

**INTEROCEPTIVE EXPOSURE IN TREATMENT OF DISABLING FEAR OF
PAIN: A SINGLE CASE SERIES.**

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Submitted in accordance with the requirements for the degree of
Doctor of Clinical Psychology (D. Clin. Psychol.)

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June, 2019

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Acknowledgements

Firstly, I would like to dedicate this thesis to the late Professor Stephen Morley, who introduced me to pain psychology and taught me to never put myself down. It was his idea to ask Dr Ciara Masterson to help see this thesis through, for which I will be forever grateful. Her enthusiasm, continuous encouragement and the time she gave me was indispensable. Both of my brilliant supervisors inspired me to be a better psychologist and a better human being. I hope that one day I will be able to help others as much as they helped me.

Secondly, to my boyfriend Andrew, who spent weeks and months looking after me during the writing. Without the countless cups of coffee, which he uncomplainingly provided, and his love and patience I would have not enjoyed completing this work as much as I did.

Finally, to all of my study participants and colleagues at Fielding House. Thank you for helping me at every step of this process, for giving your time and kind encouragement in making this study possible.

My heart is filled with gratitude for all of you.

ABSTRACT

Background. This study investigated the use of Interoceptive Exposure (IE) in treatment of disabling fear of pain using a single-case series design. IE is used in treatment of a variety of problems where body sensations are experienced as threatening. IE was used here as an extension of the Fear Avoidance Model. The main hypotheses were that the intervention will reduce fear of pain and increase activity. Additionally, we expected to see a decrease in pain distress and interference, and increase in acceptance of pain. **Method.** An ABC multiple baseline single-case series design was used. Eight adults referred to clinical psychology through a Pain Clinic were recruited; seven completed treatment. The intervention comprised: one pain education session, two sessions of training in IE plus self-monitored home practice twice daily for two weeks. Depending on the length of the baseline the study lasted between six and seven weeks. A nine-item instrument was designed to measure fear of pain, pain distress and interference on a daily basis. Physical activity was measured using wearable activity monitors. Standard outcome measures included: pain anxiety, catastrophising, disability and general anxiety and depression. **Results.** The intervention resulted in reduced fear of pain in some participants, but not all. Six participants improved on at least one of three measures of fear of pain, with two participants improving on all three measures. For one participant there were no changes in fear of pain. Our strongest finding was that the treatment reduced catastrophising, with five participants making significant reliable improvement. All study participants increased their activity levels following the intervention, but for only four participants was this change meaningful. Additionally, contrary to our hypothesis, reduction in fear of pain did not lead to increase in activity. The intervention had no effect on pain acceptance, disability, nor depression and anxiety.

Key words: chronic pain, fear of pain, pain anxiety, Fear Avoidance Model, Interoceptive Exposure, pain education, single case series

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Abbreviations

ACT: Acceptance and Commitment Therapy
AS: Anxiety sensitivity
CBT: Cognitive Behavioural Therapy
CIPA: Congenital insensitivity to pain with anhidrosis
CPAQ: Chronic Pain Acceptance Questionnaire
CSPMS UK: Core Standards for Pain Management Services in the UK
FAM: Fear Avoidance Model
GP: General practitioner
HADS: Hospital Anxiety and Depression Scale
HSCED: Hermeneutic single-case efficacy design
IBS: Irritable bowel syndrome
IE: Interoceptive Exposure
MP3: digital audio file
NHS: National Health Service
NICE: National Institute for Health and Care Excellence
NPQ-R: Revised Neurophysiology of Pain Questionnaire
NSAID: Non-steroidal anti-inflammatory drugs
PASS-20: Pain Anxiety Scale Short Form
PCS: Pain Catastrophising Scale
PDC: Pain Desensitising Chart
PDI: Pain Disability Index
PMP: Pain Management Programme
PMR: Progressive muscle relaxation
PNE: Pain neuroscience education
PPT: Pain provocation technique
PTSD: Post-traumatic stress disorder
r: reliability
R/D: Relaxation/distraction
RCI: Reliable change index
RCT: Randomized controlled trial
RNPQ: Revised Neurophysiology of Pain Questionnaire
SCEDs: Single-case experimental designs
SD: Standard deviation
SEdiff: Standard error of the difference score
Sem: Standard error of measurement
SIGN: Scottish Intercollegiate Guidelines Network
TENS: Transcutaneous electrical nerve stimulation
WHO: World Health Organization

“He who fears he shall suffer, already suffers what he fears.”

— Michel de Montaigne

INTRODUCTION

1.1 Context

The ability to experience pain is, in its very nature, an adaptive and protective mechanism. There are multiple ways that pain can be classified, one of the most important distinctions is linked to its duration and source. Most of us will be familiar with pain that lasts minutes, hours or days; caused by a specific disease or injury. This type of pain, defined as ‘acute’, gradually resolves as the injured tissues heal. However, there are situations when ‘acute pain’ turns into ‘chronic pain’. This type of pain may have its origins in an injury or illness, but in some instances it has no obvious biological cause or source. Chronic pain no longer serves a protective function; no longer warns against danger. This type of pain does not respond well to medical treatments and, in contrast to acute pain, does not necessarily get better with time. For many people the fearful and avoidant response to pain can lead to disuse, depression and disability. Chronic pain rehabilitation usually starts with helping sufferers understand the difference between ‘acute’ and ‘chronic’ pain. This can help with reducing fear, frustration, anger and hopelessness; natural human responses to the persistent experience of pain. Each personal story of pain is different; however, what they all have in common is the ongoing struggle of having to negotiate daily goals and values that are necessary to live a good life.

1.2 Literature Review

The breadth of the literature on pain made the literature search challenging. The books and articles that form the body of this literature review were identified using the advanced search services at the Leeds University Library. The following databases were consulted: PsychINFO (OVID), Medline (OVID), Medline In-Process (OVID), EMBASE (OVID), The Cochrane Library, and the Leeds University Library’s Books and Journals (OVID, full text), NHS Evidence and the Leeds University Library’s Books and Journals, grey literature (including government, business and charitable sector’s publications) and published dissertations. The initial search terms included combinations of the following words: *chronic pain*, *musculoskeletal pain*, *chronic low back pain*, *fear*, *anxiety*, *avoidance*, *‘Fear Avoidance Model’*, *‘pain anxiety’*, *‘pain avoidance’*, *‘fear of pain’*, *‘avoidance of pain’*, *‘Interoceptive Exposure’*, *‘Interoceptive Conditioning’*, *‘exposure to bodily*

sensations' and 'exposure to pain'. This search identified relevant literature reviews, quantitative and qualitative studies relating to chronic pain, fear of pain, Fear Avoidance Model and Interoceptive Exposure. Search limits used were: publication date (2012-2019), age range (studies involving adults) and language (English). Due to the fact that this study is a replication with modifications of a study by Flink, Nicholas, Boersma, and Linton (2009), and later replication by Taylor (2012), we included all literature referenced in both studies. Additionally, we limited the literature search to include articles published from 2012 onwards, as one of the replicated studies (Taylor, 2012) was carried out at the same research site and under the same academic supervision. The search identified 515 items. The following inclusion criteria were applied: items were included if they had a focus on chronic pain and the fear of pain, psychological intervention/psychotherapy, or Interoceptive Exposure. This strategy resulted in a reduced list of 167 items for inclusion in this study.

What follows is an overview of the phenomenon of pain, how it can develop into a chronic condition and what treatments are available. Furthermore, the topic of fear of pain and the Fear Avoidance Model will be outlined before providing a theoretical rationale behind the Interoceptive Exposure (IE) and describe how this technique has been used with people who suffer from chronic pain. Finally, in this chapter, we will look at how we can expand on the existing evidence.

1.3 When Pain Becomes Chronic

“Pain is a distressing experience associated with actual or potential tissue damage with sensory, emotional, cognitive, and social components” (Williams & Craig, 2016, p. 2420). Pain is also a “motivational state that initiates early defensive behaviours followed by recuperative behaviours and which has the primary function to promote recovery from injury” (Wall, 1979, p. 256). Pain does this in multiple ways, e.g. it forces us to rest, so that the injury heals better; it gives us a signal to resume aborted activities when it stops; it enhances learning to avoid certain stimuli in the future. Therefore, the main adaptive function of pain is to signal that things are ‘not alright’ and that there might be an injury or an illness that we need to pay attention to. There are several rare genetic conditions which can result in complete inability to experience pain, one such condition is known as ‘congenital insensitivity to pain with anhidrosis’, or CIPA. People diagnosed with this syndrome are very prone to life threatening injuries that would normally be prevented by experiencing pain (Indo, 2018). Despite its many adaptive functions pain experience is generally described as unpleasant, negative and aversive.

The definitions of pain highlight that it can be a response to ‘potential tissue damage’, meaning that we can experience pain without there being any actual injury or risk of injury. This complex nature of pain goes beyond the everyday understanding that most people hold. Despite the advances in modern pain science, and widely agreed upon idea that pain

perception is ‘created in the brain’, people still assume that nerves in our body are ‘sending pain signals’; a conceptualisation first proposed by Rene Descartes nearly 400 years ago (see Sullivan, 2008). The myths and misconceptions about pain, mainly the traditional view that there is an immediate link between pain, tissue damage and disability, are shared by both patients and medical professionals, and these can often lead to maladaptive coping strategies (Moseley & Butler, 2015; Vlaeyen, Crombez, & Goubert, 2007).

Humans have been interested in understanding the mechanisms of pain and finding a cure for it for thousands of years (Dormandy, 2006). However, recent developments are helping us understand the complexity of pain. New methods of assessment, research and treatment of pain from genetics, molecular biology, neuroimaging to acknowledgement of the psycho-social factors involved uncover how sophisticated and complex this protective mechanism is (Kumbhare, Elzibak, & Noseworthy, 2017).

Pain loses its regulatory function when it evolves into a chronic condition (West, Usher, Foster, & Stewart, 2012). As pointed out by Melzack and Katz: “most backaches, headaches, muscles pains, nerve pains, pelvic pains and facial pains serve no discernible purpose, are difficult to treat and are a disaster for the people who suffer them” (2013, p. 1). According to the International Association for the Study of Pain (IASP): “pain becomes chronic when it persists past the normal time of tissue healing” despite multiple interventions to provide relief (1986, p. 217). Most health authorities agree that the pain needs to last at least three (or six) months past the healing process to be classified as chronic (McCaffery & Passero, 1999; American Psychiatric Association, 2013).

As mentioned earlier, there are many ways of classifying pain. We have already made the distinction between acute and chronic pain. Within the latter we can focus on the underlying illness (e.g. fibromyalgia, cancer pain, rheumatoid arthritis, etc.), part of the body affected (e.g. headache, lower back pain etc.), specific systems in the body (e.g. urogenital pain, musculoskeletal pain etc.), the cause (e.g. whiplash pain, nerve damage), age of the patient (e.g. geriatric pain, paediatric pain), or pain pathways involved (e.g. nociceptive, peripheral neuropathic or central). There is also a group of patients who present with chronic pain caused by a non-traceable occurrence or unexplained symptoms, like phantom limb pain (Royal College of Anaesthetists, 2015), or functional pain syndrome (Crabtree & Ganty, 2016).

As outlined above chronic pain is often the main feature in a multitude of different disorders, and therefore treatments often vary; however, current evidence suggests that many chronic pain conditions share their underlying pathophysiologic mechanisms (Gereau et al., 2014).

Regardless of the type of pain or its source, the experience of pain is profoundly disruptive. When attempts to avoid or reduce pain are unsuccessful and the pain persists,

sufferers complain of distress, negative affect and reduced ability to shift their attention away from pain. For many the long term consequences of persisting pain will result in withdrawal from previously pursued behaviours, avoidance of physical activity, depression and disability (Crombez et al., 2012). Despite the wide range of sources and types of chronic pain the experience of 'living with pain' is shared among diverse groups of sufferers, therefore the literature review will include sources from various pain groups.

Due to its high prevalence and costs to the economy chronic pain has been recently called a 'disease of the century' (Prefontaine & Rochette, 2013). In 2014 the UK's Health Minister described chronic pain as a 'long term condition in its own right' (The Royal College of Anaesthetists, 2015). Chronic pain conditions are reported as a leading cause of disability worldwide (Vos et al., 2015). The prevalence of disability caused by chronic musculoskeletal conditions, such as low back and neck pain, has significantly increased in the last 25 years (Hurwitz, Randhawa, Yu, Côté, & Haldeman, 2018). The Global Burden of Disease Study led by Vos (2015), which analysed data from 188 countries across two decades (1990 to 2013) listed 25 conditions that cause people to live with disability. Chronic low back pain was ranked number one, chronic neck pain came fourth and migraine was ranked sixth. Interestingly, depression and anxiety, common comorbidities of chronic pain, were ranked second and ninth, respectively. These findings highlight how relevant the issues around chronic pain are on a global level (Vos, et al., 2015).

The main challenges for research into chronic pain are that, as noted earlier, chronic pain encompasses a very diverse group of conditions. Additionally, chronic pain patients often complain of other overlapping problems, such as anxiety and depression, sleep difficulties, disability, isolation and overuse of medication (Eccleston, Morley, & Williams, 2013).

1.3.1 Prevalence.

The prevalence of chronic pain is very difficult to define and estimates vary depending on the source of the data and definition of chronic pain. According to a recent systematic review chronic pain is estimated to affect between a third to half of the UK's population (Fayaz, Croft, Langford, Donaldson, & Jones, 2016), which translates to somewhere between 22 and 32 million people (as equated to population statistics from 2011). When taken out of context these numbers can be alarming; however, it is important to note that only a minority of chronic pain sufferers complain of disability caused by their pain. According to Fayaz and colleagues (2016) only between 10 - 14% of the UK population report 'moderately to severely limiting' levels of chronic pain.

Amongst the most robust findings is that chronic pain prevalence rises with age; it is reported that it affects 62% of adults over the age of 75 (Fayaz et al., 2016), which alarms us that with the ageing population the incidence of chronic pain will increase, unless more

effective treatments are available. Another robust statistic is that women report chronic pain more often than men (Andrews, Steultjens, & Riskowski, 2018). There are several explanations for why women are more likely to suffer from chronic pain. Firstly, biological differences between sexes imply that women are more sensitive to noxious stimuli (Fillingim, 2000). Sex hormones and greater nerve density in women, might also make women more susceptible to pain (Rhudy et al., 2013). Additionally, women are more likely to experience illnesses such as migraine headache, fibromyalgia, vulvodynia, chronic pelvic pain or chronic fatigue, where chronic pain is the main feature (Fayaz et al., 2016); however, there are other explanations, such as psychological and social factors (Wiesenfeld-Hallin, 2005) and cultural factors (Fillingim, King, Ribeiro-Dasilva, Rahim-Williams, & Riley, 2009). Amongst the non-biological explanations that might be feeding into this discrepancy are ideas around socialising men to be strong not weak and giving permission to women to express their feelings more openly (Miller & Newton, 2006).

Despite differences in definitions, diagnostic criteria and numbers reported in popular studies, there is a consensus amongst researchers that chronic pain conditions are much more common now than several decades ago (Harkness, Macfarlane, Silman, & McBeth, 2005). As reported by the Department of Health: “chronic pain is two to three times more common now than it was 40 years ago” (2009, p. 34).

There are several explanations given by experts in the field, yet strong evidence is lacking. The most popular proposition is the aging of the population and growing number of people experiencing diseases commonly associated with chronic pain, such as diabetes, arthritis, and cancer (Cherry, Lucas, & Decker, 2010). However, this fails to explain why some chronic pain conditions are on the rise across all age strata (Freburger et al., 2009). Others comment on increased population numbers, better reporting, more care seeking and better provision of healthcare, or a combination of the above (Cherry et al., 2010). An interesting reason mentioned in literature is the increasing numbers of people with chronic pain and obesity, referred to as ‘two colliding epidemics’ (Allen, Dal Grande, Abernethy, & Currow, 2016). Changes in psychosocial and physical work and rising unemployment may have also contributed to the increase in prevalence. Freburger et al. (2009) compared self-reported levels of functioning between people with chronic back pain in 1992 and 2006; they found that the levels of functioning were quite similar; however, there was a decrease in employment and more frequent reported use of sick leave and disability benefits amongst the 2006 population. Increases in chronic pain prevalence were also linked to increases in depression prevalence (Harkness, Macfarlane, Silman, & McBeth, 2005).

Table 1: Chronic Pain Statistics.

Recent data on chronic, non-cancer pain sufferers from United Kingdom and Europe	
Prevalence	33-50% of the UK's population report chronic pain, with 10-14% reporting moderately to severely limiting pain ¹ . European estimates of chronic pain prevalence are slightly lower at 12% ² .
Age	Chronic pain can affect people of all ages; however, older people are more at risk, with 62% of adults over the age of 75 reporting chronic pain. Estimates for the working population are as high as 30% ¹ .
Gender	Women are more likely to report chronic pain, especially chronic pain associated with illnesses such as chronic pelvic pain, migraine headache or fibromyalgia ^{1,4} .
Economic status	Financially and socially disadvantaged groups and some ethnic minority groups are more likely to suffer from chronic pain ¹ .
Employment	25% of people lose their jobs because of chronic pain ¹ .
Quality of Life	Chronic pain sufferers report very poor quality of life; 16% of chronic pain sufferers reported that their pain was so unbearable that they considered suicide ⁵ .
Mental health	It is estimated that between 18% (in population based settings) and 85% (in specialised pain clinics) of patients with chronic pain also have depression ⁷ ; other prevalent mental health conditions associated with chronic pain include anxiety and PTSD ³ .
Relationships	Opportunities to interact as a couple and spend leisure time together can be severely limited, with sex and intimacy being most at risk ⁶ .
Comorbidity	People living with non-cancer chronic pain are often affected by other conditions, which worsen their physical and mental health. Amongst the most popular are: obesity, heart disease, stomach disease, IBS and rheumatic disease ¹ .
Care management	Pain is one of the most common reasons for which people seek medical treatment ⁵ . It is estimated that people living with chronic pain consult their doctor up to five times more frequently than others ⁵ . Most patients are managed by their GP and their primary care team; only a small minority will have access to specialist pain services ⁵ .

Source: ¹Fayaz, Croft, Langford, Donaldson, & Jones (2016); ²Häuser, Schmutzer, Hilbert, Brähler, & Henningsen (2015); ³Pain Summit (2012); ⁴Andrews, Steultjens, & Riskowski, (2018), ⁵Donaldson (2007), ⁶The British Pain Society (2012); ⁷Bair, Robinson, Katon, & Kroenke, (2003).

1.3.2 Treatment guidelines.

Treatment of patients presenting with chronic pain poses many challenges to the NHS and other healthcare services worldwide (Johnson, Collett, & Castro-Lopes, 2013; Arnold et al., 2016). Until recently the guidance on treatment for chronic pain was fragmented and focused on different biological causes of pain, with specific guidelines for a variety of conditions, such as chronic low back pain and sciatica, headaches, neuropathic pain, endometriosis, rheumatoid arthritis, osteoarthritis, spondyloarthritis, and irritable bowel syndrome (National Institute for Health and Care Excellence [NICE], 2018). Following a request from the Department of Health, NICE is currently developing a clinical guideline on chronic pain 'independently of identified biological or psychological contributors' (NICE, 2018), following one developed by the Scottish Intercollegiate Guidelines Network (SIGN) in 2013.

The care of the majority of people suffering from chronic pain will be in the hands of their GPs and primary care team. From there they can be referred to specialist services to help manage the underlying cause of pain (e.g. rheumatology, neurosurgery, neurology or orthopaedics) or referred to specialist tertiary care pain services, commonly referred to as Pain Clinics (SIGN, 2013).

Chronic pain patients are trialled on various types of medication, depending on the underlying condition. Commonly used drugs including paracetamol, non-steroidal anti-inflammatory drugs (NSAID), antidepressants, antiepileptic medication, topical treatments, opioid analgesics, and epidural injections of local anaesthetics (NICE, 2018; NICE, 2013; SIGN, 2013). Common practice is a combination therapy; mixing different analgesics and increasing the dose. Non-pharmacological treatments include a variety of physical therapies, including physiotherapy, massage, acupuncture, or TENS machines (SIGN, 2013).

While the majority of patients will be managed in primary care, a proportion of patients, for whom the above treatments are not effective, will be referred to Pain Clinics. Pain Clinics are often able to offer more invasive treatments, such as implantation of spinal cord stimulator devices, or radiofrequency denervation, alongside specialist physiotherapy and clinical psychology (SIGN, 2013).

To set the context of this study with regards to clinical practice we reference a recent review of treatment guidelines for chronic low back pain (Verhagen et al., 2016). What this guideline illustrates is that patients presenting with an acute onset of back pain go through trials of various medications and further medical investigation in order to exclude any serious underlying conditions, such as cancer or spinal cord infection. The authors of this review also comment that many patients will go through ‘unnecessary testing’ (linked to increased risk to patients and healthcare costs), ‘unnecessary stress and anxiety’ (linked to worrying about their health) and, finally, ‘unnecessary treatment’ (linked to serious side effects).

In 1986 the World Health Organization recommended a stepped care model of medication prescribing for cancer pain, built on a principle of gradual increase in strength of medication based on pain intensity (as cited in WHO, 1996). The use of this model in the management of chronic pain has gathered criticism due to differences between cancer and non-cancer pain (Ballantyne, Kalso, & Stannard, 2016). Chronic non-cancer pain can persevere for many years, therefore unlike in cancer pain, a goal of ‘complete pain reduction’ is often unachievable (Cheatle, 2016). Secondly, reported intensity of chronic pain depends on both physiological and psychological factors, therefore by simply increasing the medication dose we might be neglecting other causes of chronic pain (Arntz & Claassens, 2004). In line with the above criticism current guidelines for management of chronic pain have made significant adaptations to the original WHO analgesic ladder, as

outlined by Vargas-Schaffer and Cogan (see Figure 1, 2014). Despite a general consensus on the best practice guidelines, recent pain audits identified large variations at local and national levels across the UK in what patients can access, with the majority of patients being managed by their GPs, with limited access to non-pharmaceutical treatments (Healthcare Quality Improvement Partnership, 2012 & 2013).

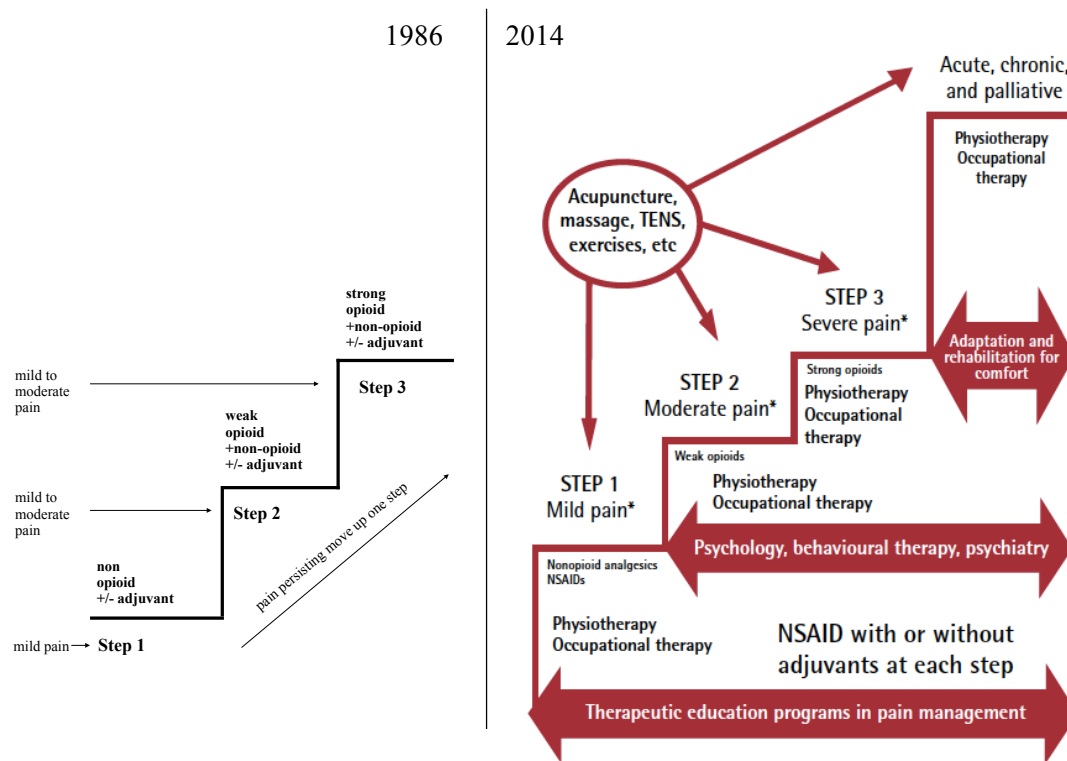


Figure 1: The use and evolution of the World Health Organization’s analgesic ladder in chronic pain management. On the left the original 1986 model, on the right the revised new leading model for treatment of chronic pain. Used with permission from Vargas-Schaffer & Cogan (2014). Note. NSAID – nonsteroidal anti-inflammatory drugs like ibuprofen or naproxen, TENS – transcutaneous electrical nerve stimulation. *Acute and chronic pain

1.3.3 Clinical effectiveness of treatments.

Despite the increase in the variety of new treatments available and the sophistication of treatment methods, available data on effectiveness is mixed (NICE, 2018). It is now widely recognised that the benefits of medical interventions, both pharmacological and non-pharmacological, in treatment of chronic pain are modest in effect size and duration and only helpful for a minority of patients (NICE, 2018). Some sources suggest that when it comes to analgesics, a reduction in reported pain of at least 50% is achieved in less than half of patients (Moore, Derry, Eccleston, & Kalso, 2013). Several studies comment that even when treatments result in pain reduction, they often fail to produce positive outcomes in physical and emotional functioning (Tompkins, Hobelmann, & Compton, 2017). Furthermore, many pain treatments come with significant risk of serious side effects and complications. For example, more than 40% of patients who are implanted with pain-

alleviating devices will experience significant adverse events and premature termination, whilst the drop-out rates from pain drug trials often exceed 30% (Turk, Audette, Levy, Mackey, & Stanos, 2010).

Despite the mixed evidence regarding efficacy of advanced analgesics, such as strong opioids, pregabalin and gabapentin, their prescription rates are increasing (NICE, 2017). Alarming reports from the United States show that rates of opioid prescription and subsequent abuse reached ‘epidemic proportions’, and with potentially severe consequences, including death from overdose (Dowell, Haegerich, & Chou, 2016). According to a recent report, opioid abuse was linked to 28,000 deaths in the USA in 2014 alone (Wang, 2017). A marked increase in opioid prescribing was also reported over the last decade in the United Kingdom (Zin, et al., 2014). Other types of analgesics are also used to manage long-term pain, particularly neuropathic pain. The NICE guideline for managing neuropathic pain recommends offering a choice of drugs, and warns prescribers that some of them, such as gabapentin and pregabalin, can lead to dependence and these medicines may be misused or diverted (NICE, 2013).

According to Peng (2016) more resources should be directed at preventing chronic pain. He specified that reducing obesity, injury prevention, more treatment for acute pain, and promotion of certain vaccines to prevent painful conditions should take priority over chronic pain treatment.

1.3.4 Pain Clinics.

An attempt to capture the characteristics of a population of people referred to specialist pain services was made by the Healthcare Quality Improvement Partnership during their National Pain Audit, a three-year study published in 2012. They surveyed a total of 9588 patients from 161 Pain Clinics across England. The average age was 53 years, majority of patients were of middle age. Many patients reported having made multiple visits to healthcare professionals for help with their pain over the preceding six months. The reported average Quality of Life score was ‘very poor’. Interestingly, 67% of patients reported musculoskeletal pain; the most common reason for referral was chronic low back pain, followed by lumbago with sciatica, neck pain and joint pain. An overwhelming 41% of pain clinic patients reported that their pain prevents them from working (The British Pain Society, 2012).

1.3.5 Psychological treatments for chronic pain.

Psychologists became interested in chronic pain in the 1960s (Vlaeyen, Morley, Linton, Boersma, & Jong, 2012), with the introduction of operant behaviour analysis. In 1965 Melzack and Wall published an article titled ‘Pain mechanisms: a new theory’, where they outlined their Gate Control Theory of Pain. This new theory has been tremendously influential in accelerating both research and treatment (Moayedi & Davis, 2012). Melzack

and Wall argued that pain is a multidimensional phenomenon, which encompasses sensory, affective, cognitive and behavioural components. This new understanding and conceptualisation of pain triggered more interest in interventions targeting the cognitive and behavioural components of pain experience. Wilbert Fordyce (1984) was first to propose that behaviours typically observed in chronic pain patients, such as limping, avoidance of movement, complaining, which he called ‘pain behaviours’ can be understood using learning theory, more specifically operant behaviour principles. He introduced behavioural pain management, aiming to increase the repertoire of ‘well behaviours’, such as participation in exercises and healthy leisure activities, which can accelerate rehabilitation.

Another milestone for psychosocial interventions used in chronic pain came with the incorporation of Aaron Beck’s theory of depression introduced in the 1970s. The link between cognitions and mood proved very relevant for chronic pain patients. What followed was a fusion of both cognitive and behavioural theories and development of Cognitive Behavioural Therapy (CBT) for depression and anxiety, which were adapted to be used with people suffering from chronic pain (Jensen, Turner, & Romano, 1991). Since then, CBT became the most practiced and researched therapeutic approach applied in the field of chronic pain (Vlaeyen et al., 2012). In the last two decades third-wave therapies, such as Acceptance and Commitment Therapy (ACT), mindfulness and Compassion Focused Therapy (CFT) gained more supporters. However, CBT is still the most prominent therapeutic approach recommended by the national guidelines (NICE, 2013, 2018; SIGN, 2013).

The last four decades changed the way that science thinks about pain. The current understanding of pain is best described by the biopsychosocial model of pain (see Figure 2). From focusing on pain and chronic pain as mostly biological phenomena, we have now started appreciating the multifaceted character of pain and utilisation of interdisciplinary care.

Biological mechanisms of pain are complex and still not fully understood (Moseley & Butler, 2017). Usually, nociception (i.e. activity of the nervous system responsible for encoding and processing temperature, mechanical and chemical stimuli) and the awareness of pain is induced when the stimulus has the potential to cause damage, such as contact with high temperatures causing burning pain or being hit with force causing immediate pain around the area of contact (Dubin & Patapoutian, 2010). Nociceptors (i.e. specialised peripheral sensory neurons) are spread throughout our bodies, both superficially and internally. Information from nociceptors travels through the peripheral sensory neurons into the spinal cord, then to the brain through spinothalamic tracts. Historically, the biological mechanisms of pain perception were understood in terms of a simple ‘stimulus-response’ relationship (Hudspith, Siddall, & Munglani, 2006). This is no longer the case following

scientific developments and discovery of pain transmission (i.e. information flow through the nerve impulses to the brain) and pain perception (i.e. reception of the signals by the brain and interpretation of them as ‘painful’). Current neuroimaging technology has allowed pain scientists to map a number of brain networks involved in pain perception, which include areas such as the limbic system, prefrontal cortex, sensory cortices, insula, and anterior cingulate cortex, all of which are also responsible for processing, amongst others, emotions, cognition, memory, and motor function (Breedon & Rowe, 2017). These technological developments allowed scientists to start to understand processes described as ‘pain modulation’, which involves processing and modulating nerve impulses, which can facilitate or inhibit pain. These mechanisms can explain why different people respond differently to the same nociceptive input; or why in some cases acute pain becomes chronic (Kirkpatrick et al., 2015). Pain can lead to changes to both central and peripheral nervous systems, causing both systems to become ‘sensitised’, and remain in a state of ‘high reactivity’ (Breedon & Rowe, 2017). Sensitisation can lead to amplification of the pain experience (i.e. hyperalgesia) or the experience of pain when the stimulus should not cause pain (i.e. allodynia). In some individuals, as the pain experience persists it can become more ‘centralised’, with peripheral triggers causing permanent changes to the central nervous system. This central sensitisation is characterised by a difficult to treat, widespread pain, with the original source of pain increasingly less likely to be identifiable and/or treatable.

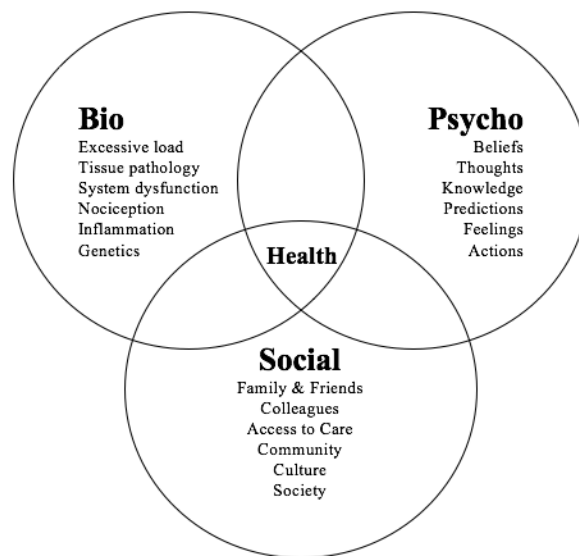


Figure 2: The Biopsychosocial Model of Pain, first proposed by George Engel (adapted from Moseley & Butler, 2017)

Current national guidelines for management and treatment of chronic pain recommend the use of psychologically based interventions along with self-management, pharmacological management and physical therapies (SIGN, 2013). Amongst the

recommended psychological treatments are: multidisciplinary biopsychosocial treatments, also known as a pain management programmes (PMP), education (brief education or pain neurophysiology education [PNE]), behavioural therapies, Cognitive Behavioural Therapy (which is also used in PMP), and third wave cognitive behavioural therapies (e.g. mindfulness and Acceptance and Commitment Therapy [ACT]). In the last three decades CBT has gathered the strongest evidence-base, and has been widely adopted as a primary treatment approach in chronic pain (Ehde, Dillworth, & Turner, 2014). Cognitive behavioural treatments for chronic pain are supported by a robust evidence base; however, most treatment protocols blend multiple components, which results in difficulty establishing which techniques and tools are responsible for change (Morley & Williams, 2015; Price, 2017). Additionally, there is a concern regarding the treatment effect of recent CBT trials; treatments seem to be less effective than four decades ago (Morley & Williams, 2015). In order to address these concerns Morley encourages researchers to focus on: practice-based research and exploration of complimentary to RCTs methodologies, improved measurement and reconceptualisation of what we mean by ‘therapeutic gain’ (Morley, 2011).

One of the biggest challenges in the field of chronic pain research is the choice of suitable outcome measures (Morley, 2011). Turk and colleagues conducted a study to identify the most important outcomes in chronic pain treatment (2008). Using focus group methodology (n=31) they constructed a survey, which they then posted on the American Chronic Pain Association website. They collected 959 responses and were able to identify that the most important outcomes from the patients’ perspective were: pain reduction, enjoyment of life, emotional well-being, fatigue, weakness, and sleep quality.

There are multiple measures available to assess pain (Hawker, Mian, Kendzerska, & French, 2011), which focus on its different qualities. At the moment the only method available for the assessment of pain is self-report; however, this could change in the future as recent study using fMRI to assess pain elicited by noxious heat reported potential for a more objective measure of pain intensity (Wager et al., 2013).

Pain intensity measures mirror the conceptualisation of pain as a dual process (Beecher, 1959). We can distinguish between the physical experience, ‘a sensation’, and the emotional response that it triggers. The physical pain sensation can be described in terms of intensity, quality, duration and location, etc. The emotional part of pain experience has been described as a level of distress, unpleasantness or interruption. Psychological interventions for chronic pain have acknowledged this distinction and are moving away from trying to reduce the intensity of pain towards reduction of pain related distress (Roditi & Robinson, 2011). According to this rationale a successful psychological intervention should reduce pain-related distress, while pain intensity might remain the same (e.g. Wells & Ridner, 2008). However, Vowles, Witkiewitz, Levell, Sowden and Ashworth questioned the

paradigm that for an intervention to be successful we need to reduce the pain-related distress, and proposed that interventions should aim at increasing functional ability (2017). They observed that following a four-week multidisciplinary group intervention, informed by an ACT framework, the improvement in function was not significantly associated with pain outcomes; i.e. significant improvements in function were not statistically related to changes in pain intensity or pain-related distress. The authors concluded that their findings fit the ACT theoretical model, as it suggests that pain intensity and distress do not need to change for an intervention to be deemed successful.

1.4 The Fear Avoidance Model (FAM)

Pain is in essence a warning signal for the organism to prompt protective behaviours, which is associated with “increased arousal, prioritization of attention to the sources of pain, instant withdrawal, facial expression, and avoidance” (Vlaeyen, Crombez, & Linton, 2016, p. 1588). Whereas escape or avoidance from actual or potential pain is a normal and helpful strategy for acute pain (e.g. moving your hand away from a burning stove), in chronic pain this is no longer the case (e.g. avoiding any movement once the injury has fully healed). This pattern inspired psychologists to think about how chronic pain develops.

The Fear Avoidance Model (FAM, see Figure 3) as presented by Vlaeyen and Linton (2000) explains how acute pain can trigger a cascade of events turning it into a chronic and disabling condition. It built upon previous work of Lethem, Slade, Troup and Bentley (1983), Philips (1987) and Waddell, Newton, Henderson, Somerville and Main (1993), who all noticed how fear of pain and avoidance behaviour contribute to the development of disability.

The Fear Avoidance Model is currently regarded as the most prominent psychological model of chronic pain (Glombiewski et al., 2015). It uses the application of psychological principles of learning (i.e. classical and operant conditioning) and psychological knowledge of fear, specifically phobias (Vlaeyen et al., 2012). It applies behavioural learning theory to explain disabling chronic pain and builds on research into phobias and panic attacks, specifically conceptualisation of cognitive model of panic disorder (Michelson et al., 1990).

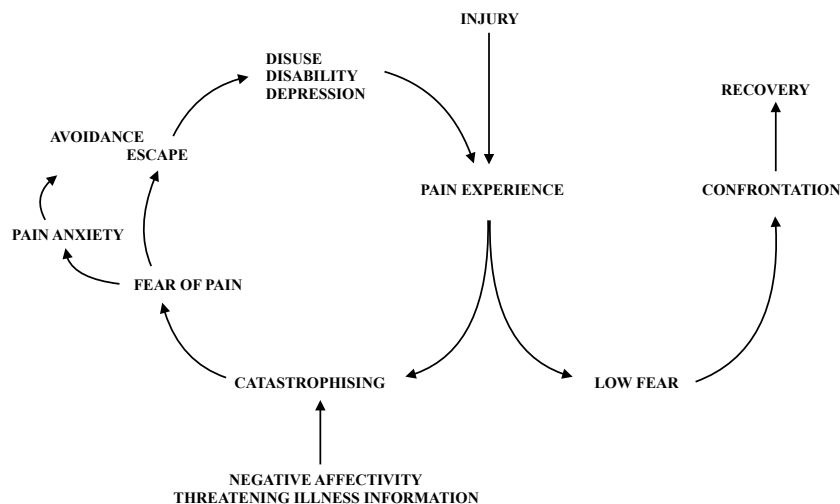


Figure 3: Fear-Avoidance Model of Chronic Pain. Adapted from Leeuw et al. (2007).

As Figure 3 shows, the model suggests that if an individual holds dysfunctional beliefs about their pain experience, which are expressed as pain catastrophising, they are likely to react in an avoidant and fearful manner, which can then lead to decline in functioning, disuse and disability. Fear fuelled by dysfunctional beliefs about the source and meaning of pain and pain anxiety can result in avoidance of movement or other activities that are associated with pain, and prevent the sufferer from recovering. Avoidance of movement and escape from situations linked to pain can subsequently lead to depression and disability. It is worth noting that over the years there have been several attempts to expand the FAM (Asmundson, Norton, & Vlaeyen, 2004; Pincus, Smeets, Simmonds, & Sullivan, 2010; Turk, 2002). Figure 3 displays one of the early versions of the model, which was chosen here for its clarity and good fit for the introductory purpose.

There are several aspects of the FAM which seem to accumulate most critique, described here in more detail. The main criticism of the FAM is that it focuses on psychopathology. Based on CBT models of phobia, its core features are dysfunctional and irrational beliefs about pain (Crombez et al., 2012). The evidence suggests the opposite; i.e. the irrational pain beliefs are not only common, but they are also culturally endorsed and shared between chronic pain patients and healthcare professionals alike (Goubert, Crombez, & De Bourdeaudhuij, 2004; Houben, Ostelo, & Vlaeyen, 2005). Crombez et al. (2012) proposed that instead of assuming that the response to a ‘normal’ situation of pain is ‘abnormal’ in patients who further develop chronic pain conditions, the FAM should clarify that the persisting pain is itself an ‘abnormal’ state to which people respond in a culturally endorsed manner.

Furthermore, Crombez and colleagues (2012) suggest that the FAM fails to capture the complexity of recovery, whilst simplifying the dynamics of living life with disability. Crombez et al. (2012) highlight the importance of motivational goals of the individual,

whilst placing avoidance of pain in the context of unsuccessful ‘problem solving’ and futile attempts to restore one’s life goals. Vlaeyen, Crombez and Linton (2016) point out that fear of pain does not always lead to avoidance, and depends on the environmental context of competing goals, especially if the life goal outweighs the need to engage in fear-related protective behaviour. Vlaeyen, Crombez, and Linton (2016) point out that positive affect and optimism might enable the individual to engage with life goals, while the negative affect and threatening information is likely to result in attempts to control pain. The authors explain the theoretical rationale behind exposure treatments in chronic pain and how, comparing to the acquisition of fear of pain and learned avoidance, the ‘inhibitory’ learning (i.e. new non-threat associations between previously feared and avoided activity and lack of harmful outcome) is “fragile, context-dependent, and it does not easily generalize to novel situations” (Vlaeyen, Crombez, & Linton, 2016, p. 1588).

A recent meta-analysis of 118 studies investigating the association between fear-avoidance and the intensity of pain in individuals with chronic pain by Kroska (2016) captured a small-to-moderate positive relationship between the two. The analysis also identified that the strength of this relationship was moderated by outcome measures used in included studies and national cultural characteristics of study populations. Interestingly, Kroska found that cultural characteristics, such as whether the individual’s culture values hierarchy or egalitarianism, individualism or collectivism, indulgence and fulfillment of human desires or restraint, affects the relationship between the intensity of pain and fear-avoidance behaviours. The study concluded that individuals with higher pain intensity rate higher on measures of fear-avoidance and vice versa; however, what is important to investigate is the function of avoidance behaviour in different cultures, and how consideration of the individual’s cultural beliefs can help in understanding their coping strategies (Kroska, 2016).

Current shift away from psychopathology models of distress, which focus on ‘vulnerability factors’ and interventions designed to fix the problem; towards understanding ‘protective factors’ and strengthening what is working, has resulted in a call for more research into mechanisms of the FAM’s recovery pathway (Boseliea & Vlaeyen, 2017). Early versions of the FAM were negligent in explaining what other factors, apart from ‘low fear’ of pain, led to confrontation and recovery. Recent attempts to expand the FAM include addition of several ‘protective factors’, such as optimism, positive affect and trait mindfulness, alongside ‘vulnerability factors’, such as negative affectivity, anxiety sensitivity, ruminative anxiety and stress (Boseliea & Vlaeyen, 2017; Curtin & Norris, 2017). Moreover, apart from individual characteristics, extensions to the FAM include social factors and cultural factors as important in explaining fear of pain and avoidance of activity (Boseliea & Vlaeyen, 2017; Kroska, 2016).

Since its refinement in 2000 the model has been supported by studies on both chronic and acute pain (Leeuw et al., 2007; Jensen, Karpatschof, Labriola, & Albertsen, 2010; Swinkles-Meewissee, Roelofs, Oostendrop, Verbeek, & Vlaeyen, 2003). The majority of evidence supporting the FAM comes from research on adults; however, there is evidence of application of this model to children and adolescents (Simons & Kaczynski, 2012), and families, where the FAM has been applied to interpersonal relationship (Caes, Orchard, & Christie, 2017; Chow, Otis, & Simons, 2016).

The model differentiates between three psychological processes leading to avoidance, disuse and disability: catastrophising, fear of pain, and pain anxiety. Although closely related, these concepts will be described separately below.

1.4.1 Catastrophising.

The meaning that individuals give to their pain and the context of pain is crucial in how they respond to it (Vlaeyen & Linton, 2012). If they see it in a non-threatening way they are most likely to resume physical activity and have good recovery. However, individuals who interpret pain as a ‘catastrophic’ event, a sign of degenerative process or illness, are more likely to avoid any kind of activity and become hypervigilant to all body sensations they experience (Vlaeyen & Linton, 2012). This then becomes a vicious cycle, when by avoiding any opportunities to disconfirm their beliefs some individuals become hypersensitive to pain and experience more pain in the future (Crombez et al., 2012). In our study we use Hirsh, George, Bialosky and Robinson’s working definition of pain catastrophising, described as a “tendency to exaggerate the threat value of pain and negatively evaluate one's ability to deal with pain” (2008, p. 806). FAM proposes that catastrophising is increased by threatening illness information and characteristics of the individual; i.e. the negative affectivity, defined as “mood-dispositional dimension featuring negative emotionality and self-concept” (Wong et al., 2015, p. 119).

Threatening illness information affects pain beliefs. Several qualitative studies have explored the nature of pain beliefs amongst chronic pain sufferers. Bunzli, Smith, Watkins, Schütze and O’Sullivan (2015) interviewed 36 adults with chronic nonspecific low back pain, finding two main themes in their responses. Firstly, participants held beliefs that engaging in a painful activity will result in damage, specifically to the structure of the spine. Secondly, that a painful activity will lead to suffering and functional loss. Some participants held both beliefs. The same research team then carried out another study aiming to understand thought processes and beliefs underlying the fear of chronic low back pain (Bunzli, Smith, Schütze, & O’Sullivan, 2015). In the second study they interviewed 36 adults with chronic back pain and high scores on a measure of fear of movement/(re)injury. Participants described their chronic pain experience as ‘unpredictable’ and ‘uncontrollable’, an experience that ‘did not make sense’ to them. Participants would describe a process in

which they were trying to make sense of their chronic pain by reminiscing on their own past experiences of chronic low back pain and social beliefs, and trying to get a diagnosis and advice from healthcare professionals. If these attempts were met with uncertainty or a diagnosis of irreversible underlying pathology, these participants were likely to become confused and fearful (2015). Similar to this Wilgen, Ittersum and Kaptein (2008) found that when met with uncertainty about the cause of their pain some people are more likely to catastrophise about it. Stenberg et al. (2014) also investigated pain beliefs, specifically related to physical activity. Participants with acute and chronic neck pain and lower back pain held fears of re-injury and further damage to their 'fragile body'. Darlow et al. (2013) found that the social narrative around chronic low back pain, especially that of healthcare staff, does influence the way an individual makes sense of their pain and constructs underlying beliefs, including presence or absence of catastrophising.

1.4.2 Fear of pain.

Fear of pain or 'fear of sensation of pain' is closely linked to the fear of death and can be described as a 'fundamental fear' (Nicholas, Carleton, Sharpe, & Asmundson, 2007). There is considerable evidence that fear can increase pain sensitivity (Carleton & Asmundson, 2009, Vlaeyen & Linton, 2000). There is also strong evidence that 'fear' is the main factor in development of disabling chronic pain (Leeuw et al., 2007; Vlaeyen & Linton, 2000). According to Vlaeyen, Kole-Snijders, Boeren and Eek (1995) fear of harm/re-injury, a major cognitive component of fear of pain, is a better predictor of disability than symptoms of pain and pain severity. Similar findings were reported by Waddell et al. (1993). They found that negative beliefs about physical activity and avoidance are more important than the severity of pain in predicting disability.

Due to their similarity and overlap, fear of pain and pain anxiety are often confused or used interchangeably (Blanchard & Blanchard, 1990). Nevertheless, these constructs are different. 'Fear' has been conceptualised as a 'pure emotion' (Izard, 1992), a reaction to immediate threat. It is described in 'here and now', a manifestation of the fight-flight-freeze response, an adaptive but phasic (transient) state. However, more complex models of fear also exist, e.g. Lang described fear as a three dimensional experience with cognitive, physiological and behavioural components (as cited in Asmundson, Norton, & Vlaeyen, 2004). The 'cognitive dimension' of fear is said to focus our attention on the source of threat, and to initiate an adequate action, whether it means escaping the situation or neutralising it in some way. These cognitions can also determine how, and to what extent, we can cope with threat (Lazarus & Folkman, 1984; Asmundson, Norton, & Vlaeyen, 2004). Once the nervous system is activated, the fight-flight-freeze response results in physiological changes responsible for getting our body ready for action (i.e. 'physiological' dimension of fear). Defensive responses to pain stimuli range from passive coping

mechanisms (e.g. inaction, avoidance of movement) to active coping, such as escaping the painful stimuli, stopping the pain-inducing activity or modifying the behaviour in some way (e.g. limping, taking painkillers). In acute pain the above strategies are often very effective; however, in the case of chronic pain they can become maladaptive (Crombez, Vlaeyen, Heuts, & Lysens, 1999). All of the three dimensions of fear of pain influence each other and can either reduce or increase the fear response. Physiological fear response affects our cognitions about pain and can increase fear response (Asmundson et al., 2004). Physiological fear response, such as muscle tension, can also increase pain intensity (Flor, Birbaumer, Schugens, & Lutzenberger, 1992).

Some researchers say that pain will always capture attention and result in distress; therefore it is helpful to look at interventions that aim at diffusing its threat value (Vlaeyen, Morley, & Crombez, 2016). Threat value is one of the cognitive dimensions of fear. Pain has a very high threat value, which depends on multiple factors, such as: pain characteristics (e.g. novelty, intensity, unpleasantness, duration), individual factors (e.g. gender, age, personality, affectivity, optimism, support, comorbidities, cultural/social norms), context (situation), knowledge about the meaning/source of pain, ability to cope/control it, expectancy and acceptance (Vlaeyen et al., 2012). While many of the above variables are fixed, there are several factors that can be influenced through psychological interventions. We can hypothesise that having ‘control’ over pain decreases its threat value based on experimental findings showing that knowing when a noxious stimulus will be applied leads to reduced task interference (Crombez, Baeyens, & Eelen, 1994). ‘Coping resources’ are among several factors that can reduce the threat value of pain, as they mean that the individual has some control over their pain (Lazarus & Folkman, 1984). Individuals with high levels of perceived control are more likely to take action and persevere despite initial drawbacks (Skinner, 1996). The underlying mechanisms of this phenomenon are thought to be attributed to cognitive reappraisal of the threatening event (Arntz & Schmidt, 1989). The analgesic effect of placebo is also believed to be caused by cognitive change in threat reduction of pain, as ‘taking a pill’ gives the sufferer the sense of having some control over pain (Moerman & Jonas, 2002). It is speculated that the expectation of reduction in symptoms promotes self-distraction and better attention control (Wiech, Ploner, & Tracey, 2008). It is suggested that feelings of ‘safety’ promote spontaneous self-distraction (Benedetti, Mayberg, Wager, Stohler, & Zubieta, 2005). According to Wiech et al. (2008) the threat value of pain can be successfully reduced through the use of: reappraisal techniques, attention modulation, and correction of expectations. Changing how we think about pain (also called ‘cognitive reappraisal’ or ‘cognitive restructuring’) is another way of defusing the threat value of pain. There are many methods of cognitive reappraisal; however, all of them require identifying the most prominent cognitions that are the source of

discomfort. ‘Shifting attention’ away or refocusing attention to the non-threatening aspects of pain experience are standard parts of CBT interventions for pain. Additionally, people who score high on measures of pain acceptance are less likely to engage in fearful thinking about pain during an episode of increased pain (Crombez, Viane, Eccleston, Devulder, & Goubert, 2012).

1.4.3 Pain anxiety.

Anxiety is described as a future-oriented state to anticipated threat (Asmundson et al., 2004). It can be defined as a “complex preparatory response comprising worry regarding a potential threat as yet unidentified or unrealized (e.g. a possible attack, somewhere, sometime) accompanied by a similar—but attenuated—version of the physiological reaction to fear” (Nicholas Carleton, Sharpe, & Asmundson, 2007, p. 2307). Anxiety can also be described as having three components: cognitive, physiological and behavioural, which are very similar to those of fear. However, it is believed that whilst anxiety’s physiological component is less prominent, the cognitive component is more developed (Barlow, 2002). The behavioural component of anxiety also differs from that of fear. Anxious behaviours tend to aim to prevent a feared situation from happening, while behaviours involved in fear are focused around the fight/flight/freeze response. Behavioural aspects of pain anxiety include avoidance, which is captured in the FAM.

‘Anxiety sensitivity’ (AS) is described in literature as ‘personality trait’, ‘dispositional trait’ or ‘fear of fear’ which describes the extent that one fears anxiety-related bodily sensations (Reiss, Peterson, Gursky, & McNally, 1986). Individuals that score highly on the Anxiety Sensitivity Index (ASI, Reiss et al., 1986) interpret bodily symptoms of anxiety as dangerous, while individuals with low scores will perceive their symptoms as unpleasant but not harmful. There is evidence that high levels of AS result in increased pain intensity, high levels of catastrophising and poor coping skills (Asmundson & Norton, 1995).

Fear of pain, pain anxiety, and anxiety sensitivity are closely linked to one another, and evidence shows that interventions aimed to reduce anxiety sensitivity resulted in reductions in both pain anxiety and fear of pain (Watt, Stewart, Lefavre, & Uman, 2006).

1.4.4 Pain and attention.

In this study we use Alan Allport’s definition of attention; as a mechanism of selection of information to protect the coherence of action (1989). In other words, attention can be seen as mechanisms responsible for choosing among competing sensory stimuli in order to: plan, prepare, proceed and terminate an action. Pain is a ‘hard-wired signal of bodily threat’ that takes priority amongst other sensory information through capturing attention and interrupting ongoing activity (Crombez, Viane, Eccleston, Devulder, & Goubert, 2013). Findings from experimental studies demonstrate the principles of how pain grabs our attention (Moore, Keogh, & Eccleston, 2012). Novel pain is more interruptive than enduring

pain, in other words it grabs attention quicker than pain that is familiar (Crombez et al., 2013). Additionally, the more intense the pain the more difficult it is to ignore; however, intensity is not the only moderator of this effect. Pain that is unpredictable is seen as more threatening (Bunzli, Smith, Schütze, & O'Sullivan, 2015). Pain that has a higher threat value is better at capturing our attention. Additionally, evidence shows that fear leads to hypervigilance (Crombez et al., 2005). Findings from experimental studies can be used to inform clinical intervention. For example; based on the above findings we can hypothesise that distraction techniques will work well when pain is of low intensity, and when its threat value is low. Distraction won't work when pain is intense, or when pain is experienced as threatening.

1.5 The Clinical Application of the Fear Avoidance Model: Interoceptive Exposure

Interoceptive Exposure (IE) is an exposure to bodily sensations used in treatment of a variety of problems where body sensations are experienced as threatening (Boettcher, Brake, & Barlow, 2016). IE techniques were first used in treatment of panic disorders, and consisted of guided physical exercises or CO₂ inhalations (Stewart & Watt, 2008). Their main goal was to induce physiological arousal and to help the person learn how to tolerate the unpleasant bodily sensations. IE has been used in treatment of: social anxiety (Dixon, Kemp, Farrell, Blakey, & Deacon, 2015), PTSD (Wald & Taylor, 2007), eating disorders (Boswell, Anderson, & Anderson, 2015), claustrophobia (Booth & Rachman, 1992), hypochondriasis (Furer & Walker, 2005), substance use disorder (Otto et al., 2014) and chronic pain (Flink et al., 2009). In the field of chronic pain Interoceptive Exposure tasks typically require people to focus their attention on pain without attempting to avoid it or distract themselves from it (e.g. shifting attention, avoiding movement, resorting to painkillers).

There has been some evidence supporting the use of IE in treatment of chronic pain (Flink et al., 2009; Linton, 2010; Wald, 2008; Wald, Taylor, Chiri, & Sica, 2010; Watt, Stewart, Lefavre, & Uman, 2006); however, in all these studies IE was either a part of bigger interventions, or combined with other techniques, such as distraction, validation, behavioural experiments, goal setting or controlled breathing (Taylor, 2012; Linton, 2010; Schmidt et al., 2000).

As noticed in literature there are subtle, yet very important differences about the way that IE is delivered (Deacon et al., 2013). Carter, Marin and Murrell reported that IE was enhanced by cognitive restructuring (1999). Whilst Deacon and colleagues' results indicate that standalone IE was as effective as IE with cognitive restructuring or breathing (2013). Deacon et al. (2013) surveyed 66 therapists about how they use IE in treatment of panic disorder; 94% reported using cognitive reappraisal techniques together with IE and 41% reported using deep breathing techniques during IE.

Using IE in clinical practice is sometimes described as ‘controversial’ (Deacon, Lickel, Farrell, Kemp, & Hipol, 2013). Some clinicians worry about safety and tolerability of the practice. According to Deacon et al., therapists delivering exposure therapy need to be free from these negative beliefs if they want to successfully deliver this treatment.

1.5.1 Theoretical rationale behind IE.

Clinical applications of the FAM focus on education, graded activity and use of exposure techniques to reduce disabling fear of pain and anxiety (Vlaeyen & Linton, 2012). Exposure in vivo, which involves performing activities previously feared due to pain or risk of re-injury, is a widely used cognitive behavioural treatment, with a substantial evidence base (Bailey, Carleton, Vlaeyen, & Asmundson, 2010). IE has been proposed as an ‘extension’ of the FAM and a technique that could enhance effectiveness of graded activity and in vivo exposure treatments (Flink et al., 2009). IE was recommended to be used in conjunction with other exposure strategies, and as a method that could benefit individuals who are less likely to engage in in vivo exposure (Flink et al., 2009).

There are several explanations of the mechanisms of IE (Stewart & Watt, 2008). Firstly, there are ‘cognitive theories’ of IE, explaining that during repeated and prolonged exposure irrational fearful beliefs about physiological sensations are challenged and disconfirmed, with new learning taking place in a process called cognitive restructuring (Beck & Shipherd, 1997).

Foa and Kozak’s (1986) ‘emotional processing model’ acknowledges learning theory and the cognitive restructuring, and highlights the importance of memory modification. A critical evidence for change in the emotional processing model is the presence of ‘habituation’, which is a physiological effect resulting from fear reduction, i.e. the previously feared stimulus no longer elicits distressing physiological arousal (Groves & Thompson, 1970).

According to ‘contemporary learning theory’ (Bouton, Mineka, & Barlow, 2001) IE reduces fear through the extinction of conditioned associations between neutral physical sensations and distressing experiences. ‘Inhibitory learning theory’ (Lang, Craske, & Bjork, 1999) proposes that the original threat association learned during fear acquisition is not simply erased by the new associations learned during exposure trials. Instead, the original feared stimulus becomes more ambiguous and turns out to be associated with other meanings, all of which remain in memory and can be retrieved during exposure. Inhibitory learning theory does not rely on presence of habituation, and is useful in explaining why the original fear-based associations can often return following successful exposure therapy.

Another theory that is being used to explain the mechanisms of IE is ‘social learning theory’ (Bandura, 1982). It also introduces the idea of ‘self-efficacy’. According to this theory, if an individual is confident that they can manage the unpleasant situation well, they

will experience less fear. More recent theoretical models explaining the mechanisms of IE can be linked to the concept of 'acceptance' (McCracken, Vowles, & Eccleston, 2004). In this framework it is hypothesised that individuals who are more accepting of their emotional states can tolerate the physiological body sensations of anxiety without trying to stop or change them, which results in less distress.

Research into the mechanisms of fear reduction in chronic pain is lacking; there is a call for studies investigating exposure techniques in chronic pain patients (Vlaeyen & Linton, 2012; Flink et al., 2009). Whilst graded activity and in vivo exposure have gathered substantial evidence, IE techniques have been overlooked by pain researchers (Flink, Nicholas, Boersma, & Linton, 2009). A study by Flink and colleagues (2009), described below, was one of the first to investigate the use of IE in chronic pain (2009).

1.5.2 Study by Flink et al. (2009).

In 2009 Flink and colleagues published a study looking into the effects of IE in treatment of chronic pain of mixed origin. In this study IE was conceptualised as an extension of the Fear Avoidance Model (Vlaeyen & Linton, 2012). Flink and colleagues proposed that chronic pain patients, despite direct exposure to the sensation of pain on a day to day basis, might be using various coping strategies to either distract themselves from pain, or to reconstruct their experience in a way that reduces its aversiveness. Researchers used replicated single-case methodology, with multiple baseline crossover design, to compare IE with relaxation/distraction (R/D). They followed six participants, randomly assigned to baselines of one, two or three weeks. Following the baseline period, participants were randomly introduced to one of two treatments: IE or R/D. Prior to treatment there was a short education session about chronic pain. Following the education, a rationale behind using IE (or R/D) was provided. Each treatment took three weeks, with weekly sessions with the therapist and an expectation to practice for at least 15 minutes twice a day using techniques taught in the sessions. In both conditions participants were given MP3 players with recorded instructions to guide their home practice. Flink et al. recruited participants from a local newspaper, which resulted in 78 people volunteering to take part, with 10 meeting the study criteria and 6 participants completing the treatment. The study used standard outcome measures of: acceptance of pain, pain catastrophising and fear of movement and disability. Flink et al. (2009) also used an original, brief daily measure, constructed using questions from PASS-20, PCS and an original question assessing pain related distress and pain intensity.

The results of the study were mixed. Daily reports of pain related distress across participants showed a slight decline throughout the intervention; however, no consistent differences were observed between IE and R/D phase. Additionally, in three cases there was a slight worsening in distress on follow up, albeit not returning to baseline levels. Mean pain

ratings were calculated at baseline, post-treatment and follow-up. Two participants reported more pain at post treatment, one participant's ratings of pain did not change, and three participants reported less pain at post-treatment. For one participant there was a substantial reduction in pain ratings at follow-up. All participants improved their ratings on the measure of acceptance; however, no differences were noticeable between IE and R/D phase. Measures of pain catastrophising, fear of movement, and disability showed improvements in four participants, with mixed outcomes for the other two.

Flink and colleagues commented that there was a general trend of reduced pain-related distress across subjects; however, no differences between IE and R/D treatment was observed. Both treatments seemed to be equally effective in reducing pain-related distress. The fact that there was no clear change in daily ratings following a change in treatment regime was commented upon by the authors as: "either the treatments are indistinguishable, contrary to their different theoretical bases, or the nature of these treatments does not easily lend itself to this sort of cross-over design" (Flink et al., 2009, p. 726).

The study had many strengths; amongst others it had a clear theoretical rationale, the method chosen allowed a close and in-depth observation of the effects of IE and R/D techniques. The study had several limitations; such as recruitment and screening of study participants, set up of the education session, measurement, and the study design, which are described below.

Recruiting study participants through a local newspaper might have resulted in a sample that is not representative of a typical therapy client. Out of 78 people who responded to the newspaper ad 71 met the basic inclusion criteria (i.e. working age, back pain lasting over 3 months, not suffering from a severe psychological disorder, no medical conditions that could interfere with treatment). However, the researchers decided to further screen potential participants using the Chronic Pain Acceptance Questionnaire (CPAQ, McCracken, Vowles, & Eccleston, 2004). Subsequently, the intervention was offered to ten people, who had the lowest scores on the CPAQ. Participants' background data show differences between duration of symptoms (2-20 years) and reasons behind pain (e.g. whiplash, 'worn-out', anxiety, failed neck operation). The participant who reported the biggest improvement described a close link between her anxiety and pain. Overall, there is a possibility of a selection bias; which undermines the external validity of this study.

One might question the choice of R/D as a treatment that IE was compared to. Relaxation and distraction techniques are often described as theoretically opposite to IE; however, research data on mechanisms of either condition is lacking (Prins, Decuypere, & Van Damme, 2014). Using both treatments in short succession might have confused participants, additionally a carry-over effect of one experimental condition to affect another, might have taken place.

1.5.3 Study by Taylor (2012).

In 2012 Taylor replicated the study by Flink and colleagues (2009). Taylor used an ABC replicated single-case design comprising: baseline, intervention and a three-month follow up. Taylor recruited participants from a Pain Clinic's psychology waiting list, which resulted in seven participants taking part and four completing treatment. Taylor's intervention consisted of four weekly sessions including: pain education, attention control, diffusion of catastrophic thoughts, and acceptance of pain. In the second week of the intervention Taylor introduced participants to the IE practice. Participants were asked to practice IE three times daily over the next three weeks and were given a written IE script to guide their practice. Additionally, participants in Taylor's study were introduced to several other exercises, including attention control exercises and relaxation exercises, which they practiced alongside the IE.

Taylor's (2012) measurement strategy included a battery of standard outcome measures (i.e. pain anxiety, catastrophising, acceptance, pain vigilance and awareness, and pain related disability). Standard measurement was taken at four different time points: baseline, pre- and post- intervention, and at three-month follow up. Taylor (2012) also used an original brief daily measure, constructed using questions from the PASS-20, PCS and CPAQ. This gave Taylor daily scores of: pain anxiety, pain catastrophising, and pain acceptance. Taylor used several process measures, including the Change Interview, to explore which aspects of the treatment were most helpful, and to aid the analysis of treatment efficacy.

The results of the study were mixed. Out of four participants, who completed the study, there was convincing evidence of change for two. The main finding was that the intervention reduced catastrophising. Daily ratings of pain distress (i.e. anxiety, catastrophising, and acceptance) showed variability across participants. One participant had improved on all three daily ratings, one participant improved on two, and two participants' daily ratings of pain distress remained stable.

Taylor found that all four participants were able to engage in IE practice, and reported it was useful. Additionally, there was a small (1-2 points on a 10-point scale) but consistent reduction in pain distress following the IE practice for all participants.

The main strengths of Taylor's study were recruitment and measurement strategy. Additionally, the sample was representative of chronic pain patients attending tertiary services. Taylor used standard, target, and process measures; including Elliott's Change Interview (2002). The main weakness was that the study protocol incorporated multiple components and techniques, which made it very complex to evaluate. Taylor's intervention consisted of attention control exercises, IE, pain education and cognitive strategies to defuse catastrophic thoughts; therefore it is difficult to say whether changes observed in

participants could be attributed to IE practice.

1.6 Implications for Future Research

According to Morley there is a “tremendous potential in the replication of single-case series” in development of interventions tailored to different diagnostic groups (2017, p.159). Our study aimed to replicate with modifications a study by Flink et al. (2009), using findings from a previous replication by Taylor (2012). Flink et al. (2009) was aiming at comparing IE with relaxation. Taylor’s replication of study by Flink et al. aimed at simplifying the original design of the study; however, the design might have been contaminated by introducing IE alongside training in attention control (paradoxical therapy), diffusion of catastrophic thoughts, and conversations about acceptance, which made interpretation of results more complex. In our study we aimed to introduce IE without training in any other therapeutic techniques, so that results of this intervention can be attributed to this technique alone.

1.7 Summary

Fear of pain is believed to be a key factor in the development and maintenance of chronic pain conditions and disability (Carleton & Asmundson, 2009). According to the Fear Avoidance Model of chronic pain (Vlaeyen & Linton, 2000) the meaning that individuals give to their pain can predict their response. If they see it in a non-threatening way they are most likely to resume physical activity and have good recovery. One way of defusing the threat value of pain is Interceptive Exposure (IE). There is evidence supporting the use of IE in treatment of chronic pain; however, in most studies the use of IE was a part of multicomponent interventions, combined with several other techniques, like distraction, relaxation, behavioural experiments, goal setting, acceptance or cognitive restructuring. The effects of this technique alone need further investigation (Taylor, 2012; Linton, 2010). Therefore, the principal aim of this study was to investigate the effects of IE as a stand-alone technique in treatment of disabling fear of pain. Foundations of this study were based on promising research done by Flink et al. (2009) and Taylor (2012). By replicating these studies, using improved methodology, we aimed to capture the specific effects and challenges that practicing IE has in the population of chronic pain patients.

2. METHOD

2.1 Overview

We aimed to investigate the use of Interoceptive Exposure (IE) in treatment of disabling fear of pain using a multiple baseline single-case series experimental design. Study participants were adults with chronic pain recruited from a Pain Clinic's psychology waiting list. Following assessment and informed consent participants were randomly allocated into a baseline of one, two or three weeks. The intervention comprised: an education session on chronic pain (90 minutes), two sessions of practicing IE with the therapist (60 minutes each), and self-monitored home practice of IE (two weeks, twice daily for 10 minutes). Participants' pain distress, pain interference, fear of pain and levels of activity (number of steps) were recorded daily. Standard outcome measures were taken at three different time points: on assessment, before the start of the intervention, and after the end of the intervention. These measured pain anxiety, pain catastrophising, pain related disability, acceptance of pain, and mood. Process measures captured participants' experiences of using IE and assessed pain knowledge before and after the education session. Finally, we used the Change Interview to explore any changes that participants had noticed themselves and allow them to feedback helpful and unhelpful aspects of the studied intervention.

2.2 Design

Replicated single-case research design gives an opportunity to establish the efficacy of treatment in the real-world context (Kazdin, 2011). This study used a multiple-baseline ABC design: Baseline (A) followed by Education (B) and Interoceptive Exposure (C). The baseline (abbreviated by the letter A) is a period of measurement before the introduction of the intervention. The Education (abbreviated by the letter B) was a single 90-minute interactive session. During the Education session the Fear Avoidance Model of chronic pain was introduced, followed by the explanation of the rationale behind the IE. We also introduced participants to some basic ideas from the neurophysiology of pain, including the role of the brain in perception of pain, context-dependent pain processing (Moseley, 2007), and the relationship between certain thoughts, emotions and increased pain distress (Crombez, Eccleston, Damme, Vlaeyen, & Karoly, 2012). The Treatment (abbreviated by the letter C) was the final phase of the study, where the therapist trained the participants in Interoceptive Exposure; i.e. focusing their attention on pain and staying with the sensation of pain rather than avoiding it or distracting themselves from it. The treatment consisted of two 60-minute sessions of guided IE practice and home practice of the exercise (two weeks of twice daily IE practice, 10 minutes each).

Our multiple baseline case-series design used three different lengths of baseline (i.e. one, two and three weeks), which staggered the introduction of the intervention across

participants. The strength of this design lies in allowing observation of effects of the intervention at different points in time, which provides confidence in attributing changes to the intervention (Kazdin, 2011). The multiple baseline design across participants was ‘non-concurrent’, in that participants started the study at different time points. We used the mobile phone app Randomizer.org to randomly allocate participants to their baselines (Haahr, 2018). Our design is especially relevant for interventions that cannot be reversed and where other designs such as ABAB or cross-over designs are not feasible. Below is a diagram of the study design explaining different phases, order of sessions and the study timeline in weeks (see Figure 4).

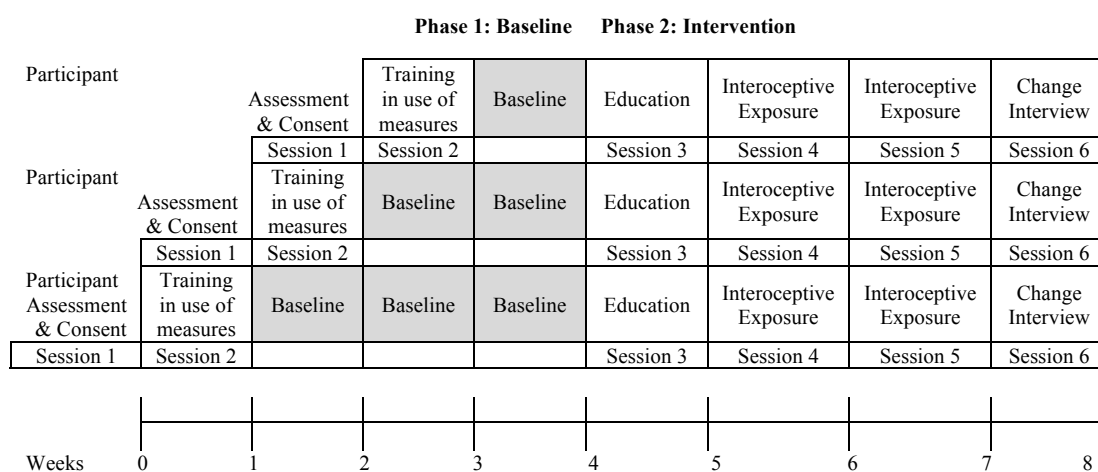


Figure 4: Overview of the design of the study.

2.2.1 Alternative designs.

During the planning of the study we considered several alternative designs. One of the options was an experimental study, where we could observe the effects of IE in a laboratory. This would allow more control of variables and make it easier to comment on cause and effect. Laboratory equipment can also allow a more objective measurement of the physiological responses linked to the fear of pain and/or behavioural variables (e.g. time spent engaging in painful activity, distance walked etc.). Due to lack of access to a laboratory facility this idea had to be abandoned. Additionally, findings from a laboratory environment might have been less useful in informing clinical interventions.

Another option was to use a between-group experimental design, where one group of chronic pain patients would be introduced to the practice of IE, and the other group would be trained in a comparable technique (e.g. relaxation, imaginary, breathing techniques). This idea was not considered practical following a discussion with a field supervisor, who described a poor attendance and high drop-out rate among chronic pain group participants.

After deciding to build on previous work by Flink et al. (2009) and Taylor (2012), the choice was limited to single-case methodology. We considered several designs, one of which was the A-B-A design, in which the intervention is followed by a withdrawal period to see if the dependent variable returns to the baseline. However, due to the fact that the study recruited patients from a psychology waiting list, adding a post-treatment follow-up phase could prolong the waiting time to receive regular treatment.

2.2.2 Rationale for methodology.

Single-case experimental designs (SCEDs) allow researchers to study individuals intensively over time (Morley, 2017). They are useful in investigating new treatments, especially if the population studied is heterogeneous or small, as SCEDs' participants serve as their own controls (Krasny-Pacini & Evans, 2018). Additionally, SCEDs allow identification of an intervention effect even when the variability of subjects' performance is high (Krasny-Pacini & Evans, 2018). SCEDs can give a detailed and 'three dimensional' picture of the intervention, as they capture not only the outcomes, but also the process and experiences of its participants.

IE is usually a part of more comprehensive treatments, as chronic pain is a complex problem. However, there is a need for research which supports tailoring interventions to individuals and developing more effective interventions based on theoretical models (Morley, 2011). Additionally, there is a lack of research examining specific components of multimodal interventions. Single-case experimental designs are therefore well suited to investigate the effects of IE in treatment of disabling fear of pain.

This study was based on the original study by Flink et al. (2009), incorporating several modifications suggested by Taylor (2012). The most prominent change from our predecessors was the change of the study design: rather than having a cross-over design, or a multicomponent intervention, we opted for a single intervention design. We made other changes, including the measurement and recruitment process.

2.2.3 Research questions and hypothesis.

The aim of this thesis is to replicate and extend the work of Flink et al. (2009) and Taylor (2012). It is important to note that the literature review and the Fear Avoidance Model (Vlaeyen & Linton, 2000), as well as the original studies of Flink et al. (2009) and Taylor (2012), have identified a number of predicted relationships between fear of pain in chronic pain patients, avoidance and functioning. These relationships will be explored further, as background hypotheses, and will be addressed in the results and discussion sections.

The research question is therefore: Does a brief intervention, consisting of Pain Education and Interoceptive Exposure, reduce the fear of pain in people living with chronic pain?

Following the literature search and analysis of the evidence gathered by Flink et al. (2009) and Taylor (2012), we generated several research questions and hypotheses. The main question that we aimed to answer was: Does the intervention reduce the fear of pain and increase the levels of physical activity?

Further specific hypotheses were proposed:

H₁: The intervention will reduce the fear of pain,

H₂: Decrease in fear of pain will lead to increase in activity levels,

H₃: The intervention will decrease the amount of daily pain distress and interference,

H₄: The intervention will increase the acceptance of pain.

Despite the fact that we were expecting to see an increase in activity levels following the intervention, we did not expect the disability scores to change significantly, as the intervention was so brief. We expected to see a reduction in disability following a longer than three weeks period of increased activity; however, due to the lack of follow up data it would not be possible to test that hypothesis. We therefore proposed an alternative:

H₅: The intervention will not reduce disability levels.

We did not expect to see changes in mood and general distress, due the fact that the intervention was so brief. Additionally, we used the measure of depression and general anxiety to monitor whether the improvement in activity or disability can be moderated by mood, rather than fear of pain.

H₆: The intervention will not affect mood as measured by HADS.

We hoped to capture the process of change and proposed separate hypotheses for the effect of Pain Education and the process of IE practice. Pain Education should help reduce the threat value of pain, which in turn should result in increased activity:

H₇: Pain Education session will reduce the Fear of Pain,

H₈: Pain Education session will increase the activity levels,

H₉: In the beginning there might be an increase in subjective pain distress following IE practice, with time and practice the distress will decrease.

2.2.4 Ethical considerations.

The NHS Health Research Authority North West - Liverpool East Research Ethics Committee approved the study (see Appendix A). We considered several ethical issues involved in our study, which we discuss below.

Increasing and/or prolonging pain experience.

Although the study did not involve inducing pain in participants, it did include instructions to pay close attention to pain, without distraction. Current evidence shows that focusing on pain may increase reported intensity of pain and produce negative affect (Linton & Shaw, 2011). We explained to all participants that paying close attention to pain could result in a perceived increase in pain; however, by focusing on their pain they could not come to any harm. We also explained that any novel pains and/or worsening in participants' condition, is not to be ignored. We advised participants to consult their GP if they were to experience any new pains and/or worsening in their health and to stop using the IE

technique. We followed the recommendations of the International Association for the Study of Pain (“Ethical Guidelines for Pain Research in Humans”, 2019) on how to introduce the IE procedure to participants.

Informed consent.

Two Clinical Psychologists working at the Pain Clinic were responsible for identifying potential study participants during a routine screening psychology appointment. During that first encounter all potential participants were given copies of the ‘Participant Information Packs’ containing Participant Invitation Letter (Appendix B), Information Sheet (Appendix C) and the Consent Form (Appendix D). Clinicians then asked potential participants for permission to be contacted by the researcher. The first contact with the researcher was by telephone. All potential participants were told more about the study, and then asked several screening questions (Appendix E). If the person expressed a wish to take part in the study, and they met all of the screening criteria, they were invited to the Pain Clinic for the informed consent procedure, which involved a more detailed description of the study and signing of the consent forms.

Use of wearable activity monitors.

An ethical difficulty regarding data protection came through fitness monitoring devices worn by participants. In the past companies responsible for fitness trackers’ monitoring software have reported problems with keeping their users’ data safe (Stach, 2018). To protect participants’ data, the devices were registered and synchronized with the research phone and the device manufacturer’s mobile phone application; therefore if there were any data breaches they could not be traced back to the participant.

Confidentiality.

We maintained participants’ confidentiality throughout. There were no safeguarding issues or disclosure of activity that required us to break the confidentiality of participants. We protected each participant’s confidentiality and anonymity by using a unique reference code for all of the forms, outcome measures, transcripts and publication purposes. Other than the reference code, no other potentially identifiable information was assigned to each set of data. In our detailed description of participants we omitted and/or changed details regarding their particular occupation, all the names of relatives were removed and some characteristics were changed to protect their anonymity.

Data gathered during the study was kept separate from participants’ clinical records. The researcher had access to participants’ clinical files in order to record attendance, and to document if there was any potential clinical risk. This was required as participants had been on the Pain Clinic’s waiting list and the staff had to be able to effectively manage their transition from the study into regular treatment, and communicate with participants if there were any issues.

Nevertheless, during the informed consent procedure we informed all participants that there remained a very small chance that they might be identifiable to a few selected people, such as their immediate family and friends, or the care team at the Pain Clinic, who will have access to published materials. In single case studies the amount of information about the research subjects, and direct quotes, does make it harder to completely exclude the risk of identification.

2.3 Recruitment

Best practice standards on single-case experimental designs recommend at least three replications/demonstrations of the effect (Kazdin, 2011; Institute of Education Sciences, 2010). Therefore our recruitment target was 8 participants, which allowed some flexibility considering anticipated drop-out rate of 33-43% as reported by Flink et al. (2009), and Taylor (2012). The recruitment process is presented in Figure 5, see below.

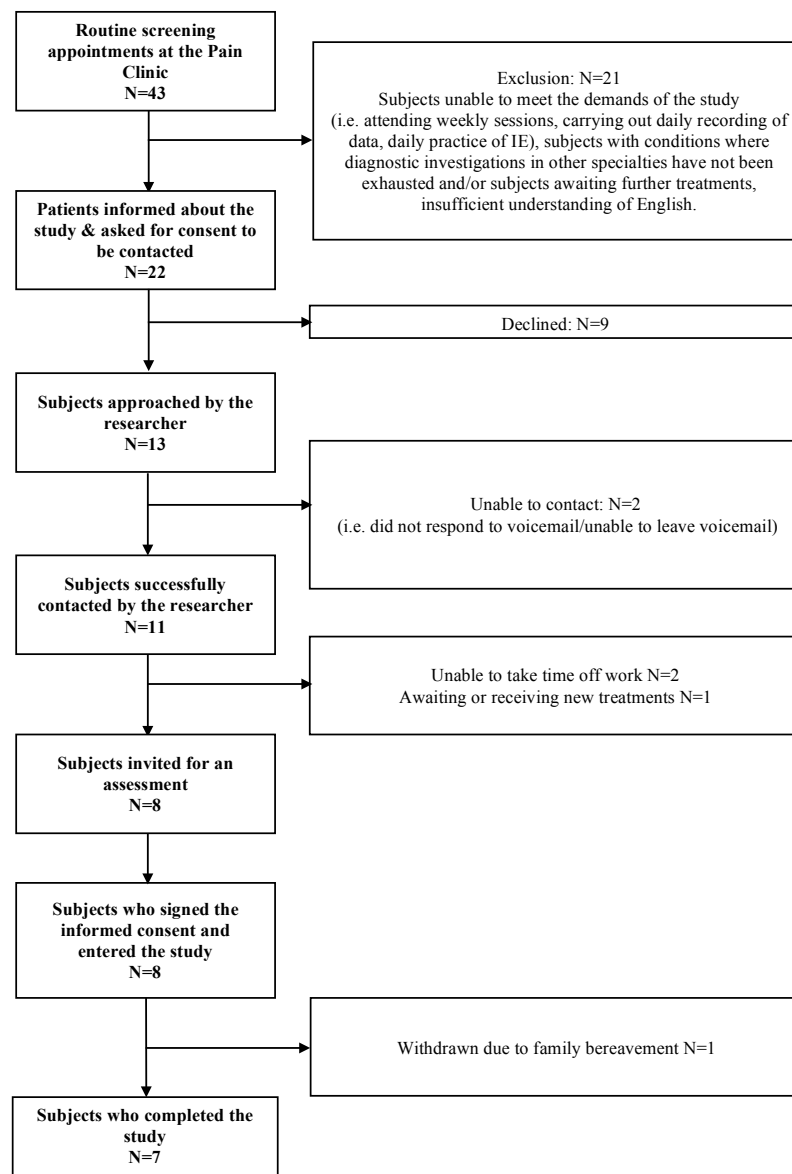


Figure 5: Flowchart of the recruitment process

2.3.1 Inclusion.

The inclusion criteria were as follows:

1. Participants had to have a diagnosis of chronic pain (i.e. pain present for minimum of 3 months following tissue damage),
2. Participants had to be aged 18 years or older,
3. Participants had to have capacity to give informed consent,
4. Participants had to have a history of appropriate diagnostic investigations, which excluded malignant and progressive causes of their pain,
5. Participants had been appropriately treated with first line treatments, such as analgesia,
6. Participants had appropriate expectations regarding psychological treatment, e.g. did not expect injections etc.

2.3.2 Exclusion.

The exclusion criteria were as follows:

1. Insufficient understanding of English or additional needs preventing participants from completing questionnaires independently,
2. Unable to meet the demands of the study (i.e. daily recording of data, daily practice of IE, attending sessions at the Pain Clinic).

The exclusion criteria had to be introduced due to the fact that the research project did not have the resources to make significant adaptations to the study, and the study materials, such as: translation into another language or into Braille, being able to deliver the intervention at participants' home or via Skype, and/or organise specialist transport for participants with mobility problems.

2.3.3 Screening, assessment and training in recording.

Due to the fact that participants recruited to this study had already been screened for their ability to engage in therapeutic intervention, the only additional screening criteria was the ability and willingness to meet the demands of the study: filling in the outcome measures, practicing the IE (10 minutes x twice daily for a period of two weeks), and the ability to attend 6 weekly sessions at Pain Clinic.

Potential participants were identified by two clinicians working at the Pain Clinic, during a routine screening appointment. Only the service users who were accepted for therapy, albeit unlikely to be offered a first therapy appointment in the next two months, were informed of the study. Consent to be approached by the researcher was obtained at this point.

Within the next week potential participants were approached by phone call by the researcher for recruitment to the study. During this phone call more details about the study were given and the researcher screened potential participants for their eligibility to take part.

If eligible the researcher invited participants for an assessment at the Pain Clinic. Informed consent was obtained during the assessment session at the Pain Clinic. Once participants read the information sheet and signed the consent form they were asked to fill in the Global Measures Booklet, consisting of five standard outcome measures of pain anxiety, catastrophising, acceptance, pain disability and mood. Following this there was a structured assessment interview with questions about the participants' experience of pain, their medical history, and any underlying diagnosis and coping strategies. During the assessment session participants were trained in the use of the Daily Diary and activity monitor. Following this, participants were asked to start using the Diary for the next week and come back to the Pain Clinic to check if everything worked as planned.

During the second assessment session, data gathered with activity monitors was checked to ensure the monitors were working, and that participants did not have any difficulties with wearing them. Additionally, the Daily Diary was collected and checked for any omissions. Participants were asked about their experiences of filling the diaries. Any difficulties were addressed, and it was ensured that all participants were using both the Daily Diary and activity monitors correctly. Feedback from participants was also sought regarding the assessment information gathered so far. If any assessment questions were missed these were asked, and some participants provided additional information to enrich the assessment data. Each second session lasted less than an hour, 40 minutes on average.

2.4 Participants

We recruited 8 individuals (five women and three men; ages 27-63), who had suffered with chronic pain for 6-30 years. One participant (SP8) had to drop out of the study due to personal circumstances, the remaining seven completed the study. Demographic details are summarised in Table 2. Please note that in order to preserve anonymity some specific characteristics of participants have been altered.

Table 2: Participants' demographics

I.D.	Participant's age group*, sex and ethnicity	Clinical presentation (i.e. underlying diagnosis, self-description, duration)	Education and employment history	Relationship status/ Reason for non-completion
SP1	Male, 50s, White British	Spondylolysis and PTSD, failed back surgery, 30 years, worsened in the last 10 years	2 years of College, left school at 18, used to work in sales, currently unemployed	Married, lives with family
SP2	Female, 60s, White British	Failed back syndrome, following back injury, 8 years	University, used to work in healthcare, currently unemployed	Married, lives with family
SP3	Female, 50s, White British	Failed back syndrome, following back injury, 17 years	Left school at 15, worked as a carer, currently unemployed	In a relationship, lives with partner
SP4	Male, 50s, White British	Failed back syndrome, over 30 years	Left school at 16, Worked in construction, currently unemployed	Single, lives alone

SP5	Male, 60s, White British	Crohn's Disease, over 10 years	University degree, worked in civil service, retired	Married, lives with wife
SP6	Female, 20s, White British	Pelvic pain in pregnancy, failed back syndrome, over 6 years	Left school at 16, worked as a carer, currently unemployed	In a relationship, lives with family
SP7	Female, 30s, White British	Chronic widespread pain following a fall, over 20 years	University degree, worked in administration, currently unemployed	Single, lives with family
SP8	Female, 30s, White British	Chronic widespread pain following an injury, over 7 years	University degree, works as a manager	In a relationship, lives with partner

* participants were classified by decade into five age groups (i.e. 20s, 30s, 40s, 50s and 60s)

2.5 Measurement

Below we will present the rationale behind the selection of measures and measurement strategy, followed by description of standard, target and process outcome measures.

2.5.1 Selection of measures.

When deciding on the use of outcome measures, and to identify data collection points, we used the Treatment Assessment Funnel (Morley, 1996), see Figure 6 below.

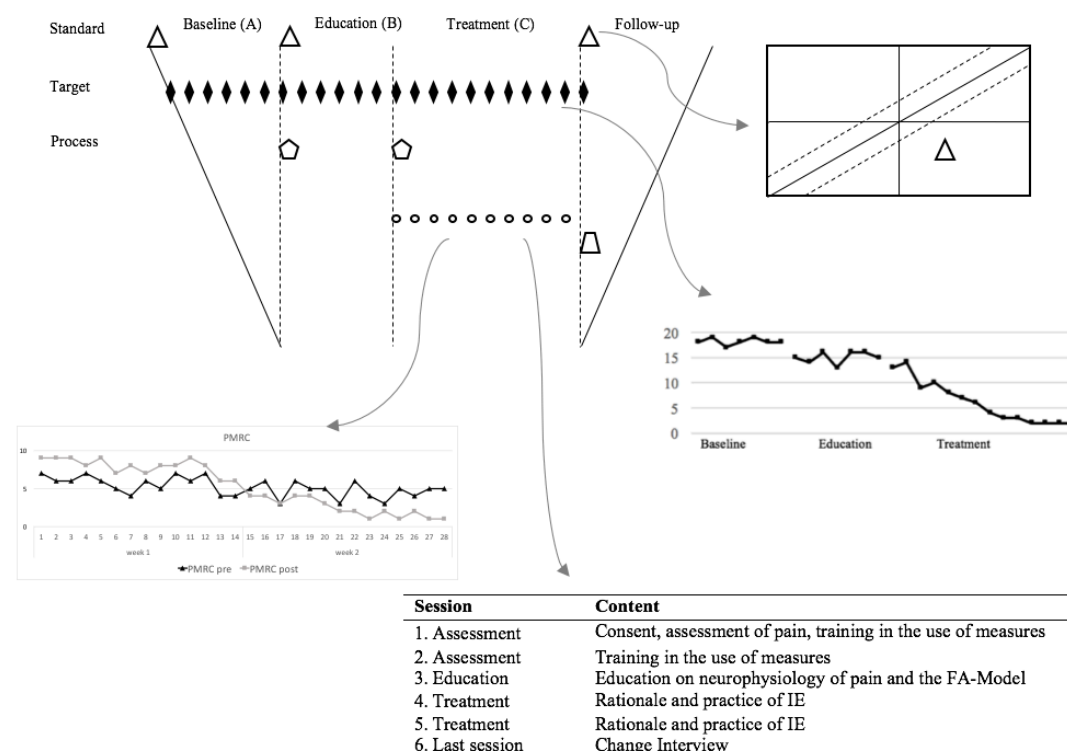


Figure 6: Outline of the current study and choice of measures using the Treatment Assessment Funnel adapted from Morley (1996).

According to this model a single case experimental design needs to incorporate the use of three types of measures: standard, target, and process, used at different data collection points and with different frequency; described below in detail.

Table 3: Types of measures used and data collection points.

Measure	Type	Collection point
Global	Standard	Baseline Pre-treatment Post-treatment
Daily Diary	Target	Daily from baseline to end of treatment
Activity	Target	Daily from baseline to end of treatment
IE practice	Process	Daily during the treatment period
Pain Education	Process	Before and after education session

2.5.2 Standard measures.

We used several standard outcome measures aiming at capturing psychological constructs derived from the theoretical framework of the Fear Avoidance Model and concepts highlighted by the literature search, including: pain catastrophising, pain anxiety, pain related disability, acceptance of pain and mood. Due to their length they are not designed for repeated use over a short period of time. The standard outcome measures were combined into the ‘Global Measures Booklet’. Participants were asked to fill in the booklet at three different time points: baseline, pre-treatment, and post-treatment. Below is a short description of each outcome measure included in the Global Measures Booklet.

Pain Anxiety Symptoms Scale Short Form 20 (PASS-20; McCracken & Dhingra, 2002) is a 20-item measure of pain-related anxiety. Each item scored using a 6-point Likert scale anchored from 0 (never) to 5 (always); higher scores indicate higher levels of pain-related anxiety. All items of PASS-20 can be added to obtain a total score, or divided into four different components of pain anxiety, including: cognitive anxiety (sample item: “When I hurt I think about pain constantly”), escape and avoidance (sample item: “I go immediately to bed when I feel severe pain”), pain-related fear (sample item: “When I feel pain I am afraid that something terrible will happen”), and physiological anxiety (sample item: “When I sense pain I feel dizzy or faint”). PASS-20 is a shortened version of the Pain Anxiety Symptoms Scale (PASS), consisting of 40-items (McCracken, Zayfert, & Gross, 1992). PASS-20 is described as more accessible for the chronic pain population, who might have reduced tolerance for long questionnaires. This measure has been shown to have good reliability and validity, in both clinical and non-clinical samples (Abrams, Carleton, & Asmundson, 2007; Coons, Hadjistavropoulos, & Asmundson, 2004). The PASS-20’s internal consistency (measured with Cronbach's alpha) has been established as $\alpha = .91$ for the Total Score (McCracken & Dhingra, 2002). Abrams et al. (2007) recommend a clinical cut-off score of 30 (i.e. caseness). The total score on the PASS-20 was used in the analyses.

Pain Catastrophising Scale (PCS; Sullivan, Bishop, & Pivik, 1995) is a 13-item self-reported measure of catastrophic thinking in relation to pain. PCS is the most widely used

measure of pain catastrophising used both in clinical practice and research (Walton, Wideman, & Sullivan, 2013). All 13 items of the PCS are rated on a five-point scale ranging from 0 (not at all) to 4 (all the time). The PCS has three subscales: rumination (sample item: “I keep thinking about how much it hurts”), magnification (sample item: “I become afraid that the pain will get worse”), and helplessness (sample item: “I feel I can’t go on”). Total scores range from 0-52, higher scores indicating higher levels of pain catastrophising. Authors of the measure recommend a clinical cut-off score of 24 (Sullivan et al., 1995). The PCS’s internal consistency (measured with Cronbach's alpha) has been established as $\alpha = .87$ for the Total Score (Sullivan et al., 1995). The total score on the PCS was used in the analyses.

Chronic Pain Acceptance Questionnaire (CPAQ; McCracken, Vowles, & Eccleston, 2004) is a 20-item self-reported measure of pain acceptance. The CPAQ has two subscales: Activity Engagement and Pain Willingness. Activity Engagement is defined as a ‘pursuit of life activities regardless of pain’ (sample item: “My life is going well, even though I have chronic pain”). Pain Willingness is defined as ‘recognition that avoidance and control are often unworkable methods of adapting to chronic pain’ (sample item: “I need to concentrate on getting rid of my pain”). Scores obtained on each subscale can be added to calculate a Total Score. Each item of the CPAQ is scored on a 7-point Likert scale (0 = Never true, 6 = Always true). Higher scores on each subscale and Total Score indicate greater acceptance. The CPAQ has good reliability ($\alpha = 0.85$) and validity, and it correlates with scales of psychological distress and functioning (McCracken et al., 2004). The total score on the CPAQ was used in the analyses.

Pain Disability Index (PDI; Pollard, 1984) is a self-reported measure of how much pain affects the everyday life of a person. It has seven subscales, which represent different ‘life domains’: family/home responsibilities, recreation, social activity, occupation, sexual behaviour, self care, and life-support activities. Each domain is scored on a 11-point numeric scale ranging from 0 (no disability) to 10 (worst disability). All scores are summed to give a total disability score, ranging between 0 (Min) and 70 (Max). Higher scores indicate higher levels of interference of chronic pain and more significant levels of disability. The PDI has fair reliability and validity ($\alpha = 0.86$, Tait, Chibnall, & Krause, 1990).

Hospital Anxiety and Depression Scale (HADS; Zigmond & Snaith, 1983) is one of the most widely used screening tools for general anxiety and depression in medical settings. The HADS has two scales: Anxiety (7 items) and Depression (7 items). Each item is scored on a 4-point scale, with higher scores indicating a higher frequency of symptoms of depression and anxiety. Scores can be added to give a separate Anxiety and Depression score. For each subscale scores range between 0 (Min) and 21 (Max), with a cut-off score of

8 for clinical levels of Depression and/or Anxiety, as suggested by authors of the measure and supported by further evidence (Löwe et al., 2004). HADS has good sensitivity and internal reliability ($\alpha = 0.83$ for HADS-A and $\alpha = 0.84$ for HADS-D; Bjelland, Dahl, Haug, & Neckelmann, 2002, Pallant & Bailey, 2005).

2.5.3 Target measures.

Target measures focus on the issues targeted by the intervention; they are usually brief and can be taken more frequently. In this study we used two target measures: Daily Diary, and activity levels, i.e. the number of steps taken per day, which was captured by a wearable activity monitoring device. Below we describe the construction of the Daily Diary, followed by description of the measurement of activity levels.

Daily Diary. Following the strategy of Vlaeyen et al. (2001) we designed a nine item instrument to measure pain experience (distress caused by pain, interference of pain with daily activities, and fear of pain). To construct it we used questions from: the Pain Rating Scale (The British Pain Society, 2006), the Pain Catastrophising Scale (PCS) and the Pain Anxiety Symptom Scale (PASS-20). The structure of the Daily Diary is presented in Table 4, for an actual copy of the Daily Diary please see Appendix G.

Early visual analysis of the data suggested that participants might have found the first four items of the Daily Diary (See Table 4) difficult to answer. It might have been caused by the difficulty to differentiate between the items, or that there was an overlap between measured concepts, as participants' ratings were very similar on all four items. It was decided that retrospective evaluation of episodes of 'average', 'most severe' and 'least severe' pain might have been too difficult for participants to recall and evaluate, and that the 'average' pain is likely to be the most representative of the daily pain experience. Finally, for the purpose of clear representation of results, and in order not to lose valuable data, it was decided to combine the average Pain Distress score with the Pain Interference score, using a scale between 0 (Min) and 200 (Max).

Fear of Pain questions were added to achieve a Total Fear of Pain Score, using a scale between 0 (Min) and 20 (Max). Higher scores on both subscales indicate greater levels of Pain Distress/Interference and Fear of Pain.

Table 4: Daily Diary. Items adapted from the PRS, PASS-20 and PCS, completed on a daily basis

Questions assessing Pain Distress and Interference:

1. Today my average pain has been:
0-100 VAS rating scale, anchors: not at all distressing/extremely distressing (PRS)
2. Today my most severe pain was:
0-100 VAS rating scale, anchors: not at all distressing/extremely distressing (PRS)
3. Today my least pain was:
0-100 VAS rating scale, anchors: not at all distressing/extremely distressing (PRS)
4. How much the pain interfered with my daily activities:
0-100 VAS rating scale, anchors: does not interfere/interferes completely (PRS)

Fear of Pain questions scored using a 5-point Likert-type scale,
anchors: not at all/all the time

1. When I feel pain, I think that something terrible may happen (PASS-20)
2. Pain sensations are terrifying (PASS-20)
3. When I am in pain I keep thinking about how badly I want the pain to stop (PCS)
4. When I am in pain I wonder whether something serious may happen (PCS)
5. When I am in pain I feel I can't go on with my daily activities (PCS)

Note. PRS = Pain Rating Scale (The British Pain Society, 2006), PCS = Pain Catastrophising Scale, PASS-20 = Pain Anxiety Symptom Scale, VAS = Visual Analog Scale.

Activity. We used a simple wearable fitness tracker called Withings Go (also known as Nokia Go) to measure the number of steps taken per day. This was to test the hypothesis whether practicing Interoceptive Exposure had any effect on the activity levels of our participants. The device was made of silicone and could be worn on a wrist, belt, shoe or in a pocket. We decided to use the Withings Go due to its long battery life (it did not require charging), simplicity (we required to measure number of steps only) and its low price. During appointments at the Pain Clinic the activity monitors were synchronised (i.e. data gathered by the device was downloaded) using the research smartphone. The activity data was stored at the device manufacturer's website under an anonymous profile. The data gathered by the device included: number of steps, amount of time spent exercising (e.g. running and swimming) and sleep tracking (if the device was worn at night). No names, personal email addresses or other identifiable information were entered into the manufacturer's website, only participants' gender, height, age and weight in order for the data to be correctly interpreted. Once participants completed the study their 'activity data' was deleted from the manufacturer's website.

Wearable activity sensors, such as Fitbit, Misfit or Jawbone have been employed in health research for a wide variety of conditions and among various populations (Evenson, Goto, & Furberg, 2015; Simpson et al., 2015). To date the use of monitors has been

demonstrated both feasible and promising in research on pain (Evenson, Goto, & Furberg, 2015). Nevertheless, researchers are cautious regarding the accuracy of the data (Singh et al., 2016) and safety of personal information (Zhou & Piramuthu, 2014).

After considering these issues we decided to use a simple activity monitor. To avoid contamination by the effect of wearing an activity monitor, which can on its own be motivating to increase the amount of activity, the feedback from the device was minimal. We decided not to share the readings from the activity monitors with participants until the end of the study.

2.5.4 Process measures.

We used several process measures in attempt to capture participants' experiences of the treatment. These were: the Revised Neurophysiology of Pain Questionnaire (NPQ-R; Catley, O'Connell, & Moseley, 2013) and the Pain Desensitisation Chart (PDC; Nicholas, 2017). Additionally, once the intervention was complete, we interviewed all participants using the Change Interview (Elliott, Slatick, & Urman, 2001) to evaluate the intervention and to find out more about participants' unique experiences of the treatment. We will discuss each process measure below in more detail.

Revised Neurophysiology of Pain Questionnaire (NPQ-R; Catley, O'Connell, & Moseley, 2013) is a measure of patients' knowledge of biological mechanisms of pain. It consists of 13 items, each one a statement about pain (sample item: "The brain decides when you will experience pain"), followed by three answer options: 'True', 'False', or 'Undecided'. Missed questions and 'Undecided' answers are scored as zero. Higher scores indicate a better understanding of pain neurophysiology. The revised version of the NPQ has adequate psychometric properties for evaluating effects of pain education interventions, as demonstrated by the authors of the measure. Due to the brevity of the pain education used in this study, not all of the items of the NPQ-R were considered likely to be impacted. The full NPQ-R was administered; however, only seven out of 13 items were used for the analysis, as the remaining six items covered material that did not fit into a 90-minute pain education session. Due to this limitation participants' scores were interpreted with caution.

Pain Desensitisation Chart (PDC; Nicholas, 2017). The PDC is a self-monitoring exposure form, designed specifically for the practice of IE. Self-monitoring is an important clinical technique used in all exposure type tasks in Cognitive Behavioural Therapy. The form asked participants to rate their distress before and after the IE, using a 11-point numeric scale, where 0 = 'does not bother me at all' and 10 = 'bothers me extremely'.

The Change Interview (Elliott, Slatick, & Urman, 2001) was used to evaluate treatment causality. The Change Interview is a semi-structured interview expected to take approximately one hour. It offers a balance between the flexibility of an open-ended interview, whilst providing a structure to ensure that all participants are asked the same pool of questions. We adapted the original protocol to reflect the context of our study, i.e. we did

not explore questions about participant's personality or aspects of themselves that they wanted to change. Instead we kept the focus of the interview on the 'Intervention' and any changes that the participant noticed since the study started. Please see Appendix I for the structure of the interview. The questions of the Change Interview explore areas such as: the changes noticed since the start of the study, what the participant attributed these changes to, and helpful and unhelpful aspects of the intervention. Moreover, participants were asked to rate the changes they noticed on three scales (expectancy, likelihood without therapy, and importance), using a 5-point rating system.

2.6 Procedure

All participants attended six sessions at the Pain Clinic. We used the first two sessions for the informed consent procedure and completion of the set-up of the study. Between the first and second assessment session there was a 'training week'. We used this week to ensure that participants got used to the Daily Diary and that the activity monitors functioned properly. During the first assessment session the researcher interviewed participants about their pain history, current coping strategies, and pain knowledge and beliefs. During the second assessment session participants had an opportunity to ask any questions about the use of the diary and/or activity monitor. Following the second assessment session we allocated all participants to their baselines. We held three consecutive treatment sessions afterwards. First was the Pain Education (90 minutes), followed by two sessions of IE practice (60 minutes each). During the final session of the study we interviewed the participants using the Change Interview. Below we present a detailed description of each step of the study procedure.

2.6.1 Assessment.

Following the informed consent procedure, described earlier in this chapter, we trained participants in how to use the Daily Diary. We then set up the activity monitors. All participants were offered to receive an automated daily text message reminder, to prevent forgetting about the Daily Diary and/or the activity monitor. Following the set up of the study we interviewed participants about their pain history and their current pain management strategies, please see Appendix K for the Assessment Interview schedule. Following the assessment, we asked participants to complete the Global Measures Booklet, see Appendix H.

Following the first assessment session, we asked participants to use their diaries and monitors for one week ('training in recording'). This period was designed to help identify any potential difficulties and limitations in using Daily Diaries and monitors, and to make appropriate adjustments to the data collection process, should any difficulties arise. We also assumed that training in recording would give participants a chance to familiarise themselves with the process and get a better understanding of the questions from the Daily

Diary before formal data collection began the following week. During the second assessment session participants Daily Diaries were checked for consistency. The activity monitors were synchronised and checked; the activity data was downloaded. Several participants had questions about the Daily Diary, and meaning behind its questions. All questions were answered and any misconceptions corrected. Additionally, it was ensured that the daily automated text message system was working. Following the second assessment session participants were asked to continue using the Daily Diary and activity monitor for the duration of the baseline.

2.6.2 Pain Education.

Before the start of the Pain Education session all participants were administered the Global Measures Booklet and the Revised Neurophysiology of Pain Questionnaire (NPQ-R). The Education session lasted 90 minutes, including a 10-minute break. The aims of the Education session were:

- 1) to introduce the Fear Avoidance Model of chronic pain,
- 2) to explain the rationale behind IE,
- 3) to familiarise participants with basic ideas from neurophysiology of pain, including the role of the brain in perception of pain,
- 4) to present the rationale behind how certain thoughts and emotions can increase pain distress.

We aimed to keep the education interactive, to help participants make links between presented theory and their own experience. Participants were encouraged to ask questions. Please see the Pain Education protocol and hand-out materials in the Appendix L and M.

2.6.3 Interoceptive Exposure.

Before the start of the first session of IE practice we asked participants to fill in the Revised Neurophysiology of Pain Questionnaire (NPQ-R). Afterwards, there was a brief recap of the most important aspects from the Pain Education session, and a reminder of the rationale behind IE.

Following this, the main researcher read out the IE script (Appendix O) and guided the participant through the use of the IE technique. Pain Distress was recorded before and after the IE practice and participants were instructed how to use the Pain Desensitisation Chart (PDC; Nicholas, 2017). At the end of the session a MP3 player with a pre-recorded instruction of IE practice was given to all participants. All participants were trained in how to use the MP3 player. We asked the participants to listen to the recording twice daily for 10 minutes, and to record their practice using the PDC. Participants were also encouraged to have additional, shorter, practice sessions of IE if they chose to do so, which they could record in the PDC. The first IE practice session took on average 57 minutes.

The second session of IE practice was scheduled a week later. We asked participants about their experiences of the IE practice so far. Participants were encouraged to ask questions and/or share any difficulties with the use of the IE exercise. There was an IE practice in session, with feedback from participants on their experiences. This was an opportunity to normalise any difficulties in using the IE exercise, such as difficulty of keeping focused attention, self-criticism and/or potential increase in pain distress. The second session of IE practice took on average 41 minutes.

2.6.4 Change Interview.

During the sixth and final session of the study, we interviewed participants using a modified version of the Change Interview (see Appendix I; Elliott, Slatick, & Urman, 2001). The Change Interview was audio-recorded to capture participants' comments about their experiences of the intervention. The Change Interview took on average 35 minutes.

2.7 Data Analysis

We assessed the efficacy and causality of the intervention using the following methods:

1. A visual analysis of the Fear of Pain, Pain Distress and Interference, and activity data (Morley, 2017),
2. Comparing standard outcome measure scores, across different study stages, using the RCI and CSC criteria (Jacobson & Truax, 1991; Evans, Margison, & Barkham, 1998),
3. Hermeneutic Single-Case Efficacy Design (Elliott, 2002).

Each of these methods will be described in more detail below.

2.7.1 Visual analysis.

Fear of Pain, Pain Distress and Interference, and activity data was displayed in graphs to enable visual inspection. The effect of treatment was evaluated through inspection of changes in patterns between the baseline and the treatment phase, according to guidelines on experimental case series using multiple baseline design (Morley, 2017; Kazdin, 2011; Kratochwill et al., 2010).

Additional visual analysis tools were used to guide the interpretation of the data, including the calculation of central tendency (mean) and mapping of a linear trend, using the split-middle method. The broaden median (BMed; Rosenberger & Gasco, 1983) was chosen for the analysis of Fear of Pain and the Pain Distress and Interference, due to its better fit with the data set, which was characterised by high variability and presence of outliers. Arithmetic mean was chosen for the analysis of the activity levels due to the fact that any 'outliers' (unusually high or low number of steps) was less likely to be a result of a measurement or recording error, and more likely to represent participants' actual levels of activity. In addition to visual analysis, percentage differences in central tendency between different phases of the study were calculated.

2.7.2 RCI and CSC calculations.

A Reliable Change Index (RCI) is a psychometric criterion which indicates whether a change in score is significantly greater than a difference that could have been recorded due to a random measurement error (Jacobson & Truax, 1991). The Clinically Significant Change (CSC) is another criterion indicating whether the change in scores is of ‘clinical importance’, which can be described as a shift from ‘clinical range of scores’ (i.e. ‘dysfunctional population range’) into ‘non-clinical range of scores’ (i.e. ‘functional population range’), which suggests a meaningful improvement (Evans, Margison, & Barkham, 1998). We calculated the RCI for all standard outcome measures. The CSC was used for measures where the clinical cut-off scores were available. This allowed us to determine whether the magnitude of change on pre to post intervention was deemed reliable and clinically significant (Jacobson & Truax, 1991; Evans, Margison, & Barkham, 1998).

To calculate the RCI for each standard outcome measure we used psychometric data from relevant validation studies, please see Table 5 for RCI Calculations. After computing a standard error of measurement (Sem) and the standard error of the difference score (SEdiff) we used the formula below to determine the Reliable Change Index (RCI):

$$\text{Sem} = \text{SD} \times \sqrt{(1-r)}$$

$$\text{SEdiff} = \sqrt{(2 \times \text{Sem}^2)}$$

$$\text{RCI} = (\text{pre-test score} - \text{post-test score}) / \text{SEdiff}$$

If the RCI is greater than 1.96 (using a $p < 0.05$) it can be concluded that the change in scores is unlikely to be attributed to a measurement error.

Table 5: RCI Calculations

test name	SD	<i>r</i>	Sem	SEdiff	RCI	Cut-off
PASS-20 Total	20.38	0.91	6.11	8.64	17	30
PCS Total	10.16	0.92	2.87	4.06	8	24
CPAQ Total	19	0.78	8.91	12.60	25	-
PDI Total	9.32	0.86	3.49	4.93	10	-
HADS-A	4.43	0.83	1.83	2.58	6	8
HADS-D	4.43	0.84	1.77	2.50	5	8

Note. Psychometric data was taken from the following sources: PASS-20: McCracken & Dhingra (2002); PCS: Osman et al. (1997); CPAQ: McCracken, Vowles, & Eccleston (2004); PDI: Tait, Chibnall, & Krause (1990); HADS: Pallant & Bailey (2005).

2.7.3 Hermeneutic Single-Case Efficacy Design (Elliott, 2002).

We used Elliott’s Hermeneutic Single Case Efficacy Design (HSCED; 2002) to guide the synthesis and interpretation of the study data. The HSCED is a useful method of combining the quantitative and qualitative data to help make a decision whether any

changes can be attributed to the effects of the intervention. Data from all the sources (i.e. standard, target and process outcome measures) is used in the HSCED, including the data from participants' Change Interviews. More comprehensive description of the HSCED is presented in the Discussion Chapter.

2.8 Quality Standards

In designing and evaluating our study we followed Morley's guidelines on evaluation of single case studies (2017). Considerable steps were taken to ensure the quality of the data (as described above). In order to apply the intervention in a standardised way all sessions followed a general script (see Appendices K, L, and O). Each script allowed some clinical flexibility; participants were encouraged to ask questions and share their experiences; however, these interactions were kept to a minimum, as the session's script had to be followed. The intervention was delivered by a Post Graduate Clinical Psychologist with three years' experience of using Cognitive Behavioural Therapy (the main researcher), who was supervised by a Clinical Psychologist working at the Pain Clinic (the research site). We used in-session checklist to ensure that the intervention was delivered in a uniform fashion. To ensure interpretation, both visual analysis and qualitative data were checked by the research supervisor. Additionally, anonymised transcripts from participants' Change Interviews were read by the research supervisor to ensure that the summarised transcripts and quotes were a fair representation of the entire interview.

3. RESULTS

3.1 Overview

This chapter will present results of participants in a structured order. Firstly, data from the initial assessment, clinical observation in sessions, process measures, and the Change Interview will be used to present each participant and describe their engagement in the intervention. Following this, we will present individual scores obtained on the Daily Diary (i.e. Fear of Pain and Distress and Interference). Individual standard measure scores (i.e. anxiety, catastrophising, acceptance, disability and mood) will be presented next, followed by activity levels. We will then share a summary of participants' answers to Change Interview questions. Finally, the study hypotheses will be explored using the findings of all participants. In the next chapter we will integrate and critique study results.

3.2 Participant 1

3.2.1 Background and pain history.

SP1 is a White British male in his 50s, experiencing chronic pain for over 30 years, which he attributed to spondylolisthesis. Nine years prior to the study, SP1's pain worsened subsequent to spinal surgery and sepsis, following which he was treated for PTSD. SP1 lived with his family. He had stopped working in sales due to pain. SP1 had had previous experience of psychotherapy: CBT and mindfulness for PTSD. Although he found mindfulness beneficial in the past, he was no longer practising it. SP1 reported being prescribed high doses of opioid pain medication, and was keen to reduce this due to side effects. SP1 believed it unlikely that his pain would ever get better. He explained that any type of physical activity could aggravate his pain. He was able to perform light housework. SP1's main coping strategy was to take medication and lie down in the foetal position.

3.2.2 Engagement in intervention.

SP1 had a good understanding of pain physiology before the study began. His score on an adapted Revised Neurophysiology of Pain Questionnaire (7 of 13 test questions administered) before the Education session was 6/7, with no change following the Education session. SP1 responded well to the FAM model, and he explained that he recognised avoidance in himself, which led to depression and disuse syndrome. His understanding was that "it [pain] means that there is something wrong (...) I saw the x-rays there is a lot of nerve damage".

During the Education session SP1 expressed some anxiety about the IE exercise. He explained that he was scared that practicing IE might trigger his PTSD. SP1 then experienced flashbacks of having sepsis. He became fidgety, his face flushed, and he started to hyperventilate and sweat profusely. The therapist used grounding techniques (i.e. focusing on hands and the here and now) followed by asking questions about memories of

how SP1 managed to overcome that distressing situation. SP1 was encouraged to focus his attention on positive elements of his intrusive memories and to contact the Pain Service should he require additional support. SP1 was also given an option to withdraw from the study at this point. The following week SP1 returned and stated that he did not experience any more flashbacks and that he was keen to continue participation in the study. Following this episode SP1 did not have any more flashbacks or intrusive memories linked to his PTSD.

Despite his fears about the IE practice SP1 had no difficulties in following the IE exercise in session. Following his first practice he experienced a small increase in pain distress (as measured by the Pain Desensitising Chart, PDC). Data kept by SP1 of his home IE practice (see Appendix R) showed that 59% of the time his pain distress would increase within a range of 1-2 points on a 10-point scale, 41% of the time it remained the same. SP1 reported listening to the recording twice a day and engaging in additional short practices on top of this. He recorded two short practices in week one, four in week two, and two in week three. SP1 commented that he did the short practices whilst out and about, he noted that his pain did not increase whilst he was doing it, and that he was able to continue with the activity afterwards. When asked about his experience of IE practice he explained: “I notice more range of pain, I notice pain in other areas of my body”. When asked about his experiences following the first week of IE practice SP1 replied: “It went quite well”; however, he also mentioned that on some days he had to start the recording again, when he “couldn’t get to it”. He was able to notice that his breathing would calm down and during the exercise he would feel “quite relaxed”, and that it was “enjoyable”. During the second week of IE practice SP1 described an episode when he was out with his family, and his pain became very severe. He said that he voluntarily sat down and focused on his pain. Following a short practice he was able to continue with his trip. SP1 explained that in the past he would have stopped what he was doing and return home. SP1 reported increased physical activity levels and growing confidence in using the exercise.

SP1 mentioned that his pain reminded him of a type of cancer his mother died of. Although this was not explored during the treatment, SP1 explained that whilst practicing IE he had not thought about his mother’s illness as often as he used to. In the last treatment session SP1 said that he realised that his pain does not mean that he also will have cancer.

In the last week of the intervention SP1 reported losing his activity monitor and forgetting to record data in the Daily Diary. It was agreed that SP1 continue with one more week of the IE practice and data collection. SP1 suggested that readings could be taken from his personal fitness tracker (which he wore anyway) rather than obtaining a replacement activity monitor. He brought the data from his personal activity tracker for comparison with the research data. The two sets of data were sufficiently similar, therefore data from SP1’s

fitness tracker was used in this study instead. SP1 commented that the last week of the study was “bad” due to a stressful incident unrelated to his pain or the study.

3.2.3 Fear of Pain results.

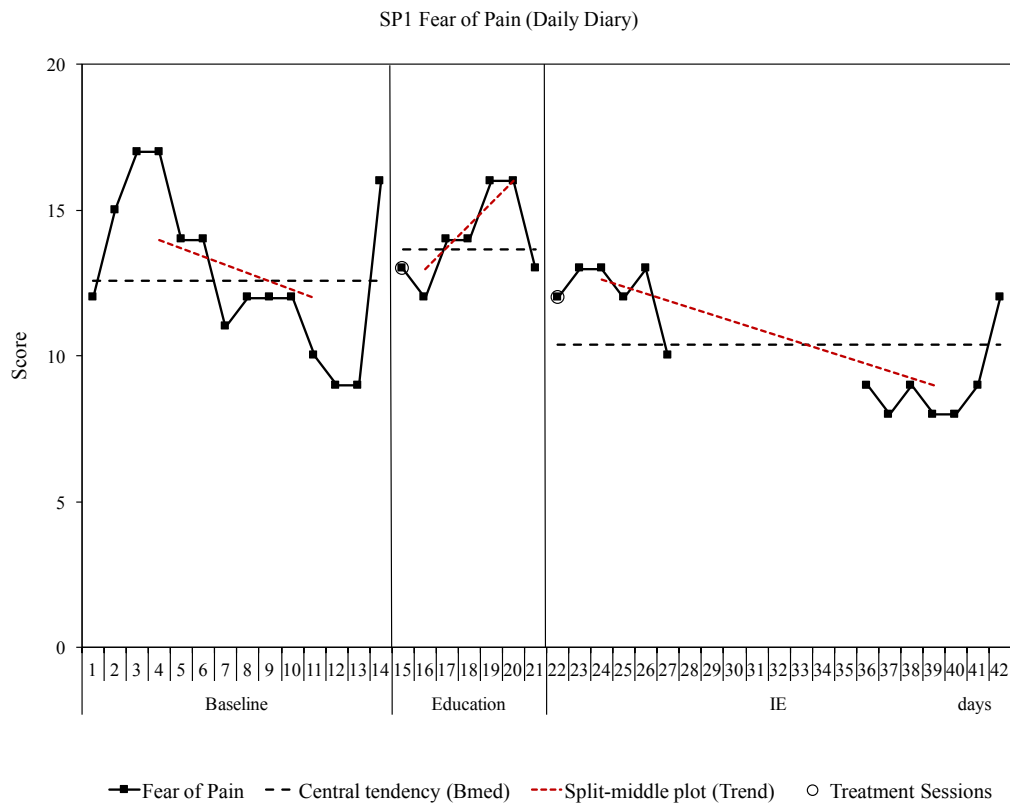


Figure 7: Visual display of SP1’s Fear of Pain (Daily Diary) scores with markers of study phases, central tendency (broadened median) and split middle line (trend) in each phase. Note: there is one week of data missing (29th to 35th day of the intervention) due to data not being collected by the participant.

There is a downward trend in baseline with high Fear of Pain scores (BMed=12.6). Following the Education session there is a steep upward trend (BMed=13.6, increase of 8% as compared to baseline), with high scores. Following the introduction of IE there is a downward trend in Fear of Pain scores (BMed=10.4, decrease of 17%).

3.2.4 Distress and Pain Interference results.

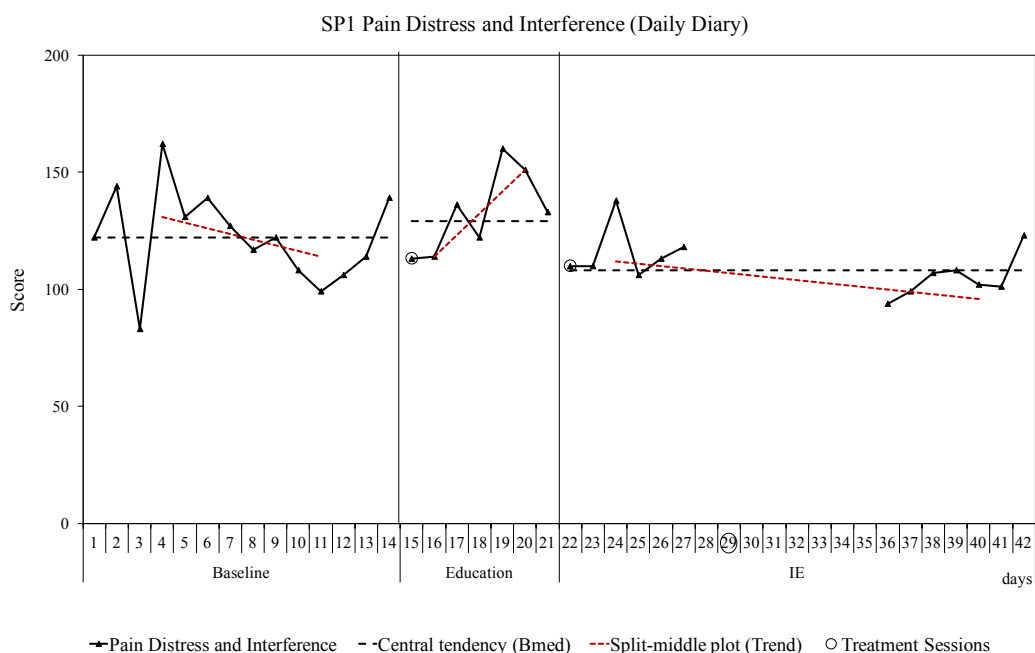


Figure 8: Visual display of SP1’s Pain Distress and Interference (Daily Diary) scores with markers of study phases, central tendency (broadened median) and split middle plot (trend) in each phase. Note: there is one week of data missing (29th to 35th day of the intervention) due to data not being collected by the participant.

SP1’s Pain Distress and Interference scores are moderate during the baseline period (Bmed=122). There is a downward trend in the baseline, followed by an upward trend following the education session, with increase in Distress and Interference scores (Bmed=129, 6% increase as compared with baseline). Following the introduction of IE practice there is a downward trend, and scores show less variability. The central tendency (Broaden Median, Bmed) shows that distress and interference scores are 11% lower during the IE phase, as compared to the baseline (Bmed=108).

3.2.5 Standard measures.

As can be seen in Table 6, SP1’s scores on standard measures of pain anxiety and catastrophising were elevated on assessment and met the caseness criterion. He had a clinically significant and reliable improvement on the PCS, and a reliable improvement on the PASS-20. SP1’s scores on measures of anxiety and depression met the caseness criterion on assessment, with the depression subscale falling out of the caseness range at the end of the intervention; however, this this does not represent a statistically reliable change. No other reliable changes were observed.

Table 6: SP1's Standard outcome measures scores

SP1	PASS-20 Total score	PCS Total score	CPAQ Total score	PDI	HADS-A	HADS-D
Ax	67	40	46	55	17	12
Pre	69	36	51	48	15	11
Post	47	23	64	41	11	8
Ax-Pre	2	-4	-5	-7	-2	-1
Pre-Post	-22*	-13 ^a	-13	-7	-4	-3 ^a

Note. Participant's scores are presented at different points in time: Assessment (Ax), Pre-intervention (Pre), Post-intervention (Post), followed by calculations of difference between phases. *significant reliable change (RCI criterion at 0.05 level), ^a clinically significant change.

3.2.6 Activity results.

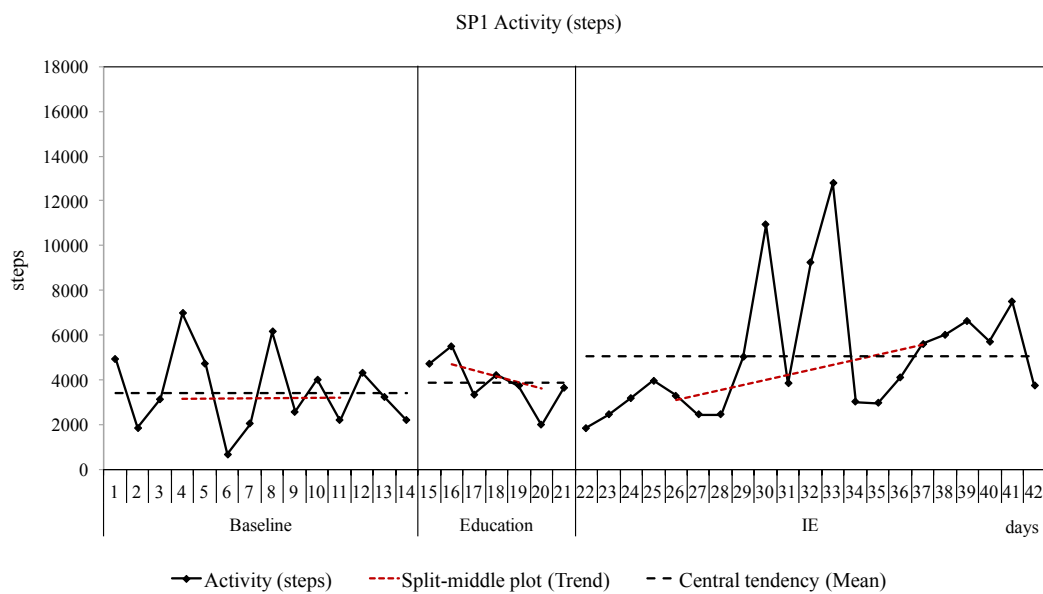


Figure 9: Visual display of SP1's Activity (steps) with markers of study phases, central tendency (mean) and split middle plot (trend) in each phase

SP1's activity levels increased following the intervention. During the baseline period the mean number of steps was 3421 (Min=666, Max=6978), during the Education phase it increased to 3875 (Min=1989, Max=5513) and in the IE phase it increased further to 5083 (Min=1868, Max=12777). This demonstrates an increase in activity from baseline by 12% during the Education phase and 48% during the treatment phase.

3.2.7 Change Interview.

SP1 reported multiple changes during the Change Interview, which he attributed to the intervention. Table 7 shows changes that SP1 experienced, and his perceptions of them.

Table 7: Changes reported by SP1 during the Change Interview rated by their expectancy, likelihood without intervention, and importance.

Change	Change was:	Without therapy:	Importance:
1. Increase in activity	Very much surprised by it	Very unlikely	Extremely
2. Able to continue with activity despite pain	Somewhat surprised by it	Very unlikely	Extremely
3. Increase in acceptance of pain, less anger	Somewhat surprised by it	Very unlikely	Extremely
4. More sexual	Very much surprised by it	Somewhat unlikely	Extremely
5. Less worried about bone cancer	Very much surprised by it	Very unlikely	Very
6. Less worry about pain and being more decisive	Somewhat surprised by it	Very unlikely	Very
7. Being more sociable	Very much surprised by it	Very unlikely	Extremely
8. Spending more time with his son and being more spontaneous in doing so	Neither expected nor surprised by it	Very unlikely	Extremely

When asked about helpful aspects of the intervention SP1 answered:

“Greater knowledge of pain, that it’s not going to destroy me, it’s not going to kill me, it’s not a catastrophe when I get the pain, there is light at the end of the tunnel, it’s not as bad, I get that with the [IE] exercise.” (SP1)

He described no unhelpful aspect of the intervention; however, he commented that during the IE practice he noticed pain in other areas of his body, which he previously did not acknowledge:

“I did not fully appreciate that I get it in all of those areas all of the time. I thought it was just when it was really bad, really painful everywhere, but even when it’s not a bad pain, I didn’t really appreciate this, I thought it was only in one spot, so I suppose you could describe that as ‘its not as good’”. (SP1)

SP1 mentioned a couple of unhelpful aspects of taking part in the study. He commented that wearing the activity monitor was ‘annoying’, as it used to catch on his clothing.

Additionally, he described filling in the daily questionnaires burdensome at times.

SP1’s suggestion on how to improve the interventions was: “duration of the exercise could be a bit longer for me, especially in the beginning”. SP1 also commented that he was sad about the end of the study, and that he would prefer for it to continue. He explained that:

“You can cope better if you know that you are seeing somebody, the saddest thing is when you finish the therapy you need to stop. It’s a scary time when you don’t have that [security] blanket.” (SP1)

SP1 reported that he reduced his opioid medication. He explained that he started the reduction before the beginning of the study, and that coming to the Pain Clinic to see the Researcher helped him to manage his anxiety about possible opioid withdrawal symptoms, and continue with the reduction:

“I was on 75 mcg of Fentanyl and in the first two weeks of the study I came down to 62 mcg, and then four weeks in the study I came down to 50 mcg. I think that the ability to come somewhere gave me an outlet (...) I felt like I had a comfort blanket there or something, in case I need it. I’m always thinking: well it’s feeling bad but I am seeing [the researcher] on Monday, and I’ll discuss it with [them], I was always able to go through the next day and the next day because I was seeing somebody. I think that if I was left on my own I would have got a bit more worried about the withdrawal.” (SP1)

3.3 Participant 2

3.3.1 Background and pain history.

SP2 is a White British female in her 40s, who experienced pain for the last 8 years, which she attributed to a back injury. She was married and lived with family. SP2 stopped working in healthcare due to her pain. She reported not being able to do any housework, and explained that on the top of her chronic pain she experienced “unbearable” painful spasms. She managed her pain by avoiding physical activity, lying down, using heat packs, taking medication, and having fortnightly beautician sessions and massage. SP2 reported taking high doses of opioid pain medication, which she was keen to reduce due to side effects.

3.3.2 Engagement in intervention.

During our sessions SP2 would often move around, as she was unable to sit for more than 15-20 minutes. She explained that she had low expectations about the intervention; however, she believed that by taking part she could be helping other patients. There was evidence of catastrophic thinking about pain: “My gut feeling is that my pain is going to be endless, maybe I will end up in a wheelchair”. SP2 would often report that coming to the clinic to take part in the study was the only reason she got out of bed that day, as her pain was so severe.

SP2’s understanding of chronic pain was that pain is associated with injury and illness. Her score on the adapted Revised Neurophysiology of Pain Questionnaire (7 of 13 test questions administered) was 4/7; her answers did not change following the Education session. During the Education session SP2 commented that she can see similarities between her pain experience and the Fear Avoidance Model.

Following in-session practice of IE, SP2 reported increased pain distress (as measured by the Pain Desensitising Chart). During home practice the self-reported pain distress (see Figure R1, Appendix R) showed fluctuations: 54% of the time it remained the same after the IE practice, 32% of the time it increased, and 14% of the time it decreased. Changes in distress were small, within 1-point range on a 10-point scale. SP2 explained that during the IE practice her pain felt more intense; however, as the practice progressed it reverted to where it was before. After the first week SP2 commented that she was “not as frightened

about focusing on pain” and that she started to “realise that it does not get worse”. During the second week of IE practice SP2 described worsening in health and increased pain due to an infection; on three days she reported not being able to listen to the IE recording. During the rest of the IE phase SP2 reported listening to the recording twice a day and engaging in additional short practices on top of this. She recorded one short practice during the first week, and four during the second week. Following the second week of IE practice SP2 described a situation when she felt a surge in pain whilst coming back from a shopping trip. When she got into a taxi she started to calmly focus on her pain, and by the time she got home she felt that her pain had eased. SP2 explained that the IE practice helped her to cope with pain, when she had no other strategies to use.

3.3.3 Fear of Pain results.

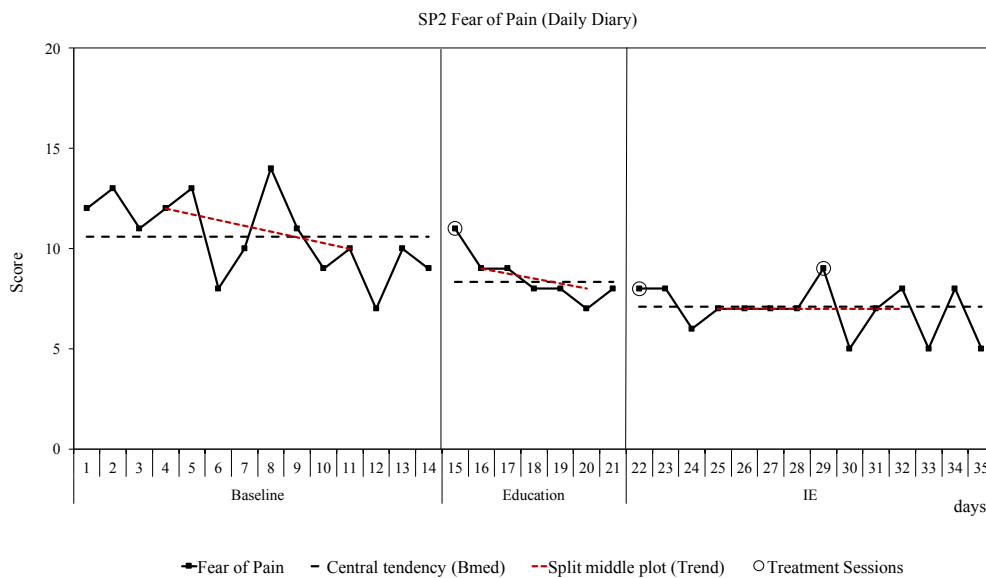


Figure 10: Visual display of SP2’s Fear of Pain (Daily Diary) scores with markers of study phases, central tendency (broadened median) and split middle line (trend) in each phase.

There was a downward trend in SP2’s Fear of Pain during the Baseline phase, scores were moderate (BMed=10.6). During the Education phase there was a slight downward trend with less variability in the scores (BMed=8.3, decrease of 21% as compared to the baseline). During the IE treatment phase there was no trend and less variability, with lower scores (BMed=7.1, decrease of 33%).

3.3.4 Distress and Pain Interference results.

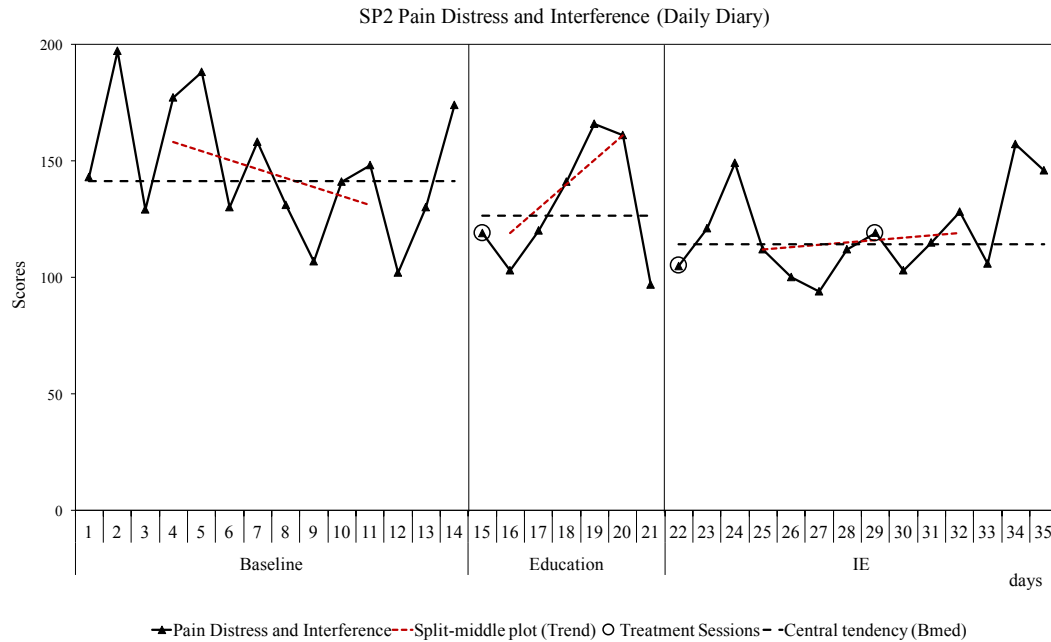


Figure 11: Visual display of SP2’s Pain Distress and Interference scores with markers of study phases, central tendency (broadened median) and split middle plot (trend) in each phase.

There was a downward trend in SP2’s Pain Distress and Interference scores during the baseline period, with high scores (Bmed=141). During the Education phase there was an upward trend; however, scores were 11% lower compared to baseline (Bmed=126). Following the introduction of IE there was a slight upward trend; however, scores were 19% lower as compared with the baseline (Bmed=114).

3.3.5 Standard measures.

As can be seen in Table 8 SP2’s scores on standard measures of pain anxiety and catastrophising were elevated on assessment, and met the caseness criterion. There was an unstable baseline on the PASS-20, showing a reliable improvement, which cannot be attributed to the intervention, and could suggest that other factors were responsible for change on this outcome measure. SP2 had a reliable improvement on the PASS-20, and a clinically significant and reliable improvement on the PCS. No other changes, meeting RCI criterion, were observed. SP2’s scores on measure of anxiety and depression met the caseness criterion on assessment, and remained high throughout the intervention.

Table 8: SP2’s Standard outcome measures scores.

SP2	PASS-20 Total score	PCS Total score	CPAQ Total score	PDI	HADS-A	HADS-D
Ax	91	42	29	69	15	18
Pre	73	42	20	69	15	19
Post	53	19	27	68	13	17
Ax-Pre	-18*	0	-9	0	0	1
Pre-Post	-20*	-23* ^a	7	-1	-2	-2

Note. Participant’s scores are presented at different points in time: Assessment (Ax), Pre-intervention (Pre), Post-intervention (Post), followed by calculations of difference between phases. *significant reliable change (RCI criterion at 0.05 level), ^a clinically significant change.

3.3.6 Activity results.

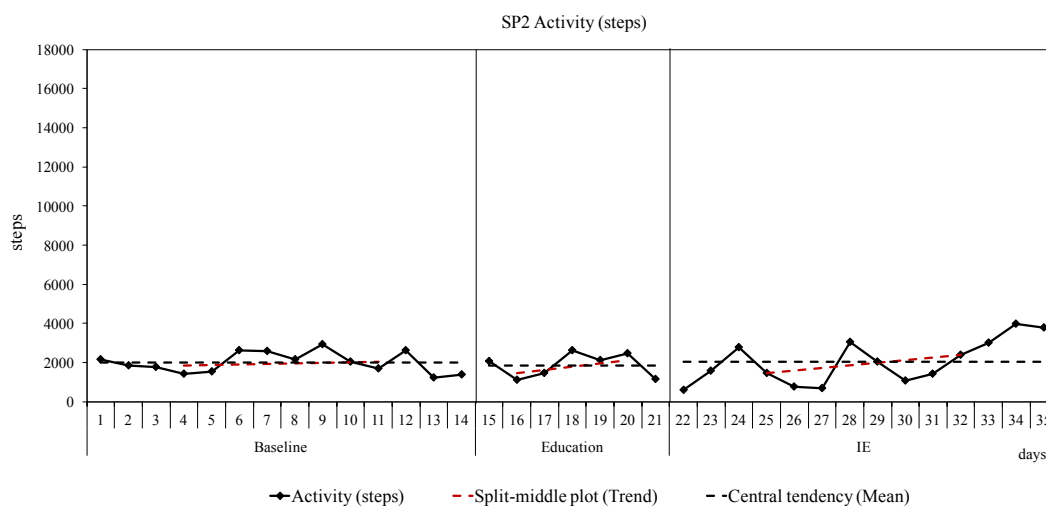


Figure 12: Visual display of SP2’s Activity (steps) with markers of study phases, central tendency (mean), and split middle plot (trend) in each phase.

SP2’s mean number of steps per day during the baseline period was 1994 (Min=1234, Max=2911). During the Education phase there was a 7% decrease (M=1854, Min=1123, Max=2628). During the IE phase SP2’s activity increased to 2039 (Min=610, Max=3982), which is an increase of 2%, as compared with baseline. Whilst there was stability in the baseline period, there is a slight upward trend in data in both the education phase and IE phase. It is important to note that SP2 experienced periods of illness during the IE phase (22nd, 25th, 26 and 27th day), when she described being bed ridden.

3.3.7 Change Interview.

SP2 reported several changes during the Change Interview, most of which she attributed to the intervention. Table 9 shows changes that SP2 experienced and her perceptions of these changes.

Table 9: Changes reported by SP2 during the Change Interview rated by expectancy, likelihood without intervention and importance.

Change	Change was:	Without therapy:	Importance:
1. Beliefs about pain changed	Very much surprised by it	Somewhat unlikely	Extremely
2. Have a new coping strategy	Neither expected nor surprised by the change	Somewhat unlikely	Very
3. Change in pain management	Very much surprised by it	Very unlikely	Extremely
4. Increased motivation to be more active	Somewhat surprised by it	Very unlikely	Extremely
5. Being more honest about how I really feel	Neither expected nor surprised by the change	Neither likely nor unlikely	Moderately

SP2 described several helpful aspects of the intervention and taking part in the study in general: “The most helpful was the recordings and setting time to do that, I am sure the forms and the wristband was helpful for you, but for me the recording was most useful”.

She described the IE practice as: “it helps you to relax and realise that it [pain] is not going to end your life”. However, SP2 also commented how difficult it was to decide whether to take part in the study:

“The commitment was scary and you commit to the trial, you commit to come here every week and it would be very easy not to bother, but I guess I got to the point that nothing was working so I thought I could give this a try.” (SP2)

SP2 had several suggestions on how to improve the intervention, including changing the visual analogue scale of the Daily Diary to a numeric scale, introducing the IE exercise earlier on: “because it just says that it can take weeks to learn how to use it, so do you not think that we should use it earlier in the study?” (SP2); or lengthening the IE phase:

“I guess I was quite lucky because I picked it [IE] up and made it a transferable skill, but for some other people it might not be enough time, so they might give up after a couple of weeks if it is not working for them, some people might need some extra weeks.” (SP2)

SP2 reported some changes in her medication regime: “I tend to use heat packs and massage more than just reaching for the morphine or diazepam for my spasms, I haven’t had as much, I purposely try not to use it as much.”

3.4 Participant 3

3.4.1 Background and pain history.

SP3 is a White British female in her 50s, who experienced pain for over 21 years having undergone three operations following a back injury at work. She lived with her partner. She had stopped working in care due to her pain. SP3 was able to perform very light house chores. She described her pain as “constant, exhausting and debilitating”. SP3’s coping strategies included: medication, using a hot water bottle, listening to music and having someone to talk to. She explained that her pain was aggravated by being alone, being scared that it will get worse, and also certain movements: “I am scared of twisting and bending” as she believed that could cause more damage to her back.

3.4.2 Engagement in intervention.

SP3’s understanding of pain prior to the Education session was that pain is a “warning signal meaning that something is wrong within the body”. SP3’s score on the adapted Revised Neurophysiology of Pain Questionnaire before the Education session was 4/7, her score increased to 5/7 afterwards. During the Change Interview SP3 commented on how helpful the Education session was, and how she referred back to it afterwards:

“The actual educational sessions have been very informative and very very [sic] interesting and I’ve re-read through those [Education session handouts] and I’ve shared them with my partner, who equally found them interesting, things that I didn’t know, so yeah I’ve really enjoyed those, that session particularly.” (SP3)

SP3 found the FAM very relatable to her own experiences of living with pain and recognised some catastrophic thinking: “It is never going to go away” and “I will end up in a wheelchair”. SP3 noted on several occasions how isolating the experience of pain is for her and how much better she copes with pain whilst being with other people.

SP3 had no difficulty in following the IE exercise with the therapist in session. Following the first practice, SP3 reported a slight increase in pain distress (as measured by the Pain Desensitising Chart). She commented that she noticed more intense pain, with her breathing becoming more irregular. IE practice records kept by SP3 showed that most of time (45%) SP3’s pain distress remained the same following the IE practice, 29% of times it decreased and 26% of times it increased (see Appendix R). All changes were within 1-2 points on a 10-point scale. There was a pattern in SP3’s PDC data: initially the distress afterwards was higher than at the start of the exercise, with more practise the distress was equal or slightly lower afterwards. Toward the end of week 3 of training in IE the distress afterwards was consistently lower than at the start.

SP3 recorded multiple brief sessions of the IE exercise on the top of her regular practice. She recorded 18 short practices in the first week, 16 in the second week, and 12 in

the last week. SP3 had an additional week of IE practice due to the Easter period, when we were unable to hold a session at the Pain Clinic.

3.4.3 Fear of Pain results.

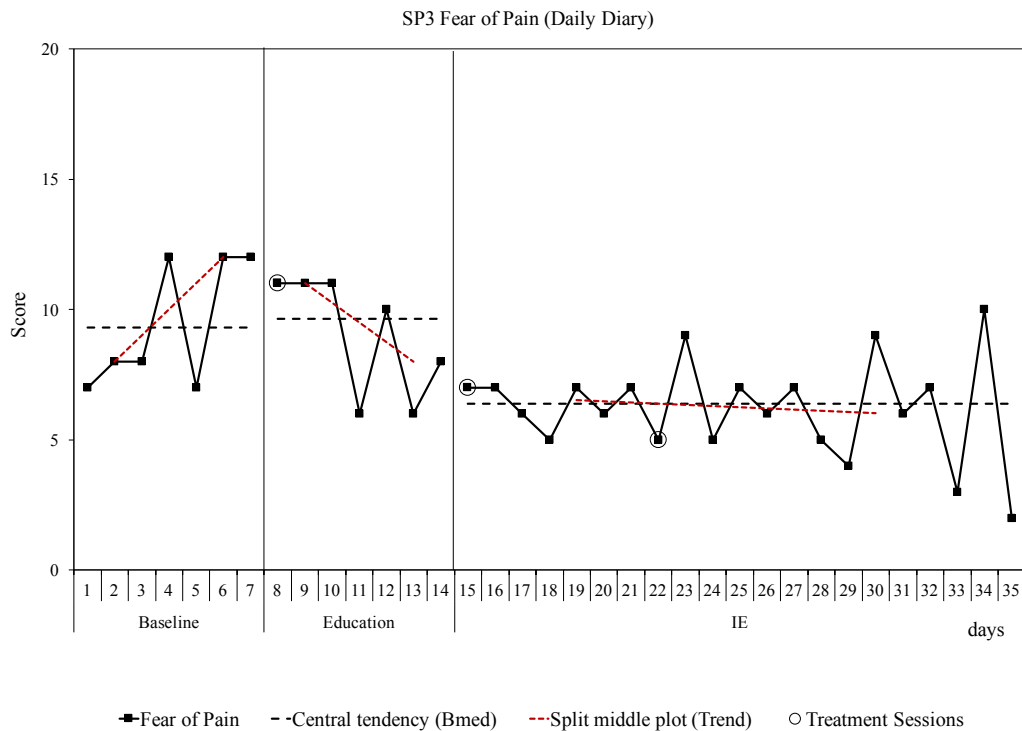


Figure 13: Visual display of SP3’s Fear of Pain scores with markers of study phases, central tendency (broadened median) and split middle plot (trend) in each phase.

There was variability in scores during the baseline phase with a steep upward trend (BMed=9.3). During the Education phase, Fear of Pain scores remained similar (BMed=9.7, 3% increase as compared to baseline); however, there was a change in trend direction. SP3’s Fear of Pain scores decreased in the IE phase (BMed=6.4, 31% decrease). In the first two weeks of IE practice Fear of Pain scores remained stable with little variability; however, in the last week of the intervention there was more variability in the Fear of Pain ratings.

3.4.4 Distress and Pain Interference results.

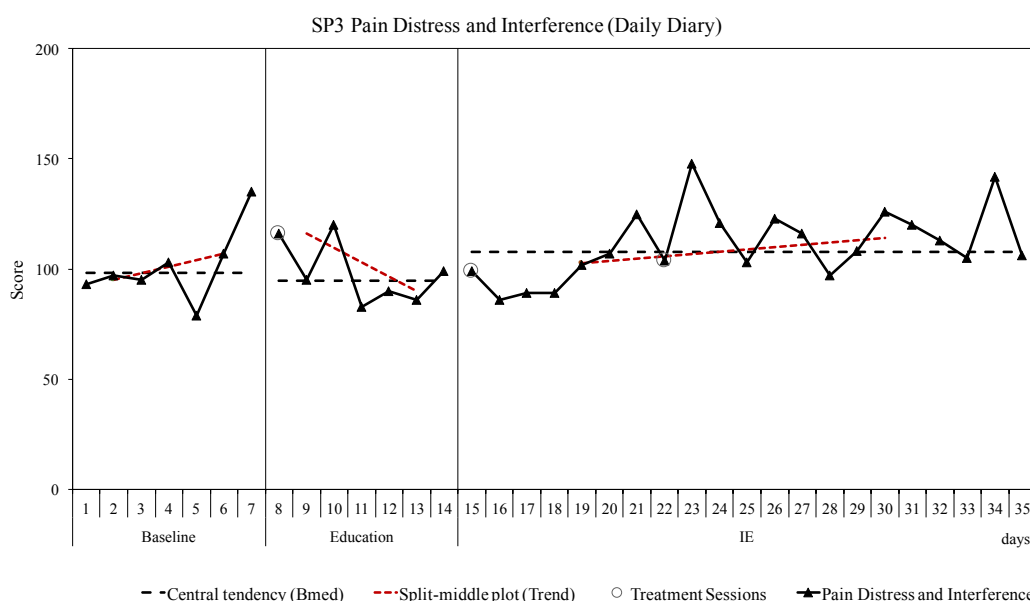


Figure 14: Visual display of SP3’s Pain Distress and Interference (Daily Diary) scores with markers of study phases, central tendency (broadened median) and split middle plot (trend) in each phase.

There was variability in Pain Distress and Interference scores across all study phases. There was an upward trend during the baseline period with moderate scores (Bmed=98). Scores remained moderate during the Education phase (Bmed=95, 4% reduction); however, direction of the trend changed. Following the introduction of IE there was a slight upward trend, with scores 10% higher than baseline (Bmed=108).

3.4.5 Standard measures.

SP3’s scores on standard measures of pain anxiety were elevated on assessment and meeting the caseness criterion; however, the pain catastrophising scores on assessment were low, and did not meet the caseness criterion. Moreover, there was an instability in baseline on the measure of catastrophising, with reliable and clinically significant worsening, which moved SP3 from non-caseness into caseness at the start of the intervention. As the worsening was observed during the baseline it cannot be attributed to the intervention. No other changes, meeting the RCI criterion, were observed. SP3’s scores on measure of depression remained low throughout the study, and within normal range; whilst anxiety scores were elevated and within the caseness range, and remained unchanged throughout the intervention.

Table 10: SP3’s Standard outcome measures scores

SP3	PASS-20 Total score	PCS Total score	CPAQ Total score	PDI	HADS-A	HADS-D
Ax	64	18	66	53	11	8
Pre	73	27	57	58	8	4
Post	60	27	57	50	12	5
Ax-Pre	9	9**	-9	5	-3	-4
Pre-Post	-13	0	0	-8	4	1

Note. Participant’s scores are presented at different points in time: Assessment (Ax), Pre-intervention (Pre), Post-intervention (Post), followed by calculations of difference between phases. *significant reliable change (RCI criterion at 0.05 level), ^a clinically significant change, **significant reliable change in the non-predicted direction (worsening).

3.4.6 Activity Results

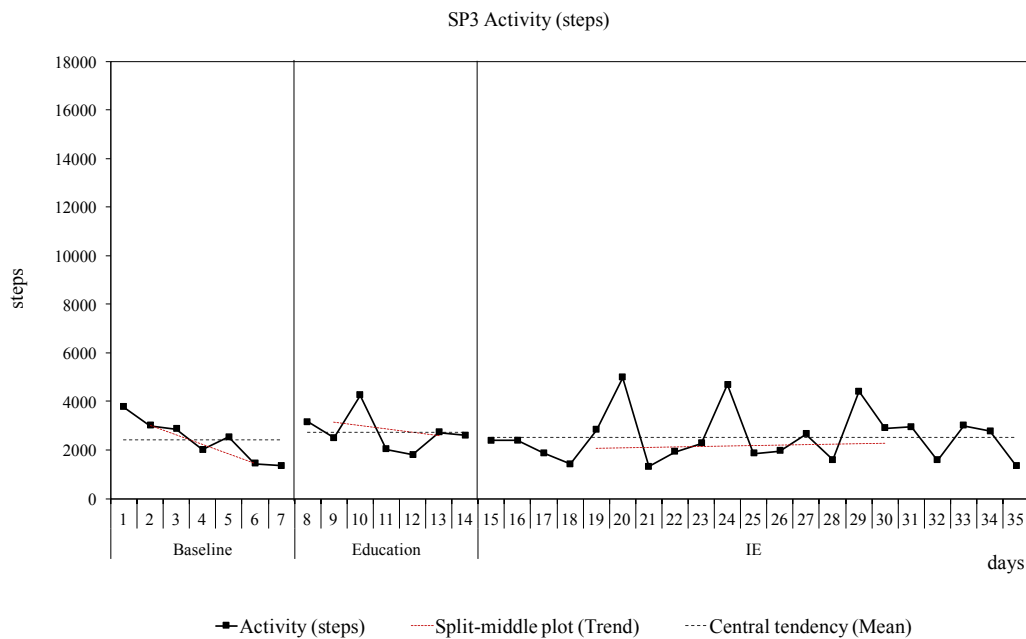


Figure 15: Visual display of SP3’s Activity (steps) with markers of study phases, central tendency (mean) and split middle plot (trend) in each phase.

During the baseline period the mean number of steps for SP3 was 2420 (Min=1342, Max=3756), and there was a downward trend in the baseline. SP3’s activity levels increased following the intervention; during the Education phase activity increased to 2723 (Min=1795 Max=4257), a 12% rise compared to baseline. The mean number of steps during the IE phase equalled 2528 (Min=1314, Max=4987), 4% higher than baseline.

3.4.7 Change Interview.

SP3 reported one change following the intervention, which was a change in her response to her pain. Table 11 shows how she described and rated that change on the expectancy, likelihood without the intervention, and importance scales.

Table 11: Change reported by SP3 during the Change Interview rated by its expectancy, likelihood without intervention and importance.

Change	Change was:	Without therapy:	Importance:
1. Being able to slow down and breathe through pain instead of panicking, trying to breathe through it and keep saying to myself that this will pass	Very much surprised by it	Very unlikely	Very

SP3 described several helpful aspects of the intervention, including the IE practice, the Pain Education session, and hand-outs:

“concentrating on the pain has helped me realise that when it comes to chronic pain the pain does not get worse, you have to breathe your way through it, having the time for me, again I try to busy myself to do anything but to think about pain, but I’ve had to think about it, so, having the time for me.” (SP3)

SP3 also said that one of the benefits of taking part in the study was having something meaningful to do during the day and somewhere to go one day a week. Additionally, SP3 found filling in the Daily Diary helpful in noticing change in how she thinks about her pain:

“On some of the forms it says ‘are the pain sensations terrifying?’ initially I would say yes, but now, not so much, because I realise that actually it will pass, so that has been a real learning curve for me.” (SP3)

SP3 commented on several less helpful aspects of the intervention, such as the IE exercise not working for the acute pain and being disappointed that the pain is still there:

“I wanted a miracle, I wanted the pain to go, of course! I am a realist, so I knew that that wasn’t going to happen, but deep down, and I think I am possibly not just talking for me, when you have a lot of pain and you live with it every day, if there is just a tiniest little glimmer that one day there will be something that can help, really help, then yeah, I’ve hope for that.” (SP3)

SP3 also commented on the practical challenges of taking part in the study, especially travelling to the sessions. SP3 had several suggestions on how to improve the intervention, including having a longer Pain Education session, or an additional session to go over the material again:

“The sessions have always went very quickly, there has always been something to do, so maybe perhaps a long, I know the session was an hour and a half, maybe even longer perhaps, maybe over two hours, maybe an extra session to go over that again.” (SP3)

SP3 reported no changes in her medication regime throughout the duration of the study.

3.5 Participant 4

3.5.1 Background and pain history.

SP4 is a White British male in his 50s, who experienced pain for over 30 years, which he attributed to wear and tear and sciatica. Four years prior to the study SP4's pain worsened following spinal surgery. His pain mostly affected one leg, causing cramps and impairing his mobility. He was single and lived alone. SP4 stopped working in construction due to pain and disability. SP4 also reported significant sleep disturbance due to leg cramps. His coping strategies included: lying down, taking painkillers, and occasionally drinking alcohol. SP4 was prescribed opioids for his pain, which he was reluctant to reduce despite experiencing side effects. He said that over the years he had gained weight and had been told he was at risk of developing diabetes. Since then he began exercising and explained that his pain bothered him less whilst swimming, and did not increase afterwards.

3.5.2. Engagement in intervention.

SP4 engaged well during the Pain Education session. He was able to recognise catastrophic thoughts about his pain. He explained that he was worried his pain will worsen and return to what it was before, when he was unable to cope. SP4 understood his pain in terms of damage to his nerves and spine. SP4's score on the adapted Revised Neurophysiology of Pain Questionnaire (NPQ-R) before the Education session was 3/7, his score did not change following the Education session.

SP4 had high expectations from the IE exercise; he said that he hoped that it will help him get rid of his pain. Regarding the first IE practice in session, SP4 reported an increase in distress following the exercise, and found it difficult to keep his attention on his pain. There was evidence that SP4 was unable to let himself experience his pain without trying to block it, as he was observed digging his nails in to his palms. When asked about it, he confirmed that he was unable to let himself feel the pain in his leg, so used that counter-stimulation to distract himself.

SP4 reported difficulties in practicing IE at home. He explained that his pain would increase, and that prevented him from focusing on it. Additionally, he had difficulties with the study equipment. His MP3 player had malfunctioned during the first week of the IE phase. He contacted the researcher and a replacement MP3 player was arranged. SP4 explained that over the two days, when he was unable to listen to the recording, he read the IE script instead. Self-rated levels of pain distress (as measured by Pain Desensitising Chart, see Appendix R) before and after the IE practice remained stable for SP4. The distress following the IE practice stayed the same 51% of the time, 47% of time it increased within one point on a 10-point scale, and there was only one instance when SP4 recorded a decrease in distress following the IE exercise.

SP4’s duration of the study was longer due to the Christmas period and him not being able to attend the final session at the Pain Clinic earlier. SP4’s IE phase was therefore extended from two weeks to four weeks. SP4 reported being able to listen to the recording twice a day; however, he did not engage in shorter practices. SP4 noticed that he generally struggled with staying focused on one thing:

“The moment I sit down quiet for any length of time I wander off, my mind goes, plays tunes or does something (...) that’s my problem, I was told to never focus on it [pain], and now you are there telling me to focus on it, and something in my head says ‘no’ and refuses, an off it goes.” (SP4)

3.5.3 Fear of Pain results.

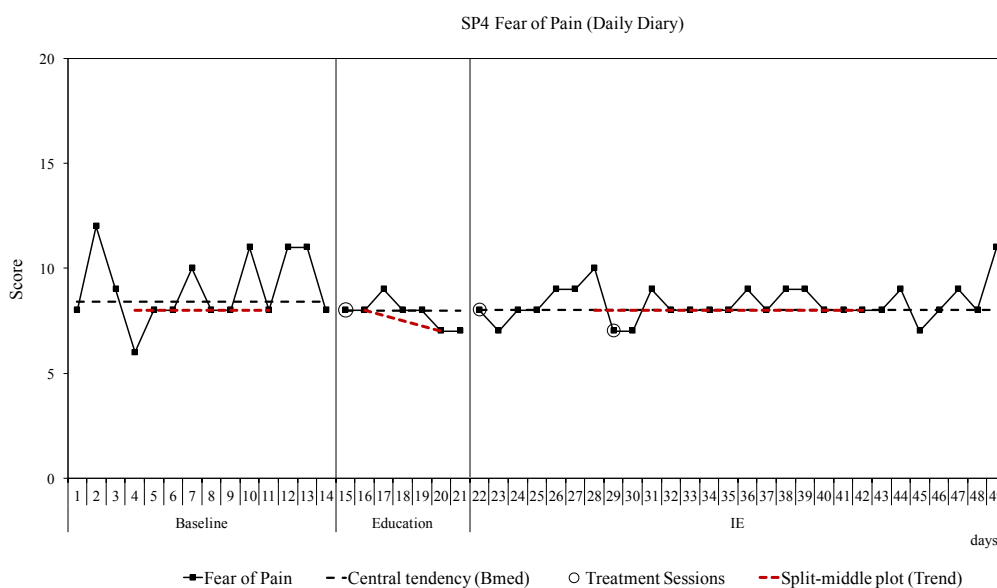


Figure 16: Visual display of SP4’s Fear of Pain scores with markers of study phases, central tendency (broadened median), and split middle plot (trend) in each phase.

The graph shows moderate Fear of Pain scores across all phases, with little variation. There was little change in scores between the baseline (BMed= 8.4), the Education phase (BMed=7.9, decrease of 5% as compared to baseline), and the IE phase (BMed=8, decrease of 5% as compared to baseline). Overall, there was no change in SP4’s Fear of Pain ratings during the intervention.

3.5.4 Distress and Pain Interference results.

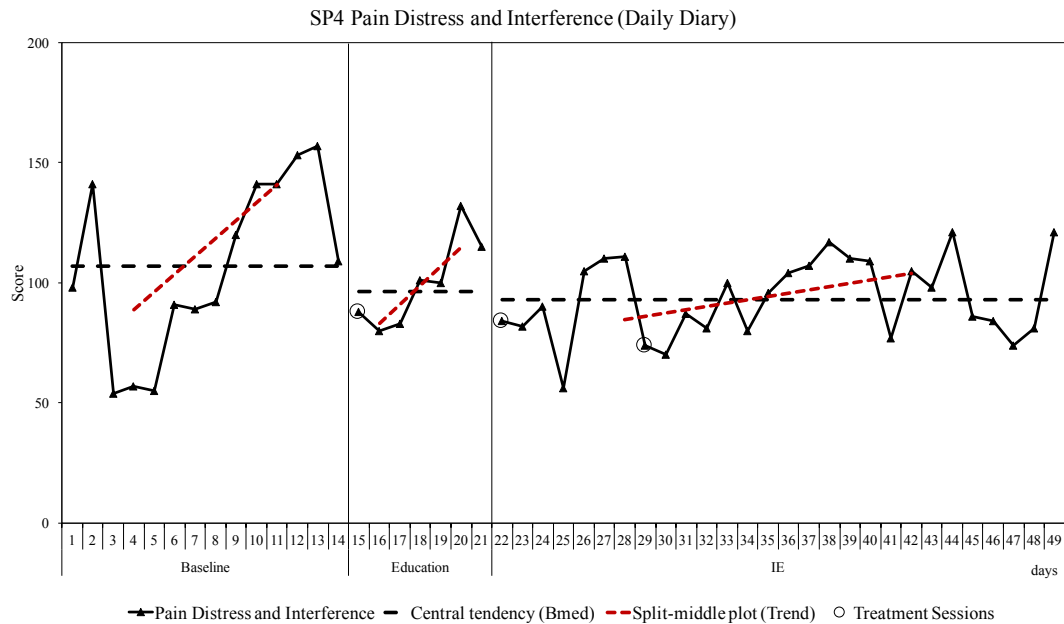


Figure 17: Visual display of SP4’s Pain Distress and Interference scores with markers of study phases, central tendency (broadened median), and split middle plot (trend) in each phase.

There was marked variability in Pain Distress and Interference scores during the baseline, with a sharp upward trend and moderate to high scores (Bmed=107). During the Education phase the scores remained similar to baseline, only 10% lower (Bmed=96). Following the introduction of IE there was a slight upward trend, scores remained variable and slightly lower (13%) as compared with the baseline (Bmed=93).

3.5.5 Standard measures.

As can be seen in Table 12 SP4’s scores on standard measures of pain anxiety and catastrophising were elevated on assessment, and met the caseness criterion. There was an instability in baseline on the measure of pain anxiety (PASS-20), with reliable improvement, which cannot be attributed to the intervention. Both PASS-20 and PCS scores improved during the intervention; however, only PCS met the reliable change criterion. SP4’s pain disability scores showed reliable improvement during the intervention. No other changes, meeting the RCI criterion, were observed. SP4’s scores on the measure of depression and anxiety remained high throughout the study.

Table 12: SP4's Standard outcome measures scores

SP4	PASS-20 Total score	PCS Total score	CPAQ Total score	PDI	HADS-A	HADS-D
Ax	66	35	42	47	13	13
Pre	46	28	49	48	10	8
Post	34	19	53	35	9	12
Ax-Pre	-20*	-7	-7	1	-3	-5
Pre-Post	-12	-9*	4	-13*	-1	4

Note. Participant's scores are presented at different points in time: Assessment (Ax), Pre-intervention (Pre), Post-intervention (Post), followed by calculations of difference between phases. *significant reliable change (RCI criterion at 0.05 level).

3.5.6 Activity results.

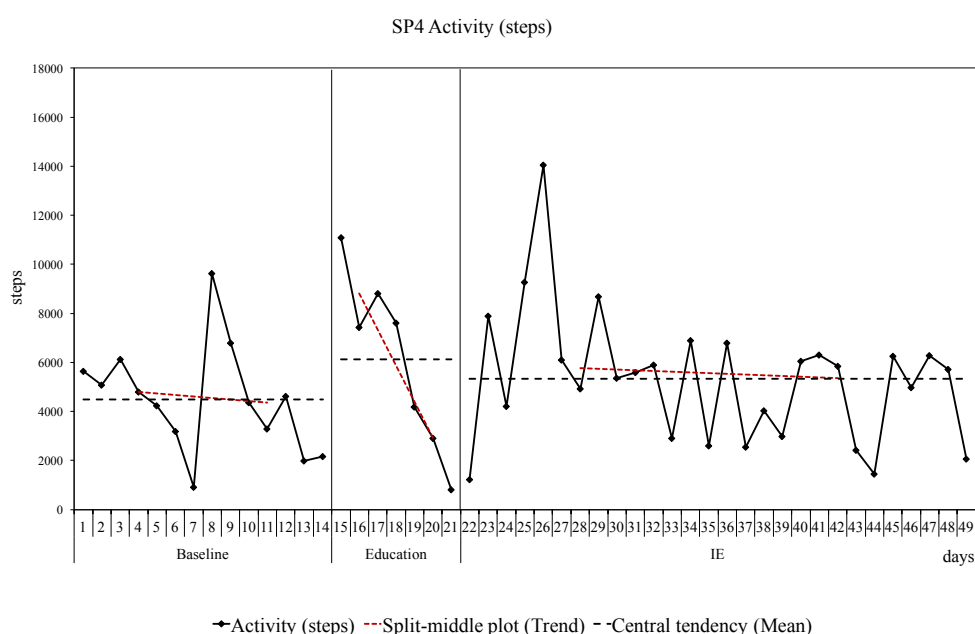


Figure 18: Visual display of SP4's Activity (steps) with markers of study phases, central tendency (mean), and split middle plot (trend) in each phase.

SP4's activity levels increased following the intervention. During the baseline phase the mean number of steps was 4485 (Min=923, Max=9632), during the Education phase it increased to 6119 (Min=819, Max=11079), which is an increase of 36% from the baseline. During the IE phase SP4's activity decreased as compared to the Education phase; however, it remained higher as compared to baseline at 5335 (Min=1210, Max=14062), with an increase of 19%. It is worth noting that the last three weeks of the IE phase (starting at day 31 of the study) fell during the festive period (Christmas and New Year), and SP4 reported being significantly less active due to spending time with his family.

3.5.7 Change Interview.

SP4 commented that he did not notice any changes in himself following the intervention. He had several ideas about why this might be, including that he might need more time to be able to use IE, as distracting himself from his pain is a ‘habit of a lifetime’.

“I’m struggling with the idea of what we’ve got going on, but I think that’s because for a length of time I’ve done it the other way. So, maybe it will slot in at some point, I don’t know, It hasn’t really, well I don’t know what I was expecting, you are telling me that it’s not going to get rid of my pain and it hasn’t, but I don’t feel any better for sitting and thinking about it.” (SP4)

He also mentioned that he might have false expectations from taking part in the study:

“Well, I just want to get rid of it [pain], I know what you are saying is that I won’t get rid of it, but if I can deal with it better, because it does rule your life, it’s always on your mind (...) I know damn well I cannot get rid of it, because we threw everything on it, all the pills and potions and everything and nothing seems to affect it, apart from morphine.” (SP4)

Despite the disappointment with lack of improvement in his pain management, SP4 commented that he found taking part in the study ‘helpful’, as he felt that it gave him “other options”, something to think about. SP4 commented that travelling to sessions was difficult due to pain, he also commented that the Daily Diary Fear of Pain questions were repetitive after a while:

“Some of the questions at the bottom of the thing [Daily Diary], maybe mixing them up a little bit, because they just become, I’m just circling the things from before, because things are the same (..) whereas when you are mixing them up a bit and asking different questions maybe you get something out of it.” (SP4)

SP4 reported no changes in his medication regime.

3.6 Participant 5

3.6.1 Background and pain history.

SP5 is a White British male in his 60s, experiencing chronic pain, which he attributed to Crohn's disease. He described that his pain became more severe in the last ten years, following multiple surgical procedures due to Crohn’s. He lived with his wife. He was able to perform light house chores and DIY. He worked as a civil servant and took early retirement due to health problems. He described his pain as: “gripping, stabbing, sort of like someone kicking me in the gut all the time”. SP5’s coping strategies included: taking medication, and going to bed. He noticed that he withdraws from his family when in pain.

3.6.2 Engagement in intervention.

During the initial assessment SP5 was visibly distressed; he was fidgety, his face was flushed and he visibly perspired. He explained that he had just come off his morphine and

was noticing symptoms of opioid withdrawal. One week later he reported feeling better in himself and able to participate in the study. SP5 engaged very well during the Education session; however, he did not perceive himself to be fearful of his pain. He explained that his pain frustrates him more than scares him, as he had pain for most of his life. SP5 was extremely motivated to reduce the use of opioids, and was hoping that this study would help him by providing an alternative to pain medication.

SP5 scored 3 out of 7 on the adapted Revised Neurophysiology of Pain Questionnaire (NPQ-R). His initial understanding of pain was that: “pain means that there is something wrong with me physically, after operations there are adhesions in bowels”. Following the Education session his score improved to 6 out of 7.

During the first IE practice in session, SP5 noticed increased pain distress. He was able to follow the instructions and he was positive that he could start practicing at home with the aid of the MP3 player. During home practice SP5 reported experiencing more distress, as recorded on the Pain Desensitising Chart (see Appendix R). Most of the time (88%) SP5’s pain distress increased following the IE practice, 10% of times it remained the same, and 2% of times it decreased. The range of change in distress was between 1 to 3 points on a 10-point scale. SP5 commented that following IE practice he was able to learn more about his pain. After the first week of using the exercise he commented that he learned that he has two types of pain:

“One starts as ache in the front, it then goes to the back and up, the other type of pain is like stabbing, it’s very difficult to deal with and you get that impulse to get some painkillers and get over it.” (SP5)

In the first week of the IE practice SP5 reported that his distress increased very slightly as he was able to notice his pain more; however, as the intervention progressed SP5 commented that he became disappointed with the exercise, as he hoped for the pain to be less distressing. He explained that he was able to focus on his pain; however, focusing on pain tended to increase its intensity, and subsequently the distress.

3.6.3 Fear of Pain results.

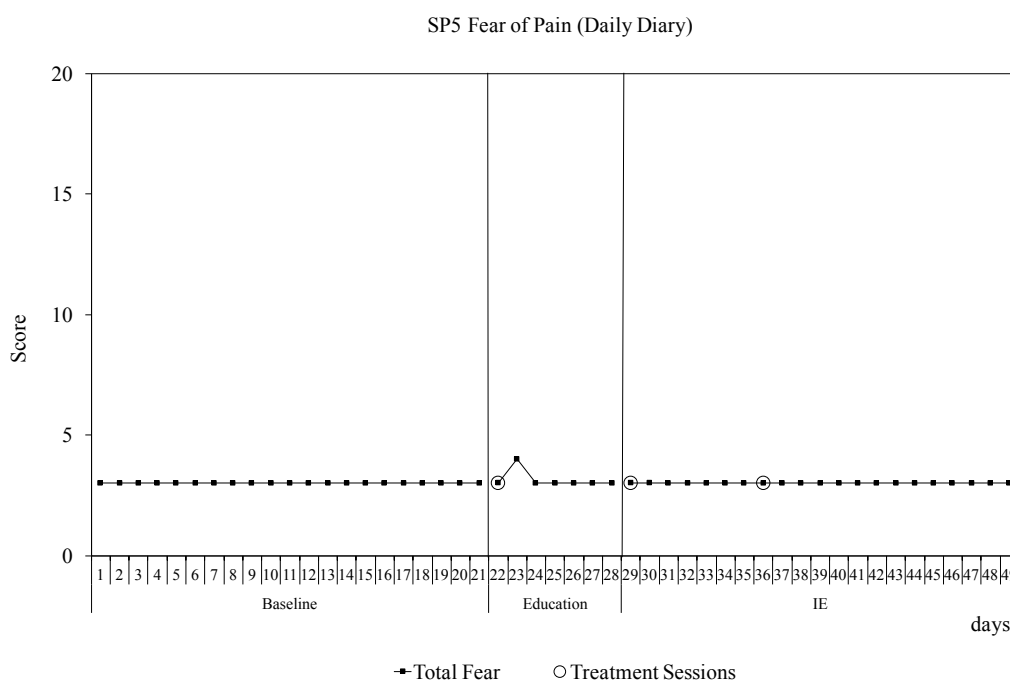


Figure 19: Visual display of SP5’s Fear of Pain (Daily Diary) scores with markers of study phases.

SP5’s data shows no changes in levels of Fear of Pain throughout the intervention, with very low scores. There were no significant events during day 23 of the intervention; however, pain distress and interference data show a concurrent increase in scores between the 22nd and 26th day of the intervention (see Figure 20 below). The increase in pain distress/interference might explain the increase in SP5’s Fear of Pain Scores, alternatively the increase in Fear of Pain might be due to a recording error.

3.6.4 Distress and Pain Interference results.

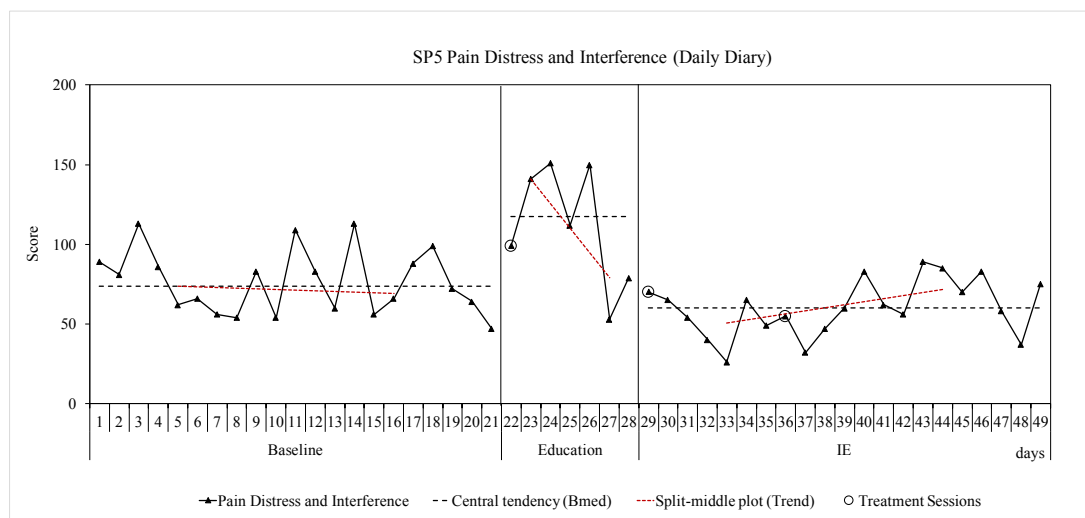


Figure 20: Visual display of SP5’s Pain Distress and Interference scores with markers of study phases, central tendency (broadened median), and split middle plot (trend) in each phase.

There is variability in SP5's Pain Distress and Interference scores throughout the intervention. During the baseline period SP5's scores were moderate (Bmed=74). Following the Education session there was a marked increase in Distress and Interference (Bmed= 117, increase of 59%, as compared with baseline). Following the introduction of IE, the scores reduced, and remained 18% lower as compared with the baseline (Bmed=60).

3.6.5 Standard measures.

As can be seen in Table 13 SP5's scores on standard measures of pain anxiety and catastrophising were low on assessment, nonetheless within the caseness range. There is an instability in baseline on the measure of pain disability (PDI), with reliable worsening, which cannot be attributed to the intervention. Both PASS-20 and PCS scores improved during the intervention; however, only the change on the PCS met a reliable and clinically significant change criterion. No other changes, meeting the RCI criterion, were observed. SP5's scores on the measure of depression and anxiety remained low, within non-caseness range throughout the study.

Table 13: SP5's Standard outcome measures scores

SP5	PASS-20 Total score	PCS Total score	CPAQ Total score	PDI	HADS-A	HADS-D
Ax	34	25	72	26	1	6
Pre	41	30	55	38	3	5
Post	27	12	80	44	2	4
Ax-Pre	7	5	-17	12**	2	-1
Pre-Post	-14	-18* ^a	25	6	-1	-1

Note. Participant's scores are presented at different points in time: Assessment (Ax), Pre-intervention (Pre), Post-intervention (Post), followed by calculations of difference between phases. *significant reliable change (RCI criterion at 0.05 level), ^a clinically significant change, **significant reliable change in the non-predicted direction (worsening).

3.6.6 Activity results.

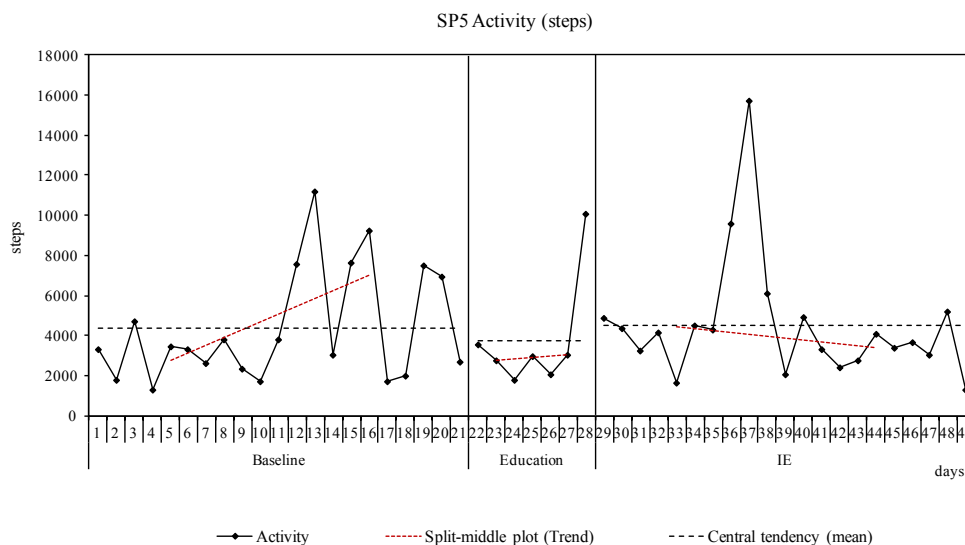


Figure 21: Visual display of SP5's Activity (steps) with markers of study phases, central tendency (mean) and split middle plot (trend) in each phase.

SP5's activity ratings show variability over the duration of the study. During the baseline period the mean number of steps was 4372 (Min=1290, Max=11194), during the Education phase it decreased slightly to 3754 (Min=1761, Max=10101), 14% reduction as compared with baseline. During the IE phase SP5's activity returned to baseline levels, with mean number of steps of 4507 (Min=1327, Max=15739), a 3% increase as compared with baseline.

3.6.7 Change Interview.

SP5 reported that he found no benefit from using the IE exercise, and that he found listening to the recording disappointing. He also commented that focusing on his pain was helpful, and that it had a paradoxical effect: "it did help me in the initial stages, it did help me to concentrate on the pain, therefore it helped me to control it a bit better". SP5 reported two changes following the study, and he rated them on the expectancy, likelihood without the intervention, and importance scales, see Table 14.

Table 14: Changes reported by SP5 during the Change Interview rated by their expectancy, likelihood without intervention and importance.

Change	Change was:	Without therapy:	Importance:
1. Understand my pain more	Somewhat surprised by it	Somehow unlikely without it	Very
2. Better at sitting and ignoring pain	Somewhat surprised by it	Somehow likely without it	Extremely

SP5 commented that the most useful and helpful element of the intervention was being able to talk to the researcher about his pain: "by talking about my pain with you it became easier for me to understand it and therefore try to ignore it". SP5 also commented on several difficult aspects of taking part in the study:

"Sometimes I had to push myself, especially towards the end, when I sort of got it in my mind that it isn't working, I thought it might be a waste of time, I gave it a go, so I've kept going, but it has been a bit more difficult than I would have thought."
(SP5)

SP5 reported significant reduction in his opioid medication one week before the commencement of the study. Throughout the study he reported a further, more gradual, reduction in opioids.

3.7 Participant 6

3.7.1 Background and pain history.

SP6 is a White British female in her 20s, who experienced chronic pain for over 6 years, which she attributed to symphysis pubis dysfunction, and failed back surgery. She explained that her pain became disabling after the birth of her first child. SP6 was in a relationship and lived with family. She had stopped working in care due to pain. She described her pain as:

“like stubbing your toe, comes in throbs, feels like when you have a toothache and you touch it you feel this kind of pain”. SP6 was unable to perform housework and relied on the help of her partner. Her coping strategies included: taking painkillers, and going to bed. SP6 reported being prescribed high doses of opioid medication.

3.7.2 Engagement in intervention.

Attending sessions was very difficult for SP6 due to high levels of anxiety. SP6 explained that for the last couple of years her confidence and ability to be sociable diminished, due to long periods of being extremely unwell. SP6’s anxiety was visible during the first two sessions, where she avoided eye contact, was fidgety, and reported very high levels of pain. During the study SP6 reported several days of being bed bound due to severe pain, which she described as ‘normal’ for her current health. During the baseline period SP6’s activity monitor got accidentally broken and had to be replaced.

Before the education session SP6 explained that pain means that “something is not right, it means that it's not normal”. SP6 engaged well during the Education session, she recognised avoidance and fear of pain in herself. She said: “I just panic when the pain gets worse”. SP6 had poor knowledge of pain physiology prior to taking part in the study, as indicated by the Revised Neurophysiology of Pain Questionnaire (NPQ-R). Her score on the adapted RNPQ was 4/7, dropping to 2/7 after the Pain Education session.

SP6’s pain distress (as measured by Pain Desensitising Chart, see Appendix R) was usually higher after practicing the IE exercise (87% of the time), 13% of the time it remained the same. The magnitude of increase in distress varied between 1 to 5 points on a 10-point rating scale. SP6 reported that each time she practised the IE exercise she noticed increase in pain; however, its nature changed. SP6 noticed that when she voluntarily focused on her pain, it came in short severe bursts, after which she was able to resume the activity she was doing before. In contrast, when distracting herself in the past, the pain seemed to have a more long-lasting effect, and forced her to stop any activity.

3.7.3 Fear of Pain results.

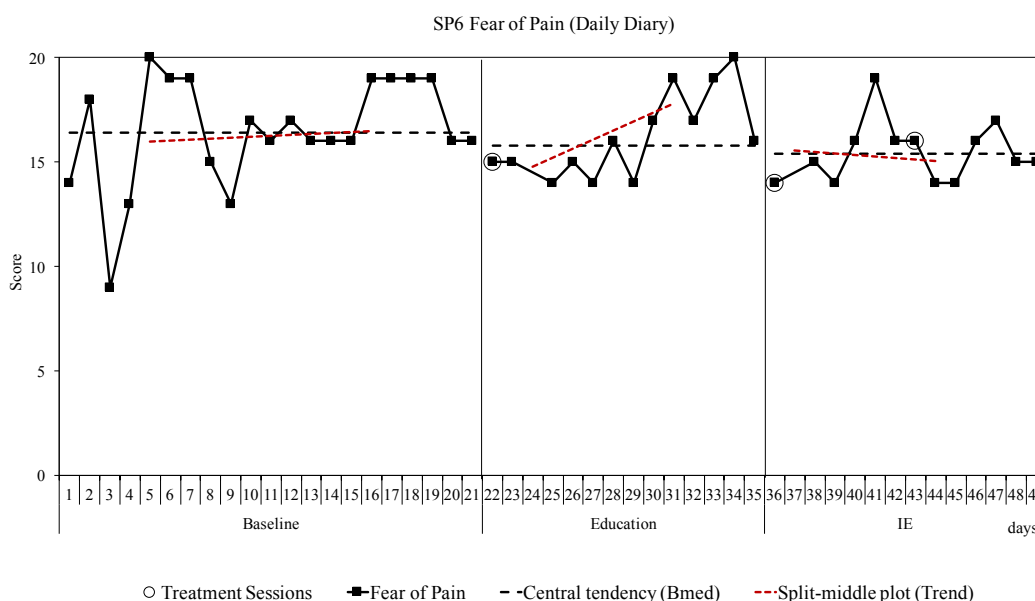


Figure 22: Visual display of SP6’s Fear of Pain scores with markers of study phases, central tendency (broadened median), and split middle plot (trend) in each phase.

SP6’s Fear of Pain scores showed variability across all phases of the study. Baseline scores were high (BMed=16.4), and remained high during the Education phase (BMed=15.8) and IE phase (BMed=15.4). SP6’s scores of Fear of Pain did not show any significant change during the intervention, and remained very high throughout. Fear of Pain levels remained high, with slight variation in scores throughout the study.

3.7.4 Distress and Pain Interference results.

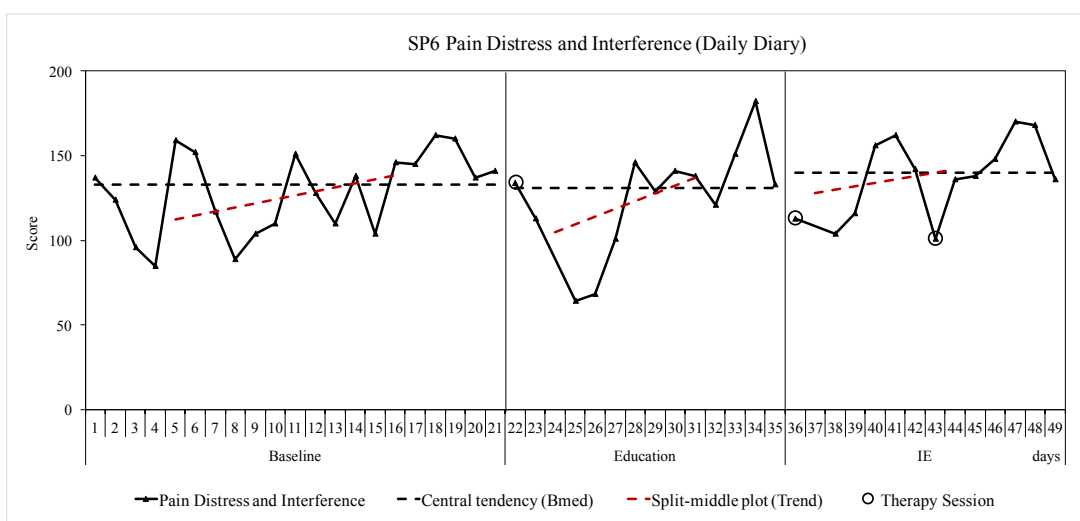


Figure 23: Visual display of SP6’s Pain Distress and Interference scores with markers of study phases, central tendency (broadened median), and split middle plot (trend) in each phase.

There was an upward trend in SP6’s Pain Distress and Interference scores during the baseline period, with moderate to high scores (Bmed=133). During the Education phase there was a sharp drop in scores, followed by a sharp increase. Pain Distress and

Interference scores remained similar between the baseline and Education phase (Bmed=131, decrease of 1%). Following the introduction of IE there was a slight upward trend: scores were 5% higher as compared with baseline (Bmed=140).

3.7.5 Standard measures.

As can be seen in Table 15, SP6's scores on standard measures of pain anxiety and catastrophising were elevated on assessment, and within the caseness range. There was an instability in baseline on the measure of pain anxiety (PASS-20), with reliable worsening, which could not be attributed to the intervention. Both PASS-20 and PCS scores improved during the intervention, and both met the reliable change criterion. SP6's scores on the measure of depression and anxiety were high on assessment, within the caseness range. SP6 improved on the measure of depression following the study. No other changes, meeting the RCI criterion, were observed.

Table 15: SP6's Standard outcome measures scores

SP6	PASS-20 Total score	PCS Total score	CPAQ Total score	PDI	HADS-A	HADS-D
Ax	68	42	38	66	16	13
Pre	87	45	52	61	15	15
Post	56	36	62	53	9	8
Ax-Pre	19**	3	14	-5	-1	2
Pre-Post	-31*	-9*	10	-8	-4	-7* ^a

Note. Participant's scores are presented at different points in time: Assessment (Ax), Pre-intervention (Pre), Post-intervention (Post), followed by calculations of difference between phases. *significant reliable change (RCI criterion at 0.05 level), ^a clinically significant change, **significant reliable change in the non-predicted direction (worsening).

3.7.6 Activity results.

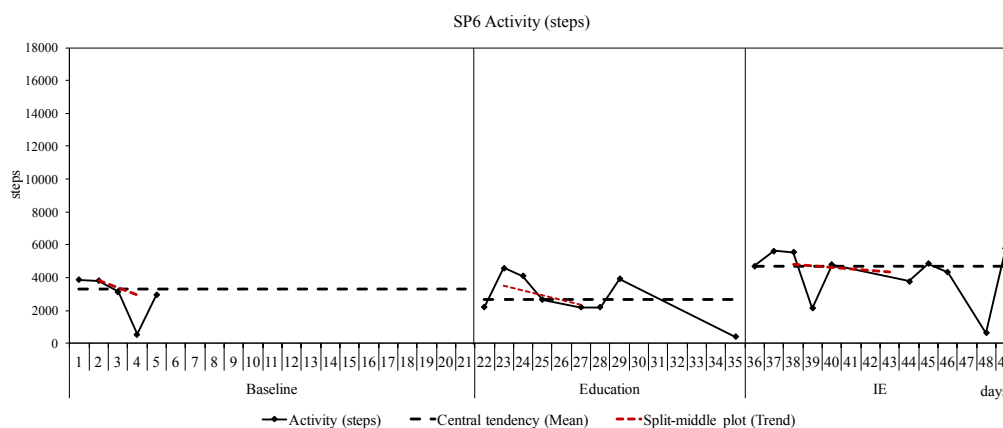


Figure 24: Visual display of SP6's Activity (steps) with markers of study phases, central tendency (mean), and split middle plot (trend) in each phase.

SP6's activity levels increased during the study; however, there was a significant amount of data missing (47%), therefore any conclusions need to be treated with caution. SP6's mean number of steps during the baseline period was 2862 (Min=542, Max=3870), during the Education phase SP6's activity decreased to 2784 (Min=391, Max=4600, 2%

reduction). During the IE phase SP6’s activity increased to 4220 (Min=633, Max=5803). This represents a 47% increase in activity as compared to baseline. This finding is consistent with SP6’s self-reported increase in activity, see SP6’s Change Interview responses below.

3.7.7 Change Interview.

SP6 reported multiple changes during the Change Interview, which she attributed to the intervention. Table 16 shows changes that she experienced and her perceptions of them.

Table 16: Changes reported by SP6 during the Change Interview rated by their expectancy, likelihood without intervention, and importance.

Change:	Change was:	Without therapy:	Importance:
1. I know now that I am not going to die because of pain	Very much surprised by it	Somewhat unlikely	Extremely
2. I don’t take myself to bed immediately	Somewhat surprised by it	Very unlikely	Very
3. I feel like I can manage the feeling of pain better	Very much surprised by it	Somewhat unlikely	Very
4. When I sit with pain it feels stronger but then it passes quicker	Very much surprised by it	Very unlikely	Extremely

SP6 commented on several helpful aspects of the intervention and, more generally, of taking part in the study, including being able to “talk to someone who understands pain”, having some time out of the house: “it’s been like my own peace and quiet from kids”, and being able to build a positive relationship with the researcher: “I’ve build kind of a bond thing with you then I do feel more relaxed”. SP6 also commented on several unhelpful aspects of the study, including travelling to sessions, sitting still during the sessions (as she did not feel comfortable to stand up), and managing her anxiety. SP6 made several suggestions on how the study could be improved, including introducing the IE exercise earlier on in the study, using a numeric scale rather than the visual analogue scale on the Daily Diary, and/or having a longer study period.

3.8 Participant 7

3.8.1 Background and pain history.

SP7 is a White British female in her 30s, who experienced chronic pain since the age of ten. She was diagnosed in the past with complex regional pain syndrome (CRPS); however, her current diagnosis was ‘chronic pain’. She had widespread pain in her back, radiating to her abdomen and hips, which would worsen towards the end of the day. SP7 described that she was unable to sit still for more than 20 minutes, and had to regularly lie down to ease her pain. She was single and lived with family. She had stopped working due to pain, her most recent job being in administration. In the past SP7 had input from an inpatient chronic pain

service. She had experience of multiple pain treatments: relaxation, calm breathing, mindfulness, physiotherapy, and others. Her current coping strategies included: using hot packs, laying down, and resting. She did not use any regular pain medication.

3.8.2 Engagement in intervention.

SP7 engaged well throughout the duration of the study. SP7 hoped that the IE exercise would be more useful than mindfulness. She explained that she found mindfulness very difficult in the past, and that she could not picture things in her mind's eye, which made her quite frustrated.

SP7 had a very good understanding of chronic pain prior to the start of the study. She explained that she learned a lot about chronic pain in the past, and was able to explain how pain does not necessarily mean damage. Her scores on the Revised Neurophysiology of Pain Questionnaire (NPQ-R) represented this. She scored 5/7 on the adapted NPQ-R before the Education session, and 6/7 afterwards.

SP7 was able to follow the instructions of the IE exercise in session; however, she noticed that her mind wandered during the exercise. She also experienced slightly more pain distress afterwards. After the first week of home practice, she reported that she struggled with the exercise. She said that it did not work, and that it was similar to Mindfulness. SP7 understood that the IE exercise was not designed to reduce the intensity of pain; however, she did not feel that it helped her to be less distressed by pain. SP7 hoped that during the next week of IE, things would improve. SP7 struggled during the second week of the IE practice, as she felt that the IE exercise did not work for her, which she blamed on her inability to use it, rather than the exercise itself. During the last week of the intervention SP7 had a family celebration, which caused her to 'overdo things' and suffer from increased pain. Self-rated levels of pain distress (as recorded on the Pain Desensitising Chart, see Appendix R) before and after the IE practice remained stable for SP7; 48% of times pain distress remained the same following IE practice, 30% of times it reduced (1 point of difference), and 22% of times it increased (1-2 points difference). SP7 recorded three brief practices of IE on top of the regular practice. She explained that she would repeat in her mind the part of the exercise about how the pain is an activity in the nerves and how it is not telling her anything new. SP7 reported not being able to focus her attention on pain during the brief practices, due to fear that it would increase the pain, and she would not be able to continue with the activity she was doing at the time.

3.8.3 Fear of Pain results.

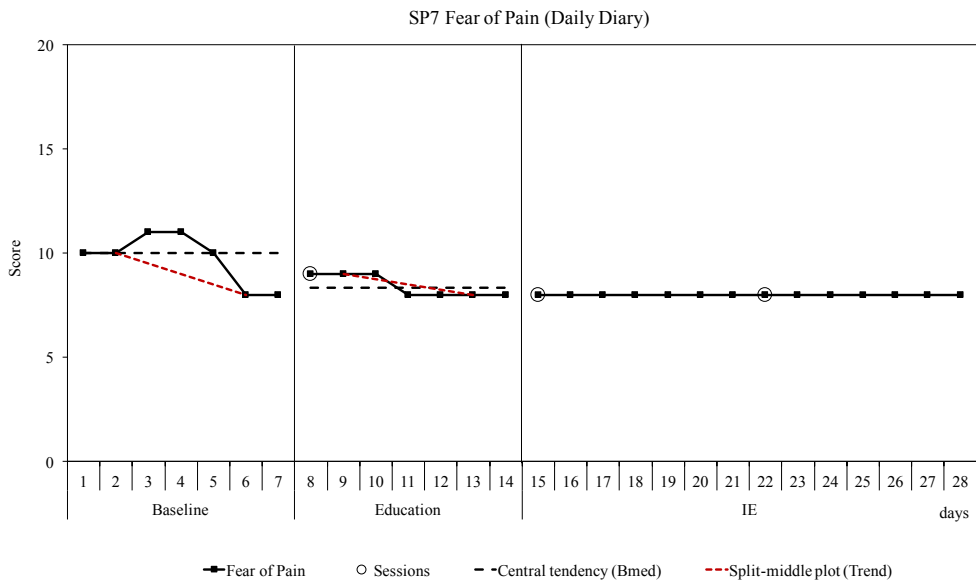


Figure 25: Visual display of SP7’s Fear of Pain (Daily Diary) scores with markers of study phases, central tendency (broadened median) and split middle plot (trend) in each phase.

SP7’s Fear of Pain scores showed stability and remained unchanged from day 11 of the intervention (baseline) onwards. The scores were moderate, with central tendency in the baseline of 10, and 8 across the Education and IE phases.

3.8.4 Distress and Pain Interference results.

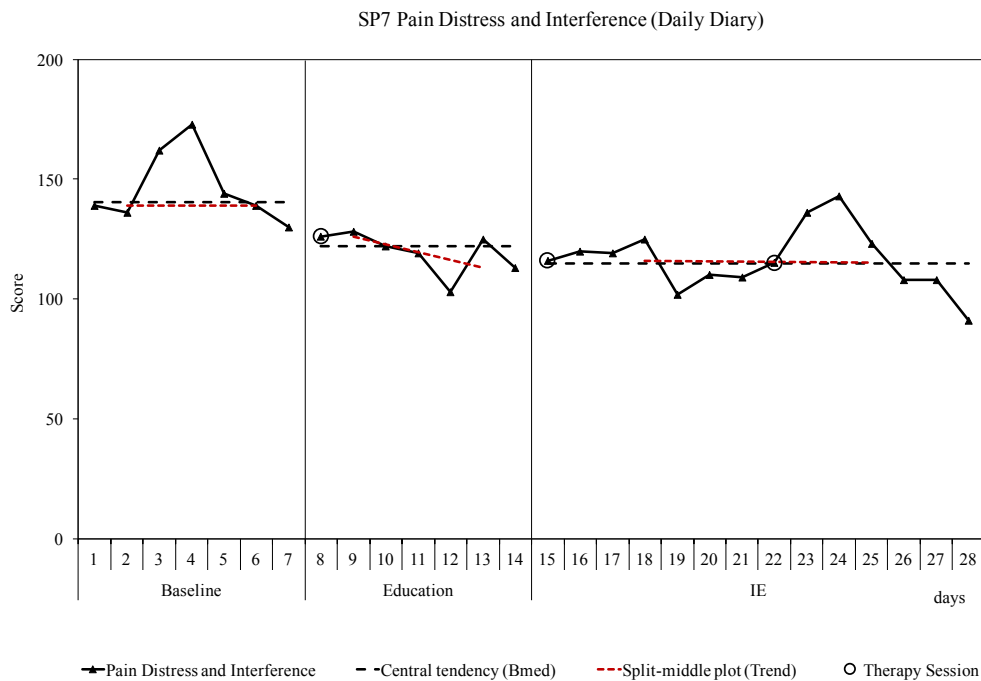


Figure 26: Visual display of SP7’s Pain Distress and Interference scores with markers of study phases, central tendency (broadened median), and split middle plot (trend) in each phase.

SP7’s Pain Distress and Interference scores during the baseline period were high (Bmed=141). During the Education phase there was a downward trend, with lower scores

(Bmed=122, reduction of 13%). During the IE phase there was some variability, with moderate to high scores (Bmed=115, reduction of 18% as compared with the baseline).

3.8.5 Standard measures.

As can be seen in Table 16, no changes, meeting the RCI criterion, were observed on any of the standard outcome measures for SP7. Her scores on standard measures of pain anxiety and catastrophising were elevated, and within the caseness range. Similarly, SP7's scores of depression and anxiety remained within the caseness range throughout the study.

Table 16: SP7's Standard outcome measures scores

SP7	PASS-20 Total score	PCS Total score	CPAQ Total score	PDI	HADS-A	HADS-D
Ax	44	31	30	53	13	10
Pre	49	32	29	57	11	10
Post	46	30	35	55	11	9
Ax-Pre	5	1	-1	4	-2	0
Pre-Post	-3	-2	6	-2	0	-1

Note. Participant's scores are presented at different points in time: Assessment (Ax), Pre-intervention (Pre), Post-intervention (Post), followed by calculations of difference between phases.

3.8.6 Activity results.

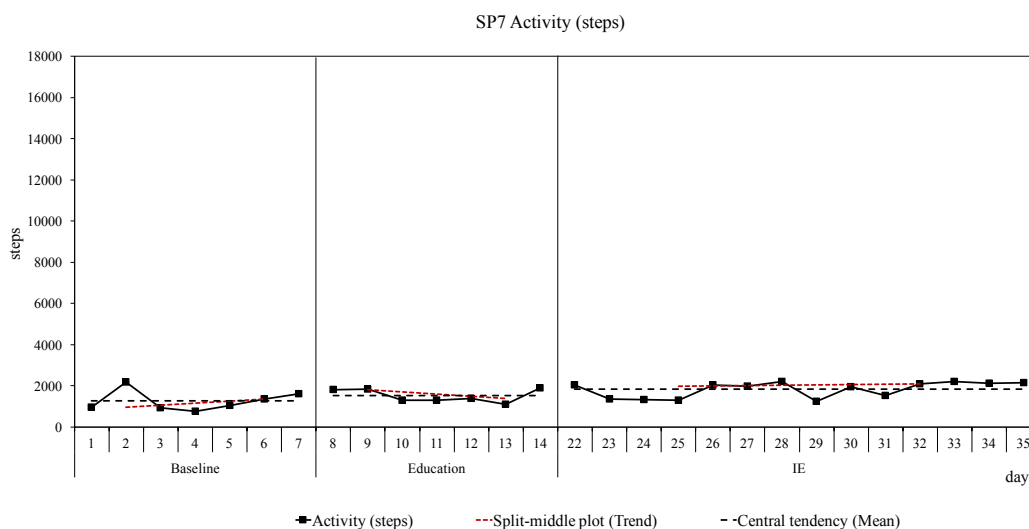


Figure 27: Visual display of SP7's Activity (steps) with markers of study phases, central tendency (mean), and split middle plot (trend) in each phase.

SP7's activity levels showed little variability. During the baseline SP7's mean number of steps was 1264 (Min=755, Max=2183), during the Education phase there was an increase of 20% (Mean=1522, Min=1105, Max=1896). During the IE phase there was an increase of 44% from baseline (Mean=1830, Min=1261, Max=2207).

3.8.7 Change Interview.

SP7 reported no changes following the intervention. However, she described the IE exercise as 'semi-helpful':

“I suppose having that time just to stop and focus on the pain, relax and do the breathing was perhaps semi-helpful, time to stop for a minute and time to practice focusing my brain, because that’s one of the things that I struggle as well, was obviously just concentrating.” (SP7)

SP7 was sceptical about the rationale behind IE in chronic pain, specifically the idea of separating pain distress from pain intensity:

“It’s difficult to understand to how you can have that amount of pain and it not bothering you, because pain is pain, even if it is not intended to bother you, because it is like ‘hello there is something wrong’, but even if you know that there isn’t something wrong the pain level is the same, so I don’t know, it’s difficult to describe, still hurts.” (SP7)

When asked about the unhelpful aspects of the study, SP7 explained that it brought up feelings she had in the past about coping with pain:

“Like that it’s me [not the intervention] that is failing, because it is not doing anything, and again that things that maybe work for other people in similar situations, which means that it must be me who is not doing it right.” (SP7)

SP7’s suggestion for the study was to extend its duration, which could allow more time to practice the IE, and maybe help notice any changes:

“Maybe this is something that needs to be done for longer to change because it’s trying to change how your brain has worked for like since the last 15 years or more, and then to try and change the way you think, I would have thought it would take quite a while for something to change, maybe it works for other people, maybe it’s just my brain that doesn’t want it to work.” (SP7)

SP7 reported no changes in her medication regime throughout the duration of the study, she explained that she was not taking any painkillers on a regular basis, as she suffered with side effects in the past.

3.9 Summary of the Results

To help summarise the results for all study participants, and answer study questions, we compiled outcomes on all target and standard outcome measures in Table 17.

Table 17: Evidence of change on target, standard, and process outcome measures for all participants following the introduction of the intervention.

Participant	SP1	SP2	SP3	SP4	SP5	SP6	SP7
Target measures							
Fear of Pain (Daily Diary)							
Distress/Interference (Daily Diary)			**				
Activity (steps)							
Standard measures							
PASS-20							
PCS							
CPAQ							
PDI							
HADS-A							
HADS-D							
Process measure							
Change Interview							

Note. Greyed out cells represent change on relevant outcome measures, meeting the appropriate criteria, as described in individual results analysis earlier in the chapter; **change in non-predicted direction (worsening).

3.10 Answering Study Questions and Testing Hypotheses

The main question this study aimed to answer was: Did the intervention reduce the fear of pain and increase the levels of physical activity? In order to answer this question, several hypotheses were explored, as described below.

H_1 : The intervention will reduce the fear of pain.

Fear of Pain was measured by the Daily Diary (target measure), PASS-20 and PCS (standard measures). Analysis of the data shows mixed results. Five participants (SP1, SP2, SP4, SP5 and SP6) made significant reliable improvement on the measure of catastrophising (PCS), and four of them (SP1, SP2, SP4 and SP4) made clinically significant change, and all fell into a normal range (non-caseness). Three participants (SP1, SP2 and SP6) made a reliable change on the measure of PASS-20; however, SP6 had an unusual score profile, where she significantly deteriorated during the baseline period, which might undermine the validity of her improvement. Visual analysis of the daily scores of Fear of Pain (Daily Diary) showed marked improvements for three out of seven participants (SP1, SP2 and SP3).

SP4, SP5 and SP7 all reported no fear of pain; however, only for SP5 was this supported by outcome measures scores (low daily scores of Fear of Pain, lower range of clinical scores on the PCS and PASS-20). For SP4 and SP7 the reported lack of fear of pain conflicted with their outcome measures scores (stable yet moderate daily scores of Fear of Pain and elevated scores on PASS-20 and PCS). No worsening on measures of fear of pain was observed.

In summary, only two participants (SP1 and SP2) improved on all three measures of Fear of Pain. SP6 improved on two out of three outcome measures of Fear of Pain (PCS and PASS-20), whilst SP3, SP4 and SP5 improved on one out of three Fear of Pain outcome measures. SP7 did not improve on any of the measures of Fear of Pain. There is strong evidence that practicing IE reduced the Fear of Pain for three out of seven participants (SP1, SP2 and SP6). For two participants (SP3 and SP5) the evidence is mixed, whilst for the remaining two (SP4 and SP7) there is little or no evidence to support reduction in Fear of Pain.

H₂: Reduction in fear of pain will increase activity levels.

According to the FAM reduction in fear of pain should encourage increase in activity levels. Two out of three participants, who improved on at least two measures of the Fear of Pain, had increased their activity levels (SP1 and SP6). Out of the two participants (SP3 and SP5) who had mixed improvement on the measures of fear of pain, neither had increased their activity levels. In summary, our prediction regarding reduction in fear of pain and increase in activity could not be confirmed. Activity levels increased in SP4 and SP7, despite lack of improvement in fear of pain. Following the above findings, we proposed an ad hoc hypothesis, which would not require improvement in fear of pain for the activity levels to increase:

H_{2.1}: The intervention will increase activity levels.

Following the intervention four participants (SP1, SP4, SP6 and SP7) made significant improvements in their activity levels (between 22 and 40% improvement as compared with baseline). Three participants (SP2, SP3, SP5) made no significant improvement (increase between 1 and 6%). No declines in activity levels were recorded following the intervention. This would indicate that the intervention did increase activity levels in four out of seven participants; however, factors other than fear of pain might be responsible for this change.

The literature review indicated the importance of measuring several other variables, linked to the fear of pain and the FAM. These were: pain distress and interference, acceptance of pain, disability, and mood. Therefore, hypotheses three, four, five and six were proposed, which we will explore next.

H₃: The intervention will reduce pain distress and interference.

Pain Distress and Interference were measured by the Daily Diary. Visual analysis of the data suggests that four participants (SP1, SP2, SP5 and SP7) improved; however, changes were small. For SP4 and SP6 Pain Distress and Interference shows variability across the duration of the study. SP3's Pain Distress and Interference data indicates worsening. In summary, the intervention was not shown to reduce Pain Distress and Interference.

H₄: The intervention will increase the acceptance of pain.

None of the study participants made significant changes on the CPAQ measure of acceptance of pain. Therefore, our prediction was not confirmed.

We did not expect to see any changes on the measure of pain disability (PDI), due to the fact that our intervention was so brief (3 weeks), and participants' problems were chronic. Additionally, we did not expect to see any changes on the measure of general anxiety and depression, as this might indicate that participants' improvement was triggered by improvement in mood, rather than reduction in fear of pain, or increase in pain acceptance.

H₅: The intervention will not reduce disability levels.

H₆: The intervention will not affect mood as measured by HADS.

Both predictions were correct, as only one participant (SP4) improved on the measure of disability, and one participant (SP6) improved on depression subscale of HADS, following the intervention. No worsening on measures of disability, nor mood, was observed following the intervention.

Based on the current evidence and theoretical rationale behind IE, we hypothesised about how participants will engage with the IE exercise:

H₇: In the beginning there will be an increase in pain distress following IE practice, with time and practise the distress will decrease.

For three participants (SP1, SP5 and SP6) pain distress would consistently increase following IE practice, this was stable across time. For three participants (SP2, SP4 and SP7) pain distress would consistently remain the same following IE practice, this was stable across time. For one participant (SP3) initially the distress would be rated as higher after the IE practice, followed by decrease in self-reported pain distress. The evidence does not support our prediction regarding the process of IE.

4. DISCUSSION

4.1 Overview

In this chapter we will present the summary of the results, followed by a discussion of findings in relation to existing literature. Theoretical and clinical implications will be discussed next, followed by strengths and limitations of the study. Finally, questions arising from the study in the context of existing evidence will be raised, with implications for future research.

4.2 Summary of the Results

4.2.1 Standard and target outcome measure results.

The intervention had resulted in reduced fear of pain in some participants, but not all. Fear of pain was measured by: an idiographic outcome measure (Daily Diary), and two standard outcome measures of related concepts of pain anxiety and catastrophising (PASS-20 and PCS). Examination of participants' scores on the above measures shows variation. Our strongest finding was that the treatment reduced pain catastrophising. Five participants made significant reliable changes on the PCS, with four participants moving into non-caseness. Three participants made reliable changes on the PASS-20 measure.

Reduction in fear of pain did not lead to increase in activity, which suggests that the relationship between activity levels and fear of pain is likely to be more complex than we predicted. Whilst all study participants increased their levels of activity following the intervention, for only four participants was this change meaningful (improvement between 19-48%, see Appendix S).

Four participants improved on the Pain Distress and Interference scale as measured by the Daily Diary; however, changes were small. For two participants Distress and Interference scores showed variability, whilst one participant's scores indicated worsening.

Opposite to our predictions, the intervention did not seem to have any effect on pain acceptance, as measured with the CPAQ.

We did not expect to see any improvement on the measures of pain related disability (PDI), which was confirmed as only one participant had a reliable change. Neither did we expect to see any changes on measures of depression and anxiety (HADS); only one participant had a reliable change on the depression subscale of HADS.

4.2.2 Process evaluation of the intervention.

Two process measures: the Pain Desensitisation Chart (PDC) and the Change Interview, were used to evaluate the experience of Interoceptive Exposure (IE). For most participants self-rated pain distress often increased during or shortly after the practice. Only SP3 reported consistent decrease in distress following the IE practice during the final week of home practice. Others, who found benefit from IE reported fluctuating distress; however, increased ability to re-engage with activities and being able to take less medication. Data

from the Change Interviews confirmed that all seven participants were able to engage in daily practice of IE; however, they all found the exercise difficult to use at times, especially in the beginning of the intervention:

“The exercise hurt me a lot, (...) it was not easy at all! The first week I could have not thought about nothing worse to do I, but this week I have noticed, you know what, it’s quick enough to be done.” (SP6)

In contrast, several participants (SP1, SP2, SP3, SP5 and SP6) also reported that there were times when they found listening to the IE exercise “relaxing” and “enjoyable”.

Four participants (SP1, SP2, SP3 and SP6) reported benefits from using IE to manage their pain. Two participants (SP7 and SP4) reported no benefit from it, whilst SP5 reported a paradoxical effect of using IE to help him ignore his pain.

SP1, SP2, SP3 and SP6 all reported that during the IE practice they were able to experience a greater quality of their pain: “I notice more range of pain” (SP1), and noticed temporary increases in pain: “it gets stronger before it gets weaker” (SP2). All four participants commented that IE practice allowed them to sit with their pain, wait for it to pass, and resume their activities afterwards:

“I sit down and breathe through it, and sort of try to ease it down myself (...) now I’ve just got short bursts of pain and in between these I can do whatever needs to be done and then just sit down, breathe.” (SP6)

All four reported confidence in using the exercise following the intervention whilst listening to the recording and without it, in shorter unstructured practice. Two participants (SP4 and SP7) found practicing IE difficult and reported not being able to let themselves feel pain without trying to distract themselves from it, or trying to reduce it: “the moment I sit down quiet for any length of time I wander off, my mind goes, plays tunes or does something” (SP4). SP5 found the technique easy to use at first; however, he became disappointed as the treatment progressed about the lack of decrease in his pain distress following IE practice. Both SP4 and SP7, despite their difficulties with the IE practice, said that they will continue listening to the IE recording after the study is over. They both explained that distracting themselves from their pain was a longstanding habit, and that they might need more time to learn how to apply IE to their pain. Several participants commented that they were unable to practice IE when their pain was most severe:

“If it’s scaled between five and seven I normally just breathe through it, I carry on (...) whatever I’m doing, and then it eases off a bit, but if I’ve done that and it’s still not easing then I take myself to bed, enough is enough.” (SP6)

These findings indicate that IE practice can be helpful for individuals suffering from chronic pain; however, experiences of practising it can vary substantially between individuals.

4.3 Critical reflections

We used Elliot's hermeneutic single-case efficacy design (HSCED) approach to evaluate our findings, make links between the intervention and outcomes, and to consider non-therapy explanations for change (2002). HSCED's method requires scientific rigor of examining factors within the intervention and outside of the intervention, that could explain observed change. If no change was observed a question of why that might be is also considered. Study outcome data was used to answer these questions, including data from the Change Interview (Elliott, Slatick, & Urman, 2001). Our results were explored on a participant-by-participant basis to consider the evidence of change and the counter-arguments. Below you will see a summary of our HSCED.

4.3.1 Evaluating evidence that changes were caused by the intervention.

The starting point of HSCED is to identify evidence behind the intervention being the major cause of change (Elliot, 2002). This involves: establishing clear links between the therapy process and outcome, asking participants what caused various changes and how likely these changes would have occurred without the intervention, mapping stages of intervention to outcomes, especially being able to identify early change in stable problems following the introduction of treatment, and analysis of process measures and comparison of them with target and standard outcome measures.

Retrospective attribution.

The five participants who reported noticing changes following the intervention rated them as unlikely to happen without the intervention. However, three participants reported more than one change, some of which could be attributed to other than intervention factors. An example of this would be SP5's change of "Better at sitting and ignoring pain", which he rated as 'somehow likely [to happen] without' the intervention. Another example is SP2's: "Being more honest about how I really feel", which she rated as 'neither likely nor unlikely' without the intervention.

Other Change Interview answers provided additional causal evidence. When asked more generally about what caused all of the various changes, the five participants reported that it was the intervention. Moreover, all five participants spontaneously listed specific components of the intervention that they attributed these changes to:

Researcher: "Were there things in the therapy which were difficult or painful but still OK or perhaps helpful? What were they?"

SP2: "The most helpful was the recording [IE exercise] and setting time to do that, I am sure the forms and the wristband [activity monitor] was helpful for you, but for me the recording was most useful (...). Who would have thought that focusing on your pain can actually make a difference! (...) Until you've been through the experience, if you said to somebody: you don't need to take medication when it gets

bad they would look at you as if you gone [mad], because obviously as soon as I feel pain the first thing that I think about is taking something to take the pain away.”

Overall, support for the therapy efficacy hypothesis can be found in SP1, SP2, SP3, SP5 and SP6’s Change Interview comments.

Outcome to process mapping.

Changes reported by five participants (SP1, SP2, SP3, SP5 and SP6) during the Change Interview were linked to specific processes and events of the intervention. Additionally, outcome measures directly linked to the intervention target (i.e. catastrophising, pain anxiety, fear of pain and pain interference/distress) showed change following the introduction of the intervention, whilst the measure of mood (which was not the target of the intervention) showed stability. There is a clear line of evidence that the intervention was responsible for changes in five participants.

Process to outcome mapping.

Data from the Daily Diary (Pain Distress/Interference and the Fear of Pain) was graphically displayed to map any changes following the introduction of the intervention. Overall, for five participants (SP1, SP2, SP3, SP5 and SP6) there is evidence that changes in daily outcomes of Fear of Pain and Pain Distress/Interference correspond to specific events and processes within the intervention (i.e. changes in scores followed the introduction of the intervention).

Early change in stable problems.

In HSCED change can be attributed to intervention when it coincides with a shift in long-standing problems in contrast to baseline. Screening assessments included questions about the chronicity of the problem, and a baseline period was introduced to check for stability of investigated variables. For all participants there was evidence that their problems were chronic. Duration of chronic pain varied between participants; between 6 and 30 years. Standard outcome measures taken at assessment, and repeated before the introduction of the intervention, show stability in baseline across participants with few exceptions. For SP2 and SP4 there was a reliable improvement on the measure of pain anxiety (PASS-20) during the baseline, which is mirrored by a decreasing trend on the daily measure of Fear of Pain. SP6 showed reliable deterioration on PASS-20 during baseline, which is mirrored by an increasing trend on daily ratings of Fear of Pain. SP3 showed reliable deterioration on PCS during the baseline, which is mirrored by a sharp increasing trend in daily ratings of Fear of Pain. Additionally, SP5 showed a reliable deterioration on the measure of disability during baseline. Daily ratings of Fear of Pain, Pain Distress/Interference, and activity show variability across participants, with few exceptions. Daily ratings of Fear of Pain and Pain Distress/Interference show fluctuations and presence of trend across the majority of

participants. Evidence for early change in stable problems for participants is weak, because of instability in baseline on target outcome measures for all participants. This is a limitation in linking the change to intervention.

Event-shift sequences.

It is assumed that important events during treatment should precede a stable shift in participants' target problems. This was observed in SP1, SP2, SP3, SP6 and SP7's daily scores of Fear of Pain and/or Pain Distress and Interference. SP4 and SP5's daily scores of Fear of Pain and Pain Distress and Interference show random fluctuations.

4.3.2 Evaluating non-treatment explanations for change.

Non-improvement or trivial change.

Reliable Change Index was calculated for all standard measures to ensure that changes are reliable and clinically significant (Jacobson & Truax, 1991). Four study participants (SP1, SP2, SP4 and SP6) had global reliable change (reliable improvement in at least two out of three standard outcome measures). Additionally, all four improved on at least one target measure. SP5's improvements met the RCI criterion only on the measure of pain catastrophising. For SP3 and SP7 there were no changes on standard outcome measures meeting the RCI criterion. SP3's only improvement was on the daily ratings of Fear of Pain; however, there are two other sources of data (i.e. Change Interview and Pain Desensitisation Chart) that support the evidence for SP3's change. SP7 improved on daily ratings of Pain Distress/Interference and activity; however, this improvement was not supported by data from her Change Interview. SP4's Change Interview does not provide any evidence for change, which undermines the causal link between the intervention and improvement in activity and daily pain distress.

Overall, there is strong evidence for reliable and significant improvement and important change for three participants (SP1, SP2 and SP6). There is less evidence supporting change for SP3 and SP5, whilst there is mixed evidence that change occurred for SP4 and SP7.

Negative changes.

For three participants (SP3, SP5 and SP6) there were isolated reliable deteriorations in one of the standard outcome measures during the baseline, before the introduction of the intervention. None of the participants commented on any factors outside or within the study that could explain the recorded deterioration. SP5's deterioration could be explained by a measurement error; however, for SP3 and SP6 there was supporting evidence of deterioration in daily ratings of fear of pain. It is possible that deterioration during baseline was an artefact of daily recording, which could make SP3 and SP6 more aware of the severity of their problems, and in turn artificially inflate their scores.

What is most relevant is that there were no significant and reliable deteriorations on standard measures for any of the participants following the introduction of the intervention. Moreover, none of the participants reported any negative changes or side effects of the intervention during the Change Interview.

Relational artefacts.

We considered whether relational artefacts could explain changes observed in participants. We analysed the data for evidence of the “hello-goodbye” effect, described by Elliot (2002) as tendency to emphasise distress at the start of the intervention, in order to justify the need for the treatment, followed by an exaggeration of improvement at discharge, to either show gratitude and/or to justify the wish to end therapy. Additionally, we looked into any evidence of participants failing to disclose any difficulties or disappointments with the treatment in order to please the researcher and act in a socially desirable manner (Gale, 2000).

During the Change Interview all participants were able to comment on both positive and negative aspects of the intervention. Additionally, participants’ answers about specific factors within the intervention were full of idiosyncratic detail. However, one participant showed evidence of relational artefacts, see below.

SP1: “I probably overthink the forms, I was analysing whether I am improving or should I be improving, is it not going to work with what she’s got [Researcher], whether, is it hypothesis that she is doing, I was thinking about your research when I was filling it in, rather than filling it in thinking truly about the moment”

Researcher: “So it might’ve been influencing your answers?”

SP1: “Yes”

Researcher: “In what way?”

SP1: “I might have been more positive, maybe not, I am more positive, I feel like I wanted it to be a little bit better as it’s gone along, so maybe it hasn’t, am I thinking too much of it, I wanted it to be good for you, rather than being a true piece of research, but there is only one way of measuring it, there ain’t [sic] other way of doing it [about self-rating scales].”

SP1 recognised the dynamic of wanting to please the researcher, and was truthful about it during the Change Interview. Contrary to relational artefact explanation for change, SP1 was able to comment on negative aspects of the intervention, for example noticing more pain following the IE practice, which was reflected in both the Change Interview and the Pain Desensitising Chart. This shows SP1’s ability to critically appraise the treatment. Another evidence undermining relational artefact was that SP1 had not improved across all outcome measures, which would be expected if he was purposely raising his scores. Additionally, SP1’s increase in activity, which was an objective outcome measure, is

unlikely to be influenced by relational artefacts. Relational artefacts could have contributed to SP1's improvement; however, it is unlikely that they are the main source of it.

In summary, there was evidence of positive interpersonal dynamics between study participants and the researcher delivering the intervention. Based on the content of the Change Interview, and collected outcome measures data, it is likely that some of the changes reported by participants during the Change Interview might have been inflated. However, it is unlikely that relational artefacts could explain all changes as determined by outcome measure scores and data from the Change Interviews.

Expectancy artefacts.

Another source of bias in attributing change to studied intervention are participants' expectations or wishful thinking. None of the participants' comments during the Change Interview indicated presence of expectancy artefact; on the contrary, a couple of participants commented on their disappointment and unfulfilled expectations. During the Change Interview SP5 said: "The results of listening to the tape were disappointing". Another participant (SP7) commented on having positive initial expectations toward the IE practice; however, during the Change Interview she expressed disappointment with the lack of change: "it [the IE exercise] is not doing anything". Overall, there is no evidence that expectancy artefact could explain changes in participants.

Self-correction.

To evaluate whether apparent changes are caused by self-help efforts of participants, or a natural maturational process/spontaneous recovery, several factors were considered. Screening assessment included question about the chronicity and severity of their problems, to ensure that participants did not present with short-term or temporary problems. During the Change Interview all participants were asked about what changes they noticed, and how likely the change would have occurred without treatment. These changes were then compared with improvements on outcome measures. SP1, SP2, SP3, SP5 and SP6 all identified changes in long-standing problems that were not resolved in previous years by the passage of time, or natural course of chronic pain. All five participants, who reported changes following the intervention, rated the majority of these changes as 'very unlikely' and 'somewhat unlikely' without the intervention. Additionally, baselines were scanned for any pre-intervention trends that might suggest self-correction artefacts. For SP5 there was evidence of self-help efforts before the start of the intervention; he reported reducing his opioid medication, and there is an upward trend in his activity levels during baseline. During the baseline SP2 had a reliable improvement on the standard measure of pain anxiety, supported by downward trend in daily measure of fear of pain. SP2 reported that taking part in the study forced her to leave the house and made her feel less isolated, which could explain why some improvement started before the intervention was introduced. SP4

and SP7 did not notice any changes following the intervention; however, several changes were registered on their target and standard measures. For more detailed analysis see Table T1 in Appendix T.

Extra-therapy life events.

It is important to consider whether factors outside of the intervention, including changes in relationships, social activities, or work etc. contributed to and/or negatively affected the outcomes. It is likely that SP4 and SP7's improvements in activity could be attributed to extra-therapy life events, as they both described changes in their daily routine caused by external factors. SP5 commented that improvement in the weather could have contributed to improvement in his mood; however, there was no evidence of such improvement in his outcome measures.

Psychobiological causes.

It is often the case that any improvement or deterioration in study participants could be explained by biological changes, such as changes in medication regime, hormonal processes, or improvements/deteriorations in health. SP2 and SP6 both commented on being ill during the intervention part of the study. These periods of illness could not be caused by the intervention itself; both participants reported experiencing intermittent periods of ill health, which exacerbate their pain but are not caused by pain. It is likely that SP2 and SP6's improvement would be greater, had they not experienced these periods of worsening health.

Four participants (SP1, SP2, SP5 and SP6) reported reducing their opioid medication during the study. The biggest change in medication regime was observed in SP5, who discontinued Oramorph (opioid medication) before the commencement of the study, and continued to reduce Fentanyl (opioid medication) throughout the study duration. Although this was not the aim of our study, and was not discussed during the intervention, these four participants saw the reduction in their opioid use as something positive and very important to them. Some commented that being enrolled in the study helped them to reduce their medication:

“I was taking the morphine to take rid of the pain but it was only lasting a couple of hours, with the breathing I can do that over and over and over again, so instead of taking the 5 ml at night I've been taking 2,5 ml [half the original dose].” (SP6).

All four participants noticed some increase in pain following the reduction of their medication; however, this was balanced by positive effects of opioid reduction, as described by SP2: “since reducing my Morphine it has been a little bit better, my mind has been a little bit clearer when I am not taking as much medicine, I can see things a little bit better”, and:

“[since reducing opioids] everything is horrendous, but I feel like I can see, because everything was just glazed over all the time, and I was putting it down to how much

pain I was in, but I think it was more down to the fact that I was just numbing it to get rid of it.” (SP6)

Reduction in opioid medication could explain some changes reported by participants, but not all. It is also possible that reduction in pain medication could limit some improvement in pain distress and interference, as increase in pain intensity is a common effect of reduction of opioid pain medication.

Reactive effects of participating in research.

Another common artefact involves changes that might be attributed to the sole fact of participation in research (Elliot, 2002). In the HSCED’s method it is explained by the sense of altruism felt by research participants (‘being able to help others’) and the rapport with the researcher. Reactive effects of participating in research can also include negative effects on outcomes, especially if the procedure is perceived as bothersome. This artefact is similar to ‘relational artefact’ explored earlier.

Literature on the subject points out several different concepts and explanations of reactive effects of participating in research. Morley points out that single-case experiments with their intense engagement, daily measurement strategy, and use of idiographic outcome measures might be a significant factor behind clinical improvement (2017). There was evidence that the process of recording data was helpful for several participants:

“The study itself has given me a greater appreciation that this pain is not as bad as I think it is (...) I’ve never been at nine, which I thought I sometimes go to nine, which I haven’t been, I’ve been at seven, maybe an odd eight.” (SP1)

Other researchers identify the ‘reactive effects of participating in research’ and comment on how ‘helpful’ research participants can be (McCambridge, Witton, & Elbourne, 2014). They identified that participants often say that they believe in the importance of research, and by adhering to study protocols they are helping the researcher, other patients, and advancing science.

Study participants were not directly asked about the ‘reactive effects of participating in the study’; however, all but one (SP4) spontaneously mentioned it during the Change Interview. Below are a couple of examples taken from the Change Interview:

“I’ve appreciated doing the study, because I’m doing something on a weekly basis, I am doing something that somebody is relying upon me to do something for them, I’ve got something constructive to do during the day, so all those things, and I feel like I am helping somebody, so all those things have been really good.” (SP1)

“You are aware of that it’s somebody’s study and you do make a bit more of an effort to go, because if you go and then not go you are not going to get accurate data.” (SP2)

The ability to talk about their problems with the researcher has been mentioned by several participants during the Change Interview:

“Talking to someone that understands pain (...) so me telling you about my pain, you understand, and I think being able to speak to someone and they understand it, that’s helped, and I know I am not the only person that has so much pain, and that you know people who are in the same situation as well. So I think speaking about it has helped more than a lot of other things.” (SP6)

Engaging in the research study may have offered ‘hope’ to participants, therefore enabling change. It can partially explain changes in SP1, SP2, SP3, SP5 and SP6.

4.3.3 Summary and conclusions of critical analysis.

The final step of the HSCED is a summary of positive and negative evidence to decide whether or not any changes were observed, and whether or not they can be attributed to the intervention. Firstly, HSCED standards require replication of positive evidence across two out of five types of direct evidence (i.e. retrospective attribution, outcome-process mapping, process-outcome mapping, early changes in stable problems, and events-shift sequences). This was established in all but one participant (SP4). Secondly, when considering negative evidence, HSCED standards emphasise that ‘no nontherapy explanation can, by itself or in combination with other nontherapy explanations, fully explain the client’s change’ (Elliot, 2002, p.16).

Overall, HSCED provided strong support for three participants (SP1, SP2 and SP6), and identified multiple lines of evidence linking their changes to the intervention. SP3 and SP5 made fewer changes, supported by less evidence, but still attributable to the intervention. For the remaining participants (SP4 and SP7) there were other nontherapy explanations that the observed changes could be attributed to. Both the negative and positive evidence for change is summarised in Table T1, Appendix T.

4.4 Comparison with Results Obtained by Flink et al. (2009) and Taylor (2012)

According to Morley (2017, p.159) there is a “tremendous potential in the replication of single-case series” in development of interventions. Our study aimed to replicate the study by Flink et al. (2009), guided by Taylor’s research (2012). Whilst there are some differences in interventions, methodology, and populations, it is relevant to compare results to learn more about the efficacy of IE in treatment of fear of pain. Below is a brief summary of similarities and differences between the three studies, followed by comparison of results. Afterwards, comparison with other relevant studies investigating IE and/or using similar methodologies in relevant populations is presented.

Flink et al. (2009) used multiple baselines to compare IE with relaxation/distraction (R/D). The intervention consisted of 6 weekly sessions (3 sessions of IE and 3 sessions of R/D). Participants, recruited through a newspaper advertisement, received a short pain

education before allocation to treatment. All participants were expected to practice IE or R/D techniques for at least 15 minutes twice daily, using MP3 players with recorded instructions. Measurement strategy used by Flink et al. included a battery of standard outcome measures: pain acceptance (CPAQ), fear of movement (TSK), catastrophising (PCS), and disability (QBPDS); at four different time points (assessment, post-intervention, and at three months follow up). In addition, Flink et al. used a brief daily measure of pain intensity and distress. Pain intensity was measured using an eleven-point numerical scale, whereas pain distress was measured using four questions from PASS-20 and PCS, and one question formulated by the research team regarding pain interference. Although the format and design of daily ‘pain distress’ measure used by Flink et al. is very similar to our Fear of Pain (Daily Diary), the concepts measured differ. Flink et al. described ‘pain distress’ as a ‘construct of pain related distress or bothersomeness on a daily basis’, included statements describing pain interference, distress, attention control, helplessness and rumination; whilst our daily measure of Fear of Pain (Daily Diary) included only questions describing fear of pain.

Taylor (2012) used an ABC design comprising of baseline, educational session, IE treatment and a three-month follow up. Participants, recruited from a Pain Clinic psychology waiting list, were asked to practice IE three times daily over three weeks using a written IE script to guide their practice. Alongside the IE practice participants were introduced to other exercises, including attention control and relaxation. Taylor’s measurement strategy included a battery of standard outcome measures: pain anxiety (PASS-20), catastrophising (PCS), acceptance (CPAQ), pain vigilance and awareness (PVAQ), and disability (PDI); at four different time points: baseline, pre- and post-intervention, and three months follow up. Taylor’s target outcome measure was a 13-item daily measure of pain distress, including three questions about pain intensity and nine questions taken from PASS-20, PCS, and CPAQ. In addition, Taylor used process outcome measures including the Change Interview and the Pain Desensitising Chart.

The ‘dose’ of IE in all three studies is similar. Both Flink et al. and Taylor held three weekly sessions when they trained participants in the use of IE. Between sessions participants were expected to practice IE at home. Flink et al. asked the participants to listen to a 15-min IE exercise twice daily, whilst Taylor asked the participants to practice it three times daily, with no time limit. In our design we planned to have two weeks of IE practice, as it turned out, four of our study participants had an additional week or two of IE practice due to being unable to attend weekly sessions at the Pain Clinic, and therefore having longer gaps between IE practice sessions.

Graphical display of daily ratings of pain distress by Flink et al., showed variation and presence of trends in baseline for four out of six participants. Similar variation and presence

of trends was observed by Taylor in three out of four participants' baseline daily ratings of pain anxiety, catastrophising, and acceptance. Our daily ratings of Fear of Pain showed similar variability and presence of trends in baseline for four out of seven participants. This might indicate that concepts of pain distress, fear of pain, pain anxiety, and acceptance tend to fluctuate daily.

Daily ratings of Pain Distress in the study by Flink et al. showed improvement in response to the intervention for three out of six participants. In Taylor's study two out of four participants showed improvements, which is comparable to three out of seven participants, who improved on daily measure of Fear of Pain in the current study.

Comparison of results on standard outcome measures between the three studies shows similarities and differences. One out of four participants in Taylor's study improved on the measure of pain anxiety (PASS-20) as compared to three out of seven participants in the current study; Flink et al. did not use PASS-20. Three out of six participants in the study by Flink et al. and two out of four participants in Taylor's study had improvements on the catastrophising scale (PCS) meeting the RCI criterion, as compared to five out of seven participants in the present study. Regarding changes on the measures of pain related disability, we obtained similar results to both Flink et al., and Taylor. Only one out of seven participants improved on the PDI, which is the same for Taylor, whilst measure of disability used by Flink et al. (The Quebec Back Pain Disability Scale, QBPDS: Kopec et al., 1995) showed improvement for two out of six participants. Acceptance of pain scores, as measured by CPAQ, were similar across all three studies. Only one participant in the study by Flink et al., and one participant in study by Taylor, had improved, whilst no participants improved in our study. Neither Flink et al., nor Taylor measured the activity levels in participants, therefore we cannot compare our findings with theirs.

Flink et al. did not focus on participants' individual experiences of the process of using IE, whilst Taylor used the Change Interview and Pain Desensitising Chart (PDC). Interestingly, the PDC data obtained in our study is different than Taylor's for whom three out of four participants consistently reported less distress following the IE practice. All but one participant in our study noticed either an increase in distress, or no change in distress following the IE practice. However, the lack of decrease in distress after IE practice did not prevent our participants from describing the IE technique as helpful. An insight into why that might have been is present in several comments made by participants during the Change Interview:

“Now I've just got short bursts of pain and in between these I can do whatever needs to be done and then just sit down, breathe, chill, sit and watch telly, which I haven't been able to do in a while, because I've been up and down or laying in bed

and just missed a lot of things, but the bursts are painful, but because they are so short it's not bothering me so much." (SP6)

"When you are doing the concentrating on the pain sometimes it gets stronger before it gets weaker." (SP2)

It seems that although distress afterwards was the same or slightly higher, the fear tolerance has increased. Moreover, it is possible that the mechanism of IE practice is less likely to be explained by habituation, but by inhibitory learning (Craske et al., 2014), or self-efficacy (McNally, 2007).

Two participants in our study found it very difficult to engage in IE practice due to wandering attention and/or internal struggle to let themselves feel pain without trying to change it in anyway. This finding is similar to Taylor's as she described that one out of four participants struggled with holding their attention on pain sensation.

Overall, whilst there are some differences in methodology and design between the three studies, the results obtained are similar. By looking at the IE technique alone, findings of all three studies suggest that it is a useful technique, which can reduce fear of pain and pain distress in some (approximately 50%) participants.

4.5 Comparison of our Findings with Wider Literature

Studies investigating IE in chronic pain populations tend to contrast it with relaxation/distraction, which is described as an opposite technique (Flink et al., 2009; Flack et al., 2018) and/or include IE in multicomponent treatments. A similar strategy was chosen by Nicholas et al. (2014) in his RCT investigating IE. The team used IE as an add-on therapeutic technique with a three week multidisciplinary CBT pain management programme. IE was compared against training in distraction; 140 chronic adult pain patients were randomly assigned into either CBT + IE or CBT + distraction. Nicholas et al. assumed that addition of IE should reduce cognitive avoidance and fear of pain, which could potentially facilitate better outcomes from the multidisciplinary programme. The IE technique was identical to the one used in our study, with participants expected to practice at least 60 minutes daily (3 x 20 minutes). The relaxation/distraction technique involved calm breathing exercises, releasing tension with each exhalation, whilst focusing attention on a pleasant, relaxing thought, image or memory not involving pain, with a daily practice regime comparable to IE conditions. Nicholas et al. found that both treatments resulted in significant improvements on measures of pain, disability, depression, and use of medication for approximately 35% of participants, regardless of the arm of the study, which is slightly lower compared to current study. In the present study we moved away from comparing IE with other techniques, as our sole focus was on exploring the efficacy of this technique in treatment of disabling fear of pain.

The IE technique used in the present study was identical to that of Flink et al. (2009), Taylor (2012), and Nicholas et al. (2014); however, there are other types of IE techniques used in chronic pain. One such technique is called ‘pain provocation’ (PPT), and it was used recently by Flack and colleagues in their RCT (2018).

Flack et al. added IE to a larger interdisciplinary pain inpatient treatment for adolescents; the comparison group was introduced to a relaxation/distraction condition (R/D). Participants (N=126) were randomly assigned to either IE or a relaxation condition. The ‘pain provocation’ technique required participants to focus their attention on pain and intentionally recall pain-related memories, emotions, and bodily sensations to “provoke increases in pain intensity”. After provoking increases in pain, participants were asked to use other strategies, learned in an interdisciplinary programme, to reduce their pain experience. The IE treatment consisted of five sessions (30 minutes each), home practice of the PPT three times a day for 30 minutes each time. The R/D comparison group was trained in progressive muscle relaxation (PMR). The R/D treatment comprised five sessions of PMR (30 minutes each), over a three-week period. After the second session, the adolescents were instructed to practice PMR everyday as homework. Flack and colleagues found large improvements in fear of pain and avoidance behaviours in all participants of the intensive 3-week interdisciplinary inpatient treatment. Flack’s main finding was that IE was not superior to R/D in reducing fear of pain and pain avoidance. After additional analysis, Flack and colleagues found that IE was more effective for patients with higher ratings of fear of pain before the treatment, and for patients with abdominal pain, in reducing the fear of pain. This is similar to findings of our study, where the IE technique was more helpful for patients with higher ratings of fear of pain at the start of the study.

Additionally, there is a group of mindfulness practices that resemble IE, an example of which was used by Cayoun, Simmons, and Shires (2017). The technique used by Cayoun et al. was a 30-second mindfulness exposure to painful sensations. This technique is used in second-generation Mindfulness integrated Cognitive Behavioural Therapy. Their sample consisted of 15 adults diagnosed with chronic pain. Participants were required to practise the technique every day for 15 days, and encouraged not to identify with their pain, and instead to calmly focus their attention on the sensation of pain, and think about it in categories of its mass, motion, temperature, and cohesiveness. Results of the study by Cayoun et al. showed significant reductions in pain anxiety, pain duration, and pain intensity, with “unanimously positive” feedback on how useful the technique was. Interestingly, only 40% of participants on follow up reported having reduced or planning to reduce their analgesic medication, which might give a more realistic picture of for how many participants this technique was genuinely helpful. It is difficult to compare the results of the study by Cayoun et al. with our findings. Both studies use different methodologies

and population samples were different. Cayoun et al. recruited their participants from multiple sources, including psychiatry referrals, and exclusion criteria included high levels of disability. Nevertheless, one stark difference is the “unanimously positive” feedback following the use of mindfulness pain exposure, as compared to 50% response rate in our study.

In their experimental study of 51 undergraduate students Prins, Decuyper, and Van Damme (2014) administered painful heat stimuli whilst asking participants to listen to either a pre-recorded story (distraction condition) or a mindfulness exercise (focusing attention on pain sensations condition). The research team found no overall group effect; however, after further analysis they identified that participants higher in catastrophising benefited from the mindfulness exercise more than the distraction task. Prins, Decuyper, and Van Damme (2014) concluded that mindfulness techniques of calmly focusing attention on pain sensations are more useful than distraction for individuals high in catastrophising.

4.6 Theoretical Implications

4.6.1 Isolation of fear of pain, pain anxiety and catastrophising.

To capture the fear of pain in our study we used the Pain Anxiety Symptoms Scale (PASS-20; McCracken et al., 1992), Pain Catastrophising Scale (PCS; Sullivan, Bishop, & Pivik, 1995), and an original idiographic measure constructed from questions from both PASS-20 and PCS. Both the PCS and PASS-20 contain questions linked to several different concepts, which is represented by each measure’s subscales. These interlinked concepts include: cognitive anxiety, escape and avoidance, fear, physiological anxiety, rumination, magnification, and helplessness. In our study we chose questions from both measures to capture ‘fear of pain’ as defined earlier in the Introduction chapter. We aimed at separating the concept of ‘fear of pain’, whilst using tools and theories in which fear of pain is used interchangeably with pain anxiety, catastrophising and avoidance.

Further research focusing on development of more precise models and measures is needed to allow us to avoid a mistake described best by Eddington (1939, as cited in Ritchie & Raven, 1948), with a tale of an ichthyologist, who wants to catalogue sea creatures. He takes his 2-inch fishing net and travels across the world collecting samples in different locations, seasons and under different weather conditions. After many years of studies, he concluded that no fish in the sea is less than two inches long! Research into psychological phenomena, such as chronic pain, where the ‘fishing net’ needs to capture very difficult to both operationalise and measure concepts, is therefore full of complexity and new challenges. Concepts of fear of pain, pain anxiety, and pain catastrophising are central elements of the Fear Avoidance Model (Vlaeyen & Linton, 2000; Leeuw et al., 2007). The FAM implies that catastrophising is a cognitive precursor of fear and anxiety; however, the mechanism and sequence of the processes have been questioned (Vlaeyen, Crombez,

& Linton, 2009). The FAM does not provide a firm conceptualisation of each element, focusing on how these concepts and processes interact, rather than how they differ (Flink, Boersma, & Linton, 2013).

The main challenge in researching fear of pain is measurement and, more specifically, our ability to separately measure the fear of pain, pain catastrophising, and pain anxiety. Whilst in theory these concepts are separate, our current ability to measure them separately is limited (Craske, 2003; McNeil et al., 2012; McNeil & Vowles, 2004). An additional challenge is that fear related to pain and activity, and its acquisition, can be non-conscious, therefore relying on self-reported measures can be misleading (Pincus et al., 2010). McNeil et al. (2017) suggest that future research should focus on development of better assessment tools to be able to untangle these different concepts.

There are tools used to measure fear of acute pain linked to medical procedures/life events. These measures are useful in studies investigating experimentally induced pain, and pain linked to medical treatments (e.g. Fear of Pain Questionnaire-III: McNeil & Rainwater, 1998; The Fear of Pain Questionnaire-9: McNeil et al., 2017; Dental Fear Survey: Kleinknecht et al., 1973). Other ‘fear of pain’ measures are designed for assessing work-related disability (e.g. The Fear Avoidance Beliefs Questionnaire: Waddell et al., 1993) or fear of re-injury through physical activity and exercise (Tampa Kinesiophobia Scale: Miller, Kori, & Todd, 1991). Pincus et al. (2010) commented further that clear distinctions between different types of fear within chronic pain should also be made, such as: the ‘fear of pain’, ‘fear of re-injury’, ‘fear of movement’, ‘fear of rehabilitation-based exercises’, and ‘fear of activity (including work)’.

4.6.2 Critique of the FAM: Other psychological factors that can lead to avoidance.

Whilst the simplicity of the FAM is a strength, it focuses on a very specific subgroup of chronic pain patients. These patients can be characterised by high levels of pain catastrophising, pain anxiety, and fear of pain, which manifests in avoidance of activities that can trigger pain. In our study we assumed that a random sample of Pain Clinic patients will score highly on measures of pain catastrophising and pain anxiety. Indeed, all of our study participants met the ‘caseness’ criteria for clinical levels of pain anxiety and catastrophising, as measured with PASS-20 and PCS, therefore no further screening was required.

The FAM has many clinical benefits: it is clear, concise and resonates with individuals’ pain experience. The pain education session included introducing participants to the FAM. All study participants recognised how this model can be used to interpret their pain experience. Especially, the avoidance of physical activity and its negative consequences, like depression, disuse and disability, was described by participants as very

familiar. All participants described passive behavioural coping strategies of resting and retreating and utilising medication as their main coping strategy to deal with pain. All participants commented that they avoid physical as well as social activities, as they perceived these to increase their pain and suffering.

However, the FAM assumes that fear, catastrophising, and pain anxiety are the main factors behind avoidance. The fear of pain is conceptualised as the key target of interventions, reduction in fear of pain is seen as a pivotal outcome leading to recovery. Despite elevated scores on the PASS-20 and PCS, some participants stressed importance of other emotions that lead them to avoidance, which felt more dominant for them than pain. Several study participants reported low levels of fear of pain or catastrophising, and identified other psychological phenomena, such as frustration, anger, self-criticism, or traumatic memories. It is possible that negative emotional states and characteristics, other than fear of pain, may also result in reduction in physical activity and withdrawal from meaningful life pursuits. Pincus and colleagues (2006) proposed two extensions to the FAM, to argue alternative pathways leading to avoidance of activities and development of disability. One alternative pathway was constructed around the role of possible ‘long-term trait-like vulnerability to negative affectivity’ and depression. They theorised that apathy and lack of motivation might lead to a ‘general’ decrease in activity, whilst fear of pain would reduce specific types of activity linked to pain symptomology. The second extension of the FAM suggested by Pincus and colleagues (2006) focused on the role of significant others and healthcare professionals, and the role of positive reinforcement in encouragement and maintenance of avoidance and reduced activity.

In our study we did not use any measures that could capture what our participants described as anger, self-criticism or traumatic memories. Therefore, the reflections presented below are based on clinical observations rather than our study’s findings. More research into other emotions that can lead to avoidance of activity is needed.

Anger.

Two participants (SP4 and SP5) commented on how pain evoked anger in them more than fear. Throughout the study SP4’s anger at the experience of his treatment and lack of a cure was present:

“It is a series of disappointments really [about his previous pain treatments] (...) then people were like ‘Why is it not working?’, I don’t know, you are the medical personnel, and I’ve shied away from morphine for a long time you know, the box I had fitted [spinal cord stimulator], they asked me to go off opioids, so I went a year, pretty much without any painkillers, I was on Tramadol, codeine, so I’ve stopped them, for that year I was on my own (...) I went for the study [spinal cord stimulation] and I had an infection, so they had to take the wires out (...) I could have done with

something like this [about present study], sitting down and dealing with my anger (...)." (SP4)

SP4 commented that he often resorts to drinking alcohol, rather than taking medication, resting or exercising to deal with pain. He recognised that this strategy is unhelpful in the long-term; however, he felt that there is nothing much he can do on days when his pain is particularly bad. Anger could be therefore another emotion that stops people from engaging in activity despite pain.

Anger is thought to be at least 'as prominent an emotion as sadness and fear in the experience of chronic pain' (Fernandez & Turk, 1995, p.169). However, most studies into chronic pain focus on fear, anxiety, and depression, rather than on exploration of anger (Trost, Vangronsveld, Linton, Quartana, & Sullivan, 2012). In model of association between anger and chronic pain by Fernandez and Turk (1995) both repressed and expressed anger could lead individuals to avoidance of pain and reduced physical activity. Fernandez and Turk hypothesised that anger in chronic pain patients can explain maladaptive health habits frequently observed in this population, poor therapeutic alliance, and treatment non-adherence (1995). Leiker and Hailey (1988) for instance found that high scores on the Cook and Medley Hostility Scale were associated with poor health habits such, as neglect of physical exercise and self-care or improper nutrition. The authors state that especially in the case of 'cynical hostility' (a trait of cynicism and anger which can present in the way that individuals manage their social relationships, also called 'chronic anger') in which there is frequent anger, resentment, and suspicion, the individuals may develop a 'why bother?' attitude to health that may predispose them to what is called an unhealthy psychosocial risk profile. Could this 'why bother?' attitude make individuals more avoidant of movement and other health orientated activities?

Helplessness.

SP5's comments regarding his pain included content suggesting that rather than reaction of fear, his experience could be described as hopelessness. In this quote he starts with generalisation about "people with chronic pain in general", which he then links to his own experience:

"Other people are resigned to their pain, had it for years, and know that they are not going to get any better. I don't worry about it, it's either there or it's not, most of the time it's there, I've lived with it for over 40 years, you just come to accept it, after a while, you know it's not going to get any better, hopefully you know that you can have flare-ups, it's going to get worse some days, better other days." (SP5)

Samwel, Evers, Crul, and Kraaimaat (2006) in their study of 169 chronic pain patients enrolled in an interdisciplinary pain programme in the Netherlands, found that helplessness was a stronger contributor to disability and pain levels than fear of pain. They hypothesised

that “helplessness might be more applicable in populations with long-term pain, due to an enduring learning history of unsuccessfully coping with pain” (2006, p.246). Once pain becomes chronic, repeated failed attempts to control it or to fix it may lead to the development of helplessness, which is consistent with the learned-helplessness theory (Abramson, Seligman, & Teasdale, 1978). Helplessness in the context of chronic pain is a component of pain catastrophising, whilst it is also a component of depression. Both of these experiences are linked to development of disability in chronic pain patients (Pincus et al., 2006; Samwel, Kraaimaat, Crul, & Evers, 2007). Some researchers claim that when pain is perceived as ‘uncontrollable’ and ‘inescapable’, helplessness is a more prominent factor in development of disability than the fear of pain (Samwel, Kraaimaat, Crul, & Evers, 2007).

Self-criticism.

SP7’s attribution of why the Interoceptive Exposure and previous treatments including mindfulness had no effect on her ability to cope with her pain included comments describing self-criticism:

“I don’t think it was, other than the fact that it brought feelings that I had before, like that it’s me that is failing, because it is not doing anything, and again that things that maybe work for other people in similar situations, which means that it must be me who is not doing it right, and someone who always wants to be right, not like, but someone who always wants to like quite competitive in quizzes, if I get everything right brilliant, when I get things wrong I get really annoyed with myself, because I shouldn’t get that wrong, when it’s something that no way I would know that’s fine (...). I like to please, I don’t want to do something and then it not, if it doesn’t work I feel like it’s my fault, like I’ve been repressing my feeling when I was saying stuff to say sorry that it didn’t work.” (SP7)

Self-criticism, defined as “individuals’ tendency to set unrealistically high self-standards and to adopt a punitive stance toward one’s self” is conceptualised more as a ‘stable personality trait’, rather than a ‘mood state’ (Rudich, Lerman, Gurevich, Weksler, & Shahar, 2008, p. 211). Concepts of ‘self’ and ‘identity’ in relation to pain have been, similarly to anger, a less researched area (Morley & Eccleston, 2004; Pincus & Morley, 2001). In a study by Kempke, Luyten, Van Wambeke, Coppens, and Morlion higher levels of self-criticism were associated with negative treatment outcomes during a multidisciplinary CBT-based intervention in a sample of 53 chronic non-cancer pain patients (2014).

There is lack of research on effects of self-criticism on coping mechanisms in chronic pain (Rudich, Lerman, Gurevich, Weksler, & Shahar, 2008). Research from the study of personality points toward a link between self-criticism and maladaptive responses

to stressful situations (Endler & Parker, 1990). According to Dunkley and Blankstein such maladaptive coping involves “emotional responses, self-blame, fantasizing reactions, engagement in another task rather than the task at hand, and less active, problem-oriented attempts to change the situation or problem” (2000, p.726). More research is needed to test the hypothesis that self-criticism can lead to maladaptive coping behaviours, avoidance of activity, and withdrawal in chronic pain.

Memories of trauma and PTSD.

During the initial assessment SP1 shared that following his failed back surgery and sepsis he suffered with PTSD. He received cognitive behavioural therapy for this, which he described as helpful and commented that his PTSD was in remission. During the Pain Education session, when the researcher explained the rationale behind IE, SP1 experienced what he described as flashbacks of the event, which triggered his PTSD. SP1 explained that he became anxious about the possibility that the IE practice can trigger reoccurrence of his PTSD. The researcher used grounding techniques to help SP1 manage his distress, which resulted in visible improvement of his distress. SP1’s daily fear of pain and pain distress ratings show a marked increase following the Education session. One week later SP1 decided to continue with the study, and willingly engaged in IE practice, which did not exacerbate his symptoms, neither did he experience any more flashbacks throughout the remainder of the study.

Co-occurrence of chronic pain and PTSD is a well established phenomenon (Asmundson, 2014, Sharp & Harvey, 2001, Asmundson & Katz, 2009). Current evidence suggests that this comorbidity is associated with poor prognosis, increased rates of disability, diminished outcomes of psychological interventions, and higher dependence on opioid medication (Asmundson, 2014). According to the ‘mutual maintenance model’ PTSD symptoms can maintain pain experience (Sharp & Harvey, 2001). It has been proposed that intrusive memories of the trauma can lead to physiological reactions, such as increased muscle tension, which can provoke pain. Equally, pain sensations can trigger reoccurrence of intrusive memories of trauma, described as a vicious cycle of PTSD and pain (Asmundson, 2014).

It was directly observed that fear of triggering PTSD in SP1 might have been one of the reasons why he avoided pain stimuli and situations that could trigger pain. Sharp and Harvey (2001) call for interventions that aim to ‘cut into’ the vicious cycle of mutual maintenance, in particular cognitive and behavioural exposure to feared experiences. Studies by Wald and Taylor (2008) show that persons with PTSD often experienced marked anxiety reactions and trauma memories during IE exercises. Therefore, a careful clinical assessment and skills in therapeutic management of trauma are required whilst using IE with patients with chronic pain and history of trauma and PTSD.

4.6.3. Critique of the FAM: reduction in fear not leading to increased activity.

We expected to see an increase in activity levels in participants for whom the intervention reduced the fear of pain. This prediction was in line with the Fear Avoidance Model (Vlaeyen & Linton, 2000). Our findings present a more complex picture of the relationship between the fear of pain and activity. Only two out of five participants, who had a reduction in fear of pain attributable to the intervention, increased their levels of activity. For the other three (SP2, SP3 and SP5) there was no change in activity following the intervention. Unpredictably, two participants for whom there was no reduction in fear of pain following the intervention (SP4 and SP7), had marked improvements in activity levels.

It is possible that the reduction in fear of pain could have a delayed effect in the case of SP2, SP3, and SP5, and any increase in activity could be noticeable after the end of the intervention. Arguably, it is also possible that the relationship between the fear of pain and avoidance is moderated by other, not accounted for by the FAM, factors. One common factor responsible for limited physical activity could be comorbidity. The population of chronic pain patients is characterised by high levels of comorbidity, including physical and mental health difficulties, and iatrogenic problems, which are likely to limit their levels of physical activity (Gore, Sadosky, Stacey, Tai, & Leslie, 2012; van Rijswijk, van Beek, Schoof, Schene, Steegers, & Schellekens, 2019; Dominick, Blyth, & Nicholas, 2012). SP2 did not improve her levels of activity despite reduction in fear of pain. She explained that she was bed ridden over three days during the intervention phase due to an infection. SP2 attributed her recurrent infections to a weakened immune system, which is a plausible explanation considering current evidence on links between opioid medication and immune function (Wiese & Grijalva, 2018; Plein & Rittner, 2018).

Utility of the FAM within the bio-psycho-social framework.

Our participants were recruited from the psychology waiting list and therefore they are representative of chronic pain patients attending tertiary services. Following the study, they were all enrolled in regular psychological treatments. Although the recruited sample included only eight individuals, we believe we have succeeded in capturing the characteristics of a 'typical pain clinic patient', which is an oxymoron, as the chronic pain population is extremely heterogeneous (Fayaz et al., 2016; Gerdle et al., 2016, Vellucci, 2012)! The data collected during this study presented a picture of different individuals, with very different levels of functioning, and different challenges. Probably the most striking difference in participants was their activity data; some participants were able to reach a step count of over 12000-16000 steps, whilst others never exceeded 4000. The depth of the data on individual experiences of pain had to be reduced to try and answer study questions; however, participants voluntarily commented on issues around economic hardship of chronic pain, strain on relationships, lack of trust toward healthcare professionals, and other

areas of struggle. We hope that the message that IE is designed as a therapeutic technique to be used in conjunction with more comprehensive and tailored to the individual treatments has not been lost. All participants were looking forward to their regular treatments so they could address other complaints related to their pain.

Researchers in the field of chronic pain agree that the relationships between pain sensations, psychological distress, avoidance, and disability are complex and dynamic (Turk & Flor, 1999). Whilst the FAM is one of the most researched psychological models of pain, praised for its utility and practicality, it also attracts criticism for being somehow ‘naïve’ and ‘oversimplified’ (Moseley, 2011; Pincus et al., 2006; Nicholas, 2009). This complexity of chronic pain might explain the poor response rates to available treatments. Poor treatment outcomes (Eccleston, Morley, & Williams, 2013) and the burden of disability add to patients’ experience, which is often described as an ‘ineffective cycle’ of going through multiple rounds of treatments which provide no benefit (Norbury, Robbins, & Seymour, 2018). The FAM is unable to account for a considerable cohort of patients, who do not report elevated levels of catastrophising, fear, or disability (Wideman et al., 2013). Wideman et al. suggest that a very promising direction of pain research is research into resilience factors, seeing them as a ‘second side of the same coin’ of the FAM’s risk factors.

4.7 Clinical implications

4.7.1 Application of IE in clinical practice.

Our study is amongst very few which investigate not only the outcomes of IE in treatment of disabling fear of pain, but also the process of using it (Taylor, 2012; Flack et al., 2018). Findings of our study are in line with earlier research that IE is an acceptable and tolerable technique in treatment of disabling fear of pain, which can be successfully administered in this population. All participants involved in our study were able to follow the instructions of the technique whilst being guided by a therapist in session, and unsupervised whilst listening to an MP3 recording. Five participants, who found benefit from the technique, were able to use the technique without the aid of the recording, four of whom reported increased confidence in using IE after two weeks of practice.

Exposure techniques in the field of psychotherapy are underutilised, which is often attributed to clinicians’ fears and reservations of using it with vulnerable patients, and hence exacerbating their suffering (Boettcher, Brake, & Barlow, 2016; Becker, Zayfert, & Anderson, 2004). This fear is likely to play a key role for clinicians working in chronic pain. Evidence from this study suggests that even the most vulnerable patients, who reported high levels of pain distress and disability (SP2 and SP6), were able to continue using IE with positive results. This suggests that this technique is highly tolerable and can be used in patients struggling with ill health and other comorbidities. However, several issues around administration of this technique need careful clinical consideration.

Firstly, IE is designed for patients with high levels of fear of pain, catastrophising, and avoidance. Therefore, a careful assessment of the patient is important for this technique to be best utilised. It is likely that the results of using this technique in patients with different psychological profiles, whilst unlikely to be detrimental, might diminish patients' satisfaction with treatment, and undermine its credibility. This has been pointed out by SP5, who reported no fear of pain, and found the technique disappointing and unpleasant, as it made him notice his pain more. When asked about any additional comments on the study SP5 answered:

“I think it [the IE technique] could be helpful for certain people, I think that because it's based on fear and panic attacks and such, certain people might be frightened of the pain, those kind of people it can help.” (SP5)

Additionally, the assessment of patients should include screening for presence of trauma and/or PTSD, as practicing IE can trigger distressing memories in some patients (Wald & Taylor, 2008).

Secondly, IE is recommended to be used following pain education and explanation of the rationale behind it. It has not been tested empirically how acceptable and efficient IE would be without prior education. However, evidence from treatment of anxiety disorders points toward the importance of presenting rationale and treatment mechanisms of exposure treatments, as a way of bolstering adherence and outcomes (Feeny, Zoellner, & Kahana, 2009). It is more than likely that most chronic pain patients would have never heard about exposure treatments, which is the evidence from mental health research (Arch, Twohig, Deacon, Landy, & Bluett, 2015). Initially, the idea of focusing attention on pain is likely to sound 'curious' at best, as explained by one of our participants:

“Who would have thought that focusing on your pain can actually make a difference! It sounds you know [sic]! Until you've been through the experience, if you said to somebody: you don't need to take medication when it gets bad they would look at you as if you gone [mad], because obviously as soon as I feel pain the first thing that I think about is taking something to take the pain away.” (SP2)

Patients' expectations are known to have a small but significant positive effect on outcomes of psychotherapy; it is therefore important to present a logical and credible rationale for IE (Constantino, Arnkoff, Glass, Ametrano, & Smith, 2011).

Thirdly, IE is likely to be difficult for participants, and will require practice before any benefits are noticeable. Common challenges in practicing IE reported by participants of our study, and previous studies by Flink et al. (2009) and Taylor (2012), were: temporary and fluctuating increase in intensity and quality of pain sensations, difficulties in keeping attention on the sensation of pain, difficulties in practicing IE when the pain is particularly bothersome, finding motivation to practice IE, finding time to allow self to experience pain

without trying to reduce it, and having rigid beliefs about how to be with pain. One of the participants described her difficulties in using the IE practice as:

“Yeah the exercise hurt me a lot, (...) It [the exercise] was not easy at all! The first week I could have not thought about nothing worse to do I, but this week, the week just gone that I’ve do it, I have noticed, you know what, it’s quick enough to be done, and if I cannot manage the full 10 minutes then I can break it up and do it in a few little bursts and things, I think if I have just started it earlier on, then coming up towards the end it would not have been so much of ‘oh my god’” (SP6)

Another participant commented on difficulty of using the IE when the pain was severe:

“I can’t especially when it gets worse, especially when it’s increasing when trying to talk to listen to someone is difficult in your brain, because it’s like someone stood next to you is screaming in your ear whilst you are trying to talk or whatever, because it hurts so much.” (SP7)

Several participants commented on finding time and motivation to listen to the exercise:

“Sometimes I had to push myself, especially towards the end, when I sort of got it in my mind that it isn’t working, I thought it might be a waste of time, I gave it a go, so I’ve kept going, but it has been a bit more difficult than I would have thought it would have been.” (SP5)

It is also likely that for some patients the IE practice can at times feel ‘relaxing’ and ‘enjoyable’. This has also been observed in participants’ comments:

“I am finding comfort in listening to the tape and enjoying the 10 minutes twice a day just ‘me time’.” (SP3)

IE practice requires focusing attention on pain and bringing it back every time it wanders away, whilst remaining calm and accepting of this experience. It might prove more difficult for individuals who struggle with attention control, and for individuals high in self-criticism, as described by SP4 and SP7:

“You are there and keep telling me to bring it back, because as I say the moment I sit down quiet for any length of time I wander off, my mind goes, plays tunes or does something, so I need a reminder and this is what it does [IE recording], I don’t think I could sit here without that and do it, because I would lose what I was thinking about.” (SP4)

“My brain would just be going ‘it’s not working’, ‘you can’t do this’, ‘you are not breathing properly’, so not thinking about what I am doing but how I cannot do it, which is massively counterproductive.” (SP7)

Given the experience of participants in this study it is clear that IE has both positive and negative effects. For some participants it did not bring about improvement and we know

from other research that the lack of change following psychological interventions can be perceived as harmful (Radcliffe, Masterson, & Martin, 2018).

Finally, we should not forget about the evidence of best applications of exposure treatments, gathered by studies of anxiety type disorders, in tailoring the IE to the individual. This will include adapting the language used in IE practice, choosing the right length and frequency of IE exercises, fitting the practice within other personal goals of the individual, utilising aids such as modern technology, audio/video recording, and the environments and situations in which IE is practised (Craske et al., 2014; De Peuter, Van Diest, Vansteenwegen, Van den Bergh, & Vlaeyen, 2011; McNally, 2007).

4.7.2 Interoceptive Exposure versus mindfulness.

Whilst IE is reported as being an underutilised technique, whether it is in the field of chronic pain or anxiety disorders (Arch, Twohig, Deacon, Landy, & Bluett, 2015), there is a growing popularity of mindfulness type interventions that seem to utilise a practice very similar to IE (Prins, Decuyper, & Van Damme, 2014). Specifically, what is described by mindfulness literature as ‘focused attention practices’, associated with Samatha tradition, where the attention is maintained on a particular object (Hanley, Abell, Osborn, Roehrig, & Canto, 2016). It has been recently recognised that ‘interoceptive awareness’ is a major mechanism of mindfulness interventions (De Jong et al., 2016). One might ask: are we dealing with the same thing? Are Interoceptive Exposure and mindfulness practice different modalities of the same intervention?

Surface level comparison of the technique used by Cayoun et al. (2017, described earlier in this chapter) and the IE script used in our study identifies more similarities than differences. Our script asks participants ‘just observe the sensations you are feeling, as calmly as possible’, whilst ‘trying to ignore thoughts about how bad it is or how much it is hurting’ (Nicholas, 2017). Mindfulness instructions used in the study by Cayoun et al. asked individuals to: ‘as much as you can, allow and accept’, ‘instead of resenting and reacting to them emotionally’. Indeed, acceptance and objective observation, without judgement, are core components of mindfulness (McCracken, Gauntlett-Gilbert, & Vowles, 2007). Current theories of using mindfulness in pain management are that it helps to regulate an individual’s emotional responses to pain through refocusing attention away from catastrophic thoughts and onto present moment with an accepting attitude (Bishop et al., 2004). As with the theoretic rationale behind IE in cognitive behavioural therapy, in mindfulness individuals are encouraged not to avoid any emotional and physical experiences, which is expected to result in new learning that these experiences, however unpleasant, are not harmful and are part of being human (Liu, Wang, Chang, Chen, & Si, 2012).

4.8 Strengths and limitations of this study

The main strengths of this study are linked to its methodology, including the use of process measures to capture the experiences of participants using IE, recruitment strategy, high adherence/attrition, and high improvement rates, as compared to more intensive interventions. These will be discussed in more detail below, followed by the analysis of limitations.

“People suffering from chronic pain are markedly heterogeneous on almost any measure one cares to consider” (Morley, 2017, p.159). Interventions used in this population are variable and complex, most often multidisciplinary. There is evidence that these interventions are effective; however, overall effect sizes are small (Morley & Williams, 2015). A call for improving treatment effectiveness has been raised by experts in the field (Morley, Williams & Eccleston, 2013). ‘Treatment tailoring’, which can be described as development of treatments that aim at a specific subgroup of chronic pain patients, has been suggested as one of the ways in which this aim can be achieved. The main strength of this study is its methodology, which allows detailed observation of individuals involved in an intervention, and collection of both outcome and process data. Specifically, the use of process measures in an attempt to link process to outcome, is not a common practice in pain research. Our study had a strong theoretical rationale and used an objective measure of activity (i.e. wearable fitness tracker) to test hypotheses linked to the interaction between fear of pain and activity levels, aiming to build more evidence to improve the Fear Avoidance Model. This study aimed to deepen our knowledge of a simple psychological technique of IE used in chronic pain. Neither is IE a popular subject in pain research, nor clinical practice (De Peuter et al., 2011). As IE has been predominantly used in conjunction with other therapeutic techniques more evidence on its efficacy alone is critical to help improve effectiveness of pain treatments. Evidence gathered by our study and our predecessors (Flink et al., 2009; Taylor, 2012) should help clinicians to tailor their interventions to patients, following the expert recommendation that no ‘one size fits all’ (Morley, 2017).

The sample of our study can be described as representative of Pain Clinic patients, bearing in mind the heterogeneity of this population. Nevertheless, we believe that we captured the complexity of chronic pain presentations and the overwhelming burden of living with persistent pain. Adherence and acceptability of treatment were high, markedly higher than previous studies by Flink et al. (2009) and Taylor (2012), and higher than reported in larger studies (Leeuw et al., 2008). We achieved to demonstrate high improvement rates for a short study, as compared to longer, more intense interventions (Leeuw et al., 2008).

The present study was not without its limitations. The main challenge in our study was measurement. This is a common difficulty in the field of psychology, because in most instances, what we attempt to measure is neither easy to define, nor does it allow direct observation. 'Fear' in context of pain research is an umbrella term used to describe a variety of concepts, including amongst others: pain-related fear, fear-avoidance beliefs, fear of movement, and others. Lundberg, Grimby-Ekman, Verbunt, and Simmonds (2011) concluded that fear of pain has a weak construct validity, and popular outcome measures fail to identify who is fearful. In order to measure daily changes in fear of pain we constructed a short five question fear of pain questionnaire (included in the Daily Diary), which utilised questions from the PCS and PASS-20. However, it is unclear how well our measure represents the concept of fear of pain, because changes in the daily measure did not always map onto changes in standardised measures.

Additionally, even standardised measures of psychological constructs have limitations (Paulhus & Vazire, 2007). The Hospital Anxiety and Depression Scale (HADS), used in our study, is a popular measure previously shown to have satisfactory psychometric properties (Bjelland, Dahl, Haug, & Neckelmann, 2002). Nevertheless, there are ambiguous results regarding its two-dimensional factor structure, and its ability to differentiate between the constructs of anxiety and depression. It has been recommended not to use the separate anxiety and depression scores, but to rely on the total score of overall emotional distress instead (Cosco, Doyle, Ward, & McGee, 2012).

Additionally, the Daily Diary could have been improved. We purposely did not ask about the intensity of pain, as our intervention aimed at decreasing pain distress, not its intensity. On reflection measuring both modalities (intensity and distress) would allow us to see if our participants were able to separate them. Despite training in the use of the Daily Diary, and explanation that pain distress is different from intensity, it is likely that our participants used these two concepts interchangeably. Additionally, separating pain distress into three categories 'average, most severe and least', based on the intensity of pain, did not yield any benefits. Accurate pain recall in chronic pain patients is challenging (Dawson et al., 2002). Separating pain distress into three categories, indisputably increased the difficulty of an accurate recall, which might explain why participants tended to report levels of distress that matched pain categories (i.e. lower distress scores for 'least severe' pain, moderate distress for 'average' and higher scores for 'most severe' pain) or they ranked all of the categories equally. Similarly, with the Daily Diary question on pain interference, it is unclear what this concept meant for participants.

We assumed that number of steps taken each day is an equivalent of activity levels. This might be an oversimplification, as we are missing engagement in meaningful activities that might not require too much movement. The degree to which this measure can be

generalised to other behavioural activities is debatable. The alternative would be self-report activity diaries or questionnaires, both methods having their own shortcomings (Sylvia, Bernstein, Hubbard, Keating, & Anderson, 2014).

As mentioned earlier the study recruitment included patients from the pain psychology waiting list, in this way we had access to a representative group of patients and did not have to screen patients for the presence of chronic pain. However, we naïvely assumed that all recruited patients will be characterised by heightened fear of pain. Whilst our standardised outcome measures of PASS-20 and PCS did ascertain that all participants were within clinical levels of ‘pain catastrophising’ and ‘pain anxiety’ before the start of the intervention, Change Interviews identified that not all participants described being fearful of their pain. Furthermore, they described other emotions/psychological experiences, such as anger, hopelessness and self-criticism. On reflection, this was a methodological flaw, as IE is a technique specifically designed to target fear of pain.

Our study had no follow-up, due to the fact that all participants were expected to start their routine treatments shortly after the end of the research study; any follow-up data would be contaminated by the effects of a new intervention. Lack of follow-up means that we do not know the durability of the intervention effects.

Four out of seven study participants reported having reduced their opioid pain medication during the study. We were unable to control for medication use; during assessment session participants were encouraged not to change their medication regime. Several participants commented that the use of the IE technique and/or the process of coming over to the pain clinic and having someone ‘to talk to’, motivated them to reduce the dose and frequency of their pain medication. All participants saw this change as extremely positive. Reduction in long-term opioid medication is typically associated with temporary increase in distress, anxiety, and reported opioid withdrawal symptoms (“Opioids Aware”, 2019), even with small rates of drug reduction. However, after a period of time, reduction of long-term opioid medication should result in health benefits, linked to improvement of common side effects of opioids, such as constipation, daytime somnolence, reduced libido, poor concentration, memory loss, and others. We can only hypothesise whether the reduction in opioid medication strengthens the findings of our study (i.e. participants were able to use IE to help them manage the withdrawal effects) or undermines them (i.e. health benefits linked to opioid reduction explain the outcomes).

Diminishing generalisability of the study is the fact that the same therapist was responsible for delivering and evaluating the intervention. In addition, the therapist was the study author and aware of the study hypotheses, which further might lend bias in treatment. As a consequence, we cannot exclude a potential therapist bias. Should this study

be replicated a different therapist could be used to deliver and evaluate the intervention, including having an external person carrying out the Change Interview.

It is important to note that this is the third single case series aiming to study IE in chronic pain patients, which builds up evidence required to establish treatment effect in accordance with the What Works Clearinghouse (WWC) standards. The WWC requires that there should be a minimum of five single-case reports, conducted by at least three different research teams in different locations, and with a minimum of 20 participants (Institute of Education Sciences; 2010). Two more replications are needed to meet the WWC standards, preferably in a different geographical location and with a minimum of three participants.

A critique of the current study would not be complete without a reflection on the ‘Equivalence Paradox’ and a possible role of ‘common factors’ that our intervention shares with other types of psychological interventions (Stiles, Shapiro, & Elliott, 1986). According to this phenomenon all therapies share what we call ‘common factors’, which are responsible for change (Ahn & Wampold, 2001). These ‘common factors’ include certain skills and qualities of the therapist, therapy procedures, and the client (Lambert & Ogles, 2004). It is possible that our intervention could result in positive changes even if it was stripped from the Pain Education and IE practice, and consisted only of talking about pain experience and being listened to by an empathetic researcher.

4.9 Future Research Directions

Further research into IE in treatment of disabling fear of pain is warranted. Therefore, a replication of this study, with modifications, could be a direction worth exploring, as two more replications would satisfy the WWC criteria. The procedure of the study could be improved, starting with measurement. The measure of daily fear of pain, pain distress and interference could be improved. The process of taking daily measurement could be improved by the use of modern technologies (i.e. online Daily Diary). The study recruitment could be improved. The participants screening could be refined to only include patients high in fear of pain, using both standardised measures and qualitative interviews. Additionally, a follow-up period could be introduced to be able to answer questions about the durability of the intervention effects.

The treatment could be improved, including changes to the Education session. Both the design of the Education session and evaluation of its efficacy could be improved. There were marked differences between participants’ knowledge of chronic pain mechanisms, and therefore the education session could be more tailored to the individual. It is possible that some individuals would benefit from additional educational sessions and/or homework assignments, to ensure that the knowledge was acquired. The Revised Neurophysiology of Pain Questionnaire (NPQ; Catley et al., 2012), seemed too advanced to be used after one 90-minute pain education session in this sample.

The IE technique could be enhanced. Firstly, the script could be tailored to the individual to include instructions and phrases that help them keep their attention calmly focused on the pain. The length and frequency of the exposure could be tailored to the individual to maximise the effectiveness of this technique. The experience of the IE practice could be explored in a more in-depth way. This could be achieved by asking participants about their preconceptions of what might happen during the IE. Additional measures could be used to capture the mechanism of threat value diffusion, whether it was the exposure and new learning that the pain sensations alone are not harmful, or the increased confidence and self-efficacy of participants that the technique gave them. Use of safety behaviours (e.g. distracting self from the pain experience) during the IE practice could also be inquired about.

Several participants commented that they would have preferred a longer intervention with more time to practice IE. Being able to lengthen the time of the intervention based on individual response to the technique could allow answering questions about what is the optimal time to benefit from IE. Finally, participants' expectations from therapy were not assessed, neither were there process measures used during sessions to monitor the process of therapy. Separately from a potential replication of this study are the more general future research directions highlighted by this study.

In our study we aimed to test whether cognitive exposure to sensations of pain (IE) will diffuse its threat value. However, our imprecise methods of measurement did not allow answering questions about what is the mechanism of this process. We saw improvements in fear of pain following the IE practice; however, we are unable to explain mechanisms of this change. Based on the Pain Desensitising Chart (PDC) scores it is unlikely that IE worked through habituation, therefore inhibitory learning (Craske et al., 2014) or self-efficacy (McNally, 2007) are more likely explanations. Comments made by participants during IE sessions and the Change Interview let us hypothesise that for some participants pain exposure allowed 'new learning' that the sensation of pain alone is not harmful. Other participants commented about feeling more in control of pain, by being able to calmly focus attention on pain experience and tolerate it. Further research could aim to investigate the mechanism behind fear reduction following IE.

More theoretically driven research is needed to explore the construct of 'fear of pain' and 'fear avoidance'. Additionally, development of better measurement tools in chronic pain is necessary, specifically ones that would allow separation of such concepts as: catastrophising, anxiety, and fear of pain (Lundberg, Grimby-Ekman, Verbunt, & Simmonds, 2011). Moreover, re-thinking the paradigm of measurement in chronic pain is important. Whilst we do recognise the importance of asking about the intensity of pain and pain distress, we need to focus more on function, length of engagement, and utilise more

objective measures of such factors. The field of pain management is slowly moving away from a focus on pain intensity toward the importance of assessing function, this should be reflected in our measurement strategy. A very promising area of pain research is the study of resilience factors (Alschuler, Kratz, & Ehde, 2016). We propose that it could be beneficial, rather than asking about distress, to ask about confidence and ability to take positive action.

4.10 Conclusions

Most participants in this study experienced some benefit from the IE practice, although the impact of participating in the research itself seemed important. IE has been shown to be effective in reducing fear of pain in previous research, and this study found that brief IE produced some changes for the majority of the participants. Changes in fear of pain were seen most clearly in pain catastrophising, suggesting that the intervention had a cognitive impact. Activity levels increased for all participants, although this did not seem to be clearly linked to change in fear.

This study's contribution to current knowledge on the application of this technique sits in line with previous studies (Flink et al., 2009; Taylor, 2012) and recommendations of Vlaeyen and Linton (2000). We propose that IE is best used in patients high in fear of pain, pain anxiety, and catastrophising. It can be used as a brief standalone treatment; however, it is likely to be most effective as an add-on to more comprehensive treatments. Perhaps using the intervention alongside one targeting valued activities would be more palatable for clients, who have to be prepared to tolerate potential increases in pain intensity, and for clinicians, who have to believe that the intervention is worth attempting.

More research is needed into best ways of delivering this technique. A promising area for clinical practice and research is the similarity of this technique with specific mindfulness interventions for chronic pain. More theoretical and clinical research is needed into understanding why and how this technique works, which might include biological studies in pain perception, and emotional and cognitive ways of pain processing.

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APPENDICES

Appendix A: NHS Favourable Ethical Opinion Letter



Health Research Authority

Ms Aleksandra Puchala
1D Southfield Terrace
Leeds
LS12 1SN

Email: hra.approval@nhs.net

22 January 2018

Dear Ms Puchala

Letter of HRA Approval

Study title: Interoceptive Exposure as a treatment option for disabling fear of pain: a single case series.
IRAS project ID: 226054
REC reference: 17/NW/0660
Sponsor University of Leeds

I am pleased to confirm that HRA Approval has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications noted in this letter.

Participation of NHS Organisations in England

The sponsor should now provide a copy of this letter to all participating NHS organisations in England.

Appendix B provides important information for sponsors and participating NHS organisations in England for arranging and confirming capacity and capability. **Please read *Appendix B* carefully**, in particular the following sections:

- *Participating NHS organisations in England* – this clarifies the types of participating organisations in the study and whether or not all organisations will be undertaking the same activities
- *Confirmation of capacity and capability* - this confirms whether or not each type of participating NHS organisation in England is expected to give formal confirmation of capacity and capability. Where formal confirmation is not expected, the section also provides details on the time limit given to participating organisations to opt out of the study, or request additional time, before their participation is assumed.
- *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* - this provides detail on the form of agreement to be used in the study to confirm capacity and capability, where applicable.

Further information on funding, HR processes, and compliance with HRA criteria and standards is also provided.

It is critical that you involve both the research management function (e.g. R&D office) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details

and further information about working with the research management function for each organisation can be accessed from the [HRA website](#).

Appendices

The HRA Approval letter contains the following appendices:

- A – List of documents reviewed during HRA assessment
- B – Summary of HRA assessment

After HRA Approval

The document “*After Ethical Review – guidance for sponsors and investigators*”, issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

In addition to the guidance in the above, please note the following:

- HRA Approval applies for the duration of your REC favourable opinion, unless otherwise notified in writing by the HRA.
- Substantial amendments should be submitted directly to the Research Ethics Committee, as detailed in the *After Ethical Review* document. Non-substantial amendments should be submitted for review by the HRA using the form provided on the [HRA website](#), and emailed to hra.amendments@nhs.net.
- The HRA will categorise amendments (substantial and non-substantial) and issue confirmation of continued HRA Approval. Further details can be found on the [HRA website](#).

Scope

HRA Approval provides an approval for research involving patients or staff in NHS organisations in England.

If your study involves NHS organisations in other countries in the UK, please contact the relevant national coordinating functions for support and advice. Further information can be found through [IRAS](#).

If there are participating non-NHS organisations, local agreement should be obtained in accordance with the procedures of the local participating non-NHS organisation.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the [HRA website](#).

IRAS project ID	226054
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HRA Training

We are pleased to welcome researchers and research management staff at our training days – see details on the [HRA website](#).

Your IRAS project ID is **226054**. Please quote this on all correspondence.

Yours sincerely

Michael Higgs

Assessor


Email: hra.approval@nhs.net

Copy to: *Faculty of Medicine and Health NHS Research Ethics Officer, University of Leeds
[Sponsor]
Mr Mohammed Khan , Leeds Teaching Hospitals NHS Trust [NHS R&D office]*

Appendix B: Participant Invitation Letter



UNIVERSITY OF LEEDS

The Leeds Teaching Hospitals 
NHS Trust

Appendix 2. Participant Invitation letter v.1.2.

Leeds, 8th of February 2018

Name of the study: Interoceptive Exposure in reduction of fear of pain.

Dear Patient,

We would like to invite you to take part in a research study of a simple psychological intervention designed to help people with chronic pain. The study is being conducted by Ms Alex Puchala a Clinical Psychologist in Training under the supervision of Dr Ciara Masterson, Clinical Psychologist and Lecturer at the University of Leeds.

We are contacting patients who are on a Psychology Pain Clinic waiting list to offer them a brief and focused intervention while they are awaiting to see a Clinical Psychologist. The purpose of the intervention is to help people understand and manage the distress caused by chronic pain better. The study takes between 5 to 8 weeks to complete and will involve, among other things, attending 6 appointments at the Pain Clinic, keeping a daily diary of your pain, practicing a simple psychological technique daily for a period of two weeks and filling in several questionnaires. Please read the "Participant Information Sheet" enclosed with this letter to find out more. All appointments will be held at the Psychology Department at St James's Hospital, for which a set rate of £4.50 travel expenses per appointment will be covered. To thank you for completing the study, which will involve attending all of your scheduled appointments and filling in all questionnaires, we will offer you a £20 Love2Shop gift voucher and a mp3 player.

If you are interested in taking part we would like to tell you more about the study and ask you several questions to find out whether you are likely to benefit from this specific type of treatment. If you meet the basic entry criteria we will invite you to come to the Psychology Department at St James's Hospital. We will give you an opportunity to ask questions about the study and discuss any concerns that you might have. If we think that you are eligible we will offer you a place in the study. You will be given a consent form and asked to decide whether or not you want to take part. If you are not eligible for the study we will thank you. Please note that whatever the outcome of this assessment, it will **not** affect the treatment that you will be offered at a later date by the Pain Clinic.

Ethical approval for this study has been given by NHS Health Research Authority North West - Liverpool East Research Ethics Committee on the 5th of January 2018. Leeds Teaching Hospitals NHS Trust has confirmed their capacity and capability to deliver the above research study on the 31st of January 2018.

Yours sincerely, Alex Puchala

Dr Ciara Masterson

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University of Leeds

Invitation letter version number: [1.2.]
Invitation letter date of issue: [11.08.2017]

Appendix C: Participant Information Sheet



UNIVERSITY OF LEEDS

The Leeds Teaching Hospitals 
NHS Trust

Participant Information Sheet version 1.6. 11/12/17

Name of the study: Interoceptive Exposure in reduction of fear of pain

You have been invited to take part in a research study of an intervention for chronic pain, conducted by Alex Puchala, a Psychologist in Clinical Training. Before making a decision about whether you would like to take part in this research, please read the following information carefully.

What is the purpose of the study?

We are interested in finding out about a simple psychological treatment called Interoceptive Exposure, used to help people with chronic pain. The purpose of this intervention is to help people to learn how to focus attention on the pain experience in a structured way, to reduce the distress it can cause.

Why have I been asked to take part?

We are contacting patients who are on the waiting list to see a Clinical Psychologist at the Pain Clinic. This Information Sheet has been given to you because you expressed interest in finding out more about this study.

What will happen if I take part?

The study will take between 5 and 8 weeks. First, you will be invited to the Pain Clinic for an assessment, which will take approximately one hour. You will get a chance to find out more about the study and ask questions. If you are not eligible or if you decline to take part you will be thanked for your time. If you are eligible and you consent to take part, you will be asked to fill in several questionnaires and talk to the Chief Investigator about your pain and how you manage it on a day to day basis. You will then be asked to keep a diary of your pain. The diary is a simple questionnaire that should take you less than 5 minutes to complete. You will be asked to fill it in every day until the end of the study. If you like we can set an automated text message service to remind you about it. You will be also given a watch with a built in activity tracker. You will be asked to wear it daily until the end of the study to monitor your physical activity levels. This is to see whether your activity levels, such as the number of steps taken, change during the treatment. Following the assessment session, we will ask you to try using the diary and the activity monitor for a week; this will be called the 'practice week'. We will then ask you to come back to the Pain Clinic to check everything worked fine for you. If for any reason you struggle with using the diary and/or the activity monitor during the 'practice week' we can either give you one more week to practice, or decide together that this research study is not for you. If you do not experience any difficulties during the practice week, we will ask you to continue recording your pain and activity levels for the next one to three weeks; this is called the 'baseline period'. The length of the baseline that you will be allocated to will be chosen using a random number generator, which basically means that it will be decided by chance how

Participant information sheet version number: [\[1.6.\]](#)
Participant information sheet date of issue: [\[11.12.2017\]](#)
IRAS Project ID: 226054

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long your baseline period lasts. The length of baseline will differ between participants. As explained above your baseline can take one, two or three weeks. The reason why we use different lengths of baseline is that when treatment is started at different times we can conclude with more certainty that changes are due to the treatment rather than to a chance factor. Once the baseline period is complete we will invite you back to the Pain Clinic for a Pain Education session, to discuss the mechanisms of pain becoming chronic and disabling. In total there will be 6 appointments at the Pain Clinic. All but one appointment will last up to an hour, with the Pain Education session lasting approximately 90 minutes. After the Pain Education session, there will be a session on Interoceptive Exposure. You will get a chance to practice this technique in session and you will be given a portable mp3 player containing an audio recording with the Interoceptive Exposure instructions to practice it at home. You will be asked to listen to this recording twice a day for about 10 minutes each time and keep a record of your practice. One week later you will be invited back into the Pain Clinic to practice this technique again, discuss your experiences so far and address any difficulties that you might have had. You will be asked to practice Interoceptive Exposure for one more week. After this time you will be invited in for the final session. You will be asked about your opinions and experiences of the treatment. We will also ask you to complete several questionnaires. All sessions will be held at the St James' Pain Clinic and will be carried out by the Chief Investigator, Alex Puchala.

Do I have to take part?

It is up to you to decide. If you do want to take part, we will ask you to sign a consent form to show you have agreed to take part. You are free to withdraw at any time, without giving a reason. If you decide not to take part this will have no effect on your treatment or your position on the Clinical Psychology waiting list.

Will my taking part in the study be kept confidential?

Yes, all the information we collect during the course of the research will be kept confidential and there are strict laws which safeguard your privacy at every stage. All of your individual research data, such as questionnaires, notes, daily diaries, and activity monitor readings will be anonymised. This data will not be kept in your clinical notes at the Pain Clinic, neither will it be shared with the clinicians working at the Pain Clinic. Only the Chief Investigator will have access to your data. Paper data will be stored in a locked cabinet at the Pain Clinic, within a locked office, accessed only by the Chief Investigator, and all electronic data will be stored on a University of Leeds password-protected secure electronic database. The only data shared with the Pain Clinic will be information on whether you are attending your appointments, and any potential clinical risk. This is to protect your place on the Pain Clinic waiting list and to effectively manage your transition from the study into regular treatment. In order to record your attendance and any potential risk the Chief Investigator will need to have access to your clinical file at the Pain Clinic for the duration of the study. With your consent we will also inform your



GP that you are taking part in this study. At no time will you be identified by name, be it in published study materials or internal reports. Direct quotations from your sessions may be used in reports and publications, however such quotes will be anonymised to protect your identity. Nevertheless, there is a very small chance that you may be identifiable to a few select people, such as your immediate family and friends, or care team at the Pain Clinic, who will have access to published materials as these people already have a lot of prior knowledge about you and about the study.

There are some limits to confidentiality: if what you say makes the Chief Investigator think that you, or someone else, is at significant risk of harm, the confidentiality will need to be broken and this information will need to be shared with other members of your care team, such as your clinical psychologist, GP and/or emergency services. If possible, you will be informed of this.

Why is the last session audio recorded and what happens with the recording afterwards?

In the last session we will interview you about your experiences of the intervention. With your permission this session will be audio recorded. This is to ensure that we capture all of your comments. The recording will be transferred from the recording device and stored together with all of your electronic data on a University of Leeds password-protected secure electronic database. Within the next 7 days the Chief Investigator will transcribe the recording and permanently delete the audio file.

What is the activity tracker used for and how does it work?

This study uses a simple wearable fitness tracker called Withings Go[®]. We use an activity tracker because we want to find out whether practicing Interoceptive Exposure has any effect on the activity levels of our participants. The device is made of silicone and can be worn on a wrist, belt, shoe or in a pocket. It has a long lasting battery so it does not need charging. During your appointments at the Pain Clinic we will synchronise it (i.e. read the data from it) using the research smartphone. The activity data will be stored at the device manufacturer's website under an anonymous profile, however to create this anonymous profile we will have to use some of your personal information, such as your gender, age, height and weight. Most importantly, the device manufacturer will not be able to link this data to you. Once the study is finished we will copy the activity data into our research database and delete the anonymous profile from the manufacturer's online database. If you are interested, we will send you a copy of your activity data once the study is finished.

What is the automated text message service about and how does it work?

Throughout the duration of the study you can opt in to receive automated text messages to remind you about filling in the daily diary and practicing Interoceptive Exposure. In order to be able to provide this service we are using an external company, called IntelliSoftware Ltd. If you opt in to receive the automated text messages we will share your mobile number and the text message reminders with IntelliSoftware Ltd; your mobile number will be stored at the



password protected IntelliSoftware Ltd database. No other personal information will be shared with IntelliSoftware Ltd, i.e. we will not use your name. IntelliSoftware does not supply phone numbers to send advertising or marketing messages. Once the study is finished your mobile number will be permanently deleted from the IntelliSoftware Ltd database.

What will happen to my data if I withdraw or am unable to complete the study?

Data already collected up to the time of your withdrawal needs to be kept in order for the study to be scientifically valid. Only anonymised data will be kept. No new data will be collected once you exit the study. Due to the fact that this research study is testing a new intervention for chronic pain we do need to keep data from all participants who started the treatment, even if this treatment did not work for them and/or they had to withdraw from the study early. Additionally, in an unlikely event of you losing capacity during the study and/or no longer being able to take part you will be thanked for your time and you will no longer be asked to participate. No new data will be collected.

What are the possible benefits of taking part?

We hope that you will benefit from learning more about chronic pain and practicing Interoceptive Exposure to aid pain management. Results we gather from this project may help inform future research in this area and could contribute to improved treatments. We are able to offer you a small amount of money to offset any travel expenses (i.e. rate of £4.50 travel expenses per session attended at the Pain Clinic). To thank you for completing the study, which will involve attending all of your scheduled appointments and filling in all questionnaires, we will offer you a £20 Love2Shop gift voucher and you will be allowed to keep the mp3 player that you were using in the study.

What are the possible disadvantages and risks of taking part?

Participating in this research study is not anticipated to cause you any disadvantages or discomfort. You will however be encouraged to focus your attention on your pain, which can in some instances temporarily increase the pain experience. During the study you will also be asked about your pain and coping strategies which might cause some emotional distress. Nevertheless, the potential burden and psychological distress will be similar to any experienced in regular psychological therapy. Additionally, wearing the activity monitor on the wrist can in rare instances cause a skin rash or irritation. Taking part in the study can also be time consuming and tiring.

Can taking part in this study delay my waiting time for psychological treatment?

While participating in this study you will stay on the Pain Clinic's Clinical Psychology waiting list and keep moving upwards. Currently, the waiting time for therapy is longer than the duration of this study, which means that it should not delay your standard treatment. If for some



reason the waiting time decreases, there is a chance that taking part in the study might delay the start of your psychological treatment.

What should I do if I experience any new pain?

This study only relates to existing pain and there are no expected side effects. If you experience any new pain please seek medical advice. In the rare situation you experience any discomfort caused by wearing the activity monitor (e.g. rash, skin irritation), stop wearing your activity monitor at the wrist and contact the Chief Investigator to discuss alternative ways of using it. If the irritation doesn't subside after a few days without wearing the device at the wrist, we recommend that you get in touch with your GP.

What will happen to the results?

Some of the results will be reported in a doctoral research thesis written by Alex Puchala at the University of Leeds. The results might also be submitted to peer-reviewed journals and presented at conferences and meetings. Your name will not be included in any research output and all data will be presented anonymously. At the end of the intervention we can send you a brief report summarising your individual outcomes. You can give a copy of this report to your clinician at the Pain Clinic. At a later date we can also send you an overall summary of the entire study, once it is written for publication.

Who has reviewed the project?

This study has been reviewed and given a favourable opinion by NHS Health Research Authority North West - Liverpool East Research Ethics Committee on 5th January 2018. Leeds Teaching Hospitals NHS Trust has confirmed their capacity and capability to deliver the above research study on 31st January 2018. (Reference number: IRAS Project ID 226054, LTHT R&I No: PY18/100386).

Where can I find out more information and/or ask for advice?

If you would like more information about taking part in this project and/or you are already a participant and want to ask for advice or report a problem please contact the Chief Investigator, Alex Puchala (please see contact details below).

Chief Investigator: Alex Puchala,
Clinical Psychologist in Training , Clinical Psychology Programme
Leeds Institute of Health Sciences
University of Leeds
Clinical Psychology Level 10, Worsley Building
Clarendon Way
University of Leeds
LS2 9NL
Tel: 07434 678 117 Monday to Saturday 9:00-17:00, **Email:** umapu@leeds.ac.uk

Participant information sheet version number: [\[1.6.\]](#)
Participant information sheet date of issue: [\[11.12.2017\]](#)
IRAS Project ID: 226054



Academic supervisor:

Dr Ciara Masterson, Clinical Psychologist and Lecturer at the University of Leeds
Tel: +44 (0) 113 343 2712, Email: C.Masterson@leeds.ac.uk

What if I have a complaint?

If you have any complaints about the project in the first instance you can contact Alex Puchala, or her supervisor, Dr Ciara Masterson. If you feel your complaint has not been handled to your satisfaction and/or you wish talk to someone else you can contact the Research Governance Office at the University of Leeds and/or The Patient Advice and Liaison Service (see below).

University of Leeds University Lead for Ethics and Governance:

Clare Skinner, Head of Research Support for the Faculty of Medicine and Health
Tel: +44 (0) 113 343 4897
Email: C.E.Skinner@leeds.ac.uk

General Advice and Information

The Patient Advice and Liaison Service (PALS) can provide confidential help, advice, information and guidance on all aspects of healthcare.

Tel: (0113) 2066261 - Available during normal working hours only (9:00am to 4:30pm Monday to Friday).

Tel: (0113) 2067168 - For queries outside of normal working hours, please leave a voicemail.

Email: patientexperience.leedsth@nhs.net

What should I do if I feel distressed?

Should you feel distressed either as a result of taking part, or in the future, please contact your GP. Alternatively, if you want to talk to someone right away the following telephone numbers may be of assistance:

- **Single Point of Access (SPA) Team** available 24 hours a day, seven days a week. SPA supports people with acute mental health problems; provides advice and support over the phone and offers a face-to-face assessment if this is required, call **0300 300 1485** (or if you are deaf or hard of hearing you can text 07983 323867).
- **The Samaritans** helpline is available 24 hours a day, 365 days a year, for people who want to talk in confidence. Call **116 123** (free).

What should I do if there is an immediate risk?

If you have concerns for your mental state and you feel there is an immediate and serious danger to yourself or another person call **999** immediately for an ambulance or the police or you can also call **111** when you need medical advice fast but it's not a 999 emergency.

Participant information sheet version number: [\[1.6.\]](#)

Participant information sheet date of issue: [\[11.12.2017\]](#)

IRAS Project ID: 226054

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Appendix D: Consent Form

11-December-17

Name of the study: Interoceptive Exposure in reduction of fear of pain.

Please initial each box that you fully agree with:

- 1) I confirm that I have read and understand the information sheet dated **11-December-17 (version 1.6.)** for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
- 2) I understand that I have been asked to participate in a research study about treatment aimed to help people with chronic pain.
- 3) I understand that my participation is entirely voluntary and I am entitled to withdraw from the project at any time without having to give a reason.
- 4) I consent to my last session being audio recorded for quality assurance purposes.
I understand and consent to the ways in which my data will be used, stored and published as explained in the information sheet.
- 5) I understand that I can withdraw from the study at any time; however, my anonymised data will be kept in order for the study to be scientifically valid and it might be included in published materials.
- 6) I understand and consent that a letter is sent to my GP telling him/her that I am taking part in this study.
- 7) I also understand that any information I offer will be treated anonymously and all material arising out of the study will be dealt with on a confidential basis by the researcher and the research team. The researcher complies with the Data Protection Act (1998).
- 8) I give my permission for the Chief Investigator, Alex Puchala, to have access to my medical file held at the Pain Clinic in order to record my attendance and any potential risk.
- 9) I understand that relevant sections of data collected during the study may be looked at by individuals from the University of Leeds, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.
- 10) I understand that while I am wearing the Withings Go[®] fitness tracker it will record data about my daily physical activity and I understand how this data will be transferred, stored, used and who will have access to it.
- 11) I understand that my mobile telephone number will be shared with IntelliSoftware Ltd. to send automated text message reminders throughout the duration of the study.
I give my permission for the Chief Investigator to use this service.
- 12) I have read and understood the above information and I agree to participate in the above named study.

Your signature below indicates that you have decided to volunteer as a research participant for this study, and that you have read and understood the information provided above. You will be given a signed and dated copy of this form to keep, a separate signed and dated copy will be kept in your clinical file.

Name of Participant Date Signature

Name of Person taking consent Date Signature

Appendix E: Screening Criteria for Clinicians

<p>Who should I be inviting to take part in the study?</p>	<p>Inclusion Criteria</p> <ol style="list-style-type: none"> 1. Patients who are offered a place on the waiting list for Psychological Therapy 2. Presence of chronic pain (i.e. pain present for minimum of 3 months following tissue damage) 3. Capacity to give informed consent 4. Appropriate diagnostic investigations in other specialties as appropriate have been exhausted and first line interventions, like analgesia, have been tried. 5. Participant has appropriate expectations regarding psychological treatment, i.e. does not expect injections etc. <p>Exclusion Criteria:</p> <ol style="list-style-type: none"> 1. Insufficient understanding of English or additional needs which mean the potential participant is unable to complete questionnaires independently.
<p>How many participants do we need?</p>	<p>Recruitment goal: 8</p>
<p>What to do if a patient meets the above criteria?</p>	<p>Inform potential participants about the study (please refer to the Invitation Letter (v.1.2) and Information Sheet (v.1.6). If the patient expresses interest in taking part please give them the “Invitation Pack” (containing Invitation Letter, Information Sheet and Consent Form) and ask their permission to pass their contact details (name and contact telephone number) to the person conducting the study. Inform the patient that they will be contacted within the next week by the Chief Investigator Aleksandra Puchala.</p>
<p>What to do next?</p>	<p>Please inform the Chief Investigator via secure NHSmail (Aleksandra.puchala@nhs.net) or face to face about any potential participants who expressed interest in participating in the study and agreed to be contacted.</p>
<p>How long will the study last?</p>	<p>Each participant will be involved in the study for up to 8 weeks, there will be 6 sessions at the Pain Clinic (unless there is a need for an additional ‘practice week’ in which case there will be one more session at the Pain Clinic, please see Study Protocol, Appendix 17). The recruitment and intervention process will begin on the xxx and will last till xxx or until the recruitment goal is reached. You will be updated on the recruitment and intervention progress on a regular basis.</p>

Appendix F: Phone Conversation and Screening Criteria

Phone Conversation and Screening Criteria

Hello, this is Alex Puchala from the University of Leeds. I would like to speak with (name of potential subject) about a clinical study he/she may be eligible for at the Pain Clinic?

- If response is “She/he is not here”: *Thank you. Is there a convenient time that I could call her/him back?*
- If no one answers: a message can be left on the answering machine. *This is Alex Puchala from the University of Leeds. I am calling to see if (patient name) is interested in information about a clinical study. If so, please can you call me back at (phone number)”.*
- If response is “This is she/he”: *I would like to provide you with some basic information about the study and ask you some questions in order to determine whether you may be eligible for it. At any time, you may decline to answer or you can stop our conversation all together. Would you like to hear more about the study? If the answer is ‘no’, the Chief Investigator will thank them for their time and hang up. If the answer is ‘yes, the Chief Investigator will briefly describe the research.*

This conversation will take about 10 minutes. You do not have to answer any question you do not wish to and you may stop at any time. Your participation is completely voluntary. A decision whether or not to participate in this conversation will not affect the care you receive at the Pain Clinic. Is this OK with you? (wait for the answer) The study takes between 5 to 8 weeks. First, there is an assessment at the Pain Clinic, which takes approximately one hour. You will get a chance to find out more about the study and ask questions. If you are eligible and you decide to take part, there will be five more appointments at the Pain Clinic.

Would you like me to continue? If no, thank the person and hang-up. If yes, continue.

During the study you will be required to fill in several questionnaires assessing your pain and mood. You will also be asked to keep a daily diary of your pain and to wear a watch with a built-in fitness tracker. One of the sessions at the Pain Clinic will focus on Pain Education and take about 90 minutes. The other sessions will last up to 60 minutes. Week after the Education there will be a practical session on learning a simple technique designed to help people to cope with chronic pain. You will be given a mp3 player with instructions for this technique so that you can practice it at home. You will be asked to listen to this recording twice a day for a week. After that you will be invited back to the Pain Clinic to check how you have managed this, we will practice this technique some more. You will be asked to keep listening to the recording twice a day for one more week. After this time, you will be invited in for the final session at the Pain Clinic to share your opinions and experiences of the treatment. So, in total there will be six sessions, all of them will be held at St James’ Pain Clinic and will be carried out by me. To help you with your travel expenses we can reimburse you £4.5 each time you come to the Pain Clinic. Additionally, study participants who complete the whole treatment, which means attending all 6 sessions and keeping a record of their pain, will be rewarded with a £20 Love2Shop® voucher to thank them for their time.

Are you interested so far? Would you like me to continue? If no, thank the person and hang-up. If yes, ask the basic screening questions.

I will now ask you several questions about your pain, is that OK? If no, thank the person and hang-up. If yes, continue.

Screening questions:

- 1) *Do you suffer from pain?*
- 1) *How long have you had this pain?*
- 2) *Do you know what is causing your pain?*
- 3) *Are you currently receiving or planning to receive any new treatments for your pain?*
- 4) *Are you going to be able to attend weekly appointments at the Pain Clinic for a period of up to 2 months on (day of the study) during regular working hours?*
- 5) *Will you be able and willing to keep a short daily diary of your pain?*

The Chief Investigator will inform the person whether they are eligible for the study, or if not eligible, explain why. If eligible, the Chief Investigator will ask if they would like to schedule an appointment and ask if they received an Invitation Pack during their appointment at the Pain Clinic (containing the Invitation letter, Information Sheet and Consent Form). If yes, the Chief Investigator will ask the person to take time to read it and to bring it with them to their next appointment. If the potential participant does not have the Invitation Pack or cannot find it the Chief Investigator will offer to send a copy of the Invitation Pack in post.

Do you have any questions about this study? If you have questions after we hang up please feel free to call me at (leave phone number and name). If you have any questions or concerns about this study and our conversation today, you may contact the The Patient Advice and Liaison Service (PALS) on 01132066261. Thank you for your time.

Appendix G: Daily Diary



Appendix 11. Daily Diary v.1.3.

Participant ID number: date:

Please rate your pain by placing a cross mark on the line nearest to the description that best fits your experience.

Today on average my pain has been:

not at all distressing _____ extremely distressing

Today my most severe pain was:

not at all distressing _____ extremely distressing

Today my least pain was:

not at all distressing _____ extremely distressing

How much the pain interfered with my daily activities

does not interfere _____ interferes completely

Below you will find a list of statements. Please rate the truth of each statement as it applies to you using the following scale:

0 – not at all **1**- a bit of the time **2**-some of the time **3**- quite a bit of the time **4**- all the time

Pain sensations are terrifying **0 1 2 3 4**

When I feel pain, I think that something terrible may happen **0 1 2 3 4**

When I am in pain I keep thinking about how badly I want the pain to stop. **0 1 2 3 4**

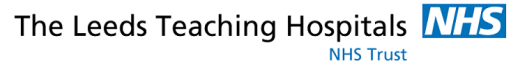
When I am in pain I wonder whether something serious may happen. **0 1 2 3 4**

When I am in pain I feel I can't go on with my daily activities. **0 1 2 3 4**

Daily Diary version number: [\[1.3.\]](#)
 Daily Diary date of issue: [\[25.08.2017\]](#)
 IRAS Project ID: 226054

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Appendix H: Global Measures Booklet



Appendix 12. Global Measures Booklet v 1.2.

GLOBAL MEASURES BOOKLET

Participant ID number:

Date:

Assessment / Pre-Treatment / Post-Treatment

Instructions: In this booklet you will find 5 measures. Please read the instructions and follow them carefully. There will be a series of statements, followed by a scale. Please indicate on each scale how much the statement applies to you.

Global Measures Booklet version number: [1.2]
Global Measures Booklet date of issue: [25.08.2017]
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Pain Anxiety Symptom Scale Short Form 20

Please rate each item in terms of frequency, from 0 (Never) to 5 (Always).

Table with 7 columns: Item Numbers, Never, 1, 2, 3, 4, Always. It lists 20 items related to pain and anxiety symptoms, such as 'I can't think straight when in pain' and 'I find it difficult to calm my body down after periods of pain'.

McCracken, L. M., Dhingra, L. A. (2002). Short version of the Pain Anxiety Symptoms Scale (PASS-20): preliminary development and validity. Pain Research and Management, 7(1), 45-50.

Global Measures Booklet version number: [1.2.]
Global Measures Booklet date of issue: [25.08.2017]
IRAS Project ID: 226054



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Pain Catastrophising Scale (PCS)

Everyone experiences painful situations at some point in their lives. Such experiences may include headaches, tooth pain, joint or muscle pain. People are often exposed to situations that may cause pain, such as illness, injury, dental procedures or surgery.

We are interested in the types of thoughts and feelings that you have when you are in pain. Listed below are thirteen statements describing different thoughts and feelings that may be associated with pain. Using the following scale, please indicate the degree to which you have these thoughts and feelings when you are experiencing pain.

0 – not at all 1 – to a slight degree 2 – to a moderate degree 3 – to a great degree 4 – all the time

When I'm in pain...

- 1 I worry all the time about whether the pain will end.
- 2 I feel I can't go on.
- 3 It's terrible and I think it's never going to get any better.
- 4 It's awful and I feel that it overwhelms me.
- 5 I feel I can't stand it anymore.
- 6 I become afraid that the pain will get worse.
- 7 I keep thinking of other painful events.
- 8 I anxiously want the pain to go away.
- 9 I can't seem to keep it out of my mind.
- 10 I keep thinking about how much it hurts.
- 11 I keep thinking about how badly I want the pain to stop.
- 12 There's nothing I can do to reduce the intensity of the pain.
- 13 I wonder whether something serious may happen.

...Total

Global Measures Booklet version number: [\[1.2.\]](#)
Global Measures Booklet date of issue: [\[25.08.2017\]](#)
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Pain Disability Index

The rating scales below are designed to measure the degree to which aspects of your life are disrupted by chronic pain. In other words, we would like to know how much pain is preventing you from doing what you would normally do or from doing it as well as you normally would. Respond to each category indicating the overall impact of pain in your life, not just when pain is at its worst. For each of the 7 categories of life activity listed, please circle the number on the scale that describes the level of disability you typically experience. A score of 0 means no disability at all, and a score of 10 signifies that all of the activities in which you would normally be involved have been totally disrupted or prevented by your pain.

Family/Home Responsibilities: This category refers to activities of the home or family. It includes chores or duties performed around the house (e.g. yard work) and errands or favors for other family members (e.g. driving the children to school).

No Disability 0 1 2 3 4 5 6 7 8 9 10 Worst Disability

Recreation: This disability includes hobbies, sports, and other similar leisure time activities.

No Disability 0 1 2 3 4 5 6 7 8 9 10 Worst Disability

Social Activity: This category refers to activities, which involve participation with friends and acquaintances other than family members. It includes parties, theater, concerts, dining out, and other social functions.

No Disability 0 1 2 3 4 5 6 7 8 9 10 Worst Disability

Occupation: This category refers to activities that are part of or directly related to one's job.

This includes non-paying jobs as well, such as that of a housewife or volunteer.

No Disability 0 1 2 3 4 5 6 7 8 9 10 Worst Disability

Sexual Behavior: This category refers to the frequency and quality of one's sex life.

No Disability 0 1 2 3 4 5 6 7 8 9 10 Worst Disability

Self Care: This category includes activities, which involve personal maintenance and independent daily living (e.g. taking a shower, driving, getting dressed, etc.)

No Disability 0 1 2 3 4 5 6 7 8 9 10 Worst Disability

Life-Support Activities: This category refers to basic life supporting behaviors such as eating, sleeping and breathing.

No Disability 0 1 2 3 4 5 6 7 8 9 10 Worst Disability



CPAQ

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

0	1	2	3	4	5	6
Never True	Very rarely true	Seldom true	Sometimes true	Often true	Almost always true	Always true

1. I am getting on with the business of living no matter what my level of pain is.
2. My life is going well, even though I have chronic pain.
3. It's OK to experience pain.
4. I would gladly sacrifice important things in my life to control this pain better.
5. It's not necessary for me to control my pain in order to handle my life well.
6. Although things have changed, I am living a normal life despite my chronic pain.
7. I need to concentrate on getting rid of my pain.
8. There are many activities I do when I feel pain.
9. I lead a full life even though I have chronic pain.
10. Controlling pain is less important than any other goals in my life.
11. My thoughts and feelings about pain must change before I can take important steps in my life.
12. Despite the pain, I am now sticking to a certain course in my life.
13. Keeping my pain level under control takes first priority whenever I'm doing something.
14. Before I can make any serious plans, I have to get some control over my pain.
15. When my pain increases, I can still take care of my responsibilities.
16. I will have better control over my life if I can control my negative thoughts about pain.
17. I avoid putting myself in situations where my pain might increase.
18. My worries and fears about what pain will do to me are true.
19. It's a relief to realize that I don't have to change my pain to get on with my life.
20. I have to struggle to do things when I have pain.



Hospital Anxiety and Depression Score (HADS)

This questionnaire helps your physician to know how you are feeling. Read every sentence. Place an “X” on the answer that best describes how you have been feeling during the LAST WEEK. You do not have to think too much to answer. In this questionnaire, spontaneous answers are more important

A	I feel tense or ‘wound up’:	
	Most of the time	3
	A lot of the time	2
	From time to time (occ.)	1
	Not at all	0
D	I still enjoy the things I used to enjoy:	
	Definitely as much	0
	Not quite as much	1
	Only a little	2
	Hardly at all	3
A	I get a sort of frightened feeling as if something awful is about to happen:	
	Very definitely and quite badly	3
	Yes, but not too badly	2
	A little, but it doesn’t worry me	1
	Not at all	0
D	I can laugh and see the funny side of things:	
	As much as I always could	0
	Not quite so much now	1
	Definitely not so much now	2
	Not at all	3
A	Worrying thoughts go through my mind:	
	A great deal of the time	3
	A lot of the time	2
	From time to time, but not often	1
	Only occasionally	0
D	I feel cheerful:	
	Not at all	3
	Not often	2
	Sometimes	1
	Most of the time	0
A	I can sit at ease and feel relaxed:	
	Definitely	0
	Usually	1
	Not often	2
	Not at all	3

D	I feel as if I am slowed down:	
	Nearly all the time	3
	Very often	2
	Sometimes	1
	Not at all	0
A	I get a sort of frightened feeling like “butterflies” in the stomach:	
	Not at all	0
	Occasionally	1
	Quite often	2
	Very often	3
D	I have lost interest in my appearance:	
	Definitely	3
	I don’t take as much care as I should	2
	I may not take quite as much care	1
	I take just as much care	0
A	I feel restless as I have to be on the move:	
	Very much indeed	3
	Quite a lot	2
	Not very much	1
	Not at all	0
D	I look forward with enjoyment to things:	
	As much as I ever did	0
	Rather less than I used to	1
	Definitely less than I used to	2
	Hardly at all	3
A	I get sudden feelings of panic:	
	Very often indeed	3
	Quite often	2
	Not very often	1
	Not at all	0
D	I can enjoy a good book or radio/TV program:	
	Often	0
	Sometimes	1
	Not often	2
	Very seldom	3

Appendix I: Modified Change Interview Protocol

Instructions

Interview Strategy: This interview works best as a relatively unstructured empathic exploration of the client's experience of therapy. Think of yourself as primarily trying to help the client tell you the story of his or her therapy so far. It is best if you adopt an attitude of curiosity about the topics raised in the interview, using the suggested open-ended questions plus empathic understanding responses to help the client elaborate on his/her experiences. Thus, for each question, start out in a relatively unstructured manner and only impose structure as needed. For each question, a number of alternative wordings have been suggested, but keep in mind that these may not be needed. The interview should take between 20 and 35 minutes.

Ask client to provide as many details as possible

Use the "anything else" probe (e.g., "Are there any other changes that you have noticed?")

Inquire in a non-demanding way until the client runs out of things to say

The interview covers

- the client's assessment of change and assesses medication change as a possible reason
- worsening and unfulfilled wants, attributions about change
- helpful aspect of therapy - and unhelpful ones
- their perception of measures

Change Interview Record

Client ID number: _____

Date: _____

1. General Questions [about 5 min]

1a. How are you doing now in general?

1b. What has therapy been like for you so far? How has it felt to be in therapy?

1c. What medications are you currently on? Have there been any changes in your drug regime (prescribed and OTC) since you started treatment?

Pharmacological Medication Record (incl. herbal remedies)

Medication Name	For what symptoms?	Dose/ Frequency	How long?	Last Adjustment?

2. Changes [about 10 min]

2a. What changes, if any, have you noticed in yourself since therapy started?

For example, are you *doing, feeling, or thinking* differently from the way you did before?

What specific ideas, if any, have you got from therapy so far, including ideas about yourself or other people? Have any changes been brought to your attention by other people?

2b. Worsening Has anything changed for the worse for you since therapy started?

2c. Wants Is there anything that you wanted to change that hasn't since therapy started?

Note them here - then insert in the change list - then rate them.

CHANGE LIST

Change	Change was: 1 - expected 3 - neither 5 - surprised by	Without therapy: 1 - unlikely 3 - neither 5 - likely	Importance: 1-not at all 2-slightly 3-moderately 4-very 5-extremely
1.	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
2.	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
3.	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
4.	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
5.	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
6.	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
7.	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
8.	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5

CHANGE SCALES

Expected vs Surprised: For each change, please rate how much you *expected* it vs. were *surprised* by it? (Use this rating scale)

- (1) Very much expected it
- (2) Somewhat expected it
- (3) Neither expected nor surprised by the change
- (4) Somewhat surprised by it
- (5) Very much surprised by it

Likely without therapy For each change, please rate how *likely* you think it would have been if you *hadn't* been in therapy? (Use this rating scale)

- (1) Very unlikely without therapy (clearly would not have happened)
- (2) Somewhat unlikely without therapy (probably would not have happened)
- (3) Neither likely nor unlikely (no way of telling)
- (4) Somewhat likely without therapy (probably would have happened)
- (5) Very likely without therapy (clearly would have happened anyway)

Importance or significance How important or significant to you personally do you consider this change to be? (Use this rating scale)

- (1) Not at all important
- (2) Slightly important
- (3) Moderately important
- (4) Very important
- (5) Extremely important

3. Attributions [about 2 min]

3a. In general, what do you think has caused these various changes? In other words, what do you think might have brought them about? (Including things both outside of therapy and in therapy)

4. Helpful Aspects [about 5 min]

4a. Can you sum up what has been helpful about your therapy so far? Please give examples. (For example, general aspects or specific events)

5. Problem Aspects [about 5 min]

5a. What kinds of things about the therapy have been hindering, unhelpful, negative or disappointing for you? (For example, general aspects, specific events)

5b. Were there things in the therapy which were difficult or painful but still OK or perhaps helpful? What were they?

5c. Has anything been missing from your treatment? (What would make/have made your therapy more effective or helpful?)

6c. Suggestions Do you have any suggestions for us, regarding the research or the therapy? Do you have anything else that you want to tell me?

6. Feedback on Measures [about 2 min]

6a. Daily diary. In general, do you think that your daily diary ratings mean the same thing now that they did before therapy? If not, how has their meaning changed? (Sometimes clients change how they use the scales; did that happen for you?)

6b. Other measures. In general, do you think that your daily diary ratings mean the same thing now that they did before therapy? If not, how has their meaning changed? (Sometimes clients change how they use the scales; did that happen for you?)

6c. Were any of these measures difficult for you to complete? Can you tell me why?

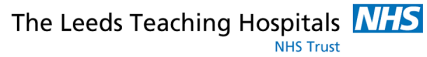
7. Any other comments you would like to make? [about 5 min]

Thank you for your time!

References:

Elliott, R., & Rogers, B. (2008). The Client Change Interview. Retrieved August 02, 2017, from <http://www.drbrianrogers.com/research/client-change-interview>.

Appendix J: Revised Neurophysiology of Pain Questionnaire



Appendix 13. Revised Neurophysiology of Pain Questionnaire

Participant ID number:

Date:

Please mark “T” for truth, “F” for false and “U” for undecided. Thank you!

	T	F	U
1. It is possible to have pain and not know about it.			
2. When part of your body is injured, special pain receptors convey the pain message to your brain.			
3. Pain only occurs when you are injured or at risk of being injured.			
4. When you are injured, special receptors convey the danger message to your spinal cord.			
5. Special nerves in your spinal cord convey ‘danger’ messages to your brain.			
6. Nerves adapt by increasing their resting level of excitement.			
7. Chronic pain means that an injury hasn’t healed properly.			
8. The body tells the brain when it is in pain.			
9. Nerves adapt by making ion channels stay open longer.			
10. Descending neurons are always inhibitory.			
11. Pain occurs whenever you are injured.			
12. When you injure yourself, the environment that you are in will not affect the amount of pain you experience, as long as the injury is exactly the same.			
13. The brain decides when you will experience pain.			

Catley, M. J., O’Connell, N. E., & Moseley, G. L. (2013)

Revised Neurophysiology of Pain Questionnaire version number: [\[1.0.\]](#)

Revised Neurophysiology of Pain Questionnaire date: [\[25.08.2017\]](#)

IRAS Project ID: 226054

Page 1 of 1

Appendix K: Assessment Session version 1.2

Name of the study: Interoceptive Exposure in reduction of fear of pain.

ID number of study participant:

Date of Assessment Session:

1. The Chief Investigator will begin by introducing herself and providing the potential participant with more information about the study (15 minutes)

This study is aiming to investigate a psychological technique of Interoceptive Exposure to help people suffering from chronic pain to cope better. Interoceptive Exposure is simply paying attention to bodily sensations, such as breathing, muscle tension or pain. People who experience chronic pain will naturally try to distract themselves from their pain.

Unfortunately, this can only work to a certain extent, as pain is very good at capturing and holding our attention. Therefore, some scientists and psychologists suggest that people who experience a persistent pain would benefit not only from learning how to distract themselves from pain but also what to do when distraction does not work. This is where Interoceptive Exposure comes in handy. This technique is about learning how to pay attention to pain in a very specific and focused way, which should help people to feel less bothered by it. It might sound like a silly idea to train people in how to focus their attention on pain, yet there is some evidence that it can work.

Interoceptive Exposure is routinely used by psychologists working in Pain Clinic, among other useful tools like relaxation, mindfulness, distraction or goal planning; however, this study looks at the effects of this tool alone. You can change your mind at any time about participating in the study, and confidentiality is assured. We will be asking you to fill in psychological questionnaires at several points during the treatment. Also you will be required to fill in a daily diary asking about your experience of chronic pain. Do you have any questions?

2. Explaining the Daily Diary and the Activity Monitor

You will have to keep a diary throughout the course of treatment. This should not take too long to fill in. Here is a copy of the diary and how to fill it in (do together, answering questions). Additionally, we will ask you to carry around with you an activity monitor to see how active you are day to day (demonstrates how to wear the device, goes through the Activity Monitors User Guide and Safety Instructions v.1.0., Appendix 23. and gives the participant a copy of it). To make this a little easier we can send you daily text message reminder to make sure you don't forget to fill in the diary and wear the monitor. In case you still forget to fill it in and you cannot remember your pain ratings from that day, please leave that page blank. Do you have any questions?

3. Weekly sessions at the Pain Clinic

Treatment will take place on *enter day* (Monday or Friday, depending on room availability), here at the Pain Clinic. After one week of completing the diary and wearing the activity monitor, you will be invited again to complete the assessment and see how you got on. After that you will be asked to continue to use the Diary and keep wearing the activity monitor for the next *xx* weeks (*5 to 8 weeks depending on the length of the baseline and whether*

participants needed the 'additional practice week'). This will be your baseline. On a *date/day* you will be invited to attend an educational session on chronic pain. One week later treatment sessions will begin. There will be two treatment sessions over the course of two weeks. During these two weeks we will give you an mp3 player and ask you to listen to it twice a day and record your practice. One week later we will invite you for the final session to ask you some questions about your experience of the treatment, and after that you will stop completing the diary. Each session will last 60 minutes, apart from the education session, which will take 90 minutes including a break half way through and the second assessment session, which will take 30 minutes. This is a diary of what the study dates and sessions are (at this point changes to dates/times might be made in case the participant is unable to attend). We can provide you with some cash to cover your travel expenses (up to £4.5 per single appointment, which is an equivalent of a DayRider bus ticket price). Additionally, if you complete the study, which means attending all scheduled appointments, filling in the diary and answering all questionnaires, you will receive a £20 Love2Shop® gift voucher and you will be allowed to keep the mp3 player that you were using. Do you have any questions?

4. **What this intervention is not**

Sadly, I cannot take away your pain, or answer all your questions about your pain. Neither, can I guarantee that practicing Interoceptive Exposure will work for you. However, once this study is over you will be seeing a Clinical Psychologist, who will have more time to talk to you, address areas that we did not cover and teach you other techniques. Additionally, if you give me your permission I can give a copy of your questionnaires and results to your therapist so they can use the information that we will be gathering to tailor their intervention to your individual needs. How do you feel about this?

5. **Time to ask questions**

After I explain the study the participant will be encouraged to ask questions. Once there is no more questions I will ask the participant whether they are still interested in taking part:

“This study asks participants to fill in a lot of questionnaires, keep a daily record of pain, wear an activity monitor, attend sessions at the Pain Clinic and practice the technique at home, do you think you are able to commit to this in the next xx* weeks?”

If the answer is yes, the researcher will go through the informed consent procedure and continue with the assessment.

If the answer is no, the researcher will thank the participant for coming and explain the they will be updated about their place on the waiting list by the Pain service. They will also give a contact telephone number if the person changes their mind or needs more time to make a decision.

If the participant is unsure about it, the Chief Investigator will thank the participant for attending today and tell them to take time to think about it and/or ask others for advice. If they decide they want to take part they should get touch with the Chief Investigator via phone, email or post.

6. **Time to read the information sheet and sign the consent form**

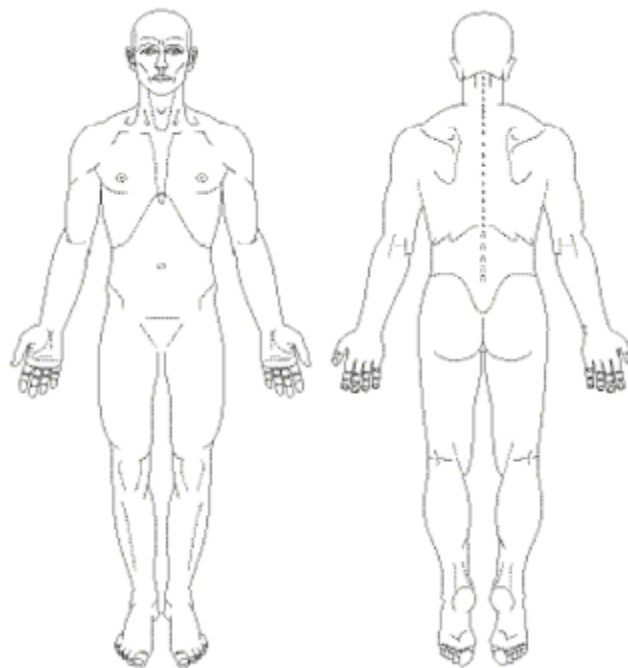
Participants, who said yes will be asked to read the information sheet and sign the consent form.

7. **Pain Assessment**

The Chef Investigator will explain that they will now ask the participant several questions about their pain.

Pain Experience

1. When did your pain start?
2. What diagnosis do you have?
3. Tell us about your pain episodes
 - How often?
 - Where do you experience pain?



4. How would you describe your pain?
5. How intense on a scale 0 (no pain) to 10 (worst imaginable)
 - on average in the day
 - the most severe in the day
 - the least severe in the day
6. When does it bother you the least?
7. When does it bother you the most?

Coping strategies

1. What makes it better?
2. What makes it worse?
3. When is it worse? What are you doing?
4. What do you currently do to manage the pain? Prompts: rest, massage, medication, watch TV, be active.
5. Does your pain prevent you from doing anything?

Pain knowledge and beliefs

1. What do you think the pain means?
2. What do you think will happen in the future with your pain?

Other

1. Are you receiving treatment for any other illness at the moment?
2. Are you planning to start or have you recently started any new treatments/therapies for your pain? If yes, can you tell me about it?
3. Do you think you will be fine with reading the questionnaires and answering independently? Any problems with this? Would you like your questionnaires to be printed in a bigger font

8. What we expect from you

We will ask you not to change any of your pain treatment during the course of the study, or if you do, could you please let us know? We need you to be committed to the project and willing to keep a daily diary. You need to be prepared to take part in all of the sessions.

9. Consent to inform the GP and Pain Clinic staff

If you consent to take part we will inform your GP and the staff at the Pain Clinic about your participation in this study.

10. Any questions?

Measures to be completed:

- 1) Pain Anxiety Symptom Scale Short Form 20 (PASS-20)
- 2) Pain Catastrophising Scale (PCS)
- 3) Pain Disability Index (PDI)
- 4) Chronic Pain Acceptance Questionnaire (CPAQ)
- 5) Hospital Anxiety and Depression Score (HADS)

Appendix L: Pain Education Session v.1.3

The session will start with the Revised Neurophysiology of Pain Questionnaire (See Appendix 13). Following this the Chief Investigator will give a brief overview of the Education Session. Participants will be asked about their experience of pain. The Chief Investigator will ask participants about their understanding of the function of pain and pain mechanisms. This will guide the Chief Investigator on how to structure and pitch the Education Session. The sections of the Education Session in bold font are compulsory, the other parts of the text are optional and will depend on the pace and timing of the session (e.g. some participants might ask more questions, others might need more time to go over the education components). This session should take approximately 90 minutes, with a 10 minutes break in the middle. The Chief Investigator will try to make links between participants' experience and theory. This session is designed to be interactive; the Chief Investigator will regularly check with participants their understanding (e.g. 'Is that making sense?', 'What do you think that means for people who suffer with chronic pain?'), ask for examples (e.g. 'Does that relate to your own experience?') and answer any questions.

What is pain?

- **Pain is basically a protective device.**
- **Due to its unpleasant character, pain is something that we want to get rid of; however, pain is a normal, effective and essential part of life.**
- **There is group of rare genetic conditions resulting in some people not being able to feel pain. One such condition is called Congenital Insensitivity to Pain with Anhidrosis, or CIPA. It is common for people with this condition to die in childhood due to injuries or illnesses going unnoticed.**
- **Pain occurs when your body's alarm system alerts the brain to actual or potential tissue damage.**
- **Pain always depends on the context. Research shows that the way we feel and think about pain can increase and/or decrease the pain response.**
- **Our thoughts, beliefs and memories are very real. They are basically nerve impulses. Thoughts are nerve impulses too, as is pain.**
- **Scientific research confirmed that thought processes are powerful enough to maintain a pain state, especially thoughts that trigger brain's alarm circuit, such as:**
 - **"I am in so much pain there must be something seriously wrong with me"**
 - **"My dad had back pain and he is now in a wheelchair"**
 - **"I cannot carry on with this level of pain, I feel I might faint"**
 - **"It hurts so badly I feel like dying"**
 - **"I am so scared of my pain and of injuring my back that I am not doing anything".**

The Fear Avoidance Model will be discussed next and the rationale for the study explained to the participants. People avoid processing pain which means that they do not get full exposure to it. They will be informed that the aim of this research study is to see whether focusing on the experience of pain can reduce the distress caused by pain.

Introducing the Fear Avoidance Model.

The Fear Avoidance Model (FAM; Vlaeyen & Linton, 2000) explains how acute pain can turn into a chronic and disabling condition. Fear fueled by dysfunctional beliefs about the source and meaning of pain will result in catastrophising which in turn prevents the sufferer from physical movement. Avoidance of movement and hypervigilance to pain can subsequently lead to depression and disability (See Figure 1).

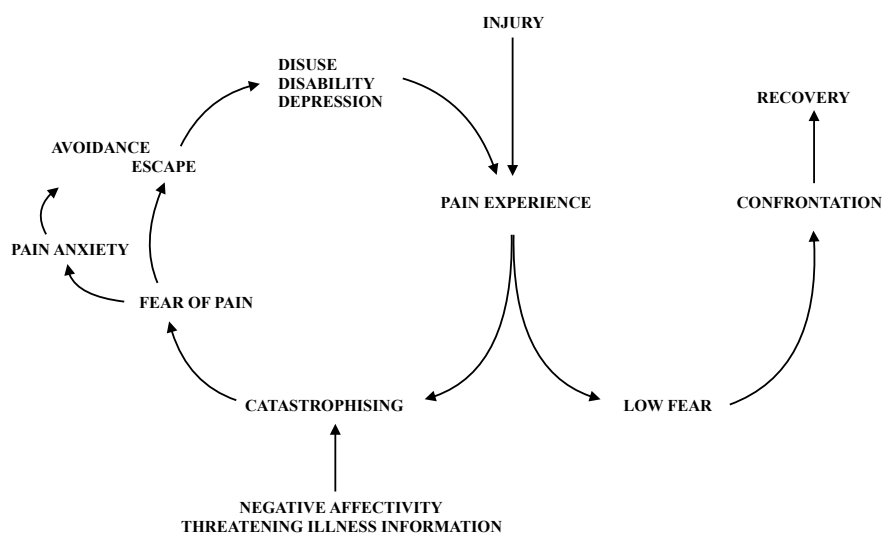


Figure 1. Fear-Avoidance Model of Chronic Pain (Vlaeyen & Linton, 2000).

The meaning that we give to our pain is crucial in how we respond to it. If we see it in a non-threatening way we are most likely to resume physical activity and have good recovery. If, however, we interpret pain as a ‘catastrophic’ event, a sign of a degenerative process or illness, we are more likely to avoid any kind of activity and become hypervigilant; constantly attentive to all body sensations. This then becomes a vicious cycle: by avoiding any opportunities to discount their beliefs, some individuals will become hypersensitive to pain and experience more pain in the future. (Crombez et al., 2012).

What is Interoceptive Exposure?

Interoceptive Exposure (IE) is exposure to bodily sensations used in the treatment of a variety of problems where body sensations are experienced as threatening. The application of IE is expected to reduce the threat value of pain and subsequently promote recovery.

When treating chronic pain IE implies that patients experience pain without trying to disrupt it in any way (e.g. shifting attention, avoiding movement, resorting to painkillers).

There has been some evidence supporting the use of IE in the treatment of chronic pain.

Desensitisation is achieved through focusing on pain, allowing ourselves to feel it, telling ourselves that we are ok. This may allow us to accept this and try to move on despite the pain. It was acknowledged that the normal response to pain is to try to get away from it, and this process can be compared to fear-avoidance, with an example of fear of heights. Those who are fearful of heights may avoid high places, but by doing so do not realise that they are not very dangerous. This avoidance can severely limit their lifestyle. The best treatment for fear is repeated exposure to the feared stimulus (i.e. going to a high place); however, this should be carried out in a safe and controlled manner. It is similar to our approach with fear of pain. Following repeated and prolonged exposure to pain, habituation should occur, which means that our brain pain response should decrease with time. Repeated exposure to pain should also decrease hyper-vigilance to it, as often trying to escape the feared stimulus results in more attention being paid to it.

The Orchestra in the Brain Metaphor (Butler & Moseley, 2015)

A skilled orchestra can play many thousands of tunes. It can play the same tunes in different tempos, in different keys, with different instruments taking on different roles. New tunes can be made up, old tunes can be revived. Pain can be thought of as one of the tunes played by the 'orchestra' of our brain cells. A good orchestra can play all the tunes and it can easily learn new ones. However, when the orchestra plays the same tune over and over, it becomes automatic, it plays by memory, and it becomes more and more difficult to play anything else. In chronic pain our brain (our orchestra) has become fixed on playing the same tune over and over. What used to be an original song (the acute pain response) introduced by neural pain circuits becomes an automatic response to more than one stimuli. Musicians from different sections in the orchestra, just like different parts of the brain, have different functions. A fear and emotion section of the brain is like a very loud section of the orchestra and it can easily hijack the concert. Pain rehabilitation is about allowing the orchestra to learn new tunes and gradually move toward enriching the repertoire of our responses. Sadly, the chronic pain tune is by then so well remembered by the orchestra that they might remember and play it occasionally even after we rehabilitated our brain. This is normal.

The brain is the most complex organ in the human body, which constantly interprets the information delivered through our senses into what makes sense for our survival.

- We 'feel pain in our body'; we can be experiencing headaches, back pains or

muscle pains. However, it is in the brain where the ‘pain is created’. **Pain is an interpretation of what is and/or what might be going on in our body.**

- There are some striking examples of how the psychology of pain works.
- Occasionally the pain system appears to act oddly, such as when surfers who get their legs bitten by a shark feel just a little ‘bump’ at the time, or a condition called “phantom limb pain”, where the area of the body that hurts is no longer there (e.g. after amputation).
- Pain is very effective at grabbing our attention. When it strikes we cannot think, feel or focus on anything else. Sometimes our brain decides that it’s not in our best interest to feel pain. Good examples of this include situations in which severely injured soldiers do not report any pain until they leave the battlefield, or when rugby players carry on playing despite serious injuries that only become painful once the game is over.
- The amount of pain you experience does not necessarily relate to the amount of tissue damage you have sustained, for example: severe pain after stubbing your toe, versus no pain with serious injuries like a gunshot or shark attack.
- **Every pain experience is created in the brain and depends on the context. Just like in this visual effect – See Figure 2. Square A appears to be darker than square B; however, they are in fact identical. Why do we still see these squares as different? It is due to our brain's incredible ability to make sense of the information it is presented with. Information reaching our brain from our eyes is processed and ‘made sense of’. Our brain has evolved to interpret a 2-D drawing as a 3-D representation. Our brain expects the cylinder in the middle of the board to cast a shadow. In addition, because our brain has learned that a checkerboard pattern is made from alternating light and dark squares, due to the positions of squares A and B, it recognizes square A as darker and square B as lighter, despite their actual color. The brain does similar work when it comes to pain; constantly interpreting information coming from the nerves and making sense of it to protect us from danger.** There are two phenomena described in chronic pain literature: **hyperalgesia** and **allodynia**. Hyperalgesia is an increased response to painful stimuli. This is common in chronic pain patients, due to the nervous system becoming more sensitive. In other words; the brain becomes an expert in noticing pain. Allodynia means a painful response to a normally non-painful stimulus. An example of allodynia can be experiencing sensations such as a stroke of a feather or a gentle touch as extremely painful. This again can be explained by the brain’s increased capacity to predict, notice and warn us about potentially painful stimuli, even if that stimuli are harmless.

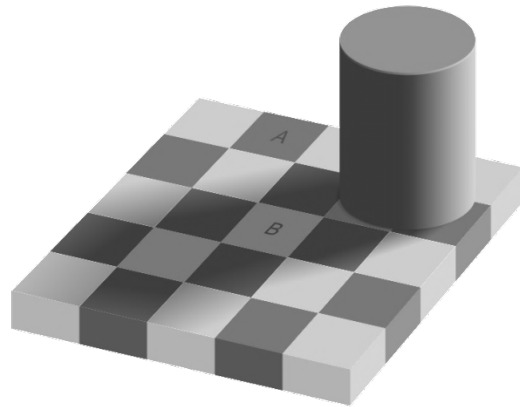


Figure 2. Gray square visual illusion (Adelson, 2008)

As mentioned earlier, there is not just one pain centre in the brain (See Figure 3). There are many areas which are involved in ‘creating’ pain. These brain regions are involved in the processing of sensations, movement, emotions and memory. In chronic pain, some of these regions become very sensitive; they become ‘hijacked’ by the pain experience.

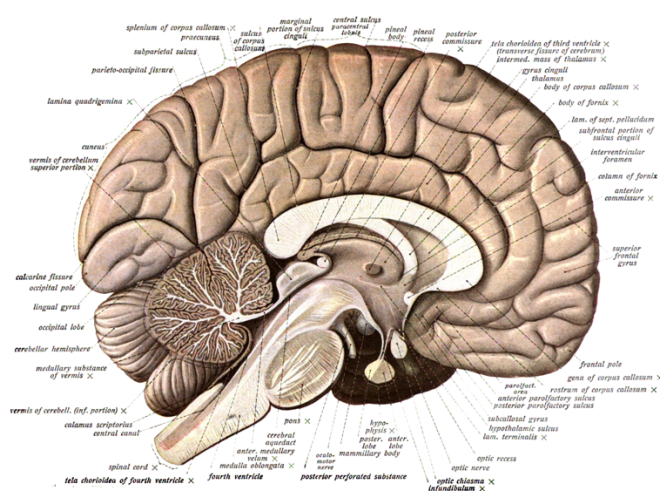


Figure 3. Human brain (Sobotta, 1908)

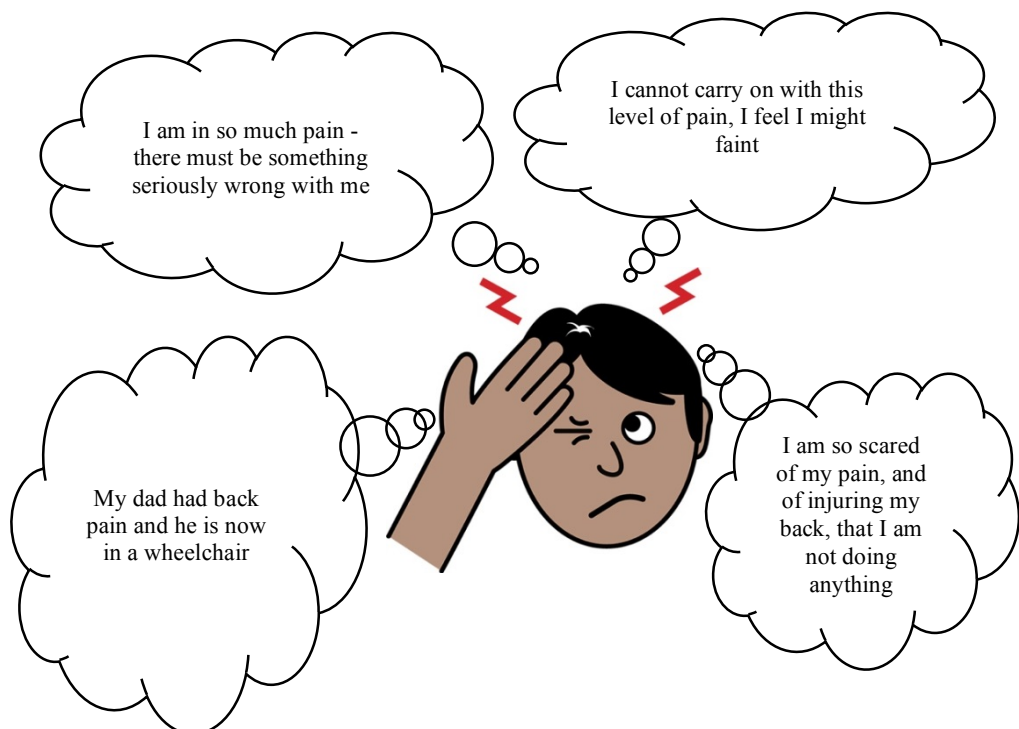
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Appendix M: Pain Education Session Hand-out v.1.2

What is pain?

- Pain is basically a protective device.
- Due to its unpleasant character, pain is something that we want to get rid of; however, pain is a normal, effective and essential part of life.
- There is group of rare genetic conditions resulting in some people not being able to feel pain. One such condition is called Congenital Insensitivity to Pain with Anhidrosis, or CIPA. It is common for people with this condition to die in childhood due to injuries or illnesses going unnoticed.
- Pain occurs when your body's alarm system alerts the brain to actual or potential tissue damage.
- Pain always depends on the context. Research shows that the way we feel and think about pain can increase and/or decrease the pain response.
- Our thoughts, beliefs and memories are very real. They are basically nerve impulses. Thoughts are nerve impulses too, as is pain.
- Scientific research confirmed that thought processes are powerful enough to maintain a pain state.



The Fear Avoidance Model

This model explains how acute pain can turn into a chronic and disabling condition. Fear fueled by dysfunctional beliefs about the source and meaning of pain will result in catastrophising which in turn prevents the sufferer from physical movement. Avoidance of movement, and hypervigilance to pain, can subsequently lead to depression and disability (See Figure 1.).

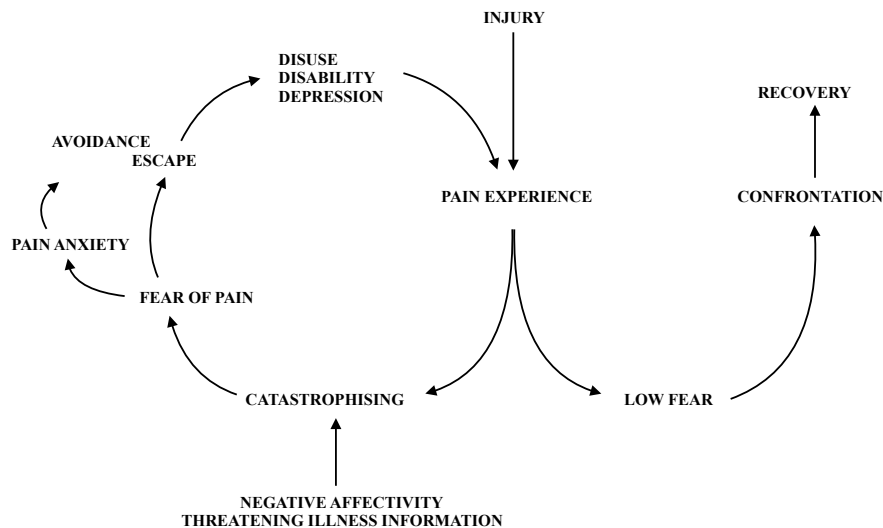


Figure 1. Fear-Avoidance Model of Chronic Pain (Vlaeyen & Linton, 2000).

The meaning that we give to our pain is crucial in how we respond to it. If we see it in a non-threatening way we are most likely to resume physical activity and have good recovery. If, however, we interpret pain as a ‘catastrophic’ event, a sign of a degenerative process or illness, we are more likely to avoid any kind of activity and become hypervigilant; constantly attentive to all body sensations. This then becomes a vicious cycle: by avoiding any opportunities to discount their beliefs, some individuals will become hypersensitive to pain and experience more pain in the future.

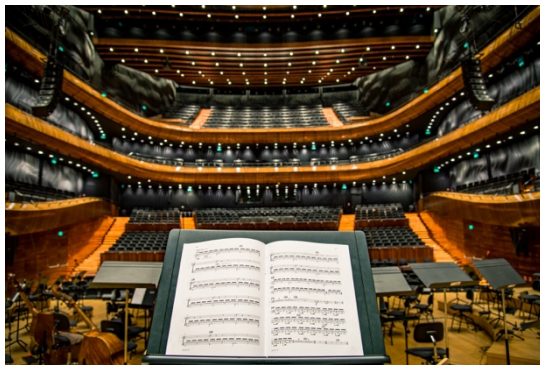
Desensitisation (reduction of sensitivity) is achieved through focusing on pain, allowing ourselves to feel it, telling ourselves that we are ok. This may allow us to accept it and try to move on despite the pain. It was acknowledged that the normal response to pain is to try to get away from it, and this process was compared to fear-avoidance, with an example of fear of heights. Those who are fearful of heights may avoid high places, but by doing so, do not realise that they are not very dangerous. The best treatment for fear is exposure to the feared stimulus; going to a high place and realising that it is ok. Following repeated and prolonged exposure **pain habituation** (being more tolerant) should occur, which means that our brain pain response should decrease with time.

What is Interoceptive Exposure?

Interoceptive Exposure (IE) is exposure to bodily sensations used in the treatment of a variety of problems where body sensations are experienced as threatening. The application of IE is expected to reduce the threat value of pain and subsequently promote recovery. When treating chronic pain IE implies that patients experience pain without trying to disrupt it in any way (e.g. shifting attention, avoiding movement, resorting to painkillers). There has been some evidence supporting the use of IE in the treatment of chronic pain.



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tunes and it can easily learn new ones. However, when the orchestra plays the same tune over and over, it becomes automatic, it plays by memory, and it becomes more and more difficult to play anything else. In chronic pain our brain (our orchestra) has become fixed on playing the same tune over and over. Musicians from different sections in the orchestra, just like different parts of the brain, have different functions. A fear and emotion section of the brain is like a very loud section of the orchestra and it can easily hijack the concert. Pain rehabilitation is about allowing the orchestra to learn new tunes and gradually move toward enriching the repertoire of our responses. Sadly, the chronic pain tune is by then so well remembered by the orchestra that they might remember and play it occasionally even after we have rehabilitated our brain. This is normal.

The brain is the most complex organ in the human body, which constantly interprets the information delivered through our senses into what makes sense for our survival.

- We ‘feel pain in our body’; we can be experiencing headaches, back pains or muscle pains. However, it is in the brain where the ‘pain is created’. Pain is an interpretation of what is and/or might be going on in our body.
- There are some striking examples of how the psychology of pain works.
- Occasionally the pain system appears to act oddly, such as when surfers who get their legs bitten by a shark feel just a little ‘bump’ at the time, or a condition called “**phantom limb pain**”, where the area of the body that hurts is no longer there (eg. after amputation).
- Pain is very effective: when it strikes we cannot think, feel or focus on anything else. However, when our brain decides that it’s not in our best interest to feel pain, we will

not feel any pain regardless of the seriousness of the injury. Good examples of this include situations in which severely injured soldiers do not report any pain until they leave the battlefield, or when rugby players carry on playing despite serious injuries that only become painful once the game is over.

- The amount of pain you experience does not necessarily relate to the amount of tissue damage you have sustained, for example: severe pain after stubbing your toe, versus no pain with serious injuries like a gunshot or shark attack.
- Every pain experience is created in the brain and depends on the context. Just like in this visual effect – See Figure 2.

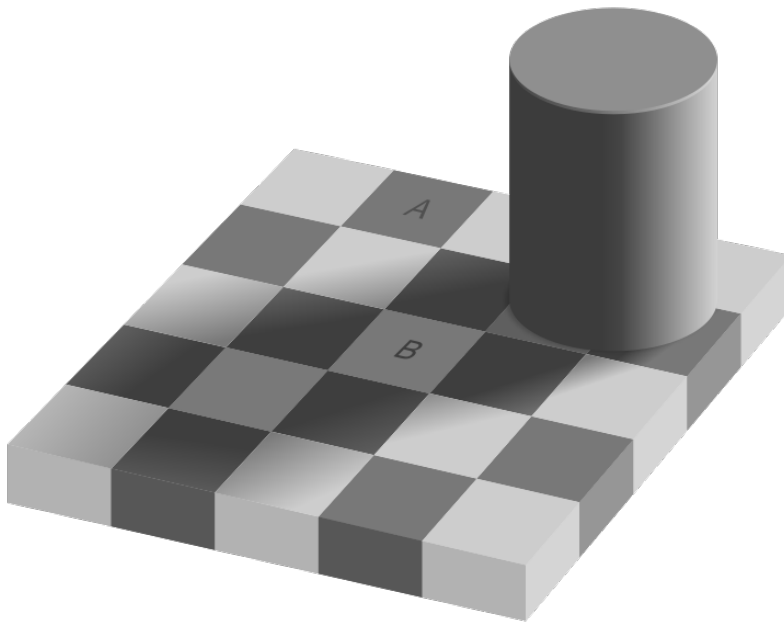


Figure 2. Gray square visual illusion (Adelson, 2008)

There is not just one pain centre in the brain (See Figure 3). Square A appears to be darker than square B; however, they are in fact identical. Why do we still see these squares as different? It is due to our brain's incredible ability to make sense of the information it is presented with. Information reaching our brain from our eyes is processed and 'made sense of'. Our brain has evolved to interpret a 2-D drawing as a 3-D representation. Our brain expects the cylinder in the middle of the board to cast a shadow. In addition, because our brain has learned that a checkerboard pattern is made from alternating light and dark squares, due to the positions of squares A and B, it recognizes square A as darker and square B as lighter, despite their actual color. The brain does similar work when it comes to pain; constantly interpreting information coming from the nerves and making sense of it to protect us from danger.

There are two phenomena described in chronic pain literature: **hyperalgesia** and **allodynia**. Hyperalgesia is an increased response to painful stimuli. This is common in chronic pain patients, due to the nervous system becoming more sensitive. In other words; the brain becomes an expert in noticing pain. Allodynia means a painful response to a normally non-painful stimulus. An example of allodynia can be experiencing sensations such as a stroke of

a feather or a gentle touch as extremely painful. This again can be explained by the brain's increased capacity to predict, notice and warn us about potentially painful stimuli, even if that stimuli is harmless.

There are many areas which might be involved in pain. These brain regions are involved in the processing of sensations, movement, emotions and memory. In chronic pain, some of these regions become very sensitive; they become 'hijacked' by the pain experience.

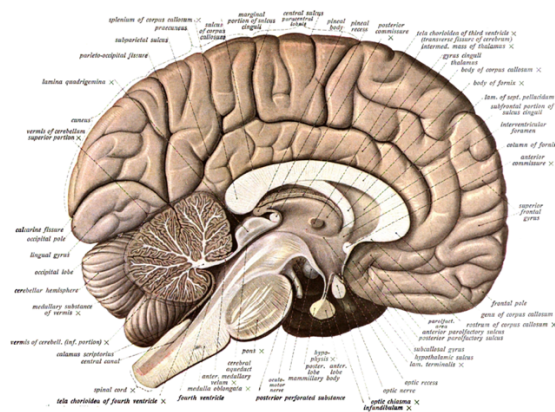


Figure 3. Human brain (Sobotta, 1908)

References:

Adelson, E. H. (2008, July 25). Gray square optical illusion [Digital image]. Retrieved August 23, 2017, from https://en.wikipedia.org/wiki/Checker_shadow_illusion#/media/File:Grey_square_optical_illusion.svg

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Sobotta, J. (n.d.). Human brain bisected in the sagittal plane, showing the white matter of the corpus callosum [Digital image]. Retrieved August 23, 2017, from https://en.wikipedia.org/wiki/Human_brain#/media/File:Sobo_1909_624.png

Images:

- “Alarm” and “Headache” images courtesy of 'Easy on the I' information design service; Learning Disability Service at Leeds and York Partnership NHS Foundation Trust. Retrieved from <http://www.easyonthei.nhs.uk/>
- Surfer photo courtesy of Tim Marshall <https://stocksnap.io/photo/VWL7YKSXDL>

Orchestra photo courtesy of Radek Grzybowski <https://stocksnap.io/photo/SORW0DPIR5>

Appendix N: Table N1. Participants' experiences of using the IE technique

	SP1	SP2	SP3	SP4	SP5	SP6	SP7
Able to engage	yes	yes	yes	yes	yes	yes	yes
Increase in distress after practice	59%	32%	26%	47%	88%	87%	22%
Distress stayed the same	41%	54%	45%	51%	10%	13%	48%
Decrease in distress after practice	0%	14%	29%	2%	2%	0%	30%
Comments	"I notice more range of pain"; "notice pain in other areas"; "quite relaxed"; "enjoyable"	"during [practice] pain feels more intense, afterwards it comes back to where it was before"	"I am finding comfort in listening to the tape and enjoying the 10 minutes twice a day just me time"; "I can slow breathing and exhale my thoughts away"	"the moment I sit down quiet for any length of time I wonder off, my mind goes, plays tunes or does something"	"able to notice pain more", "relaxing", as the intervention progressed became disappointed with the exercise	"comes in short, severe bursts", afterwards able to resume the activity she was doing before	"I can't especially when it gets worse, especially when it's increasing when trying to talk to listen to someone is difficult"
More competent with practice	yes	yes	yes	no	no	yes	no
Number of short practices	8	5	46	0	4	8	3
Used without listening to the recording	yes	yes	yes	no	yes	yes	no
How many weeks	3	2	3	4	3	2	2
Reduced medication	yes	yes	no	no	yes	yes	no

Note. Data taken from the Pain Desensitising Chart (PDC), observations and comments recorded during IE practice sessions and the Change Interview.

Appendix O: Interoceptive Exposure Session

The session will start with Revised Neurophysiology of Pain Questionnaire (Appendix 13). Following the test main points from last week's education session will be repeated. The Fear Avoidance Model will be repeated to explain why avoiding pain and/or distracting ourselves from it can result in more suffering. Participants will be encouraged to reflect on how their own worries, negative predictions and 'catastrophising' about pain can increase suffering.

Today we will practice Interoceptive Exposure to pain. This psychological technique is about focusing our attention on the pain, letting ourselves feel the pain without trying to escape it. Description from (Nicholas, 2017) will be used to explain the rationale for Interoceptive Exposure:

"At first glance this technique may seem to go against 'common sense' as it involves letting yourself feel the pain rather than trying to get away from it. To help it make more sense, think about why we get pain to start with. Broadly speaking, acute pain is a warning signal. It warns us that something is wrong, we may have an injury or be about to have an injury. Acute pain lets us know we need to investigate the cause and do something about it. Such pain can be useful to us. But that does not apply to chronic pain.

In contrast, with chronic pain any damage has already been done, so it's not really telling us anything new. The possible cause of your chronic pain will have been extensively investigated and you should have been reassured that serious or life-threatening causes have been ruled out. You can tell yourself that you are physically OK and not in danger.

Harmless nerve signals can be experienced as pain. The trouble is, our brain may still see the pain as a threat, just like acute pain. Unfortunately, just telling yourself the pain is OK is unlikely to be enough to overcome chronic pain. We have found that you also need to train your brain to learn not to react to this chronic pain as if it is acute pain. How do we train our brain to learn this new skill? Just like any other training – by practising it (a lot).

To desensitise yourself to your chronic pain you need to:

1. *Accept that it is not harmful and that it is OK to start moving and try not protecting yourself against the pain.*
2. *Acknowledge the pain is there but don't react to it.*

This requires that you don't try to avoid or escape the pain. The normal response to ongoing pain is to try to get away from it or to distract yourself from it – that is why people take pain killers. But what would happen if you didn't try to get away from it? Remember, you'll have the pain anyway. Why not see what happens if you don't try to escape the pain?

Another way of looking at our response of trying to avoid or escape from pain is to compare it with what we might do when we are afraid of something that is not really dangerous. For example, if we have a fear of heights we might avoid going to high places, even though it is very unlikely that we would fall off. By avoiding heights, we may never learn that we'd be OK after all. That fear can also limit our lifestyle. Interestingly, we know that the best treatment for these sorts of fears is confronting whatever you are afraid of (like going up to a high place) and letting yourself feel the anxiety sensations without reacting. It may take a few sessions of repeating this, but if you keep at it consistently, the method will work and you will overcome the fear. This effect can be called desensitisation or habituation (getting used to something).

Habituation is something we have all experienced. For example, if you buy a new painting or poster and put it on your wall you will notice it and admire it whenever you walk past initially. But after a few weeks you notice it less. It will start to become part of the background. You remain aware that it is there, you just don't notice it as much. This effect is called habituation. If we weren't able to do it we would be constantly distracted by everything we walked past. To become habituated to something we must not try to avoid or escape from it. Repeatedly trying to escape from or avoid something keeps us more sensitive to it. We are at risk of always being 'on the look-out' for it. It is not difficult to see how this can apply to pain.

What if we took the same approach to chronic pain? Instead of trying to avoid it or escape from it, what if we deliberately faced it for an extended period?

This method has been practiced with patients for many years. After a while, those who practise it a lot find the pain doesn't bother them as much. Of course, it's not easy for everyone and some say they can't face even the idea of doing it. (...) But overall, we have found this method very helpful in lessening the distress caused by pain. The pain will remain but you can train yourself to be less bothered by it.

We recommend you practice focussing on the pain in this way whenever your pain starts to trouble you. A good time to practice is when you are exercising or doing other activities that can aggravate your pain. Try it when you are trying to go to sleep and feel you can't get comfortable. But it does need practice.

Now participants will have a chance to practice IE following the instructions of the therapist. Participants will be asked to calmly focus their attention on their pain sensations while sitting or performing day to day activities, such as walking. It will be explained to participants how initially they might experience more pain; however, with time this should ease. They will be encouraged to allow themselves feel pain, without reacting to it or trying to change or fight it. Before the exercise starts participants will be asked whether they are experiencing any pain, they might need to stand up or move a little, as this exercise is best performed when they are actively experiencing pain sensation. A rating of how much pain bothers them at the time will be recorded on the Pain Desensitising Chart (See Appendix 10.).

“To start with, do these sessions either sitting or standing during the day and lying down at night. Do not try to make yourself so comfortable your pain is minimal before you start. Begin by taking a couple of deep breaths. As you breathe out try to let go of any tightness or tension in your body and allow yourself to relax as much as possible. After a couple of deep breaths, let your breathing return to normal but keep letting go and calming yourself each time you breathe out.

Do this for a minute or so and then focus your attention on your pain. If you have many pain sites, choose one of them. You can focus on your pain by simply allowing yourself to experience the pain – with no attempt to block it or change it. Let other thoughts or distractions from the task pass by. When focussing your attention on your pain it is especially important that you try to ignore thoughts about how bad it is or how much it is hurting. It is just pain. Remind yourself the pain is just activity in your nerves. It is not telling you anything you don't know – this pain is not acting as a warning signal – it is just pain. Remind yourself you are OK – you cannot come to any harm by experiencing your pain. To begin with many people find their pain feels stronger – this is common and you should try not to be concerned about it. It is probably because you are not trying to block it or push it away.

Any increased pain will pass if you keep your attention on it and keep relaxing each time you breathe out. Remind yourself: the goal of this method is not to relieve your pain. It is important for the success of the method that you try not to think about it in terms of pain relief (as that suggests you are still trying to get away from the pain). Instead, the goal is to accept you have the pain and that it doesn't bother you so much. Whenever your mind wanders bring it back to focusing on the pain and nothing else.” (Nicholas, 2017)

At the end of the exercise participants will be asked to rate how much pain bothers them at the time, this will be recorded on the Interoceptive Exposure record sheet (See Appendix 10).

Feedback from the exercise will be sought, any difficulties with performing the exercise (such as ‘mind wondering’, ‘increase in pain sensation’, ‘frustration’) will be addressed.

At the end of the session a MP3 player with a pre-recorded instruction of IE practice will be given to all participants. However, a separate MP3 file or a CD will be offered to these who prefer to listen to the instructions on their mobile phones or through home stereo. Participants will be asked to listen to the recording during two long sessions (10 minutes) twice a day and if they get a chance to do shorter sessions each time they experience pain (optional). Interoceptive Exposure record sheet will also be used in session to record how much the pain sensation bothered them at the start of the exercise and at the end.

References

Nicholas, M. (2017). *Background to interoceptive exposure to pain study*. Personal communication with Aleksandra Puchala.

Appendix P: Interoceptive Exposure (IE) practice instructions and recording form (Nicholas, 2017)

Name of the study: Interoceptive Exposure in reduction of fear of pain.

Some general tips on using this technique

As you will have worked out, just telling yourself that chronic pain is not a threat doesn't help. It is still unpleasant and you want it to go away. So, words or thoughts alone don't work. Instead, we have found that you also need to train your brain to learn not to react to the pain. The most effective way to achieve this is repeated practice.

This is similar to training for fitness or strength. In this case you are really training your brain instead of muscles. We recommend you try at least 2 long (10-15 minute) sessions daily, and many more short (1-5 minute) sessions whenever you feel your pain is disturbing or troubling you. Use the chart below to record your progress daily.

Remember, desensitizing takes time and no one gets good at it in a few sessions. It can take up to several weeks of regular practice before you notice the pain is less bothersome. As that starts to happen, you will feel more confident that you can limit its effects on your daily life.

When letting yourself feel your pain, try to ignore thoughts about how bad it is or how much it is hurting – just observe the sensations you are feeling, as calmly as possible.

Remind yourself the pain is just activity in your nerves. It is not telling you anything you don't know – this pain is not acting as a warning signal – it is just pain and isn't harmful.

Remind yourself you cannot come to any harm by experiencing your pain (it'll be there anyway, even if you're distracted or taking pain killers).

To begin with you may find the pain feels stronger – this is probably because you are not trying to block it or push it away. But any increase in pain will gradually pass if you just let it be there without fighting it.

If you like, as you stay with your pain, you can also try to relax yourself each time you breathe out.

Whenever your mind starts to wander off the track, bring it back to observing and experiencing the pain. This is normal and will need to be repeated many times.

As you get better at the technique, try doing it when you are active, especially when you notice your pain troubling you. Continue with the activity, but let yourself experience the pain without reacting to it. This will help you to do more despite your pain.

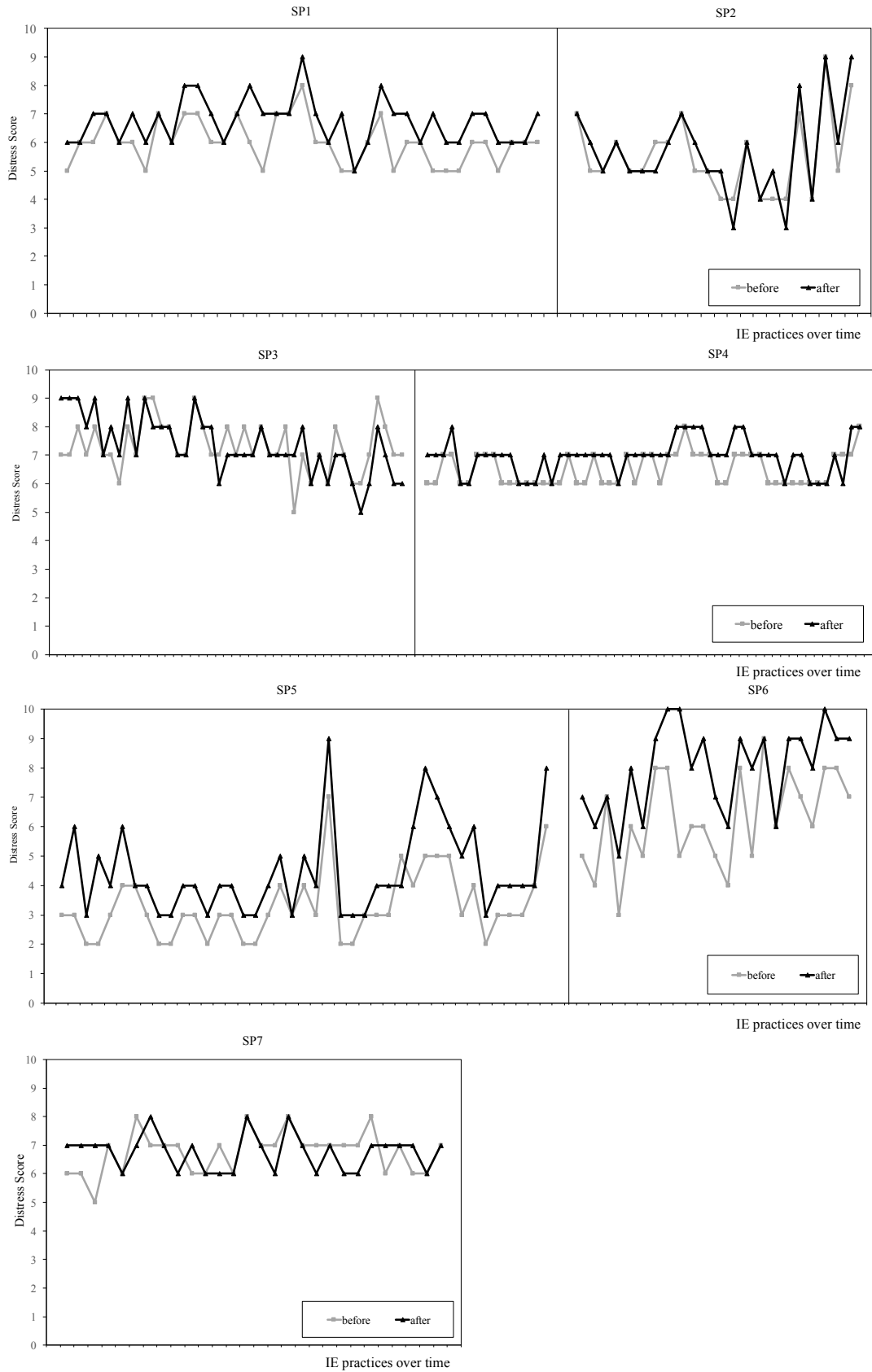
IE Instructions

1. To begin with, rate (on a 0-10 scale) on the chart how much your pain is bothering you right now.

We suggest you practice these sessions either sitting or standing during the day and lying down at night. Do not try to make yourself so comfortable your pain is minimal before you start (you should feel some pain to make it worthwhile).

2. Start playing the mp3 recording of the guided IE practice
3. Rate (on a 0-10 scale) on the chart how much your pain is bothering you now.

Appendix R: Figure R1: Distress Before and After IE Practice across Participants



Note. Data taken from participants' Pain Desensitising Charts.

Appendix S: Table S1: Changes in Activity across Participants

	Baseline Steps Average (M) (Min-Max)	Education Steps Average (M) (Min-Max)	Change Baseline/Education %	IE Steps Average (M) (Min-Max)	Change Baseline/IE %
SP1	M=3421 (666-6978)	M=3875 (1989-5513)	+12%	M=5083 (1868-12777)	+48%
SP2	M=1994 (1234-2911)	M=1854 (1123-2628)	+7%	M=2039 (610-3982)	+2%
SP3	M=2420 (1342-3756)	M=2723 (1795-4257)	+12%	M=2528 (1314-4987)	+4%
SP4	M=4485 (923-9632)	M=6119 (819-11079)	+36%	M=5335 (1210-14062)	+19%
SP5	M=4372 (1290-11194)	M=3754 (1761-10101)	+14%	M=4507 (1327-15739)	+3%
SP6	M= 2862 (542-3870)	M=2784 (391-4600)	-2%	M=4220 (633-5803)	+47%
SP7	M=1264 (755-2183)	M=1522 (1105-1896)	+20%	M=1830 (1261-2207)	+44%

Note. Data collected using the Nokia Go fitness tracker.

Appendix T: Table T1: HSCED Analysis

	Improvement on standard and target outcome measures*	Change Interview Changes (answers to Change Interview questions: How expected was the change? How likely this change was to happen without the intervention? How important was that change?) – HSCED analysis	Factors outside therapy
SP1	PCS	✓	<p>1. Increase in physical activity (Very much surprised by it, Very unlikely, Extremely) – Supported by activity data</p> <p>2. Able to continue with activity despite pain (Somewhat surprised by it, Very unlikely, Extremely) – Supported by activity data</p> <p>3. Increase in acceptance of pain, less anger (Somewhat surprised by it, Very unlikely, Extremely) – counterevidence: no reliable change on CPAQ</p> <p>4. More sexual (Very much surprised by it, Somewhat unlikely, Extremely) - Psychobiological causes?</p> <p>5. Thinks less about mum’s cancer, less worried that he will get bone cancer (Very much surprised by it, Very unlikely, Very) – Supported by reduction on PCS</p> <p>6. Less worry about pain and being more decisive (Somewhat surprised by it, Very unlikely, Very) - Supported by reduction on PASS-20</p> <p>7. Being more sociable (Very much surprised by it, Very unlikely, Extremely) – Self-correction?</p> <p>8. Spending more time with his son and being more spontaneous in doing so (Neither expected nor surprised by the change, Very unlikely, Extremely) – supported by activity data and reduction in PASS-20, Fear of Pain, Distress and Interference, Extratherapy life events?</p>
	PASS-20	✓	
	PDI		
	HADS-A		
	HADS-D		
	Fear of Pain (DD)	✓	
	Distress and Interference (DD)	✓	
	Activity	✓	
SP2	PCS	✓	<p>1. Beliefs about pain changed (Very much surprised by it, Somewhat unlikely, Extremely) - supported by reduction on PCS</p> <p>2. Have a new coping strategy (Neither expected nor surprised by the change, Somewhat unlikely, Very) – Trivial change?</p> <p>3. Change in pain management, less reliant on medication (Very much surprised by it, Very unlikely, Extremely) – supported by reduction on PCS, PASS-20 and Fear of Pain</p> <p>4. Increased motivation to be more active (Somewhat surprised by it, Very unlikely, Extremely) - Self-correction? Reactive effects of research?</p> <p>5. Being more honest about how I really feel (Neither expected nor surprised by the change, Neither likely nor unlikely, Moderately) - Self-correction? Reactive effects of research?</p>
	PASS-20	✓	
	PDI		
	HADS-A		
	HADS-D		
	Fear of Pain (DD)	✓	
	Distress and Interference (DD)	✓	
	Activity		
SP3	PCS		<p>1. Being able to slow down and breathe through pain instead of panicking, just trying to breathe through it and keep saying to myself that this will pass (Very much surprised by it, Very unlikely, Very) – supported by reduction in Fear of Pain and Pain Desensitization Record Chart</p> <p>Counterevidence: no reliable change on any other measures of Fear of Pain (i.e. PCS or PASS-20)</p>
	PASS-20		
	PDI		
	HADS-A		
	HADS-D		
	Fear of Pain (DD)	✓	
	Distress and Interference (DD)		
	Activity		
SP4	PCS	✓	<p>No changes reported during the Change Interview</p> <p>Improvement in PCS - Self-correction? Reactive effects of research?</p> <p>Improvement in PDI - Reactive effects of research?</p> <p>Improvement in activity - Self-correction? Extratherapy life events?</p>
	PASS-20		
	PDI	✓	
	HADS-A		
	HADS-D		
	Fear of Pain (DD)		
	Distress and Interference (DD)		
	Activity	✓	
SP5	PCS	✓	<p>1. Understand my pain more (Somewhat surprised by it, Somehow unlikely without it, Very)- supported by reduction in PCS, improvement in Revised Neurophysiology of Pain Questionnaire</p> <p>2. Better at sitting and ignoring pain (Somewhat surprised by it, Somehow likely without it, Extremely) - Self-correction? Reactive effects of research? Extratherapy life event? Psychobiological causes?</p>
	PASS-20		
	PDI		
	HADS-A		
	HADS-D		
	Fear of Pain (DD)		
	Distress and Interference (DD)		
	Activity		
			End of intervention coincided with period before Christmas, which involved more social gatherings and shopping trip, reduced opioid medication
			Period of illness during research, reduced opioid medication during study
			None
			Visiting family during the last week of intervention, reported better sleep and feeling more relaxed
			Came off opioid medication before the study, reported feeling better due to weather

	Improvement on standard and target outcome measures	Change Interview Changes (answers to Change Interview questions: How expected was the change? How likely this change was to happen without the intervention? How important was that change?) – HSCED analysis	Factors outside therapy	
SP6	PCS	✓	<p>1. I know now that I am not going to die because of pain (Very much surprised by it, Somewhat unlikely, Extremely) - supported by reduction in PCS</p> <p>2. I don't take myself to bed immediately (Somewhat surprised by it, Very unlikely, Very) - supported by increase in activity, Psychobiological causes?</p> <p>3. I feel like I can manage the feeling of pain better (Very much surprised by it, Somewhat unlikely, Very) - supported by reduction in PCS and PASS-20</p> <p>4. When I sit with pain it feels stronger but then it passes quicker (Very much surprised by it, Very unlikely, Extremely) - supported by reduction in PCS, Psychobiological causes?</p>	Periods of illness during study, reduced opioid medication
	PASS-20	✓		
	PDI			
	HADS-A			
	HADS-D	✓		
	Fear of Pain (DD)			
	Distress and Interference (DD)			
Activity	✓			
SP7	PCS		<p>No changes reported during Change Interview</p> <p>Improvement in Activity – Extratherapy life events?</p> <p>Improvement in Pain Distress and Interference - Reactive effects of research?</p>	Last week of the intervention coincided with family celebrations and pleasurable social events
	PASS-20			
	PDI			
	HADS-A			
	HADS-D			
	Fear of Pain (DD)			
	Distress and Interference (DD)	✓		
Activity	✓			