Four-step Mindfulness-based Therapy for Chronic Pain: A Pilot Randomized Controlled Trial

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ABSTRACT

Four-step Mindfulness-based Therapy for Chronic Pain:

A Pilot Randomized Controlled Trial

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Objective: Chronic pain is a common condition worldwide that poses significant impact to society in terms of its health and economic costs. It has been found to be related to a number of emotional and cognitive factors that are amenable to psychological treatments. Traditional cognitive-behavioral therapy (CBT) for chronic pain has become the gold standard of psychological treatment with reported efficacy. However, recent meta-analyses have found its effect size to be only modest at most. Moreover, its specific mechanisms of action are not well elucidated. With recent advances in neuroscience on possible neurocognitive processes underlying chronic pain, alternative treatment models targeting these specific neurocognitive processes are worth exploring. The present study tested the effectiveness of the Four-step

Mindfulness-based Therapy (FSMT) for chronic pain in a randomized-controlled trial. The FSMT was chosen because of its explicit emphasis on altering neurocognitive processes that appear to be highly relevant in treating chronic pain. **Method:** Ninety-nine chronic pain patients in a hospital cluster-based outpatient pain clinic were randomly allocated to either the FSMT treatment or wait-list control group. The FSMT was modified for use with chronic pain and incorporated mindfulness exercises, such as mindful breathing and mindful meditation. Treatment consisted of eight weekly two-hour group sessions conducted by a clinical psychologist experienced in the implementation of the FSMT protocol. Assessment took place at baseline and post-treatment for both the FSMT and wait-list control. For the FSMT, assessment also took place at mid-group and 3-month follow-up. **Results:** Findings showed that the FSMT produced superior outcomes in terms of activity interference (primary endpoint), pain unpleasantness, and depression when compared to the wait-list control group or over time. Improvements were also found in the process measures of pain catastrophizing and pain acceptance. All treatment effects were maintained at follow-up. Further, the effects have been shown to be clinically significant and reliable above and beyond measurement errors. Mediational analyses revealed that pain catastrophizing and pain acceptance mediated the effects of FSMT on the

outcomes of activity interference and depression; pain catastrophizing also mediated the effect of FSMT on the outcome of pain unpleasantness. **Conclusions:** The present study was the first to establish statistical and clinical evidence of the FSMT for chronic pain. It also revealed possible processes and mechanisms that might have brought about the changes in outcome, namely reduction in pain catastrophizing and improvement in pain acceptance. How the FSMT led to the outcome changes via these two processes was discussed and enriched by neurocognitive perspectives. Future studies should seek to further compare the FSMT with other active psychological treatments for chronic pain and collect neuroimaging data to further illustrate the neurocognitive processes involved.

摘要

用於長期痛症的四部內觀療法: 一個先導的隨機對照研究

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目的：長期痛症是全球的普通病症。它為社會帶來沉重的健康及經濟上的代價。長期痛症與一系列的情緒和認知因素有關，可通過心理治療更正。傳統針對長期痛症的認知行為療法已成為長期痛症心理治療的標準，並表現出高效度。但是，在近期的綜合分析中它的效應值只為中等，它的特定作用機制也並未清晰闡明。近期的腦神經研究已為長期痛症的腦神經認知過程帶來線索，故此值得探索針對這些腦神經認知過程的替代治療模式。本研究以隨機取樣方式測試了四部內觀療法用於長期痛症的效度。四部內觀療法受選，乃由於它清晰地強調改變腦神經認知過程，與長期痛症的治療尤其相關。**方法:** 本研究為一隨機對照研究，比較四步內觀療法相對於候補對照於長期痛症病人上的分別。99 位醫院聯網痛症科的門診病人隨機分派到四步內觀療法組或候補對照組。四部內觀療法已修改為適用於長期痛症上，並配合以內觀練習 (例如觀呼吸、內觀冥想) 。治療包括八節小

組，每星期一次，每次兩小時，由熟悉四部內觀療法方案的臨床心理學家帶領。評估方面，治療及對照組均在底線及治療後作評估，而治療組亦在小組中段及治療完畢三個月後作跟進評估。**結果：**本研究發現四步內觀療法在活動干擾（主要研究終點)、痛的討厭程度和憂鬱三個結果上，相對於對照組或隨時間過去，有優異的表現。在過程量度中，對痛的災難化和對痛的接受也有改善。所有治療效果都維持到三個月後。再者，治療效果也具臨床意義，並且可信賴為超越量度上的誤差。中介分析發現，對痛的災難化和對痛的接受，中介了從治療到活動干擾和憂鬱等結果的過程，而對痛的災難化也中介了也治療到痛的討厭程度這結果的過程。**結論：**本研究首次為四部內觀療法用於長期痛症建立臨床和統計學上的証據，它也揭示治療的可能過程和作用機制，包括對痛災難化的減少和對痛接受的改善。對於四部內觀療法如何通過這兩個過程而產生其效果，作出了詳細討論，並從腦神經認知角度加以理解。將來的研究應對四部內觀療法與其他活躍的心理治療應用於長期痛症上作出比較，也應收集腦神經影像資料，以印證牽涉其中的腦神經認知過程。

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Chapter 1: Introduction

1.1. Multidimensional nature of pain

According to the International Association for the Study of Pain (IASP), pain is "an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage" (IASP, 1994; Loeser & Treede, 2008). As noted by IASP, pain is a subjective experience that consists of five distinct dimensions: sensory, perceptual, emotional, evaluative, and communicative. In a similar vein, Melzack and Casey (1968) distinguished between three systems in the pain experience: sensory-discriminative, motivational-affective, and cognitive-evaluative. Although pain is typically related to tissue damage, the literature suggests that some individuals do report pain in the absence of observed tissue damage (Turk & Flor, 1999). The IASP recommends that the latter type of experience should still be categorized as pain, hence endorsing its multidimensional nature.

Depending on the duration, etiology, and region, the literature suggests that there are different forms and clinical diagnoses of pain. Whereas nociceptive pain is related to ongoing tissue damage, neuropathic pain is initiated or caused by a primary lesion or dysfunction in the nervous system. There are different diagnostic categories of pain as related to the region in which they occur. Key categories include myofascial pain,

neuropathic pain, phantom limb pain, complex regional pain syndrome, fibromyalgia, and central pain. (Loeser & Cousins, 1990).

1.2. Prevalence and impact of chronic pain

According to the IASP's guidelines (1994), pain that lasts less than three months is known as acute pain, and pain that lasts more than three months is called chronic pain. Chronic pain has been documented as a common condition with a prevalence rate of 15% worldwide (Verhaak, Kerssens, & Dekker, 1998). A recent nationwide survey in the United States found that chronic spinal pain (including chronic back pain and chronic neck pain) occurred in 19.0% of the population within a 12-month period (Von Korff, Crane, Lane, & Miglioretti, 2005). In Hong Kong, the prevalence rate of all forms of chronic pain has been reported to be 10.8% (Ng, Tsui, & Chan, 2002).

Chronic pain has been recognized by the World Health Organization as a major health care problem worldwide (Gureje, Von Korff, Simon, & Gater, 1998). In the United States, the cost incurred by chronic pain (including healthcare utilization, compensation claims, and loss in productivity) was estimated to be USD 40 billion per year (Aronoff, Evans, & Enders, 1983). Despite treatments, more than 32% chronic pain patients reported activity limitations resulting from pain, including

walking, standing, lifting, carrying (Pleis & Coles, 2002). Recent surveys in Hong Kong reported that 71% of community dwellers with chronic pain reported that the pain had interfered with their daily life, 20% of community dwellers with chronic pain took a median of five days off work due to pain during a 12-month period, 37% of chronic pain patients attending pain clinics were unemployed, and 31% of chronic pain patients were either receiving comprehensive social security allowance or disability allowance (Chen et al., 2004a; Ng et al., 2002). In sum, chronic pain appears to be a major health problem worldwide and in Hong Kong. There is therefore a critical need to develop and refine efficacious treatments of chronic pain that address its various levels of impact to society.

1.3. Psychological factors of chronic pain

Chronic pain was once viewed and treated by physicians as a medical condition, aiming to find out and remove the underlying pathology that caused the pain. However, as there are many chronic pain conditions in which the underlying pathology cannot be found, chronic pain has been increasingly recognized as a complex, multifaceted condition that also involves psychological factors (e.g., Gatchel & Turk, 1996; Pincus, Burton, Vogel, & Field, 2002; Turk & Flor, 1999; Turk & Melzack, 2001; Turk & Okifuji, 2002). While acute pain is typically associated with

injury and will usually subside upon healing, chronic pain will persist beyond the expected period of healing and may reflect nociceptive, neuropathic or even unknown origins.

The literature suggests that while in the acute pain stage, biological factors might determine the impact of pain, psychological factors that reflect the person's reaction to pain have become increasingly important in determining distress and impact when pain has progressed to the chronic stage (Pincus et al., 2002). In other words, the chronicity of pain has lent room for psychological factors to infiltrate and augment the whole experience. Empirical studies have found that psychological factors may modulate, mediate, or maintain the pain experience (Birbaumer, Flor, Lutzenberger, & Elbert, 1995; Turk, 1997). There has been a term called "psychogenic pain"; however, whether psychological factors can really cause the pain has received much less empirical support (Turk & Monarch, 2002).

In examining the literature for factors that predict the transition from acute to chronic pain, it is noted that psychological factors such as maladaptive attitudes and beliefs, pain behaviors, and psychiatric diagnoses were more powerful predictors than physical factors such as severity of injury and physical demands of the job (Boothby, Thorn, Stroud, & Jensen, 1999; Johansson & Lindberg, 2000; Linton & Hallden,

1997). In one study, psychological variables accounted for 59% of the variance in disability associated with chronic pain (Burton, Tillotson, Main, & Hollis, 1995).

In a systematic review of the psychological factors that predict the chronicity of low back pain, Pincus et al. (2002) found that several factors (distress, depressive mood, somatization) were highly predictive of the transition from acute to chronic low back pain. In another article, Turk and Okifuji (2002) highlighted a number of psychological factors that might be involved in the chronic pain experience, including beliefs about the onset of pain symptoms, and fear and harm avoidance beliefs of pain. This literature strongly suggests the need to develop and test clinical interventions in order to directly target these psychological factors, particularly subjective distress, depression, and beliefs about pain. Other lines of investigation have addressed the role played by various cognitive variables in determining the levels of pain-related distress and disability in large samples of chronic pain patients. Key variables studied include catastrophizing (Cheng & Leung, 2000; Keefe, Brown, Wallston, & Caldwell, 1989; Sullivan et al., 2001; Sullivan, Bishop, & Pivik, 1995), perceived control (Rudy, Kerns, & Turk, 1988; Turk, Okifuji, & Scharff, 1995), fear-avoidance (Klenerman et al., 1995; Vlaeyen, Kole-Snijders, Boeren, & van Eck, 1995; Vlaeyen & Linton, 2000), self-efficacy (Dolce et al., 1986; Keefe et al., 1997; Lorig, Chastain, Ung,

Shoor, & Holman, 1989; Nicholas, 1994), and acceptance (McCracken & Eccleston, 2003; McCracken, Vowles, & Eccleston, 2005)

At the affective level, chronic pain is often found to be associated with a number of negative emotions (Robinson & Riley, 1999). Firstly, it is commonly reported that chronic pain is associated with depression. Studies suggest that the rate of depression in chronic pain patients ranges from 30% to 54% (Banks & Kerns, 1996; Dersh, Gatchel, Mayer, Polatin, & Temple, 2006). For example, it was found that in a sample of 382 individuals reporting chronic pain, 20.2% also met the diagnostic criteria of depression (McWilliams, Cox & Enns, 2003). Concurrently, the prevalence of pain in patients with depression ranged from 15 to 100% with mean prevalence of 65% (Blair, Robinson, Katon, & Kroenke, 2003). Secondly, the literature suggests a clear association between anxiety and pain. Asmundson and colleagues (Asmundson, Jacobson, Allerdings, & Norton, 1997) found that 17.8 % of chronic musculoskeletal pain patients met DSM-IV criteria for a current anxiety disorder. In a later report, this research group found pain complaints to be more common in patients with posttraumatic stress disorder when compared to a sample of healthy controls (Asmundson, Coons, Taylor, & Katz, 2002). Likewise, chronic pain patients endorsed higher levels of anxiety than published norms (Brown, Robinson, Riley, & Gremilion,

1996). Thirdly, anger was also found to be elevated in chronic pain patients (Schwartz, Slater, Bircher, & Atkinson, 1991). Brown et al. (1996) demonstrated that chronic pain patients reported higher levels of anger than published norms. In another survey of chronic pain patients, up to 70% reported angry feelings (Okifuji, Turk, & Curran, 1999).

1.4. Cognitive-behavioral therapy for chronic pain

1.4.1. Traditional cognitive-behavioral therapy for chronic pain.

Given the enormous economic and psychological burden caused by chronic pain, there is a pressing and critical need to develop efficacious treatments. While medically-based treatments such as medications and injections (e.g., Bonica, 1990; Loeser & Cousins, 1990) could offer effective pain reduction, research suggests that they alone are not adequate in alleviating the severity of the psychosocial impact chronic pain poses on the individual. In recent decades, psychological treatment for chronic pain has played an increasingly important role in pain medicine (Nicholas & Wright, 2001; Turk, 2003). Of the multitude of psychological treatments that have been proposed to be effective in the treatment of chronic pain, the gold standard treatment with the most robust empirical support is cognitive-behavioral therapy (CBT). A review of the literature on CBT for chronic pain is provided below.

With the development of the gate control theory (Melzack & Wall, 1965) and the biopsychosocial model of pain (Turk & Flor, 1999), psychological factors have been given an increasingly important role to play in the pain literature. It is evident that the chronic pain experience exists far beyond the sensory-discriminative level, and manifests expansively at the affective-motivational and cognitive-evaluative levels. In the 1970s, Fordyce (1976) was the first to apply the principles of operant conditioning to "pain behaviors", which refer to observable signs of pain and suffering. Later, Turk and his colleagues extended this line of research by explaining the role of attributions, efficacy, control, and beliefs about pain in the context of a "cognitive-behavioral" perspective of chronic pain (Turk & Flor, 1999; Turk, Meichenbaum, & Genest, 1983). This important conceptual expansion spawned the emergence of a wealth of treatments utilizing the cognitive-behavioral approach to chronic pain.

Cognitive-behavioral therapy (CBT) emphasizes the active role of individual information processing. CBT operates on the primary assumption that by altering the way individuals process internal and external information as well as their thoughts and beliefs toward those events, physiological, emotional and behavioral responses may be influenced. Further, specific desirable behaviors are encouraged through the use of operant conditioning, with emphasis on repeated practice of behavioral skills.

In the CBT framework, individuals are regarded as active participants by learning skills to proactively deal with their problems (Nicholas & Wright, 2001).

The past few decades witnessed the widespread application of CBT to chronic pain with the advent of cognitive-behavioral perspectives on pain and proliferation of multidisciplinary pain clinics worldwide, particularly in Europe, Australia, and the United States (e.g., Keefe & Caldwell, 1997; Nicholas & Wright, 2001). CBT for chronic pain aims at addressing residual pain after treatment as well as factors that maintain and potentiate pain and disability. It focuses on helping patients gain a sense of control over the effects of pain on daily life through modifying his/her emotional, cognitive and behavioral responses to pain (Turk, 2003).

Currently, various versions of CBT packages are available for the treatment of chronic pain. Core components of a standard CBT package typically includes psychoeducation on chronic pain, behavioral skills training (such as goal setting, pacing), relaxation, cognitive restructuring, and relapse prevention (Gatchel & Turk, 1996, Nicholas & Wright, 2001). The CBT package may be delivered on an individual or group basis. In recent years, multidisciplinary pain programs based on the CBT model have flourished in the US and Europe (Nicholas & Wright, 2001; Turk, 2003). In most cases, CBT is delivered in a modular format and focuses on helping patients

to gradually learn and apply coping skills, and helping them to live life more effectively in spite of pain. In such programs, there is no expectation the intensity of pain will be reduced after treatment. On the other hand, there is an explicit emphasis on functional goals such as reduced use of medications, increased exercise level and goal-directed activities, and improved mood functioning (Turk, 2003).

1.4.2. Outcome studies of CBT for chronic pain.

There is considerable empirical evidence that supports the efficacy of CBT for chronic pain (Astin, Beckner, Soeken, Hochberg, & Berman, 2002; Chen et al., 2004; Eccleston, Morley, Williams, Yorke, & Mastroyannopoulou, 2002;; Keefe & Caldwell, 1997; Linton & Nordin, 2006; Morley, Eccleston, & Williams, 1999; Spinhoven et al., 2004; Turner, Mancl, & Aaron, 2006; Weydert, Ball, & Davis, 2003). In a meta-analysis, Flor and his colleagues (Flor, Fydrich, & Turk, 1992) examined psychological treatments for chronic pain and concluded that multidisciplinary treatments for chronic pain are superior to waiting list and no-treatment in terms of pain, mood, interference to return to work, and healthcare utilization. These authors reported the treatment effects to be stable over time.

In a seminal systematic review of the literature, Morley and associates (1999) compared 25 trials on the effectiveness of CBT for chronic pain. They classified trials

in two broad categories: those comparing CBT with waiting list control, and those comparing CBT with alternative treatment control conditions. They found that CBT yielded a median effect size of 0.5 when compared with waiting list control, and that the effect sizes across all domains measured were significant (including pain experience, mood/affect, cognitive coping and appraisal, pain behavior and activity level, and social role functioning). On the other hand, when compared with alternative treatment controls (e.g., electromyography biofeedback, bibliotherapy, progressive relaxation), CBT yielded smaller effect sizes that were only significant in the domains of pain experience, positive cognitive coping and appraisal, and pain behaviors. The authors concluded that CBT-based treatments are effective in the treatment of chronic pain.

Meta-analyses of CBT trials exist with regards to a variety of chronic pain conditions, including chronic back pain (Hoffman, Papas, Chatkoff, & Kerns, 2007; van Tulder et al., 2001), fibromyalgia (Rossy et al., 1999), and headache (Bogaards & ter Kuile, 1994). These papers all reported findings comparable to the seminal paper by Morley and colleagues (1999). For example, Hoffman et al. (2007) specifically reviewed 22 randomized controlled studies of psychological interventions for chronic low back pain and calculated 205 effect sizes. They found that in general,

psychological interventions were found to have better outcomes of pain intensity, pain-related interference, health-related quality of life, and depression when compared with control groups. Cognitive-behavioral treatments were specifically found to be efficacious, yielding pooled effect sizes of 0.34 to 0.62 when compared with wait-list controls.

1.4.3. Criticisms of traditional CBT for chronic pain.

Despite the popularity of CBT and its rich evidence base for the treatment of chronic pain, there remain a number of issues and criticisms. Many of these issues are similar to those raised by researchers evaluating the application of CBT treatments for other psychiatric conditions, such as depression and anxiety disorders (e.g. Wampold, 2001; Wampold et al., 1997).

Despite generally successful treatment outcomes, a significant portion of chronic pain patients still do not appear to benefit from CBT across research and clinical settings (Turk & Rudy, 1990). Specifically, the effect sizes of CBT for chronic pain were modest (median effect size=0.5, Morley et al., 1999; effect size range 0.34 to 0.62; Hoffman et al., 2007). In contrast, CBT for other psychopathologies often yielded relatively larger effects (e.g., effect size of CBT for generalized anxiety disorder has been estimated to be 0.74; cf. Gould et al., 2004). One might argue then

that the "Dodo bird effect" cannot be excluded from this range of effect sizes with regards to CBT for chronic pain (e.g., Beutler, 1998; Lambert & Bergin, 1994). Clearly, the search for additional treatment modalities that might benefit more chronic pain sufferers is needed.

Related to the above criticisms directed at CBT for chronic pain are the cogent comments that although CBT appears effective, there is no clear evidence of whether there are differential outcomes for other active psychological treatment approaches. Moreover, despite the application of CBT to chronic pain for nearly three decades, there is relatively limited information about the specific mechanisms that contribute to the reduction of chronic pain and/or disability in patients. In other words, little is known about the "active ingredients" in CBT that contribute to positive treatment outcomes (Vlaeyen & Morley, 2005). Hence, more specific and elaborated outcome research on CBT for chronic pain is needed to systematically tease apart the relative contributions of different treatment ingredients to positive outcomes.

Take one example developed by Vlaeyen and Linton (2000) – the fear avoidance model. This model proposes that those chronic pain patients with high fear of pain might show more avoidance responses in anticipation of their pain. Moreover, exposure-based treatments aiming to reduce patients' fear avoidance response to pain

have been shown to be effective (Boston & Sharpe, 2005; Leeuw et al., 2008; Vlaeyen, de Jong, Geilen, Heuts, & van Breukelen, 2002). However, it is still not understood whether all chronic pain patients, or just a subset of them with high fear responses, could benefit from this approach.

In light of the above issues, Vlaeyen and Morley (2005) raised some valuable suggestions that might remedy the current shortcomings in outcome research for chronic pain patients. They employed the concept of "aptitude treatment interactions" to illustrate that patient aptitudes are likely to interact with treatment modality and outcome. In an effort to enhance treatment effectiveness, they suggested that psychological treatments for chronic pain should be more theory-driven in order to avoid Type III errors (i.e., threats to theoretical validity). They argued that "second generation" randomized controlled trials (RCTs) of outcome research should be deliberately theory-driven and tested. Finally, the authors also noted that theory-driven treatments would be instrumental in enhancing the process variables that link chronic pain to effective psychological treatments.

1.5. Recent cognitive neuroscience findings regarding chronic pain

One recurrent issue central to CBT for chronic pain is its relatively weak theoretical base and the lack of clearly established mechanisms to account for its

"active ingredients." Due to the fact that CBT was originally developed three decades prior and its strong basis on cognitive psychology and operant conditioning, there is historically relatively limited understanding of its specific mechanisms as related to the brain and the central nervous system (Keefe et al., 2004). With the rapid advance of neuroscience and neuroimaging studies in the past few decades, much more is now known about the neural bases of the pain experience, including its sensory, affective, and cognitive dimensions. This section will highlight some key recent findings on the neurobiological underpinnings of pain. These findings will inform much about chronic pain and any theoretical basis from where more effective and specific psychological treatments of chronic pain could be developed.

1.5.1. Beyond peripheral and spinal: Cortical systems involved in pain.

Traditionally, pain is conceptualized in terms of its circuit in the peripheral nervous system. The classic mechanical stimulus-response paradigm explains pain in terms of its biological function of avoiding further harm. However, this simplistic model fails to fully account for the complex mechanisms involved in chronic pain (Bonica, 1990). The gate-control theory (Melzack & Wall, 1965) offered a much improved version of pain mechanism by specifying supraspinal processes that amplify or inhibit ongoing pain (by opening or closing the "gate" at the spinal dorsal horn).

However, the neural systems that proposed by Melzack and Wall are limited to brainstem-spinal systems with little reference to the higher cortical systems. Hence, little is known about the sequence of events that take place at the higher cortical systems once nociceptive signals pass through.

Recently, the proposal of peripheral and central sensitization processes that underlie chronic pain at the peripheral-spinal level has received increasing and definitive support (Loeser & Treede, 2008). There is also a growing body of recent neuroimaging research that shed light on the supra-spinal processes in the pain experience (Mackey & Maeda, 2004). A recent study mapped out the supra-spinal correlates of central sensitization and found that it is the brainstem that likely maintains the central sensitization in humans (Lee, Zambreanu, & Tracey, 2008).

When we look further to the processing of pain at the perceptual and affective levels, recent functional brain imaging studies have identified several key areas in the cortex that are activated during experimental pain. These include the primary and secondary somatosensory cortices, thalamus, the insula and the anterior cingulate cortex (ACC; Coghill, Sang, Maisog, & Iadarola, 1999; Mackey & Maeda, 2004; Peyron, Laurent, & Garcia-Larrea, 2000; Porro, Cettolo, Francescato, & Baraldi, 1998; Porro et al., 2002). Drawing on results from a series of hypnotic induction studies,

Rainville and associates (Hofbauer, Rainville, Duncan, & Bushnell, 2001; Rainville, Carrier, Hofbauer, Bushnell, & Duncan, 1999) differentiated between brain structures that cater more to the sensory aspect of pain (primary somatosensory cortex) and those more to the affective aspect of pain (ACC). Consistent with an attention model that supports the ACC's function as a regulator of both affective and cognitive processes (Bush, Luu, & Posner, 2000), the activation of the ACC during pain may reflect regulation of the emotional and behavioral responses to pain (Rainville, 2002). Specifically, awareness of both the pain-related affect and emotions was implicated in the ACC region, particularly the rostral ACC (Lane et al., 1998).

At the prefrontal cortex (PFC) level, a wealth of neuroimaging studies have rapidly spawned in the past decade that illuminated the likely structures and processes in the PFC that are associated with the cognitive modulation of pain (Wiech, Ploner, & Tracey, 2008). Specifically, different areas in the PFC have been proposed to modulate attention, expectation and appraisal in pain processing. These areas include the dorsolateral prefrontal cortex (DLPFC; Lorenz, Minoshima, & Casey, 2003), orbitofrontal cortex (Bantick et al., 2002; Petrovic & Ingvar, 2002), ventrolateral prefrontal cortex (VLPFC; Wiech et al., 2006), and ventromedial prefrontal cortex (VMPFC, Ploghaus, Becerra, Borras, & Borsook, 2003).

Bantick and associates (2002) employed functional magnetic resonance imaging (fMRI) techniques to illustrate the role played by attention in pain modulation in humans. Participants in this study were imaged while they were administered intermittent thermal pain stimuli. These researchers introduced a cognitively demanding task (the "counting" Stroop task, a variant of the Stroop task, which requires mental counting of the letters in words presented) and compared the participants' brain activity during the cognitively demanding task to a less demanding neutral task. Results indicate that during the cognitively demanding task, reported pain intensity scores were significantly lower than during the less demanding task. Correspondingly, the pain matrix (thalamus, insula, cognitive division of the ACC) showed reduced activation, while the affective division of the ACC and orbitofrontal regions showed increased activity. The authors concluded that the current findings provided the neural basis through which attention modulates pain. This study played an instrumental role underlying novel therapeutic approaches for chronic pain that are based on attention manipulation.

In a later study, Valet and colleagues (2004) conducted functional MRI on healthy volunteers in an attempt to investigate how experimental heat pain would be modulated by a cognitive distraction task -- the color-word Stroop task. Similar to the

findings by Bantick et al. (2002), these authors found that distraction significantly reduced the pain intensity, unpleasantness ratings, as well as pain-related activation in the brain. Conversely, distraction was also associated with increased activation of the cingulo-frontal cortex, which includes the orbitofrontal cortex, perigenual ACC, midbrain pariequeductal gray (PAG), and posterior thalamus. Valet and associates suggested that the cingulo-frontal cortex may exert top-down control on the midbrain PAG and posterior thalamus during pain modulation by way of distraction.

Lorenz et al. (2003) used positron emission typography (PET) scanning to tap the role of the DLPFC during painful thermal stimulation. Results indicate that both left and right DLPFC activities correlated negatively with pain intensity and unpleasantness. Left DLPFC activity correlated negatively with midbrain and medial thalamic activity, suggesting that its negative correlation with pain affect may result from dampening of the connectivity of the midbrain-medial thalamic pathway. Further, right DLPFC activity was associated with a weakened relationship of the anterior insula with pain intensity and affect. The authors proposed that the DLPFC exerts active executive control on pain perception through the modulation of corticosubcortical and corticocortical pathways.

Wiech and associates (2006) showed that perceived control over experimentally

induced pain likely worked via the right anterior VLPFC as the signal level in this brain region during a controllable pain condition correlated negatively with the subjective intensity of pain. It is important to note that activation of the right VLPFC was also indicated in neuroimaging studies of emotion regulation (Lieberman et al., 2007). Therefore, the right VLPFC might have a pivotal role in the modulation of aversive stimuli by way of reappraisal.

In summary, the perception of pain itself is likely represented in the areas of somatosensory cortices, thalamus, insular, and ACC. Additionally, the prefrontal cortex (DLPFC, orbitofrontal cortex, VLPFC) likely exerts top-down modulatory control on the perception and experience of pain.

1.5.2. Attention and pain.

Attention is a set of cognitive activities that prepare organisms to respond to task or environmental demands (Eccleston, 1994). In the case of pain, the literature suggests that it likely demands a large amount of attention due to its survival value in organisms, and it takes precedence over competing nonpainful stimuli (Eccleston & Crombez, 1999). Earlier experimental studies have established the existence of selective attention bias of pain-related material in healthy individuals or individuals with chronic pain. Moreover, for those who are fearful or hypervigilant of pain

showed particular difficulty in disengaging from the pain-related stimuli (Crombez, Hermans, & Andriasen, 2000; Dehghani, Sharpe, & Nicholas, 2003, Keogh, Ellery, Hunt, & Hannent, 2001; Keogh, Thompson, & Hannent, 2003).

In recent years, there have been a number of studies combining experimental and neuroimaging approach using functional magnetic resonance imaging (fMRI) and event-related potentials (ERP) to study the relationship between pain and cognition (Seminowicz & Davis, 2006, 2007a, 2007b, 2007c; Van clef & Peters, 2006; Veldhuijzen, Kenemans, de Bruin, Olivier, & Volkerts, 2006) . Taken together, these studies converged in terms of two important observations. Firstly, pain appears to draw on the same attentional network required by cognitive tasks (Seminowicz & Davis, 2007a). Secondly, in the case of acute pain, while pain does not affect the performance of cognitive tasks, cognitive tasks (especially if the task difficulty is sufficiently high) will in some cases modestly reduce the attention to pain (Seminowicz & Davis, 2007b). However, these studies have been criticized for using mainly normal volunteers whose acute pain was experimentally induced. It may be argued that given their longstanding history of experience and responses to pain, chronic pain patients would likely yield an entirely different response pattern in similar experiments.

Recent studies have shed light on the likely pattern of attention and pain in chronic pain patients. For example, Seminowicz and Davis (2006) employed healthy individuals and demonstrated that high catastrophizing subjects were more likely to be unable to disengage from and suppress pain during intense pain induction. Such inability to shut down cortical responses to pain may interrupt ongoing attention to cognitive tasks (Vancleef & Peters, 2006). For chronic pain patients who are more likely to engage in catastrophizing (cf. Severeijns, Vlaeyan, van den Hout, & Picavet, 2005), this might result in a vicious cycle of negative pain experience and prolonged interruption to daily life functioning that requires continuous performance of many tasks.

The discovery that cognitive task might reduce attention to pain may cause one to wonder whether distraction is an effective pain coping strategy. In fact, as suggested by Seminowicz and Davis (2007c), the support from the literature on this point is mixed. Some studies (e.g., Doman, 2004; Veldhuijzen et al., 2006) showed that, at least in experimental pain, pain was attenuated by a distraction task, and this effect was related to pain-evoked anterior cingulate cortex (ACC) activity. Nouwen and colleagues (2006) compared distraction to focused attention on the perception of experimental (cold pressor) pain in both chronic pain patients and normal controls.

Results showed that compared to controls, chronic pain patients showed higher pain intensity and discomfort ratings in focused attention condition, whereas in the distraction condition no significant difference in pain intensity and discomfort was found. While this may reflect distraction as a superior strategy to focused attention for experimental pain in chronic pain patients, the authors cautioned that if the relative efficacy of distraction versus focused attention were extrapolated over time, focused attention would emerge as the more effective strategy for longer pain episodes (McCaul, Monson, & Maki, 1992).

Overall, experimental and recent neuroimaging data on the relationship between attention and pain suggest the presence of attention bias in the form of selection attention to pain or pain-related stimuli and problem with disengaging from pain or pain-related stimuli. This attention bias is likely moderated by pain intensity and catastrophizing. Specifically, attention to pain is attenuated by distraction tasks in normal controls and at milder pain intensity levels. For more intense levels of pain and in chronic pain patients who are more prone to catastrophizing, however, it would be more difficult to disengage from pain.

1.6. Mindfulness-based therapies for chronic pain

1.6.1. The problem with control of pain in traditional psychological therapies

In "traditional" psychological therapies for chronic pain, much emphasis is placed on changing the control of the pain experience. For example, it has been argued that CBT functions by way of enhancing one's perceived control over pain by teaching different "active pain coping strategies" and boosting one's self-efficacy through activities (Arnstein, Wells-Federman, & Caudill, 2001; Jensen & Karoly, 1991, 1992; Turner, Holtzman, & Mancl, 2007). However, as argued in previous sections, these forms of CBT yielded moderate effect sizes at most. Additionally, traditional approaches were often plagued by threats to internal validity such as high dropout rate and attrition of subjects (Vlaeyen & Morley, 2005).

It is noted in clinical observations of chronic pain patients that their efforts to control pain frequently turn into a matter of failure. Coping strategies in the form of distracting one's attention from pain have been found to sustain only relatively short-term effects. Even more proactive strategies to increase one's control over pain, including relaxation, cognitive restructuring have been criticized for only being able to account for a modest proportion of the disability variance in chronic pain patients (McCracken, 2007; McCracken & Eccleston, 2003). A more realistic scenario

in chronic pain patients is that one's efforts to control pain does not always succeed, and patient's repeated failures in attempting to control their pain would very likely compound their psychological burden and distress.

A recent study by Crombez and colleagues (Crombez, Eccleston, De Vlieger, Van Damme, & de Clercq, 2008) demonstrated that in an experimental paradigm using healthy volunteers, those who initially gained control over pain then lost showed a more unpleasant pain experience and more fear about impending pain than yoked control subjects who lost their control pain from the outset. Further, participants were found to narrow their focus on pain and tried harder and harder to avoid pain. The key insight that can be drawn from the Crombez study is that interventions targeting control over pain may inadvertently increase one's sense of loss of control when pain persists and the relative effects of interventions fade. In the case of psychological therapies such as CBT, if too much emphasis is placed on enhancing one's control over pain and reducing pain, the "flare-up" of persistent pain may potentially compromise treatment effects, and in unfortunate cases, even increase one's fear and vigilance towards pain. Novel approaches to psychotherapies must seek to remedy this untoward effect.

1.6.2. Kabat-Zinn's mindfulness approach.

Recent years have witnessed the proliferation of mindfulness-based psychotherapies. The term "mindfulness" has roots in Eastern Buddhist mental training for thousands of years. According to Kabat-Zinn, one of the pioneers of mindfulness-based therapies in the West, mindfulness is a purposeful paying of attention to the moment-to-moment presence in a nonjudgmental manner (Kabat-Zinn, 1994). Since 1979, Kabat-Zinn and colleagues have developed and refined a mindfulness-based stress reduction (MBSR) program at the University of Massachusetts Medical Center for patients with chronic medical problems (Kabat-Zinn, 1990). The application of MBSR has been empirically studied in a number of studies that included medical patients with a variety of cancer, pain, and stress conditions. In terms of its active ingredients, MBSR consists of a number of meditative mindfulness training skills, including breathing meditation (mindful breathing), walking meditation (mindful walking), body scanning (mindful of body sensations), and yoga (mindful stretching).

1.6.3. Applying mindfulness training to pain.

Mindfulness training has long been applied in treating chronic pain, as Kabat-Zinn recruited many patients in his MBSR programs who presented with

chronic pain problems. Kabat-Zinn (1990) described succinctly how mindfulness can be applied to pain by focusing on and paying attention to pain, one can learn to disidentify with it, hence avoiding the aversion toward or catastrophizing about pain. It is encouraged that by paying attention to pain while maintaining the sense of integrity as a whole person one can avoid getting stuck with the pain. Kabat-Zinn encouraged participants to use body scanning to observe and become aware of their physical pain. He also emphasized the maintenance of a "nonjudgmental" attitude in which one should not be tempted to feel distressed about pain or expect pain to disappear during the meditation and scanning exercises. Further, consistent with the "nonjudgmental" attitude, pain-related automatic distressing thoughts such as "I can't stand it any longer" and "The pain is killing me" are just treated as transient mental activities.

Recent conceptualizations of applying mindfulness training to chronic pain began as a sequential line of research headed by McCracken and colleagues (McCracken et al., 2005) to study acceptance-based and mindfulness-based approaches to chronic pain. These authors conceptualize chronic pain patients as being afflicted with the process of restricted awareness, with overwhelming influences from distressing thoughts and emotions, and having formed habitual patterns of

ineffective avoidance of their pain experience. In their view, mindfulness-based treatment methods are one way to address the above problems in intractable chronic pain patients. In a correlational analysis of self report measures, McCracken, Gauntley-Gilbert, and Vowles (2007) found that mindfulness training significantly and uniquely predicted physical, social, cognitive, and emotional functioning. A literature review of acceptance-based approaches initiated by McCracken's group will follow in the later section entitled "*Acceptance-based approaches to chronic pain.*"

1.6.4. Outcome studies on mindfulness-based therapies.

Mindfulness-based therapies have received good empirical support for a variety of health conditions including chronic pain, cancer, stress, heart disease, immune function, depression, and anxiety (e.g., Chang et al., 2004; Davidson et al., 2003; Kabat-Zinn, Lipworth, & Burney, 1985; Kabat-Zinn et al., 1992; Tacon, Caldera, & Ronaghan, 2005; Tacon, McComb, & Caldera, & Randolph, 2003; Teasdale, Segal, Williams, Ridgeway, Soulsby, & Lau, 2000). A meta-analysis by Grossman, Nieann, Schmidt, and Walach (2004) showed that when compared with no treatment or waiting list controls, MBSR yielded medium effect sizes of approximately 0.5, suggesting its efficacy in a broad range of clinical and nonclinical problems.

In the area of chronic pain, earlier studies by Kabat-Zinn and colleagues reported

optimistic outcomes of MBSR (Kabat-Zinn, 1982; Kabat-Zinn, Lipworth, & Burney, 1985; Kabat-Zinn, Lipworth, Burney, & Sellers, 1987). Similar outcomes were noted by a more recent study that examined the efficacy of MBSR for chronic pain patients (Randolph, Caldera, Tacon, & Greak, 1999). Some studies have applied MBSR and a variant of this program to fibromyalgia (a chronic pain condition characterized by widespread pain and remissions and exacerbations, in which there is no clearly known organic pathology) and yielded positive effects (Kaplan, Goldenberg, & Galvin-Nadeau, 1993; Singh, Berman, Hadhazy, & Creamer, 1998). Taken together, results of these studies suggest that MBSR was associated with significant improvements in pain rating, other medical symptoms, activities level, and mood symptoms, with most effects maintained at follow-up (up to four years). It should be noted that the majority of the studies cited above were uncontrolled and utilized pre-post designs.

The last few years saw the emergence of randomized controlled studies of applying mindfulness training to the treatment of chronic pain. Kingston, Chadwick, Meron, and Skinner (2007) used university students in a randomized, single-blind, active-control design to compare mindfulness practice with an active control of guided visual imagery. Results showed that the mindfulness group showed

significantly improved pain tolerance (cold pressor induced), but not mood, pulse, or systolic blood pressure, over the active control group. Plews-Ogan and colleagues (Plews-Ogan, Owens, Goodman, Wolfe, & Schorling, 2007) conducted a randomized trial comparing MBSR (8 weekly sessions), massage and standard care on chronic pain patients, and found that the massage group performed significantly better than MBSR in improvements in pain unpleasantness and a mental health score at week 8, but MBSR showed more significant improvements in mental health scores at week 12.

Morone, Greco, and Weiner (2008) studied the effect of a 8-week mindfulness meditation program modeled after MBSR on older adults with chronic low back pain in a randomized controlled pilot study. They found that compared to the control group, the intervention group displayed significant improvement in pain acceptance and Physical Function scale of SF-36, a health-related quality of life scale. Effect size was medium (*physical Function*) to large (*pain acceptance*).

Zautra et al. (2008) compared CBT to mindfulness intervention (with both mindfulness and emotion regulation components) in adults with rheumatoid arthritis, a chronic pain condition in a randomized controlled study. Results showed that participants receiving cognitive behavioral therapy showed greatest improvements in self-report pain control and reductions in interleukin-6, whereas both cognitive

behavioral therapy and mindfulness intervention groups showed more improvement in coping efficacy than the education-only control group. In addition, participants with a history of depression benefited most from mindfulness intervention across several outcome measures, when compared to those without history.

However, Baer (2003) noted that the mean effect size of mindfulness-based therapies for chronic pain across four studies was a modest 0.37 (compared to 0.96 for psychiatric disorders). Hence, there appears to be much room for improvement in design rigor and effectiveness enhancement in the systematic study of mindfulness-based therapies for chronic pain.

1.6.5. Mechanisms of mindfulness therapy

In recent years, there have been a number of experimental studies that have attempted to uncover the possible working mechanisms of mindfulness. Shapiro, Carlson, Astin and Freedman (2006) proposed that mindfulness may work through three components (axioms): (1) intention (from self regulation to self exploration to self liberation), (2) attention (sustained attention, switching of attention, and cognitive inhibition), and (3) attitude (qualities of acceptance, kindness and openness). They also stipulated a process of "reperceiving", which involves a fundamental metacognitive shift in one's perspective as a result of practice in the above three

components.

A recent flourish of neuroimaging studies provide rich evidence base to the possible mechanisms of mindfulness that may be related to some of the components proposed by Shapiro et al. (2006). Mindfulness or meditation training has been found to enhance the attentional network and/or attention regulation (Jha, Krompinger, & Baime, 2007; Lutz, Slagter, Dunne, & Davidson, 2008; Slagter et al., 2007; Tang et al., 2007). Enhanced attention regulation through mindfulness has also been suggested to reduce undue elaborative processing of emotional stimuli by avoiding getting stuck in any particular stimulus (Lutz et al., 2008). Using fMRI techniques, Short et al. (2007) found that better attention regulation (sustained attention and attentional error monitoring) by way of meditation was related to activation in the DLPFC and ACC. Additionally, evidence suggests that mindfulness may work through de-coupling automaticity (habitual automatic firing patterns in the brain), thereby correcting habitual reactions (Begley, 2007; Siegel, 2007; Wenk-Zormaz, 2005).

1.7. Acceptance-based approaches to chronic pain

1.7.1. Acceptance and commitment therapy.

Acceptance-based approaches were spawned in the 1980s when Steven Hayes developed a Relational Frame Theory in dealing with human language and cognition

out of his research in functional contextualism. Subsequently, acceptance and commitment therapy (ACT; Hayes, Strosahl, & Wilson, 1999; Hayes, Wilson, Gifford, Follete, & Strosahl, 1996) was developed to help one learn to deal with private experiences (emotions, sensations, thoughts, etc.) and focus back on personal meaningful goals. Six core domains or elements are described in typical ACT: acceptance, contact with the present moment, values, committed action, self as context, and cognitive defusion (Hayes, Luoma, Bond, Masuda, & Lillis, 2006).

ACT has been hailed as the third wave of CBT (Baer, 2005; Hayes, Follete, & Linehan, 2004). While broadly grouped under the category of mindfulness- and acceptance- based approaches, ACT stands in contrast with traditional CBT in terms of a number of its tenets. Negative, distressing thoughts are not attempted to be changed, but rather being aware of and accepted as they are. What are changed are rather the contextual behavior responses to such thoughts (or emotions). In other words, ACT promotes "psychological flexibility" in individuals such that one's behaviors are not habitually driven by thoughts and emotions, especially distressing ones, as before.

1.7.2. Evidence base for ACT.

Since its inception, ACT has been successfully applied to a number of clinical

disorders, including depression, generalized anxiety disorder, social phobia, posttraumatic stress disorder, eating disorders, borderline personality disorder, substance abuse, and psychosis. It has also been applied to health problems such as smoking, diabetes, worksite stress, and chronic pain (Hayes et al., 2004, 2006). There had been eight randomized controlled trials up to 2004, demonstrating the superiority of ACT over treatment-as-usual or other forms of psychological interventions (Hayes et al., 2004; Gaudiano & Herbert, 2006; Gregg, Callaghan, Hayes, & Glenn-Lawson, 2007; Zettle & Rains, 1989).

1.7.3. Acceptance-based approaches to chronic pain.

The application of ACT to chronic pain has yielded optimistic results in recent years (Dahl, Wilson, & Nilsson, 2004; Dahl, Wilson, Luciano, & Hayes, 2005). McCracken and colleagues invented "contextual cognitive behavioral therapy (CCBT)," which applies the key ACT components of acceptance, valued-based actions, and mindfulness to chronic pain patients. It has been consistently shown that acceptance-based treatments lead to improved emotional, physical functioning, and lessened interference due to pain (McCracken, 2005; McCracken et al.,2005; McCracken, MacKichan, & Eccleston, 2007; Vowles & McCracken, 2008). Effect sizes were medium or larger (Vowles & McCracken, 2008).

Despite positive outcomes, all of the above studies employed uncontrolled research designs. The only randomized controlled study in the literature was one by Wicksell et al. (Wicksell, Ahlqvist, Bring, Melin, & Olsson , 2008). These researchers compared an exposure- and acceptance-based treatment protocol (under ACT framework) to a wait-list control in a sample of chronic pain and whiplash-associated disorders patients. They found significant differences in favor of treatment group in terms of pain disability, life satisfaction, fear of movements, depression, and psychological inflexibility. However, no change was observed in either group in terms of pain intensity.

In summary, mindfulness- and acceptance- based approaches to chronic pain appear to be a promising improvement over traditional CBT in terms of its larger effect size and more specific delineation of its mechanism of change. To date, however, neither approach has been able to tease out a single active ingredient as the central mechanism of change in CBT, at least in the context of chronic pain. It is possible that attention to pain in a mindful way in mindfulness-based approaches or acceptance of pain in acceptance-based approaches would be a good candidate of such active ingredient. However, both mindfulness- and acceptance- based approaches encompass such a number of components that one is difficult to tell which one is

indeed the central component that causes change in the case of chronic pain. For example, in MBSR, it is unclear if only one or all of its key components (i.e., mindful breathing, mindful walking, and yoga exercises) are necessary to bring about the change in mindful attention to pain. Similarly, in the ACT or CCBT paradigm with six core components, it is again unclear if only one or all of them are needed to bring about the mechanism of change.

1.8. A "cleaner" mindfulness-based approach: Four Steps by Schwartz

Owing to the spiritual underpinnings of mindfulness-based therapies including MBSR, the exact mechanisms that lead to change remain unclear. The recent decade saw the emergence of a relatively 'cleaner' mindfulness-based approach by psychiatrist Jeffrey Schwartz. Schwartz's novel approach, named "Four Steps," (FS) is based on his work with patients with obsessive-compulsive disorder (OCD). Schwartz (1996) applied the bare attention practice (that is mindful awareness) borrowed from Buddhist mindfulness training to his OCD patients in an effort to bail them out of their subjectively distressing obsessions and compulsions. He noted that the central problem of OCD does not lie in cognitive distortions; rather, he contended that it is the inability to flexibly shift distressing thoughts to more adaptive ones (a phenomenon which he likened to "brain lock") that contributes mostly to their

disturbance. Schwartz hypothesized that the therapeutic key to the treatment of OCD may be by educating patients to become aware of their excessive emotional reactions to their distressing thoughts (probably due to an overactive and 'stuck' brain circuit) and encouraging them to react nonemotionally to those thoughts. The FS approach consists of the following steps (Schwartz, 1996):

1. *Relabel*: Patients are provided with psychoeducation on OCD and are taught to correctly identify their intrusive thoughts and urges as symptoms of OCD.
2. *Reattribute*: Following Relabeling, patients are taught to correctly attribute their intrusive thoughts and urges to faulty neurocognitive mechanisms. The neurocognitive mechanisms of OCD are taught to patients to enhance awareness that there is not a real need to act on the obsessions and compulsions; they are just products of faulty brain mechanisms.
3. *Refocus*: After Relabeling and Reattributing, Schwartz (1996) applied the mindfulness training to help patient develop willful, conscious, and effortful control of their mental activities by self-directing attention towards more fruitful activities despite anxious symptoms. In other words, instead of letting anxiety hijack patients' attention and then all other mental activities, the mindfulness training enables patients to get back volitional control of their attentional

processes and other mental activities even in the midst of anxiety. It is critical to be able to "refocus attention" willfully to other meaningful activities rather than allowing anxiety fully dominating our attentional processes.

4. *Revalue*: The final step is to revalue the OCD symptoms by not taking the OCD symptoms at face value but seeing them just as what they really are: they are merely products of faulty neurocognitive processes, hence devaluing these once preoccupied and overwhelming symptoms in their lives.

Since the 1990s, Schwartz and colleagues have applied the FS approach to hundreds of OCD patients. There have been some positive results regarding its efficacy. PET scan data show that the FS treatment decreased OCD symptoms and cooled down the overactive brain circuits in OCD (Schwartz, 1997, 1998, 1999; Schwartz et al., 1996). There have been evidence of bilateral decreases in caudate nucleus metabolism and reduction in the correlation between the metabolic rates of orbitofrontal cortex and caudate nucleus. However, it is noted that the FS approach has yet been tested in controlled or randomized trials. Further, there have been limited applications of FS to other clinical conditions above and beyond OCD, including chronic pain.

1.8.1. The relevance of the FS approach to chronic pain.

Comparing to traditional CBT and other mindfulness-based therapies, strengths of the FS mindfulness approach lie in several areas. First, the development of this treatment approach is based on clear understanding of the neurocognitive mechanisms underlying the disorder. Second, FS provides patients with clear explanation of the nature and neurocognitive mechanisms of the disorder from which they are suffering. Third, its intervention strategy specifically targeted key neurocognitive processes (e.g., to replace anxiety-driven attention and cognitive processes with self-directed attention and cognitive processes) underlying the disorder. Fourth, its treatment effectiveness is supported by solid neuroimaging evidence.

The FS approach is particularly relevant to treatment of chronic pain because of its emphasis on helping patients to develop volitional control of attention and other mental activities. Recent neurocognitive model of pain and recent neuroimaging findings suggest that pain readily dominates attention (resulting in attention bias) and other cognitive processes (resulting in cognitive biases) in one's mind unless it is effortfully disrupted by active attention efforts (e.g., Bantick et al., 2002; Crombez & Eccleston, 1999). As a result, chronic pain patients readily fall prey to a habitual, pain-driven model of attention and cognitive processing.

Mindfulness-based therapies such as MBSR are generally effective for pain reduction by teaching patients to accept pain and focus their attention to observe the impermanent nature of pain in a non-judgmental manner. FS takes one step further by training patients to develop willful, conscious, and effortful control of one's mental activities by self-directing one's attention towards more fruitful activities despite anxious (or pain) symptoms (Schwartz, 1999; Schwartz & Begley, 2002). In other words, instead of letting anxiety (or pain in chronic pain patients) hijack one's attention and other mental activities, the FS training helps patients develop volitional control of their attention and other mental activities even in the midst of anxiety (or pain). The literature suggests that volitional re-direction of attention can modulate pain perception (ACC) and that voluntary, concerted efforts to actively shift attention (by DLPFC) might modulate the regulation of pain (Bantick et al., 2002; Lorenz et al., 2003). Taken together, it is reasonable to conjecture that the FS approach may help chronic pain patients to develop volitional control of their attention as well as their mental reactions to pain.

1.9. Rationale of current research

1.9.1. The FS approach targets neurocognitive processes in chronic pain.

The present study attempted to adapt the FS approach for the treatment of chronic pain. Recent neurocognitive models of pain (Wiech et al., 2008) suggests that pain goes through the mind in successive stages via the sensory/perceptual, affective/motivational and cognitive/evaluative processes, and the pain experience could be amplified or attenuated in the process, depending on how the mind reacts to pain. During the chronic pain experience, mental activities can amplify the pain experience (e.g., difficulty with disengaging from pain, catastrophizing over the threat value of pain), and mental activities can also attenuate the pain experience (e.g., ability to shift attention from pain to other constructive activities, expecting attenuation of pain in accord with past pain experiences, and reappraising and diminishing the threat value of pain). By developing mindful awareness of how the mind reacts to pain, one could learn to transform the habitual, maladaptive mental reactions to pain and replace it with volitional and adaptive mental responses.

The FS bears advantages over other mindfulness- or acceptance-based approaches for chronic pain as it clearly addresses the above neurocognitive processes. Its design is carefully informed by neurocognitive processes (in other words, how the mind

reacts to pain) in the chronic pain experience. The FS model translates the knowledge of neurocognitive processes into psychoeducation for patients so that they may obtain hands-on understanding about the nature and development of their pain-related suffering. It also directly targets the neurocognitive processes that amplify and perpetuate the pain experience. To the best of the author's knowledge, FS is the only treatment within the current mindfulness- and acceptance-based approaches for chronic pain that incorporates such features.

1.9.2. Integration with mindfulness exercises.

The current adaptation of FS (hereafter renamed Four-step Mindfulness-based Therapy, FSMT) for chronic pain patients included a number of "core" mindfulness training exercises, including mindful stretching, mindful body scan exercises, mindful breathing, and mindful meditation. Such integration complements the four steps in achieving the education and change processes within the FSMT approach. We kept the number of mindfulness exercises to a core minimum in an effort to reduce potential confounding effects.

1.9.3. Modified FSMT approach for chronic pain.

The following is a description of the modified four steps applied to chronic pain in the present treatment package.

1. Relabel. In this first step, patients learn to understand that the pain and related problems (e.g., activity interference, distress) they are experiencing are just parts of a syndrome called chronic pain disorder, and the chronicity of the pain is more closely related to how one's mind reacts to pain than to injuries in the body.
2. Reattribute. In this step, patients learn to understand how pain comes to dominate their attention and other mental processes, resulting in a habitual and maladaptive mental reaction pattern that amplifies and perpetuates their pain. In other words, they learn to reattribute the cause of chronic pain to how their minds react to pain, not some unidentified body injuries. Patients also learn to free their mind from pain-driven cognitions through a series of mindfulness training exercises (such as mindful breathing, mindful meditation).
3. Refocus. After understanding how pain comes to dominate their attention and mental processes and learning to free their mind from pain-driven cognitions, patients learn to mindfully and willfully disengage their attention from pain, and to refocus on constructive life activities instead. These new, mindful responses pave the way for attenuation of their pain experience.

4. Revalue. In this last step, patients learn to view their pain from a different perspective, and to assign less importance to pain sensation *per se*. They will see that pain is just a simple sensation, as long as our minds do not turn it into a disaster.

1.9.4. Research design.

In considering research design, it is clear that a randomized control trial is the most pertinent option over pre-post or open trials. The use of a control group allows one to eliminate the uncertainty regarding the process of change as merely due to passage of time. In evidence-based medicine, a randomized controlled trial would yield level I evidence which is of the highest quality (Guirguis-Blake, Calonge, Miller, Siu, Teutsch, & Whitlock, 2007). Moreover, the choice of sampling from clinical patients rather than the normal population will make research findings more readily applicable and generalizable to clinical practice. Additionally, under the umbrella of mindfulness- and acceptance-based therapies, FSMT has not been known to pose serious risk or side effects to patients. Hence, the ethical concerns of any adversity in carrying out a trial with clinical patients are considered minimal.

1.10. Objectives of the present study

The present study tested the effectiveness of the FSMT for chronic pain patients

with the randomized controlled trial design in which the efficacy of the FSMT was compared to a waiting list control group. The specific hypotheses of this study were: (1) comparing to waiting list control, FSMT would show greater improvement at primary endpoint or in other outcome measures (pain, physical functioning, emotional functioning, and global improvement and satisfaction rating) and process measures (catastrophizing, self-efficacy, acceptance, and mindfulness) after the treatment; (2) these improvements would be maintained at follow-up; (3) clinically significant improvement of the outcome and process measures were expected to be greater in the FSMT than in the control group, and (4) the process measures would mediate the effects of treatment (FSMT vs. control) on the outcome measures.

Chapter 2: Method

2.1. Overview

The present randomized controlled trial (RCT) was conducted in accordance with the suggestions delineated in the revised statement of the Consolidated Standards of Reporting Trials (CONSORT; Moher, Schulz ,& Altman, 2001). The revised CONSORT statement consists of a 22-item checklist and participant flowchart that specify the important details of a high-quality RCT. Adherence to the CONSORT was accomplished item-by-item in the rest of the methodology sections. In addition, the current methodological considerations also took into account the suggestions of Chambless and Hollon (1998) regarding establishment of empirically supported therapies.

This study has been approved by the joint Chinese University of Hong Kong and New Territories East Cluster (a cluster of public hospitals under the Hospital Authority of Hong Kong) Clinical Research Ethics Committee (CREC; reference number: CRE-2007.506-T).

2.2. Participants

Participants of this study were recruited from the Pain Management Clinic at the New Territories East Cluster of the Hong Kong Hospital Authority. The inclusion

criteria were: (a) age 18 years or older; (b) having chronic pain of any type for more than three months; and (c) ability to communicate in Cantonese. The exclusion criteria were: (a) chronic pain stemming from malignant conditions such as cancer; (b) need for further diagnostic workup (including radiological or imaging studies) as determined from the Clinical Management System of the Hospital Authority, the access to which has been authorized for the present approved research; (c) history of major psychiatric conditions (severe depression, bipolar, or psychotic disorders), which was also determined from the aforementioned Clinical Management System; (d) concurrent participation in other medication or psychotherapy trials; (e) previous participation in group psychotherapy of any form; and (f) inability to comprehend any of the active treatment conditions (determined by the research staff). No compensation was rendered for participation in this study. All participants were guaranteed that participation in this research will not in any way affect their eligibility to receive optimal service in the pain clinic.

2.3. Procedures

Recruitment of the participants commenced in March 2008 by identifying and contacting consecutive patients at the Pain Management Clinic of the New Territories East Cluster of the Hong Kong Hospital Authority. A total of 472 patients received

telephone contact by a research assistant regarding their initial interest to participate in a study examining a new psychological treatment for chronic pain patients. A total of 246 patients agreed and came to a briefing session to obtain information on the study. Several briefing sessions were conducted by the principal investigator and a research assistant between April and June 2008 at Alice Ho Miu Ling Nethersole Hospital. During the briefing sessions, patients were provided with information concerning the objective of the study, the treatment under investigation (four-step mindfulness-based pain management therapy, FSMT), and were screened for eligibility as noted in section *2.2 Participants*. Subsequently, patients decided whether to consent for participation. A total of 99 eligible patients consented to participate in the study and indicated their decision by signing a consent form (see appendix A).

Prior to random assignment of consented patients, a research assistant generated random numbers in blocks of four using a true random number generator available from the Internet (www.random.org). No stratification was used during the randomization. The random numbers representing treatment assignment were concealed in envelopes from all participants and research personnel.

Following the participants' consent, the research assistant randomly assigned the 99 participants to either the treatment (FSMT) or wait-list control group according to

the random numbers previously concealed in envelopes. The 99 participants were contacted by telephone regarding their randomization results. Treatment group participants then started the group, which took place at the Alice Ho Miu Ling Nethersole Hospital. They were required to pay a regular outpatient consultation fee prior to every session. Treatment group participants completed the baseline questionnaires during their first group session. They also completed the same questionnaires at mid-group (defined as the end of session 4), post-treatment (8^{th} session), and three months after the completion of the group treatment. Wait-list control group participants were sent baseline and post-control questionnaires by mail and were asked to return them at around the same time as the treatment group participants completed their baseline and post-treatment questionnaires, respectively.

A research assistant was designated to call to remind participants to return the questionnaires or to resend for those who did not return the questionnaires within two weeks after the initial mailing date. The three-month follow-up questionnaires were not mailed to control group participants.

Two rounds of treatment groups were conducted in between May-June and July-August respectively during 2008. The initial round of wait-list control subjects were invited to participate in the treatment group after they had returned the

post-control questionnaires. Participants who consented to participate in treatment were crossed over to the second round treatment group. Due to manpower limitations, however, the second round of wait-list control participants were not invited to any more treatment groups at the end of the control period. They were only guaranteed preferential admission to any treatment group in the pain clinic setting that might be offered in the future subsequent to the conclusion of the present research.

Throughout the study, all participants continued to receive treatment as usual (TAU) from the pain clinic. This consisted of medication management, injections, physiotherapy and/or individual psychotherapy as needed (individual psychotherapy was conducted by the principal investigator as part of his clinical work duties). For the sake of clarity, the treatment group is now labeled "FSMT + TAU" and the wait-list control group "TAU only" since both groups received the TAU throughout.

To avoid potential confounding effects, all participants were advised to refrain from seeking alternative therapies, such as acupuncture, massage, or chiropractic treatment during the active study period.

2.4. Treatment protocol

Participants in the treatment condition were divided into groups of 10 to 12 persons. The cross-over participants were all under an independent group. They

attended two-hour group sessions per week over the course of eight weeks, totaling 16 treatment hours. The initial session comprised of psychoeducation conducted by a pain physician to educate participants about the nature of chronic pain in order to enhance the credibility of the treatment under investigation (the pain physician was blind to the hypotheses of the study). The remaining sessions focused on providing psychoeducation and implementing the FSMT in a modified format (in an effort to adapt the original version for OCD to chronic pain) to increase patients' mindful and active attention toward their pain and life. Participants were given homework assignments on a regular basis between sessions. A booster session was offered to participants three months after the conclusion of the treatment.

The details of each session was described in the next section. For further reference, the patients education materials and complete treatment manual (in Chinese) can be found in appendix B.

2.5. Treatment sessions in detail

2.5.1. Session 1.

During the first session, participants were asked to complete the baseline questionnaire. They then introduced themselves to each other and expressed their expectations toward the group. This was followed by distribution of handouts on the

psychoeducation on chronic pain and the rationale of the FSMT. A pain physician was then invited to deliver a brief lecture on chronic pain as a persistent condition with no known cure. Subsequent to the physician's departure from the group, the treating psychologist began moderating the group. Participants were introduced to the first step Relabel by acknowledging that their pain and related experience (distress, interference with activities, etc.) were part of a disorder called chronic pain. At this time, participants were explained about the psychological factors involved in the chronicity of pain. They learned to relabel that the symptoms of their chronic pain were critically related to how their mind habitually and negatively reacted to the persistent pain, and had actually little to do with ongoing injuries in the body. The FSMT approach was then explained as systematically training mindfulness skills through mindful breathing exercise, mindful body sensations, and mindful pain sensation in order to train the mind to replace habitual negative reactions toward chronic pain sensation with more volitional and constructive responses. Lastly, participants formed dyads and explained what they have learned in the first session to each other as a way of reinforcing their learning. This concluded the first step Relabel, during which participants learned about the nature of chronic pain and relabel their pain just as symptoms of the condition called chronic pain. The homework assignment

for the week involved requesting the participants to explain to their significant others what they had learned about the nature of chronic pain in the first session. It served to consolidate their understanding of the Relabel step.

2.5.2. Session 2.

In the second session, Reattribute - the second step of FSMT was introduced. Participants were taught that in their chronic pain experience, their attention and other mental activities were driven by ongoing pain, resulting in a habitual and maladaptive mental reaction pattern that amplified and perpetuated their experience of pain. They were informed that the mindfulness exercises they were to practice in the upcoming sessions would form a basis for them to reattribute the cause of chronic pain to how their minds reacted to pain.

A fundamental mindfulness skill, mindful breathing was then introduced and practiced during the session. Any prior misconception toward mindful breathing, such as over-controlling one's breath, was addressed and participants were asked to practice this skill on a daily basis using a mindfulness exercise CD (recorded specifically for the purpose of the present study) provided to them during the session. A 10-way stretching exercise handout was also distributed to the participants. The homework assignments for the week were daily practice of mindful breathing and

stretching exercise.

2.5.3. Session 3.

In the third session the group began with a review of the skills covered during the previous session prior to the introduction of a new mindfulness practice. Mindful breathing was reviewed as in the previous week's homework. A short "3-minute breathing space" exercise was then introduced as a quick way to access one's awareness of the present moment and space. Subsequently, the body scan was practised in the group. Participants' misconceptions or problems encountered during the exercise were addressed or corrected (e.g., falling asleep during the body scan exercise). The homework assignments for this session are daily mindful breathing, body scan, and stretching scan.

2.5.4. Session 4.

The fourth session began with a review of the body scan homework. This was followed by the introduction and practice of a new mindfulness practice, mindful stretching. Mindful stretching emphasizes the need for participants to become mindful of every movement or sensation (including pain) during the whole stretching exercise introduced to participants in prior sessions. The homework assignments for this week included daily mindful breathing, body scan, and mindful stretching. At the

end of the session, all participants were asked to complete a mid-group questionnaire.

2.5.5. Session 5.

This session began with a review of mindful stretching homework followed by introduction of participants to the last mindfulness practice, mindful mediation on pain. This served as a pre-requisite for the change in step 2 Reattribute. Participants learned to observe their own pain sensations through a meditation exercise in which they were asked to become aware of the sensations, thoughts, or emotions that went through their mind. They were to see them as though they were leaves on a stream before their mind. Subsequently, they were invited to discuss any problems encountered during the exercise. Participants then engaged in a discussion of the second step Reattribute in dyads. Specifically, they were asked to discuss with each other how they began to experience that their pain and suffering was related to the ongoing reactions of their minds. In other words, their pain and suffering was not a part of "themselves", but rather reflection of their mind's struggle with pain. They also discussed how they built upon the mindfulness exercises they practised so far to free themselves from their own pain experience, hence rendering themselves in a better position to relinquish habitual mental reactions to pain and lessen their own suffering. The homework assignments for this week included mindful breathing,

mindful meditation on pain, mindful stretching, and validation from significant others that they had learned to reattribute their pain experience as their own habitual reactions to pain.

2.5.6. Session 6.

This session began with participants' review of the mindful meditation on pain exercise followed by introduction of the third step, Refocus. Introduction of this step was attained by building on the changes participants went through during the first two steps. Participants were reminded that now that they have relabelled and reattributed the nature of accumulation of their pain-related distress, they should be in a better position to volitionally shift focus of their mind away from pain preoccupation to other constructive mental activities. They learned to make a list of preferred activities (e.g., reading, listening to music) and to set a 15-minute rule to perform such activities during which they could also experience pain at the same time. The emphasis was on the fact that despite their pain and pain-driven attention bias, they would be able to direct their mind volitionally and focus on other constructive life activities with sufficient mindfulness training. The in-vivo exercise during this session consisted of a short walk around the hospital block, with mindful attention devoted to the entire process, including the walking sensation and experience interaction with each other,

as well as the pain that could wax and wane during the activity. Homework for this week included mindful breathing, mindful meditation on pain, mindful stretching, and refocusing exercise.

2.5.7. Session 7.

The beginning of session 7 consisted of a review of the refocus homework troubleshooting for the problems participants encountered during the homework practice. At this time, participants were introduced to an integrative exercise in which participants were asked to form dyads and role-play a common example in their life that reflected distress and suffering caused by their chronic pain. They were asked to apply the mindfulness skills they learned during the previous sessions in an attempt to cope with the difficult situation. As a homework assignment, participants were asked to apply the mindfulness skills in a real situation they encountered during the week.

2.5.8. Session 8.

The final session began with a review of the situation application homework assignment. Participants were then introduced to the concept of relapse prevention (e.g., identifying triggers to pain and distress) and possible actions to address relapse. Participants were asked to devise their relapse prevention plans on paper to be

implemented in the future weeks. Finally, the fourth step Revalue was re-iterated now that participants should be able to understand the true nature of chronic pain experience from a very different perspective. The session ended with participants completing the post-treatment questionnaire.

2.5.9. Booster session.

The booster session was implemented three months following treatment completion. It was intended as an opportunity for participants to gather together, recapitulate themselves with the four steps, and share their practice of mindfulness to deal with pain during the past three months. They were also afforded with the opportunity to problem-solve any issues that might have arisen as impediment to their maintenance of progress (e.g., intense pain flare-up), and to encourage each other to continue the mindfulness practice in the future. At the end of the booster session, participants were asked to complete the three-month follow-up questionnaires.

2.6. Treatment fidelity and clinical significance: Competence, adherence, credibility and helpfulness

The treatment was implemented by two clinical psychologists (the principal investigator and another experienced clinical psychologist). Treatment fidelity was enhanced in multiple ways. Firstly, both treating clinical psychologists had more than

10 years of clinical experience and received training in mindfulness-based therapies (a seven-day professional training course in mindfulness-based stress reduction in the United States). The principal investigator was a Ph.D. candidate and the other treating psychologist had a Psy.D., both in Clinical Psychology. Secondly, the treatment protocols for FSMT were manualized. Thirdly, 20% of all treatment sessions were videotaped and was subject to a stringent adherence check by an independent clinical psychologist who was blind to the purpose of the study. Fourthly, weekly supervision meetings were held between the treating psychologists to discuss and troubleshoot issues that arose during treatment. Fifthly, there was an incorporation of physician education in the treatment protocol to enhance treatment credibility. The physicians who delivered such education were pain specialists with Diploma in Pain Management. Sixthly, pre-treatment credibility rating was obtained by asking participants to rate (on 11-point scales), how logical and useful the treatment appeared and how confident they felt that the treatment could help them control their pain and related problems. Finally, post-treatment global impression of change ratings (Guy, 1976) were obtained by asking participants to rate (on 7-point scales) the extent to which they believed the treatment helped them and their satisfaction with the treatment.

2.7. Measures

The primary measures used in this study were guided by the recommendations outlined by the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT; Dworkin et al., 2005). Specifically, these include the domains of pain, physical functioning, emotional functioning, and participant ratings of global improvement and satisfaction. Additionally, healthcare use pattern data were collected as secondary outcome measures. Several process measures of interest were also used. Chinese validated versions of empirical instruments were employed whenever feasible. Chinese versions of all questionnaires are attached in appendix C.

2.7.1. Pain.

Pain intensity and unpleasantness averaging across the previous week were measured by 11-point (0-10) numerical rating scales (Jensen, 2003).

2.7.2. Physical functioning.

The Multidimensional Pain Inventory Interference Scale (MPI; Kerns, Turk, & Rudy, 1985) was used to measure interference of general activity, work, relationship with others, and sleep due to pain. The MPI-Interference is an 11-item scale with robust reliability (alpha = 0.86-0.90) as well as construct and predictive validity (e.g., Dijkstra et al., 2001). It has been used in a number of empirical investigations on the

interference of pain with physical functioning. The MPI Interference was selected as the primary endpoint measure of this study as we regard this as the most important outcome for FSMT.

2.7.3. Emotional functioning.

The Beck Depression Inventory II (BDI-II; Beck, Steer, &Brown, 1996) was used. It has robust reliability and validity in measuring symptoms of depression and emotional distress. It comprises 21 items on a four-point scale ranging from 0 to 3. A Chinese version of BDI-II was available (Chinese Behavioral Sciences Society, 2000). The original Beck Depression Inventory was used in numerous chronic pain clinical trials (Kerns, 2003).

2.7.4. Global improvement and satisfaction rating.

The Patient Global Impression of Change Scale (PGIC; Guy, 1976) was employed to assess for global improvement and participant satisfaction. PGIC is a single-item rating on a 7-point Likert scale ranging from *very much improved* to *very much worse* with *no change* at midpoint.

2.7.5. Healthcare use patterns.

The frequency of sick leave (if applicable) taken in the past month due to pain, frequency of A&E visit due to pain in the past month, and frequency of visits to

general practitioner in the past month were measured.

2.7.6. Process measures.

The process measures used in this study were guided by the literature review in the introduction section in order to explore the likely processes of change by the FSMT treatment.

2.7.6.1. Pain Catastrophizing Scale (PCS; Sullivan et al., 1995). The PCS is a 13-item questionnaire used to assess the catastrophizing cognitions of individuals by asking them to reflect on their thoughts or feelings that were associated with past painful experiences. It has good temporal stability, internal consistency (alpha = 0.87), and validity. A validated version in Chinese is currently available (Yap et al., 2004, 2008).

2.7.6.2. Pain Self Efficacy Questionnaire (PSEQ; Nicholas, 1994). The PSEQ is a 10-item self-report inventory that assesses the strength and generality of a patient's self-efficacy beliefs and his/her confidence to accomplish a range of activities despite chronic pain. A Chinese validated version of the PSEQ with good reliability (alpha=0.93) and construct validity is available (Lim et al., 2007).

2.7.6.3. Chronic pain acceptance questionnaire (CPAQ). It is a 20-item inventory designed to measure acceptance of pain (McCracken et al., 2004). There are two principle factors measured by this questionnaire: activities engagement and pain

willingness. All items are rated on a 0 (*never true*) to 6 (*always true*) scale. Nine items measuring pain willingness were reverse-keyed. Following the scoring procedure of McCracken and colleagues, a single total score was calculated based on the nine reverse-keyed items and the other eleven items measuring activities engagement. The maximal possible total score is 120, with a higher score indicating better acceptance. A Chinese validated version is available (Cheung, Wong, Yap, & Chen, 2008).

2.7.6.4. Mindfulness Alertness and Attention Scale (MAAS). This is a 15-item questionnaire measuring individual differences in the frequency of mindful states over time. It focuses on the presence or absence of attention to and awareness of what is occurring in the present (Brown & Ryan, 2003). All items are rated as the frequency of which one has the experience described in the item, using a 6-point Likert scale from 1 (*almost always*) to 6 (*almost never*). It showed good test-retest reliability (intraclass correlation .81) and stability (confirmatory factor analyses confirmed a one-factor model). It also reported established good convergent and discriminant validity (Brown & Ryan, 2003). A Chinese version was translated by the principal investigator, then back-translated by an independent psychologist. The back translation was compared with the original English version for establishment of semantic equivalence. The Chinese version was then fielded tested by five chronic

pain patients who provided minor feedback on the measure's wording. These changes were reflected in the final version of the measure following field testing.

2.8. Statistical power and analyses

A priori sample sizes for each group were calculated ($n = 40$ for each group) to ensure that they are large enough to yield reasonable power (0.60), assuming medium effect size (0.5). Assuming an attrition of 20% after randomization, a total of 100 participants were estimated to need to be randomized for this study.

An "intention-to-treat" approach was adopted in the data analyses. All randomized participants who provided at least some midgroup, post-treatment or follow-up data were included. Missing values were handled by the last value carrying forward method. All variables were tested for normality. In cases when nonnormality was found, transformation of the variable to reduce skewness and kurtosis or an adjustment procedure in inferential statistics was carried out.

We did not make any statistical adjustments (e.g., Bonferroni method) for the multiple statistical comparisons in the present study. Due to the fact that we have chosen the primary endpoint as activity interference and other outcome measures (pain intensity, pain unpleasantness, and depression) are regarded as moderately correlated with the primary endpoint, findings of significant difference between the

two groups on these related outcomes would add credence to the treatment effect. Hence, adjustment for multiple comparisons was not necessary (Schulz & Grimes, 2005).

T-tests and chi-square tests were performed to detect any pretreatment differences between the FSMT + TAU and TAU only groups. Two-way mixed-design analyses of variance (*ANOVA*s), with the between-subject factor being treatment (FSMT + TAU vs. TAU only) and the within-subject factor being time (baseline vs. post-treatment), were then performed to compare the pre to post-treatment changes between the groups. Repeated-measure *ANOVA*s were also performed to assess for changes over time (baseline, midgroup, post-treatment, and three-month follow-up) in outcome measures within the treatment group.

Effect sizes were expressed as conventional Cohen's *d* (converted from partial eta squared) to show (a) the differences between the FSMT + TAU and TAU only group from baseline to post-treatment, and (b) overall differences in the FSMT + TAU over all time points of the study (baseline, mid-group, post-treatment, and follow-up).

Reliable change index (RCI) analyses were performed for both FSMT + TAU and TAU only groups. For each outcome and process variable, RCI was computed by dividing the difference between the baseline and post-treatment scores by the standard

error of the difference between the two scores.

Clinical significance change analyses were also performed for the FSMT + TAU and TAU only groups. The choice for the cutoff for each measures are delineated below. Measures of pain intensity and unpleasantless were employed in accordance with established criteria for pain intensity change of 30% as the clinical cutoff (Farrar, 2000, Farrar, Berlin, & Strom, 2003; Farrar, Young Jr, LaMoreaux, Werth, & Poole, 2001)). Due to the absence of clearly established norms in the literature for MPI Interference, we decided to adopt Jacobson, Roberts, Berns, & McGlinchey (1999)'s criterion of post-treatment score lying outside 2 *SD* beyond the mean of that population.

Either western or local (Hong Kong) norms for pain patients were available for all other measures. For BDI-II, a British norm for the chronic pain patient population (Poole, Bramwell, & Murphy, 2008) was used. Due to the availability of large Hong Kong pain patients samples (n >100) for PCS, CPAQ and PSEQ, the cutoffs were derived from their sample means and standard deviations (Cheung et al., 2008; Lim et al., 2007; Yap et al., 2008). Evans, Margison, & Barkham (1998)'s formula (illustrated below) was used to derive the cutoffs.

$$\frac{(M_{\text{post-treatment clinical}} \times SD_{\text{normative}}) + (M_{\text{normative}} \times SD_{\text{post-treatment clinical}})}{SD_{\text{normative}} + SD_{\text{post-treatment clinical}},}$$

where suffix "clinical" denotes the present group (FSMT + TAU or TAU only) and suffix "normative" denotes the respective normative values as above.

It should be noted that for the use of Evans' procedure, those participants whose baseline scores lied within the boundaries of the normative sample were excluded, as they did not show clinical significant change via this method.

We also tested whether any baseline variables served as moderators of outcome by constructing linear regression models for each outcome measure, with the dependent variable being the post-treatment value of the outcome measure and the independent variables being the baseline value of the outcome measure, the potential baseline predictor or moderator, the treatment group, and the interaction between the treatment group and the potential predictor/moderator. According to Kraemer, Wilson, Fairburn, and Agras (2002), baseline variables that showed main effect but not interaction effect with treatment group in regression models are nonspecific predictors of outcome. In contrast, those that showed interaction effect with treatment group are moderators of outcome.

Finally, to test mediation effects, we used three regression analyses for each outcome variable: (a) the treatment group (FSMT + TAU vs. TAU only) as predictor on the post-treatment score of each outcome measure, controlling for baseline score of the outcome measure; (b) the treatment group as predictor on the post-treatment score of each process measure, controlling for baseline score of the process measure; and (c) post-treatment score of the process measure as predictor on the post-treatment score of each outcome measure, controlling for baseline scores of the process and outcome measures and the treatment group. We then tested the indirect effect of treatment on the outcome through the mediator via a version of the Sobel test (Sobel, 1982) to see whether it is significantly different from zero. We also used the bootstrap method of Preacher and Hayes (2008) to estimate the unstandardized regression coefficient (*B*) and bias-corrected 95% confidence interval for each putative mediator based on 1000 bootstrap samples. Confidence intervals that do not include zero are regarded as showing a significant indirect effect.

We used the Statistical Package for the Social Sciences (SPSS) version 16.0 in all data analyses.

Chapter 3: Results

3.1. Adherence, attrition, cross-over group, and adverse effects

The flow of participants during the study can be found in Figure 1. For the four FSMT + TAU groups, out of 50 randomized participants assigned, six dropped out before the beginning of treatment. Possible reasons for pre-treatment dropout were the onset of acute depression, conflict of treatment with work schedule, or lack of interest. A further of nine dropped out during the treatment (defined as attending less than 50% of sessions, i.e. four sessions) during the treatment due to a lack of interest, conflict of treatment with work schedule, or hospitalization for other reasons not related to pain. Of the 35 remaining participants who completed the treatment, 16 (46%) completed all sessions, 17 (49%) completed six to seven sessions, and two (5%) completed four to five sessions. Overall, the completion rate of the treatment group was 70% (35 out of 50).

For the cross-over FSMT + TAU group, the completion rate was 69% (9 out of 13). The small size (n=13) of the cross-over group precluded any detection of significance in terms of pre- and-post treatment differences. Hence their data were not analyzed or reported in this study.

No observable adverse events took place during sessions in all treatment groups.

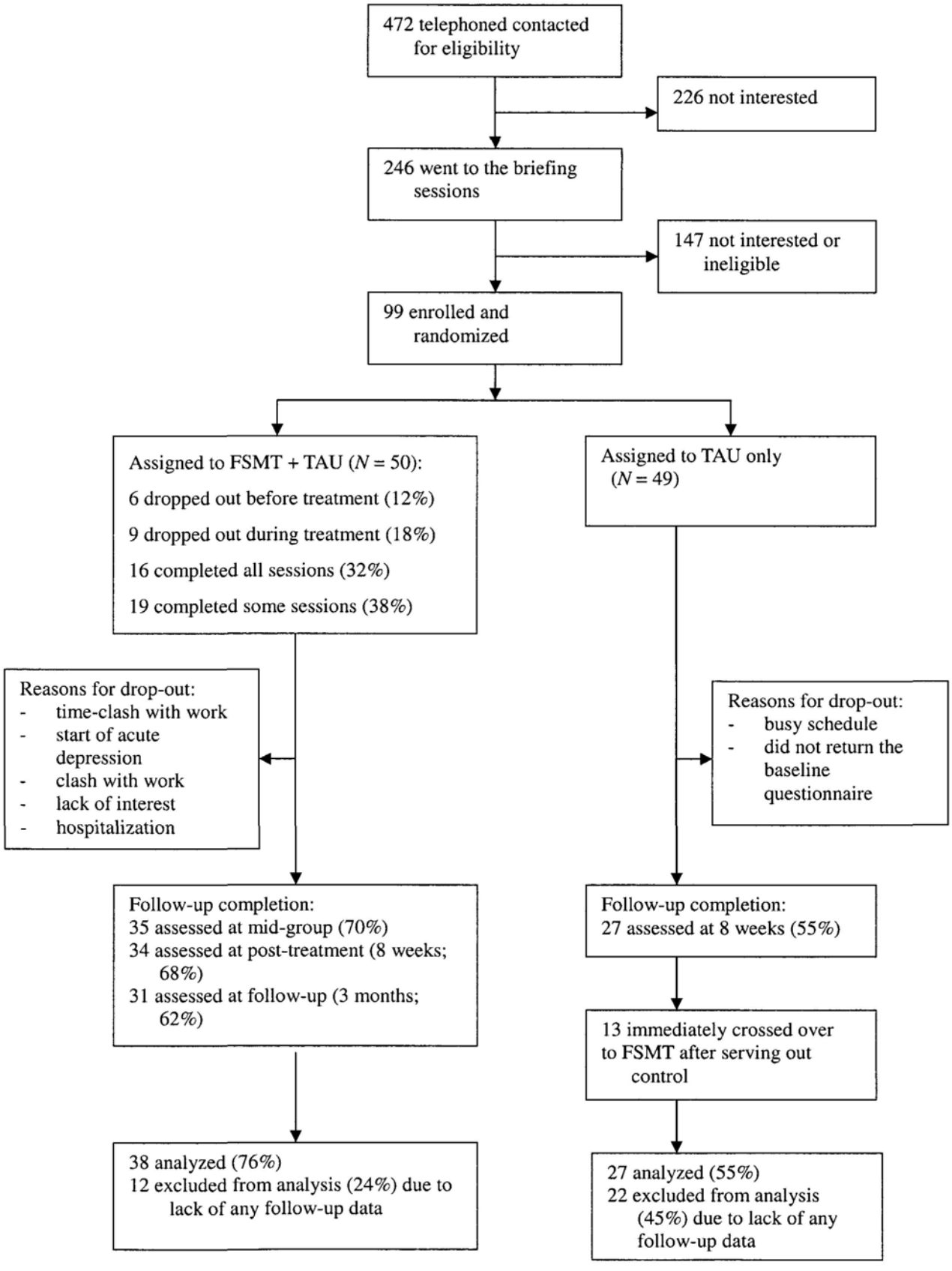

Figure 1. Participants flow of the study

For the control participants, 49 participants were randomized to the TAU only condition. Twelve did not finish serving as controls, due to busy schedules or the fact that they did not return the baseline questionnaire. A further 10 participants in the TAU only condition did not return the questionnaire. Twenty seven TAU only participants were able to provide post-treatment data. Thirteen crossed over to the FSMT + TAU condition after serving as control.

3.2. Intention-to-treat sample

The intention to treat sample consisted of all randomized participants who provided at least some mid-group, post-treatment, or follow-up data. Comparison was made between the intention-to-treat (ITT) sample (N=65) and those randomized participants who failed to provide at least some mid-group, post-treatment, or follow-up data (n=19). No significant difference was found between the two groups on any baseline variables (gender, education level, work status, duration of pain, type of pain, or work accident status), outcome, or process measures, except for the fact that the ITT sample reported significantly longer days of sick leave during the previous month (Ms = 15.3 vs. 2.3, $p < 0.001$). *Post-hoc* power for the primary

endpoint, activity interference, which showed an effect size (Cohen's *d*) of 0.66, with $N = 65$, was calculated to be 0.74.

Table 1 shows the demographic characteristics of this sample according to FSMT + TAU ($n = 38$) or TAU only ($n = 27$) groups. Compared to the TAU only group, the FSMT + TAU group tended to be older ($Ms = 48.3$ vs. 40.1, $p < 0.05$) and more likely to be married ($p < 0.05$). Otherwise, the two groups did not differ by gender, education level, work status, duration of pain, type of pain, or work accident status. Regarding the ITT sample, 45.5% were males, their mean age was 45.9 years (range = 18 - 63), 38.9 % received senior secondary education or above, their mean duration of pain was 73.4 months (range = 15 - 600), and 44.2% reported full-time or self-employed work. In addition, the type of pain comprised mostly of back pain (42.9 %) and neck/shoulder pain (17.5 %).

Table 1

Sample characteristics

Variable	Treatment condition		*p*
	FSMT + TAU (n = 38)	TAU only (n = 27)	
Age, mean (SD)	48.3 (8.2)	40.1 (12.9)	0.027
Gender (%)	Male 47.4	Male 41.2	0.670
	Female 52.6	Female 58.8	
Marital (%)	Single 10.8	Single 43.8	0.049
	Married 70.3	Married 50.0	
	Separated 2.7	Separated 6.3	
	Widowed 5.4	Widowed 0.0	
	Divorced 10.8	Divorced 0.0	
Education (%)	Primary 26.3	Primary 12.5	0.393
	Junior Secondary 2.1	Junior Secondary 31.3	
	Senior Secondary 15.8	Senior Secondary 37.5	
	Matriculation/Diploma 2.6	Matriculation/Diploma 6.3	
	Degree or above 13.2	Degree or above 12.5	
Work status (%)	Full time or self employed 42.1	Full time or self employed 50.0	0.611

	Part time or unemployed 57.9	Part time or unemployed 50.0	
Duration of pain	77.0 (109.1)	65.1 (59.1)	0.684
Mean months (SD)			
Type of pain (%)	Neck/Shoulder 18.2	Neck/Shoulder 15.8	0.770
	Back 43.2	Back 42.1	
	Arm/hands/wrists 4.5	Arm/hands/wrists 0.0	
	Buttock/hips 2.3	Buttock/hips 0.0	
	Legs/knees/feet 2.3	Legs/knees/feet 10.5	
	Chest 4.5	Chest 5.3	
	Head 2.3	Head 10.5	
	Neuropathic 6.8	Neuropathic 5.3	
	Joint 4.5	Joint 5.3	
	Multiple 4.5	Multiple 5.3	
	Others 6.8	Others 0.0	
Work accident (%)	55.3	40.0	0.317

Pretreatment analyses of outcome and process variables at baseline between the two groups were also performed. The two groups did not differ at any of the baseline levels (all independent sample t tests have p values of > 0.05). It is clear that the two groups were not different in terms of any outcome or process variables used in this study. Additionally, the two groups also did not differ in pretreatment usefulness and pretreatment helpfulness ratings ($p > 0.05$).

3.3. Post-treatment effectiveness of FSMT + TAU relative to TAU only: Changes in primary and secondary outcome measures

Table 2 shows the post-treatment changes in primary outcome measures. Overall, there was significant time effect in pain unpleasantness, ($F(1, 55) = 9.99$, $p = 0.003$) and BDI-II, ($F(1, 51) = 8.13$, $p = 0.006$). Post-treatment scores were lower than baseline scores, indicative of improvement over the treatment period. The time x condition effects were both not significant for pain unpleasantness and BDI-II, showing that there was no difference in the FSMT + TAU versus TAU only condition in improvement over time. There was a significant time x condition effect for MPI interference, ($F(1, 53) = 5.85$, $p = 0.019$). Inspection of the interaction effect (see Figure 2) showed that while FSMT + TAU group improved in MPI interference over time, the TAU only group worsened. For pain intensity, neither time nor

time-condition effect was significant. There was no statistical change in pain intensity over the treatment period. The effect size was calculated as Cohen's *d*. The mean difference between FSMT + TAU and TAU only conditions showed that for the outcome measures, the *d*'s ranged between *small* (*d* pain unpleasantness = 0.33) and *moderate* (*d* MPI Interference = 0.66, *d* BDI-II = 0.51).

All the secondary outcome measures of healthcare utilization used in this study (frequency of sick leave taken in the past month due to pain, frequency of A&E visit due to pain in the past month, and frequency of visits to general practitioner in the past month) were found not to show any post-treatment effects.

Table 2

Comparison of FSMT + TAU versus TAU only in primary outcome variables during the baseline to post-treatment period

Measure	Group	Baseline	Post-treatment	Time	Time	Time *x*	Time *x*	Effect
		mean (*SD*)	mean (*SD*)	*F*	*p*	condition	condition	size
						F	*p*	*d*
Outcome								
Pain intensity	F	7.0 (1.8)	6.8 (1.6)	1.25	0.268	0.01	0.925	0.00
	T	6.7 (2.0)	6.5 (2.1)					
Pain	F	7.4 (2.0)	6.0 (2.4)	9.99	0.003	1.51	0.225	0.33
Unpleasantness	T	7.0 (2.3)	6.4 (2.4)					
MPI Pain	F	43.6 (11.3)	40.7 (14.1)	0.08	0.781	5.85	0.019	0.66
Interference	T	38.9 (15.4)	42.5 (12.5)					
BDI-II	F	28.1 (16.6)	21.4 (15.6)	8.13	0.006	3.25	0.078	0.51
	T	28.8 (14.4)	27.3 (15.2)					

Note. F = FSMT + TAU; T = TAU only

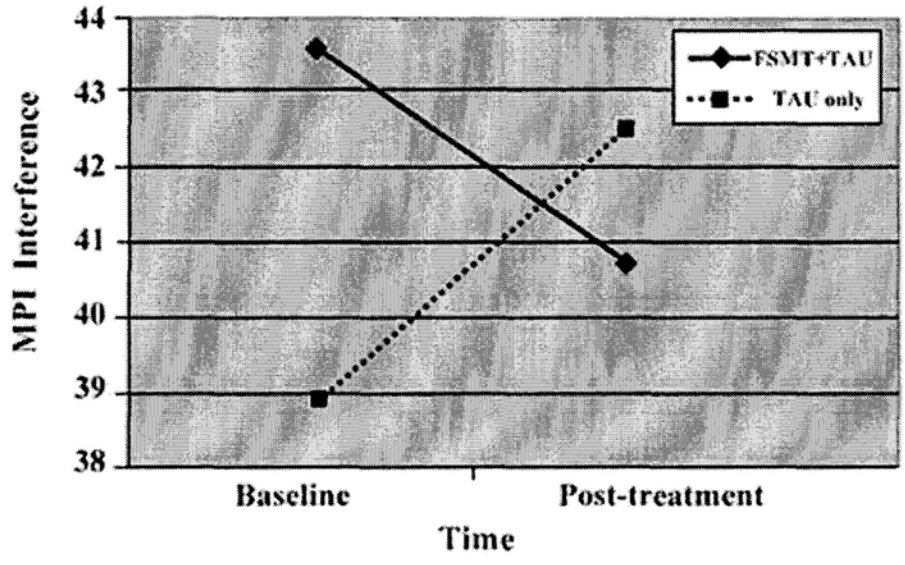

Figure 2. Interaction effects of time (baseline and post-treatment) by condition (FSMT + TAU and TAU only) illustrated for MPI Interference

3.4. *Post-treatment effectiveness of FSMT + TAU relative to TAU only: Changes in process measures*

Post-treatment changes in process measures were illustrated in Table 3. Significant time and time *x* condition effects were present for PCS, (time $F(1, 52) = 13.34$, $p = 0.001$); (time *x* condition $F(1, 52) = 10.31$, $p = 0.002$) and CPAQ, (time $F(1, 55) = 4.78$, $p = 0.033$); (time x condition $F(1, 55) = 7.44$, $p = 0.009$). Figure 3 and 4 examine the two interaction effects in detail. It can be seen that FSMT + TAU showed a shaper slope of decline than TAU only in PCS. Further, while FSMT + TAU showed improvements in CPAQ over time, TAU only showed a slight decline.

Table 3

Comparison of FSMT + TAU versus TAU only in process variables during the baseline to post-treatment period

Measure	Group	Baseline	Post-treatment	Time	Time	Time x	Time x	Effect
		mean (*SD*)	mean (*SD*)	*F*	*p*	condition	condition	size
						F	*p*	*d*
Process								
PCS	F	35.1 (12.7)	27.0 (12.5)	13.34	0.001	10.31	0.002	0.89
	T	33.7 (12.0)	33.1 (11.5)					
PSEQ	F	29.5 (14.0)	33.8 (13.8)	0.202	0.655	3.27	0.076	0.50
	T	33.6 (12.9)	31.0 (12.3)					
CPAQ	F	48.8 (13.8)	58.7 (15.4)	4.78	0.033	7.44	0.009	0.74
	T	48.8 (16.7)	47.7 (14.7)					
MAAS	F	49.5 (13.8)	49.5 (13.5)	0.000	0.988	0.000	0.988	0.00
	T	48.3 (14.1)	48.3 (12.2)					

Note. F = FSMT + TAU; T = TAU only

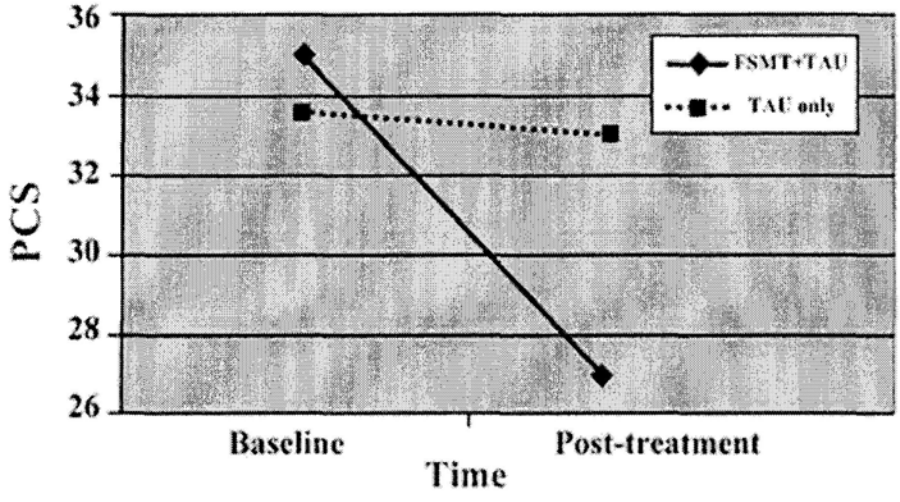

Figure 3. Interaction effects of time (baseline and post-treatment) by condition (FSMT + TAU and TAU only) illustrated for PCS.

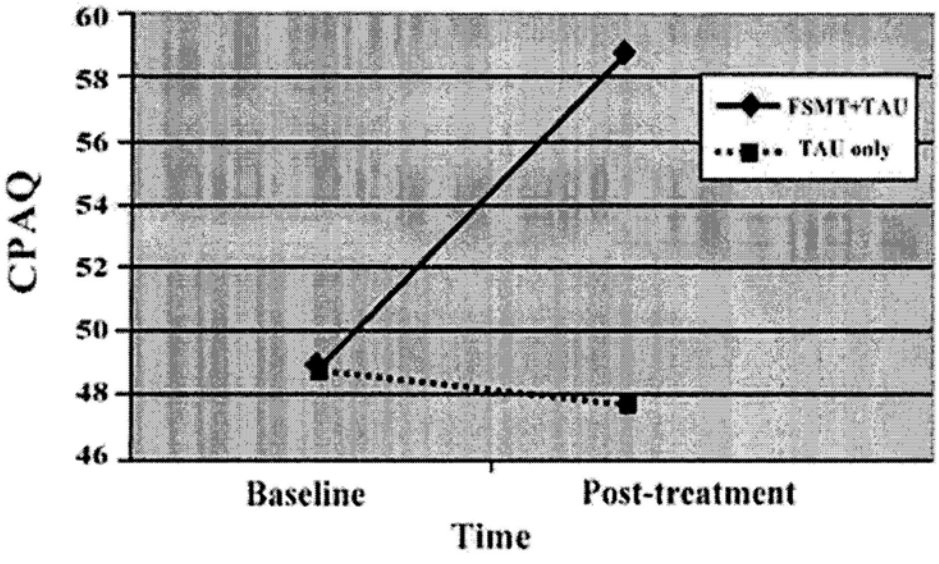

Figure 4. Interaction effects of time (baseline and post-treatment) by condition (FSMT + TAU and TAU only) illustrated for CPAQ.

The other two process variables (PSEQ and MAAS) did not show significant time or time *x* condition effect, although the PSEQ showed a trend toward significance ($p = 0.076$). Overall, the effect sizes of the process variables were in the *medium* (d PSEQ = 0.50 and d CPAQ = 0.74) to *large* (d PCS = 0.89) range.

Combining all outcome and process measures together, the median effect size at post-treatment (compared with TAU only) of the present study is calculated to be 0.51.

3.5. Maintenance of FSMT + TAU group in outcome and process variables from post-treatment to three-month follow-up

Three-month follow-up data were available for the FSMT + TAU group. Table 4 showed that there was no difference between post-treatment and follow-up for all outcome and process variables. This suggests that any change in outcome or process gained over the treatment period was maintained until follow-up for the FSMT + TAU condition.

Table 4

Maintenance effects of FSMT + TAU group in outcome and process variables from post-treatment to three-month follow-up

Measure	Post-treatment mean (*SD*)	3-month follow-up mean (*SD*)	Time *F*	Time *p*
Outcome				
Pain intensity	6.9 (1.6)	6.5 (2.3)	1.30	0.260
Pain unpleasantness	5.8 (2.6)	6.0 (2.8)	0.24	0.631
MPI Pain interference	40.5 (13.1)	39.3 (14.5)	0.30	0.586
BDI-II	22.8 (16.2)	26.5 (16.9)	2.06	0.160
Process				
PCS	28.3 (13.0)	30.5 (13.4)	2.20	0.148
PSEQ	33.0 (13.4)	32.4 (15.3)	0.06	0.809
CPAQ	58.2 (16.0)	58.7 (14.4)	0.05	0.825
MAAS	52.6 (14.7)	51.5 (15.8)	0.32	0.577

3.6. Contrast analyses of FSMT + TAU group from baseline to follow-up

The available data for FSMT + TAU in the outcome and process variables at the time points of baseline, midgroup (process variables only), post-treatment, and follow-up were subject to contrast analysis. Table 5 showed that there were significant main effects of time in pain unpleasantness, ($F(2, 26) = 7.16$, $p = 0.002$), BDI-II ($F(2, 23) = 3.64$, $p = 0.034$), PCS ($F(3, 21) = 7.20$, $p = 0.000$), and CPAQ ($F(3, 26) = 7.21$, $p = 0.001$). Contrast analyses showed that for outcome measures, there were significant linear and quadratic trend for pain unpleasantness, linear trend for MPI Interference, and quadratic trend for BDI-II. Regarding process measures, there were significant linear and quadratic trend for PCS and linear trend for CPAQ.

Table 5

Change of FSMT + TAU in outcome and process measured from baseline to follow-up

Measure	Baseline mean (*SD*)	Mid-group mean (*SD*)	Post-treatmen t mean (*SD*)	3-month follow-up mean (*SD*)	Time *F*	Time *p*	Contrast (*p*)	Effect size *d*
Outcome								
Pain intensity	7.1 (1.78)	NA	6.9 (1.6)	6.5 (2.3)	1.66	0.199	NS	0.50
Pain Unpleasantness	7.3 (1.9)	NA	5.8 (2.6)	6.0 (2.8)	7.16	0.002	Linear (0.016) Quadratic (0.008)	1.03
MPI Interference	44.3 (9.8)	NA	40.5 (13.1)	39.3 (14.5)	2.63	0.082	Linear (0.041)	0.65
BDI-II	29.4 (17.2)	NA	22.8 (16.2)	26.5 (16.9)	3.64	0.034	Quadratic (0.039)	0.78

Process								
PCS	37.1 (11.8)	31.5 (12.5)	28.0 (12.6)	31.1 (13.4)	7.20	0.000	Linear (0.005) Quadratic (0.002)	1.12
PSEQ	28.9 (13.4)	32.6 (14.1)	33.5 (13.4)	33.5 (14.7)	1.46	0.233	NS	0.48
CPAQ	48.0(12.6)	51.9 (15.0)	58.2 (16.0)	58.7 (14.4)	7.21 HF epsilon corrected	0.001	Linear (0.001)	1.02
MAAS	50.3 (13.4)	47.7 (13.2)	50.5 (12.9)	49.8 (15.1)	0.73	0.539	NS	0.34

Inspection of the contrasts showed that for the outcome measures, the linear trend pertained to the gains over the treatment period to maintain or carry over to the follow-up period (pain unpleasantness and MPI Interference, see Figures 5 and 6). Regarding the BDI-II, there was a quadratic trend indicating that the gain relapsed at follow-up (see Figure 7).

For the process variables, the quadratic trend of PCS showed that progress was steady from baseline through mid-group to post-treatment, followed by a relapse back to the mid-group level during follow-up (see Figure 8). The linear trend of CPAQ showed steady gains from baseline from mid-group to post-treatment, and the gain was maintained at follow-up (see Figure 9).

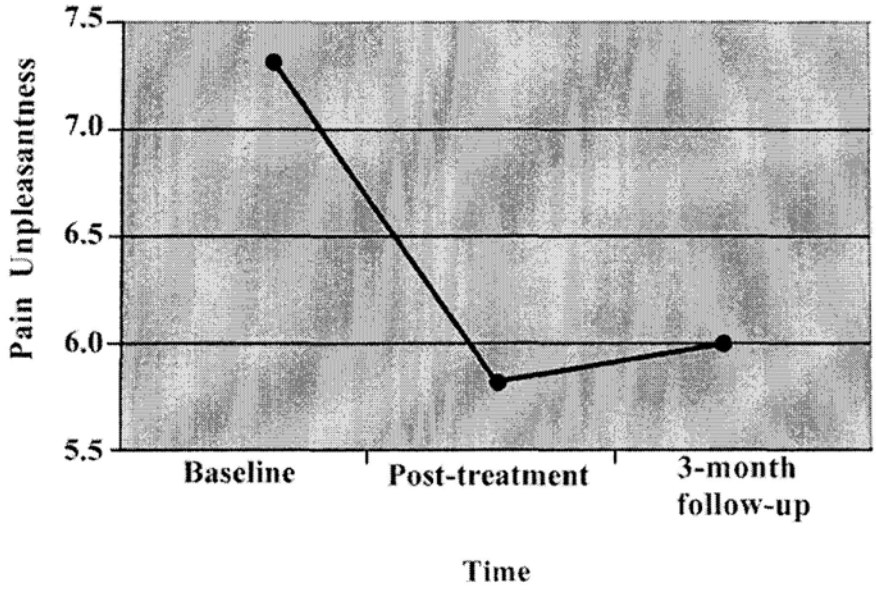

Figure 5. Change of FSMT + TAU in pain unpleasantness from baseline to follow-up.

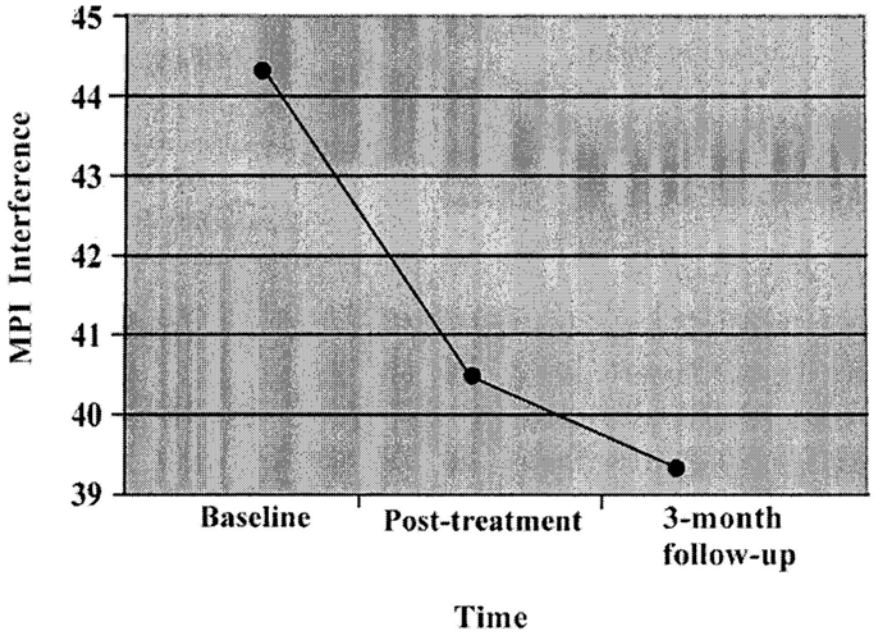

Figure 6. Change of FSMT + TAU in MPI Interference from baseline to follow-up

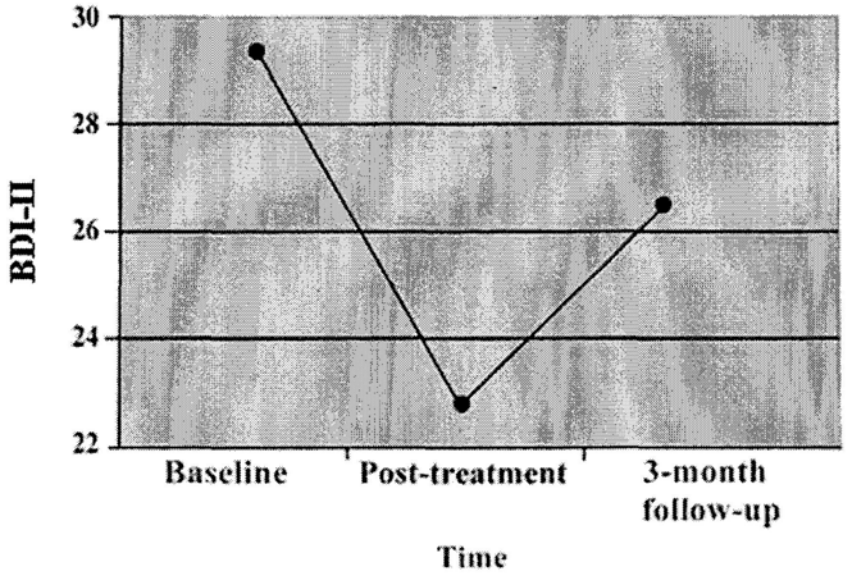

Figure 7. Change of FSMT + TAU in BDI-II from baseline to follow-up

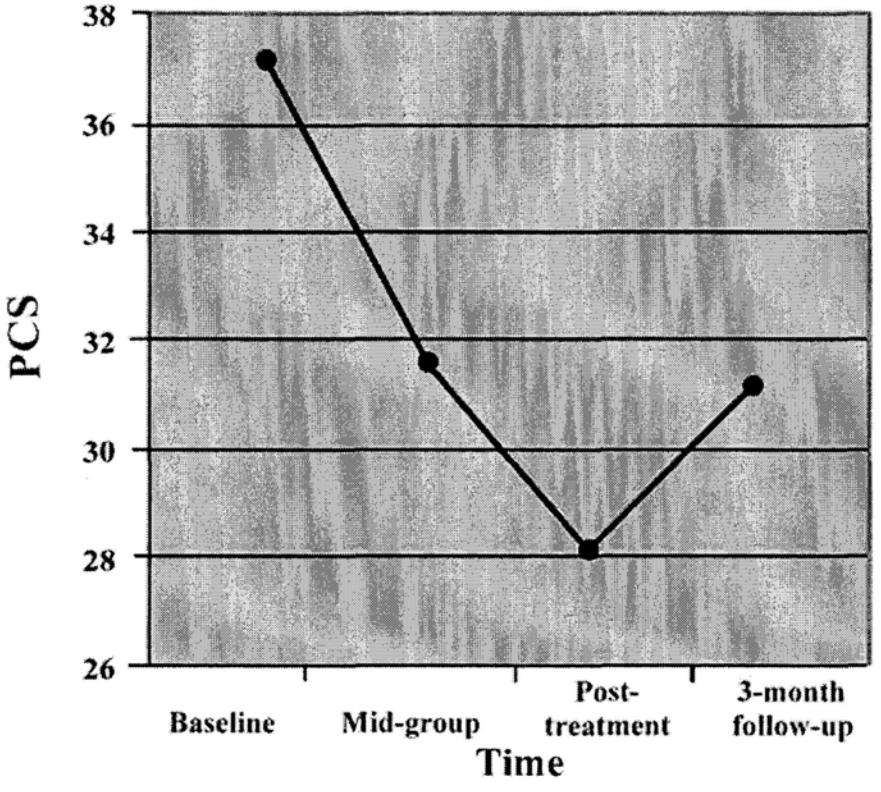

Figure 8. Change of FSMT + TAU in PCS from baseline to follow-up

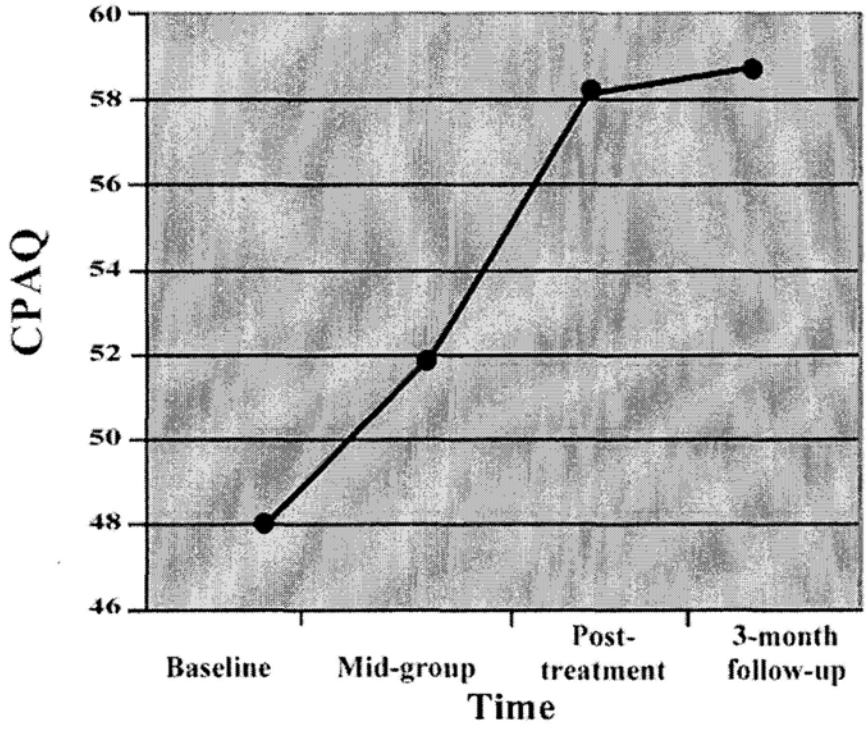

Figure 9. Change of FSMT + TAU in CPAQ from baseline to follow-up

3.7. *Nonspecific predictors and moderators of outcome*

Table 6 depicts some of the baseline variables that emerged to be nonspecific predictors for one or more of the outcome measures. Participants with longer duration of pain were more likely to report higher 8-week pain intensity levels. Moreover, participants with longer duration of pain, higher baseline pain intensity, higher baseline activity interference (MPI Interference), or higher baseline depression (BDI-II) were more likely to report higher 8-week pain unpleasantness.

In the tests for moderation effects, as shown in Table 6, pretreatment usefulness ($p = 0.036$) and pre-treatment helpfulness ($p = 0.028$) emerged as significant moderators of the treatment for the outcome of pain unpleasantness. Baseline pain intensity ($p = 0.013$) and pain unpleasantness ($p = 0.047$) significantly moderated treatment for the outcome of MPI Interference.

Table 6

Non-specific predictors/moderators of outcomes

Variable	Slope (β)	p
Pain intensity		
Duration of pain (predictor)	0.24	0.017
Pain unpleasantness		
Baseline pain intensity (predictor)	0.59	0.000
Baseline MPI Interference (predictor)	0.27	0.037
Baseline BDI-II (predictor)	0.34	0.021
Duration of pain (predictor)	0.27	0.038
Pre-treatment usefulness (moderator)	-0.33	0.036

Pre-treatment helpfulness (moderator)	-0.33	0.028
<u>MPI Pain interference</u>		
Baseline pain intensity (moderator)	-0.26	0.013
Baseline pain unpleasantness (moderator)	-0.24	0.047

3.8. Mediators for outcomes

Mediation analyses for putative mediators (process measures) of the FSMT + TAU (relative to TAU only) were conducted for each outcome. Following the advice by Preacher and Hayes (2008), the mediation analyses were performed even when there was no significant overall treatment effect for the outcome.

As depicted in Table 7, for the outcome of pain intensity, none of the process variables emerged as significant mediators. For the outcome of pain unpleasantness, however, PCS emerged as a significant mediator (B = 0.92, CI = 0.38, 1.80). For the outcome of MPI Interference, CPAQ (B = 4.04, CI = 1.08, 9.48) and PCS (B = 3.58, CI = 1.02, 7.98) emerged as significant mediators. For the outcome of BDI-II, CPAQ (B = 4.10, CI = 0.99, 7.77) and PCS (B = 2.68, CI = 0.46, 6.43) again emerged as significant mediators.

When both PCS and CPAQ were included as mediators, only PCS retained the statistically significant mediator effect for the outcome of MPI interference (B = 2.51, CI = 0.06, 5.77), and only CPAQ retained the statistically significant mediator effect for the outcome of BDI-II (B = 3.89, CI = 0.67, 9.18). Note that these results have not been illustrated in the table.

Table 7

Mediators of FSMT + TAU effects

Mediator	Estimate (95% CI)	Significance
Outcome: Pain intensity		
CPAQ	0.22 (-0.13, 0.68)	no
PCS	0.23 (-0.09, 0.79)	no
PSEQ	0.12 (-0.04, 0.51)	no
MAAS	0.01 (-0.06, 0.31)	no
Outcome: Pain unpleasantness		
CPAQ	0.56 (-0.21, 1.43)	no
PCS	0.92 (0.38, 1.80)	yes
PSEQ	0.27 (-0.07, 1.20)	no
MAAS	0.07 (-0.13, 0.67)	no
Outcome: MPI Interference		

CPAQ	4.04 (1.08, 9.48)	yes
PCS	3.58 (1.02, 7.98)	yes
PSEQ	2.71 (-0.17, 6.80)	no
MAAS	0.36 (-1.65, 3.22)	no
CPAQ + PCS	4.77 (1.50, 9.43)	yes
Outcome: BDI-II		
CPAQ	4.10 (0.99, 7.77)	yes
PCS	2.68 (0.46, 6.43)	yes
PSEQ	1.29 (-0.80, 4.62)	no
MAAS	0.17 (-0.82, 2.60)	no
CPAQ + PCS	4.90 (1.27, 9.20)	yes

3.9. Reliable change

To determine how many participants changed reliably over treatment, reliable change index (RCI) was calculated for each outcome and process measure for both FSMT + TAU and TAU only group participants. Table 8 shows the RCI and according percentage of reliable improvement for each measure, tabulated across FSMT + TAU and TAU only groups. In general, FSMT + TAU group participants showed more percentage of improvement compared with TAU only group in every measure. Statistically significant percentage difference between the FSMT + TAU and TAU only group was present for the measures of PCS ($p = 0.000$) and PSEQ ($p = 0.011$).

For the previously statistically significant outcome measures (pain unpleasantness, activity interference, and depression), FSMT + TAU achieved reliable of change in an average of 17.5% of sample, compared to an average of 2.9% of the TAU only sample. For the previously statistically significant process measures (pain catastrophizing and pain acceptance), FSMT + TAU achieved reliable change in an average of 31.3% of the sample, compared to an average of only 2.2% of the TAU only sample.

Table 8

Reliable change index of FSMT + TAU versus TAU only group

Measure	FSMT + TAU	TAU only	*p*
Pain intensity (r = 0.69)			
Reliable change index	2.86	2.90	
% Reliable improvement	2.9	0.0	0.405
Pain unpleasantness (r = 0.69)			
Reliable change index	3.29	3.40	
% Reliable improvement	14.7	4.3	0.211
MPI Pain interference (r = 0.86)			
Reliable change index	11.58	15.13	
% Reliable improvement	15.2	0.0	0.056
BDI-II (r = 0.92)			
Reliable change index	12.36	11.64	

% Reliable improvement	22.6	4.5	0.071
PCS ($r = 0.93$)			
Reliable change index	9.08	9.39	
% Reliable improvement	41.9	0.0	0.000
CPAQ ($r = 0.79$)			
Reliable change index	18.32	22.97	
% Reliable improvement	20.6	4.3	0.083
PSEQ ($r = 0.93$)			
Reliable change index	9.93	10.25	
% Reliable improvement	33.3	4.5	0.011
MAAS ($r = 0.90$)			
Reliable change index	12.85	12.96	
% Reliable improvement	9.4	9.1	0.972

3.10. Clinical significance change

Another important index of clinical significance is the clinical significant change. Table 9 shows the percentage of reaching clinical significance, according to pre-set cut-off or criterion, tabulated across FSMT + TAU and TAU only group for each measure. Similar percentage clinical improvement was obtained for the measures of pain intensity, MPI Interference, BDI-II, and MAAS (all differences were nonsignificant). On the other hand, FSMT + TAU achieved superior clinical improvement compared to TAU only in the measures of pain unpleasantness, PCS, CPAQ and PSEQ. Statistically significant differences between the two groups were found for CPAQ and PSEQ.

For the previously statistically significant outcome measures (pain unpleasantness, activity interference, and depression), FSMT + TAU achieved clinical significance in an average of 24.6% of sample, compared to an average of 21.2% of the TAU only sample. For the previously statistically significant process measures (pain catastrophizing and pain acceptance), FSMT + TAU achieved clinical significance in an average of 58.8% of the sample, compared to only 10.5% of the TAU only sample.

Table 9

Clinical significant change (CSC) for the FSMT + TAU versus TAU only group

	FSMT + TAU	TAU only	*P*
Pain intensity (cutoff = reduction in 30%)			
% CSC	5.9	8.7	0.683
Pain unpleasantness (cutoff = reduction in 30%)			
% CSC	29.4	17.4	0.301
MPI Pain interference (cutoff = 21.36)			
% CSC	9.1	7.7	0.848
BDI-II (cutoff = 26.00)			
% CSC	35.3	38.5	0.858

PCS (cutoff = 30.90)			
% CSC	31.8	6.7	0.068
CPAQ (cutoff = 46.26)			
% CSC	85.7	14.3	0.001
PSEQ (cutoff = 28.63)			
% CSC	50.0	0.0	0.021
MAAS (cutoff = 78.37)			
% CSC	2.9	4.0	0.824

Putting it altogether, a higher percentage of the FSMT + TAU group achieved reliable change on the outcome and process measures than the TAU only group (average of 17.5% vs. 2.9% for three outcome variables and 31.3% vs. 2.2% for two process variables). Further, the FSMT + TAU also showed a significantly higher percentage of clinical significance change than the TAU only group (average of 24.6 % vs. 21.2% for three outcome variables and 58.8% vs. 10.5% for two process variables). Summing up the five previously statistically significant outcome and process variables, we found that an average of 24.4% of the FSMT + TAU group changed reliably, compared to only 2.6% of the TAU only group on average. Additionally, an average of 41.7% of the FSMT + TAU group demonstrated a clinically significant change, compared to only 15.9% of the TAU only group on average.

3.11. Treatment fidelity report

Twenty percent of all treatment sessions were videotaped. The taped sessions were checked for adherence according to the list of items to be covered in each group session (as depicted in the treatment manual) by an independent clinical psychologist. Overall, the adherence rate was estimated to be 92%. Pretreatment credibility ratings showed an overall rating of $M = 5.5$ ($SD = 2.0$) for both pre-treatment usefulness and

helpfulness (the FSMT + TAU and TAU only groups did not differ significantly). This indicated a moderate level of pretreatment credibility for the FSMT.

Post-treatment global impression of change ratings (FSMT + TAU group only) showed high ratings for both satisfaction (M = 2.6, SD = 1.3) and helpfulness (M = 2.1, SD = 1.0).

3.12. Homework analysis

A simple analysis of the homework comparing those FSMT + TAU participants who turned in their homework assignments (regardless of the degree of homework completion) to those who did not showed that over 70% of FSMT + TAU participants completed homework after each session. Homework completion can also be interpreted as an indirect index of treatment compliance.

Chapter 4: Discussion

4.1. Overview

The current study presents a pilot randomized controlled trial of the four-step mindfulness-based therapy for chronic pain. It is the first ever of its kind put to trial in chronic pain patients. Methodological strengths of the present study include use of a wait-list control, randomly assigned to the treatment and control groups, and adherence to the CONSORT guidelines for a sound randomized controlled trial.

4.2. Attrition/attendance rate

The present study treated chronic pain patients. The overall completion rate of the study is 70%, which is comparable with similar outcome studies (e.g., Morone et al., 2008). We have attempted to examine the reasons for attrition in the current study. One of the major reasons appeared to be conflicts with work or other important commitments, which is quite understandable, as the requirement for chronic pain patients to attend eight weekly sessions is not a light demand. However, the second major reason given was lack of interest, which is somewhat difficult to comprehend, given that all participants had attended a briefing session to obtain an overview of the treatment and all had signed a consent form. It should be noted that our sample consisted of many patients who were either having hard time working to earn their

living (up to 55% were unemployed or only had part-time work) or were receiving financial assistance due to lack of work (up to 32% received either comprehensive social security assistance or disability allowance). Therefore the need for participants to pay for eight treatment sessions might not be without burden for this group of patients. Future research should consider waiving their participation fee in order to increase incentive for participation.

4.3. Treatment effects

When the FSMT + TAU group was directly compared with the TAU only group from baseline to post-treatment, small to medium effect sizes in several outcome and process variables were detected. Comparing baseline to follow-up changes within the FSMT + TAU group itself showed small to large effect sizes. We found evident treatment effect (compared to TAU only) for the outcome variable of activity interference. We also detected clear effect sizes for the process measures of reduction in pain catastrophizing and increase in pain acceptance compared to TAU only. All effects that were present at post-treatment were statistically maintained at the three-month follow-up. The treatment effects and its maintenance over follow-up were clearly demonstrated.

In comparison to similar studies, we first compared the present results to a recent pilot randomized controlled study of mindfulness meditation (MBSR) for older adults by Morone et al. (2008). One comparable outcome measure is physical function. The effect size was 0.66 (MPI Interference) in the present study, and 0.46 (SF-36 Physical Function) in Morone's study. Another comparable outcome measure is pain acceptance (as measured by CPAQ). The effect size of CPAQ in the present study was 0.74, and 0.83 in Morone et al. (2008). Compared to meta-analyses, if we take the median effect size of 0.51 in the present study, it is higher than the mean effect size of 0.37 of mindfulness-based therapies for chronic pain across four studies (Baer, 2003), and on par with the estimated effect size of approximately 0.5 for MBSR across different conditions (Grossman, Nieann, Schmidt, & Walach, 2004). It is also on par with the median effect size of 0.50 in studies of traditional CBT for chronic pain (Morley et al. 1999).

Results of the current study contribute to the existing literature base of mindfulness-based and cognitive-behavioral therapies for chronic pain with comparable effect sizes. FSMT thus provides a solid efficacy basis with the present pilot randomized controlled trial.

In the following sections, detailed treatment effects and noneffects will be considered for each primary and secondary outcome as well as process measure.

4.4. Pain intensity versus pain unpleasantness

The current study differentiated between pain intensity and unpleasantness. This is in line with many researchers who found dissociation in some circumstances between these two dimensions (e.g., Rainsville et al., 1999). Current findings did not show effects of treatment over TAU only or over time in pain intensity, but there was a significant effect of reduction in pain unpleasantness over time. Hence, these results suggest a differential improvement in the affective dimension (pain unpleasantness) but not the sensory dimension (pain intensity) of pain. Research suggests that distinct neural substrates are responsible for the presentation of the affective and sensory dimensions of pain (Hofbauer et al., 2001; Rainville et al., 1999). It was argued that the affective dimension of pain specifically recruits the anterior cingulate cortex (ACC), especially when pain unpleasantness is more likely to be determined by cognitive factors such as meaning and interpretations of pain. The current finding that FSMT changed pain unpleasantness but not pain intensity may indicate possible changes in the activity of the ACC over the course of therapy.

The current results are also discrepant from other outcome studies that found reduction in pain intensity (e.g. McCracken et al., 2005; Turner, Mancl, & Aaron, 2006; Vowles & McCracken, 2008). However, it should be noted that pain in these studies was measured only by intensity without a separate unpleasantness component. Under such constraints, it was not possible to clearly differentiate between the components of pain intensity and unpleasantness. An outcome study using acceptance-based approach for a group of highly-disabled chronic pain patients (McCracken et al., 2007) reported similar trend of improvement in pain distress but not in pain intensity.

4.5 Activity interference

The finding of post-treatment reduced activity interference due to pain compared to TAU only is consistent with many outcome studies (e.g., McCracken et al., 2005; Morley et al., 1999; Turner et al., 2006; Vowles & McCracken, 2008;). The significant result for this primary endpoint offers direct support for the efficacy of FSMT.

4.6. Emotional functioning

In terms of emotional functioning, results from the present study indicate that reduction in depression symptoms was significant for the FSMT over time. Again, the

finding is consistent with other outcome studies showing that negative affect reduced over the course of therapy (e.g., McCracken et al., 2005; Turner et al., 2006; Zultra et al., 2008). It should be noted that the effect size of affect change is generally small in previous outcome studies, with Cohen's *d* in the small range (Morley et al., 1999). Recent mindfulness-based outcome studies either did not include a measure of affect (e.g., Morone et al., 2008) or found that negative affect change in the mindfulness group was not significant at post-treatment (Kingston et al., 2007).

Zultra and colleagues (Zultra et al., 2008) found that rheumatoid arthritis patients with a history of depression benefited more from mindfulness-based therapy (with emotional regulation components) compared to those without a history of depression, and argued that patients with stronger affective disturbance might especially benefit from the emotion regulation properties of their mindfulness-based approach. While the present study did not explicitly include an emotion regulation component, it achieved similar results of reduced negative affect. Hence, it will be important to explore the underlying processes that mediate the improvement in negative affect in this group of patients over therapy. This will be explored in a later section regarding the process of change.

We will discuss the significant effects of the two process measures of pain catastrophizing and pain acceptance in the later section on process of change. The ensuing space will be devoted to discussion of the two nonsignificant processes: self-efficacy and mindfulness.

4.7. Self-efficacy

Self-efficacy is an important construct in many CBT outcome studies. Pain self-efficacy has been highlighted as a key outcome variable in studies using CBT to treat chronic pain (e.g., Morley et al., 1999; Turner et al., 2007). In the present study, pain self-efficacy did not improve significantly for FSMT + TAU participants when compared to TAU only or over time. This suggests an important difference of mindfulness-based approaches (such as FSMT used in this study) from traditional CBT approaches where there is an explicit focus on self-efficacy or perceived control over the pain. In contrast, pain self-efficacy was not significantly increased in our study, indicating that it may not be an important process or outcome *per se* for the FSMT approach.

4.8. Mindfulness

The present study did not detect any significance in improvement of mindfulness in the FSMT + TAU group either compared to TAU only group or over

time. This is a surprising finding, as it stands in contrast to some recent studies that support the role of change in mindfulness to change in disability in chronic pain patients (McCracken et al., 2007). It is speculated that since the current measure for mindfulness, MAAS, is a dispositional one, it may not accurately measure change over an 8-week course of mindfulness-based treatment (Brown & Ryan, 2003). Due to the fact that the group of chronic pain patients in the present study were naïve to mindfulness before the treatment (as reflected from their experience sharing during treatment), it is likely that the 8-week treatment may not be long enough to reflect improvement in MAAS for this group of patients. Alternatively, unlike many other measures used in the study, the MAAS has not been validated locally in Hong Kong. Although it has been pilot-tested in a small group of chronic pain patients prior to the main study, it is still unclear if the current translated version is strong enough in terms of cross-cultural validity. Finally, it is also possible that MAAS may not measure a construct relevant to changes in the present group of chronic pain patients.

4.9. Secondary outcome measures

The secondary outcome measures of health utilization used in this study did not show any treatment effects. It is speculated that sick leave days, visits to accident and emergency, and visits to general practitioners may be influenced by a host of

other factors that are beyond the effects of the treatment package currently under investigation. For example, sick leave days may be mostly determined by compensation-related sick leave (51% of our sample are work accident-related compensation cases). Regarding visits to accident and emergency and visits to general practitioners, the analysis of change was also likely influenced by the heavy skewness of the variables (over 90% and over 70% respectively of them are zero to one in our samples both at baseline and post-treatment). Floor effects may preclude one from effectively detecting any change over the treatment.

4.10. Reliable change index and clinical significance change

In an effort to enhance our understanding of the effectiveness of FSMT over control, we also conducted two analyses of clinical significance: reliable change index (RCI) and clinical significance change (CSC). Such data would add to the evidence that whether changes in FSMT + TAU over TAU only were truly beyond measurement errors (reliable) and meaningful according to preset criteria (i.e., clinically important). The present study provided further reliable change and clinical significance change results for the FSMT approach. If we focus mainly on the outcome and process variables that achieved statistical significance in our previous analyses (pain unpleasantness, activity interference, depression, pain catastrophizing,

and pain acceptance), we can conclude that the FSMT + TAU leads to better outcomes than TAU only in a reliable and clinically meaningful way. Such findings add a level of meaningfulness to the efficacy of FSMT.

The degrees of reliable change and clinical change should be subject to cautious interpretation, due to various factors such as like the estimates of reliability and sample variance (Morley, Williams, & Hussain, 2008)). In our study, only a few participants achieved reliable change for pain intensity and unpleasantness, likely due to the relatively low reliability estimate (0.69). Further, for measures of clinical significance change without previously established normative values (MPI Interference), we used Jacobson's method of two *SD*s beyond the treatment sample mean, rendering a "difficult" criterion for activity interference reduction (down to 21.36). Considering these shortcomings, there is a need for the field to devise more reliable measures with normative values. Nonetheless, since we always compare between the FSMT + TAU and TAU only groups, the differential performance in the two groups in the reliable and clinical significant change aspects will be relatively intact, regardless of the choice of reliable change index or clinical significance criterion.

Additionally, given that for the primary outcomes, more than 60% of the FSMT + TAU group participants still had not met the clinical significance criteria, it raised the issue of whether the length the present FSMT was long enough to promote treatment benefits or rather a stepped care approach of longer term FSMT would be preferred for the present sample of participants.

4.11. Nonspecific predictors and moderators

The study found that longer duration of pain predicted higher 8-week pain intensity and pain unpleasantness. Additionally, it was also found that higher baseline pain intensity, higher baseline activity interference, or higher baseline depression predicted higher 8-week pain unpleasantness. One implication is that patients presenting with such characteristics may need more intensive FSMT. Further, depression should preferably be treated before or in conjunction with the FSMT.

We also found four moderators of treatment in this study: pre-treatment usefulness and pre-treatment helpfulness moderated treatment effect towards pain unpleasantness, and baseline pain intensity and baseline pain unpleasantness moderated treatment effect towards activity interference. Examination of these moderator effects revealed that for participants with lower baseline pain intensity or unpleasantness, the treatment effect for activity interference tended to be higher. This

finding poses implication that participants with low baseline pain intensity or unpleasantness may benefit more from the present FSMT in terms of activity interference reduction. For pretreatment usefulness and helpfulness, there is an intriguing finding that for the TAU only group, higher pre-treatment usefulness and helpfulness correlated with lower post-treatment pain unpleasantness. This is somewhat akin to a treatment expectancy effect because while the TAU only group never received the treatment, they might be expecting to receive the treatment after serving as control. In contrast, for the treatment group, no correlation seemed to exist between pre-treatment usefulness and helpfulness and post-treatment pain unpleasantness, showing a lack of treatment expectancy effect. However, no such differential existence of treatment expectancy was found in other outcome variables.

4.12. Processes of change

Having examined the effectiveness of FSMT at both statistical and clinical levels, we have come to an unequivocal conclusion that FSMT is indeed efficacious beyond the comparison with control or constraints of measurement error. It is beyond reasonable doubt that FSMT shows effects that cannot be explained by the mere passage of time. We have now come to a position to ask the question of "how does it

work", tapping on the processes or mechanisms of change. Results of the meditational analyses may provide some insights in this respect.

Meditational analyses showed that for the four process variables tested, two showed clear mediation effects. Pain catastrophizing mediated the treatment effects for pain unpleasantness, activity interference, and depression. Pain acceptance showed mediation effects from treatment to activity interference and depression. The other two process variables, pain self-efficacy, and a general mindfulness measure did not establish any mediation effects.

First, we examine why some process measures did not mediate the treatment effects. Previous outcome studies have shown self-efficacy to mediate the effects of CBT for chronic pain. Keefe and colleagues (Keefe et al., 2004) found early increases in self-efficacy predicted increased physical fitness and decreased psychological disability after a coping skills plus exercise training for osteoarthritic knee pain. Turner et al. (2007) found that self-efficacy changes during a CBT treatment mediated outcomes of one-year activity interference, pain intensity, and jaw use limitations in a group of chronic temporomandibular disorder pain patients. However, mindfulness- and acceptance- based therapy outcome studies have not been observed to use pain

efficacy as outcome or process variable. Thus, the current study uniquely found that self-efficacy was likely not an important process in the working of FSMT.

When we look at the present FSMT package, all of the components asked participants to observe their pain along with other sensations, feelings and thoughts. There was nil component designed to train the improvement in perceived control or self-efficacy over pain, or change the patients' maladaptive beliefs about their pain. It is therefore not surprising to find the absence of significant change in self-efficacy after treatment or mediation of self-efficacy for the treatment effects. The present results also validated the deliberate design of FSMT in eliminating any element of control over distress, which is in accord with the mindfulness-based therapies that emphasize nonstriving and relinquishing futile attempts to control. This also echoes the likelihood that increasing perceived control or self-efficacy over pain might not be crucial or necessarily lead to better outcomes.

The lack of mediation effects for mindfulness, as argued previously, may be related to the relative lack of change in MAAS itself in a relatively short period of eight weeks. Until another mindfulness measure with more potent sensitivity to change during this type of treatment is identified, we still cannot yet tell if overall increase in mindfulness mediates the change in outcome variables.

4.13. The process of change in pain catastrophizing

Next we return to the mediators that are significant: pain catastrophizing and pain acceptance. Pain catastrophizing has emerged as a significant predictor of pain intensity, disability, and distress in chronic pain (Keefe et al., 2004; Geisser, Robinson, Keefe, & Weiner, 1994; Martin et al., 1996; Turner, Jensen, Warms, & Cardenas, 2002). It has been shown to mediate outcomes of CBT for chronic pain in several outcome studies, including outcomes of a multidisciplinary chronic pain treatment (Burns, Kubilus, Bruehl, Harden, & Lofland, 2003) and outcome measures of disability and pain intensity in CBT for chronic low back pain patients (Smeets, Vlaeyan, Kester, & Andre Knottnerus, 2006). However, again, pain catastrophizing has not yet been commonly included as an outcome or process measure in mindfulness- or acceptance-based therapies for chronic pain. The only study that used pain catastrophizing found that rheumatoid arthritis patients with a history of depression demonstrated significant decrease in catastrophizing when compared to the control group (Zultra et al., 2008).

In the present study, pain catastrophizing mediated the majority of outcomes. The fact that it mediated pain unpleasantness but not intensity showed that it may be more related to the affective rather than the sensory dimension of pain. It also

suggests that FSMT worked by way of decreasing catastrophizing with regards to pain, leading to decreased unpleasant feelings about pain. Then finding of mediating effects of pain catastrophizing toward activity interference and depression was consistent with the CBT literature showing that decreased catastrophizing led to decreased activity interference and distress (Burns et al. 2003; Turner et al, 2006). Decrease in pain catastrophizing likely leads to the common pathway of reduced activity interference and reduced distress, regardless of the causal agent of change.

4.14. The process of change in pain acceptance

Chronic pain acceptance was a concept developed by McCracken in search of an ingenious way to give up futile attempts to control unrelenting pain and keep up with activities with the presence of the pain (McCracken, 2005). It has not yet been well documented in the CBT literature, possibly due to its conceptual disparity with the usual CBT concept of control over pain. Amongst outcome studies of acceptance- and mindfulness- based therapies for chronic pain, increase in pain acceptance has been frequently reported as an outcome (e.g., McCracken et al., 2005; Morone et al., 2008; Vowles & McCracken. 2008). In terms of mediation, research suggests that changes in pain acceptance over the course of an acceptance-based treatment were related to

changes in depression, pain anxiety, and physical and psychosocial disability (McCracken et al., 2005; Vowles & McCracken 2008).

The present study found that pain acceptance mediated the treatment effects toward activity interference and depression. These findings are consistent with those documented by McCracken and colleagues. It appears that another common pathway, at least for mindfulness- and acceptance- based approaches, is to work through increases in acceptance of pain, which will then lead to reduced activity interference and improved mood.

4.15. Weighing pain catastrophizing and pain acceptance

If pain catastrophizing and pain acceptance both mediate the present treatment to the outcomes, what are the relationships between the two? When we included both measures into the mediation model, it was found that only pain catastrophizing retained as a significant mediator for activity interference, and only pain acceptance retained to significantly predict depression. It is possible that each of the two processes plays a unique role in mediating the outcomes. Vowles, McCracken, and Eccleston (2008) suggested that acceptance might mediate the relationship between catastrophizing and outcomes (e.g., depression, physical/psychosocial functioning) as the variance in functioning predicted by catastrophizing became significantly reduced

with the inclusion of acceptance. In this view, it is possible that acceptance and catastrophizing may share some variance such that the effect of decreased pain catastrophizing in achieving better functioning may be explained by the acceptance of pain.

One caveat to be stated here is that due to design constraints we have only included simultaneous measures of the processes and outcomes in the present meditational analyses. As argued by Laurenceau, Hayes, and Feldman (2007), this is a less than satisfactory approach, as inference of causality is weak with this design. Hence, while the present results may inform the underlying working mechanisms of FSMT, definite conclusions cannot be drawn.

4.16. Proposed processes of change in FSMT

Given the empirical findings of mediation thus far, one may speculate about the processes by which FSMT achieved its effects. With its emphasis on psychoeducation on the nature and accumulation of the chronic pain experience (i.e., normalized as sensitized signals and ongoing mental reactions to pain in the brain rather than ongoing injuries in the body) and mindfulness exercises to train one as an observer to pain-related sensations, thoughts, and feelings, the FSMT treatment may be especially effective in helping participants feel less catastrophic about pain.

Participants also increased their acceptance of pain in the sense of allowing themselves to carry on their lives in the presence of ongoing pain and relinquishing further preoccupations to get rid of their pain. They did not necessarily feel more in control of their pain or more efficacious about their ability to cope with their pain with this training. However, their behavioral responses towards their pain appeared to have changed. Finally, lower pain unpleasantness and improved physical and emotional functioning (less activity interference and less depression) followed as a result of this renewed relationship with pain.

While it is now clear that pain catastrophizing and pain acceptance both mediated the effects of FSMT, it remains important to answer the question of how FSMT led to the changes in these processes. In the FSMT, four distinct steps are incorporated into its package: Relabel, Reattribute, Refocus, and Revalue. During the first two steps Relabel and Reattribute, which were covered during the first five sessions, efforts were made to transform participants' understanding about chronic pain and relationship to pain by way of successive mindfulness exercises, such as mindful breathing, mindful stretching, body scan, as well as mindful observation of pain-related sensations, feelings, and thoughts. Although it is unclear when the changes in pain catastrophizing and pain acceptance occurred exactly, it is evident

from the present findings that during midgroup the participants had already demonstrated substantial changes in these two aspects, and the changes continued in a linear fashion throughout the end of treatment. Hence, it is reasonable to conjecture that the first two steps Relabel and Reattribute likely laid a foundation on which the participants' catastrophizing and acceptance improved.

In the subsequent step Refocus, participants were instructed to deliberately engage in different behaviors in response to the pain, in contrast to their previous habits of engaging in avoidance or overcontrolling behaviors. The fact that pain catastrophizing and pain acceptance continued to improve after midgroup offered indirect support that changes in new behaviors in response to pain had been taking place. Therefore, the Refocus step may work by disengaging the participant from previous habits of preoccupations with pain (catastrophizing) and reengaging one in meaningful activities despite the presence of pain (acceptance). To the extent that participants had succeeded in the previous two steps and the accompanying mindfulness exercises, they could harness this new ability to mindfully observe their pain, then disengage from it and refocus onto other activities.

4.17. Neurocognitive perspectives

The process of change in FSMT can also be viewed from a cognitive

neuroscience perspective. Studies have shown that pain catastrophizing was related to the inability to disengage from attention to and pre-occupations with pain (Seminowicz & Davis, 2006), which interrupts attention to ongoing cognitive tasks (Vancleef & Peters, 2006). This reflects a fundamental attention bias in chronic pain patients with a tendency to catastrophize. In neuroimaging studies, pain catastrophizing was also correlated with DLPFC and ACC activity (Gracely et al., 2004; Seminowicz & Davis, 2006). The present FSMT was shown to reduce catastrophizing by educating participants about pain and including exercises of mindful attention to pain. This may be attributed to enhancements in attention regulation (better ability to disengage from pain and shifting of attention from pain to different stimuli), which could be reflected in activation of the attention modulation network, including DLPFC and ACC.

Further, the emphasis of FSMT on refocusing on other activities may account for successful increase of pain acceptance during FSMT. It has been noted that successful implementation of the Four Steps could entail acceptance (Schwartz, 2005). Pain acceptance is behaviorally correlated with the ability to keep on with meaningful activities despite the presence of pain (McCracken & Eccleston, 2003). Improvement in pain acceptance in the present FSMT may serve as evidence for changes in habitual

mental reactions to pain. Neurobiologically, this may correspond to the de-coupling of some automatic firing patterns in the mind state of the present participants, and may also be reflected in activation of the DLPFC in enhancing the executive control on pain versus other activities (Lorenz et al., 2003).

Overall, successful reduction in pain catastrophizing via the four steps in FSMT likely reflected enhanced attention regulation and hampering of elaborative emotional processing (catastrophizing) through activation of the executive top-down control by DLPFC toward ACC and related areas. Additionally, improvement in pain acceptance might reflect change in habitual mental reactions to pain via enhanced executive control by DLPFC. The present FSMT approach provided evidence that habitual neurocognitive processes once driven by pain were replaced by more self-directed neurocognitive processes that attenuated the chronic pain experience. Nonetheless, given the lack of neuroimaging data to support these speculations, further studies that incorporate neuroimaging measures are needed before definite conclusions can be made.

Since the above explanations implicate a change of state in the attentional regulation of the participants via FSMT, a more direct measure of change of process may be to employ a measure of attention shifting that taps the ability to switching of

attention and/or response inhibition (such as Stroop task). Previous studies have found attention and working memory deficits in chronic pain patients (Dick & Rashiq, 2007; Grisart & Plaghki, 1997). Improvement in the performance of the Stroop task may be interpreted as direct evidence that FSMT leads to improvement in attention regulation.

4.18. Limitations

The present study, due to its preliminary nature, has several limitations which we have summed up in the categories of generalizability, control, measurement, and study time-frame below.

4.18.1. Generalizability.

Generalizability across the patient population is critical in establishing the external validity of a treatment (Green & Glasgow, 2006). In the present study, the participants were solely recruited from a cluster-based outpatient pain clinic. It may not be representative of the wider population of chronic pain patients in other medical specialties, such as orthopedics or neurosurgery. Its generalizability to chronic pain patients represented in other medical settings such as primary care or in-patient settings is also unknown. Further, no participants were recruited directly from the community-dwelling population, hence it is unclear whether the present treatment may be applicable to community dwellers who present with chronic pain but may not

have sought help from helping professionals. In terms of age group, because this study only consisted of participants aged 18 to 65, the applicability of the present findings to children or older adults with chronic pain is yet to be established.

Attrition and completion rates should also be considered. Although the present study had a completion rate of 70%, which is generally conforming to that of other CBT or mindfulness-based outcome studies of chronic pain, the drop-out from the control arm after randomization was particularly notable. Despite the fact that the ITT sample did not differ from randomized participants who failed to provide midgroup, post-treatment, or follow-up data in baseline and demographic characteristics, it remains important to analyze the reasons for drop-outs (Hayes, Hope, & Hayes, 2007; Morley & Williams, 2006). In the current study, participation in treatment was on a self-financed basis and no incentive was given for control subjects who returned the questionnaires by mail. Future studies may consider using monetary incentives to increase participation, such as waiving the group treatment fee and offering store coupons to control group participants.

4.18.2. Control.

Proper control is key to internal validity. The present study adopted a wait-list control in an effort to enhance internal validity. While it allowed for control for the

passage of time, one still could not rule out nonspecific group participation factors or demand characteristics for this type of passive control. Further studies that aim at strengthening the internal validity of the FSMT should employ active controls, such as an attention control with a general discussion or education group (without any four-step mindfulness component) or another active treatment condition (e.g., traditional CBT).

A portion of the wait-list control participants were crossed over to the FSMT after their serving as control. However, their small group size (n=13) precluded any detection of significance in terms of pre- and-post treatment differences. If more control group participants could be allowed to cross over to the treatment group, one may have stronger statistical power to evaluate the changes in the cross-over group independently.

Since the principal investigator was involved in conducting part of the treatment groups, there was a possibility of experimenter allegiance effect incorporated into the outcome. Although vast majority of the participants did not receive any individual psychotherapy input from the principal investigator (who was involved in such clinical duties) during the study period, there remained a likelihood that there was differential treatment by the principal investigator between the FSMT + TAU and

TAU groups within the treatment-as-usual context. Future studies should seek to avoid involvement of the investigator(s) in the treatment-as-usual duties within the study period. Moreover, to further determine any potential experimenter allegiance, outcome data from the principal investigator and other treating psychologist(s) could be separately analyzed and compared with each other.

4.18.3. Measures.

Self-report measures were used exclusively in this study. Exclusive use of paper-and-pencil tests may increase the method variance and enlarge the margin of measurement errors. As a remedy to this concern, however, this study included reliable change analysis to indicate reliable changes in the outcome and process measures above and beyond possible measurement errors. Future studies are strongly encouraged to include measures of a different modality in order to counteract such problems. Additionally, as FSMT arguably might have changed the attention regulation of participants, the use of a more direct measure, such as Stroop test, to tap such changes would be desirable. Inclusion of neuroimaging outcomes in future trials should provide further support for treatment effects of this approach.

As argued before, some of the measures used in this study (e.g., MAAS) may not be appropriate for the time span and purpose of this treatment. Selection of a

different and more change-sensitive mindfulness measure is therefore recommended. The present study also did not include a measure of sleep in the outcome, which is indeed a commonly reported problem in chronic pain patients. Future studies should seek to improve upon the selection of outcome and process measures in order to subject the FSMT treatment effects to more rigorous test.

4.18.4. Study time-frame.

The present study adopted a timeline of baseline, midgroup, post-treatment, and follow-up design. It could at best allow one to discern a quadratic trend of change but its ability to measure any non-linear change still remains imprecise. Further, only simultaneous pre- and-post-treatment measure of the outcome and process variables were adopted for the examination of mediation effects. In order to better establish likely causality of the mediation, more time-points are needed within the treatment period to gauge the changes in the process variables. Inclusion of these data would also be useful for mediation analysis of later outcomes in treatment (Laurenceau et al.,2007). Since FSMT includes four discrete steps, it is also theoretically prudent if the process variables can be measured at the time-point of the completion of every step. Alternatively, a session-by-session measure, though time- and labor-consuming,

may potentially allow one to document the changes in and processes of FSMT more precisely.

The length of the FSMT was set at eight weeks, which is more or less compatible with the length of standard mindfulness-based therapies (Baer, 2003). However, the present data revealed that a large proportion of participants still did not show clinically significant changes in outcome measures at the end of eight weeks. Future studies of FSMT for chronic pain may consider a stepped care approach to increase the treatment period for chronic pain patients with characteristics similar to the present sample.

The follow-up period of the present study was set at three months post-treatment. Some researchers have argued for the longer follow-up periods of up to 12 months to determine the long term maintenance effects of treatment (Morley & Williams, 2006). Moreover, some control participants were lost at follow-up due to their cross-over to the treatment group. Future studies should seek to employ a larger sample with active controls in order to allow for the study for the treatment effects over a longer period of time.

4.19. Conclusion and future directions

The present study presents a pilot randomized control trial of a neurobiologically informed mindfulness-based approach, Four-step Mindfulness-based Therapy (FSMT), for chronic pain. It is the first to establish level I evidence of FSMT for chronic pain in the literature, and contributes to evidence base of mindfulness- and acceptance-based approaches to chronic pain. Despite the fact that its effect size in the current study was found to be similar to the gold-standard CBT, its results have shed light on the possible processes and mechanisms that brought about the changes. While broadly theoretically similar to other mindfulness-based therapies, FSMT appears to pose itself in a unique position through the use of four streamlined steps interwoven with core mindfulness exercises. It is also neurobiologically informed to function by likely altering neurocognitive processes often present in chronic pain patients.

Results of the present study provide important implications for further development of active and specific psychological treatments of chronic pain. Development of the FSMT for chronic pain was based on a neurocognitive model of how pain-related distress was accumulated in chronic pain and how the four steps in association with mindfulness training could dislodge such distress. Results of the present study lend support to the process of reduction in catastrophizing and

improvement in pain acceptance as likely active ingredients of FSMT, and refuted the process of increasing efficacy or perceived control toward pain. Future studies may seek to further clarify if theory-driven mindfulness-based or acceptance-based approaches (such as FSMT) would be more pertinent in chronic pain by comparing it with another active treatment such as CBT. Studies should also actively compare the proposed mediating processes or mechanisms (e.g., catastrophizing, acceptance, self-efficacy) in active treatment comparisons in an effort to dismantle one or more "robust" active ingredient emergent from the comparison of process variables.

The present study also paves the way for future neuroscience approaches that can further elucidate the active neural pathways of positive therapeutic outcomes of FSMT. In recent years, incorporation of the neural substrates in the treatment of psychological disorders has been suggested to improve the understanding of mechanisms and therapeutic outcomes. For example, Siegle, Ghinassi, and Thase (2007) proposed a "neurobehavioral therapy" approach that links neuroscience to the design, working mechanisms, and evidence of outcome of the therapy. The original Four-step approach for OCD has been suggested as a "neurobehavioral" approach as it proposed dysfunctional basal ganglia and limbic function as the underlying neural substrates of OCD and targets such disruptions in the treatment (Siegle et al., 2007).

The present FSMT for chronic pain was also designed with the underlying dysfunctions in the attentional network and habitual (automatic) mental reactions (reflected in the activation patterns of DLPFC and ACC) in chronic pain in mind, and targeted changes in these neural pathways. Future studies should seek to further illuminate changes in activations of these areas following FSMT using neuroimaging methods. Such neuroimaging data could cross-validate whether the proposed underlying neural mechanisms of change have indeed taken place and whether the changes in brain function have translated into proposed changes in symptom or outcome.

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Appendix A

Consent form for participation in the study

雅麗氏何妙齡那打素醫院

四步內觀抗痛療法之隨機對照研究

接受研究同意書

本人 _____ 現居 _____

（姓名及香港身份證號碼） （地址）

同意參與以上之研究，而此研究之性質、目的及檢查程序已經由 _____ 先生 / 女士詳細解釋。本研究的目的是評估四步內觀抗痛療法用於長期痛症病人的效用。大約有 80 位病人會參與此項研究。本人的個人資料如姓名，年齡，性別，身份証號碼，地址，電話號碼，及填寫於問卷上的資料將會被記錄，這些資料將會保密及只用於此項研究。本人明白參與此項研究可能可以增加本人處理長期痛症的技巧。本人明白本人可被隨機選入治療組或對照組。若被選入治療組，本人明白需要在研究前、後及三個月後，填寫數份問卷，並以門診方式參與一個為期八個星期，每星期一次兩小時的四步內觀抗痛療法小組治療。若被選入對照組，本人明白須等侯八個星期，才有選擇參與四步內觀抗痛療法小組治療的權利。本人明白此研究純屬自願性質。本人明白不參與此研究將不會對本人的治療有任何影響。本人亦了解到本人可以隨時通知有關人仕退出此項研究。如本人對此項研究有任何疑問，可聯絡雅麗氏何妙齡那打素醫院臨床心理學家黃志明先生，電話：2689-3155。

病人姓名： _____

病人簽名： _____

研究人員姓名：_____

研究人員簽名：_____

見證人姓名：_____

見證人簽名：_____

日期：_____

Appendix B

Patient education materials and treatment manual

醫生短講

在本治療小組開始之先必須先說明，我們明白你所感受到的痛楚是十分真實及令你不便的，你參加本治療小組的目的，正是要學習應付它的方法。你和其它在痛症診所求診的病人並沒有甚麼不同，你在本治療小組將有機會學習到一些幫你自我管理痛症的方法，特別是如何避免將痛的感覺在心中轉為痛苦。有需要的話你可繼續服用醫生處方的藥物。

在本課第一節，我們也借此機會向你說明長期痛症的本質。凡持續三個月以上的痛症，便稱為長期痛症。它與短期痛症（持續少於三個月）不同的是，短期痛症通常有確切的成因（例如受傷、骨折），並於成因治愈後消失。但在長期痛症中，即使成因已受治理，患者仍然繼續感到痛楚，而且在客觀的成象檢查，例如X光、磁力共振中，並不一定有所發現。即使有清晰的發現，它與痛楚出現的位置或比例也可以有所不同。現在國際公認這種情況稱之為長期痛症。

現今醫學界的共識是，並沒有根治長期痛症的方法。故此，無論用盡各種醫療方法，長期痛症仍可能會維持一段長時間。我們相信，你很可能之前已經嘗試過不同類型的治療方法，包括藥物、注射、甚至手術等。重要的是，你須要知道本治療小組並非另一種醫學上減痛的方法，相反地，它透過心理學的原理，去幫助長期痛症病人學會接受痛症，減少困苦。治療的效果，並不是基於直接減少痛楚的感覺，而是改變對痛楚的慣性心理反應。研究表明，在人腦中有機制可以放

大或減少身體痛楚的感覺，這機制受一系列因素，如過往經驗、情緒、背景等所影響。以聲音的傳播作為比喻，我們並非去除聲音的來源，而是幫助你學會調校聲音的大小和音色。

你在本治療學習到的各種冥想練習，會訓練你改變對痛楚的反應，以致能更自然及舒適地進行生活上的各種活動。在練習過程中，即使你感到痛楚有所增加，也不表示身體受傷加劇，所以是十分安全的。你可以放心地根據治療師的指引，去進行這些練習。最後補充一點：這個治療小組和你現行使用的治痛方法（例如藥物、按摩）並沒有衝突，你可以在療程中繼續使用它們。但為了充份留意並改變你對痛楚的慣性心理反應方式，應儘可能不在療程中增加止痛藥份量或其他治痛方法。如有需要，可向你的痛症科醫生查詢。

長期痛症教育資料

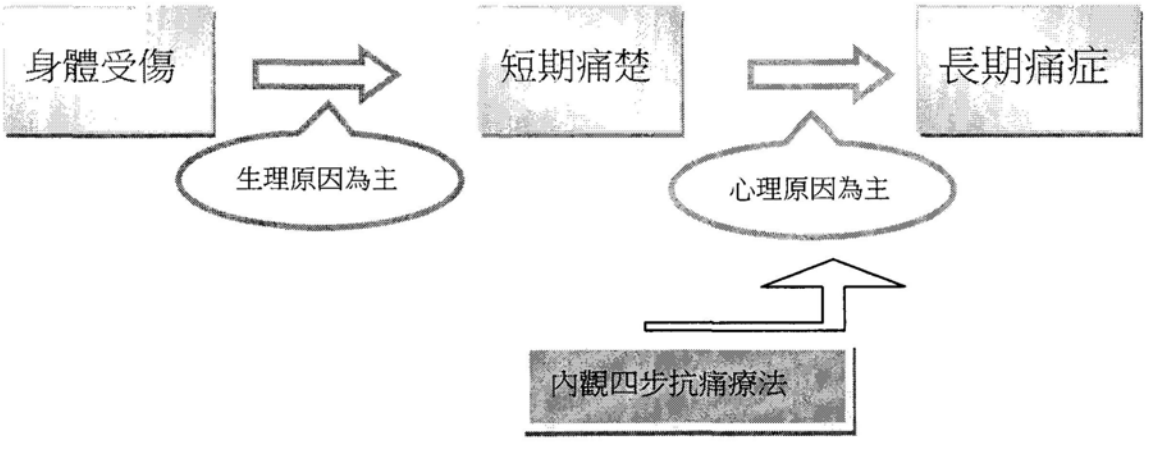
痛楚的生存價值

痛楚是一種身體感官訊號，它有著重要的生存價值，因為它提醒我們，身體可能受傷，須及早治療。

長期痛症

但是，你現有的長期痛症的徵狀在身體內找不出嚴重受傷的證據。這反映出，痛楚的訊號可能受到其他因素影響，變成了持續的痛楚，它影響生活，如日常自理、走路、外出購物、乘搭交通工具、家務、工作等等。你發覺自己經常受到痛楚的困擾，不自禁地用盡各種辦法去減低痛楚。但是你發覺痛楚揮之不去，心中感覺越來越困苦。

要特別留意的是，雖然短期或急性痛楚反映身體的問題，在長期痛症中，痛楚的徵狀多數已不只是身體的問題。反之，最近的科學研究結果顯示，持續的痛楚很多時和慣性的負面心理反應有關。換句話說，從短期痛楚發展到長期痛症的過程中，很可能已經由主要反映生理問題，轉化為主要反映心理問題。這樣的話，我們便明白為甚麼傳統的醫學方法不能根治長期痛症；另一方面，一些改變我們心理反應的治療方法卻可能對長期痛症起重要的作用。



「內觀四步抗痛療法」資料

內觀四步抗痛療法，源自現有的四步療法及內觀減壓訓練。內觀是指以一種特殊的方式去注意各種生活經驗，這種方式特色為活在此時此刻，並對每一經驗不加以任何評判。它透過逐步的對呼吸、身體感覺及痛楚感覺的覺知練習，去訓練我們對痛楚感覺的包容，改變慣性的心理反應方式，及重新體驗生活過程的各種樂趣。本療法包括以下四步的練習：

1. *再確認 (Relabel) -- 療程第一週*

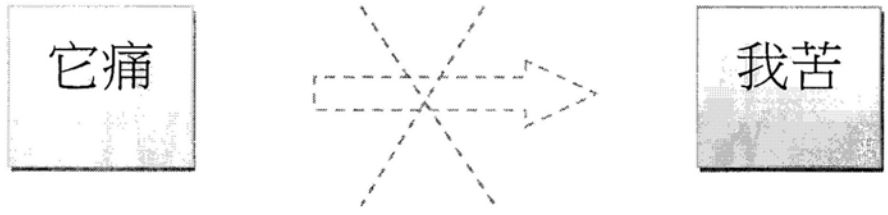
這是第一步。我們先要學習認請長期痛症的特質。透過第一堂的教育資料，我們學習確認，我們經常感覺到的痛楚，是長期痛症的病徵。而這些痛楚，主要並非基於身體原因，反而與心理原因有關。

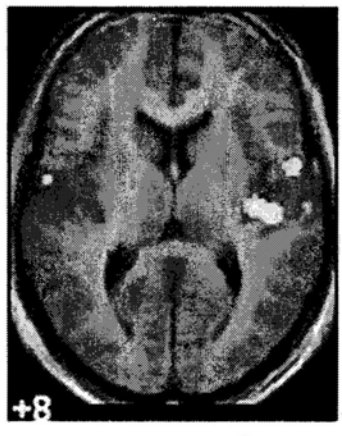
每次痛楚出現，我們都在心裡覺知，並對自己說：「這是長期痛症的病癥」。

2. *再歸因 (Reattribute) -- 療程第二至五週*

第二步緊接著第一步，要學習進一步認清長期痛症對我們的影響。由於痛楚的本質是厭惡性的，我們很想把它除掉，但愈是在心中執著地要驅逐它，它愈是揮之不去。這是由於我們的腦神經有一些處理和痛楚有關的情緒及思想的機制，它會受到我們的執著心激活，從而進一步擴大痛楚引起的負面經驗，這變成一種不良的心理習慣。久而久之，我們會慣性地很容易便引發出和痛有關的負面經驗。這樣，**持續的痛楚就在心中不斷擴大，形成不斷的痛苦經驗**。

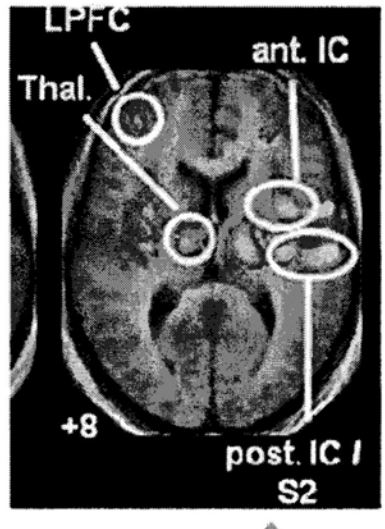
在再歸因的一步中，將透過療程中的內觀練習，覺知到痛楚的特質是它來而復去，去而復來，我們學習毋須在心中驅趕它，反而把它再歸因為一種身體及腦神經的經驗，能夠對自已說：**「痛症不是我，它是我身體及腦神經的經驗」**，這樣我們會慢慢放下要趕走痛楚的心理習慣，而培養出一種與痛共處的新經驗及新習慣。





痛而不苦

大腦中只有痛的感覺激活。



痛苦

大腦中許多和痛有關的網絡（感覺、情緒）都激活了。

這情況和許多對痛楚的慣性心理反應有關。

3. *轉移注意力 (Refocus) -- 療程第六至七週*

我們承接上一步的經驗，將痛楚經驗重新歸因後，不再重覆地作出對痛楚經驗的不良心理反應（例如不斷執着地要減痛、除痛）。在轉移注意力一步中，便練習在日常生活中，擴闊內心的選擇空間，透過內觀將注意力從痛楚移開，並開展預先選好的有益有趣的活動，例如：散步、聽音樂、伸展運動、讀書、做小食、種花等。你可以運用十五分鐘法則，在痛楚出現後，就立即反應，在 15 分鐘內，我們做「再確認」、「再歸因」、「轉移注意力」，然後你要做其他有興趣、有建設性的活動。目標是明確地去除困苦，並重拾之前因痛楚而放棄的活動。

4. *再評價 (Revalue) -- 療程第八週*

來到最後一步，我們學會運用內觀，重新評價長期痛症。我們檢視前七週所慢慢學到的一種新習慣，看看自己能否不再執着在減少痛楚上，在不同場合能與痛共處，做到自己訂下的事情。我們也預備將這種新習慣繼續應用到未來的不同場合上。

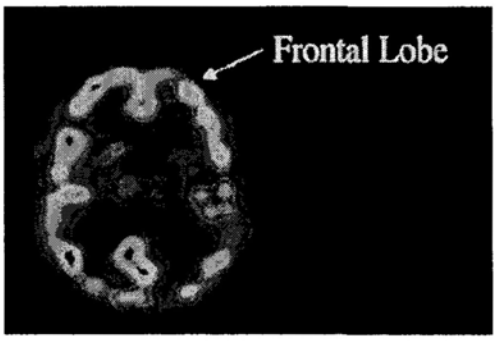
本治療計劃共八節，每星期上一節，共二小時，八星期上畢。在其中你會與其他病人一同參與，並須在家練習功課，包括不同形式的「內觀」練習。

「內觀四步抗痛療法」怎樣發揮作用？

一些腦神經研究顯示，內觀四步抗痛療法採用的冥想練習，可以舒緩我們的負面情緒系統，並且激活腦前額葉，使它提高注意力，提升我們專注於某種活動上的能力。在長期痛症的情況下，我們估計內觀四步抗痛療法可以幫助患者將心智脫離與痛有關的負面經驗，並且能轉移注意力到其他的活動上。換句話說，患者的注意力將不再被動地受痛楚帶導，改為重新由自己主動引導，以至更能配合生活上的需要。患者雖然仍感覺到痛楚，但就學會更隨心所欲地離開痛所帶來的困苦所豁制。

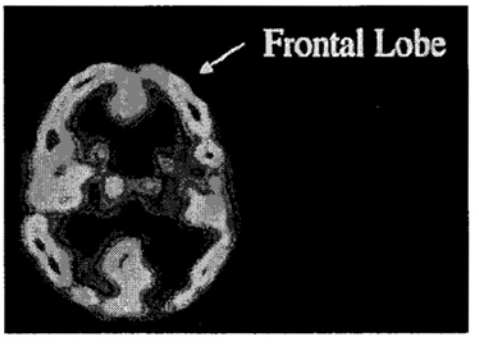
冥想前

腦前額葉較少活躍的地方



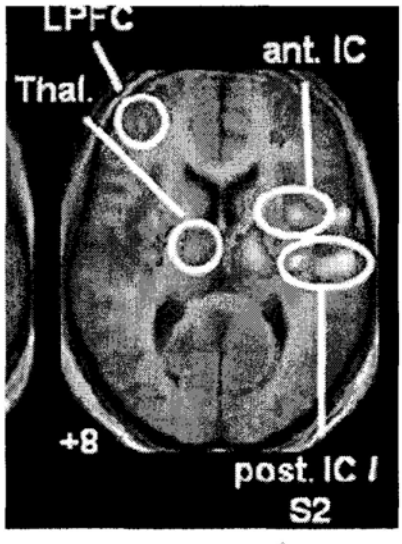
冥想後

腦前額葉較多活躍的地方



我應怎樣做去配合這套療法？

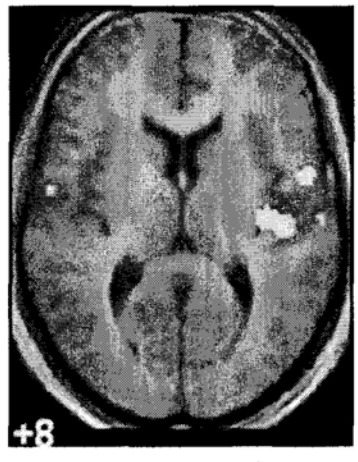
很多時候，長期痛症所帶來的負面經驗是相當深遠的，要改變因應這些負面經驗帶來的不良習慣也非一日可成。根據臨床經驗，我們強烈建議你跟從療程指示，每日都練習不同的內觀方法，持之以恆下去，這樣，我們的心智和腦神經才會作出相應的調節。換言之，**每天不斷練習是使療法見效的關鍵**。



痛苦

大腦中許多和痛有關的網絡（感覺、情緒）都激活了。

這情況和許多對痛楚的慣性心理反應有關。



痛而不苦

大腦中只有痛的感覺激活，其他網絡靜下來了。

我能透過內觀不斷練習這種痛而不苦的狀態嗎？

Four-step Mindfulness-based Pain Management Therapy

TRAINER'S MANUAL

By

Tony Chi Ming Wong

Clinical Psychologist

April 2008

(Chinese Script)

目錄

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1. 第一週課程

2. 第二週課程

I) 課程大綱

第一週課程

	內容	時間
1.1	互相認識及講解一般小組守則	10 分鐘
1.2	自我介紹病情及對治療期望	25 分鐘
1.3	醫生講座	15 分鐘
1.4	講解「長期痛症教育資料」	15 分鐘
1.5	講解「內觀四步抗痛療法資料」	15 分鐘
1.6	進行第一步「再確認」	30 分鐘
1.7	本週家課： ➢ 向家人及朋友講解「長期痛症教育資料」（特別是痛苦形成過程）二至三次 ➢ 每次痛楚出現，我們都在心裡覺知，並對自己說：「這是長期痛症的病癥」	5 分鐘

第二週課程

	內容	時間
2.1	回顧上週家課	10 分鐘
2.2	介紹第二步再歸因及數種內觀練習	15 分鐘
2.3	介紹「觀呼吸」	15 分鐘
2.4	「觀呼吸」練習	20 分鐘
2.5	堂上討論及更正誤解	30 分鐘
2.6	分發「伸展運動」單張及練習	20 分鐘
2.7	本週家課： ➢ 每天進行「觀呼吸」15 分鐘 ➢ 每天做「伸展運動」二次 ❋ 本週暫時毋須練習觀伸展感覺	5 分鐘

第三週課程

	內容	時間
3.1	回顧上週家課	10 分鐘
3.2	重溫「觀呼吸」	10 分鐘
3.3	「三分鐘呼吸空間」練習	15 分鐘
3.4	介紹「身體掃描冥想」	15 分鐘
3.5	「身體掃描冥想」練習	40 分鐘
3.6	堂上討論及更正誤解	25 分鐘
3.7	本週家課： ➢ 每天進行「觀呼吸」15 分鐘 ➢ 每天進行「身體掃描冥想」30-45 分鐘 ➢ 每天做「伸展運動」二次	5 分鐘

第四週課程

	內容	時間
4.1	回顧上週家課	15 分鐘
4.2	重溫「身體掃描冥想」	15 分鐘
4.3	介紹「觀伸展感覺」	15 分鐘
4.4	「觀伸展感覺」練習	25 分鐘
4.5	堂上討論及更正誤解	30 分鐘
4.6	本週家課： ➢ 每天進行「觀呼吸」15 分鐘 ➢ 每天進行「身體掃描冥想」30-45 分鐘 ➢ 每天做「伸展運動」連「觀伸展感覺」二次	5 分鐘

第五週課程

	內容	時間
5.1	回顧上週家課	15 分鐘
5.2	重溫「觀伸展感覺」	15 分鐘
5.3	介紹「觀痛楚感覺及經驗」	20 分鐘
5.4	「觀痛楚感覺及經驗」練習	25 分鐘
5.5	分二人小組討論*再歸因*「痛楚不是我，它只是我的經驗」	35 分鐘
5.6	本週家課 ➢ 每天進行「觀呼吸」15 分鐘 ➢ 每天做「觀痛楚感覺及經驗」練習 20 分鐘 ➢ 每天做「伸展運動」連「觀伸展感覺」二次 ➢ 向家人及朋友講解自己再歸因「痛楚不是我，它只是我的經驗」的經驗二至三次	5 分鐘

第六週課程

	內容	時間
6.1	回顧上週家課	15 分鐘
6.2	重溫「觀痛楚感覺及經驗」	15 分鐘
6.3	介紹「轉移注意力」	20 分鐘
6.4	「轉移注意力」練習連集體「轉移行動」	35 分鐘
6.5	訂立「轉移活動」列表	20 分鐘
6.6	本週家課 ➢ 每天進行「觀呼吸」15 分鐘 ➢ 每天做「觀痛楚感覺及經驗」練習 20 分鐘 ➢ 每天做「伸展運動」連「觀伸展感覺」二次 ➢ 每天做「轉移注意力」練習連「轉移活動」一項	5 分鐘

第七週課程

	內容	時間
7.1	回顧上週家課	15 分鐘
7.2	重溫「轉移注意力」	15 分鐘
7.3	介紹「情境演練」	20 分鐘
7.4	「情境演練」練習	60 分鐘
7.5	本週家課 ➢ 每天做「伸展運動」連「觀伸展感覺」二次 ➢ 每天做「轉移注意力練習」連「轉移活動」一項 ➢ 做「情境演練」家課一次	5 分鐘

第八週課程

	內容	時間
8.1	回顧上週家課	15 分鐘
8.2	介紹「復發處理」及練習	40 分鐘
8.3	第四步再評價(Revalue)討論	30 分鐘
8.4	課程總結及維持進步	30 分鐘
8.5	未來三個月家課： ➢ 進行每天預定的「內觀練習」 ➢ 進行復發處理應變計劃	5 分鐘

三個月後的增益療程

	內容	時間
1.	分享處理痛楚復發的成效	45 分鐘
2.	分享持續運用「內觀練習」的經驗及遇到的問題	45 分鐘
3.	鼓勵組員繼續堅持「內觀練習」	10 分鐘

II) 每週的課程內容

第一週

1.1	互相認識及講解一般小組守則	10 分鐘
1.2	自我介紹病情及對治療期望	25 分鐘
1.3	醫生講座	15 分鐘
1.4	講解「長期痛症教育」資料	15 分鐘
1.5	講解「內觀四步抗痛療法」資料	15 分鐘
1.6	進行第一步*再確認*: 分二人小組，互相討論教育質料	30 分鐘
1.7	家課： ➢ 向家人及朋友講解「長期痛症教育資料」(特別是痛苦形成過程）二至三次 ➢ 每次痛楚出現，我們都在心裡覺知，並對自己說：「這是長期痛症的病癥」	5 分鐘

1.1 互相認識及講解一般小組守則

1.2 自我介紹病情及對治療期望

1.3 醫生講座

1.4 講解「長期痛症教育」資料

1.5 講解「內觀四步抗痛療法」資料

1.6 進行第一步「再確認」

➢ 分二人小組，互相討論教育資料，並互相「再確認」長期痛症徵狀

1.7 本週家課

- 向家人及朋友講解長期痛症教育資料（特別是痛苦形成過程）二至三次
- 每次痛楚出現，我們都在心裡覺知，並對自己說：「這是長期痛症的病癥」

第一週家課記錄表

向家人及朋友講解長期痛症資料（特別是痛苦形成過程）二至三次

	講解一	講解二	講解三
完成			

第二週

	內容	時間
2.1	回顧上週家課	10 分鐘
2.2	介紹第二步再歸因及數種內觀練習	15 分鐘
2.3	介紹「觀呼吸」	15 分鐘
2.4	「觀呼吸」練習	20 分鐘
2.5	堂上討論及更正誤解	30 分鐘
2.6	分發「伸展運動」單張及練習	20 分鐘
2.7	本週家課： ➢ 每天進行「觀呼吸」15 分鐘 ➢ 每天做「伸展運動」二次 ➢ 本週暫時毋須練習觀伸展感覺	5 分鐘

2.1 回顧上週家課

2.2 介紹第二步再歸因及數種內觀練習

➢ 觀呼吸、觀身體感覺、觀伸展感覺、觀痛的經驗及感受

呼吸 (分發資料)

呼吸就是生活。你可以把呼吸想像為線或者鏈子，連接了你從出生到死亡、從開始到結束的所有事情。呼吸無時無刻都在發生，就像一條小河自由流淌。

你曾注意過呼吸會隨著我們情緒的變化而發生變化嗎？當我們緊張或生氣時，呼吸會變得短而淺；當我們激動時，呼吸會加快；當我們愉悅時，呼吸會緩慢而均勻；而當我們恐懼時，呼吸甚至可以好像消失一樣。只要我們的生命存在，它就一直伴隨我們存在著。當我們有意識地去覺知它時，它可以像一個錨那樣穩定我們的身體和大腦。我們可以在日常生活的每時每刻覺知到它。

大多數時候，我們不會注意到呼吸的存在，它被遺忘在那裏。所以我們在以內觀為基礎的訓練中，首先要做的就是注意到它的存在，注意呼吸是怎麼隨著我們的情緒、想法和身體動作的改變而改變的。我們不需要去控制它，就像對待朋

友那樣注意並瞭解它就可以了。帶著興趣，放鬆地去觀察和感覺。

我們隨練習對呼吸有更多的覺知，就可以用它來更直接地關注生活的不同方面。例如，放鬆緊張的肌肉，或者關注需要關注的情境。呼吸還有助於幫你處理疼痛、不高興的情緒、日常生活的關係或壓力。在這一練習過程中，我們會更加詳盡地進行探討。

2.3 介紹「觀呼吸」

在內觀的訓練中，我們學習將注意力聚焦在一個點上，訓練時間將持續 15 分鐘，將對呼吸的覺知作為主要目標。這樣做的目的是能夠更好地對已有的心理習慣作出反應，我們需要認識這些心理習慣，並從自動的惡性循環中學會把自己解放出來。很重要的一步是要學會將注意力集中在一個地方，在這裏就是要將注意力集中於呼吸，接納不同想法、情緒、感覺進入我們的大腦，但它們並不控制我們的注意力。

參與練習者開始只是把注意力放在呼吸上，嘗試保持將注意力集中于呼吸，看看會發生些什麼。我們先讓參與你們(練習者)選擇一個的舒服的姿勢，然後讓注意力放到呼吸上，注意呼吸時的情感：每一次吸氣和每一次呼氣。一般來說，內心就會逐漸地發生遊移，給許多雜念或感受牽引。每次當你們注意到內心遊移，脫離了呼吸，就注意是什麼將他們的注意力帶走，然後再溫和地將注意力帶回到呼吸上來。內心會經常性地從呼吸上遊移開，仍然要做相同的事情，那就是：不管注意力到了哪里，每次都要將它帶回到呼吸上。就算是一千次內心遊移，也一千次把注意力溫和地帶回到呼吸上來。

要注意我們反復強調的一點是：覺知到你的內心遊移，要將它帶回到選定的注意目標上（這裏就是指呼吸）。這就是我們學習集中注意的新方法，就是有意識地，此時此刻的，不加判斷的專注。

2.4 「觀呼吸」練習

1、坐在一個舒服的位置上，坐在靠背椅或是表面柔軟的地板上。要是坐在椅子上，背不要靠在椅背上。把腳放在地板上，兩腿不要交叉。調整一下高度直到你坐穩、坐舒服了。慢慢閉上眼睛。
2、把你的注意力放到觸覺，以及你的身體與地面或椅面接觸所感覺到的壓力上來。花一到兩分鐘的時間來探索這種感覺。

3、隨著吸氣和呼氣的進行，覺知吸氣和呼氣的感覺。當吸氣時覺知「我正在吸氣」，當呼氣時覺知「我正在呼氣」。
4、不需要以任何方式來控制呼吸——只要讓它自然進行就可以了。沒有什麼問題需要去解決，也不需要達到任何特殊的狀態。亦不須要強迫自己專注在呼吸上任何時候覺知到自己呼吸的狀態便可以了
5、當吸氣短時，覺知「我作短的吸氣」。當吸氣長時，覺知「我作長的吸氣」。
6、當呼氣短時，覺知「我作短的呼氣」。當呼氣長時，覺知「我作長的呼氣」。
7、或早或遲（通常很快），你的內心會開始遊移，從呼吸到想法、計畫、白日夢或者其他任何東西。這很好——這就是內心會做的，並不是什麼錯誤。當你注意到你的意識不再在呼吸上時，在心裏小聲地祝賀一下——你已經回來並且再次意識到了你的體驗！你可能想簡單瞭解一下自己的意識去了哪兒（哦，正在想某件事情），然後慢慢再回到呼吸的感覺變化上，再次將注意力放到正在進行的吸氣和呼氣上來。
8、無論多少次你注意到內心遊移了（這一過程會不斷地重複），盡你可能，每次祝賀一下你已經回來並且再次意識到了你的體驗，慢慢再回到呼吸的感覺變化上，再次將注意力放到正在進行的吸氣和呼氣上來。
9、盡可能地去完成，友善地關注，把一次次內心的遊移看作體驗耐心和好奇心的機會。
10、繼續練習 15 分鐘，或者你希望持續的更長的時間。不時提醒自己只要去關注此刻正體驗的就可以了。盡可能地去做，每當你的意識發生遊移時，用呼吸作為錨點，再次聯接此時此刻。接下來繼續呼吸。

心數呼吸練習

1. 坐在一個舒服的位置上，坐在靠背椅或是表面柔軟的地板上。要是坐在椅子上，最好背不要靠在椅背上；坐在地板上的話，雙膝最好能碰到地板。調整一下高度直到你坐穩、坐舒服了。
2. 背挺直，保持一個舒服的姿勢。坐在椅子上的話，就把腳放在地板上，兩腿不要交叉。慢慢閉上眼睛。
3. 每吸氣時，提示「我現在吸氣」；呼氣時，內心數「 一」。跟着吸氣時，提示「我現在吸氣」；呼氣時，內心數「二」。如是者, 數到十，然後回到一。
4. 不需要以任何方式來控制呼吸——只要讓它自然進行就可以了。盡可能地去做，在其他練習中也是一樣。沒有什麼問題需要去解決，也不需要達到任何特殊的狀態。盡可能去做，當作正在體驗的就可以。
5. 或早或遲（通常很快），你的內心會開始遊移，從呼吸到想法、計畫、白日夢或者其他任何東西。這很好——這就是內心會做的，並不是什麼錯誤。當你

注意到你的意識不再在呼吸上時，在心裏小聲地祝賀一下——你已經回來並且再次意識到了你的體驗！你可能想簡單瞭解一下自己的意識去了哪兒（哦，正在想事兒），然後慢慢再回到呼吸的感覺變化上，再次將注意力放到正在進行的吸氣和呼氣上來。

6. 無論多少次你注意到內心遊移了（這一過程會不斷地重複），盡你可能，每次祝賀一下你已經回來並且再次意識到了你的體驗，慢慢再回到呼吸的感覺變化上，再次將注意力放到正在進行的吸氣和呼氣上來。
7. 盡可能地去完成，友善地關注，把一次次內心的遊移看作體驗耐心和好奇心的機會。
8. 繼續練習 15 分鐘，或者你希望持續的更長的時間。不時提醒自己只要去關注此刻正體驗的就可以了。盡可能地去做，每當你的意識發生遊移時，用呼吸作錨點再次聯接此時此刻。接下來繼續呼吸。

2.5 堂上討論及更正誤解

E.g. distraction, loss of attention, "right" breathing, boredom, drowsiness, not liking it, pain, negative feelings/emotions

2.6 分發「伸展運動單張」及練習

2.7 本週家課

- 每天進行「觀呼吸」15 分鐘
- 每天做「伸展運動」二次
- 本週暫時毋須練習觀伸展感覺

第二週家課記錄表

1. 每天進行「觀呼吸」15 分鐘

日期	完成觀呼吸／心數呼吸 15 分鐘

2. 每天做「伸展運動」二次

日期	伸展運動一	伸展運動二

第三週

	內容	時間
3.1	回顧上週家課	10 分鐘
3.2	重溫「觀呼吸」	10 分鐘
3.3	「三分鐘呼吸空間」練習	15 分鐘
3.4	介紹「身體掃描冥想」	15 分鐘
3.5	「身體掃描冥想」練習	40 分鐘
3.6	堂上討論及更正誤解	25 分鐘
3.7	本週家課： ➢ 每天進行「心智覺知呼吸」15 分鐘 ➢ 每天進行「身體掃描冥想」30-45 分鐘 ➢ 每天做「伸展運動」二次	5 分鐘

本週家課:

- 每天進行觀呼吸 15 分鐘
- 每天進行身體掃描冥想 30-45 分鐘
- 每天做伸展運動二次

3.1 回顧上週家課

3.2 重溫「觀呼吸」

3.3 「三分鐘呼吸空間」練習

1. 覺知 -- 首先，有意識的坐直，從而把你帶到此時此刻來。如果可能，閉上眼睛，然後問：“什麼是我現在的體驗，我有哪些想法、情感、身體的感覺？”認可並記錄你的體驗，即使它是你不想要的。

2. 聚集 -- 然後，漸漸地把注意力轉換到呼吸，轉換到自然地持續呼氣和吸氣，

一個接著一個。你的呼吸活動好像一個錨點，幫助你調整到此時此刻，並幫助你進入覺知和穩定的狀態。

3. 擴展 -- 圍繞著你的呼吸擴展覺知領域，從而將你的軀體感覺為一個整體，還有你的姿勢、你的表情。*呼吸空間提供了一個與現在聯繫，離開自動引導模式的方式。*

在以後的每一項內觀練習中，你都可以先進行先進行三分鐘呼吸空間練習，幫自己維持對此刻的覺知。

3.4 介紹「身體掃描冥想」

身體掃描冥想的主要目的，是詳細地覺知軀體的每一個部分。你會學習將注意力保持一段時間，這樣也可以幫助他們培養集中的、平靜的、靈活的注意力和覺知。這提供了一個機會來以逐步的、好奇的方式去覺知身體。

患有痛症的人也完全可以進行身體掃描冥想。他們學習覺知身體的每一個部份，也學習透過呼吸放開每一個部份的身體感覺。這樣的話，我們也訓練調節對身體不同部分的痛的感覺的注意。開始的時候，有時病人會覺得把注意力放到身體上，會令他們更加感到痛楚。但通過每天連續數個星期的練習，他們會發覺漸漸能夠接受身體給他們的這些訊息，從而對痛楚更加習慣了。

在身體掃描開始之前，坐在椅子上或是平躺在墊子上或床上。接下來，我們用幾分鐘來進行呼吸活動，然後依着指導語進行身體掃描。你需要將注意力在身體的不同部位之間轉移，目的就是依次地有意識地覺知身體的各個部位，來探索此時此刻在該部位的感覺。在這三十分鐘的身體掃描之中，你有很多機會來練習——覺知軀體的特定部位，保持覺知這個部位一段時間，在將注意力轉移到下一個區域前，放開正在覺知的這個部位。

3.5 「身體掃描冥想」練習

1. 平躺在一個温暖、舒服和不被打擾的地方，例如床上或地板的墊上，慢慢閉上眼睛。

2. 開始的時候，先留意你的呼吸和身體的感覺。開始注意你整個身體的感覺，尤其是你的身體和床或墊子接觸部位的觸覺。每次呼氣，放鬆你自己，讓身

體稍微下沉。

3. 注意這個練習的重點，不是要自己放鬆或者平靜，而是讓自己一步步地注意軀體的各個部位，覺知你身上的各種感覺。

4. 現在把注意力集中在下腹部的感覺上，在你吸氣和呼氣時，覺知下腹感覺的變化。隨著你的呼吸，用幾分鐘去感受這些感覺。

5. 在覺知下腹之後，將注意轉到你的左腿，放到左腳掌及左腳的腳趾上，輪流注意左腳的每一個腳趾，體驗你每一個感覺，例如麻痺、溫暖，或沒有任何感覺。

6. 準備好後，吸氣的時候，想像空氣進入肺內，下傳到小腹、左腳。左腳掌，並從左腳腳趾排出體外。呼氣的時候則剛剛相反，由左腳掌上傳到左腳，並到小腹、胸口，然後從鼻孔排出。儘可能記住這樣的呼吸，由鼻孔向下到腳趾，並從腳趾回來。這可能有點困難，盡量以玩耍的心情去練習便可以了。

7. 現在準備好的時候，放開對腳趾的注意，把注意力集中到於左腳掌上。溫柔地逐步覺知腳底、腳背、腳踝（注意腳踝和墊子或床接觸地方的感覺）。同樣地伴隨呼吸的韻律去探索這些部份的腳的感覺。

8. 現在把注意力擴展到整個左腳上 -- 腳趾、腳踝、腳跟、腳面和關節上去。再深呼吸一下，把氣傳到整個左腳上，呼氣的時候把左腳完全放開，將注意力轉到左腿——依次為小腿、皮膚、膝蓋等等。

9. 繼續輪流將注意力帶到身體的其他部位——左腿上部、右腳趾、右腳掌、右腿、盆骨、後背、腹部、胸部、手指、手臂、肩膀、頸、頭部和臉。在每一個位置，盡可能以同等程度的注意及好奇心去探索當前的身體感覺。離開每個主要部位的時候，在吸氣時把氣吸入這個部位，在呼氣的時候離開那個地方。

10. 當你覺知到緊張或在身體的某一部位的緊張感，利用吸氣慢慢將注意力放到那些感覺上面，然後盡可能地在呼氣的時候讓那些感覺釋放。

11. 你會留意，你的內心不可避免地從呼吸和身體不斷地遊移到其他地方去，你不能經常集中注意力。這是完全正常的，這是心靈的功能。當你注意到這情

況的時候，留意心靈跑到那裏，溫柔地將注意力回到你剛才集中的身體部位上面便可以了。

12. 當你用這方法將全身都掃描了一遍之後，用數分鐘集中於整個身體上的感覺，讓呼吸自由地進出身體。

13. 假如你發覺自己昏昏欲睡，幫自己用枕頭墊高你的頭，張開眼睛，或是坐著而不要躺著去練習。

3.6 堂上討論及更正誤解

- 例如: 過高要求、控制呼吸、執著某些身體感覺、分心

3.7 本週家課

- 每天進行心智覺知呼吸 15 分鐘
- 每天進行身體掃描冥想 30-45 分鐘
- 每天做伸展運動二次

第三週家課記錄表

1. 每天進行「觀呼吸」15 分鐘

日期	完成觀呼吸／心數呼吸 15 分鐘

2. 每天做「伸展運動」二次

日期	伸展運動一	伸展運動二

3. 每天進行「身體掃描冥想」30-45 分鐘

日期	身體掃描冥想

第四週

	內容	時間
4.1	回顧上週家課	15 分鐘
4.2	重溫「身體掃描冥想」	15 分鐘
4.3	介紹「觀伸展感覺」	15 分鐘
4.4	「觀伸展感覺」練習	25 分鐘
4.5	堂上討論及更正誤解	30 分鐘
4.6	本週家課： ➢ 每天進行「心智覺知呼吸」15 分鐘 ➢ 每天進行「身體掃描冥想」30-45 分鐘 ➢ 每天做「伸展運動」連「觀伸展感覺」二次	5 分鐘

4.1 回顧上週家課

4.2 重溫「身體掃描冥想」

4.3 介紹「觀伸展感覺」

進行過兩個星期的呼吸及身體掃描練習之後，我們對這些狀態已有一定的覺知。現在我們把內觀放到一直練習的伸展運動上，做每一個伸展動作的時候，覺知身體的感覺，同樣地，毋須控制這些感覺或是動作本身，只需要原原本本地覺知身體的每一個感覺便可以了。

有些組員會發覺，自己做某些伸展運動的動作時，會有不自然，甚至恐懼的感覺。這或多或少由於那些動作帶來一定程度的痛楚，那麼，在今次觀伸展感覺練習中，這些感覺會更為明顯，這是自然的。我們練習的目的，也在於覺知這些不自然，甚至恐懼的感覺。記著，痛楚是長期痛症的病徵，並不代表身體有傷，而且你對這些伸展運動練過很多次，他們是十分安全的，所以，在本練習中純粹學習覺知這些感覺便可以了。

4.4 「觀伸展感覺」練習

1. 首先，端正地站著，預備好做伸展運動的姿勢，留意自己的呼吸。
2. 現在，開始第一個動作。將手伸到頸旁，向側邊拉。留意頸旁肌肉拉緊的感覺，如果頸旁或手部有輕微痛楚的感覺，也一併覺知到它。留意拉緊或痛楚感覺的變化。
3. 放開手，頸部回復原狀。留意頸旁肌肉舒緩的感覺，也留意痛楚感覺任何的變化。
4. 用另一隻手伸到頸旁向另一邊拉，同樣留意肌肉拉緊或痛楚的感覺。放開手，回復原狀，同樣留意肌肉舒緩及痛楚變化的感覺。
5. 進行第二個動作，手托肘部向上側拉，重複以上第一個動作的覺知方法。如是者一直做到第十個動作。
6. 做任何一個動作的時候，假如痛楚十分強烈，可以把動作的幅度減少，但同樣必須留意肌肉拉緊及痛楚的感覺。假如有不自然，甚至恐懼的感覺，也一併覺知它。
7. 最後做完第十個動作，將注意力放回自己的呼吸上。

4.5 堂上討論及更正誤解

- 例如: 過高要求、執著某些身體感覺、執著於痛楚的感覺

4.6 本週家課

- 每天進行「心智覺知呼吸」15 分鐘
- 每天進行「身體掃描冥想」30-45 分鐘
- 每天做「伸展運動」連「觀伸展感覺」二次

第四週家課記錄表

1. 每天進行「觀呼吸」15 分鐘

日期	完成觀呼吸／心數呼吸 15 分鐘

2. 每天做「伸展運動」連「觀伸展感覺」二次

日期	伸展運動一	觀伸展感覺一	伸展運動二	觀伸展感覺二

3. 每天進行「身體掃描冥想」30-45 分鐘

日期	身體掃描冥想

第五週

	內容	時間
5.1	回顧上週家課	15 分鐘
5.2	重溫「觀伸展感覺」	15 分鐘
5.3	介紹「觀痛楚感覺及經驗」	20 分鐘
5.4	「觀痛楚感覺及經驗」練習	25 分鐘
5.5	分二人小組討論*再歸因*「痛楚不是我，它只是我的經驗」	35 分鐘
5.6	本週家課 ➢ 每天進行「觀呼吸」15 分鐘 ➢ 每天做「觀痛楚感覺及經驗」練習 20 分鐘 ➢ 每天做「伸展運動」連「觀伸展感覺」二次 ➢ 向家人及朋友講解自己再歸因「痛楚不是我，它只是我的經驗」的經驗二至三次	5 分鐘

5.1 回顧上週家課

5.2 重溫「觀伸展感覺」

5.3 介紹「觀痛楚感覺及經驗」

通過觀呼吸、觀身體感覺，及觀伸展感覺的經驗，我們現在來到一個較好的位置去進行四步中的第二步 -- 再歸因。首先留意呼吸，然後擴展到身體的感覺及痛楚的感覺上，留意這些感覺帶出來的任何情緒或想法。觀察這些感覺情緒或想法的變化，留意到他們而來而復去，去而復來，並非永久不變的。由於放開內心要驅走痛楚的執著，我們比較容易找到空間，不至於很快墮入痛楚的陷阱裏面，覺知到「痛楚不是我，它只是我的經驗」。

5.4 「觀痛楚感覺及經驗」練習

1. 坐在一個舒服的位置上，坐在靠背椅或是表面柔軟的地板上。要是坐在椅子

上，背不要靠在椅背上。把腳放在地板上，兩腿不要交叉。調整一下高度直到你坐穩、坐舒服了。慢慢閉上眼睛。

2. 隨著吸氣和呼氣的進行，覺知吸氣和呼氣的感覺。當吸氣時覺知「我正在吸氣」，當呼氣時覺知「我正在呼氣」。
3. 想像自己坐在一條溪水的旁邊，看見水中的樹葉，由左邊慢慢地流去右邊，流到下游，然後消失了。
4. 現在將每一個你覺知到的身體感覺、情緒或想法，放在水中的樹葉上，隨着樹葉由左邊慢慢地流去右邊，流到下游，然後消失了。
5. 無論多少次你覺知到新的身體感覺、情緒或想法（這一過程會不斷地重複），盡你可能，放新的想法或擔在水中的樹葉上，隨着樹葉由左邊慢慢地流去右邊，流到下游，然後消失了。
6. 或早或遲，你會留意到一些痛楚的感覺，厭惡痛的情緒，又或是痛楚帶來的想法（例如：「為什麼這樣也會痛，真要命」）。把這些痛楚有關的經驗或感受都放在水中的樹葉上，看著它同樣地流去一邊，慢慢消失。
7. 看著越來越多痛楚有關的經驗或感受出現、流動，然後慢慢消失，漸漸覺知到它們來而復去，去而復來。覺知這個「我」正在觀察他們。
8. 繼續練習 20 分鐘，或者你希望持續的更長的時間。不時提醒自己只要去關注此刻正體驗的就可以了。

5.5 討論「*再歸因*」

- 分二人小組討論「痛楚不是我，它只是我的經驗」

5.6 本週家課

- 每天進行「心智覺知呼吸」15 分鐘
- 每天做「觀痛楚感覺及經驗」練習 20 分鐘
- 每天做「伸展運動」連「觀伸展感覺」二次
- 向家人及朋友講解自己再歸因「痛楚不是我，它只是我的經驗」的經驗二至三次

第五週家課記錄表

1. 每天進行「觀呼吸」15 分鐘

日期	完成觀呼吸／心數呼吸 15 分鐘

2. 每天做「伸展運動」連「觀伸展感覺」二次

日期	伸展運動一	觀伸展感覺一	伸展運動二	觀伸展感覺二

3. 每天做「觀痛楚感覺及經驗」練習 20 分鐘

日期	觀痛楚感覺及經驗

4. 向家人及朋友講解自己再歸因「痛楚不是我，它只是我的經驗」的經驗二至三次

	講解一	講解二	講解三
完成			

第六週

	內容	時間
6.1	回顧上週家課	15 分鐘
6.2	重溫「觀痛楚感覺及經驗」	15 分鐘
6.3	介紹「轉移注意力」	20 分鐘
6.4	「轉移注意力」練習連集體「轉移行動」	35 分鐘
6.5	訂立「轉移活動」列表	20 分鐘
6.6	本週家課 ➢ 每天進行「觀呼吸」15 分鐘 ➢ 每天做「觀痛楚感覺及經驗」練習 20 分鐘 ➢ 每天做「伸展運動」連「觀伸展感覺」二次 ➢ 每天做「轉移注意力」練習連「轉移活動」一項	5 分鐘

6.1 回顧上週家課

6.2 重溫「觀痛楚感覺及經驗」

6.3 介紹「轉移注意力」

來到第三步轉移注意力，我們承接上一步的經驗，將痛楚經驗重新歸因和定位，便練習在日常生活中，透過內觀將注意力從痛楚移開，並回到呼吸上，內心保持平靜和放鬆，開展預先選好的有益有趣的活動，例如：散步、聽音樂、伸展運動、讀書、做小食、種花等。你可以運用 15 分鐘法則，在痛楚出現後，就立即反應，在 15 分鐘內，透過以下的冥想練習，去注意那些伴隨著痛的感覺、焦慮的情緒，或是負面的想法的慣性行動傾向。在覺知到這些慣性行動傾向的時候，我們便可以訓練自己，將注意焦點轉移到預先選好的有益有趣的活動上。

6.4 「轉移注意力」練習

1. 開始三分鐘呼吸練習，將注意力轉移到身體上的感覺。呼氣和吸氣的時候專

注到身體上面。

2. 當你留意到痛楚的感覺的時候，將注意力溫柔地放在上面，並覺知自己的呼吸。
3. 現在留意痛的感覺有沒有將你帶到一些令你蠢蠢欲動的慣性反應。練習將注意力集中在你想做的行動上面。會否想停止手頭上的活動，立刻坐下，或者想躺在床上減輕痛楚？留意這些反應一向以來是否經常發生，自己是否習慣了這些行動傾向？覺知這些慣性反應的傾向，並不時回到呼吸的基礎上。
4. 現在嘗試於呼吸的的空間上作出另外一些選擇，去繼續手頭正在做的事情，又或是選擇做一件你想做的事情，而不選擇痛楚的感覺引發的慣性行動方向。覺知自己已經將注意力放到這些另外的選擇上面。
5. 現在將注意力放到現在的行動上，留意到它並不是受痛楚或有關的感受推動，而是發自你感興趣的目標，例如看書、種花、閱讀、和人談話，等等。
   * 堂上練習時將行動目標放到集體的行動上，例如到附近的小徑散步，欣賞花草 15 分鐘。
6. 最後將注意力轉回到呼吸上，繼續練習數分鐘。

6.5 訂立「轉移活動」列表

請預先制定一系列的轉移活動，以便未來數個星期之用。轉移活動是一些有益有趣的活動，可以隨時進行。帶著痛的時候，也全心全意地轉移注意力，投入其中。

以下是一些例子：買東西給自己（最好不要過重）、到公園呼吸新鮮空氣、讀出一篇有趣的文章、笑一頓、和小動物或寵物玩耍、慢慢地洗澡、做小食、唱歌給自己聽、聽收音機、影相等等。

在以下的空位上，寫出十項你可以進行的轉移活動，也寫上合適的場合。記著，這些活動要有益有趣，並且實際可行。

轉移活動	場合（例：家裏、工作間、學校...）
1.	
2.	
3.	
4.	
5.	
6.	

7.	
8.	
9.	
10.	

6.6 本週家課

- 每天進行「心智覺知呼吸」15 分鐘
- 每天做「觀痛楚感覺及經驗」練習 20 分鐘
- 每天做「伸展運動」連「觀伸展感覺」二次
- 每天做「轉移注意力練習」連「轉移活動」一項

第六週家課記錄表

1. 每天進行「觀呼吸」15 分鐘

日期	完成觀呼吸／心數呼吸 15 分鐘

2. 每天做「伸展運動」連「觀伸展感覺」二次

日期	伸展運動一	觀伸展感覺一	伸展運動二	觀伸展感覺二

3. 每天做「觀痛楚感覺及經驗」練習 20 分鐘

日期	觀痛楚感覺及經驗

4. 每天做「轉移注意力練習」連「轉移活動」一項

日期	轉移注意力練習	轉移活動（可寫號碼）

第七週

	內容	時間
7.1	回顧上週家課	15 分鐘
7.2	重溫「轉移注意力」	15 分鐘
7.3	介紹「情境演練」	20 分鐘
7.4	「情境演練」練習	60 分鐘
7.5	本週家課 ➢ 每天做「伸展運動」連「觀伸展感覺」二次 ➢ 每天做「轉移注意力練習」連「轉移活動」一項 ➢ 做「情境演練」家課一次	5 分鐘

7.1 回顧上週家課

7.2 重溫「轉移注意力」

7.3 介紹「情境演練」

在本節中，我們會將過往數節內觀練習綜合起來，並應用到不同的情景中。這些情景，都是大家常常經歷，因長期痛症而引發出來的困苦情況。在當中的時候，大家可能會不自覺地作出慣常的情緒或行為反應，從而陷在困苦的惡性循環中。

在今天的情境演練當中，我們練習應用以往數周所學習的內觀方法，去處理及面對這些情況。

現在，請大家分為二人一組，二人輪流扮演當事人及評估員。

首先，由評估員想出一個他最常遇到的，因長期痛症引起最令他困苦的情況，描述出來，然後由當事人慢慢想出怎樣應用各種內觀方法，包括觀呼吸、觀身體及痛楚感覺、轉移注意力等等，去面對這個情況。之後，在評估員面前演習

一次，再由評估員給分（分數由一至十）。之後，二人轉換角色再演習一次。

本週我們會有情境演練家課。請大家選一個情況，容易讓自已好好綜合應用所學過的各種內觀練習，寫在家課的空間上。在一星期內應用出來，完成後再在最後一格填上效果。

7.4 「情境演練」練習

7.5 本週家課

- 每天做「伸展運動」連「觀伸展感覺」二次
- 每天做「轉移注意力練習」連「轉移活動」一項
- 做「情境演練」家課一次

第七週家課記錄表

1. 每天做「伸展運動」連「觀伸展感覺」二次

日期	伸展運動一	觀伸展感覺一	伸展運動二	觀伸展感覺二

2. 每天做「轉移注意力練習」連「轉移活動」一項

日期	轉移注意力練習	轉移活動（可寫號碼）

3. 做「情境演練」家課一次

情境	選定的內觀方法	效果

第八週

	內容	時間
8.1	回顧上週家課	15 分鐘
8.2	介紹「復發處理」及練習	40 分鐘
8.3	第四步*再評價*(Revalue)討論	30 分鐘
8.4	課程總結及維持進步	30 分鐘
8.5	未來三個月家課： ➢ 進行每天預定的「內觀練習」 ➢ 進行復發處理應變計劃	5 分鐘

8.1 回顧上週家課

8.2 介紹「復發處理」及練習

經過多個星期以來的內觀練習，我們學習覺知到達長期痛症的特性 --它不會完全消失，只會來而復去，去而復來，我們知道痛楚必然會復發。在最後一周的療程裏，我們學習復發處理的方法，這包括留意痛楚復發的早期警號，預先作好處理復發的準備，並評估處理的成效。

首先，我們請組員分享他們最常遇到標示著痛楚復發的早期警號，例如天氣變化、活動過多、壓力增加等等，也討論一下內觀怎樣可以幫助我們及早覺察這些早期警號。

接著，大家討論一下，怎樣運用所學習過的內觀方法，預先制定好痛楚復發的應變計劃，例如留意自己的痛楚及情緒變化並預早計劃好轉移行動。最後鼓勵組員互相聯絡，以支持雙方堅持內觀練習，並及早處理復發的警號。

痛楚復發的早期警號

痛楚復發的應變計劃

8.3 第四步*再評價* (Revalue)

來到課程最後，亦是四步療法的最後一步：*再評價*。由組員互相分享，從課程開始到結束，有否將痛楚在他們生命中的位置重新定位，亦有沒有重新建立自己的價值；如何帶著痛楚，繼續有意義地生活下去。

8.4 課程總結及維持進步

8.5 未來三個月家課：

- 進行每天預定的「內觀練習」
- 進行復發處理應變計劃

「內觀練習」記錄表（療程完結後使用）

日期	內觀練習類別（呼吸、身體、伸展、痛楚、轉移活動）	備註

痛楚復發的早期警號	痛楚復發的應變計劃	效果

三個月後的增益療程

1. 分享處理痛楚復發的成效

2. 分享持續運用「內觀練習」的經驗及遇到的問題

3. 鼓勵組員繼續堅持「內觀練習」

Appendix C

Chinese versions of all questionnaires

內觀四步抗痛療法研究問卷

Demographics

1．填寫日期：_____ 2．姓名：

_____

3．性別：□男 □女 4．年齡：_____

5．婚姻狀況：

□未婚 □已婚 □分居 □鰥寡 □離婚

6．子女數目（如適用）：_____ 7.子女年齡：

_____

8．現在你與誰一同居住？

□獨居 □配偶 □子女 □配偶及子女

□配偶、子女及長輩 □親戚 □朋友

□其他：_____

9．教育水平：

□沒有受教育 □小學 □初中 □高中

□預科／文憑 □大學或以上

10．出現痛症前的主要職業：

_____

11. 現時的工作狀況:

□全職受薪工作 (請註明職業:_____)

□自僱 (請註明職業:_____; 平均每星期開工時數: _____小時)

□兼職 (請註明職業:_____; 平均每星期開工時數: _____小時)

□散工 (請註明職業:_____; 平均每星期開工時數: _____小時)

□照顧家庭 □學生 □退休

□義務工作(請註明性質:_____; 平均每星期服務時數: _____小時)

□失業 - 正找尋工作

□失業 – 沒有找尋工作

□其他 (請註明:_____)

12. 過去三個月內，你總共返了多少天有入息的工作？ _____天

13. 痛症對工作的影響:

□能夠維持與病發前大致相同的工作性質

□已轉職到體力要求較少或工作時數較短的工作崗位

□因痛症不能再工作

14. 你的痛症從那時開始？□□□□年□□月

15. 如你的痛症隔一段時間才出現，請寫上最近一次的痛楚從哪時開始？□□□□年□□月

16. 你的痛症是怎樣開始的？(如多於一項適用，請填上<u>最適合的一項</u>)

□工作中發生意外 □工作中，但不涉及意外 □家居意外

□交通意外 □手術後 □病後

□沒有明確原因 □其他：_____

24. 你是否因工受傷（即是工傷）？□是　□否

25. 你的痛症是否涉及訴訟？　□是　□否

26. 你的痛症是否涉及保險賠償？□是　□否

27. 你現時有否獲得以下的援助？□綜援 □傷殘津貼　□沒有

Pain Intensity and Unpleasantness

請圈出在過去的一星期內，你感受到的平均痛楚強烈程度： （0 表示沒有痛，10 表示可想像到最劇烈的痛楚） 沒有痛　0　1　2　3　4　5　6　7　8　9　10　可想像到最劇烈的痛
請圈出在過去的一星期內，你感受到的平均痛楚令你討厭的程度： （0 表示完全不討厭，10 表示可想像到最討厭的程度） 完全不討厭　0　1　2　3　4　5　6　7　8　9　10　可想像到最討厭的程度

MPI-Interference

完全沒有　0　1　2　3　4　5　6　7　完全受影響

1. 一般來說，你的痛楚干擾你日常的生活有多少？	
2. 自從有了痛症，你的工作能力受了多大影響？	

3. 你的痛楚影響你從社交和娛樂活動得到的滿足感或樂趣有多少？	
4. 你的痛楚影響你參予娛樂和其他社交活動的能力有多少？	
5. 你的痛楚影響你從和家庭有關的活動得到的滿足感或樂趣有多少？	
6. 你的痛楚影響你和配偶、家人或其他重要人仕的關係有多少？	
7. 你的痛楚影響你從工作得到的滿足感或樂趣有多少？	
8. 你的痛楚影響你做家務的能力有多少？	
9. 你的痛楚影響你和朋友的關係有多少？	

PGIC

請圈出在本療程中你的進步程度為：

1 改善十分多
2 頗有改善
3 少許改善
4 無改變
5 少許變差
6 頗有變差
7 變差十分多

請圈出在本療程中你的滿意程度為：

1 改善十分多
2 頗有改善
3 少許改善
4 無改變
5 少許變差
6 頗有變差
7 變差十分多

Healthcare Use

過往一個月內，你因為痛而放的病假有多少天 _____ 天 或 _____不適用

過往一個月內，你因為痛而到急症室有多少次 _____ 次

過往一個月內，你因為痛而看私家醫生有多少次 _____ 次

PSEQ

即使痛楚，請評估你**現在**有幾多信心能夠做到以下的事情，請你在量表上，圈出適當的答案。
請記著，這問卷不是問你有沒有做過那些事情，而是**即使痛楚**，你現在有幾多信心能夠做到以下的事情。

完全沒有**信心** 0 1 2 3 4 5 6 非常有信心

1.	即使痛楚，我仍能享受日常生活中的事物。	0	1	2	3	4	5	6
2.	即使痛楚，我仍能做大部份的家務。(如打掃、洗碗碟等)	0	1	2	3	4	5	6
3.	即使痛楚，我仍能與我的朋友或家人如常交往。	0	1	2	3	4	5	6
4.	在大多數情況下，我都能應付我的痛楚。	0	1	2	3	4	5	6
5.	即使痛楚，我仍能做一些工作。(「工作」包括家務、有薪金或無薪金的工作)	0	1	2	3	4	5	6
6.	即使痛楚，我仍能做很多我享受做的事情。(如我的興趣及娛樂活動)	0	1	2	3	4	5	6
7.	不用藥物，我仍能應付我的痛楚。	0	1	2	3	4	5	6
8.	即使痛楚，我仍能完成我生命中大部份的目標。	0	1	2	3	4	5	6
9.	即使痛楚，我能過一個正常的生活。	0	1	2	3	4	5	6
10.	即使痛楚，我能漸漸變得更加活躍。	0	1	2	3	4	5	6

PCS

每個人都會經歷過痛楚的情況，這些經歷可能包括牙痛、頭痛、關節或肌肉痛，

人們遇到某些情況(如疾病、受傷、牙齒治理程序、或手術)都會經歷痛楚。我們想了解當你痛楚時所出現的思想及感受，請在下列 13 項可能與痛楚有關的思想及感受的句子，**用以下的量表，圈上你痛楚時它們出現的程度**。

		完全沒有	輕微不多	一般中度	甚多出現	常常出現
1.	當我痛楚時，我常常不知究竟痛楚會否完結。	0	1	2	3	4
2.	當我痛楚時，我感到不能再繼續下去。	0	1	2	3	4
3.	當我痛楚時，它是可怕的，我估計永遠也不可能轉好。	0	1	2	3	4
4.	當我痛楚時，它是恐怖的，痛楚將我完全淹沒 (包圍著)。	0	1	2	3	4
5.	當我痛楚時，我感到不能再支持下去。	0	1	2	3	4
6.	當我痛楚時，我害怕痛楚會越來越嚴重。	0	1	2	3	4
7.	當我痛楚時，我不斷想著其他痛楚事情。	0	1	2	3	4
8.	當我痛楚時，我焦慮地希望痛楚離去。	0	1	2	3	4
9.	當我痛楚時，我似乎不能將它排出我的思想。	0	1	2	3	4
10.	當我痛楚時，我不斷思想它帶來多少傷害。	0	1	2	3	4
11.	當我痛楚時，我不斷思想我是多麼的渴望痛楚停止。	0	1	2	3	4
12.	當我痛楚時，我不能做任何事情，減少痛楚的程度。	0	1	2	3	4
13.	當我痛楚時，我擔心會否一些嚴重的事情 (後果) 會出現。	0	1	2	3	4

CPAQ

指引：以下是一系列的陳述句子。請跟據每一句反映你自己情況的真確性來計分，並且按以下計分尺度來選擇分數。例如，如果你認為一句是「永遠正確」，你可在句後括弧內填寫一個 **6** 字。

0 = 從不正確　**1** = 極少正確　**2** = 很少正確　**3** = 有時正確
4 = 經常正確　**5** = 幾乎永遠正確　**6**= 永遠正確

1.	無論我的痛有多嚴重，我都可以照常生活。	(　)
2.	雖然我有慢性痛症，我的生活依然過得頗好。	(　)
3.	就算感到痛楚也是沒有問題的。	(　)
4.	我願意犧牲生命中一些重要的東西去將痛控制得好一些。	(　)
5.	我不需要為了將生活處理得更好而去控制我的痛。	(　)
6.	雖因慢性疼痛而導致我的身心出現變化，我依然過著正常的生活。	(　)
7.	我需要專注於把痛除去。	(　)
8.	在我感覺痛楚的同時，我依然有很多活動可做。	(　)
9.	雖然我有慢性疼痛，我依然過著完整充實的生活。	(　)
10.	控制痛楚比起我生命中其它目標來說是**次要**的。	(　)
11.	在我踏出生命中重要的步伐之前，我對痛的想法和感受必須改變。	(　)
12.	雖然有疼痛，我現在依然緊貼生命前進。	(　)
13.	每逢我做任何事的時候，將我的痛楚水平控制好總是佔著首要位置。	(　)
14.	我必須要先控制一下我的痛楚，然後才能做出任何重要計劃。	(　)
15.	當我的痛楚加劇時，我依然能完成我要負責的事。	(　)
16.	如果我能控制我對於痛楚的負面想法，我將更好的掌握我的生活。	(　)
17.	我避免將自己置於可能會令我痛楚加劇的情形中。	(　)
18.	對於痛楚將如何影響我，我的憂慮和恐懼是真實的。	(　)
19.	當知道不需要改變我的痛楚而仍能繼續生活，對我來說是一種解脫。	(　)
20.	當我有痛時，我必須幾經掙扎才能做到一些事情。	(　)

MAAS

請根據最近一周的情況來考慮每個條目，請如實地憑著您的直覺去回答每個問題並在合適的答案上打圈。這些答案沒有所謂的“對”與“錯”、“好”與“壞”

之分。我們最希望得到的是您自己真正的體驗。

		總是	經常	有時	有時不	經常不	決不
1.	我可能會經歷某些情緒，直至一段時間以後 才意識到它。	1	2	3	4	5	6
2.	我可能會因為不小心、沒有注意或者在 想別的事情從而打碎或倒翻一些東西。	1	2	3	4	5	6
3.	我很難把注意力集中在當前發生 的事情上。	1	2	3	4	5	6
4.	通常我會快步走到要去的地方，而根本沒有注意到 走路的過程中有甚麼經驗。	1	2	3	4	5	6
5.	如果身體的緊張或不適沒有嚴重到一定 的程度，我通常是不會注意到它們的。	1	2	3	4	5	6
6.	別人第一次告訴我她（他）名字的時候， 我通常很快就忘了。	1	2	3	4	5	6
7.	我好像是自動化地在做一些事情， 而沒有注意到自己在做甚麼。	1	2	3	4	5	6
8.	我趕快做完事情，而沒有真正留意那些事物本身。	1	2	3	4	5	6
9.	我太專注於所追求的目標而忽略了做時的過程。	1	2	3	4	5	6
10.	我總是在沒有意識的情況下，機械地工作 或完成某項任務。	1	2	3	4	5	6
11.	我發覺自己一邊聽人說話，一邊又在做另外的事情。	1	2	3	4	5	6
12.	我去地方時會進入「自動導航」狀態，	1	2	3	4	5	6

	有時事後也想不起怎樣到達那裏。						
13.	我發覺自己過分地專注於未來或者是過去的事情。	1	2	3	4	5	6
14.	我發覺自己做事情時沒有專注於其中。	1	2	3	4	5	6
15.	我吃東西時，總沒有留意自己吃時的感覺。	1	2	3	4	5	6

BDI - 2

姓名：_____ 性別：_____ 年齡：_____ 日期：_____

婚姻狀況：_____ 職　業：_____ 教育程度：_____

指示：這份問卷有 21 組句子。請仔細閱讀每一句，然後在每組句子中，選出一句最能貼切地形容你過去兩個星期（包括今天）的感覺。請你把所選句子旁邊的數字圈上。若在一組中超過一句同時能夠形容你的感受，請你圈上數字最大的一句。請你緊記不要在任何一組句子挑選超過一句，包括第 16 組（睡眠模式的轉變）及第 19 組（胃口轉變）。

1. 悲哀
   - 0　我不感到悲哀。
   - 1　在大部份時間，我感到悲哀。
   - 2　無論何時，我都感到悲哀。
   - 3　我實在不能忍受我的悲哀和不快樂。

2. 悲觀
   - 0　我對將來並不感到沮喪。
   - 1　跟以前比較，現在我對我的將來感到更加沮喪。
   - 2　我不期望事情會得到解決。
   - 3　我感到我的將來沒有希望，而且會轉壞。

3. 過去的失敗
   - 0　我不覺得我是一個失敗者。
   - 1　我失敗的次數比我預期的多。
   - 2　回望過去，我失敗了很多次。
   - 3　我覺得我是一個完全失敗的人。

4. 失去快樂 / 滿足感
   - 0　我和以往一樣，在我喜歡做的事中，得到滿足。
   - 1　我沒有以往般享受我喜歡做的事。
   - 2　過往我喜歡做的事，現在我做起來，很少樂趣。
   - 3　過往我喜歡做的事，現在我不能得到任何樂趣。

5. 內疚感

0 我不感到特別內疚。

1 對於很多我所做的事，或應做（但沒有做）的事，我感到內疚。

2 大部份時間，我感到內疚。

3 任何時間，我都感到內疚。

6. 被懲罰的感覺

0 我不感到我正在被懲罰。

1 我感到我可能會被懲罰。

2 我預期會被懲罰。

3 我感到我正在被懲罰。

7. 不喜歡自己

0 我對自己的感覺和以往一樣。

1 我對自己失去信心。

2 我對自己失望。

3 我不喜歡自己。

8. 自我挑剔

0 我沒有比平時更挑剔自己。

1 我比以往更挑剔自己。

2 我為我每一樣過錯而責備自己。

3 我因一切已發生的不幸事件而責備自己。

9. 自殺念頭

0 我沒有想過自殺。

1 我有想過自殺，但我不會實行。

2 我想自殺。

3 如果我有機會，我會自殺。

10. 哭

0 我沒有比平常哭得多。

1 我比以往哭得多。

2 我為著每件小事而哭。

3 我想哭，但哭不出來。

11. 煩亂

0 我不比平日煩亂。
1 我比平日不安。
2 我很不安，以致難以安定下來。
3 我很不安，我要不斷郁動或做些什麼。

12. 失去興趣

0 我對別人或活動沒有失去興趣。
1 相比以前，我對人或事的興趣減少了。
2 我已失去大部份對人或事的興趣。
3 我很難對任何事發生興趣。

13. 猶疑不決

0 我做決定的能力，跟平時一樣。
1 我比平日難做決定。
2 我做決定的能力比過往差了很多。
3 我做任何決定也很困難。

14. 一無是處

0 我不覺得自己一無是處。
1 我不覺得我和以前一般有用。
2 與他人比較，我覺得我自己有用。
3 我覺得自己極之無用。

15. 失去精力

0 我的精力和平時一樣。
1 我的精力比以前少了。
2 我不夠精力去做很多事。
3 我沒有足夠精力做任何事。

16. 睡眠模式轉變

0 我的睡眠模式沒有任何轉變。
1a 我睡得比平時多一些。
1b 我睡得比平時少一些。
2a 我睡得比平時多很多。
2b 我睡得比平時少很多。
3a 全日大部份時間，我都睡覺。
3b 我早了一至兩個小時起床，而不能再入睡。

17. 容易發怒

0 我不比平時容易發怒。

1 我比平時容易發怒。

2 我比平時非常容易發怒。

3 我經常容易發怒。

18. 胃口轉變

0 我的胃口沒有任何轉變。

1a 我的胃口比平時少了一些。

1b 我的胃口比平時大了一些。

2a 我的胃口比以前少了很多。

2b 我的胃口比平時大了很多。

3a 我完全沒有胃口。

3b 我整天都想吃東西。

19. 難於集中精神

0 我能夠像平時一樣集中精神。

1 我不能夠像平時一樣集中精神。

2 我很難很長時間專注於任何事。

3 我發覺我不能集中精神於任何事。

20. 疲累

0 我不比平時疲累。

1 我比平時易於疲累。

2 我太疲累，以至我不能做很多我以前常做的事。

3 我太疲累，以至我不能做絕大部份我以前常做的事。

21. 對性失去興趣

0 我不覺得最近我對性的興趣有任何改變。

1 我對性的興趣，比以往減少一些。

2 我現在對性的興趣減少了很多。

3 我對性的興趣完全失去了。

— 完 —