A CBT inpatient chronic pain management model:

Factors impacting treatment outcomes

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Declarations

Statement of Originality

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Thesis Abstract

Scope: This paper reviews the current understanding of chronic pain and how it is managed. It also discusses perpetuating factors of chronic pain and the importance of a broad biopsychosocial approach to treatment. Currently, research into chronic pain interventions has neglected the common factors of effective treatments, that is, extra-therapeutic factors, the therapeutic alliance and the client's confidence in the treatment, in addition to the treatment model and techniques.

Purpose: The purpose of this article is to assess the impact of extra therapeutic factors on the effectiveness on an inpatient chronic pain management program. This is a pilot study to demonstrate the applicability of research into extra therapeutic factors in chronic pain interventions.

Methodology: A two week in-patient Cognitive Behaviour Therapy (CBT) pain management program was conducted. Outcome measurements were obtained for 23 participants at pre-treatment, 23 at 2 weeks and 20 at 12 weeks. These included the Chronic Pain Acceptance Questionnaire Revised (CPAQ-R), Pain Beliefs Questionnaire (PBQ), Depression Anxiety Stress Scale 21 (DASS 21), Posttraumatic Stress Disorder Checklist-Specific (PCL-S), State-Trait Anger Expression Inventory 2 (STAXI-2) and the Impact Event Scale - R (IES-R). Inferential statistics were used to investigate bivariate relationships between the psychometric outcomes and potential factors, including demographics and predictive scales.T tests or *F* tests, or their non-parametric equivalents,were used depending on the distributions of the outcome variables.

Results: The authors found that participants increased their pain acceptance and their belief in psychological aspects of pain over the course of the pain intervention. They also decreased their symptoms of depression and beliefs that their experience of pain is only physical. They found that there were client factors that impacted the effectiveness of

treatment. For example, greater pain acceptance was achieved with age; the fewer previous interventions the participants undertook, the greater the decrease in depressive symptoms; and the lower the distress in previous treatments, the greater the increase in psychological pain beliefs. These results show that here there are a range of identifiable factors that can influence pain management intervention outcomes.

General Conclusions and Implications: This study had a small participant size and low statistical power. As a pilot study, this study therefore serves to highlight areas of future research particularly psychosocial therapeutic factors that impact pain management outcomes. Its findings suggest that a broader psychosocial approach as an adjunct to medical intervention offers practical common factors for use in chronic pain programs. Shifting the culture of pain management to focus on the client as a source of information about what works in pain management rather than the treatment itself has implications for future treatment.

Contents

Critical Review

In the past, illness and disease was understood only in terms of organic changes with biological processes and physical methods of treatment as their means of recovery (R. C. Smith, 2002) However, a more holistic approach to health has emerged to include the human factors in disease and recovery. This is due to the significance of the individual's role in their own health and recovery has grown in appreciation, The biopsychosocial model views health as a complex interaction between biological processes, psychological responses and the social environment (Engel, 1980; Turk & Okifuji, 2002). It promotes a comprehensive assessment and treatment of disease and disability, rather than focusing on structural physical condition of the body. This has an advantage in the assessment and management of chronic pain where structural changes, such as herniated disks, are common in those without chronic pain (Jensen et al., 1994).

Background

Chronic pain is the experience of having persistent and enduring pain for longer than six months beyond the duration of the injury (Merskey & Bogduk, 1994; Nicholas, Molloy, Tonkin, & Beeston, 2011). It has been estimated that over one in five Australians will suffer from chronic pain in their life, leading to a cost of $34.3 billion to the Australian economy each year (The MBF Foundation & Access Economics, 2007). This includes costs to the health care system, the individual sufferers and the friends and families who care for them. The costs come in the forms of the extra health services required, medication, and lost productivity. It is essential that pain management programs validate the complexity of chronic pain in individual lives and work effectively to reduce the impact on the individual, families, and the community.

Co-occurring conditions of Chronic Pain

The biopsychosocial model has progressed with awareness of illness, pain and recovery are impacted at various levels from broad social factors down to the molecular level. For example, the pain experience two years after a back injury has been found to relate to nutrition (Bell, Borzan, Kalso, &Simonnet, 2012), depression (Blyth et al., 2001), social support (Lopez-Martinez, Esteve-Zarazaga, & Ramirez-Maestre, 2008) and exercise (Cramer et al., 2013). The biomedical model was unable to explain the reciprocal process of experiences of pain impacting the biological, psychological and social attributes of a person, while these attributes in turn have a significant effect on the experience of pain (Suprina, 2003). By contrast, the biopsychosocial model is a holistic framework for understanding how hope, therapeutic relationships and psychosocial stressors can impact illness and recovery beyond injury and treatment.

The biospychosocial model of pain, as the name suggests, is concerned with the biological, psychological and social impacts on pain and recovery. First, direct biological impacts on pain include tissue damage, nerve damage and disease. There are also indirect biological processes that mediate the pain experience, such as the Hypothalamic-Pituitary-Adrenal Axis (HPA) and autonomic system (Delgado, Postigo, & Rodriguez, 2012; Jamani & Clyde, 2008; Kalina, 2012). Second, impacting psychological factors include depression, stress, aggression and hope (Bair, Robinson, Katon, & Kroenke, 2003; Goldenberg, 2010).Third, the social context of the pain sufferer, including socioeconomic, church membership and family support play an important role in the vulnerability, development and treatment of chronic pain (Astrand & Isacsson, 1988; Hoogendoorn, van Poppel, Bongers, Koes, & Bouter, 2000; Koleck, Mazaux, Rascle, & Bruchon-Schweitzer, 2006; Rippentrop, 2005). All of these factors are dynamic and interact with the symptoms and experience of pain, yet each has their own specific relationship with pain. How these social and

psychological factors impact on the experience of pain can also be understood in terms of pain specific models.

Gate Control Theory of chronic pain posits the complex interplay between the central nervous system and the peripheral nervous system, both of which process pain signals independently, and psychological factors (Melzack & Wall, 1967). Gate Control Theory recognises that pain messages encounter nerve 'gates' that allow access or not to the brain and consciousness. Though these processes are still poorly understood, more recent studies show that physical and psychological distress do share neurotransmitter processes (Eisenberger, 2012; Moskowitz & Fishman, 2006). This overlap is also seen in the interaction of chronic pain and stress with HPA axis and the autonomic nervous system activation (Delgado, Postigo, & Rodriguez, 2012; Jamani & Clyde, 2008; Kalina, 2012; McBeth et al., 2005).

More recent theories of pain perception include the 'neuromatrix' theory of pain perception (Melzack & Katz, 2013). This theory suggests a more brain centric theory of pain, where a sensory representation of the body is maintained in the brain, called the neuromatrix. This representation is influenced by sensory, affective and cognitive inputs. This neuromatrix establishes a homeostatic sensory experience. However, when there are changes in the neuromatrix in the form of pain, injury or cancer, the autonomic nervous system and HPA Axis are activated to re-establish homeostasis.

Stress resulting from chronic pain excites the autonomic nervous system and HPA Axis. The autonomic nervous system activates the sympathetic nervous system for prolonged periods of time, accelerating heartbeat, interfering with digestion, promoting the secretion of adrenaline and noradrenaline and increasing muscle tension. Stimulation of the HPA axis ultimately results in the production of the stress hormone Cortisol. Prolonged elevated production of Cortisol leads to high blood pressure, muscle atrophy, an impaired ability for

tissue repair, and a depressed immune system, along with anxiety and depressive symptoms. Cortisol can also inhibit the reproductive system increasing the chance of miscarriages in females (Nepomnaschy et al., 2006) and sexual dysfunction in males (Uckert et al., 2003). Subsequently, prolonged physiological stress in response to chronic pain often creates a feedback loop between the chronic pain and stress reactivity. Thus chronic pain increases physiological and psychological stress, while the stress exacerbates the experience of pain. However, psychotherapies and pharmacotherapies have been successful in reducing these aggravating biological factors by decreasing psychological stress and anxiety subsequently reducing the activation of the HPA axis and the autonomic nervous system (Delgado, et al., 2012; Jamani & Clyde, 2008; Kalina, 2012). Therefore, activation of these systems appears to be mediated by how the sufferer reacts to the pain rather than the quality of the pain itself. This creates an opportunity for psychological interventions that promote change in the client's relationship with pain. Psychological interventions also give chronic pain sufferers a means of personal control over their pain rather than a reliance on pharmacotherapy or surgery.

Pharmacotherapy is the primary method of treating the biological factors involved with chronic pain. How this therapy interacts with chronic pain depends on the type of pharmaceuticals administered. Non-steroidal anti-inflammatory drugs, such as aspirin, are popular for their affective pain relief and ability to reduce inflammation. However, long term use carries a risk of painful gastrointestinal side effects as well cardiovascular complications (Kroenke, Krebs, & Bair, 2009). Long term Opioid use also carries the risk of addiction, impactingon the ability to cope with and maintain quality of life, for example mental illness, having more severe pain or multiple areas of pain (Sehgal, Manchikanti, & Smith, 2012). In the United States, prescription medication is associated with more deaths than cocaine and heroin combined (Paulozzi, Kilbourne, & Desai, 2011). Additionally, opioid pain

medications typically sedate the prescription user and can cause nausea which puts further stress on their physical health (Buenaventura, Adlaka, & Sehgal, 2008). It is essential that alternate interventions are researched and developed to reduce the dependence on pharmacotherapy and potentially replace it.

Anti-depressants can effectively decrease the experience of pain and comorbid depression. However, there are a range of potential side effects that suggest that they are not suitable for all chronic pain sufferers and can actually inhibit personal chronic pain coping strategies. Tri-cyclic's have a range of side-effects, including cardiovascular disturbances, dizziness and drowsiness (Lynch & Watson, 2006). Conversely,selective Serotonin Reuptake Inhibitors (SSRIs) have less side effects but appear to have no analgesic affect (Kroenke, et al., 2009). Therefore, while medications can have a mild positive affect, they do not promote healthy long term coping strategies.

Pharmacotherapy for chronic pain over the long term is expensive, vulnerable to drug tolerance, and often has side effects (Kouyanou, Pither, & Wessely, 1997). Alternately, effective psychological interventions may provide better health outcomes and quality of life while simultaneously reducing the dependence on medication. By taking a more holistic perspective to include both social and psychological interventions the risks associated with long term use of powerful medication can be modified while offering individuals greater personal control and even mastery over their recovery (Onac, Moldovan, Onac, Igna, & Pop, 2012; Von Korff, Dworkin, & Le Resche, 1990).

Chronic pain is associated with a vast array of negative social consequences. Those with chronic pain often isolate themselves, decrease their physical activity and struggle with relationships and employment (Cano, 2004). These difficulties often arise from, and intensify, the biological and psychological symptoms of chronic pain (Gatchel, Peng, Peters, Fuchs, & Turk, 2007). This interaction between symptom severity and maladaptive defensive

behaviours also results in the persistent arousal of the limbic system and sensitising the central nervous system (Yunus, 2009). . Subsequently, these social consequences of chronic pain are associated with poor prognosis for recovery, intensifying poor health and pain (Kerns, Rosenberg, & Jacob, 1994).

Chronic pain has additional social implications and stressors.. For example, the process of workers compensation is often perceived as unjust and adversarial, carrying high financial burdens (Elbers, Akkermans, Cuijpers, & Bruinvels, 2013; Guest & Drummond, 1992). The accumulative effect social stressors can be overwhelming, especially when employment opportunities shrink and treatment costs escalate. These personal struggles may lead to feelings of frustration, even increased violence and aggression sometimes directed towards family, friends and even treating physicians (Bruns, Disorbio, & Hanks, 2007). Without support specifically directed at mitigating these complicating psychosocial factors, drug addiction and abuse (Edlund, Steffick, Hudson, Harris, & Sullivan, 2007), criminal charges, financial loss and interpersonal conflict are all possible outcomes for those struggling with chronic pain (Birnbaum et al., 2011).

Increased social support improves the adjustment to chronic pain and promotes passive coping strategies (Lopez-Martinez, Esteve-Zarazaga, & Ramirez-Maestre, 2008). Perhaps social support validates the sufferer and encourages different and more positive coping skills. The therapeutic challenge has been to facilitate social supports to reduce social isolation (Charmaz, 1983; Forgeron et al., 2010; Smith, 2011) or responding with aggression (Daniel Bruns, John M. Disorbio, & Richard Hanks, 2007; Fishbain et al., 2011). Education and psychotherapy helps patients utilise important protective supports of peers and family. The promotion of social skills and the improvement of social supports was a key priority in the psychological component of the Creative Self program along with strategies for reducing emotional distress.

Depression has a strong comorbidity with chronic pain. For example, chronic pain sufferers are three times more likely than the general population to have high levels of psychological distress (Blyth et al., 2001). Bair, Robinson, Katon and Kroenke's (2003) literature review of the MEDLINE database assessed the prevalence of clinical depression amongst study participants undergoing treatment for chronic pain. Of the 15 studies of pain clinic or in-patient programs (2245 participants in total), they found that 53% of the participants had comorbid clinical depression. They also found that of the fourteen clinical depression studies that controlled for chronic pain (1912 participant total), 65% was the mean prevalence of chronic pain amongst those with depression (Bair, Robinson, Katon & Kroenke, 2003). When compared with the approximate 6.7% population average for clinical depression in the North American adult population (Kessler, Chiu, Demler, & Walters, 2005), those suffering pain long term are eight times more likely to suffer depression than the general adult population. Cultural and social practices may well have impacted on these findings as these results are not mirrored elsewhere. In a survey of over 7,500 Australians approximately 20% of those with chronic pain in the general population, also suffered from depression (Blyth, et al., 2001).

The positive interaction between chronic pain and depression is known in the literature as the pain-depression dyad (Bair, et al., 2003; Goldenberg, 2010). For example, depression exacerbates pain symptoms, while the experience of pain is also known to increase depressive symptoms (Bair, et al., 2003). What this means is that depression, when left untreated, will impair an individual's ability to manage their pain and even predict future development of pain in those without current pain symptoms (Leino & Magni, 1993). Conversely, treatments that decrease depression diminish the experience of pain and lower the risk of developing chronic pain. This relational dyad has implications for therapy

particularly the prevention of future pain and for reduction in the distress associated with chronic pain.

Vulnerability to chronic pain is also associated with increased anxiety and hypervigilance (Dersh, Polatin, & Gatchel, 2002). As such, anxiety reduces pain tolerance, increases cortisol levels, amplifies vigilance and avoidance of activities, promoting isolation, irritability and even aggression (Erickson, 2005). Unfortunately, these ruminative processes associated with anxiety and hypervigilance around pain can impact on lifestyle with individuals tending to avoid activities that risk short term pain (Erickson, 2005). Similarly, it predisposes and perpetuates chronic pain while reducing the ability to cope with the symptoms of pain (Asmundson, et al., 1999; Bair et al., 2013; Cornwall & Donderi, 1988). Therefore, just as depression may increase pain perception by increasing the tendency to think the worst of the pain, those with anxiety may overreact to pain increasing their distress while reducing their ability to cope with pain (Asmundson, Norton, & Norton, 1999; Cornwall & Donderi, 1988).

Almost half of those suffering chronic pain who seek treatment meet the criteria for Posttraumatic Stress Disorder (PTSD) (Asmundson, Coons, Taylor, & Katz, 2002; Roth, Geisser, & Bates, 2008). The Mutual Maintenance Model (Asmundson, et al., 2002; Sharp & Harvey, 2001) may best explain this link between trauma and chronic pain. This model suggests that the function of psychological and physical pain is to motivate avoidance of the activating stimuli. This overlap in brain reactivity to chronic pain and traumatic events, results in a mutual triggering of painful reactions. The association is so strong, that recall of the traumatic event can increase the experience of pain. Furthermore, trauma, although not strictly a chronic pain symptom has the potential to decrease coping and complicate recovery through associated psychopathology. It is not uncommon for chronic pain to be associated with a work injury or other accident creating a complex picture with the potential for

interpersonal responses such as frustration, aggression and anger to emerge. This is particularly evidenced for example, when feelings of disempowerment during workers compensation claims or court procedures, exacerbate tolerance to pain and affect responses (i.e. depression, anxiety etc.) and physical factors (i.e. muscle tension, cortisol increases etc.). The trauma/pain relationship is intrinsically interwoven and likely to complicate human behaviour and coping skills when chronic pain and trauma collide (Bruehl, Liu, Burns, Chont, & Jamison, 2012).

Beliefs Around Disability

While self-reported pain intensity is a common and important measure of the severity of painbeliefs, pain has a stronger relationship with associated disability (Crombez, Vlaeyen, Heuts, & Lysens, 1999; Turk & Okifuji, 2002; Turner, Jensen, & Romano, 2000). Beliefs that pain is a sign of further damage to an injury or that the site will heal as long as they do not aggravate it, leads to increased disability and inactivity. For this reason it is important to understand the psychological context of pain experience as well as the physiology. The development of chronic pain is largely established through a process of sensitization and classic conditioning (Apkarian, 2008; Flor, 2012). As such, sufferers become conditioned to avoid actions and behaviours associated with pain through positive punishment. They also are negatively rewarded by not having pain when they stay still.

Similarly, the pain experience itself is a pain response that is reinforced, sensitized and generalised in chronic pain sufferers (Sandkuhler, 2000). Just as an amputated limb can produce pain, a previously injured body sitecan experience chronic pain long after it has healed (Flor, Nikolajsen, & Jensen, 2006; Katz & Melzack, 1990). This phenomenonis caused through a conditioned (i.e. learned) response independent of nociceptors. For this reason, and in both cases, it is important that the psychological beliefs around pain are central

to management of pain. This involves the extinction of pain responses by working to reduce pain while increasing activity.

Fears of re-injury often lead to declines in movement and the avoidance of tasks (Pincus, Smeets, Simmonds, & Sullivan, 2010). These cognitions are self-reinforcing as tasks become more painful and difficult with reduced activity. It is these beliefs about the pain that leads to further disability and reduced quality of life and daily functioning. As disability increases, so too does the associated anxiety, depression and pain (Asmundson, et al., 1999; Crombez, Eccleston, Van Damme, Vlaeyen, & Karoly, 2012; Rainville et al., 2011). This cycle of pain, fear and disability is a key component in the progression of chronic pain.

Beliefs around origin of pain have powerful agency. For example, in chronic pain sufferers, beliefs pertaining to psychological origins are associated with personal agency, whereas beliefs pertaining to organic origins of pain are associated with the feeling that others are in control of their pain management (Edwards, Pearce, Turner-Stokes, & Jones, 1992). As such, individuals might believe that they can only be helped by doctors, medications or by luck leaving them bereft of personal agency, feeling helpless, and at risk of anxiety or depression. It is unlikely in such circumstances that they will take steps to cope with their pain. A good psychological intervention should address these beliefs and restore any lost sense of capacity to improve their lives.

Common Factors Approach to Treatment Evaluation

The biopsychosocial model of chronic pain is congruent with a common factors approach to treatment evaluation. The common factors theory posits that what is effective in treatments is found in common components of treatments, such as the therapeutic alliance, the expectation of success and the client's personality, rather than the components unique to the treatment (Asay & Lambert, 1999). Randomised controlled treatments have been the gold standard for establishing the efficacy of interventions for evidence based practice by showing

when treatments are better than control groups or placebos. However, studies to date have been unable to delineate between the processes that are effective or not. As evidence mounted for the effectiveness for a large range of therapeutic approaches and meta-analysis became wide spread, it became apparent that the established approaches were equally effective. This was named the 'Dodo bird verdict' as the dodo in Alice in Wonderland states, "Everyone has won, and all shall have prizes". Furthermore, a meta-analysis of 27 component studies found that treatments were as effective with or without a component they had considered critical to the treatment (Ahn & Wampold, 2001).The medical model of "treatment and outcome" focuswas thus found to be insufficient in the care and support of chronic pain (Wampold, 2010). As a consequence, there is mounting evidence that there are broader holistic factors involved in psychotherapy directed change known as the common factors.

There are four common factors found to have an impact on the effectiveness of therapy. These include the approach/technique of the therapist; the therapeutic alliance; hope and expectancy; and extra therapeutic factors. The therapeutic alliance is simply the quality of the professional relationship between the therapist and the client. Quality can be measured by how closely client and therapist's goals align and how much they value the relationship and want to engage reciprocally (Elvins & Green, 2008). High quality therapeutic relationships are associated with a stronger accordance with intervention and willingness to engage in different thinking patterns.

Extra-therapeutic factors have been found in general to have a stronger influence on treatment outcome than the type of treatment used (Asay & Lambert, 1999). These factors are components that constitute the individual differences of clients, such as mental fortitude, age, social supports, belief systems, resources, cultures and life events. Salient extra-therapeutic factors have been identified in past research across the clinical psychology discipline. A holistic approach relies on focusing on people as complex dynamic participants in the process

of therapy rather than a diagnosis with symptoms to minimise. It is possible that extra-therapeutic factors relevant to those undertaking pain management therapies may include age, religious beliefs, and acceptance of things they cannot change, beliefs about pain and past experiences of surgery.

If investigation is narrowed to the treatment itself, those working in the field of chronic pain are limiting their ability to observe other important processes involved in modifying the individual's ability to manage their pain and to understand the mechanisms of change (Laska, Gurman, & Wampold). The current reliance on randomised controlled trials to establish interventions may mean that treatments with real world validity and appreciation of the wider factors for change can be missed.

While there is no argument that these studies are important in establishing techniques that work and have moved clinical psychology forward, it is also important to expand our knowledge, increase our scope and ensure the ecological validity of these evidence based treatments. This broader approach is advocated in the APA's Presidential Task Force on Evidence-Based Practice (2006). Empirically Supported Treatments (ESTs) are established through a focus on the treatment first and secondly, whether such treatment works for specific diagnoses. Evidence Based Psychological Practices (EBPPs) however, focus on the patient first and then investigate what research supports the best outcome for that specific patient (American Psychological Association Presidential Task Force on Evidence-Based Practice, 2006). If research neglects the broad patient factors involved in therapeutic change, then EBPPs will have a limited ability to tailor therapy to specific individuals.

Hope and Extra Therapeutic Factors

Hope and the expectation of positive results are estimated to be as important to therapy outcomes as the type of treatment used (Asay & Lambert, 1999). However, as discussed in this paper, those who suffer from chronic pain often have a range of social, biological and

psychological profiles. Part of their pain management often involves addressing depression, anxiety, isolation, physical impairments and dependence on medications, which are not always successful. As they undertake multiple unsuccessful attempts at psychological interventions, the expectation that future treatments can be successful will dwindle (Davies, Crombie, Brown, & Martin, 1997). For this reason, it is important that a chronic pain management program works to overcome this loss of hope. It is also important to establish which interventions are the most successful and best fit for sufferers of chronic pain to enhance chances for success early in treatment. Without early hope, chronicity of pain is likely to engender hopelessness.

A study by Goossens et al, (2005) explored the impact of different outcome expectations on chronic pain interventions. By pooling the data from two randomised controlled studies that used Cognitive Behaviour Therapy (CBT) interventions, the researchers found that the expectations of participants prior to treatment significantly predicted the effectiveness of the treatment immediately after the treatment had been completed, and 12 months following. Those who believed the treatment would be successful were more likely to tolerate and manage their pain. They were also more active, had less emotional distress and rated their quality of life higher. However, their ability to hope for success was not independent from their pain beliefs, level of disability or level of support.

The expectation of success is a key motivating factor in behaviour change. These results are consistent with the self-determination theory of motivation (Ryan & Deci, 2000). If individuals do not feel confident in their ability to achieve a good outcome, are not able to see themselves as the agent of change, or if the intervention is not strongly correlated with their own needs, motivation will be lost. Low expectations often lead to self-fulfilling prophesies, through conforming, and individual bias, anxiety and despair. If an individual believes that they will fail, they will seek signs that confirm that belief and disregard

evidence for success, known in psychology as selective encoding (Mathews & MacLeod, 1994). This bias promotes anxiety as the task becomes perceived as too difficult and individuals search for more signs of failure (MacLeod, Rutherford, Campbell, Ebsworthy, & Holker, 2002). Consequently, avoidance behaviours (i.e. behaviours used to avoid difficult and important tasks) and procrastination follow. The implementation of helpful strategies is then delayed and finally the individual discontinues the practice of these learned strategies. This cycle of failure increases stress, anxiety and further avoidance behaviours.

CBT

There is support for CBT as an effective psychological intervention that can reduce symptoms and minimise the additional impairments that co-occur with chronic pain (Dysvik, Kvaloy, Stokkeland, & Natvig, 2010; McCracken & Turk, 2002). CBT is particularly useful for alleviating anxiety, depression, and distress by addressing the way individuals think about their pain and react to it. Many people with chronic pain become focused only on the pain and ways to escape it. This can lead to abuse of prescription and non-prescription medications. Pain avoidance also leads to a reduced ability to pursue personal goals and narrows the individual's repertoire of activities in which they can engage. The primary goal of CBT in pain management is to help the client overcome avoidance of pain which may be a short term safety goal, but which tends to cause more problems over time. Reframing beliefs that lead to changed behaviours underpins CBT.

CBT programs have consistently been found to be effective in alleviating symptoms associated with chronic pain. A large meta-analysis of 65 multidisciplinary chronic pain interventions by Flor, Fydrich and Turk (1992) were found to be effective immediately at the end of treatment and after longitudinal measurements. This early meta-analysis found that patients not only improved in psychological and pain measurements, but were also more likely to go back to work and used the health care system less. A more recent and rigorous

meta-analysis conducted later by Williams, Eccleston and Morley (2012) analysed 25 CBT studies where there was a control group and longitudinal measurements. They found CBT to be effective in reducing the emotional distress (such as depression and anxiety) caused by pain, a reduction in the experienced disability, and an increase in helpful pain beliefs (instead of catastrophic thinking) when compared to no treatment. Furthermore, many of these improvements lasted beyond the treatment, when measured six months later.

These studies, along with other individual studies, provide good support for the efficacy of CBT in the management of chronic pain. However, a biopsychosocial understanding of chronic pain and its treatment suggests there are many more factors involved that could be addressed by CBT or other psychological strategies. While CBT aims to challenge unhelpful thoughts and behaviours, acceptance therapies seek to empower helpful thoughts while weakening negative thoughts. The evidence suggests that they are both equally effective in the management of chronic pain symptoms (Veehof, Oskam, Schreurs, &Bohlmeijer, 2011).

Acceptance

Acceptance based strategies promote the nonjudgmental acceptance of experiences that are outside our personal control while focusing on values-based commitment towards improving quality of life (Hayes, Strosahl, & Wilson, 2011). Meta-analysis has shown acceptance based interventions can be effective for alleviating chronic pain symptoms (Veehof, Oskam, Schreurs, & Bohlmeijer, 2011). These interventions were not found to be better than CBT programs, yet they were qualitatively different. It is expected that any amalgamation of these approaches would be complementary and provide participants with lasting improvements.

A follow up study by Wetherell et al. (2011) compared an acceptance based chronic pain intervention to a CBT chronic pain intervention. They found that both were effective in reducing chronic pain related disability, depression and anxiety and that these improvements

were sustained at 6 weeks following the intervention. The gains in the acceptance intervention group were higher for those that were already acceptance minded. This suggests there is variance in how predisposed participants were to acceptance strategies and this was influenced by how intuitive and similar these strategies were to their pre-intervention thinking. This study highlights that while participants varied in whether they benefited more from an acceptance based or CBT approach, there was a significant reduction of chronic pain symptoms across the participants.

In-Patient Programs

Most programs using CBT are out-patient programs often conducted once weekly with the distraction of family life, work and everyday responsibilities (Dysvik, Kvaloy, & Natvig, 2012; Keller, Ehrhardt-Schmelzer, Herda, Schmid, & Basler, 1997; Wetherell, et al., 2011). However, there is a small body of research that supports an intensive in-patient program approach with better outcomes being maintained over a twelve month period (Williams et al., 1996).

A study by Peters and Large (1990) compared the effectiveness of in-patient to out-patient pain management interventions using a randomised controlled treatment methodology. The out-patient program consisted of two hour multidisciplinary sessions weekly, conducted in the hospital over a period of nine weeks. This program took a multidisciplinary approach and included psychoeducation, psychological interventions, exercise, goal setting and medication management. Psychoeducation focused on the psychology of pain and relevant physiology; the psychological interventions were CBT based techniques. The control group received standard medical interventions only if required. The in-patient group was compared to the out-patient intervention and a control group.. In total, they used results from 29 in-patients, 23 out-patients and 16 control participants.

Essentially, the study by Peter and Large (1990) and their longitudinal follow up (Peters, Large, & Elkind, 1992), found that both the in-patient and out-patient programs were effective in reducing pain severity, psychological distress and pain related behaviour. Participants were more active and more likely to gain employment. Furthermore, the benefits were still clinically significant over nine months after the intervention. However, what can be seen in the results, were that the severity of symptomology was greater in the in-patient participants. This suggests that in-patient programs can be as successful in improving pain outcomes for severe symptom profiles as out-patient programs are for less severe symptom profiles.

The 'Creative Self' Program

This study evaluated a multidisciplinary 2-week inpatient chronic pain management program called 'Creative Self' which included Cognitive Behavioural Therapy. The programme was conducted on three occasions, with six to eight participants in each programme. For each program data was collected immediately preceding and following treatment, and at 6, 12, 26 and 52 weeks post treatment. The research is focused on the psychological outcomes of the treatment and the demographic factors that impact on the success of the treatment. Information was collected regarding non-prescribed drug use, current distress including levels of depression, anxiety, disability, trauma exposure, and beliefs about pain. Participants completed a Chronic Pain Acceptance Questionnaire Revised (CPAQ-R), Pain Beliefs Questionnaire (PBQ), Depression Anxiety Stress Scale 21 (DASS 21), Posttraumatic Stress Disorder Checklist-Specific (PCL-S), State-Trait Anger Expression Inventory 2 (STAXI-2) and the Impact Event Scale - R (IES-R).

Hypothesis

This pilot study presents a biopsychosocial evaluation of a CBT inpatient chronic pain management program exploring biopsychosocial factors that influence successful outcomes in chronic pain management. A number of hypotheses were generated:

1)The 'Creative Self' pain management program will lead to increases in pain acceptance;

2) Increases in acceptance will be maintained 12 weeks post treatment;

3) There will be significant reductions in comorbid affective symptoms over the duration of the program;

4) Alleviation of affective symptoms will be maintained 12 weeks post treatment;

5) Extra therapeutic factors have a relationship with the success of the treatment outcomes;

6) Hope and expectation will have a positive relationship with treatment outcomes.

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For submission to: Chronic Illness

A CBT inpatient chronic pain management model: Factors impacting treatment outcomes

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Perspective: This pilot study evaluated a CBT inpatient chronic pain management program exploring biopsychosocial factors that impact successful outcomes in chronic pain management. Common client factors included hope, prior beliefs, and acceptance, impacted on by previous treatments and the experiences that informed participants' beliefs about pain. Several key interactions demonstrated the importance of holistic idiographic approaches for cognitive and behaviour change in intensive treatment settings.

Abstract

Biopsychosocial factors are increasingly recognised as important factors in the treatment of chronic pain. This pilot study seeks to identify those psychosocial factors that impact successful treatment outcomes of chronic pain in patients attending a 2 week intensive pain management program. Treatment targeted beliefs, psychological distress (trauma, anxiety and depression), and disability associated with chronic pain. The DASS-21 and Chronic Pain Acceptance questionnaires administered prior to, at completion of, and at 12 weeks post treatment revealed a significant decrease in depression and a significant increase in pain acceptance respectively and maintained over the 12 weeks. The Pain Beliefs Questionnaire results showed significant change in pain beliefs post treatment, however, this was not maintained at 12 weeks post treatment. Outcomes related to biopsychosocial factors, with age positively correlating with gains in acceptance, and number of interventions attempted correlating with poorer reductions in depression. Changes in pain beliefs and maintenance of those changes had a relationship with the distress from previous interventions and surgery. However, of interest in this study were client factors influencing treatment outcomes for example hope, prior beliefs, and acceptance. Both qualitative and quantitative future studies would broaden our understanding of common factors impacting the management of chronic pain.

Key Words: *Chronic pain; inpatient program; psychosocial factors; pain beliefs, acceptance, hope.*

Introduction

The biopsychosocial model of chronic pain is congruent with a common factors approach to treatment evaluation which focuses on the underlying processes of change (Wampold, 2001). This allows a comprehensive assessment of patient-treatment efficacy. Common factors are those that affect treatment outcomes, including treatment type, the therapeutic relationship, client expectations and client factors (a range of demographics and past experiences that constitute individual differences in clients). In general, client factors have a stronger influence on treatment outcomes than the type of treatment used with hope and expectancy estimated to be just as important as the treatment type (Asay & Lambert, 1999). This pilot study seeks to identify those psychosocial factors that impact on successful treatment outcomes for chronic pain maintained over time, in patients attending a 2 week intensive biopsychosocial pain management program.

A small body of research suggests an intensive inpatient program approach to chronic pain offers sustained outcomes (Williams et al., 1996). Increasingly, programs are combining biopsychosocial factors in the treatment of chronic pain (Engel, 1980; Turk & Okifuji, 2002) irrespective of whether the program is inpatient or outpatient, intensive or weekly. What has been neglected is a measure of biopsychosocial factor effects on treatment outcomes. The belief that pain is a sign of further damage to an injury and can be physically explained is associated with higher ratings of disability than predicted by pain intensity (Crombez, Vlaeyen, Heuts, & Lysens, 1999; Turner, Jensen, & Romano, 2000). However, by developing accepting attitudes towards pain related disability, depression and anxiety can be reduced (2011). Similarly, beliefs pertaining to psychological origins of pain are associated with personal agency (Edwards, Pearce, Turner-Stokes, & Jones, 1992). Consequently, interventions that lower belief in the organic/physical aspects of chronic pain while strengthening psychological tractable beliefs result in better health outcomes.

Evidence exists for the use of Cognitive Behavioural Therapy (CBT) as an effective psychological intervention for chronic pain (Dysvik, Kvaloy, Stokkeland, & Natvig, 2010; McCracken & Turk, 2002; Williams, Eccleston, & Morley, 2012) . CBT reduces emotional distress comorbid with chronic pain such as anxiety (Norton & Philipp, 2008), depression(Cuijpers, van Straten, Andersson, & van Oppen, 2008) and aggression (Del Vecchio & O'Leary, 2004; DiGuiseppe & Tafrate, 2003). The process of CBT involves reframing beliefs and attitudes towards pain (Flor, Nikolajsen, & Jensen, 2006) and promoting the proactive life goals that reduce pain avoidance and inactivity. Anxiety and depression can perpetuate chronic pain (Bair, Robinson, Katon, & Kroenke, 2003; Dersh, Polatin, & Gatchel, 2002; Goldenberg, 2010). This relationship may be explained by anxiety and depression's tendency to reduce pain tolerance, increase cortisol levels, amplify vigilance and the avoidance of activities, or promote isolation, irritability and even aggression (Erickson, 2005). As a strong trigger for emotional distress, Posttraumatic Stress Disorder (PTSD) is also predictive of chronic pain. Some reports showed almost half of those with chronic pain seeking treatment met the criteria for Posttraumatic Stress Disorder (PTSD) (Asmundson, Coons, Taylor, & Katz, 2002; Roth, Geisser, & Bates, 2008). This may be best explained by the Mutual Maintenance Model (Asmundson et al., 2002; Sharp & Harvey, 2001) which posits there is an overlap between the reaction to chronic pain and traumatic events, resulting in mutual triggering of painful reactions.

This pilot study targeted emotional distress, trauma, anger, pain beliefs and pain acceptance in chronic pain during an intensive 2-week inpatient program. It is hypothesised that there will be significant improvements in each respective psychometric measure over the course of the program and over the 12 week period following completion. It is also hypothesised that there will be biopsychosocial factors that impact these treatment outcomes.

Method

Participants

The 23 participants were adults over 18 years of age and chronic pain sufferers who had exhausted all surgical and medical intervention for their pain. All participants had suffered from chronic pain for greater than 12 months before commencement of the program.

Potential participants who had not exhausted future pain reduction surgery were excluded from this study. As the study was an inpatient program, only those who were able to commit to the full two week program entered the program. Applicants were also required to reduce or cease current pain medication, and any non-prescription drugs under the supervision of a consultant pain management physician. Alcohol consumption was assessed and screened for suitability using the AUDIT, a screen developed by the World Health Organisation to determine whether an individual's alcohol use is harmful (Allen, Litten, Fertig, & Babor, 1997). Only those who reported non-problematic use of alcohol were admitted to the program. Participants were required to abstain from alcohol during the program.

Nine of those recruited were excluded from the program because their medication use was not reduced to minimal levels prior to the commencement of the program or there was non-prescription medication use.

Demographics

There was a high attrition rate. Of the 23 participants who completed the program, 17 completed outcome measures at 6 weeks, 20 completed outcome measures at 12 weeks, 9 completed outcome measures at 26 weeks and 3 completed outcome measures at 52 weeks. Due to the difficulty in tracking participants post program, power was compromised for some of the time frames. For the purpose of the study, only baseline, post treatment, and 12 week outcomes were analysed. The sample of twenty three participants consisted of 13 males and

10 females with an age range 24 to 57, *M* = 44.09. The sample included 11 (47.83%) participants who indicated they had previously undertaken unsuccessful surgery to alleviate their pain. Three (13%) participants had suffered chronic pain for greater than 1 year but less than 2 years, 10 (43.5%) had suffered for over five years, with the remaining 10 (43.5%) participants having suffered with chronic pain between 2-5 years.

All participants were recruited through Pain Specialists who were informed of the protocols of the programs. Following assessment for suitability for the program, participants were offered the CBT program

Outcome Measures

Chronic Pain Acceptance Questionnaire (CPAQ): The Chronic Pain Acceptance Questionnaire (CPAQ) is a two factor scale of the ability overcome negative thoughts and behaviours associated with pain (McCracken, Vowles, & Eccleston, 2004).The two factors are termed 'Activity Engagement' and 'Pain Willingness'. 'Activity Engagement' is the level of physical activities pursued regardless of the degree of pain experienced, and 'Pain Willingness' is the cognitive awareness of the adverse effects of using avoidance and control to manage chronic pain. From these subscales, a 'Total' measure of pain acceptance was calculated that includes both physical and mental aspects.

The CPAQ consists of 20 items, with 11 forming the 'Activity Engagement' subscale and the remaining 9 forming the 'Pain Willingness' subscale. An item from this scale is 'My life is going well, even though I have chronic pain. 'Participants responded to each item using a Likert-type scale, ranging from 0 (never true) to 6 (always true). It has been found in several studies that the CPAQ total score correlates to other standardised measures of pain-related symptoms and has a good predictive validity for disability and distress (McCracken, 1998; McCracken & Eccleston, 2003; McCracken & Turk, 2002). There is a high level of

internal consistency in the subscales 'Activity Engagement' (Cronbach's alpha of .82) and 'Pain Willingness' (Cronbach's alpha of .78) (McCracken et al., 2004).

Depression, Anxiety and Stress Scale (DASS-21): The 'Depression, Anxiety and Stress Scale' (DASS-21 is a brief scale provides measures of the severity for depression, anxiety and stress. The DASS-21 comprises 21 items with 7 items for each of the three subscales. An item from the scale is 'I couldn't seem to experience any positive feeling at all'. Participants indicated on the Likert-type scale how much each item on the scale applied to them over the preceding week, from 0 (did not apply to me at all) to 3 (applied to me very much, or most of the time).

The DASS-21 has been shown as a valid and reliable outcome measure for inpatient settings, with high convergent validity with the Health of the Nation outcomes scales (HoNOS), Clinical Global Impressions (CGI) Scale, and the Mental Health Questionnaire (MHQ-14)(Ng et al., 2007). It was also shown that the scale is able to detect changes in each of the three factors that occur during an admission. The scale is valid and reliable for chronic pain sufferers and the elderly (Gloster et al., 2008; Wood, Nicholas, Blyth, Asghari, & Gibson, 2010). The internal validity, construct validity and reliability of the DASS-21 has been upheld by multiple studies across participants with clinical (Brown, Chorpita, Korotitsch, & Barlow, 1997) and non-clinical (Crawford & Henry, 2003) levels of psychological distress (Antony, Bieling, Cox, Enns, & Swinson, 1998; Ng et al., 2007).

Pain Beliefs Questionnaire (PBQ: The Pain Beliefs Questionnaire (PBQ) is a 12 item 2 subscale self-report measure of beliefs around chronic pain. The two subscales provide a measure of how strongly participants believe that the cause and treatment of their pain is organic or psychological. An example of an item includes 'Experiencing pain is a sign that something is wrong with the body'. The subscales demonstrated a high level of internal consistency with Cronbach's alphas of 0.71 and 0.73 for the organic and psychological

subscales respectively. The construct validity of the PBQ was demonstrated with high convergent validity with the Multidimensional Locus Of Health Control (MLHC). The PBQ was chosen for its brevity and ability to accurately measure pain beliefs associated with level of physical functioning.

The Impact of Event Scale-Revised: Two measures of current trauma-specific morbidity were included with the questionnaire, the Impact of Event Scale-Revised (IES-R) and PTSD Checklist-Specific (PCL-S). The IES-R included three subscales hyperarousal, intrusion, and avoidance (Weiss & Marmar, 1996). The response categories for both the IES-R and the PCL-S are: not at all; a little bit; moderately; quite a bit; extremely. IES-R severity is measured on a 5 point Likert Scale (0-4). Thus, 2.75 would be closer to "quite a bit" than to "moderately" and so on.

The Posttraumatic Stress Disorder Checklist Specific (PCL-S): The PCL-S (Weathers, Litz, Herman, Huska & Keane, 1993) is a reliable diagnostic measure of PTSD. It is a self-reported rating scale for assessing the 17 DSM-IV symptoms of PTSD. It has been found to have excellent test-retest reliability (r = .96) over a 2-3 day period. Each of the three groups of items corresponding to the DSM-IV symptom clusters, as well as the full 17-item scale, have very high internal consistency (r = .97). The PCL-S correlates strongly with other measures of PTSD, such as the Mississippi Scale (r = .93), the PK scale of the MMPI-2 (r = .77), and the Impact of Event Scale (r = .90). It also correlates moderately with level of combat exposure (Weathers et al., 1993).

State-Trait Anger Expression Inventory-2 (STAXI-2): The State-Trait Anger Expression Inventory-2 (STAXI-2) is a 57-item measure of Anger consisting of 5 scales (Spielberger, 1999). These scales include 'State Anger', 'Trait Anger', 'Anger Expression inward' and 'Anger Expression Outward', 'Anger Control'. The items range from 1: 'not at

all' to 4: 'very much so', with higher scores indicate higher levels of danger. Normative tables are used to convert raw scores of the scales into T-Scores.

Research Design

The study was a repeated measures design, following a cohort with measurements being taken at baseline, immediately following treatment, then at 6, 12, 26 and 52 weeks post treatment. Data analysis included a descriptive analysis of the categorical demographics and continuous outcome variables, including the testing of distributions for characteristics of normality, kurtosis and skewness.

The demographic variables included the participants' sex, age, marital status, household, religion, the role of that religion in their life, level of education and duration of chronic pain. Participants also indicated how they dealt with their pain and medical and surgical interventions prior to the program. This was followed by five ten point scales that ask how prepared they were for that treatment, how satisfied they were with that treatment, how distressing the treatment was, how prepared they felt leading up to this program and how satisfied they expected to feel. The outcome variables consisted of the results from the previously mentioned psychometric scales at the different time points. Due to the high attrition rate, outcome variables from 26 and 52 weeks were not included in the statistical analyses of this study. Inferential statistics were used to investigate bivariate relationships between the psychometric outcomes and potential factors, including demographics and predictive scales, using T tests or *F* tests, or their non-parametric equivalents, Wilcoxon and Kruskal-Wallis respectively, depending on the distributions of the continuous outcome variables. Models will be developed using regression analysis, parametric and non-parametric as appropriate, to establish the strength, direction and functional form of the impact of significant factors on changes that occur in chronic pain management programs.

Interventions

The ‘Creative Self’ program was a two week inpatient program for the duration of the program (see Table 1). Patients were admitted on a Sunday afternoon, commencing the program on Monday morning. From Monday to Friday each week they participated in the program components with leave from Friday evening until Sunday. They were discharged on the final Friday afternoon. The program was an active, two week structured intervention that included seventy-four sessions of approximately one hour in duration. A multidisciplinary team that included a psychologist, physiotherapist, pain specialist physician, occupational therapist, dietician, social worker and a treatment nurse coordinator conducted them. These sessions included individual and group psychoeducational therapy inclusive of CBT, exercise and stretches, hydrotherapy, workbook exercises and diary for reflection and incubation of achieved skills during the day. Within the program, twenty-three sessions of the seventy four sessions were dedicated to psychological interventions grounded in CBT and Mindfulness (Grant & Haverkamp, 1995; Nicholas, Molloy, Tonkin, & Beeston, 2011; Winterowd, Beck, & Gruener, 2003). The principle focus of the CBT portion of the program was to improve physical function and quality of life that was diminished by chronic pain. Consequently, the key psychological outcomes of the ‘Creative Self’ program included the adoption of realistic, informed and flexible thoughts and behaviours around their pain. The program endeavoured to challenge their pain beliefs by incorporating previous triggers of distress and then helping the participants engage in the repetitive practice of realistic thoughts and established coping strategies.

Success for this program was measured by the patient’s continued reduction in prescription medication usage, an increase in quality of life, and sustained cognitive changes in their beliefs and attitude towards their pain. The design of the program was underpinned by Gate Control Theory of chronic pain which recognises the complex interplay between psychological factors, and the central nervous system and the peripheral nervous system both

of which process pain signals independently (Melzack & Wall, 1967). Gate Control Theory recognises that pain messages encounter nerve 'gates' whereby pain messages can access or are prevented from accessing the brain and consciousness. Though these processes are still poorly understood, more recent studies show that physical and psychological distress do share neurotransmitter processes (Eisenberger, 2012; Moskowitz & Fishman, 2006). This overlap is also seen in the interaction of chronic pain and stress with HPA axis and the autonomic nervous system activation (Delgado et al., 2012; Jamani & Clyde, 2008; Kalina, 2012; McBeth et al., 2005). Additionally learned helplessness responses are commonly associated when both emotional and physical pain co-exist (Abramson, Seligman, & Teasdale, 1978; Maier & Seligman, 1976). With Gate Control Theory in mind, the program's outcomes were measured by the changes in participants' psychological distress, pain beliefs and pain acceptance. Aspects that affected these outcomes are also explored.

Insert Table 1 here

Procedure

The inpatient program followed the same structured protocol for each group. Participants were requested to give consent for the data from questionnaires to be used for further research into chronic pain in conjunction with Newcastle University (please see appendix for the consent form). Participants completed the psychometric measures and had their final assessment of suitability for the program (i.e. have they maintained reduced alcohol consumption as assessed by the AUDIT measure). The main components of the psychological interventions were developed in accordance with the framework of the ADAPT program (Nicholas et al., 2011). The program started with psycho-education about pain, the difference between acute pain and chronic pain and philosophy of the program. The program emphasised the patient's active role in the program and pain management as they were assisted in their goal setting. These goals were gradually paced, had clearly defined

steps and used systematic and personally relevant behavioural reinforcement. These goals were focused on health, quality of life, and vocational objectives. Coping skills were developed to facilitate goals and overcome identified personal obstacles. Throughout the psychological components of the program, unhelpful thoughts regarding pain as an obstacle to physical activity continued to be challenged. Inclusive in the program relaxation techniques, problem solving (recovery and relationships), relapse prevention and progress maintenance strategies were taught.

Data Analysis

The raw data from the surveys were entered into Excel spread sheets. For the purpose of this study, outcome measures were analysed at the commencement of the program, at completion, and at 12 weeks following the treatment. These calculations were systematically performed through Excel for the Pre Treatment, Post Treatment and the 12 weeks Post Treatment measures.

Results

Insert Table 2 here

CPAQ Total – Normal Distribution and Wicoxon Signed Ranks Test

Insert Figure 1 Here

As seen in Figure 1, there was a significant increase in pain acceptance during chronic pain intervention. This change is in the direction consistent with an effective intervention and a trend of increased pain acceptance over the course of the treatment. Parametric tests paired sample t-tests were used where the differences between pairs are normally distributed and the variances between the groups are equal. Otherwise, the Wilcoxon Signed Ranks tests were used because of its robustness. The Cronbach's alpha was calculated as the reliability statistic of CPA Total (Cronbach's $\alpha = .80$). While the CPAQ Total score post-treatment was normally distributed with a skewness of -.333 (.481), kurtosis of -1.065 (.935) and non-

significant Kolmogorov-Smirnov test of normality (D = .144, p = .200), pre-treatment was not normally distributed with a skewness of .534 (.481), kurtosis of -1.196 (.935) and significant Kolmogorov-Smirnov test of normality (D = .204, p = .014). For this reason the non-parametric equivalent of the paired-samples t-test, the Wilcoxon Signed Ranks test, was conducted to compare total Chronic Pain Acceptance using the CPAQ at post-treatment to pre-treatment scores. The Wilcoxon Signed Ranks test indicated the CPAQ total at post-treatment (Mdn = 62) was significantly higher than at pre-treatment (Mdn = 40) conditions; Z = -3.529, p< .001, r = -.735.

CPAQ Total Post – 12 Weeks & Age Correlations and Distributions

Insert Figure 2 here

This study found that the older the participant was during the program, the better pain acceptance outcomes were achieved (See Figure 2). The CPAQ Total Post to 12 Weeks Post variable is the difference between participant's scores at twelve weeks after the treatment and at the conclusion of the treatment. The CPAQ Total Post to 12 Weeks Post was non-normally distributed, with a skewness of -1.54 (.60), a Kurtosis of 2.69 (1.15) and significant Kolmogorov-Smirnov test of Normality (D = .264, P = .014). Age was significantly and positively correlated with an increase in median pain acceptance, Spearman's rho r(14) = .68, p = .007. The distribution of the independent variable of age, for participants with a CPAQ Total 12 Weeks Post score was normal, with a skewness of .745 (.616), a Kurtosis of .441 (1.191) and a non-significant Kolmogorov-Smirnov test of Normality (D = .171, P = .200).

DASS-21 Depression pre & post distributions and Paired Samples T test.

Insert Figure 3 here

This study also found that depression decreased during the chronic pain intervention between pre-treatment and post-treatment (See figure 3). A paired-samples t-test was conducted to compare each of these subscales at post-treatment to pre-treatment scores. The

DASS-21 Depression at both times had normal distributions, with non-significant Kolmogorov-Smirnov tests of Normality (D = .142, p = .200) and (D = .167, p = .115) respectively. There was a significant difference in the scores for the depression subscale at post-treatment (M = 11, SD = 10.6) and pre-treatment (M = 18.7, SD=13.7) conditions; $t(21)$=2.526, p=.02. Both conditions had normally distributed variables with the DASS 21 Post Treatment. Paired T tests were conducted on the other subscales of anxiety and stress however there was no statistically significant change. The Cronbach's alpha was calculated as the reliability statistic of DASS Depression (Cronbach's α = .92).

DASS-21 Depression Pre-Post & Interventions Distributions

Insert Figure 4 Here

As seen in Figure 4, the best decreases in depression outcomes correlated with those that had fewer previous interventions. The independent variable (Interventions) is the number of unsuccessful treatments attempted preceding the program. This was normally distributed with a skewness of .159 (.512), a Kurtosis of .254 (.992) and a non-significant Kolmogorov-Smirnov test for normality (D =.182, p = .082). The dependent variable of the difference in DASS Depression Scores at completion of the program compared to commencement (DASS Depression Pre-Post) was also normally distributed with a skewness of .303 (.512), a kurtosis of .201 (.992) and a non-significant Kolmogorov-Smirnov test for normality (D = .131, p = .200). As the assumption of normality for both distributions could be assumed, the Pearson parametric test for correlation was performed on the DASS Depression Pre-Post and Intervention variables showing a positive correlation, Pearson's $r(20)$ = .698. p = .001. The average change in depression score positively correlated with the number of interventions previously attempted. This suggests that outcomes of the 'Creative Self' chronic pain program are impacted by the experience of past pain treatments. .

Changes in PBQ scores for Organic pain beliefs Pre & Post

Insert Figure 5 here

As expected, during intervention the participants' beliefs of pain being organic decreased (See Figure 5) and the belief in psychological aspects increased (See Figure 6). A Wilcoxon Signed Ranks test was conducted and found that the post-treatment measure of organic pain beliefs as measured by the PB Organic scale (*Mdn* = 16) was significantly lower than at pre-treatment (*Mdn* = 27), ($Z = 3.989$, $p < .001$, $r = .832$). The scores for the PBQ Organic beliefs at pre-treatment did not meet the assumption of normal distribution for a parametric paired t-test, with a significant Kolmogorov-Smirnov test for normality ($D = .182$, $p = .046$), while the post treatment scores did, ($D = .128$, $p = .200$). The Cronbach's alpha was calculated as the reliability statistic for the subscale PBQ Organic (Cronbach's α = .86).

The change PBQ organic pain beliefs in the 12 weeks post treatment

Insert Figure 7 here

As seen in Figure 7, a paired samples t test identified a significant increase in PBQ score of organic pain beliefs in the 12 weeks following the program, $t(19) = 2.608$, $p = .017$. This was not consistent with our expectations as it shows that the benefit of low organic pain beliefs achieved during the intervention was not maintained. Both pain beliefs organic at post treatment and 12 weeks following treatment met the assumption for a normal distribution with a non-significant Kolmogorov-Smirnov test for normality ($D = .108$, $p = .200$) and ($D = .126$, $p = .200$).

The effect of surgery on PBQ organic pain beliefs in the 12 weeks post treatment

Insert Table 8 here

The change in the participant's belief in organic origins of pain, as measured by the PBQ, in the 12 weeks following the program depended on whether the participant had undertaken previous surgery in an attempt to reduce their pain (See Figure 8). An

independent t test showed participants who had undertaken surgery previously, continued to decrease their organic pain beliefs (M = -3.50, SD = 4.986) in accordance with the aims of the program, while those who had not had surgery increased their organic pain beliefs (M = 2.333, SD = 3.830), $t(12) = 2.379$, $p = .035$). The assumption of normal distribution according to the Kolmogorov-Smirnov test of normality, $D = .143$, $p = .200$.

Insert Figure 6 here

Over the duration of the two week program, beliefs in the psychological aspects of chronic pain significantly increased as measured by the PBQ (see figure 6). This was consistent with the aims of the intervention and supports the hypothesis that the intervention can change beliefs about pain. The PBQ Psychological Variable for pre-treatment met the assumption for a normal distribution with a non-significant Kolmogorov-Smirnov test for normality ($D = .108$, $p = .200$) while the post-treatment variable did not ($D = .198$, $p = .019$). For this reason a Wilcoxon Signed Ranks Test was performed that showed the participant's belief in the psychological aspects of their pain increased during the program ($Z = 2.770$, $p = .006$, $r = .278$).

The relationship between distress from previous treatments and changes in PBQ psychology beliefs during the intervention

Insert Figure 9 here

As seen in Figure 9, it was found that the rating for distress from previous interventions attempted correlated negatively with the change in beliefs around the psychological aspects of their chronic pain, Pearson's $r(22) = -.479$, $p = .024$. This supported the hypothesis that hope and expectations can affect treatment outcomes. Both the change in psychological pain beliefs between pre-treatment and post-treatment and the rating of distress for the previous treatment variables met the assumption of normal distribution according to Kolmogorov-Smirnov results, ($D = .131$, $p = .200$) and ($D = .148$, $p = .200$) respectively. The Cronbach's

alpha was calculated as the reliability statistic for the subscale PBQ Psychology (Cronbach's α = .85).

PBQ psychological pain belief changes in the post intervention

Insert Figure 10 here

There was a decrease in psychological beliefs around pain from immediately post treatment to 12 weeks post treatment (See Figure 10). These changes were counter to the aims of the intervention and suggest that changes achieved previously were not maintained. The post treatment measure of psychological pain beliefs did not meet the assumption for a normal distribution with a significant Kolmogorov-Smirnov test for normality (D = .198, p = .019). For this reason the difference in psychological pain beliefs at 12 weeks post intervention (Mdn = 28.0) was compared to those beliefs at immediately following the intervention (Mdn = 32.0) with a Wilcoxon Signed Ranks Test. This test showed a significant decrease in pain beliefs pertaining to the psychological aspects during the 12 weeks following intervention, Z = 2.047, p = .041, r = .458.

The PCL-S, IES-R, STAXI-2 and DASS Anxiety and Stress Subscales

Though there were positive changes, no significant changes were found in the PCL-S or the STAXI-2 scores over the course of the program. The Anxiety and Stress subscales of the DASS also did not show a significant change across the group. The IES-R Intrusive thoughts did show a significant improvement, however the other subscales did not. The range of effects that influence these changes over the course of the treatment and during the post treatment period was not included in this analysis. Table 3 and Table 4, show the changes in outcome measures Pre-Treatment to Post Treatment.

High levels of emotional distress were expected for the participants, however not all participants had clinically significant symptomatology. The DASS scores prior to treatment indicated 68% of participants report moderate or higher severity of depression, 41% for

anxiety and 50% for stress (see Table 5). According to the PCL-S, only half of the participants had clinically significant trauma symptoms.

Discussion

This study found some support for the effectiveness of the Creative Self program, an intensive 2 week CBT program for chronic pain management. The program experienced an increase in pain acceptance and less emotional distress which were maintained 12 weeks after the completion of the program. However, statistically, there was no significant reduction in anxiety or stress and there was no significant improvement in the trauma symptoms found, such as hypervigilance, intrusive thoughts and behavioural avoidance. This is likely due to the low number of participants with clinically significant anxiety (N = 11) or trauma (N = 9) responses pre-program. According to the DASS 21, almost half of the participants had moderate or higher anxiety symptoms pre-treatment . Post hoc assessment showed with the effect size (d = .34) from the treatment and an n of 9, the power achieved was .11. Similarly, PCL-S scores indicated half of the participants reported moderate or higher post-traumatic stress disorder symptomology at program commencement. Unfortunately, given the small number of participants for this study, the statistical power to detect change was low. For those with clinical needs, targeted goals were individualised and one-on-one therapy offered trauma and anxiety intervention.

This study found some support for a relationship between the extra therapeutic factors and the success of the treatment outcomes. Age had a positive relationship with increase in chronic pain acceptance over the intervention. This is consistent with current research which posits life experience that comes with age is associated with a greater capacity for acceptance of distressing health events (Politi, Enright, & Weihs, 2007), along with decreased anxiety and irritability (Charles, Reynolds, & Gatz, 2001; Gallegos, Hoerger, Talbot, Moynihan, &

Duberstein, 2013; Shallcross, Ford, Floerke, & Mauss, 2013). Given the gains that come with age, it may be that age facilitated acceptance techniques taught in the program.

Similarly, functionality of anger and intolerance decreases over the lifespan. When young, displays of displeasure promote assistance from others while older people have a greater expectation of self-reliance and gain support through sophisticated relationships. As there was no significant difference in acceptance by age before the program, it is possible that interventions introduced during the program promoting acceptance stimulated age-related behaviours related to acceptance, particularly in relation to pain. Further investigation into the relationship between chronic pain acceptance and age may help advance our understanding of the processes that promote acceptance of and tolerance to pain.

The impact of hope and expectations on treatment outcomes was partially supported. There was no relationship between treatment outcomes and expectations of success indicated on the pre-treatment questionnaire. However, the present study found that the fewer intervention participants had undergone prior to the program, the greater the decrease in depression symptoms. This result supports previous findings that expectation is a key factor in treatment outcomes as the impact of past failed interventions would seem a likely trigger for increasing pessimism and vigilance for signs of failure (Asay & Lambert, 1999).It may be that the strength of confidence in a program rather than the initial magnitude of hope would be the more salient predictor of an intervention's success. Furthermore, self-reporting of treatment expectations without anonymity is more likely to be impacted by demand characteristics and bias.

Belief in the psychological aspects of pain increased, and biological aspects decreased over the program, consistent with the aims of the intervention. Unexpectedly, the decrease in biological pain beliefs was not maintained over the following 12 weeks in participants who had not had surgery. These participants tended to lose changes in their organic pain beliefs.

Conversely, those participants previously treated through surgery tended to maintain and even continue to decrease their biological pain beliefs. Though unsuccessful, participants who had attempted surgery and had therefore exhausted biological recovery pathways for pain had already tried a number of ways to improve their situation non-biologically on commencing the program. Understandably, they would be less likely to maintain a strong belief in biological treatment options and a belief that pain is solely a biological experience. However, those who had not attempted surgery despite being told surgery was not a suitable option for them, may have still maintained hope in the possibility of future surgery for reducing pain. It is likely that these participants who did not find immediate relief through psychological interventions would revert back to stronger beliefs in biological pain origins.

Furthermore, prior to the program, those who had exhausted surgery might still have retained the view that pain management was external to themselves. When engaged in the program and associated psychological components of pain management, locus of control in self may have restored hope and future direction. The treatment was shown to be generally effective but evidence of maintenance of gains trajectory would have benefitted from a full set of data across the 52 weeks. It may be that the 12 week trough in some measures was not predictive of long term gains and beliefs that pain/life balance can be self-managed would reassert itself. The biological aspects of pain are consistent with pain management being something that needs to be controlled externally. This would explain why those that had sought and undertaken surgery would have increased their biological pain beliefs following the completion of the intervention.

The psychological aspects of chronic pain were increased during the program, only to diminish in the weeks following the treatment for many of the participants. However, of particular interest was that the success of the intervention was not consistent over the participant sample. The more distressing the previous treatments were preceding this

intervention, the worse the gains in psychological beliefs. Those who had low to no levels of distress had the greatest increases in their belief in psychological aspects of pain. This result is counter intuitive, as it would be expected that those who have experience of higher levels of psychological distress affecting their chronic pain experience would maintain their higher psychological chronic pain beliefs. This result may suggest that those that have negative associations with interventions may be less likely to maintain the empowering beliefs taught during the program. One of the primary empowering messages from the interventions introduced in this program was that there are psychological strategies that can be used to manage pain. It may be possible that had negative association with previous pain management interventions been addressed early, participants may have been able to maintain positive gains and faith in techniques advocated in the program. This is a poorly researched area of pain management. The relationship between pain belief mutability and previous interventions needs further investigation.

Limitations

As a pilot study, the current research was low in statistical power. Unfortunately data collection was restricted to 4 programs with long term measure collection suffering from attrition. Future research would benefit from a larger participant size and selective inclusion criteria. The focus of this study was to assess a psychological intervention over an intensive period in a group setting for those suffering chronic pain and to identify idiographic features associated with successful outcomes. A randomised control study would have produced greater internal validity but would require a much larger pool of participants than was available for this study. To assist in identifying idiographic needs, future research may benefit from qualitative enquiries that seek to identify the subjective phenomenological experiences of those with chronic pain.

Finally, an intensive inpatient program offers a level of effectiveness particularly when it includes a multidisciplinary CBT focus pertinent to chronic pain sufferers. Of particular interest were the client factors that influenced the treatment outcomes. Of note were: 1) participants' capacity for acceptance associated with their age, hope and confidence in the program, impacted on from previous treatments and; 2) the experiences which inform their beliefs about pain.

Currently, chronic pain interventions are still under-researched and the role, delivery and pain specific techniques of CBT not yet refined. The experience of chronic pain is uniquely personal and idiographic enquiry could inform how best to tailor program interventions to the complex and individual clinical profiles associated with chronic pain.

Conclusions

This study highlights some of the challenges of changing beliefs around pain and its treatment through a group inpatient program. Beliefs tend to conform to those of the group and this effect is optimal when the size is around 4 to 5 (Asch, 1955; Cialdini & Goldstein, 2004). Beliefs are also vulnerable to the power of authority (Milgram & Van den Haag, 1978). These factors may have helped influence pain beliefs while participants are in the group working with peers and professionals, and dissipated over time after the program. This is an issue neglected in past inpatient programs and bears further inquiry.

The study benefited from a high ecological validity. The first priority of the program was to provide high quality evidence based best practice. The outcome measures were important instruments for feedback and ongoing quality assurance. The participants were recruited based on their needs and were a diverse sample, as is expected in practice in the field of clinical psychology.

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Table 1

Topics covered in psychology sessions

Session #	Session Name	Content
Session 1	What is Cognitive Behaviour Therapy	Psychoeducation
Session 2	Individual Session	Psychological assessment
Session 3	Do I believe things can change?	Cognitive flexibility/ Mindfullness
Session 4	Pacing	Coping strategies
Session 5	What are support networks	Social/psychological support
Session 6	Individual/Group sessions	Patient informed therapy
Session 7	Nobody understands	Thought challenging
Session 8	I'd rather walk away	Thought challenging/ Mindfullness
Session 9	Setting realistic goals	Goal Setting
Session 10	Individual/Group sessions	Goals/ Problem solving
Session 11	When I feel like I'm in a black hole	Coping strategies/ Mindfullness
Session 12	I don't cope like I used to	Coping strategies
Session 13	My relationship with pain	Thought challenging/ Mindfullness
Session 14	Individual/Group sessions	Patient informed therapy
Session 15	Weekend Debrief/Family session	Patient informed therapy
Session 16	What's Sex?	Thought challenging
Session 17	Family Dynamics & Conflict Resolution	Behaviour management
Session 18	Individual/Group sessions	Patient informed therapy
Session 19	Individual/Group sessions	Patient informed therapy
Session 20	What it's all about	Mindfullness
Session 21	Video Session	Behaviour Management
Session 22	Where to from here	Relapse prevention and progress maintenance
Session 23	Individual/Group sessions	Patient informed therapy
Session 24	Detaching/Reattaching the honeymoon	relapse prevention/ Mindfulness

Table 2

Demographic Frequencies

	Category	Frequency (%)
Sex:	Female	10(43.48%)
	Male	13(56.52%)
Relationship Status:	Single	2(8.7%)
	CoHab	4(17.4%)
	Married	16(69.6%)
Religion:	Atheist	2(8.7%)
	Catholic	8(34.8%)
	Anglican	10(43.5%)
	Protestant	2(8.7%)
Previous coping strategies:	Push 100%	3(13%)
	Medication	7(30.4%)
	Meds and Ex	4(17.4%)
	Meds and Rest	6(26.1%)
	Exercise with No Meds	1(4.3%)
	Don't deal	1(4.3%)
Past Surgery:	No Surgery	11(47.8%)
	Surgery	11(47.8%)
	Missing Data	1(4.3%)

Table 3
Pre Treatment and Post Treatment Means, Paired T Test Statistic and 2-Tailed Significance for Parametric Tested Outcome Measures

Variables	Pre-Treatment Mean (SD)	Post-Treatment Mean (SD)	Paired t	*p*
Cpaq PW	**15.74(9.64)**	**19.61(9.4)**	**-2.06**	**0.05**
Cpaq Total	**46(18.33)**	**61.7(13.24)**	**-4.89**	**0**
Dass Depression	**18.73(13.7)**	**11(10.56)**	**2.53**	**0.02**
IES Avoidance	**2.45(0.99)**	**2.14(1.05)**	**1.23**	**0.23**
IES Hypervigilance	**2.81(1.21)**	**2.27(1.29)**	**1.79**	**0.09**
IES Intrusive	**2.93(1.16)**	**2.23(1.29)**	**2.28**	**0.03**
IES Total	**8.18(3.23)**	**6.64(3.49)**	**1.88**	**0.07**
PB Org	**25.22(5.98)**	**17.26(6.82)**	**6.44**	**0**
RMPD	**13.57(5.54)**	**10.74(5.65)**	**1.91**	**0.07**

Table 4
Pre-Treatment and Post Treatment Median, Wilcoxon Signed Ranks Test Statistic and 2-Tailed Significance For Non-Parametric Tested Outcome Measures

Variables	Pre-Treatment Median	Post-Treatment Median	Test Statistic	*p*
Cpaq AE	**27**	**42**	**-3.671b**	**0**
PB Psych	**20**	**30**	**-2.770b**	**0.006**
Dass Stress	**24**	**16**	**-1.781b**	**0.075**
PCL	**47**	**36.5**	**-1.343b**	**0.179**
Dass Anxiety	**6**	**7**	**-1.142b**	**0.254**

Table 5

Number of Clinically Significant Symptomologies

Scale	Clinically Significant #	Total Participants	%
PCL	11	22	50%
Dass Depression	15	22	68.18%
Dass Anxiety	9	22	40.91%
Dass Stress	11	22	50%

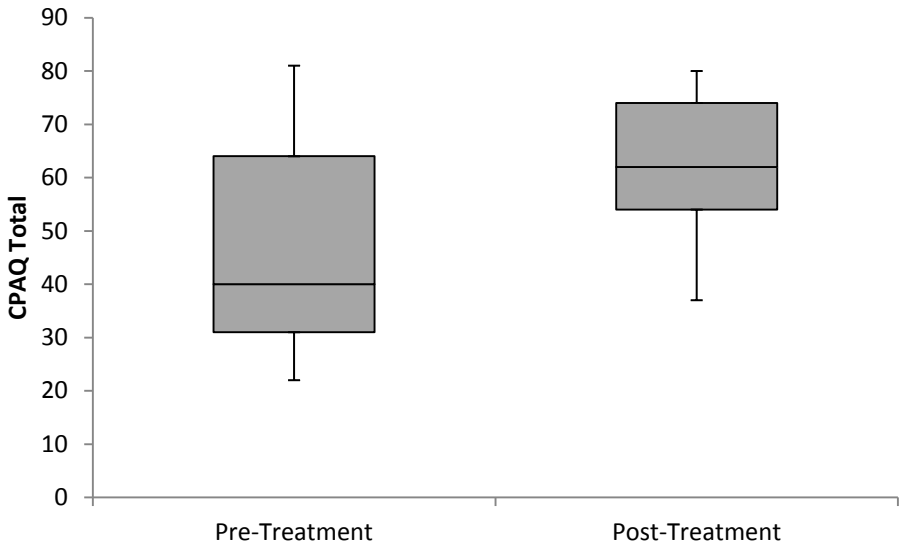

Figure 1: A graphical comparison of Chronic Pain Acceptance Questionannaire's measure of total pain acceptance before treatment and immediately following treatment.

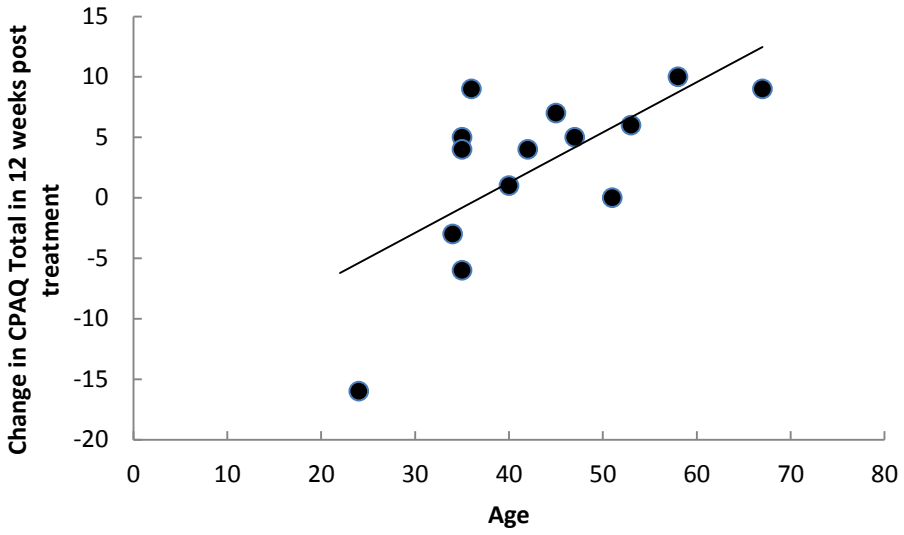

Figure 2. Relationship between the change in CPAQ Totals scores in the 12 weeks following the program and the age of the participant, r = .68.

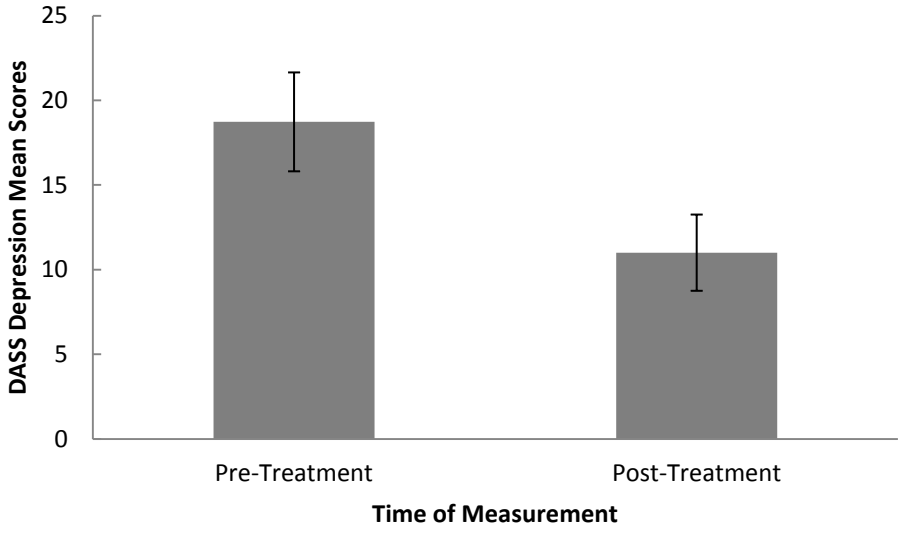

Figure 3. Comparing the mean DASS Depression Scale scores at pre-treatment to post treatment.

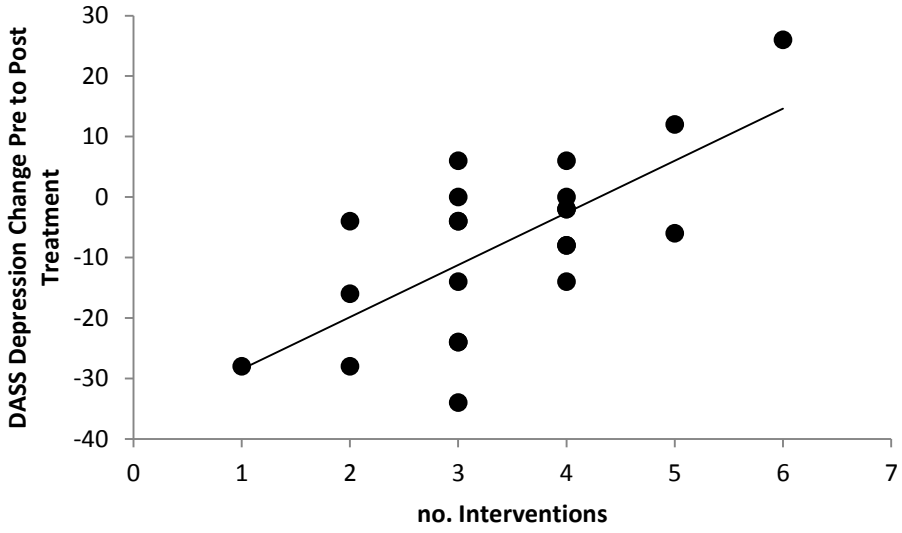

Figure 4. The relationship between the mean change in depression scores from pre-treatment to post treatment and the number of interventions attempted prior to the program.

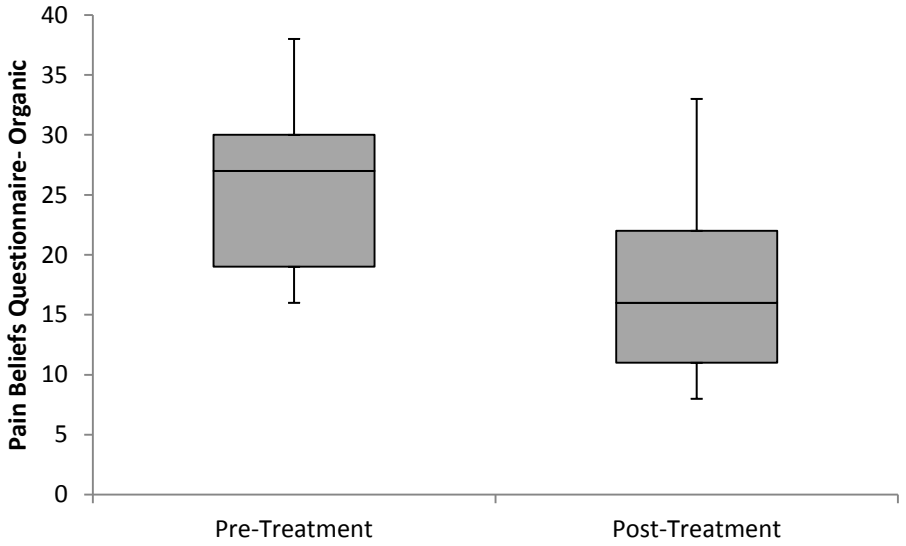

Figure 5. A comparison of the Organic Pain Belief subscale scores at pre-treatment to post-treatment.

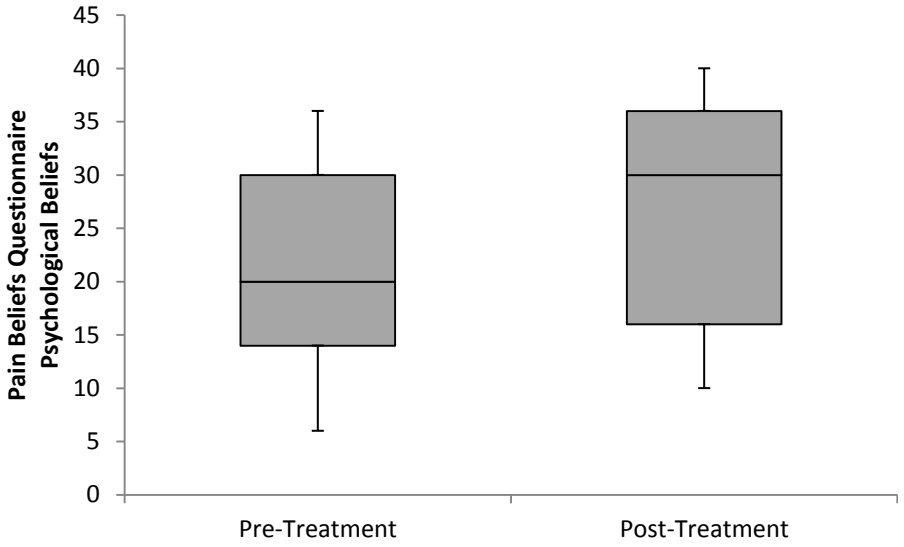

Figure 6. Comparing the Psychological Pain Beliefs at pre-treatment and post-treatment.

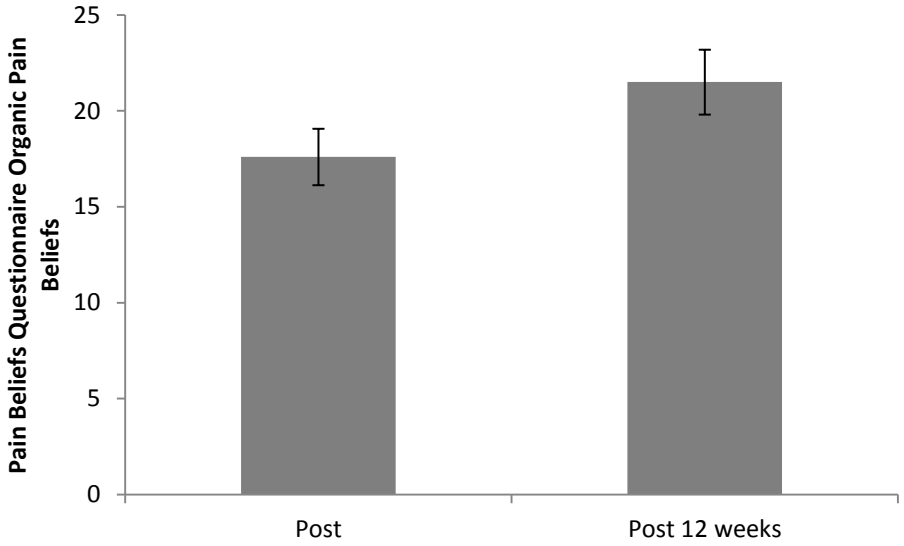

Figure 7. Comparing Organic Pain Beliefs scores at post treatment to 12 weeks following treatment.

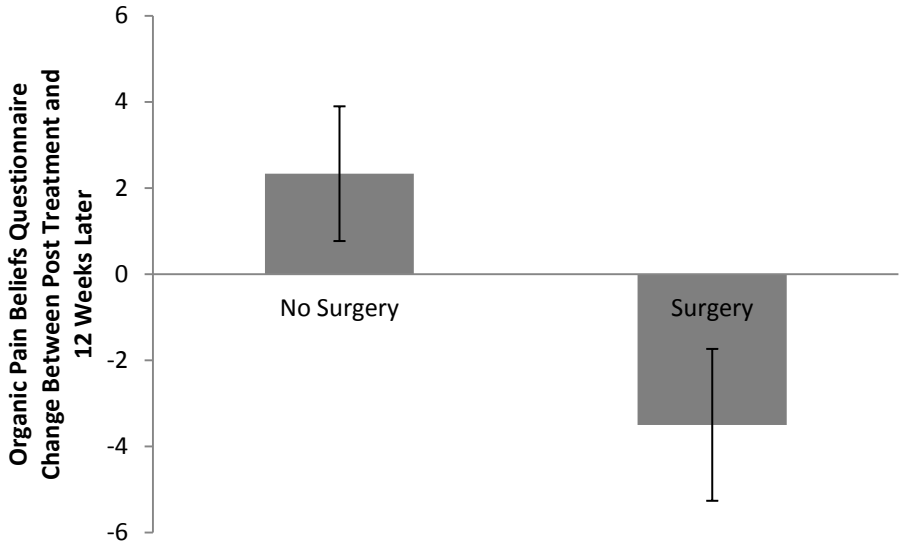

Figure 8. Comparing the mean change in Organic Pain Beliefs during the 12 weeks following the program by whether they had previously had surgery for their chronic pain.

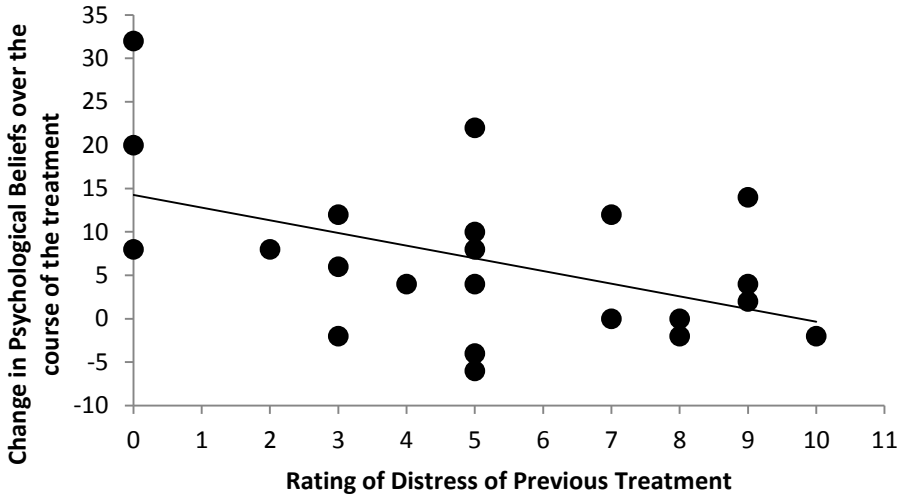

Figure 9. The relationship between the mean change in Psychological Pain Beliefs during the program and the distress experienced in the treatment prior to the program, r = -.479.

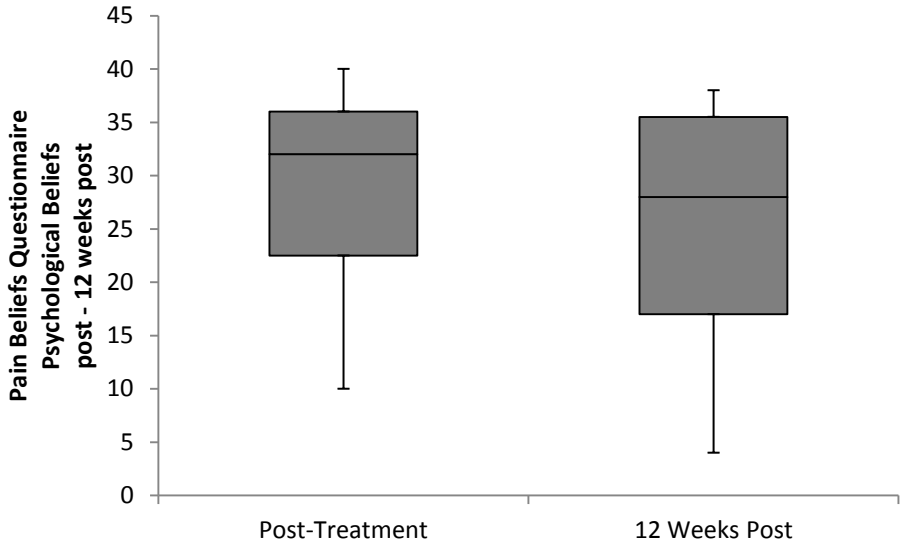

Figure 10. Comparing Psychological Pain Beliefs at post-treatment to 12 weeks post treatment.

Appendix A

Notification of Expedited Approval

This form has been included to outline the ethical consideration completed as part of this research study.

HUMAN RESEARCH ETHICS COMMITTEE

THE UNIVERSITY OF NEWCASTLE AUSTRALIA

Notification of Expedited Approval

To Chief Investigator or Project Supervisor:	**Doctor Lynne McCormack**
Cc Co-investigators / Research Students:	**Mr Christopher Maddison**
Re Protocol:	**A CBT inpatient chronic pain management program: A pilot analysis of factors impacting treatment outcomes.**
Date:	**09-Oct-2013**
Reference No:	**H-2013-0322**
Date of Initial Approval:	**09-Oct-2013**

Thank you for your **Initial Application** submission to the Human Research Ethics Committee (HREC) seeking approval in relation to the above protocol.

Your submission was considered under **L2 Low Risk Research Expedited** review by the HREC Panel.

I am pleased to advise that the decision on your submission is **Approved** effective **09-Oct-2013**.

In approving this protocol, the Human Research Ethics Committee (HREC) is of the opinion that the project complies with the provisions contained in the National Statement on Ethical Conduct in Human Research, 2007, and the requirements within this University relating to human research.

Approval will remain valid subject to the submission, and satisfactory assessment, of annual progress reports. *If the approval of an External HREC has been "noted" the approval period is as determined by that HREC.*

The full Committee will be asked to ratify this decision at its next scheduled meeting. A formal *Certificate of Approval* will be available upon request. Your approval number is **H-2013-0322**.

If the research requires the use of an Information Statement, ensure this number is inserted at the relevant point in the Complaints paragraph prior to distribution to potential participants You may then proceed with the research.

For Noting:
1. Application Queries

a. On page 5 – Type of Research section of the application it has been noted that no boxes have been ticked 'yes'. Please change the tick from 'no' to 'yes' for the fourth question – Access to existing data sets, databanks, or human tissue banks and answer any subsequent questions.

b. On page 12 – Storage, Access and Disposal of Data please amend and provide details regarding who has access to the stored data and also provide details about data disposal. Please also advise that the data will be stored for a minimum of five years.

Conditions of Approval

This approval has been granted subject to you complying with the requirements for *Monitoring of Progress*, *Reporting of Adverse Events*, and *Variations to the Approved Protocol* as detailed below.

PLEASE NOTE:
In the case where the HREC has "noted" the approval of an External HREC, progress reports and reports of adverse events are to be submitted to the External HREC only. In the case of Variations to the approved protocol, or a Renewal of approval, you will apply to the External HREC for approval in the first instance and then Register that approval with the University's HREC.

- ***Monitoring of Progress***

Other than above, the University is obliged to monitor the progress of research projects involving human participants to ensure that they are conducted according to the protocol as approved by the HREC. A progress report is required on an annual basis. Continuation of your HREC approval for this project is conditional upon receipt, and satisfactory assessment, of annual progress reports. You will be advised when a report is due.

- ***Reporting of Adverse Events***

1. It is the responsibility of the person **first named on this Approval Advice** to report adverse events.
2. Adverse events, however minor, must be recorded by the investigator as observed by the investigator or as volunteered by a participant in the research. Full details are to be documented, whether or not the investigator, or his/her deputies, consider the event to be related to the research substance or procedure.
3. Serious or unforeseen adverse events that occur during the research or within six (6) months of completion of the research, must be reported by the person first named on the Approval Advice to the (HREC) by way of the Adverse Event Report form (via RIMS at https://rims.newcastle.edu.au/login.asp) within 72 hours of the occurrence of the event or the investigator receiving advice of the event.
4. Serious adverse events are defined as:
    - Causing death, life threatening or serious disability.
    - Causing or prolonging hospitalisation.
    - Overdoses, cancers, congenital abnormalities, tissue damage, whether or not they are judged to be caused by the investigational agent or procedure.
    - Causing psycho-social and/or financial harm. This covers everything from perceived invasion of privacy, breach of confidentiality, or the diminution of social reputation, to the creation of psychological fears and trauma.
    - Any other event which might affect the continued ethical acceptability of the project.
5. Reports of adverse events must include:
    - Participant's study identification number;
    - date of birth;
    - date of entry into the study;
    - treatment arm (if applicable);
    - date of event;
    - details of event;
    - the investigator's opinion as to whether the event is related to the research procedures; and
    - action taken in response to the event.
6. Adverse events which do not fall within the definition of serious or unexpected, including those reported from other sites involved in the research, are to be reported in detail at the time of the annual progress report to the HREC.

- ***Variations to approved protocol***

If you wish to change, or deviate from, the approved protocol, you will need to submit an *Application for Variation to Approved Human Research* (via RIMS at https://rims.newcastle.edu.au/login.asp). Variations may include, but are not limited to, changes or additions to investigators, study design, study population, number of participants, methods of recruitment, or participant information/consent documentation. **Variations must be approved by the (HREC) before they are implemented** except when Registering an approval of a variation from an external HREC which has been designated the lead HREC, in which case you may proceed as soon as you receive an acknowledgement of your Registration.

Linkage of ethics approval to a new Grant

HREC approvals cannot be assigned to a new grant or award (ie those that were not identified on the application for ethics approval) without confirmation of the approval from the Human Research Ethics Officer on behalf of the HREC.

Best wishes for a successful project.

Professor Allyson Holbrook
Chair, Human Research Ethics Committee

For communications and enquiries:
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T +61 2 492 17894
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Human-Ethics@newcastle.edu.au

RIMS website - https://RIMS.newcastle.edu.au/login.asp

Linked University of Newcastle administered funding:

Funding body	Funding project title	First named investigator	Grant Ref

Appendix B

Pre-Treatment Questionnaire

'Creative Self'
Inpatient Pain Management Programme

NEWCASTLE PRIVATE
HOSPITAL

'Creative Self'
Inpatient Pain Management Programme

BEFORE YOU BEGIN THE QUESTIONNAIRES

Thank you for your co-operation in responding to these questionnaires.

The BACKGROUND and STRESSFUL LIFE EVENTS questionnaire may take approximately 15 minutes to complete. The other questionnaires together may take approximately 60-90 minutes. Do not feel that you need to complete them all at one time, but it is important that you complete all questions. There are no right or wrong answers to the questions.

It is a requirement of the programme that all questionnaires be completed and returned before attendance on the programme can begin. Should you wish to have more information before completing and returning the questionnaires in the stamped/addressed envelopes, you can contact:

Lynne McCormack on (0249) 418706
or

Debra Smith on (0249) 418533

PERSONAL DETAILS

(Personal information will be stored separately from questionnaires)

YOUR NAME ..... **MALE/FEMALE:**.....

DATE OF BIRTH:..... **CURRENT AGE:**.....**YEARS**

ADDRESS: .....

TELEPHONE CONTACT: .....

NUMBER OF PEOPLE IN CURRENT HOUSEHOLD:.....

NUMBER OF CHILDREN (including those living elsewhere).....

PLEASE CIRCLE THE MOST APPROPRIATE ANSWER TO THE FOLLOWING QUESTIONS

DURING YOUR LIFETIME, WHICH OF THE FOLLOWING RELATIONSHIP SITUATIONS HAVE YOU BEEN IN?

1. single (never married) 2. living with partner 3. separated
4. divorced 5. widowed 6. married

WHAT IS YOUR CURRENT RELATIONSHIP SITUATION?.....

RELIGION OF UPBRINGING:

1. Catholic 2. Anglican 3. Protestant 4. Buddhist 5. Moslem 6. Other (which?)

ROLE OF RELIGION IN UPBRINGING:

1. minor 2. major/positive 3. major/negative 4. none

EDUCATION:

1. completed some high school 2. completed high school 3. technical training
4. specialist qualification 5. some tafe/university attendance 6. tafe/universitydegree
7. postgraduate education 8. postgraduate degree 9. Other.....

NPH *Creative Self* Pain Management Programme Project Identity Number .....

Before you begin this questionnaire:

- Thank you for your co-operation in responding to this questionnaire and ask that you answer each question.
- Individual responses to questions will be confidential to the researcher.
- There are no right or wrong answers to the questions.

What is the cause of your current pain?

_____

_____

_____

How long have you had your pain condition?

☐ Less than 6 months ☐ 6 months to 2 years

☐ Greater than 2 to 5 years ☐ Greater than 5 years

What types of formal treatment have you had for your pain condition?

☐ Surgery. Specify _____ ☐ Physiotherapy

☐ Chiropractic manipulation ☐ Remedial massage

☐ Medication under the direction of a medical practitioner

☐ Other. Please specify _____

How do you deal with your pain on a daily basis? _____

_____

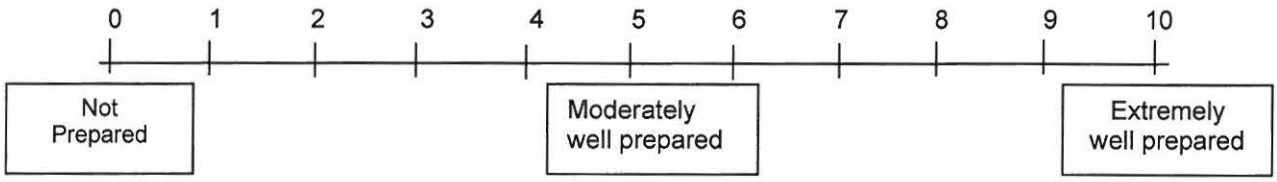
When did you last have formal treatment for your pain condition? ____/____/____

What did this treatment consist of? _____

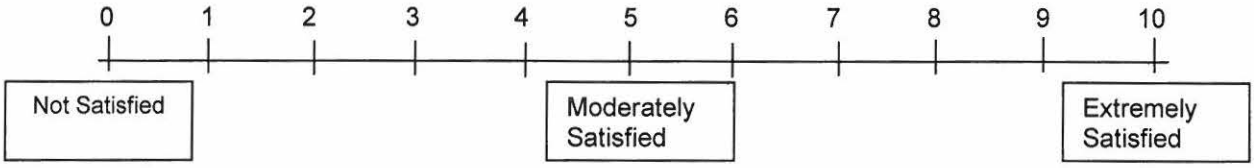
_____

NPH *Creative Self* Pain Management Programme Project Identity Number .....

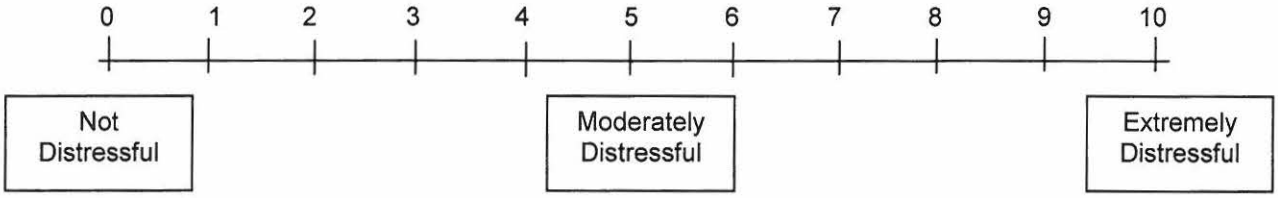
On the following scale, how well prepared were you for that treatment?



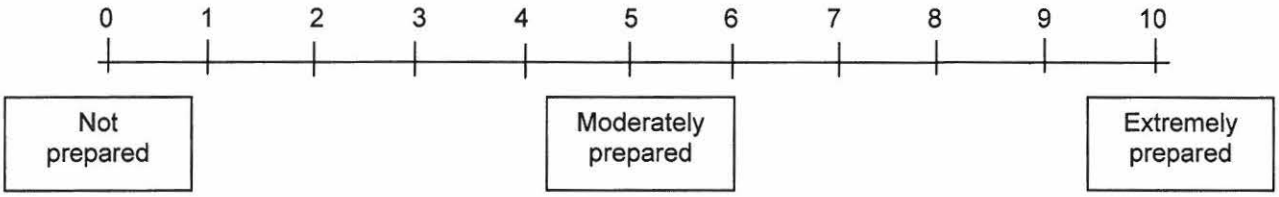
On the following Scale, how satisfied were you with the treatment outcome?



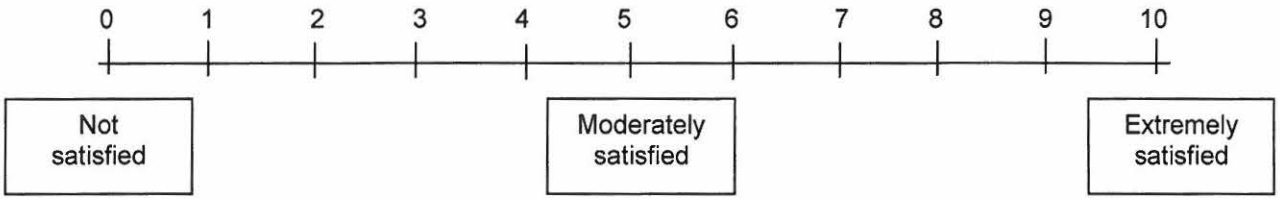
On the following scale, how would you rate your most recent formal treatment experience prior to this programme?



On the following scale, how well prepared do you feel you are for this programme?



On the following scale, how satisfied do you expect to be at the end of this treatment programme?



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CPAQ

Directions: Below you will find a list of statements. Please rate the truth of each statement as it applies to you by circling a number. Use the following rating scale to make your choices. For instance, if you believe a statement is "Always True", you would circle the 6 next to that statement.

0 Never True	1 Very Rarely True	2 Seldom True	3 Sometimes True	4 Often True	5 Almost Always True	6 Always True

1. I am getting on with the business of living no matter what my level of pain is	0	1	2	3	4	5	6
2. My life is going well, even though I have chronic pain	0	1	2	3	4	5	6
3. It's O.K. to experience pain	0	1	2	3	4	5	6
4. I would gladly sacrifice important things in my life to control this pain better	0	1	2	3	4	5	6
5. It's not necessary for me to control my pain in order to handle my life well	0	1	2	3	4	5	6
6. Although things have changed, I am living a normal life despite my chronic pain	0	1	2	3	4	5	6
7. I need to concentrate on getting rid of my pain	0	1	2	3	4	5	6
8. There are many activities I do when I feel pain	0	1	2	3	4	5	6
9. I lead a full life even though I have chronic pain	0	1	2	3	4	5	6
10. Controlling pain is less important than other goals in my life	0	1	2	3	4	5	6

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0 Never True	1 Very Rarely True	2 Seldom True	3 Sometimes True	4 Often True	5 Almost Always True	6 Always True

11. My thoughts and feelings about pain must change before I can take important steps in my life	0	1	2	3	4	5	6
12. Despite the pain, I am now sticking to a certain course in my life	0	1	2	3	4	5	6
13. Keeping my pain level under control takes first priority whenever I am doing something	0	1	2	3	4	5	6
14. Before I can make any serious plans, I have to get some control over my pain	0	1	2	3	4	5	6
15. When my pain increases, I can still take care of my responsibilities	0	1	2	3	4	5	6
16. I will have better control over my life if I can control my negative thoughts about pain	0	1	2	3	4	5	6
17. I avoid putting myself in situations where pain might increase	0	1	2	3	4	5	6
18. My worries and fears about what pain will do to me are true	0	1	2	3	4	5	6
19. It's a relief to realize that I don't have to change my pain to get on with my life	0	1	2	3	4	5	6
20. I have to struggle to do things when I have pain	0	1	2	3	4	5	6

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Pain Beliefs Questionnaire

Instructions.

For each item please indicate your opinion by circling one of the following words (always, almost always, often, sometimes, rarely, never) that appears beside each of the sentences. There are no right or wrong answers. It is important that you respond to each according to your actual beliefs, not according to how you feel you should believe, or how you think we want you to believe.

Item	Always	Almost Always	Often	Sometimes	Rarely	Never
1. Pain is the result of damage to the tissues of the body						
2. Physical exercise makes pain worse						
3. It is impossible to do much for oneself to relieve pain						
4. Being anxious makes pain worse						
5. Experiencing pain is a sign that something is wrong with the body						
6. When relaxed pain is easier to cope with						
7. Being in pain prevents you from enjoying hobbies and social activities						
8. The amount of pain is related to the amount of damage						
9. Thinking about pain makes it worse						
10. It is impossible to control pain on your own						
11. Pain is a sign of illness						
12. Feeling depressed makes pain seem worse						

Adapted from Edwards, L.; Pearce, S.; Turner-Stokes, I. and Jones, A. (1992) The Pain Beliefs Questionnaire: an investigation of beliefs in the causes and consequences of pain, *Pain, 51*, 267-272.

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IMPACT OF EVENT SCALE - Revised

INSTRUCTIONS: Below is a list of difficulties people sometimes have after stressful life events. Please read each item, and then indicate how distressing each difficulty has been for you and how much were you distressed or bothered by these difficulties DURING THE LAST SEVEN DAYS, with respect to the EVENT that contributed to your current pain problems?
EVENT_____DATE_____

	Not at all	A little bit	Moder-ately	Quite a bit	Extremely
1. Any reminder brought back feeling about it.	0	1	2	3	4
2. I had trouble staying asleep.	0	1	2	3	4
3. Other things kept making me think about it.	0	1	2	3	4
4. I felt irritable and angry.	0	1	2	3	4
5. I avoided letting myself get upset when I thought about it or was reminded of it.	0	1	2	3	4
6. I thought about it when I didn't mean to.	0	1	2	3	4
7. I felt as if it hadn't happened or wasn't real.	0	1	2	3	4
8. I stayed away from reminders about it.	0	1	2	3	4
9. Pictures about it popped into my mind.	0	1	2	3	4
10. I was jumpy and easily startled.	0	1	2	3	4
11. I tried not to think about it.	0	1	2	3	4
12. I was aware that I still had a lot of feelings about it, but I didn't deal with them.	0	1	2	3	4
13. My feelings about it were kind of numb.	0	1	2	3	4
14. I found myself acting or feeling like I was back at that time.	0	1	2	3	4
15. I had trouble falling asleep.	0	1	2	3	4
16. I had waves of strong feelings about it.	0	1	2	3	4
17. I tried to remove it from my memory.	0	1	2	3	4
18. I had trouble concentrating.	0	1	2	3	4
19. Reminders of it caused me to have physical reactions, such as sweating, trouble breathing, nausea, or a pounding heart.	0	1	2	3	4
20 I felt watchful and on-guard.	0	1	2	3	4
21. I had dreams about it	0	1	2	3	4
22. I tried not to talk about it.	0	1	2	3	4

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PCL-S (Weathers et al., 1994)

INSTRUCTIONS: Below is a list of problems and complaints that people sometimes have in response to stressful experiences. Please read each one carefully, then circle one of the numbers to the right to indicate how much you have been bothered by the **EVENT** that contributed to your current pain problems.

EVENT_____DATE_____

	Not at all	A little bit	Moder-ately	Quite a bit	Extremely
1. Repeated, disturbing *memories, thoughts*, or *images* of a stressful experience?	1	2	3	4	5
2. Repeated, disturbing dreams of a stressful experience?	1	2	3	4	5
3. Suddenly acting or feeling as if a stressful experience *were happening again* (as if you were reliving it)?	1	2	3	4	5
4. Feeling *very* upset when something reminded you of a stressful experience?	1	2	3	4	5
5. Having *physical reactions* (eg. heart pounding, trouble breathing, sweating) when *something* reminded you of a stressful experience?	1	2	3	4	5
6. Avoiding *thinking about or talking about* a stressful experience or avoiding *having feelings* related to it?	1	2	3	4	5
7. Avoiding *activities or situations* because they reminded you of a stressful experience?	1	2	3	4	5
8. Trouble *remembering important* parts of a stressful experience?	1	2	3	4	5
9. *Loss of interest* in activities that you used to enjoy	1	2	3	4	5
10. Feeling *distant or cut off* from other people?	1	2	3	4	5
11. Feeling *emotionally numb* or being unable to have loving feelings for those close to you?	1	2	3	4	5
12. Feeling as if your *future* somehow will be cut short?	1	2	3	4	5
13. Trouble falling or *staying* asleep?	1	2	3	4	5
14. Feeling *irritable* or having *angry outbursts?*	1	2	3	4	5
15. Having *difficulty concentrating?.*	1	2	3	4	5
16. Being *"superalert"* or watchful or on guard?	1	2	3	4	5
17. Feeling jumpy or easily startled?.	1	2	3	4	5

DASS21 (Lovibond & Lovibond, 1993)

Please read each statement and circle a number 0,1,2,or 3 which indicates how much the statement applied to you over the past week. There are no right or wrong answers. Do not spend too much time on any statement.

The rating scale is as follows:

0 Did not apply to me at all
1 Applied to me to some degree, or some of the time
2 Applied to me to a considerable degree, or most of the time
3 Applied to me very much, or most of the time.

1.	I found it hard to wind down	0 1 2 3
2.	I was aware of dryness of my mouth	0 1 2 3
3.	I couldn't seem to experience any positive feeling at all	0 1 2 3
4.	I experienced breathing difficulty (e.g. excessively rapid breathing, breathlessness in the absence of physical exertion)	0 1 2 3
5.	I found it difficult to work up the initiative to do things	0 1 2 3
6.	I tended to over-react to situations	0 1 2 3
7.	I experienced trembling (e.g. in the hands)	0 1 2 3
8.	I felt that I was using a lot of nervous energy	0 1 2 3
9.	I was worried about situations in which I might panic and make a fool of myself	0 1 2 3
10.	I felt that I had nothing to look forward to	0 1 2 3
11.	I found myself getting agitated	0 1 2 3
12.	I found it difficult to relax	0 1 2 3
13.	I felt down-hearted and blue	0 1 2 3

The rating scale is as follows:

0 Did not apply to me at all
1 Applied to me to some degree, or some of the time
2 Applied to me to a considerable degree, or most of the time
3 Applied to me very much, or most of the time.

14.	I was intolerant of anything that kept me from getting on with what I was doing	0 1 2 3
15.	I felt I was close to panic	0 1 2 3
16.	I was able to become enthusiastic about anything	0 1 2 3
17.	I felt I wasn't worth much as a person	0 1 2 3
18.	I felt that I was rather touchy	0 1 2 3
19.	I was aware of the action of my heart in the absence of physical exertion (e.g. sense of heart rate increase, heart missing a beat)	0 1 2 3
20.	I felt scared without any good reason	0 1 2 3
21.	I felt that life was meaningless	0 1 2 3

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AUDIT

Because alcohol use can affect health and interfere with certain medications and treatments, it is important that we ask you some questions about your use of alcohol. Many people also use alcohol to relax and to cope with their pain. Your answers will remain confidential, so please be as accurate as possible. Try to answer the questions in terms of *'standard'* drinks. Refer to the pictures to determine what is a standard drink.

- **Below you will see those serves of alcohol that are <u>STANDARD</u> drinks found in typical serving containers.**

30ml **Spirit Nip** **40% ALC/VOL**	**100ml** **Standard Serve of Wine** **12% ALC/VOL**	**60ml** **Port/Sherry** **18% ALC/VOL**	**285ml** **Middy/Pot Full Strength Beer** **4.9% ALC/VOL**
			
1	**1**	**1**	**1**

- **Below you will see common serves of alcohol that are <u>MORE</u> than a standard drink.**

375ml Full Strength Beer 4.9% ALC/VOL	**375ml** Full Strength Beer 4.9% ALC/VOL	**170ml** Average Serve of Sparkling Wine/Champagne 11.5% ALC/VOL	**425ml** Schooner Full Strength Beer 4.9% ALC/VOL
			
1.5	**1.5**	**1.5**	**1.5**

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Please answer the following questions as accurately as possible by circling the appropriate answer:

1. How often do you have a drink containing alcohol?	Never (Skip to Qs. 9 & 10)	Monthly or Less	2-4 times a month	2 to 3 times a week	4 or more times a week	
Each one of these drinks is equivalent to one standard drink	1 middy/pot standard beer 285 mls	1 schooner light beer 425 mls	1 glass of wine 100 mls	1 glass of sherry or port 60 mls	1 nip of spirits 30 mls	
2. How many drinks containing alcohol do you have on a typical day when you are drinking?	1 or 2	3 or 4	5 or 6	7 to 9	10 or more	
3. How often do you have 6 or more drinks on one occasion?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily	
4. How often during the last year have you found that you were not able to stop drinking once you had started?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily	
5. How often during the last year have you failed to do what was normally expected of you	Never	Less than monthly	Monthly	Weekly	Daily or almost daily	
6. How often during the last year have you needed a first drink in the morning to get yourself going after a heavy drinking session	Never	Less than monthly	Monthly	Weekly	Daily or almost daily	
7. How often during the last year have you had a feeling of guilt or remorse after drinking?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily	
8. How often during the last year have you been unable to remember what happened the night before because of your drinking?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily	
9. Have you or someone	No		Yes, but		Yes,	

else been injured because of your drinking?			not in the last year		during the last year	
10. Has a relative, friend, doctor, or other health care worker been concerned about your drinking or suggested you cut down?	No		Yes, but not in the last year		Yes, during the last year	
Score Qs 11 and 12 'a' to 'e' and write response in shaded box						
11. Do you think you presently have a problem with drinking?	(a) No	(b) Probably not	(c) Unsure	(d) Possibly	(e) Definitely	
12. In the next three months, how difficult would you find it to cut down or stop drinking?	(a) Very easy	(b) Fairly easy	(c) Neither difficult nor easy	(d) Fairly difficult	(e) Very difficult	

Thank you very much for taking the time to complete the questionnaires, as your answers will help us understand your needs better.

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Appendix C

The Journal of Pain Scope and Instructions to Authors

Journal: Chronic Illness

Aims & Scope

Chronic illnesses are prolonged, do not resolve spontaneously, and are rarely completely cured. The most common are cardiovascular diseases (hypertension, coronary artery disease, stroke and heart failure), the arthritides, asthma and chronic obstructive pulmonary disease, diabetes and epilepsy. There is increasing evidence that mental illnesses such as depression are best understood as chronic health problems. HIV/AIDS has become a chronic condition in those countries where effective medication is available.

As life expectancy increases, so does the likelihood that people will become susceptible to chronic illness. Between 1996 and 2020, the population aged over 65 is projected to increase by about 82% globally (110% in less developed countries, and 40% in more developed countries). Chronic disease is now the main reason why people seek health care in the developed world. Because of the difficulty and duration of treatment, the costs of chronic health conditions are enormous: in the USA it now consumes 70% of health care spending [Holman H., Lorig K. Patients as partners in managing chronic disease. BMJ 2000, 320.526-7].

Awareness is increasing that similar strategies can be effective in treating many different conditions. These are likely to involve the proactive identification of relevant populations; to provide support for the relationship between people living with long term health conditions and health and social care professionals; to develop evidence-based care guidelines which emphasise the prevention of exacerbation and complications; and promote empowerment strategies for people living with chronic illness, such as self-management and education. They also require continuous evaluation of clinical, humanistic and economic outcomes.

1. Peer review policy

The journal's policy is to obtain at least two independent reviews of each article. The peer review process will be double-blind, i.e. neither reviewers nor authors will be informed of the identity of each other. Referees will be encouraged to provide substantive, constructive reviews that provide suggestions for improving the work and distinguish between mandatory and non-mandatory recommendations.

All manuscripts accepted for publication are subject to editing for presentation, style and grammar. Any major redrafting is agreed with the author but the Editor's decision on the text is final.

2. Article types

The journal publishes original papers, reviews, discussions of topical issues, case studies and meeting reports. The journal reproduces photographs in full colour. The suggested word counts only refer to the body of the text and exclude references etc.

2.1 Summary of manuscript structure:

When preparing your paper:

Review papers, discussion papers, and papers including substantive qualitative research should be no more than 5000 words in length, excluding structured abstracts, quantitative tables and figures, and references. We welcome systematic reviews and syntheses on areas of interest and importance to those concerned with chronic illness. A clear research question and a description of methods, including search strategies and quality appraisal, should be provided. Methods for synthesis, including meta-analysis, narrative summary, meta-ethnography etc., should be clearly explained.

Quantitative research papers should be no more than 3000 words in length, excluding structured abstracts, tables and figures, and references.

Short reports, commentaries on classic papers and patients' comments should be no more than 1000 words in length, including abstracts, tables and figures, and references. These are a useful method for reporting circumscribed research where the study or the results may not justify a full report. It does not imply a lower standard for the quality of the work reported. The guidance is the same as for original articles with the following exceptions: the summary need not be a structured abstract; authors should limit themselves to no more than ten references and two figures or tables.

Original papers

Should include:

- Title page: (1) title of the article; (2) first name(s) or initial(s) and surname of each author; (3) address of the department or institution to which the work should be attributed; (4) full postal address of each author; (5) name, telephone, email address and fax number of the author responsible for correspondence and to whom requests for offprints should be sent. (This is particularly important where the corresponding author is not the first named author.)

- Abstract (<200 words): a short inclusive statement suitable for direct electronic abstracting identifying the purpose of the study, key methods, the main results and the main conclusion. Structured abstracts are essential for research and review papers, and should be submitted under the headings: objectives, methods, results, and discussion.

- Key words: maximum of 5 key words for indexing.

- Introduction: concise description of background, sufficient for the non-specialist to appreciate the context of the work. Clear statement of the purpose of the study. Authors should avoid obviously partisan selection and quotation of literature.

- Methods: should demonstrate a clear and documented design or strategy directed towards a specific research question. The study design should be appropriate to the aims of the study and be clearly described. The criteria for selecting the sample should be clearly described and justified. A clear description of sampling, recruitment to the study, data collection, and data analysis should be provided. Full details of interventions should be given for intervention studies. This section should also include details of approval from a named Research Ethics Committee, and any arrangements for data oversight.

- Results: should contain all the information required by referees and readers to assess the validity of the conclusions. The characteristics of the sample included in the study should be clearly described. For quantitative studies, the section should include details of the response rates and numbers lost to follow-up. The analysis should be clear and systematic. Results of statistical tests should be reported with confidence intervals in order to provide an estimate of precision. No more than six tables should be included.

- Discussion: an interpretation of the study placed within the context of current knowledge leading to specific conclusions where possible. We recommend that this covers the following sections, using sub-headings: summary of main findings; the strengths and the limitations of this study; how and why it agrees or disagrees with the existing literature, in particular including any papers published since the study was designed and carried out; the implications for future research or clinical practice.

- Each of the above sections should use subheadings as appropriate.

- Acknowledgements.

- References (ideally max. 25), figures and tables (see 9.4.3 for more details).

- Patient comments: we welcome submissions of articles, including comments on published papers, from people who experience chronic illness or their carers

- Commentaries on classic papers: these will normally be commissioned, but the Editor will also be pleased to consider unsolicited copy.

3. How to submit your manuscript

Before submitting your manuscript, please ensure you carefully read and adhere to all the guidelines and instructions to authors provided below. Manuscripts not conforming to these guidelines may be returned.

Chronic Illness has a fully web-based system for the submission and review of manuscripts. All submissions should be made online at the *Chronic Illness* SAGE track website:

http://mc.manuscriptcentral.com/chronicillness

Note: Online submission and review of manuscripts is now mandatory for all types of papers.

New User Account
Please log onto the website. If you are a new user, you will first need to create an account. Follow the instructions and please ensure to enter a current and correct email address. Creating your account is a three-step process that takes a matter of minutes. When you have finished, your User ID and password is sent immediately via email. Please edit your user ID and password to something more memorable by selecting 'edit account' at the top of the screen. If you have already created an account but have forgotten your details type your email address in the 'Password Help' to receive an emailed reminder. Full instructions for uploading the manuscript are provided on the website.

New Submission
Submissions should be made by logging in and selecting the Author Centre and the 'Click here to Submit a New Manuscript' option. Follow the instructions on each page, clicking the 'Next' button on each screen to save your work and advance to the next screen. If at any stage you have any questions or require the user guide, please use the 'Get Help Now' button at the top right of every screen. Further help is available through ScholarOne'sÂ® Manuscript CentralTM customer support at +1 434 817 2040 x 167 or email the editor with your manuscript as an attachment(s) and write a note to explain why you need to submit via this route. Â

To upload your files, click on the 'Browse' button and locate the file on your computer. Select the designation of each file (i.e. main document, submission form, figure) in the drop down menu next to the browse button. When you have selected all the files you wish to upload, click the 'Upload Files' button.

Review your submission (in both PDF and HTML formats) and then click the Submit button You may suspend a submission at any point before clicking the Submit button and save it to submit later. After submission, you will receive a confirmation e-mail. You can also log back into your author centre at any time to check the status of your manuscript.

Please ensure that you submit editable/source files only (Microsoft Word or RTF) and that your document does not include page numbers; the SAGE track system will generate them for you, and then automatically convert your manuscript to PDF for peer review. All correspondence, including notification of the Editor's decision and requests for revisions, will be by email.

If you would like to discuss your paper prior to submission, or seek advice on the submission process please contact the Editor-in-Chief, Chris Dowrick: cfd@liverpool.ac.uk.

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6. Other conventions

6.1 Informed Consent

Authors are required to ensure that the following guidelines are followed, as recommended by the International Committee of Medical Journal Editors ("Uniform Requirements for Manuscripts Submitted to Biomedical Journals": http://www.icmje.org/urm_full.pdf).

Patients have a right to privacy that should not be infringed without informed consent. Identifying information, including patients' names, initials, or hospital numbers, should not be published in written descriptions, photographs, and pedigrees unless the information is essential for scientific purposes and the patient (or parent or guardian) gives written informed consent for publication. Informed consent for this purpose requires that a patient who is identifiable be shown the manuscript to be published.
Complete anonymity is difficult to achieve, however, and informed consent should be obtained if there is any doubt. For example, masking the eye region in photographs of patients is inadequate protection of anonymity. If identifying characteristics are altered to protect anonymity, such as in genetic pedigrees, authors should provide assurance that alterations do not distort scientific meaning and editors should so note.

When informed consent has been obtained it should be indicated in the submitted article.

Authors should identify individuals who provide writing/administrative assistance, indicate the extent of assistance and disclose the funding source for this assistance.
Identifying details should be omitted if they are not essential.

6.2 Randomised Controlled Tests

Authors submitting randomised controlled trials (RCTs) should follow the revised CONSORT guidelines, including a completed CONSORT checklist and flowchart of participants in the trial. Guidance can be found at http://jama.ama-assn.org/site/misc/auinst_chk.pdf or JAMA 2003; 291:125.