Assessing the Impact of a Brief CBT Intervention and a Sonification-of-Movement Device on Pain Anxiety in Chronic Pain: A Mixed Methods, Multiple Single-Case Design

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D.Clin.Psy Thesis (Volume 1), 2019

University College London

UCL Doctorate in Clinical Psychology

Thesis declaration form

I confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis.

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Overview

Part 1 of this thesis is a conceptual introduction literature review that presents an overview of the current theoretical understanding of chronic pain, with a specific focus on psychological theories and the role of fear avoidance in the development of chronicity and disability. It explores the efficacy of Cognitive Behavioural Therapy (CBT) in the treatment of chronic pain, and highlights the need for treatments that increase accessibility to psychologically-informed intervention, and enable people to build on their clinical treatment once it concludes.

Part 2 is an empirical paper that explores the effects of two interventions, 'brief' CBT and the 'Go-With-the-Flow' (GWtF) sonification of movement device, on pain anxiety when trialled by participants at home. It uses a mixed methods, multiple single case design to quantitively track pain anxiety associated with a bend-based experimental movement (that is usually painful) for six individuals living with chronic pain. Interviews were used to qualitatively explore participants' experiences of the two interventions. The impact of each intervention on pain anxiety was variable across participants. Qualitative data indicates that brief CBT was generally the preferred intervention but, based on quantitative data, neither intervention yielded a statistically significant improvement in pain anxiety in most cases. GWtF was associated with a statistically significant increase in bend achieved from baseline for the group as a collective, but most participants indicated that they would not use it in its current format.

Part 3 is a critical appraisal that considers the researcher's clinical and personal experiences that have motivated the research. It also reflects on the experience of conducting the research, with a particular focus on the methodological decisions taken and the challenges encountered in relation to recruitment and data collection.

IMPACT STATEMENT

Chronic pain, defined as pain that persists beyond twelve weeks, is a prevalent condition (estimated to affect between 35% and 51% of the population) that is recognised to have disabling effects physically, psychologically and socially. The fear avoidance model is a biopsychosocial approach to understanding chronic pain that considers the key role that anxiety about pain plays in the development and maintenance of chronicity. While the impact of pain anxiety in chronic pain is increasingly recognised and there are a range of nonpharmacological treatments (e.g. Cognitive Behavioural Therapy; CBT) that may be beneficial, accessibility can be poor and maintenance of gains upon completion of clinical treatment can be weak. As such, the present study explored the impact of two interventions intended to be accessible and suitable for home-use (brief CBT and Go-With-the-Flow sonification) on pain anxiety.

The findings are promising from a clinical perspective, as they indicate that each intervention was associated with benefit for some participants, while Go-With-the-Flow was associated with a collective increase in bend for the group as a whole. Furthermore, as both interventions were successfully used at home without significant difficulty, they both could, with further development, increase accessibility to psychologically-informed intervention in the context of chronic pain. The findings warrant a closer look at the interventions over a longer period, incorporating a wider range of measurement, to try and better understand the trajectory of change associated with each, the sustainability of any benefit, and the patient presentations that each would best support.

From a research perspective, the present study is impactful as it demonstrates the suitability of a multiple single-case design in a community context, whereby participants largely utilised the interventions and conducted measurement tasks independently. It also emphasises the value of qualitative data in contextualising quantitative findings, given the

indication that, despite a collective increase in bend, participants largely reported that they would not use the Go-With-the-Flow in its current format.

The research highlights design and analysis issues specific to single case methodology (regarding phase lengths and Tau-U statistical methods) that could helpfully inform the design of future single-case projects. As single case methodology is an active area of development, all studies that adopt it will hopefully contribute to the progression and refinement of the approach.

The research also highlights the complexity of pain anxiety as a construct, and the need for further research that seeks to understand pain anxiety and how best to assess it. This would enable accurate measurement and monitoring of fear and avoidance, and the development of treatments that target pain anxiety specifically.

TABLE OF CONTENTS

LIST OF TABLES AND FIGURES

ACKNOWLEDGEMENTS

Assessing the Impact of a Brief CBT Intervention and a Sonification-of-Movement Device on Pain Anxiety in Chronic Pain: A Mixed Methods, Multiple Single-Case Design

PART 1: Conceptual Introduction Literature Review

Abstract

A narrative review was used to summarise the current theoretical understanding of chronic pain, with a specific focus on the psychological theories and neural pain mechanisms that support a biopsychosocial approach to chronic pain conceptualisation and management. A key focus of the review is on fear avoidance, given the indication that higher levels of pain-related fear and avoidance predict subsequent chronicity and disability in chronic pain.

The efficacy of Cognitive Behavioural Therapy (CBT) treatment in chronic pain is also reviewed (using evidence generated through both systematic and conventional methods). CBT is indicated to have a small to moderate effect on pain, disability and mood, but maintenance of gains beyond six months is weak and access to treatment is poor. As such, the need is indicated for nonpharmacological interventions that are accessible and support people to build on their clinical treatment once it concludes. Two potentially plausible at-home treatments are considered; 'Brief' CBT and a sonification of movement device called 'Go-With-the-Flow'. The rationale for a multiple single case project that explores the effect of each on pain anxiety in the context of chronic pain is presented.

Introduction

Acute pains are common somatic experiences. However, in a minority of cases the pain persists and can have a significant longer-term impact, physically, emotionally and socially (Crombez, Eccleston, Van Damme, Vlaeyen & Karoly, 2012). Chronic pain is defined as pain that persists beyond twelve weeks; the timepoint after which most tissue damage associated with acute injury would normally have healed (British Pain Society, 2013). A key systematic review and meta-analysis by Fayaz, Croft, Langford, Donaldson & Jones (2016) suggests that between 35.0% and 51.3% of the UK population have some form of chronic pain, while the Global Burden of Disease Study (Vos, Flaxman, Naghavi, 2010) identifies chronic pain as one of the leading causes of disability worldwide. The consequent strain on healthcare systems and impact on the psychological wellbeing of individuals living with pain is significant (Farezadi, Normah, Zubaidah & Maria, 2008; Fayaz et al., 2016; Vos, Flaxman & Naghavi, 2010).

Cognitive Behavioural Therapy (CBT) is a psychological intervention that yields small but consistent improvements in pain, disability and mood in the context of chronic pain. However, maintenance of these gains over six months (or over years, the time course of chronic pain) is weak, with only small effects on mood at follow-up (Williams, Eccleston & Morley, 2012). Further, CBT provision can never meet the extent of need, so interventions are required that improve access and support people to maintain and generalise their treatment gains once clinical intervention finishes (Buhrman, Gordh & Andersson, 2016; Dear, Gandy, Karin, Staples, Johnston, Fogliati, Wootton, Terides, Kayrouz, Nicholson Perry, Sharpe & Nicholas, 2015; Singh, Piana, Pollarolo, Volpe, Varni, Tajadura-Jiménez, Williams, Camurri & Bianchi-Berthouze, 2016).

Additionally, higher levels of pain-related fear and avoidance have been shown to predict subsequent chronicity and disability in chronic pain, which highlights the importance of targeting fear and avoidance specifically in psychological intervention (Borkum, 2010;

Wertli, Rasmussen-Barr, Held, Weiser, Bachmann & Brunner, 2014).   The current project therefore utilises a multiple single-case design to explore the impact of two interventions, intended to be more accessible than full CBT treatment, on pain anxiety in the context of chronic pain: 1) brief CBT and 2) a wearable sonification device (explained below).

The intention of this literature review is to provide the context and rationale for the current study and justify the research design used. It consists of three sections, with the first summarising the theoretical understanding of chronic pain with a specific focus on neural pain mechanisms and psychological theories of chronic pain.   The second uses literature gathered through both a systematic search (please see Appendix 1 for details of the search), as well as conventional (less-systematic) search methods, to review the evidence for cognitive-behavioural therapy in the treatment of chronic pain broadly, as well as the evidence that has shaped the present study's use of brief CBT and sonification specifically. The final section concludes the review by firstly, outlining the key research questions that have arisen from the reviewed literature, and secondly, summarising the methodology for the present study.

Theories of Chronic Pain

In 1965, Melzack & Wall proposed their Gate Control Theory of Pain; the first model to integrate psychological processes into the biomedical understanding of pain which dominated at the time (whereby level of pain experienced was believed to correspond with amount of damage to tissues; Gatchel, Peng, Peters, Fuchs, & Turk, 2007).

The Gate Control Theory posited that incoming sensory input (such as touch, pressure, temperature) evokes signals that are transmitted by nerve fibres to the dorsal horn of the spinal cord, which acts as a gating mechanism and modulates transmission of the signals to the brain (Moayedi & Davis, 2012).   The gate is modulated by both incoming sensory inputs and by descending fibres from the brain, such that Central Nervous System (CNS) activities associated with memory, emotion, cognition and attention, exert direct

control over sensory input. This has the effect of amplifying or inhibiting the transmission of pain signals.

The Gate Control Theory revolutionised the field of pain research and was the initial basis for the modern biopsychosocial understanding of chronic pain, which recognises the key role of psychosocial influences in pain perception (Moayedi & Davis, 2012). A biopsychosocial perspective considers both disease and illness, with disease referring to biological events associated with anatomical, pathological or physiological changes, while illness is the subjective experience of those changes that is shaped by biological, psychological and social factors (Gatchel et al., 2007).

Evidence of the central role that psychosocial factors play in pain processing arises from research that demonstrates that pathology and pain are not correlated in the way predicted by a biomedical formulation. A research overview by Okifuji & Turk (2015) highlights that 1) the presence of pain does not indicate tissue damage (Baranto et al. 2009), 2) many people have structural abnormalities (e.g. herniated discs) that would be expected to be painful but are not (Baranto et al. 2009), 3) level of functional impairment associated with pain only modestly correlates with amount of tissue damage (Jarvik & Deyo, 2002), and 4) patients can have vastly different post-operative outcomes (with regards to pain levels) despite similar initial pathology and surgical treatment (North et al., 1991). An integrative review by Knoerl, Lavoie Smith & Weisberg (2016) highlighted that the first-line treatment of pain is typically pharmacological, although only 50% of people taking medication for chronic pain report a meaningful change in pain, and many discontinue treatment due to adverse effects (Machado, Kamper, Herbert, Maher & McAuley, 2009; McNicol, Midbari, & Eisenberg, 2013).

Neural Pain Mechanisms

Since the Gate Control Theory, the field of neuroscience has significantly advanced the understanding of the neural mechanisms involved in pain processing. Neuroimaging

studies have highlighted a variety of specific regions in the brain that become activated

during painful stimulation in individuals without chronic pain, including areas associated with

attention, emotional response, motor function and sensory integration (Derbyshire, Jones,

Gyulai, Clark, Townsend & Firestone, 1997; Mason, 2015). However, in the context of chronic

pain, many changes to pain processing occur, with increased activity in areas associated with

memory, threat processing, emotional response, fear aversion and attention. Multiple

neural mechanisms play a role in pain perception in the context of chronic pain, including

descending modulation, central sensitisation, the role of attention, and predictive coding.

These mechanisms will now be considered in more detail.

Descending Modulation

A modulatory system, with both ascending and descending pathways, exists within

the nervous system and serves to facilitate or inhibit afferent inputs. The descending pain

modulation system is a top-down process that incorporates input from higher brain systems

and affects their interaction with nociceptive input (nerve transmission of potential tissue

damage from body tissues) to influence pain experience. One such system is the limbic

system which is involved with emotional processing, meaning that psychological factors

(relating to anxiety, depression, attention etc.) modulate pain intensity (Mason, 2015). In

individuals with pain, there is evidence to suggest that the dysregulation of descending pain

modulation (due to dysfunctional pain inhibition) may promote and maintain chronicity

(Ossipov, Morimura & Porreca, 2014).

Central Sensitisation

The fact that someone can be catastrophically injured and initially experience no

pain, while a headache or toothache (which usually involves minimal tissue damage) can be

excruciating, highlights the disconnect between nociception and pain (Salomons, Moayedi,

Erpelding & Davis, 2014). The process of central sensitisation contribRisk of Biasutes to this

discrepancy and increases the risk of chronicity in pain that persists (Salomons, 2014). Central sensitisation is a form of neuroplasticity where neural signalling within the CNS becomes amplified, resulting in pain hypersensitivity (Woolf, 2011). It is an adaptive process in the short-term as it promotes protection against further damage in the context of acute injury, and normal sensitivity levels are typically restored during healing (Latremoliere & Woolf, 2009). However, in instances where pain persists in the absence of tissue damage, the notion of central sensitisation may provide an explanation.

Central sensitisation arises following repeated noxious stimulation that results in CNS changes (Mason, 2015), including to spinal mechanisms (e.g. increased sensitisation within the spinal cord, enhanced neuronal firing in the dorsal horn leading to a greater receptive field and increased responsiveness; Mason, 2015) and supraspinal mechanisms (e.g. the descending pain modulation system influencing the amount of pain perceived; Mason, 2015). So, psychological processes are central in sensitisation, with cognitive and affective processes exerting control over incoming sensory information through descending modulatory pathways. Enhanced attention (e.g. hypervigilance) has also been shown to increase the risk of sensitisation (Mason, 2015; Salomons, 2014). These examples highlight the potential role of psychological intervention in mitigating and reversing central sensitisation in the context of chronic pain (Salomons, 2014).

Latremoliere & Woolf (2009) outline the common effects of central sensitisation, including pain that 1) arises spontaneously, 2) can be elicited by innocuous stimulation (termed allodynia), 3) is prolonged or exaggerated in the face of noxious stimulation (termed hyperalgesia), and 4) extends beyond the original site of tissue injury (termed secondary hyperalgesia). Central sensitisation "represents a major functional shift in the somatosensory system, from high-threshold nociception to low-threshold pain hypersensitivity" (Latremoliere & Woolf, 2009; p. 2).

Attention

Pain is evolutionarily predisposed to demand attention in order to protect from potential harm and is thus intrinsically salient. Interruption of attention by pain is moderated by both pain-related characteristics (e.g. its intensity and novelty) and environmental characteristics (e.g. the presence of a threat). However, pain is also subject to competition from other demands on attention, and actions that are interrupted by pain are maintained until fulfilled. Given that attention has limited capacity, pain is therefore affected by competition from other important events and concerns (Eccleston & Crombez, 1999; Kucyi & Davis, 2015).

There are three distinct neural circuits involved in attentional fluctuations in pain; the salience network, the default mode network and the descending pain modulatory system (described above). The salience network becomes activated in response to an event that 'grabs' attention, while the default mode network is active when there is no dominant input (Kucyi & Davis, 2015; Wiech, 2016). In people with chronic pain, alterations in interactions between the salience network, default mode network and descending pain modulatory system result in heightened attention to pain (Kucyi & Davis, 2015; Wiech, 2016).

Predictive Coding

The wide range of hypothesised pain mechanisms support a move away from locating specific functions, to instead considering the notion of integrated functions and a dynamic pain connectome in the brain (Kucyi & Davis, 2015). One such approach is the model of predictive coding which, outside the pain literature, informs broader understanding about perception and action (Wiech, 2016). The theory posits that prior experience generates a 'template of expectation' that shapes the interpretation of future sensory inputs (Clark, 2013; Park & Friston, 2013; Wiech, 2016).

In the context of pain, prior information, including pain-related cues and sensory input, shape pain expectation which is then compared with nociceptive input. If the two

24

match, then the association of cues and pain are strengthened but no action or change of expectation is required. If they conflict then a prediction error occurs, and the problem is passed to higher processing levels that may then update expectations (i.e. learning) or prompt the subject to act on the environment (Wiech, 2016). For example, the response to a needle-pricking sensation in the context of knowingly receiving an injection would be negligible compared to the response if that same sensation was experienced while in a crowd of strangers, when a search would occur for the source(s) of the sensation and possible environmental danger. Resulting actions might, for instance, involve increasing interpersonal distance to minimise recurrence. However, individuals with chronic pain may have suboptimal information integration and learning, and overgeneralised cues associated with pain, and thus mental representations of pain that are resistant to change (Wiech, 2016).

Clinical Psychology and Chronic Pain

Improved understanding of the neural mechanisms involved in chronic pain has highlighted the important role of psychological factors in pain processing. The potential contribution of clinical psychology to the treatment of chronic pain is therefore a valuable one (Jensen & Turk, 2014). The evidence base for psychological intervention for chronic pain is dominated by studies using contemporary Cognitive Behavioural Therapy (CBT) for chronic pain (Williams et al. 2012); an approach which is the culmination of many theoretical ideas and developments spanning more than half a century (Morley, 2011).

Psychological Theories of Chronic Pain

Behavioural Theories

Operant Principles

In the 1970s, an operant conceptualisation of behaviour associated with pain (Fordyce, 1976; Patterson, 2005) superseded earlier psychoanalytic ideas applied to pain,

25

and the false distinction between organic and functional pain (Patterson, 2005). Fordyce's (1976) framework applied learning processes that affected other types of behaviour to pain-related behaviours (such as limping, taking analgesics, seeking social support, taking sick days from work, and so on). He distinguished between respondent pain behaviours (e.g. those that are reflexive in response to an antecedent) and operant pain behaviours that are reinforced by environmental contingencies (Maclean, 2009).

Fordyce's (1976) hypothesis was that acute pain behaviours (e.g. inactivity, altered posture; Maclean, 2009), initially reinforced by temporary pain relief, are inadvertently maintained by other contingent outcomes (e.g. the addition of caring responses from loved ones; the removal of negative experiences such as a stressful job), thereby maintaining the pain behaviours and contributing to pain chronicity (Henschke, Ostelo, van Tulder, Vlaeyen, Morley, Assendelft & Main, 2010). Successful management of pain therefore involved 1) the adjustment of environmental contingencies to abolish reinforcement of pain behaviours, and 2) the use of positive reinforcement to develop and sustain more adaptive 'well' behaviours (Fordyce, 1976; Patterson, 2005).

Respondent principles

The respondent model of pain, proposed by Gentry and Bernal (1977), posits that pain and tension become classically conditioned in the acute phase, such that pain becomes both an antecedent and consequence of muscular tension (i.e. pain causes tension, which in turn exacerbates pain). This 'pain-tension-pain' cycle was theorised to result in avoidance, increased pain perception and ultimately increased disability (Lethem et al., 1983).

Biofeedback and relaxation training were introduced into behavioural treatment protocols for chronic pain with the aim of disrupting this cycle by reducing muscular tension (Frank, Khorshid, Kiffer, Moravec, & McKee, 2010; Morley, 2011; Turk, Meichenbaum & Genest, 1983). Biofeedback involves the provision of real-time physiological data, such as heart rate, to train the individual to recognise and voluntarily control automatic physiological

responses to pain. Given that the influences of descending modulation and sensitisation were not yet appreciated, these models reflect the focus of the time on trying to find local rather than systemic causes of pain.

<u>Cognitive-Behavioural Theories</u>

The importance of cognitive factors in shaping emotional and behavioural responses was a concept that gained in popularity in the late 1970s, following a wealth of research that indicated that disability in the context of chronic pain was determined more by beliefs than by pain intensity (Zale & Ditre, 2015) The consideration that cognitions (rather than just observable behaviours and associated environmental contingencies) could be the target of intervention, led to the application of CBT to chronic pain (Patterson, 2005). The introduction of cognitive methods into the behavioural approaches outlined above, and the progression of CBT for pain to its present-day form, will now be considered in more detail.

Self-Control

With its roots in radical behaviourism, early theoretical ideas about self-control moved away from the notion that the therapist 'does to' a patient and instead centred on teaching the individual to control themselves, by learning to identify and adjust antecedents and consequences of target behaviours to bring about desired behavioural change (Brigham, 1980; Mahoney & Thoresen, 1972). However, Mahoney & Thoresen (1974) posited that it is a person's perception of their environment that dictates their behavioural response to it, highlighting the importance of cognitive factors in shaping human behaviour. Self-control was a central concept in early CBT, with a key treatment focus being on the individual developing coping skills through the acquisition of cognitive strategies such as distraction and relabelling (Hadjistavropoulos & Williams, 2004). However, the evidence for efficacy in chronic pain was poor.

Stress Management

The field of stress management in mainstream psychological treatment was also a key theoretical influence in early CBT for chronic pain (Hadjistavropoulos & Williams, 2004). The consideration of pain as a stress-response was informed by the work of Lazarus (1966), who studied factors that shape differential responses to perceived threat. They proposed that a person's response to a stressor depends on their appraisal of the amount of threat associated with the situation and their perceived capacity to cope with that threat (Turk & Meichenbaum, 1983); ideas that are still current and influencing treatment today (Morley, 2011).

When the amount of pain-related stress is appraised as outweighing coping resources, wellbeing is affected (Dysvik, Natvig, Eikeland & Lindstrøm, 2005). A distinction between threat and challenge appraisals was made: perceiving a stressor (e.g. pain) as a threat leads to a negative emotional response, while considering it as a challenge provides opportunity for growth and mastery (Dysvik et al., 2005). A stress-management treatment approach centred on the acquisition of new cognitive and behavioural resources, to increase capacity to manage the challenge associated with threatening situations more effectively (Turk & Meichenbaum, 1983).

Cognitive Theory

Beck, Rush, Shaw & Emery (1979) devised a cognitive model of depression which considered the critical role of idiosyncratic interpretation (Morley, 2011). With respect to depression, Beck et al. (1979) identified key cognitive mechanisms hypothesised to be central to development and maintenance of clinical depression, including negative self-schemas and information-processing biases. Cognitive therapy is based on a theory of information processing in which core beliefs or schemas emerge as part of normal development; experiences are organised to help make sense of the world, leading to enduring cognitive structures that help to meaningfully categorise and interpret new information (Padesky,

1994; Beck, 1967). Vulnerability to depression was theorised to relate to the development of negative schemas in childhood that are then activated by adverse events later in life. This results in distorted and negatively-biased information processing and involuntary negative automatic thoughts, both of which serve a key maintaining function (Beck, 1967).

Given the marked overlap between depression and pain (with chronic pain patients four times more likely to experience depression than pain-free individuals; Kleiber, Jain & Trivedi, 2005), elements of Beck's model were soon applied to the psychological treatment of chronic pain (Morley, 2011). Two concepts have subsequently emerged as key cognitive factors in chronic pain - 'Pain Catastrophising' and 'Pain Self-Efficacy' (Amtmann, Liljenquist, Bamer, Bocell, Jensen, Wilson & Turk, 2018):

1) *Pain Catastrophising*

The concept of catastrophising (originally developed by Ellis, 1962) was revised by Beck (1979) to define a maladaptive cognitive style that is commonly associated with depression and anxiety disorders (Quartana, Campbell & Edwards, 2009). Individuals prone to catastrophising have cognitive and emotional schemas that result in the overestimation of negative future outcomes (Quartana et al., 2009). In the context of pain, catastrophising refers to an elevated negative cognitive response to painful stimuli (Pedler, 2010; Sullivan, Bishop & Pivik, 1995), such that the perceived threat-value associated with a painful situation is greatly amplified (Chaves & Brown, 1987; Quartana et al., 2009). This results in increased anxiety and rumination about pain, which consequently leads to hypervigilance, (Spanos, Radtke-Bodorik, Ferguson & Jones, 1979; Quartana et al., 2009), and increased feelings of helplessness (Quartana et al., 2009). Catastrophising increases activity in the areas of the brain associated with pain intensity and selective attention; by intensifying the extent to which pain captures attention, catastrophising is hypothesised to contribute to the process of central sensitisation (Borkum, 2010).

Increasing evidence suggests that, particularly in the context of musculoskeletal pain, catastrophising is an important contributory factor in the development of chronic pain and associated disability (Smeets, Vlaeyen, Kester & Knottnerus, 2006). Catastrophising influences emotional, functional and physiological responses to pain and is associated with increased chronicity and poorer prognosis, as well as greater psychological distress and pain intensity (Amtmann et al., 2018; Darnall, 2019; Leung, 2012; Quartana et al., 2009; Sullivan et al., 1995). Catastrophising has been found to mediate the negative effects of pain behaviour and pain interference on mental health (Heirich, Ziadni, Gross, Manber, Darnall, Law, Kong, Sinjary, Ng, Cogan & Mackey, 2018), and to have a negative impact on quality of life and health ratings (Börsbo, Gerdle & Peolsson (2010).

In summary, a wealth of evidence supports the hypothesis that catastrophising is an important variable in pain, and one that is crucial in shaping our understanding of and approach to chronic pain and its management (Quartana et al., 2009). Psychosocial interventions have been found to reduce pain catastrophising, resulting in positive and long-term outcomes with respect to pain intensity, disability and psychological functioning (Keefe, Rumble, Scipio, Giordano & Perri, 2004; Smeets et al., 2006). However, more recent research suggests that the relationship between catastrophising and pain may be described as mutual causation, with reductions in catastrophising found to predict pain improvement, while improvements in pain predict subsequent reductions in catastrophising. This suggests that catastrophising may be a key process to address in treatment (Racine, Moulin, Nielson, Morley-Forster, Lynch, Clark, Stitt, Gordon, Nathan, Smyth, Ware & Jensen, 2016).

2) *Pain Self-Efficacy*

Self-efficacy describes a person's confidence in her or his ability to achieve a desired outcome and, in chronic pain specifically, the extent to which an individual continues doing things despite their pain (Costa, Maherl, McAuley, Hancock & Smeets, 2011; Bandura, 1986). Self-efficacy is a central construct of Bandura's social cognitive theory (1986), which

incorporates both cognitive and behavioural theories of behaviour change to propose that learning takes place within a social context and is dependent on a reciprocal interaction between the individual, her/his behaviour and the environment (LaMorte, 2018). Self-efficacy theory posits that two factors in particular are central to behavioural acquisition; perceived self-efficacy and anticipated outcome (Sutton, 2001). The theorised mechanism of change is thus the alteration of an individual's appraisal of their ability to master and succeed (Sherer, Maddux, Mercandante, Prentice-dunn, Jacobs, & Rogers, 1982; Bandura, 1986), which psychological intervention has been proven to enhance (Keefe, Rumble, Scipio, Giordano & Perri, 2004).

There is a strong indication that self-efficacy about one's capacity to manage their pain serves a significant protective function in the context of chronic musculoskeletal pain (Martinez-Calderon, Zamora-Campos, Navarro-Ledesma & Luque-Suarez, 2018). Higher self-efficacy has been linked with better prognosis and adjustment to diagnosis, increased physical activity and capacity to work, better physical and mental health, improved quality of life, as well as lower levels of pain intensity, disability and functional impairment (Jackson, Wang, Wang & Fan, 2014; Martinez-Calderon et al., 2018). Furthermore, self-efficacy plays a mediatory role in the relationships between pain and disability, and between depression and pain severity (Costa et al., 2011; Skidmore, Koenig, Dyson, Kupper, Garner & Keller, 2015).

Contemporary CBT for Chronic Pain - the Fear Avoidance Model

The application of the generalised fear and avoidance model to chronic pain has been described by Morley (2011; p. 100) to reflect the "final strand of current CBT". The concept was applied in the model of Linton, Melin & Gotestam (1984), which was grounded in both classical and operant theory and centred on avoidance of activity (Vlaeyen & Linton, 2000). Linton et al. (1984) theorised that when a previously neutral stimulus (e.g. bending) becomes

paired with a negative experience (e.g. pain) this leads to avoidance of that activity, which is then reinforced by the resultant reduction in pain and fear (Vlaeyen & Linton, 2000).

While the terms fear and avoidance place emphasis on the affective (fear) and behavioural (avoidance) components of chronic pain (Gatchel et al., 2007), Vlaeyen & Linton's (2000) model incorporated a cognitive focus, and posited that beliefs about pain, rather than pain itself, dictate its course. If pain is perceived to be non-threatening, the individual typically resumes normal activity as s/he recovers.   However, if pain is catastrophically misinterpreted (e.g. as an indication of serious injury), it can lead to fear of pain, avoidance of movements and situations that have become associated with pain, and increased sensitivity to pain sensations (Crombez et al., 2012; Vlaeyen & Linton, 2000).

Both avoidance and hypervigilance are adaptive responses when pain is acute, but in the longer-term reduced movement can lead to physical deconditioning, resulting in a progressive increase in the pain and disability associated with it (Wicksell, Ahlqvist, Bring, Melin & Olsson, 2008). This serves to reinforce the individual's fear and avoidance in relation to movement and its consequences (Crombez et al., 2012).

There are several different terms used in the literature that relate to a fear of pain and associated avoidance of movement/activity in the context of chronic pain. The term 'fear-avoidance' is popular but is somewhat ambiguous: does it reflect avoidance of fear; a fear of avoidance? Another common phrase is 'fear-avoidance beliefs' which is somewhat restrictive given the central role of emotion and behaviour in the process. To ensure consistency throughout, the term 'fear and avoidance' will be adopted in this review to encompass the different terms used in research.

While they are distinct concepts, catastrophising and self-efficacy play a significant role in shaping fear and avoidance (Gatchel et al., 2007). Level of catastrophising has been found to both precede and significantly predict the development of fear of pain/re-injury (Smeets et al., 2006; Vlaeyen, Kole-Snijders, Rotteveel, Ruesink & Heuts, 1995). A significant

negative correlation between self-efficacy and fear and avoidance has also been reported, such that higher self-efficacy is associated with lower fear and avoidance and vice versa (de Moraes Vieira, de Góes Salvetti, Damiani & de Mattos Pimenta, 2014).

There is a strong evidence base to support the applicability of the fear and avoidance model to chronic pain presentations (Leeuw, Goossens, van Breukelen, de Jong, Heuts, Smeets, Koke & Vlaeyen, 2008). Fearful anticipation of pain has been found to activate areas of the brain that are associated with both the sensory and emotional perception and processing of pain, leading to a greater initial pain response (Borkum, 2010). In addition, several studies indicate an association between pain-related fear and avoidance in acute pain, and subsequent chronicity and disability (Borkum, 2010). Indeed, the presence of fear and avoidance in the acute stage is associated with increased sick leave from work, and an increased risk of pain recurrence and help-seeking four years later (Boersma & Linton, 2005; Burton, McClune, Clarke & Main, 2004; Leeuw et al., 2008; Picavet, Vlaeyen & Schouten, 2002; Swinkels-Meewisse, Roelofs, Schouten, Verbeek, Oostendorp & Vlaeyen, 2006).

Similarly, in individuals with chronic pain, the belief that movement will exacerbate pain has been found to increase the risk of disability at one-year follow-up (Waddell, Newton, Henderson, Somerville & Main, 1993), while in pain-free individuals, higher levels of fear and avoidance are associated with an increased risk of subsequent lower-back pain (Linton, Buer, Vlaeyen & Hellsing, 1999). This suggests that fear and avoidance may play a significant predisposing role in chronic pain development and associated disability (Leeuw et al., 2008).

The maintaining function of fear and avoidance has also been demonstrated. Larsson, Hansson, Sundquist & Jakobsson (2016) found that physical activity levels were significantly reduced among older adults with chronic pain compared to healthy controls, with lower levels of fear and avoidance associated with greater physical activity. These outcomes reflect an increased risk of functional disability in individuals with chronic pain that may be mediated by fear and avoidance (Larsson et al., 2016).

It is hypothesised that reduced movement in the context of fear and avoidance leads to, and is consequently maintained by, functional decline and associated physical deconditioning and guarded movement (Vlaeyen, De Jong, Onghena, Kerckhoffs-Hanssen & Kole-Snijders, 2002). Functional decline and physical deconditioning affect meaningful activity engagement, which has implications with respect to mood (with low mood associated with reduced pain tolerance; Vlaeyen et al., 2002). Similarly, guarding behaviours (rigidity and stiffness when moving) can be reliably observed and their observed frequency positively correlates with patient ratings of pain intensity (Borkum, 2010; Keefe & Block, 1982; Vlaeyen et al., 2002). So, protective responses to pain appear to inadvertently reinforce and exacerbate it, which highlights the powerful maintaining function of fear and avoidance in the context of pain (Vlaeyen, 2016).

Fear and avoidance are associated with higher levels of self-reported depression and help-seeking, increased hypervigilance to pain sensations, and reduced pain coping (Keefe, Rumble, Scipio, Giordano & Perri, 2004). Furthermore, two key meta-analyses have identified a small to moderate positive association between fear and avoidance and pain intensity (Kroska, 2016), and a positive to large relationship between pain-related fear and disability in both acute and chronic pain samples (Zale, Lange, Fields & Ditre, 2013). Evidence from a systematic review by Wertli et al. (2014) suggests that a decrease in fear and avoidance during treatment is associated with less pain and disability at follow-up, and that treatments that target fear and avoidance are more effective than approaches based solely on a biomedical formulation of pain.

The above summary highlights the importance of fear and avoidance as a target in psychological treatment (Vlaeyen, 2016), but also the success of the fear avoidance model in incorporating the main cognitive and behavioural ideas about chronic pain (Morley, 2011). The fear and avoidance model "captures the essence of CBT… the careful formulation of an individual's problem followed by treatment that is devised to test their assumptions and

alternative ways of responding via individualised behavioural experiments" (Morley, 2011 p. 100).

Evidence for the Effectiveness of CBT Treatment in Chronic Pain

Behavioural intervention

While many studies emphasise the usefulness of behavioural methods in the treatment of chronic pain, the evidence of effectiveness is rather sparse (Williams et al., 2012). In their Cochrane review, Williams et al. (2012) found that many behavioural trials had small participant numbers and were methodologically weak, and thus did not meet the stringent criteria of the review. When compared with treatment as usual or a wait list control, behavioural therapy had a small effect on catastrophising immediately post-treatment, but not on pain, disability or mood. There was a lack of evidence to assess effectiveness at six to 12 months follow-up for all outcomes except disability, which was found to be non-significant. There was also insufficient evidence for meta-analysis of behavioural intervention compared to an active control (e.g. a protocolised treatment such as an exercise programme, a medical procedure, an educational programme etc.). So, in conclusion, there is an absence of evidence for the effectiveness of behavioural therapy in the context of chronic pain (Williams et al., 2012).

CBT Intervention

The findings of Williams et al. (2012) were more promising with respect to CBT. When compared with an active control, CBT was found to be significantly more effective with respect to two outcomes: disability immediately post-treatment and at six to 12 months follow-up, and catastrophic thinking immediately post-treatment (albeit with small effect sizes). No such effects were observed for catastrophising at follow-up, or for pain or mood at either time point.

The effects of CBT were stronger when compared with treatment as usual or a wait list control, with small but significant improvements in pain, disability and mood immediately post-treatment, with only the improvements in mood sustained at six to 12 months follow-up. Moderate effects were also observed for catastrophising post-treatment, but insufficient data meant it was not possible to assess whether this was maintained. Across the CBT analyses, effects were found to be strongest for mood, followed by catastrophic thinking, disability, and finally, pain (Williams et al., 2012).

Knoerl et al. (2016) sought to further the findings of Williams et al. (2012), by exploring the most efficacious doses, strategies and delivery methods of CBT for chronic pain with respect to a wider range of outcomes (based on the Initiative on Methods, Measurement and Pain Assessment in Clinical Trials (IMMPACT) guidelines; Dworkin et al., 2005). The outcomes included pain, physical functioning, emotional functioning, participant ratings of improvement, symptoms and adverse events, and participant disposition (e.g. adherence to treatment). The review considered 35 studies and found in-person delivered CBT to be effective at reducing pain intensity in approximately 57% of studies, and improving one or more IMMPACT outcomes in 86% of trials (Knoerl et al., 2016).

Knoerl et al. (2016) also found that in 73% of the studies with a follow-up, improvements in various IMMPACT outcomes were sustained at six months. Thirty-six percent also indicated sustained improvements in pain intensity ratings. Of the six studies that examined 12-month follow-up, 67% and 50% reported sustained improvements in IMMPACT outcomes and pain intensity respectively (Knoerl et al., 2016).

In their review of meta-analyses examining the efficacy of CBT applied to a wide range of difficulties, Hofmann, Asnaani, Vonk, Sawyer & Fang (2012) found the evidence to be very mixed for chronic pain, due to the wide range of pain conditions and combinations of CBT techniques used in studies. However, they concluded that CBT treatments for chronic

pain consistently yielded small to medium effect-sizes. In terms of symptom reduction, CBT has been found to be more beneficial than control treatments in a wide range of pain conditions, including orofacial pain (Aggarwal, Lovell, Peters, Javidi, Joughin & Goldthorpe, 2011), headaches (Andrasik, 2007) and fibromyalgia (Glombiewski, Sawyer, Gutermann, Koenig, Rief & Hofmann, 2010). Furthermore, Ang, Jensen, Steiner, Hilligoss, Gracely & Saha, (2013) found that, in the context of fibromyalgia, pharmacological treatment (milnacipran) combined with CBT was significantly more effective in terms of reducing pain intensity and increasing physical functioning than either treatment alone. The authors concluded that CBT has significant additional benefits when used alongside milnacipran medication, while the additive benefits of the medication over and above CBT may be minimal.

With respect to the effects of CBT on fear and avoidance specifically, Dehghani, Sharpe & Nicholas (2004) found that participation in a multidisciplinary CBT pain programme reduced selective attention towards sensory pain stimuli at one-month follow-up; a change which was predicted by changes in fear of movement during treatment. Bergbom, Flink, Boersma & Linton (2014) also found that a seven-week CBT group significantly reduced fear and avoidance, as well as perceived disability, sick leave, pain catastrophising and distress, in individuals deemed at risk of future pain-related disability; a finding that was supported with a medium effect-size.

The benefits of CBT have also been demonstrated in neuroimaging studies. Chronic pain is associated with decreased weight/volume of cortical matter in regions that are relevant to pain, including the frontal and sensorimotor cortex (Apkarian, Sosa, Sonty, Levy, Harden, Parrish & Gitelman., 2004; Okifuji & Turk, 2015). A key study by Seminowicz, Shpaner, Keaser, Krauthamer, Mantegna, Dumas, Newhouse, Filippi, Keefe & Naylor (2013) indicated a significant increase in the grey matter volume in these areas following an 11-week group CBT intervention that centred on the development of coping strategies including

relaxation training, attention diversion and restructuring of maladaptive cognitions. This finding supports the hypothesis that by modifying cognitive and behavioural appraisals of pain, CBT may directly alter the neural processes that underlie pain modulation (Seminowicz et al., 2013; Okifuji & Turk, 2015). Similarly, Jensen, Kosek, Wicksell, Kemani, Olsson, Merle, Kadetoff & Ingvar (2012) found that CBT intervention resulted in increased activation of the prefrontal cortex in individuals with fibromyalgia, indicating that CBT alters the way that pain is processed in the brain.

In summary, the effectiveness of CBT has been demonstrated when compared to no-treatment controls, and there is some evidence to support the hypothesis that CBT is more effective than other treatments with respect to certain outcomes (Morley, 2011). However, any conclusions about the efficacy of CBT treatment in chronic pain are complicated by the heterogeneity of the studies that can be included in meta-analysis or systematic review, with respect to sample, intervention, controls, outcome measures etc. (Morley, 2011). This is problematic with all interventions/presentations but is notably challenging with CBT in the context of pain, given the variable components and possible formats of CBT (Gatchel et al., 2007), and the complexity of chronic pain as a condition (Morley, 2011).

The finding by Williams et al. (2012), that only improvements in mood (and not pain or disability) were sustained at six to 12 months could lead to us to conclude that maintenance of CBT gains post-treatment is poor. This outcome would perhaps not be surprising given that chronic pain is a disability that is established over many years and is sustained by a complex array of biological, psychological and social influences; environmental factors which likely undermine the maintenance of treatment gains associated with psychological and behavioural adaptation (Morley, Williams & Eccleston, 2013).

However, the nature of the data reported in trials means that the review by Williams et al. (2012) reported standardised mean differences between intervention and control across groups of participants. This does not allow for consideration of individual differences

with respect to treatment responsiveness (Morley, Williams & Eccleston, 2013). The effectiveness of pharmacological treatment in chronic pain is bimodal, such that a minority experience a significant effect while the majority do not (Morley, Williams & Eccleston, 2013). It is possible that the same is true for particular psychological interventions or outcomes; some individuals may achieve longer-term improvements in pain, disability and mood while others benefit little. It is not possible to be clear about the proportion of people that experience longer-term, meaningful change in response to CBT intervention, but we can be confident that some will (Morley, Williams & Eccleston, 2013).

A further problem is the fact that the evidence base supporting the use of CBT treatment in chronic pain is dominated by studies of efficacy (Burns, Nielson, Jensen, Heapy, Czlapinski & Kerns, 2015). Such evidence is effective in identifying whether a given treatment produces significant change compared to a control condition, but it does not tell us about the mechanisms underlying the change; whether change is occurring for the reasons hypothesised (Burns et al., 2015).

Cognitive-behavioural models of chronic pain propose that cognitive factors and coping responses play a significant role in the development and maintenance of chronic pain. Successful intervention therefore involves altering the individual's cognitive and behavioural responses to their pain (Nielson & Jensen, 2004; Jensen, Turner & Romano, 2001). Jensen et al. (2001) sought to test this hypothesis by exploring the relationship between pain-related beliefs, coping responses and improvement post-treatment (with respect to pain intensity, disability, depression and health-care use) in a group of individuals with wide-ranging chronic pain presentations. Changes in both cognitions and coping were found to account for large and statistically significant amounts of the observed variance in changes in self-reported mood, pain intensity and physical disability (Jensen et al., 2001). Guarding behaviours have also been found to decrease following psychological intervention that promotes self-

regulation of pain, with reductions in guarding and resting associated with a decrease in physical disability (Jensen et al., 2001; Keefe & Block, 1982).

Furthermore, Burns, Glenn, Bruehl, Harden & Lofland (2003) found that reductions in both catastrophising and pain-related anxiety at the early stages of treatment were found to predict late-treatment reductions in pain severity. The converse however, was not true i.e. early changes in pain severity predicting late-treatment reductions in catastrophising and pain anxiety. Turner, Holtzman & Mancl (2007) similarly found that decreased catastrophising, as well as increased self-efficacy and a decrease in the belief that pain is both disabling and a signal of harm, significantly mediated the effects of CBT on pain intensity and activity interference. These findings support the theory that cognitive change is an active ingredient in CBT treatment and one that influences subsequent outcomes.

However, further research is required to help us truly understand the reasons for treatment effectiveness (Burns et al., 2015). Williams et al. (2012) concluded that additional Randomised Controlled Trials (RCTs) exploring the efficacy of CBT in the context of chronic pain will no longer add value to the evidence-base, and different types of research such as N-of-1 designs have the potential to make more valuable contributions for populations, interventions, or outcomes not included in standard RCTs (Morley, 2011; Williams et al., 2012). Such designs, that closely track change, may enable us to better understand mediators of change and increase awareness of the context in which change occurs (Morley & Keefe, 2007). The use of mixed measures can also help to determine which outcomes are meaningful to patients (Morley, 2011).

The Need for More Accessible Treatment in Chronic Pain

While CBT is considered the current "gold standard" psychological intervention for chronic pain (Sturgeon, 2014; p. 118), such treatment is resource-intensive and often inaccessible to people living with pain due to long waiting lists, mobility limitations, stigma, availability and other factors (Dear et al., 2015). Also, as indicated in the literature review

above, improvements that arise from CBT intervention may be difficult to sustain longer-term once clinical support finishes (Donaldson, 2009). As such, the need for different approaches to treatment that increase accessibility and support people to build on their clinical treatment once it finishes, has been highlighted (Buhrman et al., 2016; Singh et al., 2016). This has led to a wealth of research exploring alternative methods of delivery (e.g. internet CBT; Buhrman et al., 2016), and level of therapist-involvement (e.g. guided self-help interventions, reduced doses etc.; Liegl, Boeckle, Leitner & Pieh, 2016; Mignogna, Hundt, Kauth, Kunik, Sorocco, Naik, Stanley, York & Cully (2014).

This review will now consider two key papers in further depth. The first, by Salomons et al. (2014), highlights the effectiveness of a brief CBT intervention at reducing pain unpleasantness in the context of experimental pain applied to healthy subjects, while the second presents a technological intervention. Singh et al., (2016) developed a wearable sonification device called Go-With-the-Flow (GWtF) that aims to enhance psychological and physical capabilities in the context of chronic pain. The concepts of both brief CBT and GWtF represent possibilities for intervention that are potentially more accessible and flexible for individuals living with pain.

Brief CBT

Salomons et al. (2014) considered the potential role of cognitive and affective factors in mitigating and/or reversing the process of central sensitisation. While an individual may have limited control over the nociceptive inputs they experience, it was hypothesised that by changing their psychological responses to pain stimuli, they would be able to exert top-down control via descending cognitive modulatory processes and change central sensitisation (Salomons et al., 2014).

Salomons et al. (2014) therefore designed a brief course of CBT (comprised of eight five-minute CBT sessions delivered over a 21-day period) and monitored the impact of intervention on secondary hyperalgesia and affective responses to experimental heat pain.

The brief CBT protocol focused on cognitive and affective responses to pain and taught participants to alter their responding by identifying unhelpful cognitions and reframing the experimental pain to represent a challenge rather than a threat. Throughout their involvement in the trial, participants (N=34) experienced eight one-hour test sessions, each of which involved 45 eight second exposures to noxious heat stimuli. Those in the CBT condition (N=17) received one of their five-minute interventions directly before administration of thermal stimulation, while those in the control condition (N=17) instead received a five-minute intervention on interpersonal effectiveness.

Several key findings emerged. The change in the sensory dimension of pain (as measured by pain intensity ratings) was found to be consistent across conditions, but the affective dimension (as measured by unpleasantness ratings) reduced significantly more in the CBT group. Furthermore, the CBT condition significantly reduced secondary hyperalgesia, with improvements in secondary hyperalgesia found to correlate with reductions in pain catastrophising. So, as well as changing the affective experience of pain, a brief CBT intervention was found to significantly reduce central sensitisation in the context of experimental pain. This change was directly associated with changes in pain-related beliefs.

These findings are striking, but there is a significant difference between experimental pain in a lab-based setting, and chronic pain in a real-world context. The present study therefore applies a brief CBT intervention to chronic pain in a community setting, and considers the impact of intervention on pain anxiety specifically.

Go-With-the-Flow (GWtF)

Technological advancements in the field of chronic pain have centred on both assessment and intervention. With respect to assessment, a wealth of activity monitoring devices have been developed to try to represent activity more accurately than patient self-

report, by objective and cumulative measurement (Rodríguez, Herskovic, Gerea, Fuentes, Rossel, Marques & Campos, 2017). Activity monitoring devices allow healthcare professionals to access a more comprehensive and objective assessment of the patient's difficulties through their measurement of many different factors, both directly (e.g. posture, movement) or by prompting self-rating (e.g. pain, fear or catastrophising; Rodríguez et al., 2017).

Many technological interventions have also been developed for use by individuals with chronic pain. Targets of intervention have included behaviour change (as with the SMART2 device, which incorporates activity planning and review; Duggan, Keogh, Mountain, McCullagh, Leake & Eccleston, 2015), pain reduction (e.g. virtual-reality distraction-based devices that have proven effective at reducing experimental pain; Malloy & Milling, 2010), and treatment compliance (as with a video-game based physical therapy intervention, which improved compliance and yielded outcomes comparable to standard physiotherapy treatment with respect to pain, range of motion and function; Dahl-Popolizio, Loman & Cordes, 2014).

Given that the barriers to improved quality of life and physical function in the context of chronic pain are largely psychological, (e.g. anxiety, in the context of fear and avoidance) and this consideration has shaped clinical treatment of chronic pain, Singh et al. (2016) highlighted the need for technological intervention to support both the physical and psychological needs of the condition. This represents a move away from the technological approaches reviewed above, which are largely extrapolated from games designed for pain-free individuals. This assumes a subject has no problem with motivation to compete or with pain from exertion, and typically focuses on 1) activity monitoring, and 2) enhancing physical progress through progressive physical challenge, shifting of attention to facilitate endurance, etc. (Lewis & Rosie, 2012; Singh et al., 2016).

Individuals with chronic pain adopt protective strategies (e.g. guarding behaviours) to reduce anxiety about movement, a phenomenon which overlaps with the concept of safety-seeking behaviours in anxiety disorders, including health anxiety (Tang, Salkovskis, Poplavskaya, Wright, Hanna & Hester, 2007). Without addressing psychological factors in chronic pain, individuals may achieve physical progress but do so with increased anxiety, which is countertherapeutic and usually leads to abandoning the intervention (Singh et al., 2016).

To support their goal of integrating psychological support into technological intervention, Singh et al., (2014) conducted a study of individuals with chronic pain and the physiotherapists treating them, to identify requirements and strategies that encourage increased physical activity. A key finding was that the focus of the physiotherapists was not on correcting movement (a construct which may reinforce anxiety about harm), but on supporting the individual to relearn their body's capabilities, and to utilise pleasurable sensations (e.g. calm breathing) to facilitate movement by diverting attention away from anxiety (Singh et al., 2014).

The study identified key strategies to facilitate physical activity despite pain that shaped the development of the authors' GWtF wearable device, including the need to: 1) provide an enhanced and pleasurable perception of moving through sonification, 2) provide a sense of progress through movement (by assigning different sounds to different phases of an exercise) to increase self-efficacy, 3) facilitate going-with-the-flow (as opposed to correcting movement), 4) provide a sense of achievement/reward by using specific sounds to signal target attainment, 5) increase awareness of avoidance by altering the sound, but in a way that encourages movement exploration and does not increase anxiety or communicate that movement is incorrect or dangerous, 6) develop self-management skills by allowing sound feedback to be updated to reflect current physical/psychological capabilities and pain-

level, to allow the recognition of progress and gradual building of capabilities, and 7) encourage movement but not overactivity (to reduce the risk of setbacks; Singh et al., 2016).

While initial plans focused on the provision of visual feedback using a motion sensor and handheld screen, there were practical constraints associated with this design as users were required to stay within range of a motion sensor and visually fixate on a screen. GWtF therefore uses a sonification framework to try and enhance awareness of, and motivate body movement through, the provision of sound feedback. This is based on the established understanding that sensory feedback enables the tracking of physiological processes during movement to support in adjusting actions, if necessary (Singh et al., 2016). Sound feedback can facilitate awareness of body positioning and movement, and improve motor control and potentially motor learning (Singh et al., 2016). The association between sound and movement makes sense in the context of tight links between the motor and auditory areas of the brain (Singh et al., 2016).

The notion of using sound feedback to aid physical rehabilitation is not new, but GWtF is unique in that it was designed using a full biopsychosocial model of pain and aims to enhance both psychological and physical capabilities (Singh et al. 2016; Singh, Bianchi-Berthouze & Williams, 2017). In practice, the device (an adapted Android phone) is worn in a pocket on the back that is calibrated to the current range of movement that is comfortable to the individual, and movement is represented using a sound which varies in pitch. GWtF thereby provides tailored sound feedback as an individual moves, to reflect the extent of the movement achieved. The sound is intended to be a pleasurable means of providing movement feedback and aims to "increase awareness of physical capability, normalise body cues, highlight use of protective behaviour, increase motivation, and facilitate transfer of skills to everyday activities" (Singh et al. 2016; p. 367).

The technology has been applied to structured tasks such as physiotherapy-style exercises, as well as functional, day-to-day activities such as housework, and has been found to increase performance, motivation, awareness of movement, awareness of physical capability, sense of control, and relaxation during movement (Singh et al., 2016; Singh, Bianchi-Berthouze & Williams, 2017).

The Present Study

Building on the works of Singh et al. (2016), Singh et al. (2017), and Salomons et al. (2014), the present study aims to explore the effects of both a brief CBT intervention and the GWtF sonification technology on anxiety about movement that is expected to exacerbate pain or the anticipation of injury in the context of chronic pain – the fear aspect of the fear and avoidance model (which, for simplicity, will be termed 'pain anxiety').

Research Questions

The study aims to answer the following questions:

1. Does a brief CBT intervention lead to a reduction in pain anxiety during movement?

2. Does the GWtF sonification technology lead to a reduction in pain anxiety during movement?

3. Is one superior to the other in terms of anxiety reduction?

Methodology

A brief overview of the study's methodology will now be presented, with further detail regarding methodology provided in the empirical paper that follows. The project utilised a multiple single-case design to explore the impact of brief CBT and GWtF intervention on anxiety about movement that may contribute to pain or affect movement in the context of chronic pain. The selection of this design reflects the call for a move away from RCTs that explore efficacy in the context of CBT for chronic pain (Williams et al., 2012; Morley, 2011). Single case studies involve the collection of baseline data prior to the

introduction of an intervention, so that any change in measures (relative to baseline) that occur during the intervention phase can be directly and meaningfully attributed to it. In this instance, there were two baseline and two intervention phases that followed an A-B-A-C design: baseline one (A), intervention one (B), baseline two (A), intervention two (C). Each phase was two to three days in length, and the order of interventions was counterbalanced across participants.

Single case designs have strong internal and external validity as they facilitate the demonstration of a causal relationship between intervention and outcome, as well as the generalisation of findings to wider populations (Lobo, Moeyaert, Baraldi Cunha & Babik, 2017). They also allow for the exploration of meaningful change at the individual participant level, and thus provide important information about individual differences that is lost in trials that report mean group effects.

Furthermore, as each participant acts as their own comparison, the effect of confounding variables (e.g. age, gender, socioeconomic status etc.) on outcome is effectively controlled (Lobo et al., 2017). The use of a *multiple* single case design incorporates the benefits of single case methodology, but also allows for the replication and comparison of findings across participants (Flanagan, 2014, Yin, 1994). The required sample is nonetheless small, with data from two to three participants considered compelling (Flanagan, 2014; Yin, 1994).

A mixed measures approach was employed to enable both the quantitative analysis of any change in pain anxiety associated with either intervention, and qualitative analysis of participants' experiences of using both the brief CBT and GWtF in the context of their chronic pain. Quantitative measurement centred on completion of a once-daily bend-based movement that is associated with pain for the individual. Participants rated the level of anxiety and pain associated with the movement each day using a 0-10 numerical rating scale.

47

Heart rate and the degrees of bend achieved were tracked during the movement using an ECG heart rate sensor and smartphone gyroscope. The daily data collection enabled the close tracking of any change in the measures across phases. At the end of each phase, participants additionally completed a measure of catastrophising (the Pain Catastrophising Scale; Sullivan et al., 1995) and self-efficacy (the Pain Self Efficacy Questionnaire; Nicholas, 2007; Nicholas, 1989). Participants also videoed themselves completing the experimental movement at these set timepoints, and the videos were independently rated for guarding by physiotherapists who specialise in chronic pain, using a 0-7 scale.

With respect to qualitative measurement, the researcher conducted a semi-structured interview with each participant on the final day of participation to find out more about their experience of each intervention. This is in recognition of the value of qualitative data in contextualising and enriching quantitative findings (Bowen, Rose, & Pilkington, 2017).

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Assessing the Impact of a Brief CBT Intervention and a Sonification-of-Movement Device on Pain Anxiety in Chronic Pain: A Mixed Methods, Multiple Single-Case Design

PART 2: Empirical Paper

Abstract

Aim- To explore the effects of two interventions on pain anxiety in the context of chronic pain.

Methods- The study used a mixed measures, multiple single-case A-B-A-C design. Six participants (adults with chronic pain) received two baseline (A) and two intervention phases (B and C): a brief CBT intervention and the 'Go-With-the Flow' (GWtF) sonification of movement. Participants completed a daily movement (that is usually painful) with associated measures (anxiety and pain ratings, heart-rate and degrees of bend achieved). At the end of each phase, participants additionally videoed their movements (which were independently rated for 'guarding' by pain physiotherapists) and completed the Pain Self-Efficacy and Pain Catastrophising Scale questionnaires (PSEQ/PCS). Qualitative data about participants' experiences of the two interventions were collected at the end of participation. Quantitative data were analysed visually and statistically using Tau-U methods and McNemar tests. PSEQ and PCS data were assessed for reliable change, and qualitative data were thematically analysed.

Results- The impact of each intervention on pain anxiety was variable across participants. Qualitative data indicated that brief CBT was generally the preferred intervention but neither intervention yielded a statistically significant improvement in pain anxiety in most cases. GWtF was associated with a statistically significant increase in bend achieved from baseline for the group as a collective. However, this finding was balanced by qualitative data which indicated that most participants would not use GWtF in its current format.

Conclusion- Both interventions were associated with benefit for some participants, and successfully used at home without significant difficulty. As such, both could, with further development, increase accessibility to psychologically-informed intervention for problems associated with chronic pain.

Introduction

Chronic pain is defined as pain that persists beyond twelve weeks (British Pain Society, 2013; Okifuji & Turk, 2015). It is a disabling and prevalent condition that can have a significant impact physically, emotionally and socially (Crombez, Eccleston, Van Damme, Vlaeyen & Karoly, 2012). A biopsychosocial approach to chronic pain considers the biological (e.g. pathophysiological factors), psychological (e.g. emotions, beliefs, behaviours) and sociocultural (e.g. social support, cultural norms, socioeconomic status) processes that contribute to the development and maintenance of chronic pain (Crombez et al., 2012). The model recognises the complex dynamic and reciprocal interaction between these factors, which account for the diverse range of patient experiences of/responses to chronic pain (Turk, 2014).

The fear avoidance model is grounded in a biopsychosocial understanding of pain, and posits that it is beliefs about pain, rather than the pain itself, that guide its course. If pain is perceived to be non-threatening, the individual typically resumes normal activity after a period of rest. However, if pain is catastrophically misinterpreted (e.g. as an indication of serious injury), pain evokes fear that generalises to associated cues, resulting in an avoidance of movements/situations that have become associated with pain, and an increased sensitivity to pain and related sensations (Crombez et al., 2012).

Such misinterpretations are reflective of the established association between tissue damage and pain. However, iatrogenic harm also plays a role (Lin, O'Sullivan, Coffin, Mak, Toussaint & Straker, 2013). Iatrogenic harm refers to symptoms that are induced or exaggerated by the diagnostic processes intended to support them (Krishnan & Kasthuri, 2005). With chronic pain, the clinical language and diagnostic terms used within healthcare (e.g. 'degenerative discs') imply irreparable and ongoing damage, and the attribution of pain to underlying disease can magnify disability (Stewart, M. & Loftus,2018; Loeser. & Sullivan, 1995).

Avoidance of activity and hypervigilance to possible harm are adaptive when pain is acute and healing is in progress, but longer-term, reduced activity can lead to physical deconditioning and generalisation of fears, resulting in a progressive increase in disability (Wicksell, Ahlqvist, Bring, Melin & Olsson, 2008). This reinforces the individual's anxiety about movement and its consequences (Crombez et al., 2012). Research indicates a growing evidence base to support the applicability of the fear avoidance model to chronic pain presentations, and several studies indicate that pain anxiety may influence the development of acute pain into chronic disability (Crombez et al., 2012, Leeuw, Goossens, Linton, Crombez, Boersma & Vlaeyen, 2007)

The fear avoidance model, and biopsychosocial approaches more broadly, recognise the complexity of the pain experience and have transformed the treatment of chronic pain. The key focus of pain rehabilitation is on improving wellbeing and promoting behaviour change (The Faculty of Pain Medicine, 2015); as such, the contribution of clinical psychology to the treatment of chronic pain is a valuable one (Jenson & Turk, 2014).

The evidence base for psychological interventions for chronic pain is dominated by studies using Cognitive Behavioural Therapy (CBT) interventions, and a Cochrane review indicated 'small to moderate' effects of CBT on pain, disability, mood and catastrophising post-treatment (Williams, Eccleston & Morley, 2012). Research by Salomons, Moayedi, Erpelding & Davis (2014) found that even a brief CBT intervention (focused on cognitive reappraisal of pain-related threats, and development of positive self-statements) led to a significant reduction in reported pain unpleasantness of experimental pain applied to healthy subjects, and in secondary hyperalgesia (where pain sensitivity extends beyond the original area of injury). The latter finding demonstrates the effect to be more than experimental demand.

However, there is evidence to suggest that improvements associated with CBT treatment are difficult to sustain once clinical support finishes (Donaldson, 2009).

Technology therefore has a valuable role to play in aiding self-management and supporting people to maintain and build on their clinical treatment gains (Singh, Piana, Pollarolo, Volpe, Varni, Tajadura-Jiménez, Williams, Camurri & Bianchi-Berthouze, 2016). One such technology involves sonification, which provides tailored sound feedback as an individual moves that represents the extent of that movement. This is based on the established understanding that sensory feedback enables the tracking of physiological processes during movement to support awareness and (where necessary) adjustment of movement (Singh et al., 2016).

Singh et al. (2016) developed the 'Go-With-the-Flow' (GWtF) wearable sonification technology, which is calibrated to the range of movement that is comfortable to the individual. This range is represented using sound that varies in pitch; intended to be a non-threatening means of establishing physiological feedback. The design of GWtF was informed by a biopsychosocial understanding of pain and intends to target both physiological and psychological processes, by increasing awareness of movement and facilitating exploration of helpful movements, while reducing pain-monitoring and associated anxiety (Singh et al. 2016). It has been applied to structured tasks such as physiotherapy exercises as well as functional, day-to-day activities such as housework, and has been found to increase performance, motivation, awareness of movement, awareness of physical capability, sense of control, and relaxation during movement (Singh et al., 2016; Singh, Bianchi-Berthouze & Williams, 2017).

Building on the works of Singh et al. (2016), Singh et al. (2017), and Salomons et al. (2014), the present study aims to explore the effects of both a brief CBT intervention and GWtF on anxiety experienced about movement that is expected to exacerbate pain or risk injury– the 'fear' aspect of the fear avoidance model. For simplicity, this will be termed 'pain anxiety' from this point onwards.

68

The decision to compare the two interventions was informed by a hypothesis that both could have a positive impact on pain anxiety, but also a curiosity about whether any change associated with each is achieved by a similar, or alternatively quite contrasting, therapeutic process. The current study aims to answer the following questions:

1. Does a brief CBT intervention lead to a reduction in pain anxiety during movement?

2. Does the GWtF sonification technology lead to a significant reduction in pain anxiety during movement?

3. Is one superior to the other in terms of anxiety reduction?

Methodology

Ethical approval for this study was granted by the UCL Research Ethics Committee (12997/001; please see Appendix 2). The costs associated with the project were funded by the UCL Doctorate in Clinical Psychology.

Design

The study used a multiple single-case design in which all participants received two, three-day periods of intervention. Traditional A-B single case designs involve the consistent collection of measurement data across both a baseline phase (A) and subsequent intervention phase (B). Participants provide their own baselines, and data are analysed individually, rather than as group means. The design choice was informed by the conclusion of Williams et al. (2012) that the evidence-base is saturated with Randomised Controlled Trials (RCTs) exploring efficacy of CBT treatment in chronic pain, and there is now a need for different types of research that closely track change associated with an intervention, to better understand change processes.

If A represents baseline, and B and C represent the treatment conditions, the design was A-B-A-C. The order of treatment conditions was counterbalanced across participants to minimise order effects, and baseline lengths (of either two or three days) were randomised

to avoid bias. The Risk of Bias in N-of-1 Trials (RoBiNT) scale (Tate, Perdices, Rosenkoetter, Wakim, Godbee, Togher & McDonald, 2013), which outlines requirements in single case methodology to reduce the risk of bias, informed the design of the study. Please see Appendix 3 for an overview of the RoBiNT scale criterion and the present study's compliance with the instrument.

The Single-Case Reporting Guideline In BEhavioural Interventions (SCRIBE) guideline (Tate, Perdices, Rosenkoetter, McDonald, Togher, Shadish, Horner, Kratochwill, Barlow, Kazdin, Sampson, Shamseer & Vohra, 2016) was also used to inform the reporting of the study. SCRIBE is a guideline of 26 items that should be addressed when writing up single-case research, that was developed to address the often incomplete and highly variable reporting of such studies (Tate et al., 2016). Please see Appendix 4 for an overview of the SCRIBE guideline and the present study's compliance with it.

Participants

Participants were six adults aged over 18 with a diagnosis of chronic back pain. As GWtF is currently designed specifically for bend-based movements, it was a requirement that participants' pain be related specifically to bending. Participants were also required to have smartphone and internet access to enable completion of online questionnaires and video-recording of experimental movements.

Individuals were unable to participate if they had previously received CBT for pain at any point/for anxiety in the last five years; had had spinal surgery in the last six months, had any other medical condition that affected their movement, or were unable, for any reason, to complete the required research tasks. Please see Figure 1 for a display of participant flow through the study.
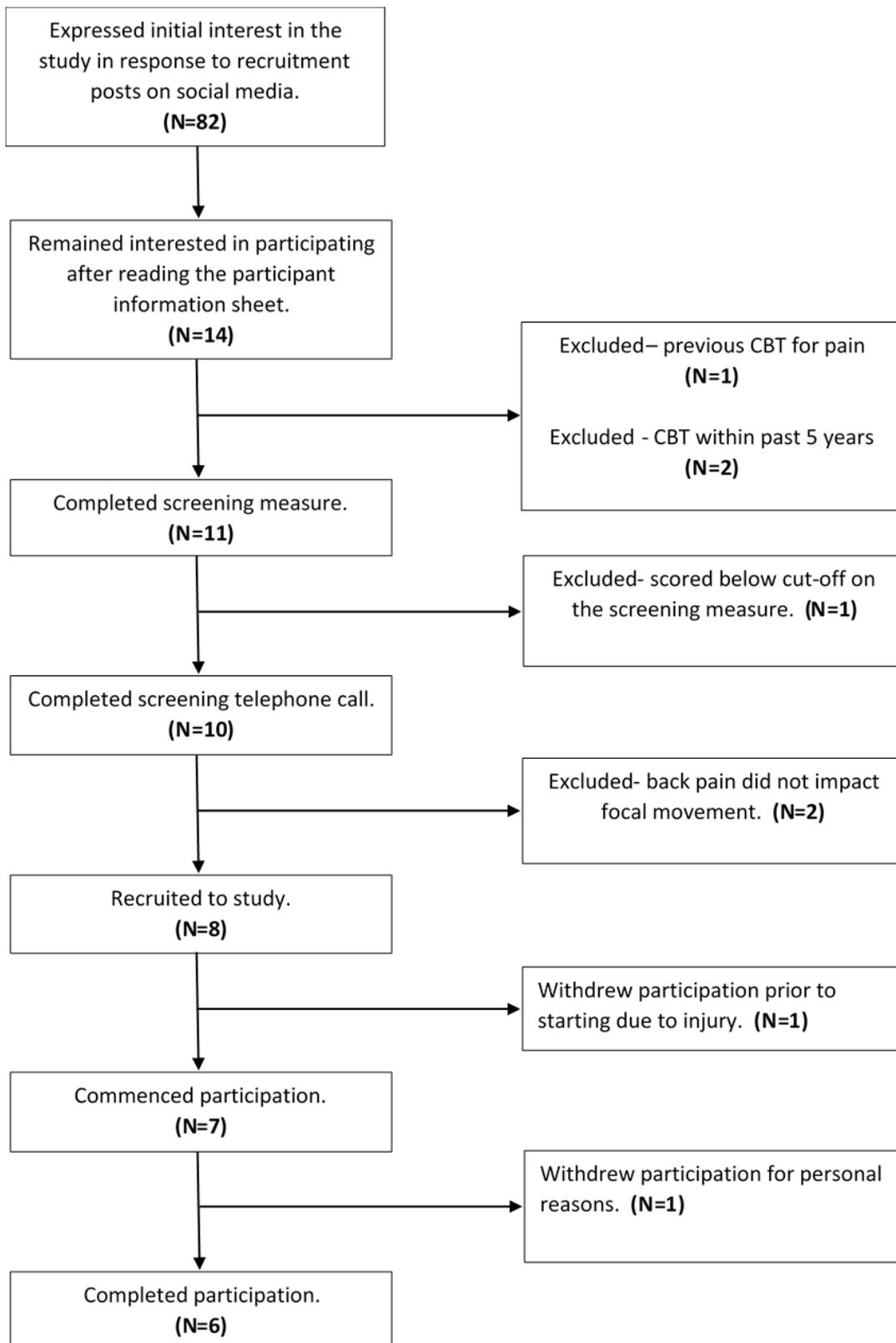
Figure 1: Participant flow through the study

Measures

The study employed mixed methods, with quantitative measurement of pain anxiety centred on a daily bend-based experimental movement (associated with pain for the individual). The primary outcome was self-reported anxiety, as measured by an anxiety Numerical Rating Scale (NRS). Self-reported pain, degrees of bend achieved, heart rate, Pain Catastrophising Scale (PCS) scores, Pain Self-Efficacy Questionnaire (PSEQ) scores and guarding ratings were secondary outcomes. Further detail about each outcome and the frequency with which they were collected across participation will now be outlined.

Outcomes Collected Daily:

Anxiety Numerical Rating Scale

The level of anxiety associated with the daily movement was measured by self-report Numerical Rating Scale (NRS). Participants were asked: *'Please indicate (on a scale of 0-10, with 0 being 'not at all anxious' and 10 being 'extremely anxious'), how anxious you felt about experiencing pain when completing your target movement today'.*

The anxiety NRS has shown good comparability with the State Trait Anxiety Inventory (Spielberger, Gorsuch, Lushene, Vagg & Jacobs, 1983); an established and psychometrically sound instrument for assessing situational anxiety (Davey, Barratt, Butow & Deeks, 2006). Davey et al. (2006) concluded that an anxiety NRS is an adequate measure that is particularly useful in research contexts given its simplicity and accessibility.

Pain Numerical Rating Scale

Similarly, the reliability and validity of a pain intensity NRS has been indicated across many populations. For example, good test-retest reliability (r=.96) has been indicated in adults with rheumatoid arthritis, and the correlation of the pain intensity NRS with the Visual Analogue Scale (ranging from .86-.95) in patients with chronic pain

conditions supports its construct validity (Hawker, Mian, Kendzerska & French, 2011; Ferreira-Valente, Pais-Ribeiro & Jensen, 2011).

Measurement of pain intensity was felt to be important given that pain anxiety increases pain intensity, and pain reduction is (understandably) a priority for many individuals living with chronic pain (Henry, Bell, Fenton & Kravitz, 2017). Participants were asked: *'Please indicate (on a scale of 0-10, with 0 being 'no pain' and 10 being 'extreme pain'), how much pain you experienced* while completing your target movement today'. It was anticipated that pain intensity ratings would decrease in line with anxiety ratings.

Degrees of Bend Achieved

In recognition of the link between pain anxiety and reduced movement (Larsson, Hansson, Sundquist & Jakobsson, 2016), the amount of bend achieved during the experimental movement was measured using a smartphone gyroscope. It was anticipated that as anxiety decreased, the amount of bend achieved would increase.

Heart Rate (HR)

HR (in beats per minute; BPM) was measured using the Polar V800 watch and H7 HR sensor, which use ECG technology. When an individual experiences anxiety the sympathetic and parasympathetic systems become activated and HR increases; indeed, there is evidence to suggest that HR may be a useful physiological indicator of acute anxiety (Hoehn-Saric & McLeod, 2000; Hollander, Schortinghuis & Vissink, 2016; Kothgassner, Felnhofer, Hlavacs, Beutl, Palme, Kryspin-Exner & Glenk, 2016). It was therefore anticipated that HR would decrease in line with anxiety ratings.

Outcomes Collected on the Final Day of Each Phase:

Pain Self-Efficacy Questionnaire (PSEQ)

Given that higher self-efficacy is associated with lower pain anxiety (de Moraes Vieira, de Góes Salvetti, Damiani & de Mattos Pimenta, 2014), the PSEQ (Nicholas et al., 2007) was used to monitor self-efficacy across phases. The PSEQ is a ten-item measure that assesses the confidence one has in his or her ability to perform daily activities and engage with general aspects of life despite pain. Items are scored on a 7-point scale from 0 (not at all confident) to 6 (completely confident), with total scores ranging from 0 to 60. Higher scores reflect stronger self-efficacy beliefs (Nicholas, 1989); as such, it was anticipated that lower anxiety ratings would be associated with higher PSEQ scores. The PSEQ has strong psychometric properties (with a Cronbach's alpha of 0.92), and a high PSEQ score following pain management treatment has been shown to predict clinically significant functional gains (Nicholas, 2007).

Pain Catastrophising Scale (PCS)

Catastrophising in this context refers to an elevated negative cognitive response to painful stimuli, with increased catastrophising found to predict fear and avoidance (Pedler, 2010; Smeets, Vlaeyen, Kester & Knottnerus, 2006). The PCS (Sullivan, Bishop & Pivik, 1995) is a reliable and valid measure (Cronbach's alpha = .92; Osman, Barrios, Gutierrez, Kopper, Merrifield, & Grittmann, 2000) containing 13 items that describe common pain-related thoughts and feelings (e.g. 'I feel I can't go on'). Items are scored on a 5-point scale from 0 (not at all) to 4 (all the time), with lower scores reflecting less catastrophising (total scores range from 0 to 52). As such, it was anticipated that a decrease in anxiety ratings would be associated with lower PCS scores.

<u>Guarding Ratings</u>

'Guarding', defined by rigidity and stiffness when moving, is a nonverbal indicator of pain anxiety in chronic pain (Aung, Bianchi-Berthouze, Watson & Williams, 2014). Guarding behaviours can be reliably observed, and their observed frequency correlates with pain intensity and decreases with treatment that promotes self-regulation of pain (Keefe & Block, 1982).

Participants recorded their movement at the end of each phase and the videos were independently rated for guarding on an eight-point NRS ranging from 0 ('no guarding') to 7 ('severe guarding') by four specialist pain physiotherapists (blinded to the condition that each video corresponded with). Ratings were averaged, so each participant had one guarding estimate per phase. It was anticipated that as anxiety ratings decreased, guarding ratings would also decrease.

Qualitative Data

The researcher conducted a semi-structured interview with each participant on their final day, to explore their experience of using the two interventions. Please see Appendix 5 for the proforma used to guide the interviews.

<u>Procedure</u>

Participants were recruited through social media (see Appendix 6 for the study advert). Individuals that expressed interest in taking part were sent a message containing the Participant Information Sheet (see Appendix 7). S/he was then sent a link to complete an online version of the Keele 'STarT Back' Screening Tool (Hill, Dunn, Lewis, Mullis, Main, Foster & Hay, 2008).

The tool is used clinically to categorise an individual in terms of risk of chronic pain, based on biomedical and psychosocial risk factors (Robinson & Dagfinrud, 2017). For individuals identified as low risk (scoring 3 or less), minimal treatment (e.g. self-management)

is advised. For medium/high risk (a score of 4-9), physical and/or psychological therapy is recommended (Robinson & Dagfinrud, 2017). Therefore, only individuals who scored four or above were considered for participation.

An initial telephone conversation was then arranged (during which the details of the study were discussed and participants' queries addressed), and if interest continued and all criteria were met, a home visit was arranged. Informed consent was obtained at this meeting (see Appendix 8). The researcher then explained how to operate the HR monitor and smartphone gyroscope, and demonstrated the physiotherapy exercises. Participants were also shown how to calibrate the GWtF device to their current range of movement, which involves the identification of three positions: 1) standing vertical (start position), 2) a bending forward position that they felt confident to perform in spite of their pain (comfortable position), and 3) a maximum bending forward position (maximum position). Written instructions for all devices/exercises were also provided, alongside a timetable detailing the order of phases and associated measurement tasks. It was also agreed that the researcher would send participants twice daily reminders to outline the day's tasks.

The researcher then supported the participant in completing her/his first experimental movement and associated measures, marking the start of the first baseline phase. Thereafter, participants largely utilised the interventions and conducted measurement tasks independently.

Once the initial baseline phase had been completed, participants were either instructed to start using the GWtF device, or visited at home by the researcher to enable delivery of the CBT intervention (depending on intervention order; the other intervention followed the second baseline phase). During each intervention phase, participants were invited to use the device/strategies as they went about their daily activities, to whichever extent felt appropriate. They were also asked to utilise the intervention while completing a

brief series of exercises each day, to ensure that all participants had a baseline level of experience in applying the device/strategies to movement. This was separate to the specified movement (and associated measurement tasks), which they continued to complete once per day.

Upon completion of all phases, the researcher attended for the third home visit to retrieve the devices/materials, conduct the semi-structured interview, and provide participants with a £30 gift voucher to thank them for participation. Please see Figure 2 for an overview of the different phases of the study and their associated measures.

CBT Intervention

The development of the brief CBT intervention was informed by the researchers' experiences in working clinically with chronic pain, and the manual used in the study by Salomons et al. (2014). This led to the inclusion of psychoeducation about the role of cognitive and emotional factors in pain, and the use of cognitive strategies including restructuring, reframing (from threat to challenge) and positive self-statements. An early draft of the intervention was discussed with clinical psychologists at a UCLH Pain Management Service team meeting, where the suggestion to include diaphragmatic breathing as an additional strategy was adopted.   The decision to include the PCS and PSEQ as additional measures was also informed by this meeting. Please see Appendix 9 for the brief CBT intervention manual used in the present study.

As per RoBiNT guidance (Tate et al., 2013), a recording of one of the CBT intervention sessions was independently rated by a Trainee Clinical Psychologist against the Cognitive Therapy Rating Scale (please see Appendix 10 for the rating sheet) to assess therapist competence in delivering CBT. The session met the 80% compliance threshold stipulated by RoBiNT criteria.

First Baseline Phase: 2-3 days (randomised)

<u>Completed Daily:</u>

Experimental movement and associated pain, anxiety, heart rate and degrees of bend measures

<u>Final Day:</u>

Experimental movement was recorded

PSEQ and PCS completed

First Intervention Phase: 3 days (intervention order counterbalanced)

<u>Completed Daily:</u>

Five minutes of physiotherapy exercises (while utilising the specified intervention)

Experimental movement and associated pain, anxiety, heart rate and degrees of bend measures

<u>Final Day:</u>

Experimental movement was recorded

PSEQ and PCS completed

Second Baseline Phase: 2-3 days (randomised)

<u>Completed Daily:</u>

Experimental movement and associated pain, anxiety, heart rate and degrees of bend measures

<u>Final Day:</u>

Experimental movement was recorded

PSEQ and PCS completed

Second Intervention Phase: 3 days (intervention order counterbalanced)

<u>Completed Daily:</u>

Five minutes of physiotherapy exercises (while utilising the specified intervention)

Experimental movement and associated pain, anxiety, heart rate and degrees of bend measures

<u>Final day:</u>

Experimental movement was recorded

PSEQ and PCS completed

Semi-structured interview

Figure 2: Overview of the different phases of the study and their associated measures.

Data Analysis

The measures that were collected daily throughout participation (pain and anxiety ratings, HR, degrees of bend) were primarily analysed in two ways:

Visual Analysis

Data for each participant/measure were plotted graphically using Excel™, before being visually analysed using guidance by Morley (2017) pertaining to visual analysis of single case data.

Tau-U

Data were then statistically analysed using Tau-U (Parker, Vannest, Davis & Sauber, 2011). Tau-U was developed as a non-parametric method of establishing effect size in single case data (Klingbeil, Van Norman, McLendon, Ross & Begeny, 2018). It is a dominance test that enables comparison of the slope of an intervention trend line (B) with the slope of the associated baseline trend (A), to see whether they differ significantly (with a negative Tau-U value indicating a downward slope in data from baseline to treatment in an A vs. B comparison). Tau-U addresses a key criticism of other single-case statistical methods as it allows for the control of baseline trend where this is indicated (Klingbeil et al., 2018; Parker et al., 2011).

Given that the study design was A-B-A-C and Tau-U analyses phase pairs, data for each participant were analysed in two separate phase comparisons and are thus presented as such; 1) baseline vs. CBT (AB) and 2) baseline vs. GWtF (AC). Tau-U calculations were made using a free online calculator (http://www.singlecaseresearch.org/calculators; Vannest, Parker, Gonen & Adiguzel, 2016). Calculation for each participant/measure involved three stages, with the first being the identification of baseline slope by completing an A vs. A comparison. On the guidance of Vannest & Ninci (2015), if baseline trend exceeded .10 it was corrected for in the final analysis. The second stage involved the identification of

treatment slope in a B vs. B comparison/C vs. C comparison (depending on the intervention). Finally, the A vs. B/C comparison was conducted (with baseline trend corrected by the calculator where necessary).

Tau-U also enables the combining of separate phase comparisons to explore group trend. The Tau-U results for all participants with respect to 1) baseline vs. CBT trend and 2) baseline vs. GWtF trend were therefore combined in a meta-analysis, to explore collective trends across participants for each measure.

The calculator outputs offer two sets of confidence intervals (85% and 90%) for each analysis. The highest level of confidence was chosen for all analyses to ensure a more precise estimate of the true effect (Schünemann, Oxman, Vist, Higgins, Deeks, Glasziou & Guyatt, 2011)

Minimum Clinically Important Difference (MCID)

In addition, the pain, anxiety and guarding ratings were analysed for Minimum Clinically Important Difference (MCID). MCID refers to the smallest amount of change in a given treatment outcome that could be considered important and meaningful (Cook, 2008). With respect to the anxiety, pain and guarding NRS, baseline-endpoint data for each intervention were analysed to establish whether MCID was achieved. MCID has not been established for a pain anxiety NRS, so was based on the determination by Salaffi, Stancati, Silvestri, Ciapetti & Grassi, (2003) that the MCID of a pain intensity NRS is a change of one point. The researchers specified that for the purposes of the current research, and because there was no pre-existing standard, a one-point change on the guarding scale would be considered meaningful.

McNemar tests were then conducted to establish whether there was a significant difference between the two interventions in terms of how consistently MCID was achieved on each measure. McNemar's Test is similar to χ^2 (in that it tests for group differences on a dichotomous dependent variable), but it is intended for designs such as this one, where the

same participants completed both interventions (Adedokun & Burgess, 2012). As the sample was small, the binomial distribution was used in the analysis as it is suited to cell counts of less than 10 (Adedokun & Burgess, 2012).

Reliable Change Index (RCI)

The PSEQ and PCS data were assessed for reliable change. The RCI was developed by Jacobson, Follette & Revenstorf, (1984) as a measure of the amount of change that must be achieved on a psychometric instrument before it can be considered reliable, and beyond that which could be attributed to measurement error alone. The RCI value for each measure was calculated using the mean and standard deviation (SD) of clinical norms and the Cronbach's alpha reliability coefficient, and if the level of pre/post change observed exceeded the RCI value it was considered reliable.

Reliable change on the PSEQ and PCS was calculated using the Leeds Reliable Change Index Calculator (Morley & Dowzer, 2014). The required information about each measure was obtained from the literature, with the mean, SD and Cronbach's alpha set at 20.7, 13.3 and 0.92 respectively for the PSEQ, yielding an RCI value of 10.43 (Nicholas, Costa, Blanchard, Tardif, Asghari & Blyth, 2019; Nicholas et al., 2005), and 20.22, 10.26 and 0.92 respectively for the PCS, yielding an RCI value of 8.04 (Wheeler, Williams & Morley, 2019).

Thematic Analysis

Thematic analysis was the process used to analyse the qualitative data. Thematic analysis is a method of organising and richly describing the dataset, by identifying patterns and themes within it. The semi-structured interview and subsequent analysis was guided by curiosity about participants' experiences of using each intervention. This focus was partly motivated by a desire to understand how accessible and applicable the interventions were felt to be day-to-day, given the need for treatments that increase accessibility and enable patients to build on clinical pain management (Buhrman, Gordh & Andersson, 2016; Singh et

al., 2016). It was also motivated by a recognition of the limitations of quantitative data; numbers may suggest that an intervention is associated with change but if people would not use it then any benefits are meaningless.

Given the specific intention of the thematic analysis, a theoretical, deductive approach to data processing was taken. Similarly, the motivation to present a realistic and descriptive account of participants' experiences prompted analysis at the explicit semantic level, rather than the more interpretive latent level.

As per Braun & Clarke's (2006) guidance, all data were initially transcribed verbatim before being repeatedly read to enable initial ideas about potential meanings within the data to emerge. Initial codes were then generated before being sorted into broader themes. These were reviewed and refined until themes and associated subthemes were established that were felt to represent the dataset as a whole. A credibility check of the analysis was conducted by a Clinical Psychologist and Systemic Psychotherapist who is experienced in qualitative research.

Results

Participant Demographic Data

Please see Table 1 for a description of participants' baseline characteristics.

Intervention Sequence Completed

Please see Table 2 for an overview of the intervention sequence completed by each participant.

Table 1: Participant Characteristics

Participant Number	Gender	Age	Ethnicity	Participants' accounts of diagnoses given in relation to pain
1	Female	32	White British	None.
2	Female	42	White British	Slipped disc.
3	Female	73	White British	Degenerative disk disease, prolapsed disk.
4	Female	31	White British	Chronic back pain, fibromyalgia (distinct from the back pain, which preceded fibromyalgia).
5	Female	41	White British	Dehydrated and compacted discs.
6	Male	33	White British	Pulled disc, possible sciatica.

Quantitative Data Analysis

Anxiety

Single Case Analysis

Graphical Analysis

Please see Figure 3 for graphical displays of all participants' self- report anxiety data. For P1, there was a spike in anxiety at the start of the GWtF phase which then returned to baseline levels, as well as a slight spike on day two of the CBT phase, indicating that anxiety levels were marginally higher for both intervention phases than baseline. In the case of P2, the CBT phase saw a sharp decline in anxiety from baseline, while anxiety levels were notably and consistently higher than baseline during the GWtF phase. Data for P3 indicates that anxiety was notably elevated relative to baseline during the GWtF phase, while for CBT the ratings initially remained low (and consistent with baseline) but there was a marked spike in

Table 2: Intervention Sequence Completed by Each Participant

Participant	Intervention Sequence Completed (A= Baseline, B=CBT, C=GWtF)
1	A-C-A-B
2	A-B-A-C
3	A-C-A-B
4	A-B-A-C
5	A-C-A-B
6	A-B-A-C

anxiety on the final day of the phase. There is therefore an increase trajectory for anxiety in the context of CBT but overall, anxiety appears lower for CBT than for GWtF. For P4, overall there was a decrease trajectory associated with anxiety ratings across the CBT phase (despite a notable spike on the second day) while the GWtF phase saw a striking increase in anxiety initially which was followed by a sharp and consistent decline. The data for P5 indicates that both interventions were associated with a decline in anxiety from baseline. For P6, there was an increase in anxiety from baseline during the CBT phase, and a reduction in anxiety relative to baseline during the GWtF phase.

Statistical Analysis- Tau-U

Please see Tables 3 and 4 for the baseline trend (A vs. A) and treatment trend (B vs. B/C vs. C) of anxiety data for each participant/intervention.

CBT

As indicated in Table 5, the difference in anxiety ratings between baseline and CBT treatment phases was variable across participants, with three (P1, P3 and P6) displaying an
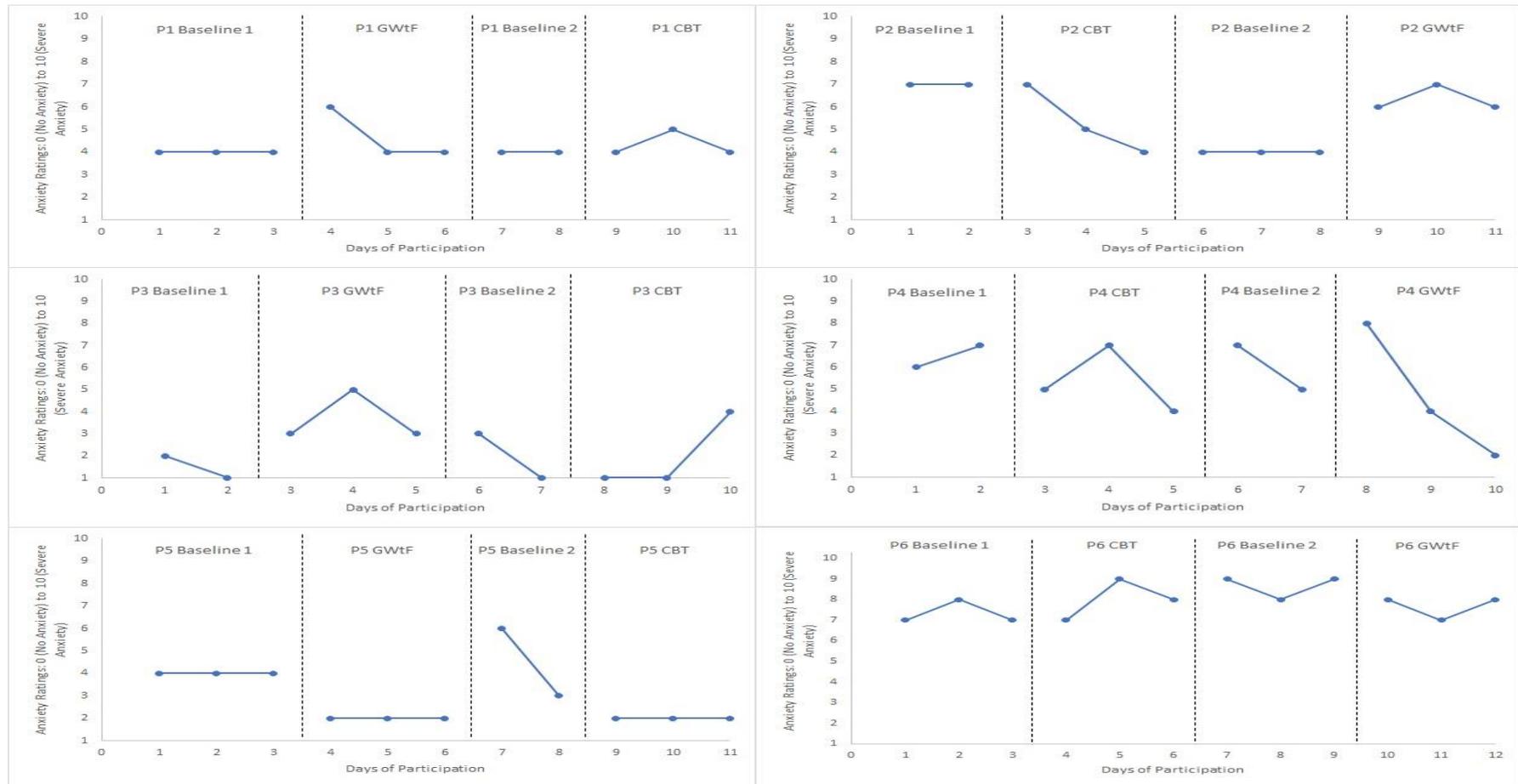
Figure 3: Graphical displays of participants' anxiety data associated with the daily experimental movement

Table 3: Tau-U anxiety baseline trend (A vs. A) and CBT treatment trend (B vs. B) data for each participant. (*) marks baseline trend that exceeds .20 and was thus corrected for (on the guidance of Vannest & Ninci, 2014) in the final baseline vs. treatment (A vs. B) analysis.

Participant Number	Anxiety Trend A (Baseline Trend)			Anxiety Trend B (Treatment Trend- CBT)		
	Tau	P-value	CI (90%)	Tau	P-value	CI (90%)
1	0	1.00	-1.00 to 1.00	0	1.00	-1.00 to 1.00
2	0	1.00	-1.00 to 1.00	-1.00	0.12	-1.00 to 0.05
3	-1.00	0.32	-1.00 to 0.65*	0.67	0.30	-0.38 to 1.00
4	1.00	0.32	-0.65 to 1.00*	-0.33	0.61	-1.00 to 0.72
5	-1.00	0.32	-1.00 to 0.65*	0	1.00	-1.00 to 1.00
6	0	1.00	-1.00 to 1.00	0.33	0.61	-0.72 to 1.00

Table 4: Tau-U anxiety baseline trend (A vs. A) and GWtF treatment trend (C vs. C) data for each participant. (*) marks baseline trend that exceeds .20 and was thus corrected for (on the guidance of Vannest & Ninci, 2014) in the final baseline vs. treatment (A vs. C) analysis.

Participant Number	Anxiety Trend A (Baseline Trend)			Anxiety Trend C (Treatment Trend- GWtF)		
	Tau	P-value	CI (90%)	Tau	P-value	CI (90%)
1	0	1.00	-1.00 to 1.00	-0.667	0.30	-1.00 to 0.39
2	0	1.00	-1.00 to 1.00	0	1.00	-1.00 to 1.00
3	-1.00	0.32	-1.00 to 0.65*	0	1.00	-1.00 to 1.00
4	-1.00	0.32	-1.00 to 0.65*	-1.00	0.12	-1.00 to 0.05
5	0	1.00	-1.00 to 1.00	0	1.00	-1.00 to 1.00
6	0	1.00	-1.00 to 1.00	0	1.00	-1.00 to 1.00

Table 5: Tau-U anxiety baseline vs. treatment trend (A vs. B/C) for each participant/intervention. A negative Tau indicates a downwards slope. (*) baseline trend was corrected for in the analysis. Significant scores are emboldened

Participant Number	Anxiety Tau-U (A vs. B; Baseline vs. CBT)			Anxiety Tau-U (A vs. C; Baseline vs. GWtF)		
	Tau	p-value	CI (90%)	Tau	p-value	CI (90%)
1	0.33	0.57	-0.62 to 1.00	0.33	0.51	-0.50 to 1.00
2	-0.67	0.25	-1.00 to 0.28	**1.00**	**0.05**	**0.16 to 1.00**
3	0.17	0.77	-0.78 to 1.00*	**1.17**	**0.04**	**0.22 to 1.00***
4	-0.67	0.25	-1.00 to 0.28*	-0.17	0.77	-1.00 to 0.78*
5	-0.83	0.15	-1.00 to 0.12*	**-1.00**	**0.05**	**-1.00 to -0.16**
6	0.44	0.39	-0.39 to 1.00	-0.78	0.13	-1.00 to 0.06

increase in anxiety, and three (P2, P4 and P5) showing decreased anxiety during the CBT phase. However, the changes were non-significant in all cases.

GWtF

Table 5 indicates that the difference in anxiety ratings between baseline and GWtF was variable, with three participants (P1, P2 and P3) displaying increased anxiety, and three (P4, P5 and P6) showing a reduction in anxiety during the GWtF phase. This was statistically significant in the cases of P2, P3 and P5, meaning that GWtF was associated with a statistically significant increase in anxiety relative to baseline for P2 (Tau-U=1.00, p=.05) and P3 (Tau-U=1.17, p=-.04), and a statistically significant decrease in anxiety for P5 (Tau-=1.00, p=.05).

<u>Group Analysis</u>

Group Phase Comparison- Tau-U

Table 6 demonstrates that when Tau-U scores were combined across participants, there was an overall indication of decreased anxiety relative to baseline for CBT intervention (Tau-U=-.19, p=.41) and a slight increase in anxiety across GWtF intervention (Tau-U=0.08, p=0.73). However, in both instances this was not statistically significant.

Minimum Clinically Important Difference (MCID)- McNemar's Test

A McNemar's test confirmed that there were no differences between the CBT and GWtF interventions with respect to MCID for anxiety (p=1.00; see Table 7), with 50% of participants meeting MCID following each intervention.

Table 6: Combined participant Tau-U baseline vs. treatment trend (A vs. B/C) scores, indicating overall trend for each measure/intervention. A negative Tau indicates a downwards slope. Significant scores are emboldened.

Measure	Intervention	Combined Tau-U (Baseline vs. Intervention)	
		Tau	p-value
Anxiety	CBT	-0.19	0.41
	GWtF	0.08	0.73
Pain	CBT	0.08	0.74
	GWtF	-0.02	0.93
Heart Rate	**CBT**	**0.49**	**0.04**
	GWtF	0.02	0.94
Bend	CBT	-0.09	0.71
	GWtF	**0.46**	**0.03**

Order of Interventions

Order of interventions does not appear to have had a significant bearing on anxiety ratings, with 50% of participants displaying a reduction in anxiety associated with their first intervention, and 50% showing reduced anxiety following their second.

Pain

Pain ratings were found to be consistent with anxiety ratings (such that a change in anxiety ratings yielded a change in pain ratings in the expected direction) 92% of the time (with a shift in the unexpected direction for the remaining 8%). Please see Table 8 for an overview of the direction of change on each measure associated with each participant/intervention.

Table 7: MCID achieved across the two interventions with respect to pain, anxiety and guarding ratings, and McNemar's Test data regarding the statistical significance of any differences between interventions with respect to MCID achieved.

Measure	CBT		GWtF		CBT vs. GWtF-McNemar Test
	MCID Achieved	MCID Not Achieved	MCID Achieved	MCID Not Achieved	P-value
Anxiety	3	3	3	3	1.00
Pain	3	3	2	4	1.00
Guarding	1	5	1	5	1.00

Table 8: The direction of change on each measure associated with each intervention (relative to baseline) for each participant. + indicates an increase, - a decrease and = indicates no change. Significant change (based on Tau-U for anxiety/pain/heart rate/bend, RCI for PCS/PSEQ and MCID for guarding) is marked with an asterisk

Participant	Intervention	Measure						
		Anxiety	**Pain**	**Heart Rate**	**Bend**	**PCS**	**PSEQ**	**Guarding**
1	CBT	+	+	+	-	-	-	+
	GWtF	+	-	-	+	-	+	+
2	CBT	-	-	+	+	-	=	-
	GWtF	+*	+*	-	+	+	-	+
3	CBT	+	+	+*	-	+	-*	-
	GWtF	+*	+	-	+	+	-	-
4	CBT	-	-	+	-	-*	+*	-*
	GWtF	-	-	+	+	-	-	+
5	CBT	-	-	+	+	=	=	+
	GWtF	-*	-	+	+	-	=	-*
6	CBT	+	+*	+	+	-	+	+
	GWtF	-	-	+	+	-	-	=

<u>Single Case Analysis</u>

Graphical Analysis

Please see Figure 4 for graphical displays of all participants' self-report pain data. For P1, her pain ratings steadily declined across the initial baseline phase and into the GWtF phase and remained stable thereafter apart from a slight spike on the second day of the CBT phase. The data for P2 indicates that pain steadily declined across the initial baseline and CBT phases, but there was a notable increase in pain during the GWtF phase.

Both intervention phases were associated with an increase in pain for P3, but pain was higher overall for GWtF. For P4, the data indicates a decline in pain from the start to the end of her participation, with a sharp spike in pain on day two of the CBT phase and a consistent decline in pain ratings across the GWtF phase (with pain lower for GWtF than CBT overall). For P5, both treatment phases were associated with consistently lower pain ratings than their associated baseline phases, with marginally less pain during the GWtF phase than the CBT phase. Finally, the data for P6 indicates a sharp increase in pain from baseline associated with the CBT phase, but a decrease trajectory for the GWtF phase, with pain consistently lower for GWtF than for CBT.

Statistical Analysis- Tau-U

Please see Tables 9 and 10 for the baseline trend (A vs. A) and treatment trend (B vs. B/C vs. C) of pain data for each participant/intervention.

CBT

As indicated in Table 11 the difference in pain ratings between baseline and CBT treatment phases was variable across participants, with three (P2, P4 and P5) displaying pain reduction, and three (P1, P3 and P6) showing an increase in pain during the CBT phase. This was statistically significant only in the case of P6 (Tau-U=1.00, p=.05).
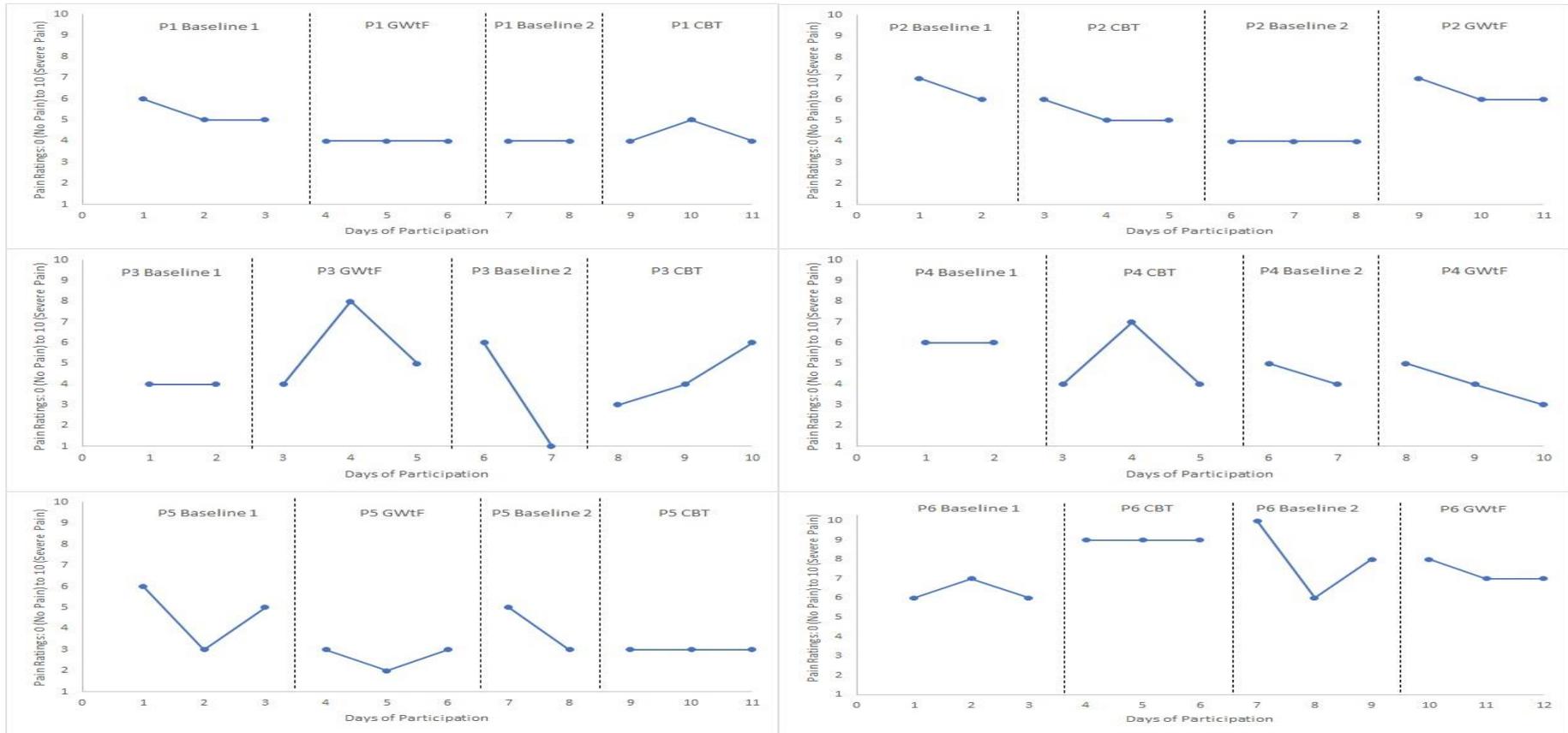
Figure 4: Graphical displays of participants' pain data associated with the daily experimental movement

Table 9: Tau-U pain baseline trend (A vs. A) and CBT treatment trend (B vs. B) data for each participant. (*) marks baseline trend that exceeds .20 and was thus corrected for (on the guidance of Vannest & Ninci, 2014) in the final baseline vs. treatment (A vs. B) analysis.

Participant Number	Pain Trend A (Baseline Trend)			Pain Trend B (Treatment Trend- CBT)		
	Tau	P-value	CI (90%)	Tau	P-value	CI (90%)
1	0	1.00	-1.00 to 1.00	0	1.00	-1.00 to 1.00
2	-1.00	0.32	-1.00 to 0.65*	-0.67	0.30	-1.00 to 0.38
3	-1.00	0.32	-1.00 to 0.65*	1.00	0.12	-0.05 to 1.00
4	0	1.00	-1.00 to 1.00	0	1.00	-1.00 to 1.00
5	-1.00	0.32	-1.00 to 0.65*	0	1.00	-1.00 to 1.00
6	0	1.00	-1.00 to 1.00	0	1.00	-1.00 to 1.00

Table 10: Tau-U pain baseline trend (A vs. A) and GWtF treatment trend (C vs. C) data for each participant. (*) marks baseline trend that exceeds .20 and was thus corrected for (on the guidance of Vannest & Ninci, 2014) in the final baseline vs. treatment (A vs. C) analysis.

Participant Number	Pain Trend A (Baseline Trend)			Pain Trend C (Treatment Trend- GWtF)		
	Tau	P-value	CI (90%)	Tau	P-value	CI (90%)
1	-0.67	0.30	-1.00 to 0.38*	0	1.00	-1.00 to 1.00
2	0	1.00	-1.00 to 1.00	-0.67	0.30	-1.00 to 0.38
3	0	1.00	-1.00 to 1.00	0.33	0.60	-0.72 to 1.00
4	-1.00	0.32	-1.00 to 0.65*	-1.00	0.12	-1.00 to 0.05
5	-0.33	0.61	-1.00 to 0.72*	0	1.00	-1.00 to 1.00
6	-0.30	0.61	-1.00 to 0.72*	-0.67	0.30	-1.00 to 0.38

Table 11: Tau-U pain baseline vs. treatment trend (A vs. B/C) for each participant/intervention. A negative Tau indicates a downwards slope. (*) baseline trend was corrected for in the analysis. Significant scores are emboldened

Participant Number	Pain Tau-U (A vs. B; Baseline vs. CBT)			Pain Tau-U (A vs. C; Baseline vs. GWtF)		
	Tau	p-value	CI (90%)	Tau	p-value	CI (90%)
1	0.33	0.56	-0.62 to 1.00	-0.78	0.13	-1.00 to 0.06*
2	-0.67	0.25	-1.00 to 0.28*	**1.00**	**0.05**	**0.16 to 1.00**
3	0.33	0.56	-0.62 to 1.00*	0.67	0.25	-0.28 to 1.00
4	-0.33	0.56	-1.00 to 0.62	-0.17	0.77	-1.00 to 0.78*
5	-0.33	0.56	-1.00 to 0.62*	-0.67	0.19	-1.00 to 0.17*
6	**1.00**	**0.05**	**0.16 to 1.00***	-0.11	0.83	-0.95 to 0.73*

GWtF

Table 11 indicates the variable nature of pain ratings between baseline and GWtF treatment phases across participants, with four (P1, P4, P5 and P6) displaying pain reduction, and two (P2 and P3) showing an increase in pain during the GWtF phase. This was statistically significant in the case of P2 (Tau-U=1.00, p=-0.05).

<u>Group Analysis</u>

Group Phase Comparison- Tau-U

Table 6 demonstrates that when Tau-U scores were combined across participants for each intervention, there was an overall indication of an increase in pain relative to baseline associated with CBT intervention (Tau-U=.08, p=.74) and a decrease in pain across GWtF intervention (Tau-U=-0.02, p=0.93). However, in both instances this was marginal and not statistically significant.

Minimum Clinically Important Difference (MCID)- McNemar's Test

With respect to mean pain scores following CBT intervention, 50% of participants met MCID, compared with 33.33% following GWtF intervention. As shown in Table 7, a McNemar Test showed that this difference between groups with respect to pain MCID was not statistically significant (p=1.00).

<u>Order of Interventions</u>

Order of interventions does not appear to have affected pain ratings, given that four participants showed a reduction in pain ratings from baseline associated with their first intervention, and three showed a reduction following their second.

Heart Rate (BPM)

HR data was consistent with anxiety ratings (such that a change in anxiety ratings yielded a change in HR in the expected direction) 25% of the time (with a shift in the unexpected direction for the remaining 75%).

Single Case Analysis

Graphical Analysis

Please see Figure 5 for graphical displays of all participants' heart rate data. For P1, the HR readings across the initial baseline and GWtF phases were quite variable, but the two phases overall were relatively consistent with one another. The CBT phase was associated with a slight increase in HR relative to baseline. The initial baseline HR data for P2 was very variable, which makes it difficult to meaningfully compare the first intervention phase (CBT) with baseline. There was a spike in HR on the first day of the GWtF phase, followed by a steep decline meaning that the final GWtF HR scores were marginally lower than those associated with CBT. For P3, the HR data for baseline one, GWtF and baseline two were relatively consistent, but there was a striking and consistent increase in HR associated with the CBT phase. For P4, it is notable that for both intervention phases there was a slight increase in HR as the phase progresses. The increase trajectory was steeper for the GWtF phase, but overall the data across the two intervention phases looks relatively comparable. For P5, GWtF was associated with marginally higher HR data than baseline. The second baseline is quite variable making a meaningful comparison with the CBT phase more difficult, but both intervention data sets look relatively consistent with one another. Finally, for P6, the HR data during his initial baseline phase was quite variable which makes comparison with the first treatment phase (CBT) difficult. There was a slight dip and subsequent consistent increase in HR during the GWtF phase relative to baseline, such that the highest HR reading across his participation is associated with GWtF.
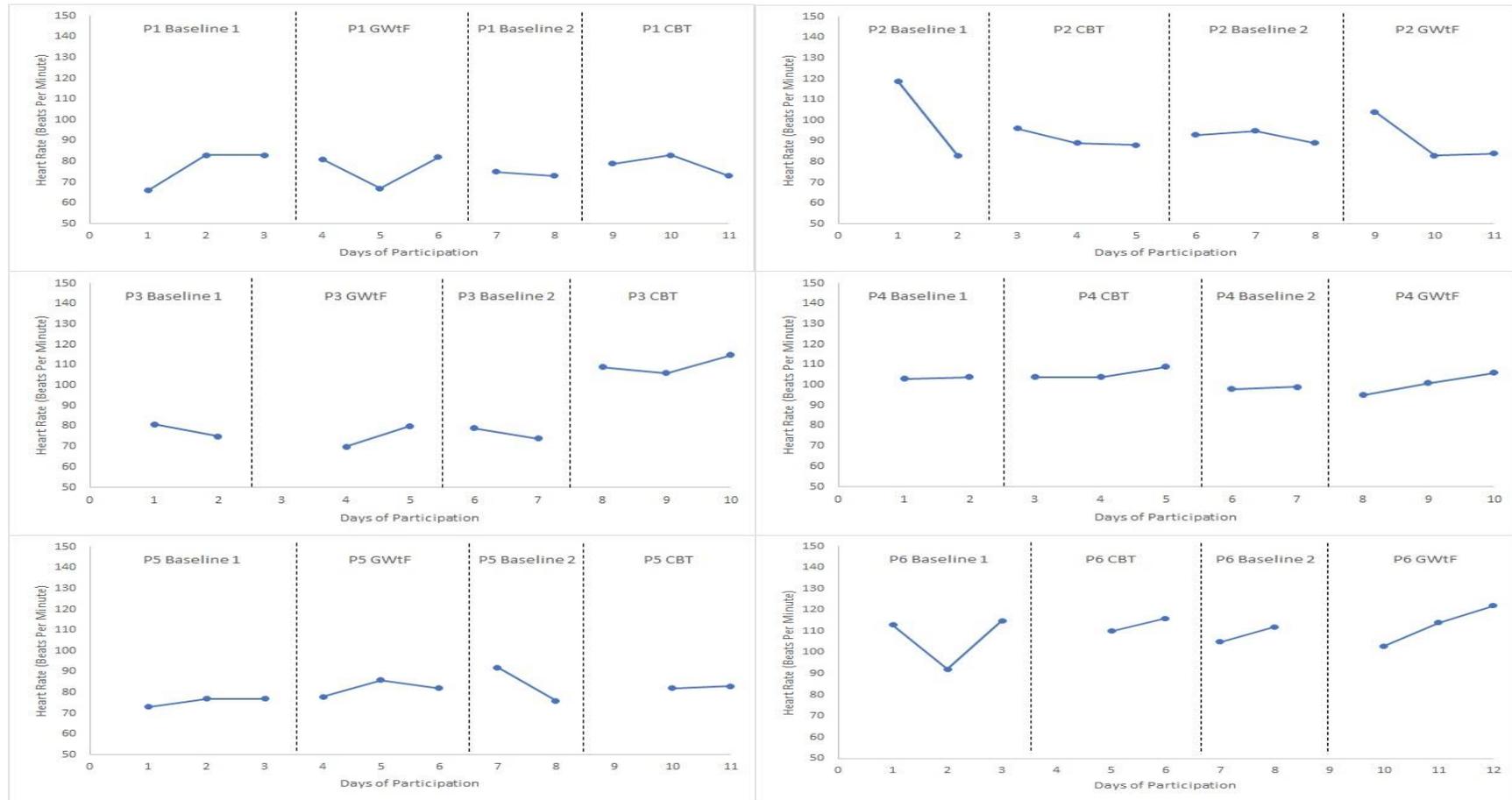
Figure 5: Graphical displays of participants' heart rate data associated with the daily experimental movement

Statistical Analysis- Tau-U

Please see Tables 12 and 13 for the baseline trend (A vs. A) and treatment trend (B vs. B/C vs. C) of HR data for each participant/intervention.

CBT

As indicated in Table 14, all participants displayed increased HR (bpm) relative to baseline during the CBT treatment phase. However, this only achieved statistical significance in the case of P3 (Tau-U=1.17, p=.04).

GWtF

As indicated in Table 14, the difference in HR data between baseline and GWtF treatment phases was variable across participants, with three (P1, P2 and P3) displaying a decrease in HR, and three (P4, P5 and P6) showing increased HR during the GWtF phase. However, the change in HR data relative to baseline was non-significant in all cases.

<u>Group Analysis</u>

Group Phase Comparison- Tau-U

Table 6 demonstrates that when Tau-U scores were combined across participants for each intervention, there was an overall increase in HR relative to baseline in the case of both CBT (Tau-U=.49, p=0.04) and GWtF interventions (Tau-U=.02, p=.94). This was statistically significant in the case of CBT.

<u>Order of Interventions</u>

Order of interventions does not appear to have had a notable bearing on HR data, given that four participants showed an increase in HR from baseline associated with their first intervention, and five showed an increase following their second.

Table 12: Tau-U heart rate baseline trend (A vs. A) and CBT treatment trend (B vs. B) data for each participant. (*) marks baseline trend that exceeds .20 and was thus corrected for (on the guidance of Vannest & Ninci, 2014) in the final baseline vs. treatment (A vs. B) analysis.

Participant Number	Heart Rate Trend A (Baseline Trend)			Heart Rate Trend B (Treatment Trend- CBT)		
	Tau	P-value	CI (90%)	Tau	P-value	CI (90%)
1	-1.00	0.32	-1.00 to 0.65*	-0.33	0.60	-1.00 to 0.72
2	-1.00	0.32	-1.00 to 0.65*	-1.00	0.12	-1.00 to 0.05
3	-1.00	0.32	-1.00 to 0.65*	0.33	0.60	-0.72 to 1.00
4	1.00	0.32	-0.65 to 1.00*	0.67	0.30	-0.39 to 1.00
5	-1.00	0.32	-1.00 to 0.65*	1.00	0.32	-0.65 to 1.00
6	0.33	0.60	-0.72 to 1.00*	1.00	0.32	-0.65 to 1.00

Table 13: Tau-U heart rate baseline trend (A vs. A) and GWtF treatment trend (C vs. C) data for each participant. (*) marks baseline trend that exceeds .20 and was thus corrected for (on the guidance of Vannest & Ninci, 2014) in the final baseline vs. treatment (A vs. C) analysis.

Participant Number	Heart Rate Trend A (Baseline Trend)			Heart Rate Trend C (Treatment Trend- GWtF)		
	Tau	P-value	CI (90%)	Tau	P-value	CI (90%)
1	0.67	0.30	-0.38 to 1.00*	0.33	0.60	-0.72 to 1.00
2	-0.33	0.60	-1.00 to 0.72*	-0.33	0.60	-1.00 to 0.72
3	-1.00	0.32	-1.00 to 0.65*	1.00	0.32	-0.65 to 1.00
4	1.00	0.32	-0.65 to 1.00*	1.00	0.12	-0.05 to 1.00
5	0.67	0.30	-0.38 to 1.00*	0.33	0.60	-0.72 to 1.00
6	1.00	0.32	-0.65 to 1.00*	1.00	0.12	-0.05 to 1.00

Table 14: Tau-U heart rate baseline vs. treatment trend (A vs. B/C) for each participant/intervention. A negative Tau indicates a downwards slope (*) baseline trend was corrected for in the analysis. Significant scores are emboldened.

Participant Number	Heart Rate Tau-U (A vs. B; Baseline vs. CBT)			Heart Rate Tau-U (A vs. C; Baseline vs. GWtF)		
	Tau	p-value	CI (90%)	Tau	p-value	CI (90%)
1	0.67	0.25	-0.28 to 1.00*	-0.56	0.28	-1.00 to 0.28*
2	0.17	0.77	-0.78 to 1.00*	-0.22	0.66	-1.00 to 0.62*
3	**1.17**	**0.04**	**0.22 to 1.00***	-0.25	0.70	-1.00 to 0.81*
4	0.50	0.39	-0.45 to 1.00*	0.17	0.77	-0.78 to 1.00*
5	0.25	0.69	-0.81 to 1.00*	0.78	0.13	-0.06 to 1.00*
6	0.17	0.77	-0.78 to 1.00*	0.17	0.77	-0.78 to 1.00*

Degrees of Bend

Degrees of bend achieved was consistent with anxiety ratings (such that a change in anxiety ratings yielded a change in bend in the expected direction) 42% of the time (with a shift in the unexpected direction for the remaining 58%).

<u>Single Case Analysis</u>

Graphical Analysis

Please see Figure 6 for graphical displays of all participants' bend data. For clarity, references to less bend or a decrease/decline in the degrees of bend achieved indicate that the bend was a smaller movement and the participant did not bend as low to the floor as previously.

For P1, the GWtF phase was associated with an increase in degrees of bend achieved from baseline. Less bend was achieved during the CBT phase than the preceding phases, despite a sharp increase in bend on the final day of this phase. The data for P2 indicates that while there was not a significant increase in bend achieved during the CBT phase compared to baseline, the scores were a little more consistent across the three days (as they were very variable across the two days of baseline one). The GWtF phase was associated with a steady decline in the degree of bend achieved across the phase, with greater bend achieved during the CBT phase compared to GWtF. For P3, the degree of bend achieved steadily increased across the GWtF phase relative to baseline, while there was a slight decrease in bend relative to baseline during the CBT phase. Overall, the GWtF phase is associated with more bend than the CBT phase. For P4, the degree of bend achieved is relatively consistent across all phases, with no marked difference between the CBT and GWtF phases in this regard. For P5, there was a striking increase in bend achieved during the GWtF phase compared to the initial baseline. There was then a slight decline in bend achieved during the CBT phase relative to baseline, with more achieved during the GWtF phase overall. Finally, for P6, marginally
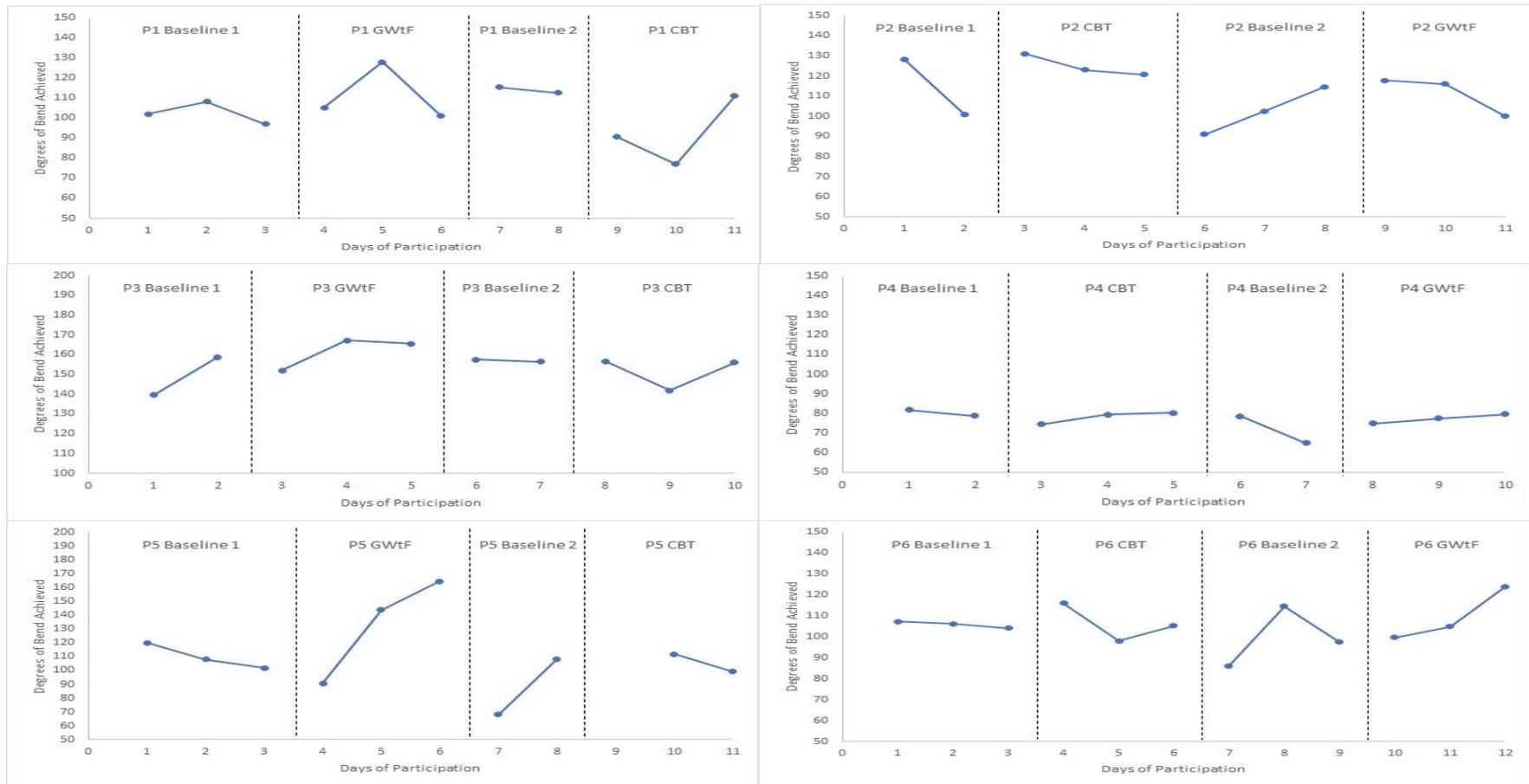
Figure 6: Graphical displays of participants' bend data associated with the daily experimental movement

greater bend was achieved during CBT compared to baseline, while GWtF was associated with a steeper and more consistent increase in bend relative to baseline. While visually there does not appear to be a stark difference between the bend scores registered during the CBT and GWtF phases, there was a decline in the degree of bend achieved across the CBT phase (so a downwards trajectory), whereas the opposite was true for GWtF.

Statistical Analysis- Tau-U

Please see Tables 15 and 16 for the baseline trend (A vs. A) and treatment trend (B vs. B/C vs. C) of bend data for each participant/intervention.

CBT

As indicated in Table 17, the difference in bend achieved between baseline and CBT treatment phases was variable across participants, with three (P1, P3 and P4) displaying a decrease in bend, and three (P2, P5 and P6) showing increased bend. However, the change in bend achieved relative to baseline was non-significant in all cases.

GWtF

As demonstrated in Table 17, all participants displayed an increase in bend relative to baseline during the GWtF treatment phase. However, in all cases this did not achieve statistical significance.

Group Analysis

Group Phase Comparison- Tau-U

Table 6 demonstrates that when Tau-U scores were combined across participants for each intervention, there was a slight decrease in bend achieved relative to baseline in the case of CBT intervention (Tau-U=-.09, p=.71) and an increase in bend achieved across GWtF intervention (Tau-U=.46, p=0.03). This was statistically significant in the case of GWtF intervention.

Table 15: Tau-U bend baseline trend (A vs. A) and CBT treatment trend (B vs. B) data for each participant. (*) marks baseline trend that exceeds .20 and was thus corrected for (on the guidance of Vannest & Ninci, 2014) in the final baseline vs. treatment (A vs. B) analysis.

Participant Number	Bend Trend A (Baseline Trend)			Bend Trend B (Treatment Trend- CBT)		
	Tau	P-value	CI (90%)	Tau	P-value	CI (90%)
1	-1.00	0.32	-1.00 to 0.65*	0.33	0.60	-0.72 to 1.00
2	-1.00	0.32	-1.00 to 0.65*	-1.00	0.12	-1.00 to 0.05
3	-1.00	0.32	-1.00 to 0.65*	-0.33	0.60	-1.00 to 0.72
4	-1.00	0.32	-1.00 to 0.65*	1.00	0.12	-0.05 to 1.00
5	1.00	0.32	-0.65 to 1.00*	-1.00	0.32	-1.00 to 0.65
6	-1.00	0.12	-1.00 to 0.05*	-0.33	0.60	-1.00 to 0.72

Table 16: Tau-U bend baseline trend (A vs. A) and GWtF treatment trend (C vs. C) data for each participant. (*) marks baseline trend that exceeds .20 and was thus corrected for (on the guidance of Vannest & Ninci, 2014) in the final baseline vs. treatment (A vs. C) analysis.

Participant Number	Bend Trend A (Baseline Trend)			Bend Trend C (Treatment Trend- GWtF)		
	Tau	P-value	CI (90%)	Tau	P-value	CI (90%)
1	-0.33	0.60	-1.00 to 0.72*	-0.33	0.60	-1.00 to 0.72
2	1.00	0.12	-0.05 to 1.00*	-1.00	0.12	-1.00 to 0.05
3	1.00	0.32	-0.65 to 1.00*	0.33	0.60	-0.72 to 1.00
4	-1.00	0.32	-1.00 to 0.65*	1.00	0.12	-0.05 to 1.00
5	-1.00	0.12	-1.00 to 0.05*	1.00	0.12	-0.05 to 1.00
6	0.33	0.60	-0.72 to 1.00*	1.00	0.12	-0.05 to 1.00

Table 17: Tau-U degrees of bend baseline vs. treatment trend (A vs. B/C) for each participant/intervention. A negative Tau indicates a downwards slope. (*) baseline trend was corrected for in the analysis.

Participant Number	Bend Tau-U (A vs. B; Baseline vs. CBT)			Bend Tau-U (A vs. C; Baseline vs. GWtF)		
	Tau	p-value	CI (90%)	Tau	p-value	CI (90%)
1	-0.83	0.15	-1.00 to 0.12*	0.44	0.38	-0.39 to 1.00*
2	0.50	0.39	-0.45 to 1.00*	0.22	0.66	-0.20 to 1.00*
3	-0.50	0.39	-1.00 to 0.45*	0.50	0.39	-0.45 to 1.00*
4	-0.17	0.77	-1.00 to 0.78*	0.50	0.39	-0.45 to 1.00*
5	0.25	0.70	-0.81 to 1.00*	0.67	0.19	-0.17 to 1.00*
6	0.22	0.66	-0.62 to 1.00*	0.44	0.38	-0.39 to 1.00*

Order of interventions does not appear to have had a significant bearing on degrees of bend achieved, given that five participants showed an increase in bend from baseline associated with their first intervention, and four showed an increase associated with their second.

Catastrophising- (PCS)

PCS scores were consistent with anxiety ratings (such that a change in anxiety ratings yielded a change in PCS scores in the expected direction) 67% of the time (with no change 8% of the time, and a shift in the unexpected direction for the remaining 25%).

Overview of Catastrophising Data

Four participants' catastrophising scores reduced (an improvement) following CBT intervention with one participant showing no change and one displaying an increase. Similarly, four participants displayed a reduction in catastrophising following GWtF intervention, with the remaining two showing an increase.

Based on norms outlined in Sullivan (1995), a PCS score of 30 indicates a clinically significant level of catastrophising (75th percentile). Three participants (coincidentally, the three participants who started with CBT intervention) were within the clinical range at the start of their participation (as displayed in Table 18). One participant remained in the clinical range throughout. Two participants' scores reduced such that they were no longer in the clinical range at the end of the CBT phase, with one sustaining this across the second baseline and GWtF phase. However, the other participant's scores had returned to the clinical range by the end of the second baseline, but again fell below it by the end of GWtF intervention.

Table 18: Participants' pre/post PSEQ and PCS scores and level of reliable change for both interventions.

Participant	Pain Self-Efficacy Questionnaire (PSEQ)						Pain Catastrophising Scale (PCS)					
	Baseline Score	Post-CBT Score	RCI	Baseline Score	Post-GWtF Score	RCI	Baseline Score	Post-CBT Score	RCI	Baseline Score	Post-GWtF Score	RCI
1	35	34	NC	30	35	NC	21	13	NC	15	13	NC
2	31	31	NC	36	27	NC	43	35	NC	31	37	NC
3	40	29	RD*	39	30	NC	21	27	NC	21	26	NC
4	19	39	RI*	45	43	NC	40	20	RI*	15	7	NC
5	36	36	NC	33	33	NC	8	8	NC	11	8	NC
6	25	29	NC	29	26	NC	33	27	NC	31	28	NC

Please note: NC indicates no change, RD indicates reliable deterioration, and RI indicates reliable improvement. Significant scores (reflecting either reliable improvement or deterioration) are marked with an asterisk. Clinically significant scores are underlined.

Reliable Change Index (RCI)

As displayed in Table 18, there was no reliable change from baseline on the PCS associated with GWtF intervention, while CBT intervention was associated with a reliable improvement for P4.

Order of Interventions

It is possible that the intervention order had some bearing on change in catastrophising scores, given that five out of six participants showed a reduction in catastrophising following their first intervention, and three out of six displayed a reduction after intervention two.

Self-Efficacy- Pain Self-Efficacy Questionnaire (PSEQ)

PSEQ scores were consistent with anxiety ratings (such that a change in anxiety ratings yielded a change in PSEQ scores in the expected direction) 42% of the time (with no change 25% of the time, and a shift in the unexpected direction for the remaining 33%).

Overview of Self-Efficacy Data

Two participants displayed an increase in self-efficacy scores (an improvement), two showed no change and two displayed a decline following CBT intervention. Four participants showed a decline in self-efficacy scores following GWtF treatment, with one participant displaying an increase and the remaining participant showing no change.

Research by Nicholas et al. (2019) indicated that the 75th centile of the distribution of PSEQ scores, based on data from 36 pain clinics in Australia, was a score of 29, so this is used for clinical significance, with scores that fall below this considered clinically relevant. As indicated in Table 18, only scores for P4 and P6 were below this cut-off initially. The score for P4 improved such that it was no longer in the clinical range following CBT intervention; a

change sustained across subsequent baseline and GWtF phases. Scores for P6 were variable

across phases but did not exceed 29 at any point.

The data for P2, above the cut-off initially, remained stable across CBT intervention

and increased across the second baseline, then entered the clinically significant range

following GWtF intervention. Similarly, P3, whose PSEQ data was not initially clinically

meaningful, displayed a decrease in scores associated with both interventions, with her PSEQ

score falling below the cut-off following CBT intervention.

Single Case Analysis

Reliable Change Index (RCI)

As indicated in Table 18 there was no reliable change from baseline on the PSEQ

associated with GWtF intervention, while CBT intervention was associated with a reliable

deterioration on the measure for P3 and a reliable improvement for P4.

Order of Interventions

Order of interventions may have had some bearing on PSEQ scores, given that three

participants' displayed an increase, two remained the same and one decreased following

their first intervention. Following the second intervention, five participants' scores declined,

with one remaining unchanged.

Guarding

Guarding ratings were consistent with anxiety ratings (such that a change in anxiety

ratings yielded a change in guarding ratings in the expected direction) 58% of the time (with

no change 8% of the time, and a shift in the unexpected direction for the remaining 34%).

Overview of Guarding Data

Please see Table 19 for participants' pre/post guarding ratings. The physiotherapists

provided guarding ratings for all participants, but consistency across raters was poor: 28%

Table 19: Participants' pre/post guarding ratings for both interventions. Scores where Minimum Clinically Important Difference (an improvement of one point) was met are emboldened.

Participant	Guarding Data			
	Mean Baseline Rating	Mean Post-CBT Rating	Mean Baseline Rating	Mean Post-GWtF Rating
1	5.00	5.25	4.75	5.50
2	2.25	2.00	1.75	2.25
3	4.75	4.50	5.00	4.75
4	2.50	**1.50**	1.00	2.00
5	1.75	2.25	2.75	**1.50**
6	0.25	0.75	0.25	0.25

inter-rater reliability (RoBiNT guidance is 80%). However, visual analysis of ratings highlights that ratings typically changed consistently even though the values assigned differed.

CBT intervention was associated with a decrease in guarding for three participants but an increase for the remaining three. Guarding ratings decreased from baseline for GWtF in the case of two participants, increased for three and remained the same for one.

Group Analysis

Minimum Clinically Important Difference (MCID)- McNemar's Test

There were no differences between the CBT and GWtF interventions with respect to MCID for guarding (p=1.00; see Table 7), with one participant meeting MCID (of at least a one-point pre-post improvement) following each intervention.

<u>Order of Interventions</u>

It appears that order of interventions may have had some impact on guarding, given that four participants displayed a decrease in guarding following their initial intervention compared with just one following the second intervention.

Qualitative Data- Thematic Analysis

What became clear in the early stages of thematic analysis is that the data pertaining to the two interventions felt very separate, so they are presented as distinct analyses. Two key domains emerged from the qualitative data in both analyses: 1) Perceived Change, and 2) Experience of Intervention.

CBT

Please see Figure 7 for a thematic map of participants' experiences of the brief CBT intervention.

<u>Perceived Change</u>

Pain

Impact on Pain

The impact of CBT intervention on pain varied across participants. Three participants (P1, P3, P4) felt that the CBT led to reduced pain during the experimental movement, with two (P1 and P4) reflecting that the reduction in pain felt secondary to a change in anxiety:

<u>P4: "I still felt pain but I felt I could manage it… I think that having reduced stress reduced the intensity of the pain, so that was really helpful."</u>

P3 did not experience any change in pain associated with CBT intervention.
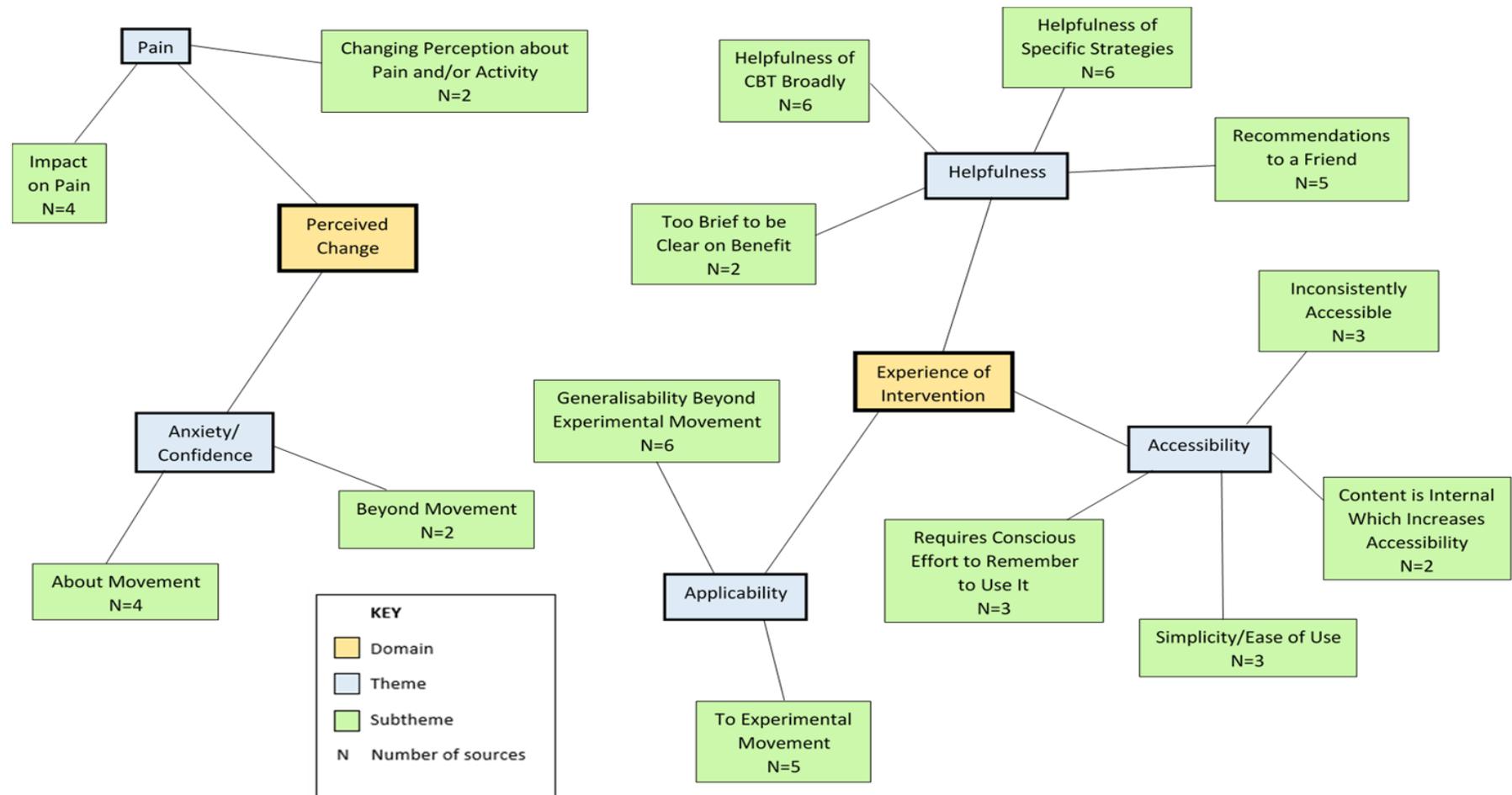
Figure 7: Thematic map displaying themes and subthemes derived from the thematic analysis of data pertaining to participant's experiences of using the CBT intervention

Changing Perception about Pain and/or Activity

Two participants (P2 and P3) spoke about CBT changing the way they thought about their pain and/or their activity levels in the context of their pain:

P2: "The main thing for me was actually the CBT and being conscious that perhaps I can change my perception about certain things, and it's not necessarily that, as we know, it would take the pain away, but my ideas about it would hopefully change."

Anxiety/Confidence

About Movement

Three participants (P1, P4 and P5) spoke about CBT reducing anxiety and increasing confidence in the context of their daily experimental movement:

P4: "I'd try to jump in, as I was setting myself up to do it, like thinking 'I can do this, I've done… I did it yesterday and I was alright' so I think it kind of lessened… the anxiety changed."

However, P3 experienced no change with respect to the anxiety/confidence associated with bending.

Beyond Movement

Two participants (P1 and P5) spoke about CBT reducing anxiety more generally:

P1: "The CBT makes you think a lot more, like obviously to calm you down… because sometimes I think 'I've got a headache, it must be a brain tumour'… it really did calm you down."

Accessibility

Content is Internal Which Increases Accessibility

Two participants (P2 and P6) spoke about the internal nature of the CBT strategies increasing accessibility:

P6: "The CBT one was obviously a bit easier to make use of day-to-day because it's internal as opposed to external."

Simplicity/Ease of Use

The simple and easy-to-use nature of the CBT strategies was also reflected on by three participants (P1, P4 and P6):

P1: "They're so simple to do, just something simple that you could sit there and, just for a couple of minutes, sit there and do while it's quiet in the house."

Requires Conscious Effort to Remember to Use It

One of the challenges of accessibility that was described by participants (P2, P4 and P6) was that CBT requires conscious effort to remember to use it:

P4: "I had to try and actively remind myself to use them because it didn't come naturally."

Inconsistently Accessible

Three participants (P1, P4 and P6) commented on the fact that the accessibility of CBT could feel quite variable across different contexts/situations:

P4: "If I wasn't quite in the right space or I didn't do it soon enough, I felt like it… overwhelmed me and I kind of almost missed the boat for it… In most of the situations I used it in it really helped to balance and bring it down. And then on a couple of occasions I just felt a bit overwhelmed by it."

Applicability

To Experimental Movement

Participants were asked how able they felt to apply the CBT ideas and strategies to the daily experimental movement, and the response was varied. Four participants (P1, P3, P4 and P6) felt that CBT did apply to the specific movement.

P4: That's when I'd try to jump in, as I was setting myself up to do it [the bend], like thinking 'I can do this, I've done… I did it yesterday and I was alright'

However, P2 did not feel that she utilised the strategies when completing her movement:

P2: "I think when you're actually doing the movement it's probably hard… I wouldn't say I necessarily very consciously thought of it whilst I was doing it."

Generalisability Beyond Experimental Movement

All six participants referenced the fact that CBT felt more broadly applicable across different aspects of their lives:

P4: "It works with pain, I'm sure you could apply it to most parts of your life… it's something I will carry on doing."

Helpfulness

Helpfulness of CBT Broadly

The perception of the helpfulness of CBT overall was quite variable across participants. P3 appeared to find it the least helpful, while P6 had a mixed experience with regards to its helpfulness:

P6: "I think it was relatively helpful. It didn't always stop it, you know… I'm not going to sugar coat it… You know, there were some times when it didn't help and that was unfortunate."

However, the remaining participants (P1, P2, P4 and P5) appeared to find it helpful and spoke of their motivation to continue using it:

P4: "I think they've been really helpful… Learning to control your breathing or breathing from the correct space to bring your whole system down a little bit, and reduce that anxiety, and processing any worries or whatever I've got in a more balanced way… I think the CBT was brilliant."

Helpfulness of Specific Strategies

All six participants referenced specific strategies when reflecting on the helpfulness of the CBT intervention:

P2: "The reframing part of it is very beneficial and also, the first strategy we were saying about weighing up the pros and cons of something; of a statement, you realise that actually often what you're saying isn't... not a hundred percent true."

Too Brief to be Clear on Benefit

Two participants (P2 and P3) spoke about the fact that their experience of using the CBT had been so brief that they didn't yet feel clear on the change or benefit associated with it:

P2: "Again I think maybe the time's too short. Over a longer period of time I might have noticed more of a difference..."

Recommend to a Friend

When asked whether they would recommend the CBT intervention to a friend, four participants (P1, P2, P4 and P5) said that they would "definitely" recommend it, while P6 said he would "probably" recommend it.

GWtF

Please see Figure 8 for a thematic map of participants' experiences of the GWtF intervention.

<u>Perceived Change</u>

Pain

All participants reported that GWtF did not have any impact on their pain:

<u>P5: "The sound I wouldn't have said any impact at all."</u>

Movement

Awareness of Movement

Three participants (P1, P4 and P6) reflected on the fact that the GWtF increased their awareness of their movement:

<u>P1: "I wouldn't say helpful but... it was nice to see how much you do move, and how much I do stretch... you don't realise how much you do."</u>

Anxiety/Confidence about Movement

However, the helpfulness of this increased awareness appeared to be variable. For P5 the GWtF did not impact on her anxiety about movement, while for P3, the sound appeared to increase her confidence in bending:

<u>P5: "When it goes louder you're telling yourself in your mind that you're working harder... 'I'm doing good things… I'm getting more movement'."</u>

For P1 and P4, the impact on anxiety and confidence in the context of movement appeared to be quite mixed. They reflected on the awareness of movement increasing their confidence in their capacity to move, but also
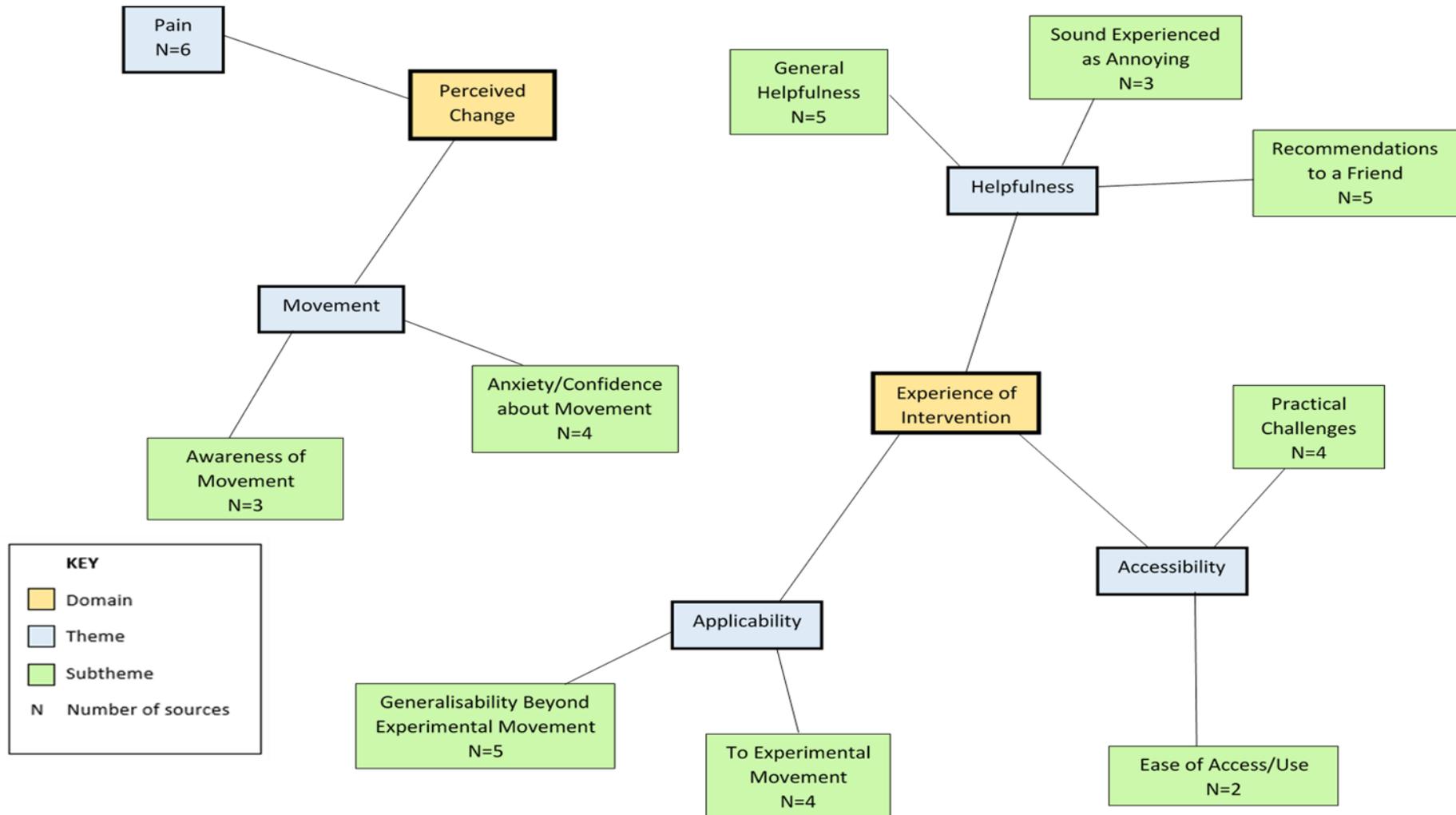
Figure 8: Thematic map displaying themes and subthemes derived from the thematic analysis of data pertaining to participant's experiences of using the GWtF intervention

being a trigger to their anxiety about movement:

P4: "It tells me 'actually I could do those movements'" / "I didn't find it helpful because I think the sound… it was just like a constant reminder for me of 'I'm monitoring myself in case I do something that hurts'… Overall I think it just like triggered it a bit."

Experience of Intervention

Accessibility

Ease of Access/Use

With respect to accessibility, two participants (P1 and P6) commented on how easy the GWtF was to access and use:

P1: "It was quite simple, easy to use, just on your back."

Practical Challenges

Four participants (P1, P2, P3 and P6) reflected on the practical challenges associated with the GWtF in its current format, and provided recommendations about changes to design that could increase its accessibility and usability:

P2: "I mean it would have to be done in a different way because just, just having it on your back... You know, I'm thinking I can't turn it off because I can't reach it, going to have to take the shirt off first you know, and accidentally pressing things."

Applicability

To Experimental Movement

The feedback about the applicability of the GWtF to the experimental movement was mixed. Two participants (P2 and P5), who had spoken about not

generally finding the GWtF helpful, did say that it was more useful when applied to a specific movement:

P2: "Yes, that I think, if it was just for that [a painful bend], yes I'd be much more likely to… So whilst I was actually just doing the movement it would be OK, for those 10 seconds of my life, but I kind of think I can live with this."

Conversely, P6 found the GWtF less helpful when it was applied to his experimental movement than when used in other contexts:

"Because I'm still relatively mobile, when I did move it would just go straight through the range and then back again, and it didn't feel like there was a way to connect the different parts of the movement… It was a bit kind of intangible. Whereas when I was doing the [physiotherapy] exercises, because they're quite slow movements it made much more sense."

Generalisability Beyond Experimental Movement

Again, the perception of how generalisable the GWtF is to day-to-day life was variable. Most participants indicated that they would not use it in its current format, but P3 and P6 did feel it would be something that they could make use of in relation to certain activities around the house:

P6: "If I was pottering around in the garden or doing something in the house or whatever… I can't see any drawbacks."

Helpfulness

General Helpfulness

The views about how helpful the GWtF is were again split. P2 and P5 spoke about not finding it helpful:

P5: "I found it a bit strange. For me personally I don't think it would be something I would find productive or helpful."

While P1 and P3 were more positive:

P3: "I think it helped"

The participant that appeared to find it most helpful was P6. He reflected on the fact that the sound feedback motivated him to try and achieve a greater bend:

P6: "It kind of almost became a goal… You'd get to where you thought you should and then you'd think 'oh maybe I can make it plink one more time'. The goal-setting during the exercise was brilliant… that really worked for me."

Sound Experienced as Annoying

Three participants (P2, P5 and P6) spoke about the sound being annoying and reflected on this being a potential barrier to its use:

P2: "I would say that the noise that the go with the flow thing makes... I wouldn't use it… Oh my goodness every time you moved it's like woah… It was quite annoying!"

Recommend to a Friend

Five participants (P1, P3, P4, P5 and P6) said they would recommend the GWtF, although it was notable that the recommendations were generally more specific than for the CBT:

P1: "Yes, for somebody who is on their feet quite a lot, maybe like a nurse or somebody like that if they had a back problem, then yes."

Discussion

The study used a mixed measures, multiple single case design to explore the impact of two interventions, brief CBT and GWtF, on pain anxiety. The three research questions outlined in the introduction will now be addressed in turn, followed by a consideration of the consistency of the current findings with prior research.

Does a brief CBT intervention lead to a reduction in pain anxiety during movement?

The quantitative findings indicate that the impact of brief CBT intervention on pain anxiety varied across participants. Half displayed a reduction in pain and anxiety ratings that met MCID following brief CBT, indicating that this intervention was associated with a meaningful reduction in pain and anxiety 50% of the time (although these reductions from baseline did not achieve statistical significance with Tau-U testing). For one participant (P4), the brief CBT intervention was also associated with a reliable improvement in catastrophising and self-efficacy, and a reduction in guarding that met MCID. This indicates a significant change in pain anxiety for this participant at both a cognitive (catastrophising/self-efficacy) and behavioural (guarding) level.

However, it appears to have been less helpful for two participants. P3 displayed a significant increase in HR and a reliable deterioration in self-efficacy scores associated with brief CBT, while Tau-U data indicates that the intervention was associated with a significant increase in pain relative to baseline for P6. Also, when Tau-U data was combined in a meta-analysis, brief CBT intervention was found to be associated with a statistically significant increase in HR from baseline for the group as a collective.

However, the qualitative data feels somewhat inconsistent with the quantitative findings, as it indicates that the majority of participants found the CBT intervention beneficial. Half of the participants perceived the brief CBT to be associated with a reduction in both anxiety and pain in relation to the experimental movement, and all felt that the

benefits of CBT were generalisable beyond this. The majority spoke of finding brief CBT intervention helpful and said they would recommend it to a friend, and all six referenced specific strategies that they had found useful. Indeed, two participants indicated an interest in seeking full treatment upon completion of their participation.

Does the 'Go-With-the-Flow' sonification technology lead to a significant reduction in pain anxiety during movement?

As with the brief CBT intervention, the impact of GWtF on pain anxiety varied across participants. Half of the participants displayed a reduction in anxiety ratings that met MCID; Tau-U analysis indicated this reduction from baseline to be statistically significant in the case of P5. The reduction in anxiety for P5 also coincided with a reduction in guarding that met MCID. Two participants also displayed a reduction in pain that met MCID (although these reductions from baseline did not achieve statistical significance with Tau-U testing). Furthermore, when Tau-U data was combined in a meta-analysis, GWtF intervention was associated with a statistically significant increase in bend achieved from baseline for the group overall. This indication of increased bend, alongside the finding that the intervention is associated with a meaningful reduction in guarding for P5, suggests that GWtF (when used in the short-term) may target primarily behavioural (rather than cognitive) change.

However, GWtF was also associated with a statistically significant increase in anxiety ratings from baseline for P2 and P3, and a statistically significant increase in pain ratings for P2. The qualitative data was also generally less positive for GWtF than for brief CBT. Participants largely did not feel GWtF had an impact on their pain or anxiety in relation to the experimental movement. However, half felt that GWtF increased their awareness of the specific movement and their capacity to move more generally, although this was not consistently experienced to be a positive thing with two participants reflecting that this inadvertently increased the anxiety they experienced about movement. Most participants

indicated that they would not use GWtF in its current format, citing issues with design and the fact that the sound feedback is 'annoying'.

Is one superior to the other in terms of anxiety reduction?

McNemar tests indicated that there were no significant differences between the two interventions with respect to MCID for pain, anxiety and guarding ratings. Based on qualitative data, one could conclude that the brief CBT was generally the preferred intervention, and was the intervention that was most associated with a perceived reduction in pain anxiety for participants. Based on quantitative data, neither intervention was associated with a statistically significant improvement in pain anxiety for the majority of participants.

However, based on the group Tau-U analyses, there is a clear indication of benefit in the context of GWtF given its association with increased bend. Conversely, the brief CBT intervention was associated with a group increase in HR relative to baseline which, given that HR was used as a measure of pain anxiety, could be taken to indicate increased anxiety in the context of brief CBT intervention. However, anxiety ratings and HR data were inconsistent, and it is likely that HR was a poor indicator of anxiety in these circumstances. So, in conclusion, there appear to be benefits and drawbacks associated with both interventions, and there is no clear indication that one is superior to the other with regards to pain anxiety reduction.

Consistency of findings with prior research

Brief CBT

Based on the quantitative data alone, the findings appear inconsistent with the study by Salomons et al. (2014), in which brief CBT was found to significantly reduce pain unpleasantness. However, this was in the context of lab-based experimental pain applied to healthy participants, which is obviously very different to chronic pain. Given this important

difference, the fact that brief CBT trialled at home over such a limited period did produce meaningful change for some participants living with chronic pain (based on both the quantitative and qualitative findings) is promising.

GWtF

The present findings are somewhat consistent with the findings of Singh et al. (2016) that GWtF increases performance, and awareness of both movement and physical capability. However, there appear to be some discrepancies given that participants in the Singh et al. (2016) study indicated increased motivation, sense of control and relaxation during movement. While P6 reported that the sound feedback motivated him to try and achieve the next note, this was not a finding that was reported by others. Also, far from the sound being experienced as relaxing (which no participants reported in the present study), two participants found that it triggered their movement-related anxiety. However, GWtF intervention was associated with benefit (based on quantitative and qualitative data) for some participants individually, and with regards to bend as a group, which is promising for an intervention that is still very much in development.

Several themes touched upon above will now considered in further depth, including 1) the process of change associated with each intervention, 2) the inconsistency of quantitative and qualitative findings regarding CBT treatment, 3) the significant increase in bend associated with GWtF, and 4) measurement considerations (with a specific focus on HR data).

Process of change associated with each intervention

One of the motivations for this research was to try to understand whether any change associated with each intervention is achieved by a similar, or by a contrasting, therapeutic process. As brief CBT was the only intervention that yielded a reliable change in self-efficacy and catastrophising (albeit for only one participant), and GWtF intervention was

associated with increased bend, we could hypothesise that perhaps initially, brief CBT treats cognitive processes while GWtF achieves behavioural change. This idea is based on very limited findings but makes theoretical sense given the specific cognitive focus of CBT and the movement focus of GWtF. It is a hypothesis that would be interesting to consider further in future research through the close tracking of cognitive and behavioural measures over a longer period. This would also enable us to explore whether initial cognitive change produces subsequent behavioural change, and vice versa.

The finding that the two interventions appear to have opposing effects (based on the collective Tau-U data) with respect to anxiety, pain and bend (with CBT associated with reduced anxiety, but increased pain and less bend, and the opposite true for GWtF) is, while largely not statistically significant, nonetheless interesting. It lends support to the above hypothesis that the two interventions are associated with different therapeutic processes, and it has also led the researchers to consider the potential effects of combining the two (such that participants utilise the sound feedback and CBT strategies in combination).

It is hypothesised that this combination of approaches could emulate the joint physiotherapy and psychology focus of a Pain Management Programme (PMP) in a more accessible way; a hypothesis that would be interesting to explore further. PMPs are multidisciplinary (usually psychology and physiotherapy led) group interventions that focus on increasing movement and decreasing pain-related distress. They have been shown to reduce anxiety about movement and improve physical functioning in the context of chronic pain, but generalisation of gains to everyday life is often rather disappointing (Williams et al., 2012).

Increase in bend associated with GWtF

The finding that GWtF was associated with a statistically significant increase in bend is striking, particularly as it was also associated with a group (albeit nonsignificant) *increase* in anxiety, suggesting that this increase in bend was not secondary to a reduction in anxiety

but occurred in spite of it. This notion is somewhat supported by the qualitative data, given that two participants (P1, P4) who reflected on GWtF intervention *increasing* their anxiety about movement, both displayed an (albeit nonsignificant) increase in bend associated with it.

It also feels consistent with the qualitative data more broadly, given that the benefit associated with GWtF was largely experienced by participants to be quite specific to movement, while CBT was perhaps less targeted but more broadly applicable and generalisable beyond this.

While promising, it is important to balance the findings regarding increased bend in the context of GWtF intervention with the feedback relating to its perceived helpfulness. The majority of participants indicated that GWtF would not be something they would use in its current format. Any benefits associated with GWtF are therefore irrelevant if people would not use it.

It feels important to improve the accessibility and design of GWtF, and the qualitative feedback will be invaluable in supporting this process. It would also be interesting to trial the GWtF at home with participants over a longer period to see if the sound is something that people adjust to in time, and whether the perceived benefit attributed to the device improves if/as people become aware of an increase in their movement.

Inconsistency of quantitative and qualitative findings regarding CBT intervention

Based on the qualitative data, the researcher was left with the impression that CBT was the preferred intervention for the majority of participants, yet there was a lack of statistically significant findings to support this. Given that CBT intervention is less specific to movement than GWtF, it may be the case that the measures used (which largely centred on the once-daily bend) were not effectively capturing the benefits experienced by participants in relation to it. As such, it would be interesting to incorporate a wider range of more generic measures to try and monitor psychological change more broadly.

As with the GWtF, it would also be interesting to track the brief CBT intervention over a longer period, particularly as CBT treatment is associated with so-called 'delayed effects' in other contexts (Hollon, Stewart & Strunk, 2006). However, it is likely that the brief CBT was just too brief to significantly affect pain anxiety in this instance. Given the biopsychosocial complexity of chronic pain as a condition, further research is required to explore the length of brief CBT intervention and amount of therapist input etc. that's associated with meaningful change, but that also retains benefits associated with accessibility, efficiency and suitability for home-use.

However, it may also be the case that the researcher's impression of a preference towards CBT intervention was shaped by bias associated with researcher allegiance. The same researcher who delivered the brief CBT intervention also conducted the semi-structured interview exploring participants' experiences of it. It is therefore possible that the feedback about brief CBT may have been more positive than if it had been collected by an independent researcher.

Measurement Considerations

The quantitative measures were selected based on evidence regarding their relationship with pain anxiety, and it was anticipated that an increase in anxiety ratings would be associated with increases in pain intensity, HR, catastrophising and guarding, and a decrease in degrees of bend achieved and self-efficacy. However, the measures did not change in this way. While change in anxiety and pain was largely consistent, that was less true for all other outcomes, particularly self-efficacy and heart rate.

Heart rate data

In the case of HR, this finding is not too surprising given the indication in the literature that HR can be an inconsistent measure of anxiety due to the "non-linear dynamics of cardiac responses to stressors or emotional stimuli" (p. 5, Azevedo, Bennett, Bilicki, Hooper,

Markopoulou & Tsakiris, 2017). As heart rate continually fluctuates due to excitatory and inhibitory regulatory processes, and in association with physical demands, average HR is an insensitive marker of stress (Azevedo et al., 2017). The choice to monitor HR over other psychophysiological markers (e.g. galvanic skin response, respiratory rate) was determined by budget constraints and practical limitations.

Self-efficacy scores

There are two interesting findings that may help to make sense of why self-efficacy scores changed less consistently with anxiety ratings than other measures. Four out of six participants either sustained or improved their self-efficacy scores following CBT intervention, compared with just two participants following GWtF. Indeed, four participants' self-efficacy scores decreased after GWtF intervention. Obviously, in a sample of this size, and given that the changes were largely non-reliable, such a finding has limited weight, but it does enable hypothesising about why GWtF might have less of a positive impact on self-efficacy than CBT.

In the qualitative feedback, participants reflected on the CBT strategies being internalised and recognised their own role in consciously using them. This appears to reflect a key aspect of CBT intervention; empowering patients to *self*-regulate their emotions, which can play an important role in enhancing self-efficacy (Roditi. & Robinson, 2011). Perhaps then if an intervention is perceived to be external and separate to the individual, as with GWtF intervention, improvement may be attributed to the device rather than internalised. So, GWtF may detract from a personal sense of agency and self-efficacy.

It would be interesting to explore this hypothesis further, and to track the effects of GWtF intervention over a longer period to see if improvements in self-efficacy occur later in the process. Perhaps if, over time, people became aware of an increase in their movement in spite of anxiety, this might generalise to other contexts where pain may limit them, and self-efficacy may be enhanced through this process.

However, the order of interventions may also have affected self-efficacy, given the finding that five participants showed a decrease in self-efficacy scores following their second intervention compared with only one participant following the first. This could reflect an interference or combination effect, particularly if the two interventions are experienced to be quite different and the requirements of each feel at odds with one another. For example, if someone is developing a sense of self-agency through the use of CBT strategies during their bend, this may then conflict with the need to externalise their focus to the sound feedback (or vice versa). Perhaps the introduction of a second intervention so soon undermines the therapeutic progress associated with the first, which could then affect engagement with the second. The same may also be true for guarding, given that this measure was similarly associated with less improvement following the second intervention. It would be interesting to see if a potential order effect is replicated to a significant extent in a future study, and to further explore the hypotheses outlined in relation to this above.

Catastrophising scores

It was also interesting to note that both interventions were associated with a (largely nonsignificant) reduction in catastrophising scores for four out of six participants. As CBT specifically targets cognitions and there is good evidence that it reduces pain catastrophising (Schütze, Rees, Smith, Slater, Campbell & O'Sullivan, 2018), it would perhaps not have been surprising if brief CBT had been more effective than GWtF in this regard.

Perhaps the two interventions target catastrophising through different means. In the case of CBT intervention, the talking through of anxieties and the development of cognitive strategies may support the management of catastrophising thoughts, while with GWtF, sound feedback may serve as a distraction from them. Alternatively, perhaps awareness of increased movement associated with GWtF serves to challenge catastrophising ideas for the individual, or perhaps cognitions are challenged through a process of exposure if feared movements are less painful than predicted. Again, it would be interesting to explore

the effects of GWtF intervention on catastrophising over a longer period to try to better understand the processes through which an effect, if there is one, is achieved.

Collectively, the inconsistency with which the different measures change in the expected direction in accordance with anxiety ratings highlights how complex a construct pain anxiety is, and how variable an experience it appears to be across individuals. It raises the question about the extent to which the measures used in the current study are actually measuring what we intended them to. However, given that the anxiety data is based on self-report ratings, inconsistency between measures could also reflect a fundamental lack of insight about anxiety associated with movement in the context of chronic pain. It could be the case that pain anxiety is operating at a different level of awareness to other forms of acute anxiety (e.g. exam stress) that people generally display quite good insight about. Given the attention-grabbing nature of pain, a lack of insight into underlying anxiety when pain is present may be unsurprising. Again, it would be interesting to explore these ideas further in future research.

Strengths and Limitations:

The use of a both a multiple single-case and mixed methodology approach yielded a rich dataset with a focus on individual details and effects that would have been lost in a group comparison study. The range of quantitative measures supported a thorough exploration of the impact of the two interventions, while the qualitative feedback helped to contextualise quantitative findings. The use of multiple modes of analysis is also a strength, and is well suited to exploratory investigations. Design strengths include the randomising of baseline lengths, counterbalancing of intervention order and blinding of guarding raters. The replication of the study across six participants, and the use of both specific and generic measures also reflect strengths of the design according to RoBiNT criteria.

However, there are also several limitations. Phase lengths were too brief, with some baselines only two days. Given the variance inherent in measures used, data should ideally

be collected over a longer baseline to ensure a more reliable estimate of change with intervention.

The brevity of intervention also felt problematic at times, particularly when the phase coincided with important events in participants' personal lives. For example, P6 described a busy time at his (manual) work during the CBT phase, which may have impacted his scores. The brevity of phases was to prevent the overall study length deterring participation, but longer phases might have reduced such effects.

Also, while cited above as a strength, the range of outcome measures used and statistical comparisons conducted (in combination with a small sample size) means there was an increased risk of type I and type II error (the risk of falsely rejecting the null hypothesis (a 'false positive' finding), and falsely failing to reject the null hypothesis (a 'false negative' finding), respectively; Cohen, 1992). The majority of significant effects that were reported only narrowly met the significance threshold of .05, so if a correction for multiple comparisons had been conducted it is likely that many of these effects would have been eliminated. However, the research is exploratory in nature, so while issues of power have prevented the drawing of firm conclusions, the findings have supported the development of hypotheses which can be taken forward in future research.

Another limitation of the study is that statistical analysis of the data relied heavily on Tau-U methods, which produced problematic Tau-U values (the GWtF anxiety and CBT HR Tau-U scores for P3). The possibility of out-of-bounds scores is recognised as a problem with Tau-U calculation, making interpretation of correlation coefficients (when they are not bounded between -1 and +1) difficult (Brossart, Laird & Armstrong, 2018).

Also, while Tau-U has been recommended for the analysis of small datasets, there is a lack of information detailing minimum sample requirements (Brossart, Laird & Armstrong, 2018). Given that Tau-U compares the trend of two phases, this raises questions about the suitability of this analysis in this context given that some phases contain only two datapoints,

which should not be considered a trend (Graban, 2019). However, single case methodology is an active area of development, so issues with design and analysis are to be anticipated.

Clinical and Research Implications

The variability of participants' experiences with chronic pain and the interventions used makes broad conclusions unsafe. At present there are a range of nonpharmacological treatment options, with information on likely benefit and harm, but no effective matching of intervention to person. This highlights the importance of methods such as single case designs in supporting the development of hypotheses about which interventions are better suited to specific presentations, e.g. substantial catastrophising or guarding, so that support can be tailored.

The current research indicates that neither intervention was associated with significant harm. As the two interventions were successfully used at home without great difficulty, both could, with further development, increase accessibility to psychologically-informed intervention for problems associated with chronic pain.

These findings justify further research on the effects of each intervention over a longer period, and a wider range of measurement, to try and identify the benefits of each and their match with patient needs and strengths.   Research on the effects of different 'doses' of brief CBT for this population seems worthwhile, as does exploration of combined CBT and movement sonification.

Finally, given the central role that pain anxiety plays in chronic pain and its complexity as a construct, it is crucial that future research seeks to better understand the construct, and ways to assess it, to enable more accurate monitoring of fear and avoidance in real time, and the development of methods to reduce pain anxiety as it occurs.

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Assessing the Impact of a Brief CBT Intervention and a Sonification-of-Movement Device on Pain Anxiety in Chronic Pain: A Mixed Methods, Multiple Single-Case Design

PART 3: Critical Appraisal

<u>Reflections on my Motivations for Conducting the Research</u>

My interest in conducting research in the field of physical health, and chronic pain more specifically, has been informed by personal experience in two key ways; firstly through my experience of working clinically in the field of chronic pain, and secondly, my experience of living with a chronic physical health condition.

Clinical Experience in Chronic Pain

Before training, I worked as an Assistant Psychologist in a chronic pain service where my role primarily involved supporting the delivery of CBT-based Pain Management Programmes. The experience was incredibly rewarding, and one that appealed to me for many reasons. Stigma was such a strong theme within the work and I heard the same story from many different patients: a story of significant suffering, of struggling for months or years to feel heard and responded to by medical professionals. Of being bounced between different NHS services/departments, having numerous examinations and tests and when no conclusive answer could be found, being given a diagnosis of chronic pain.

This is a well-recognised experience in the literature that is associated with a group of conditions (including chronic pain, chronic fatigue, fibromyalgia, etc.) that are not associated with a clear etiology or underlying pathology, are determined by an inexact process of elimination, and thus do not have a clear 'solution' (Barker, 2011). Such conditions are at odds with the biomedical model of illness which underpins the healthcare system and informs societal attitudes about health and wellbeing more broadly (Wade & Halligan, 2004). The model is based on key assumptions that 1) all illness has an underlying cause, 2) disease is always that cause, and 3) removal of the disease will restore health (Wade & Halligan, 2004).

The unfortunate effect of this approach is that when a person's experience is incongruent with this model and cannot easily be explained by an organic abnormality, it can be met with scepticism (Barker, 2011). Indeed, patient accounts of feeling misunderstood,

ignored, rejected, blamed for their condition, and being given a solely psychological conceptualisation of their pain, are common (Werner & Malterud, 2003).   The latter point was one that many patients I met as an Assistant Psychologist reflected on.   Repeatedly hearing the message, subtly or explicitly, that their pain was 'all in the mind' appeared to, understandably, affect patients' acceptance of the diagnosis of chronic pain given the incongruence of its psychogenic associations with their own lived experience. Consequently, this impacted their engagement with healthcare professionals and services in relation to their pain.

Given that clinicians are trained and work within a primarily biomedical system, situations where diagnosis is not straightforward and there is significant medical uncertainty can be very challenging and stressful for them (Kim & Lee, 2018; Wade & Halligan, 2004, Werner & Malterud, 2003).   Alexander, Humensky, Guerrero, Park & Loewenstein, (2010) highlight that medical uncertainty may serve to threaten clinicians' professional self-esteem and sense of competence, given the reliance of the healthcare system on the identifying and labelling of problems (in order to access funding, interventions etc.).

In a qualitative research project exploring constructions of chronic pain in doctor-patient relationships, Kenny (2004) identified a key theme relating to the incongruence of the needs and motivations of doctors and patients in the context of a chronic pain consultation.   It highlighted the motivation of physicians, when all tests and interventions had been utilised to no avail, to try and disqualify patients' biomedical perspectives of their pain (given the lack of physical evidence) and instead promote a psychosocial formulation. However, patients were equally invested in having their biomedical stance validated by their doctor, given their perspective that the perceived legitimacy of their pain and credibility as patients depended on the identification of an underlying biological cause (Kenny, 2004). Kenny (2004) summarised this conflict with the reflection that "both [doctors and patients]

were strongly invested in their positions, because to be otherwise would imply a failure of their respective roles of expert physician and good patient" (p. 303).

This clash in motivations can become a vicious cycle if not skilfully managed by healthcare professionals. If patients feel unsupported and invalidated, and their symptoms persist, they are likely to present more frequently and to work hard at trying to be believed by healthcare professionals (Werner & Malterud, 2003). Unfortunately, in the context of services that are under-resourced, and clinicians that are overworked and insufficiently supported, this may lead them to be experienced by healthcare professionals as 'difficult' or 'anxious'. This may serve to exacerbate any scepticism experienced and/or reinforce a psychosocial conceptualisation of the pain (Werner & Malterud, 2003).

Indeed, Kenny (2004) highlighted another key theme of doctors feeling helpless and frustrated when patients do not change what doctors perceive to be unhelpful and inaccurate beliefs about their pain; a perspective which is presumably intensified, rather than resolved, when patients continue to present. Additionally, as society places great value on the opinions of medical professionals, when doctors cannot find a cause it can lead family members and friends of the patient also to question the validity or severity of the experience (Dumit, 2006). As such, chronic pain can be a very lonely, isolating and frustrating condition (Clarke & Iphofen, 2007).

Of course, the above summary presents one aspect of the chronic pain patient experience, and the process of reviewing literature for the conceptual introduction has helped me to appreciate how significantly the theoretical understanding of the condition, and the biological, psychological and social factors that shape the experience of it, has progressed in a relatively short time. This is clearly translating to routine practice, as many people with chronic pain that I have worked with clinically, and met through the course of this research, spoke of receiving fantastic support from services, encountering very kind and caring healthcare professionals, and feeling validated and contained as a result. But it was

also striking that many patients had, at some stage, faced a version of the experience outlined above, and consequently (and understandably) appeared frustrated and defensive at the notion of working with a psychologist in relation to their pain.

This highlights the significant challenge that a clinical psychologist faces in this setting. I recall being struck by the fact that as a profession we have an invaluable contribution to make in the treatment of chronic pain, but the very provision of clinical psychology in this context may inadvertently reinforce unhelpful messages for patients about the pain experience being 'all in the mind'.

A study exploring patient perceptions of psychological treatment in a chronic pain service in Singapore highlighted themes of initial scepticism and ambivalence. However, once patients experienced it, they were largely positive about psychological intervention and spoke of finding it helpful (Yang, Bogosian, Moss-Morris & McCracken, 2015). The research also highlighted that the advice given to patients about psychological treatment was quite variable across healthcare professionals, which was felt to reflect an inconsistent understanding of the role of clinical psychology in chronic pain more broadly, across both patients and clinicians.

Yang et al. (2015) also highlighted that professionals who listen, are empathetic and are knowledgeable about chronic pain are more likely to engage patients in psychological intervention. This serves as a helpful reminder about the importance of core person-centred principles (striving to be genuine, caring, respectful, accepting, understanding) and their invaluable role in supporting the development of a positive therapeutic relationship, which may be especially important in situations where people have had negative patient-clinician relationships previously. Indeed, Becker, Dorflinger, Edmond, Islam, Heapy & Fraenkel (2017) highlighted that improving patient-clinician interactions is central to addressing unhelpful or inaccurate treatment beliefs and improving knowledge and awareness of non-pharmacological chronic pain treatments.

The study emphasised the need for more training about the role of psychology in chronic pain (e.g. through public talks, lectures, community outreach programmes, published literature, advertising campaigns, the use of social media and technological platforms etc.), and more training in effective communication for healthcare professionals working with chronic pain patients. I have therefore come to appreciate the importance of clinical psychology input in chronic pain as extending beyond just intervening at the patient level, to try and instead change attitudes about chronic pain more broadly, through the types of projects suggested above, but also through the continued contribution of clinical psychology to the chronic pain evidence-base.

Finally, a key contribution that I feel clinical psychology can make in this field is to try and increase access to intervention. As highlighted in the conceptual introduction, access to intervention (particularly non-pharmacological intervention) is poor. Increased education about the role of psychology in chronic pain could reduce some of the stigma about psychological intervention, but there are nonetheless many practical barriers (e.g. waiting lists, availability etc.) that hinder access. I was taken aback by the initial number of respondents when I posted about my research on social media; it seemed that people were crying out for support. Indeed, many patients I worked with as an Assistant Psychologist had struggled with pain for years, or even decades, before being offered psychologically-informed pain management. The experience made me interested in how we can improve access to psychologically-informed intervention for those in chronic pain, and was a strong motivator for the current research.

Personal Experience of a Chronic Health Condition

Upon reflection, I can see that my experience of living with a chronic health condition has significantly influenced my journey into clinical psychology in many ways, and shaped my interest in physical health more specifically. My condition starkly contrasts with a condition like chronic pain; it has a very scientific-sounding name and its presence is reliably confirmed

by clear diagnostic testing. It is congruent with the medical model, and the fact that it has clear biological and genetic markers means it that it is 'validated' from a biomedical perspective.

I have never once encountered a hint of scepticism about my experience of the condition, and I have always had confidence in the fact that if I were to talk with supervisors, employers, or friends, for instance, when feeling unwell, I would find support and empathy. The process of conducting this research has made me reflect on how much harder it would be to live with a health condition if there were significant stigma associated with it, and to consider how isolating and invalidating it would feel if I ever had to question whether others would try to understand my experience.

I have also found it striking that when the narrative about a condition is more psychological, there is an implication that it is less valid or real than a condition with a more biological and medical explanation. This feels like a powerful reflection of the lack of equality of physical and mental health, and highlights just how far we have yet to go with regards to parity of esteem. It also reflects the prevalence of mind-body dualism within healthcare. The focus on making sense of a set of symptoms by categorising them as reflecting *either* a biological *or* a psychological etiology is incredibly problematic.

Living with a condition that is understood in a very biological way has meant that the consideration of 1) the psychological factors that shape my experience of the condition 2) the psychological effects of living with a long-term condition and 3) the resultant value of psychological intervention in this context, has been largely neglected. Conversely, as established, the emphasis on a psychological formulation can shut down thinking about the biological factors that shape the experience of a condition like chronic pain. Nimnuan, Hotopf & Wessely, (2000) highlight the need to think about the mind and body in an integrated way in relation to health and wellbeing, in their reflection that "there are psychological contributions to the experience of symptoms in even the most 'organic'

medical condition, whilst there are many physiological explanations for so called 'unexplained' symptoms" (p. 25).

The biopsychosocial model enables a more holistic and complete understanding of a patient's experience. The model considers the interplay between biological, psychological and social factors, and how these aspects affect the experience of health and disease. The model is a powerful and important framework that can help to bridge the gap between different physical health conditions, as well as physical and mental health more broadly, in terms of how we conceptualise and work with illness within the healthcare system, and wider society.

Epstein, Quill & McWhinney (1999) also proposed that the biopsychosocial model, used alongside a person-centred approach, can help to address some of the difficulties that can arise (e.g. contrasting motivations) in the doctor-patient relationship, when conditions do not have a clear organic cause. The model can support a shared understanding of the symptoms between patient and clinician, allow both perspectives to be represented and reconciled, and hopefully support the patient to feel validated and understood in their experience of the condition.

Reflections on the Experience of Conducting the Research

When the opportunity arose to focus my thesis research on chronic pain and to work with Dr Amanda Williams, such a prominent figure in the field, in the process, I did not hesitate. I think that the personal motivations for conducting this research that I have outlined above have made the process much more meaningful and rewarding for me.

Prior to training I lacked confidence in my research abilities, and after completing my undergraduate degree I focused my efforts on gaining clinical experience (and avoiding research at all costs!) I felt that my strengths centred more on being able to engage and establish a therapeutic relationship with someone, and, given my lifelong fear of anything maths-related, research (which I associated with 'statistics') was considered a definite

weakness. The two aspects, clinical and research, felt very distinct to me, and I didn't really understand the relevance of research skills in my day-to-day practice; a 'justification' which served to reinforce my avoidance. As such, the prospect of the thesis loomed large when starting the course.

However, my relationship with research has completely changed throughout the course of training and, more specifically, conducting this study. Our statistics teaching helped to break down my fear of stats and developed my confidence, knowledge and skills in quantitative analysis. Learning more about qualitative analysis during the research methods teaching also helped me to realise the innate bias that I held towards quantitative methodology; a sense that quantitative research was superior in some way. This was inevitably shaped by the narrative that RCTs are the 'gold standard' in research, with the National Institute for Clinical Excellence (NICE) stating that RCTs are typically the "most appropriate source of evidence" when considering the efficacy of treatments (p. 17, NICE, 2012).

Indeed, quantitative and qualitative methods are often considered to be at odds with one another, with the perception in quantitative circles that qualitative research is less objective, vulnerable to bias as it is interpreted through the lens of the researcher, and less generalisable due to small sample sizes (Hammarberg, Kirkman & de Lacey, 2016). On the other hand, qualitative researchers have criticised quantitative methodology for oversimplifying the complex human experience and using 'guesswork' when applying meaning to aggregate data (Hammarberg, Kirkman & de Lacey, 2016). Upon reflection, I can see that I too considered the methodologies to be juxtaposed.

However, the experience of using mixed methods in this project has completely transformed my view. It has been very interesting to be able to focus on and track the quantitative measures for each participant, but so much meaning would have been lost without the qualitative data to help contextualise the findings. For example, one

participant's pain and anxiety decreased and her degrees of bend achieved increased during the Go-With-the-Flow (GWtF) phase, but she spoke very openly during the closing interview about not experiencing GWtF to be helpful and finding the sound irritating. Indeed, she did not feel that GWtF would be something she would use. Conversely, another participant showed an increase in pain and anxiety as well as a decrease in bend across the CBT phase, despite her description of finding the CBT intervention very beneficial. This really highlights that without both parts of the dataset, it would have been easy to draw conclusions about the two interventions that would have been far too simplistic.

I have also found the multiple single case methodology to be hugely beneficial. It has been a real privilege to be able to look in such fine detail at the experiences of the six participants, and the dataset has been so rich as a result. While we have been unable to come to any kind of definitive conclusion about either intervention and the impact of each on pain anxiety, what the data has hopefully highlighted is the complexity of the chronic pain experience. This emphasises the challenges associated with trying to apply broad conclusions (e.g. those drawn from RCT data) to individual patients.

Upon reflection, I can see that this project has been ambitious and challenging alongside the other demands of training. There was not an established participant pool to draw from and recruitment through social media was more challenging and time-consuming than I anticipated. The sample size was also a significant concern, as (predictably) initial interest did not usually translate into participation. When two participants dropped out, I was very concerned that I might end up with only three or four people in the sample, so the decision was made to do another recruitment phase on social media at quite a late stage, which required an ethics extension. Also, because I only had one GWtF device and one heart rate monitor, I could not run more than one participant at a time which meant that data collection spanned many months.

Data collection itself was also logistically very tricky. The randomised baseline lengths meant that I had to see participants at set points throughout their involvement, which needed to fit around placement days, lectures and participants' own schedules. Despite not being there with participants to collect measures each day, my role in reminding participants of the daily tasks (and the fact that I could track whether pain/anxiety ratings had been completed on the online system), meant that participants were never far from my mind throughout their involvement.

With regards to intervention, I developed the brief CBT materials and delivered the intervention in all cases. On the other hand, the GWtF was already established, and it was really interesting and helpful to work closely with Dr Aneesha Singh (from the UCL Interaction Centre; UCLIC) to learn how to set up, use and meaningfully explain the device to participants. However, working with an intervention that felt quite outside of my comfort zone presented challenges. There were technological issues along the way that were always resolvable but nonetheless anxiety-provoking. Similarly, interpreting the GWtF outputs felt very challenging and unfamiliar, but again, having the support of UCLIC (in this case Joe Newbold) made the challenge so much more manageable.

Being involved in every step of the research process, from design through to analysis and interpretation, has given me an in-depth and complete research experience. As such, my confidence in my capacity to conduct meaningful research has developed significantly, along with my appreciation of the invaluable contribution of clinical psychology to the evidence-base. Given that involvement with research improves visibility and influence within the profession and is associated with better clinical performance and health outcomes (Smith & Thew, 2017), I feel motivated to make research an important focus in my career moving forwards.

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APPENDICES

Appendix 1

Details of the systematic literature search.

The included literature was gathered in a number of ways. Firstly, a search was conducted (on the 14th September 2018) using the PsycINFO database on the Ovid platform, using the following search terms: (chronic pain OR back pain OR chronic back pain OR long term pain OR long-term pain OR persistent pain OR pain) AND (cbt OR cognitive behavioural therapy OR cognitive therapy OR behaviour therapy OR behaviour modification) AND (anxiety OR fear OR avoidance), as well as (chronic pain OR back pain OR chronic back pain OR long term pain OR long-term pain OR persistent pain OR pain) AND (physical therapy) OR (technology OR assistive technology) OR (sonification). The search also ensured that variants of these terms would be included, e.g. 'behaviour therapy' was entered as 'behavio?r* therap*', to account for different potential spellings and endings of the words (e.g. behaviour/behavior, behaviour/behavioural, therapy/therapies). Key terms (e.g. anxiety, physical therapy, technology, assistive technology) were also 'exploded' meaning that any narrower, more-specific variants of the term would be included. This returned 1635 results which were processed to assess relevance, leaving 22 studies. Relevant literature cited in these studies, as well as other studies that the author found using conventional (less systematic) search methods, were also included.

Appendix 2

UCL Research Ethics Committee approval letter.

UCL RESEARCH ETHICS COMMITTEE
OFFICE FOR THE VICE PROVOST RESEARCH

3rd August 2018

Dr Amanda Williams
Research Department of Clinical, Educational and Health Psychology
UCL

Dear Dr Williams,

Notification of Ethics Approval with Provisos
Project ID/Title: 12997/001: Assessing the Impact of a Brief CBT Intervention and the 'Go-With-the-Flow' Sonification Technology on Pain Anxiety

Further to your satisfactory responses to the Committee's comments, I am pleased to confirm in my capacity as Joint Chair of the UCL Research Ethics Committee (REC) that the UCL REC has ethically approved the study until **1st March 2019.**

Ethical approval is also subject to the following conditions:

1. The consent form must make it clear that the participants may withdraw from the study at any time.

Notification of Amendments to the Research
You must seek Chair's approval for proposed amendments (to include extensions to the duration of the project) to the research for which this approval has been given. Each research project is reviewed separately and if there are significant changes to the research protocol you should seek confirmation of continued ethical approval by completing an 'Amendment Approval Request Form'
http://ethics.grad.ucl.ac.uk/responsibilities.php

Adverse Event Reporting – Serious and Non-Serious
It is your responsibility to report to the Committee any unanticipated problems or adverse events involving risks to participants or others. The Ethics Committee should be notified of all serious adverse events via the Ethics Committee Administrator (ethics@ucl.ac.uk) immediately the incident occurs. Where the adverse incident is unexpected and serious, the Joint Chairs will decide whether the study should be terminated pending the opinion of an independent expert. For non-serious adverse events the Joint Chairs of the Ethics Committee should again be notified via the Ethics Committee Administrator within ten days of the incident occurring and provide a full written report that should include any amendments to the participant information sheet and study protocol. The Joint Chairs will confirm that the incident is non-serious and report to the Committee at the next meeting. The final view of the Committee will be communicated to you.

Final Report
At the end of the data collection element of your research we ask that you submit a very brief report (1-2 paragraphs will suffice) which includes in particular issues relating to the ethical implications of the research

i.e. issues obtaining consent, participants withdrawing from the research, confidentiality, protection of participants from physical and mental harm etc.

In addition, please:

- ensure that you follow all relevant guidance as laid out in UCL's Code of Conduct for Research: http://www.ucl.ac.uk/srs/governance-and-committees/resgov/code-of-conduct-research
- note that you are required to adhere to all research data/records management and storage procedures agreed as part of your application. This will be expected even after completion of the study.

With best wishes for the research.

Yours sincerely
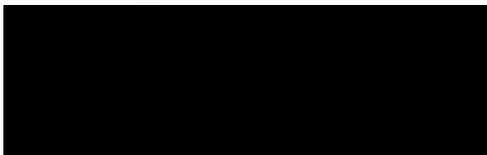
Professor Michael Heinrich
Joint Chair, UCL Research Ethics Committee

Appendix 3

Table describing the Risk of Bias in N-of-1 Trials (RoBiNT; Tate et al., 2013) criterion and the

present study's adherence with the instrument.

REDACTED

Appendix 4

Table describing the Single-Case Reporting Guideline In BEhavioural Interventions (SCRIBE;

Tate et al., 2016) criterion and the present study's adherence with the guideline.

Item Number	Topic	Item Description	Notes
TITLE and ABSTRACT			
1	Title	Identify the research as a single-case experimental design in the title	The nature of the research design is identified in the title.
2	Abstract	Summarise the research question, population, design, methods including intervention/s (independent variable/s) and target behaviour/s and any other outcome/s (dependent variable/s), results, and conclusions	Each of these points are summarised in the abstract.
INTRODUCTION			
3	Scientific Background	Describe the scientific background to identify issue/s under analysis, current scientific knowledge, and gaps in that knowledge base	The scientific background is described in both the conceptual introduction and empirical paper introduction.
4	Aims	State the purpose/aims of the study, research question/s, and, if applicable, hypotheses	Clear aims and research questions are specified in the introduction of the empirical paper.
METHODS			
	DESIGN		
5	Design	Identify the design (e.g., withdrawal/reversal, multiple-baseline, alternating-treatments, changing-criterion, some combination thereof, or adaptive design) and describe the phases and phase sequence (whether determined a priori or data-driven) and, if applicable, criteria for phase change	The design, phases and phase sequences are outlined in the methodology section.

6	Procedural Changes	Describe any procedural changes that occurred during the course of the investigation after the start of the study	No procedural changes occurred.
7	Replication	Describe any planned replication	The replication across six participants is described in the methodology section.
8	Randomisation	State whether randomisation was used, and if so, describe the randomisation method and the elements of the study that were randomized	The randomisation method (alternating intervention-order across participants, and randomising intervention-onset by differing baseline lengths) is described in the methodology section.
9	Blinding	State whether blinding/masking was used, and if so, describe who was blinded/masked	The use of blinding is described in the methodology section.
	PARTICIPANT/S or UNIT/S		
10	Selection Criteria	State the inclusion and exclusion criteria, if applicable, and the method of recruitment	Inclusion/exclusion criteria and recruitment methods are described in the methodology section of the empirical paper.
11	Participant Characteristics	For each participant, describe the demographic characteristics and clinical (or other) features relevant to the research question, such that anonymity is ensured	Participant characteristics are outlined in Table 1, which is found in the results section.
	CONTEXT		
12	Setting	Describe characteristics of the setting and location where the study was conducted	The setting of the study was participants' homes, which is indicated in the empirical paper.
	APPROVALS		

13	Ethics	State whether ethics approval was obtained and indicate if and how informed consent and/or assent were obtained	Details of ethical approval is outlined in the methodology section, and the associated documentation is presented as Appendix 2. Similarly, detail about how informed consent was obtained is presented under 'methodology', and the consent form is attached as Appendix 8.
MEASURES and MATERIALS			
14	Measures	Operationally define all target behaviours and outcome measures, describe reliability and validity, state how they were selected, and how and when they were measured	Details about outcomes, their reliability and validity, the rationale for their selection, and how/when they were measured, are outlined in the methodology section.
15	Equipment	Clearly describe any equipment and/or materials (e.g., technological aids, biofeedback, computer programs, intervention manuals or other material resources) used to measure target behaviour/s and other outcome/s or deliver the interventions	The equipment used is detailed in the methodology section.
INTERVENTIONS			
16	Intervention	Describe intervention and control condition in each phase, including how and when they were actually administered, with as much detail as possible to facilitate attempts at replication	Clear details about the interventions and the administration of both baseline and intervention phases are outlined in the methodology section.
17	Procedural Fidelity	Describe how procedural fidelity was evaluated in each phase	Adherence to procedures was supported by use of a clear timetable and reminders that prompted participants about the daily tasks (which is outlined in the methodology section). Treatment fidelity was also

				assessed by an independent Trainee Clinical Psychologist, who rated one of the six sessions against the "gold standard" Cognitive Therapy Rating Scale (CTRS); her rating sheet is attached as Appendix 10.
ANALYSIS				
	18	Analyses	Describe and justify all methods used to analyse data	A description and justification of analysis methods is outlined in the methodology section.
RESULTS				
	19	Sequence Completed	For each participant, report the sequence actually completed, including the number of trials for each session for each case. For participant/s who did not complete, state when they stopped and the reasons	The intervention sequence completed by each participant is outlined in Table 2 of the results section.
	20	Outcomes and estimation	For each participant, report results, including raw data, for each target behaviour and other outcome/s	Results are presented for both individuals and the group as a collective. Word count considerations and the significant amount of data collected (given the number of measures used (quantitative and qualitative) and the length of each participant's involvement), mean that a complete record of raw data is not provided. However, complete datasets for some measures, as well as aggregated datasets for others, are included.
	21	Adverse events	Say whether or not any adverse events occurred for any participant and the phase in which they occurred.	There were no adverse events to report.
DISCUSSION				

22	Interpretation	Summarise findings and interpret the results in the context of current evidence	The findings are summarised and the results interpreted in the context of current evidence in the discussion section.
23	Limitations	Discuss limitations, addressing sources of potential bias and imprecision	Limitations of the research are considered in the discussion section.
24	Applicability	Discuss applicability and implications of the study findings	The applicability and implications of the findings are considered in the discussion section.

DOCUMENTATION

25	Protocol	If available, state where a study protocol can be accessed	There is no study protocol available.
26	Funding	Identify source/s of funding and other support; describe the role of funders	The source of funding (UCL DClinPsy) and the support received from UCLIC is outlined in the methodology section.

Appendix 5

Semi-structured interview proforma used to guide the qualitative interviews exploring

participants' experience of the two interventions.

Semi-structured qualitative interview schedule

What drew you to taking part in this research?

What were some of the benefits/challenges of taking part?

> How did you find the experience of using the CBT strategies and sonification device over the last week or so?

Can you tell me about your experience of using the CBT strategies?

> *How acceptable did the strategies feel?*

> *What felt helpful/unhelpful about them?*

>> *How able did you feel to make use of them when doing a movement that is usually painful?*

> *How feasible would it feel to apply the strategies to day-to-day life?*

Can you tell me about your experience of using the sonification device?

> *How acceptable did the device feel?*

> *What felt helpful/unhelpful about it?*

>> *How able did you feel to make use of it when doing a movement that is usually painful?*

> *How feasible would it feel to apply the device to day-to-day life?*

What impact did the two interventions have in terms of your pain?

> *If they focus on one intervention, then prompt them about the second intervention.*

> What impact did the two interventions have in terms of your confidence in doing movements that are usually painful?

> *If they focus on one intervention, then prompt them about the second intervention.*

Would you recommend either of these interventions to a friend?

> *Why?*

> *What in particular would you tell them about it/them?*

Appendix 6

Study Advert

ᴹUCL

Are you living with chronic back pain?

- **Does your pain make it hard to do certain tasks or movements?**
- **Are you interested in trying two pain management techniques at home?**

My name is Laura Harvey; I am a Trainee Clinical Psychologist studying at UCL. I am carrying out research on the impact of two methods of addressing the worry that people with chronic pain often experience before doing movements that they expect to be painful. The interventions are quite different:

- **One is a psychological technique that targets thoughts and feelings**

- **The other is a wearable device which provides a sound (that changes in pitch) as you move.**

Participation will involve using each of these techniques in turn at home as you go about your daily activities, over a two-week period. You will also be required to complete some brief tasks that should take no longer than 5-10 minutes per day.

All participants will receive a £30 gift voucher to thank them for their participation!

If you think you might be interested in taking part, or would like more information, please contact me to find out more:

laura.harvey.16@ucl.ac.uk

177

Appendix 7

Participation Information Sheet

UCL Research Ethics Committee Approval ID Number: 12997/001

YOU WILL BE GIVEN A COPY OF THIS INFORMATION SHEET

Title of Study:
Assessing the Impact of a Brief CBT Intervention and the 'Go-With-the-Flow' Sonification Technology on Pain Anxiety
Department:
Department of Clinical, Educational and Health Psychology
Name and Contact Details of the Researcher(s):
Laura Harvey, laura.harvey.16@ucl.ac.uk
Name and Contact Details of the Principal Researcher:
Dr Amanda Williams, amanda.williams@ucl.ac.uk

1. **Invitation Paragraph**

You are being invited to take part in a research project. Before you decide, it is important for you to understand why the research is being done and what participation will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this.

2. **What is the project's purpose?**

The purpose of this research is to consider the impact of two chronic pain treatments on 'pain anxiety'- the worry that people often experience before doing movements that they believe will be painful. The two interventions are quite different:

One is based on a psychological treatment for pain that targets the impact that our thoughts and feelings about pain, and our responses to it, have on the anxiety we experience about pain.

The second is a wearable device called 'Go-With-the-Flow', which is set up for you based on your current range of comfortable movement. It then provides a sound (which changes in pitch) as you move, which provides feedback about the movement as you are doing it. Users have found this to help by informing them about their movement without attending to pain.

3. **What will I have to do?**

If you choose to take part, it will involve you using both treatments at home across a two-week period. We will require you to do a series of movements and complete some measures every day. However, this will be brief (it should take less than 10 minutes per day). You will only be using one treatment at a time, and we will give you clear instructions about when you should start/stop using each treatment, and when you should be completing measures.

Other than the daily exercises, you will be invited to make use of each intervention whenever feels appropriate/helpful as you go about your daily activities. The daily measures will centre around you completing one particular movement (which will be agreed with you before you start)- you will be asked to wear a special wristband (which monitors heart rate) as you do it, and to a) rate how anxious you feel about it just beforehand and b) how bad the pain was. The two devices (Go-With-the-Flow and the wristband) will give us information about your body's response to the movement, and the anxiety rating will give us an insight in to how you feel about it emotionally.

4. Why have I been chosen?

If you are reading this, it is because you have responded to information about this research that was either presented online in social media pages, or accessed through your involvement with a chronic pain group. As this research is focusing on chronic pain, it is a requirement that all participants have been living with their pain for a minimum of 12 weeks. Taking part in this research will mean that you need to complete daily online surveys, so it does require that you have computer skills and internet access. We also need you to record yourself doing an agreed movement on some of the days, so it is necessary to have a means of recording yourself (e.g. a camera phone). It is important that you can speak and read English, as the written materials and discussions with researchers will require this.

Unfortunately, we must ask you not to participate if you feel it would not be possible for you to complete the research tasks for any reason, if you have had spinal surgery in the last six months, have had Cognitive Behavioural Therapy for pain at any point, or for anxiety in the last 5 years, or if you have any other medical condition that affects your movement.

5. Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep, and will be asked to sign a consent form. You can stop taking part and withdraw your consent at any time without giving a reason. If you do decide to withdraw, you will be asked about what you would like to happen to the data you have provided up to that point.

6. What will happen to me if I take part?

Once you have read this information sheet you will be asked to sign a consent form. The 'Go-With-the-Flow' device will then be set up to your individual specifications, which will involve you doing a variety of different movements while wearing it. You will also be given information about the daily measurement tasks that you will be required to complete, irrespective of which treatment you are using. It is during this daily movement that you will be required to wear the wristband (as well as the Go-With-the-Flow device). For the first few days of the study you will not be required to use either of the treatments, although you will still be required to complete the daily measurement tasks.

You will be told what the next step will be at this initial meeting too- you will either a) be visited at home again by the researcher in a few days and she will talk through the psychological treatment with you then, or b) be contacted by phone and asked to switch on the sound aspect of the 'Go-With-the-Flow' device. You will then be asked to use the intervention for a few days while continuing to complete the daily measurement tasks. While using an intervention, you will be required to do a few extra movement exercises per day- this is just to ensure that all participants have the same minimum amount of experience in applying the treatment to movement.

You will be advised ahead of time when the first treatment stage will finish, and you will be contacted by the researcher on the day to advise you to stop. This will then be followed by a few more days where you don't use either of the treatments (but you still do the daily measurement tasks). You will be told when to start using the second treatment (which, as before, will involve the researcher either visiting you at home, or contacting you by phone).

You will receive daily reminders to complete the measurement tasks either by text/email (whichever you'd prefer). These messages will also advise you about what you should be doing on that particular day (e.g. whether you should be using one of the treatments or not). At certain points we will require you to film yourself doing the daily movement- this will only be necessary a few times throughout the two weeks, and we will let you know on the day when we require this.

At the end of the two weeks the researcher will visit you at home to retrieve the materials and to hear about how you have found the experience. The researcher will ask you some questions about the two interventions; this conversation will be recorded. This final visit will also provide an opportunity for the researcher to answer any of the questions you may have about the research. If you feel like you need any ongoing support, the researcher can also think with you about how best to access this.

7.   Will I be recorded and how will the recorded media be used?

The audio and video recordings of your activities made during this research will be used only for analysis, and they will be stored securely. The videos of your movements (that you will be recording on your camera phone) will be independently rated by specialist physiotherapists, and after they have viewed them they will be returned to us and securely destroyed. The audio recordings will be transcribed and then securely destroyed. No other use will be made of your video/audio recordings without your written permission.

8.   What are the possible disadvantages and risks of taking part?

The risks involved with your participation are minimal. The research will involve you completing different movement exercises which may lead to some discomfort. However, it is not the intention that these movements will make your pain worse or could cause you injury, and the discomfort should not exceed that which you currently experience day-to-day. You can stop doing the movement exercises at any point.

A potential outcome of participation in any type of psychological treatment is that you may speak about things that feel distressing to you. The treatment you will be receiving will be focused on your current experience of pain, and we will not be asking you about painful things from your past or other areas of your life. However, if at any point you feel distressed, you would be free to withdraw your participation. You can also talk to the researcher (Laura Harvey, Trainee Clinical Psychologist) or principal researcher (Dr Amanda Williams, Consultant Clinical Psychologist) if things feel difficult, and they will be able to advise you about how to access resources or services that may be helpful.

Another potential disadvantage is that you may find one or both of the treatments helpful, only for them to be removed upon completion of the research. While the strategies learnt and the materials used in the psychological treatment will of course remain available to you, the 'Go-With-the-Flow' device will not. It is not possible to access this device either through the NHS or privately at present; however, research into devices such as this will hopefully mean that new technological treatments for chronic pain may became more widely accessible in the future. The researcher will be able to think with you about where you might be able to access ongoing support, if this were to feel necessary.

9.   What are the possible benefits of taking part?

While there is no guarantee that you will benefit directly from your participation in the study, you will be receiving brief versions of two separate treatments that have benefitted other people who are living with chronic pain. It is certainly hoped that some of the strategies you learn may be useful to you moving forwards. Furthermore, research studies such as this can

help us to understand the types of treatment that may be helpful for people living with pain, which will hopefully lead to the development of new treatments longer-term.

10. What if something goes wrong?

If you are unhappy with any part of your participation in the study you can contact the principle investigator Dr Amanda Williams on amanda.williams@ucl.ac.uk or 02076791608. If you feel your complaint has not been handled satisfactorily please contact the Chair of the UCL Research Ethics Committee on ethics@ucl.ac.uk

11. Will my taking part in this project be kept confidential?

All the information that we collect about you during the course of the research will be strictly confidential. It will be stored confidentially, and only the researchers involved will have across to your data (except for the videos you take of yourself doing a movement, which will also be shared with specialist physiotherapists before being securely destroyed). You will not be identifiable in

any ensuing reports or publications. If you choose to withdraw your participation you can also request that any data collected up to that point be deleted.

12. Limits to confidentiality

Please note that confidentiality will be maintained as far as is possible, unless during our interactions together I hear anything which makes me worried that someone might be in danger of harm. If this were the case I would have to inform the relevant agencies of this, but I would always have a conversation with you about this first.

13. Data Protection Privacy Notice:

The data controller for this project will be University College London (UCL). The UCL Data Protection Office provides oversight of UCL activities involving the processing of personal data, and can be contacted at data-protection@ucl.ac.uk. UCL's Data Protection Officer is Lee Shailer and he can also be contacted at data-protection@ucl.ac.uk.

Your personal data will be processed for the purposes outlined in this notice. The legal basis that would be used to process your personal data will be the provision of your consent. You can provide your consent for the use of your personal data in this project by completing the consent form that has been provided to you

Your personal data will be processed for as long as it is required for the research project, and will be destroyed upon completion of the study. If we are able to anonymise or pseudonymise the personal data you provide we will undertake this, and will endeavour to minimise the processing of personal data wherever possible.

If you are concerned about how your personal data is being processed, please contact UCL in the first instance at data-protection@ucl.ac.uk. If you remain unsatisfied, you may wish to contact the Information Commissioner's Office (ICO). Contact details, and details of data subject rights, are available on the ICO website at: https://ico.org.uk/for-organisations/data-protection-reform/overview-of-the-gdpr/individuals-rights/

14. Who is funding the research?

The UCL Clinical Psychology Doctoral Training Course

15. Contact for further information

If you need any further information or have any queries, please don't hesitate to contact us. In the first instance, please contact:

- Laura Harvey, laura.harvey.16@ucl.ac.uk or:

- Dr Amanda Williams, amanda.williams@ucl.ac.uk, 02076791608

Thank you for reading this information sheet and for considering taking part in this research study.

Appendix 8

Participant Consent Form

CONSENT FORM FOR ADULTS IN RESEARCH STUDIES

Please complete this form after you have read the Information Sheet and/or listened to an explanation about the research.

Title of Study: Assessing the Impact of a Brief CBT Intervention and the 'Go-With-the-Flow' Sonification Technology on Pain Anxiety

Department: Research Department of Clinical, Educational, and Health Psychology

Name and Contact Details of the Researcher(s): Laura Harvey, laura.harvey.16@ucl.ac.uk

Name and Contact Details of the Principal Researcher: Dr Amanda Williams, amanda.williams@ucl.ac.uk

Name and Contact Details of the UCL Data Protection Officer: Lee Shailer, data-protection@ucl.ac.uk

This study has been approved by the UCL Research Ethics Committee: Project ID number: 12997/001

Thank you for considering taking part in this research. The person organising the research must explain the project to you before you agree to take part. If you have any questions arising from the Information Sheet or explanation already given to you, please ask the researcher before you decide whether to join in. You will be given a copy of this Consent Form to keep and refer to at any time.

I confirm that I understand that by ticking/initialling each box below I am consenting to this element of the study. I understand that it will be assumed that unticked/initialled boxes means that I DO NOT consent to that part of the study. I understand that by not giving consent for any one element that I may be deemed ineligible for the study.

	Tick Box
I confirm that I have read and understood the Information Sheet for the above study. I have had an opportunity to consider the information and what will be expected of me. I have also had the opportunity to ask questions which have been answered to my satisfaction and would like to take part in the all of the research tasks associated with the above study.	
I understand that the last point at which I will be able to withdraw my data from the study will be 1st March 2019.	
I consent to the processing of my personal information (your demographic data, such as age, gender, ethnicity, occupation) for the purposes explained to me. I understand that such information will be handled in accordance with all applicable data protection legislation.	
I understand that all personal information will remain confidential and that all efforts will be made to ensure I cannot be identified. I understand that my data gathered in this study will be stored anonymously and securely.	
I understand that my participation is voluntary and that I am **free to withdraw at any time without giving a reason**. I understand that if I decide to withdraw, any personal data I have provided up to that point will be deleted unless I agree otherwise.	
I understand the potential risks of participating and the support that will be available to me should I become distressed during the course of the research.	
I understand the direct/indirect benefits of participating.	
I understand that the data will not be made available to any commercial organisations but is solely the responsibility of the researcher(s) undertaking this study.	
I understand that, apart from the £30 gift voucher I will receive for my participation, I will not benefit financially from this study or from any possible outcome it may result in in the future.	
I understand that the information I have submitted will be published as a report and I wish to receive a copy of it. Yes/No	
I consent to my interview being audio/video recorded and understand that the recordings will be stored securely, using password-protected devices/software and will be destroyed as soon as it is transcribed/independently rated by specialist physiotherapists.	
I hereby confirm that I understand the inclusion criteria as detailed in the Information Sheet and explained to me by the researcher.	
I hereby confirm that: (a) I understand the exclusion criteria as detailed in the Information Sheet and explained to me by the researcher; and (b) I do not fall under the exclusion criteria.	
I have informed the researcher of any other research in which I am currently involved or have been involved in during the past 12 months.	
I am aware of whom I should contact if I wish to lodge a complaint.	
I voluntarily agree to take part in this study.	

_____   _____   _____

Name of participant   Date   Signature

_____   _____   _____

Researcher   Date   Signature

Appendix 9

Brief CBT intervention manual

Pain

For a long time, it was thought that the amount of pain experienced was directly linked to how much damage there was in the body. So, the more damage to tissues in the body, the greater the pain that will be experienced. However, this idea just isn't true in practice- there are many examples of people being critically injured but not feeling pain (e.g. people who are injured on the front line), and also of people experiencing significant pain when the amount of actual damage to the body is very small (e.g. toothache, headache).

What's more, two different people with the same injury or illness can have very different experiences in terms of the amount of pain they have and the impact it has on their life. So, clearly the injury/illness can't be the only factor that determines the pain experience they will have.

So, what *is* pain?

Pain feels like it's located in the area of the body that's hurting. However, what we know is that it's the brain that plays the biggest role in shaping our experience of pain. This doesn't mean that pain isn't real or is 'all in the mind', it just means it's a different part of the body that's responsible for our experience of it.

If we are out walking and our foot brushes past something that causes a scratch, signals would travel via the nervous system to the brain to let the brain know about this. The brain would then have to make an interpretation of the information it has received to decide how to respond. If the brain decides the information means that there is a threat and we are in danger (e.g. we've been bitten by a venomous snake!), it will respond in a big way to try and protect us (e.g. by producing a lot of pain in the foot to prompt us to move it out of harm's

way). If it decides that there is no threat and we are safe (e.g. we just brushed past a stick), it may not respond at all. So, the brain has the power to TURN UP or TURN DOWN the pain response depending on how protective and helpful pain would be to us in that moment. The same experience (a scratch on the foot) could therefore result in two very different experiences of pain.

The role of thoughts and emotions...

Based on the traditional idea of pain (that pain is just a response to injury to the tissues) we might expect that activation in the brain when we feel pain would only happen in the parts associated with sensory information.
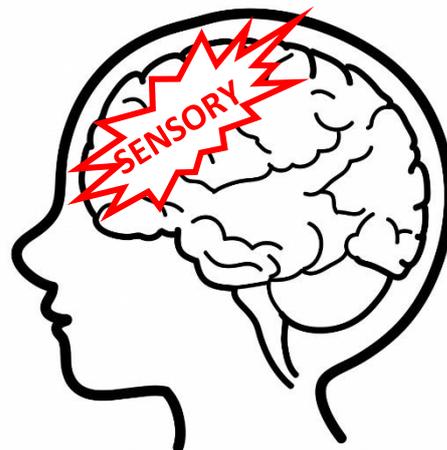
However, what brain scans have told us is that areas associated with thoughts and emotions also become activated too.
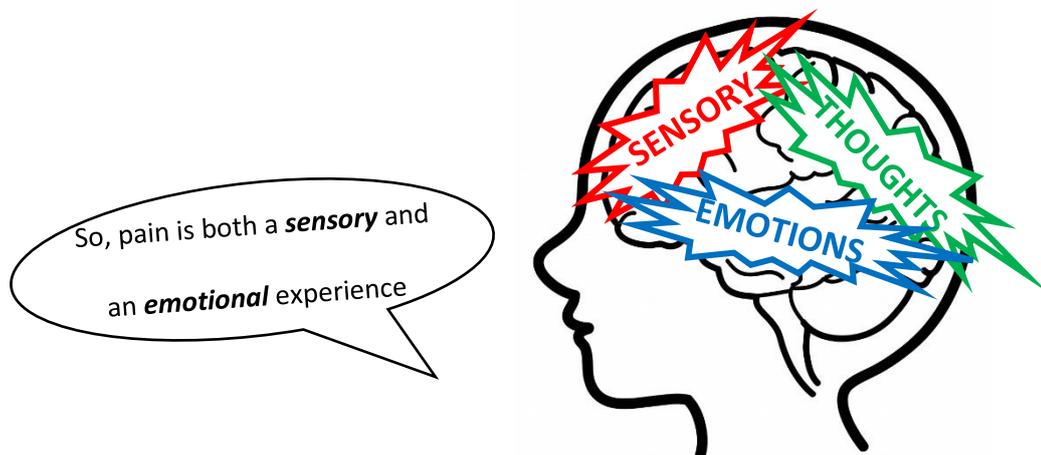
This makes sense when you think about it. The thoughts and beliefs we have about an experience will inevitably impact how we interpret it. The beliefs and thoughts we have will be influenced by all sorts of factors, including our current context, our past experiences, our mood etc. (to name a few). Let's use the example of being out walking and feeling a scratch on our foot again to help us think about this further:

SNAKE OR STICK?

Many different factors will influence how the scratch is interpreted by the brain:

- **Context, memories and experience**
  - e.g. 'what's happened previously when we've been in this situation?'
  - If we spent our childhoods playing in the woods and were constantly scratching our legs on sticks and brambles, the brain is probably not going to associate much real danger with this situation.
  - However, if we have previously been bitten by a snake/know of someone else that was bitten/have heard that there are snakes in this wood, the brain might be much more likely to think 'SNAKE!!!'

- **Beliefs and thoughts**
  - If we think 'the woods are full of horrible bugs and creepy crawlies that could harm me', we might be much more likely to think 'Arghhhhh! Something's on me- get it off!'
  - Whereas if being out and about and at one with nature is something we associate with wellbeing, calm and peace, we may think 'Aaah, it's all part of being in the great outdoors!'

- **Mood**
 - Our feelings are like a filter through which we see the world- if we are in a happy mood, everything can seem much more positive. We might be much more likely to think 'it's just a little scratch- nothing to worry about!'
  - However, if we are feeling stressed and anxious the smallest thing can feel threatening- we might be much more likely to interpret the scratch to be significant.

This process is circular- our experience, thoughts and feelings don't just shape the pain experience we have; the pain then impacts our thoughts and feelings! Understandably, pain often brings about negative, unhelpful thoughts e.g. 'I can't cope', 'this will never get better', 'this is ruining my life'. This inevitably make us feel even more anxious, sad, angry etc., and all of this will impact how respond/what we do in that moment (e.g. avoid going out). This experience then becomes a memory that feeds into our interpretation of the pain the next time- It's a vicious cycle!

Now I'm going to invite you to think about a recent experience of your pain that stands out to you- perhaps your pain got in the way of doing something, or it was particularly bad on a given day? Together we can think about the memories/experiences/thoughts/feelings that may have played a role in your experience of the pain in that moment, but also the impact in terms of the thoughts, feelings and reactions you had in response to the pain.

Situation:

Important context, memories and experiences:

How I respond/what I do:

Thoughts:

Feelings (emotional, and physiological):
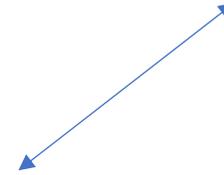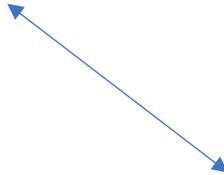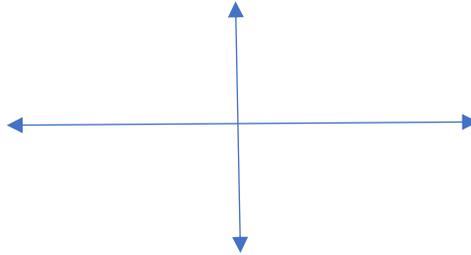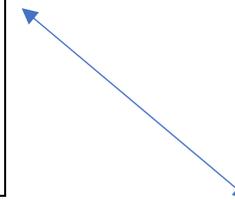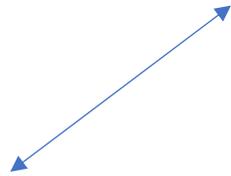
So, to recap, there are two different parts to our experience of pain:

1.   The pain itself (e.g. the scratch)
2.   Our *response* to the pain- the way that we think and feel about it, and the way we react to it (which will be shaped by context, and our memories and experiences)

Anxiety and pain...

Anxiety is a key emotion that shapes our experience of pain; often when people are talking about their pain, anxiety is a key part of the story. This is completely understandable- pain is very stressful, but in turn stress makes pain worse!

PAIN

ANXIETY

Anxiety is the body's response to potential threat. Threat can come in many different forms, e.g. walking alone late at night, being ignored by a friend, or exams, are all threats that can make us feel very anxious. Sometimes that anxiety helps by making us alert and focused; other times it can make things worse. Pain is a significant threat, so often causes anxiety, but at the same time, pain and anxiety amplify each other in the threat areas of the brain. So, anxiety can make the experience of pain worse.

People often have examples where their pain was really bad on a given day, but then they did something that was enjoyable, (e.g. they watched their favourite programme, met up with a good friend) and their pain eased. This highlights the powerful role of anxiety in the

pain experience- when anxiety is reduced because we are relaxed/distracted/having fun, pain can feel more manageable!

Our brains are programmed to detect threats as quickly as possible, to allow us to try and do something to protect ourselves from harm. This means that when pain is around, we become hyper-alert to it which only serves to amplify the pain and intensify our emotional responses to it. When there's nothing we can do to remove the threat, it can just mean we are helplessly stuck in a horrible situation where our pain is amplified for no good or protective reason.

What's more, having this unpleasant experience just means that next time the same threat will seem *even more* threatening- it confirms to the brain that there really was something wrong. And after repeated exposure to the same threat, changes will start to happen in the brain to allow it to detect the threat even faster. Over time it takes less and less sensory information to trigger the same response.

For example…

Activities that involved lots of bending (e.g. unloading the dishwasher) used to be a bit painful for Chris. However, over time they have become virtually impossible - now even the slightest bend causes a great deal of pain. This is very frustrating for Chris.

Can you think of an example of this based on your own experience?

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So, what can we do about all of this?

The brain and the body interact - the brain is constantly trying to figure out which events need our attention and which can be ignored. When it receives sensory information from

the body it has to determine whether this is worrying and unusual, or whether it's an experience we've had before that is nothing to worry about. The brain's appraisal of the situation will then affect its response, e.g. whether it turns up or turns down the pain response. Based on what we've discussed so far and your own experience of living with pain, can you think of factors that make your brain turn up or turn down your pain?

THINGS THAT TURN UP MY PAIN	THINGS THAT TURN DOWN MY PAIN

So, if we can find a way to change our emotional relationship with the pain and learn strategies to manage the stress it causes, over time the brain will change the way it responds to it.

Managing anxiety using breathing…

One way to counteract anxiety is to use breathing to try and relax the body and mind. Deep breathing helps to slow things down and restore a state of calm, and it can stop the pain-anxiety vicious cycle we discussed above.

I'm going to invite you to put one hand on your chest and one on your stomach, and just try to notice which hand moves more as you breathe.

If you watch a baby or a dog breathing you will notice that when they breathe in, their stomachs go out, and then go in again when they breathe out. Their stomachs go out because their diaphragms contract downwards as the lungs fill up with air, and that pushes the

stomach forward. This is our natural way of breathing when we are calm. However, it's easy to get into a habit of shallow breathing, with a lot of tension in the shoulder and chest area. When this happens, you're using mostly the top part of the lungs which results in your chest moving much more than the stomach.

Keeping one hand on your chest and the other on your stomach, I'm going to invite you to practice breathing in and out deeply. Try and breathe right into your stomach on the in-breath to allow the lungs to completely fill with air. Ideally the hand on your stomach should be doing the majority of the moving- your chest should only be moving a little bit. We're going to practice this for a few minutes.

How did you find that? What did you notice as you were doing it? How do you feel now?

_____

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I'm going to invite you to practice this deep breathing over the next few days, and to use it when you notice that you're experiencing stress in relation to your pain.

Working with thoughts...

Our brains produce a constant stream of thoughts about the things that we're seeing or experiencing. Most of the time these thoughts just come and go and we aren't necessarily aware of them; they happen in the background. They are 'automatic thoughts'- we don't consciously conjure them, they just happen, and generally speaking they don't have much of an impact on us. However, certain thoughts can seem more significant (particularly if they are negative), and when this is the case we tend to really notice and hone in on the thought, meaning that it doesn't just pass by like all the other thoughts do. When we become aware of a thought, it tends to affect how we feel and how we act in that moment.

For example…

James often has the thought 'my pain is never going to get better', which leaves him feeling hopeless, stressed, frustrated and low. Understandably, this makes him feel unmotivated to go out and do things, so he often cancels his plans and stays at home on his own.

Here we can see how James' thought has affected the way he feels and acts in that moment.

Can you think of an example of this from your own experience?

```
            ┌─────────────┐
            │  THOUGHTS   │
            │             │
            └─────────────┘
          ↗                 ↘
┌─────────────┐       ┌─────────────┐
│   ACTIONS   │  ←→   │  FEELINGS   │
│             │       │             │
└─────────────┘       └─────────────┘
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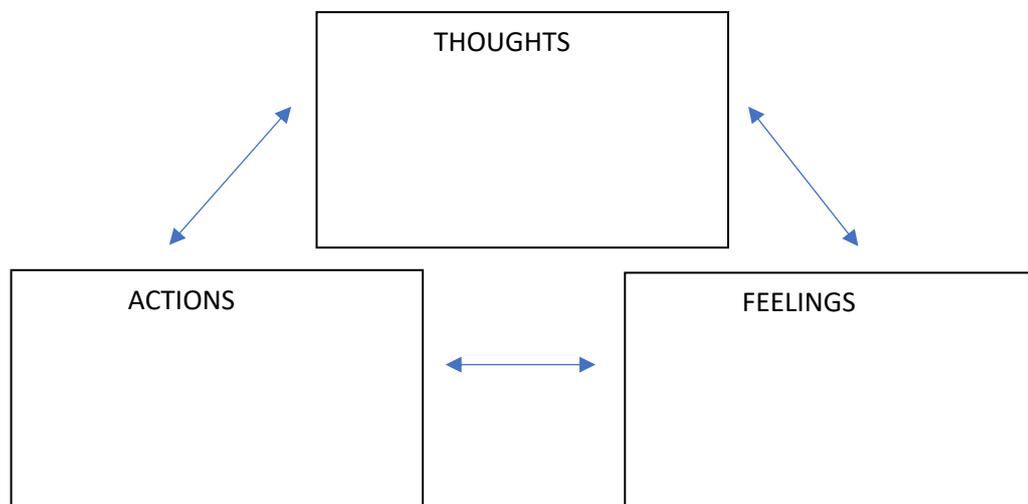
How did all of this affect your pain in that moment?

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Negative automatic thoughts about pain are unhelpful for lots of reasons - they tend to make us feel anxious, meaning that the brain becomes hyperalert and tuned in to the pain. It becomes very difficult to focus on anything but the pain, which can leave us feeling helpless and as though there is nothing we can do the change the pain.

Being able to notice our thoughts as they happen can be a helpful first step in trying to change the process of our thoughts affecting how we feel and what we do. Over the next few days

I'm going to invite you to try and notice the thoughts that pop up automatically for you in relation to your pain. This will then allow you to change the impact of the thought, by practising the following strategies:

1. TAKE THE THOUGHT TO COURT!

We don't tend to challenge our thoughts very much and often just accept them to be true, and before we know it they have affected how we feel and what we do. However- thoughts aren't facts! There are common types of thoughts that we all have that affect how we perceive things:

- **Fortune-telling**
- o Predicting the future! Believing we know an outcome for certain, when in reality we can never *know* what hasn't happened yet- 'If I go tonight I won't be able to cope because of my pain'.
- **Emotional reasoning**
- o Using our feelings about a situation as evidence of the outcome- 'I'm worried about it, so it will go badly'.
- **Overgeneralisation**
- o Taking one disappointing experience/outcome and generalising it the other aspects of our lives- 'I can't do my dance class anymore; I'm never going to be able to do anything fun again'
- **Mountains and molehills**
- o Making mountains out of negative experiences, and molehills out of positive ones- 'I had to leave work early today- this pain will ruin my career!'

Do any of these feel familiar to you? Which ones are around the most?

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One way of managing the unhelpful automatic thoughts associated with pain is to try and challenge the thought by finding all the evidence *for* and *against* it. You start by identifying the thought and how strongly you believe the thought to be true (out of 10), before coming

up with evidence for and against the thought. After reviewing this evidence, you can then rate the thought again in terms of how true you think it is now before coming up with a more 'balanced' thought.

Let's use an example to help us understand what thought challenging might look like in practice. Thalia has been invited out for drinks with her friends but she thinks 'I won't be able to cope if I go because my pain will be too bad':

Thought
'I won't be able to cope with going out for drinks with friends because my pain will be too bad'
<u>*How much I believe the thought:*</u>
9/10

Evidence FOR
I had to go home last time because I didn't feel well
I struggle to be on my feet for too long
My pain is quite bad today

Evidence AGAINST
Every other time we've been out apart from last time my pain has been fine and I've really enjoyed myself
I normally feel better after a night with my friends, not worse
We're going to a quiet bar where I'll be able to sit down

<u>*How much I believe the thought now:*</u>
5/10
A new, more balanced thought:
The thought of going out feels worrying, but once I get there I will likely have a good time with my friends and feel better for going. Even if my pain is bad I will be able to sit down, and I can always leave early if I need to.

Can you think of an example of a negative automatic thought you have had in relation to your pain, that had an impact on how you felt and what you did in that moment?

Thought

_____
_____
_____
_____
How much I believe the thought: **/10**

Evidence FOR

_____
_____
_____
_____
_____
_____

Evidence AGAINST

_____
_____
_____
_____
_____
_____

How much I believe the thought now: **/10**

A new, more balanced thought:

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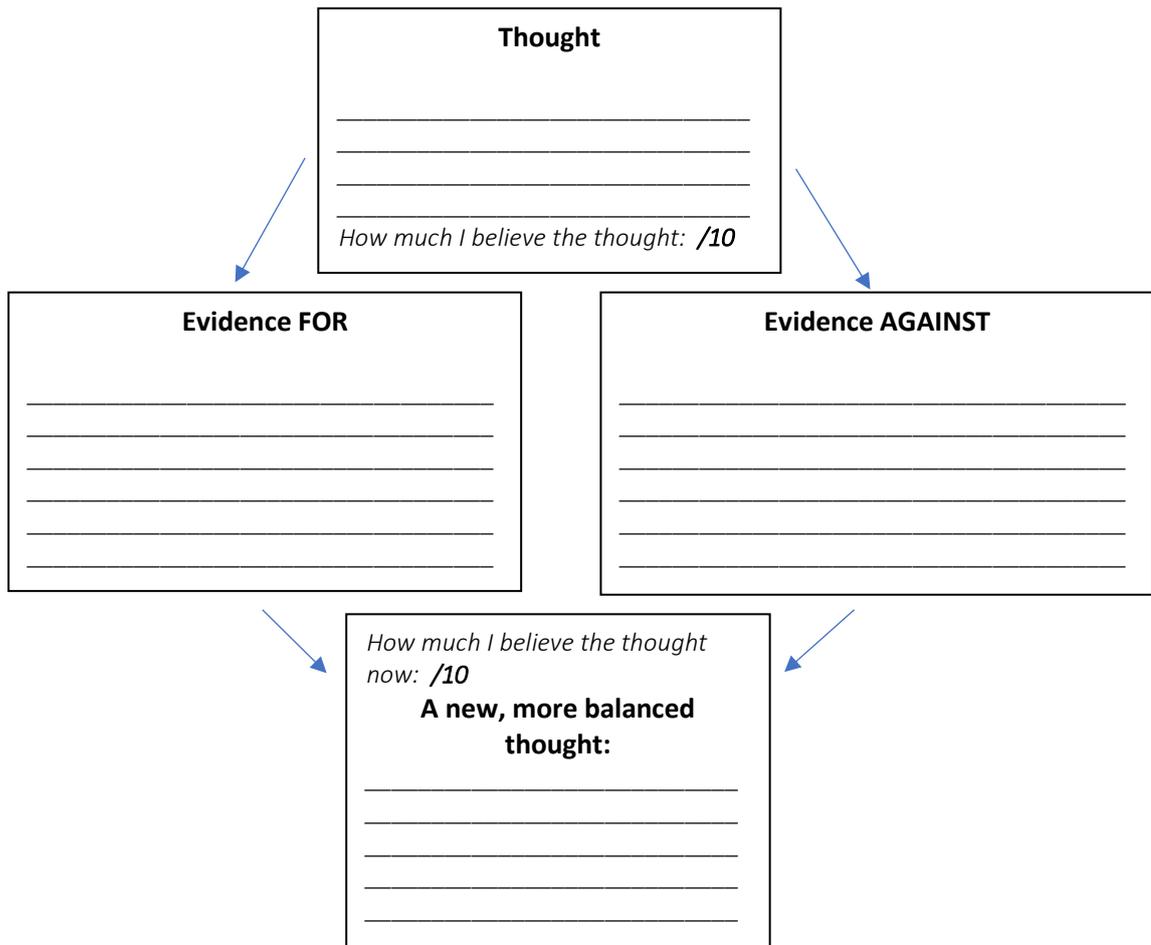
Over the next few days I'm going to invite you to challenge unhelpful, negative thoughts that come up for you in relation to your pain. You can use the above template if that feels helpful.

2.   REFRAMING- FROM **THREAT** TO **CHALLENGE**!

Thoughts about pain can often be 'threatening'. They tend to be negative in nature (understandably!) and focused on: a) what is causing the pain e.g. 'there is something really wrong with me that the doctors just haven't found yet', b) what the pain means e.g. 'I'm not going to be able to do any of the things that are important to me because of my pain' and c) the amount of control we have over the pain e.g. 'my pain is going to get worse and worse and there's nothing I can do about it'.

Negative automatic thoughts tend to pop up for people when they are faced with situations that are stressful because of pain. Interpreting stressful situations to be THREATENING will

trigger the stress response, which we now know inadvertently makes pain worse. If we can instead interpret stressful situations to be a CHALLENGE (something that we can cope with, and that will benefit us) this will reduce the stress response and lead to less pain.

For example…

Let's use Thalia's example again. The thought that 'I won't be able to cope if I go because my pain will be too bad' makes Thalia feel very stressed about the prospect of going, but also sad and disappointed as she really wants to see her friends. She decides to turn down the invitation.

If Thalia decided to reappraise this situation to be a CHALLENGE rather than a THREAT, how might this affect her thoughts/feelings and actions?

_____

_____

_____

_____

Can you think of an example of a situation that you interpreted to be a THREAT because of your pain, and can we reframe it as a CHALLENGE?

Situation_____

_____

_____

_____

THREAT THOUGHTS		CHALLENGE THOUGHTS	
ACTIONS	FEELINGS	ACTIONS	FEELINGS
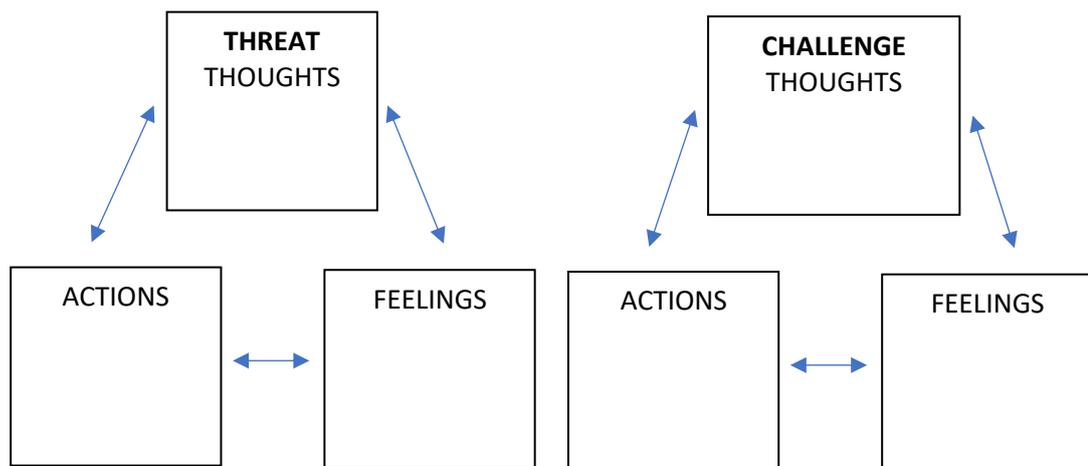
Over the next few days I'm going to ask you to try and notice when a situation seems threatening, and invite you to try and reframe it as a challenge.

3.   COPING STATEMENTS

We have thought about how to develop alternative responses to specific thoughts, and now we are going to think about developing broader positive statements about ourselves to help us cope with challenging situations. These are the kinds of things that those who love and support us would say to motivate us if they were there in that moment, and they can also help to remind us of our strengths when we are struggling.   Examples of coping self-statements include:

- My pain does not control me
- I am a strong and determined person
- I have overcome difficult situations before
- I have people in my life that care about me
- I am a loving and caring person
- I can do so much in spite of my pain

Can you develop some statements that you can use to motivate you in challenging

situations?

_____

_____

I'm going to invite you to use your coping statements to help you manage any challenging

situations that arise over the next few days.

Appendix 10

Completed Cognitive Therapy Rating Scale sheet that was used to assess one of

the brief CBT intervention sessions.

REDACTED