript{24} states that the internal reliability and specificity of the SF-MPQ when comparing pre and post scores are as high and as sufficient as the full MPQ. Additionally the SF-MPQ has the sensitivity to ‘sufficiently, detect differences among different treatment methods to relieve pain...at statistical levels comparable to those obtained with the standard form’. The SF-MPQ is a useful tool in situations in which the standard MPQ takes too long to administer, yet qualitative information is desired.\textsuperscript{24}

2) Chronic Pain Acceptance Questionnaire (CPAQ)

The chronic pain acceptance questionnaire (CPAQ) aims to measure acceptance in relation to chronic pain. An increased acceptance of pain suggests that an individual has reduced unsuccessful attempts to avoid or control pain and focuses instead on participation in valued activities and the pursuit of personally relevant goals.\textsuperscript{25} The CPAQ is a 20 question inventory that relates to two factors; (1) activity engagement and (2) pain willingness. Each question consists of a 7 point scale (0=never true; 6=always true), with total scores being obtained by adding all of the scales together. Higher scores for each factor indicate higher levels of acceptance. Sensitivity and reliability testing has shown that the CPAQ demonstrates fully adequate internal consistency and has positive correlations with other measures of psychosocial distress and physical functioning.

3) Quality of Life

The Short Form 36 version 2.0 (SF-36), 4 week scale, is the most evaluated health outcome measure\textsuperscript{26} proving to be an effective tool for evaluating change across a broad spectrum of physical and mental components of health.\textsuperscript{27} It is useful in measuring health improvement or decline, assessing treatment effectiveness, predicting the burden of a disease and to compare disease-specific markers between disease populations and the general population.\textsuperscript{27} The SF-36 consists of 36 items which are allocated into eight scales (see Figure 1) which are sub-scales of physical or mental health outcomes. The eight scales each consist of a multi-item measurement and measure the following health components: 1) Physical functioning (PF); 2) role limitations due to health problems (RP); 3) bodily pain (BP); 4) general health perception (GH); 5) vitality/fatigue (VT); 6) social functioning (SF); 7) role limitations due to emotional problems (RE); and 8) mental health status (MH). At completion, each sub-scale is given a score, as is the overall physical and mental health categories which are then summarised and analysed to provide a picture of functional wellbeing and general health for the individual.\textsuperscript{27,28} Higher scores on a 0-100 scale represent greater functionality and wellbeing i.e. higher scores on the bodily pain measure represent less severe and debilitating pain.
4) Resilience

The brief resilience scale (BRS) was added to this study to pilot its use in a chronic pain population undertaking a mindfulness based stress reduction program. The BRS aims to detect the patient’s ability to bounce back or recover from stress. The BRS is a new construct in measuring resilience and has thus far been tested in student, cardiac and chronic pain populations. The results of the validation studies demonstrated that the measure was predictably related to personal characteristics, social relations, coping, and health in all samples. The BRS was found to negatively relate to anxiety, depression, negative effect, and physical symptoms. The BRS consists of six items. Items 1, 3, and 5 are positively worded, and items 2, 4, and 6 are negatively worded. The BRS is scored by reverse coding items 2, 4, and 6 and finding the mean of the six items. The following instructions are used to administer the scale: “Please indicate the extent to which you agree with each of the following statements by using the following scale: 1 = strongly disagree, 2 = disagree, 3 = neutral, 4 = agree, 5 = strongly agree”.

Collection of measures

All measures were administered online to participants prior to the scheduled completion date using an online survey website (http://www.surveymonkey.com; SurveyMonkey.com, LLC)

Data Analysis

Raw data were explored for normality using Shapiro-Wilk tests and inspection of P-P and Q-Q plots. Wilcoxon-rank tests were performed to investigate the comparison between intra and inter-individual scores on all measures to establish a group effect for all pre and post measures. A pre and post comparison was completed for all time measures i.e. pre/post, pre/1 month, pre/2month, pre/3month. Data was analysed using IBM SPSS statistics 19 (SPSS, Chicago, IL, USA). Cohen’s d effect size for paired observations, also known as the standardised response mean, was utilised to estimate the magnitude of treatment-related effects. Pearson product moment correlations were calculated to examine associations between change scores (post-intervention minus pre-intervention)
Study Flow

Participants

Fifteen participants were recruited (14 females and 1 male; mean age = 52.9y), \( n = 15 \). No participants were excluded.

- Assessed for eligibility \( (n=15) \)
- Eligible, informed and consented to intervention \( (n=15) \)
- Complete pre-intervention measures \( (n=14) \)
  - Withdrawal: increase in pain \( (n=1) \)
  - Commence 8-week MBSR program \( (n=14) \)
  - Withdrawal: increase in pain \( (n=2) \)
  - Complete MBSR program and baseline measures \( (n=12) \)
  - Withdrawal: unable to commit \( (n=1) \)
  - Complete 1-month follow up measures \( (n=9) \)
    - Did not complete measures \( (n=2) \)
  - Complete 2-month follow up measures \( (n=6) \)
    - Did not complete measures \( (n=5) \)
  - Complete 3-month follow up measures \( (n=10) \)
    - Did not complete measures \( (n=1) \)

Figure 1. Participant flow diagram.
### Table 2. Participant baseline characteristics

<table>
<thead>
<tr>
<th>ID</th>
<th>Sex</th>
<th>Age</th>
<th>Employed</th>
<th>Diagnosis</th>
<th>Secondary Diagnosis</th>
<th>Duration of symptoms (y)</th>
<th>Concurrent treatment</th>
<th>Meditation Experience</th>
<th>Mindfulness Experience</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>M</td>
<td>39</td>
<td>Y</td>
<td>Low back pain</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>N</td>
<td>N</td>
<td>Enrolled</td>
</tr>
<tr>
<td>2</td>
<td>F</td>
<td>46</td>
<td>Y</td>
<td>Low back pain</td>
<td>• Repetitive Strain Injury</td>
<td>13</td>
<td>Podiatrist, GP</td>
<td>Y</td>
<td>N</td>
<td>Withdrew</td>
</tr>
<tr>
<td>3</td>
<td>F</td>
<td>53</td>
<td>Y</td>
<td>Low back pain</td>
<td>-</td>
<td>3</td>
<td>Osteopath</td>
<td>Y</td>
<td>N</td>
<td>Enrolled</td>
</tr>
<tr>
<td>4</td>
<td>F</td>
<td>57</td>
<td>Y</td>
<td>Rheumatoid arthritis</td>
<td>-</td>
<td>4</td>
<td>Rheumatologist, GP</td>
<td>Y</td>
<td>N</td>
<td>Enrolled</td>
</tr>
<tr>
<td>5</td>
<td>F</td>
<td>**</td>
<td>Y</td>
<td>Trigeminal neuralgia</td>
<td>-</td>
<td>14</td>
<td>Osteopath, Medication</td>
<td>Y</td>
<td>N</td>
<td>Enrolled</td>
</tr>
<tr>
<td>6</td>
<td>F</td>
<td>66</td>
<td>N</td>
<td>Stress</td>
<td>-</td>
<td>12</td>
<td>Osteopath, GP</td>
<td>Y</td>
<td>N</td>
<td>Enrolled</td>
</tr>
<tr>
<td>7</td>
<td>F</td>
<td>54</td>
<td>N</td>
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<td>-</td>
<td>10</td>
<td>Rheumatologist, Dentist, Podiatrist, GP, Ophthalmologist, Occupational Therapist</td>
<td>Y</td>
<td>Y</td>
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<tr>
<td>8</td>
<td>F</td>
<td>50</td>
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<td>Rheumatoid arthritis</td>
<td>-</td>
<td>10</td>
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<td>Y</td>
<td>N</td>
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<tr>
<td>9</td>
<td>F</td>
<td>58</td>
<td>N</td>
<td>Osteoarthritis</td>
<td>-</td>
<td>26</td>
<td>GP – MSK medicine, GP general</td>
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<td>Y</td>
<td>Withdrew</td>
</tr>
<tr>
<td>10</td>
<td>F</td>
<td>**</td>
<td>Y</td>
<td>Carer – no pain</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>Y</td>
<td>Y</td>
<td>Withdrew</td>
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<tr>
<td>11</td>
<td>F</td>
<td>57</td>
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<td>Fibromyalgia</td>
<td>Lumbar spine disc fusion</td>
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<td>Withdrew</td>
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<td>12</td>
<td>F</td>
<td>42</td>
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<td>Pelvic pain</td>
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<td>13</td>
<td>F</td>
<td>69</td>
<td>N</td>
<td>Anxiety &amp; Depression</td>
<td>-</td>
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<td>61</td>
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<td>36 LBP 4 OA</td>
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<td>Y</td>
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<tr>
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<td>F</td>
<td>36</td>
<td>Y</td>
<td>Low back pain</td>
<td>-</td>
<td>2</td>
<td>Osteopath, GP</td>
<td>N</td>
<td>N</td>
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Notes: ** Participant declined to disclose age; GP = General Practitioner; LBP = Low back pain; OA = osteoarthritis
**Adverse reactions**

During the course of the intervention there were 2 reports of increased physical pain which resulted in the participants withdrawing after the second group session.

There were no reported adverse psychological reactions to the MBSR program either during the intervention or post-hoc.
Results

Perceived Pain Intensity (SF-MPQ)

Clinically significant changes (>5 points) in the median MPQ score was observed at pre – post, 1 and 3 month contrasts. McGill pain questionnaire (MPQ) pre -intervention median scores (Mdn = 20) decreased at the immediate 8-week post-intervention follow up (Mdn = 8) (difference in Mdn 12-points). This represents a 60% reduction in pain scores for the 9 individuals for whom pre and post measures were obtained and is significant in the pre-post statistical comparison ($z=-1.99$, $p = .046$, $r=-.67$). Improvement in MPQ scores were maintained at 1-month ($Mdn=9.50$, $z=-1.89$, $p=.058$, $r=-.68$) and 2-months ($Mdn = 19$, $z=-1.75$, $p=.080$, $r=-.73$) with the 3-month comparison revealing the most significant change ($Mdn = 14$, $z=-2.19$, $p=.028$, $r=-.73$).

The sensory and affective components were individually plotted to detect inter-participant variation. Participants 6 – (sensory only), 12 (sensory and affective) and 15 (sensory only) showed post-intervention change greater than MCID in at least one of either the sensory or affective components. However, the majority of participants did not demonstrate significant change between the two components. [See thesis Appendix B]

Health Related Quality of Life (SF-36)

The physical health subcategories of the SF-36 demonstrated change in the anticipated direction on 4 out of 5 subcategories, at varying time points. Similarly the mental health subcategories demonstrated change in the anticipated direction on 3 out of 5 subcategories, with 2 changes of significance being observed in 2 out of the 3 subcategories during comparison statistics. The SF-36 total component scores (combined physical and mental health sub-scales) increased between the pre intervention median (Mdn=45) to the immediate 8-week post-intervention follow-up (Mdn=67.5) (difference in Mdn 22.5-points; $z=-1.99$, $p = .046$, $r=-.63$). This increase represents a 50% improvement in the 9 individual participants for whom pre-post measures were obtained. Improvement in pre and post intervention medians was maintained at 1-month ($Mdn=60$, $z=1.57$, $p=.116$, $r=.52$) and 2-months ($Mdn=53$, $z=1.60$, $p=.109$, $r=.66$). A significant difference was observed between the pre and 3-month comparison ($Mdn=68.5$, $z=-2.19$, $p=.028$, $r=-.70$). [See thesis Appendix C].

SF-36 sub-scales where no significant change was observed

Three subscales of SF-36 measuring mental health, role-emotional (mental health component) and role-physical (physical health component) demonstrated no substantial change between all pre and post intervention time points. [See thesis Appendix D]

Pain Acceptance and Psychological Resilience

There was no substantial change in the CPAQ and BR scores between pre-intervention and all post-intervention time points [See thesis Appendix E].
Discussion

Overview

The aim of this preliminary observational pre-post study was to investigate the effectiveness of a mindfulness based stress reduction (MBSR) program on self reported pain, acceptance, resilience and quality of life in a mixed chronic pain population. All participants were interested in exploring the proposed benefits of mindfulness, attended the majority of classes and adhered as best as possible to the homework assignments. The MBSR program was observed to have a positive effect on self-reported pain and factors in the health related quality of life scales. However the program did not substantially influence pain acceptance or resilience. The observed improvements in self-reported pain and improvements in quality of life were consistent with previous findings from similar studies. 7,11-13,21,35

Perceived pain – Short form McGill Pain Questionnaire

A large reduction in self-reported pain (SF-MPQ and SF-36 Body Pain scale) was evident in the week following the conclusion of the intervention. The proposed benefit of using mindfulness as a self-regulation tool for chronic pain patients is believed to be due to the development of a detached observational stance, which with continued practise enables an unconscious uncoupling of the sensory and affective components of pain.7,12,29,30 The SF-MPQ consists of 2 independent factors, sensory, described as the nociceptive pain experience of the individual, and the other affective, which is described as the emotional impact of the nociceptive pain experience.31 Uncoupling of the sensory and affective factors of pain is believed to result in reduced emotional reactivity to stressful thoughts and feelings that accompany the pain experience.7,12,29,30 Kabat-Zinn7 reports that with continued practice of detached observation the sensory aspect of pain may not change, however, a reduction in the “alarm reaction” of the pain experience as monitored by the affective component can be achieved. The result of decreased affective activation is a reduction in the emotional and cognitive aspects of the pain experience i.e. hurt and suffering.7,12,29

The sensory and affective components of pain were analysed separately within this study. Both components demonstrated significance changes at differing time points. The effect sizes were similar across all time points in both components and there was no pattern of significant reduction of the affective component of the SF-MPQ detected. However the sensory and affective total scores and the individual data analysis did not indicate that the uncoupling process had occurred within this sample. Evidence of sensory and affective uncoupling was not evident in this study.

The nature of the MBSR intervention requires participants to engage actively and frequently with the technique including regular informal mindful meditation practice in addition to the formal group sessions. The importance of duration13 and frequency of home practice is reported to be a key role in the development of beneficial effects of participation in MBSR programs.12,13 Rosenzweig et al12 identified a moderate correlation between an increased frequency of MBSR practice and
beneficial change in psychological distress and physical symptoms. In the present study, significant change was detected in self-reported pain immediately and was found to have been maintained at 1-month and 3-month follow ups. The decrease in participants overall pain is supported by the body pain scale of the SF-36, however, we are unable to describe the relationship between the observed effect and the duration and frequency of home practice as it was not recorded. The observed beneficial changes and effect sizes are comparable with those of Rosenzweig et al\(^\text{12}\) who also saw beneficial reductions in not only body pain but several other factors of the SF-36 when the frequency of home practise (41% participants) was positively correlated with changes in physical function.

**Health related quality of life - Short-form 36**

Measuring the functional health status of participants in health interventions has become increasingly important for many reasons, including validation of the cost of health interventions.\(^\text{32}\) The Medical Outcomes Study 36 Item Short-Form (SF-36) has been widely utilised as a sole measure or alongside specific measures for disease, and treatment modality. The widespread use, has demonstrated reliability in informing users of the broader context of the effect of health interventions in general and disease specific populations.\(^\text{27,32}\) The SF-36 is reported as a valid measure to differentiate the physical and mental benefits of different treatment modalities\(^\text{27}\) which in the context of MBSR, is useful due to the broad range of physical and mental effects attributed to it as a treatment.

Mindfulness based stress reduction is theorised to impact the conscious perception of pain through enhanced appraisal and stability of the emotional and cognitive mind\(^\text{8,21,33}\) as well as altering the contextual evaluation of sensory events.\(^\text{33}\) These cognitive alterations are proposed to develop through regular practice of a non-judgemental awareness of momentary sensations\(^\text{7,8,33}\) as emphasised within the technique of MBSR. The result is a decreased activation of the cortical regions associated with the processing and modulation of pain.\(^\text{7,8,29,30,33,34}\) These cortical reductions are tangibly demonstrated as improvements in the mental and physical health and functioning of individuals as observed in studies investigating the effects of MBSR in clinical populations.\(^\text{8,11-13,17,20,35}\)

The current study of MBSR in a mixed chronic pain population utilised the SF-36 and found significant reductions in several subscales and observed moderate to large effect sizes. The immediate post intervention measure demonstrated clinically and statistically significant reductions in body pain, physical function, overall physical and mental health measures which were observed to have been maintained at the 3-month follow-up period. The findings of the current study reflect those of Rosenzweig et al\(^\text{12}\) who used the SF-36 in a mixed chronic pain cohort \(n=133\). Rosenzweig et al\(^\text{12}\) detected small to moderate effect sizes and clinically and statistically significant changes in several subscales including body pain and physical function. Additionally the overall physical and mental health subscales demonstrated moderate to large effect sizes that were both clinically and statistically significant. There was no follow-up period in this study. However, a second MBSR study utilising SF-36 in an older adult population with chronic low back pain\(^\text{8}\) detected significant change in only one subscale with a small effect size observed. The physical function subscale demonstrated a statistically significant change at post intervention \((P=.03, r=.46)\) that was also maintained at the 3-
month follow up. The body pain and overall physical and mental health scales did move in the anticipated direction but were not clinically or statistically significant and all demonstrated small effect sizes. The use of a general symptoms measure that includes dimensions for both psychological and physical health (e.g. SF-36) is not common within the research on MBSR, with only three studies identified in review articles\(^{20,35}\) between 2003-2012 using the SF-36. SF-36 maybe useful in reporting MBSR outcomes but appears to be under utilised to date.

**Pain Acceptance - Chronic Pain Acceptance Questionnaire**

Acceptance is a behavioural trait which has been shown to have a positive effect on people with chronic pain.\(^{8,36}\) Higher levels of pain acceptance have been correlated with: improved quality of daily functioning in people with chronic pain, reports of lower pain intensity,\(^{6,12}\) less pain-related anxiety and avoidance, less physical disability, depression, and psychosocial distress as well as better work status.\(^{8,25,36,37}\) Additionally, it is a core construct of mindfulness to accept that most sensations, thoughts, and emotions fluctuate, or are transient, passing by “like waves in the sea”.\(^{38}\)

The CPAQ scale has been found to consistently measure 2- factors which have been identified as accurately representing ‘acceptance’.\(^{25,39}\) The first factor, described as activity engagement measures the engagement of an individual in normal life activities regardless of pain. This factor is described as more than a mental process, requiring the individual to actively engage in ‘positive and functional everyday activities under the influence of circumstances separate from pain’.\(^{39}\) The second factor, pain willingness, represents the patients’ willingness to experience pain without adopting strategies to avoid or control painful sensations.\(^{25,35,36}\) In a CPAQ confirmatory analysis study, patients who reported high pain willingness were found to use less health care services, be more likely to be working and were less psychologically distressed and disabled by their pain.\(^{39}\) The suggested use of the CPAQ when a discrepancy between activity engagement and pain willingness is detected is to focus treatment on enhancing the psychological aspect of pain willingness to decrease the psychological distress and disability associated with activity.\(^{39}\)

The current study was unable to detect if MBSR, an intervention based on improving the psychological awareness and detachment from pain, has an effect on acceptance. There are two factors that may contribute to this a) high total scores at baseline and b) the inability to definitively conclude that MBSR has no effect due to a small sample. The literature investigating MBSR includes one other study utilising the CPAQ. A randomised controlled study of MBSR in an elderly population living with chronic low back pain\(^8\) \((n=19)\), demonstrated similar baseline levels of acceptance as the current study. The study by Morone et al\(^8\) identified small incremental improvements within the meditation group during the pre and post contrast. However when the MBSR group was compared to a control group who received usual care while wait listed for the intervention, a significant improvement \((P=0.008)\) in acceptance was detected. This may indicate that MBSR has a capacity to influence acceptance when compared with non-psychological forms of treatment,\(^8\) although the within-group effect for the MBSR group was not reported, but appears to be small \((ES = 0.24)\). The study, although methodologically sound, was unable to identify any significant changes or detect if
MBSR has the capacity to affect the behavioural construct of acceptance. The CPAQ literature reports that higher scores on the CPAQ correspond to higher levels of acceptance. However, it has not currently been established if in the absence of treatment, or while undertaking an acceptance focussed treatment, the CPAQ measures would remain stable, move in the direction of greater pain willingness, or in the direction of less activity engagement. Further investigation of MBSR on acceptance is required in a robust adequately powered controlled study, particularly in populations demonstrating low levels of acceptance.

**Resilience, the ability to bounce back – Brief Resilience Scale**

Resilience as defined and measured within the brief resilience scale (BRS) is "the ability to bounce back or recover from stress". The BRS is a relatively new scale that has shown promising psychometric properties in measuring resilience. However the measure still requires further testing to demonstrate its full face validity and psychometric properties, as very little literature currently exists. The BRS differs from previous resilience measures which assess the internal resources that may promote resilience rather than recovery, resistance, adaptation, or thriving. The BRS was added as a secondary measure to this study to assess its face validity and to gain experience with it as a measure of resilience. Additionally the constructs of acceptance and resilience are inter-related in the literature discussing acceptance but have not been tested concurrently in the same sample. The utility of a measure that assesses the internal resistance and optimism to move forward in a situation of stress is worthy, in an MBSR study, where the primary focus is on improving the psychological and physical symptoms that threaten an individual's psychological and physical wellbeing, function and coping. Within this study no significant changes in BRS were detected at any timepoint. However, the BRS was straightforward to administer yet some difficulty was encountered when interpreting the measure due to the absence of psychometric properties including minimum clinically important difference.

**Internal Validity Limitations**

There are several limitations inherent in this study. Firstly, due to the observational design of this study, there is an inability to draw firm conclusions about the observed effects on chronic pain, quality of life, acceptance and resilience. However, positive changes in body pain were identified on two measures which increase the confidence that MBSR has an effect on this domain rather than a factor other than the MBSR. Furthermore the positive pain outcomes corroborate those of other MBSR studies utilising control groups.

Secondly, a limited number of pre-intervention data points meant that the temporal variation was not established. It is therefore possible that the observed results were within their typical range.

Thirdly, an absence of data regarding participants home practise (at any stage of the study) decreases the ability to draw conclusions on the relationship between MBSR and the sustained benefits detected in quality of life (SF-36) and pain immediately and at the 3-month follow-up.
Fourthly, there was an unexpected reduction of data in the second month which precluded the analysis of change over the course of the intervention. However the third month data point was completed by all participants and therefore provides a clearer estimate of the changes at the endpoint. In small sample sizes, missing data has a more visible influence on analysis than in large samples.

External Validity Limitations

There a number of external limitations within this study, firstly, there is an inability to generalise the findings of the study due to: a small sample size; lack of baseline data points; a small female Caucasian sample that was motivated and open to undertaking the skills of meditation. This demographic is well researched within MBSR studies and is known to be compliant with the protocols, yet there is little knowledge of other demographics and their response to an MBSR intervention.

Secondly, barriers to participation for potential participants may have included the large time and effort commitment inherent to the program. The commitment for an MBSR program is significantly greater than many health-related interventions which may have lower commitment burden. The commitment from participants to attend a weekly group session and daily home practice may have deterred some potential participants. In addition, transportation to the group sessions and coping with bodily pain whilst undertaking the initial stages of mindfulness, were all sighted as reasons for lack of participation and drop-out. The cost of participation was not identified as a barrier to participation as the course was offered on a donation only basis.

Recommendations for further study

The recommendations for further research as identified from within the current study are;

- Implement the study within a demographic in which MBSR has not previously been researched, ideally with a well-defined target disorder within a specific setting i.e. psychological stress in an occupational setting; defined chronic pain condition within a regional pain service.

- Replicate the study in a specific New Zealand health care environment because there are unique differences in the prevalence and management of chronic pain in different cultures and health care models.41

- Utilisation of a more robust study design including an active control group.

- A more sensitive measure of general psychological acceptance may be indicated for future studies to provide greater insight into the connection between the moderate levels of pain acceptance (CPAQ) and the significant changes in the quality of life (SF-36) and pain (SF-MPQ) measures.

- Inclusion of a basic means to record frequency, duration and quality of home practise diaries, may provide greater clarity on the dose/response relationship.13 Being mindful of participant burden, recent technological innovations in online medical research tools may be appropriate.42
- Increased number of baseline data points prior to the intervention, to quantify temporal patterns of dependent variables in the sample group.
- Incorporation of a mixed methods or qualitative study to investigate the wider effects of MBSR on factors of daily living. A subjective account of the lived experience may give a broader understanding of the intricacies associated with learning the skills of mindfulness; the incorporation into daily life; and the influence(s) it may have had on various quality of life factors.

**Conclusion**

The findings of this study indicate that the mindfulness based stress reduction program has potential health benefits on a mixed chronic pain population. Moderate to large effect sizes were observed on the health related quality of life, and large effect sizes were observed on the perceived pain levels in this mixed cohort of people experiencing chronic pain. The beneficial effects were maintained at 3-month follow up for the majority of participants in both quality of life and pain, however, any potential benefit on participants’ acceptance and resilience levels was unable to be detected.
References


36. McCracken LM. Zhao-O'Brien J. General psychological acceptance and chronic pain: There is more to accept than the pain itself. Euro J Pain 2010;14:170-75.


SECTION III: THESIS APPENDICES
Appendix A: Typical Mindfulness Based Stress Reduction Format

Frequency and Setting

Once a week for the duration of the 8 week course, participants gather for a group session, 90mins in duration. The session is led by a qualified mindfulness based therapist, in the case of this research study, the therapist is Dr Nick Penney (D.O., B.Sc. (Hons) Ost. Med. Ph.D). Dr Penney has completed 70 hrs of MBSR teacher training in a retreat led by Professor Mark Williams in Adelaide 2009 and to date has co-taught 2 x 8-week MBSR programmes for people suffering from chronic pain. Dr Penney is a practising osteopath with a Ph.D in musculoskeletal medicine. He has a personal five year history of mindful meditation practice including completion of an 8-week MBSR course and a nine day silent insight retreat. The setting for the group sessions was in a private function room in the Sands Tavern, Maroochydore, a local venue for all participants.

Program Technique

The program is modelled on the original MBSR program of Kabat-Zinn and the University of Massachusetts Medical Centre (1980). Three techniques of mindfulness meditation were taught and applied to the individuals’ life in regular day to day activities i.e. sitting, walking, lying. The activities of daily life are transformed into a meditative activity through directed breathing and mindful awareness of thoughts and sensations (Morone, 2008)

The techniques of meditation taught are; 1) body scanning – in a supine position, the individuals conscious attention is guided in a non-judgmental stance to each area of the body from the toes to the top of the head. 2) Sitting practice – while seated on the floor or chair the individuals attention is guided solely to the incoming and outgoing breath and 3) walking mediation – mindful slow walking, with focused attention on body sensation and/or breathing.

The personality traits of patience, non-judgment, open-mindedness, acceptance, letting go, non-striving and trust are emphasised throughout each session to support the constructs of mindfulness meditation and the development of foundation skills in it.

Program Protocol

The first week of the program is an introduction to the principles and practice of mindfulness meditation and an outline of the course and expectations. The first group session involves the teaching of the body scanning technique. Within this first session and in all successive home or group
practice it is stressed, that if physical discomfort arises during any meditation practise that participants should change to a more comfortable position. Homework recommendations are set at daily meditation for 6 out of 7 days per week lasting for a minimum of 45-50mins, with 5mins to complete a meditation diary. Support materials of guided meditations on cd, daily diaries and reading materials are provided to participants at the first session. The CD contains a 45minute recording of the body scan technique and a guided 30 minute sitting meditation. The diary is a brief review of the duration, quality and frequency of meditation plus any additional comments. The reading materials are not mandatory homework but are provided as a background for participants if they are interested in pursuing further information on mindfulness.

The second and following week’s group sessions consists of general discussion of the previous week’s home practice and any challenges or breakthroughs that may have arisen. Discussion of the theoretical basis for meditation and its relationship to pain, stress, coping and the mind/body connection were gradually presented during the group sessions, for a rough duration of 45minutes. The second meditation technique of quiet sitting meditation is introduced in the second week. The group practises all together and utilises the quiet sitting at the start of each successive group session. Therefore the third and successive group sessions follow the format of 45minutes of group meditation and 45minutes of discussion. Walking meditation is introduced in the fifth week.

The original program format, includes an all day silent retreat on the 8th week and the inclusion of yoga related meditation as a fourth technique. This research project did not include these components due to the time constraints of the therapist, the lack of a qualified yoga instructor which would make this component safe for all participants nor recourse to funds to provide this service.
Appendix B: Short Form McGill Pain Questionnaire

A: SF-MPO Total Scores

B: SF-MPO Sensory Scores

C: SF-MPO Affective Scores
Appendix C: Short Form 36 Medical Outcomes Survey Subscales (Physical Health)

A: Physical Function

B: Body Pain

C: General Health

D: Physical Health Summary
Appendix C: Short Form 36 Medical Outcomes Survey Subscales (Mental Health)

A: Vitality

B: Social Function

C: Mental Health Summary
Appendix D: Short Form 36 Medical Outcomes Survey
Subscales (No change)

Mental Health subscale

A: Role Emotional

B: Mental Health

Physical Health subscale

C: Role Physical
Appendix F: Participant Information Sheet

You are invited to participate in a research project conducted within the Masters of Osteopathy program at Unitec Auckland, New Zealand. The aim of this research is to identify the potential effects of a mindfulness meditation based stress reduction (MBSR) programme on chronic musculoskeletal pain experienced in moderate/severe Rheumatoid Arthritis people.

Inclusion criteria for participants in this study

- Diagnosis of Rheumatoid Arthritis that is currently moderate/severe
- Experience chronic musculoskeletal pain associated with Rheumatoid Arthritis for longer than 6 months (including periods of remission)
- No awareness or current treatment for any psychological disorders
- Be available for approximately 6 months in order to complete the program requirements and follow up data collection

Mindfulness Stress Based Reduction

Mindfulness is a way of learning to relate directly to whatever is happening in your life, a way of taking charge of your life, a way of doing something for yourself that no one else can do for you — consciously and systematically working with your own stress, pain, illness, and the challenges and demands of everyday life. Mindfulness ‘emphasises detached observation’ from moment to moment of the intero and exteroceptive experiences on the human body. The end goal for mindfulness is a development of non-judgmental, non-reactive form of awareness in all aspects of life, not just while meditating. MBSR is a combination of activities aimed at teaching mindfulness.

The Study

Participants will be enrolled in an eight week programme of MBSR which consists of group and individual home practice. Participants are required to attend a group session once a week that is led by Dr Nick Penney (a qualified MBSR therapist) and lasts for two and a quarter hours. Group sessions involve instruction and practice in mindfulness meditation skills, along with discussions about stress, coping, and home practice assignments. Home practice assignments are set at a minimum of 60 minutes, six days per week. Audiotapes, a daily diary and reading materials are provided to support home practice. It is intended that participants will attend all group classes and undertake daily practice in order to have officially completed the course.
Information Collection

Participants will be contacted by the researcher (Leigh Townsend) via phone after the initial expression of interest in the research. You will then be asked a series of questions and asked to complete a consent form allowing us to contact you as a participant in the study. You will be asked to complete a series of questionnaires (maximum of four at any one time) at specific times prior, during and (up to 3 months) after the completion of the MBSR course.

The information from these questionnaires will go towards the analysis of the effect of a MBSR program on daily pain, pain acceptance, resilience and quality of life of Rheumatoid Arthritis sufferers. Personal details will be required to generate a demographic profile of the participants in the study, however this information will remain confidential and will only be utilised initially to code participants. Participants will in each subsequent communication receive questionnaires with only their unique identifying code as the main identifier, this code will also be utilised in all communication regarding participants to protect anonymity.

Withdrawal

There are no disadvantages / penalties / adverse consequences to not participating or withdrawing from the research. Participants may withdraw from the research project up to 2 weeks after the initial registration and prior to the commencement of the MBSR program. If participants withdraw from the research it will not affect their participation within the MBSR course.

Use of information

Information from questionnaires will be used in preparing a research dissertation. You have right to see this dissertation when it is completed. This dissertation may also be used for future purposes as part of a journal article and/or presenting findings at a conference or an osteopathic educational institute. Your name and any information that may identify you will be kept confidential and not used in the dissertation or any articles or presentations. The only persons who will have access to your responses will be the principal researcher, research associate and the researcher’s supervisors. All information will be stored securely on a password secured computer and in hard copy at Unitec for a minimum period of 5 years.

If you would like more information or you have any concerns about this research project you can contact the researcher Leigh Townsend phone +64 21 0512 748 or email leigh.townsend00@gmail.com, the research associate Dr Nick Penney, email nickpenney@theosteopath.net.au or alternatively you may contact the research supervisor Rob Moran email rmoran@unitec.ac.nz

This study has been approved by the Unitec Research Ethics Committee from (24-09-2010) to (31-12-2011). If you have any complaints or reservations about the ethical conduct of this research, you may contact the Committee through the UREC Secretary (Ph: 09 815 4321 ext.7254). Any issues you raise will be treated in confidence and investigated fully, and you will be informed of the outcome.
Appendix G: Participant Consent Form

Thank you for agreeing to participate in this research project being undertaken for the Master of Osteopathy programme at Unitec New Zealand.

Consent Form

The effectiveness of a mindfulness based stress reduction programme on self-reported pain, pain acceptance, resilience and quality of life in people with moderate/severe Rheumatoid Arthritis.

Name of Participant:___________________________________________________

I have had the research project explained to me and I have read and I understand the information sheet given to me.
I have had the opportunity to ask questions and have them answered.
I understand that I don't have to be part of this if I don't want to and I may withdraw from participating in the research at any time without it affecting my participation within the MBSR course.
I may withdraw or edit any or all of my contribution to the data collection at any point until the conclusion of the eight week MBSR programme.

I understand that everything I write is confidential with the researcher and none of the information I give will be used in a way that identifies me. I understand that the only persons who will know what I have said will be the researcher, research associate and the researcher's supervisors. I also understand that all the information that I give will be stored securely on a computer and in hard copy for a minimum period of five years.
I understand that I can see the finished research document.
I have had time to consider everything and I give my consent to be a participant in this study.

Participant Signature: ………………………… Date: …………………………

Project Researcher: ………………………… Date: …………………………

Participant/Researcher Copy

This study has been approved by the Unitec Research Ethics Committee from (date) to (date). If you have any complaints or reservations about the ethical conduct of this research, you may contact the Committee through the UREC Secretary (Ph: 09 815 4321 ext.7254). Any issues you raise will be treated in confidence and investigated fully, and you will be informed of the outcome.
Appendix H: MBSR Program Advertisement

Moment by Moment

An Eight Week Mindfulness Based Stress Reduction Program
Specifically for People with Chronic Pain

An opportunity to move toward greater balance, control and participation in your life...

Mindfulness meditation has been practiced for around two and a half thousand years and there is now a good deal of scientific evidence supporting mindfulness as a useful approach in managing many conditions including chronic pain. One recent study for instance, reported a 57% reduction in pain unpleasantness, and 40% reduction in pain intensity (Zeidan,F et al Journal of Neuroscience April 2011)

Mindfulness is a way of learning to relate directly to whatever is happening in your life, a way of taking charge of your life, a way of doing something for yourself that no one else can do for you — consciously and systematically working with your own stress, pain, illness, and the challenges and demands of everyday life.

Twenty years of published research indicates that the majority of people who complete the course report:

- Lasting decreases in physical and psychological symptoms
- An increased ability to relax
- Reductions in pain levels and an enhanced ability to cope with pain that may not go away
- Greater energy and enthusiasm for life
- Improved self-esteem
- An ability to cope more effectively with both short and long-term stressful situations.

Orientation Wednesday 27 July 1.30 pm Please ring 5451 1599 to reserve a place. The program will in part be funded by voluntary donations from the participants. Numbers are limited

Orientation will give you the chance to:

- Learn about the Stress Reduction Program and explore whether it is right for you
- Meet the program instructor and hear about the associated research project
- Experience, first-hand, mindfulness methods and approaches you will be learning during the program
- Enrol in the program, 8 classes of 2.5hrs commencing 1.30 Wednesday 3rd August

For more information please call Dr Nick Penney 0414441319
Appendix I: Instruction for authors manuscript submission to the International Journal of Osteopathic medicine

An official journal of:
• General Osteopathic Council (UK)
• Australian Osteopathic Association
• Ontario Association of Osteopathic Manual Practitioners
• Society for Promotion of Manual Practice of Osteopathy

Officially recognised by the Commission for Osteopathic Research, Practice and Promotion (CORPP)

Guide for Authors
The Editors of the Journal welcome contributions for publication from the following categories: Letters to the Editor and Editorials, Reviews and Original Research articles, Commentaries, Clinical Practice articles (Case Studies) with educational value and Protocols.

The Guidelines are separated into the following sections:
A Online Submission
B Types of Contributions
C General Guidance
D Preparation of the Manuscript
E Specific Guidance for Original Research Articles
F Specific Guidance for Protocols
G Post Acceptance

(A) ONLINE SUBMISSION
Submission to this journal proceeds totally online at (http://ees.elsevier.com/ijom). You will be guided stepwise through the creation and uploading of the various files. The system automatically converts source files to a single Adobe Acrobat PDF version of the article, which is used in the peer-review process. Please note that even though manuscript source files are converted to PDF at submission for the review process, these source files are needed for further processing after acceptance. All correspondence, including notification of the Editor's decision and requests for revision, takes place by e-mail and via the Author's homepage, removing the need for a hard-copy paper trail.

The above represents a very brief outline of this form of submission. It can be advantageous to print this "Guide for Authors" section from the site for reference in the subsequent stages of article preparation.

Submission of an article implies that the work described has not been published previously (except in the form of an abstract or as part of a published lecture or academic thesis), that it is not under consideration for publication elsewhere, that its publication is approved by all authors and tacitly or explicitly by the responsible authorities where the work was carried out, and that, if accepted, it will not be published elsewhere in the same form, in English or in any other language, without the written consent of the Publisher.

(B) TYPES OF CONTRIBUTIONS - word limits exclude tables, figures and references.
Letters to the Editor (up to 1,000 words)
As is common in biomedical journals the Editorial Board welcomes critical responses to any aspect of the journal. In particular, letters that point out deficiencies and that add to, or further clarify points made in a recently published work, are welcomed. The Editorial Board reserves the right to offer...
authors of papers the right of rebuttal, which may be published alongside the letter.

Reviews and Original Articles (2,000 - 5,000 words)
These should be either (i) reports of new findings related to osteopathic medicine that are supported by research evidence. These should be original, previously unpublished works; or (ii) a critical or systematic review that seeks to summarise or draw conclusions from the established literature on a topic relevant to osteopathic medicine.

Short review (1,500-3,000 words)
The drawing together of present knowledge in a subject area, in order to provide a background for the reader not currently versed in the literature of a particular topic. Shorter in length than and not intended to be as comprehensive as that of the critical or systematic review paper. These papers typically place more emphasis on outlining areas of deficit in the current literature that warrant further investigation.

Research Note (up to 1,500 words)
Findings of interest arising from a larger study but not the primary aim of the research endeavour, for example short experiments aimed at establishing the reliability of new equipment used in the primary experiment or other incidental findings of interest, arising from, but not the topic of the primary research. Includes further clarification of an experimental protocol after addition of further controls, or statistical reassessment of raw data.

Preliminary Findings (1,500-2,500 words)
Presentation of results from pilot studies which may establish a solid basis for further investigations. Format similar to original research report but with more emphasis in discussion of future studies and hypotheses arising from pilot study.

Commentaries (up to 2,000 words)
Includes articles that do not fit into the above criteria as original research. Includes commentaries and essays especially in regards to history, philosophy, professional, educational, clinical, ethical, political and legal aspects of osteopathic medicine.

Clinical Practice
Authors are encouraged to submit papers in one of the following formats: Case Report, Case Problem, and Evidence in Practice.

i. Case Reports - usually document the management of one patient, with an emphasis on presentations that are unusual, rare or where there was an unexpected response to treatment (e.g. an unexpected side effect or adverse reaction). Authors may also wish to present a case series where multiple occurrences of a similar phenomenon are documented. Preference will be given to reports that are prospective in their planning and utilise Single System Designs, including objective measures.

ii. The aim of the Case Problem is to provide a more thorough discussion of the differential diagnosis of a clinical problem. The emphasis is on the clinical reasoning and logic employed in the diagnostic process.

iii. The purpose of the Evidence in Practice report is to provide an account of the application of the recognised Evidence Based Medicine process to a real clinical problem. The paper should be written with reference to each of the following five steps: 1. Developing an answerable clinical question. 2. The processes employed in searching the literature for evidence. 3. The appraisal of evidence for
usefulness and applicability. 4. Integrating the critical appraisal with existing clinical expertise and with the patient's unique biology, values, and circumstances. 5. Reflect on the process (steps 1-4), evaluating effectiveness, and identifying deficiencies.

Protocols (1,500 - 2,000 words)
The IJOM accepts the submission of protocols of randomised interventions, systematic reviews and meta-analyses, observational studies, and selected phase I and II studies (novel intervention for a novel indication; a strong or unexpected beneficial or adverse response; or a novel mechanism of action), with the overall aim to encourage good principles in clinical research design.

The editors are looking for studies that will appeal to a wide general readership. The question being addressed and the planned design and analysis will need to be as original as possible, topical, and valid. All protocols will be subject to the journal's usual peer review process.

(C) GENERAL GUIDANCE
Submission Declaration
Submission of an article implies that the work described has not been published previously (except in the form of an abstract or as part of a published lecture or academic thesis), that it is not under consideration for publication elsewhere, that its publication is approved by all authors and tacitly or explicitly by the responsible authorities where the work was carried out, and that, if accepted, it will not be published elsewhere in the same form, in English or in any other language, without the written consent of the copyright-holder.

Ethical considerations
Human subjects. Work on human beings that is submitted to The International Journal of Osteopathic Medicine should comply with the principles laid down in the declaration of Helsinki; Recommendations guiding physicians in biomedical research involving human subjects. Adopted by the 18th World Medical Assembly, Helsinki, Finland, June 1964, amended by the 29th World Medical Assembly, Tokyo, Japan, October 1975, the 35th World Medical Assembly, Venice, Italy, October 1983, and the 41st World Medical Assembly, Hong Kong, September 1989. The manuscript should contain a statement that the research has been approved by the appropriate ethical committees related to the institution(s) in which it was performed and that subjects gave informed consent to the work. Studies involving experiments with animals must state that their care was in accordance with institution guidelines. Patients' and volunteers' names, initials, and hospital numbers should not be used. In a case report, the subject's written consent should be provided. It is the author's responsibility to ensure all appropriate consents have been obtained.

Patient anonymity. Studies on patients or volunteers require ethics committee approval and informed consent which should be documented in the manuscript.

Patients have a right to privacy. Therefore identifying information, including patients' images, names, initials, or hospital numbers, should not be included in videos, recordings, written descriptions, photographs, and pedigrees unless the information is essential for scientific purposes and you have obtained written informed consent for publication in print and electronic form from the patient (or parent, guardian or next of kin where applicable). If such consent is made subject to any conditions, Elsevier must be made aware of all such conditions. Evidence of written consent must be provided to Elsevier on request.

Even where consent has been given, identifying details should be omitted if they are not essential. If identifying characteristics are altered to protect anonymity, such as in genetic pedigrees, authors should provide assurance that alterations do not distort scientific meaning and editors should so note.
Authors submitting manuscripts as Case Reports, Case Problems, and Evidence in Practice should ensure that they have received consent from patients who are the subject of such reports. A statement to this effect should be included in the manuscript.

If such consent has not been obtained, personal details of patients included in any part of the paper and in any supplementary materials (including all illustrations and videos) must be removed before submission.

Role of the funding source
You are requested to identify who provided financial support for the conduct of the research and/or preparation of the article and to briefly describe the role of the sponsor(s), if any, in study design; in the collection, analysis and interpretation of data; in the writing of the report; and in the decision to submit the paper for publication. If the funding source(s) had no such involvement then this should be stated. Please see http://www.elsevier.com/funding .

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Acknowledgments
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Sponsored Articles
The IJOM now offers authors the option to sponsor non-subscriber access to individual articles. The access sponsorship contribution fee per article is $3,000. This contribution is necessary to offset publishing costs - from managing article submission and peer review, to typesetting, tagging and indexing of articles, hosting articles on dedicated servers, supporting sales and marketing costs to ensure global dissemination via ScienceDirect, and permanently preserving the published journal article. The sponsorship fee excludes taxes and other potential author fees such as colour charges which are additional.

Authors can specify that they would like to select this option after receiving notification that their article has been accepted for publication, but not before. This eliminates a potential conflict of interest by ensuring that the journal does not have a financial incentive to accept an article for publication.

English Language Service
Please write your text in good English. Authors who require information about language editing and
Review Process
The decision to publish a paper is based on an editorial assessment and peer review. Initially all papers are assessed by an editor of the journal. The prime purpose is to decide whether to send a paper for peer review and to give a rapid decision on those that are not.

Manuscripts going forward to the review process are reviewed by members of an international expert panel. All such papers will undergo a double blind peer review by two or more reviewers. All papers are subject to peer review and the Journal takes every reasonable step to ensure author identity is concealed during the review process. The Editors reserve the right to the final decision regarding acceptance.

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Contact details for questions arising after acceptance of an article, especially those relating to proofs, will be provided by the publisher.

(D) PREPARATION OF THE MANUSCRIPT
Submitted papers should be relevant to an international audience and authors should not assume knowledge of national practices, policies, law, etc. Authors should consult a recent issue of the journal for style if possible. Since the journal is distributed all over the world, and as English is a second language for many readers, authors are requested to write in plain English and use terminology which is internationally acceptable.

Abbreviations - Avoid the use of abbreviations unless they are likely to be widely recognised. In particular you should avoid abbreviating key concepts in your paper where readers might not already be familiar with the abbreviation. Any abbreviations which the authors intend to use should be written out in full and followed by the letters in brackets the first time they appear, thereafter only the letters without brackets should be used.

Statistics - Standard methods of presenting statistical material should be used. Where methods used are not widely recognised explanation and full reference to widely accessible sources must be given.

Manuscript Layout
The manuscript with a font size of 12 or 10 pt double-spaced with wide margins (2.5 cm at least) and number pages consecutively beginning with the Title Page. Depending on the paper type (see above) this should include the title, abstract, key words, text, references, tables, figure legends, figures, appendix. Microsoft Word or similar programme should be used.
Please check your typescript carefully before you send it off, both for correct content and typographic errors. It is not possible to change the content of accepted typescripts during production.

To facilitate anonymity, the author's names and any reference to their addresses should only appear on the title page. Please check your typescript carefully before you send it off, both for correct content and typographic errors. It is not possible to change the content of accepted typescripts during production.

Papers should be set out as follows, with each section beginning on a separate page:

**Title page**
To facilitate the blinded peer-review process, two title pages are required. The first should carry just the title of the paper and no information that might identify the author or institution. The second should contain the following information: title of paper; full name(s) and address(es) of author(s) clearly indicating who is the corresponding author; you should give a maximum of four degrees/qualifications for each author and the current relevant appointment only; institutional affiliation; name, address, telephone, fax and e-mail of the corresponding author; source(s) of support in the form of funding and/or equipment.

**Keywords**
Include four to ten keywords in alphabetical order, which accurately identify the paper's subject, purpose, method and focus. These should be indexing terms that may be published with the abstract with the aim of increasing the likely accessibility of your paper to potential readers searching the literature. Therefore, ensure keywords are descriptive of the study. Use the Medical Subject Headings (MeSH®) thesaurus or Cumulative Index to Nursing and Allied Health (CINAHL) headings where possible (see [http://www.nlm.nih.gov/mesh/meshhome.html](http://www.nlm.nih.gov/mesh/meshhome.html)).

**Abstract**
Both qualitative and quantitative research approaches should be accompanied by a structured abstract of no more than 250 words. Commentaries and Essays may continue to use text based abstracts of no more than 150 words. All original articles should include the following headings in the abstract as appropriate: Background, Objective, Design, Setting, Methods, Participants, Results, and Conclusions. As an absolute minimum: Objectives, Methods, Results, and Conclusions must be provided for all original articles. Abstracts for reviews of the literature (in particular systematic reviews and meta-analysis) should include the following headings as appropriate: Objectives, Data Sources, Study Selection, Data Extraction, Data Synthesis, Conclusions. Abstracts for Case Studies should include the following headings as appropriate: Background, Objectives, Clinical Features, Intervention and Outcomes, Conclusions.

**Text**
The text of observational and experimental articles is usually, but not necessarily, divided into sections with the headings: introduction, methods, results, results and discussion. In longer articles, headings should be used only to enhance the readability. Three categories of headings should be used:

- major headings should be typed in capital letter in the centre of the page and underlined (i.e. **INTRODUCTION**)
- secondary ones should be typed in lower case (with an initial capital letter) in the left hand margin and underlined (i.e. **Participants**),
- minor ones typed in lower case and italicised (i.e. questionnaire).
Do not use 'he', 'his' etc. where the sex of the person is unknown; say 'the patient' etc. Avoid inelegant alternatives such as 'he/she'.

Statement of Competing Interests
When submitting a manuscript you will need to consider if you, or any of your co-authors, are an Editor or Editorial Board member of the International Journal of Osteopathic Medicine. If this is the case you will need to include a section, at the end of your manuscript immediately before the reference section, called "Statement of Competing Interests". Example statement, which may require editing, is as follows: (Name of author) is an Editor of the Int J Osteopath Med; (Name of author) is a member of the Editorial Board of the Int J Osteopath Med but was not involved in review or editorial decisions regarding this manuscript.

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Responsibility for the accuracy of bibliographic citations lies entirely with the authors.

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Text: Indicate references by superscript numbers in the text. The actual authors can be referred to, but the reference number(s) must always be given.

List: Number the references in the list in the order in which they appear in the text.

Examples:
Reference to a journal publication:


Reference to a book:


Reference to a chapter in an edited book:


For journal articles, the abbreviated title of the journal should be used. Authors should refer to the National Library of Medicine database for journal abbreviations (http://www.ncbi.nlm.nih.gov/nlmcatalog/journals).

Note shortened form for last page number. (e.g., 51-9), and that for more than 6 authors the first 6 should be listed followed by "et al." For further details you are referred to "Uniform Requirements for Manuscripts submitted to Biomedical Journals" (J Am Med Assoc 1997;277:927-934) (see also http://www.nejm.org/general/text/requirements/1.htm).
Web references - As a minimum, the full URL and access date should be given. Any further information, if known (DOI, author names, dates, reference to a source publication, etc.), should also be provided. Web references should be included in the reference list.

Tables, Illustrations and Figures
Tables, illustrations and figures should be placed on separate pages as separate electronic files and not placed within the manuscript. Each table, illustration or figure should be accompanied by a number (e.g. Table 1) and a brief description of the content of the table, figure or illustration, below the table, illustration or figure. All tables, illustrations or figures should be referred to in the manuscript.

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- Number the illustrations according to their sequence in the text.
- Use a logical naming convention for your artwork files.
- Provide captions to illustrations separately.
- Produce images near to the desired size of the printed version.
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Appendices - Ordinarily there should be no appendices although in the case of papers reporting tool development or the use of novel questionnaires authors must include a copy of the tool as an appendix unless all items appear in a table in the text. Appendices may be published as online supplementary files to which a reference should be made in the printed article.

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Implications for Clinical Practice
At submission stage, authors of reviews and original research articles are required to provide three to four bullet points outlining the manuscript implications for clinical practice.

(E) SPECIFIC GUIDANCE FOR ORIGINAL RESEARCH ARTICLES
The text of original research for a quantitative or qualitative study is typically subdivided into the following sections:
Introduction
State the purpose of the article. Summarise the rationale for the study or observation. Give only
strictly pertinent references and do not review the subject extensively. Do not include data or
conclusions from the work being reported.

Materials and Methods
Describe your selection of observational or experimental participants (including controls). Identify the
methods, apparatus (manufacturer's name and address in parenthesis) and procedures in sufficient
detail to allow workers to reproduce the results. Give references and brief descriptions for methods
that have been published but are not well known; describe new methods and evaluate limitations.

Indicate whether procedures followed were in accordance with the ethical standards of the institution
or regional committee responsible for ethical standards. Do not use patient names or initials. Take
care to mask the identity of any participants in illustrative material.

Results
Present results in a logical sequence in the text, tables and illustrations. Do not repeat in the text all
the data in the tables or illustrations. Emphasise or summarise only important observations.

Discussion
Emphasise the new and important aspects of the study and the conclusions that follow from them. Do
not repeat in detail data or other material given in the introduction or the results section. Include
implications of the findings and their limitations, and include implications for future research. Relate
the observations to other relevant studies. Link the conclusion with the goals of the study, but avoid
unqualified statements and conclusions not completely supported by your data. State new hypothesis
when warranted, but clearly label them as such. Recommendations, when appropriate, may be
included.

Conclusion
A summary of the pertinent findings and, relevance of the study and implications of the study for
future research.

CONSIDERATIONS SPECIFIC TO TYPES OF RESEARCH DESIGNS
Manuscripts are required to adhere to recognized reporting guidelines relevant to the research design
used. These identify matters that should be addressed in your paper. These are not quality
assessment frameworks and your study need not meet all the criteria implied in the reporting
guideline to be worthy of publication in the journal.

You are encouraged (but not required) to provide a brief description of the reporting tool employed in
your manuscript to guide the editors and reviewers.

Reporting guidelines endorsed by the journal are listed below:

Observational cohort, case control and cross sectional studies - STROBE - Strengthening the
Reporting of Observational Studies in Epidemiology http://www.equator-
network.org/index.aspx?o=1032

Quasi-experimental/non-randomised evaluations - TRENDS - Transparent Reporting of Evaluations

Randomised (and quasi-randomised) controlled trial - CONSORT - Consolidated Standards of


Qualitative researchers might wish to consult the guideline listed below:


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All manuscripts submitted to the journal should be accompanied by an Author Contribution Statement. The purpose of the Statement is to give appropriate credit to each author for their role in the study. All persons listed as authors should have made substantive intellectual contributions to the research. To qualify for authorship each person listed should have made contributions in each of the following:
1) Contributions to conception and design; data acquisition; data analysis and interpretation;
2) Drafting of manuscript, or critical revision for important intellectual content;
3) All authors must have given approval to the final version of the manuscript submitted for consideration to publish.

Acquisition of funding; provision of resources; data collection; or general supervision, alone, is not sufficient justification for authorship. Contributors who do not meet the criteria for authorship as outlined above should be listed in the Acknowledgements section. Acknowledgements may include contributions of technical assistance, proof reading and editing, or assistance with resources and funding. The statement may be published in the paper as appropriate.

Example of suggested format (note the use of author initials).
AB conceived the idea for the study. AB and CD contributed to the design and planning of the research. All authors were involved in data collection. AB and EF analysed the data. AB and CD wrote the first draft of the manuscript. EF coordinated funding for the project. All authors edited and approved the final version of the manuscript.

(F) SPECIFIC GUIDANCE FOR PROTOCOLS
Organisation of a Protocol - the following need to be adequately addressed.

• Title
• Abstract/Summary - this should provide a concise description of the purpose of the Protocol and should not exceed 200 words.
• Background, including rationale and any previous systematic review(s).
• Keywords - provide 4-10 keywords.
• Principal investigator(s); contact details.
• Aim(s).
• Design (randomised, double-blind) - including inclusion and exclusion criteria; intervention(s)/method; primary and secondary endpoint(s); side-effects reporting and quantification
• Statistical analysis - including sample size and power calculations; type of analysis; statistical
• Testing.
  • Ethical issues - including ethics committee approval; informed consent form and information sheet.
  • Publication plan.
  • Time required - an estimation of the time required to run the protocol should be given per separate step and for the whole protocol, including reporting.
  • Funding source(s).
  • References.

(G) POST ACCEPTANCE
Changes to authorship
This policy concerns the addition, deletion, or rearrangement of author names in the authorship of accepted manuscripts:

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Proofs
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Please check the manuscript carefully before it is sent off to the Editorial Office, both for correct content and typographical errors, as it is not possible to change the content of accepted typescripts during the production process. As a guide, please ensure the following had been included:
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